# Appendix A. Search Strings

April 14, 2009

| Literature Strings | Result |
|---|---|
| Search ("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) Limits: Humans, Randomized Controlled Trial, English | 612 |
| Search ("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) Limits: Humans, Journal Article, English | 9,182 |
| Search "Epidemiologic Studies"[Mesh] AND #4 Limits: Humans, Journal Article, English | 2,367 |
| Search "Epidemiologic Studies"[Mesh] Limits: Humans, Journal Article, English | 901,758 |
| Search ("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) | 13,222 |

April 16, 2009
Question 1.
Database: Ovid MEDLINE(R) <1950 to April Week 1 2009> Search Strategy:
>----------
>1 exp Urinary Incontinence/di [Diagnosis] (2,523)
>2 limit 1 to (english language and humans and (guideline or practice guideline)) (13)
>3 exp Clinical Protocols/ (91,702)
>4 1 and 3 (18)
>5 exp Decision Trees/ (6,776)
>6 1 and 5 (19)
>7 6 or 4 (34)
>8 limit 7 to (English language and humans) (25)
>9 2 or 8 (37)

Question 3.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp urinary incontinence/dh, th, su, rt (9,205)
>2 exp urinary incontinence/dt (1,539)
>3 1 not 2 (8,998)
>4 (non pharmacologic or nonpharmacologic).mp. (2,448)
>5 1 and 4 (8)
>6 exp treatment outcome/ (383,394)
>7 exp epidemiologic studies/ (1,103,515)
>8 3 or 5 (9,001)
>9 6 and 7 and 8 (939)
>10 exp quality of life/ (73,696)
>11 7 and 8 and 10 (230)
>12 9 or 11 (1,032)
>13 limit 12 to (English language and humans) (908)
>14 limit 13 to journal article (893)

Questions 2, 5, and 9
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp urinary incontinence/dt (1,539)
>2 exp treatment outcome/ (383,394)
>3 exp quality of life/ (73,696)
>4 3 or 2 (444,907)
>5 4 and 1 (365)
>6 exp epidemiologic studies/ (1,103,515)
>7 6 and 5 (96)
>8 limit 7 to (English language and humans) (85)
>9 limit 8 to journal article (84)

Question 4.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp Urinary Incontinence/dh, nu, th, su, rt, dt, rh [Diet Therapy, Nursing, Therapy, Surgery, Radiotherapy, Drug Therapy, Rehabilitation] (12,453)
>2 exp Office Visits/ or exp Medical Office Buildings/ (4554)
>3 exp Hospitals/ (161857)
>4 exp Nursing Homes/ (26676)
>5 4 or 3 or 2 (191276)
>6 1 and 5 (314)
>7 exp epidemiologic studies/ (1103515)
>8 6 and 7 (52)
>9 limit 8 to (English language and humans) (48)

Question 6.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp urinary incontinence/ (20,881)
>2 exp primary health care/ (55,252)
>3 1 and 2 (124)
>4 exp epidemiologic studies/ (1,103,515)
>5 4 and 3 (16)
>6 exp physician-patient relations/ (48,990)
>7 6 and 4 and 1 (12)
>8 7 or 5 (26)
>9 limit 8 to English language (23)
>10 limit 9 to journal article (22)

Question 7.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp Urinary Incontinence/di [Diagnosis] (2,529)
>2 exp Diagnosis, Differential/ (316,330)
>3 1 and 2 (190)
>4 limit 3 to (English language and humans) (115)

Question 8.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp Urinary Incontinence/th, su, dt, rh [Therapy, Surgery, Drug Therapy, Rehabilitation] (11,383)
>2 exp Treatment Outcome/ (383,394)
>3 1 and 2 (2,157)
>4 exp Evidence-Based Practice/ or exp Evidence-Based Medicine/ or evidence.mp. (756,148)
>5 4 and 3 (146)
>6 limit 3 to "therapy (optimized)" (399)
>7 6 or 5 (502)
>8 limit 7 to (English language and humans) (463)
>9 exp epidemiological studies/ (1,103,515)
>10 8 and 9 (180)
>11 limit 10 to journal article (177)

April 27, 2009

| Literature Strings | Results |
|---|---|
| Search "Health Services Research"[Mesh] AND "Urinary incontinence" [Mesh] NOT review Limits: Humans, Journal Article, English | 137 |

April 20, 2009
#10 Select 12 document(s) 17:17:22 12 #9 Search "Evidence-Based Medicine"[Mesh] Urinary incontinence Limits: Humans, English 17:03:46 124
#17 Search "Caregivers"[Mesh] AND "Urinary Incontinence"[Mesh] NOT review Limits: Humans, Journal Article, English 17:32:56 22

May 26, 2009

| Search | Literature Strings | Result |
|---|---|---|
| #12 | Search #6 or #7 Limits: Humans, Randomized Controlled Trial, English | 46 |
| #8 | Search #6 or #7 Limits: Humans, English | 758 |
| #11 | Search #9 and #1 and #3 Limits: Humans, Randomized Controlled Trial, English | 402 |
| #10 | Search #9 and #1 and #3 Limits: Humans, English | 5,442 |
| #9 | Search clinic or office or hospital or nursing home or longterm care, Limits: Humans, English | 1,645,316 |
| #7 | Search "health services research"[MeSH Terms] and urine incontinence Limits: Humans, English | 214 |
| #6 | Search #4 or #5 Limits: Humans, English | 588 |
| #5 | Search "Physician's Practice Patterns"[MeSH Terms] and urine incontinence Limits: Humans, English | 64 |
| #4 | Search #1 and #2 and #3 | 539 |
| #3 | Search treatment or outcome | 3,837,858 |
| #2 | Search primary care or specialized care or urologist or urogynecologist | 118,680 |
| #1 | Search urine incontinence | 18,607 |
| Search urine incontinence and professional practice Limits: Humans, English | | 228 |
| Stem cell AND "urinary incontinence" Limits: Humans, Journal Article, English | | 42 |
| Estrogen AND "urinary incontinence" Limits: Humans, Journal Article, English | | 368 |
| Adrenergic Uptake Inhibitors AND "urinary incontinence" Limits: Humans, Journal Article, English | | 162 |
| Imipramine hydrochloride AND "urinary incontinence" Limits: Humans, Journal Article, English | | 76 |
| Tricyclic antidepressant AND "urinary incontinence" Limits: Humans, Journal Article, English | | 81 |
| Botulinum toxin AND "urinary incontinence" Limits: Humans, Journal Article, English | | 109 |
| Alpha-blockers AND "Urinary Incontinence" Limits: Humans, Journal Article, English | | 101 |
| Solifenacin AND "Urinary Incontinence" Limits: Humans, Journal Article, English | | 48 |
| Vesicare AND "Urinary Incontinence" Limits: Humans, Journal Article, English | | 4 |
| Enablex AND "Urinary Incontinence" Limits: Humans, Journal Article, English | | 54 |
| Sanctura AND "Urinary Incontinence" Limits: Humans, Journal Article, English | | 3 |
| Ditropan AND "Urinary Incontinence" Limits: Humans, Journal Article, English | | 286 |
| Detrol AND "Urinary Incontinence" Limits: Humans, Journal Article, English | | 198 |
| "Urinary Incontinence" Limits: Humans, Randomized Controlled Trial, English | | 789 |
| ("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) Limits: Humans, Randomized Controlled Trial, English | | 621 |
| ("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) | | 13,302 |
| "Caregivers"[Mesh] AND "Urinary Incontinence" Limits: Humans, Journal Article, English | | 40 |
| "Physician-Patient Relations" [Mesh] AND "Urinary incontinence" | | 48 |
| "Delivery of Health Care"[Mesh] AND "Urinary incontinence" Limits: Humans, Journal Article, English | | 1,438 |
| "Health services re"[MeSH] AND "Urinary incontinence" Limits: Humans, Journal Article, English | | 186 |
| "Physician's Practice Patterns"[MeSH] AND "Urinary incontinence" Limits: Humans, Journal Article, English | | 57 |
| "Quality of life" AND "Urinary incontinence" Limits: Humans, Journal Article, English | | 1,689 |
| "Urinary Incontinence/diagnosis"[Mesh] Limits: Humans, Randomized Controlled Trial, English | | 83 |

| | |
|---|---|
| "Urinary Incontinence/diagnosis"[Mesh] Limits: Humans, Journal Article, English | 2,328 |
| "Epidemiologic Studies"[Mesh] AND "Urinary Incontinence/diagnosis"[Mesh] Limits: Humans, Randomized Controlled Trial, Controlled Clinical Trial, Multicenter Study, Validation Studies, English | 66 |
| "Urinary Incontinence" AND urologist Limits: Humans, Journal Article, English | 78 |
| "Urinary Incontinence" AND urogynecologist Limits: Humans, Journal Article, English | 7 |
| "Urinary Incontinence" AND gynecologist Limits: Humans, Journal Article, English | 29 |

June 26, 2009

| | |
|---|---|
| Search (Urinary incontinence) AND systematic[sb] | 581 |
| Search diary AND "urinary incontinence" AND sensitivity Limits: Humans, English | 20 |

July 20, 2009
Cochrane RCT database:

| | |
|---|---|
| Urinary incontinence and Women | 457 |
| Urinary incontinence NOT surgery | 138 |

Updated search August 20, 2009

| | |
|---|---|
| Search ("Urinary Incontinence/diagnosis"[Mesh] OR "Urinary Incontinence/diet therapy"[Mesh] OR "Urinary Incontinence/drug therapy"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) Limits: published in the last 180 days, Humans, Journal Article, English, All Adult: 19+ years | 86 |

October 13, 2009

| | |
|---|---|
| Search "Duloxetine Urinary Incontinence Study Group"[Corporate Author] | 4 |

Updated search November 10, 2009:

| | |
|---|---|
| Search (("Urinary incontinence"[Text Word]) AND ("2009/04/01"[Publication Date] : "3000"[Publication Date])) AND (Urinary incontinence) Limits: Randomized Controlled Trial English | 33 |

March 25, 2010

| | |
|---|---|
| Search tolterodine Limits: Randomized Controlled Trial ("2009/04/01"[Publication Date] : "3000"[Publication Date])) AND (Urinary incontinence) Limits: Randomized Controlled Trial, English | 134 |
| Search fesoterodine | 48 |
| Search Solifenacin | 194 |

Grey Literature search using key words ”Urinary incontinence” on July 27, 2010:

**Regulatory Information**
FDA
Health Canada
Authorized Medicines for EU

**Clinical Trial Registries**
ClinicalTrials.gov - 120
Search for UI among all close studies: additional -100 records
Australian New Zealand Clinical Trials Registry (ANZCTR) - 1
Clinical Study Results - 4
WHO Clinical Trials - 18
Clinical Trials Registry - India (CTRI) - 1
Japanese Registry of clinical trials (JPRN) - 4
Netherlands Trial Register - 6

**Grants and Federally Funded Research**
NIH RePORTER (a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions)- 487

**Abstracts and Conference Papers**
Conference Papers Index - 318
Scopus - 243
International Continence Society and the International Urogynecological Association – 2010 meeting

September 2010

| | |
|---|---|
| "Urinary incontinence" OR "overactive bladder" OR fesoterodine OR oxybutynin OR trospium OR solifenacin OR tolterodine Limits: Female, Randomized Controlled Trial, English, All Adult: 19+ years | 794 |
| "Urinary incontinence" Limits: Humans, Journal Article, English, All Adult: 19+ years, Publication Date from 2009/01/01 to 2010/12/31 | 903 |

**Results of the request for Scientific Information Packets (SIP) by the Scientific Resource Center**

| Company | SIP Letter Sent | SIP Received |
|---|---|---|
| Abbott Laboratories | 8/13/2010 | [no SIP] |
| Accelerated Care Plus | 8/13/2010 | [no SIP] |
| ACP - Accelerated Care Plus Corporation | 8/13/2010 | [no SIP] |
| Actavis US | 8/13/2010 | [no SIP] |
| AL Voss Associates | 8/13/2010 | [no SIP] |
| Allergan, Inc. | 8/13/2010 | [no SIP] |
| Astellas Pharmaceuticals | 8/13/2010 | [no SIP] |
| AstraZeneca Pharmaceuticals, LP | 8/13/2010 | [no SIP] |
| Bioness, Inc. | 8/13/2010 | [no SIP] |
| BIOTEQUE AMERICA, INC. | 8/13/2010 | [no SIP] |
| Bristol-Myers Squibb | 8/13/2010 | [no SIP] |
| Duramed Subsidiary of Barr Pharmaceuticals | 8/13/2010 | [no SIP] |
| Eli Lilly & Co | 8/13/2010 | [no SIP] |
| Hollister Incorporated | 8/13/2010 | [no SIP] |
| Impax Laboratories, Inc. | 8/13/2010 | [no SIP] |
| Ivax Pharmaceuticals (Teva Pharmaceuticals) | 8/13/2010 | [no SIP] |
| Laborie Medical Technologies | 8/13/2010 | [no SIP] |
| Mentor Corp | 8/13/2010 | [no SIP] |
| Mikart | 8/13/2010 | [no SIP] |
| Mutual Pharma (URL Pharma Inc) | 8/13/2010 | [no SIP] |
| Mylan Pharmaceuticals | 8/13/2010 | [no SIP] |
| New River Pharmaceuticals | 8/13/2010 | [no SIP] |
| Nexstim Inc | 8/13/2010 | [no SIP] |
| Novartis Pharmaceuticals Corporation | 8/13/2010 | [no SIP] |
| Novavax Inc. | 8/13/2010 | [no SIP] |
| Nycomed US Inc | 8/13/2010 | [no SIP] |
| Odyssey Pharmaceuticals, Inc | 8/13/2010 | [no SIP] |
| Ortho-McNeil Janssen Scientific Affairs, LLC | 8/13/2010 | 8/31/2010 |
| Osmotica Pharmaceutical Corp | 8/13/2010 | [no SIP] |
| Pfizer Inc | 8/13/2010 | [no SIP] |
| Purepac Pharmaceuticals | 8/13/2010 | [no SIP] |
| Ranbaxy | 8/13/2010 | [no SIP] |
| Reliant Technologies, Inc. | 8/13/2010 | [no SIP] |
| Roche Laboratories | 8/13/2010 | [no SIP] |
| Rochester Medical Corporation | 8/13/2010 | 9/10/2010 |
| Roxane | 8/13/2010 | [no SIP] |
| Sandoz Inc | 8/13/2010 | [no SIP] |
| Sanofi Aventis US | 8/13/2010 | [8/27/2010 nothing to supply] |
| Schering-Plough Corporation | 8/13/2010 | [no SIP] |
| Silarx Pharmaceuticals, Inc. | 8/13/2010 | [no SIP] |
| Somaxon Pharmaceuticals | 8/13/2010 | [no SIP] |
| Taro Pharmaceuticals | 8/13/2010 | [no SIP] |
| Teva Pharmaceuticals USA | 8/13/2010 | [no SIP] |
| UCB, Inc | 8/13/2010 | [no SIP] |
| USL Pharmaceuticals | 8/13/2010 | [no SIP] |
| Vanguard Pharma | 8/13/2010 | [no SIP] |
| Warner Chilcott Company, Inc. | 8/13/2010 | [no SIP] |
| Wockhardt | 8/13/2010 | [no SIP] |
| Wyeth Pharmaceuticals Headquarters | 8/13/2010 | [no SIP] |
| PLIVA HRVATSKA DOO | 8/13/2010 | [no SIP] |
| Tyco Healthcare UK Commercial Ltd. | 8/13/2010 | [no SIP] |

# Appendix B. Excluded Studies

(Note that this set of references is different from those in the text, and the numbers are different.)


1. Evaluation and treatment of urinary incontinence. Urologic Clinics of North America 1991; 18(2):175-407. *Level of evidence*
2. Safety in the therapy of urinary incontinence. II. Specialty workshop, 22nd Congress of the International Society of Urology. Seville, 4 November 1991. Sicherheit in der Harninkontinenz-therapie. II. Fachpresse-workshop, 22. Kongresses der Societé International d'Urologie. Sevilla, 4 November 1991. 1992; 25(1 Suppl):1-12. *Level of evidence*
3. Safety in the therapy of urinary incontinence. A workshop on the occasion of the 22nd Congress of the International Urology Society, Seville, 4 November 1991. Sicherheitin der Harninkontinenz-Therapie. Workshop anlässlich des 22. Kongresses der Societé International d'Urologie, Sevilla, 4, November 1991. 1992; 31(2 Suppl):1-12. *Level of evidence*
4. Effects of terodiline on urinary incontinence among older non-institutionalized women. Terodiline in the Elderly American Multicenter Study Group. J Am Geriatr Soc 1993 Sep; 41(9):915-22. *Not eligible exposure*
5. Incontinence. Causes, management and provision of services. A Working Party of the Royal College of Physicians. J R Coll Physicians Lond 1995 Jul-Aug; 29(4):272-4. *Guideline*
6. A modest proposal: patient underwear in OR. OR Manager 1997 Jun; 13(6):23. *Comment*
7. Establishment of wound ostomy continence clinics. J Wound Ostomy Continence Nurs 1998 Sep; 25(5):22A, 4A, 6A passim. *Comment*
8. One nurse is sick of care homes that smell of incontinence. Nurs Times 1998 Jul 1-7; 94(26):59. *Comment*
9. Dealing sensitively with incontinence. Aust Nurs J 1999 Jun; 6(11):29. *Comment*
10. Clinical advances in incontinence management. A sampling of products now available to manage urinary incontinence. Adv Skin Wound Care 2000 Nov-Dec; 13(6):290-2. *Comment*
11. S-oxybutynin. Drugs R D 2002; 3(2):84-5. *Comment*
12. Developing a unique patient advocate. Ostomy Wound Manage 2003 Dec; 49(12):11-2. *Comment*
13. Stress urinary incontinence in clinical practice. Advanced Studies in Medicine 2003; 3(8 E). *Level of evidence*
14. Trospium chloride (Sanctura): another anticholinergic for overactive bladder. Med Lett Drugs Ther 2004 Aug 2; 46(1188):63-4. *Comment*
15. Advancing the treatment of fecal and urinary incontinence through research: trial design, outcome measures, and research priorities. Proceedings of a consensus conference. November 3-5, 2002. Milwaukee, Wisconsin, USA. Gastroenterology 2004; 126(1 Suppl 1). *Level of evidence*
16. Successful treatment possibilities for urinary incontinence - The 2 <sup>nd</sup> Urogynecology Congress in St. Veit a.d. Glan. Erfolgreiche behandlungs-möglichkeiten bei harninkontinenz - 2. Urogynäkologie-Kongress in St. Veit a.d. Glan 2004; 11(2):43. *Level of evidence*
17. Duloxetine: new drug. For stress urinary incontinence: too much risk, too little benefit. Prescrire Int 2005 Dec; 14(80):218-20. *Comment*
18. Stem cells may cure urinary incontinence. In this experimental treatment, a patient's own cells can stop leaks in as little as one day. Health News 2005 Mar; 11(3):4-5. *News*
19. Urinary incontinence. Know your drug options. Mayo Clin Health Lett 2005 Nov; 23(11):6. *Comment*
20. Solifenacin and darifenacin for overactive bladder. Obstet Gynecol 2005 Aug; 106(2):401-2. *Comment*
21. Tolterodine. Nurs Times 2006 Jun 6-12; 102(23):27. *Comment*
22. Promoting urinary continence in older people. Nurs Older People 2006 Apr; 18(3):35-6. *Comment*
23. Hormone replacement therapy aggravates postmenopausal urinary incontinence. Prescrire Int 2006 Aug; 15(84):137-8. *Comment*
24. Continence assessment. Paediatric nursing 2008 Apr; 20(3):23. *Comment*
25. Expression of concern--autologous myoblasts and fibroblasts versus collagen [corrected] for treatment of stress urinary incontinence in women: a [corrected] randomised controlled trial. Lancet 2008 May 3; 371(9623):1490. *Comment*
26. Hormone therapy. An update on risks and benefits. Mayo Clin Womens Healthsource 2009 Mar; Suppl:1-8. *Comment*
27. Shaw C, Williams KS, Assassa RP. Patients' views of a new nurse-led continence service. J Clin Nurs 2000 Jul; 9(4):574-82. *Did not provide comparative assessment of the outcomes among different treatments for female UI*
28. Aaron R, Muliyil J, Abraham S. Medico-social dimensions of menopause: a cross-sectional study from rural south India. Natl Med J India 2002 Jan-Feb; 15(1):14-7. *Not eligible targe tpopulation*
29. Aaronson PS, Loehner D, Bingham W, et al. Intravaginal electrical stimulation in the treatment of genuine stress urinary incontinence and detrusor instability: A controlled study. Paper presented at: American Urological Society 90th Annual Meeting, Las Vegas, NV (USA), 23-28 April 1995. (World Meeting Number 952 0772). *Level of evidence*

30. Abdelbary A. Evaluation of prolene mesh as a trans-obturator tape for treatment of female stress urinary incontinence. Paper presented at: 38th Annual Meeting of the International Continence Society (ICS 2008), Cairo International Congress Center (CICC), Cairo (Egypt), 20-24 Oct 2008. *Level of evidence*
31. Abdel-Fattah M, Barrington JW, Arunkalaivanan AS. Pelvicol pubovaginal sling versus tension-free vaginal tape for treatment of urodynamic stress incontinence: a prospective randomized three-year follow-up study. Eur Urol 2004 Nov; 46(5):629-35. *Not eligible exposure*
32. Abdel-Fattah M, Ramsay I. Transobturator tension free vaginal tapes: are they the way forward in the surgical treatment of urodynamic stress incontinence? Int J Surg 2007 Feb; 5(1):3-10. *Not eligible exposure*
33. Abdel-Hady el S, Constantine G. Outcome of the use of tension-free vaginal tape in women with mixed urinary incontinence, previous failed surgery, or low valsalva pressure. J Obstet Gynaecol Res 2005 Feb; 31(1):38-42. *Not eligible exposure*
34. Abdel-Karim AM, Hassouna ME, Koraitem MA, et al. Vaginal Inter-Pubic Perineorraphy for Treatment of Female Stress Urinary Incontinence: A New Technique. Paper presented at: 31st Annual Meeting of the International Urogynecological Association, Athens Hilton Hotel, Athens (Greece), 6-9 Sep 2006. *Level of evidence*
35. Abdel-Mageed AB, Bajwa A, Shenassa BB, et al. NF-kappaB-dependent gene expression of proinflammatory cytokines in T24 cells: possible role in interstitial cystitis. Urol Res 2003 Oct; 31(5):300-5. *Not eligible outcomes*
36. Abdul MA, Yusuf MD, Liadi S, et al. Congenital vaginal fistula from a single system ectopic ureter: A case report. Niger J Med 2006 Oct-Dec; 15(4):441-3. *Not eligible target population*
37. Abeygunasekera AM. Clean intermittent catheterisation. Ceylon Med J 2004 Dec; 49(4):107-9. *no associative hypothesis tested*
38. Aboseif S, Tamaddon K, Chalfin S, et al. Sacral neuromodulation as an effective treatment for refractory pelvic floor dysfunction. Urology 2002 Jul; 60(1):52-6. *Not eligible exposure*
39. Aboseif SR, Kim DH, Rieder JM, et al. Sacral neuromodulation: cost considerations and clinical benefits. Urology 2007 Dec; 70(6):1069-73; discussion 73-4. *Not eligible outcomes*
40. Abouassaly R, Lane BR, Lakin MM, et al. Ejaculatory urine incontinence after radical prostatectomy. Urology 2006 Dec; 68(6):1248-52. *Not eligible target population*
41. Abouassaly R, Steinberg JR, Lemieux M, et al. Complications of tension-free vaginal tape surgery: a multi-institutional review. BJU Int 2004 Jul; 94(1):110-3. *Not eligible exposure*
42. Abramov Y, Rosen T, Feiner B, et al. Does a 'One Stop' Urogynecologic Clinic Improve Patients' Compliance for Behavioral Therapy for Urinary Incontinence? Paper presented at: 31st Annual Meeting of the International Urogynecological Association, Athens Hilton Hotel, Athens (Greece), 6-9 Sep 2006. *Level of evidence*
43. Abrams P. Identifying and evaluating urinary incontinence in a female population. Eur Urol 1997; 32 Suppl 2:1-2. *Comment*
44. Abrams P. Impact of Stress Urinary Incontinence on Quality of Life. Advanced Studies in Medicine 2003; 3(8 E). *Review*
45. Abrams P, Donovan JL, de la Rosette JJ, et al. International Continence Society "Benign Prostatic Hyperplasia" Study: background, aims, and methodology. Neurourol Urodyn 1997; 16(2):79-91. *Not eligible target population*
46. Abrams P, Kaplan S, De Koning Gans HJ, et al. Safety and tolerability of tolterodine for the treatment of overactive bladder in men with bladder outlet obstruction. J Urol 2006 Mar; 175(3 Pt 1):999-1004; discussion *Not eligible target population*
47. Abrams P, Klevmark B. Frequency volume charts: an indispensable part of lower urinary tract assessment. Scand J Urol Nephrol Suppl 1996; 179:47-53. *Did not provide comparative assessment of the outcomes among different treatments for female UI*
48. Abrams P, Swift S. Solifenacin is effective for the treatment of OAB dry patients: a pooled analysis. Eur Urol 2005 Sep; 48(3):483-7. *Not eligible target population*
49. Accorsi-Neto AC. Long-term evaluation of patients with Kelly Kennedy surgery for urinary incontinence treatment. Paper presented at: XVII FIGO World Congress of Gynecology and Obstetrics, Santiago (Chile), 2-7 Nov 2003. (World Meeting Number 000 7240). *Level of evidence*
50. ACTRN12605000755639. Efficacy of non-invasive magnetic stimulation of the pelvic floor in the control of urinary incontinence. *Not eligible exposure*
51. Adamiak A, Jankiewicz K, Miotla P, et al. Efficacy and safety of transobturator approach in the treatment of female stress urinary incontinence. Paper presented at: 12th World Congress on Human Reproduction, Venice (Italy), 10-13 Mar 2005. (World Meeting Number 000 0000). *Level of evidence*
52. Adamiak A, Milart P, Skorupski P, et al. The efficacy and safety of the tension-free vaginal tape procedure do not depend on the method of analgesia. Eur Urol 2002 Jul; 42(1):29-33. *Not eligible exposure*
53. Adamyan L, Kozachenko I, Sashin B. Treatment of Mixed Urinary Incontinence with Intra-Detrusor Injection of Botulinuma Toxin. Paper presented at: 34th Annual Meeting of the International Urogynecological Association, Villa Erba, Como, 16-20 Jun 2009. *Not eligible case reports*

54. Addington-Hall J, Lay M, Altmann D, et al. Symptom control, communication with health professionals, and hospital care of stroke patients in the last year of life as reported by surviving family, friends, and officials. Stroke 1995 Dec; 26(12):2242-8. *Not eligible target population*
55. Addison R. Intermittent self-catheterisation. Nurs Times 2001 May 17-23; 97(20):67-9. *Not eligible exposure*
56. Adekanmi OA, Freeman RM, Bombieri L. How colposuspensions are performed in the UK: a survey of gynecologists' practice. Int Urogynecol J Pelvic Floor Dysfunct 2003 Aug; 14(3):151-9; discussion 9. *Not eligible exposure*
57. Adile B. New treatment for stress urinary incontinence. Paper presented at: XVII FIGO World Congress of Gynecology and Obstetrics, Santiago (Chile), 2-7 Nov 2003. (World Meeting Number 000 7240). *Level of evidence*
58. Adile B, Gugliotta G, Adile G. A two-year follow-up of a new readjustable transobturator approach for surgical treatment of female stress urinary incontinence. Urogynaecologia International Journal 2006; 20(2):307-9. *Level of evidence*
59. Adile B, Liguori P, Pisapia G, et al. Tension-free vaginal tape for surgical treatment of stress urinary incontinence. An Italian multicenter study and two year follow-up. TVT per il trattamento chirurgico della incontinenza urinaria da sforzo. Studio multicentrico italiano. Follow-up a due anni 2001; 15(1 SUPPL.):68. *Level of evidence*
60. Adile B, Palma P, Thiel R, et al. Female sexual function before and after treatment of urinary incontinence. Urogynaecologia International Journal 2005; 19(1 SUPPL.):365-72. *Level of evidence*
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2133. NCT00282490. Surface Nerve Stimulation Treatment for OAB in Children; 2008. *Not eligible exposure*
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2153. NCT00475839. Study Comparing Tension-Free Vaginal Tape With the Monarc Procedure for Stress Urinary Incontinence; 2007. *Not eligible exposure*
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2156. NCT00525291. Triple Target Treatment (3T) Which Combines Stimulation With Amplitude Modulated Middle Frequency (AM-MF), Electromyography (EMG)-Triggered Stimulation and EMG-Biofeedback Compared With EMG-Biofeedback in Anal Incontinence; 2008. *Not eligible exposure*
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2165. NCT00662909. Study to Test the Efficacy and Safety of the Beta-3 Agonist YM178 in Patients With Symptoms of Overactive Bladder; 2009. *Not eligible exposure*
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2168. NCT00691093. Study In Patients With Overactive Bladder Treated With Toviaz® After Failure Of Previous Therapy; 2009. *Not eligible exposure*
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2172. NCT00747370. Dynamic MRI of the Behaviour of Female Pelvic Floor; 2008. *Not eligible exposure*
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2174. NCT00765622. Assessment of Pelvic Floor Function in Elderly; 2007. *Not eligible exposure*
2175. NCT00782990. A 3 Year Follow-up Prospective Open Randomized Trial of TVT Versus Colposuspension for Primary Stress Incontinence; 2007. *Not eligible exposure*
2176. NCT00795925. Dose-Escalating Study of Propiverine Hydrochloride in Children Suffering From Overactive Bladder; 2005. *Not eligible exposure*
2177. NCT00801203. A Study to Evaluate the Effectiveness of the Induced Reflex Cough Test Plus Urodynamics to Identify Stress Urinary Incontinence in Female Subjects With a History of Stress Urinary Incontinence; 2009. *Not eligible exposure*
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2179. NCT00850590. Study of Escalating Doses of NRL001 Given in Slow-release Rectal Suppositories of Different Weights. *Not eligible exposure*
2180. NCT00850733. 516-BOTOX Urinary Incontinence Detrusor; 2009. *Not eligible exposure*
2181. NCT00857467. Study to Investigate Safety and Response to 1 or 2 g Rectal Suppositories Containing 5 or 10 mg NRL001. *Not eligible exposure*
2182. NCT00880880. Improving Women's Health by Using an Electronic Pelvic Floor Questionnaire. *Not eligible exposure*
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2186. NCT00906854. Urinary Incontinence and Practice of Physical Exercises; 2008. *Not eligible exposure*

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2190. NCT00939432. Taboo Perception of Incontinence, Depression and Cancer; 2007. *Not eligible exposure*
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3376. Zhu L. A Prospective Randomised Trial Comparing Tension Free Vaginal and Transobturator Suburethral Tape for Surgical Treatment of Slight and Moderate Stress Urinary Incontinence. Paper presented at: XVIII FIGO World Congress of Gynecology and Obstetrics (FIGO 2006), Kuala Lumpur Convention Centre (KLCC), Kuala Lumpur (Malaysia), 5-10 Nov 2006. *Level of evidence*
3377. Zhu L, Lang J, Feng R, et al. Estrogen receptor in pelvic floor tissues in patients with stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2004 Sep-Oct; 15(5):340-3. *Not eligible outcome*
3378. Zhu L, Lang J, Hai N, et al. Comparing vaginal tape and transobturator tape for the treatment of mild and moderate stress incontinence. Int J Gynaecol Obstet 2007 Oct; 99(1):14-7. *Not eligible exposure*
3379. Zhu L, Lang J, Wang H, et al. The prevalence of and potential risk factors for female urinary incontinence in Beijing, China. Menopause 2008 May-Jun; 15(3):566-9. *Not eligible outcomes*
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3383. Ziv E, Stanton SL, Abarbanel J. The Leak Score - a novel instrument to assess subjective severity of female stress urinary incontinence and efficacy of treatment. Paper presented at: 38th Annual Meeting of the International Continence Society (ICS 2008), Cairo International Congress Center (CICC), Cairo (Egypt), 20-24 Oct 2008. *Level of evidence*
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3390. Zullo MA, Plotti F, Calcagno M, et al. One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. Eur Urol 2007 May; 51(5):1376-82; discussion 83-4. *Not eligible exposure*
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# Appendix C. Technical Expert Panel Members and Affiliation

| TEP Member | Affiliation |
|---|---|
| Alan M. Adelman, MD, MS | Penn State University<br>Hershey, Pennsylvania |
| Apostolos Panagiotis Dallas, MD | Carilion Roanoke Memorial Hospital<br>Roanoke, Virginia |
| Catherine DuBeau, MD | UMass Memorial Medical Center<br>Worcester, Massachusetts |
| Mary Forciea, MD, FACP | University of Pennsylvania<br>Philadelphia, Pennsylvania |
| Leah Hole-Curry, JD | Washington Health Care Authority<br>Olympia, Washington |
| Diane Newman, RNC, MSN, CRNP FAAN | University of Pennsylvania Medical Center<br>Philadelphia, Pennsylvania |
| Ingrid Nygaard, MD | University of Utah School of Medicine<br>Salt Lake City, Utah |
| Mary Patrick, RN | Department of Public Health & Human Services<br>Helena, Montana |
| Suzanne Pope, MBA | American Urological Association<br>Linthicum, Maryland |
| Amir Qaseem, MD, PhD, MHA, FACP | American College of Physicians<br>Philadelphia, Pennsylvania |
| Kenneth G. Schellhase, MD MPH | Medical College of Wisconsin<br>Milwaukee, Wisconsin\ |
| Paul Shekelle, MD | RAND Corporation<br>Santa Monica, California |
| J. Christian Winters, MD, FACS | LSU Health Sciences Center<br>Metairie, Louisiana |

# Appendix D. Analytical Framework

## Algorithm to Define Eligibility of Studies

Research Question.

1. What constitutes an adequate diagnostic evaluation in the primary care setting on which to base treatment of UI?

### Verification/Selection of Study Eligibility

Criteria 1 - Confirm eligibility of the target population
Eligible descriptors:

| | | | |
|---|---|---|---|
| Adult women in the community | Yes | No | Combined |
| Elderly women in the community | Yes | No | Combined |

If NO – exclude

Criteria 2 - Confirm eligibility of the outcomes
Eligible descriptors:

| | | | |
|---|---|---|---|
| Diagnosis of urinary incontinence | Yes | No | Combined |
| Incidence of urinary incontinence | Yes | No | Combined |

If NO – exclude

Criteria 3 - Confirm eligibility of diagnostic strategies
Questionnaire
Scale
Diary
Interview
Pad test
Multichannel urodynamics
If NO – exclude

Criteria 4 – Confirm eligibility of the outcomes assessment:
Eligible descriptors:

| | | |
|---|---|---|
| True positive | Yes | No |
| True negative | Yes | No |
| False positive | Yes | No |
| False negative | Yes | No |
| Sensitivity | Yes | No |
| Specificity | Yes | No |
| Positive predictive likelihood of the test | Yes | No |
| Validity of the scale | Yes | No |
| Validity of the questionnaire | Yes | No |
| Reliability of the scale | Yes | No |
| Reliability of the questionnaire | Yes | No |

If NO for all descriptors – exclude

Criteria 5. Confirm eligible level of evidence
Eligible descriptors:

| | | |
|---|---|---|
| Randomized controlled clinical trials | Yes | No |
| Multicenter controlled clinical trials | Yes | No |
| Large (>100 subjects) observational studies | Yes | No |
| Case-control studies with >10 cases | Yes | No |

If NO for all descriptors – exclude

2-3. How effective is the pharmacologic treatment of UI? How effective is the nonpharmacologic treatment of UI?

**Verification/Selection of Study Eligibility**

Criteria 1 - Confirm eligibility of the target population
Eligible descriptors:

| | | | |
|---|---|---|---|
| Adult women with urinary incontinence in the community | Yes | No | Combined |
| Elderly women with urinary incontinence in the community | Yes | No | Combined |

If NO – exclude

Criteria 2 – Confirm eligibility of the outcomes
Eligible descriptors:

| | | | |
|---|---|---|---|
| Prevalence of urinary incontinence/types | Yes | No | Combined |
| Progression of urinary incontinence/types | Yes | No | Combined |
| Improvement in urinary incontinence/types | Yes | No | Combined |
| Continence | Yes | No | Combined |
| Changes in severity or frequency of urinary incontinence/types | Yes | No | Combined |
| Quality of life related to urinary incontinence/types | Yes | No | Combined |
| Adverse events | Yes | No | Combined |

If NO – exclude

Criteria 3 – Confirm eligibility of interventions
Eligible drugs and nonpharmacologic treatments
If NO – exclude

Criteria 4 – Confirm eligible level of evidence
Eligible descriptors for clinical outcomes:

| | | |
|---|---|---|
| Randomized controlled clinical trials | Yes | No |
| Multicenter controlled clinical trials | Yes | No |
| Large (>100 subjects) observational studies | Yes | No |

If No for all descriptors – exclude
If adverse events reported – include

## Definitions of Population, Interventions, Comparators, Outcomes, and Settings (PICOS) framework

### Population(s):

For KQ1. Adult and elderly women with symptoms of UI.
For KQ2 and KQ3. Adult and elderly women with diagnosed UI.

### Interventions:

**For KQ1 about diagnostic methods, the method that was defined as the gold standard**

**Gold standard**

Multichannel urodynamics
Bladder diary

**For KQ2 and KQ3 about treatments for urinary incontinence:**

| Variable | Definition |
|---|---|
| Health education | Education that increases the awareness and favorably influences the attitudes and knowledge relating to the early detection and prevention of urinary incontinence |
| Behavioral therapy | The application of behavioral changes to detect and manage incontinence, including: education about urinary structure and function; development of individualized diaries of daily dietary, physical activities, urinary habits; pelvic floor muscle exercises; voiding schedules: prompted, timed, habit retraining, patterned urge response toileting |
| Biofeedback | Process by which a person uses biofeedback information to gain voluntary control over the function of pelvic floor muscles and urination process |
| Pelvic floor muscle training for urinary incontinence | A systematic program of pelvic floor muscle exercises (Kegel exercises) designed to improve the strength and coordination of the pelvic floor muscles in order to improve urinary sphincter function and to control urgency |
| Vaginal cones | Insertion of vaginal cone (weighted device) into the vagina and contraction of the pelvic floor muscles in an effort to hold the device in place |
| Electrical stimulation | Application of electric current in treatment without the generation of perceptible heat<br>Using low-voltage electric current to stimulate the correct group of muscles by using an anal or vaginal probe for delivery |
| Urethral plugs and patches | Insertion of plastic shapes into the urethra to stop the flow of urine or placed externally at the urinary meatus to prevent urine leakage; used for female stress urinary incontinence |
| Pessaries | A plastic or silicone device that is inserted into the vagina to provide support to the uterus, vagina, bladder, or rectum when there is pelvic organ prolapse; special pessaries with knobs are available to treat urinary incontinence |
| Magnetic stimulation | Stimulation with a brief magnetic field on the pelvic floor muscles and sacral roots without insertion of an anal or vaginal probe |
| Urethral bulking:<br>Transurethral or periurethral injection techniques for women | Artificially inflating the submucosal tissues of the bladder neck;<br>FDA-approved urethral bulking agents include collagen (Contigen®), autologous fat, and carbon bead particles (Durasphere®). |
| Topical estrogen therapy | Topical vaginal administration of estrogen |
| Pharmacological interventions | Ditropan® (oxybutynin chloride)<br>Sanctura® (trospium chloride)<br>Enablex® (darifenacin)<br>Vesicare® (solifenacin succinate) |
| Other tested pharmaceuticals | Botulinum toxin injections<br>Tricyclic antidepressants<br>Imipramine hydrochloride |

**Devices that have been examined in women with urinary incontinence available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070852.htm**

| Classification (21 CFR) | Class | Product Code | Description |
|---|---|---|---|
| **Gastrolenterology-Urology Devices** | | | |
| 876.5270 Implanted electrical urinary continence device | III | EZT | Pacemaker, bladder |
| III | EZW | Stimulator, electrical, implantable, for incontinence | |
| 876.5280 Implanted mechanical/hydraulic urinary continence device | III | EZY | Device, incontinence, mechanical/hydraulic |
| | III | LNM | Agent, bulking, injectable for gastro-urology use |
| | III | OCK | Transurethral occlusion insert, urinary incontinence-control, female |
| **Classification (21 CFR)** | **Class** | **Product Code** | **Description** |
| **Gastrolenterology-Urology Devices** | | | |
| 876.5310 Nonimplanted, peripheral electrical continence device | II | NAM | Stimulator, peripheral nerve, nonimplanted, for pelvic floor dysfunction |
| 876.5320 Nonimplanted electrical continence device | II | KPI | Stimulator, electrical, nonimplanted, for incontinence |
| 876.5920 Protective garment for incontinence | I 510(k) Exempt | EYQ | Garment, protective, for incontinence |
| N/A | Unclassified | MNG | External urethral occluder, urinary incontinence-control, female |
| **Obstetrical and Gynecological Devices** | | | |
| 884.1425 Perineometer | II | HIR | Perineometer |
| 884.3575 Vaginal pessary | II | HHW | Pessary, vaginal |

## Comparator

| **For KQ1 about diagnostic methods, the index methods that were tested:** |
|---|
| Questionnaires |
| Checklists and scales |
| Self-reported UI during a clinical examination |
| Provocation stress test |
| Frequency volume chart |
| Pad tests |
| Paper towel test |
| Ultrasound |

For KQ2 and KQ3 about treatments:

| Efficacy | Placebo, no active treatment, or regular care |
|---|---|
| Comparative effectiveness | Active pharmacological treatment, education, behavioral therapy, biofeedback, bladder retraining (Kegel exercises), electrical stimulation, pads, and urethral plugs and pessaries in women |

## Outcomes

Outcomes for KQ1 about diagnostic methods:

- True positive for any, stress, and urgency incontinence
- True negative for any, stress, and urgency incontinence
- False positive for any, stress, and urgency incontinence
- False negative for any, stress, and urgency incontinence
- Sensitivity for any, stress, and urgency incontinence
- Specificity for any, stress, and urgency incontinence
- Positive predictive likelihood ratio for any, stress, and urgency incontinence

Primary outcomes after treatments (clinical outcomes):

- Continence
- Quality of life: measured by using a validated generic or condition-specific measure of quality of life developed to address issues related specifically to UI

| Secondary outcomes | Definition |
|---|---|
| Remission of incontinence | Diminution of symptoms and signs of incontinence |
| Contained incontinence | Urine contained with pads or appliances |
| Dependent continence | Dry with toileting assistance, behavioral treatment, and/or medications |
| Independent continence | Dry, not dependent on ongoing treatment |
| Symptoms of incontinence[1,2] | The subjective indicator of incontinence or change in its severity, as perceived by the patient, caregiver, or partner, and may lead her to seek help from health-care professionals |
| Signs of incontinence | Observed by the physician, including simple means, to verify symptoms and quantify them |
| Urodynamic observations | Observations made during urodynamic studies that have a number of possible underlying causes and do not represent a definitive diagnosis of a disease |
| Measures of the frequency, severity, and impact of urinary incontinence[2] | |
| Micturition time chart | Records of times of micturitions (day and night) for at least 24 hours |
| Frequency volume chart (FVC) | Records of volumes voided and the time of each micturition (day and night) for at least 24 hours |
| Bladder diary | Records of times of micturitions, voided volumes, incontinence episodes, pad usage, and other information, such as fluid intake, the degree of urgency, and the degree of incontinence |
| Daytime frequency | The number of voids recorded during waking hours, including the last void before sleep and the first void after waking and rising in the morning |
| 24-hour frequency | The total number of daytime voids and episodes of nocturia during a specified 24-hour period |
| 24-hour production | All urine produced during 24 hours |
| Maximum voided volume | The largest volume of urine voided during a single micturition, as determined either from the frequency/volume chart or the bladder diary |
| Pad testing | The amount of urine lost during incontinence episodes (comparison of a short provocative test to a 24-hour pad test) |

| | |
|---|---|
| Improvement in incontinence | Reduction frequency and severity of incontinence episodes<br>Reduction in restrictions of daily activities due to incontinence |
| Progression of incontinence | Increase in frequency and severity of incontinence episodes<br>Increase in restrictions of daily activities because of incontinence<br>Continence not achieved<br>No reduction in the frequency and severity of incontinent episodes |

## Harms

Adverse events resulting from drugs
Adverse events resulting from nonpharmacological treatments

## Settings

Primary care clinic
Specialized clinic (nurse practitioners)
Cointerventions as reported in the studies

## Definition of Terms

The first step is to define what is meant by the term "incontinence," which has many different implications for different groups of patients. Treating incontinence as a universal construct may impede understanding of the condition and its treatment. For example, incontinence in younger women occurs most likely because of pelvic floor failure, whereas in frail older persons it is often the result of problems with mobility or intellectual performance.

Definitions of urinary incontinence:

| Variable | Definition |
|---|---|
| Symptoms of urinary incontinence[2] | Any involuntary leakage of urine |
| Signs of urinary incontinence | Urine leakage seen during physical examination; this leakage may be urethral or extraurethral |
| Extra-urethral incontinence | Urine leakage occurring through channels other than the urethra |
| Uncategorized incontinence | Involuntary urine leakage that cannot be classified into any of the categories listed above on the basis of signs and symptoms |
| Transient urinary incontinence[3,4] | Potentially reversible incontinence resulting from conditions that may resolve if the underlying cause is managed: delirium/confusional state; urinary tract infection (symptomatic); atrophic urethritis/vaginitis; use of pharmaceuticals; psychological conditions, especially depression; excessive urine output related to another medical condition (e.g., congestive heart failure, hyperglycemia); restricted mobility; stool impaction |
| Established urinary incontinence[3,4] | Urinary incontinence that is attributed to bladder or urethral dysfunction, such as: detrusor overactivity; detrusor underactivity; urethral obstruction; urethral incompetence |
| Stress urinary incontinence | Involuntary urine leakage on physical exertion or effort or with sneezing or coughing |
| Urgency UI[5] | Involuntary leakage accompanied by or immediately preceded by urgency |
| Overflow incontinence[6] | Urinary incontinence associated with: bladder overdistention; a contractile detrusor; hypotonic or underactive detrusor, occurring secondarily to drugs, fecal impaction, diabetes, lower spinal cord injury, or disruption of the motor innervation of the detrusor muscle |
| Mixed urinary incontinence[1,2] | Involuntary leakage associated with urgency and also with exertion, effort, sneezing, or coughing |
| Situational urinary incontinence | Incontinence during sexual intercourse or when giggling |
| Continuous urinary leakage | Continuous urinary leakage |
| Acute incontinence[7] | Sudden onset of symptoms related to an illness, treatment, or medication |
| Chronic incontinence | Persistent urinary incontinence, including disorders of storage (stress and urgency) and of emptying (overflow) and functional and mixed incontinence |

| Variable | Definition |
|---|---|
| Severity of incontinence | Measured as incontinent episodes/unit time; pad changes/unit time; pad weight/unit time; number of micturitions/unit time; urine loss on a pad test<br><br>Also indicated by urodynamically diagnosed detrusor overactivity; urodynamic stress incontinence |
| Sandvik's severity index[8] | Multiplied reported frequency (4 levels) by the amount of leakage (2 levels). |
| Slight incontinence | Leakage of drops a few times a month (~6 g/24 hours, 95% confidence interval 2–9) |
| Moderate incontinence | Daily leakage or drops (~17 g/24 hours, 95% confidence interval 13–22) |
| Severe incontinence | Leakage of large amount of urine at least once a week (~56 g/24 hours, 95% confidence interval 44–67) |

We prioritized clinical outcomes and measure of quality of life following the FDA guideline for UI[9]

| Endpoint | Potential Advantages | Potential Disadvantages |
|---|---|---|
| 1-Hour Pad Weight Test<br>(Amount of urine leakage experienced by the subject in 1 hour during a standardized series of activities or exercises in the investigator's office) [2] | * Objective<br>* Standardized<br>* Assesses severity of urine leakage | * Outcomes other than dryness may not be meaningful to patients<br>* Not correlated with patients' daily activities<br>* Poor to moderate sensitivity<br>* Subject to variability |
| 24-Hour Pad Weight Test<br>(Amount of urine leakage experienced by the subject at home during a 24-hour period; all pads used during the test period are weighed before and after use) | * Objective<br>* Correlated with patients' daily activities<br>* High sensitivity<br>* Assesses severity of urine leakage | * Outcomes other than dryness may not be meaningful to patients<br>* Less standardized<br>* Subject to variability<br>* Requires patient compliance |
| Number of Incontinence Episodes/Day<br>(Obtained using a voiding diary) | * Objective<br>* Meaningful to patients<br>* Correlated with patients' daily activities | * May not directly correlate with the severity of urine leakage<br>* Less standardized<br>* Subject to variability<br>* Requires patient compliance |
| Number of Pads Used/Day<br>(Obtained using a voiding diary) | * Objective<br>* Meaningful to patients<br>* Correlated with patients' daily activities | * May not directly correlate with the severity of urine leakage<br>* Less standardized<br>* Subject to variability<br>* Requires patient compliance |
| Quality of Life<br>(Assessed using a validated questionnaire) | * Meaningful to patients<br>* Standardized<br>* Patient's daily activities taken into account | * Significant placebo effect<br>* Subjective<br>* Subject to variability<br>* Not correlated with the severity of urine leakage |
| Urodynamics Measure<br>(Measurement such as leak point pressure, cystometric outcome, etc.) | * Objective<br>* Standardized<br>* Less subject to variability | *Not Meaningful to patients<br>* Not correlated with patients' daily activities |

# Refinement of the questions following PICOS framework

| Question | Population | Intervention (Independent Variable) | Comparator | Outcomes (dependent variables) | Settings |
|---|---|---|---|---|---|
| What constitutes an adequate diagnostic evaluation on which to base treatment of UI?<br>Are there validated tools to distinguish stress from urge incontinence in primary care?<br>Do validated tools to distinguish stress from urge incontinence in primary care make a clinical difference in response to treatment? | Adult and elderly women with symptoms of UI | Questionnaires<br>Checklists and scales<br>Self reported UI during clinical exam<br>Provocation stress test<br>Frequency volume chart<br>Pad tests<br>Paper towel test<br>Ultrasound | Gold standard: multichannel urodynamics;<br>Diary | Diagnostic value of the tests, validity of questionnaires for any, stress, urgency, mixed UI<br>Patient outcomes | Primary Care<br>Specialized on UI clinic (nurse practitioners) |
| How effective is pharmacologic treatment of UI?<br>Do medication interventions with their adverse drug reactions make QoL sense vs. pads?<br>Do medications have evidence of clinical benefit in the treatment of patients with incontinence?<br>Are there clinical predictors of response to the (above) interventions? | Adult and elderly women with diagnosed UI<br>Patient adherence and overcoming of barriers<br>Clinical predictors of the effects :<br>Patient age, comorbities, baseline disease/condition for UI | Detrol (tolterodine tartrate), Ditropan (oxybutynin chloride), Sanctura (trospium chloride), Enablex (darifenacin), and Vesicare (solifenacin succinate).<br>- Other tested therapy: botulinum toxin injections, tricyclic antidepressant imipramine hydrochloride | Placebo<br><u>Comparative effectiveness with:</u><br>Active pharmacological treatment<br>Education<br>Behavioral therapy<br>Biofeedback<br>Bladder retraining (“Kegel exercises”)<br>Electrical stimulation<br>Pads<br>Urethral "plugs" and pessaries in females | Continence<br>Quality of life<br>Improvement in frequency and severity of incontinence<br>Adverse effects<br>Differences in outcomes among subgroups of patients with different categories of the predictor (interaction models)<br>Level of outcomes in subgroups of patients with different levels of predictors (subgroup analyses) | Primary Care<br>Specialized on UI clinic (nurse practitioners) |
| How effective is non-pharmacologic treatment of UI?<br>Do any of the | Adult and elderly women with diagnosed UI<br>Patient adherence | Education<br>Behavioral therapy<br>Biofeedback<br>Bladder retraining | No active treatment<br><u>Comparative effectiveness with:</u><br>Pharmacological | Continence<br>Quality of life<br><br>Improvement in frequency and severity of | Primary Care<br>Specialized on UI clinic (nurse practitioners) |

| Question | Population | Intervention (Independent Variable) | Comparator | Outcomes (dependent variables) | Settings |
|---|---|---|---|---|---|
| following have evidence of clinical benefit in the treatment of patients with incontinence: Kegel exercises<br>Minimally invasive techniques (e.g. collagen injection, etc.)<br>Pessary<br>Are there clinical predictors of response to the (above) interventions? | and overcoming of barriers<br>Clinical predictors of the effects :<br>Patient age, comorbities, baseline disease/ condition for UI | ("Kegel exercises")<br>External electrical stimulation (tibial nerve stimulation<br>Urethral "plugs" and pessaries in females<br>Collagen injection devices | treatment<br>Other nonpharmacological treatments | incontinence<br>Adverse effects<br>Differences in outcomes among subgroups of the patients with different categories of the predictor (interaction models)<br>Level of outcomes in subgroups of patients with different levels of predictors (subgroup analyses) | |

Data Synthesis

For question 1 we calculated diagnostic values of different tests to diagnose incontinence:
Sensitivity=TP/(TP+FN)
Specificity=TN/(FP+TN)
Prevalence=(TP+FN)/(TP+FN+FP+TN)
Predictive value positive=TP/(TP+FP)
Positive predictive likelihood ratio:

$$\frac{\text{probability of an individual } \textbf{with} \text{ the condition having a positive test}}{\text{LR+ = probability of an individual } \textbf{without} \text{ the condition having a positive test}}$$

$$\text{LR+} = \frac{\text{sensitivity}}{\text{1-specificity}}$$

Clinical interpretations of likelihood ratios[10]

| LR | Interpretation |
|---|---|
| **> 10** | Large and often conclusive increase in the likelihood of disease |
| **5 - 10** | Moderate increase in the likelihood of disease |
| **2 - 5** | Small increase in the likelihood of disease |
| **1 - 2** | Minimal increase in the likelihood of disease |
| **1** | **No change in the likelihood of disease** |
| **0.5 - 1.0** | Minimal decrease in the likelihood of disease |
| **0.2 - 0.5** | Small decrease in the likelihood of disease |
| **0.1 - 0.2** | Moderate decrease in the likelihood of disease |
| **< 0.1** | Large and often conclusive decrease in the likelihood of disease |

Algorithms of meta-analysis[11]

Pooled estimate as a weighted average:

$$\theta_{IV} = \frac{\sum_i w_i \theta_i}{\sum_i w_i}$$

Weights are inverse of variance (standard error):

$$w_i = \frac{1}{SE(\theta_i)^2}$$

Standard error of pooled estimate:

$$SE(\theta_{IV}) = \frac{1}{\sqrt{\sum_i w_i}}$$

Heterogeneity (between-study variability) measured by:

$$Q = \sum_i w_i (\theta_i - \theta_{IV})^2$$

Assumptions for random effects model: true effect sizes *qi* have a normal distribution with mean *q* and variance *t2*; *t2* is the between-study variance

Between study variance:

$$\tau^2 = \frac{Q - (k-1)}{\sum_i w_i - \left( \frac{\sum_i w_i^2}{\sum_i w_i} \right)}$$

Where:

*wi* are the weights from the fixed effect inverse-variance method

*Q* is the heterogeneity test statistic from before (either from inverse-variance method or Mantel-Haenszel method)

*k* is the number of studies, and

*t2* is set to zero if *Q*<*k*-1

Random effect pooled estimate is weighted average:

$$\theta_{DL} = \frac{\sum_i w'_i \theta_i}{\sum_i w'_i}$$

Weights used for the pooled estimate are similar to the inverse-variance, but now incorporate a component for between-study variation:

$$w'_i = \frac{1}{SE(\theta_i)^2 + \tau^2}$$

Standard error of pooled estimate

$$SE(\theta_{DL}) = \frac{1}{\sqrt{\sum_i w'_i}}$$

Meta regression with random effects was obtained using aggregate level data.

Additive component of variance tau2 was estimated:

y[i] = a + B*x[i] + u[i] + e[i],

where u[i] is a normal error (standard deviations that may vary across units), e[i] is a normal error with variance tau2 to be estimated, assumed equal across units.
t-distribution was used calculating p-values and confidence intervals[12,13]
Attributable risk was calculated as the outcome events rate in patients exposed to different clinical interventions[14-16]
Attributable risk of the outcome = rate of events in patients in the control group x (relative risk -1)

Number needed to treat to prevent one event of incontinence was calculated as reciprocal to absolute risk differences in rates of outcomes events in the active and control groups:[15,17]
1/(control group event rate - treatment group event rate).

The number of avoided or excess events (respectively) per 1000 population is the difference between the two event rates multiplied by 1000:

(control group event rate - treatment group event rate)*1000

## Pharmacological treatments for UI

**Table. Drugs that have been examined in women with urinary incontinence[9]**

| Drug Name | Active Ingredients | Dose | Dosage Form/Route |
|---|---|---|---|
| **Labeled for UI** | | | |
| DETROL | TOLTERODINE TARTRATE | 1MG | TABLET; ORAL |
| DETROL | TOLTERODINE TARTRATE | 2MG | TABLET; ORAL |
| DETROL LA | TOLTERODINE TARTRATE | 2MG | CAPSULE, EXTENDED RELEASE; ORAL |
| DETROL LA | TOLTERODINE TARTRATE | 4MG | CAPSULE, EXTENDED RELEASE; ORAL |
| OXYTROL | OXYBUTYNIN | 3.9MG/24HR | FILM, EXTENDED RELEASE; TRANSDERMAL |
| GELNIQUE | OXYBUTYNIN CHLORIDE | 10%(100MG/ PACKET) | GEL; TRANSDERMAL |
| DITROPAN XL | OXYBUTYNIN CHLORIDE | 5MG | TABLET, EXTENDED RELEASE; ORAL |
| DITROPAN XL | OXYBUTYNIN CHLORIDE | 10MG | TABLET, EXTENDED RELEASE; ORAL |
| DITROPAN XL | OXYBUTYNIN CHLORIDE | 15MG | TABLET, EXTENDED RELEASE; ORAL |
| DITROPAN | OXYBUTYNIN CHLORIDE | 5MG | TABLET; ORAL |
| SANCTURA | TROSPIUM CHLORIDE | 20MG | TABLET; ORAL |
| SANCTURA XR | TROSPIUM CHLORIDE | 60MG | CAPSULE, EXTENDED RELEASE; ORAL |
| ENABLEX | DARIFENACIN HYDROBROMIDE | EQ 7.5MG BASE | TABLET, EXTENDED RELEASE; ORAL |
| ENABLEX | DARIFENACIN HYDROBROMIDE | EQ 15MG BASE | TABLET, EXTENDED RELEASE; ORAL |

| Drug Name | Active Ingredients | Dose | Dosage Form/Route |
|---|---|---|---|
| VESICARE | SOLIFENACIN SUCCINATE | 5MG | TABLET; ORAL |
| VESICARE | SOLIFENACIN SUCCINATE | 10MG | TABLET; ORAL |
| TOVIAZ | FESOTERODINE FUMARATE | 4MG | TABLET, EXTENDED RELEASE; ORAL |
| TOVIAZ | FESOTERODINE FUMARATE | 8MG | TABLET, EXTENDED RELEASE; ORAL |
| **Off label use** | | | |
| BOTOX | Botulinum Toxin Type A | 100U/VIAL | VIAL; SINGLE-USE |
| CYMBALTA | DULOXETINE HYDROCHLORIDE | EQ 20MG BASE | CAPSULE, DELAYED REL PELLETS; ORAL |
| CYMBALTA | DULOXETINE HYDROCHLORIDE | EQ 30MG BASE | CAPSULE, DELAYED REL PELLETS; ORAL |
| CYMBALTA | DULOXETINE HYDROCHLORIDE | EQ 60MG BASE | CAPSULE, DELAYED REL PELLETS; ORAL |
| IMIPRAMINE HYDROCHLORIDE | IMIPRAMINE HYDROCHLORIDE | 50MG | TABLET; ORAL |
| PREMARIN | ESTROGENS, CONJUGATED | 0.625MG/GM | CREAM; TOPICAL, VAGINAL |
| SYNTHETIC CONJUGATED ESTROGENS A | ESTROGENS, CONJUGATED SYNTHETIC A | 0.625MG/GM | CREAM; VAGINAL |

Pharmacological classification of the drugs for UI that was used by the l4th International Consultation on Incontinence[18] served as a guide to synthesize comparative effectiveness and harms from available treatments.

**Drug therapy for stress urinary incontinence**[18]

## SEROTONIN-NORADRENALINE UPTAKE INHIBITORS

Duloxetine
Imipramine

## ESTROGENS

Estrogen topical

***Drugs used in the treatment of OAB/ DO***[1:]

**Antimuscarinic drugs**

Tolterodine
Trospium
Solifenacin
Darifenacin
Fesoterodine
Propantheline

**Drugs with mixed actions**

Oxybutynin
Propiverine
Flavoxate

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# Appendix E. Abstraction Forms

## Data Abstraction Form for Question 1
## What constitutes an adequate diagnostic evaluation in the primary care setting on which to base treatment of UI?

(Complete for each study)

---

Number of the study in the database (PubMed ID, Cochrane accession number, ISBN)_____
First author_____
Year of the publication_____
Purpose/aim of study_____
Sponsorship_____

Conflict of interest_____

Design of the study (check one)
☐ prospective cohort
☐ retrospective cohort
☐ cross-sectional
☐ descriptive study
☐ case-control
☐ case-series
☐ randomized controlled clinical trial
☐ not randomized clinical interventions
☐ other (specify)

**Population variables** (target population)

Data source for population variables (define) _____
Recruitment_____
Consent _____

**Settings:**
Community (general population)_____
Primary clinic_____
Specialized clinic_____

**Location:**
Country _____
Urban _____
Rural _____

**Subjects:**
**Race**
Define _____
African Continental Ancestry Group, %_____
Asian Continental Ancestry Group, %_____
European Continental Ancestry Group, %_____
**Ethnicity:**
Define _____
African Americans, %_____
Arabs, %_____
Asian Americans, %_____
Hispanic Americans, %_____
**Age:**
Mean age, years_____ Standard deviation_____
Age intervals:_____

**Health status**
Primary Health Condition, Diagnosis _____
Sample size:

**Sampling strategy:**
Random _____
Self-selected _____
Inclusion criteria:_____

**Incontinence (dependent variable)**
Definition of incontinence _____
Urinary_____
Combined_____

"Gold standard" to detect urinary incontinence used in the article_____

**Multichannel urodynamics cut points of continence**
- Maximal urethral pressure (MUP)_____
- Functional urethral length (FUL)_____
- Maximal cystometric capacity (MCC)_____
- Abdominal leak point pressure (ALPP)_____

**Index diagnostic tests for urinary incontinence:**
Define_____
Cut points of continence_____

**Clinical history**
Nature _____
Duration _____
Symptoms and their severity _____
Symptom bothersomeness or impact _____
Functional and mental status _____
Medical, surgical and gynecological history _____
Exacerbating factors: diet, fluid, and medications _____

**Diagnostic tests for urinary incontinence:**
Provocation stress test_____
Frequency volume chart_____
Post-void residual volume (PVR)_____
Distal Urethral Electrical Conductance test_____
Pad tests_____
Paper towel test_____
Ultrasound_____
Q-Tip test_____

Questionnaire _____
Scales_____
Define_____

**For each test provide comparison with "gold standard":**
True positives_____
False positives_____
False negatives_____
True negatives
Sensitivity, % _____
Specificity, % _____

**Reliability**:
Cronbach alpha _____
Kappa statistics _____
Correlation coefficients _____

**Inter-observer variability_____**

Level of evidence of the individual study (check one)

Interventions:
☐ I Well-designed randomized controlled trial
☐ II-1A Well-designed controlled trial with pseudo-randomization
☐ I-1B Well-designed controlled trial without randomization

Observational studies
☐ I-2A Well-designed cohort (prospective) study with concurrent controls
☐ I-2B Well-designed cohort (prospective) study with historical controls
☐ II-2C Well-designed cohort (retrospective) study with concurrent controls
☐ II-3 Well-designed case-controlled (retrospective) study
☐ III Large differences from comparisons between times and/or places
☐ IY Opinion of respected authorities based in clinical experience

## Data Abstraction Form for Questions 2 and 3
## How effective is the pharmacologic treatment of UI?
## How effective is the nonpharmacologic treatment of UI?

(Complete for each study)

---

Number of the study in the database (PubMed ID, Cochrane accession number, ISBN) _____
First author_____
Year of the publication _____
Purpose/aim of study _____
Sponsorship_____

Conflict of interest_____

Design of the study (check one)
☐ prospective cohort
☐ retrospective cohort
☐ cross-sectional
☐ descriptive study
☐ case-control
☐ case-series
☐ randomized controlled clinical trial
☐ not randomized clinical interventions
☐ other (specify)

Length of intervention_____
Length of followup_____

**Population variables** (target population)
Recruitment of the subjects

**Settings**
Community (general population)_____
Primary care_____
Specialized clinic_____

**Subjects**
**Race**
African Continental Ancestry Group, %_____
Asian Continental Ancestry Group, %_____
European Continental Ancestry Group, %_____
**Ethnicity**
African Americans, %_____
Arabs, %_____
Asian Americans, %_____
Hispanic Americans, %_____
**Age**_____
**Health status**_____
**Sample size:**_____
Inclusion criteria _____
Exclusion criteria _____
Loss of followup _____

**Incontinence (dependent variable)**

1. Provide the definition of urinary incontinence used in the article.
2. Provide the data source to measure incontinence.
3. Mark how the outcome was reported.

/*Complete with values reported in article with page number in articles where data was extracted for quality control*/
/*Add as many lines for categories as necessary*/
/*Median is calculated when ranges only reported assuming normal distribution*/
/*Increment is analyzed when regression coefficients only reported*/
/*Provide means and standard deviation (95% CI) when reported*/

**Methods to assess urinary incontinence:**
Self report_____
Medical diagnosis_____
Medical procedure_____

**Urinary Incontinence, Incidence**
Define _____
**Symptoms**_____
Signs_____
Acuity_____
Severity_____
Length_____
Bothersomeness_____

**Urinary Incontinence, Progression**
Define _____
Symptoms_____
Signs_____
Acuity_____
Severity_____
Frequency_____

**Urinary Continence**
Define _____
Dependent Continence_____
Independent Continence_____

**Clinical Interventions (independent variables)**
Provide the definition of each variable used in the article.
For drug and devices: Manufacturing company with the address, trade name

**Health Education**
Define _____
**Behavioral Therapy**
Define_____
Education _____
Development of individualized diaries of daily dietary, physical activities, urinary habits
Development of individualized voiding schedules
Voiding schedules: prompted, timed, habit retraining
Patterned urge response toileting
Dose of intervention:
Length of therapy_____
Intensity of therapy, section number _____

**Biofeedback**
Define_____
Dose of intervention:
Length of therapy_____
Intensity of therapy _____
Monitoring device_____

**Pelvic Floor Muscle Training**
Define_____
Dose of intervention:
Length of training_____ Intensity of training _____

**Weight Loss**
Define _____
Dose of intervention:
Length of therapy_____
Intensity of therapy _____

**Diet Therapy**
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

**Vaginal Cones**
Define _____

**Electrical Stimulation**
Define_____
Dose of intervention:
Length of therapy_____
Intensity of therapy _____

**Inserts Urethral Patch or Urethral Insert**
Define_____

**Vaginal Pessary**
Define_____

**Detrol** (tolterodine tartrate)
Define_____
Dose of intervention:
Length of therapy_____
Dose _____

**Ditropan**
Define _____
Dose of intervention:
Length of therapy_____
Dose _____

**Sanctura** (trospium chloride)
Define_____
Dose of intervention:
Length of therapy_____
Dose _____

**Enablex (**darifenacin)
Define_____
Dose of intervention:
Length of therapy_____
Dose _____

**Vesicare** (solifenacin succinate)
Define_____
Dose of intervention:
Length of therapy_____
Dose _____

**Botulinum Toxin Injections**
Define _____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

**Oral Estrogen Therapy**
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

**Topical Estrogen Therapy**
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

**Magnetic Stimulation**
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

**Urethral Bulking Procedures**
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

| Intervention | Control | Outcomes Definition | Number in Active | Number in Control | Outcome Level in Active Group | Outcome Level in Control Group | Events in Active Group | Events in Control Group | Relative Risk, 95% CI | Absolute Risk Difference, 95% CI |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Urinary in-continence | | | | | | | | |

**Quality of the studies:**
For clinical trials
Random allocation ☐ Yes ☐ No
Intention to treat:
☐ Yes ☐ No ☐ not stated but all subjected included in analysis

**Masking of treatment status:**
Double blind _____
Single blind _____
Open label _____

**Randomization regime**_____
Adequate: computer-generated random numbers or random numbers tables
Inadequate: alternation, case record numbers, birth dates, or days of the week

**Adequacy of randomization**_____
Baseline data not reported_____
Baseline data confirmed the adequacy of randomization_____

**Allocation concealment _____**
Not reported_____
Adequate_____
Not adequate_____
Adequate approaches to concealment of allocation:
Centralized or pharmacy-controlled randomization
Serially-numbered identical containers
On-site computer based system with a randomization sequence that is not readable until allocation
Inferior approaches to concealment of allocation:
Use of alternation
Case record numbers
Birth dates or days of the week
Open random numbers lists
Serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation)

**For observational studies**
Strategies to reduce bias_____
Relevant characteristics of providers_____
Justification for sample size_____

**Level of evidence of the individual study (check one)**
Interventions:
☐ I Well-designed randomized controlled trial
☐ II-1A Well-designed controlled trial with pseudo-randomization
☐ I-1B Well-designed controlled trial without randomization

Observational studies
☐ I-2A Well-designed cohort (prospective) study with concurrent controls
☐ I-2B Well-designed cohort (prospective) study with historical controls
☐ II-2C Well-designed cohort (retrospective) study with concurrent controls
☐ II-3 Well-designed case-controlled (retrospective) study
☐ III Large differences from comparisons between times and/or places
☐ IY Opinion of respected authorities based in clinical experience

# Appendix F. Evidence Tables


Table F1 Grading the level of evidence for clinical outcomes that were examined in RCTs (direct evidence) ..... F-8
Table F2. Review of grey literature ..... F-12
Table F3. Quality Assessment of Diagnostic Accuracy Studies (QUADAS) ..... F-21
Table F4. Eligible studies of diagnostic methods ..... F-24
Table F5. Diagnostic value of symptoms of stress incontinence compared to multichannel urodynamics (“gold standard”) for stress UI ..... F-34
Table F6. Pooled diagnostic value of symptoms of stress incontinence compared to multichannel urodynamics (“gold standard”) for any stress UI ..... F-37
Table F7. Diagnostic value of urge symptoms compared to multichannel urodynamics (“gold standard”) for detrusor overactivity ..... F-38
Table F8. Diagnostic value of urge symptoms compared to multichannel urodynamics (“gold standard”) for pure detrusor overactivity ..... F-41
Table F9. Pooled Diagnostic value of urge symptoms compared to multichannel urodynamics (“gold standard”) for pure detrusor overactivity ..... F-44
Table F10. Diagnostic value of urgency symptoms compared to multichannel urodynamics (“gold standard”) for detrusor overactivity ..... F-45
Table F11. Pooled diagnostic value of urgency symptoms compared to multichannel urodynamics (“gold standard”) for any detrusor overactivity ..... F-48
Table F12. Diagnostic value of urgency symptoms compared to multichannel urodynamics (“gold standard”) for pure detrusor overactivity ..... F-49
Table F13. Pooled diagnostic value of urgency symptoms compared to multichannel urodynamics (“gold standard”) for pure detrusor overactivity ..... F-52
Table F14. Diagnostic value of mixed symptoms compared to multichannel urodynamics (“gold standard”) for mixed UI ..... F-53
Table F15. Pooled Diagnostic value of mixed symptoms compared to multichannel urodynamics (“gold standard”) for mixed UI ..... F-56
Table F16. Diagnostic value of pad test compared to multichannel urodynamics (“gold standard”) for stress UI ..... F-57
Table F17. Pooled Diagnostic value of pad test compared to multichannel urodynamics (“gold standard”) for any stress UI ..... F-60
Table F18. Pooled diagnostic value of pad test compared to multichannel urodynamics (“gold standard”) for any detrusor overactivity ..... F-63
Table F19. Diagnostic value of symptoms compared to clinical diagnosis (“gold standard”) for different types of urinary incontinence ..... F-64
Table F20. Pooled Diagnostic value of symptoms compared to clinical diagnosis (“gold standard”) for any detrusor overactivity ..... F-67
Table F21. Pooled diagnostic value of symptoms compared to clinical diagnosis (“gold standard”) for any stress UI ..... F-70
Table F22. Diagnostic value of mixed symptoms compared to clinical diagnosis (“gold standard”) for mixed UI ..... F-73
Table F23. Diagnostic value of urge symptoms compared to clinical diagnosis for detrusor overactivity ..... F-74
Table F24. Pooled diagnostic value of urge symptoms compared to clinical diagnosis for detrusor overactivity ..... F-77
Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity(DO) (results from individual RCT) ..... F-78

Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies ..... F-87
Table F27. Pharmacological treatments for female UI ..... F-99
Table F28. Quality of the studies that examined pharmacological treatments for UI..... F-199
Table F29. Effects from local estrogen therapy compared to no active treatment..... F-208
Table F30. Continence after topical estrogen treatment compared to no active treatment (individual RCTs) ..... F-209
Table F31. Improvement in incontinence after topical estrogen treatment compared to no active treatment (individual RCTs) ..... F-210
Table F32. Clinical outcomes after topical estrogen therapy compared to no treatment (individual RCTs) ..... F-212
Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies..... F-214
Table F34. Continence after duloxetine vs. placebo, random effects model ..... F-244
Table F35. Continence after different doses of duloxetine ..... F-245
Table F36. Improvement in UI after duloxetine vs. placebo (random effects model)..... F-246
Table F37. Perceived treatment success after different doses of duloxetine ..... F-247
Table F38. Treatment failure after duloxetine vs. placebo (random effects model)..... F-249
Table F39. Adverse effects after duloxetine vs. placebo, random effects model..... F-251
Table F40. Adverse effects after duloxetine treatments compared to placebo (pooled results from RCTs).....F258
Table F41. Outcomes after different doses of duloxetine ..... F-260
Table F42. Adverse effects that result in discontinuation of the treatment after duloxetine vs. placebo, random effects models..... F-272
Table F43. Exploring clinical diversity in discontinuation rates due to adverse effects after duloxetine when compared to placebo..... F-275
Table F44. Exploring heterogeneity in discontinuation rates due to adverse effects after duloxetine compared to placebo (results from meta-regression)..... F-277
Table F45. Exploring methodological diversity in discontinuation rates due to adverse effects after duloxetine compared to placebo..... F-278
Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) ..... F-279
Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported)..... F-314
Table F48. Severity and quality of life after oxybutynin (individual RCTs)..... F-327
Table F49. Domains of quality of life after oxybutynin treatments (individual RCTs)..... F-329
Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) ..... F-331
Table F51. Clinical outcomes after tolterodine vs. placebo in secondary data analyses ..... F-343
Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine..... F-348
Table F53. Clinical outcomes after tolterodine vs. placebo, the results from randomized controlled clinical trials pooled with random effects models ..... F-359
Table F54. Clinical outcomes after darifenacin vs. placebo analyses of individual patient data from RCTs (high level of evidence) ..... F-361
Table F55. Dose response association between clinical outcomes and darifenacin in pooled analyses of individual patient data from RCTs (high level of evidence)..... F-364
Table F56. Significant dose response association with clinical outcomes after darifenacin (individual RCTs) ..... F-366
Table F57. Clinical outcomes after solifenacin vs. placebo, pooled individual patient data from RCTs (high level of evidence)..... F-367
Table F58. Evidence of dose response association in clinical outcomes after solifenacin 5 vs. 10mg/day (pooled individual patient data from RCTs) ..... F-369
Table F59. Results from VIBRANT trial..... F-370

Table F60. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses ... F-371
Table F61. Significant dose response effects of fesoterodine ... F-376
Table F62. Clinical outcomes after fesoterodine vs. placebo ... F-377
Table F63. Clinical outcomes after propiverine vs. placebo, individual RCTs ... F-378
Table F64. Clinical outcomes after botulinum toxin vs. placebo, individual RCTs Table ... F-379
Table F65. Quality of life after botulinum toxin vs. placebo, individual RCTs ... F-380
Table F66. Outcomes after intravesical 100ml of 50nM-single dose injection of resiniferatoxin vs. placebo, individual RCTs ... F-381
Table F67. Outcomes after nimodipine, 60mg/day, vs. placebo, individual RCT ... F-382
Table F68. Comparative effectiveness of local estrogen therapy ... F-383
Table F69. Comparative effectiveness of estrogen topical treatments (individual RCTs) ... F-384
Table F70. Adverse effects of pharmacological treatments for UI when compared to each other ... F-385
Table F71. Dry mouth after pharmacological treatments for UI when compared to each other ... F-387
Table F72. Constipation after pharmacological treatments for UI when compared to each other ... F-391
Table F73. Discontinuation due to adverse effects after pharmacological treatments for UI when compared to each other ... F-393
Table F74. Comparative effectiveness of drugs on continence ... F-395
Table F75. Comparative effectiveness of oxybutynin vs. tolterodine (secondary data analyses using individual patient data from RCTs) ... F-396
Table F76. Comparative effectiveness of drugs on improved UI ... F-399
Table F77. Comparative effectiveness of tolterodine-ER 4mg/day vs. fesoterodine, evidence secondary data analysis ... F-400
Table F78. Improvement in UI after pharmacological treatments for UI ... F-403
Table F79. Blurred vision after pharmacological treatments for UI when compared to each other ... F-404
Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI ... F-405
Table F81. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI ... F-442
Table F82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI ... F-450
Table F83. Comparative effectiveness of nonpharmacological treatments on improvement of incontinence ... F-465
Table F84. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials ... F-467
Table F85. Clinical outcomes after bladder training compared to no active treatment (results from RCTs pooled with random effects models) ... F-472
Table F86. Improvement in UI after nonpharmacological treatments compared to no active treatment ... F-473
Table F87. Clinical outcomes after pelvic floor muscle training compared to no active treatment (results from RCTs pooled with random effects models) ... F-474
Table F88. Clinical outcomes after pelvic floor muscle training combined with bladder training compared to no active treatment (results from RCTs pooled with random effects models) ... F-476
Table F89. Clinical outcomes after pelvic floor muscle training combined with bladder training when compared to no active treatment, individual RCTs ... F-477
Table F90. Clinical outcomes after nonpharmacological treatments compared to no active treatment ... F-479
Table F91. Scoring of quality of life after pelvic floor muscle training combined with bladder training compared to no active treatment (individual RCT) ... F-481

Table F92. Clinical outcomes after pelvic floor muscle training combined with biofeedback compared to no active treatment (results from RCTs pooled with random effects models) ..... F-482
Table F93. Scoring of quality of life after pelvic floor muscle training with biofeedback using vaginal EMG probe compared to no active treatment (individual RCT)..... F-483
Table F94. Continence after supervised pelvic floor muscle training when compared to no active treatment, individual RCTs ..... F-484
Table F95. Scoring of quality of life after supervised pelvic floor muscle training compared to no active treatment (individual RCTs)..... F-485
Table F96. Clinical outcomes after electrical intravaginal stimulation compared to no active treatment (results from RCTs pooled with random effects models)..... F-486
Table F97. Clinical outcomes after electrical stimulation compared to no active treatments, results from individual RCT ..... F-488
Table F98. Clinical outcomes after percutaneuous electrical stimulation compared to no active treatment (results from RCTs pooled with random effects models)..... F-489
Table F99. Clinical outcomes after continence service compared to no active treatment (results from RCTs pooled with random effects models)..... F-490
Table F100. Improvement in urinary incontinence after interventions that were implemented by continence specialists when compared to no active treatment, individual RCTs ..... F-491
Table F101. Quality of life after interventions that were implemented by continence specialists when compared to no active treatment, individual RCTs..... F-492
Table F102. Scoring of quality of life after interventions that were implemented by continence specialists when compared to no active treatment, individual RCTs ..... F-455
Table F103. Clinical outcomes after magnetic stimulation compared to no active treatment (results from RCTs pooled with random effects models)..... F-495
Table F104. Pooled analysis of improvement in incontinence after magnetic stimulation when compared to no active treatment, random effects model ..... F-496
Table F105. Scoring of quality of life after magnetic stimulation compared to no active treatment (results from RCTs) ..... F-497
Table F106. Clinical outcomes after vaginal cones compared to no active treatment (results from RCTs pooled with random effects models) ..... F-499
Table F107. Scoring of quality of life after vaginal cones compared to no active treatment (results from individual RCT) ..... F-500
Table F108. Clinical outcomes after weight loss program compared to no active treatment (results from RCTs pooled with random effects models)..... F-501
Table F109. Quality of life after intensive weight loss programs when compared to no active treatment (individual RCTs) ..... F-502
Table F110. Urinary incontinence, treatment failure and discontinuation after intensive weight loss programs when compared to no active treatment, individual RCTs ..... F-503
Table F111. Urinary incontinence after the diet high in soy protein (individual RCT)..... F-504
Table F112. UI after acupuncture compared to no active treatment (results from individual RCTs)..... F-505
Table F113. Scoring of quality of life after acupuncture compared to no active treatment (results from individual RCTs)..... F-506
Table F114. Improvement in incontinence after injection of bulking agents when compared to no active treatment, results from individual RCTs ..... F-507
Table F115. Scoring of quality of life after bulking agent when compared to no active treatment, results from individual RCT ..... F-508
Table F116. Clinical outcomes compared after different nonpharmacological treatments (results from individual RCTs)..... F-509
Table F117. Quality of life scoring after continence program vs. PFMT (individual RCT) ..... F-513

Table F118. Comparative effectiveness of nonpharmacological treatments on continence (insufficient evidence) ..... F-514
Table F119. Clinical outcomes after PFMT combined with bladder training compared to PFMT alone (results from RCTs pooled with random effects models) ..... F-516
Table F120. Clinical outcomes after PFMT combined with bladder training compared to bladder training alone (results from RCTs pooled with random effects models ..... F-517
Table F121. Clinical outcomes after supervised PFMT combined with bladder training compared to self administered PFMT (results from RCTs pooled with random effects models) ..... F-518
Table F122. Improvement in UI rates compared between nonpharmacological treatments ..... F-519
Table F123. Failure rates compared between nonpharmacological treatments ..... F-520
Table F124. Quality of life after supervised vs. self-administered PFMT programs (individual RCTs) ..... F-521
Table F125. Scoring of quality of life after supervised vs. self-administered PFMT programs (individual RCTs) ..... F-522
Table F126. Continence and improvement in incontinence after complex group and individual pelvic floor muscle training programs, individual RCTs ..... F-523
Table F127. Scoring of quality of life after PFMT with biofeedback using vaginal EMG probe when compared to PFMT (individual RCTs) ..... F-525
Table F128. Clinical outcomes after pelvic floor muscle trainings with biofeedback using vaginal EMG probe when compared to pelvic floor muscle trainings, individual RCT ..... F-528
Table F129. Clinical outcomes after PFMT compared to electrical stimulation (results from RCTs pooled with random effects models) ..... F-529
Table F130. Clinical outcomes after PFMT compared to vaginal cones (results from RCTs pooled with random effects models) ..... F-530
Table F131. Scoring of quality of life after PFMT with biofeedback vs. medical devices (individual RCTs) ..... F-531
Table F132. Comparative effectiveness of circular muscle exercises (Paula method) vs. PFMT (individual RCT) ..... F-533
Table F133. Scoring of quality of life after circular muscle exercises (Paula method) vs. PFMT (individual RCTs) ..... F-534
Table F134. Clinical outcomes after circular muscle exercises (Paula method) vs. PFMT (individual RCTs) ..... F-535
Table F135. Comparative effectiveness on quality of life after PFMT vs. active controls (individual RCTs) ..... F-536
Table F136. Scoring of quality of life after PFMT (individual RCTs) ..... F-537
Table F137. Continence after PFMT with personal reminders and self-help guides or different positions during exercise (individual RCTs) ..... F-538
Table F138. Comparative effectiveness of medical devices (individual RCTs) ..... F-539
Table F139. Scoring of quality of life after medical devices compared to active controls (individual RCTs) ..... F-541
Table F140. Comparative effectiveness of medical devices on quality of life (individual RCT) ..... F-542
Table F141. Comparative comfort in using different pads for urinary incontinence (individual RCT) ..... F-543
Table F142. Comparative effectiveness of bulking agents (individual RCTs) ..... F-544
Table F143. Quality of life scores after bulking agents (individual RCTs) ..... F-548
Table F144. Clinical outcomes after bulking agents (individual RCTs) ..... F-549
Table F145. Nonsignificant differences in comparative effectiveness of oxybutynin when compared to nonpharmacological treatments (results from individual randomized controlled clinical trials) ..... F-551
Table F146. Comparative effectiveness of combined therapy with tolterodine ER, 4 mg daily and behavioral intervention with pelvic floor muscle training vs. tolterodine ER, 4 mg

daily monotherapy. Urinary Incontinence Treatment Network: behavior enhances drug reduction of incontinence, (BE-DRI) randomized controlled clinical trial ..... F-552
Table F147. Comparative effectiveness of percutaneous tibial nerve stimulation versus extended-release tolterodine (results from overactive bladder innovative therapy trial) ..... F-553
Table F148. Nonsignificant differences in comparative effectiveness of flexible-dose solifenacin 5/10 mg with and without simplified bladder training in patients with overactive bladder syndrome (results from individual randomized controlled clinical trial) ..... F-554
Table F149. Comparative effectiveness of intravaginal electrical stimulation and trospium hydrochloride in women with overactive bladder syndrome (results from individual randomized controlled clinical trial)..... F-555

## Appendix F. Evidence Figures

Figure F1. Distribution of sample sizes of studies of diagnostic values of tests for UI ..... F-33
Figure F2. Sensitivity of symptoms of stress incontinence compared to multichannel urodynamics (“gold standard”) for any stress UI ..... F-35
Figure F3. Specificity of symptoms of stress incontinence compared to multichannel urodynamics (“gold standard”) for any stress UI ..... F-36
Figure F4. Sensitivity of urge symptoms compared to multichannel urodynamics (“gold standard”) for any detrusor overactivity ..... F-39
Figure F5. Specificity of urge symptoms compared to multichannel urodynamics (“gold standard”) for any detrusor overactivity ..... F-40
Figure F6. Sensitivity of urge symptoms compared to multichannel urodynamics (“gold standard”) for pure detrusor overactivity..... F-42
Figure F7. Specificity of urge symptoms compared to multichannel urodynamics (“gold standard”) for pure detrusor overactivity..... F-43
Figure F8. Sensitivity of urgency symptoms compared to multichannel urodynamics (“gold standard”) for any detrusor overactivity ..... F-46
Figure F9. Specificity of urgency symptoms compared to multichannel urodynamics (“gold standard”) for any detrusor overactivity ..... F-47
Figure F10. Sensitivity of urgency symptoms compared to multichannel urodynamics (“gold standard”) for pure detrusor overactivity..... F-50
Figure F11. Specificity of urgency symptoms compared to multichannel urodynamics (“gold standard”) for pure detrusor overactivity..... F-51
Figure F12. Sensitivity of mixed symptoms compared to multichannel urodynamics (“gold standard”) for mixed UI..... F-54
Figure F13. Specificity of mixed symptoms compared to multichannel urodynamics (“gold standard”) for mixed UI..... F-55
Figure F14. Sensitivity of pad test compared to multichannel urodynamics (“gold standard”) for any stress UI ..... F-58
Figure F15. Specificity of pad test compared to multichannel urodynamics (“gold standard”) for any stress UI ..... F-59
Figure F16. Sensitivity of pad test compared to multichannel urodynamics (“gold standard”) for any detrusor overactivity ..... F-61
Figure F17. Specificity of pad test compared to multichannel urodynamics (“gold standard”) for any detrusor overactivity ..... F-62
Figure F18. Sensitivity of urge symptoms compared to clinical diagnosis (“gold standard”) for any detrusor overactivity ..... F-65
Figure F19. Specificity of urge symptoms compared to clinical diagnosis (“gold standard”) for any detrusor overactivity ..... F-66

Figure F20. Sensitivity of symptoms compared to clinical diagnosis (“gold standard”) for any stress UI ..... F-68
Figure F21. Specificity of symptoms compared to vlinical diagnosis (“gold standard”) for any stress UI ..... F-69
Figure F22. Sensitivity of mixed symptoms compared to clinical diagnosis (“gold standard”) for mixed UI ..... F-71
Figure F23. Specificity of mixed symptoms compared to clinical diagnosis (“gold standard”) for mixed UI ..... F-72
Figure F24. Sensitivity of urge symptoms compared to clinical diagnosis for pure detrusor overactivity ..... F-75
Figure F25. Specificity of urge symptoms compared to clinical diagnosis for pure detrusor overactivity ..... F-76
Figure F26. Gain in quality adjusted life years per 1,000 treated patients ..... F-390

Appendix F. References ..... F-556

**Appendix Table F1. Grading the level of evidence for clinical outcomes that were examined in RCTs (direct evidence)**

| Treatment | Outcome | Studies | Assumed Risk of Bias | Consistency | Statistical Heterogeneity Relative/Absolute Sscale | Precision | Dose Response | Magnitude of the Effect | Evidence |
|---|---|---|---|---|---|---|---|---|---|
| Duloxetine vs. placebo | Continence | 2 | Low | No | NS/Yes | No | NS | Low | Low |
| Duloxetine vs. placebo | Improved UI | 4 | Low | Yes | NS/Yes | Yes | NS | Low | High |
| Duloxetine vs. placebo | Discontinuation due to adverse effects | 9 | Low | Yes | NS/Yes | Yes | Yes | Moderate | High |
| Darifenacin vs. placebo | Improved UI | 3 | Low | Yes | NS/NS | Yes | NS | Low | High |
| Darifenacin vs. placebo | Discontinuation due to adverse effects | 7 | Low | Yes | NS/NS | NA | Yes | Low | High |
| Darifenacin vs. placebo | Discontinuation due to failure | 4 | Low | Yes | NS/NS | NA | NS | Low | Moderate |
| Fesoterodine vs. placebo | Continence | 2 | Low | Yes | Yes/NS | No | | Low | Low |
| Fesoterodine vs. placebo | Improved UI | 4 | Low | Yes | NS/NS | Yes | Yes | Low | High |
| Fesoterodine vs. placebo | Adverse effects | 4 | Low | Yes | Yes/NS | Yes | Yes | Low | High |
| Fesoterodine vs. placebo | Discontinuation due to adverse effects | 6 | Low | Yes | NS/Yes | Yes | Yes | Moderate | High |
| Fesoterodine vs. placebo | Discontinuation due to failure | 4 | Low | No | NS/Yes | NA | | Low | Moderate |
| Oxybutynin vs. placebo | Continence | 5 | Low | Yes | NS/NS | Yes | | Low | High |
| Oxybutynin vs. placebo | Improved UI | 12 | Low | No | Yes/Yes | No | Yes | Low | Moderate |
| Oxybutynin vs. placebo | Discontinuation due to adverse effects | 6 | Low | Yes | NS/NS | Yes | Yes | Low | High |
| Propiverine vs. placebo | Continence | 2 | Medium | Yes | NS/NS | No | | Low | Low |
| Propiverine vs. placebo | Improved UI | 3 | Medium | Yes | NS/NS | Yes | | Low | Moderate |

**Appendix Table F1. Grading the level of evidence for clinical outcomes that were examined in RCTs, (direct evidence) (continued)**

| Treatment | Outcome | Studies | Assumed Risk of Bias | Consistency | Statistical Heterogeneity Relative/Absolute Sscale | Precision | Dose Response | Magnitude of the Effect | Evidence |
|---|---|---|---|---|---|---|---|---|---|
| Propiverine vs. placebo | Discontinuation due to adverse effects | 2 | Medium | Yes | NS/NS | Yes | | Moderate | Low |
| Solifenacin vs. placebo | Continence | 5 | Low | Yes | NS/Yes | Yes | Yes | Low | High |
| Solifenacin vs. placebo | Improved UI | 2 | Low | Yes | Yes/NS | No | | Low | Low |
| Solifenacin vs. placebo | Adverse effects | 4 | Low | Yes | Yes/Yes | Yes | Yes | Low | High |
| Solifenacin vs. placebo | Discontinuation due to adverse effects | 8 | Low | Yes | NS/NS | Yes | Yes | Low | High |
| Solifenacin vs. placebo | Discontinuation due to failure | 4 | Low | No | NS/NS | NA | | Low | Moderate |
| Tolterodine vs. placebo | Continence | 4 | Low | Yes | NS/NS | Yes | | Low | High |
| Tolterodine vs. placebo | Improved UI | 8 | Low | Yes | Yes/Yes | Yes | | Low | High |
| Tolterodine vs. placebo | Adverse effects | 12 | Low | Yes | NS/NS | Yes | | Low | High |
| Tolterodine vs. placebo | Discontinuation due to adverse effects | 13 | Low | No | NS/NS | NA | | Low | High |
| Tolterodine vs. placebo | Discontinuation due to failure | 5 | Low | No | NS/NS | NA | | Low | High |
| Trospium vs. placebo | Continence | 4 | Low | Yes | NS/NS | Yes | | Low | High |
| Trospium vs. placebo | Improved UI | 2 | Low | Yes | NS/Yes | NA | | Low | Low |
| Trospium vs. placebo | Adverse effects | 5 | Low | Yes | Yes/NS | Yes | | Low | Moderate |
| Trospium vs. placebo | Discontinuation due to adverse effects | 6 | Low | Yes | NS/NS | Yes | | | High |
| Fesoterodine vs. tolterodine | Continence | 2 | Medium | Yes | NS/NS | Yes | | Low | Low |
| Fesoterodine vs. tolterodine | Improved UI | 4 | Low | Yes | NS/NS | No | | Low | High |

**Appendix Table F1. Grading the level of evidence for clinical outcomes that were examined in RCTs, (direct evidence) (continued)**

| Treatment | Outcome | Studies | Assumed Risk of Bias | Consistency | Statistical Heterogeneity Relative/Absolute Sscale | Precision | Dose Response | Magnitude of the Effect | Evidence |
|---|---|---|---|---|---|---|---|---|---|
| Fesoterodine vs. tolterodine | Discontinuation due to adverse effects | 4 | Low | Yes | NS/NS | No | | Low | Moderate |
| Oxybutynin vs. tolterodine | Improved UI | 3 | Low | No | NS/NS | NA | | Low | Moderate |
| Oxybutynin vs. tolterodine | Discontinuation due to adverse effects | 10 | Low | Yes | Yes/Yes | Yes | | Low | High |
| Solifenacin vs. tolterodine | Discontinuation due to adverse effects | 4 | Low | No | NS/NS | NA | | Low | Moderate |
| Trospium vs. oxybutynin | Discontinuation due to adverse effects | 2 | Low | No | NS/NS | NA | | Low | Low |
| Bladder training vs. no active treatment | Improved UI | 2 | Medium | Yes | NS/NS | Yes | | High | Low |
| Continence service vs. no active treatment | Continence | 3 | Medium | Yes | NS/Yes | NA | | Moderate | Moderate |
| Continence service vs. no active treatment | Improved UI | 2 | Medium | Yes | Yes/Yes | NA | | Moderate | Low |
| Electrical stimulation vs. no active treatment | Continence | 9 | Low | Yes | NS/NS | Yes | | Moderate | High |
| Electrical stimulation vs. no active treatment | Improved UI | 8 | Low | Yes | NS/NS | Yes | | Moderate | High |
| Magnetic stimulation vs. no active treatment | Improved UI | 3 | Medium | Yes | NS/NS | Yes | | High | Moderate |
| Magnetic stimulation vs. no active treatment | Continence | 3 | Medium | No | NS/NS | NA | | Low | Moderate |
| Percutaneous electrical stimulation vs. no active treatment | Improved UI | 2 | Medium | Yes | NS/NS | Yes | | Low | Low |
| PFMT vs. no active treatment | Continence | 10 | Medium | Yes | Yes/Yes | Yes | | High | High |

**Appendix Table F1. Grading the level of evidence for clinical outcomes that were examined in RCTs, (direct evidence) (continued)**

| Treatment | Outcome | Studies | Assumed Risk of Bias | Consistency | Statistical Heterogeneity Relative/Absolute Sscale | Precision | Dose Response | Magnitude of the Effect | Evidence |
|---|---|---|---|---|---|---|---|---|---|
| PFMT vs. no active treatment | Improved UI | 6 | Medium | Yes | Yes/Yes | Yes | | High | High |
| PFMT + bladder training vs. no active treatment | Improved UI | 4 | Medium | Yes | Yes/Yes | Yes | | High | High |
| PFMT with biofeedback vs. no active treatment | Continence | 2 | Medium | No | NS/Yes | NA | | High | Low |
| PFMT with biofeedback vs. no active treatment | Improved UI | 4 | Medium | Yes | Yes/Yes | NA | | High | High |
| PFMT with bladder training vs. no active treatment | Continence | 5 | Medium | Yes | Yes/Yes | Yes | | Moderate | High |
| Weight Loss vs. no active treatment | Improved UI | 2 | Medium | Yes | NS/NS | Yes | | High | Moderate |
| PFMT + bladder training vs. bladder training | Continence | 3 | Medium | Yes | NS/NS | NA | | Low | High |
| PFMT + bladder training vs. no active treatment | Improved UI | 4 | Medium | Yes | Yes/Yes | Yes | | High | High |
| PFMT vs. electrical stimulation | Continence | 3 | Medium | Yes | NS/NS | NA | | Low | Moderate |
| PFMT vs. electrical stimulation | Improved UI | 4 | Medium | Yes | NS/NS | NA | | Low | Moderate |
| PFMT vs. vaginal cone | Continence | 3 | Medium | No | NS/NS | NA | | Low | Moderate |
| PFMT vs. vaginal cone | Improved UI | 4 | Medium | No | NS/NS | NA | | Low | Moderate |
| PFMT with biofeedback vs. PFMT | Continence | 6 | Medium | Yes | NS/NS | NA | | Low | High |
| Supervised PFMT vs. self PFMT | Continence | 4 | Medium | No | Yes/Yes | NA | | Moderate | High |
| Supervised PFMT vs. self-PFMT | Improved UI | 4 | Medium | No | Yes/Yes | NA | | Low | Moderate |

PFMT = Pelvic floor muscle training
NS = Not significant
NA = Not applicable

**Appendix Table F2. Review of grey literature**

| Title References | Type of Review | Title | ID | Manufacturer | Trade Name | Common Name | Classification Number |
|---|---|---|---|---|---|---|---|
| 510(k) Summary for Pelvex hometrainer U.S. Food and Drug Administration, 2001[1] | FDA 510 (K) review | 510(k) Summary for pelvex hometrainer | K002043 | Purdue Technology Park, West Lafayette, IN | pelvex | Perineometer | 884.1425 |
| 510(k) summary for Vitala(tm) continence Control Device U.S. Food and Drug Administration, 2008[2] | FDA 510 (K) review | 510(k) summary for Vitala(tm) continence Control Device | K083785 | ConvaTec Inc. Skillman, Nj | Vitala Continence Control Device | Not reported | EZQ -C.F.R. Section 876.5900 |
| 510(k) Summary for uresta pessary U.S. Food and Drug Administration, 2008[3] | FDA 510 (K) review | 510(k) Summary for uresta pessary | K081385 | EastMed Inc., Halifax, Nova Scotia | Uresta Pessary | Vaginal Pessary | 21CFR 884.3575 |
| 510(k) Summary for PelvicFlexer U.S. Food and Drug Administration, 2001[4] | FDA 510 (K) review | 510(k) Summary for PelvicFlexer | K011688 | PelvicFlex Inc., Sarasota, FL | PelvicFlexer Exercise Device | Pelvic Muscle Exerciser | 884.1425 |
| 510(k) Summary for Hollister Contimed Pressure Biofeedback device U.S. Food and Drug Administration, 1996[5] | FDA 510 (K) review | 510(k) Summary for Hollister Contimed Pressure Biofeedback device | K960311 | Hollister Incorporated, Libertyville, IL | Hollister Contimed Pressure Biofeedback device | Not reported | Not reported |
| 510(k) Summary of pathway vaginal emg/stimulation perineometer sensor U.S. Food and Drug Administration, 2000[6] | FDA 510 (K) review | 510(k) Summary of pathway vaginal emg/stimulation perineometer sensor | K993976 | The Prometheus Group, Dover, NH | Pathway Vaginal EMG/Stimulation Perineometer; Pathway Anal EMG/Stimulation Perineometer | Perineometer Sensor | 876.5320; 884.1425 |
| 501(k) summary for UroMed Alternative Bladder Control Continence Device U.S. Food and Drug Administration, 1997[7] | FDA 510 (K) review | 501(k) summary for UroMed Alternative Bladder Control Continence Device | K971992 | UroMed Corporation, Needham, MA | UroMed Alternative Bladder Control Continence Device | Penile Clamp/Urological Clamp | 21 CFR 876.5160 |

**Appendix Table F2. Review of grey literature (continued)**

| Title References | Type of Review | Title | ID | Manufacturer | Trade Name | Common Name | Classification Number |
|---|---|---|---|---|---|---|---|
| 510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer U.S. Food and Drug Administration, 1997[8] | FDA 510 (K) review | 510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer | K974048 | Hollister Incorporated, Libertyville, IL | InCare Pelvic Floor Therapy System with Desktop Computer | Not reported | 876.5320; 884.1425 |
| 510(k) summary review for perineometer and vaginal probe U.S. Food and Drug Administration, 1997[9] | FDA 510 (K) review | 510(k) summary review for perineometer and vaginal probe | K970145 | BioSearch Medical Products, Inc., Somerville, NJ | Perineometer and Vaginal Probe | Not reported | 884.1425 |
| 510(k) summary for vaginal stimulation/emg probe - tampon U.S. Food and Drug Administration, 1997[10] | FDA 510 (K) review | 510(k) summary for vaginal stimulation/ emg probe - tampon | K971541 | Hollister Incorporated, Libertyville, IL | Vaginal Stimulation/EMG Probe -Tampon | | 876.5320; 884.1425 |
| 510(k) Summary for innoSense pelvic floor stimulation and electromyography system U.S. Food and Drug Administration, 1997[11] | FDA 510 (K) review | 510(k) Summary for innoSense pelvic floor stimulation and electromyography system | K971527 | Empi Inc., St.Paul, Minnesota | Innosense Pelvic Floor Stimulation and Electromyography System | Pelvic Floor Stimulation and BioFeedback Device | 876.5320; 884.1425 |
| 510(k) summary for vaginal stimulation/emg probe - small U.S. Food and Drug Administration, 1997[12] | FDA 510 (K) review | 510(k) summary for vaginal stimulation/ emg probe - small | K970602 | Hollister Incorporated, Libertyville, IL | Vaginal Stimulation/EMG Probe -Small | Not reported | Not reported |
| 510(k) summary for periform perineometric probe and pelvic floor contraction indicator U.S. Food and Drug Administration, 1998[13] | FDA 510 (K) review | 510(k) summary for periform perineometric probe and pelvic floor contraction indicator | K981277 | NEEN Healthcare, England, UK | Periform | Perineometer Probe | 884.1425 |

**Appendix Table F2. Review of grey literature (continued)**

| Title References | Type of Review | Title | ID | Manufacturer | Trade Name | Common Name | Classification Number |
|---|---|---|---|---|---|---|---|
| 510(k) summary review for peritron perineometer U.S. Food and Drug Administration, 1998[14] | FDA 510 (K) review | 510(k) summary review for peritron perineometer | K983052 | Cardio Design Pty Ltd | Peritron, Model 9300A with Anal Sensor; Model 9300V with Vaginal Sensor | Not reported | 884.1425 |
| 510(k) summary for reflex treatment system U.S. Food and Drug Administration, 1999[15] | FDA 510 (K) review | 510(k) summary for reflex treatment system | K994079 | DesChutes Medical Products, Inc., Bend, OR | The Reflex Treatment System | Pelvic Muscle Exerciser | 884.1425 |
| 510(k) Summary for Mentor EvaCare Vaginal Pessaries U.S. Food and Drug Administration, 1999[16] | FDA 510 (K) review | 510(k) Summary for Mentor EvaCare Vaginal Pessaries | K993308 | Mentor Corporation, Santa Barbara, CA | Mentor EvaCare Vaginal Pessaries | Vaginal Pessary | 884.3575 |
| 510(k) Summary for PelvX Incontinence Dish U.S. Food and Drug Administration, 1999[17] | FDA 510 (K) review | 510(k) Summary for PelvX Incontinence Dish | K990593 | DesChutes Medical Products, Inc., Bend, OR | PelvX Incontinence Dish | Vaginal Pessary | 884.3575 |
| Summary for pelvic muscle therapy U.S. Food and Drug Administration, 2000[18] | FDA 510 (K) review | 510(k) Summary for pelvic muscle therapy | K002830 | Colonial Medical Supply, Las Vegas, Nv | Pelvic Muscle Therapy | Pelvic Muscle Exerciser | 884.1425 |
| 510(k) summary accuset sensor U.S. Food and Drug Administration, 2000[19] | FDA 510 (K) review | 510(k) summary accuset sensor | K001386 | PelviCare Inc., Laguna Niguel,CA | Accuset Sensor | Not reported | 876.1620; 884.1425 |
| 510(k) summary for femiscan clinic system and personal system U.S. Food and Drug Administration, 2000[20] | FDA 510 (K) review | 510(k) summary for femiscan clinic system and personal system | K993411 | Mahoney Enterprises, East Longmeadow, MA | FemiScan Clinic System and the FemiScan Personal System | Biofeedback Monitoring device with vaginal EMG probe | 876.5320; 884.1425 |
| Summary Review for InCare Pelvic Floor Therapy System U.S. Food and Drug Administration, 2001[21] | FDA 510 (K) review | 510(k) Summary Review for InCare Pelvic Floor Therapy System | K013612 | Hollister Incorporated, Libertyville, IL | InCare Pelvic Floor Therapy System | Not reported | 876.5320; 884.1425 |

**Appendix Table F2. Review of grey literature (continued)**

| Title References | Type of Review | Title | ID | Manufacturer | Trade Name | Common Name | Classification Number |
|---|---|---|---|---|---|---|---|
| 510(k) Summary for InCare Pressure Biofeedback Vaginal and Anal Pressure Probes U.S. Food and Drug Administration, 2001[22] | FDA 510 (K) review | 510(k) Summary for InCare Pressure Biofeedback Vaginal and Anal Pressure Probes | K013653 | Hollister Incorporated, Libertyville, IL | InCare Pressure Biofeedback Vaginal Pressure Probe; InCare Pressure Biofeedback Anal Pressure Probe | Not reported | 884.1425 |
| 510(k) Summary for MTI ST#1 Silicone Pessary U.S. Food and Drug Administration, 2002[23] | FDA 510 (K) review | 510(k) Summary for MTI ST#1 Silicone Pessary | K020512 | Medical Technology & Innovations, Inc., Lee's Summit, MO | MTI ST#1 Silicone Pessary | Vaginal Pessary | 884.3575 |
| 510(k) Summary for Portex Ring Pessary U.S. Food and Drug Administration, 2002[24] | FDA 510 (K) review | 510(k) Summary for Portex Ring Pessary | K012277 | SIMS Registration Manager, Kent, CT | Portex Ring Pessary | Not reported | 884.3575 |
| 510(k) Summary for marina Medical Silicone Pessary U.S. Food and Drug Administration, 2003[25] | FDA 510 (K) review | 510(k) Summary for marina Medical Silicone Pessary | K031463 | Marina Medical Instruments, Inc., Alpharetta, GA | Marina Medical silicone Pessary | Not reported | 884.3575 |
| 510(k) Summary for Kolpexin Sphere U.S. Food and Drug Administration, 2004[26] | FDA 510 (K) review | 510(k) Summary for Kolpexin Sphere | K032644 | ADAMED ltd., Poland | KOLPEXIN Sphere | Training Aid for Pelvic Floor Muscle or Kegel Exercise and Pessary for Vaginal Prolapse | 884.3575 |
| 510(k) Summary for Intra-vaginal stress incontinence device U.S. Food and Drug Administration, 2006[27] | FDA 510 (K) review | 510(k) Summary for Intra-vaginal stress incontinence device | K060526 | ConTIPI Ltd., Israel, c/o ProMedic, Incorporated, Mccordsville, IN | Vaginal Pessary | Intra-vaginal stress incontinence device | 884.3575 |
| 510(k) Summary for pathway vaginal/rectal perineometer probe U.S. Food and Drug Administration, [28] | FDA 510 (K) review | 510(k) Summary for pathway vaginal/rectal perineometer probe | K974036 | The Prometheus Group, Portsmouth, NH | Pathway Vaginal/Rectal Perineometer Probe | Perineometer Probe | 884.1425 |

**Appendix Table F2. Review of grey literature (continued)**

| Title References | Type of Review | Title | ID | Manufacturer | Trade Name | Common Name | Classification Number |
|---|---|---|---|---|---|---|---|
| 510(k) summary for anal stimulation/emg probe - w/Stop<br>U.S. Food and Drug Administration, 1999[29] | FDA<br>510 (K) review | 510(k) summary for anal stimulation/ emg probe - w/Stop | K990456 | Hollister Incorporated, Libertyville, IL | Anal Stimulation/EMG Probe-w/Stop | Not reported | 876.5320; 884.1425 |
| 510(k) Summary for uresta Pessary<br>U.S. Food and Drug Administration, 2008[3] | FDA<br>510 (K) review | 510(k) Summary for uresta Pessary | K083769 | EastMed Inc., Halifax, Nova Scotia B3J 1S5 | Uresta Pessary | Vaginal Pessary | 884.3575 |
| 510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer<br>U.S. Food and Drug Administration, 1996[30] | FDA<br>510 (K) review | 510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer | K961872 | Hollister Incorporated, Libertyville, IL | InCare Pelvic Floor Therapy System with Desktop Computer | Not reported | Not reported |
| 510(k) Summary for liberty plus system pfs-300<br>U.S. Food and Drug Administration, 1997[31] | FDA<br>510 (K) review | 510(k) Summary for liberty plus system pfs-300 | K970077 | Utah Medical Products Inc. | Liberty Plus System, PFS-300 | Electical Pelvic Floor Stimulation System with Biofeedback | 876.5320; 884.1425 |
| Medical Review for Gelnique (oxybutynin chloride) 10% gel<br>U.S. Food and Drug Administration, 2009[32]<br>Staskin, 2009[33] | Medical review | Medical Review for Gelnique (oxybutynin chloride) 10% gel | 22-204 | Watson's laboratories | Gelnique | oxybutynin choride | Not reported |
| Medical Review for PAMELOR (Brand Name Drug)<br>U.S. Food and Drug Administration, 2001[34]<br>No information about trials | Medical review | Medical Review for PAMELOR (Brand Name Drug) | 18-012/S-024 & 18-013/S-053 | Tyco Healthcare | Pamelor | Nortriptyline | Not reported |
| Medical Review for Sanctura (Trospium Chloride) Tablets<br>U.S. Food and Drug Administration, 2004[35]<br>Rudy, 2006[36]<br>Zinner, 2004[37] | Medical review | Medical Review for Sanctura (Trospium Chloride) Tablets | 21-595 | Indevus Pharmaceuticals | Sanctura | Trospium chloride | Not reported |
| Medical Review for VesiCare (Solifenacin Succinate) | Medical review | Medical Review for | 21-518 | Yamanouchi Pharma | Vesicare | Solifenacin Succinate | Not reported |

**Appendix Table F2. Review of grey literature (continued)**

| Title References | Type of Review | Title | ID | Manufacturer | Trade Name | Common Name | Classification Number |
|---|---|---|---|---|---|---|---|
| Tablets<br>U.S. Food and Drug Administration, 2004[38]<br>Staskin, 2006[39] | | VesiCare (Solifenacin Succinate) Tablets | | America, Inc | | | |
| Medical Review for Sanctura XR (Trospium Chloride) Extended Release Capsules<br>U.S. Food and Drug Administration, 2007[40]<br>Not published | Medical review | Medical Review for Sanctura XR (Trospium Chloride) Extended Release Capsules | NDA 22-103 | Indevus Pharmaceuticals | Sanctura | Trospium chloride | Not reported |
| Medical Review for Ditropan XL(Oxybutinin Chloride) Tablets<br>U.S. Food and Drug Administration, 1998[41]<br>Versi, 2000[42] | Medical review | Medical Review for Ditropan XL (Oxybutinin Chloride) Tablets | NDA-20-897 | Alza Corporation | DitropanXL | oxybutynin | Not reported |
| Medical Review for Enablex (Clarifenacin) Extended Release Tablets<br>U.S. Food and Drug Administration, 2004[43]<br>Hill, 2006[44]<br>Steers, 2005[45] | Medical review | Medical Review for Enablex (Clarifenacin) Extended Release Tablets | NDA-21-513 | Novartis | Enablex | Darifenacin | Not reported |
| Statistical Review for Sanctura (Trospium Chloride) Tablets<br>U.S. Food and Drug Administration, 2007[46]<br>Staskin, 2007[47]<br>Dmochowski, 2008[48] | Statistical review | Statistical Review for Sanctura (Trospium Chloride) Tablets | 22-103 | Indevus Pharmaceuticals | Sanctura XR | Trospium chloride-extended release | Not reported |
| Product Monograph for ENABLEX<br>Health Canada, 2006[49]<br>Abrams, 2008[50] | Statistical review | Product Monograph for ENABLEX | Not reported | Novartis | Enablex | Darifenacin-extended release | Not reported |
| Product Monograph for SANCTURA XR<br>U.S. Food and Drug Administration, 2010[51]<br>Staskin, 2009[52] | Statistical review | Product Monograph for SANCTURA XR | Not reported | Indevus Pharmaceuticals | Sanctura XR | Trospium chloride-extended release | Not reported |
| Product Monograph for VESICARE | Statistical review | Product Monograph | Not reported | Astellas Pharma | Vesicare | Solifenacin Succinate | Not reported |

**Appendix Table F2. Review of grey literature (continued)**

| Title References | Type of Review | Title | ID | Manufacturer | Trade Name | Common Name | Classification Number |
|---|---|---|---|---|---|---|---|
| Health Canada, 2006[49]<br>Cardozo, 2004[53]<br>Chapple, 2004[54] | | for VESICARE | | Canada, Inc. | | | |
| NCT00168454<br>Posted results<br>NCT00168454, 2008[55]<br>Not published | Completed unpublished study from Clinicaltrials.gov | A Research Study for Patients With Overactive Bladder | 191622-077 | Allergan | botulinum toxin Type A | botulinum toxin | Not reported |
| NCT00178191<br>Posted results<br>NCT00178191, [56]<br>Not published | Completed unpublished study from Clinicaltrials.gov | Randomized Trial for Botox Urinary Incontinence | 10466 | University of Rochester \|National Institutes of Health (NIH) | Bladder diary; Questionnaires;Urodynamics | Bladder diary; Questionnaires;Urodynamics | Not reported |
| NCT00269750<br>A Study Comparing the Efficacy and Safety of OROS® Oxybutynin to That of Ditropan® (Immediate-release Oxybutynin) for the Treatment of Patients With Urge or Mixed Urinary Incontinence<br>NCT00269750, 2005[57]<br>Not published | Completed unpublished study from Clinicaltrials.gov | A Study Comparing the Efficacy and Safety of OROS® Oxybutynin to That of Ditropan® (Immediate-release Oxybutynin) for the Treatment of Patients With Urge or Mixed Urinary Incontinence | CR005968 | Alza Corporation | OROS | oxybutynin choride | Not reported |
| NCT00444925<br>Posted results<br>NCT00444925, [58]<br>Not published | Completed unpublished study from Clinicaltrials.gov | Clinical Trial to Evaluate the Efficacy and Safety of Fesoterodine in Comparison to Tolterodine for Overactive Bladder (OAB) | A0221008 | Pfizer | Fesoterodine fumarate | Fesoterodine | Not reported |

**Appendix Table F2. Review of grey literature (continued)**

| Title References | Type of Review | Title | ID | Manufacturer | Trade Name | Common Name | Classification Number |
|---|---|---|---|---|---|---|---|
| NCT00536484<br>Posted results<br>NCT00536484, [59]<br>Not published | Completed unpublished study from Clinicaltrials.gov | Fesoterodine Flexible Dose Study | A0221014 | Pfizer | Fesoterodine | Fesoterodine | Not reported |
| 905-EC-001<br>Solifenacin in a flexible dose regimen with tolterodine as an active comparator in a double-blind, double-dummy, randomized overactive bladder symptom trial (STAR)<br>U.S. Food and Drug Administration, [60]<br>Chapple, 2005[61] | Synopsis posted in the website http://www.clinicalstudyresults.org | Solifenacin in a flexible dose regimen with tolterodine as an active comparator in a double-blind, double-dummy, randomized overactive bladder symptom trial (STAR) | 905-EC-001 | Astellas Pharma Europe B.V. | Solifenacin Succinate | Solifenacin | Not reported |
| Solifenacin in the treatment of urgency symptoms of overactive bladder in a rising dose, randomized, placebo-controlled, double-blind trial (SUNRISE)<br>U.S. Food and Drug Administration, [62]<br>Cardozo, 2008[63] | Synopsis posted in the website http://www.clinicalstudyresults.org | Solifenacin in the treatment of urgency symptoms of overactive bladder in a rising dose, randomized, placebo-controlled, double-blind trial (SUNRISE) | 905-EC-002 | Astellas Pharma Europe B.V. | Solifenacin Succinate | Solifenacin | Not reported |
| Solifenacin succinate in a flexible dose regimen with simplified bladder training versus solifenacin succinate in a flexible dose regimen alone in a prospective, randomized, parallel group, overactive bladder symptom study<br>U.S. Food and Drug Administration, [64]<br>Mattiasson, 2009[65] | Synopsis posted in the website http://www.clinicalstudyresults.org | Solifenacin succinate in a flexible dose regimen with simplified bladder training versus solifenacin succinate in a flexible dose | 905-EC-003 | Astellas Pharma Europe B.V. | Vesicare | Solifenacin Succinate | Not reported |

**Appendix Table F2. Review of grey literature (continued)**

| Title References | Type of Review | Title | ID | Manufacturer | Trade Name | Common Name | Classification Number |
|---|---|---|---|---|---|---|---|
| | | regimen alone in a prospective, randomized, parallel group, overactive bladder symptom study | | | | | |

**Appendix Table F3. Quality Assessment of Diagnostic Accuracy Studies (QUADAS)[66,67]**

| Criteria* Reference | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Digesu, 2003[68] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Khan, 2004[69] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | yes | not relevant | yes | yes |
| Versi, 1996[70] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | no |
| Sandvik, 1995[71] | no | unclear | yes | unclear | yes | yes | no | yes | unclear | yes | yes | not relevant | yes | no |
| Clarke, 1997[72] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Jarvis, 1980[73] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Hilton, 1981[74] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Dundiff, 1997[75] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Brown, 2006[76] | yes | yes | yes | unclear | yes | no | no | yes | unclear | yes | yes | not relevant | yes | yes |
| Costantini, 2008[77] | no | yes | no | unclear | yes | yes | yes | yes | unclear | yes | unclear | not relevant | yes | yes |
| Ishiko, 2000[78] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Shepherd, 1982[79] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | yes | not relevant | yes | yes |
| Versi, 1988[80] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Bradley, 2005[81] | no | yes | yes | unclear | yes | yes | no | yes | no | yes | unclear | not relevant | yes | yes |
| FitzGerald, 2002[82] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Sand, 1988[83] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Cantor, 1980[84] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Valente, 1988[85] | no | no | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Hastie, 1989[86] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Bent, 1983[87] | no | unclear | yes | unclear | yes | yes | no | yes | no | yes | unclear | not relevant | no | yes |
| De Muylder, 1992[88] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Farrar, 1975[89] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Lagro-Janssen, 1991[90] | yes | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Ouslander, 1987[91] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Bergman, 1990[92] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Haylen, 1989[93] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Versi, 1986[94] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Bates, 1973[95] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Arnold, 1973[96] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Moolgaoker, 1972[97] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Warrell, 1965[98] | unclear | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Klingele, 2002[99] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Niecestro, 1992[100] | no | yes | no | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Diokno, 1990[101] | yes | unclear | no | unclear | yes | yes | no | yes | no | yes | unclear | not relevant | yes | yes |
| Tyagi, 2010[102] | no | yes | yes | unclear | unclear | yes | yes | yes | yes | yes | unclear | not relevant | yes | no |
| Thiede, 1987[103] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Awad, 1983[104] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Glezerman, 1986[105] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Walters, 1988[106] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |

**Appendix Table F3. Quality Assessment of Diagnostic Accuracy Studies (QUADAS)[72,82] (continued)**

| Criteria* Reference | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Versi, 1991[107] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Bump, 2003[108] | unclear | yes | yes | unclear | unclear | yes | yes | yes | yes | yes | yes | not relevant | yes | unclear |
| Yalcin, 2004[109] | unclear | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes | not relevant | yes | unclear |
| Videla, 1998[110] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Dinokno, 1999[111] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | yes | not relevant | yes | yes |
| Lemack, 1999[112] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Ramsay, 1995[113] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | yes | not relevant | yes | yes |
| Ramsay, 1993[114] | unclear | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Montz, 1986[115] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | yes | not relevant | yes | yes |
| Haeusler, 1995[116] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Nager, 2007[117] | unclear | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Matharu, 2005[118] | no | unclear | yes | no | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Coyne, 2005[119] | yes | yes | no | unclear | yes | yes | no | yes | no | yes | unclear | not relevant | yes | yes |
| Lukacz, 2005[120] | no | unclear | no | unclear | yes | yes | no | yes | yes | yes | yes | not relevant | unclear | yes |
| Diokno, 1990[101] | yes | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Fischer-Rasmussen, 1986[121] | no | unclear | yes | unclear | yes | yes | unclear | yes | unclear | yes | unclear | not relevant | yes | yes |
| Summitt, 1992[122] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Griffiths, 1992[123] | no | yes | yes | yes | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Chen, 1997[124] | no | no | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Kiilholma, 1994[125] | unclear | no | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Contreras Ortiz, 1993[126] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Bergman, 1988[127] | no | yes | yes | yes | yes | yes | yes | yes | yes | yes | yes | not relevant | yes | yes |
| Bergman, 1988[128] | no | yes | yes | yes | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Bergman, 1987[129] | no | yes | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Klovning, 1996[130] | no | no | yes | unclear | yes | yes | yes | yes | yes | yes | yes | not relevant | yes | yes |
| Sunshine, 1989[131] | unclear | no | yes | no | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Kujansuu, 1982[132] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Diokno, 1987[133] | no | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Korda, 1987[134] | unclear | unclear | yes | unclear | yes | yes | yes | yes | yes | yes | unclear | not relevant | yes | yes |
| Quinn, 1989[135] | no | unclear | yes | unclear | yes | yes | unclear | yes | unclear | yes | yes | not relevant | no | yes |

| *QUADAS Criteria | Used Codes |
|---|---|
| 1) Was the spectrum of patients representative of the patients who will receive the test in practice? | Yes if community or primary care; no if others; unclear if not specified |
| 2) Were the selection criteria clearly described? | Yes if inclusion and exclusion criteria exist; unclear if missing one of them; no if missing both |
| 3) Is the reference standard likely to correctly classify the target intervention? | Yes if UD or clinical diagnosis; no if others |

**Appendix Table F3. Quality Assessment of Diagnostic Accuracy Studies (QUADAS)[72,82] (continued)**

| | |
|---|---|
| 4) Is the time period between reference standard and index test short enough to be reasonably sure the target condition did not change between the two tests? | Yes if no more than 2 weeks, no if more than 2 weeks, unclear if unknown |
| 5) Did the whole sample or a random selection of the sample receive verification using a reference standard of diagnosis? | Yes if random selection or no sampling; no if non-random selection; unclear is unknown |
| 6) Did the patients receive the same reference standard regardless of the index test? | Yes if all received gold standard method |
| 7) Was the reference standard independent of the index test (i.e., the index test did not form part of the reference standard)? | Yes if UD as gold standard; no if clinical diagnosis |
| 8) Was the execution of the index test described in sufficient detail to permit replication of the test? | All yes (inclusion criteria of the studies) |
| 9) Was the execution of the reference standard described in sufficient detail to permit its replication? | Y if UD or ICS; unclear if clinical diagnosis without clear definitions |
| 10) Were the index test results interpreted without knowledge of the results of the reference standard? | All yes |
| 11) Were the reference standard results interpreted without knowledge of the index test? | Yes if blinding, no if not blinding; unclear if not mentioned |
| 12) Were the same clinical data available when test results were interpreted as would be available when the test is used in practice? | Not relevant-omitted from quality assessment as Whiting's suggestions[66] |
| 13) Were uninterpretable/intermediate test results reported? | No if the results did not have mixed UI |
| 14) Were withdrawals for the study explained? | No if there are withdraw cases |

**Appendix Table F4. Eligible studies of diagnostic methods**

| Reference<br>Country<br>Funding and Sample Size | Settings, % of Women, Age | Inclusion and Exclusion Criteria |
|---|---|---|
| Abdel-fattah, 2004[136]<br>Country: UK<br>Funding: not reported<br>Sample: 160 | Settings: District general hospital<br>% of women: 100<br>Age: 58; Range: 42-73 | Inclusion: Women undergoing surgical treatment for urodynamic stress incontinence<br>Exclusion: Not reported |
| Amarenco, 2003[137]<br>Country: Europe<br>Funding: not reported<br>Sample: 505 | Settings: A multicentre clinical study<br>% of women: 100<br>Age: 51; Range: 18-75 | Inclusion: Women enrolled in a European multicentre clinical study, ages 18-75, good health, mild to moderate genuine stress incontinence GSI with at least 3 leakages per week and 24 hour pad test 8-100g<br>Exclusion: Not reported<br>Only Cronbach's alpha coefficients in the English language group were abstracted |
| Amundsen, 1999[138]<br>Country: USA<br>Funding: not reported<br>Sample: 115 | Settings: urogynecologic clinic<br>% of women: 100<br>Age: 53; Range: 21-79 | Inclusion: Consecutive women with various complaints of urinary symptoms completed a 27-item questionnaire<br>Exclusion: Not reported |
| Arnold, 1973[96]<br>Country: UK<br>Funding: not reported<br>Sample: 217 | Settings: urodynamic unit<br>% of women: 100<br>Age : Not available; Range: Not reported | Inclusion: Women with incontinence<br>Exclusion: Women with neurologic disease, pelvic disease, a history of major pelvic operations, and the urethral syndromes |
| Awad, 1983[104]<br>Country: Canada<br>Funding: other<br>Sample:108 | Settings: urodynamic unit<br>% of women:100<br>Age: Not available; Range: Not available | Inclusion: Women referred to authors' department for symptomatic UI<br>Exclusion: Not available |
| Bates, 1973[95]<br>Country: UK<br>Funding: not reported<br>Sample: 75 | Settings: referral clinic<br>% of women: 100<br>Age: 56; Range: 33-72 | Inclusion: Patients referred for investigation of recurrent or persistent incontinence after one or more operations for presumed stress UI<br>Exclusion: Neurologic disorders |
| Bent, 2005[139]<br>Country: USA<br>Funding: not reported<br>Sample: 723 | Settings: The principal investigators included urologists, gynecologists, and primary care physicians<br>% of women: 100<br>Age: 53.6; Range: 19-85 | Inclusion: Women older than 18 years, an average of at least 4 incontinence episodes per week, could not have received treatment for incontinence by a continence expert within the past 5 years, prior surgery, including correction of incontinence, was allowed if the procedure was completed 6 months before a subject entered the study; participants who performed pelvic floor muscle training could not initiate or change their regimen within 3 months before study entry or during the study, and written informed consent<br>Exclusion: Not reported |
| Bent, 1983[87]<br>Country: USA<br>Funding: not reported<br>Sample: 100 | Settings: urodynamic unit<br>% of women: 100<br>Age: Over age 60; Range: Not reported | Inclusion: Consecutive patients over age 60 referred to authors' institute and a negative urine culture<br>Exclusion: Not reported |
| Bergman,1990[92]<br>Country: USA<br>Funding: not reported<br>Sample: 154 | Settings: referral clinic<br>% of women: 100<br>Age: 54; Range: 17-78 | Inclusion: 122 women referred for evaluation of urinary complaints and 32 no complaints as control<br>Exclusion: Mixed urinary incontinence |
| Borup, 2008[140]<br>Country: Denmark<br>Funding: government<br>Sample: 96 | Settings: community-dwelling<br>% of women: 100<br>Age: Not reported; Range: 20-59 | Inclusion: Women with symptomatic UI invited in a stress UI test<br>Exclusion: Not reported |
| Bradley, 2005[81]<br>Country: USA<br>Funding: other<br>Sample: 117 | Settings: tertiary referral<br>% of women: 100<br>Age: 56; Range: 22-87 | Inclusion: Consecutive women have symptoms of UI and agree to participate<br>Exclusion: A history of current pregnancy or within 6 months after delivery, extraurethral UI, urethral diverticulum, and active UTI |

**Appendix Table F4. Eligible studies of diagnostic methods (continued)**

| Reference<br>Country<br>Funding and Sample Size | Settings, % of Women, Age | Inclusion and Exclusion Criteria |
|---|---|---|
| Brown, 2006[76]<br>Country: USA<br>Funding: industry<br>Sample: 301 | Settings: community-dwelling<br>% of women: 100<br>Age: 56.4; Range: 40-94 | Inclusion: Ambulatory, were 40 years of age or older, reported 3 or more episodes of incontinence per week for at least 3 months, did not have urinary tract infection, and were bothered enough by their incontinence to seek treatment<br>Exclusion: Women with incontinence who had complex problems that were more appropriate for specialist referral, including 4 or more urinary tract infections in the preceding year; pregnancy within 6 months; previous anti-incontinence or urethral surgery or procedures; previous major pelvic or abdominal surgery; pelvic radiation within 6 months; or known diseases of the genitourinary tract, such as lower urinary tract or rectal fistula, congenital abnormality leading to incontinence, interstitial cystitis, severe symptomatic pelvic prolapse, current or past urogenital cancer, spinal cord lesions, multiple sclerosis, stroke with clinically significant residual disability, Parkinson disease, or other major central nervous system abnormality affecting the lower urinary tract, or women who had been treated for incontinence in the previous 3 months |
| Bump, 2003[108]<br>Country: USA<br>Funding: industry<br>Sample: 553 | Settings: Randomized clinical trial<br>% of women: 100<br>Age: 49.6; Range:18-65 | Inclusion: Female outpatients ages 18 to 65 years who had a clinical diagnosis of stress UI for at least 3 months in duration<br>Exclusion: If they had prolapse stage II or greater; had a postvoid residual volume of 50 mL or more; were using any pharmacologic agent or device for urinary incontinence; had adopted or changed behavioral management for urinary incontinence |
| Byrne,1987[141]<br>Country: UK<br>Funding: not reported<br>Sample: 69 | Settings: hospital<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Women with the complaint of stress UI unassociated with other symptoms<br>Exclusion: Not reported |
| Cantor, 1980[84]<br>Country: UK<br>Funding: not reported<br>Sample: 214 | Settings: urodynamic unit<br>% of women: 100<br>Age: 47; Range: 16-84 | Inclusion: Women complaining of urine incontinence<br>Exclusion: Under age 16 |
| Caputo, 1993[142]<br>Country: USA<br>Funding: not reported<br>Sample: 114 | Settings: urodynamic unit<br>% of women:100<br>Age: Not reported; Range: Not reported | Inclusion: Women with UI or genital prolapse<br>Exclusion: Genital prolapse that protruded beyond the introitus while straining in the upright position |
| Cardozo, 1980[143]<br>Country: UK<br>Funding: not reported<br>Sample: 100 | Settings: urogynecologic clinic<br>% of women: 100<br>Age: 50; Range: Not reported | Inclusion: All patients with stress incontinence complaints with GSI or DI confirmed<br>Exclusion: Not reported |
| Chiarelli, 1999[144]<br>Country: Australia<br>Funding: government +industry<br>Sample: 41,724 | Settings:<br>% of women:100<br>Age: Not reported; Range: 18-75 | Inclusion: The women were selected randomly from the national health insurance (Medicare) database<br>Exclusion: Not reported<br>Only “lower quality of life among women who report leaking urine, compared with those who do not” was abstracted. |
| Clarke, 1997[72]<br>Country: Australia<br>Funding: not reported<br>Sample: 1000 | Settings: urogynecologic clinic<br>% of women:100<br>Age: Not reported; Range: Not reported | Inclusion: Consecutive women with lower urinary tract symptomatology referred for UD<br>Exclusion: Those records did not conform to the standard diagnoses (18 cases) |
| Costantini, 2008[77]<br>Country: Italy | Settings: tertiary referral<br>% of women:100 | Inclusion: Consecutive women with or without UI referred for pelvic organ prolapse repair or anti-UI |

**Appendix Table F4. Eligible studies of diagnostic methods (continued)**

| Reference<br>Country<br>Funding and Sample Size | Settings, % of Women, Age | Inclusion and Exclusion Criteria |
|---|---|---|
| Funding: not reported<br>Sample: 158 | Age: 69; Range: 20-90 | surgery<br>Exclusion: Patients with a specific condition known to adversely affect the way the test works and that would inflate diagnosis accuracy |
| Cundiff, 1997[75]<br>Country: USA<br>Funding: not reported<br>Sample: 535 | Settings: Medical college of Virginia or Duke university medical center<br>% of women: 100<br>Age: 55.7; Range: 21-95 | Inclusion: Consecutive women with urinary incontinence.<br>Exclusion: Without incontinence or advanced pelvic organ prolapse (stage III or IV) |
| De Muylder, 1992[88]<br>Country: Belgium<br>Funding: not reported<br>Sample: 408 | Settings: Urodynamic unit<br>% of women: 100<br>Age: 48.2; Range: 18-78 | Inclusion: Women with UI<br>Exclusion: Not reported |
| Digesu, 2003[68]<br>Country: UK<br>Funding: not reported<br>Sample: 4500 | Settings: tertiary referral<br>% of women: 100<br>Age: 55.4; Range: 22-73 | Inclusion: Women with lower urinary tract symptoms referred to a tertiary urodynamic clinic<br>Exclusion: Women with neurological disorders |
| Diokno,1990[101]<br>Country: USA<br>Funding: not reported<br>Sample: 167 | Settings: community-dwelling<br>% of women: 100<br>Age: Not reported; Range: 60-86 | Inclusion: Noninstitutionalized elderly participated in a household survey and 60 years and older accepted to free urodynamic testing<br>Exclusion: Not reported |
| Dinokno, 1999[111]<br>Country: USA<br>Funding: not reported<br>Sample: 101 | Settings: Continence clinic<br>% of women: 100<br>Age: No response; Range: No response | Inclusion: Women with incontinence seen at the Continence Clinic and underwent office based basic evaluation<br>Exclusion: Incomplete documentation of office based or urodynamic data |
| Drutz, 1979[145]<br>Country: Canada<br>Funding: not reported<br>Sample: 188 | Settings: urodynamic unit<br>% of women: 100<br>Age: 50.2; Range: 20-84 | Inclusion: Women with complaints of UI and/or other lower urinary tract symptoms<br>Exclusion: Not reported |
| Eastwood, 1984[146]<br>Country: UK<br>Funding: not reported<br>Sample: 65 | Settings: referral clinic<br>% of women: 100<br>Age: 82; Range: 68-94 | Inclusion: Consecutively women referred for UD<br>Exclusion: Not reported |
| Eastwood,1979[147]<br>Country: No response<br>Funding: not reported<br>Sample: 30 | Settings: urodynamic unit<br>% of women:0<br>Age: 84; Range: 64-96 | Inclusion: Elder patients referred to a geriatric service with the main presenting clinical features of UI<br>Exclusion: Not reported |
| Farrar,1975[89]<br>Country: UK<br>Funding: not reported<br>Sample: 251 | Settings: urodynamic unit<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Women with mainly complaints of UI, normal bladder capacity, normal pressure and flow rates, and be able to void to completion<br>Exclusion: Women with overt or possible neurologic disorders, fistula, and ectopic ureter as well as those who have had extensive surgical procedures of the pelvis<br>Results were abstracted from a review by Jensen, 1994[148] |
| FitzGerald, 2002[82]<br>Country: USA<br>Funding: not reported<br>Sample: 293 | Settings: tertiary referral<br>% of women: 100<br>Age: 57; Range: 15-87 | Inclusion: Women referred to a tertiary urogynecology practice who completed all the questionnaires and underwent UD<br>Exclusion: Not reported |
| Glezerman, 1986[105]<br>Country: Israel<br>Funding: not reported<br>Sample:130 | Settings: medical center<br>% of women:100<br>Age:47.8; Range:22-74 | Inclusion: Women referred to authors' department for stress incontinence<br>Exclusion: Not available |
| Gunthorpe, 2000[149]<br>Country: Australia<br>Funding: government | Settings: Primary care<br>% of women: 100<br>Age: 42.4; Range: 19-79 | Inclusion: Patients were invited to participate in the study with 89 consented to complete the ISQ and 48h pad test |

**Appendix Table F4. Eligible studies of diagnostic methods (continued)**

| Reference<br>Country<br>Funding and Sample Size | Settings, % of Women, Age | Inclusion and Exclusion Criteria |
|---|---|---|
| Sample: 89 | | Exclusion: younger than 18 years or too ill to participate |
| Haeusler,1995[116]<br>Country: Austria<br>Funding: not reported<br>Sample: 1938 | Settings: referral clinic<br>% of women: 100<br>Age: 52.4; Range: 26-78 | Inclusion: Consecutively patients referred for UD<br>Exclusion: Pathologic types of incontinence due to calculi, fistula, upper motor neuron lesion, or carcinoma |
| Harvey, 2001[150]<br>Country: United Kingdom<br>Funding: not reported<br>Sample: 154 | Settings: A prospective before/ after clinical trial<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Ambulatory women with symptoms of UI<br>Exclusion: Women who were pregnant or had recently given birth, those with urinary tract infections, those presently undergoing treatment for UI, and patients with other debilitating medical conditions |
| Hastie,1989[86]<br>Country: No response<br>Funding: not reported<br>Sample: 89 | Settings: urodynamic unit<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Women whose only reason for referral was symptom of stress incontinence<br>Exclusion: Patients with urge incontinence and mixed incontinence |
| Haylen, 1989[93]<br>Country: Australia<br>Funding: not reported<br>Sample: 494 | Settings: referral clinic<br>% of women:100<br>Age: Not reported; Range: Not reported | Inclusion: Women with complain of stress incontinence<br>Exclusion: Previous surgery for urine incontinence |
| Hilton, 1981[74]<br>Country: UK<br>Funding: other<br>Sample: 100 | Settings: Urodynamic unit<br>% of women: 100<br>Age: 74.6; Range: 65-93 | Inclusion: Women referred to the urodynamic unit for urine incontinence<br>Exclusion: Not reported |
| Homma, 2004[151]<br>Country: Japan<br>Funding: not reported<br>Sample: 293 | Settings: A randomized controlled trial<br>% of women: 67<br>Age: 65.6; Range: Not reported | Inclusion: Details were presented in an abstract<br>Exclusion: Details were presented in an abstract<br>Only women's results were abstracted |
| Ishiko, 2000[78]<br>Country: Japan<br>Funding: not reported<br>Sample: 198 | Settings: tertiary referral<br>% of women: 100<br>Age: 59.1; Range: 27-73 | Inclusion: Women with UI<br>Exclusion: Not reported |
| Jackson,1996[152]<br>Country: UK<br>Funding: not reported<br>Sample: 105 | Settings: Urodynamic unit<br>% of women: 100<br>Age: 51; Range: 24-80 | Inclusion: Consecutive women attending the department for a urodynamic assessment<br>Exclusion: Not reported |
| James,1999[153]<br>Country: UK<br>Funding: not reported<br>Sample: 555 | Settings: urodynamic unit<br>% of women: 100<br>Age: 50; Range: 18-88 | Inclusion: All women undergoing urodynamic studies<br>Exclusion: Women with bladder filling symptoms (frequency, urgency, urge incontinence or bladder pain) or an abnormal urinary diary (daytime frequency ≥8, nighttime frequency ≥2, or a fluid intake of ≥4L/24 hours) |
| Jarvis, 1980[73]<br>Country: UK<br>Funding: not reported<br>Sample: 100 | Settings: urogynecologic clinic<br>% of women:100<br>Age: Not reported; Range: Not reported | Inclusion: Consecutive women with urinary incontinence.<br>Exclusion: Not reported |
| Khan, 2004[69]<br>Country: UK<br>Funding: not reported<br>Sample: 114 | Settings: tertiary referral<br>% of women: 100<br>Age: 55.5 or 52.9; Range: 24-86 | Inclusion: Women with lower urinary tract symptoms referred to a tertiary urogynecology clinic<br>Exclusion: Abnormal urinalysis |
| Kinchen, 2007[154]<br>Country: USA<br>Funding: industry<br>Sample: 3344 | Settings: community-dwelling<br>% of women: 100<br>Age: Not reported; Range: 21-75 | Inclusion: All members aged 21-75 within 1 week of seeking care for any reason from a primary care physician<br>Exclusion: Not reported |
| Klingele, 2002[99]<br>Country: USA | Settings: urogynecologist clinic<br>% of women: 100 | Inclusion: Consecutive women referred to a urogynecologist for UI |

**Appendix Table F4. Eligible studies of diagnostic methods (continued)**

| Reference<br>Country<br>Funding and Sample Size | Settings, % of Women, Age | Inclusion and Exclusion Criteria |
|---|---|---|
| Funding: not reported<br>Sample: 239 | Age: 54.1(s),54.7(m), 52.3(DO);<br>Range: Not reported | Exclusion: No symptoms or missing data |
| Kulseng-Hanssen, 2003[155]<br>Country: Norway<br>Funding: not reported<br>Sample: 628 | Settings: Tertiary referral urogynaecology units<br>% of women:100<br>Age: Not reported; Range: Not reported | Inclusion: Pre-operative forms from 20 departments<br>Exclusion: Not reported |
| Lagro-Janssen, 1991[90]<br>Country: Netherlands<br>Funding: not reported<br>Sample: 103 | Settings: general practice<br>% of women: 100<br>Age: Not reported; Range: 20-65 | Inclusion: Women with UI in general practitioner setting<br>Exclusion: A previous operation for UI, underlying neurological etiology, DM, a temporary cause of UI, or UTI |
| Lagro-Janssen, 1990[156]<br>Country: Netherlands<br>Funding: not reported<br>Sample: 1442 | Settings: community-dwelling<br>% of women: 100<br>Age: Not reported; Range: 50-65 | Inclusion: 2400 women were randomly selected in the eastern part of the Netherlands, and 1442 consented to take part<br>Exclusion: Not reported |
| Lemack, 1999[112]<br>Country: USA<br>Funding: not reported<br>Sample: 128 | Settings: tertiary referral<br>% of women:100<br>Age:61 Range:27-86 | Inclusion: Women for an initial evaluation of LUTS or incontinence who had completed a UDI-6 questionnaire and UD study; patients with previous vaginal surgery were included<br>Exclusion: Women with known neurologic diagnoses |
| Lemack,2000[157]<br>Country: USA<br>Funding: not reported<br>Sample: 174 | Settings: medical center<br>% of women: 100<br>Age: No response; Range: No response | Inclusion: All women completed UDI-6 and underwent UD<br>Exclusion: With known neurological conditions |
| Lin, 2004[158]<br>Country: Taiwan<br>Funding: not reported<br>Sample: 120 | Settings: tertiary referral<br>% of women: 100<br>Age: 51; Range: 43-64 | Inclusion: Consecutive women complaining of lower urinary tract symptoms<br>Exclusion: Women without symptoms suggestive of OAB |
| Lowenstein, 2008[159]<br>Country: USA<br>Funding: industry<br>Sample: 47 | Settings: tertiary referral<br>% of women: 100<br>Age: 62; Range: 34-86 | Inclusion: Women with MUI<br>Exclusion: Not reported |
| Lukacz, 2005[120]<br>Country: USA<br>Funding: not reported<br>Sample: 120 | Settings: In either the general gynecology or the pelvic floor disorders clinic<br>% of women: 100<br>Age: 52.6; Range: 25-84 | Inclusion: Women awaiting appointments in either the general gynecology or the pelvis floor disorders clinic<br>Exclusion: The inability to read or to participate in the informed consent process |
| Massolt, 2005[160]<br>Country: Netherlands<br>Funding: not reported<br>Sample: 109 | Settings: urogynecologic clinic<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: All women visiting the authors' urogynecologic practice with complaints of UI<br>Exclusion: Not reported |
| Matharu, 2005[118]<br>Country: UK<br>Funding: government<br>Sample: 1003 | Settings: community<br>% of women: 100<br>Age: 56.3; Range: 40-88 | Inclusion: Women aged 40 years or over living in the community in Leicestershire and Rutland, who responded to a questionnaire and home interview, with symptoms of UI, enrolled in CNP arm, completed urodynamics.<br>Exclusion: Not reported |
| Miller,1999[161]<br>Country: USA<br>Funding: government<br>Sample: 51 | Settings: community-dwelling<br>% of women: 100<br>Age: 69; Range: 59-84 | Inclusion: Female, >60 years, ambulatory, mental intact (Mini-Mental State score >23, community dwelling, and history of leakage with coughing<br>Exclusion: Prior urethral or bladder surgery, UTI, prolapse below the level of the hymenal ring |
| Montz, 1986[115]<br>Country: UK<br>Funding: not reported<br>Sample: 100 | Settings: urodynamic unit<br>% of women: 100<br>Age: 49.7; Range: Not reported | Inclusion: Consecutive women with complaints of UI<br>Exclusion: Not reported |

**Appendix Table F4. Eligible studies of diagnostic methods (continued)**

| Reference<br>Country<br>Funding and Sample Size | Settings, % of Women, Age | Inclusion and Exclusion Criteria |
|---|---|---|
| Moolgaoker,1972[97]<br>Country: UK<br>Funding: not reported<br>Sample: 95 | Settings: referral clinic<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Women with UI and no neurological abnormalities<br>Exclusion: neurological lesions or fistulae |
| Morkved,1999[162]<br>Country: Norway<br>Funding: not reported<br>Sample: 144 | Settings: local hospital<br>% of women: 100<br>Age: 28; Range: 19-40 | Inclusion: All women delivering at the local hospital and gave their written consent<br>Exclusion: Those who did not understand or speak Norwegian |
| Nager, 2007[117]<br>Country: USA<br>Funding: government<br>Sample: 655 | Settings: A multicenter surgical trial<br>% of women: 100<br>Age: 52; Range: 28-81 | Inclusion: (1) predominant SUI with MESA3 stress score >MESA urge score; (2) positive stress test (observed leakage from the external urethral meatus coincident with a cough or Valsalva maneuver) with a bladder volume ≤300 ml; (3) urethral hypermobility as evidenced by Q-tip angle; (4) maximum cystometric capacity (MCC) ≥200 ml; and (5) non-obstructed voiding in the absence of Stage II–IV prolapse5 defined as: (a) postvoid residual (PVR) <150 ml; (b) maximum flow rate (Qmax) ≥12 ml/sec; and (c) detrusor pressure (pdet) at Qmax <50 cm H2O<br>Exclusion: Not reported |
| Niecestro,1992[100]<br>Country: USA<br>Funding: not reported<br>Sample: 66 | Settings: urodynamic unit<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Women >18 years referred to the urodynamic center for voiding symptoms<br>Exclusion: Presence of UTI, patients with STD, and judged unfit for participation by the investigator |
| Oh, 2005[163]<br>Country: Korea<br>Funding: not reported<br>Sample: 109 | Settings: tertiary referral<br>% of women: 100<br>Age: 54.9; Range: 31-77 | Inclusion: Age 18 years or older, good visual acuity, and the ability to communicate, understand, and comply with the study requirements<br>Exclusion: A confused state or depression, an inability to read the questionnaire, urinary tract infection, malignancy, pregnancy, or failure to provide consent, or incomplete workup and incomplete information |
| Ouslander,1978[91]<br>Country: USA<br>Funding: not reported<br>Sample: 135 | Settings: referral clinic<br>% of women: 100<br>Age: Not reported; Range: 65-95 | Inclusion: Consecutive women referred to the clinics<br>Exclusion: Not reported |
| Phua, 1992[164]<br>Country: Singapore<br>Funding: not reported<br>Sample:84 | Settings: hospital<br>% of women:100<br>Age: Not available; Range: Not available | Inclusion: Women complained of UI and/or other urinary symptoms and were suspected of suffering from stress incontinence or detrusor instability<br>Exclusion: With known or suspected neurological disease, urinary fistula or ectopic ureters |
| Ramsay, 1993[114]<br>Country: UK<br>Funding: not reported<br>Sample: 200 | Settings: No response<br>% of women: 100<br>Age: 51.6; Range: Not reported | Inclusion: Patients with either pure DI or pure GSI<br>Exclusion: Incontinence during intercourse |
| Ramsay, 1995[113]<br>Country: UK<br>Funding: not reported<br>Sample: 207 | Settings: urogynecology clinic<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Consecutive women attending urogynecology clinics<br>Exclusion: Not reported |
| Rosenzweig, 1992[165]<br>Country: USA<br>Funding: not reported<br>Sample: 22 | Settings: gynecology clinic of medical center<br>% of women: 100<br>Age: 60.3; Range: 34-77 | Inclusion: Women with severe genitourinary prolapse (prolapse of pelvic structure through the vaginal introitus) and with no symptoms of UI except for an occasional episode (less than 1 per week)<br>Exclusion: Not reported |
| Sand, 1991[166]<br>Country: USA<br>Funding: not reported<br>Sample: 100 | Settings: urodynamic unit<br>% of women: 100<br>Age: 51.6; Range: 20-84 | Inclusion: Consecutive neurologically normal women with complaint of UI who agreed to undergo two cystometrogram on two different days<br>Exclusion: Not reported |

**Appendix Table F4. Eligible studies of diagnostic methods (continued)**

| Reference<br>Country<br>Funding and Sample Size | Settings, % of Women, Age | Inclusion and Exclusion Criteria |
|---|---|---|
| Sand,1988[83]<br>Country: USA<br>Funding: not reported<br>Sample: 218 | Settings: urodynamic unit<br>% of women: 100<br>Age: 51.8; Range: 18-80 | Inclusion: Patient referred for UD for lower urinary tract complaints<br>Exclusion: Without thorough, detailed histories and preliminary evaluations |
| Sandvik,1995[71]<br>Country: Norway<br>Funding: not reported<br>Sample: 250 | Settings: Outpatient clinic of University hospital<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Consecutive patients referred for urine incontinence<br>Exclusion: Not reported |
| Scarpero,2003[167]<br>Country: USA<br>Funding: not reported<br>Sample: 1232 | Settings: urology practice<br>% of women: 100<br>Age: 54.6; Range: 18-93 | Inclusion: Women presenting to a female urology practice, and all those who completed the AUASI, SPI, and QOL questions<br>Exclusion: Younger than 18 years, with neurogenic diseases, and missing information |
| Shepherd, 1982[79]<br>Country: UK<br>Funding: other<br>Sample: 1800 | Settings: urodynamic unit<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Women referred to the urodynamic unit<br>Exclusion: Not reported |
| Shimabukuro, 2006[168]<br>Country: Japan<br>Funding: not reported<br>Sample: 1052 | Settings: community-dwelling<br>% of women: 100<br>Age: 46.8; Range: 18-83 | Inclusion: Apparently health participants for medical checkup<br>Exclusion: Not reported |
| Shumaker,1994[169]<br>Country: USA<br>Funding: not reported<br>Sample: 162 | Settings: community-dwelling<br>% of women: 100<br>Age: 61.3; Range: ≥45 | Inclusion: >45 years, mentally competent, capable of independent toileting, at least 1 episode of UI per week, and fulfilling urodynamic criteria of GSI and/or DI<br>Exclusion: Metabolic decompensation, marked cyclical variation in UI, lower UTI, urinary obstruction, diverticulum, fistula, persistent indwelling catheter, and reversible cause of UI |
| Stach-Lempinen, 2001[170]<br>Country: Finland<br>Funding: not reported<br>Sample: 82 | Settings: University hospital<br>% of women: 100<br>Age: 52; Range: 25-80 | Inclusion: Women referred to authors' department for symptomatic UI<br>Exclusion: Diabetic neuropathy, recently diagnosed cancer or other serious chronic conditions that may have caused neurogenic bladder disease and patients with incontinence surgery within the past 5 years |
| Stav, 2009[171]<br>Country: Australia<br>Funding: not reported<br>Sample: 601 | Settings: medical center<br>% of women: 100<br>Age: 59.2; Range: 30-91 | Inclusion: The medical records of 1,136 consecutive women who had urodynamic stress UI and underwent a suburethral sling operation at authors' institute<br>Exclusion: Not reported |
| Sutherst, 1984[172] Country: UK<br>Funding: not reported<br>Sample:100 | Settings: Incontinent clinic<br>% of women:100<br>Age:47 Range:22-78 | Inclusion: Women enrolled in a single blind crossover trial<br>Exclusion: Not reported |
| Swift, 1995[173]<br>Country: USA<br>Funding: not reported<br>Sample: 108 | Settings: referral clinic<br>% of women: 100<br>Age: 57.9; Range: Not reported | Inclusion: Consecutive women with lower urinary tract complaints referred for UD<br>Exclusion: Not reported |
| Swithinbank,1999[174]<br>Country: UK<br>Funding: not reported<br>Sample: 2075 | Settings: community-dwelling<br>% of women: 100<br>Age: 52; Range: 19-97 | Inclusion: All women aged 19 years and over, registered with one group general practice of 7000 patients, were invited to participate<br>Exclusion: Not reported |
| Thiede, 1987[103]<br>Country: USA<br>Funding: other<br>Sample:200 | Settings: urogynecologic clinic<br>% of women:100<br>Age: Not available; Range: Not available | Inclusion: Women referred to authors' department for symptomatic UI<br>Exclusion: Not available |

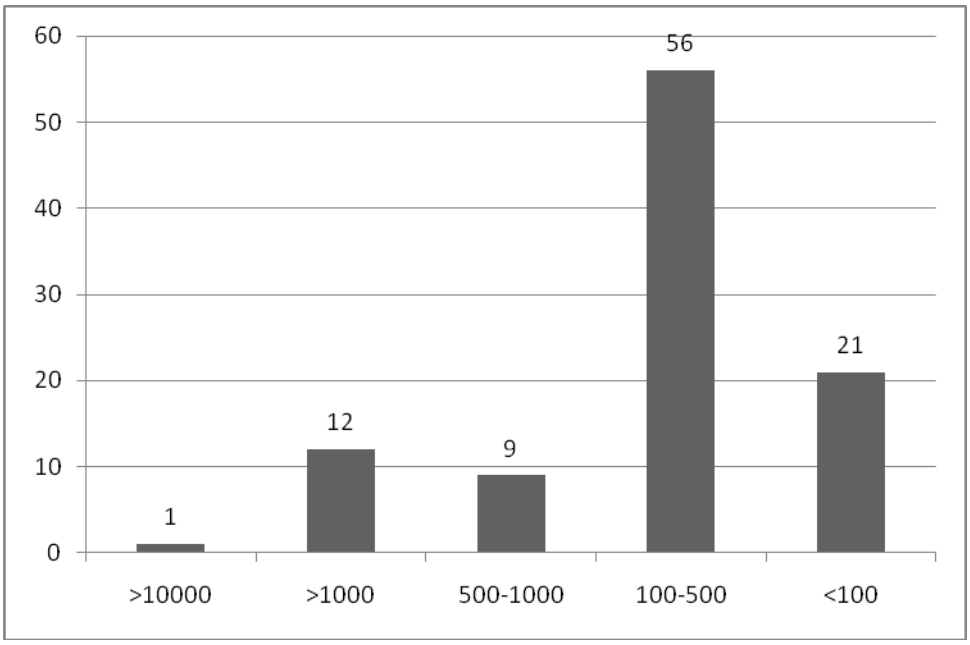
**Appendix Table F4. Eligible studies of diagnostic methods (continued)**

| Reference<br>Country<br>Funding and Sample Size | Settings, % of Women, Age | Inclusion and Exclusion Criteria |
|---|---|---|
| Theofrastous, 1996[175]<br>Country: USA<br>Funding: not reported<br>Sample: 120 | Settings: referral clinic<br>% of women:100<br>Age: 57; Range: 22-81 | Inclusion: Consecutive women who were referred to the urodynamic lab for evaluation of their UI<br>Exclusion: Not reported |
| Tyagi, 2010[102]<br>Country: UK<br>Funding: not reported<br>Sample:159 | Settings: urodynamic unit<br>% of women:100<br>Age: Not available; Range: Not available | Inclusion: patients referred for urodynamic investigations<br>Exclusion: recurrent SUI after failed surgery for SUI or prior to POP surgery |
| Valente,1998[85]<br>Country: Italy<br>Funding: not reported<br>Sample: 102 | Settings: urodynamic unit<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: consecutive women with clinical diagnosis of UI<br>Exclusion: Not reported |
| Versi, 1996[70]<br>Country: UK<br>Funding: not reported<br>Sample: 161 | Settings: urogynecologic clinic<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Patients presenting to a urogynecologic clinic at a teaching hospital<br>Exclusion: 44 detrusor instability, sensory urgency, voiding difficulties or a combination of these diagnosis |
| Versi, 1991[107]<br>Country: UK<br>Funding: other<br>Sample: 252 | Settings: referral urodynamic center<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Consecutive patients studied with a urodynamic diagnosis<br>Exclusion: Not reported |
| Versi, 1988[80]<br>Country: UK<br>Funding: other<br>Sample: 311 | Settings: urodynamic unit<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Women presenting to the urodynamic unit for investigation of their urinary complaints<br>Exclusion: Not reported |
| Versi, 1986[94]<br>Country: UK<br>Funding: other<br>Sample: 99 | Settings: urodynamic unit<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: 99 postmenopausal women with urodynamic proven GSI and 90 women without UI as control group<br>Exclusion: Not reported |
| Videla, 1998[110]<br>Country: USA<br>Funding: not reported<br>Sample: 74 | Settings: urogynecologic clinic<br>% of women: 100<br>Age: 54; Range: 30-86 | Inclusion: Women with a variety of lower urinary tract complaints and 1) a predominant complaint of stress incontinence, 2) positive cough stress-test results, 3) postvoid residual urine volume no more than 50 mL, 4) a functional bladder capacity of at least 400 mL as determined by a completed 24-hour frequency-volume chart, and 5) a full multichannel urodynamic evaluation<br>Exclusion: The absence of any of five criteria |
| Walters, 1988[106]<br>Country: USA<br>Funding: not reported<br>Sample:106 | Settings: urodynamic unit<br>% of women:100<br>Age:46.3; Range: Not available | Inclusion: consecutive women complaining of urine incontinence who were referred to the authors' department<br>Exclusion: postmenopausal women who became asymptomatic after estrogen therapy |
| Warrell, 1965[98]<br>Country: UK<br>Funding: not reported<br>Sample: 81 | Settings: Not reported<br>% of women: 100<br>Age: Not reported; Range: Not reported | Inclusion: Women with UI despite prolapse repair have been investigated<br>Exclusion: Not reported |
| Weidner, 2001[176]<br>Country: USA<br>Funding: not reported<br>Sample: 950 | Settings: urogynecologic clinic<br>% of women: 100<br>Age: 55.4 Range: Not reported | Inclusion: Consecutive patients referred for multichannel UD testing<br>Exclusion: Women with stage III or IV pelvic organ prolapse, no reports of urinary incontinence, and undergoing repeated examinations |
| Wyman,1988[177]<br>Country: USA<br>Funding: government<br>Sample: 50 | Settings: Community dwelling<br>% of women: 100<br>Age: 65.1; Range: 55-86 | Inclusion: 55 years or older, ambulatory, mental intact (Mini-Mental State score >23), independent residence in the community, and at least one episode of incontinence reported per week<br>Exclusion: Percent catheterization, persistent UTI, |

**Appendix Table F4. Eligible studies of diagnostic methods (continued)**

| Reference<br>Country<br>Funding and Sample Size | Settings, % of Women, Age | Inclusion and Exclusion Criteria |
|---|---|---|
| | | reversible cause of incontinence, metabolic decompensation, or outlet obstruction |
| Wyman, 1987[178]<br>Country: USA<br>Funding: government<br>Sample: 69 | Settings: Community-dwelling<br>% of women: 100<br>Age: 67.8; Range: No response | Inclusion: Women had to be 55 years or older, reside independently in the community, mentally intact, ambulatory, and at least one episode of incontinence per week<br>Exclusion: Permanent catheterization, intractable UTI, reversible cause of incontinence, metabolic decompensation, bladder atony or obstruction, and no evidence of urodynamic abnormality |
| Yalcin, 2004[109]<br>Country: Europe and North America<br>Funding: not reported<br>Sample: 1455 | Settings: 3 randomized trials<br>% of women: 100<br>Age: 51.3; Range: 28-81.7 | Inclusion: Female outpatients aged 18 to 65 (phase 2 study) years who had a clinical diagnosis of SUI for at least 3 months in duration enrolled in 1 phase 2 study and 2 phase 3 studies<br>Exclusion: if they had stage II or greater anterior segment prolapse, a post-void residual volume of 50 ml or greater, were on any pharmacological agent or device for UI, or had adopted or changed behavioral management for UI within the last 3 months, or women with previous continence surgery were excluded from the phase 2 study but not from the phase 3 studies. |
| Yoon, 1998[179]<br>Country: USA<br>Funding: not reported<br>Sample: 174 | Settings: Not reported<br>% of women: 100<br>Age: 52; Range: 22-89 | Inclusion: Women presented with primary complaints of UI and successfully completed a 24 hour voiding diary<br>Exclusion: Not reported |

**Appendix Figure F1. Distribution of sample sizes of studies of diagnostic values of tests for UI**

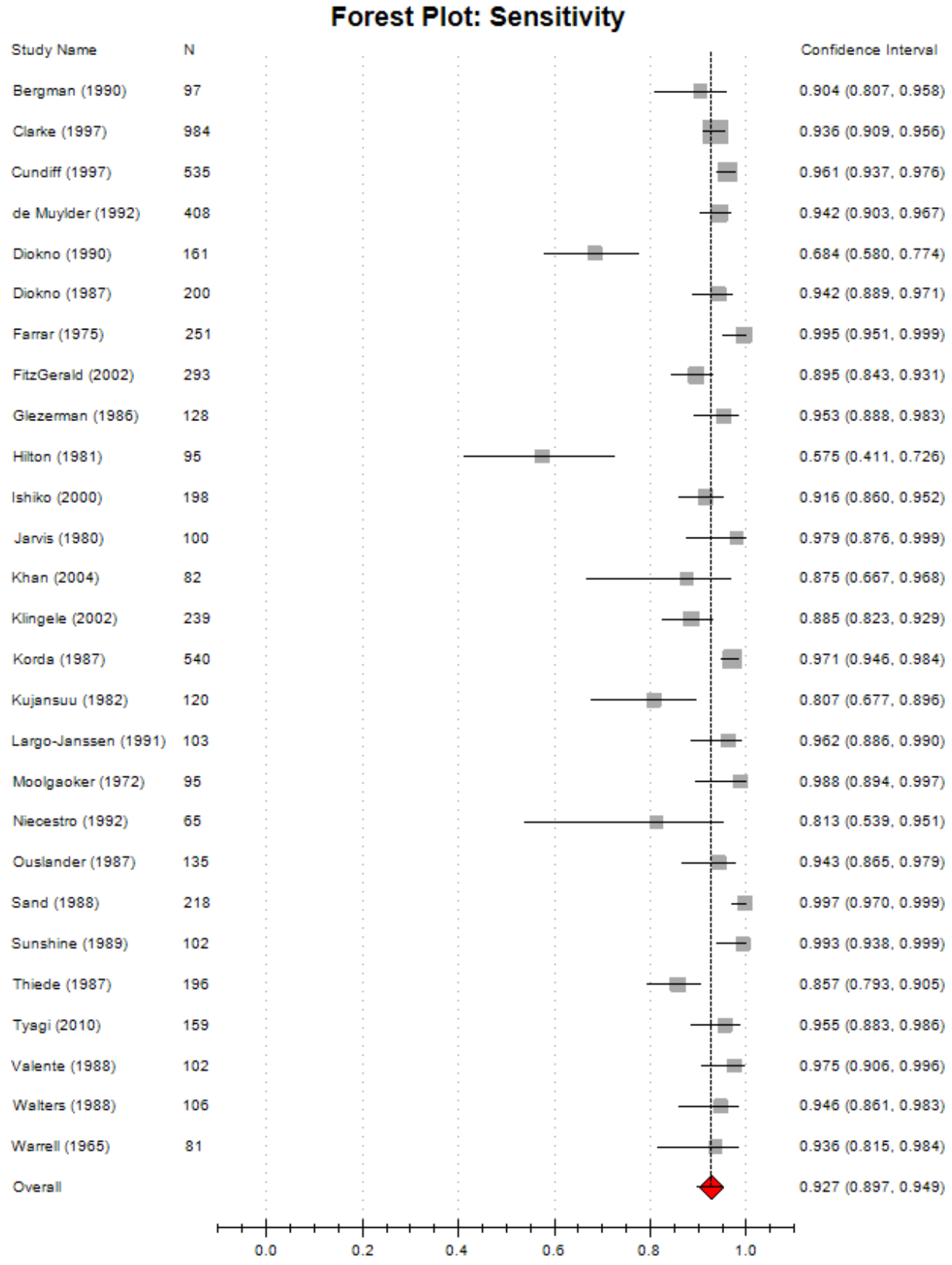



Horisonal axis - categories of the sample size of the studies
Vertical axis - number of studies

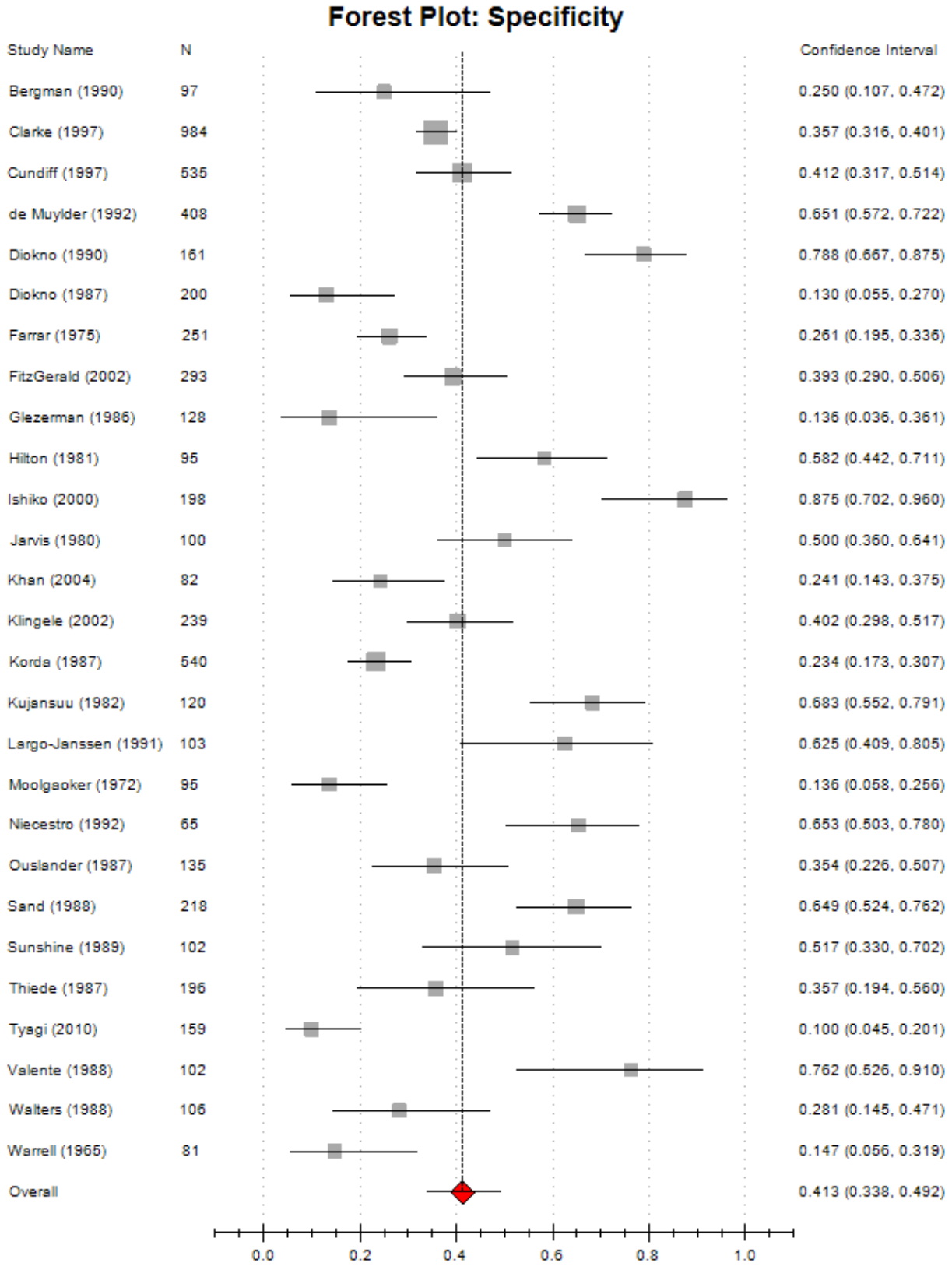
**Appendix Table F5. Diagnostic value of symptoms of stress incontinence compared to multichannel urodynamics ("gold standard") for stress UI**

| Reference | True Positive | False Negative | True Negative | False Positive | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio |
|---|---|---|---|---|---|---|---|---|
| Bergman, 1990[92] | 66 | 7 | 6 | 18 | 0.90 | 0.25 | 1.21 | 0.38 |
| Clarke, 1997[72] | 439 | 30 | 184 | 331 | 0.94 | 0.36 | 1.46 | 0.18 |
| Cundiff, 1997[75] | 416 | 17 | 42 | 60 | 0.96 | 0.41 | 1.63 | 0.09 |
| De Muylder, 1992[88] | 228 | 14 | 108 | 58 | 0.94 | 0.65 | 2.70 | 0.09 |
| Diokno, 1990[101] | 65 | 30 | 52 | 14 | 0.68 | 0.79 | 3.23 | 0.40 |
| Diokno, 1987[133] | 145 | 9 | 6 | 40 | 0.94 | 0.13 | 1.08 | 0.45 |
| Farrar, 1975[89] | 93 | 0 | 41 | 117 | 1.00 | 0.26 | 1.35 | 0.00 |
| FitzGerald, 2002[82] | 187 | 22 | 33 | 51 | 0.90 | 0.39 | 1.47 | 0.27 |
| Glezerman, 1986[105] | 101 | 5 | 3 | 19 | 0.95 | 0.14 | 1.10 | 0.35 |
| Hilton, 1981[74] | 23 | 17 | 32 | 23 | 0.58 | 0.58 | 1.38 | 0.73 |
| Ishiko, 2000[78] | 152 | 14 | 28 | 4 | 0.92 | 0.88 | 7.33 | 0.10 |
| Jarvis, 1980[73] | 47 | 1 | 26 | 26 | 0.98 | 0.50 | 1.96 | 0.04 |
| Khan, 2004[69] | 21 | 3 | 14 | 44 | 0.88 | 0.24 | 1.15 | 0.52 |
| Klingele, 2002[99] | 139 | 18 | 33 | 49 | 0.89 | 0.40 | 1.48 | 0.29 |
| Korda, 1987[134] | 362 | 11 | 39 | 128 | 0.97 | 0.23 | 1.27 | 0.12 |
| Kujansuu, 1982[132] | 46 | 11 | 43 | 20 | 0.81 | 0.68 | 2.55 | 0.28 |
| Lagro-Janssen, 1991[90] | 76 | 3 | 15 | 9 | 0.96 | 0.63 | 2.57 | 0.06 |
| Moolgaoker, 1972[97] | 41 | 0 | 7 | 47 | 1.00 | 0.13 | 1.15 | 0.00 |
| Niecostro, 1992[100] | 13 | 3 | 32 | 17 | 0.81 | 0.65 | 2.34 | 0.29 |
| Ouslander, 1987[91] | 82 | 5 | 17 | 31 | 0.94 | 0.35 | 1.46 | 0.16 |
| Sand, 1988[83] | 152 | 0 | 43 | 23 | 1.00 | 0.65 | 2.87 | 0.00 |
| Sunshine, 1989[131] | 73 | 0 | 15 | 14 | 1.00 | 0.52 | 2.07 | 0.00 |
| Thiede, 1987[103] | 144 | 24 | 10 | 18 | 0.86 | 0.36 | 1.33 | 0.40 |
| Tyagi, 2010[102] | 85 | 4 | 7 | 63 | 0.96 | 0.10 | 1.06 | 0.45 |
| Valente, 1988[85] | 79 | 2 | 16 | 5 | 0.98 | 0.76 | 4.10 | 0.03 |
| Walters, 1988[106] | 70 | 4 | 9 | 23 | 0.95 | 0.28 | 1.32 | 0.19 |
| Warrell, 1965[98] | 44 | 3 | 5 | 29 | 0.94 | 0.15 | 1.10 | 0.44 |

**Appendix Figure F2. Sensitivity of symptoms of stress incontinence compared to multichannel urodynamics ("gold standard") for any stress UI**[69,72-75,78,82,83,85,88-92,97-103,105,106,131-134]



**Appendix Figure F3. Specificity of symptoms of stress incontinence compared to multichannel urodynamics ("gold standard") for any stress UI**[69,72-75,78,82,83,85,88-92,97-103,105,106,131-134]



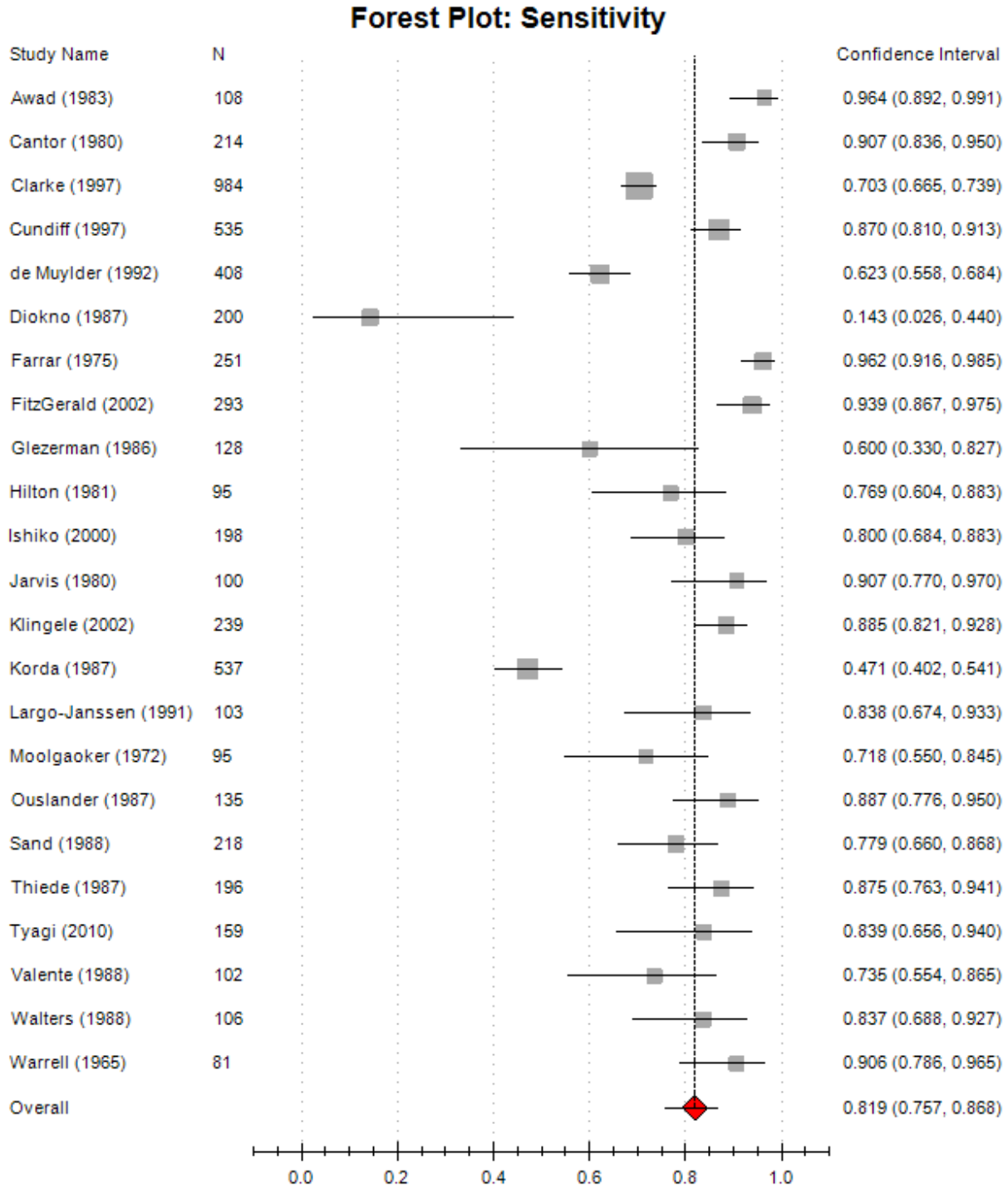
**Appendix Table F6. Pooled diagnostic value of symptoms of stress incontinence compared to multichannel urodynamics ("gold standard") for any stress UI**[69,72-75,78,82,83,85,88-92,97-103,105,106,131-134]

| | Estimate | Lower 95% CI | Upper 95% CI | Tau-sq | I^2 | Q statistics | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|---|---|
| Specificity | 0.413 | 0.338 | 0.492 | 0.605 | 0.906 | 266.152 | 26.000 | 0.000 |
| Sensitivity | 0.927 | 0.897 | 0.949 | 0.698 | 0.855 | 171.848 | 26.000 | 0.000 |
| Positive Predictive Value | 0.743 | 0.683 | 0.795 | 0.548 | 0.943 | 438.683 | 26.000 | 0.000 |
| Negative Predictive Value | 0.743 | 0.669 | 0.805 | 0.571 | 0.786 | 116.605 | 26.000 | 0.000 |
| Accuracy | 0.745 | 0.699 | 0.786 | 0.321 | 0.926 | 338.902 | 26.000 | 0.000 |
| Diagnostic Odds Ratio | 9.226 | 6.190 | 13.753 | 0.714 | 0.765 | 106.452 | 26.000 | 0.000 |
| Positive Likelihood Ratio | 1.542 | 1.398 | 1.700 | 0.048 | 0.880 | 207.663 | 26.000 | 0.000 |
| Negative Likelihood Ratio | 0.196 | 0.142 | 0.270 | 0.457 | 0.796 | 122.714 | 26.000 | 0.000 |

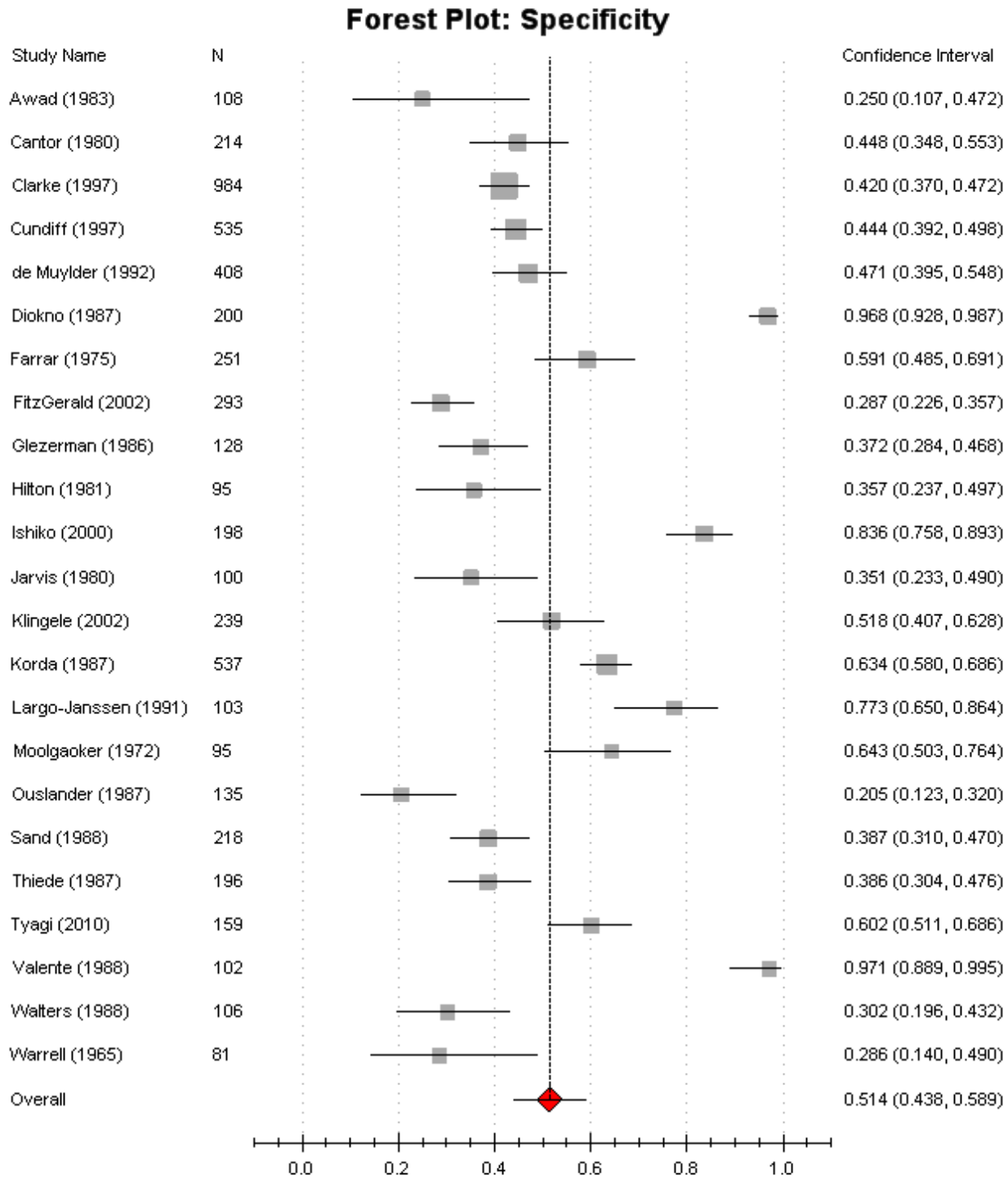
**Appendix Table F7. Diagnostic value of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for detrusor overactivity**

| Reference | True Positive | False Negative | True Negative | False Positive | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio |
|---|---|---|---|---|---|---|---|---|
| Awad, 1983[104] | 81 | 3 | 6 | 18 | 0.96 | 0.25 | 1.29 | 0.14 |
| Cantor, 1980[84] | 107 | 11 | 43 | 53 | 0.91 | 0.45 | 1.64 | 0.21 |
| Clarke, 1997[72] | 429 | 181 | 157 | 217 | 0.70 | 0.42 | 1.21 | 0.71 |
| Cundiff, 1997[75] | 160 | 24 | 156 | 195 | 0.87 | 0.44 | 1.56 | 0.29 |
| De Muylder, 1992[88] | 147 | 89 | 81 | 91 | 0.62 | 0.47 | 1.18 | 0.80 |
| Diokno, 1987[133] | 2 | 12 | 180 | 6 | 0.14 | 0.97 | 4.47 | 0.89 |
| Farrar, 1975[89] | 152 | 6 | 55 | 38 | 0.96 | 0.59 | 2.35 | 0.06 |
| FitzGerald, 2002[82] | 92 | 6 | 56 | 139 | 0.94 | 0.29 | 1.32 | 0.21 |
| Glezerman, 1986[105] | 9 | 6 | 42 | 71 | 0.60 | 0.37 | 0.96 | 1.08 |
| Hilton, 1981[74] | 30 | 9 | 20 | 36 | 0.77 | 0.36 | 1.20 | 0.65 |
| Ishiko, 2000[78] | 56 | 14 | 107 | 21 | 0.80 | 0.84 | 4.88 | 0.24 |
| Jarvis, 1980[73] | 39 | 4 | 20 | 37 | 0.91 | 0.35 | 1.40 | 0.26 |
| Klingele, 2002[99] | 138 | 18 | 43 | 40 | 0.89 | 0.52 | 1.84 | 0.22 |
| Korda, 1987[134] | 97 | 109 | 210 | 121 | 0.47 | 0.63 | 1.29 | 0.83 |
| Lagor-Janssen, 1991[90] | 31 | 6 | 51 | 15 | 0.84 | 0.77 | 3.69 | 0.21 |
| Moolgaoker, 1972[97] | 28 | 11 | 36 | 20 | 0.72 | 0.64 | 2.01 | 0.44 |
| Ouslander, 1987[91] | 55 | 7 | 15 | 58 | 0.89 | 0.21 | 1.12 | 0.55 |
| Sand, 1988[83] | 53 | 15 | 58 | 92 | 0.78 | 0.39 | 1.27 | 0.57 |
| Thiede, 1987[103] | 56 | 8 | 51 | 81 | 0.88 | 0.39 | 1.43 | 0.32 |
| Tyagi, 2010[102] | 26 | 5 | 77 | 51 | 0.84 | 0.60 | 2.11 | 0.27 |
| Valente, 1988[85] | 25 | 9 | 66 | 2 | 0.74 | 0.97 | 25.34 | 0.27 |
| Walters, 1988[106] | 36 | 7 | 19 | 44 | 0.84 | 0.30 | 1.20 | 0.54 |
| Warrell, 1965[98] | 48 | 5 | 8 | 20 | 0.91 | 0.29 | 1.27 | 0.33 |

**Appendix Figure F4. Sensitivity of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for any detrusor overactivity**[72-75,78,82-85,88-91,97-99,102-106,133,134]



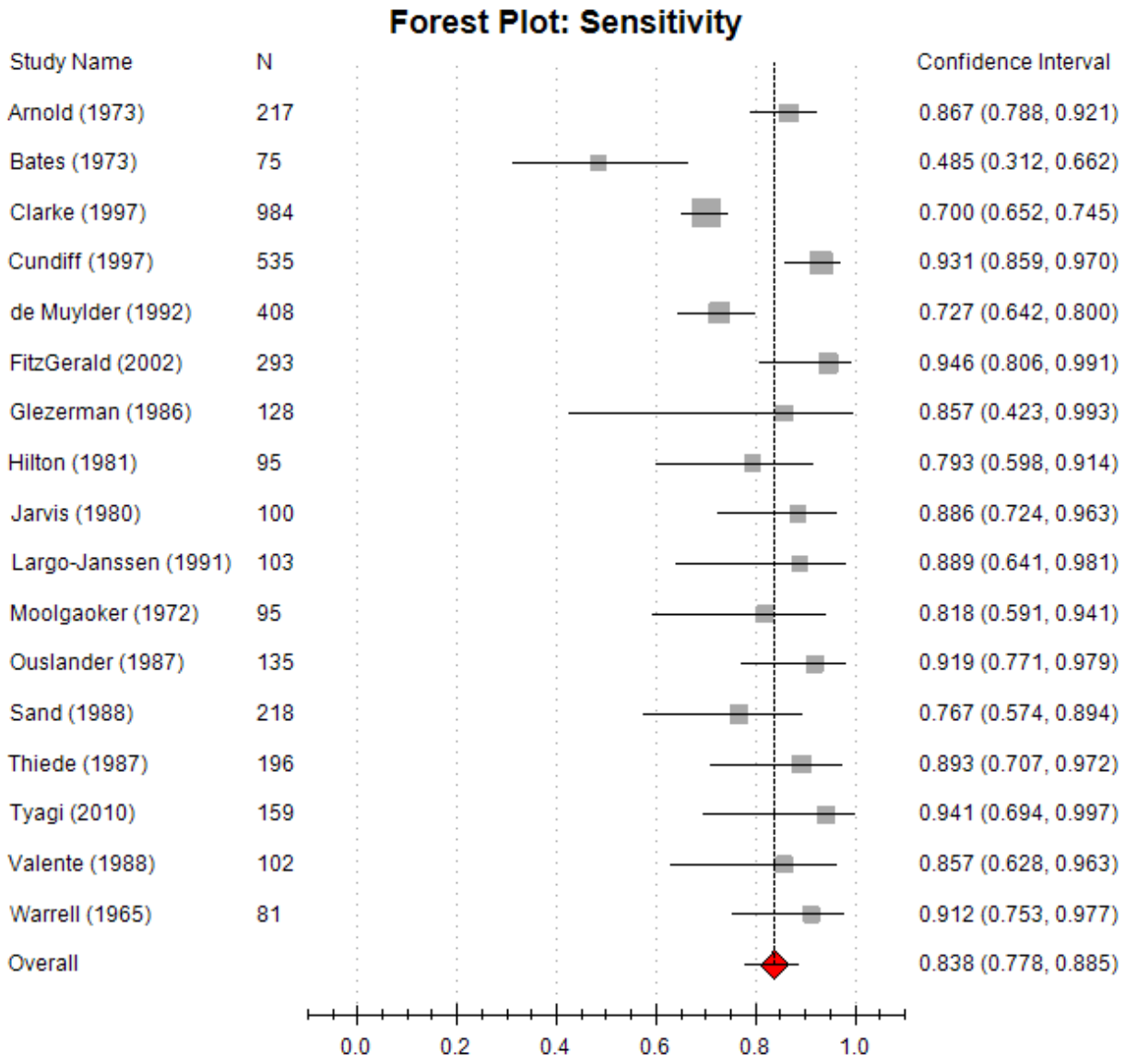
**Appendix Figure F5. Specificity of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for any detrusor overactivity**[72-75,78,82-85,88-91,97-99,102-106,133,134]



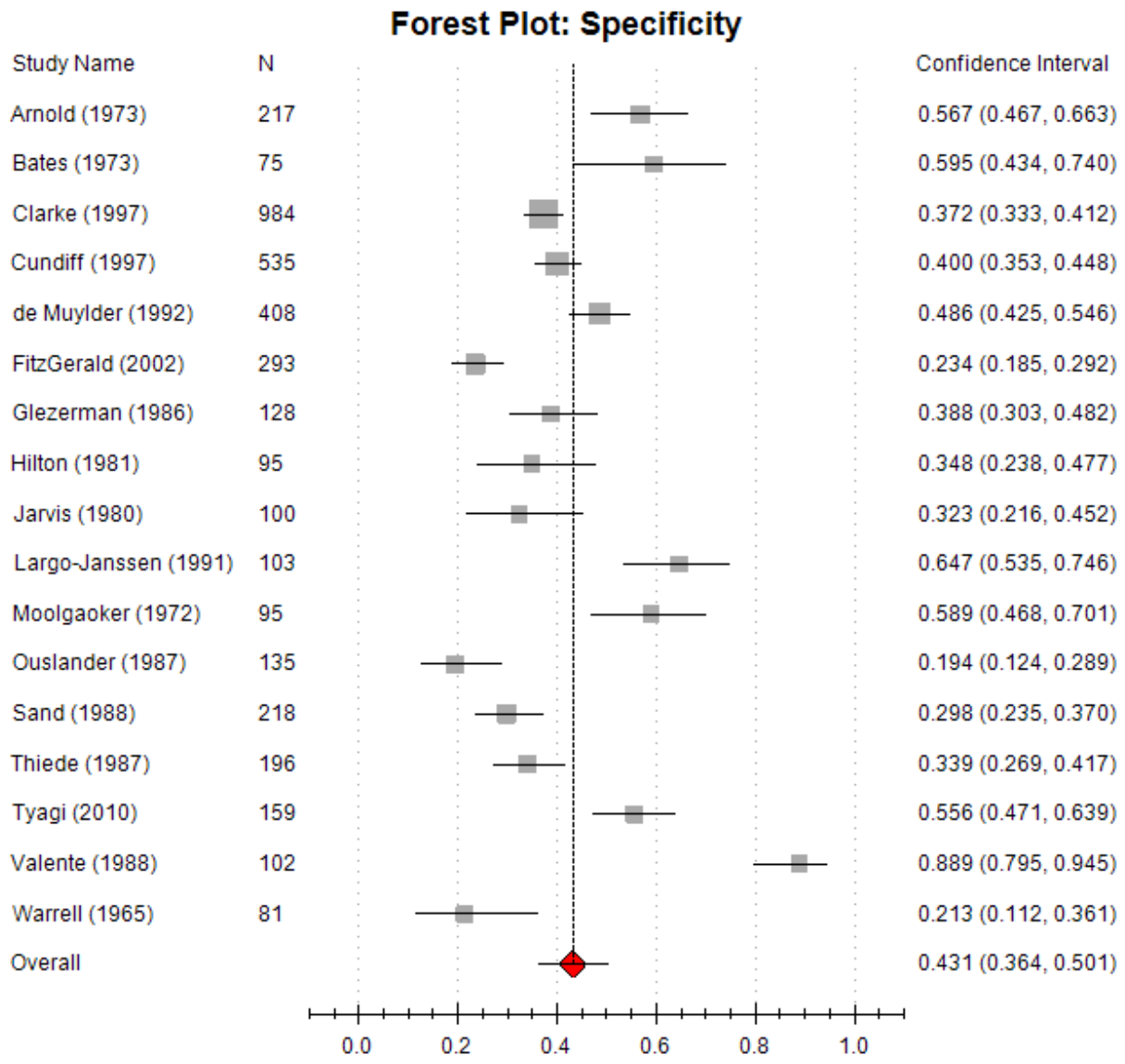
**Appendix Table F8. Diagnostic value of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity**

| Reference | True Positive | False Negative | True Negative | False Positive | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio |
|---|---|---|---|---|---|---|---|---|
| Arnold, 1973[96] | 98 | 15 | 59 | 45 | 0.87 | 0.57 | 2.00 | 0.23 |
| Bates, 1973[95] | 16 | 17 | 25 | 17 | 0.49 | 0.60 | 1.20 | 0.87 |
| Clarke, 1997[72] | 271 | 116 | 222 | 375 | 0.70 | 0.37 | 1.11 | 0.81 |
| Cundiff, 1997[75] | 95 | 7 | 173 | 260 | 0.93 | 0.40 | 1.55 | 0.17 |
| De Muylder, 1992[88] | 96 | 36 | 134 | 142 | 0.73 | 0.49 | 1.41 | 0.56 |
| FitzGerald, 2002[82] | 35 | 2 | 60 | 196 | 0.95 | 0.23 | 1.23 | 0.23 |
| Glezerman, 1986[105] | 6 | 1 | 47 | 74 | 0.86 | 0.39 | 1.40 | 0.37 |
| Hilton, 1981[74] | 23 | 6 | 23 | 43 | 0.79 | 0.35 | 1.22 | 0.59 |
| Jarvis, 1980[73] | 31 | 4 | 21 | 44 | 0.89 | 0.32 | 1.31 | 0.35 |
| Lagor, Janssen, 1991[90] | 16 | 2 | 55 | 30 | 0.89 | 0.65 | 2.52 | 0.17 |
| Moolgaoker, 1972[97] | 18 | 4 | 43 | 30 | 0.82 | 0.59 | 1.99 | 0.31 |
| Ouslander, 1987[91] | 34 | 3 | 19 | 79 | 0.92 | 0.19 | 1.14 | 0.42 |
| Sand, 1998[83] | 23 | 7 | 56 | 132 | 0.77 | 0.30 | 1.09 | 0.78 |
| Thiede, 1987[103] | 25 | 3 | 57 | 111 | 0.89 | 0.34 | 1.35 | 0.32 |
| Tyagi, 2010[102] | 16 | 1 | 79 | 63 | 0.94 | 0.56 | 2.12 | 0.11 |
| Valente, 1988[85] | 18 | 3 | 72 | 9 | 0.86 | 0.89 | 7.72 | 0.16 |
| Warrell, 1965[98] | 31 | 3 | 10 | 37 | 0.91 | 0.21 | 1.16 | 0.41 |

**Appendix Figure F6. Sensitivity of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity**[72-75,82,83,85,88,90,91,95-98,102,103,105]



**Appendix Figure F7. Specificity of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity**[72-75,82,83,85,88,90,91,95-98,102,103,105]



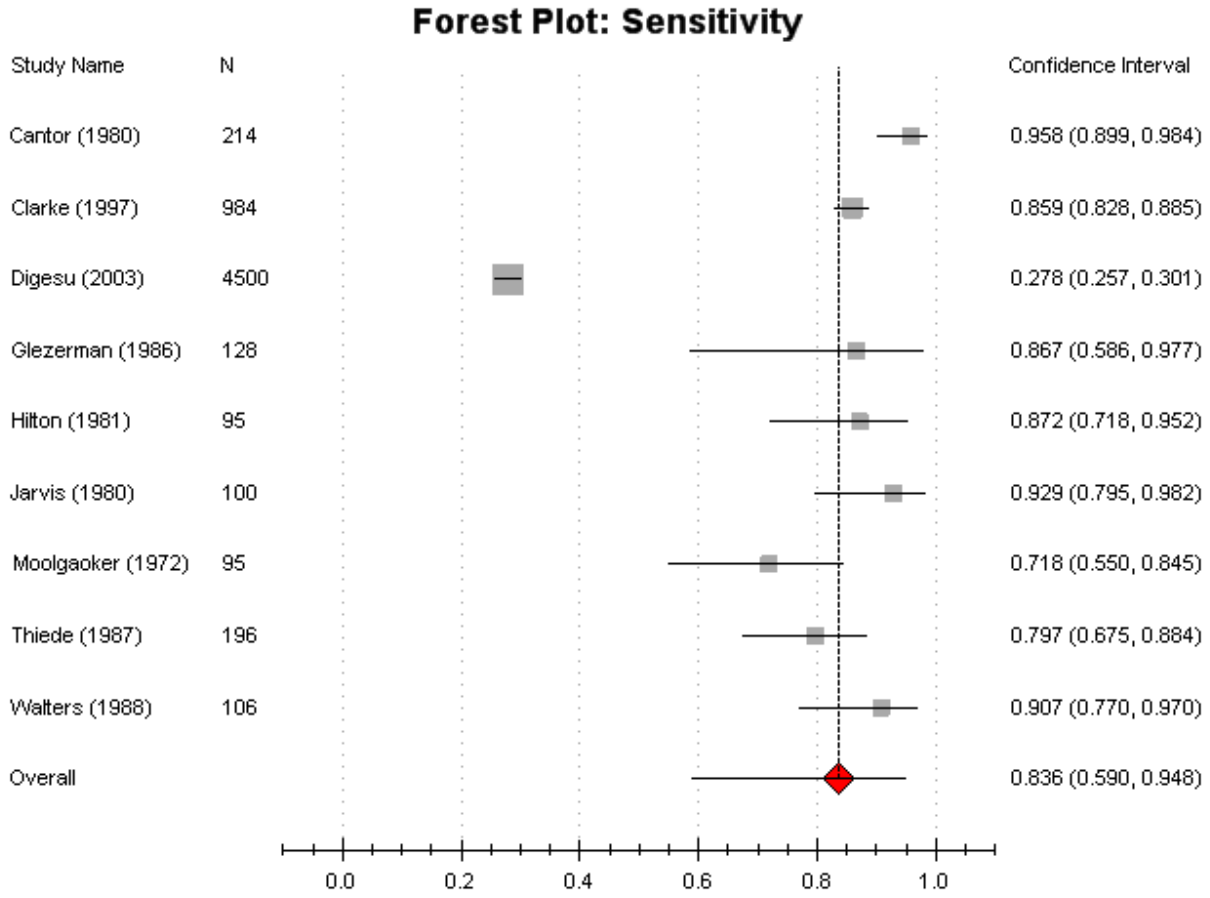
**Appendix Table F9. Pooled Diagnostic value of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity**[72-75,82,83,85,88,90,91,95-98,102,103,105]

| | Estimate | Lower 95% CI | Upper 95% CI | $Tau^2$ | $I^2$ | Q-statistic | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|---|---|
| Specificity | 0.43 | 0.36 | 0.50 | 0.30 | 0.92 | 184.82 | 16.00 | 0.00 |
| Sensitivity | 0.84 | 0.78 | 0.89 | 0.41 | 0.77 | 66.16 | 16.00 | 0.00 |
| Positive predictive value | 0.33 | 0.26 | 0.41 | 0.44 | 0.93 | 209.80 | 16.00 | 0.00 |
| Negative predictive value | 0.89 | 0.83 | 0.93 | 0.86 | 0.88 | 123.86 | 16.00 | 0.00 |
| Accuracy | 0.53 | 0.48 | 0.59 | 0.21 | 0.92 | 183.24 | 16.00 | 0.00 |
| Diagnostic odds ratio | 4.17 | 2.59 | 6.70 | 0.66 | 0.80 | 75.47 | 16.00 | 0.00 |
| Positive likelihood ratio | 1.48 | 1.31 | 1.66 | 0.05 | 0.87 | 117.02 | 16.00 | 0.00 |
| Negative likelihood ratio | 0.40 | 0.29 | 0.54 | 0.24 | 0.74 | 58.69 | 16.00 | 0.00 |

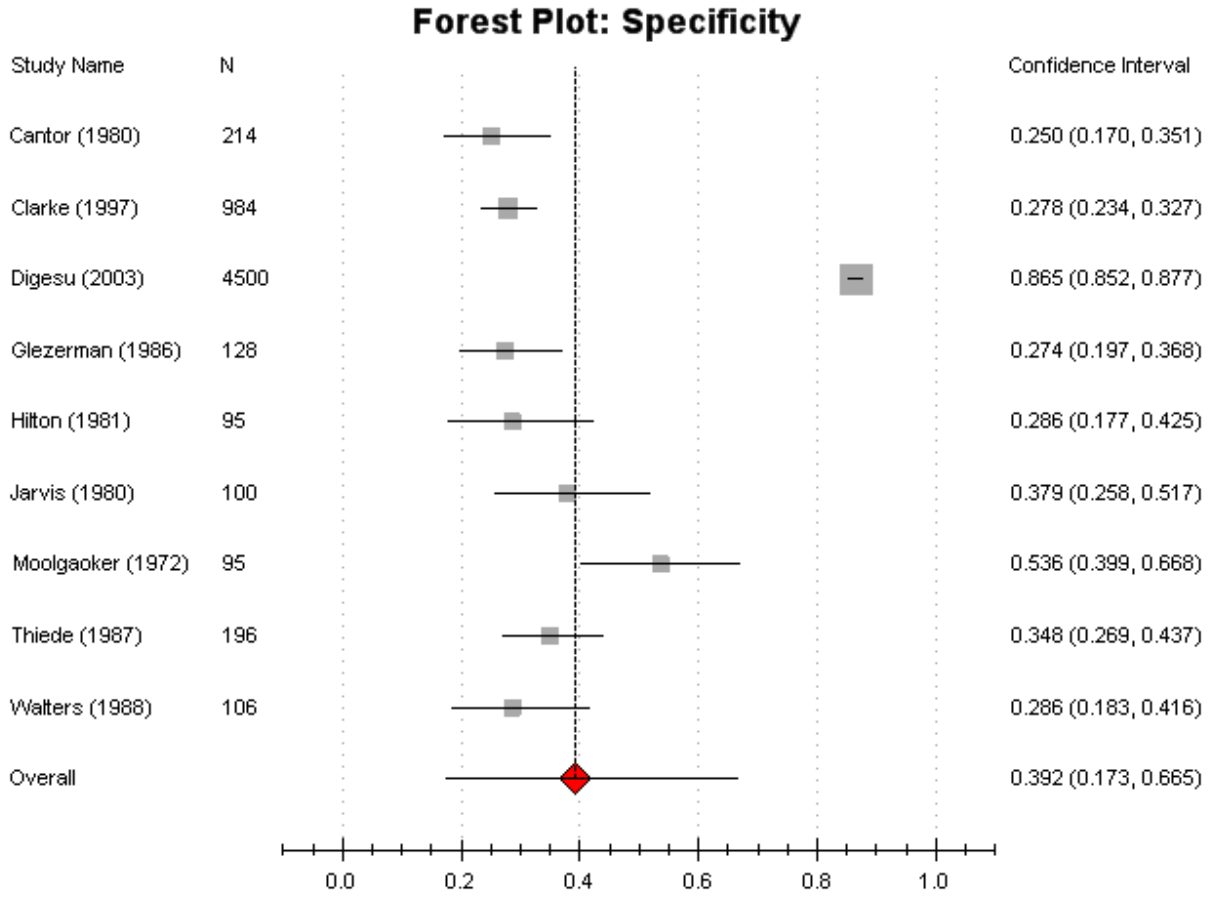
**Appendix Table F10. Diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for detrusor overactivity**

| Reference | True Positive | False Negative | True Negative | False Positive | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio |
|---|---|---|---|---|---|---|---|---|
| Cantor, 1980[84] | 113 | 5 | 24 | 72 | 0.96 | 0.25 | 1.28 | 0.17 |
| Clarke, 1997[72] | 524 | 86 | 104 | 270 | 0.86 | 0.28 | 1.19 | 0.51 |
| Digesu, 2003[68] | 457 | 1184 | 2473 | 386 | 0.28 | 0.87 | 2.06 | 0.83 |
| Glezerman, 1986[105] | 13 | 2 | 31 | 82 | 0.87 | 0.27 | 1.19 | 0.49 |
| Hilton, 1981[74] | 34 | 5 | 16 | 40 | 0.87 | 0.29 | 1.22 | 0.45 |
| Jarvis, 1980[73] | 39 | 3 | 22 | 36 | 0.93 | 0.38 | 1.50 | 0.19 |
| Moolgaoker, 1972[97] | 28 | 11 | 30 | 26 | 0.72 | 0.54 | 1.55 | 0.53 |
| Thiede, 1987[103] | 51 | 13 | 46 | 86 | 0.80 | 0.35 | 1.22 | 0.58 |
| Walters, 1988[106] | 39 | 4 | 18 | 45 | 0.91 | 0.29 | 1.27 | 0.33 |

**Appendix Figure F8. Sensitivity of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for any detrusor overactivity**[68,72-74,84,97,103,105,106]



**Appendix Figure F9. Specificity of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for any detrusor overactivity**[68,72-74,84,97,105 103,106]



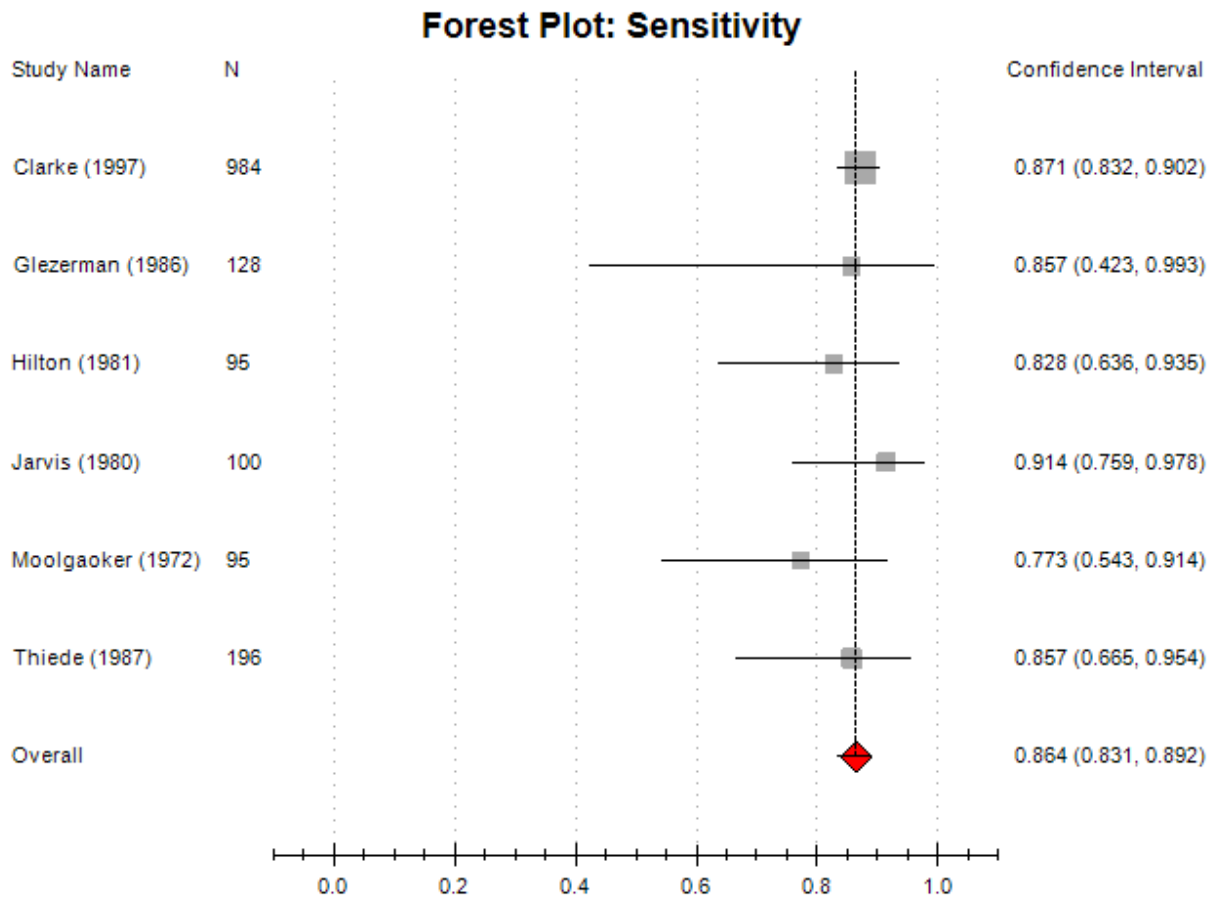
**Appendix Table F11. Pooled diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for any detrusor overactivity**[68,72-74,84,97,105 103,106]

| | Estimate | Lower 95% CI | Upper 95% CI | $Tau^2$ | $I^2$ | Q-statistic | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|---|---|
| Specificity | 0.39 | 0.17 | 0.67 | 2.91 | 0.99 | 898.68 | 8.00 | 0.00 |
| Sensitivity | 0.84 | 0.59 | 0.95 | 3.54 | 0.99 | 640.98 | 8.00 | 0.00 |
| Positive predictive value | 0.48 | 0.39 | 0.57 | 0.25 | 0.94 | 109.04 | 8.00 | 0.00 |
| Negative predictive value | 0.75 | 0.67 | 0.81 | 0.18 | 0.798 | 34.63 | 8.00 | 0.00 |
| Accuracy | 0.57 | 0.51 | 0.62 | 0.09 | 0.90 | 72.29 | 8.00 | 0.00 |
| Diagnostic odds ratio | 2.60 | 2.19 | 3.09 | 0.01 | 0.20 | 8.75 | 8.00 | 0.36 |
| Positive likelihood ratio | 1.36 | 1.18 | 1.58 | 0.04 | 0.89 | 64.89 | 8.00 | 0.00 |
| Negative likelihood ratio | 0.47 | 0.33 | 0.67 | 0.17 | 0.83 | 41.66 | 8.00 | 0.00 |

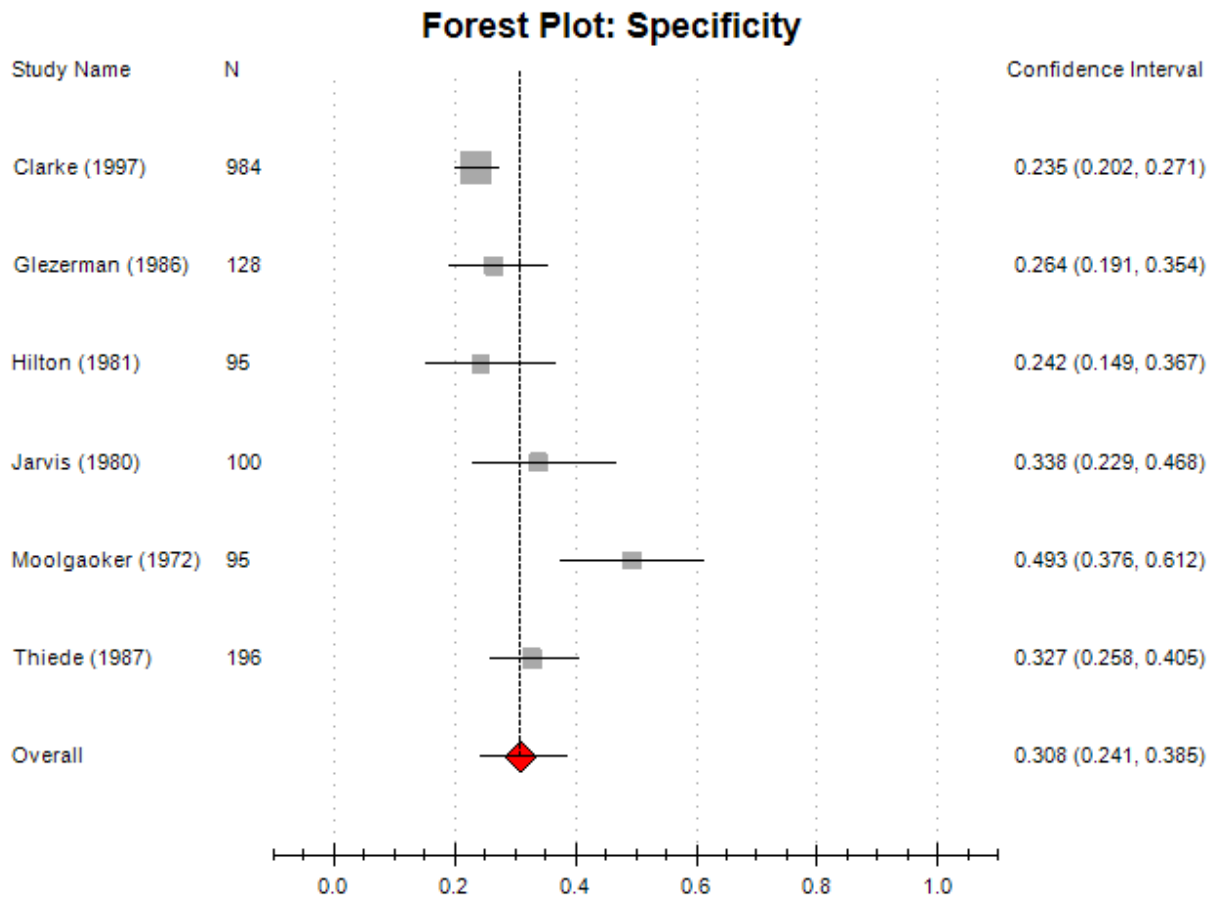
**Appendix Table F12. Diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity**

| Reference | True Positive | False Negative | True Negative | False Positive | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio |
|---|---|---|---|---|---|---|---|---|
| Clarke, 1997[72] | 337 | 50 | 140 | 457 | 0.87 | 0.24 | 1.14 | 0.55 |
| Glezerman, 1986[105] | 6 | 1 | 32 | 89 | 0.86 | 0.26 | 1.16 | 0.54 |
| Hilton, 1981[74] | 24 | 5 | 16 | 50 | 0.83 | 0.24 | 1.09 | 0.71 |
| Jarvis, 1980[73] | 32 | 3 | 22 | 43 | 0.91 | 0.34 | 1.38 | 0.25 |
| Moolgaoker, 1972[97] | 17 | 5 | 36 | 37 | 0.77 | 0.49 | 1.52 | 0.46 |
| Thiede, 1987[103] | 24 | 4 | 55 | 113 | 0.86 | 0.33 | 1.27 | 0.44 |

**Appendix Figure F10. Sensitivity of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity**[72-74,97,103,105]



**Appendix Figure F11. Specificity of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity**[72-74,97,103,105]



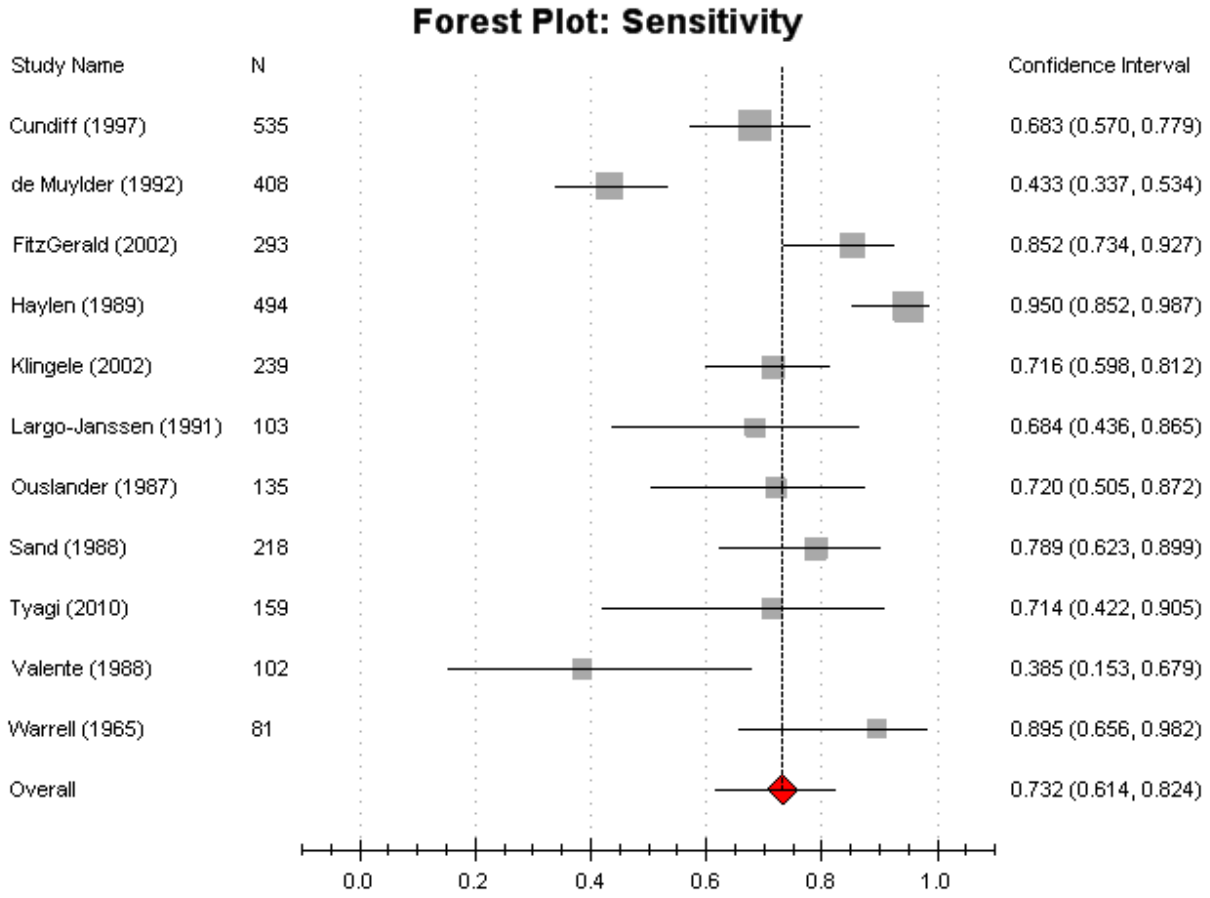
**Appendix Table F13. Pooled diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity**[72-74,97,103,105]

| | Estimate | Lower 95% CI | Upper 95% CI | $Tau^2$ | $I^2$ | Q-statistic | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|---|---|
| Specificity | 0.31 | 0.24 | 0.39 | 0.14 | 0.84 | 25.01 | 5.00 | 0.00 |
| Sensitivity | 0.86 | 0.83 | 0.89 | 0.00 | -0.46 | 2.74 | 5.00 | 0.74 |
| Positive predictive value | 0.27 | 0.17 | 0.40 | 0.45 | 0.93 | 58.88 | 5.00 | 0.00 |
| Negative predictive value | 0.86 | 0.76 | 0.93 | 0.47 | 0.77 | 17.05 | 5.00 | 0.00 |
| Accuracy | 0.45 | 0.38 | 0.52 | 0.09 | 0.84 | 24.71 | 5.00 | 0.00 |
| Diagnostic odds ratio | 2.26 | 1.68 | 3.04 | 0.00 | -0.26 | 3.18 | 5.00 | 0.67 |
| Positive likelihood ratio | 1.21 | 1.11 | 1.32 | 0.00 | 0.46 | 7.35 | 5.00 | 0.20 |
| Negative likelihood ratio | 0.52 | 0.41 | 0.67 | 0.00 | -0.69 | 2.37 | 5.00 | 0.80 |

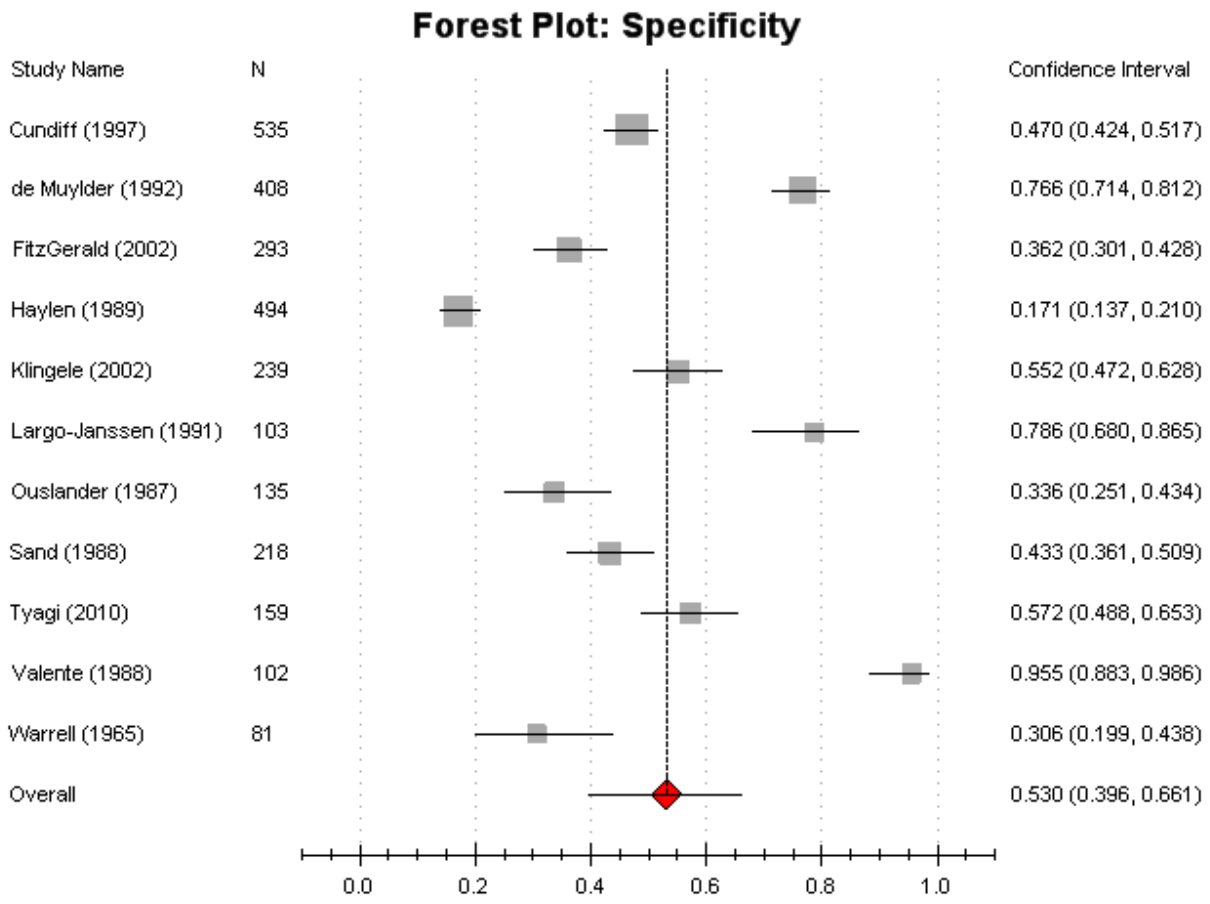
**Appendix Table F14. Diagnostic value of mixed symptoms compared to multichannel urodynamics ("gold standard") for mixed UI**

| Reference | True Positive | False Negative | True Negative | False Positive | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio |
|---|---|---|---|---|---|---|---|---|
| Cundiff, 1997[75] | 56 | 26 | 213 | 240 | 0.68 | 0.47 | 1.29 | 0.67 |
| De Muylder, 1992[88] | 45 | 59 | 233 | 71 | 0.43 | 0.77 | 1.85 | 0.74 |
| FitzGerald, 2002[82] | 52 | 9 | 84 | 148 | 0.85 | 0.36 | 1.34 | 0.41 |
| Haylen, 1989[93] | 57 | 3 | 74 | 360 | 0.95 | 0.17 | 1.15 | 0.29 |
| Klingele, 2002[99] | 53 | 21 | 91 | 74 | 0.72 | 0.55 | 1.60 | 0.51 |
| Lagro-Janssen, 1991[90] | 13 | 6 | 66 | 18 | 0.68 | 0.79 | 3.20 | 0.40 |
| Ouslander, 1987[91] | 18 | 7 | 37 | 73 | 0.72 | 0.34 | 1.08 | 0.83 |
| Sand, 1988[83] | 30 | 8 | 78 | 102 | 0.79 | 0.43 | 1.39 | 0.49 |
| Tyagi, 2010[102] | 10 | 4 | 83 | 62 | 0.71 | 0.57 | 1.67 | 0.50 |
| Valente, 1988[85] | 5 | 8 | 85 | 4 | 0.39 | 0.96 | 8.56 | 0.64 |
| Warrell, 1965[98] | 17 | 2 | 19 | 43 | 0.90 | 0.31 | 1.29 | 0.34 |

**Appendix Figure F12. Sensitivity of mixed symptoms compared to multichannel urodynamics ("gold standard") for mixed UI**[75,82,83,85,88,90,91,93,98,99,102]



**Appendix Figure F13. Specificity of mixed symptoms compared to multichannel urodynamics ("gold standard") for mixed UI**[75,82,83,85,88,90,91,93,98,99,102]



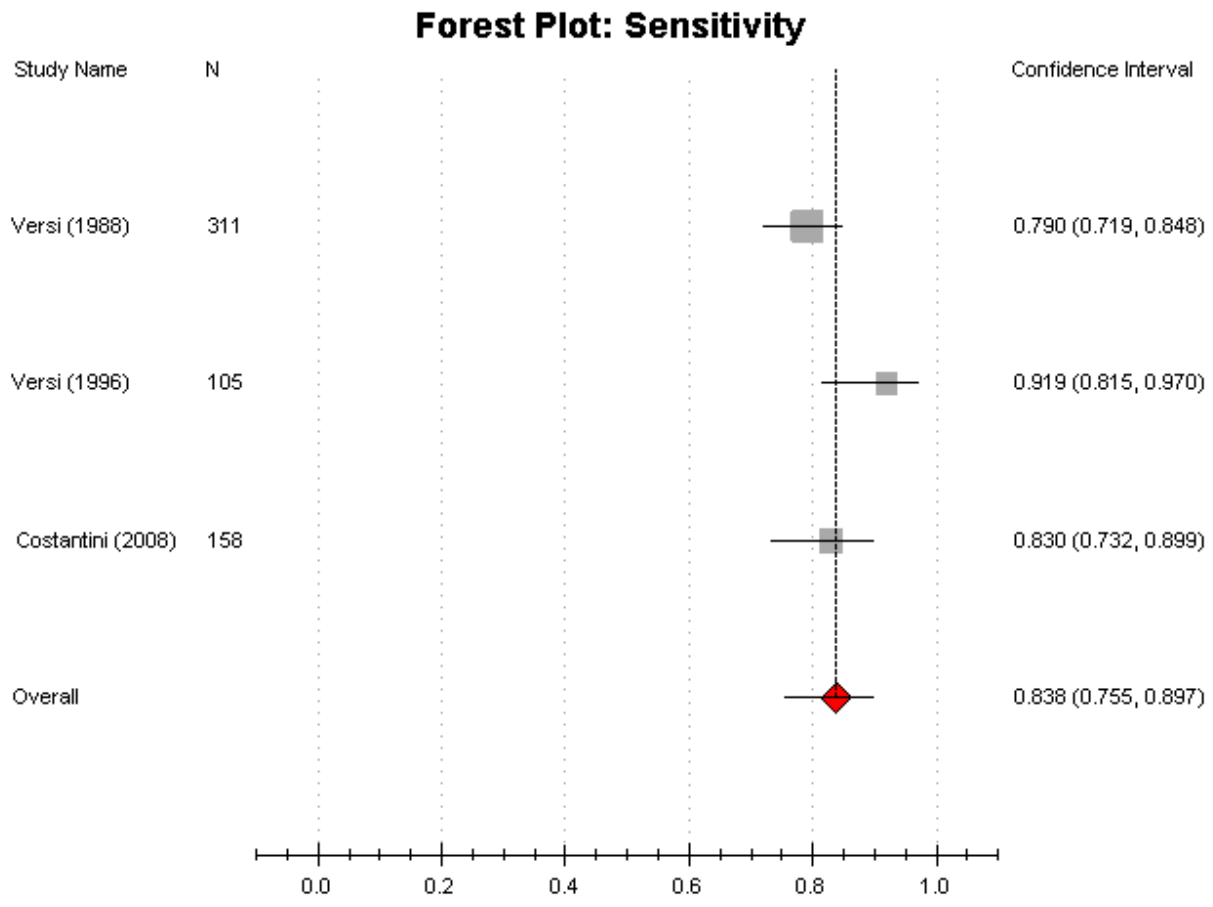
**Appendix Table F15. Pooled Diagnostic value of mixed symptoms compared to multichannel urodynamics ("gold standard") for mixed UI**[75,82,83,85,88,90,91,93,98,99,102]

| | Estimate | Lower 95% CI | Upper 95% CI | $Tau^2$ | $I^2$ | Q-statistic | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|---|---|
| Specificity | 0.53 | 0.40 | 0.66 | 0.80 | 0.97 | 327.20 | 10.00 | 0.00 |
| Sensitivity | 0.73 | 0.61 | 0.82 | 0.63 | 0.85 | 58.61 | 10.00 | 0.00 |
| Positive predictive value | 0.26 | 0.20 | 0.34 | 0.30 | 0.88 | 76.99 | 10.00 | 0.00 |
| Negative predictive value | 0.89 | 0.85 | 0.92 | 0.21 | 0.72 | 31.88 | 10.00 | 0.00 |
| Accuracy | 0.56 | 0.46 | 0.66 | 0.43 | 0.96 | 241.00 | 10.00 | 0.00 |
| Diagnostic odds ratio | 2.90 | 2.18 | 3.86 | 0.05 | 0.32 | 13.29 | 10.00 | 0.21 |
| Positive likelihood ratio | 1.45 | 1.27 | 1.67 | 0.04 | 0.80 | 45.18 | 10.00 | 0.00 |
| Negative likelihood ratio | 0.61 | 0.52 | 0.71 | 0.01 | 0.25 | 11.97 | 10.00 | 0.29 |

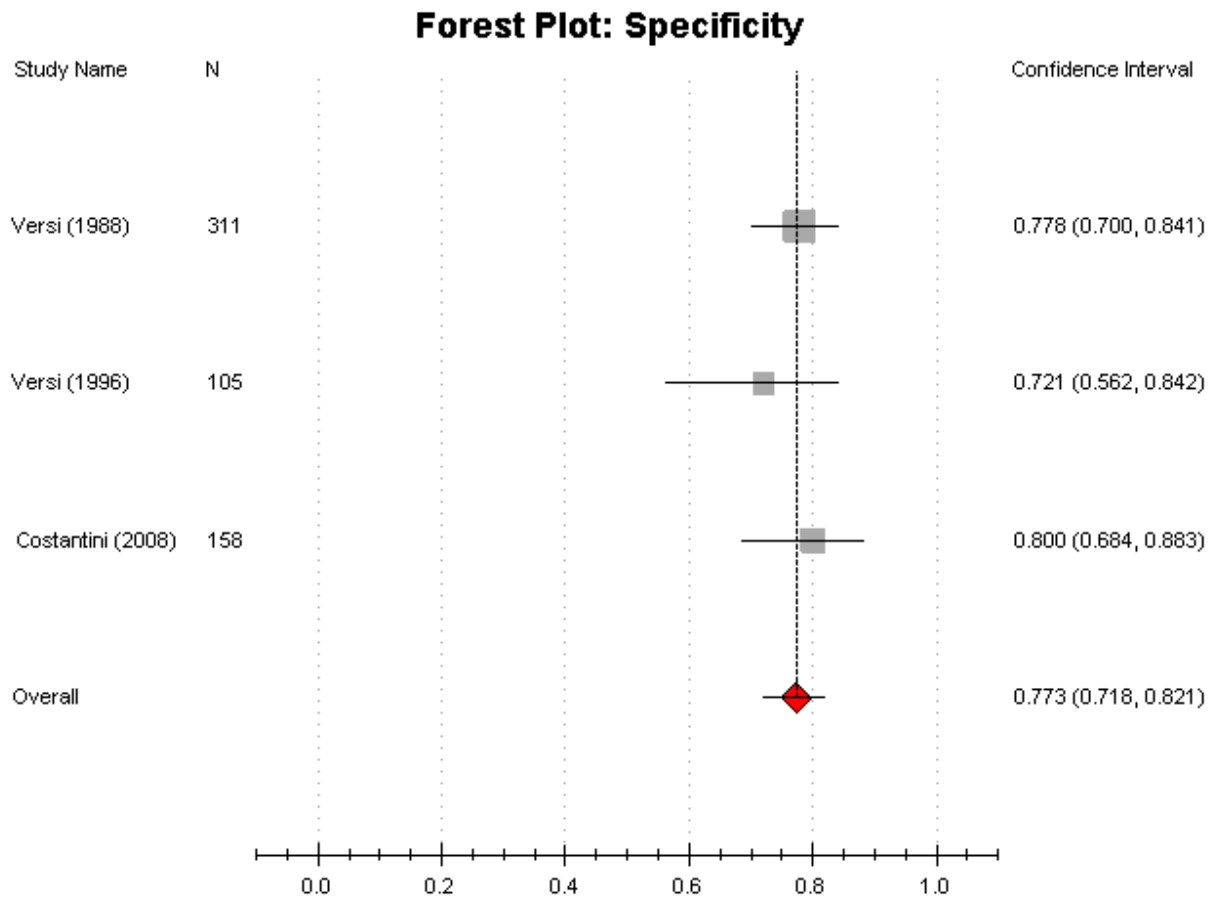
**Appendix Table F16. Diagnostic value of pad test compared to multichannel urodynamics ("gold standard") for stress UI**

| Reference | True Positives [False Negatives] | False Positives [True Negatives] | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio |
|---|---|---|---|---|---|---|
| **1 hour pad test vs. UD** | | | | | | |
| Versi, 1988[80] | 20 [19] | 144 [128] | 0.51 | 0.47 | 0.97 | 1.01 |
| Costantini, 2008[77] | 53 [8] | 34 [63] | 0.87 | 0.65 | 2.48 | 0.2 |
| **Pad test vs. UD** | | | | | | |
| Versi, 1988[80] | 132 [35] | 32 [112] | 0.79 | 0.78 | 3.56 | 0.27 |
| Versi, 1996[70] | 57 [5] | 12 [31] | 0.92 | 0.72 | 3.29 | 0.11 |
| Costantini, 2008[77] | 73 [15] | 14 [56] | 0.83 | 0.80 | 4.15 | 0.21 |

**Appendix Figure F14. Sensitivity of pad test compared to multichannel urodynamics ("gold standard") for any stress UI**[70,77,80]



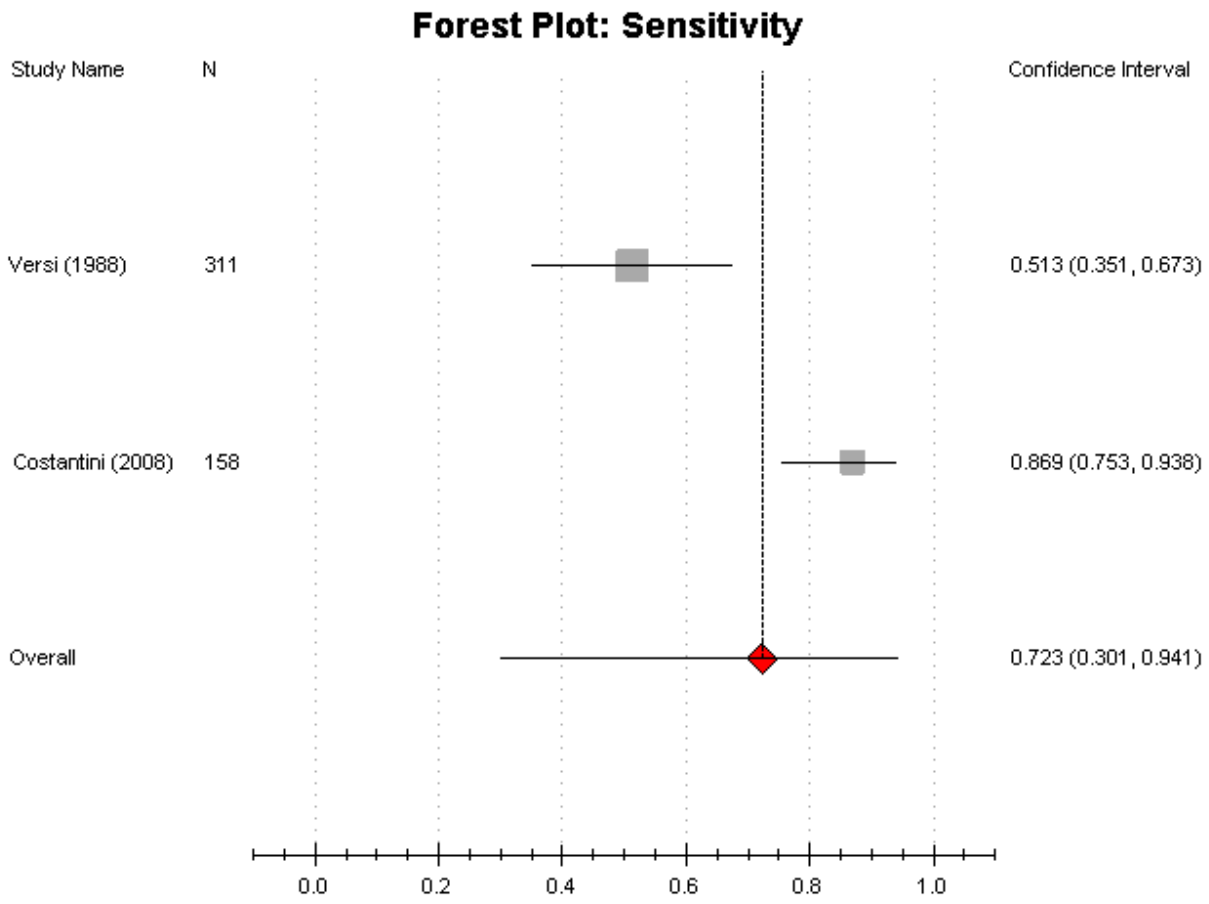
**Appendix Figure F15. Specificity of pad test compared to multichannel urodynamics ("gold standard") for any stress UI**[70,77,80]



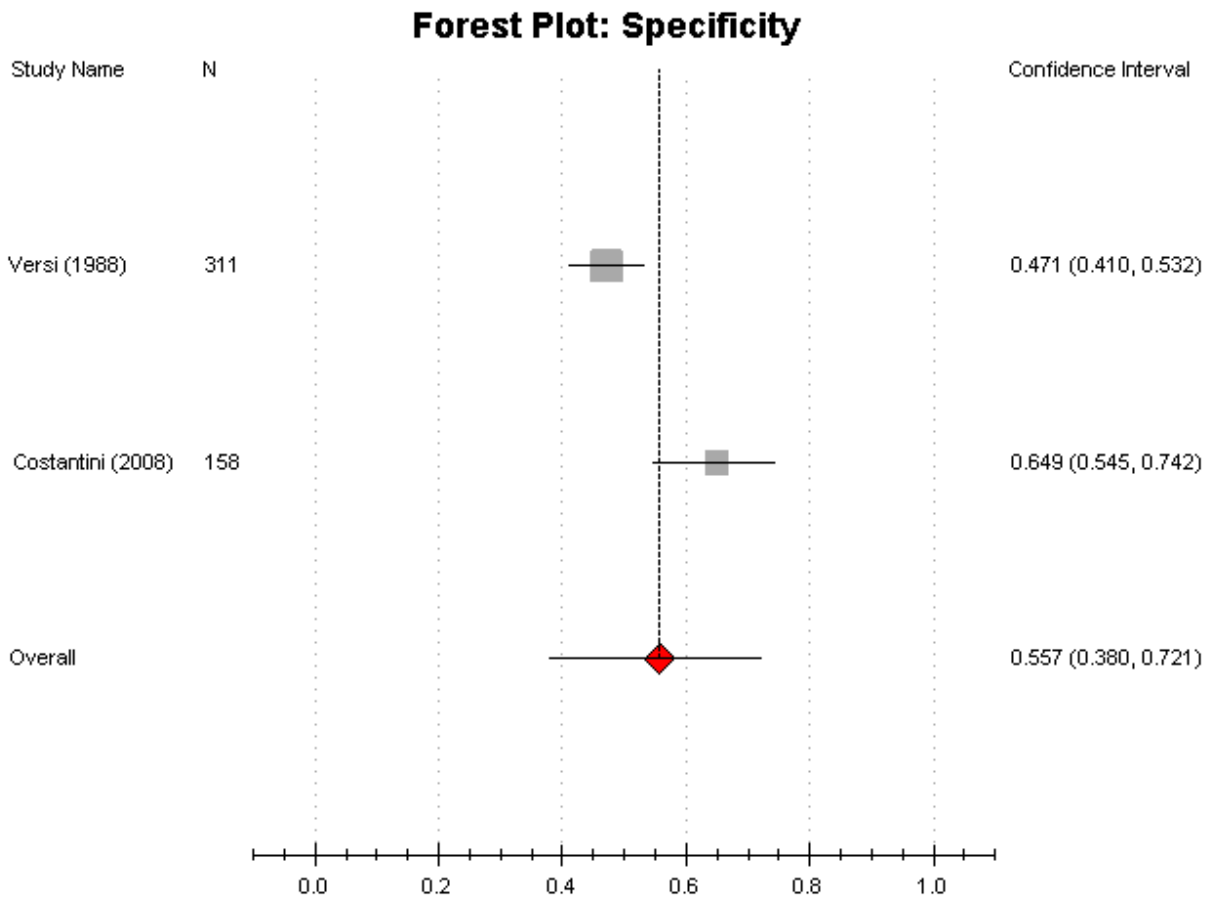
**Appendix Table 17. Pooled Diagnostic value of pad test compared to multichannel urodynamics ("gold standard") for any stress UI**[70,77,80]

| | Estimate | 95% CI | Tau-sq | I^2 | Q-statistic | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|---|
| Specificity | 0.773 | 0.718; 0.821 | 0.000 | -0.032 | 0.969 | 2.000 | 0.616 |
| Sensitivity | 0.838 | 0.755; 0.897 | 0.123 | 0.796 | 4.908 | 2.000 | 0.086 |
| Positive predictive value | 0.818 | 0.772; 0.857 | 0.000 | -1.088 | 0.479 | 2.000 | 0.787 |
| Negative predictive value | 0.781 | 0.726; 0.828 | 0.000 | 0.396 | 1.655 | 2.000 | 0.437 |
| Accuracy | 0.802 | 0.767; 0.833 | 0.000 | 0.397 | 1.660 | 2.000 | 0.436 |
| Diagnostic odds ratio | 16.343 | 10.761; 24.821 | 0.000 | 0.450 | 1.819 | 2.000 | 0.403 |
| Positive likelihood ratio | 3.624 | 2.875; 4.568 | 0.000 | -1.138 | 0.468 | 2.000 | 0.791 |
| Negative likelihood ratio | 0.216 | 0.146; 0.319 | 0.057 | 0.736 | 3.782 | 2.000 | 0.151 |

**Appendix Figure F16. Sensitivity of pad test compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[77,80]**



**Appendix Figure F17. Specificity of pad test compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[77,80]**



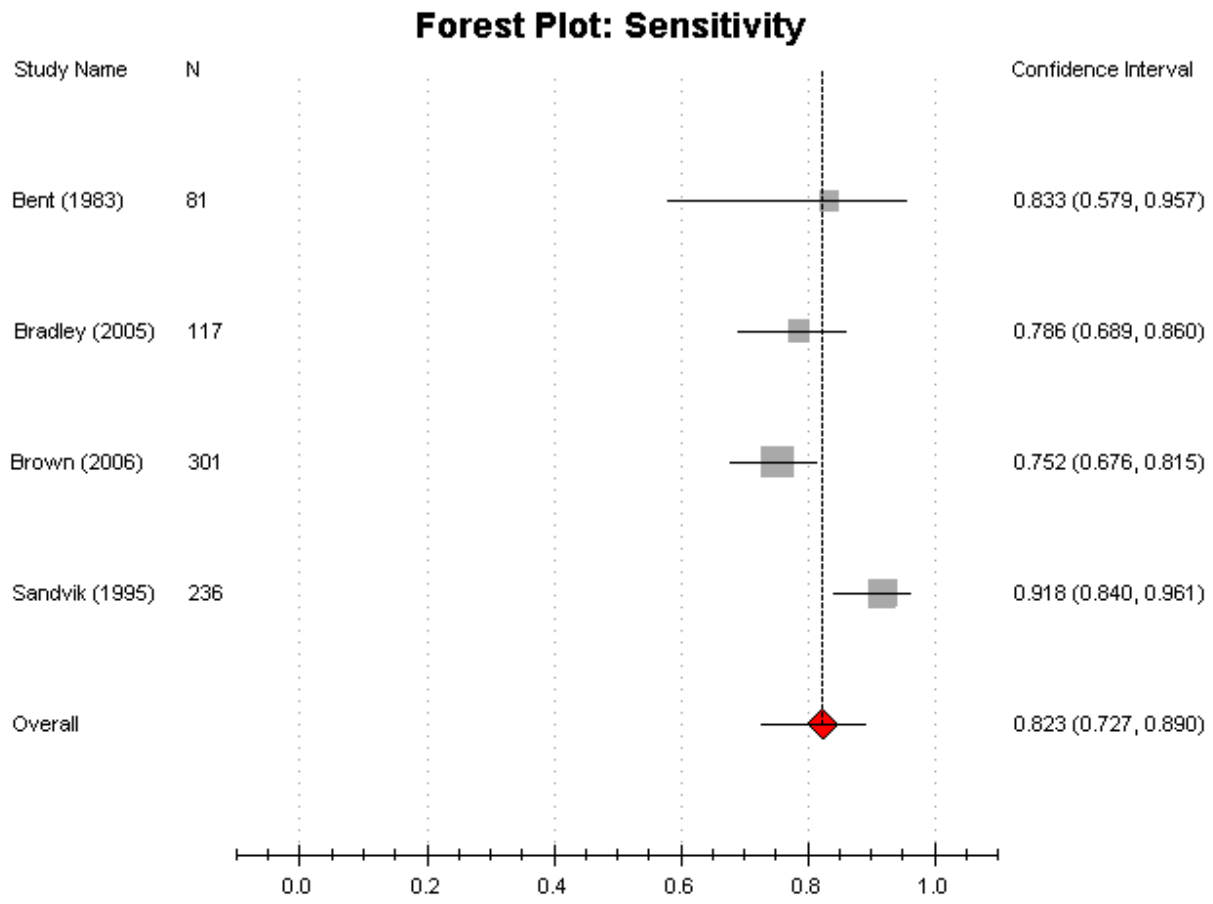
**Appendix Table F18. Pooled diagnostic value of pad test compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[77,80]**

| | Estimate | 95% CI | Tau-sq | Q statistics | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|
| Specificity | 0.557 | 0.380; 0.721 | 0.240 | 8.987 | 1.000 | 0.003 |
| Sensitivity | 0.723 | 0.301; 0.941 | 1.569 | 13.728 | 1.000 | 0.000 |
| Positive predictive value | 0.318 | 0.042; 0.833 | 2.871 | 55.565 | 1.000 | 0.000 |
| Negative predictive value | 0.876 | 0.825; 0.914 | 0.000 | 0.121 | 1.000 | 0.728 |
| Accuracy | 0.611 | 0.345; 0.824 | 0.596 | 27.306 | 1.000 | 0.000 |
| Diagnostic odds ratio | 3.342 | 0.268; 41.640 | 3.160 | 21.616 | 1.000 | 0.000 |
| Positive likelihood ratio | 1.555 | 0.619; 3.904 | 0.417 | 17.943 | 1.000 | 0.000 |
| Negative likelihood ratio | 0.469 | 0.095; 2.325 | 1.263 | 18.387 | 1.000 | 0.000 |

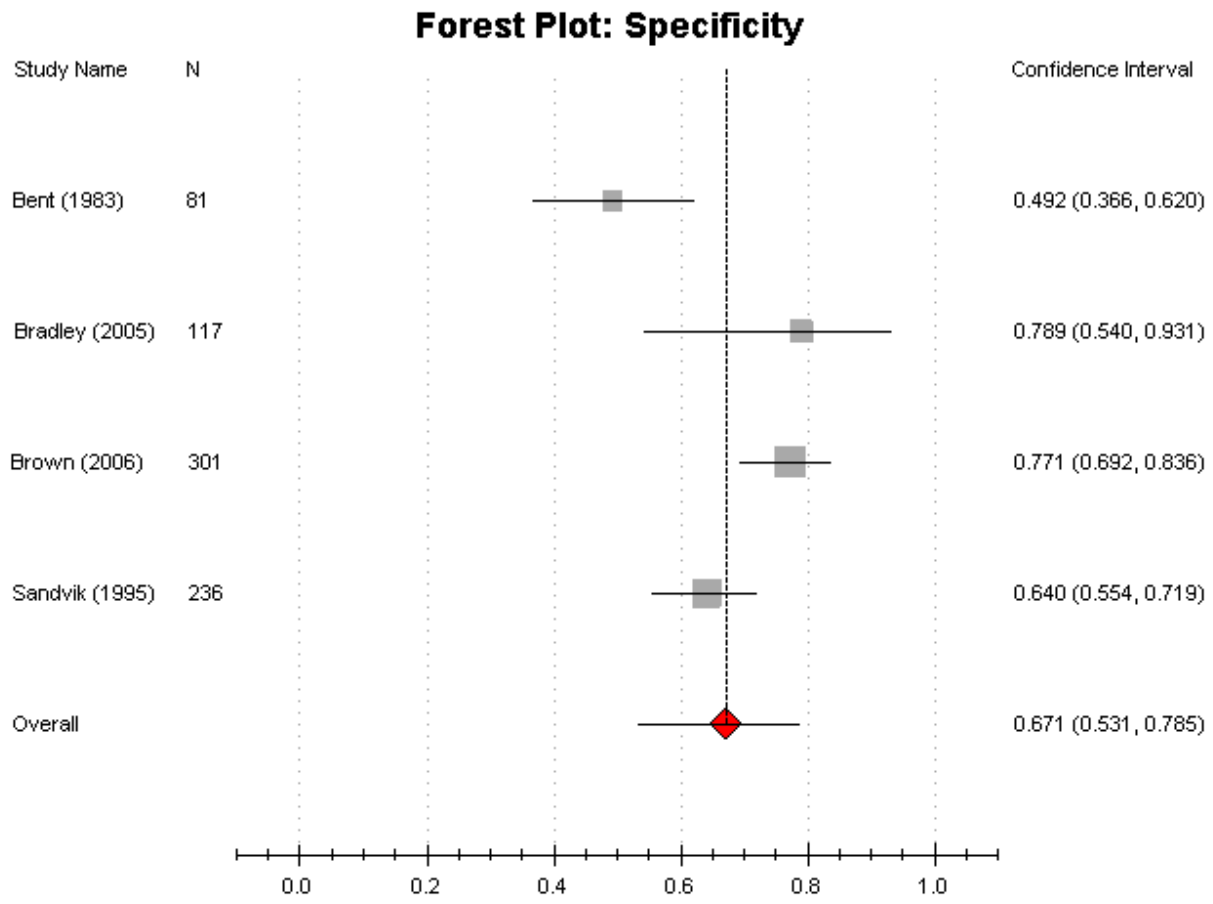
**Appendix Table F19. Diagnostic value of symptoms compared to clinical diagnosis ("gold standard") for different types of urinary incontinence**

| Type of UI | Reference | True Positives [False Negatives] | False Positives [True Negatives] | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio |
|---|---|---|---|---|---|---|---|
| Urgency UI | Bent, 1983[87] | 15 [3] | 32 [31] | 0.83 | 0.49 | 1.64 | 0.34 |
| Urgency UI | Bradley, 2005[81] | 77 [21] | 4 [15] | 0.79 | 0.79 | 3.76 | 0.27 |
| Urgency UI | Brown, 2006[76] | 121 [40] | 32 [108] | 0.75 | 0.77 | 3.29 | 0.32 |
| Urgency UI | Sandvik, 1995[71] | 89 [8] | 50 [89] | 0.92 | 0.64 | 2.55 | 0.13 |
| Urgency | Bent, 1983[87] | 16 [2] | 37 [26] | 0.89 | 0.41 | 1.51 | 0.27 |
| Stress UI | Bent, 1983[87] | 20 [1] | 22 [38] | 0.95 | 0.63 | 2.60 | 0.08 |
| Stress UI | Bradley, 2005[81] | 75 [13] | 8 [21] | 0.85 | 0.71 | 2.93 | 0.21 |
| Stress UI | Brown, 2006[76] | 149 [25] | 51 [76] | 0.86 | 0.60 | 2.13 | 0.24 |
| Stress UI | Sandvik, 1995[71] | 179 [4] | 26 [27] | 0.98 | 0.51 | 1.99 | 0.04 |
| Stress UI | Fischer-Rasmussen[121] | 68[62] | 12[70] | 0.52 | 0.85 | 3.6 | 0.6 |
| Mixed UI | Bradley, 2005[81] | 50 [22] | 78 [13] | 0.70 | 0.86 | 5.00 | 0.35 |
| Mixed UI | Brown, 2006[76] | 15 [27] | 47 [212] | 0.36 | 0.82 | 1.97 | 0.79 |
| Mixed UI | Sandvik, 1995[71] | 47 [9] | 61 [119] | 0.84 | 0.66 | 2.48 | 0.24 |

**Appendix Figure F18. Sensitivity of urgency UI symptoms compared to clinical diagnosis ("gold standard") for any detrusor overactivity (Bradley et al uses a composite diagnostic score)[71,76,81,87]**



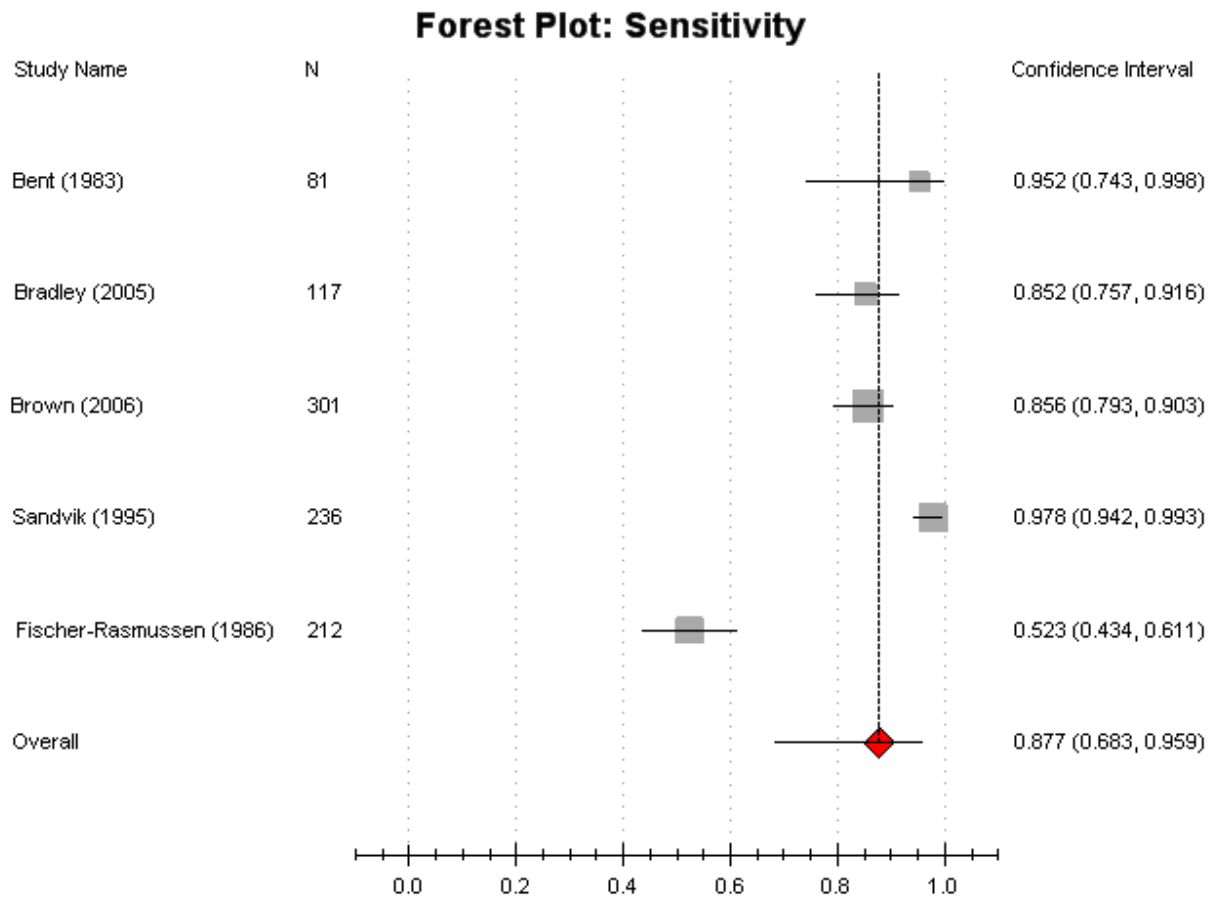
**Appendix Figure F19. Specificity of urgency UI symptoms compared to clinical diagnosis ("gold standard") for any detrusor overactivity (Bradley et al uses a composite diagnostic scores)[71,76,81,87]**



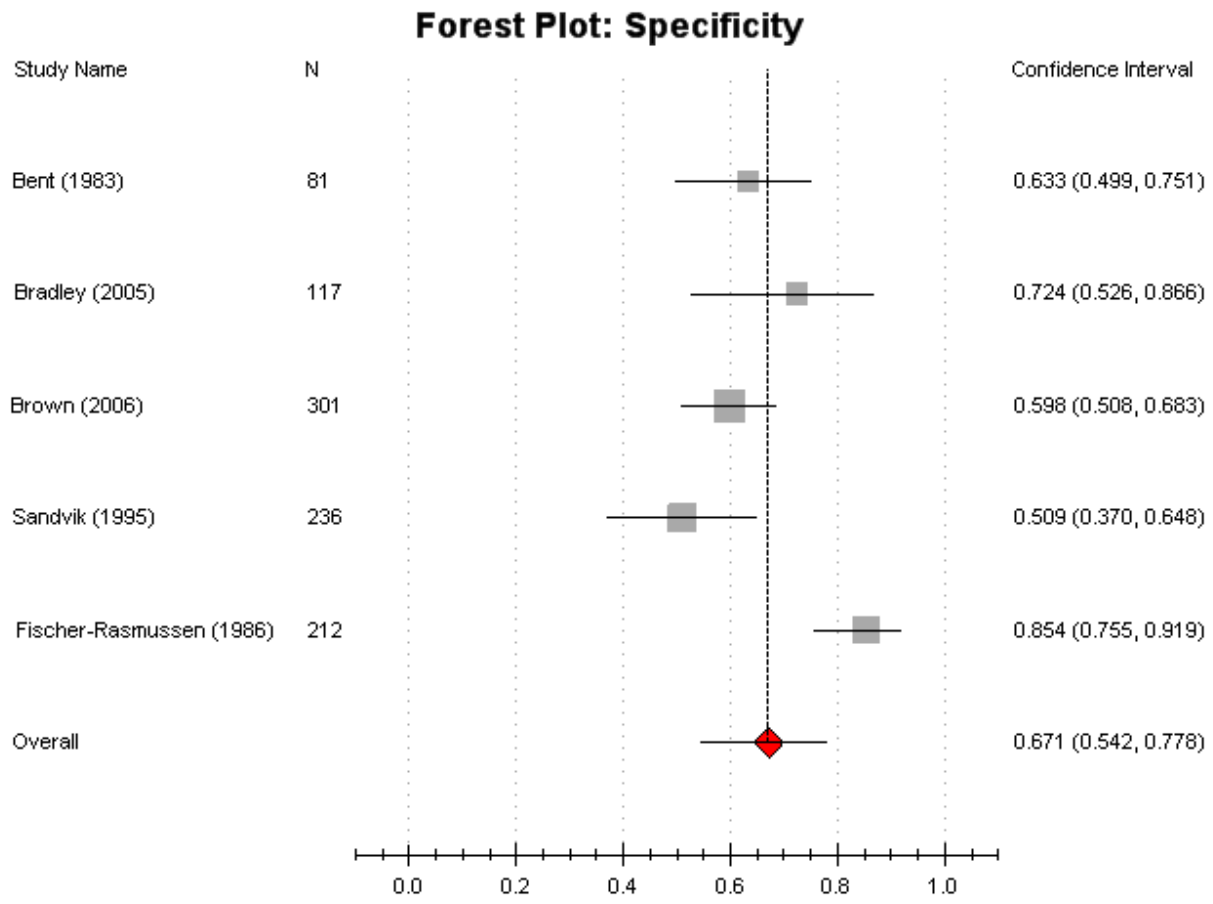
**Appendix Table F20. Pooled Diagnostic value of urency UI symptoms compared to clinical diagnosis ("gold standard") for any detrusor overactivity[71,76,81,87]**

| | Estimate | 95% CI | Tau-sq | I^2 | Q statistic | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|---|
| Specificity | 0.671 | 0.531; 0.785 | 0.271 | 0.880 | 16.715 | 3.000 | 0.001 |
| Sensitivity | 0.823 | 0.727; 0.890 | 0.209 | 0.804 | 10.221 | 3.000 | 0.017 |
| Positive predictive value | 0.724 | 0.479; 0.882 | 1.040 | 0.961 | 51.159 | 3.000 | 0.000 |
| Negative predictive value | 0.786 | 0.543; 0.919 | 1.168 | 0.943 | 34.992 | 3.000 | 0.000 |
| Accuracy | 0.727 | 0.646; 0.796 | 0.114 | 0.858 | 14.083 | 3.000 | 0.003 |
| Diagnostic odds ratio | 11.684 | 7.321; 18.648 | 0.044 | 0.452 | 3.651 | 3.000 | 0.302 |
| Positive likelihood ratio | 2.516 | 1.808; 3.502 | 0.073 | 0.807 | 10.374 | 3.000 | 0.016 |
| Negative likelihood ratio | 0.257 | 0.176; 0.375 | 0.071 | 0.675 | 6.156 | 3.000 | 0.104 |

**Appendix Figure F20. Sensitivity of stress UI symptoms compared to clinical diagnosis ("gold standard") for any stress UI[71,76,81,87,121]**



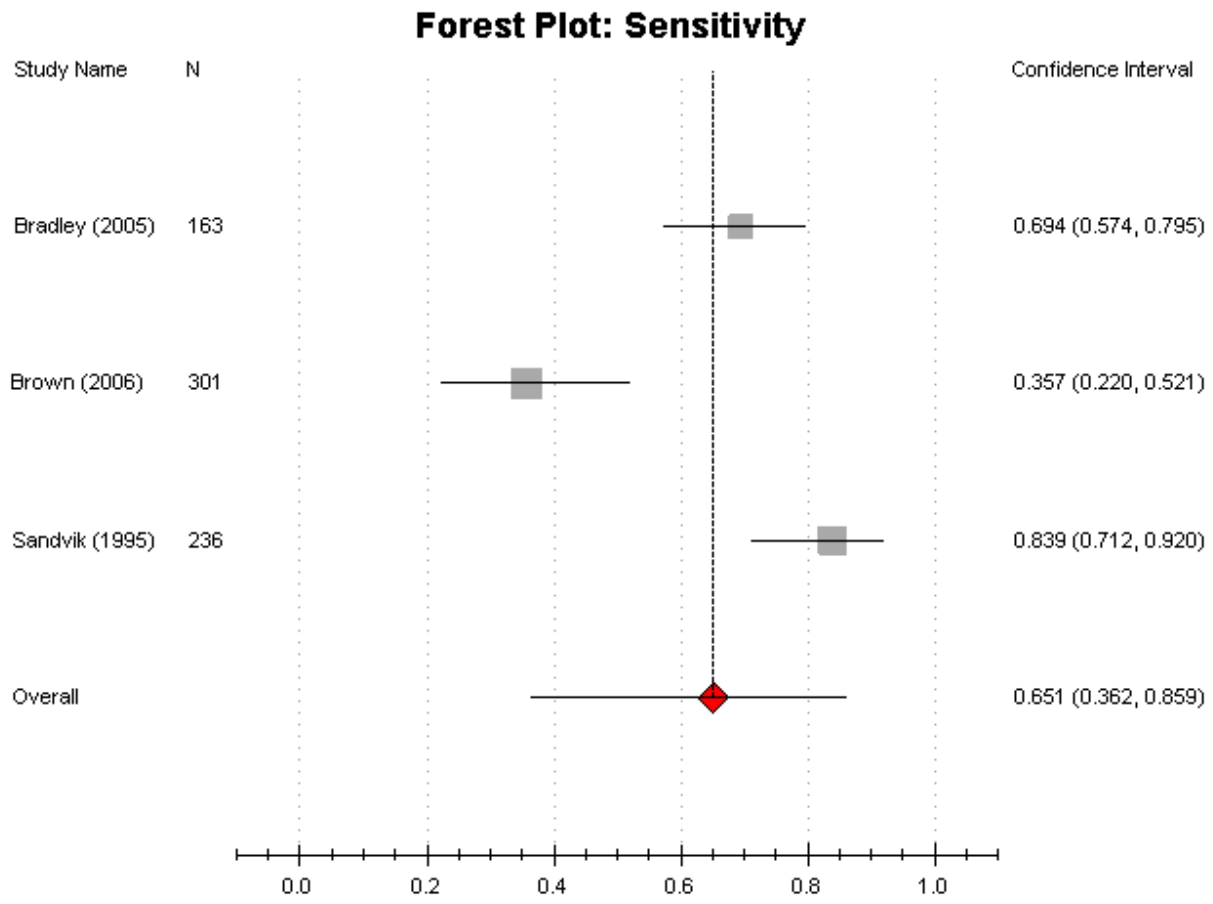
**Appendix Figure F21. Specificity of stress UI symptoms compared to clinical diagnosis ("gold standard") for any stress UI[71,76,81,87,121]**



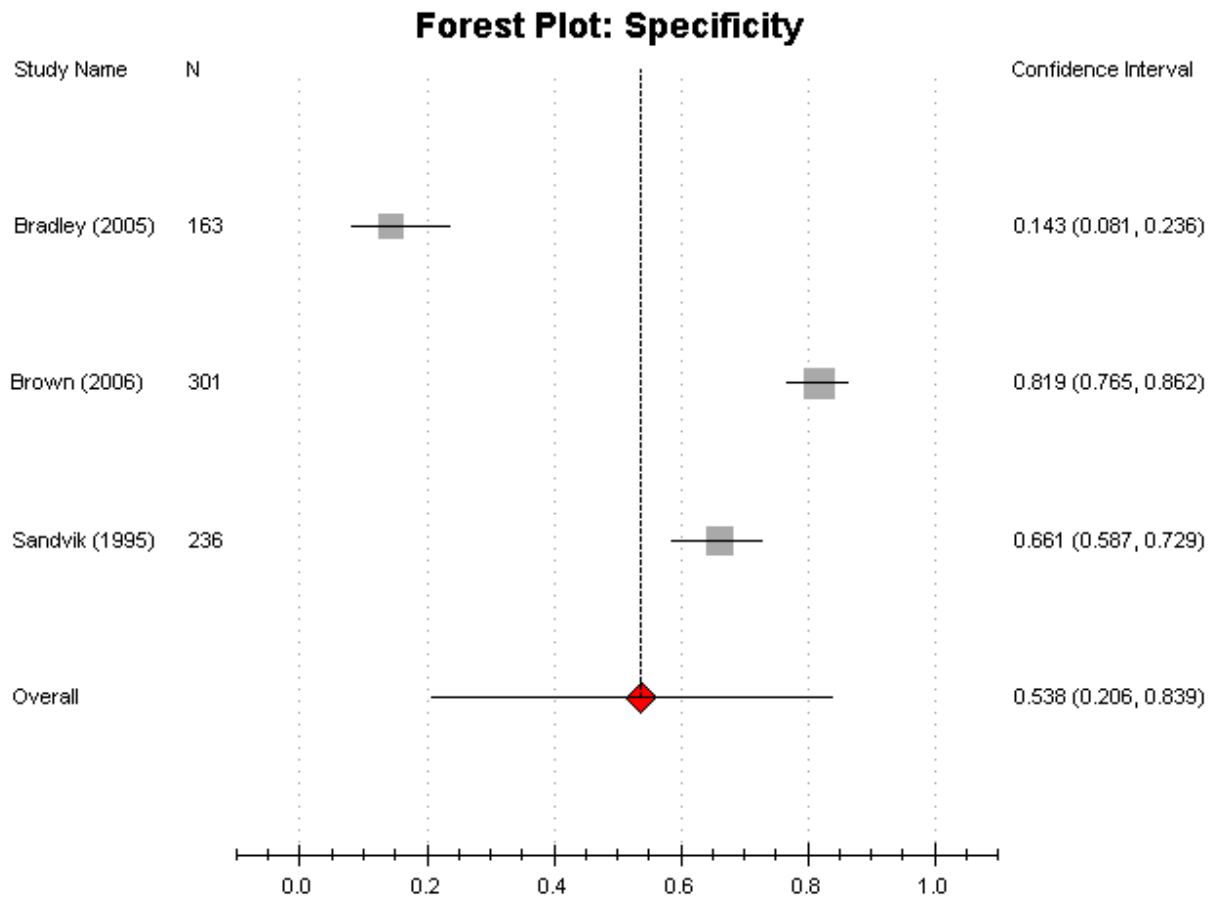
**Appendix Table F21. Pooled diagnostic value of stress UI symptoms compared to clinical diagnosis ("gold standard") for any stress UI[71,76,81,87,121]**

| | Estimate | Lower (95% CI) | Upper (95% CI) | Tau-sq | I^2 | Q-statistic | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|---|---|
| Specificity | 0.67 | 0.54 | 0.78 | 0.30 | 0.85 | 20.10 | 4 | 0 |
| Sensitivity | 0.88 | 0.68 | 0.96 | 1.64 | 0.96 | 79.62 | 4 | 0 |
| Positive predictive value | 0.80 | 0.66 | 0.89 | 0.56 | 0.92 | 39.59 | 4 | 0 |
| Negative predictive value | 0.75 | 0.58 | 0.87 | 0.58 | 0.89 | 27.54 | 4 | 0 |
| Accuracy | 0.77 | 0.68 | 0.84 | 0.23 | 0.91 | 32.37 | 4 | 0 |
| Diagnostic odds ratio | 13.65 | 6.91 | 26.97 | 0.34 | 0.72 | 10.69 | 4 | 0.03 |
| Positive likelihood ratio | 2.35 | 1.97 | 2.81 | 0.01 | 0.44 | 5.39 | 4 | 0.25 |
| Negative likelihood ratio | 0.19 | 0.09 | 0.41 | 0.61 | 0.93 | 44.83 | 4 | 0 |

**Appendix Figure F22. Sensitivity of mixed symptoms compared to clinical diagnosis ("gold standard") for mixed UI**[71,76,81]



**Appendix Figure F23. Specificity of mixed symptoms compared to clinical diagnosis ("gold standard") for mixed UI**[71,76,81]



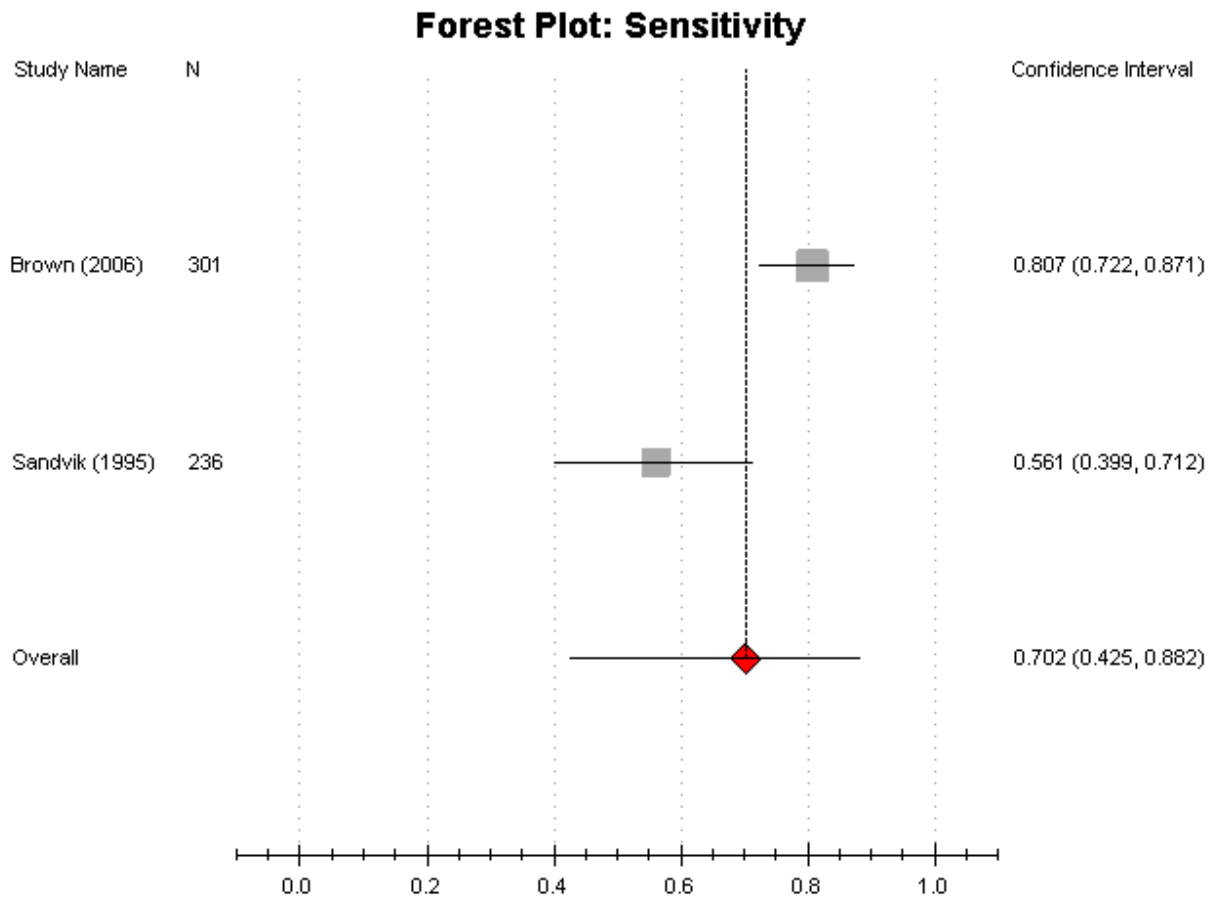
**Appendix Table F22. Diagnostic value of mixed symptoms compared to clinical diagnosis ("gold standard") for mixed UI**[71,76,81]

| | Estimate | 95% CI | Tau-sq | I^2 | Q-statistic | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|---|
| Specificity | 0.538 | 0.206; 0.839 | 1.707 | 0.989 | 94.201 | 2.000 | 0.000 |
| Sensitivity | 0.651 | 0.362; 0.859 | 1.003 | 0.956 | 22.724 | 2.000 | 0.000 |
| Positive predictive value | 0.363 | 0.269; 0.469 | 0.101 | 0.841 | 6.293 | 2.000 | 0.043 |
| Negative predictive value | 0.799 | 0.428; 0.955 | 2.092 | 0.980 | 50.001 | 2.000 | 0.000 |
| Accuracy | 0.625 | 0.400; 0.807 | 0.635 | 0.984 | 62.148 | 2.000 | 0.000 |
| Diagnostic odds ratio | 2.131 | 0.347; 13.073 | 2.423 | 0.971 | 35.002 | 2.000 | 0.000 |
| Positive likelihood ratio | 1.567 | 0.684; 3.587 | 0.509 | 0.983 | 59.879 | 2.000 | 0.000 |
| Negative likelihood ratio | 0.743 | 0.284; 1.947 | 0.657 | 0.959 | 24.565 | 2.000 | 0.000 |

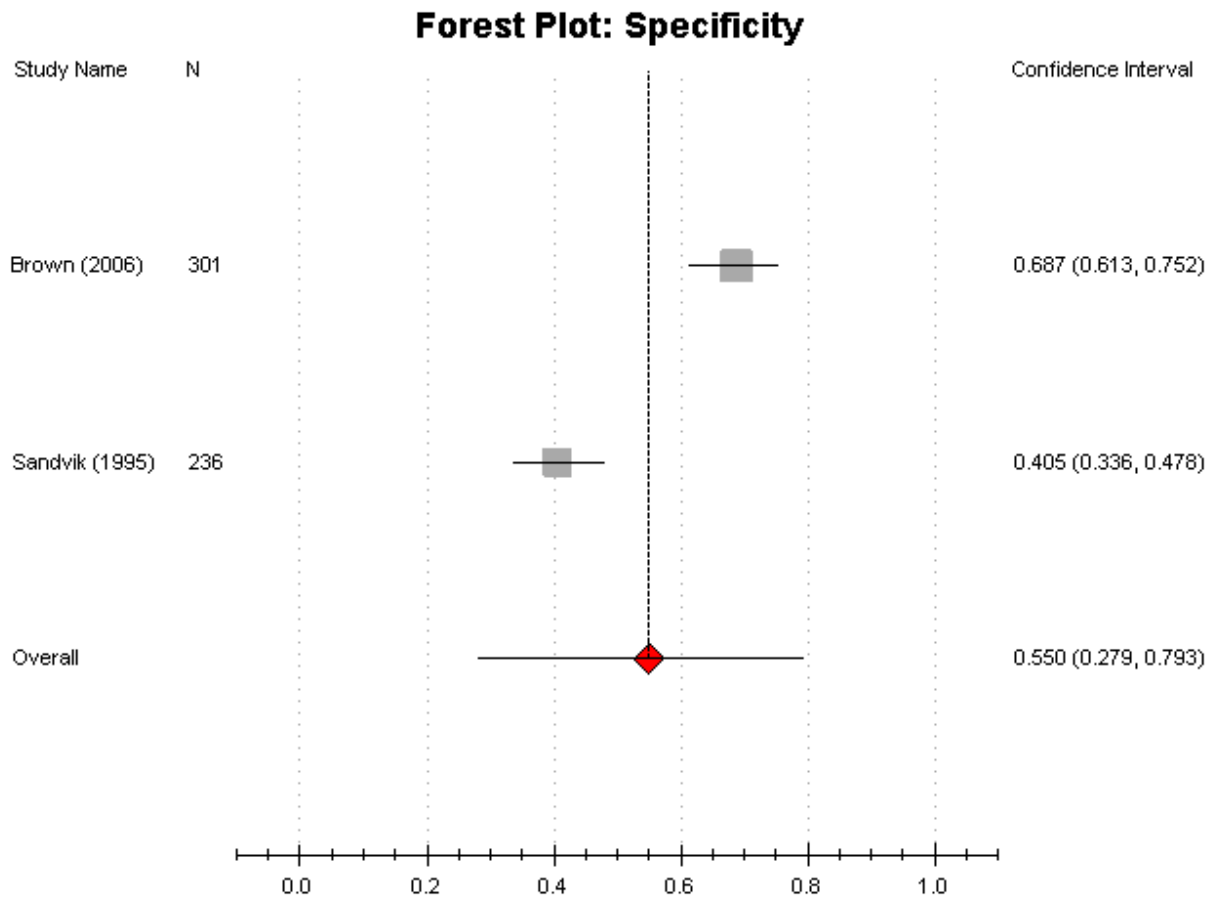
**Appendix Table F23. Diagnostic value of urgency UI symptoms compared to clinical diagnosis for detrusor overactivity**

| Reference | True Positives [False Negatives] | False Positives [True Negatives] | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio |
|---|---|---|---|---|---|---|
| Brown, 2006[76] | 96 [23] | 57 [125] | 0.81 | 0.69 | 0.63 | 0.84 |
| Sandvik, 1995[71] | 23 [18] | 116 [79] | 0.56 | 0.41 | 0.17 | 0.81 |

**Appendix Figure F24. Sensitivity of urgency UI symptoms compared to clinical diagnosis for pure detrusor overactivity[71,76]**



**Appendix Figure F25. Specificity of urgency UI symptoms compared to clinical diagnosis for pure detrusor overactivity[71,76]**



**Appendix Table F24. Pooled diagnostic value of urgency UI symptoms compared to clinical diagnosis for detrusor overactivity**[71,76]

| | Estimate | 95% CI | Tau-sq | Q- statistic | Degree of Freedom | P-Value |
|---|---|---|---|---|---|---|
| Specificity | 0.550 | 0.279; 0.793 | 0.660 | 29.206 | 1.000 | 0.000 |
| Sensitivity | 0.702 | 0.425; 0.882 | 0.624 | 9.163 | 1.000 | 0.002 |
| Positive predictive value | 0.368 | 0.067; 0.825 | 2.248 | 57.170 | 1.000 | 0.000 |
| Negative predictive value | 0.832 | 0.780; 0.874 | 0.000 | 0.382 | 1.000 | 0.537 |
| Accuracy | 0.592 | 0.291; 0.837 | 0.814 | 48.453 | 1.000 | 0.000 |
| Diagnostic odds ratio | 2.847 | 0.284; 28.566 | 2.669 | 27.721 | 1.000 | 0.000 |
| Positive likelihood ratio | 1.565 | 0.585; 4.190 | 0.487 | 27.556 | 1.000 | 0.000 |
| Negative likelihood ratio | 0.552 | 0.147; 2.069 | 0.871 | 23.833 | 1.000 | 0.000 |

**Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180]**

| Outcome | Predictor of Effect | Fesoterodine Daily Dose | Control Treatment | Daily Dose of Control Treatment | Events/ Randomized to Active | Events/ Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|
| Discontinued | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 4/25 | 6/28 | 0.75 (0.24; 2.35) | -0.05 (-0.26; 0.15) | | |
| Discontinued | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 4/25 | 4/22 | 0.88 (0.25; 3.11) | -0.02 (-0.24; 0.19) | | |
| Discontinued | Patients with DO and urgency | 4mg | Placebo | | 4/25 | 7/24 | 0.55 (0.18; 1.64) | -0.13 (-0.36; 0.10) | | |
| Discontinued | Patients with DO and urgency | 8mg | Placebo | | 6/28 | 7/24 | 0.73 (0.29; 1.89) | -0.08 (-0.31; 0.16) | | |
| Discontinued | Patients with DO and urgency | 12mg | Placebo | | 22/22 | 7/24 | 3.26 (1.79; 5.95) | 0.71 (0.52; 0.90) | 1 | 708 |
| Discontinued | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 6/28 | 4/22 | 1.18 (0.38; 3.67) | 0.03 (-0.19; 0.25) | | |
| Discontinued | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 1/18 | 3/19 | 0.35 (0.04; 3.08) | -0.10 (-0.30; 0.09) | | |
| Discontinued | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 1/18 | 1/16 | 0.89 (0.06; 13.08) | -0.01 (-0.17; 0.15) | | |
| Discontinued | Patients with no DO | 4mg | Placebo | | 1/18 | 1/19 | 1.06 (0.07; 15.64) | 0.00 (-0.14; 0.15) | | |
| Discontinued | Patients with no DO | 8mg | Placebo | | 3/19 | 1/19 | 3.00 (0.34; 26.33) | 0.11 (-0.09; 0.30) | | |
| Discontinued | Patients with no DO | 12mg | Placebo | | 1/16 | 1/19 | 1.19 (0.08; 17.51) | 0.01 (-0.15; 0.17) | | |
| Discontinued | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 3/19 | 1/16 | 2.53 (0.29; 21.98) | 0.10 (-0.11; 0.30) | | |

**Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT) (continued)**

| Outcome | Predictor of Effect | Fesoterodine Daily Dose | Control Treatment | Daily Dose of Control Treatment | Events/ Randomized to Active | Events/ Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|
| Any adverse effects | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 22/25 | 25/28 | 0.99 (0.81; 1.20) | -0.01 (-0.18; 0.16) | | |
| Any adverse effects | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 22/25 | 20/22 | 0.97 (0.80; 1.18) | -0.03 (-0.20; 0.15) | | |
| Any adverse effects | Patients with DO and urgency | 4mg | Placebo | | 22/25 | 16/24 | 1.32 (0.96; 1.81) | 0.21 (-0.01; 0.44) | | |
| Any adverse effects | Patients with DO and urgency | 8mg | Placebo | | 25/28 | 16/24 | 1.34 (0.98; 1.83) | 0.23 (0.01; 0.45) | 4 | 226 |
| Any adverse effects | Patients with DO and urgency | 12mg | Placebo | | 20/22 | 16/24 | 1.36 (1.00; 1.86) | 0.24 (0.02; 0.47) | 4 | 242 |
| Any adverse effects | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 25/28 | 20/22 | 0.98 (0.82; 1.18) | -0.02 (-0.18; 0.15) | | |
| Any adverse effects | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 11/25 | 17/28 | 0.72 (0.43; 1.24) | -0.17 (-0.43; 0.10) | | |
| Any adverse effects | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 11/25 | 14/22 | 0.69 (0.40; 1.19) | -0.20 (-0.48; 0.08) | | |
| Any adverse effects | Patients with DO and urgency | 4mg | Placebo | | 11/25 | 3/24 | 3.52 (1.12; 11.09) | 0.32 (0.08; 0.55) | 3 | 315 |
| Dry mouth | Patients with DO and urgency | 8mg | Placebo | | 17/28 | 3/24 | 4.86 (1.62; 14.59) | 0.48 (0.26; 0.71) | 2 | 482 |
| Dry mouth | Patients with DO and urgency | 12mg | Placebo | | 14/22 | 3/24 | 5.09 (1.69; 15.36) | 0.51 (0.27; 0.75) | 2 | 511 |
| Dry mouth | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 17/28 | 14/22 | 0.95 (0.62; 1.47) | -0.03 (-0.30; 0.24) | | |
| Headache | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 5/25 | 7/28 | 0.80 (0.29; 2.20) | -0.05 (-0.27; 0.17) | | |

**Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT) (continued)**

| Outcome | Predictor of Effect | Fesoterodine Daily Dose | Control Treatment | Daily Dose of Control Treatment | Events/ Randomized to Active | Events/ Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|
| Headache | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 5/25 | 4/22 | 1.10 (0.34; 3.59) | 0.02 (-0.21; 0.24) | | |
| Headache | Patients with DO and urgency | 4mg | Placebo | | 5/25 | 5/24 | 0.96 (0.32; 2.90) | -0.01 (-0.23; 0.22) | | |
| Headache | Patients with DO and urgency | 8mg | Placebo | | 7/28 | 5/24 | 1.20 (0.44; 3.29) | 0.04 (-0.19; 0.27) | | |
| Headache | Patients with DO and urgency | 12mg | Placebo | | 4/22 | 5/24 | 0.87 (0.27; 2.84) | -0.03 (-0.26; 0.20) | | |
| Headache | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 7/28 | 4/22 | 1.38 (0.46; 4.11) | 0.07 (-0.16; 0.30) | | |
| Influenza-like symptoms | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 6/25 | 3/28 | 2.24 (0.62; 8.03) | 0.13 (-0.07; 0.34) | | |
| Influenza-like symptoms | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 6/25 | 3/22 | 1.76 (0.50; 6.22) | 0.10 (-0.12; 0.32) | | |
| Influenza-like symptoms | Patients with DO and urgency | 4mg | Placebo | | 6/25 | 2/24 | 2.88 (0.64; 12.90) | 0.16 (-0.04; 0.36) | | |
| Influenza-like symptoms | Patients with DO and urgency | 8mg | Placebo | | 3/28 | 2/24 | 1.29 (0.23; 7.07) | 0.02 (-0.14; 0.18) | | |
| Influenza-like symptoms | Patients with DO and urgency | 12mg | Placebo | | 3/22 | 2/24 | 1.64 (0.30; 8.90) | 0.05 (-0.13; 0.23) | | |
| Influenza-like symptoms | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 3/28 | 3/22 | 0.79 (0.18; 3.52) | -0.03 (-0.21; 0.15) | | |
| Dizziness | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 0/25 | 1/28 | 0.37 (0.02; 8.73) | -0.04 (-0.13; 0.06) | | |
| Dizziness | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 0/25 | 2/22 | 0.18 (0.01; 3.50) | -0.09 (-0.23; 0.05) | | |

**Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT) (continued)**

| Outcome | Predictor of Effect | Fesoterodine Daily Dose | Control Treatment | Daily Dose of Control Treatment | Events/ Randomized to Active | Events/ Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|
| Dizziness | Patients with DO and urgency | 4mg | Placebo | | 0/25 | 2/24 | 0.19 (0.01; 3.81) | -0.08 (-0.21; 0.05) | | |
| Dizziness | Patients with DO and urgency | 8mg | Placebo | | 1/28 | 2/24 | 0.43 (0.04; 4.44) | -0.05 (-0.18; 0.08) | | |
| Dizziness | Patients with DO and urgency | 12mg | Placebo | | 2/22 | 2/24 | 1.09 (0.17; 7.10) | 0.01 (-0.16; 0.17) | | |
| Dizziness | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 1/28 | 2/22 | 0.39 (0.04; 4.06) | -0.06 (-0.19; 0.08) | | |
| Nausea | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 2/25 | 3/28 | 0.75 (0.14; 4.11) | -0.03 (-0.18; 0.13) | | |
| Nausea | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 2/25 | 3/22 | 0.59 (0.11; 3.20) | -0.06 (-0.23; 0.12) | | |
| Nausea | Patients with DO and urgency | 4mg | Placebo | | 2/25 | 3/24 | 0.64 (0.12; 3.50) | -0.05 (-0.21; 0.12) | | |
| Nausea | Patients with DO and urgency | 8mg | Placebo | | 3/28 | 3/24 | 0.86 (0.19; 3.86) | -0.02 (-0.19; 0.16) | | |
| Nausea | Patients with DO and urgency | 12mg | Placebo | | 3/22 | 3/24 | 1.09 (0.25; 4.85) | 0.01 (-0.18; 0.21) | | |
| Nausea | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 3/28 | 3/22 | 0.79 (0.18; 3.52) | -0.03 (-0.21; 0.15) | | |
| Constipation | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 1/25 | 5/28 | 0.22 (0.03; 1.79) | -0.14 (-0.30; 0.02) | | |
| Constipation | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 1/25 | 4/22 | 0.22 (0.03; 1.82) | -0.14 (-0.32; 0.04) | | |
| Constipation | Patients with DO and urgency | 4mg | Placebo | | 1/25 | 0/24 | 2.88 (0.12; 67.53) | 0.04 (-0.07; 0.15) | | |

**Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT) (continued)**

| Outcome | Predictor of Effect | Fesoterodine Daily Dose | Control Treatment | Daily Dose of Control Treatment | Events/ Randomized to Active | Events/ Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|
| Constipation | Patients with DO and urgency | 8mg | Placebo | | 5/28 | 0/24 | 9.48 (0.55; 163.15) | 0.18 (0.03; 0.33) | 6 | 179 |
| Constipation | Patients with DO and urgency | 12mg | Placebo | | 4/22 | 0/24 | 9.78 (0.56; 171.91) | 0.18 (0.01; 0.35) | 5 | 182 |
| Constipation | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 5/28 | 4/22 | 0.98 (0.30; 3.23) | 0.00 (-0.22; 0.21) | | |
| Abdominal pain | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 2/25 | 2/28 | 1.12 (0.17; 7.37) | 0.01 (-0.13; 0.15) | | |
| Abdominal pain | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 2/25 | 3/22 | 0.59 (0.11; 3.20) | -0.06 (-0.23; 0.12) | | |
| Abdominal pain | Patients with DO and urgency | 4mg | Placebo | | 2/25 | 0/24 | 4.81 (0.24; 95.25) | 0.08 (-0.05; 0.21) | | |
| Abdominal pain | Patients with DO and urgency | 8mg | Placebo | | 2/28 | 0/24 | 4.31 (0.22; 85.62) | 0.07 (-0.04; 0.19) | | |
| Abdominal pain | Patients with DO and urgency | 12mg | Placebo | | 3/22 | 0/24 | 7.61 (0.42; 139.47) | 0.14 (-0.02; 0.29) | | |
| Abdominal pain | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 2/28 | 3/22 | 0.52 (0.10; 2.87) | -0.06 (-0.24; 0.11) | | |
| Diarrhea | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 8mg | 4/25 | 0/28 | 10.04 (0.57; 177.65) | 0.16 (0.01; 0.31) | 6 | 160 |
| Diarrhea | Patients with DO and urgency | 4mg | Fesoterodine-extended release | 12mg | 4/25 | 1/22 | 3.52 (0.42; 29.18) | 0.11 (-0.05; 0.28) | | |
| Diarrhea | Patients with DO and urgency | 4mg | Placebo | | 4/25 | 0/24 | 8.65 (0.49; 152.58) | 0.16 (0.00; 0.32) | 6 | 160 |
| Diarrhea | Patients with DO and urgency | 8mg | Placebo | | 0/28 | 0/24 | 0.00 (0.00; 0.00) | 0.00 (-0.07; 0.07) | | |

**Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT) (continued)**

| Outcome | Predictor of Effect | Fesoterodine Daily Dose | Control Treatment | Daily Dose of Control Treatment | Events/ Randomized to Active | Events/ Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|
| Diarrhea | Patients with DO and urgency | 12mg | Placebo | | 1/22 | 0/24 | 3.26 (0.14; 76.10) | 0.05 (-0.07; 0.16) | | |
| Diarrhea | Patients with DO and urgency | 8mg | Fesoterodine-extended release | 12mg | 0/28 | 1/22 | 0.26 (0.01; 6.19) | -0.05 (-0.16; 0.07) | | |
| Any adverse events | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 14/18 | 14/19 | 1.06 (0.73; 1.52) | 0.04 (-0.23; 0.32) | | |
| Any adverse events | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 14/18 | 13/16 | 0.96 (0.68; 1.35) | -0.03 (-0.31; 0.24) | | |
| Any adverse events | Patients with no DO | 4mg | Placebo | | 14/18 | 17/19 | 0.87 (0.65; 1.16) | -0.12 (-0.35; 0.12) | | |
| Any adverse events | Patients with no DO | 8mg | Placebo | | 14/19 | 17/19 | 0.82 (0.60; 1.12) | -0.16 (-0.40; 0.08) | | |
| Any adverse events | Patients with no DO | 12mg | Placebo | | 13/16 | 17/19 | 0.91 (0.69; 1.20) | -0.08 (-0.32; 0.15) | | |
| Any adverse events | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 14/19 | 13/16 | 0.91 (0.63; 1.30) | -0.08 (-0.35; 0.20) | | |
| Dry mouth | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 8/18 | 8/19 | 1.06 (0.50; 2.21) | 0.02 (-0.30; 0.34) | | |
| Dry mouth | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 8/18 | 10/16 | 0.71 (0.37; 1.35) | -0.18 (-0.51; 0.15) | | |
| Dry mouth | Patients with no DO | 4mg | Placebo | | 8/18 | 4/19 | 2.11 (0.77; 5.81) | 0.23 (-0.06; 0.53) | | |
| Dry mouth | Patients with no DO | 8mg | Placebo | | 8/19 | 4/19 | 2.00 (0.72; 5.53) | 0.21 (-0.08; 0.50) | | |
| Dry mouth | Patients with no DO | 12mg | Placebo | | 10/16 | 4/19 | 2.97 (1.15; 7.68) | 0.41 (0.11; 0.71) | 2 | 414 |
| Dry mouth | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 8/19 | 10/16 | 0.67 (0.35; 1.29) | -0.20 (-0.53; 0.12) | | |

**Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT) (continued)**

| Outcome | Predictor of Effect | Fesoterodine Daily Dose | Control Treatment | Daily Dose of Control Treatment | Events/ Randomized to Active | Events/ Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|
| Headache | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 3/18 | 0/19 | 7.37 (0.41; 133.37) | 0.17 (-0.02; 0.35) | | |
| Headache | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 3/18 | 3/16 | 0.89 (0.21; 3.80) | -0.02 (-0.28; 0.24) | | |
| Headache | Patients with no DO | 4mg | Placebo | | 3/18 | 3/19 | 1.06 (0.24; 4.57) | 0.01 (-0.23; 0.25) | | |
| Headache | Patients with no DO | 8mg | Placebo | | 0/19 | 3/19 | 0.14 (0.01; 2.59) | -0.16 (-0.34; 0.02) | | |
| Headache | Patients with no DO | 12mg | Placebo | | 3/16 | 3/19 | 1.19 (0.28; 5.09) | 0.03 (-0.22; 0.28) | | |
| Headache | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 0/19 | 3/16 | 0.12 (0.01; 2.19) | -0.19 (-0.39; 0.02) | | |
| Influenza-like symptoms | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 2/18 | 2/19 | 1.06 (0.17; 6.72) | 0.01 (-0.19; 0.21) | | |
| Influenza-like symptoms | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 2/18 | 1/16 | 1.78 (0.18; 17.80) | 0.05 (-0.14; 0.24) | | |
| Influenza-like symptoms | Patients with no DO | 4mg | Placebo | | 2/18 | 3/19 | 0.70 (0.13; 3.73) | -0.05 (-0.27; 0.17) | | |
| Influenza-like symptoms | Patients with no DO | 8mg | Placebo | | 2/19 | 3/19 | 0.67 (0.13; 3.55) | -0.05 (-0.27; 0.16) | | |
| Influenza-like symptoms | Patients with no DO | 12mg | Placebo | | 1/16 | 3/19 | 0.40 (0.05; 3.44) | -0.10 (-0.30; 0.11) | | |
| Influenza-like symptoms | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 2/19 | 1/16 | 1.68 (0.17; 16.91) | 0.04 (-0.14; 0.22) | | |
| Dizziness | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 2/18 | 0/19 | 5.26 (0.27; 102.66) | 0.11 (-0.06; 0.28) | | |
| Dizziness | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 2/18 | 3/16 | 0.59 (0.11; 3.11) | -0.08 (-0.32; 0.16) | | |
| Dizziness | Patients with no DO | 4mg | Placebo | | 2/18 | 2/19 | 1.06 (0.17; 6.72) | 0.01 (-0.19; 0.21) | | |

**Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT) (continued)**

| Outcome | Predictor of Effect | Fesoterodine Daily Dose | Control Treatment | Daily Dose of Control Treatment | Events/ Randomized to Active | Events/ Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|
| Dizziness | Patients with no DO | 8mg | Placebo | | 0/19 | 2/19 | 0.20 (0.01; 3.91) | -0.11 (-0.27; 0.06) | | |
| Dizziness | Patients with no DO | 12mg | Placebo | | 3/16 | 2/19 | 1.78 (0.34; 9.38) | 0.08 (-0.15; 0.32) | | |
| Dizziness | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 0/19 | 3/16 | 0.12 (0.01; 2.19) | -0.19 (-0.39; 0.02) | | |
| Nausea | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 4/18 | 3/19 | 1.41 (0.36; 5.43) | 0.06 (-0.19; 0.32) | | |
| Nausea | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 4/18 | 4/16 | 0.89 (0.26; 2.98) | -0.03 (-0.31; 0.26) | | |
| Nausea | Patients with no DO | 4mg | Placebo | | 4/18 | 5/19 | 0.84 (0.27; 2.66) | -0.04 (-0.32; 0.23) | | |
| Nausea | Patients with no DO | 8mg | Placebo | | 3/19 | 5/19 | 0.60 (0.17; 2.16) | -0.11 (-0.36; 0.15) | | |
| Nausea | Patients with no DO | 12mg | Placebo | | 4/16 | 5/19 | 0.95 (0.31; 2.95) | -0.01 (-0.30; 0.28) | | |
| Nausea | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 3/19 | 4/16 | 0.63 (0.17; 2.41) | -0.09 (-0.36; 0.18) | | |
| Constipation | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 1/18 | 2/19 | 0.53 (0.05; 5.33) | -0.05 (-0.22; 0.12) | | |
| Constipation | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 1/18 | 3/16 | 0.30 (0.03; 2.57) | -0.13 (-0.35; 0.09) | | |
| Constipation | Patients with no DO | 4mg | Placebo | | 1/18 | 2/19 | 0.53 0.05; 5.33) | -0.05 (-0.22; 0.12) | | |
| Constipation | Patients with no DO | 8mg | Placebo | | 2/19 | 2/19 | 1.00 (0.16; 6.38) | 0.00 (-0.20; 0.20) | | |
| Constipation | Patients with no DO | 12mg | Placebo | | 3/16 | 2/19 | 1.78 (0.34; 9.38) | 0.08 (-0.15; 0.32) | | |
| Constipation | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 2/19 | 3/16 | 0.56 (0.11; 2.96) | -0.08 (-0.32; 0.15) | | |

**Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT) (continued)**

| Outcome | Predictor of Effect | Fesoterodine Daily Dose | Control Treatment | Daily Dose of Control Treatment | Events/ Randomized to Active | Events/ Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|
| Abdominal pain | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 0/18 | 2/19 | 0.21 (0.01; 4.11) | -0.11 (-0.27; 0.06) | | |
| Abdominal pain | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 0/18 | 3/16 | 0.13 (0.01; 2.30) | -0.19 (-0.39; 0.02) | | |
| Abdominal pain | Patients with no DO | 4mg | Placebo | | 0/18 | 2/19 | 0.21 (0.01; 4.11) | -0.11 (-0.27; 0.06) | | |
| Abdominal pain | Patients with no DO | 8mg | Placebo | | 2/19 | 2/19 | 1.00 (0.16; 6.38) | 0.00 (-0.20; 0.20) | | |
| Abdominal pain | Patients with no DO | 12mg | Placebo | | 3/16 | 2/19 | 1.78 (0.34; 9.38) | 0.08 (-0.15; 0.32) | | |
| Abdominal pain | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 2/19 | 3/16 | 0.56 (0.11; 2.96) | -0.08 (-0.32; 0.15) | | |
| Diarrhea | Patients with no DO | 4mg | Fesoterodine-extended release | 8mg | 1/18 | 1/19 | 1.06 (0.07; 15.64) | 0.00 (-0.14; 0.15) | | |
| Diarrhea | Patients with no DO | 4mg | Fesoterodine-extended release | 12mg | 1/18 | 2/16 | 0.44 (0.04; 4.45) | -0.07 (-0.26; 0.12) | | |
| Diarrhea | Patients with no DO | 4mg | Placebo | | 1/18 | 2/19 | 0.53 (0.05; 5.33) | -0.05 (-0.22; 0.12) | | |
| Diarrhea | Patients with no DO | 8mg | Placebo | | 1/19 | 2/19 | 0.50 (0.05; 5.06) | -0.05 (-0.22; 0.12) | | |
| Diarrhea | Patients with no DO | 12mg | Placebo | | 2/16 | 2/19 | 1.19 (0.19; 7.50) | 0.02 (-0.19; 0.23) | | |
| Diarrhea | Patients with no DO | 8mg | Fesoterodine-extended release | 12mg | 1/19 | 2/16 | 0.42 (0.04; 4.23) | -0.07 (-0.26; 0.12) | | |

DO- detrusor overactivity

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| Weight loss | Auwad, 2008[181] | Effects of moderate weight loss in obese women with urodynamically stress UI | 64 | 100 | 100 | Weight reduction programm low calorie diet + exercise with a target loss of 5-10% | 2 years | Obese women with urodynamic stress UI, 52.5 years old | Weight loss was associated with a significant reduction in pad test loss and significant improvement in quality of life. |
| Weight loss | Wing, 2010[182] | To examine the relationship between magnitude of weight loss and changes in urinary incontinence frequency. | 338 | 100 | 100 | Patients were randomly assigned to a 6 month weight loss program followed immediately by a 12-month weight maintenance program or to a structured education program. These groups were combined to examine the effects of the magnitude of weight loss on changes in urinary incontinence | 18 months | Program to Reduce Incontinence by Diet and Exercise (PRIDE) trial: Women aged 30 years or older, having a body mass index (BMI) of 25–50, and reporting at least 10 urinary incontinent episodes (including both stress and urge incontinent episodes) on a 7-day voiding diary at baseline. | The adjusted odds (adjusted for treatment group, use of incontinence behavioral treatment booklet, clinic, age, alcohol use, smoking status, race, number of live births, and amount of calories burned) of at least 70% reduction in number of incontinent episodes per week reported in voiding diary in those who had more than 10% weight loss: At 6 months: Total UI: OR=3.8 (95% CI=1.5-9.6); Stress UI: OR=1.6 (95% CI=0.6-3.9); and Urge UI: OR=4.5 (95% CI=1.4-14.1). At 18 months: Total UI: OR=3.3 (95% CI=1.7-6.4); Stress UI:OR=2.3 (95% CI=1.0-5.1); and Urge UI: OR=4.0 (95% CI=2.1-7.9) |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| Pelvic floor muscle training | Hines, 2007[183] | To assess factors predictive of high adherence to a behavioral intervention to prevent UI | 359, but data used for instrument - development project reported in the article were from participants in the treatment arm only (n=164) | 100 | 100 | Pelvic floor muscle training and bladder training | 1 year | 359 community-dwelling, post-menopausal women, aged 55 to 80 years old | Women incorporated PFMT into their lives using either a routine or ad hoc approach (Routine approach=Doing PME at set times of the day or linking with a daily routine that occurs at a set time; ad hoc approach=Doing PME when they think of it or by linking with a sporadic cue or situation). Those using a routine approach at 3 months were 12 times more likely to adhere (odds ratio=12.4, CI=4.0-38.8,p<0.001) at a high level at 3 months and significantly more likely to maintain that level 12 months post-intervention (OR=2.7,CI=1.2-6.0,p<0.014). High adherence to PFMT was operationally defined as an adherence score of 5 to 7 (reporting adherence of >=1 1 set of PFMT each day). |
| Pelvic floor muscle training | Sugaya, 2003[184] | Effects of the device to promote adherence to pelvic floor muscle exercise in women | 46 | 100 | 100 | Device with a chime to sound three times a day when exercise sessions were scheduled and set | 8 weeks | women with stress UI | Quality of life category was delighted, pleased, or mostly satisfied in 15% patients from the control group |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | with stress UI | | | | a rhythm for the muscle contractions vs. pelvic floor muscle exercise alone | | | and 48% from the device groups |
| Pelvic floor muscle training | Brubaker, 2008[185] | Effectiveness of nonmedical pelvic floor muscle training class on UI | 102 | 100 | 99 | Pelvic fitness and education class taught by a lay instructor | 11 weeks, 1 year of followup | Adult women with urgency or urge UI 57.9 year, 11% after surgery for UI or prolapse | The training improved quality of life and sexual function improvements in after vs. before UDI-SF scores. Achievement of self selected goal- 71% at 11 weeks, 67% at 1 year |
| Pelvic floor muscle training | Wang, 2000[186] | Efficacy of bladder-sphincter-biofeedback in women with detrusor instability who failed to respond to oxybutynin treatment | 31 | 100 | 100 | Bladder sphincter biofeedback vs. pelvic floor muscle training | 5 months | Women with urge syndrome 44,.3 years who failed previous Oxybutynin treatment | Continence 12.5% in biofeedback and 13.33% in exercise group. Improvement 87.5% in biofeedback and 86.67% in exercise group. 140 significant differences were found. |
| Pelvic floor muscle training | Wang, 2000[186] | Efficacy of bladder-sphincter-biofeedback as a secondary treatment for those women with detrusor instability who failed to respond to oxybutynin chloride | 31 | 100 | 100 | Bladder-sphincter-biofeedback training group or control pelvic floor exercise group | Not reported | women with detrusor instability who failed to respond to oxybutynin chloride | The cure rate or improvement rate of subjective changes (urgency, and frequency and episodes of urge incontinence) did not significantly differ |
| Medical device | Bellin, 1998[187] | Efficacy of CapSure (Re/Stor) continence shield for stress UI in females | 100 | 100 | 100 | CapSure (Re/Stor) continence shield : no control | 12 weeks | Women 40-69 years old (mean 54) with pure stress moderate UI and no urgency | Continence - 82%, negative pad stress test - 91%; no UI episodes in diary - 48%, Bothersome |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | or urge UI | vaginal or urethral irritation - 12%, positive urine culture - 1.56 |
| Medical device | Crivellaro, 2010[188] | To examine effects of the Adjustable Continence Therapy on female UI | 60 | 100 | 100 | Adjustable Continence Therapy implantation that involves two silicone balloons sited on either side of the proximal urethra under the bladder neck, each attached to a titanium port buried in the labia allowing post operative titration of the balloons. | Once | Adult women with stress urinary incontinence resulting from intrinsic sphincteric deficiency | 82% were significantly improved, 8% were moderately improved and 10% remained unchanged. Post-operative complications necessitating device removal included migration seen in 8% of patients and urethral erosion in 3.5% of patients |
| Medical device | Morris, 2003[189] | Efficacy of contiform incontinence device in women with stress UI and no prolapse | 59 | 100 | 100 | Contiform incontinence device no control | 3 weeks | Women, 42-53 years old, with urodynamic mild to severe stress UI and no prolapse | Continence - 20%, withdrawal - 31%, acute bacterial cystitis - 5%, small degree of fracture of the curvature of device - 22% |
| Medical device | Allen, 2008[190] | Efficacy of contiform intravaginal device for stress UI | 73 | 100 | | Contiform intravaginal device, no control | 4 weeks | Women 41-54 years old with predominant stress UI and no prolapse | Continence - 54%, withdrawal, 29%, residual volume >100 ml - 5.4% |
| Medical device | Sander, 2008[191] | The effect of a vaginal device (Continence Guard) on urine leakage and quality of life in women with stress UI | 55 | 100 | 100 | Continence Guard | 12 weeks | Women with stress incontinence | Completion -74.5%; subjective cure 20% and improvement in 49%. Score of the Incontinence Impact Questionnaire showed highly significant improvement |
| Medical device | Hahn, 1996[192] | Effectiveness of vaginal device for the treatment of | 90 | | | Conveen Continence Guard | 4 weeks | 90 women with stress incontinence | Continence - 46% Improvement - 29% ; objective |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | female stress UI | | | | | | (mean age 47.5 years, range 31-65). | improvement - 75%; Failure- 25% 72% of the women considered the product to function satisfactorily and 60% expressed a wish to continue with the treatment; local discomfort - 62% |
| Medical device | Nilsson, 2000[193] | Efficacy of the conveen continence guard (a disposable vaginal device) in the treatment of complicated female stress incontinence | 28 | | | Decreases from baseline in RR, QRS and QT intervals for patients receiving duloxetine Conveen continence guard (a disposable vaginal device) | 3 weeks | Women, with a urodynamically proven stress UI | Completion rate 68%; continence or improved incontinence 58%; objective improvement 55% |
| Medical device | Pieper, 1993[194] | The efficacy of external urine-collection device for women with UI | 7 | | | External urine-collection device | 5 days | Black women with UI, 21-35 years old | 1 woman had vulvar irritation and redness; all were satisfied with the device |
| Medical device | Versi, 1998[195] | Efficacy of external urethral device in women with genuine stress urinary incontinence | 14 | | | FemAssist- non-invasive supple silicone domed cap that fits over the external urethral meatus | 3-4 weeks | Women with symptoms of urinary incontinence and a videourodynamic diagnosis of genuine stress incontinence; mean age was 55 years | >50% improvement on their IIQ - 50% ; improvement in UDI -21.4% UDI. |
| Medical device | Versi, 1998[196] | Efficacy of external urethral device in women with genuine stress UI | 131 | | | FemAssist- non-invasive supple silicone domed cap that fits over the external urethral meatus | 4 weeks | Ambulatory women with symptoms of UI | Withdrawal -27%; >50% improvement on the Incontinence Impact Questionnaire 59%; in the Urogenital Distress Inventory- 33% |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| Medical device | Sirls, 2002[197] | Efficacy of FemSoft urethral insert for female stress urinary incontinence | 150 | | | FemSoft urethral insert no control | 48-96 weeks | women with mean age of 53.5 years, stable stress urinary incontinence, mixed UI with predominant stress UI | Continence -93% at 48 months, withdrawal rate - 41%. Adverse effects: urinary tract infection - 31.3%, mild trauma - 6.7%, hematuria - 3.3%. Significant improvement in quality of life. |
| Medical device | Macaulay, 2007[198] | The effects of Non-Invasive Continence Management System (NICMS) on women with UI | 80 | | | Non-Invasive Continence Management System (NICMS) | 15 months | Women over 18 years of age with UI | Overall satisfaction 34%; among wheel chair users 21% |
| Medical device | Donnelly, 2004[199] | Predictors of successful fit and continuous use of pessaries | 239 | | | Pessaries | 2 weeks, 48 weeks | Women with stress or mixed UI, 57.4 years old | Successful fit- 89.1%, Discontinuation-45%; Reason for discontinuation %: Persistent UI-58%; Discomfort using pessary-33%; Frequent pessary expulsion-18%; Women with pulmonary disease and those who used diuretics were more likely to use pessaries. |
| Medical device | Brincat, 2004[200] | Predictors of discontinuation of pessaries use | 136 | | | Pessaries: dishes with and without floor, rings with and without floor, pessary rings with floor | 96 weeks | Women with UI | Table - abstract reason for pessary discontinuation and % Sexually active women and women with prolapse used pessaries during study period; more after |
| Medical device | Maito, 2006[201] | Predictors of continuous use of | 120 | | | Pessary | 24 weeks | Women with UI and/or pelvic floor | Successful fit - 86% Discontinuation - |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | pessaries | | | | | | organ prolapse, 61 years of age | 11%<br>Predictors of unsuccessful fit - history of prolapse procedure or hysterectomy.<br>Predictors of discontinuation- severe posterior prolapse; Improved stress UI- 94% |
| Medical device | Sulak, 1993[202] | Effectiveness of pessaries in women with pelvic relaxation. | 107 | | | Pessary Gelhorn | 3 years | Women with symptomatic pelvic relaxation, 65.5 years | Discontinuation - 47/101<br>Table IV abstract reasons for discontinuation and % |
| Medical device | Clemons, 2004[203] | Patient satisfaction and UI after pessary use | 100 | | | Pessary ring with floor, Gellhorn (Milex) | | Women with systematic pelvic organ prolapse. Stage II or greater; 71 years old | Successful fit-73%<br>Improved stress UI- 45%<br>Improved urge UI - 21%.<br>De novo urge UI - 6%<br>Dissatisfaction 18% was associated with stress UI ( or 17.1; 95% CI, 1.9, 206; |
| Medical device | Farrell, 2007[204] | Effectiveness of a new self-positioning women's pessary | 32 | | | Pessary Uresta/ EastMed Inc | 48 weeks | Women with 41, 50 years old | Satisfaction with pessary - 66%<br>Discontinuation - 34%<br>Continence -47% (among stress UI), 36% (among urge UI<br>Improved UI- 53%<br>No significant predictions for successful fitting were found |
| Medical device | Nguyen, 2005[205] | Predictors of successful pessary fitting and | 130 | | | Pessary: Milex products, PelX/Des Chutes medical | 4 years | Women with pelvic relaxation 66-69 years old | Successful fit- 74%<br>Reasons for unsuccessful fit % |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | continence pessary use | | | | products | | | Prolapse repair 29%<br>Cystocele repair 21%<br>Stress UI 69%<br>Discontinuation among successfully fitted/ 50 %<br>Table 3- abstract reasons for discontinuing and % |
| Medical device | Staskin, 1996[206] | Efficacy of urethral insert for female stress or mixed UI | 135 | | | Reliance urinary control insert no control | 12 weeks | Women with mean age of 52.6 years of age with pure stress or mixed UI | continence - 80%, improvement with >80& decrease in urine loss - 95%, adverse events - 13%, bacteriuria - 8%, withdrawal, - 37% |
| Medical device | Kocjancic, 2008[207] | Effectiveness of adjustable device for the treatment of recurrent stress UI | 49 | | | The Adjustable Continence Therapy (ACT®) | 1 year | Women with stress UI who previously failed anti-incontinence surgery | Continence -53%; improvement in UI - 16%; failure- 12%; migrations -12% and urethral or portal erosions -4% |
| Medical device | Brubaker, 1999[208] | The efficacy and safety of an external urethral barrier for mild/moderate stress UI in adult women. | 411 | | | Urethral barrier device | 12 weeks | Women with mild to moderate stress 41 or mixed 41 | Withdrawal - 65/411<br>comfortable use - 90%<br>Significant reduction in the member of UI episodes<br>Systems of urinary trek infections 26411<br>Positive urine culture - 4.1%<br>Trace of blood in urine - 21%<br>Bacterial vaginosis - 16% |
| Medical device | Moore, 1999[209] | The efficacy and user acceptability of the urethral | 97 | | | Urethral occlusive device (FemAssist*) | 1 month | Women with UI 65 years of age with UI, 37% with | Discontinuation rate 41%; Continence 47%; >50% |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | occlusive device (FemAssist*) for incontinence | | | | | | severe UI | reduction in UI- 33% . Response did not differ by baseline severity of UI or type of UI (stress, urge or mixed incontinence) |
| Medical device | Sand, 1999[210] | Efficacy of reliance urinary control insert in women with stress UI | 63 | | | Uromed Corp, Needham, MA - reliance urinary control insert-no control | 48 weeks | Women with mean age of 55 years old, predominant stress UI | Continence - 79%, urinary tract infection - 29%, gross hematuria - 22%, improved physical functioning and quality of life |
| Medical device | Aboseif, 2009[211] | Efficacy of adjustable continence device in women with recurrent stress UI | 162 | | | Uromedica, Plymouth, Minnesota - adjustable continence device. No control | 48 weeks | women 67.4 years old with recurrent stress UI after 6 months of prior conservative or surgical therapy | Continence - 52%, improvement >50% reduction on stress pad test - 80%, complications - 24.4%, most common adverse effect port erosion - 7.5% |
| Stimulation | Indrekvam, 2001[212] | Effectiveness of home managed electrical stimulation in women with stress or mixed UI | 3,198 | | | Home managed 2 main types of vaginal/anal electro stimulators, Vitacon Norway AS and Conmax Sports Enterprises | 2 years | Women with urge stress, or mixed UI | Discontinuation of treatment - 12% Continence, doctor assessment - 7%, continence patient self report - 4%. Compliers, doctor assessment - 14%, patient self report - 8%. Continence or much better, doctor assessment - 43%, patient self report - 31%. OR of treatment effect assessed by women : Increasing frequency of leakage - 0.82 (0.69;0.96), increasing amount of |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | leakage - 0.77 (0.62;0.95), increasing discomfort with treatment - 0.77 (0.7;0.84) |
| Stimulation | Galloway, 2000[213] | Effects of extracorporeal magnetic innervation for stress 111 in women | 111 | | | Extracorporeal magnetic innervation (ExMI) therapy using Neocontrol chair, 20 minutes, 2 times/ week; 5-50h2 | 6 weeks, 6 month of followup | Women with stress UI, 55 years old | Countenance - 28% No pad or <1 pad per day- 53% Reduced pad use- 70% In women with recurrent after therapy stress UI or hysterectomy countenance rate was 18% and + improvement - 40% |
| Stimulation | Bergstrom, 2000[214] | Efficacy of manual acupuncture could influence urge- or mixed-type incontinence among elderly women who failed previous treatments | 15 | | | Manual acupuncture | 12 times, 3 months of followup | Elderly women with stress or mixed UI who failed previous treatments | Improvement rate 80% |
| Stimulation | Nuhoglu, 2006[215] | the efficacy of Stoller afferent nerve stimulation (SANS) in women with overactive bladder who failed anticholinergic treatment | 35 | | | Stoller afferent nerve stimulation (SANS) | 10 weeks | With overactive bladder who failed therapy with oxybutynin | 54% (n=19) women were continent at the end of the treatment but only 23% at followup |
| Stimulation | van Kerrebroeck, 2004[216] | Efficacy of copolymer system on female UI | 42 | | | Nonanimal stabilized hyaluronic acid/dextranomer copolymer injected transurethrally into the urethra via the Implacer TM device | 1 year | Women not previously treated by invasive therapy and with urodynamically verified SUI | Satisfaction rate at 3 months -71%, at 9 months- 60%; failure 43% |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| Stimulation | van Kerrebroeck, 2004[217] | Effects of the novel system (NASHA/Dx copolymer insertion using the Implacer) on female UI | 42 | | | Nonanimal stabilized hyaluronic acid/dextranomer (NASHA/Dx) copolymer for transurethral injection | 12 months | Therapy-naive female patients with stress UI | Improvement - 76%; improvement by at least one category on the 6-point patient perception scale - 69%; Treatment-related AEs-36%. |
| Stimulation | Chapple, 2005[218] | Efficacy of non-endoscopic injection of nonanimal stabilized hyaluronic acid/dexranomer (NASHA/Dx) gel and Implacer device on female stress UI | 142 | | | Zuidex TM system for injection of bulking agent NASHA/Dx gel and Implacer TM device | 8 weeks, 12 months | Women with stress UI for >12 months 55.7 years old, who failed prior nonsurgical treatments and were not treated with invasive methods. | Reduction in provocation test leakage 750% vs. baseline - 77% at 1 year<br>Continuance- 62% at 1 year<br>Improvement of quality of life - 67%<br>Adverse effects:<br>Urinary retention - 29/142<br>Urinary tract infection - 17/142<br>Micturition urgency - 17/142<br>Injection sit reaction- 11/142<br>Vaginal discomfort- 10/142<br>Injection in injection site- 3 serious/142 |
| Evidence-based self-management tool | Tannenbaum, 2010[219] | To develop and evaluate an evidence -based self-management urinary incontinence risk factor modification tool designed specifically for older women. | 103 | 100 | 100 | Self-management tool developed using evidence from a systematic review on risk factor modification for incontinence and input from focus groups of health care experts and incontinent women. Six risk factors were incorporated into a | 3 months without intervention and 3 months with intervention | English and French speaking incontinent women 50 years of age and older who reported experiencing urinary incontinence at least twice a week for a period lasting at least 3 months during the | Self-Efficacy Index (max score 150): Coefficient (mean change)=8.7 with 95% highest posterior density interval (CI)=3.6-13.7. UDI-6 (max score 100): Coefficient (mean change )=-7.3 with 95% highest posterior density |

**Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | self-management tool with associated strategies for change and self-monitoring: 1) weak pelvic floor muscles, high caffeine intake (>400mg/day), high body mass index, vision and hearing impairment, smoking and constipation | | prior 2 years were recruited via community-advertising. MMSE scores >24/30 | interval (CI) =-12.3- -2.1. IIQ-7 (max score 100):Coefficient (mean change) =-0.5 with 95% highest posterior density interval (CI) =-5.4-4.9 |
| Adjustable continence therapy | Crivellaro, 2010[188] | The Adjustable Continence Therapy is a minimally invasive treatment for females with Stress Urinary incontinence resulting from Intrinsic Sphincteric Deficiency (ISD). This study represents the term results of the first series of patients | 60 | 100 | 100 | Adjustable Continence Therapy implantation that involves two silicone balloons sited on either side of the proximal urethra under the bladder neck, each attached to a titanium port buried in the labia allowing post operative titration of the balloons | Once | 82% were significantly improved, 8% were moderately improved and 10% remained unchanged. Post-operative complications necessitating device removal included migration seen in 8% of patients and urethral erosion in 3.5% of patients | |

**Appendix Table F27. Pharmacological treatments for female UI**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Abrams, 1998[220]<br>Study: RCT<br>Sample: 293 | Men and women aged ≥18 years having urodynamically confirmed bladder overactivity, an increased frequency of micturition (≥8 micturitions/24h) and urge incontinence (≥1 incontinent episode/24h) and /or urgency during a 2-week washout/run-in period | Clinically significant stress incontinence; detrusor hyper-reflexia; hepatic, renal or hematological disorders; symptomatic or recurrent urinary tract infection; bladder outlet obstruction; those receiving bladder training, electrostimulation therapy; those with an indwelling catheter or who were on intermittent catheterization; pregnant or nursing women; or women of childbearing age who were not using reliable contraception | tolterodine | oxybutynin | Pharmacia and Upjohn AB, Uppsala. Sweden | Not reported |
| Abrams, 2006[221]<br>1032 Study Group.<br>UK<br>N: 77 | Men and women (aged >18 years) with a clinical diagnosis of idiopathic OAB with detrusor overactivity and two or more of the following OAB symptoms during the 2-week run-in period were enrolled: urinary frequency(7 or more micturitions/day), urgency incontinence (one or more episodes necessitating a change of clothing or pad), or urinary urgency(7 or more episodes preceding micturition/week) | Clinically significant hepatic, renal, or cardiac abnormalities; stress incontinence; evidence of untreated narrow angle glaucoma; urinary and gastric retention; bladder outlet obstruction >40 (Abrams-Griffiths number); indwelling catheter; recent urogenital surgery; and use of investigational drugs in the 30 days preceding the study | Propiverine 20 mg once daily or propiverine 15 mg three times daily or oxybutynin 5 mg three times daily | Placebo | Not reported | Not reported |
| Abrams, 2008[50]<br>Pooled<br>Country: not reported<br>N: 1,059 | Pooled analysis of three RCTs: Women and men, age >18 years with reported symptoms of OAB for >6 months, 5–50 episodes of UI per week during the treatment-free or placebo run-in periods, together with an increased | The presence of clinically significant stress UI (i.e., >1 episode of stress UI per week), BOO and/or a postvoid residual urine volume of >200 mL (as measured by pelvic ultrasound); contraindications to antimuscarinic therapy (e.g,. uncontrolled narrow-angle glaucoma, urinary retention, gastric retention). | Darifenacin 7.5 mg and 15 mg once daily | Placebo | ACUMED® provided editorial and project management services for this manuscript. Funding for | Paul Abrams is a consultant to Novartis Pharma AG and Jasper Huels, Erhard Quebe- Fehling, Mohamed A. Omar and Michael Steel are all employees of Novartis Pharma AG. |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | frequency of micturition (a mean of at least 8 voids per day) and urgency (a mean of at least one episode per day) | | | | this was provided by Novartis Pharma AG. | |
| Altan-Yaycioglu, 2005[222]RCT Turkey N: 52 | Women with urodynamic diagnosis of overactive bladder | History of ocular disease or surgery; dry eyes, ocular surface disorders, glaucoma, or issues that could affect visual acuity or accommodation (such as cataract, macular degeneration, or history of ocular surgery) | 2 mg tolterodine bid | 5 mg oxybutynin tid | Not reported | Not reported |
| Appell, 1997[223] Pooled Country: not reported N: 1120 | Pooled analysis of 4 RCTS: men and women with detrusor overactivity (phasic detrusor contraction with an amplitude 2 10 cm H,O); and 4) urinary frequency (an average of 28 micturitions/24 hours) and urge incontinence (an average of ≥1 incontinence episode/24 hours) or urinary frequency. | Clinically significant stress incontinence; hepatic or renal disease; recurrent urinary tract infections (UTIs); interstitial cystitis; uninvestigated hematuria or hematuria secondary to malignant disease; indwelling catheter or intermittent catheterization; treatment with any investigational drug in the 2 months prior to entry; previous treatment with Tolterodine; electrostimulation therapy or bladder training within 14 days prior to entry or initiation during the study; treatment with any anti-cholinergic drug or any drug for urinary incontinence within 14 days prior to the baseline visit or initiation during the study; unstable dosage of any treatment with anticholinergic side effects of initiation of such treatment during the study; previously demonstrated serious side effects on oxybutynin; an average total voided volume >3,000ml/24 hours; and clinically significant voiding difficulty with risk of urinary retention. | Tolterodine 2 mg twice daily; tolterodine 1 mg twice daily; oxybutynin (5 mg three times daily) | Placebo | Not reported | Not reported |
| Appell, 2001[224]The OBJECT (Overactive | Participants with overactive bladder who had between 7 and 50 episodes of urge | Urinary tract infection, prostatitis, interstitial cystitis, urinary tract obstruction, urethral diverticulum, bladder tumor, bladder stone, | 10 mg/d of extended-release oxybutynin | 2 mg twice daily of tolterodine tartrate | AlZA Corporation, Mountain View, | Dr Appell is an adviser, investigator, and speaker for ALZA Corporation and a |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Bladder: Judging Effective Control and Treatment) US N: 378 | incontinence per week and 10 or more voids per 24 hours were included. Those with mixed stress and urge incontinence were eligible if the majority of the leakage accidents were related to urge incontinence. | prostate cancer were excluded, as were those who had delivered a baby or undergone pelvic, vaginal, bladder, or prostate surgery less than 6 months before study enrollment; participants with a post-void residual urine volume of more than 150ml at the time of screening; those at considerable risk of developing complete urinary retention if placed on an anti-muscarinic agent; those with clinically important medical problems or other organ abnormalities or pathologies for whom administration of extended-release oxybutynin or Tolterodine would present undue risk (medically uncontrolled cardiovascular, pulmonary, gastrointestinal, renal, endocrine, neurological, autoimmune, hematological, urological, or psychiatric disorders; severely reduced hepatic function or renal impairment); subjects with hematuria, or a positive urine culture; those with narrow-angle glaucoma; obstructive uropathy; myasthenia gravis; pelvic organ prolapse to the hymenal ring; gastrointestinal conditions such as partial or complete obstruction, preexisting severe gastrointestinal narrowing (pathologic or iatrogenic), decreased gastrointestinal motility (paralytic ileus, intestinal atony, chronic and severe constipation), or risk of gastric retention; those who had taken an investigational drug within the previous month; those with known allergies or hypersensitivities to oxybutynin chloride, tolterodine tartrate, or components of the respective drugs; current alcohol or | chloride | | California | speaker and investigator for Pharmacia Corporation. Dr Sand is an adviser, investigator, and speaker for ALZA Corporation and an investigator for Pharmacia Corporation |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | other drug abuse; women who were pregnant or breastfeeding; those who were not capable of following the study schedule or directions; and those who were not able to swallow the medication without chewing, crushing, biting, dividing, or dissolving the capsule | | | | |
| Armstrong, 2005[225]RCT NR N: 790 | Post hoc analysis of the OPERA study: Women 18 years and older, with urinary urge incontinence (21–60 episodes/week), urinary urgency, and frequency (on average at least 10 voids per day); may have a history of prior treatment with an antimuscarinic drug for overactive bladder | Treatable genitourinary conditions that could cause incontinence, 2 postvoid residual urine volumes greater than 150 ml at the time of screening, significant risk of developing complete urinary retention, clinically significant medical condition that could put the patient at undue risk from anti-cholinergic effects, hematuria, uncontrolled narrow-angle glaucoma, obstructive uropathy, reduced gastrointestinal motility, or known hypersensitivity to the study medications. | Extended release oxybutynin 10 mg once daily | Extended release tolterodine 4 mg once daily | Not reported | Not reported |
| Armstrong, 2007[226] Pooled USA N: 1168 | OBJECT and OPERA trials: men and women 18 years of age and older with a diagnosis of overactive bladder with 7–50 episodes of urge UI/week in the OBJECT study and 21–60 episodes/week in the OPERA study | Reported previously | Extended-release oxybutynin 10 mg qd | Extended-release tolterodine 4 mg qd; Immediate-release tolterodine 2 mg bid | This report was supported by Ortho Women's Health and Urology Division of Ortho Pharmaceutical, Inc. | Not reported |
| Barkin, 2004[227] UROMAX Study Group. Canada N: 125 | Men and women with UI (≥7 episode/week) and frequency (≥8 micturitions/day) | Postvoid residual volume >100 mL; unstable dosage of any drug with anticholinergic or diuretic/antidiuretic side effects; allergy or previous life-threatening side effects with anticholinergic/antispasmodic medications; primary diagnosis of stress UI; conditions contraindicating anticholinergic therapy; daily fluid intake >3L; hepatic/renal disease; | CR oxybutynin 15 mg every morning | IR oxybutynin 5 mg TID | Purdue Pharma | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | diagnosed painful bladder syndrome; uninvestigated voiding difficulty with risk of urinary retention, uninvestigated hematuria, hematuria secondary to malignant disease; urinary tract infaction (UTI) or history of recurrent UTI (>3 UTIs/year); indwelling catheter or bladder training within 14 days of screening; drug/alcohol abuse; untreated psychiatric conditions affecting completion of voiding diaries; chronic untreated constipation; bladder outlet obstruction; pregnancy or breastfeeding; failure to use reliable contraception in women of childbearing potential. | | | | |
| Bent, 2008[228]<br>RCT<br>USA<br>N: 588 | Women, 19-85 years old with ≥4 incontinence episodes/week (at least one SUI and at least one UUI episode) for a minimum of three consecutive months prior to study entry | Treatment of UI by a specialist (a urologist, urogynecologist, gynecologist whose practice emphasized incontinence, continence nurse or advisor, or physiotherapist) within the past 5 years; an active urinary tract infection; the use of medication for UI within 3 months; any previous use of duloxetine; surgery within 6 months; pelvic organ prolapse greater than ICS Stage II; any non-pharmacological intervention (e.g., electrical stimulation, bladder training, continence devices) within 3 months; pelvic floor muscle training that had not been stable for 3 months or would not remain stable during the trial; and a major neurological lesion affecting lower urinary tract function. | Duloxetine 40 mg twice daily | Placebo | Eli Lilly and Company; Boehringer Ingelheim GmbH | Not reported |
| Birns, 2000[229]<br>Study: The Oxybutynin CR Clinical Trial Study<br>Sample: 130 | Outpatients of either sex, aged 18-76 years, with voiding problems which were currently stabilized on and tolerant to treatment with the referent | Patients with any medical condition for which anticholinergic medication is contraindicated or with a history of myasthenia gravis, glaucoma or functional or organic gastrointestinal obstructive disorders; patients with | oxybutynin - controlled release | oxybutynin | Funded by Leiras Oy and Pharmacia & UpJohn | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | drug, were recruited. | symptomatic UTIs, clinically significant BOO or symptoms of only nocturnal enuresis; female patients who were pregnant, lactating, or of child-bearing age and using adequate contraceptive measures | | | | |
| Blom, 1995[230]<br>RCT<br>The Netherlands<br>N: 19 | 19 ambulant elderly women (52 years and older) with confirmed urge incontinence. | History of breast and endometrial cancer, thromboembolic disorders, severe hypertension, cardiac failure, diabetes mellitus, peptic ulceration. | 1. Estradiol transdermal therapeutic system (0.05mg estradiol/day).<br>2. Estradiol transdermal therapeutic system (0.05mg estradiol/day) combined with naproxen 250mg tablets twice daily. | Placebo | CIBA, Isando, South Africa supplied Estraderm TTS and PHARMATEZ Pharmaceuticals. Lyndhurst, Johannesburg, South Africa supplied naproxen tablets | Not reported |
| Bodeker, 2010[231]<br>Study: Post-hoc J6<br>N: 1,658 | Men and women 18 years of age or older with urinary frequency (8 or more micturitions every 24 hours) plus urge incontinence (5 or more episodes per week) | Subjects with a total daily urine volume of 2.8L or more, a mean micturition volume of more than 250mL, and/or a clinically significant bladder outlet obstruction (i.e., post void residual urine volume of more than 100mL); those with indwelling catheter or intermittent self-catheterization; urinary tract infection at the screening visit; interstitial cystitis and/or hematuria; contraindications to anticholinerigc therapy (e.g., untreated narrow-angle glaucoma, mechanical gastrointestinal stenosis, myasthenia gravis syndrome), tachycardiac arrhythmia, severe psychiatric illnesses, hypersensivity to trospium or oxybutynin or one of the vehicle ingredients; participation in a bladder training or electro stimulation program, or in another study within the past 30 days. | Trospium chloride | Oxybutynin chloride | Dr. R .Pfleger GmbH (Bamberg, Germany) sponsored the parent study and the post hoc analysis | Rolf-Hasso Bodekar is paid consultant to Dr.R.Pfleger GmbH. Claudia Neumeister is Proejct Manager Clinical Research of Dr.R.Pfleger GmbH. Helmut Madersbacher and Michael Zellner declare that they have no competing interests to disclose |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Brubaker, 2008[232] Pelvic Floor Disorders Network. USA N: 43 | Women at least 21 years with refractory urge incontinence, detrusor overactivity incontinence and 6 or greater urge incontinence episodes in 3 days | Not reported | BoNT-A (200 U) | Placebo | Grants from the National Institute of Child Health and Human Development | Not reported |
| Brunton, 2010[233] Study: RCT Sample: 17822 | 52 multicenter studies with data from 17822 patients. All patients were at least 18 years of age | NR | duloxetine | Placebo | Sponsored/supported by Eli Lilly and Company and Boehringer Ingelheim, GmbH | Fujun Wnag, S.Beth Edwards, Antonio Crucitti, Melissa Ossana, Daniel Walker and Michael Robinson own stock in and are employees of Eli Lilly and Company. Stephen Brunton has acted as consultant for Eli Lilly and Company, Novo Nordisk and Amylin Pharmaceuticals, Inc. |
| Bump, 2003[108] Duloxetine Urinary Incontinence Study Group. USA N: 553 | The Duloxetine Urinary Incontinence Study Group: Women aged 18–65 years with urinary incontinence of at least 3 months' duration. The case definition included a predominant symptom of stress urinary incontinence with a weekly incontinent episode frequency of at least four; the lack of predominant symptoms of enuresis or urge urinary incontinence; diurnal and nocturnal frequencies less than eight and less than three, respectively, on screening history; negative funnel infusion | Prolapse stage II or greater; had a postvoid residual volume of 50 mL or more; were using any pharmacologic agent or device for urinary incontinence; had adopted or changed behavioral management for urinary incontinence within 3 months; or had a history of prior continence surgery. | Duloxetine 20 mg per day (20 mg once daily), duloxetine 40 mg per day (20 mg twice daily), duloxetine 80 mg per day (40 mg twice daily) | Placebo | This work was sponsored by Eli Lilly and Company. Dr. Bump and Dr. Yalcin are full-time employees of Eli Lilly and Company and hold stock and stock options in the company. | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | cystometry with a first sensation greater than 100ml and a bladder capacity of at least 400ml; and a positive fixed volume cough stress test and stress pad test (greater than 2g). | | | | | |
| Bump, 2008[234]<br>Pooled<br>Europe<br>N: 3939 | Women were >18 years with a clinical diagnosis of predominant SUI (an incontinence episode frequency, IEF of >7/week) identified with an identical, validated clinical algorithm that required a retrograde-filling bladder capacity of 400 mL and a positive cough-stress test and stress pad test. For study 4, the major diagnostic criteria were age >18 years and predominant SUI symptoms with an IEF >4/week and urine leakage most often associated with activity. Cohort B included 2,515 patients from not published RCT with predominant SUI that was defined as twice as many SUI episodes as urge UI episodes on the S/UIQ. | Not reported | Duloxetine 40-mg twice daily | Placebo | The studies and these analyses were sponsored by Eli Lilly and Company and by Boehringer Ingelheim GmbH. | Not reported |
| Burgio, 2001[235]<br>RCT<br>NR<br>N: 197 | Older, community-dwelling women at least 55 years of age, ambulatory, with predominant urge incontinence (the number of urge accidents had to exceed the number of | Continual leakage, postvoid residual urine volume greater than 200 ml, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina, decompensated congestive heart failure, history of malignant arrhythmias, or impaired mental | Four clinic visits at 2-week intervals; biofeedback-assisted behavioral treatment | Placebo; self-monitoring (bladder diary), and therapist contact | Supported by Grants AG 08010 | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | stress and other accidents) at least twice per week and persisting for at least 3 months. | status (MMSE score below 20). | implemented by nurse specialist, or drug treatment with oxybutynin chloride 2.5 mg of oxybutynin chloride three times a day | | | |
| Burgio, 2000[236] RCT analysis USA N: 197 | Older, community dwelling women with urge incontinence at least twice per week (the number of urge accidents had to exceed the number of stress accidents) and persisting for at least 3 months; urodynamic evidence of bladder dysfunction (detrusor instability during filling or provocation or maximal cystometric capacity of 350ml or less). | Continual leakage, postvoid residual urine volume >200ml, uterine proplapse past the introitus, narrow-angle glaucoma, unstable angina, decompensated congestive heart failure, history of malignancy arrhythmias, or impaired mental status (MMSE score <20). | Oxybutynin chloride individually titrated from 2.5 mg to 15 mg daily | 2.5 to 5mg t.i.d./Placebo | Supported by Grants AG 08010 | Not reported |
| Burgio, 1998[237]RCT USA N: 197 | Adults with at least 2 urge accidents per week on the 2-week baseline bladder diary, and urge incontinence had to be the predominant pattern (the number of urge accidents had to exceed the number of stress accidents). Also, there had to be urodynamic evidence of bladder dysfunction (detrusor instability filling or provocation or maximal cystometric capacity of ≤350ml). | Continual leakage, postvoid residual urine volume >200 mL, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina, decompensated congestive heart failure, history of malignant arrhythmias, or impaired mental status (MMSE score <20). | Oxybutynin chloride, possible range of doses, 2.5 mg daily to 5.0 mg 3 times daily | Behavioral Training: biofeedback-assisted PFMT/ placebo | Grants AG08010 | Not reported |
| Burgio, 2008[238] Fitzgerald, | The BE-DRI (Behavior Enhances Drug Reduction | Age <21 years; pregnancy, plan to become pregnant in the next 8 | Tolterodine tartrate | Tolterodine tartrate | Grant support by the National | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| 2008[239]<br>Zimmern, 2010[240]<br>Urinary Incontinence Treatment Network.<br>USA<br>N: 307 | of Incontinence) trial: at least 7 episodes of incontinence in the diary, persistent incontinence for at least 3 months, no current use of antimuscarinic or other medications that could affect UI, and no evidence that incontinence was secondary to neurologic or other systemic diseases. | months, or declining medically acceptable birth control; <6 months postpartum delivery or other termination after 20 weeks of gestation; inability to contract pelvic floor muscles during evaluation; participated in a formal behavioral therapy program of >2 months in the past 2 years; reported continual leakage or always being damp; hypersensitive to study drug (extended-release tolerodine); systemic disease known to affect bladder function (e.g., Parkinson's disease, multiple sclerosis, spina bifida, or spinal cord injury or trauma); currently using catheter to empty bladder; postvoid residual volume >150ml; treatment for pelvic organ prolapsed with pessary <3 months; incontinence, vaginal, bladder, or prolapse surgery in the past 6 months; urethral diverticulum, current or repaired; previous augmentation cystoplasty or artificial sphincter; neuromodulation for pelvic indications; currently using anticholinergic agents, cholinergic agonists, tricyclic antidepressants, or duloxetine-must have discontinued use for ≥4 weeks; currently using diuretics with dosage change in past 3 months; uncontrolled medical problem (e.g., poorly controlled diabetes or decompensated congestive heart failure); history of bladder or pelvic cancer or pelvic radiation therapy; glaucoma, with or without ophthalmologist clearance; gastric retention (by medical history); non-ambulatory (may use assisted device); and participation in another | (extended-release capsules), 4 mg/day + behavioral intervention: teaching pelvic floor muscle control and exercises; behavioral strategies to diminish urgency, suppress bladder contractions, and prevent both stress and urge | (extended-release capsules), 4 mg/day | Institute of Diabetes and Digestive and Kidney diseases. Additional support, including provision of study drugs and funding, was contributed by Pfizer | |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | intervention trial that might influence the results of the trial. | | | | |
| Burgio, 2010[241] Study: RCT Sample: 64 | Community dwelling women with urge predominant incontinence. Incontinence for 3 or more months, no formal behavioral therapy, an average of 2 or more urge incontinence episodes per week on bladder diary, number of urge incontinence episodes exceeding other types and cystometric evidence of bladder dysfunction (detrusor overactivity or reduced bladder capacity) | NR | Pelvic Floor Muscle training +Urge suppression techniques+Oxy butynin | Oxybutynin | Supported by a grant from the Department of Veterans Affairs, Veterans Health Administration, Rehabilitation Research and Development Service, and the Female Veterans Project, Birmingham/Atlanta Geriatric Research Education and Clinical Center, Birmingham VA Medical Center | Kathryn Burgio has financial interest and/or other relationship with Pfizer and Astellas; Patricia Goode has financial interest and/or other relationship with Pfizer; Holly Richter has financial interest and/or other relationship with Xanodyne, Pfizer and Astellas; Theodore Johnson has financial interest and/or other relationship with Aventis, Yamanouchi, Ortho McNeil, Boehringer Ingelheim, Johnson & Johnson and Pfizer |
| But, 2010[242] Study: SOLIDAIR Sample: 77 | Women with OAB symptoms | NR | solifenacin | darifenacin | Funded by a research grant from Astellas, Europe | NR |
| Cardozo, 2010[243] Study: RCT followed by open-label Sample: 2758 | Women aged >=18 years with SUI, defined by either urodynamic evaluation within 12 months before study entry without intervening continence surgery or significant change in symptoms, or by episodes of SUI confirmed by question 1 of the validated Stress/Urge Incontinence Questionnaire(S/UIQ). In | Pregnancy; alcohol abuse; active or chronically recurring urinary tract infection; presence of ureteric, bladder, urethral or rectal fistula; uncorrected congenital abnormality leading to incomplete emptying or advanced pelvic organ prolapse(stage III or IV by ICS POP-Q criteria); active or chronic hepatitis A, B or C; previous urinary incontinence surgery; or any other condition that, in the opinion of the investigator, precludes evaluation of | duloxetine | Placebo | Sponsored by Eli Lilly and Company and by Boehringer Ingelheim GmbH | L.C. has disclosed being in receipt of funding for research, lecturing, and/or advice/consultancies from Astellas, Pfizer, UCB Pharma, Plethora, cook, Organon, Bioxell, and Sanofi-Aventis. R.L. is a member of European and German advisory |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | addition, eligible patients had at least twice as many SUI episodes as urge incontinence episodes as defined by question 2 of the S/UIQ and an average of >=7 incontinence episodes | response to duloxetine hydrochloride. Patients were not allowed to be on a medication regimen that included diuretics where dose and/or frequency were unstable, nor did they allow taking other medications that were demonstrated to be effective for SUI. Subjects who regularly performed pelvic floor muscle exercises could not change their exercise regimen during the course of the study and subjects who did not perform pelvic floor exercises were not permitted to start during the study | | | | boards and speaker in Lilly-sponsored congresses or training sessions. S.V., A.B., M.M., L.V. and Y.D.Z. are employed by Eli Lilly and Company and potentially own stock and/or hold stock options in the company |
| Cardozo, 2006[244]<br>Pooled<br>NR<br>N: 3,298 | Men and women at least 18 years of age with a mean of >8 micturitions/day; >1 incontinence episode/day; >1 urgency episode/day | Reported previously | Solifenacin 5 mg; solifenacin 10mg | Placebo | Grant from Yamanouchi Pharmaceutical Co., Ltd., Tokyo, Japan. | Not reported |
| Cardozo, 2004[245]<br>RCT<br>Performed in 14 tertiary urogynecological or urological centers in Australia, Canada, the Netherlands, and the United Kingdom<br>N: 109 | Women aged 18–75 years with severe stress urinary incontinence defined with both urodynamic and severity criteria. Pure urodynamic stress incontinence was defined as a predominant complaint of stress urinary incontinence and the finding of urodynamic stress incontinence without detrusor overactivity and with normal compliance on a urodynamic study within 6 months of enrollment. All urodynamic diagnoses conformed to the standards of the International Incontinence Society. Severity criteria | Not reported | Duloxetine (40 mg twice daily for 4 weeks, escalating to 60 mg twice daily for another 4 weeks) | Placebo | This work was sponsored by Eli Lilly and Company and Boehringer Ingelheim. | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | included both 1) that the subject have at least 14 incontinence episodes per week and 2) that she had scheduled her continence surgery after having discussed all other reasonable options for stress urinary incontinence with her physician. Intrinsic sphincteric deficiency was defined as urodynamic stress incontinence with a maximum straining urethral axis less than 20°, maximum urethral closure pressure less than 20cm $H_2O$, or Valsalva leak-point pressure less than 60 cm $H_2O$. | | | | | |
| Cardozo, 2004[53]<br>RCT<br>NR<br>N: 911 | Men and women 18 years old or older with symptoms of OAB (including urinary frequency with urgency and/or urge incontinence) for 3 months or more with an average micturition frequency of >8 times/day, with >3 episodes of urgency and/or >3 episodes of UI during the 3-day micturition period. | Reported previously | Solifenacin 5 mg, solifenacin 10 mg | Placebo | Not reported | Not reported |
| Castro, 2008[246]<br>Study: RCT<br>Sample: 118 | Women with proven urodynamic stress urinary incontinence and no detrusor overactivity; positive cough stress test; and >3g leakage measured by a pad test with a standardized | Patients with chronic degenerative diseases that would affect muscular and nerve tissues, advanced genital prolapses, pregnancy, active or recurrent urinary tract infections, vulvovaginitis, continence surgery within one year, patients with cardiac pacemakers, patients with intrinsic | Pelvic Floor Muscle Training/electrical stimulation/vaginal cone | No treatment | NR | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | bladder volume(200ml). All subjects had symptoms of SUI with an average of at least 3 stress incontinence episodes a week | sphincteric deficiencies identified by the Valsalva leak point pressure<=60cm H2O measurement in the sitting position with a volume of 250ml in the bladder and/or by the measurement of a urethral closure pressure<=20cm H2O in the sitting position at maximum cystometric capacity. | | | | |
| Castro-Diaz, 2007[247] Duloxetine Dose Escalation Study Group. 64 study centers in 8 countries N: 516 | Duloxetine Dose Escalation Study Group: women ≥18 years old with symptoms of predominant SUI using the validated Stress/Urge Incontinence Questionnaire (S/UIQ), with ≥7 SUI episodes per week and at least twice as many SUI episodes as urge UI episodes, urodynamic diagnosis of incontinence within the 6 months of study entry or an average daytime voiding interval >2 hours, a nocturnal voiding frequency ≤2 per day and a positive cough stress test. | Continence surgery within 6 months or pharmacological treatment for symptoms of overactive bladder within 14 days of visit 1, pelvic organ prolapse beyond the hymen and previous participation in a duloxetine clinical trial. | Duloxetine 40 mg BID for 8 weeks, duloxetine 40 mg daily for 2 weeks escalating to 40 mg BID for 6 weeks, duloxetine 20 mg BID for 2 weeks escalating to 40 mg BID for 6 weeks | Placebo | This study was sponsored and funded by Eli Lilly and Company and by Boehringer Ingelheim GmbH | Commercial or other associations that might pose a conflict of interest: Drs. Voss, Yalcin and Bump are full-time employees of Lilly Research Laboratories and Eli Lilly and Company. |
| Chancellor, 2001[248] RCT USA N: 36 | Subjects were healthy men and women who were within 15% of ideal weight for height and had no clinically relevant abnormalities, as determined by medical history, physical examination, blood chemistry, complete blood count, urinalysis, and electrocardiography. | Clinically significant medical problems, glaucoma, obstructive uropathy, partial or complete obstruction or narrowing of the gastrointestinal tract, paralytic ileus, intestinal atony, colitis, or myasthenia gravis; male subject with hemoglobin levels <13 g/dL and female subjects with hemoglobin levels <11.5 g/dL; subjects using prescription medications (except for estrogen replacement or birth control) within 14 days before start of the study; known | ER-oxybutynin 10mg, tolterodine 2mg, IR-oxybutynin 5mg | Placebo | This study was sponsored by ALZA Corporation, Mountain View, California. | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | allergies to the study drugs; who had smoked tobacco within the past 3 months, or who drank ≥2 ounces of alcoholic beverages per day or >40 ounces of caffeine-containing beverages per day. | | | | |
| Chancellor, 2008[249]<br>The ABLE trial<br>USA<br>N: 395 | Male and female patients >18 years old with symptoms of OAB for at least 6 months; >8 micturitions on average per day, >2 episodes of UUI on average per day and/or >2 episodes of urgency on average per day | Use of any drug that could affect bladder function within 2 weeks prior and during the study, participation in any formal bladder-training program within 30 days of screening, predominant stress urinary incontinence and any bladder or neurological condition that could affect urinary bladder function or in which use of anti-cholinergic drugs was contraindicated. | Darifenacin with voluntary up-titration from 7.5 mg once daily (qd) to 15 mg qd and Behavioral Modification Program: brochures on modification of diet and daily habits; training in a primary physician's office about pelvic muscle exercises and urgency control techniques including timed voiding, dietary modifications and Kegel-type exercises. | Darifenacin with voluntary up-titration from 7.5 mg once daily (qd) to 15 mg qd | Funding for this study was provided by Novartis Pharmaceuticals Corp., who was involved in study design, data collection and analysis. | Michael Chancellor has no potential conflicts of interest within International Journal of Clinical Practice guidelines for financial disclosure. |
| Chancellor, 2010[250]<br>Study: Post-hoc A4,T3<br>N: 1,156 | Male or female patients aged ≥18 years with OAB for ≥6 months; required to have urinary frequency (an average of ≥10 toilet voids per day); symptoms of urgency (at least 1 "severe" urgency severity rating associated with a toilet void per 3 days, as measured by the Indevus | Total void volume of >3000mL per day, stress incontinence, insensate continence; history of neurogenic bladder; significant renal disease; urinary tract infections; and bladder obstructions | Trospium chloride XR | Placebo | Not reported | Dr. Oefelein-Director: Allergan; Dr. Chancellor-Consultant, Speaker honorarium, trial participant: Allergan |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | Urgency Severity Scale [IUSS]); and an average of ≥1 urge urinary incontinence (UUI) episode per day, as recorded in a baseline 3-day patient urinary diary | | | | | |
| Chapple, 2005[251] RCT USA N: 65 | Men and women aged 18–75 years with cystometric evidence of detrusor overactivity within the previous 6 months, either idiopathic or neurogenic (secondary to a neurological lesion present for >12 months), with >2 associated symptoms (average of >7 micturitions/day, >7 episodes of urgency/week, >1 urge incontinence episode/week necessitating change of clothing or pads). | Previous bladder surgery for detrusor overactivity; prostatectomy in the last 6 months; bladder stones; treatment with diuretics, antimuscarinic, tricyclic antidepressants or digoxin within the previous 2 weeks; stress and mixed incontinence, unless detrusor overactivity was the principal urodynamic observation and the patient was experiencing normal recommended limits, contraindiciations to anticholinergics (e.g. untreated or narrow angle glaucoma, bladder outlet obstruction). | Darifenacin immediate release (IR) 2.5 mg three times a day (t.i.d.); darifenacin controlled release (CR) 15 mg once daily (q.d.); darifenacin CR 30 mg q.d. | Oxybutynin 2.5 mg t.i.d.; oxybutynin 5 mg t.i.d.; oxybutynin 5 mg t.i.d. | Pfizer Inc | Not reported |
| Chapple, 2007[252] RCT Belgium, Bulgaria, Czech Republic, Estonia, France, Germany, Hungary, Italy, the Netherlands, Poland, Romania, Russia, Spain, Sweden, Ukraine, the United Kingdom, South Africa, | Men and women with OAB symptoms with urinary urgency for >6 months and >3 UUI episodes per 24 hours (symptoms were recorded in a 3-day diary). | Pregnancy ;non adequate contraception throughout the trial; lower urinary tract pathology that could, in the investigator's opinion, be responsible for urgency or incontinence (e.g., genuine stress incontinence, bladder stones, interstitial cystitis urothelial tumours), pelvic prolapse of grade III or higher, clinically relevant bladder outlet obstruction, polyuria (>3 l per 24 hours), symptomatic or recurrent urinary tract infections, or postvoid residual (PVR) urine volume >100 ml; currently receiving treatment, were treated within 2 weesk of screening visit with antimuscarinic agents, were | Tolterodine ER 4 mg, fesoterodine 4 mg, fesoterodine 8 mg | Placebo | Schwarz BioSciences GmbH and Pfizer Inc | Professor Chapple is a consultant/ investigator/speaker for Astellas (Yamanouchi), Pfizer Inc, Novartis, and Schwarz BioSciences GmbH, and has acted as a consultant for UCB. Professor Van Kerrebroeck is an investigator and lecturer for Astellas |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Australia, and New Zealand<br>N: 1,135 | | treated within the past 4 weeks with electrostimulation for bladder training, or had an active urinary tract infection or an underlying neurological disease responsible for their OAB; cardiac arrhythmia and/or unstable angina or a QTcB interval >500 ms. | | | | |
| Chapple, 2008[253]<br>RCT analysis<br>Country: not reported<br>N: 1,135 | Men and women aged ≥18 years with OAB syndrome for ≥ 6 months; urinary frequency (≥8 voids/24 hours), and urinary urgency (≥6 episodes during the 3-day diary period) or UUI (≥3 episodes during the 3-day diary period, and at least moderate bladder problems on a six-point Likert scale. | The presence of lower urinary tract pathology that could, in the investigator's opinion, be responsible for urgency or UI (e.g. significant stress UI, urolithiasis, interstitial cystitis, urothelial tumors); pelvic organ prolapse grade >III; clinically relevant BOO; a postvoid residual urine volume of >100 mL; polyuria (>3 L/24 hours); symptomatic or recurrent UTIs; current treatment with antimuscarinic agents; a neurogenic cause for OAB; clinically relevant arrhythmia, unstable angina, or a QTcB interval of >500 ms; and current treatment, or treatment within the past 4 weeks, with electrostimulation or bladder training. | Fesoterodine 8 mg, tolterodine ER 4 mg | Placebo | Schwarz BioSciences GmbH and Pfizer Inc. | Philip E. Van Kerrebroeck and Christopher R. Chapple are Study Investigators funded by the Sponsor, and Joseph T. Wang and Marina Brodsky are Employees of the Sponsor. |
| Chapple, 2007[254]<br>RCT<br>USA, Poland, South Africa, Hungary, Sweden, UK and Germany<br>N: 400 | Men and women >65 years of age with OAB for at least 6 month with >1 urge UI/day and >10 micturitions/day | Dependent toileting, dependent diary completion, taking drugs that can affect bladder function or external urethral sphincter, total daily volume >3000ml, mean volume/micturition >300ml, clinically significant stress UI or bladder outlet obstruction (postvoid residual volume >100ml); marked cystocele, stage 3 or 4 pelvic prolapse; participation in bladder training program or electrical stimulation therapy within 3 months of screening; intermittent urinary tract infection, clinically significant congenital or acquired disorder of the urinary tract, chronic pain syndrome | Darifenacin (7.5 mg once daily for 2 weeks, then optional titration to 15 mg daily) | Placebo | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | or other clinically significant medical conditions including cognitive impairment, uncontrolled severe hypertension, uncontrolled severe heart failure, recent myocardial infarction, or uncontrolled thyroid disease. | | | | |
| Chapple, 2005[255] Pooled Country: not reported N: 1,059 | Men and women aged ≥18 years with symptoms of OAB for ≥6 months, and capable of independent toileting, with 5–50 episodes of incontinence per week during the run-in period, and a high voiding frequency (a mean of ≥8 voids/24 hours) and urgency (a mean of ≥1 episode/24 hours); women of childbearing potential required to use an adequate method of contraception throughout the study; those taking hormone–replacement therapy had to have received such therapy for ≥2 months before entering the study; men taking finasteride for BPH had to be on a stable dose for ≥2 months; those receiving long-term therapy with diuretics, antihypertensive medications, benzodiazepines or antihistamines had to be taking a stable dose before study recruitment, with no plans to change treatment during the | Initiation of a bladder training; pregnancy and lactation; clinically significant stress incontinence (i.e.>1 episode of stress incontinence per week), BOO and/or a postvoid residual urine volume of > 200 mL (as measured by pelvic ultrasonography); clinically important medical problems that would interfere with the patient's participation in the study; patients with interstitial cystitis, severe constipation (two or fewer bowel movements per week), hematuria or intermittent UTI; cystocele or other clinically significant pelvic prolapsed; patients with an indwelling catheter and those who practiced intermittent self-catheterization; urogenital surgery in the previous 6 months; patients with contraindications to antimuscarinic therapy (e.g., uncontrolled narrow-angle glaucoma, urinary retention, gastric retention); history of alcohol/drug abuse; and known hypersensitivity to study medication. | Darifenacin 7.5 mg or 15 mg/day | Placebo | The studies were funded by Pfizer Inc. | All authors are investigators in the study and/or have acted as consultants to Pfizer or Novartis. |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | study; and patients on bladder training program were not to modify or discontinue their training during the course of the study. | | | | | |
| Chapple, 2007[60,61,256] U.S. Food and Drug Administration[60] STAR study group Country: not reported N: 1,177 | The STAR study :men and women aged at least 18 years who had OAB symptoms (including urinary frequency, urgency or urgency incontinence) for 3 months or more; with an average of >8 micturitions/day; >1 incontinence episode/day, or an average of >1 urgency episode/day. | Stress incontinence or mixed incontinence where stress was predominant (mixed incontinence was allowed otherwise) and patients with a neurological cause of abnormal detrusor activity. | Solifenacin 5 mg | Tolterodine ER 4 mg | Grant from Yamanouchi Pharmaceutical Co, Ltd (now Astellas Pharma Inc). Tokyo, Japan. | Professor Chapple is a consultant, investigator, and speaker for Astellas Pharma Inc (Yamanouchi), Pfizer, Novartis, and Schwarz, and has acted as a consultant to UCB. |
| Chapple, 2006[257] Study: RCT Sample: 3032 | Outpatient men and women, at least 18 years of age, with symptoms of OAB. During a baseline 3-day micturition diary period, patients were required to report a mean of ≥8 micturitions per 24 h ,and either a mean of ≥1 incontinence episode per 24 h or a mean of ≥1 urgency episode per 24 h. | Patients with at least one on-treatment efficacy assessment | solifenacin 5mg or 10mg | placebo | Funded by an educational grant from Astellas. | Christopher Chapple is an investigator/consultant for Pfizer, Astellas, Schwarz Pharma, Novartis and UCB Pharma. Linda Cardozo receives money for consultancy and/or advisory work, or research or lecturing from Astellas, Lilly/Boehringer Ingelheim, UCB Pharma, Pfizer, Gynecare, Plethora and Cook. William D.Steers is an investigator/consultant for Sanofi, Pfizer, Lilly and Astellas. Fred E.Govier has nothing to disclose |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Chapple, 2004[258]<br>Study: RCT<br>Sample: 225 | Men and women aged 18-80 years were eligible to enter the study if they had idiopathic detrusor overactivity (defined in this study as phasic contractions of ≥10 cmH20, assessed by filling cystometry) within 6 months of study initiation; a mean of ≥8 voids/24h for 3 days and ≥3 episodes of incontinence or urgency during the 3-day urinary diary period before randomization | Neurogenic detrusor overactivity, significant outlet obstruction, urinary retention, urodynamic stress incontinence, bladder stones, UTI, interstitial cystitis, previous or current malignant disease of the pelvic organs, previous pelvic radiation, and diabetic neuropathy; those taking concomitant anticholinergic medications, or had known or suspected hypersensitivity to anticholinergic medications or lactose; pregnant or lactating women and those not taking approved contraception methods | Solifenacin | Tolterodine and placebo | NR | NR |
| Chapple, 2004[259]<br>Study: RCT<br>Sample: 728 | NR | NR | fesoterodine | Placebo | NR | NR |
| Chapple, 2004[54]<br>Study: RCT<br>Sample: 1081 | Men and women aged>=18 years with symptomatic OAB(including urgency, urge incontinence, or frequency) for >=3 months. After run-in period patients had to have had an average frequency of >=8 voids/24 hours and have experienced at least 3 episodes of urgency and/or three episodes of incontinence during the 3-day voiding diary period. | Significant BOO, a postvoid residual volume of >200mL, incontinence for which stress was determined to be the predominant factor, presence of a neurological cause for detrusor muscle overactivity, evidence of UTI or bladder stones, previous pelvic irradiation, or previous or current malignant disease of the pelvic organs, any medical condition contraindicating the use of antimuscarinic medication (including narrow-angle glaucoma and urinary or gastric retention), nonpharmacological treatment for OAB including electrostimulation therapy or start of a bladder training program during the 2 weeks before or during the study, diabetic neuropathy, use of drugs intended to treat incontinence, use of any drugs with cholinergic or anticholinergic side- | solifenacin 5mg and 10mg | Tolterodine 2mg twice daily or placebo | Yamanouchi Pharma Co., Ltd, Tokyo,Japan | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | effects, and participation in a clinical trial within 30 days before the study entry; pregnant or nursing women, women of child-bearing potential intending to become pregnant during the study or who were not going to use reliable contraceptive methods. | | | | |
| Chompootaweep, 1998[260]<br>RCT<br>Thailand<br>N: 40 | 40 postmenopausal women with urogenital symptoms related to estrogen deficiency. | Thromboembolic disorders, severe liver diseases, estrogen-dependent tumors, high blood pressure (diastolic >100mm/Hg), those who had received oral estrogen in the 3 months before the study. | Combined contraceptive intravaginal 1 pill/week at bedtime with 250mg levonorgestrel +30mg ethinyl estradiol. | Intravaginal conjugated estrogen cream (1g=0.625mg conjugated equine estrogens) at bedtime, 3/week in week 1, 2/week in week 2, and then 1/week for 6 weeks | Grant from the Rhatchada-Pisakessompoj Fund, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand | Not reported |
| Choo, 2008[261]<br>Study: H5<br>Sample: 357 | Men and women aged ≥18 years with symptoms of OAB for ≥3months; average frequency of ≥8 voids per 24h and experienced at least three episodes of urgency or three episodes of urgency incontinence during the 3-day voiding diary period | Clinically significant bladder outlet obstruction, a PVR volume of >200ml, incontinence for which stress was determined to be the predominant factor, presence of a neurological cause for detrusor muscle overactivity, evidence of urinary tract infection or bladder stones, previous pelvic irradiation, or previous or current malignant disease in the pelvic organs, any medical condition contraindicating the use of antimuscarinic medication(including narrow angle glaucoma and urinary or gastric retention), non-pharmacological treatment for OAB including electrostimulation therapy or start of a bladder training program during the 2 weeks before or during the study, diabetic neuropathy, use of | solifenacin 5mg/10mg | tolterodine 4mg | Research grant from Astellas Pharma Inc., Tokyo, Japan | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | drugs intended to treat incontinence, use of any drugs with cholinergic or anitcholinergic side effects and participation in a clinical trial within 30 days before study entry; women of child-bearing potential who were pregnant or nursing, intending to become pregnant during the study, or who were not using reliable contraceptive methods. | | | | |
| Chu, 2009[262]<br>Study: RCT<br>Sample: 672 | Men and women aged ≥18 years with a diagnosis of OAB made by an investigator based on symptoms (urinary frequency, urgency, or urge incontinence); had to record a mean of >=8 micturitions per 24 hours plus a mean of ≥1 incontinence episode per 24hours and/or a mean of ≥1 urgency episode per 24 hours | Stress urinary incontinence or mixed urinary incontinence in which stress was predominant (mixed incontinence was otherwise allowed), a neurologic cause of detrusor overactivity, urinary retention, grade III/IV prolapse with cystocele, and recurrent or active urinary tract infection; patients with abnormal findings on 12-lead ECG or abnormal laboratory findings. Women of childbearing potential were required to have a negative serum pregnancy test at screening and to use a medically acceptable form of contraception during study participation | Solifenacin | Placebo | Funded and sponsored by Astellas Pharma Inc., Tokyo, Japan | No |
| Corcos, 2006[263]<br>Uromax Study Group<br>Canada<br>N: 237 | Men and women (aged ≥18 years) with UUI | A screening postvoid residual urine volume of >100 mL; allergy/serious side-effects with anticholinergic medications; primary diagnosis of stress UI; conditions contraindicating anticholinergic therapy; hepatic/renal disease; interstitial cystitis, hematuria secondary to malignancy; recurrent UTI (more than three/year); indwelling catheter/bladder training within 14 days of screening; drug/alcohol abuse; untreated psychiatric conditions affecting participation; pregnant/nursing women; and women of childbearing | Daily dose of 5, 10, and 15 mg controlled-release oxybutynin | Daily dose of 5, 10 and 15 mg controlled-release oxybutynin | Purdue Pharma | J. Corcos, A. Patrick, C. Andreou and R. Casey are study investigators funded by sponsor; P. Miceli is a paid consultant/writer; and A. Darke, J. Reiz and Z. Harsanyi are sponsor employees. |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | potential not using reliable contraception. A urine sample was collected and analyzed at the first study visit. Confirmed UTI at study entry was treated, and initiation of the washout/baseline period followed confirmation of absence of bacteria. Use of pharmacotherapy for UUI was terminated at or before the baseline evaluation (if applicable). | | | | |
| Davila, 2001[264] Transdermal Oxybutynin Study Group. N: 76 | Men or women 18 years or older with a history of urge or mixed urinary incontinence with a predominance of urge symptoms, previously diagnosed with motor urge urinary incontinence and had symptomatic improvement during a minimum of 6 weeks of oral oxybutynin; a minimum of 3 incontinent episodes daily, and a greater than 30% increase after 2 week washout from current treatment. | Allergy to oxybutynin, intolerability of transdermal system, current pregnancy or lactation, overflow incontinence secondary to underactive or non-contractile detrusor or outlet obstruction, impaired bladder compliance, including tonic increase in pressure greater than 15 cm. water during filling cystometry, or current medical conditions or pharmacological therapies that could contribute to or cause urinary incontinence; medical conditions that could be worsened by oxybutynin. | Transdermal system with 1.3 mg. oxybutynin daily + oral placebo | Oral capsules with 2.5 mg. oxybutynin + transdermal placebo | Watson Laboratories, Inc. | Not reported |
| Dessole, 2004[265] RCT Italy N: 88 | 88 postmenopausal women with incontinence confirmed by the direct visualization of loss of urine from the urethra during the standard stress test and by urodynamic investigation. | Estrogen treatment, anatomical lesions of the urogenital tract, detrusor over activity and abnormal maximal cystometric capacity; presence of severe systemic disorders, thromboembolic diseases, biliary lithiasis, previous breast or uterine cancer, abnormal uterine bleeding, and body mass index of 25 $kg/m^2$ or higher. | Intravaginal estriol ovules: 1 ovule/day (1mg) for 2 weeks and then 2 ovules/ week for 6 months. | Placebo: vaginal suppositories | Not reported | Not reported |
| Diokno, 2003[266] Chu, 2005[267] Anderson, 2006[268] OPERA | OPERA (Overactive bladder: Performance of Extended Release Agents):Women with OAB, aged 18 years and | Treatable genitourinary conditions that could cause incontinence, 2 postvoid residual urine volumes shown by ultrasonography to exceed 150 mL; pronounced risk of | Extended-release formulations of oxybutynin at 10 mg/d | Tolterodine at 4 mg/d | ALZA Corporation, Mountain View, California, and Ortho-McNeil | Dr. Diokno is a medical consultant for Ortho-McNeil Pharmaceutical. Dr. Appell is on the |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| (Overactive bladder: Performance of Extended Release Agents) trial<br>USA<br>N: 790 | older, who documented 21 to 60 UUI episodes per week and an average of 10 or more voids per 24 hours; predominant urge UI; with or without history of prior treatment with an anticholinergic drug for OAB. | developing complete urinary retention, clinically important medical problems that would put a participant at undue risk of anticholinergic effects, hematuria, uncontrolled narrow-angle glaucoma, obstructive uropathy, reduced gastrointestinal motility, and known hypersensitivity to the study medications. | | | Pharmaceutical, Raritan, NJ | Medical Advisory Board of Ortho-McNeil Pharmaceutical, Watson Pharmaceuticals, Inc, and Indevus Pharmaceuticals, Inc. Dr. Sand is an investigator/advisor for Pharmacia Corporation. Dr. Dmochowski is a consultant for Ortho-McNeil Pharmaceutical. Dr. Kell is a full-time employee of ALZA Corporation, a subsidiary of Johnson & Johnson; she owns Johnson & Johnson stock and has Johnson & Johnson stock options. |
| Dmochowski, 2002[269]<br>Transdermal Oxybutynin Study Group.<br>USA<br>N: 520 | Male and Female patients at least 18 years old with a history of overactive bladder, with or without neurological disease, 10 or more urge urinary incontinent episodes/week, with either pure urge or a predominance of urge episodes, 56 or more voids and an average recorded voided volume of 350 ml. or less. | Incontinence related to chronic illness, anatomical weakness/abnormalities or concomitant medications, lower urinary tract surgery in the previous 6 months; a diagnosis of interstitial cystitis, urethral syndrome, painful bladder syndrome and overflow urinary incontinence; alcohol/drug abuse within the previous year; known hypersensitivity to oxybutynin, similar compounds or transdermal medications; active skin disorder; narrow-angle glaucoma or shallow anterior chamber evident on physical examination; prostate specific antigen greater than 4ng./ml. or a history of | 1.3, 2.6, or 3.9 mg Oxybutynin twice weekly to the abdomen | Placebo twice weekly to the abdomen | Not reported | All authors have financial interest and/or other relationships with Watson Pharmaceuticals; Roger R. Dmochowski has financial interest and/or other relationship with Lilly, Surx, Alza, Pharmacia, Bioform, and Genyx; Norman ZInner has financial interest and/or other relationship with |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | biopsy positive prostate cancer in men, and excessive consumption of caffeine, defined as greater than 5 cups of caffeine–containing beverages daily. | | | | Bayer, Lilly, Abbott, Praecis, Pharmacia, Interneuron, Alza, Amgen, AstraZeneca, and Roche; Marc Gittelman has financial interest and/or other relationship with Alza, Interneuron, Yamanouchi, Merck, Pfizer, Seprecor, Otsulta, Glaxo, Pharmacia, Praecis, Synthelabo, and Vivus; Sydney Lyttle has financial interest and/or other relationship with PPD Development. |
| Dmochowski, 2008[48] RCT USA N: 564 | Men and women aged 18 years or older with OAB of 6 months' or longer duration with symptoms of urinary frequency (a mean of 10 or more toilet voids per day), urgency (1 or more episodes of severe urgency associated with a toilet void), and UUI (a mean of 1 or more UUI episodes per day). | Total voided volumes greater than 3000 mL/day or a mean volume voided/void greater than 250 mL; predominantly stress, insensate, or overflow incontinence; history of neurogenic bladder, indwelling or intermittent catheterization, significant renal disease (defined as serum creatinine greater than 1.5 mg/dL), uninvestigated hematuria or urinary tract infection during screening, or a history of more than 3 urinary tract infections in the previous 12 months; other bladder pathologies, including clinically significant retention (defined as postvoid residual urine volume greater than 100 mL), cancer, and interstitial cystitis; prostate specific antigen level greater than 4 ng/mL, prostate cancer, or chronic prostatitis. | Trospium chloride 60 mg once daily | Placebo | Esprit Pharma and Indevus Pharmaceuticals Inc. | Dr. Dmochowski has acted as a consultant for Esprit Pharma, Indevus Pharmaceuticals Inc, Allergan, Novartis, Pfizer, and Watson; Dr Sand has acted as a consultant for Esprit Pharma, Indevus Pharmaceuticals Inc, Ortho, Allergan, Watson, GSK, Astellas, and Schwarz Pharma. In addition, Dr Sand has also been an investigator in clinical trials forEsprit Pharma, Indevus Pharmaceuticals Inc, Ortho, Allergan, |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | Watson, and Astellas, and has participated in meetings for Esprit Pharma, Indevus Pharmaceuticals Inc, Ortho, Allergan, Watson, GSK, and Astellas; Dr Zinner has acted as a consultant for Esprit Pharma, Indevus Pharmaceuticals Inc, Novartis, Watson, Eli Lilly, GSK, Allergan, Astellas, and Medtronics. In addition, Dr Zinner has also been an investigator on clinical trials for Esprit Pharma, Indevus Pharmaceuticals Inc, Novartis, Watson, GSK, Allergan, and Astellas, and has participated in meetings for Esprit Pharma, Indevus Pharmaceuticals Inc., Eli Lilly, and Astellas; Dr. Staskin has acted as a consultant for Esprit Pharma, Indevus Pharmaceuticals Inc, Ortho-McNeil, Novartis, Watson, Pfizer, and Astellas. |
| Dmochowski, 2005[270]<br>Pooled<br>USA | Pooled analysis of RCTs: men and women with urge or mixed urinary incontinence with a | Postvoid residual (PVR) volume >250 mL; Abnormal physical, laboratory, or ECG examination; Lower urinary tract surgery within preceding 6 months; An | 3 dosages of oxybutynin-TDS 1.3 mg/d , 2.6 mg/d , or 3.9 | Placebo | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| N: 241 | predominance of urge symptoms with >10 urge incontinence episodes/week and 56 or more micturitions (>8 micturitions per day). For study 2 patients had to have a beneficial response to previous anticholinergic OAB treatment, at least 4 incontinence episodes, 24 or more voids, and a mean void volume of 350 mL or less over 3 days. | active dermatologic disorder; Known narrow–angle glaucoma; Shallow anterior chamber, evident on physical examination (study 1 only); Hypersensitivity to oxybutynin or other anticholinergic medications; Hypersensitivity to transdermal drug delivery systems; History of overflow incontinence caused by underactive or acontractile detrusor or outlet obstruction; A prostate-specific antigen level >4 ng/mL; A history of biopsy-positive prostate cancer; Failure to complete urinary diary during washout period; Recent (within 1 year) alcohol and/or drug abuse; Inability to maintain nonpharmacologic urinary; incontinence management program during study; Consumption of 5 or more cups of caffeinated beverages per day; Use of medications that affect detrusor activity; Use of medications that interfere with oxybutynin or tolterodine (study 2 only). | mg/d for 12-week (double-blind)+ 12-week (open-label)+ 28-week (open-label extension) | | | |
| Dmochowski, 2003[271] Transdermal Oxybutynin Study Group. USA N: 361 | Men and women at least 18 years of age taking current pharmacologic treatment for OAB with beneficial response to the pre-study treatment; four or more urge urinary incontinent episodes, with either pure urge or a predominance of urge episodes, 24 or more voids, and an average recorded urinary void volume of 350 mL or less. | History of lower urinary tract surgery in the previous 6 months and a diagnosis of interstitial cystitis, urethral syndrome, painful bladder syndrome, and overflow urinary incontinence. | Transdermal oxybutynin 3.9 mg/day or oral tolterodine 4 mg/day | Placebo | Watson Pharma | R.R. Dmochowski, P.K. Sand, N.R. Zinner, M.C. Gittelman, and G.W. Davila are study investigators funded by, and members of the medical advisory board, the sponsor. S.W. Sanders is an employee of the sponsor. |
| Dmochowski, 2003[272] Duloxetine Urinary | Non-pregnant women 18 years and older with a clinical diagnosis of bothersome SUI at least 3 | Inability to tolerate retrograde bladder filling to 400 ml or who had a first sensation of bladder filling at less than 100 ml; treatment with other | 80 mg duloxetine daily | Placebo | Supported by Eli Lilly and Co. | Roger Dmochowski has financial interest and/or other relationship with Lilly |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Incontinence Study Group Canada and the United States N: 683 | months in duration, with predominant symptom of SUI with 7 or greater stress incontinent episodes weekly; daytime voiding frequency less than 8 times daily, nocturnal frequency less than 3 times daily and no predominant urge incontinence symptoms. After filling a positive cough stress test and stress pad test were required. This clinical algorithm has been demonstrated to predict urodynamic stress incontinence with 92% accuracy. | antidepressants. | | | | Pharmaceuticals, Watson Pharmaceuticals, Ortho McNeil and Indevus Pharmaceuticals; John Miklos, Ilker Yalcin and Richard Bump have financial interest and/or other relationship with Eli Lilly; Peggy Norton has Financial interest and/or other relationship with Eli Lilly, Pharmacia and Pfizer; Norman Zinner has Financial interest and/or other relationship with Lilly, Watson, Kyowa and Schwarz Pharmaceuticals. |
| Dmochowski, 2007[273] RCT USA N: 1015 | Post hoc analysis of RCT: men and women aged ≥18 years and reported symptoms of urinary frequency (≥ 8 voids/24 hours) and UUI (≥5 episodes/week) for ≥6 months. | Significant hepatic or renal disease, current or recurring UTI, stress UI, clinically relevant BOO, indwelling catheter or intermittent self-catheterization, and any condition for which antimuscarinic treatment was contraindicated; taking any anticholinergic drug or treatment for OAB and those who showed a mean of 200 mL/void or total daily of 3000 mL. | Tolterodine-ER (4 mg once daily) | Placebo | Pfizer Inc | Dr. Dmochowski is an advisor to Pfizer. Dr Kreder is a speaker for Astellas, Lilly, Merck, Novartis, and Pfizer; serves as a paid consultant to Astellas, Lilly, and Pfizer; receives research support from Lilly, Merck, and Pfizer; and holds stock options from Merck. Dr MacDiarmid is a speaker for Pfizer, Ortho-McNeil, Esprit, Astellas, Watson, and Novartis; he is a paid |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | consultant to Pfizer, Ortho-McNeil, Esprit, Astellas, and Watson. Martin Carlsson and Zhonghong Guan are employees of Pfizer Inc. |
| Dmochowski, 2010[274] Study: RCT K6 N: 313 | Men and women 18 to 85 years old with symptoms of idiopathic OAB with UUI for 6 or more months who were not adequately treated with anticholinerigc therapy (defined as inadequate response or intolerable side effects) were included in the study following informed consent. At baseline patients were required to have 8 or more UUI episodes a week, with no more than 1 incontinence-free day, and an average of 8 or more micturitions daily. | If patients used CIC (clean intermittent catheterization), had a history or evidence of pelvic or urological abnormalities, or diseases affecting bladder function, had been treated for 2 or more UTIs within 6 months, or had 24-hour total urine volume voided greater than 3, 000ml or PVR urine volume greater than 200ml at screening | OnabotulinumtoxinA | Placebo | Supported by Allergen, Inc. | Roger Dmochowski has financial interest and/or other relationship with Allergen, Pfizer, Astellas, and Contura; Christopher Chapple has financial interest and/or other relationship with Pfizer, Allergen, Astellas, Novartis, Ono, and Recordati; Victor Nitti has financial interest and/or other relationship with Allergen, Astellas, Coloplast, Ethicon, Medtronic, Pfizer, Serenity, Uroplasty and Watson; Michael Chancellor, Catherine Thompson, Grace Daniell, Jihao Zhou and Cornelia Haag-Molkenteller have financial interest and/or other relationship with Allergen; and Karel Everaert has financial interest and/or other relationship with Allergen and Medtronic |
| Dorschner, 2000[275] | Men and women older than 60 years of age with | Acute urinary tract infections, mechanical or functional bladder- | Propiverine (15 mg t.i.d.) | Placebo | Grant provided by Apogepha | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| RCT<br>Country: Not reported<br>N: 107 | urgency, urge incontinence, or mixed urge-stress incontinence, >1 episode of UI/day and micturition volume <300ml/micturition | emptying disorders, residual urine >20% of voided volume by ultrasound, micturition volume >300ml in uroflow, renal insufficiency, concomitant medications interfering with the drug studied (neurotropic/ musculotropic spasmolytics, centrally acting muscle relaxants, psychopharmacological agents or drugs for the treatment of Parkinson's disease, anti-arrhythmics), serious life threatening cardiovascular diseases (myocardial infarction within the previous 3 months, unstable coronary heart disease, implanted cardiac pace-maker, decompensated myocardial insufficiency, tachycardia or bradycardia at rest, second-or third-degree atrio-ventricular block, complete bundle branch interventricular heart block, chronic atrial fibrillation and ventricular extrasystoles Lown IVb in the pre-study ECG monitoring. | | | | |
| Drutz, 1999[276]<br>RCT<br>United States and Canada<br>N: 277 | Age ≥18 years; all female patients were to be postmenopausal, surgically sterile, or using an adequate contraceptive method before and during the study; evidence of detrusor overactivity on subtracted cystometry (phasic detrusor contraction with an amplitude ≥10cm$H_2O$), along with urinary frequency (≥8 micturitions on average per 24 hours) and either urge incontinence (≥1 incontinence episode on | Clinically significant stress incontinence as determined by the investigator during a cough stress test maneuver; hepatic or renal disease; any disease which the investigator thought made the patient unsuitable for inclusion; recurrent urinary tract infections; interstitial cystitis; uninvestigated hematuria or hematuria secondary to malignant disease; indwelling catheter or intermittent catheterization; treatment with any investigational drug in the 2 months prior to entry; previous treatment with tolterodine; electro-stimulation therapy or bladder training within 14 days prior to entry or initiation during the study; treatment | Tolterodine 2mg b.i.d. or oxybutynin 5mg t.i.d. | Placebo | The study was funded by Pharmacia & Upjohn AB, Uppsala, Sweden | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | average per 24 hours), as confirmed by micturition diaries during the run-in period, and/or urinary urgency. | with any anticholinergic drug, or any drug for urinary urge incontinence within 14 days prior to the baseline visit or initiation during the study; unstable dosage of any treatment with anticholinergic adverse effects or initiation of such treatment during the study; previously demonstrated serious adverse effects on oxybutynin average total voided volume/24 hours of >3000 ml; or clinically significant voiding difficulty with risk of urinary retention (such as residual volume >200 ml or urine flow rate <10ml/s). | | | | |
| DuBeau, 2005[277]<br>RCT analysis<br>Europe (Denmark, Finland, Ireland, Norway, Sweden, and United Kingdom)<br>N: 854 | Exploratory analysis of RCT: women aged >18 years with urge-predominant mixed incontinence (>5 episodes of urge UI per week), urinary frequency (mean > voids per 24 hours), and urgency (strong and sudden need to urinate), together with stress incontinence symptoms. | Any contraindication to antimuscarinic therapy (narrow angle glaucoma, urinary retention, gastric retention, allergy, or hypersensitivity); treatment within 2 weeks of randomization with any anticholinergic drug, or any drug for UI (excluding stable doses of estrogen and a-adrenergic agonists); interstitial cystitis, uninvestigated hematuria, bladder outlet obstruction, indwelling or intermittent catheterization; urinary tract infection during the run-in period or greater than three times in the last year; hepatic or renal dysfunction; use of inhibitors of cytochrome P450 3A4 isoenzymes; 24-hour urine volume >3L; significant renal or hepatic dysfunction; pregnancy, lactation, or childbearing potential without use of adequate contraception; and behavioral therapy for UI within 4 weeks of initial study visit. | Tolterodine 4 mg once daily | Placebo | Pfizer | Not reported |
| Duckett, 2007[278]<br>Obs<br>USA<br>N: 222 | Women with a diagnosis of urodynamic stress incontinence, with mixed USI and detrusor | Women not assessed with cystometry and women who declined drug therapy were excluded from further analysis. | Duloxetine 40 mg twice a day | None | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | overactivity (DOA) if they were predominantly complaining of moderate/severe stress incontinence | | | | | |
| Enzelsberger, 1995[279]<br>RCT<br>Austria<br>N: 52 | 52 women complaining of frequency (more than five times per 12 hours), nocturia (more than twice per night) and urgency. | Women with urodynamically assessed genuine stress incontinence and with neurologic disorders. | Oxybutynin | Placebo | Not reported | Not reported |
| Flynn, 2009[280]<br>RCT<br>Country: Not reported<br>N: 22 | Overactive bladder refractory to anticholinergic medications (at least 1 anticholinergic medication and behavioral modifications must have failed), multiple daily incontinence episodes and a 24-hour pad weight of 100 gm or greater; subjects with coexisting severe OAB and mild stress incontinence were allowed to enter the study; demonstrate willingness and ability to perform self-catheterization, and have negative urine culture. | Low leak point pressures, increased post-void residual volume or neurological etiologies; gross fecal incontinence or an absent detrusor contraction on pressure flow. | Cystoscopic administration of botulinum-A toxin 200 U and 300 U | Placebo | Supported by National Institutes of Health National Institute on Aging Grant #R21 AG25490-01. | Cindy L. Amundsen has financial interest and/or other relationship with Pfizer; George D. Webster has financial interest and/or other relationship with Lifetech and AMS. |
| Foote, 2005[281]<br>Pooled<br>Country: Not reported<br>N: 317 | Men and women with symptoms of OAB for at least 6 months and capable of visiting a toilet unaided with 5–50 episodes of incontinence per week, along with elevated micturition frequency (mean 8 voids/24 hours) and urgency (mean 1 episode/ 24 hours). | Clinically significant stress incontinence (i.e. 1 episode of stress incontinence per week); bladder outlet obstruction and/or post-void residual urine volume >200 ml; concomitant medical problems that would interfere with the patient's participation in the study; severe constipation (2 bowel movements per week); haematuria, intermittent urinary tract infection, cystocele or other clinically significant pelvic prolapse; use of an indwelling | Darifenacin 7.5 mg or 15 mg once daily | Placebo | The studies were funded by Pfizer Inc. Preparation of the manuscript was supported by an educational grant from Novartis Pharma AG. | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | catheter or intermittent self-catheterisation; urogenital surgery in the previous 6 months; contra-indications to antimuscarinic therapy (e.g,. uncontrolled narrow-angle glaucoma, urinary retention or gastric retention); and a history of alcohol/drug abuse or known hypersensitivity to study medications; treatment with potent cytochrome P450 (CYP) 3A4 inhibitors (e.g., ketoconazole), opioids (or other drugs that could cause significant constipation), non-study antimuscarinic agents or other drugs with significant anticholinergic effects (e.g. tricyclic antidepressants); concomitant treatment with CYP2D6 inhibitors such as cimetidine, fluoxetine and paroxetine; initiation of bladder-training program was not permitted during the study. | | | | |
| Freeman, 2003[282] RCT analysis N: 1015 | Tolterodine Study Group (secondary analysis): men and women at least 18 years old with urinary frequency (eight or more micturitions per 24 hours) and urge incontinence (five or more episodes per week) irrespective of whether they had received prior antimuscarinic therapy and the outcome of that treatment. | Stress incontinence, total daily urine volume greater than 3 L, any contraindications to antimuscarinic treatment, significant hepatic or renal disease, symptomatic or recurrent urinary tract infections, interstitial cystitis, hematuria or bladder outlet obstruction, electro-stimulation or bladder training, indwelling catheter, or intermittent self-catheterization; pregnancy or nursing; any treatment for overactive bladder, including use of anticholinergic drugs or drugs that inhibit cytochrome P450 3A4 isoenzymes, within 14 days preceding randomization. | Tolterodine extended release 4 mg | Placebo | Pharmacia Corporation, Peapack, New Jersey | Investigator fees were paid by Pharmacia into the research funds of the authors and used to employ research staff, fund research, and purchase equipment. None of the authors own stock in Pharmacia or hold stock options. |
| Gahimer, 2007[283] Duloxetine exposures | Reported previously for 64 pooled studies | Not reported | Duloxetine 20-120mg/day | None | Eli Lilly | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| integrated safety database<br>USA<br>N: 23983 | | | | | | |
| Ghei, 2005 [284]<br>RCT<br>Country: Not reported<br>N: 20 | Men and women 18 to 80 years old with urodynamic detrusor overactivity unresponsive to oral antimuscarinic agents willing to use intermittent self-catheterization. | Known bladder malignancies, previous bladder surgery, active urinary tract infections, known major drug allergies, prostatic cancer, major urethral access problems and children; anticholinergics during the study period were not permitted. | Botulinum toxin B (5,000 IU diluted up to 20 ml) intravesically | Placebo | Not reported | The trial was independent of industry sponsorship and involvement. |
| Ghoniem, 2005[285]<br>Duloxetine/ Pelvic Floor Muscle Training Clinical Trial Group. Subjects were enrolled at 16 tertiary continence centers in the Netherlands, United Kingdom and United States.<br>N: 201 | Women 18 to 75 years old with SUI; urodynamic stress incontinence and no detrusor overactivity on studies within 6 months before entry (36 subjects) or a positive cough stress test and normal micturition frequency (less than 8 voids daily) at entry (165 subjects). All subjects had predominant symptoms of SUI with an average of at least 2 stress incontinent episodes daily. | Advanced pelvic organ prolapse, active or recurrent urinary tract infections, continence surgery within 1 year, current device or pharmaceutical incontinence treatment, prior hip fracture or replacement and any prior formal PFMT with a continence nurse or physical therapist. | 40 mg duloxetine twice daily plus imitation PFMT (duloxetine only), duloxetine plus PFMT (combined treatment), placebo plus PFMT (PFMT only). PFMT groups received 30 minutes of instruction and feedback initially and 15 minutes of re-instruction | Placebo plus imitation PFMT (no active treatment) | Supported by Eli Lilly and Company and Boehringer Ingelheim. | Not reported |
| Goode, 2002[286]<br>RCT<br>USA<br>N: 105 | To be included, patients had to average at least two urge accidents per week documented in the 2-week bladder diary, and urge incontinence had to be the predominant pattern (the number of urge accidents had to exceed the number of stress and other accidents). Also, there | Patients were excluded if they had continual leakage, postvoid residual urine volume greater than 200 mL, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina pectoralis, decompensated congestive heart failure, history of malignant arrhythmias, or impaired mental status (Mini-Mental State Examination (MMSE) score <20). | Behavioral treatment | Oxybutynin treatment 2.5mg three times a day, placebo | Grants AG 08010 and K00431 from the National Institute on Aging to Dr.Burgio | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | had to be urodynamic evidence of bladder dysfunction (DI during filling or provocation or bladder capacity of 350 mL or less). | | | | | |
| Goode, 2004[287]<br>RCT analysis<br>USA<br>N: 197 | Subjects were community-dwelling women aged ≥55 years who were recruited to a university based continence clinic through professional referrals and advertising. They had urge incontinence or mixed incontinence with urge as the predominant pattern. All patients were ambulatory and not demented. They had urodynamic evidence of bladder dysfunction, either detrusor overactivity (DO) or a maximal cystometric capacity ≥350 mL. | Not reported | Behavioral therapy | Oxybutynin 2.5mg/day to 5mg t.i.d. or Placebo | NIH Grant | Patricia S. Goode has been a paid consultant to Alza, Eli Lilly, Pharmcia, and Yamanouchi |
| Gupta, 1999[288]<br>RCT<br>Scotland<br>N: 13 | To be included in the study, sub subjects must have been at least 40 years of age, within 20% of the Metropolitan Life Insurance Table ideal weight for height value, normotensive with no clinically significant postural hypotension, and using a birth control method if premenopausal. | Volunteers were excluded for known sensitivity to any anti cholinergic drug; recent (or planned) medication usage other than estrogen replacement therapy (ERT) or birth control pills; recent alcohol, caffeine, or investigational drug use; history of drug abuse; a positive urine drug screen; or recent smoking. | Three 5 mg OROS® oxybu tynin chlo ride tab lets at 0700 every day for 4 days | IR oxybutynin 5 mg administered at 0700, 1500, and 2300 every day for 4 days | Not reported | Not reported |
| Gupta, 1999[289]<br>Pooled<br>Country; Not reported<br>N: 187 | Women and men with urge urinary incontinence or mixed urinary incontinence with a clinically significant urge component who were | Not reported | Oxybutynin XL (Ditropan XL) 5 to 30mg once daily | Oxybutynin - immediate release 5mg once/twice/ thrice or four times a day | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | known to be responsive to anticholinergic treatment of urinary incontinence but who might have discontinued such treatment because of side effects. Patients were allowed to enroll if they had at least six urge urinary incontinence episodes per week (based on off-medication run-in patient urinary diary results) and could distinguish between urge and non-urge episodes. | | | | | |
| Gousse, 2010[290]<br>Study: RCT<br>Sample: 60 | Patients with refractory idiopathic overactive bladder symptoms | NR | Botulinum toxin Type A | Botulinum toxin Type A | Funded by Allergan Inc., USA | NR |
| Haab, 2006[291]<br>RCT analysis<br>Country: Not reported<br>N: 719 | Successful completion of previous 12-week darifenacin studies without major protocol violation; few concomitant medications, a maximum darifenacin dose of 7.5 mg for patients taking potent inhibitors of cytochrome P450 3A4 and patients with moderate hepatic impairment (Child Pugh B); adequate contraception ; ability to complete patient diaries independently; capable of independent toileting. | Reported previously | Patients received darifenacin CR 7.5 mg irrespective of previous study treatment, for the first 2 weeks of the extension followed by self-selected individualized dosing: patients were permitted to increase their dose to 15 mg or decreased from 15 to 7.5 mg. | None, all patients received darifenacin | Funded by Pfizer, Inc. and Novartis Pharma AG. Preparation of this manuscript was supported by an educational grant from Novartis Pharma AG and editorial and project management services were provided by ACUMED®. | F. Haab is a consultant for Novartis and Astellas and is a study investigator funded by sponsor; J. Corcos, P. Siami and P. Dwyer are study investigators funded by sponsor; J. Corcos is also a member of the board of sponsor; M. Steel, F. Kawakami and K. Lheritier are employees of sponsor; W. Steers is a paid consultant to sponsor and is a study investigator funded by sponsor. |
| Haab, 2005[292]<br>RCT analysis | Solifenacin Study Group: Patients completing | Clinically significant outflow obstruction, postvoid residual urine | Solifenacin 5 mg daily for 4 | No control | Grant from Yamanouchi | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Country: Not reported<br>N: 1633 | treatment in the two previous RCTs <14 days prior to extension-study; with symptoms of OAB (including urinary frequency, urgency, or urge incontinence) for >3 months, with >8 micturitions /day, either >1 urgency episode or >1 incontinence episode/day. | >200 ml, persistent or recurrent urinary tract infection, bladder stones, chronic interstitial cystitis, previous pelvic irradiation or previous or current malignant disease of the pelvic organs, and any medical condition contraindicating the use of anticholinergic medication (including narrow-angle glaucoma and urinary or gastric retention); pregnancy or nursing, or intention to become pregnant during the study, or unreliable method of contraception. | weeks, after which a flexible dosing regimen based on patient satisfaction (5 mg or 10 mg) | | Pharmaceutical Co., Ltd., Tokyo, Japan. | |
| Haab, 2004[293]<br>RCT<br>N: 561 | Men and women 19–88 years old , 85% females with symptoms of OAB for at least 6 months with urge incontinence (5-50 episodes per week); frequency of micturition (a mean of >8 voids per 24 hours); and urgency (a strong desire to void at least once per day). Those who did not benefit from other antimuscarinic agents or participated in previous double-blind studies of darifenacin were eligible for inclusion if the intervening period was >4 months. | Contraindications to the use of antimuscarinic drugs (e.g. uncontrolled narrow-angle glaucoma, urinary or gastric retention), clinically significant stress incontinence (more than one episode per week), clinically significant bladder outlet obstruction and/or a post-void residual volume >200 ml, genitourinary conditions that could cause urinary symptoms, recent urogenital surgery, or hepatic disease; bladder training program while in the study; known hypersensitivity to the study medication. | Darifenacin controlled-release tablets 3.75 mg ; 7.5 mg or 15 mg/day | Placebo | The study was funded by Pfizer Inc. Preparation of the manuscript was supported by an educational grant from Novartis PharmaAG. Editorial and project management services were provided by Thomson ACUMED1 | Not reported |
| Halaska, 2003[294]<br>RCT<br>Austria, Bulgaria, Czechoslovakia, Germany, Russia and Spain<br>N: 358 | Men and women >18 years of age with urge syndrome (undue frequency of micturition, nocturia, overwhelming urge, wetting), urge incontinence, urge incontinence as one component of mixed incontinence, or urge | Absolute tachycardia; closed-angle glaucoma; myasthenia gravis; severe arteriosclerosis of the cerebral vessels; stress incontinence; undue frequency of micturition due to heart failure, renal failure or diuretic therapy; Bladder outlet obstruction; Acute urinary tract infection at the beginning of the trial; Hiatus hernia in combination with reflux oesophagitis; | Trospium chloride (20 mg twice daily) or | Oxybutynin (5 mg twice daily). | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | incontinence due to a neurological condition (detrusor hyperreflexia) as confirmed using urodynamic measurements. | stenoses in the gastrointestinal tract; megacolon; colonic ulceration; allergy or intolerance towards atropine, OXY, TCI or other constituents of the trial medication; concurrent medication with anticholinergics, tricyclic or tetracyclic antidepressants, a-blockers or b-sympathomimetics within the last 7 days before starting the trial; urological or gynecological operations within the last 3 months before starting the trial; serious illnesses or conditions which would preclude participation in any clinical trial (malignant neoplasms, alcoholism, drug misuse); pregnancy or lactation; participation in any other study. | | | | |
| Herschorn, 2004[295]<br>RCT<br>Country: Not reported<br>N: 138 | Male and female adults older than 50 years of age with OAB symptoms (urinary urgency, frequency >8 micuritions/day, nocturia >2/night) with or without urge UI who would benefit from tolterodine administration (according to physician's opinion). | Stress UI only, abnormal cognitive function, non English speakers; interstitial cystitis, acute urinary tract infections, taking investigational drug. | Tolterodine combined with an education intervention: printed information and an explanation about OAB, medication use, and behavioral treatments (kegel exercise, bladder stretching, fluid regulation). Previously trained nurse or physician provided education. | Tolterodine alone | Pharmacia Corporation and Pfizer | Not reported |
| Herschorn, 2010[296]<br>Study: VECTOR<br>Sample: 132 | 18 years old or older with OAB symptoms (more than 1 urgency episode per 24 hours and 8 | Significant stress incontinence, active urinary tract infection or another significant lower urinary tract pathology, clinically significant | solifenacin 5mg | oxybutynin IR5mg thrice daily | NR | Sender Herschorn has financial interest and/or other relationship with Astellas, Pfizer, |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | micturitions or greater per 24 hours) | outflow obstruction, urinary retention and the use of concomitant tricyclic antidepressants, α-blockers, 5α-reductase inhibitors or anti-Parkinson's disease agents | | | | Allergan, American Medical Systems, Jonhson &Johnson and Coloplast; Lynn Stothers has financial interest and/or other relationship with Astellas Canada, Merck, Urodynamix, Allergan, UBC; Kevin Carlson has financial interest and/or other relationship with Astellas Canada, Pfizer Canada, GlaxoSmithKline, American Medical Systems, BR Capital Inc. and Health Education United Partnership Inc.; Blair Egerdie has financial interest and/or other relationship with Astellas Canada, Amgen, bayer, Protox Therapuetics and Pfizer; Jerzy Gajewski has financial interest and/or other relationship with Astellas Canada, Allergan, pfizer, Snaofi-Aventis, Johnson & Johnson and Medtronic; Peter Pomerville has financial interest and/or other relationship with Astellas Canada, Aeterna Zentralis, American Medical |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | Systems, Amgen, AstraZeneca, Dendreon, Eli Lilly, Ferring, Pfizer, Protox Therapeutics, Spectrum Uromedica, Bioniche Inc., Sanofi-Aventis, GlaxoSmithKline, Schering Plough, Amgen,and Abbott; Jane Schulz has financial interest and/or other relationship with Astellas, Gynecare, Pfizer and Triton; Sidney Radomski has financial interest and/or other relationship with Astellas Canada, Pfizer, Bayer and Lilly; Harold Drutz has financial interest and/or other relationship with Astellas, Lilly, Pfizer, Calldion, Gynecare, Troton and Watson; Jack Barkin has financial interest and/or other relationship with Astellas, GlaxoSmithKline, Merck, AstraZeneca and Pfizer; Fran Paradiso-Hardy has financial interest and/or other relationship with Astellas Pharma Canada |
| Herschorn, 2008[297] Study: RCT | ≥18 years of age; mean of ≥8 micturitions per 24 hours and ≥3 episodes of | If received any drug used to treat UUI or OAB within 14 days before the study treatment period | tolterodine-ER | Placebo | Funded by Pfizer Inc | Sender Herschorn has served as an advisory board |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Sample: 617 | urgency or urgency urinary incontinence (UUI) in a 3-day bladder diary before randomization; experienced OAB symptoms for ≥3 months and at least moderate problems associated with their most bothersome OAB symptom, as reported on the OAB Bother Rating Scale | | | | | member for Pfizer Inc. and as a study investigator sponsored by Pfizer Inc., Astellas Pharma Inc., Johnson & Johnson, Sanofi Aventis, and Allergan Inc. John Heesakkers has no conflict of interest to declare. David Castro-Diaz has served as a study investigator sponsored by Pfizer Inc. Joseph Wang, marina Brodsky and Zhonghong Guan are employed by Pfizer Inc. |
| Hill, 2006[44] Darifenacin Study Group. Country: Not reported N: 439 | Male and female patients, aged >18 years, with urge incontinence (>10 episodes over 14 days), high micturition frequency (mean of >8 eight voids per day), and urinary urgency (a strong desire to void on average at least once per day) for at least 6 months, regardless of previous antimuscarinic treatment. | Clinically significant stress incontinence, bladder outlet obstruction or a postvoid residual urinary volume >200 ml; local pathology that could cause urinary symptoms (e.g., interstitial cystitis, bladder stones, severe constipation (≤2 bowel movements per week), history of intermittent urinary tract infections; those who had undergone urogenital surgery within the previous 6 months, or cystoscopy in the previous 30 days; patients with indwelling catheter or using intermittent self-catheterization; presence of clinically significant systemic disease; patients who intended to start a bladder-training program during the study, or had contraindications to antimuscarinic therapy; pregnant and lactating women; no concomitant treatment | Oral Darifenacin (Novartis Pharma AG, Basel, Switzerland) once-daily 7.5, 15, 30 mg | Placebo | The study was funded by Pfizer Inc. | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | with drugs (including drugs with significant anticholinergic effects), opioids, hormone replacement therapy (unless taken for >2 months), and drugs known to be significant inhibitors of cytochrome P450 2D6 or 3A4 isoenzymes (cimetidine, fluoxetine, ketoconazole, itraconazole, etc.). | | | | |
| Ho, 2010[298]<br>Study: RCT L6<br>N: 75 | 1) male or female aged ≥18 years; 2) informed consent had been obtained; 3) the patient was willing and able to complete the micturition diary correctly; 4) the OAB symptoms, including urinary frequency, urgency, or urge incontinence, had persisted for ≥3 months; 5) the patient must have experienced frequency, defined as ≥8 micturitions per 24 hours | 1) pregnant and lactating women or those who intended to become pregnant during the study; 2) clinically significant bladder outflow obstruction (such as men with benign prostatic hyperplasia or women with bladder outlet obstruction); 3) significant post-void residual (PVR) volume (>200mL); 4) genuine stress incontinence; 5) evidence of symptomatic urinary tract infection, chronic inflammation, bladder stones, previous pelvic radiation therapy, or previous or current malignant disease of the pelvic organs; 6) patients with any medical condition that contraindicated the use of antimuscarinic medication; 7) uncontrolled narrow angle glaucoma, urinary or gastric retention, or any other medical condition that, in opinion if the investigator, contraindicated the use of antimuscarinic | Solifenacin | Tolterodine | NR | NR |
| Holtedahl, 2000[299]<br>RCT analysis<br>Norway<br>N: 87 | Women 50-74 years of age reporting two or more leakage episodes per month. | Reported previously | Oestriol and pelvic floor exercise (PFE) for all patients, plus bladder training and maximal electrical stimulation in patients with urge, vaginal | Oestriol and pelvic floor exercise (PFE) for all patients, plus bladder training and maximal electrical stimulation in patients with | The Norwegian Medical Association Fund no. 1, Odd Berg Medical Research Fund, Finnmark County Research | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | long-term electrical stimulation in patients with stress, and all elements in patients with mixed incontinence. | urge, vaginal long-term electrical stimulation in patients with stress, and all elements in patients with mixed incontinence. | Fund, Medicon A/S, Organon A/S, Coloplast A/S, SABA Mo¨lnlycke A/S, and LIC Hygiene A/S. | |
| Holtedahl, 1998[300]<br>RCT<br>Norway<br>N: 90 | Women, 50-74 years of age with regular incontinence (>2 leakage episodes per month) diagnosed during gynecological examinations, with positive pad test, or self reported in 48 hour chart. | Cardiac pacemaker, dementia, medical conditions that would prevent following the protocol. | Local estrogen in vagitories or jelly plus physiotherapy and electro-stimulation | Usual care | Financial and material (pads, estriol) support from The Norwegian Medical Association Fund no. 1, Odd Berg Medical Research Fund, Finnmark County Research Fund, Medicon A/S, Organon A/S, Coloplast A/S, SABA Mo¨ lnlycke A/S, LIC Hygiene A/S. | Not reported |
| Homma, 2006[301]<br>RCT analysis<br>Japan<br>N: 637 | Adult patients with OAB syndrome and having experienced urge incontinence one or more times a day on average with urinations eight or more times a day during the preceding week. | 22 patients were excluded from FAS for the following reasons: (1) non-OAB patients (n =8), (2) not treated (n = 2), (3) no efficacy data after randomization (n =11), (4) duplicated enrollment (n =1). | Three sizes of oxybutynin transdermal patch (26, 39, and 52 cm2) were used | Placebo | Not reported | Not reported |
| Homma, 2004[302]<br>RCT | Men and women aged ≥20 years were eligible for | Demonstrable stress incontinence, total daily urine volume >3 l, average | Tolterodine ER 4 mg once daily | Oxybutynin 3 mg three | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Japan and Korea<br>N: 293 | inclusion if they had symptoms of OAB for ≥6 months and urinary urgency, urinary frequency (≥8 micturitions/ 24 oursh), urge incontinence (≥5 episodes/week) as assessed by micturition diaries during the wash-out/run-in period. Patients were recruited solely on the basis of their OAB symptoms, irrespective of whether they had received prior antimuscarinic treatment and irrespective of their response to such therapy. | volume voided/ micturition >200 ml, significant hepatic or renal disease, any contraindication for anticholinergic treatment (e.g., uncontrolled narrow-angled glaucoma, urinary retention, or gastric retention), symptomatic or recurrent urinary tract infection, interstitial cystitis, hematuria or bladder outlet obstruction, an indwelling catheter or intermittent self-catheterization, electro-stimulation or bladder training within 14 days before randomization or expected to commence during the study period. | | times daily, placebo | | |
| Homma, 2003[303]<br>Japanese and Korean Tolterodine Study Group<br>Korea and Japan<br>N: 608 | Men and women aged >20 years with symptoms of urinary urgency, urinary frequency (> 8 voids/24 hours), urge incontinence (>5 episodes/ week) and symptoms of OAB for >6 months were eligible for inclusion. Patients were recruited based solely on their symptoms of OAB, irrespective of whether they had received previous antimuscarinic treatment and irrespective of their response to such therapy. | Demonstrable stress incontinence; total daily urine volume of >3 L; average volume voided/ void of >200 mL; significant hepatic or renal disease; any contraindication to anticholinergic treatment, e.g. uncontrolled narrow-angled glaucoma, urinary retention or gastric retention; symptomatic or recurrent UTI; interstitial cystitis; haematuria or BOO; an indwelling catheter or intermittent self-catheterization; and electro-stimulation or bladder training within 14 days before randomization or expected to commence during the study period; pregnant or nursing women and women of childbearing potential not using reliable contraception. | Tolterodine 4mg capsules once daily | Oxybutynin 3mg tablets three times daily, placebo | This study was supported by a grant from Pharmacia Corporation. | Not reported |
| Hurley, 2006[304]<br>Viktrup, 2007[305]<br>Pooled<br>The four studies | 1,913 women with SUI who participated in four controlled clinical trials of duloxetine vs. placebo. All | Subjects who received lower doses of duloxetine (20 or 40 day, n = 275) in the phase 2 trial. Active substance abuse disorder within the 5 years | Duloxetine (80 mg per day).All subjects were given the option | Placebo | This work was sponsored by Eli Lilly and Company and | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| were conducted at 186 sites in Africa, Australia, Europe, North America, and South America<br>N: 2,188 | had predominant SUI were enrolled using a clinical algorithm validated to be 90.2% predictive for urodynamic SUI. | prior to study entry. Regular consumption of 21 or more alcoholic drinks per week. Use of monoamine oxidase inhibitors (MAOIs) or antidepressants within 14 days prior to study entry.<br>A current diagnosis of a voiding abnormality or significant diseases of the genito-urinary tract.<br>A history of urogenital cancer.<br>Symptomatic arrhythmia despite antiarrhythmic medication.<br>Uncontrolled angina, or a significant abnormality on electrocardiogram (ECG) at screening.Any active cardiac ischemic condition, including myocardial infarction within 6 months prior to study entry.<br>Uncontrolled or poorly controlled hypertension.<br>An active seizure disorder.<br>Unstable diabetes mellitus.<br>A spinal cord lesion, multiple sclerosis, or neurological abnormality that affected the lower urinary tract.<br>A history of severe allergies requiring emergency medical treatment or multiple adverse drug reactions.<br>Active or chronic hepatitis A, B, or C. | to continue taking duloxetine in open-label extensions of these studies. Those randomized to duloxetine 80 mg per day in the phase 2 study were dose escalated over the first 2 weeks from 20 mg twice daily for the first week to 30 mg twice daily for the second week before taking 40 mg twice daily. At the end of the active-treatment phase, subjects had their duloxetine dose tapered over 2 weeks (30 mg twice daily for the first week and 20 mg twice daily for the second week) before duloxetine was discontinued. | | Boehringer Ingelheim. | |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Ishiko, 2001[306]<br>RCT<br>Japan<br>N: 73 | 73 women with postmenopausal stress incontinence. | Urge or mixed incontinence | Combination of estriol (1 mg/day) and pelvic floor muscle exercise or Pelvic floor muscle exercise alone. | Pelvic floor muscle exercise | Not reported | Not reported |
| Jackson, 1999[307]<br>RCT<br>UK<br>N: 67 | Postmenopausal women with symptoms of urinary incontinence. If genuine stress incontinence was diagnosed, and the woman was more than 12 months post-menopausal and had not taken hormone replacement therapy in the previous 12 months, she was fully informed about her options for treatment as well as being offered recruitment to the clinical trial. | History of cancer of the endometrium, liver, or breast; endometrial thickness >4mm | Post oestradiol valerate 2mg/day | Placebo | Industry+grant | Not reported |
| Jacquetin, 2001[308]<br>RCT<br>Belguim and France<br>N: 251 | Male and female patients aged ≥18 years were eligible for inclusion in the study if they had urodynamically proven overactive bladder, and symptoms of urgency and/or urge incontinence (≥1 incontinence episode/24 hours) with increased frequency of micturition (≥8 micturitions/24 hours) irrespective of prior treatment or treatment failure. | Significant stress incontinence; hepatic or renal disease; symptomatic or recurrent urinary tract infection (UTI); interstitial cystitis; haematuria; clinically significant voiding difficulty; patients receiving bladder training, electro-stimulation therapy or having an indwelling catheter or on intermittent catheterization; pregnant or nursing women, or women of childbearing age who were not using reliable contraception. | Tolterodine 1 or 2mg twice daily | Placebo | Pharmacia Corporation | Not reported |
| Johnson, 2005[309] | To be included in the study, participants had to | Participants with continual leakage, elevated postvoid residual urine | Behavioral training, drug | Placebo | Supported by grant from the | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| RCT analysis<br>USA<br>N: 131 | report at least two accidents per week and to demonstrate the ability to complete an interpretable bladder diary that confirmed this frequency of urine loss. Urge incontinence had to be the predominant pattern (urge accidents exceeded the number of stress and other accidents), with urodynamic evidence of bladder dysfunction. Two-channel supine water cystometry was performed to demonstrate detrusor instability (defined as urodynamic observation of involuntary detrusor contractions during the filling phase) or sensory urgency (defined as bladder capacity of less than 350 mL) for inclusion in the study. | volume (4200 mL), narrow angle glaucoma, uterine prolapse past the vaginal introitus, unstable angina pectoris, decompensated congestive heart failure, or impaired mental status (MMSE score 20) were excluded. | treatment (oxybutynin IR titrated from 2.5 mg per day to 5.0 mg three times a day) | | National Institute on Aging. Dr. Johnson received additional support from the Emory University Center for Health in Aging. The John A. Hartford Foundation Southeast Center of Excellence in Geriatric Medicine and the Birmingham/ Alabama VA GRECC provided infrastructural support that enabled this inter-institutional collaboration. | |
| Jonas, 1997[310]<br>The International Study Group<br>Country: Not reported<br>N: 242 | Men or women >18 years and presenting with detrusor overactivity, defined as the existence of any phasic detrusor contraction with an amplitude of >10 $cmH_20$ or the existence of one strong detrusor contraction that caused the end of the infusion, with frequency (> 8 micturitions/24 hours) in combination with urge | Significant stress incontinence hepatic disease, defined as twice the upper limit of the reference range for liver function tests, renal disease, defined as twice the upper limit of the reference range for creatinine, any condition contraindicating anticholinergic therapy, recurrent urinary tract infections (UTIs), interstitial cystitis, uninvestigated hematuria, or clinically significant voiding difficulty with risk of urinary retention; any anticholinergic treatment; using an indwelling | Tolterodine 1 or 2 mg b.i.d | Placebo | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | incontinence (>1 incontinence episode/24 hours), urinary urgency, or both. | catheter, history of electro-stimulation therapy or bladder training (last 14 days prior to the inclusion visit).Concomitant treatment with anticholinergic drugs or treatment with any agent for urinary urge incontinence (with the exception of any estrogen treatment started at more than 2 months prior to entry) was not permitted in the 14 days prior to entry or during the study. | | | | |
| Junemann, 2006[311] Study: RCT Sample: 988 | Patients with overactive bladder who met all of the following inclusion criteria were allowed to participate in the study: female and male patients >=18 years, voluntarily signed informed consent, at least 2 incontinence episodes within 3 days, and at least 10 micturitions within 24h | Stress incontinence; intermittent catheterization; neurogenic detrusor under- and overactivity; postvoid residual urine >=100ml; acute urinary tract infections; electrostimulation therapy, bladder training if performed within 4 weeks before run-in period of this study; anomalies of the lower genitourinary tract (e.g.ectopic ureters, fistulas, urethral stenosis); pre-existing medical contraindications for anticholinergics (e.g. obstruction of the bowel, toxic megacolone, severe colitis ulcerosa, bladder or intestinal atony, significant degree of bladder outflow obstruction where urinary retention could be anticipated, pollakisuria of cardiac or renal genesis, tachyarrthythmia, narrow-angle glaucome, myasthenia gravis); cardiac insufficiency(New York Heart Association stage III/IV); multiple sclerosis; evidence of severe renal, hepatic or metabolic disorders; history of drug or alcohol abuse; concomitant medications known to have a potential to interfere with the study medication; pregnant or breastfeeding women, or women of childbearing potential without using any reliable contraceptive method | Propiverine hydrochloride IR | Propiverine hydrochloride ER and placebo | Funded by Apogepha Arzneimittel GmbH | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Junemann, 2000[312]<br>Study: RCT<br>Sample: 234 | Patients with urge - syndrome (motor urge, sensory urge and combined motor urge and stress incontinence). Patients medical history and a urodynamic measurement (minimum one unstable detrusor contraction of 10 cm H2O or first desire to void at a bladder filling of <150ml) verified the diagnosis of urge-syndrome | NR | trospium hydrochloride | tolterodine and placebo | NR | NR |
| Junemann, 2005[313]<br>RCT<br>31 centers in Europe (Bosnia, Czech Republic, Germany, Poland, Slovenia, United Kingdom).<br>N: 201 | Men and women aged >18 years with overactive bladder, defined as at least one unstable detrusor contraction at a minimum of 10 cmH2O combined with an increased frequency of micturition (>8 micturitions/24 hours); sensoric urge incontinence, defined as at least one incontinence episode/24 hours combined with increased frequency of micturition (>8 micturitions/24 hours). | Maximum cystometric bladder capacity 300 ml; post void residual >50 ml; acute urinary tract infection (>106 bacteria/ml urine); electro-stimulation therapy, bladder training if performed <4 weeks before run-in period of this study; intermittent catheterization; anomalies of the lower genitourinary tract (e.g. ectopic ureters, fistulas, urethral stenosis, etc.); operations of the lower urinary tract within the last 4 weeks; pre-existing medical contraindication for anticholinergics. | 15 mg propiverine twice daily | 2mg tolterodine twice daily | APOGEPHA Arzneimittel GmbH. | Not reported |
| Kaplan, 2010[314]<br>Study: RCT<br>Sample: 2417 | Subjects with OAB symptoms for >=months and recorded micturitions and >=1 urgency urinary incontinence episode per 24h in 3-day baseline diaries | NR | Fesoterodine | Tolterodine/ Placebo | Sponsored by Pfizer Inc. | NR |
| Karademir, 2005[315]RCT<br>Turkey<br>N: 43 | A total of 43 patients (5 males, 38 females; mean age 41.7 years; range 21-69 years) with a >6-month | Urinary tract obstruction, urinary retention, a neurologic or metabolic disorder; any kind of intervention for urinary incontinence. | Stoller afferent neurostimulation (SANS) with low-dose | Stoller afferent neurostimula tion (SANS) | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | history of overactive bladder symptoms and who had detrusor overactivity findings on urodynamic studies (UDS). | | anticholinergic (oxybutynin hydrochloride) | | | |
| Karram, 2009[316]<br>Toglia, 2009[317]<br>Study: VENUS<br>Sample: 739 | This study, that is, the VENUS study enrolled patients aged>=18 years with OAB (at least 1 urgency episode with or without incontinence and >=8 micturitions per 24 hours) for >=3 months | Presence of stress or stress-predominant mixed urinary incontinence, chronic inflammation or cystitis, and clinically significant bladder outlet obstruction | Solifenacin | Placebo | Research grant from Astellas Pharma US, Inc. and GlaxoSmithKline | Marc Toglia discloses conflict of interest with Astellas Pharma US, Inc. and Ethicon Women's Health. Scott R.Serels discloses conflicts of interest with Astellas Pharma US, Inc., GlaxoSmithKline, and Takeda. Mickey Karram discloses conflict of interest with Allergan, Astellas Pharma US, Inc., Cooper, and Ehticon. Indrani Nandy discloses conflict of interest with GlaxoSmithKline. Masakazu Andoh discloses no conflict of interest. Raafat Seifeldin discloses conflict of interest with AStellas Pharma US, Inc.Sergio Forero-Schwanhaeuser discloses conflict of interest with GlaxoSmithKline |
| Kelleher, 2006[318]<br>RCT<br>USA<br>N: 3032 | Pooled analysis of 4 RCTs: men and women at least 18 years of age with either MUI or UUI based on their history and the | Predominant stress UI. | 5 mg solifenacin once daily, 10 mg solifenacin once daily | Placebo | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | results of a cough test; a mean of ≥8 micturitions per 24 hours in addition to a mean of ≥1 incontinence episode per 24 hours or a mean of ≥1 urgency episode per 24 hours during the baseline 3-day micturition diary period. | | | | | |
| Kelleher, 2002[319]<br>RCT<br>USA<br>N: 1015 | Male and female patients aged 18 years or older with urinary frequency (average of ≥8 micturitions/24 hours over a 7-day period), urge incontinence (≥5 episodes/week), and symptoms of OAB for at least 6 months. | Other types of bladder dysfunction, with diseases that may have affected urinary output. | Tolterodine extended-release (ER) 4 mg once/day, or tolterodine immediate-release (IR) 2 mg twice daily | Placebo | Pharmacia Corporation | Not reported |
| Kelleher, 2008[320]<br>Study: pooled analysis E4,X3<br>N: 1,971 | Men and women aged ≥18 years with OAB syndrome for ≥6 months; patients had to report at least moderate problems related to their bladder condition on a six-point Likert scale | Presence of lower urinary tract pathology that could, in the investigator's opinion, be responsible for urgency or UI (e.g. significant stress UI, interstitial cystitis, urothelial tumors); pelvic organ prolapse grade ≥III; clinically relevant BOO; a post void residual urine volume of >100mL; polyuria (>3L/24h); symptomatic or recurrent UTI; current treatment with antimuscarinic agents; a neurogenic cause of OAB; clinically relevant arrhythmia, unstable angina, or a QTcB interval of >500ms; and current treatment, or treatment within the past 4 weeks, with electro stimulation or bladder training | Fesoterodine | Tolterodine/ Placebo | Funded by Schwarz BioSciences GmbH and Pfizer Inc | Con J.Kelleher is an Advisor to Astellas and Novartis and a Lecturer for Pfizer. Andrea Tubaro is a paid Consultant and study investigator funded by the sponsor. Joseph is an employee of the sponsor |
| Van Kerrebroeck, 2004[321]<br>Duloxetine Urinary Incontinence | Women aged 24–83 years with predominant symptoms of stress urinary incontinence (according to clinical algorithm that was 100% | Inability to tolerate the filling to 400 mL or who experienced a first sensation of bladder filling <100 mL. | Duloxetine 40 mg BD | Placebo | Funded by Eli Lilly and Boehringer Ingelheim. | Dr Yalcin and Dr Bump are both full-time employees of Eli Lilly and hold stock and stock options in the company. |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Study Group. 46 study centres in Belgium, Canada, Denmark, France, Germany, the Netherlands, Sweden and the United Kingdom N: 494 | predictive of urodynamic stress urinary incontinence), with >7 weekly incontinence episode, without predominant symptoms of urge incontinence, normal diurnal and nocturnal frequencies, a bladder capacity >400 mL and both a positive cough stress test and positive stress pad test. | | | | | |
| Van Kerrebroeck, 2001[322] Tolterodine Study Group. 167 centers in Australasia (n 54), Europe (n 589), and North America (n 574). N: 1529 | Men and women with urinary frequency (eight or more micturitions every 24 hours) and urge incontinence (five or more episodes per week) irrespective of whether they had received prior treatment and irrespective of their response to prior prior antimuscarinic therapy. | Demonstrable stress incontinence, total daily urine volume greater than 3 L, any contraindications to antimuscarinic treatment, significant hepatic or renal disease (biochemical markers twice the upper limit of the normal reference range), symptomatic or recurrent urinary tract infections, interstitial cystitis, hematuria or bladder outlet obstruction, current electro-stimulation or bladder training therapy, and indwelling catheter or intermittent self-catheterization, pregnancy, breastfeeding, unreliable contraceptive methods; other treatments for an overactive bladder such as anticholinergic drugs or drugs that inhibit cytochrome P450 3A4 isoenzymes; treatment with an investigational drug in the 2 months before study entry. | Tolterodine ER 4 mg once daily | Placebo | Not reported | Not reported |
| Khullar, 2004[323] RCT UK N: 854 | Women 18 years or older with urge-predominant mixed incontinence, including urge incontinence (five or more episodes per week), urinary frequency (eight or | Pure stress urinary incontinence; predominant stress urinary incontinence; a total daily urine volume greater than 3 L; suspected or documented hepatic or renal dysfunction; symptomatic urinary tract infection; interstitial cystitis, | Tolterodine tartrate extended-release (ER) 4 mg | Placebo | Pfizer Inc | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | more micturitions on average in 24 hours), and urgency in combination with stress incontinence irrespective of the use of previous antimuscarinic treatment. | uninvestigated hematuria, or clinically significant bladder obstruction; any contraindication to antimuscarinic treatment; and any nonsurgical treatment for incontinence within 4 weeks of the first study visit; treatment within 2 weeks before randomization with any drug for incontinence (except estrogen therapy started more than 2 months before the first visit); agonist or potent inhibitors of cytochrome P450 3A4 isoenzymes; pregnancy, lactation, or inadequate contraception. | | | | |
| Khullar, 2008[324]<br>Pooled<br>USA<br>N: 1674 | Pooled analysis of two RCTs: men and women 18 years of age or older with OAB syndrome for 6 or more months; urinary frequency (8 or more micturitions per 24 hours) and urinary urgency (6 or more episodes during the 3-day diary period) or UUI (3 or more episodes during the 3-day diary period). | Presence of lower urinary tract pathology that could, in the investigator's opinion, be responsible for urgency or incontinence (for example, significant stress incontinence, urolithiasis, interstitial cystitis, urothelial tumors); pelvic organ prolapse grade III or higher; clinically relevant bladder outlet obstruction; postvoid residual urine volume greater than 100mL; polyuria (more than 3L/24 hours); symptomatic or recurrent urinary tract infections; current treatment with anitmuscarinic agents; a neurogenic cause of OAB symptoms; clinically relevant arrhythmia, unstable angina, or a QTcB interval greater than 500 ms; current treatment, or treatment within the past 4 weeks, with electro-stimulation or bladder training during the past 4 weeks. | Fesoterodine 4 mg, or fesoterodine 8 mg | Placebo | Schwarz BioSciences GmbH and Pfizer Inc | Dr.Vik Khullar has been a consultant and investigator in clinical trials by Pfizer Inc. Drs. Eric Rovner and Roger Dmochowski have served as consultants and investigators on clinical trials sponsored by Pfizer Inc. Dr. Victor Nitti has been a consultant and lecturer sponsored by Pfizer Inc. Joseph Wang and Dr. Zhonghong Guan are employed by Pfizer Inc. |
| Kinchen, 2005[325]<br>RCT<br>Country: Not reported<br>N: 451 | Ambulatory women with symptoms of SUI 18 years of age or older, >1 episode per week of urinary incontinence due to activities such as | Pregnancy, breastfeeding, having an active urinary tract infection, participation in a previous trial of duloxetine, or having conditions such as arrhythmias, poorly controlled or uncontrolled hypertension, liver | Duloxetine (40 mg b.i.d.) but dose adjustment was allowed | Placebo | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | coughing, sneezing, lifting, and exercising. Women had to have experienced stress symptoms for >3 months but may have predominant symptoms of urge incontinence | disease, seizure disorders, or an unstable cardiac condition. | | | | |
| Kreder, 2003[326] RCT analysis Country: Not reported N: 994 | Age >18 years with OAB, diagnosed by a physician assessment based on self-reported symptoms with urinary frequency (>8 voids/24 hours) and either urgency or UI (>1 incontinence episode/24 hours). | Predominating stress UI; contraindications to antimuscarinic therapy; significant hepatic or renal disease; symptomatic UTI or history of recurrent UTI; haematuria or interstitial cystitis; significant voiding difficulty with risk of urinary retention; and bladder training, electrostimulation therapy, or having an indwelling catheter or an intermittent catheterization, women with reproductive potential; pregnancy or nursing; concomitant treatment for OAB (other than oestrogen-replacement therapy started at least 2 months before study commencement) and use of anticholinergic agents. | Tolterodine 1 mg twice daily for 4 weeks, after which the dose could be increased to 2 mg twice daily (and subsequently reduced to 1 mg if necessary), based on the patient's response | None. Outcomes were compared among patients with urge UI vs. mixed UI | Pharmacia Corporation. | Not reported |
| Lackner, 2008[327] RCT USA N: 50 | Nursing home resident for at least 3 months; aged ≥65; not residing in a subacute, transitional care, or rehabilitation unit of the nursing home; not enrolled in hospice; bladder incontinence (Minimum Data Set 2.0 score of 1–4); 12 no indwelling catheter; able to swallow medication intact and obtained permission from potential participants or their designated proxies for chart review by the NP; | Terminal illness; bed-bound; non-communicative; delirium (Confusion Assessment Method feature 1 (acute onset) and 2 (inattention) plus feature 3 (disorganized thinking) or 4 (altered level of consciousness)); Lewy body dementia; history of ≥3 urinary tract infections in previous year or current infection; postvoid residual urine volume ≥150 mL (bladder ultrasound); urethral diverticulum; bladder tumor or stone; severe pelvic organ prolapse or vaginitis; genitourinary surgery within past 6 months; hepatic disease; severe cardiovascular disease; myasthenia gravis; spinal cord injury; bowel | Extended release oxybutynin 5mg once daily | Placebo | Funded by a research grant from Ortho-McNeil Pharmaceutical, Raritan, New Jersey. ALZA Corporation, Mountain View, California, supplied oxybutynin extended-release (Ditropan XL) 5-mg tablets | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | Mini-Mental State Examination score of 5–23; Global Deterioration Scale score of 3–6; ≥1 symptom or sign of urge urinary incontinence (≥4 micturitions or wet checks or requests to toilet within an 8-hour period of prompted voiding schedule on 2 consecutive days (8:00 a.m. to 4:00 p.m.); nocturia or nocturnal enuresis 42 times per night; staff observation that incontinence occurs on way to toilet or resident reports urgency; or medical record documentation of detrusor overactivity or urgency); Medication adherence rate ≥80% during the week before screening. | movement <every 3 days; history of gastrointestinal obstruction or decreased motility; current drug therapy for urinary incontinence; current use of acetylcholinesterase inhibitor or bisphosphonate; investigational drug, systemic or ophthalmic cholinomimetic drug, diphenhydramine, or gastrointestinal antispasmodic within 2 weeks before trial. | | | and matching placebo tablets. | |
| Landis, 2004[328]<br>RCT<br>159 centers in North America, Europe and Australia/New Zealand.<br>N: 1529 | Men and women 18 years old or older with urinary frequency (8 micturitions or greater per 24 hours), urge incontinence (5 episodes or greater a week) and symptoms of overactive bladder for 6 months; severe incontinence defined as 21 episodes or greater per week at baseline irrespective of prior antimuscarinic treatment and response to such treatment. | Reported previously | 4 mg tolterodine ER once daily | Placebo | Pharmacia Corporation, Peapack, New Jersey | J. Richard Landis has financial interest and/or other relationship with Alza Pharmaceuticals, Pharmacia and Bristol-Myers Squibb; Eboo Versi has financial interest and/or other relationship with Pharmacia. |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Lee, 2002[329]<br>RCT<br>South Korea<br>N: 228 | Male and female subjects aged ≥18 years with symptoms of overactive bladder for ≥6 months were eligible for enrolment in the study. Symptoms, as measured by micturition diaries, were defined as urinary urgency and frequency (≥8 micturitions on average per 24 hours), with or without urge incontinence. Patients were enrolled exclusively on the basis of symptoms (i.e. urodynamics was not performed), irrespective of whether they had received prior antimuscarinic therapy. | (i) significant stress incontinence; (ii) women of childbearing age who were not using reliable contraception; (iii) pregnant or nursing women; (iv) treatment with any drug with known anticholinergic side-effects in the in the 2 weeks prior to the study; (v) significant renal or hepatic disease; (vi) any contraindication to antimuscarinic therapy (e.g. narrow-angle glaucoma, urinary or gastric retention, known hypersensitivity to tolterodine or oxybutynin); (vii) symptomatic acute or recurrent urinary tract infection; (viii) interstitial cystitis or hematuria; (ix) bladder outlet obstruction; and (x) patients receiving bladder training, electro-stimulation therapy or having an indwelling catheter or on intermittent catheterization. | Tolterodine 2mg bid | Oxybutynin 5mg bid | Grant from Pharmacia | Not reported |
| Lee, 2010[330]<br>Study: Propiverine study on overactive bladder including urgency data<br>N: 264 | Men and women ages ≥18 years who had self-reported symptoms of OAB for ≥3months; average urinary frequency of ≥10 voids/24h and urgency of two or more episodes/24h defined as 'moderate to severe' in the Indevus Urgency Severity Scale(IUSS) during the 3-day voiding diary period before randomization | Clinically significant stress urinary incontinence (more than one episode per week); genitourinary conditions that could cause OAB symptoms, such as UTI; and contraindications to the use of antimuscarinic drugs | Propiverine hydrochloride 60 mg/d | Placebo | Sponsored by Jeil Pharmaceutical Co. Ltd., Seoul, Korea | NR |
| Lehtoranta, 2002[331]<br>RCT<br>Finland<br>N: 9 | Female or male patients aged 18–75 years were recruited to the study. They had to have a history of urgency or urge incontinence and cystometrically proven detrusor hyperreflexia or | Stress incontinence and pure nocturnal enuresis were excluded. | OXYBUTYNIN 5mg/30ml three times daily | PLACEBO 30ml of sterile saline | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | instability according to the ICS criteria (International Continence Society). | | | | | |
| Leung, 2002[332]<br>RCT<br>Hong Kong Chinese<br>N: 106 | (i) age ≥18 years; (ii) a diagnosis of overactive bladder confirmed by urodynamic test (phasic detrusor contraction with an amplitude ≥15cm$H_2O$) in accordance with ICS criteria; (iii) urinary frequency (an average of ≥8 voids/24 hours), urgency or urge incontinence (an average of ≥1 incontinence episode/24 hours); and (iv) willing to give written informed consent. | (i) a diagnosis of genuine stress incontinence; (ii) clinically significant voiding difficulty (maximum flow rate <10 mL/s with a residual volume of >200 mL); (iii) recurrent or acute UTIs; (iv) require intermittent catheterization or an indwelling catheter; (v) uninvestigated haematuria or bladder cancer; (vi) currently on treatment for an overactive bladder or on anticholinergic medications; (vii) presence of psychiatric disease or cognitive impairment, as shown by their history or an abnormal Mini Mental State Examination; (viii) clinically significant cardiac, hepatic, renal or hematological disorders, as shown by their history; (ix) the presence of contraindications for antimuscarinic agents; (x) pregnant or lactating women and women of childbearing age who were not using reliable contraception. | Tolterodine 2mg twice daily | Oxybutynin 5mg twice daily | Financial Assistance from Pharmacia Limited | Not reported |
| Lin, 2008[333]<br>RCT<br>Taiwan<br>N: 121 | Non-pregnant women 20 years of age and older with predominant symptoms of SUI during the last 3 months with an average of ≥1 incontinent episode/day, positive cough stress test after filling the bladder, daytime voiding frequency ≤8 voids daily, nocturnal frequency ≤ 2 voids daily and no predominant urge incontinence symptoms. | Inability to tolerate retrograde bladder filling to 400 mL or who had a first sensation of bladder filling at ≤100 mL. Concomitant medications including urinary continence promoting drugs, antidepressants, drugs for obesity (including over the counter appetite suppressants and diet pills), and illicit drugs. | 80 mg duloxetine (40 mg twice daily) | Placebo | This study was supported by Eli Lilly and Company and Boehringer Ingelheim. | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Lipton, 2005[334]<br>RCT<br>Country: Not reported<br>N: 129 | Male and female volunteers 65 years or older with a score of 10 or less on the Short Orientation Memory and Concentration Test,12 which is a short version of the Blessed Information-Memory Concentration (no clinical dementia). | A diagnosis of clinical dementia, depression or any other medical, psychological or social condition that would impair participation in the study, clinically significant or unstable hematological, renal, hepatic or cardiac disease, or the use of cimetidine, psychotropic drugs, anticholinergic drugs, antihistamines or other drugs known to affect cognitive function; severe drug allergy or contraindications to antimuscarinic therapy (e.g., narrow angle glaucoma, significant urinary outflow obstruction or obstructive bowel disease); treatment with another investigational drug within the previous 3 months. | Darifenacin controlled release (3.75, 7.5 or 15 mg once daily), darifenacin immediate-release (5 mg 3 times daily) | Placebo | Supported by Pfizer, Inc. and an educational grant from Novartis Pharma AG. | Not reported |
| Lose, 2000[335]<br>RCT<br>Denmark<br>N: 254 | 251 women reporting at least one bothersome lower urinary tract symptom after spontaneous or surgical post menopause. | Known or suspected estrogen-dependent neoplasia or mammary, ovarian (endometroid) or corpus uteri malignancies, vaginal bleeding, clinically significant liver diseases, acute or intermittent porphyria, uterovaginal prolapse II-III, sex hormone treatment within the last 6 months, vaginal irritation other than atrophy derived or signs of vaginal ulceration; participation in clinical trials within last 3 months prior to inclusion. | 1. Oestradiol-releasing ring, 7.5mg oestradiol. | Oestriol pessaries 0.5 mg every second day | Not reported | Not reported |
| MacDiarmid, 2005[336]<br>Pooled<br>USA<br>N: 420 | Men and women with UUI or mixed incontinence with a predominating urge component; with at least 6 (studies 1 and 3) or 7 (study 2) UUI episodes weekly when unmedicated; with known response to oxybutynin in study 1 or to anticholinergic medications in study 2. | Reported previously | ER oxybutynin was then initiated at 5 mg daily and adjusted in 5 mg increments at intervals of approximately 1 week until continence achieved | None | Grant from ortho-McNeil Pharmaceutical, Inc. | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Madersbacher, 1999[337]<br>RCT<br>USA<br>N: 366 | History of urgency or urge incontinence, a maximum cystometric bladder capacity of ≤300 ml, age ≥18years and body weight ≥45kg. | Detrusor hyperreflexia, postoperative (bladder) incontinence, intravesical obstruction, a postvoid residual urine (PVR) of >15% of the maximal cystometric bladder capacity, acute UTIs, angina pectoris, glaucoma, megacolon, clinically relevant cardiac, renal or hepatic dysfunctions, tachy/dysrhythmias, frequency or nocturia due to heart or renal insufficiency, or overt cerebral sclerosis. | Propiverine 15mg three times a day | Oxybutynin 5mg twice a day, placebo three times a day | Not reported | Not reported |
| Malhotra, 2010[338]<br>Study: RCT<br>Sample: 261 | Healthy subjects aged 45-65 years with a body mass index between 19 and 32kg/m2(inclusive); had no clinically relevant abnormal findings on the physical examination, ECG, blood pressure, pulse rate, medical history, or clinical laboratory results at the eligibility assessment visit and were characterized as extensive metabolizers for CYP2D6 | Medical history of any serious disease of the internal organs or of the central nervous system; a history or presence of urinary retention, obstructive disturbance of bladder emptying, micturition disturbance, nocturia, or pollakiuria, for example, prostatic hyperplasia, or urethral stricture; a history of ischemic heart disease or a positive diagnostic cardiac stress test within 12 weeks before the start of the trial; a supine systolic blood pressure of<100mg or>160mmHg or a supine diastolic blood pressure of >95mmHg; a supine pulse rate of <50bpm or >100bpm; and any clinically relevant changes in ECG such as second-or third-degree AV block, or prolongation of the QRS interval to >110ms, the PR interval to >240ms, or QTc(Bazett's correction, machine read) to >480ms | fesoterodine 4mg/28mg | Placebo/Moxifloxacin | Funded bySchwarz BioSciences GmbH and Pifizer Inc. | Bimal Malhotra and Kuan Gandelman are employees of Pfizer Inc., New York, NY, USA.Nolan Wood was an employee of Pfizer Inc., Sandwich, Kent, UK at the time the study was conducted. Richard Sachse is an employee of Schwarz BioSciences, Monheim, Germany |
| Malone-Lee, 2009[339]<br>RCT<br>UK<br>N: 307 | Male and female subjects aged ≥18 years with urinary frequency (defined as an average of ≥8 voids/24 hours, measured over a 7-day period) and urgency (with or without | Mean volume voided of >300 mL/void or a mean total volume of urine >3000 mL/24 hours; significant hepatic or renal disease, symptomatic UTI, diagnosed interstitial cystitis, un-investigated hematuria, or clinically significant | Tolterodine-ER (4 mg capsule od) | Placebo | Pharmacia (now Pfizer Ltd) | James Malone-Lee has received travel expenses for attending professional conferences from Pharmacia & Upjohn and Pfizer Inc, and |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | UUI), symptoms of OAB for ≥6 months before randomization, with no significant stress UI and adequate contraception. | BOO; anticholinergic drugs or other treatments for OAB in the 14 days before randomization; known hypersensitivity to tolterodine-ER or any of its excipients; oral cytochrome P450 3A4 inhibitors (e.g. macrolide antibiotics), and electro-stimulation or bladder retraining in the 3 months before randomization. | | | | has served as a consultant and received research funds from Pfizer Inc. |
| Malone-Lee, 2001[340]<br>RCT<br>United Kingdom, France, and the Republic of Ireland<br>N: 177 | Older men and women (age ≥65 years) with symptoms of urinary urgency, increased frequency of micturition (≥8 micturitions/24 hours), and/or urge incontinence (≥1 episode/24 hours). | Significant stress incontinence, urinary outflow obstruction, urinary retention (as determined by palpation after voiding), symptomatic urinary infection, interstitial cystitis, unexplained hematuria, use of urinary catheterization or electro-stimulation, hepatic and renal disease with biochemical markers twice the upper limit of the normal reference range, concomitant antimuscarinic medication, previous treatment with tolterodine, and exposure to any other investigational drug in the preceding 2 months. | Tolterodine 1 mg or 2 mg twice daily | Placebo | Pharmacia & Upjohn AB | Not reported |
| Mattiasson, 2009[65]<br>U.S. Food and Drug Administration,[64]<br>Study: SOLAR<br>Sample: 643 | Men or women aged >=18 years with OAB symptoms were eligible if they gave written informed consent, were capable of completing a simplified bladder training regimen correctly, and were willing and able to complete a voiding diary correctly | Patients should not have received non-drug treatment for OAB, including electrostimulation therapy and pelvic floor exercises, in the 4 weeks before starting the study, or during the study except for those randomized to receive bladder training instructions. Patients were also excluded if they had received cognitive bladder training in the previous 6 months, or if they intended to commence bladder training other than the study regimen during the study. | Simplified Bladder training + Solifenacin | solifenacin 5mg or 10mg | Research Grant from Astellas Pharma Europe Ltd. | Anders Mattiason:Astellas, Ferring: Pfizer; Alberto Masala: Astellas, Angelini Group; Richard Morton and John Bolodeoku:employees of Astellas |
| Mattiasson, 2003[341]<br>Study: RCT<br>Tolterodine | Men and women aged ≥18 years with symptoms of urinary frequency (≥8 micturitions/24h on | Any contraindication to antimuscarinic therapy; use of electro stimulation therapy or behavioral therapy within the previous 3 months; | Tolterodine + Simplified Bladder training | Tolterodine | Supported by Pharmacia Corporation | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Scandinavian Study Group<br>N: 501 | average) and urgency (a strong and sudden desire to urinate), with or with no urge incontinence. Women of child-bearing potential were required to be using a reliable birth control method to enter the study | patients with an indwelling catheter or on intermittent catheterization; pregnancy and lactation; and use of anticholinerigc agents or concomitant treatment for an overactive bladder (other than estrogen replacement therapy started at least 2 months before study commencement) | | | | |
| Milani, 1993[342]<br>RCT<br>Milan<br>N: 50 | Women over 18 years of age with motor or sensory urgency | Severe illness, overt neurological diseases, acute or chronic urinary tract infections or obstructive diseases, pregnancy, taking concomitant medication which could affect urinary symptoms, continence or bladder function. | Flavoxate was 1 200 mg (400 mg t.i.d.) | Oxybutynin 15 mg (5 mg t.i.d.) | Not reported | Not reported |
| Millard, 1999[343]<br>RCT<br>Sweden<br>N: 316 | Male and female patients 18 years old or older with cystometrically proved detrusor overactivity (idiopathic instability or detrusor hyperreflexia, or uninhibited phasic detrusor contractions with an amplitude of 10 cm. water or greater) and average urinary frequency of 8 or more voids per 24 hours; urge incontinence (an average of 1 or more incontinence episodes per 24 hours on the frequencyvolume chart) and/or urinary urgency. | Inadequate contraception; demonstrable stress incontinence (fluid escaping from the external urethral orifice during coughing when the bladder was stable), clinically significant voiding difficulty (maximum flow rate less than 10 ml. per second with post-void residual volume greater than 200 ml.), proved recurrent urinary tract infection, interstitial cystitis, uninvestigated hematuria or any bladder cancer; catheterization, indwelling catheterization , hepatic or renal disease, or narrow angle glaucoma, electro-stimulation therapy or bladder training, any primarily anticholinergic drug initiated 14 days before or at any time during the study, an unstable dose of any treatment with anticholinergic side effects; average total voided volume of greater than 3,000 ml/24 hours, or treatment with any investigational drug during or 2 months before the study. | 1 or 2 mg. tolterodine twice daily | Placebo | Pharmacia and Upjohn AB | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Millard, 2004[344] Duloxetine UI Study Group Country: Not reported N: 458 | Duloxetine UI Study Group: Women aged ≥18 years with a clinical diagnosis of troublesome SUI of at least 3 months' duration with the predominant symptom of SUI with ≥7 incontinent episodes per week. An 'episode' was defined as an easily noticed leakage of urine that wet a pad or clothing and occurred with a physical stress such as coughing, sneezing or exercising. Patients also needed to report a diurnal frequency of <9 per day, nocturnal frequency of and the absence of predominant symptoms of urge incontinence. In addition, objective testing was used to confirm normal bladder capacity and the sign of SUI. With the patient supine the bladder was filled with saline at 100 mL/min with no pressure measurements; positive cough-stress test (visualization of urine leakage concurrent with a cough) and a positive stress pad test (leakage of >2.0 g) ( clinical algorithm has a sensitivity of 92% for urodynamic stress incontinence). | Inability to tolerate filling to 400 mL were excluded, as were those who experienced a first sensation of bladder filling at <100 mL, or who had no sensation at any time during the filling. | Duloxetine 40 mg twice daily | Placebo | Sponsored by Eli Lilly and Company and Boehringer Ingelheim. | Not reported |
| Moore, 1990[345] Study: RCT Sample: 53 | Patients with involuntary detrusor contractions >30cm H2O during the filling phase of cystometry | Those with neurological and other urological disorders; patients with coexistent genuine stress incontinence, low compliance | oxybutynin hydorchloride | Placebo | Tillots Laboratories provided oxybutynin and | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | bladder, bacterial or interstitial cystitis, age greater than 75 years or previous treatment with oxybutynin | | | placebo tablets | |
| Naglie, 2002[346]<br>RCT<br>USA<br>N: 86 | Men and women 65 years or older with a history, physical exam and urodynamic findings consistent with urge incontinence, and at least 4 documented episodes of urinary incontinence on a 5-day voiding record. | An indwelling or condom catheter, or intermittent catheterization; a clinical history of stress urinary incontinence; a history of >2 urinary tract infections per year; insulin dependent diabetes; spinal cord pathology; symptomatic orthostatic hypotension, congestive heart failure or ventricular arrhythmia; taking any calcium channel blocker; cognitive impairment; evidence of prostate or bladder cancer; cystoscopic or urodynamic evidence of outlet obstruction; post-void residual urine volume >100 cc or >trivial urinary leakage occurring with coughing/straining in the sitting or standing position; unable to complete a 5-day voiding record during the run-in period. | 30 mg. nimodipine twice daily | Placebo | Research grant from the Physicians' Services Incorporated | Not reported |
| NCT00269750[57]<br>Study: RCT<br>N: 105 | Men and women, age 40 to 75, with urge or mixed UI provided that stress UI was not the predominant manifestation of mixed UI. Patients who were currently taking immediate-release oxybutynin (Ditropan□), hyoscyamine (Levsin□ Cystospaz□), or propantheline (Pro-Banthine□), or who had taken Ditropan® in the past for urge or mixed UI. Patients who had taken and discontinued Ditropan® for urge or mixed UI should not have discontinued due to failure | NR | oxybutynin chloride | oxybutynin chloride IR | Alza Corporation | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | of efficacy; patients who had at least six urge UI episodes per week recorded on the Run-in Diary after washout of anticholinergic medications. Patients who were able to differentiate incontinent episodes associated with urgency from incontinent episodes not associated with urgency when recording incontinent episodes in the diary.The Run-in Diary after washout of all anticholinergic medications must have demonstrated that the number of urge incontinent episodes per week was greater than the number of incontinent episodes not associated with urgency per week. | | | | | |
| NCT00168454[55]<br>Study: RCT<br>N: 313 | Must be between 18-85 years old; must have been diagnosed by his/her doctor with overactive bladder at least 6 months ago; must weigh at least 50 kg (110 lbs); must be willing and able to record information regarding bladder function into a diary (provided); and must be willing and able to complete the entire course of the study | Cannot currently be catheterizing as a way to control incontinence and must not have used botulinum toxin type A or any other botulinum toxin previously for any condition | Botulinum toxin Type A | Placebo | Sponsored by Allergan, Inc. | Principal Investigators are **NOT** employed by the organization sponsoring the study. |
| NCT00444925[58]<br>Study: RCT<br>N: 1712 | Adult overactive bladder (OAB) patients who present with OAB | Patients with conditions that would contraindicate for fesoterodine use, e.g, hypersensitivity to the active | Fesoterodine | Tolterodine/ Placebo | Sponsored by Pfizer Inc. | Principal Investigators are **NOT** employed by the organization |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | symptoms, including urinary frequency ≥ 8 per day and urgency urinary incontinence ≥1 per day | substance (fesoterodine) or to peanut or soya, urinary retention, and gastric retention; patients with significant hepatic and renal disease or other significant unstable diseases; and OAB symptoms caused by neurological conditions, known pathologies of urinary tract, etc. | | | | sponsoring the study. |
| NCT00536484[59]<br>Study: RCT<br>N: 883 | Adults 18 Years and older; # Overactive bladder symptoms for greater than or equal to 3 months; # Mean urinary frequency of greater than or equal to 8 micturitions per 24 hours in bladder diary; and Mean number of Urgency episodes greater than or equal to 3 per 24 hours in bladder diary. | Known etiology of OAB (e.g., neurogenic, local urinary tract pathology); Previous history of acute urinary retention requiring catheterization or severe voiding difficulties in the judgment of the investigator, prior to baseline; and Unable to follow the study procedures, including completion of self-administered bladder diary and patient reported outcome questionnaires. | Fesoterodine | Placebo | Sponsored by Pfizer Inc. | Principal Investigators are **NOT** employed by the organization sponsoring the study. |
| NCT00178191[56]<br>Study: RCT<br>N: 28 | Adults 21 Years and older; subjects must have completed a routine evaluation of incontinence (urodynamics, bladder diaries, and pad weights) through the urogynecology clinic at SMH within 3 months of the screening visit; symptoms of urge incontinence associated with leakage on bladder diary; 24-hour pad weight >100 cc's (volume requiring multiple daily diaper changes); absence of a bladder infection or other condition that could explain urinary leakage; Absence of stress incontinence or a cough | Children (< 21 years old), pregnant women and prisoners; History of carcinoma of the bladder; # Absence of a measurable detrusor contraction on a pressure flow micturition study; A foreign body in the bladder or other correctable etiology for the UUI; Prior documented resistance to Botox; Gross fecal incontinence (due to confounding effects on pad weights and counts); Known allergy to lidocaine or related compounds (used for local analgesia); Known allergy to or inability to take both Bactrim DS or Ciprofloxacin (used for urinary tract infection prophylaxis); Current use of an aminoglycoside or preparing for general anesthesia within 1 week (risk of synergetic effects); and known neurologic conditions such as Parkinson's disease, myasthenia gravis, multiple sclerosis, autonomic | Botulinum toxin Type A | Placebo | Sponsored by University of Rochester, New York, USA | Principal Investigators are **NOT** employed by the organization sponsoring the study. |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | leak point pressure > 100 cm H2O on cystometry (this correlates with mild stress incontinence); failed anticholinergic therapy; willingness and ability to perform intermittent clean catheterization (due to the risk of prolonged urinary retention from Botox); the ability and willingness to return for surveillance evaluations; a negative urine pregnancy test if at risk for pregnancy; and competent to give signed consent and complete all of the study measures. | dysfunction, Lambert-Eaton syndrome, Amyotrophic Lateral Sclerosis or other neurologic disorder that may impact urinary function or the effect of Botox. | | | | |
| Nitti, 2007[347]<br>RCT<br>USA<br>N: 836 | Men and women 18 years or older with OAB syndrome for 6 months or greater, including urinary frequency (8 micturitions or greater per 24 hours) and urinary urgency (6 episodes or greater during the 3-day diary period) or UUI (3 episodes or greater during the 3-day diary period).The amended inclusion criterion required 3 or greater UUI episodes in 3-day diary; at least moderate bladder problems on a Likert scale that was almost identical to the patient perception of bladder condition. | Positive pregnancy test and non adequate contraception throughout the trial; lower urinary tract pathology that could in the opinion of the investigator be responsible for urgency or incontinence, such as significant stress incontinence, urolithiasis, interstitial cystitis or urothelial tumors; pelvic organ prolapse grade III or greater; clinically relevant bladder outlet obstruction; PVR volume greater than 100 ml; polyuria (greater than 3 l/24 hours); symptomatic or recurrent urinary tract infections; current treatment with antimuscarinic agents; a neurogenic cause of OAB; clinically relevant arrhythmia, unstable angina or a corrected QT interval (Bazett's formula) of greater than 500 milliseconds; or current treatment or treatment within the last 4 weeks with electro-stimulation or bladder training. | 4 mg fesoterodine or 8 mg fesoterodine once daily | Placebo | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Norton, 1994[348]<br>RCT<br>USA<br>N: 93 | Women 18-86 years old with at least 4 episodes of urge UI/week, detrusor instability, negative urine culture, and post-void residual volume <100ml. | Stress UI, contraindication to terodiline, concomitant use of medications affecting bladder function (diuretics, calcium antagonists), pregnancy, neurologic disease, abnormal biochemical profiles. | Terodiline, 25 mg twice daily | Placebo | Not reported | Not reported |
| Norton, 2002[349]<br>Sahai, 2006[350]<br>Duloxetine Urinary Incontinence Study Group.<br>USA<br>N: 553 | Women aged 18 to 65 years with a predominant symptom of stress urinary incontinence for at least 3 months with ≥4 incontinent episodes per week (easily noticeable leakage of urine that wets a pad or clothing and occurs with a physical stress such as coughing, sneezing, or exercising); urinary diurnal frequency ≤7 per day, nocturnal frequency ≤2 per day; both a positive cough stress test (CST, visualization of urine leakage concurrent with a cough) and SPT (leakage of >2.0 g). | Predominant symptoms of enuresis or urge incontinence, and no previous continence or prolapse surgical procedure, inability to tolerate the filling, who had a first sensation of bladder filling at <100 mL, or who had no sensation at any time during the filling. | Duloxetine at one of three doses (20 mg/d, n = 138 women; 40 mg/d, n = 137 women; or 80 mg/d, n = 140 women) | Placebo | Supported by Eli Lilly and Company. | Not reported |
| , 1993[351]<br>the Elderly American Multicenter Study Group<br>USA<br>N: 98 | Terodiline in the Elderly American Multicenter Study Group: women, age 60 or older, with symptoms of urge incontinence and self-reported frequency of incontinence >4/week and detrusor instability with involuntary bladder contractions on dual-channel water cystometry; non predominant stress UI. | Predominant stress UI; Mini Mental State score <26, clinically significant urologic, gynecologic diseases, or neurologic diseases, potentially reversible causes of UI; contraindication for anticholinergic medication (glaucoma, inflammatory bowel disease, unstable cardiovascular condition) | Terodiline 25mg twice/day | Placebo | Forest Laboratories | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Ozdedeli, 2010[352]<br>Study: RCT<br>Sample: 35 | 35 female patients who presented to the University Departments of Urology and Physical Medicine and Rehabilitation for urge incontinence and had overactive bladder or mixed incontinence with predominantly overactive bladder symptoms | History of pelvic surgery, a neurological deficit or peripheral neuropathy that may cause neurogenic bladder, presence of a medical condition that may preclude anticholinergic drug use, pregnancy or suspicion of pregnancy, cardiac pacemaker, genitourinary infection or hemorrhage, deterioration in cognitive or intellectual functions, anatomical abnormality that hinders the use of vaginal probe, and post-voiding residual volume >100mL | trospium hydrochloride | electrical stimulation | Not reported | Not reported |
| Peters, 2009[353]<br>The Overactive Bladder Innovative Therapy<br>USA<br>N: 100 | The Overactive Bladder Innovative Therapy trial : ambulatory men and women with OAB symptoms, with or without a history of previous anticholinergic drug use, with at least 8 voids per 24 hours | OAB pharmacotherapy within the previous month, primary complaint of stress urinary incontinence, demonstrated sensitivity to tolterodine or its ingredients, pacemakers or implantable defibrillators, excessive bleeding, urinary or gastric retention, nerve damage or neuropathy, uncontrolled narrow angle glaucoma, positive urinalysis for infection or pregnancy, or current pregnancy or planning to become pregnant during the trial. | Weekly percutaneous 30-minute tibial nerve stimulation | 4 mg daily extended-release tolterodine with a subsequent decrease to 2 mg daily if intolerability was experienced | Supported by Uroplasty Inc. | Kenneth Peters has financial interest and/or relationship with Medtronic Inc., Advanced Bionics, Boston Scientific, Allergean, Pfizer, Celegene and Trillium Therapeutics; Scott MacDiarmid has financial interest and/or other relationship with Watson, Pfizer, Astellas, Allergan, Novartis and Uroplasty; Leslie S. Wooldridge has financial and /or relationship with Astellas, Uroplasty and Watson; Eric Rovner has financial and/or relationship with Novartis, Astellas, Allergan, Contura, Solace, Tengion and Pfizer; Steven Siegel has financial and/or relationship with Medtronic, American |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | Medical Systems, Uroplasty, Uromedica, North Central Section of the American Urological Association, and Society for Urodynamics and Female Urology; Susan B. Tate has financial and/or relationship with C.R. Bard; Peter Rosenblatt has financial and/or relationship with Pfizer; Brian A. Feagins has financial and/or relationship with Medtronic, American Medical Systems, Novartis, Astellas, Uroplasty and Boston Scientific. |
| Peters, 2010 [354]<br>Study: RCT<br>Sample: 220 | Women and men >=18 years of age; a score of >=4 on the OAB-q short form for urgency; average urinary frequency of >=10 voids per day; self-reported bladder symptoms >=3 months; self-reported failed conservative care; discontinued all antimuscarinics for >=2 weeks; capable of giving informed consent; ambulatory and able to use toilet independently without difficulty; and capable and willing to follow all study-related procedures | Pregnant or planning to become to pregnant during the study; neurogenic bladder; Botox use in bladder or pelvic floor muscles within the past one year; pacemakers or implantable defibrillators; current urinary tract infection; current vaginal infection; use of Interstim; use of Bion; current use of TENS in pelvic region, back or legs; previous PTNS treatment; use of investigational drug/device therapy within past 4 weeks; and participation in any clinical investigation involving or impacting gynecologic, urinary or renal function within past 4 weeks | Percutaneous Tibial nerve stimulation | Placebo | Supported by Uroplasty Inc. | Kenneth Peters has financial interest and/or relationship with Medtronic and Urolplasty; Ramon Perez-Marrero has financial interest and/or relationship with Solvay, GSK and Novartis; Leslie Wooldridge financial interest and/or relationship with Uroplasty, Astellas and Watson; Gregory Davis financial interest and/or relationship with Orhto Women's Health and Urology |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | Speaker Bureau; and Scott MacDiarmid financial interest and/or relationship with Astellas, Allergan, Pfizer, Watson and Uroplasty |
| Pontari, 2010[355] Study: RCT Sample: 20 | Female gender, age 18 years or older, with symptoms of urinary frequency of at least 8 voids per day for at least 6 months | Stress incontinence, total daily volume greater than 3 L, significant hepatic or renal disease, symptomatic or recurrent urinary tract infections, concomitant sacral neurostimulation therapy, claustrophobia with magnetic resonance imaging, bladder outlet obstruction, self-catheterization, post-void residual volume greater than 100 ml, women who pregnant or nursing, or women of child bearing potential not using reliable contraceptive methods, or any neurological condition which may contribute to bladder dysfunction such as multiple sclerosis. | tolterodine | placebo | Supported by an educational grant form Pfizer | Michel Pontari has financial interest and/or relationship with Pfizer, Sanofi and Endo Pharmaceuticals |
| Rentzhog, 1998[356] Study: RCT Sample: 81 | Men and women aged 18-75 years; presence of symptoms of urinary urgency, increased frequency of micturition (at least 8 micturitions per 24 hours) and/or urge incontinence (at least one episode of incontinence per 24 hours) during a 1-week pre-study run-in period. All eligible patients should have had urodynamically confirmed detrusor instability (defined as a phasic increase in detrusor pressure in the presence of typical symptoms) and a maximum urinary flow rate | Stress incontinence or detrusor hyperreflexia; clinically significant cardiac, hepatic, renal or hematological disorders; patients with contraindications to antimuscarinic agents; and pregnant or lactating women and women of childbearing age who were not using reliable contraception. | tolterodine | Placebo | Pharmacia and Upjohn AB, Uppsala. Sweden | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | (Q max)of >=15mL/s (patients with a lower Qmax were eligible for inclusion provided there was no evidence of clinically significant bladder outlet obstruction), either sterile urine or clinically insignificant bacteriuria, and normal routine laboratory tests | | | | | |
| Richter, 2010[357] Study: ATLAS Sample: 446 | Women at least 18 years old with symptoms of stress only or stress-predominant mixed-incontinence symptoms. | NR | behavioral therapy | pessary or pessary+behavioral therapy | Grants from the Eunice Kennedy Shriver National Institute of Child Health and Human Development; National Institute of Diabetes and Digestive and Kidney Diseases, and National Institutes of Health Office of Research on Women's Health | Dr.Burgio is a consultant for Pfizer(New York) and on the advisory board for Astellas(Deerfield, IL). Dr. Brubaker is a Research Consultant for Pfizer(New York, NY) and a Research Investigator for Allergan(Irvine, CA). Dr.Zyczynski has performed contract research for Johnson and Johnson(New Brunswick, NJ). Dr. Lukacz is a consultant for Pfizer(New York, NY), Medtronic(Minneapolis, MN) and Watson Pharmaceuticals(Corona, CA). She has served on the speaker's bureau for Novartis(Basel, Switzerland) and Proctor and Gamble(Cinncinati, Ohio). She has been a consultant and |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | proctor for Intuitive Surgical Corporation(Sunnyvale, CA),and she has been an editor First Consult. Dr.Schaffer is on the Speaker's bureau and National Advisory Board of Astellas/GlaxoSmithKline(Deerfield, IL; Philadelphia, PA) and on the Specialty Surgeons Advisory Board of Cadence Pharmaceuticals(San Diego, CA) |
| Rios, 2007[358]RCT USA N: 58 | Women clinically diagnosed with urgency incontinence and proven urodynamic DO for at least 6 months prior to the study | The use of anticholinergics or tricyclic antidepressants in the last 2 months, neurologic conditions, urinary tract infection, pelvic prolapses (greater than grade 2), history of pelvic radiation or bladder tumor, poor bladder wall compliance, and detrusor underactivity. | Single intravesical dose of 100 ml of resiniferatoxin 50 nM | Single intravesical dose of 100 ml placebo | Departments of Urology of the Federal University of Sa˜o Paulo, Paulista School of Medicine and Hospital do Servidor Pu´blico Estadual de Sa˜o Paulo. | Not reported |
| Robinson, 2007[359] Study: The Tamsulosin Study Group Sample: 364 | Women aged 18-75 years with symptoms of OAB (urinary urgency and frequency, with or without urge incontinence) for >=3 months; patients must have recorded a mean of at least eight voids/24h in the previous 3 days and one or more of the following during the 3-day period)at least 3 episodes | Stress incontinence or mixed incontinence where stress symptoms were predominant and women with neurogenic DOA | tolterodine | Placebo | Funded by Astellas | Gerben Terpstra and John Bolodeoku are both employees of the sponsor |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | of urinary urge incontinence; or ii) at least three episodes of urgency | | | | | |
| Rogers, 2009[360]<br>Rogers, 2008[361]<br>Study: C<br>Sample: 413 | Women ≥18 years with OAB symptoms for>=3 months; mean of >=8 micturitions per 24 hours, including ≥0.6 UUI episodes and ≥3 OAB micturitions (i.e. micturitions associated with at least a moderate degree of urgency), in a 5-day bladder diary at baseline; subjects also reported being in a stable, sexually active relationship (self-defined) for ≥6 months and having at least some moderate problems related to their bladder condition on the Patient Perception of Bladder Condition. Heterosexual. | One subject in the tolterodine group with an extreme increase in the number of UUI episodes per 24 hours from baseline to week 12 was identified as an influential outlier and was excluded from all efficacy analyses | tolterodine-ER | Placebo | Funded by Pfizer Inc. | Zhanna Jumadilova, Franklin Sun, Jon Morrow and Zhonghong Guan have disclosed that they are employed by Pfizer Inc. Rebecca Rogers has disclosed that she received speaker honoraria and research funding support from Pfizer Inc., and has served a consultant for Pfizer Inc. She has also disclosed that she serves on the advisory board for American Medical Systems. Gloria Bachmann has disclosed that she has served as a consultant and received research funding support from Astellas Pharma Inc., Wyeth, and other pharmaceutical companies. Harriett Scraper has disclosed that she has received speaker honoraria from Pfizer Inc., Astellas Pharma, Inc., and Watson Inc. All peer reviewers receive honoraria from CMRO for their |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | review work. Peer reviewer 1 has disclosed that he/she is on the speakers' bureau of Watson Pharmaceuticals. Reviewer 2 has no relevant financial relationships |
| Rogers, 2009[362]<br>RCT<br>USA<br>N: 202 | Sexually active women (≥18 years) reported OAB symptoms for ≥3 months, mean of ≥8 micturitions per 24 hour, including ≥0.6 UUI episodes and ≥3 OAB micturitions (i.e., micturitions associated with at least a moderate degree of urgency), in 5-day bladder diaries at baseline; reported being in a stable sexually active relationship (self-defined) with a male partner for ≥6 months; and indicated at least "some moderate problems" related to their bladder condition on the Patient Perception of Bladder Condition questionnaire. | Reported previously. Women who did not complete active treatment in the original study, women who were randomized to placebo were excluded from the analysis. | Tolterodine extended release 4 mg/day | Placebo for 12 weeks, none for 24 weeks | Pfizer Inc | Gloria Bachmann: Grant/Research Support: Astellas, Wyeth, Bayer, Duramed, Pfizer, Boehringer-Ingelheim, Roche, Merck, QuatRx, Bionovo, Glaxo Smith Kline, Femme Pharma, Hormos, Covance, Novartis, Johnson & Johnson, Boston Scientific, Novonordisk |
| Rogers, 2008[361]<br>RCT<br>USA<br>N: 413 | Women (aged ≥18 years) with a mean of greater than or equal to eight micturitions, ≥0.6 UUI episodes, and greater than or equal to three OAB micturitions (i.e., micturitions associated with moderate or severe urgency or UUI) per 24 hours with at least "some | Stage ≥3 pelvic organ prolapse, history of lower urinary tract surgery, lifelong sexual dysfunction unrelated to lifelong UUI, or predominant stress UI. | Tolterodine ER (4 mg) | Placebo | Pfizer Inc | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
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| | moderate problems" on the Patient Perception of Bladder Condition Questionnaire ; with OAB symptoms for ≥3 months and to have been in a stable, sexually active relationship (self-defined) with a male partner for ≥6 months. | | | | | |
| Rudy, 2006[363]<br>RCT<br>USA<br>N: 658 | Female and male patients were 18 years or older with OAB symptoms for at least 6 months; a minimal urinary frequency average of >10 toilet voids/day, symptoms of urgency (i.e., at least one "mild," "moderate," or "severe" urgency severity rating under the "degree of urgency," associated with "toilet void" events); >7 urge urinary incontinence episodes/week. | Predominately stress, insensate, or overflow UI; neurogenic bladder disorders, significant renal disease, uninvestigated hematuria, and urinary tract infection at washout or more than twice during the prior year; significant bladder outlet obstruction defined as a postvoid residual volume >100 mL and in the clinical judgment of the investigator; using any anticholinergic drug or other drug therapy for OAB within 21 days before randomization, history of bladder surgery. | Trospium chloride 20 mg twice daily | Placebo | Indevus Pharmaceuticals | D. Rudy, K. Cline, R. Harris, K. Goldberg, and R. Dmochowski are study investigators funded by the sponsor |
| Rudy, 2006[36]<br>RCT analysis<br>USA<br>N: 658 | Men and women ≥18 years old with OAB symptoms for ≥6 months, a minimum urinary frequency of 70 toilet voids per 7 days (i.e. mean ≥10 voids/day), and symptoms of urgency ; with at least seven UUI episodes/week. | Predominately stress, insensate, or overflow; neurogenic bladder disorders, significant renal disease, uninvestigated haematuria, >2 UTIs during the previous year; significant BOO, concurrent anticholinergic drug use or other drug therapy for OAB within 21 days before randomization, bladder surgery within 6 months, cancer, interstitial cystitis, men with PSA levels of ≥10 ng/mL, diuretic use, oestrogen therapy, and non-pharmacological bladder therapy that were not part of a stable, long-term program. | Trospium chloride 20 mg twice daily | Placebo | Indevus Pharmaceuticals | Not reported |
| Rufford, 2003[364]<br>RCT | Postmenopausal women (>1 year at menopause) | Medication treatment of urge syndrome, diuretics, HRT, history of | 25mg 17 beta-estradiol implant | Placebo | Educational grant from | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| England<br>N: 40 | with the 'urge syndrome'; with estradiol <150pmol/l in women after hysterectomy with no contraindication for estrogen therapy. | diabetes, endometrial thickness >4mm urinary tract infection, pelvic masses and urogenital prolapse. | subcutaneous tissue. | | Organon | |
| Salvatore, 2005[365]<br>RCT<br>UK<br>N: 96 | Over a period of 1 year women with urinary symptoms referred to the Urogynecology Department of the King's College Hospital in London were recruited into this study after approval of our Ethical Committee. We only included those who had a videourodynamic diagnosis of detrusor overactivity or low bladder compliance and who signed an informed consent. | Not reported | Oxybutynin 2.5 mg twice a day We instructed all our patients, orally and with written information, to increase oxybutynin to a maximum dose of 5 mg three times a day over a period of 6 weeks at fortnightlal intervals. | Oxybutynin 5 mg nocte We instructed all our patients, orally and with written information, to increase oxybutynin to a maximum dose of 5 mg three times a day over a period of 6 weeks at fortnightlal intervals. | Not reported | Not reported |
| Sand, 2009[366]<br>Pooled<br>USA<br>N: 1971 | Men and women ≥18 years of age who reported OAB symptoms for ≥6 months and demonstrated urinary frequency (≥8 micturitions per 24 hours) and either urinary urgency (≥6 total episodes) or UUI (≥3 total episodes) in 3-day bladder diaries at least moderate bladder problems on a six-point Likert scale: "My bladder causes me no problems (0), very minor problems (1), minor problems (2), | Lower urinary tract pathology that could (in the investigator's opinion) be responsible for urgency or incontinence, significant pelvic prolapse (grade III or higher), clinically relevant bladder outlet obstruction, polyuria (>3 L/24 hours), symptomatic or recurrent urinary tract infections, postvoid residual volume >100 mL, and recent treatment with an antimuscarinic agent. | Fesoterodine 4 or 8 mg, or tolterodine extended release (ER) 4 mg | Placebo | Schwarz Bio-Sciences GmbH and Pfizer Inc. | Peter Sand is an advisor for Astellas, Allergan, American Medical Systems, Boston Scientific, Coloplast, Glaxo-SmithKline, Ortho McNeil, Pfizer Inc, and Watson Pharma; an investigator for Allergan, Boston Scientific, Ortho McNeil, Pfizer Inc, and Watson Pharma and a speaker for Allergan, Astellas, |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | moderate problems (3), severe problems (4), or very severe problems (5)." | | | | | GlaxoSmithKline, Ortho McNeil, and Watson Pharma. Jon Morrow and Tamara Bavendam are employees of Pfizer Inc. Dana Creanga is a consultant for Pfizer Inc. Victor Nitti is an investigator for Schwarz Pharma, a consultant and lecturer for Pfizer Inc and Novartis, a consultant and investigator for Allergan, a consultant for Astellas, an advisor for Watson Pharma, Serenity Pharmaceuticals, and Coloplast Corp, and a lecturer for American Medical Systems. |
| Sand, 2004[367]<br>RCT<br>USA<br>N: 276 | Participants with overactive bladder who had ≥7 and ≤50 urge incontinence episodes/ week and ≥10 voids/24 hours were included. | Those with mixed stress and urge incontinence were eligible if the majority of the leakage accidents were related to urge incontinence. Participants with other causes of incontinence (e.g. urinary tract infection, interstitial cystitis, urinary tract obstruction, urethral diverticulum, bladder tumor, bladder stone) were excluded, as were those who had delivered a baby or undergone pelvic, vaginal or bladder surgery fewer than 6 months before study enrollment. Participants with a postvoid residual (pVR) urine volume of >150 ml at the time of screening were also excluded. In addition, those with clinically significant medical | ER Oxybutynin Chloride | Tolterodine Tartrate | ALZA Corporation, Mountain View, California | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
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| | | problems, or other organ abnormalities or pathologies for whom the administration of extended-release oxybutynin chloride or tolterodine tartrate would present an undue risk (medically uncontrolled cardiovascular, pulmonary, gastrointestinal, renal, endocrine, neurological, autoimmune, hematological, urological or psychiatric disorders, significantly reduced hepatic function or renal impairment) were excluded. Participants with hematuria or a positive urine culture, those with uncontrolled narrow-angle glaucoma, obstructive uropathy, myasthenia gravis, pelvic organ prolapse to the hymeneal ring, gastrointestinal conditions such as partial or complete obstruction, pre-existing severe gastrointestinal narrowing (pathologic or iatrogenic), decreased gastrointestinal motility (paralytic ileus, intestinal atony, chronic and severe constipation), or those at risk of gastric retention, were excluded. Subjects were recruited regardless of whether or not they had received prior treatment and regardless of their response to prior anticholinergic therapy. Any medications used for the treatment of overactive bladder, or medications with anticholinergic activity used to treat other conditions, had to be discontinued at screening. Participants who had taken an investigational drug within the last month or had known allergies or hypersensitivities to oxybutynin chloride, tolterodine tartrate, or components of the respective tablets | | | | |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | were excluded. Participants with current drug or alcohol abuse, female participants who were pregnant or breastfeeding, and participants who were not capable of following the study schedule or directions were excluded. Those who were not able to swallow the medication without chewing, crushing, biting, dividing or dissolving the capsule were also excluded. | | | | |
| Sand, 2009[368] Dmochowski, 2010[369] Pooled Country not reported N: 989 | Subgroup analysis of women aged ≥18 years with OAB of ≥6 months' duration with urinary urgency (≥1 severe urgency severity rating on the validated Indevus urgency severity scale); urinary frequency (average ≥10 voids/day, occurring at any time of the 24-hour period); and pure urge or mixed urinary incontinence with predominant UUI, with an average of ≥1 UUI episode/day. | Predominantly stress, insensate, or overflow incontinence (as determined by investigators), demonstrable renal or urinary disorders including neurogenic bladder disorders, significant renal disease, uninvestigated hematuria, current or a history of ≥3 episodes of urinary tract infection in the preceding year, bladder outlet obstruction, interstitial cystitis, or bladder cancer; subjects requiring long-term diuretic or estrogen therapy. | Trospium ER (60-mg capsules) | Placebo | Allergan, Inc. and Endo Pharmaceuticals (formerly Indevus Pharmaceuticals Inc.). | Peter K. Sand, MD, serves as an advisor and speaker for Allergan, Inc., Astellas Pharma US, Inc., Pfizer, Ortho-McNeil, Colplast, and Watson Pharmaceuticals. Dr. Sand has received grants from Allergan, Inc., Astellas Pharma US, Inc., Boston Scientific, Pfizer, Ortho-McNeil, Watson Pharmaceuticals, and Antares Pharma. Roger R. Dmochowski, MD, has financial relationships with Allergan, Inc., Pfizer, Watson Pharmaceuticals, Novartis, and Astellas Pharma US, Inc. David R. Staskin, MD, serves as a consultant and lecturer for Allergan, Inc., Pfizer, Watson |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | Pharmaceuticals, and Astellas Pharma US, Inc. Norman R. Zinner, MD, serves as a consultant, speaker, and/or for a clinical trial for Allergan, Inc., Actelion, Watson Pharmaceuticals, Pfizer, Novartis, Ferring Pharmaceuticals, and GlaxoSmithKline. Rodney A. Appell, MD (deceased), was on the advisory board for Pfizer, Boston Scientific, and Astellas Pharma US, Inc. Dr. Appell held stock in American Medical Systems. Dr. Appell served as an investigator for Allergan, Inc., Astellas Pharma US, Inc., Watson Pharmaceuticals, American Medical Systems, Boston Scientific, Solace Technology, Bulkamid, and Novasys Medical. |
| Sand, 2006[370] Sand, 2007[371] The Multicenter Assessment of Transdermal Therapy in Overactive | At least 18 years of age; have 1 or more symptoms of OAB (urge urinary incontinence, urgency, and/or frequency); be willing to discontinue any over-the-counter and/or | Urinary retention or uncontrolled narrow-angle glaucoma or risk for these conditions; demonstrated hypersensitivity to oxybutynin or other components of the product; had 1 or more treatable conditions that might cause urinary incontinence or | Transdermal oxybutynin 3.9 mg plus behavioral intervention of enhanced patient | Transdermal oxybutynin alone | Supported by Watson Laboratories (Morriston, NJ) | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Bladder with Oxybutynin trial USA N: 2592 | prescription treatment for OAB for the duration of the study; be capable of completing Quality of Life Questionnaires without assistance; be willing and able to comply with the protocol; and for females of childbearing potential, have a negative urine pregnancy test and have used a medically acceptable contraceptive method. | urgency (i.e., urinary tract infection, prostatitis, bladder tumor, bladder stone, prostate cancer); had received an investigational product within 30 days prior to participation in this study; had been previously treated with transdermal oxybutynin; resided in long-term care facilities or nursing homes; or were judged by the investigator to be unsuitable for enrollment into the study. | education | | | |
| Schagen van Leeuwen, 2008[372] RCT Germany, France, The Netherlands, Spain, Sweden, Switzerland and South-Africa N: 265 | Community-dwelling women of ≥65 years with symptoms of SUI or S-MUI for ≥3 consecutive months and ≥7 incontinence episodes per week as determined by the stress/urge incontinence questionnaire S/UIQ; predominant stress UI with ≥50% of incontinence episodes had to be due to stress UI; post-void residual ≤100mL. | Language or significant cognitive barriers (modified mini-mental state exam [3MS] score <80; >>4 urinary tract infections in the preceding year or a positive urine culture at visit 1, any nonpharmacological intervention (surgery, bulking agents, initiation of pelvic floor muscle training) for incontinence or prolapse within 3 months before study entry or throughout the study, increased suicidal risk (score ≥2 on question 9 of the Beck depression inventory [BDI-II]), history of syncopal episodes, or hepatic dysfunction, defined as serum glutamate–pyruvate–transaminase (alanine aminotransferase) or glutamate–oxaloacetate–transaminase (aspartate aminotransferase) ≥3 times upper limit of normal (ULN) or bilirubin ≥1.5 times ULN. | Duloxetine 20 mg twice daily | Placebo | Funding was provided by Eli Lilly and Company, and Boehringer Ingelheim, GmbH | Not reported |
| Staskin, 2006[39] Pooled Country not reported N: 3298 | Pooled analysis of 4 RCTs of men and women over 18 years with OAB (mean of ≥8 voids/24 hours, plus ≥1 incontinence episode or ≥1 urgency episode/24 | Women with a history of stress-predominant UI, positive cough-provocation test; no baseline assessment or no episodes of the individual diary symptom during the baseline diary screening period. | Solifenacin 5mg; Solifenacin 10mg; | Placebo | Yamanouchi Pharma Inc. | D. Staskin is a consultant for Pfizer, Ortho- McNeil, Indevus, Watson, Astellas and Novartis; A. Te is an |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | hours) | | | | | investigator for Sanofi- Aventis, Pfizer and NIH, and is a consultant for Sanofi-Aventis, Glaxo and Astellas. Source of funding: Astellas. |
| Staskin, 2007[47] Trospium Study Group. USA N: 601 | Not reported | Not reported | Trospium chloride 60 mg/day | Placebo | Esprit Pharma and Indevus Pharmaceuticals | Not reported |
| Staskin, 2004[373] RCT USA N: 658 | Not reported | Not reported | Trospium chloride 20-mg twice daily | Placebo | Not reported | Not reported |
| Staskin, 2009[33] RCT US N: 789 | Men and women with OAB who were 18 years or older; urge or mixed UI with a predominance of urge UI episodes as well as a mean of 8 or more urinary voids per day and 4 or more urge UI episodes per day on a baseline 3-day bladder diary regardless of whether symptoms were of neurological origin. The bladder diary was to be independently completed by the patient. Patients needed to have a mean voided volume of 350 ml or less during a 2-day urine collection period and a PVR of 250 ml or less on ultra-sonography or catheterization. | Potential participants were excluded from study based on criteria designed to rule out incontinence related to chronic illness, anatomical abnormality and concomitant medication. | OTG (oxybutynin chloride) | Placebo | Laboratory assessments were performed at Mayo Laboratory for Clinical Trials, Rochester, Minnesota | Not reported |
| Staskin, 2009[374] Study: Post-hoc A4,T3 | Adult men and women with OAB of ≥6 months' duration with urgency and | NR | Trospium chloride | Placebo | Supported by Allergen, Inc. and Indevus | Dr. Staskin has been an advisor and speaker for Allergen, |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| N: 1165 | an average of ≥1UUI episode/day and ≥10 toilet voids/day, as assessed using 3 -day bladder diaries | | | | Pharmaceuticals Inc. | Astellas Pharma, Pfizer and Watson. Professor Cardozo has received funding as a speaker, consultant or researcher from Astellas, Bioxell,Pfizer, Recordati, Rottapharm and Allergan within the last year |
| Staskin, 2009 [52] Study: pooled analysis Sample: 1165 | Adults with OAB of >=6 months' duration with urinary urgency (>=1 severe urgency severity rating/3 days on the validated Indevus Urgency Severity Scale [IUSS]), frequency (mean >=10 voids/day), and UUI (mean of>=1 UUI episode/day), as assessed using the 3-day bladder diaries. Subjects undergoing current pharmacological therapy for OAB eligible after a 7-day washout period prior to 3-day bladder diary data collection. | A mean total volume voided of >3000 ml/day; a mean voided volume of >250 ml/void; predominantly stress, insensate, or overflow incontinence; interstitial cystitis; bladder or prostate cancer; and a history of neurogenic bladder; clinically significant renal disease (defined as screening serum creatinine values >1.5mg/dl), urinary tract infection or clinically significant urinary retention (defined as postvoid residual urine volume >100ml); subjects who and been treated with or received trospium chloride in previous trials. | trospium XR 60 mg once daily | placebo | Supported by Allergan, Inc. and Endo Pharmaceuticals Inc. (formerly Indevus Pharamceuticals, Inc.)Editorial support funded by Allergan, Inc. | David R. Staskin is a consultant and speaker for Allergan, Astellas, Pfizer, and Watson. Matt T. Resenberg receives grant/research support from Ortho-McNeil and Sanofi-Synthelabo and serves as a consultant for Ortho-McNeil, Sanofi-Sythelabo, Pfizer, GlaxoSmithKline, Endo Pharmaceuticals (formerly Indevus Pharmaceuticals), Lilly, and Novartis. He is also on the Speakers' Bureau for Ortho-McNeil, Endo Pharmaceuticals, GlaxoSmithKline, Pfizer, Lilly and AstraZeneca. Peter K.Sand is an advisor and speaker for |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | Allergan, Astellas, Pfizer, Ortho, Colplast, and Watson. He has received grants from Allergan, Astellas, Boston Scientific, Pfizer, Ortho-McNeil, Watson, and Antares. Norman R.Zinner is a consultant, clinical trial investigator , and/or speaker for Allergan, Watson, Pfizer, Novartis, Ferring, GlaxoSmithKline and Astellas. Roger R. Dmochowski is a consultant for Allergan, Astellas, Novartis, Pfizer, and Watson. |
| Steers, 2005[45]<br>RCT<br>Canada, USA<br>N: 395 | Patients aged >18 years with symptoms of OAB for at least 6 months, capable of independent toileting. Irrespective of response to previous treatments patients had to have urge incontinence (>5 episodes per week), voiding frequency (>8 voids per day), and urgency (a strong desire to void at least once per day). Adequate method of contraception throughout the study for young women. | Contraindications to anticholinergic therapy (e.g., uncontrolled narrow-angle glaucoma, urinary retention or gastric retention); clinically significant stress incontinence, BOO and/or a postvoid residual urinary volume (PVR) of >200 mL ; pregnancy and lactation; genitourinary conditions that could cause urinary symptoms; fecal impaction or severe constipation (two or fewer bowel movements per week); urogenital surgery within the previous 6 months; bladder biopsy in the previous 30 days; indwelling catheter and intermittent self-catheterization; clinically significant disease; bladder-training program during the study; concomitant treatment with anticholinergic or | Darifenacin controlled-release tablets 7.5 mg | Placebo | This study was funded by Pfizer Inc. | Jacques Corcos is a member of the board of Sponsor; Georg Kralidis is an employee of Sponsor; Jenelle Foote is a study investigator funded by Sponsor. |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | antispasmodic drugs (including drugs with significant anticholinergic effects, e.g., imipramine), opioids and other drugs known to cause significant constipation, hormone replacement therapy (unless taken for >2 months), and drugs known to be potent cytochrome P450 3A4 inhibitors (e.g., ketoconazole). | | | | |
| Steers, 2007[375] Duloxetine OAB Study Group. Australia, Canada, USA N: 306 | Duloxetine OAB Study Group: women aged ≥18 years and to be identified as having predominant symptoms of OAB for ≥3 consecutive months before study entry; no SUI, including a negative cough stress. The case definition for OAB : bothersome urinary urgency or urge UI+ abnormal voiding frequency (≥2 hours mean daytime voiding interval, VI) documented by ≥2 days of recording of a screening urinary diary + urodynamic testing detected DOA or sensory urgency(urgent desire to void during the testing session in the absence of a DOA, with a maximum cystometric capacity (MCC) of □400 mL, both with no SUI, including a negative cough stress test at MCC after the urethral catheter was removed. | A postvoid residual urine volume (PVR) of >100 mL; a mean 24-hour total voided volume of < 3 L, documented on a 2-day frequency-volume chart (FVC); a positive urine culture (>100 000 colony-forming units/mL) or four or more UTIs during the year before enrolment; the regular use of medications for OAB symptoms within a month of enrolment; any previous use of duloxetine; continence surgery within 6 months or any major surgery within 3 months of enrolment; pelvic organ prolapse greater than ICS Stage II; any nonpharmacological intervention (e.g., electrical stimulation, bladder training, continence devices) within 3 months of enrolment; and pelvic floor muscle training 3 months before the study. | Duloxetine (40-mg twice daily). After 4 weeks, the dose of duloxetine was increased to 60-mg twice daily | Placebo | Eli Lilly and Company and by Boehringer Ingelheim GmbH. | William D. Steers and Sender Herschorn are paid consultants and study investigators funded by the sponsor. Karl J. Kreder, Kate Moore and Kris Strohbehn are study investigators funded by the sponsor. Ilker Yalcin and Richard C. Bump are employees of Eli Lilly and company. Sponsored by Eli Lilly and Company and by Boehringer Ingelheim GmbH. |
| Swift, 2003[376] Tolterodine Study Group 167 centers in | The Tolterodine Study Group: age 18 years or more with urinary frequency (58 | Demonstrable stress incontinence, total daily urine volume >3 L, any contraindications to antimuscarinic treatment, significant hepatic or renal | Tolterodine ER 4 mg capsules once daily, tolterodine IR | Placebo | This study was sponsored by a grant from Pharmacia | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Europe (n=89), North America (n=74), Australia and New Zealand (n=4)<br>N: 1235 | micturitions/24 hours) and urge incontinence (55 incontinence episodes/week), having had these symptoms of overactive bladder for 6 months or more whether or not they were treatment naïve, and irrespective of response to prior antimuscarinic therapy. | disease (with biochemical markers twice the upper limit of the normal reference range), symptomatic or recurrent urinary tract infections (diagnosed by urinalysis), interstitial cystitis (diagnosed by clinical suspicion), hematuria or bladder outlet obstruction, current electro-stimulation or bladder training therapy, an indwelling catheter or intermittent self-catheterization; pregnant or nursing women; women of child-bearing potential not using reliable contraceptive methods; other treatments for overactive bladder, such as anticholinergic drugs, or drugs that inhibit cytochrome P450 3A4 isoenzymes were not permitted; treatment with an investigational drug in the 2 months prior to study entry was prohibited. | tablets 2 mg twice daily | | Corporation. | |
| Szonyi, 1995[377]<br>RCT<br>Country not reported<br>N: 60 | Outpatients of either sex aged over 70 with symptoms of urinary frequency, urgency and urge incontinence were recruited. Patients had to be mobile, able to attend an outpatient department, able to keep a diary chart and willing to give consent. | Urinary infections at the time of recruitment, patients with severe hepatic or renal disease, glaucoma, or uncontrolled diabetes. Patients on concomitant anticholinergic therapy with imipramine were excluded. | Oxybutynin 2.5 mg twice daily | Placebo | Funded by Smith and Nephew Pharmaceuticals Ltd. | Not reported |
| Takei, 2005[378]<br>Japanese Tolterodine Study Group.<br>Japan<br>N: 293 | Eligible Japanese patients completing 12 weeks' treatment in a randomized, double-blind trial 20 continued with 12 months' open-label treatment with tolterodine ER 4 mg once daily, irrespective of (and without unblinding) the | Demonstrable stress incontinence, total daily urine volume >3 L, average volume voided/micturition >200 mL, significant hepatic or renal disease, any contraindication for anticholinergic treatment, symptomatic or recurrent urinary tract infection, interstitial cystitis, hematuria or bladder outlet obstruction, indwelling catheter or | Tolterodine ER | Oxybutynin, Placebo | Pfizer Japan Inc | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | treatment received during the doubleblind study (tolterodine ER 4 mg capsules once daily [Detrol capsule, Detrusitol, Pharmacia Corporation, Peapack, NJ], oxybutynin 3 mg tablets three times daily [Pollakisu, Aventis Pharma Ltd, Tokyo, Japan] or placebo). | intermittent self-catheterization, electro-stimulation or bladder training within 14 days before randomization or expected to commence during the study. Patients who were poorly compliant (missed >25% of prescribed medication), had an ongoing serious adverse event and pregnant or nursing women and women of childbearing potential not using reliable contraception were also excluded. | | | | |
| Tapp, 1990[379]<br>RCT<br>Country not reported<br>N: 37 | Postmenopausal women, with a mean age of 61 years (SD 13, range 41-87) | Not reported | Oxybutynin 5mg four times daily | Placebo | Support fromTillots Laboratories | Not reported |
| Tincello, 2000[380]<br>RCT<br>UK<br>N: 67 | Urodynamically confirmed diagnosis of idiopathic detrusor instability. | All patients were screened for UTI using commercially available reagent test-strips before cystometry, and those with positive results were deferred until appropriate treatment had been given. All patients had a urinary flow rate and residual volume volume measured. Fluid-filled rectal and vesical pressure catheters were used and cystometry performed with the patient either sitting or recumbent. Warm saline (37$^{o}$C) was used as the filling fluid, at 50-75 mL/min. At cystometric capacity, provocation tests were conducted with the patient standing, which consisted of three strong coughs, jumping on the spot, and hearing running water. The ICS criteria were used for diagnosis. Patients with a residual volume of ≥100mL and those with a maximum flow rate of <15mL/s were excluded. | Oxybutynin with salivary stimulant pastilles | Oxybutynin only | Drugs were supplied by Lorex Synthelabo and Thames Laboratories, Consolidated Chemicals, Wrexham, UK | Not reported |
| Thuroff, 1991[381]<br>Study: RCT | 15 years old and older complaining of symptoms | Pregnancy, congestive heart failure, severe renal/liver disease, | oxybutynin chloride | propantheline and placebo | Pharmcia Leo Therapeutics, | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| N: 169 | of frequency, urgency and/or incontinence, in whom cystometry findings were related to detrusor hyperactivity, whether idiopathic (unstable detrusor) or neurogenic (detrusor hyperreflexia) in origin. | myasthenia gravis, unable to swallow/uncooperative patient, hiatal hernia/reflux esophagitis, gastrointestinal tract obstruction, urinary tract obstruction, residual urine greater than 50ml, untreated urinary tract infection and hyperreflexia without urge | | | Helsingborg, Sweden provided the pharmaceutical preparations used in this study | |
| Toglia, 2010[382]<br>Study: Post-hoc Karram, 2009[316]<br>VENUS<br>N: 739 | Patients aged ≥18 years with OAB symptoms for ≥3 months | Reported previously-18995887 | Solifenacin | Placebo | Supported by Astellas Pharma US, Inc. and GlaxoSmithkline | Dr. Toglia is a consultant and speaker for Astellas; Dr. Ostergard is a consultant and speaker for Astellas, GlaxoSmithKline, Novartis, Pfizer and Watson. Dr. Fakhoury is an employee of Astellas. Mr. Andoh and Dr. Hussain were employees of Astellas at the time the study was conducted and have no other conflicts of interest to disclose |
| U.S. Food and Drug Administration[62]<br>Cardozo, 2008[63]<br>Study: SUNRISE<br>N: 865 | Male of female aged ≥18 years, from whom written consent had been obtained, and who were willing and able to complete a voiding diary correctly; symptoms of OAB (including urinary frequency, urgency or urgency incontinence) for ≥3 months and three or more episodes of urgency with or without incontinence in the last 3 days | NR | Solifenacin | Placebo | Research grant from Astellas Pharma Europe Ltd. | Linda Cardozo:Astellas, Lilly, UCB Pharma, Pfizer, Gynecare, Plethora, Cook, Organon; Elke Heβdörfer:Astellas, Pfizer, Bayer-Schering, Snaofi Aventis, Apogepha, Merckle Recordati, Lilly; Rodolfo Milani:Astellas, BARD, Recordati; Pedro Arano: Astellas; Luc Dewilde:Astellas,; Mark Slack:Astellas, |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | | | Pfizer, Lilly, Johnson & Johnson, Boston Scientific; Ted Drogendijk, Mark Wright and John Bolodeoku:employees of Astellas |
| U.S. Food and Drug Administration, 2004[383] Study: RCT Sample: 509 | Male or female, 18 years and older, with symptoms of overactive bladder for at least 6 months prior to enrollment | NR | trospium chloride | Placebo | Indevus Pharmaceuticals, Inc. | NR |
| U.S. Food and Drug Administration, 2004[35] Study: RCT Sample: 509 | Male or female, 18 years and older, with symptoms of overactive bladder for at least 6 months prior to enrollment | NR | trospium chloride | Placebo | Indevus Pharmaceuticals, Inc. | NR |
| U.S. Food and Drug Administration, 2004[43] Study: RCT Sample: 680 | Male and female subjects, aged 18 years and older with symptoms of overactive bladder for at least 6 months. Subjects must exhibit all of the following symptoms of overactive bladder during the run-in period: 1) incontinence 2) frequency of micturition -at least 8 times per 24 hours, on average, over the run-in period 3) urgency -at least once per 24 hours, on average, over the run-in period | | darifenacin | Placebo | NR | NR |
| U.S. Food and Drug Administration, 2004[384] Study: RCT N: 562 | Male and female subjects, aged 18 years and older with symptoms of overactive bladder for at least 6 months. Subjects must exhibit all of the | | darifenacin | Placebo | NR | NR |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | following symptoms of overactive bladder during the run-in period: 1) incontinence 2) frequency of micturition -at least 8 times per 24 hours, on average, over the run-in period 3) urgency -at least once per 24 hours, on average, over the run-in period | | | | | |
| U.S. Food and Drug Administration, 2007[40]<br>Study: RCT<br>N: 601 | Patients currently undergoing OAB therapy at the time of enrollment were required to undergo 7-day wash-out period, followed by 3-day baseline urinary diary collection, prior to randomization. Patients not under OAB therapy could begin treatment after 3-days of baseline diary collection | NR | trospium chloride ER | Placebo | Indevus Pharmaceuticals, Inc. | NR |
| U.S. Food and Drug Administration, 2007[46]<br>Study: RCT<br>N: 564 | Patients currently undergoing OAB therapy at the time of enrollment were required to undergo 7-day wash-out period, followed by 3-day baseline urinary diary collection, prior to randomization. Patients not under OAB therapy could begin treatment after 3-days of baseline diary collection | NR | trospium chloride ER | Placebo | Indevus Pharmaceuticals, Inc. | NR |
| U.S. Food and Drug Administration, 1998[41]<br>Anderson, 1999[385,386]<br>Study: RCT | Female patients aged 40 years and older with urge urinary incontinence. Non-pregnant women determined to be in good health; patients with mixed urinary incontinence, | Patients with known genitourinary conditions that may cause incontinence; those receiving any drugs that are considered effective in the treatment of incontinence less than the equivalent of 5 times the half-life of the drug and patients who | Oxybutynin as OROS-O5mg to 30mg/day based on achieved continence | oxybutynin IR 5mg to 20mg/day based on achieved continence | Alza Corporation Mountain View, California | M. Preik is an employee of Jansen-Cilag GmbH, Germany. A Albercht and M O'Connell are employees of ALZA Corp., USA. R. |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| OROS Oxybutynin Study Group N: 134 | provided that symptoms and/or signs of stress incontinence are not the predominant manifestation of UI and UUI episodes associated with urgency can be differentiated from urge incontinence episodes not associated with urgency; normotensive, with or without hypertensive medication; no postural hypotension; patients who successfully completed the screening urinary diary for 7 days | have been treated with anticholinergic agents for urge UI and were found to be refractory to these agents | | | | Anderson is a shreholder of Johson and Johson stock, is a member of the national advisory board for Ditropan Xl, and also acts on behalf of the Speaker's Bureau of Ortho-McNeil. |
| Vella, 2008[387] CT UK N: 228 | Women with a diagnosis of urodynamic stress incontinence (USI) or mixed USI and detrusor overactivity. | Concurrent prolapse or contraindications to drug therapy | 148 Duloxetine: 40 mg bid (140 women). 80 women received an escalating dose; initially 20 mg bid escalating to 40 mg bid after 2 weeks | None | Not reported | Jonathan Duckett has received funding to attend conferences from the makers of duloxetine. |
| Versi, 2000[42] Gleason, 1999[388] U.S. Food and Drug Administration, 1998[41] The Ditropan XL Study Group United States N: 226 | Patients were included only if they had previously responded to treatment with anticholinerigc medications or to a trial of oxybutynin before enrollment. | Patients with clinically significant medical problems, a postvoid residual urine volume over 100 mL, or other conditions in which oxybutynin is contraindicated were excluded. | Controlled-release oxybutynin tablets containing 5 mg oxybutynin or a placebo were placed in identical hard gelatin capsules and packaged in cards that provided total doses of 5, 10, 15, and 20 mg. | Immediate-release oxybutynin tablets containing 5 mg oxybutynin or a placebo were placed in identical hard gelatin capsules and packaged in cards that provided total | Grant from ALZA Corporation | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | | | doses of 5, 10, 15, and 20 mg. | | |
| Von Holst, 2000[389] RCT Germany N: 186 | Hysterectomised women age 40-65 years, with postmenopausal complaints, normal gynecological history and examination, serum estradiol <30pg/ml and follicle stimulating hormone >30IU/ml. | Use of sex hormones taken orally within the last 28 days; locally-applied sex hormones within the last 21 days or injectable sex hormones within the last 6 months. | 7-day-Estradiol patch (1.5mg estradiol/week or 50mg estradiol/24 hours). All patients received active drug therapy (7-days). Estradiol patch) for a further 3 months (three cycles). | Placebo once-weekly | Not reported | Not reported |
| Waetjen, 2005[390] RCT USA N: 417 | Postmenopausal women age 60-80 years, with a uterus and at least 5 years after menopause, with normal bone mineral density for age (z score not below –2.0 at the lumbar spine). | Use of estrogen or progestin within 3 months of randomization or having unexplained uterine bleeding, endometrial hyperplasia or an endometrium 5mm or more in double-wall thickness, abnormal mammogram, breast cancer, a history of metabolic disease, cancer, coronary disease, cerebrovascular disease, uncontrolled hypertension, uncontrolled thyroid disease, liver disease, fasting triglycerides more than 300 mg/dL, or fasting glucose more than 180 mg/dL. | 14mg of transdermal E2 per day. | Placebo | Grant from Berlex laboratories inc, Montville, NJ; Grant IND No. 98188 from the U.S. Food and Drug administration | Dr. Pinkerton is on the Berlex speaker's bureau |
| Wagg, 2006[391] Study: pooled analysis Sample: 1045 | Mean of ≥8 micturitions/24 hours and at least I of the following:1)a mean of ≥1 incontinence episode/24 hours; or 2)a mean of ≥1 urgency episode/24 hours | existing urinary tract dysfunction including postvoid residual volume of >150 or >200mL (depending on the trial), stress incontinence or mixed urinary incontinence with stress urinary incontinence predominating, neurologic dysfunction or injury affecting detrusor function or other lower urinary tract function, absolute urinary retention, grade III/IV prolapse with cystocele, recurrent or active urinary tract infection, bladder | solifenacin 5 or 10 mg | placebo | Yamanouchi Pharma Co., Ltd, Tokyo,Japan | Dr.Wagg has received consultancy, lecture, and writing fees relating to OAB from Yamanouchi. Dr.Sieber is a member of the speaker's bureau for Yamanouchi and was also a principal investigator. Professor Wyndaele |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | stones, current or previous bladder neoplasm, or history of interstitial cystitis. To discontinue any drug for treatment of urinary incontinence. Use of anticholinergic or antimuscarinic agents only allowed only if receiving a stable dose. Electro-stimulation, biofeedback, or bladder-training therapy not allowed during the study and not permitted during the 2 to 4 weeks immediately before the trials. | | | | has no financial involvement with Yamanouchi |
| Wang, 2006[392]<br>RCT<br>Taiwan<br>N: 74 | Age: 16 to 80 years; OAB for more than 6 months. No patients had taken anticholinergics or tricyclic antidepressants and none had been treated with pelvic floor muscle training, bladder training, or pelvic prolapse repair. | Pregnancy, neurologic disorders, diabetes mellitus, demand cardiac pacemaker or intrauterine device use, genital prolapse greater than Stage II of the International Continence Society grading system, a postvoid residual urine volume greater than 100 mL, overt urinary stress incontinence, a history of anriincontinence surgery, and urinary tract infection. | Electrical stimulation (ES) | Oxybutynin, placebo | Grant from National Science Council, Taiwan. | Not reported |
| Wang, 2009[393]<br>RCT<br>Taiwan<br>N: 73 | Women with OAB for more than 6 months, and the symptom of urgency three times or more per day. | Treatment with anticholinergics or tricyclic antidepressants; treatment with pelvic floor or bladder training and pelvic prolapse repair, participation in prior trials; pregnancy, neurologic disorders, diabetes mellitus, demand cardiac pacemaker or intrauterine device use, genital prolapse greater than the International Continence Society (ICS) grading system stage II, overt urinary stress incontinence, a history of antiincontinence surgery, urinary tract infection and patients receiving any OAB treatment during the 14-day washout/run-in period preceding randomization. | Vaginal electric stimulation (20 minutes per session, twice a week) or oxybutynin (2.5 mg) three times per day | Placebo three times per day | Grant from the National Science Council, Taiwan (NSC95-2314-B-182-062). | Not reported |
| Mazur, 1995[394]<br>RCT | Men and women with urge urinary incontinence or | Neurogenic bladder dysfunctions, urinary tract infections, | Propiverine hydrochloride | Propiverine hydrochloride | Not reported | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Country not reported<br>N: 185 | urgency | gastrointestinal obstructions, cardiovascular diseases, potential pregnancy. | 60 mg/d | 15, or 45 mg/d | | |
| Weil, 1998[395]<br>RCT<br>Country not reported<br>N: 105 | Women with a history of mild to moderate stress urinary incontinence, age between 18 and 70 years old, stress urinary incontinence was proven during urodynamic filling cystometry (up to 75% of bladder capacity) | Body weight deviating >45% from the Broca Index, arterial hypertension, urinary tract infections, positive urine cytology, with motor urge incontinence, a bladder compliance of <20 ml/cmH20, detrusor activity while coughing or >50 ml of residual urine after voiding; patients who had undergone extensive pelvic surgery or surgery to correct urinary incontinence; patients with vaginal descent grade III, or who had undergone pelvic irradiation; patients taking diuretics, adrenergic agonists or antagonists, other drugs which act on smooth muscle, or other drugs used to control urinary incontinence; patients using other treatments for urinary incontinence; patients with significant renal, hepatic, or hematological disease, a history of cardiac disease, pheochromocytoma, thyrotoxicosis, uncontrolled diabetes mellitus, seizures, mental impairment or a history of cerebrovascular accident; and pregnant or breast feeding women. Patients who were unlikely to be compliant with protocol requirements were also excluded. | Oral midodrine (5, 7.5 and 10 mg/day) | Placebo | Not reported | Not reported |
| Wein, 2007[396]<br>RCT analysis<br>Australia, Europe and North America<br>N: 1005 | Men and women aged ≥18 years with symptoms of urinary frequency (≥8 voids/24 hours) and urgency UI (≥5 episodes/ week) for ≥6 months. | Stress UI, as determined by the investigator and confirmed by a cough provocation test; significant hepatic or renal disease, current or recurring UTI, clinically relevant BOO (defined by investigator's judgment based on a patient's history), indwelling catheter or intermittent self-catheterization, and any condition for which antimuscarinic | Tolterodine-ER (4 mg) | Placebo | Not reported | Alan J. Wein is a consultant to Astellas, Novartis, Pfizer and Indevus; Vik Khullar is a speaker and investigator for Pfizer on tolterodine; Joseph T. Wang and Zhonghong Guan are employees of Pfizer |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | treatment was contraindicated; anticholinergic drug or treatment for OAB during the 14-day washout/run-in period preceding randomization, and those with a mean micturition volume of 200 mL or total daily volume of 3 L on bladder diaries. | | | | Inc. |
| Weinstein, 2006[397] DESIRE (Duloxetine Efficacy and Safety for Incontinence in Racial and Ethnic populations). USA N: 3983 | DESIRE Study Group: women >18 years old with stress urinary incontinence (>1 episode/week) or stress predominant mixed incontinence (frequency of stress at least twice higher than urge) | Prior treatment with monoamine oxidase inhibitors and duloxetine; depression; diabetic peripheral neuropathic pain | Duloxetine 40 mg twice daily | Not controlled trial | Funded by Eli Lilly and Boehringer Ingelheim. | Not reported |
| Wiseman, 1991[398] RCT UK N: 37 | Men and women over 70 mobile and able to use a toilet or commode independently, able to understand and complete a bladder diary chart properly, and able to give informed consent with symptoms of urinary frequency and urge incontinence caused by detrusor instability. | Urinary infections during the previous four weeks; women with bladder neck prolapse; and patients with severe liver or renal disease, uncontrolled diabetes mellitus, glaucoma, or other contraindications to antimuscarinic treatment; taking other antimuscarinic drugs, calcium channel blockers, and non-steroidal anti-inflammatory drugs as these all affect the bladder. | Terodiline 25 mg +bladder retraining | placebo+ bladder retraining | Not reported | Not reported |
| Yalcin, 2006[399] Pooled USA N: 1133 | 1133 women with SUI who were enrolled in two double-blind, controlled, randomized studies of duloxetine versus placebo having predominant SUI that was diagnosed using a clinical algorithm demonstrated to be 90.2% predictive of urodynamic stress. | Reported previously in individual studies | Duloxetine 80mg/day | Placebo | This study was sponsored by Eli Lilly and Company and Boehringer Ingelheim. | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Yalcin, 2004[400] the Duloxetine UI Study Group one phase 2 study in the US, and 3 phase 3 studies in 16 countries in Africa, Australia, Europe, and North and South America<br>N: 1913 | Women with SUI of at least 3 months' duration predominant symptom of SUI with a weekly IEF >4 in phase 2 and IEF >7 in the 3 phase 3 studies, where an episode was defined as an easily noticeable leakage of urine that wet a pad or clothing, and that occurred with a physical stress such as coughing, sneezing, or exercising; the lack of predominant symptoms of enuresis or urge urinary incontinence, daytime frequency mL per minute, without pressure measurements; a positive cough stress test (visualization of urine leakage concurrent with a cough) and a positive stress pad test (leakage of >2.0 g). | Inability to tolerate filling to 400 mL a first sensation of bladder filling <100 mL, or who had no sensation at any time during the filling; previous continence surgery. | All phase 3 studies included only duloxetine 40 mg bid as an active treatment. The phase 2 study included 3 duloxetine treatment groups (20 mg qd, 20 mg bid, and 40 mg bid); however, data from subjects taking duloxetine doses <40 mg bid were not included in the analyses to avoid any potential confounding effects of lower efficacy (duloxetine 40 mg bid has been demonstrated to be the optimum dose). Subgroup analysis was performed within each treatment group based on baseline incontinence severity. | Placebo | This work was sponsored by Eli Lilly and Company | Not reported |
| Yamaguchi, 2007[401]<br>Study: RCT<br>N: 1593 | Men and women aged ≥20 years and with symptoms of OAB reported for ≥6 months were eligible for screening and study enrolment. To be eligible for | Significant BOO, an assessment based on measuring the postvoid residual urine volume(PVR); patients with a PVR of ≥100mL; presence of BOO symptoms assessed by investigators(who were all urologists); urinary retention, demonstrable | solifenacin 5mg or 10mg | Propiverine or placebo | Funded and sponsored by Astellas Pharma Inc.(formerly Yamanouchi Pharmaceutica | Osamu Yamaguchi and Eji Marui are consultants to Atellas Pharma |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | randomization after the 2-week placebo run-in period, patients had to report a mean number of voids/24 hr of ≥8, ≥3 episodes of urgency and/or ≥3 episodes of urgency incontinence during a 3-day voiding - diary period. | stress incontinence, bladder stones, UTI, interstitial cystitis, previous or current malignant disease of the pelvic organs; those taking concomitant anticholinergic medications; known hypersensitivity to anticholinergic medications or lactose. | | | l Co. Ltd), Tokyo, Japan | |
| Zellner, 2009[402]<br>Study: RCT<br>N: 1659 | Male or female outpatients aged ≥18 years with urinary frequency ≥8 micturitions per day) and urge incontinence (≥5 episodes per week), as verified in the micturition diary. | Patients were excluded if they did not complete the micturition diary correctly for 7 consecutive days to confirm that they met the inclusion criteria and to establish baseline symptoms and urgency severity before the entrance visit. Based on this diary, patients with a total daily urine volume ≥2.8 L (determined by total daily urine for 2 days, divided by 2), a mean micturition volume of >250 mL, and/or a clinically significant bladder outlet obstruction (ie, postvoid residual urine volume of >100 mL, determined via sonography) were also excluded as were those with an indwelling catheter or intermittent self-catheterization. Those with other significant medical problems or urogenital conditions, including urinary tract infection at the screening visit (or before or at the entrance visit), interstitial cystitis and/or hematuria (as determined via urinalysis), contraindications to anticholinergic therapy (eg, untreated narrow-angle glaucoma, mechanical gastrointestinal stenosis, myasthenia gravis syndrome), tachycardiac arrhythmia, severe psychiatric illnesses, or hypersensitivity to trospium chloride or oxybutynin or 1 of the vehicle ingredients, were also | Oxybutynin Hydrochloride | Trospium Chloride | Dr. R. Pfleger GmbH (Bamberg, Germany) sponsored this study. Petra Schwantes, PhD, Biomedical Services, assisted with the writing of this article; she received compensation from the sponsor. | Petra Schwantes, PhD, Biomedical Services, assisted with the writing of this article; she received compensation from the sponsor. The authors have indicated that they have no other conflicts of interest regarding the content of this article. |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | | excluded. Patients who had participated in a bladder-training program, or in another study within 30 days before screening, were also prohibited, as were those undergoing electrostimulation programs. Further reasons for exclusion were alcohol and/or drug abuse, pregnancy, breastfeeding, and insufficient contraception among women of childbearing age. | | | | |
| Zinner, 2005[403]<br>RCT<br>US<br>N: 76 | Males and non-pregnant (nor breastfeeding) females aged 18–85 years with urge incontinence (>4 significant incontinent episodes per week, where significant was defined as leakage that would normally require a change of clothing or absorbent pad) and urinary frequency (≥8 voids per day, on average). | Neurogenic bladder or stress incontinence, contraindications to antimuscarinic therapy, previous bladder or prostate surgery, bladder stones (as demonstrated by pelvic x-ray or ultrasound), acute or chronic urinary tract infection, significant urinary outflow obstruction, and clinically significant concomitant disease; Patients intending to start or modify either an existing bladder training program or existing treatment with thyroid or estrogen hormone replacement therapy; those who had received treatment with drugs that affect bladder function/urine production in the previous 2 weeks. | Darifenacin controlled-release tablets 15 mg and 30 mg once/daily | Oxybutynin 5 mg three times daily, Placebo | IND+Grant | Disclosure |
| Zinner, 2008[404]<br>CT<br>Country not reported<br>N: 500 | Men and women (>18 years of age) with OAB symptoms [an average of > 8 micturitions/ 24 hours; >1 urgency episode/24 hours, with or without urgency urinary incontinence; >2 scores on the Patient Perception of Bladder Condition (PPBC) questionnaire; naive to darifenacin, dissatisfaction with previous oxybutynin ER or | Mean daily urinary volume >3000 ml or a mean volume micturition of >300 ml (in micturition diary); clinically predominant and bothersome stress urinary incontinence, urinary retention, clinically significant bladder outlet obstruction, an indwelling catheter or intermittent self-catheterization; significant medical problems or urogenital conditions, including neurogenic bladder, cystocele or distal pelvic organ prolapse, frequent urinary tract infections (>3 over the preceding year) or urogenital surgery in the | Darifenacin 7.5 mg once daily (qd) for the first 2 weeks with voluntary up-titration to darifenacin 15 mg if the patient required additional efficacy, and treatment was well tolerated | Placebo | Funding for this study and for the editorial and project management services of ACUMED in the preparation of this manuscript were provided by Novartis Pharma AG. | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| | tolterodine ER administration after at least 1 week of taking these medications. | previous year or unexplained hematuria at screening; bladder-training program or any electro-stimulation therapy within 2 weeks prior to screening; pregnancy or inadequate contraception. Concomitant treatment with anticholinergics, antispasmodics, serotonin-noradrenaline-reuptake-inhibitors; cholinergic agonists, cholinesterase inhibitors (e.g. bethanecol, donepezil and rivastigmine), potent inhibitors of cytochrome CYP3A4 (e.g., ketoconazole, itraconazole, ritonavir, nelfinavir, clarithromycin and nefazadone), potent P-glycoprotein inhibitors (e.g. cyclosporine and verapamil), drugs with significant anticholinergic side effects (e.g. tricyclic antidepressants, selective-serotonin-reuptake-inhibitors and first generation antihistamines) or any other investigational drug. | | | | |
| Zinner, 2006[405]<br>RCT<br>Country not reported<br>N: 445 | Men and women aged >18 years with a history of OAB for >6 months and on average >1 urge incontinence episodes/day; >8 micturitions/day; >4 urgency episodes/day and mean warning time of <15 minutes during 12 consecutive hours. | Stress urinary incontinence; marked cystocele or pelvic prolapse; those taking the following drugs in the 2 weeks prior to the screening visit: anticholinergic/antispasmodic drugs, or those with anticholinergic effects, cholinergic agonists, potent cytochrome P450 3A4 inhibitors, opioids and drugs that cause significant constipation; those who have contraindications to anticholinergic drugs, clinically significant bladder outlet obstruction, have the intention to start a bladder training program and an indwelling catheter or intermittent self-catheterization. | Darifenacin 15 mg controlled release qd | Placebo | This study was funded by Novartis Pharma AG | Not reported |

**Appendix Table F27. Pharmacological treatments for female UI (continued)**

| Reference Study, Sample | Inclusion Criteria | Exclusion Criteria | Active | Control | Sponsorship | Conflict of Interest |
|---|---|---|---|---|---|---|
| Zinner, 2004[37]<br>Trospium Study Group.<br>USA<br>N: 523 | The Trospium Study Group: male and female 18 years or older with OAB symptoms for at least 6 months; with urinary urgency, a minimum voiding frequency of 70 voids per week with at least 7 urge incontinence episodes per week. | Predominantly stress UI , insensate or overflow in nature; with neurogenic bladder disorders, significant renal disease, uninvestigated hematuria and urinary tract infection at washout or more than twice during the prior year; significant bladder outlet obstruction (post-void residual volume >100 ml); concurrent use of any anticholinergic drug or other drug therapy for overactive bladder within 21 days before randomization, history of bladder surgery within 6 months before randomization, bladder cancer or interstitial cystitis were excluded from study; diuretic use, estrogen therapy and nonmedical bladder therapy that was not part of a stable, long-term program. | 20 mg trospium twice daily | Placebo | Indevus Corporation | Not reported |
| Zinner, 2002[406]<br>RCT<br>Europe, United States, Canada, Australia, and New Zealand<br>N: 1015 | Men and women aged 18 and older with urinary frequency (>8 micturitions/24 hours), urge incontinence (>5 episodes per week), symptoms of overactive bladder for 6 months or more, and ability and willingness to complete micturition charts. | Stress incontinence; total daily urine greater than 3 L; significant hepatic or renal disease; symptomatic or recurrent urinary tract infections; interstitial cystitis, hematuria, or clinically relevant bladder obstruction; bladder training or electro-stimulation within 14 days before randomization; and indwelling catheter or intermittent self-catheterization, pregnancy and breastfeeding; unreliable contraceptive methods; Treatments for overactive bladder (excluding estrogen treatment started more than 2 months before randomization), anticholinergic drugs, or potent inhibitors of cytochrome P450 3A4 isoenzymes. | Tolterodine ER 4 mg once daily | Placebo | Pharmacia Corporation | Not reported |
| Zinner, 2005[407]<br>Pooled<br>USA<br>N: 1157 | Symptoms of urgency, an average of 10 or greater toilet voids daily and an average of 1 or greater UUI episode daily. | Reported previously | 20 mg trospium chloride twice daily | Placebo | Indevus, Lilly, Pfizer, Watson, Bayer and Glaxo Smith Kline | Not reported |

NR = Not reported

**Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI**

| Reference | Study | Masking of the Treatment Status | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Sample Size Justification |
|---|---|---|---|---|---|---|
| Abrams, 2006[221] | 1032 Study Group. | Double blind | Yes | Unclear | Adequate | No |
| Abrams, 1998[220] | RCT | double-blind | Yes | NR | Adequate | Yes |
| Abrams, 2008[50] | Pooled | Double blind | Yes | Previously reported | Adequate | No |
| Altan-Yaycioglu, 2005[222] | RCT | Single blind | Not stated | Unclear | Adequate | No |
| Anderson, 1999[385] U.S. Food and Drug Administration, 1998[41] | OROS Oxybutynin Study Group | Double blind | No | Not reported | Adequate | No |
| Appell, 1997[223] | Pooled | Double blind | Yes | Unclear | Adequate | No |
| Appell, 2001[224] | OBJECT (Overactive Bladder: Judging Effective Control and Treatment) | Double blind | Yes | All medications were encased in identical gelatin capsules | Adequate | No |
| Armstrong, 2005[225] | RCT | Double blind | No | Previously reported | Previously reported | Previously reported |
| Armstrong, 2007[226] | Pooled | Double blind | Yes | Previously reported | Adequate | Previously reported |
| Rios, 2007[358] | RCT | Double blind | Yes | Unclear | No | Yes |
| Barkin, 2004[227] | UROMAX Study Group. | Double blind | Yes | Unclear | Adequate | No |
| Bent, 2008[228] | RCT | Double blind | Yes | Adequate | Adequate | Yes |
| Birns, 2000[229] | The Oxybutynin CR Clinical Trial Study | double-blind | Yes | Adequate | Adequate | Yes |
| Blom, 1995[230] | RCT | Single blind | No | NR | NR | No |
| Bodeker, 2010[231] | Post-hoc | Double blind | Reported previously[408] | Reported previously[408] | Adequate | Previously reported |
| Brubaker, 2008[232] | Pelvic Floor Disorders Network. | Double blind | Not stated | Unclear | Adequate | Yes |
| Brunton, 2010[233] | RCT | Double-Blind | NR | NR | Adequate | NR |
| Bump, 2003[108] | Duloxetine Urinary Incontinence Study Group. | Double blind | No | Previously reported | Adequate | Yes |
| Bump, 2008[234] | Pooled | Combination | Not stated | Previously reported | Previously reported | No |
| Burgio, 2001[235] | RCT | Double blind | No | Unclear | Not reported | No |
| Burgio, 2000[236] | RCT analysis | Double blind | Not reported | Not reported | Not reported | No |
| Burgio, 1998[237] | RCT | Double blind | Yes | Unclear | No | No |
| Burgio, 2008[238] | Urinary Incontinence | Open label | Yes | Unclear | Not reported | Yes |

**Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)**

| Reference | Study | Masking of the Treatment Status | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Sample Size Justification |
|---|---|---|---|---|---|---|
| | Treatment Network | | | | | |
| Burgio, 2010[241] | RCT | Open-label | Yes | NR | Not-adequate | Yes |
| But, 2010[242] | SOLIDAIR | Open-Label | Yes | NR | Not-adequate | NR |
| Cardozo, 2006[244] | Pooled | Double blind | No | Previously reported | Adequate | Previously reported |
| Cardozo, 2004[245] | RCT | Double blind | Yes | Adequate | Adequate | Yes |
| Cardozo, 2004[53] | RCT | Double blind | No | Previously reported | Adequate | Yes |
| Cardozo, 2010[243] | RCT followed by open-label | Double blind | Yes | Adequate | Adequate | Yes |
| Cardozo, 2008[63] | SUNRISE | Double blind | Yes | NR | Adequate | Yes |
| Castro, 2008[246] | RCT | Single blind | No | NR | Not Adequate | Yes |
| Castro-Diaz, 2007[247] | Duloxetine Dose Escalation Study Group. | Double blind | Yes | Unclear | Adequate | Yes |
| Chancellor, 2001[248] | RCT | Double blind | No | Not reported | Adequate | No |
| Chancellor, 2008[249] | The ABLE trial | Open label | Yes | Adequate | Adequate | Yes |
| Chancellor, 2010[250] | Post-hoc | Double blind | NR | Unclear | NR | NR |
| Chapple, 2005[251] | RCT | Double blind | No | Adequate | Adequate | Yes |
| Chapple, 2007[252] | RCT | Double blind | No | Adequate | Adequate | No |
| Chapple, 2008[253] | RCT analysis | Double blind | No | Adequate | Previously reported | No |
| Chapple, 2007[254] | RCT | Double blind | Yes | Unclear | Adequate | Yes |
| Chapple, 2005[255] | Pooled | Double blind | Yes | Previously reported | Previously reported | No |
| Chapple, 2004[258] | RCT | double-blind | Yes | NR | Adequate | Yes |
| Chapple, 2004[259] | RCT | double-blind | No | NR | NR | NR |
| Chapple, 2007[254] | RCT | Double blind | yes | Unclear | Adequate | Yes |
| Chapple, 2007[256] | STAR study group | Double blind | Yes | Adequate | Adequate | Previously reported |
| Chapple, 2005[61] | The STAR study group. | Double blind | Yes | Adequate | Adequate | Yes |
| Chapple, 2006[257] | RCT | Single-blind | No | NR | Not adequate | Yes |
| Chapple, 2004[54] | RCT | Double blind | NR | NR | Adequate | Yes |
| Chompootaweep, 1998[260] | RCT | NR | NR | Unclear | Adequate | No |
| Choo, 2008[261] | RCT | Double blind | No | NR | Adequate | No |
| Chu, 2009[262] | RCT | Double blind | No | Adequate | Adequate | Yes |
| Corcos, 2006[263] | Uromax Study Group | Double blind | Yes | NR | Adequate | Yes |
| Davilla, 2001[264] | Transdermal Oxybutynin Study | Double blind | Not stated | Unclear | Adequate | Yes |

**Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)**

| Reference | Study | Masking of the Treatment Status | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Sample Size Justification |
|---|---|---|---|---|---|---|
| | Group. | | | | | |
| Dessole, 2004[265] | RCT | Double blind | Yes | Adequate | Adequate | Yes |
| Diokno, 2003[266] Anderson, 2006[268] Chu, 2005[267] | OPERA (Overactive bladder: Performance of Extended Release Agents) trial | Double blind | Yes | Unclear | Adequate | No |
| Dmochowski, 2002[269] | Transdermal Oxybutynin Study Group. | Double blind | No | Unclear | Adequate | Yes |
| Dmochowski, 2008[48] | RCT | Double blind | Not stated | Unclear | Adequate | No |
| Dmochowski, 2005[270] | Transdermal Oxybutynin Study Group. | Double blind | Yes | Previously reported | Previously reported | Previously reported |
| Dmochowski, 2003[271] | Transdermal Oxybutynin Study Group. | Double blind | Yes | Unclear | Adequate | Yes |
| Dmochowski, 2003[272] | Duloxetine Urinary Incontinence Study Group | Double blind | Yes | Adequate | Adequate | Yes |
| Dmochowski, 2007[273] | RCT | Double blind | Yes | Previously reported | Previously reported | Previously reported |
| Dmochowski, 2010[369] | RCT | Double blind | Yes | Reported previously | Adequate | Yes |
| Dmochowski, 2010[274] | RCT | Double blind | Yes | Unclear | Adequate | Yes |
| Dorschner, 2000[275] | RCT | Double blind | No | Unclear | Adequate | No |
| Drutz, 1999[276] | RCT | Double blind | No | NR | Adequate | Yes |
| DuBeau, 2005[277] | RCT analysis | Double blind | No | Adequate | Adequate | Yes |
| Duckett, 2007[278] | Observational study | Open label | No | Not relevant | Not relevant | No |
| Enzelsberger, 1995[279] | RCT | Open label | Not reported | Adequate | Adequate | No |
| Fitzgerald, 2008[239] | Urinary Incontinence Treatment Network. | Open label | Yes | Unclear | Not reported | Yes |
| Flynn, 2009[280] | RCT | Double blind | Yes | Adequate | Adequate | Yes |
| Foote, 2005[281] | Pooled | Double blind | Yes | Unclear | Adequate | No |
| Freeman, 2003[282] | RCT analysis | Double blind | No | Adequate | No | Previously reported |
| Gahimer, 2007[283] | The duloxetine exposures integrated | Open label | Yes | Previously reported | Not relevant | No |

**Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)**

| Reference | Study | Masking of the Treatment Status | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Sample Size Justification |
|---|---|---|---|---|---|---|
| | safety database | | | | | |
| Ghei, 2005[284] | RCT | Double blind | Yes | Adequate | Not reported | Yes |
| Ghoniem, 2005[285] | Duloxetine/Pelvic Floor Muscle Training Clinical Trial Group. | Double blind | Yes | Adequate | Adequate | Yes |
| Gleason, 1999[388] | Ditropan XL Study Group | Open label | No | Not relevant | Not relevant | No |
| Goode, 2002[286] | RCT | Double blind | No | NR | Adequate | No |
| Goode, 2004[287] | RCT analysis | Double blind | No | Not reported | Not reported | No |
| Gupta, 1999[288] | RCT | Open label | No | Not reported | Not relevant | No |
| Gupta, 1999[289] | Pooled | Double blind | Not reported | Not reported | Not reported | No |
| Gousse, 2010[290] | RCT | NR | NR | NR | Adequate | NR |
| Haab, 2006[291] | RCT analysis | Open label | Yes | Not relevant | Not relevant | No |
| Haab, 2005[292] | RCT analysis | Open label | Yes | Previously reported | Previously reported | Previously reported |
| Haab, 2004[293] | RCT | Double blind | Yes | Adequate | Adequate | Yes |
| Halaska, 2003[294] | RCT | Double blind | Yes | Unclear | Adequate | No |
| Herschorn, 2004[295] | RCT | Open label | Yes | Adequate | No | No |
| Herschorn, 2010[296] | VECTOR | double-blind | Yes | NR | Adequate | Yes |
| Herschorn, 2008[297] | RCT | Double blind | Yes | NR | Adequate | Yes |
| Hill, 2006[44] | Darifenacin Study Group. | Double blind | Yes | Unclear | Adequate | Yes |
| Ho, 2010[298] | RCT | Open label | Yes | Unclear | Adequate | NR |
| Holtedahl, 2000[299] | RCT analysis | NR | Yes | Not adequate | Adequate | Reported previously |
| Holtedahl, 1998[300] | RCT | Not reported | No | Unclear | Adequate | Yes |
| Homma, 2006[301] | RCT analysis | Double blind | No | Not reported | Adequate | No |
| Homma, 2004[302] | RCT | Double blind | Yes | Not reported | No | No |
| Homma, 2003[303] | Japanese and Korean Tolterodine Study Group | Double blind | Yes | Not reported | Adequate | Yes |
| Hurley, 2006[304] Viktrup, 2007[305] | Duloxetine Urinary Incontinence Study Group | Double blind | No | Previously reported | Not reported | Pooled analysis |
| Ishiko, 2001[306] | RCT | Open label | No | Unclear | Adequate | No |
| Jackson, 1999[307] | RCT | Double blind | Not reported | Not reported | Adequate | Yes |
| Jacquetin, 2001[308] | RCT | Double blind | Yes | Unclear | No | Yes |
| Johnson, 2005[309] | RCT analysis | Double blind | Not reported | Adequate | Adequate | Yes |

**Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)**

| Reference | Study | Masking of the Treatment Status | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Sample Size Justification |
|---|---|---|---|---|---|---|
| Jonas, 1997[310] | International Study Group | Double blind | Not stated | Unclear | Adequate | No |
| Junemann, 2000[312] | RCT | Double blind | No | NR | NR | NR |
| Junemann, 2005[313] | RCT | Double blind | Yes | Unclear | Not reported | No |
| Junemann, 2006[311] | RCT | Double blind | No | NR | NR | NR |
| Kaplan, 2010[314] | RCT | Double blind | NR | NR | NR | Yes |
| Karademir, 2005[315] | RCT | Open label | No | Not reported | Adequate | No |
| Karram, 2009[316] | VENUS | Double blind | No | NR | Adequate | Yes |
| Kelleher, 2006[318] | RCT | Double blind | No | Previously reported | Previously reported | No |
| Kelleher, 2002[319] | RCT | Double blind | Yes | Unclear | Adequate | No |
| Kelleher, 2008[320] | Pooled analysis | Double blind | NR | Unclear | Adequate | NR |
| van Kerrebroeck, 2004[321] | Duloxetine Urinary Incontinence Study Group. | Double blind | Yes | Adequate | No | Yes |
| Van Kerrebroeck, 2001[322] | Tolterodine Study Group. | Double blind | Yes | Unclear | Adequate | No |
| Khullar, 2004[323] | RCT | Double blind | Yes | Adequate | Adequate | Yes |
| Khullar, 2008[324] | Pooled | Double blind | Yes | Previously reported | Previously reported | Previously reported |
| Kinchen, 2005[325] | RCT | Double blind | Yes | Adequate | Adequate | Yes |
| Kreder, 2003[326] | RCT analysis | Single blind | No | Unclear | Adequate | No |
| Lackner, 2008[327] | RCT | Double blind | Yes | All study personnel were blinded to group assignment until data collection was complete. | Adequate | Yes |
| Landis, 2004[328] | RCT | Double blind | No | Previously reported | No | Previously reported |
| Lee, 2002[329] | RCT | Double blind | Yes | Not reported | Adequate | No |
| Lee, 2010[330] | Propiverine study on overactive bladder including urgency data | Double blind | No | Not adequate | Adequate | Yes |
| Lehtoranta, 2002[331] | RCT | Double blind | Yes | Not reported | Not reported | No |
| Leung, 2002[332] | RCT | Open label | Yes | Not reported | Adequate | Yes |
| Lin, 2008[333] | RCT | Double blind | Yes | Adequate | No | Yes |
| Lipton, 2005[334] | RCT | Double blind | No | Unclear | Not reported | Yes |

**Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)**

| Reference | Study | Masking of the Treatment Status | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Sample Size Justification |
|---|---|---|---|---|---|---|
| Lose, 2000[335] | RCT | Open label | Yes | Unclear | Adequate | Yes |
| MacDiarmid, 2005[336] | Pooled | 2 Double blind and one open label | Yes | Previously reported | Previously reported | Previously reported |
| Madersbacher, 1999[337] | RCT | Double blind | Yes | Not reported | Adequate | No |
| Malhotra, 2010[338] | RCT | Double blind | Yes | NR | Not adequate | Yes |
| Malone-Lee, 2009[339] | RCT | Double blind | No | Unclear | Adequate | Yes |
| Malone-Lee, 2009[340] | RCT | Double blind | Yes | Adequate | No | No |
| Mattiasson, 2009[65] | SOLAR | Single blind | Yes | NR | Adequate | Yes |
| Mattiasson, 2003[341] | RCT Tolterodine Scandinavian Study Group | Single blind | Yes | Adequate | Adequate | Yes |
| Milani, 1993[342] | RCT | Double blind | No | Unclear | Not relevant | No |
| Millard, 1999[343] | RCT | Double blind | Yes | Unclear | No | Yes |
| Millard, 2004[344] | Duloxetine UI Study Group | Double blind | Yes | Adequate | No | Yes |
| Moore, 1990[345] | RCT | Double blind | No | Adequate | Adequate | NR |
| Naglie, 2002[346] | RCT | Double blind | Yes | Unclear | Adequate | Yes |
| NCT00269750, 2005 [57] | RCT | double-blind | NR | NR | NR | NR |
| NCT00168454, 2008 [55] | RCT | double-blind | NR | NR | NR | NR |
| NCT00444925, [58] | RCT | double-blind | NR | NR | NR | NR |
| NCT00536484, [59] | RCT | double-blind | NR | NR | NR | NR |
| NCT00178191, [56] | RCT | double-blind | NR | NR | NR | NR |
| Nitti C, 2007[347] | RCT | Double blind | No | Adequate | Adequate | No |
| Norton, 1994[348] | RCT | Double blind | Yes | Not adequate | Adequate | Yes |
| Norton, 2002[349] Sahai, 2006[350] | Duloxetine Urinary Incontinence Study Group. | Double blind | Yes | Adequate | Adequate | Yes |
| , 1993[351] | Elderly American Multicenter Study Group | Double blind | Yes | Unclear | Adequate | Yes |
| Ozdedeli, 2010[352] | RCT | Open-label | No | Not adequate | Adequate | NR |
| Peters, 2009[353] | Overactive Bladder Innovative Therapy | Open label | No | Unclear | Adequate | Yes |
| Pontari, 2010[355] | RCT | Double blind | Yes | NR | Not adequate | No |
| Preik, 2004[386] | RCT | Double blind | No | Not reported | Adequate | No |
| Rentzhog, 1998[356] | RCT | double-blind | No | NR | Adequate | Yes |

**Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)**

| Reference | Study | Masking of the Treatment Status | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Sample Size Justification |
|---|---|---|---|---|---|---|
| Richter, 2010[357] | ATLAS | Open label | Yes | Not adequate | Adequate | Yes |
| Robinson, 2007[359] | The Tamsulosin Study Group | double-blind | No | Adequate | Adequate | Yes |
| Rogers, 2009[360] | RCT | double-blind | No | NR | Adequate | NR |
| Rogers, 2009[362] | RCT | Open label | No | Previously reported | Previously reported | Previously reported |
| Rogers, 2008[361] | RCT | Double blind | No | Unclear | Adequate | Yes |
| Rudy, 2006[363] | RCT | Double blind | Yes | Unclear | Adequate | Yes |
| Rudy, 2006[36] | RCT analysis | Double blind | Yes | Unclear | Adequate | Yes |
| Rufford, 2003[364] | RCT | Double blind | No | Adequate | Adequate | Yes |
| Salvatore, 2005[365] | RCT | Open label | No | Not reported | Not reported | Yes |
| Sand, 2009[366] | Pooled | Double blind | No | Previously reported | Adequate | No |
| Sand, 2004[367] | RCT | Double blind | Yes | Not reported | Adequate | No |
| Sand, 2009[368] | Pooled | Double blind | Yes | Unclear | Adequate | Previously reported |
| Sand, 2006[370]<br>Sand, 2007[371] | Multicenter Assessment of Transdermal Therapy in Overactive Bladder with Oxybutynin trial | Open label | Yes | Not adequate | Adequate | Yes |
| Schagen van Leeuwen, 2008[372] | RCT | Double blind | Yes | Unclear | Adequate | Yes |
| Staskin, 2006[39] | Pooled | Double blind | No | Previously reported | Not reported | Previously reported |
| Staskin, 2007[47] | Trospium Study Group | Double blind | Yes | Adequate | Adequate | Yes |
| Staskin, 2004[373] | RCT | Double blind | Yes | Unclear | Adequate | Yes |
| Staskin, 2009[33] | RCT | Double blind | Yes | Not reported | Adequate | Yes |
| Staskin, 2009[374] | Post-hoc | Double blind | Yes | Reported previously | Adequate | NR |
| Staskin, 2009 [52] | RCT | double-blind | Yes | NR | Adequate | Yes |
| Steers, 2005[45] | RCT | Double blind | No | Unclear | Adequate | Yes |
| Steers, 2007[375] | Duloxetine OAB Study Group | Double blind | Yes | Unclear | Adequate | Yes |
| Swift, 2003[376] | Tolterodine Study Group | Double blind | Yes | Unclear | Adequate | No |
| Szonyi, 1995[377] | RCT | Double blind | No | Not reported | Adequate | Yes |
| Takei, 2005[378] | Japanese Tolterodine Study Group. | Combination | Yes | Not reported | Adequate | No |
| Tapp, 1990[379] | RCT | Double blind | No | Adequate | Adequate | Yes |
| Tincello, 2000[380] | RCT | Open label | Not reported | Adequate | Not adequate | Yes |
| Thuroff, 1991[381] | RCT | Double blind | No | Adequate | Adequate | NR |

**Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)**

| Reference | Study | Masking of the Treatment Status | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Sample Size Justification |
|---|---|---|---|---|---|---|
| Toglia, 2009[317] | VENUS | Double blind | No | NR | Adequate | Yes |
| Toglia, 2010[382] | Post-hoc VENUS | Double blind | NR | Unclear | Not adequate | Previously reported |
| U.S. Food and Drug Administration, 2004[383] | RCT | double-blind | NR | NR | NR | NR |
| U.S. Food and Drug Administration, 2004[35] | RCT | double-blind | NR | NR | NR | NR |
| U.S. Food and Drug Administration, 2004[43] | RCT | double-blind | Yes | NR | NR | NR |
| U.S. Food and Drug Administration, [62] | SUNRISE | double-blind | Yes | NR | Adequate | Yes |
| U.S. Food and Drug Administration, 2004[384] | RCT | double-blind | Yes | NR | NR | NR |
| U.S. Food and Drug Administration, 1998[41] | RCT | double-blind | NR | NR | NR | Yes |
| U.S. Food and Drug Administration, [64] | SOLAR | Single blind | Yes | NR | Adequate | Yes |
| U.S. Food and Drug Administration, 2007[40] | RCT | 12 weeks double-blind followed by 9 months open-label | Yes | NR | Adequate | Yes |
| U.S. Food and Drug Administration, 2007[46] | RCT | 12 weeks double-blind followed by 9 months open-label | Yes | NR | Adequate | Yes |
| U.S. Food and Drug Administration, [60] | STAR | double-blind | NR | NR | Adequate | NR |
| Vella, 2008[387] | RCT | Open label | No | Not relevant | Not relevant | No |
| Versi, 2000[42] | Ditropan XL Study Group | Double blind | Not reported | Adequate | No | No |
| von Holst[389] | RCT | Double blind | Yes | Unclear | Adequate | Yes |
| Waetjen, 2005[390] | RCT | Double blind | Yes | Adequate | Adequate | Yes |
| Wagg, 2006[391] | pooled analysis | 4 double-blind studies and one open-label | NR | NR | NR | NR |
| Wang, 2006[392] | RCT | Single blind | No | Not adequate | Adequate | Yes |
| Wang, 2009[393] | RCT | Double blind | Yes | Adequate | Adequate | Yes |

**Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)**

| Reference | Study | Masking of the Treatment Status | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Sample Size Justification |
|---|---|---|---|---|---|---|
| Mazur, 1995[394] | RCT | Open label | No | Unclear | Not reported | No |
| Weil, 1998[395] | RCT | Double blind | Yes | Unclear | No | No |
| Wein, 2007[396] | RCT analysis | Double blind | Yes | Previously reported | Adequate | No |
| Weinstein, 2006[397] | DESIRE (Duloxetine Efficacy and Safety for Incontinence in Racial and Ethnic populations). | Open label | Yes | Not relevant | Not adequate | No |
| Wiseman, 1991[398] | RCT | Double blind | No | Unclear | Adequate | Yes |
| Yalcin, 2006[399] | Pooled | Double blind | Yes | Previously reported | Previously reported | Previously reported |
| Yalcin, 2004[400] | Duloxetine UI Study Group | Double blind | Yes | Previously reported | Adequate | Pooled analysis |
| Yamaguchi, 2007[401] | RCT | Double blind | No | NR | Adequate | Yes |
| Zellner, 2009[402] | RCT | Double blind | Yes | Not adequate | Adequate | Yes |
| Zinner, 2005[403] | RCT | Double blind | No | Unclear | Adequate | Yes |
| Zinner, 2008[404] | RCT | Open label | No | Not relevant | Not reported | Yes |
| Zinner, 2006[405] | RCT | Double blind | Yes | Unclear | Adequate | Yes |
| Zinner, 2004[37] | Trospium Study Group. | Double blind | Yes | Unclear | Adequate | No |
| Zinner, 2002[406] | RCT | Double blind | Yes | Adequate | Adequate | Yes |
| Zinner, 2005[407] | Pooled | Double blind | Yes | Previously reported | Adequate | No |

NR = Not reported

**Table F29. Effects from local estrogen therapy compared to no active treatment**

| Treatments | Reference Studies | Subjects | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1,000 Treated (95% CI) | Evidence |
|---|---|---|---|---|---|---|---|
| **Continence** | | | | | | | |
| Estrogen in tablets or jelly | 1[300] | 80 | 20.68 (1.23;3 46.46) | 0.22 (0.08; 0.36) | 5 (3; 12) | 222 (83; 361) | Insufficient |
| Estradiol implant | Rufford, 2003[364] | 40 | Not Significant | | | | Insufficient |
| **Improvement** | | | | | | | |
| Estrogen in tablets or jelly | 1[300] | 80 | 4.28 (1.54; 11.87) | 0.30 (0.12; 0.48) | 3 (2; 9) | 298 (117; 478) | Insufficient |
| Intravaginal estriol ovules | 1[265] | 88 | 4.29 (2.11; 8.71) | 0.52 (0.35; 0.70) | 2 (1; 3) | 523 (348; 698) | Insufficient |
| Transdermal E2 | 1[390] | 417 | Stress 0.53 (0.36; 0.79) – Not significant in urgency UI | -0.13 (-0.21; -0.05) | -8 (-19 ;-5) | -128 -205; -52) | Insufficient |

**Appendix Table F30. Continence after topical estrogen treatment compared to no active treatment (individual RCTs)**

| Reference N | Active | Definition of Continence | Randomized Active/ Control | Active Events/Rate | Control Events/Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1,000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Holtedahl, 1998[300] 80 | Local estrogen in tablets or jelly plus physiotherapy and electro stimulation | Number of cured: no reported leakage and no wet episodes | 36/44 | 8/22 | 0/0 | 20.68 (1.23; 346.46) | 0.22 (0.08; 0.36) | 5 (3; 12) | 222 (83; 361) |
| Rufford, 2003 40 | 25 mg 17 beta-estradiol implant | Urgency, % of cured | 20/20 | 3/15 | 2/10 | 1.50 (0.28; 8.04) | 0.05 (-0.15; 0.25) | | |
| Rufford, 2003 40 | 25 mg 17 beta-estradiol implant | Stress incontinence, % cured | 20/20 | 4/20 | 3/15 | 1.33 (0.34; 5.21) | 0.05 (-0.18; 0.28) | | |
| Rufford, 2003 40 | 25 mg 17 beta-estradiol implant | Dysuria, % of cured | 20/20 | 4/20 | 3/15 | 1.33 (0.34; 5.21) | 0.05 (-0.18; 0.28) | | |
| Rufford, 2003 40 | 25 mg 17 beta-estradiol implant | Urge incontinence, % of cured | 20/20 | 7/35 | 6/30 | 1.17 (0.48; 2.86) | 0.05 (-0.24; 0.34) | | |

**Appendix Table F31. Improvement in incontinence after topical estrogen treatment compared to no active treatment (individual RCTs)**

| Reference N | Active | Definition of Outcome | Randomized Active/ Control | Active Events/Rate | Control Events/Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1,000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Holtedahl, 1998[300] 80 | Local estrogen in tablets or jelly | Number of improved: reduction in frequency amount, or wet episodes | 36/44 | 14/39 | 4/9 | 4.28 (1.54; 11.87) | 0.30 (0.12; 0.48) | 3 (2; 9) | 298 (117; 478) |
| Dessole, 2004[265] 88 | Intravaginal estriol ovules: 1 ovule (1 mg) once daily for 2 weeks and then 2 ovules once weekly for 6 months. | Rate of cured and improved | 44/44 | 30/68 | 7/16 | 4.29 (2.11; 8.71) | 0.52 (0.35; 0.70) | 2 (1; 3) | 523 (348; 698) |
| Waetjen, 2005[390] 417 | 14 mg of transdermal E2 per day for 4 months | Improved incontinence: the number of incontinence episodes per week decreased by 2 or more, 4 months | 208/209 | 52/25 | 74/35 | 0.71 (0.52; 0.95) | -0.10 (-0.19; -0.02) | | |
| Waetjen, 2005[390] 417 | 14 mg of transdermal E2 per day for 4 months | Improved incontinence: the number of incontinence episodes per week decreased by 2 or more, 2 years | 208/209 | 57/27 | 80/38 | 0.72 (0.54; 0.95) | -0.11 (-0.20; -0.02) | -9 (-52; -5) | -109 (-198; -19) |
| Waetjen, 2005[390] 417 | 14 mg of transdermal E2 per day for 4 months | Improved stress incontinence: the number of incontinence episodes per week decreased by 2 or more, 4 months | 208/209 | 30/14 | 57/27 | 0.53 (0.36; 0.79) | -0.13 (-0.21; -0.05) | -8 (-19; -5) | -128 (-205 ;-52) |

**Appendix Table F31. Improvement in incontinence after topical estrogen treatment compared to no active treatment (individual RCTs) (continued)**

| Reference N | Active | Definition of Outcome | Randomized Active/ Control | Active Events/Rate | Control Events/Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1,000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Waetjen, 2005[390] 417 | 14 mg of transdermal E2 per day for 4 months | Improved stress incontinence: the number of incontinence episodes per week decreased by 2 or more, 2 years | 208/209 | 37/18 | 61/29 | 0.61 (0.43; 0.87) | -0.11 (-0.19; -0.03) | -9 (-30; -5) | -114 (-195; -33) |
| Waetjen, 2005[390] 417 | 14 mg of transdermal E2 per day for 4 months | Improved urge incontinence: the number of incontinence episodes per week decreased by 2 or more, 4 months | 208/209 | 25/12 | 26/13 | 0.97 (0.58; 1.62) | 0.00 (-0.07; 0.06) | | |
| Waetjen, 2005[390] 417 | 14 mg of transdermal E2 per day for 4 months | Improved urge incontinence: the number of incontinence episodes per week decreased by 2 or more, 2 years | 208/209 | 27/13 | 35/17 | 0.78 (0.49; 1.23) | -0.04 (-0.11; 0.03) | | |

**Appendix Table F32. Clinical outcomes after topical estrogen therapy compared to no treatment (individual RCTs)**

| Reference Sample | Active | Definition of Outcome | Randomized Active/ Control | Active Events/Rate | Control Events/Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1,000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Waetjen, 2005[390] 417/0 | 14 mg of transdermal E2 per day for 4 months | Worsened urge incontinence: the number of incontinence episodes per week increased by 2 or more. | 208/209 | 5/2 | 21/10 | 0.24 (0.09; 0.62) | -0.08 (-0.12; -0.03) | -13 (-33; -8) | -76 (-122; -31) |
| Waetjen, 2005[390] 417/0 | for 2 years | Worsened urge incontinence: the number of incontinence episodes per week increased by 2 or more. | 208/209 | 27/13 | 38/18 | 0.71 (0.45; 1.12) | -0.05 (-0.12; 0.02) | | |
| Waetjen, 2005[390] 417/0 | for 2 years | Worsened incontinence | 208/209 | 35/17 | 35/17 | 1.00 (0.66; 1.54) | 0.00 (-0.07; 0.07) | | |
| Waetjen, 2005[390] 417/0 | for 2 years | Worsened stress incontinence | 208/209 | 20/10 | 19/9 | 1.06 (0.58; 1.92) | 0.01 (-0.05; 0.06) | | |
| Waetjen, 2005[390] 417/0 | for 4 months | Unchanged stress incontinence | 208/209 | 136/66 | 124/59 | 1.10 (0.95; 1.28) | 0.06 (-0.03; 0.15) | | |
| Waetjen, 2005[390] 417/0 | for 4 months | Unchanged urge incontinence | 208/209 | 178/86 | 162/77 | 1.10 (1.01; 1.21) | 0.08 (0.01; 0.15) | 12 (6; 152) | 81 (7; 155) |
| Waetjen, 2005[390] 417/0 | for 4 months | Unchanged incontinence | 208/209 | 106/51 | 95/46 | 1.12 (0.92; 1.37) | 0.06 (-0.04; 0.15) | | |
| Waetjen, 2005[390] 417/0 | for 2 years | Unchanged urge incontinence | 208/209 | 154/74 | 136/65 | 1.14 (1.00; 1.29) | 0.09 (0.00; 0.18) | 11 (6; 568) | 90 (2; 178) |
| Waetjen, 2005[390] 417/0 | for 2 years | Unchanged stress incontinence | 208/209 | 151/73 | 129/62 | 1.18 (1.03; 1.35) | 0.11 (0.02; 0.20) | 9 (5; 52) | 109 (19; 198) |
| Waetjen, 2005[390] 417/0 | for 2 years | Unchanged incontinence | 208/209 | 116/56 | 94/45 | 1.24 (1.02; 1.50) | 0.11 (0.01; 0.20) | 9 (5; 80) | 108 (13; 203) |

**Appendix Table F32. Clinical outcomes after topical estrogen therapy compared to no treatment (individual RCTs) (continued)**

| Reference Sample | Active | Definition of Outcome | Randomized Active/ Control | Active Events/Rate | Control Events/Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1,000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Waetjen, 2005[390] 417/0 | for 4 months | Worsened incontinence | 208/209 | 50/24 | 40/19 | 1.26 (0.87; 1.82) | 0.05 (-0.03; 0.13) | | |
| Waetjen, 2005[390] 417/0 | for 4 months | Worsened stress incontinence | 208/209 | 42/20 | 28/14 | 1.51 (0.97; 2.34) | 0.07 (0.00; 0.14) | | |
| Waetjen, 2005[390] 417/0 | for 2 years | New developed incontinence at 2 years | 208/209 | 81/39 | 77/37 | 1.06 (0.83; 1.35) | 0.02 (-0.07; 0.11) | | |
| Dessole, 2004[265] 88/0 | Intravaginal estriol ovules: 1 ovule (1 mg) once daily for 2 weeks and then 2 ovules once weekly for 6 months. | Subjective complaints of stress urinary incontinence. | 44/44 | 14/32 | 37/84 | 0.38 (0.24; 0.59) | -0.52 (-0.70; -0.35) | -2 (-3; -1) | -523 (-698; -348) |
| Holtedahl, 1998[300] 80/0 | Local estrogen in tablets or jelly | Worse incontinence: self reported worsening of severity or impact | 36/44 | 4/11 | 13/30 | 0.38 (0.13; 1.05) | -0.18 (-0.35; -0.01) | -5 (-67; -3) | -184 (-354; -15) |
| Holtedahl, 1998[300] 80/0 | Local estrogen in tablets or jelly | Unchanged incontinence: no changes in frequency, amount, or wet episodes | 36/44 | 10/28 | 27/61 | 0.45 (0.25; 0.81) | -0.34 (-0.54; -0.13) | -3 (-8; -2) | -336 (-541; -131) |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| Adherence to the drugs | Yeaw, 2009[409] | To assess variations in adherence and persistence for antimuscarinic medications (overactive bladder) | 7,722 | 78.20% | NR | Retrospective analysis | 1 year | PharMetrics Patient-Centric Database, a nationally representative database of more than 64 million individual members enrolled in 100 U.S. health plans. Patients were included in the analysis if they initiated a retail or mail-order prescription drug of interest between January 1 and December 31, 2005. | At 6 months post-index, with the application of a 60-day refill grace period, persistence rate (A patient was considered persistent until an excessive gap in days supplied occurred; refill gaps of 30, 60, and 90 days were used to calculated persistence for all cohorts) for OAB medications was 28% and at 1-year it was 18%. Mean (SD) patient adherence calculated as a continuation measure of PDC over a 12-month followup period was 35% (32%) for OAB medications. |
| Drug fesoterodine | Michel, 2008[410] | To review the preclinical and clinical data on fesoterodine | NR | NR | NR | 2, 4, 8, or 12mg/day of fesoterodine | NA | 20 phase 1, three phase II and two phase III studies | 4 and 8mg once daily doses were consistently superior to placebo in improving the symptoms of overactive bladder syndrome, with 8mg/day having significantly greater effects than 4mg/day |
| Drug fesoterodine | Cole, 2004[411] | NR | 728 | NR | NR | 4, 8 and 12mg fesoterodine once daily | 12 weeks | Phase II clinical trial in 728 patients with OAB at sites in Europe, Israel and South Africa | Dropout rates due to adverse events were 4% in the placebo group, 6%, 2% and 12% in the 4mg, 8mg and 12mg groups, respectively. Dry |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | mouth was reported in 9%, 25%, 26% and 34% of patients in placebo and fesoterodine 4-, 8-, and 12-mg groups, respectively |
| Drug fesoterodine | Kelleher, 2008[412] | To present an overview of the components and construction of an economic model using the costs and outcomes associated with fesoterodine | NR | NR | NR | Fesoterodine 4mg daily and fesoterodine 8mg daily | 12 weeks | NR | The QALS (Quality-adjusted life year) gained were 0.0111 for tolterodine 4mg/d, 0.0115 for solifenacin, 0.0124 for fesoterodine 4mg/d and 0.0143 for fesoterodine 8mg/d. Fesoterodine may result in fewer overall costs and greater QALYs gained than treatment with tolterodine and solifenacin for the management of patients with OAB and incontinence |
| Drug tolterodine | Kelleher, 2002[413] | To evaluate the long-term effects of tolterodine on the health-related quality of life (HRQoL) of patients diagnosed with overactive bladder with incontinence | 1077 | 82.00% | NR | Tolterodine 4mg once daily | 12 weeks of RCT followed by 12 months of open - label | Participants of 12 weeks RCT continued a one-year open-label, uncontrolled, nonrandomized study at 138 research centers and clinics. They were eligible if they had an average of 8 or more micturitions per 24 hours over a | Mean changes in the KHQ scores from rollover (start of open-label study) and month 12: in PT (placebo-treated group: incontinence impact=-12.7 (1.8) and in TT (tolterodine-treated) group=-5.9 (1.2); role limitations in PT=-11.6 (1.8) and in TT=-4.1 (1.2); physical limitations in PT=-10.1 (1.7) and in TT=-2.9 (1.2) severity (coping) measures in PT=-5.1 |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | 7-day period and at least 5 urge incontinence episodes per week | (1.3) and in TT= -2.1 (0.9) and symptom severity in PT=-6.6 (0.9) and in TT=-0.8 (0.6) |
| Drug tolterodine | Siami, 2002[414] | To assess the speed of onset of therapeutic benefit with tolterodine extended-release 4mg | 1138 | 73.46% | NR | Tolterodine extended-release 4mg once daily | 12 weeks | The Speed of Onset of Therapeutic Assessment Trial (STAT). Men and women aged ≥18 years with a diagnosis of OAB, with symptoms of urinary frequency (≥8 micturitions/24 hours) and urgency with or without urge incontinence. Patients were categorized into drug-naïve and previously treated (that is those receiving pharmacologic treatment other than tolterodine for OAB) | 72% of the maximum effect on urge incontinence was observed in both groups; and 84.7% of drug-naïve patients and 83.6% of previously treated patients perceived a benefit from benefit. Dry mouth was reported in 15.5% of drug naïve patients and 15.5% of previously treated patients also. In drug -naive group:10.8% had mild dry mouth, 3.1% had moderate and 1.6% had severe and in previously treated patients 11.85 had mild dry mouth, 3% had moderate and 0.7% had severe dry mouth |
| Drug tolterodine | Kreder, 2002[415] | To examine the long-term safety, tolerability and efficacy of tolterodine extended-release in patients who had completed | 1077 | 82% | NR | Tolterodine extended-release 4mg once daily | 12 month open-label after 12 weeks RCT | Men and women aged ≥18 years with urinary frequency (≥8 micturitions/24 hours; urge incontinence | A total of 75% of patients had an improvement in their bladder condition and 51% had an improvement in their urgency. 139 (12.9%) reported dry mouth, 35 |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | 12 weeks of treatment in a randomized, double-blind study comparing tolterodine ER4mg once daily, tolterodine immediate-release 2mg twice daily and placebo | | | | | | (≥5 incontinence episodes per week) and urgency; and symptoms of overactive bladder for ≥6 months | (3.3%) had constipation, 24 (2.2%) had dyspepsia, 43 (4%) had upper respiratory tract infection, 28 (2.6%) had bronchitis, 44 (4.1%) had UTI, 23 (2.1%) had cystitis, 26 (2.4%) had headache |
| Duloxetine | Wernick, 2007[416] | The cardiovascular safety profile of the SNRI duloxetine through evaluation of cardiovascular-related parameters and adverse events | Data from 42 placebo-controlled clinical trials of 8,504 patients | | | Duloxetine 40-80mg vs. placebo | Varied | Adults with major depressive disorder (15 studies), diabetic peripheral neuropathic pain (3 studies), fibromyalgia (2 studies), generalized anxiety disorder (3 studies) and lower urinary tract disorders (19 studies, all related to incontinence). | Duloxetine resulted in decrease from baseline in RR, QRS and QT intervals but not clinically significant |
| Duloxetine | Michel, 2009[417] | To evaluate the safety and tolerability of duloxetine in the treatment of female stress incontinence in women greater than 18 years of age | 5879 | 100 | 100 | 20mg duloxetine daily | Not reported | Female patients with stress incontinence and greater than 18 years of age | Adverse events occurred at a rate of 9.1& in the duloxetine group and 5.7% in the control group |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| Estrogen combined with tolterodine | Serati, 2009[418] | To compare the efficacy of antimuscarinics alone versus antimuscarinics combination with local estrogens for OAB; to verify whether risk factors for lower antimuscarinic efficacy can be overcome by the concomitant use of local estrogens | 236 | 100 | Not reported | Subjects in group 1 were prescribed only tolterodine ER 4mg once daily to be taken at night for at least 12 weeks; subjects in group 2 were prescribed both tolterodine ER 4mg and concomitant estrogen cream application once daily to be taken at night for at least 12 weeks | 12 weeks | Postmenopausal (women were considered postmenopausal if they were >40 years old and reported absence of menses for at least 12 months) women with symptomatic urodynamically proven detrusor overactivity | The efficacy of the therapy was 80.6% in the tolterodine group and 82% in the tolterodine and estrogen group. 62.8% were cured, 17.8% showed improvement, and 19.4% were nonresponders in the tolterodine alone; and 62% were cured, 20% showed improvement, and 18% were nonresponders in the tolterodine and estrogen group |
| Antimuscarinic drugs and bladder training vs. bladder training alone | Ghei, 2006[419] | Cooperative effectiveness of antimuscarinic drugs and bladder training vs. bladder training alone in adults with urge UI | 664 women and 44 men | 93.8 | 100 | Oxybutynin, tolterodine, or imipramine combined with antimuscarinic drugs and bladder | 16 weeks | Adults with mean 54 years and overactive bladder and no significant stress UI | Antimuscarinic drugs were more effective reducing UI |
| Solifenacin VOLT (VESIcare Open-Label Trial) | Garely, 2006[420] | VOLT study: perceptions of improvements in symptom bother and health-related quality of life with solifenacin succinate 5- and 10-rag treatments in patients with OAB | 2,225 | 82.2 | 100 | Solifenacin succinate 5- and 10-rag | 12 weeks | VOLT (VESIcare Open-Label Trial):adult (aged >18 years) men and women (82.2%) with OAB (urgency, urge UI, frequency, and/or nocturia for ≥3 months) | Some improvement-73%;improvement in UI-60%; Treatment-emergent adverse events -59%; 10% discontinued treatment due to adverse events |
| Solifenacin VOLT (VESIcare | Garely, 2006[420] | VOLT study: OAB patients' perceptions of | 582 | 92.1 | 100 | Flexibly dosed, once-daily solifenacin | 12 weeks | VOLT (VESIcare Open-Label | 80% of patients achieved improvement in their PPBC score. |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| Open-Label Trial) | | improvements in symptom bother and quality of life after solifenacin under conditions reflecting day- to day practice. | | | | | | Trial): Adults who had OAB symptoms and urge UI for 3 months or longer | (61.3%) experienced an adverse event during treatment. Adverse Event: Dry mouth 104 (17.9) |
| Solifenacin VOLT (VESIcare Open-Label Trial) | Capo, 2008[421] | To report patient satisfaction with treatment, as measured by symptom bother and HRQoL, in a subgroup of Hispanics participating in an open-label study of solifenacin succinate | 94 | 74 | 63 | Solifenacin 5m/d with a dosing option of 5 or 10mg/d at weeks 4 and 8 | 12 weeks | This is a subset analyses of Hispanic patients enrolled in the VOLT study. Ambulatory men and women 18 years of age and older with symptoms of OAB for at least 3 months and able to use the toilet without difficulty | Over 72% of patients experienced PPBC score improvement. Hispanics receiving solifenacin for OAB reported improvement from baseline in symptom bother and HTQoL |
| Solifenacin VOLT (VESIcare Open-Label Trial) | Sand, 2009[422] | To determine the efficacy of solifenacin to improve subjects' MBS (Most Bothersome Symptom) based on PRO (Patient-Reported-Outcome) measures | 2225 | 74.56% | 26.16% | Solifenacin 5m/d with a dosing option of 5 or 10mg/d at weeks 4 and 8 | 12 weeks | VOLT is a study in adults with OAB symptoms for >=3 months | The UUI group showed the largest VAS(Visual Analogue Scale), OAB-q, and PPBC improvements. 90.7% of patients whose MBS was UUI showed improved VAS score; 94% of patients whose MBS was UUI showed improved VAS:UUI score; 88.8% of patients whose MBS was UUI showed improved VAS: daytime urinary frequency, and 86.6% of patients whose MBS was UUI showed |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | improvement in VAS: Nocturia score |
| Solifenacin VOLT (VESIcare Open-Label Trial) | Mallett, 2007[423] | To present patient-reported outcomes, as measured by symptom bother and HRQoL, in black patients participating in an open-label study of solifenacin succinate | 274 black and 2205 white patients | 81.73% | 26.83% | Solifenacin 5mg or 10mg once daily according to an individualized flexible-dosing regimen | 12 weeks | VOLT study: Men and women aged 18 years or older with symptoms of OAB for 3 months or longer; ambulatory who were able to use the toilet without difficulty and who had not received solifenacin | 86.5% of black patients with urinary urgency found it bothersome after solifenacin treatment than at baseline; 87.9% found urge incontinence less bothersome. 46.4% of black subjects experienced an adverse event ; of these 30.1% had at least one treatment-related adverse event; 13% had dry mouth, 6.9% had constipation, 2.5% had blurred vision, 2.5% had nausea, and 2.2% had rash. A total of 7.6% black subjects discontinued treatment due to an adverse event. |
| Solifenacin VERSUS study | Chancellor, 2008[424] | To assess the efficacy, tolerability, and effects on HRQL of solifenacin in patients with residual urgency after ≥4 weeks of treatment with tolterodine extended release 4mg | 441 | 88.2 | 69.39% | Solifenacin 5m/d with dose adjustment at weeks 4 and 8 | 12 weeks | VERSUS study: patients ages >18 years who had symptoms of OAB for ≥3 months, had been treated with tolterodine ER 4mg for ≥4 weeks and wished to switch therapy because of a lack of sufficient subjective | A mean decrease of 3.4 urgency episodes/24 hours (95% CI,-3.8 to -3.0; p<0.001); a mean improvement of 1.2 points (95% CI, -1.3 to -1.1; p<0.001) in PPBC score; changes in all OAB-q scales and domains (symptom bother, coping, concern, sleep, social interaction, and total HRQL) were also |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | improvement in urgency. | statistically significant(p<0.0001). Treatment emergent AEs such as dry mouth (77[17.5%]), constipation (51[11.6%]), and blurred vision (10[2.3%]). |
| Solifenacin VERSUS study | Swift, 2009[425] | To evaluate the effects of solifenacin in OAB patients with high symptom bother, this post hoc analysis focuses on the VERSUS 'severe cohort', as defined by patients with scores ≥5 on the PPBC scale at baseline (on tolterodine ER mg/d) who remained severe at post-washout (when the patients were receiving no drug) | 440, but 116 were from the severe cohort | 88.8 | Not reported | Solifenacin 5m/d with dose adjustment at weeks 4 and 8 | 12 weeks | VERSUS study: Men and women ages >18 years with symptoms of OAB for ≥3 months who were ambulatory and able to use the toilet without difficulty and who had received tolterodine ER 4mg/d for ≥4 weeks but wished to switch therapy because of lack of sufficient subjective improvement in urgency | In the severe OAB cohort, the mean number of urgency episodes/24 hours decreased by 3.95(97% CI: -4.81, -3.08; p<0.0001) |
| Solifenacin VERSUS study | Zinner, 2009[426] | To assess changes in health-related quality of life, medical care resource utilization, work, and activity impairment, and | 441 | 88 | Not reported | Solifenacin 5mg/d with dosing adjustments allowed at week 4 (to 10mg/d) and at week 8 (back to 5mg/d for patients whose dose was increased to | 12 weeks | Patients who have been treated with tolterodine 4mg/d for ≥4 weeks immediately preceding study entry without | Subgroup analysis included 108 patients 65 to 74 years of age and 86 patients ≥75 years of age. Patients in both groups experienced significant improvement in HRQoL (p<0.001), as |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | health utility among elderly patients with OAB who continued to have urgency symptoms with tolterodine and were willing to try solifenacin | | | | 10mg/d at week 4) | | sufficient improvement in urgency episodes | well as significant reduction in non protocol-related office visits (p<0.001) and activity management (p<0.025). A significant reduction in the use of pads/diapers was reported for patients 65 to 74 years of age (p<0.018), and patients in this age group who were working reported significantly less impairment related to OAB while working during solifenacin treatment than during tolterodine treatment (p<0.042). No significant differences in HUI2/3 scores were observed in either of the elderly groups. Solifenacin was found to improve symptom bother, HRQoL, work productivity, activity participation, and reduced medical care resource utilization in the elderly subjects with OAB who continued to have urgency symptoms with tolterodine and were willing to try solifenacin |
| Solifenacin VERSUS study | Zinner, 2008[427] | To evaluate the health outcomes, in terms of | 441 | 88.2 | Not reported | Solifenacin 5m/day with dose adjustment at | 12 weeks | Men and women aged >=18 years with | 3.9% discontinued treatment due to adverse events. |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | medical resource use, work and activity impairment, and health utility, of these patients | | | | weeks 4 and 8 | | symptoms of OAB for >=3 months who were ambulatory and bale to use the toilet without difficulty and who had been treated with tolterodine ER 4mg/d for at least 4 weeks immediately preceding study entry, but failed to achieve satisfactory improvement in urgency episodes | Patients who were working reported a reduction in percent of work time missed (0.2% vs. 2.1%; p=0.0017), a reduction in percent of impairment while working (11.3% vs. 22.9%; p<0.0001), and a reduction in percent of overall work impairment (11.9% vs. 24.0%; p<0.0001), while a larger group of patients reported a reduction in percent of activity impairment (18.4% vs. 31.6%; p<0.0001) |
| Treatments for overactive bladder | Sexton, 2009[428] | To assess the impact of OAB on work productivity among employed men and women under the age 65 in the United States | 5696 | 52.92% | 7.86% | OAB | NA | Cross-sectional survey of working (full-or part-time) men and women aged 40 to 65 years. This study is part of a study conducted in the US, UK and Sweden. This study focused only on US participants. | Work limitations questionnaire total score, mean (SD): men and continent OAB group=9.3 (14.3) and women and continent group=10.8 (15.6); men and incontinent group=12.5 (16.7) and women and incontinent group=12.6 (16.7); men and no/minimal symptoms=0.6 (4.2) and women and no/minimal symptoms=1.0 (5.3) The regression coefficient in men: urgency with fear of leaking vs. urinary - |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | specific work impairment scores (higher scores indicate greater impairment)=2.232 and in women=0.960; UUI and urinary-specific work impairment scores in men=0.832 and in women=0.941; SUI and urinary-specific impairment scores in men=1.189 and in women=1.312 and nocturnal enuresis and urinary-specific impairment scores in men=1.318 and in women=1.025 |
| Treatments for overactive bladder | Irwin, 2006[429] | To determine the impact of overactive bladder symptoms on issues related to employment, social interactions, and emotional well-being in a population aged 40-64 years | 1272 | 50.80% | NR | OAB | NA | Cross-sectional survey of 11,521 individuals aged 40-64 years and 1,272 of them had OAB | Of those with OAB, approx. 32% reported that having these symptoms made them feel depressed and 28% reported feeling very stressed. 36.4% of OAB with incontinence patients reported emotional stress as compared to 19.6% of patients with OAB and no incontinence. 39.8% of OAB with incontinence patients reported depression as compared to 23.3% patients with OAB and no incontinence. Overall, 76% of individuals reporting |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | OAB symptoms stated that this condition interfered with or made it more difficult to perform daily activities |
| Treatments for overactive bladder | Wu, 2005[430] | To assess the indirect work loss costs to employers as the result of employees with overactive bladder | 21,087 | NR | NR | OAB | NA | There were two samples: Sample1 was used to analyze OAB employees' work loss patterns and costs and sample2 was used to assess OAB employees' time to disability and related risk factors. Individual enrollees in both samples were active employees, 18 to 64 years, with at least one diagnostic code to identify OAB | Employees with OAB had 2.2 excess days of work loss absenteeism to medically related absenteeism and 3.4 excess days attributable to disability compared with control subjects (p<0.01 for both comparisons).Multivariate regression analysis revealed that employees with AOB had 4.4 more days of work loss per year than control subjects(p<0.05).The average annual indirect work loss cost of an employee with OAB was $1220 from an employer's prospective, which was 1.7 times the indirect work loss cost of a control employee (i.e., $715) (p<0.01). Multivariate regression analysis showed that OAB imposes an indirect work loss cost burden of $391 per OAB employee per year from an employers' perspective (p<0.05). Kaplan - |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Meier analysis showed that employees with OAB had significantly shorter times to disability than did their non-OAB controls |
| Treatments for overactive bladder | Pelletier, 2009[431] | To evaluate adherence with overactive bladder pharmacotherapy and compare costs between patients receiving pharmacotherapy versus nonpharmacological management | 86,734 | 78% | NR | OAB therapy | 1 year | Anonymous, patient-level data were obtained from the PharMetrics Patient-Centric Database (Watertown, MA) which contains adjudicated medical and pharmaceutical claims for more than 90 US managed health care plans across the United States. Patients were 18 years or older and had at least 1 OAB diagnostic code or at least 1 prescription for an antimuscarinic OAB medication during a 24-month index window from January 1, 2005 through December 31, 2006. Subjects | 14.4% of the aggregate OAB therapy cohort (43, 576) reached a PDC (proportion of days covered) of 80% or higher, with an average PDC of 32.4%. Following pharmacotherapy initiation, OAB therapy subjects had significantly higher mean (median) total costs compared with nonpharmacological managed subjects ($9917 [$4598] vs. $9657 [$4299]; p<0.001). Nonpharmacologically managed subjects averaged $277 for OAB-related outpatient services compared with $176 for OAB therapy subjects (p<0.001), with 69% more OAB-related physician office visits and more than double the number of OAB-related laboratory tests among nonpharmacologically managed subjects |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | were required to have continuous health plan enrollment for a minimum of 6 months before and 12 months after the index date; during periods of continuous enrollment, all medical (inpatient and outpatient) and pharmacy (retail and mail order) claims are captured. | contributing to this difference |
| Treatments for overactive bladder | Schabert, 2009[432] | To describe the challenges to improving management of overactive bladder outcomes and summarize research findings on critical success factors for supporting OAB treatment | 5392 | NR | NR | OAB therapy | NA | OAB Persistence Survey: respondents who had been prescribed one antimuscarinic or more for OAB over the prior 12 months | 24.5% reported discontinuing one antimuscarinic prescription medication or more during the prior 12 months. Among these patients discontinuing medications, 45.4% reported unmet treatment expectations as the reason for discontinuation |
| Treatments for overactive bladder | Bolge, 2006[433] | To examine the impact of overactive bladder on health care resource utilization, daily activities, work productivity, and health complications | 441 | 76.40% | 76.40% | Presence of OAB | NA | US National Health and Wellness Survey, 18, and internet population-based survey conducted annually by Consumer | Of the 196 patients receiving prescription medication, 147 (75%) reported satisfaction with therapy. Of the 31 patients receiving behavioral therapy, 21 (67.7%) were satisfied with treatment. 63 of (48.8%) the 129 |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Health Sciences. It was administered to a representative sample of registered adult panelists aged 18 years or older in the United States. There were 2602 respondents who reported a history of OAB diagnosed by a physician and out of these 441 respondents were administered the survey for the study. | respondents taking Kegel exercises were satisfied with this treatment. Impairment in productivity was primarily attributed to lack of concentration (40%), followed by inability to complete tasks (5.4%). OAB reduced their daily activities but 27.6%. Successful treatment of OAB was associated with a significantly lower incidence of complications than unsuccessful treatment($p < 0.05$) |
| Treatments for overactive bladder | Dmochowski, 2007[434] | To examine the effects of OAB on participants; treatment-seeking behaviors, patient satisfaction with oral OAB therapies, and desirable characteristics of new treatments | 1228 | 100% | 43% | Cross-sectional survey | NA | Women with symptoms of OAB , aged 40-65 years | 87% of current users of OAB medications took their medication daily, with 70% taking it once daily. Only 32% were completely satisfied with their medications. Among respondents with OAB symptoms, 61% felt that less frequent dosing was 'very important' or 'extremely important. Among lapsed users of OAB medications, as compared with current users, significantly higher percentages |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | indicated that it was extremely or very important to not feel nausea (79% vs. 59%), not have dry eyes (68% vs. 54%), not experience constipation as often(71% vs. 59%) and not have to take a high dose of medication (75% vs. 64%) |
| Treatments for overactive bladder | Zhou, 2001[435] | To identify components of costs attributable to OAB, using medical claims data on insured patients with OAB between 18 and 64 years of age; to examine the demographic and health risk characteristics of patients with a primary or secondary diagnosis of OAB; and to suggest cost-effective treatment strategies for OAB | 148,697 | NR | NR | Presence of OAB | NA | Two cohorts were identified on the basis of whether individuals had received formal OAB treatment based on the ICD-9 codes for bladder disorders in the claims data. The OAB cohort consisted of 2385 persons with an outpatient claim, primary or secondary ICD-0 code specified for OAB; or persons with an inpatient claim, primary ICD-9 code specified for OAB. The non-OAB cohort included 146, 312 patients | The probability of hospital admission during the year was 20.65 among OAB patients compared with 7% among non-OAB patients. After adjustment for patient risk characteristics, total annual claims for a patient with OAB were 45% higher (p=0.0001), than for a patient without OAB. Annual inpatient claims were 23% higher but not significantly different form claims for a non-OAB patient. Much of the significance in cost for the OAB patients was due to age, sex, and the presence of non-OAB medical conditions. |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | whose claims over the entire period showed none of the specified ICD-9 codes for OAB | |
| Treatments for overactive bladder | Brubaker, 2010[436] | To identify predictors of self-reported discontinuation of overactive bladder medication using a three-phase survey | 5392 | 76% | NR | OAB therapy | 1 year | OAB Medication Use Survey. Participants were representatives of the USA population identified from the Taylor Nelson Sofres (formerly National Family Opinion) household panel | Among 2838 respondents at phase3, 1194 had recently discontinued and 1644 were persistent with medications at phase2. Among phase3 respondents who were persistent at phase2, 1040 continued to be persistent at phase3, 280 had discontinued between phases 2 and 3, and 261 had switched medication between phases 2 and 2; 63 had missing prescription at phase 3. Predictors of discontinuing at phase3 included smoking (OR:1.80; 95%CI=1.15-2.83, p=0.010), not knowing whether treating bladder problems requires multiple daily doses of medications (1.71, 1.10-2.67 ;p=0.018), believing (2.11, 1.34-3.33, p=0.001) or not knowing (1.76, 1.23-2.52, p=0.002) whether adverse |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | effects of OAB medications are often severe, and being bothered 'quite a bit or more' by a sudden urge to urinate (1.54, 1.05-2.26; p=0.028). Respondents taking 2 or more medications were less likely to discontinue (OR: 0.45-0.58, p<0.05) |
| Treatments for overactive bladder | Benner, 2010[437] | To evaluate patient-reported reasons for discontinuing antimuscarinic prescription medications for OAB | 5392 | 77.60% | 26.80% | OAB therapy | 1 year | Representative sample of households in the USA (260,000) that agreed to participate in surveys from the Taylor Nelson Sofres (formerly National Family Opinion) | Among the 5392 phase2 respondents, 1322 (24.5%) reported discontinuing one or more antimuscarinic prescription AOB medication during the previous 12 months. Most respondents (89%) reported discontinuing OAB medication primarily due to unmet treatment expectations (46.2%) and/or tolerability (21.1%); many respondents in this class switched to a new antimuscarinic agent. A smaller group (11%) indicated a general aversion to taking medication. |
| Tolterodine | Coyne, 2008[438] | The IMPACT trial: Relationship between treatment-related improvements in overactive bladder (OAB) symptoms | 863 | 82 | | Tolterodine ER (4 mg once daily) | 12 weeks | >18 years of age (82% women) and have frequency (>8 micturitions per 24 hours) and either | Tolterodine ER-related improvements in OAB symptoms (assessed by diary variables) and patients' perceptions of changes in symptom bother, bladder-related |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | as recorded in bladder diaries and patient reported symptom bother, bladder-related problems and health-related quality of life (HRQL). | | | | | | urgency (strong, sudden desire to urinate) or urgency urinary incontinence (UUI) (>2 episodes per day as recorded in 3-day bladder diaries) | problems and HRQL (assessed by PPBC and OAB- were significantly correlated). |
| Tolterodine | Elinoff, 2006[439] | The IMPACT trial: the efficacy of tolterodine extended release (ER) for patients' most bothersome overactive bladder (OAB) symptom in a primary care setting | 863 | | | Tolterodine ER (4 mg q.d.) | 12 weeks | >18 years of age (82% women) and have frequency (>8 micturitions per 24 hours) and either urgency (strong, sudden desire to urinate) or urgency urinary incontinence (UUI) (>2 episodes per day as recorded in 3-day bladder diaries) | Discontinuation due to adverse events-7%; improvement in bladder condition (1 point) - 78.8% and 74.6% of the UUI group; all-cause AE-51%; treatment-related adverse events -23% |
| Tolterodine | Michel, 2007[440] | The association between symptoms of UI, bother, and patient satisfaction with treatment using tolterodine in overactive bladder | 3,824 | | | Tolterodine ER (4 mg q.d.) | 9 months | Adults with OAB | Patient bother was the strongest individual predictor of patient treatment satisfaction in overactive bladder. Changes in episodes of the four symptoms of OAB were not associated with patient satisfaction |
| Tolterodine | Michel, 2004[441] | The impact of concomitant stress incontinence (SI) on the | 2,250 | | | 2 mg tolterodine twice daily | 12 weeks | Adults with OAB | Patients with concomitant III degree SI (but not I or II degree) have significantly less |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | therapeutic effects of tolterodine in patients with OAB with and without concomitant SI. | | | | | | | improvement |
| Tolterodine | Michel, 2002[442] | The association between patient age and gender and the therapeutic response to tolterodine in adults with OAB | 2,251 | | | 2 mg tolterodine twice daily | 12 weeks | Adults with OAB | Age (OR/yr. 0.978 (0.968–0.987)) and baseline Incontinence (OR 0.744 (0.716–0.774)) was negatively associated with treatment success. Increasing of tolterodine dose was associated with worse response (OR 0.866 (0.784–0.956)) and less tolerance (OR 1.114 (1.028–1.206) |
| Tolterodine | Roberts, 2006[443] | The IMPACT trial: the effect of tolterodine extended release (ER) on patient- and clinician-reported outcomes in a primary care setting | 863 | | | Tolterodine ER (4 mg once daily) | 12 weeks | Adults with overactive bladder (OAB) symptoms for ≥3 months and were at least moderately bothered by their most bothersome symptom | improvement in their overall bladder condition - 79%; Major improvement (improvement of two or more points) - 50.4% and 49.7% of the UUI group |
| Tolterodine | Sussman, 2007[444] | Timing of the efficacy of tolterodine extended release (ER) in patients with overactive bladder | 698 | | | Tolterodine ER (4 mg qd) | 12 weeks | Adults (aged ≥18 years) with urinary frequency ≥8 micturitions/24 hours) and urgency (strong and sudden desire to urinate) with or | Patients with OAB experienced significant reductions in OAB symptoms as early as Day 5 of treatment with tolterodine ER |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | without urgency urinary incontinence (UUI). | |
| Tolterodine vs. Oxybutynin | Lawrence, 2000[445] | Adherence to treatment with immediate-release (IR) oxybutynin and Tolterodine` | 1531 | | | Tolterodine, IR Oxybutynin | 6 months | All patients age 18 years and over who began therapy with either Tolterodine or IR Oxybutynin during April or May 1998 | The proportion of patients continuing therapy for 6 months was statistically superior for Tolterodine (32%) Compared with IR Oxybutynin 22% Oxybutynin was switched to another therapy more commonly than Tolterodine (19% and 14%, respectively) Patients discontinuing all therapy within 6 months Men: Tolterodine 33%; Oxybutynin 39 % Women: Tolterodine 67%; Oxybutynin 61% Only 35 (32%) of IR Oxybutynin recipients were fully adherent compared with 87 (53%) of Tolterodine recipients. |
| Tolterodine vs. Oxybutynin | Shaya, 2005[446] | Predictions of persistence with Tolterodine or Oxybutynin in patients with over active bladder | 3,054, 1,637, included in analysis | 75 | | Tolterodine ER, Oxybutynin ER, Oxybutynin 1r 4 weeks | | Adults, 75% women, 45% African-American 26% younger than 18, with prescriptions of Tolterodine or Oxybutynin for over active bladder. | Hazard ratio of non persistence adjusted for age, sex, race Oxybutynin 1R vs. Tolterodine ER 30 days 1.09 (0.88; 1.35) >30 days 1.13 (0.84; 1.51) Oxybutynin ER vs. Tolterodine ER |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | <30 days 0.96 (0.6; 1.53)<br>> 30 days 1.47 (1.01; 2.14)<br>Age <18 vs. 18-39 1.56 (1.33; 1.82)<br>> 40 vs. 18-39 0.85 (0.74, 0.97)<br>African Americans vs. Whites 1.22 (1.09; 1.36) |
| Oxybutynin | Hussain, 1996[447] | Effect of oxybutynin on the QTc interval in elderly patients with UI | 21 | | 100 | Oxybutynin | 4 weeks | Elderly | No QTc interval prolongation or ventricular arrhythmias |
| Oxybutynin | Nilsson, 1997[448] | The efficacy and tolerability of controlled release vs. 5-mg conventional oxybutynin twice daily | 17 | 100 | 100 | 10-mg Controlled Release Oxybutinin vs. a 5-mg Oxybutynin Tablet | 9 weeks | women with urge UI | No difference in efficacy or safety of two formulations |
| Oxybutynin | Bemelmans, 2000[449] | The efficacy of a low-dose oxybutynin (2.5 mg three times daily) in men and women with symptomatic urge incontinence | 416 | | | Oxybutynin (2.5 mg three times daily) | 6 weeks | Men and women in primary care practice with symptomatic urge incontinence | Complete symptomatic cure -95%; side effects attributable to the use of oxybutynin - 30%; 10% had to stop the medication because of the severity of these side effects. |
| Oxybutynin | Radomski, 2004[450] | The efficacy of controlled-release (CR) oxybutynin tablet taken once-daily in patients with urinary urge incontinence | 12 | | | Oxybutynin (2.5-5 mg bid) | 8 weeks | Men and women with urodynamically-confirmed detrusor instability, micturition frequency (≥8 voids/day) and/or urinary | CR oxybutynin (15 mg OD) was at least as effective as the patients' previous dose of IR oxybutynin (mean dose: 6.7 +/- 2.5 mg/day). |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | incontinence (≥2 incontinence periods/day) | |
| Oxybutynin | Wang, 2002[451] | Risk of ventricular arrhythmia or sudden death after treatment with oxybutynin or other urinary antispasmodics | 14,368, 67-75 4% women | 70.5 | | Oxybutynin or flavoxate | Not specified | Adults who filled prescriptions for Oxybutynin or Flavoxate via Medicaid program. | Relative risk of ventricular arrhythmias adjusted for age gender time - varying exposure urinary antispasmodic use 1,23 (0.87-1.75) Concurrent antihistamine/ cytochrome inhibitor use 5.47/1.34- 22.26) Relative risk of sudden death adjusted for age gender, and full of exposure urinary antispasmodic use 0.7 (0.28-1.74) Concurrent antihistamine/ cytochrome inhibitor use 21.5 (5.23-88.32) |
| Oxybutynin | Diokno, 2002[452] | Long-term safety of Oxybutynin in adults with over active bladder | 904 women and 163 men | 84.7 | 100 | Oxybutynin ER | 12 weeks-1 year | Adults with urge or mixed UI, mean age 64 years | Discontinuations during 3 month - 25.5%, 1 year-53.8% Discontinuations due to adverse events 15.6% Dry mouth- 5.6% Lack of efficacy -4.9% Central nervous system at 91-180 days Headache-0.6% Dizziness- 0.4% Blurred vision-0.4% Somnolence 0.2% (181 day) Confusion 0.1% |
| Oxybutynin MATRIX | Pizzi, 2009[453] | To evaluate the impact of | 2878 and 1112 were | 92.2 | 53.51% | OXY-TDS 3.9mg/day, twice | 6 months | MATRIX study: Community - | Participants experienced significant |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| study | | oxybutynin transdermal system (OXY-TDS) and subsequent treatment on productivity among working participants | employed (that formed the study population ) | | | weekly patch applications | | based; 2978 adults aged ≥18 years with symptoms of OAB | improvements in mean scores for all four WPQ (Work Productivity Questionnaire) scales (p<=0.0002) and the mean WPQ Index decreased from 8.2 to 5.5 (p<0.0001). The WPLS (Work Productivity Loss Score) decreased from 7.7% to 5.2% (p<0.0001) |
| Oxybutynin MATRIX study | Newman, 2008[454] | To evaluate the effectiveness of transdermal oxybutynin (OXY-TDS) in improving HRQoL in a community - based adult population | 2878 | 87.2 | NR | OXY-TDS 3.9mg/day, twice weekly patch applications | 6 months | MATRIX study: community-based; men and women aged ≥18 years having at least one symptom of OAB, such as urge UI, urgency, and/or frequency | Among all participants, 16.5% discontinued OXY-TDS due to adverse events. Overall, this study found that OXY-TDS administered resulted in improvement in HRQoL, with the medication having its greatest effect on the impact of incontinence, severity of symptoms, and role limitations |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| Darifenacin | Zinner, 2008[404] | To investigate patient -reported outcomes and clinical parameters during darifenacin treatment in OAB patients who expressed dissatisfaction with prior extended -release oxybutynin or tolterodine therapy | 497 | 84.1 | 82.9 | 7.5mg darifenacin once daily with the possibility of up-titrating to 15mg after 2 weeks, for up to 12 weeks | 12 weeks | Men and women (≥18 years of age) with OAB symptoms [an average of ≥8 micturitions/24 hours and ≥1 urgency episode/24 hours, with or without urgency urinary incontinence episodes] for at least 6 months prior to randomization, and with a baseline score of ≥2 on the Patient Perception of Bladder Condition questionnaire at screening. Patients were required to be naive to darifenacin treatment, to have received at least 1 week of treatment with oxybutynin ER or tolterodine ER within the year prior to this trial and to report that they were dissatisfied with the most recent of these | Darifenacin treatment resulted in statistically significant improvements in PPBC scores, micturition frequency, urgency , and UUI episodes from baseline at 12 weeks. More than 85% of patients expressed satisfaction with darifenacin. The odds (and 95% CI) for improvement in PPBC amongst previous recipients of oxybutynin ER or tolterodine ER were 2.08 (1.48, 2.92) and 1.77(1.29, 2.43). The odds for reporting satisfaction (and 95%CI) were 4.35 (2.90, 6.53) amongst previous oxybutynin ER recipients and 5.23 (3.50, 7.80) for tolterodine ER recipients, representing an odd ratio (95% CI) of 0.83 (0.50, 1.40). 14.2 % discontinued in group who had prior treatment with oxybutynin and 10.4 % in group who had prior treatment with tolterodine. 58.4% had AEs, 20.1% dry mouth, 14.1% constipation, 6.6% urinary tract |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | treatments | infection, 3.6% headache, 3.2% nausea, 2.6% dyspepsia, 2.2% dry eye, and 2% upper respiratory tract infection. 40.1% of total patients reported ≥90% improvement in number of UUI episodes/week, 39.1% of patients in group that had prior treatment with oxybutynin reported ≥90% improvement, and 40.4% in group that had prior treatment with tolterodine reported ≥90% improvement. |
| Fesoterodine | Wyndaele, 2009[455] | To evaluate the efficacy and tolerability of flexible -dose fesoterodine in subjects with overactive bladder who were dissatisfied with previous tolterodine treatment | 516 | 77 | 50 | Fesoterodine 4mg once daily for 4 weeks; thereafter, daily dosage maintained at 4mg or increased to 8mg | 12 weeks | Men and women aged ≥18 years with self-reported OAB symptoms for ≥3 months with a mean micturition frequency of ≥8 micturitions per 24 hours and mean number of urgency episodes ≥3 per 24 hours in a 5-day bladder diary; they had to rate their bladder condition as causing at least | Approximately 80% of subjects who responded to the TSQ (Treatment Satisfaction Question) at week 12 reported satisfaction with treatment; 38% reported being very satisfied. 8.5% of patients reported no problems on the PPBC scale; 38.9% patients reported 'Usually able to finish what I am doing' on the UPS (Urgency Perception Scale) scale. Significant improvements from baseline (p<0.0001) |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | 'some moderate problems' on the PPBC questionnaire at baseline; they were required to have been treated with tolterodine or tolterodine ER for OAB within 2 years of screening | exceeding the minimally important difference (10 points) were observed in OAB-q Symptom Bother and Health-Related Quality of Life scales and all four HRQL domains. |
| Botulinum-A toxin | Werner, 2005[456] | To investigate the efficacy and safety of botulinum -A toxin treatment for non-neurologic detrusor overactivity incontinence | 26 | 100 | 100 | 100 units of botulinum -A toxin(BTX-A) injected into the detrusor at 30 sites | One day | Women with urge incontinence and urodynamically demonstrable detrusor overactivity incontinence who failed to respond to various antimuscarinics | 53.8% women were dry after 4 weeks, 65% after 12 weeks, and 60% after 36 weeks. 2 women failed to respond. 15.4% showed subjective improvement in effect on life and 11.5% showed subjective improvement in urge incontinence after 36 weeks. Within the 51 followup visits, 30.8% patients had 9 urinary tract infections |
| Role of urodynamics in evaluation of outcomes | Malone-Lee, 2009[339] | The place of urodynamics in the evaluation of patients with symptoms of the overactive bladder by comparing the response to antimuscarinic therapy in those with and with no urodynamically | 356 | | | Oxybutynin 2.5 mg twice daily and bladder retraining | 6-8 weeks | Women ≥18 years with symptoms of an overactive bladder and urgency, with or without urge incontinence | Patients respond equally to antimuscarinic therapy independent of urodynamic results.<br>Detrusor instability-no detrusor<br>Change from baseline<br>0 (2-6) / 0 (2-6)<br>Dry mouth<br>84% / 70%<br>Constipation<br>32% / 22% |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | verified symptoms | | | | | | | Heartburn<br>27% / 23%<br>Dry skin<br>18% / 5%<br>Headache<br>10% / 3.5%<br>Dry eyes / 5% / 1%<br><br>4 were excluded<br>76% had detrusor instability on cystometry |
| Adherence to antimuscarinic medication | Balkrishnan, 2006[457] | Relationship between adherence to antimuscarinic medication and health care services utilization. | 275 | 76 | 100 | Antimuscarinic medications; medications possessions score was calculated as the days of antimuscarinic prescriptions supply dispensed divided by the number of days between these prescription refills. | 6 months or more | Enrollees in Medicare magnet care plan in the southern US, 16-24% men; 73-74 years old who dispensed antimuscarinic drugs every 6 months | Charlson index comorbidity, patient perception of quality of life, and total number of prescribed medications during the year before enrollment in Medicare where predictors of poor adherence to antimuscarinic drugs. |
| Adherence to antimuscarinic medication | Yu, 2005[458] | Predictors of adherence to medications for over active bladder syndrome | 2,496 | 80 | | Tolterodine, Oxybutynin, Oxybutynin ER | 6-12 months | 20% random sample of California Medicaid program 20-25% men, 63-64 years old who dispersed any OAB/UI medication | Discontinuation-16%<br>Hazard ratios of drug persistence<br>White race -insignificant<br>Tolterodine vs. Oxybutynin 0.7(0.67; 0.81)<br>Previous antipsychotics use 0.85; 0.83; 0.88)<br>Hazard ratios of drug adherence; Tolterodine vs. Oxybutynin 1.75 (1.10; 2.78)<br>Oxybutynin ER vs. Oxybutynin 2.25 (1.36; 3.75) |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| Cost effectiveness | Perfetto, 2005[459] | 1-year total healthcare costs for patients with overactive bladder | Simulation model | | | Tolterodine tartrate extended release capsules (tolterodine ER) versus extended release oxybutynin chloride (oxybutynin ER). | | | Tolterodine ER had lower monthly drug and medical management costs |
| Cost effectiveness | Hughes, 2004[460] | Cost-Effectiveness Analysis of Extended-Release Formulations of Oxybutynin and Tolterodine for the Management of Urge Incontinence | Simulation study | | | Oxy-IR 5mg tablets<br>Oxy-XL 10mg tablets<br>Tol-IR 2mg tablets<br>Tol-ER 4mg tablets | | | The incremental cost per incontinent-free week for Oxy-IR (versus no treatment) ranged from £2.58 to £16.59. Oxy-XL and Tol-ER were more effective than Oxy-IR but at additional costs per incontinent-free week. Tol-IR did not appear to be a cost-effective option as it was less effective and more costly than the extended-release formulations |
| Cost effectiveness | O'Brien, 2001[461] | Cost-effectiveness of Tolterodine for Patients with urge incontinence who discontinue initial therapy with Oxybutynin | Simulation study with Markov model | | | Tolterodine in patients who discontinued Oxybutynin | | | The incremental cost per QALY was Can $9982 and appeared to be robust |
| Cost effectiveness | Varadharajan, 2005[462] | Post treatment medical costs for patients with overactive bladder | | | | Oxybutynin chloride immediate release (oxybutynin IR), oxybutynin chloride extended release (oxybutynin ER), or tolterodine extended-release | | | Costs for patients taking oxybutynin IR were 48% higher than costs for patients taking tolterodine ER (P = .026), and costs for patients taking oxybutynin ER were |

**Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)**

| Treatment | Reference | Aim | Number | % Women | % with UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | tartrate capsules (tolterodine ER). | | | 191% higher than costs for patients taking tolterodine ER (P <.0001). |
| Cost effectiveness | Ko, 2006[463] | The cost-effectiveness of various antimuscarinic agents for the treatment of overactive bladder | Decision-analysis model | | | Darifenacin, solifenacin, trospium, immediate release oxybutynin, extended-release oxybutynin, transdermal oxybutynin, immediate-release tolterodine, and extended-release tolterodine | | | Expected costs for each patient with OAB ranged from $3373 when treated with solifenacin to $3769 when treated with immediate-release oxybutynin. The average cost/patient with continued and successful treatment was lowest for solifenacin ($6863). Solifenacin dominated all other antimuscarinic agents because they were associated with high costs and low effectiveness. |
| Cost effectiveness | Yu, 2005[458] | Cost effectiveness of antimuscarinic medications | 2,496 | 80 | Not reported | Tolterodine<br>Oxybutynin extended-release<br>Oxybutynin<br>Other OAB drugs | 6 months-12 months | 20% random sample of the administrative files provided by the California Medicaid program (Medi-Cal) from January 1999 to April 2002 with chronic OAB/UI | Expected costs for each patient with OAB ranged from $3373 when treated with solifenacin to $3769 when treated with immediate-release oxybutynin. The average cost/patient with continued and successful treatment was lowest for solifenacin ($6863). Solifenacin |

**Appendix Table F34. Continence after duloxetine vs. placebo, random effects model**

| Reference | Active Events/Randomized | Control Events/Randomized | Relative Risk (95% CI) | Weight | Absolute Risk Difference (95% CI) | Weight |
|---|---|---|---|---|---|---|
| Norton, 2002[349] | 123/140 | 132/138 | 0.92 (0.86; 0.99) | 98.96 | -0.08 (-0.14; -0.01) | 46.58 |
| Millard, 2004[344] | 16/227 | 14/231 | 1.16 (0.58; 2.33) | 1.04 | 0.01 (-0.04; 0.06) | 53.42 |
| Pooled estimate | | | 0.92 (0.86; 1.0) | 100 | -0.03 (-0.12; 0.06) | 100 |
| I squared | | | 0.00% | | 79.30% | |
| p value for heterogeneity | | | 0.507 | | 0.028 | |

**Appendix Table F35. Continence after different doses of duloxetine**

| Reference Sample Size | Outcome as Reported | Daily Dose mg/day | Events in Active Group/Randomized to Active | Events in Control Group/Randomized to Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|
| Norton, 2002[349] 275 | SPT ≤2G | 20mg/day vs. 40mg/d | 110/138 | 111/137 | 0.98 (0.88; 1.11) | -0.01 (-0.11; 0.08) |
| Norton, 2002[349] 275 | Negative CST | 20mg/day vs. 40mg/d | 112/138 | 112/137 | 0.99 (0.89; 1.11) | -0.01 (-0.10; 0.09) |
| Norton, 2002[349] 275 | Zero incontinent episodes of diary | 20mg/day vs. 40mg/d | 128/138 | 123/137 | 1.03 (0.96; 1.11) | 0.03 (-0.04; 0.10) |
| Norton, 2002[349] 278 | SPT ≤2G | 20mg/day vs. 80mg/d | 110/138 | 113/140 | 0.99 (0.88; 1.11) | -0.01 (-0.10; 0.08) |
| Norton, 2002[349] 278 | Negative CST | 20mg/day vs. 80mg/d | 112/138 | 114/140 | 1.00 (0.89; 1.12) | 0.00 (-0.09; 0.09) |
| Norton, 2002[349] 278 | Zero incontinent episodes of diary | 20mg/day vs. 80mg/d | 128/138 | 123/140 | 1.06 (0.98; 1.14) | 0.05 (-0.02; 0.12) |
| Norton, 2002[349] 277 | SPT ≤2G | 40mg/day vs. 80mg/d | 111/137 | 113/140 | 1.00 (0.90; 1.13) | 0.00 (-0.09; 0.10) |
| Norton, 2002[349] 277 | Negative CST | 40mg/day vs. 80mg/d | 112/137 | 114/140 | 1.00 (0.90; 1.12) | 0.00 (-0.09; 0.09) |
| Norton, 2002[349] 277 | Zero incontinent episodes of diary | 40mg/day vs. 80mg/d | 123/137 | 123/140 | 1.02 (0.94; 1.11) | 0.02 (-0.05; 0.09) |

**Appendix Table F36. Improvement in UI after duloxetine vs. placebo (random effects model)**

| Outcome | Reference | Active Events/Randomized | Control Events/Randomized | Relative Risk (95% CI) | Weight | Absolute Risk Difference (95% CI) | Weight |
|---|---|---|---|---|---|---|---|
| Improvement in PGI rating | Schagen van Leeuwen, 2008[372] | 18/131 | 14/134 | 1.32 (0.68; 2.53) | 29.16 | 0.03 (-0.05; 0.11) | 25.46 |
| Improvement in PGI rating | Millard, 2004[344] | 167/227 | 148/231 | 1.15 (1.01; 1.3) | 45.4 | 0.10 (0.01; 0.18) | 24.16 |
| Improvement in PGI rating | Steers, 2007[375] | 5/153 | 1/153 | 5 (0.59; 42.30) | 6.39 | 0.03 (-0.01; 0.06) | 35.95 |
| Improvement in PGI rating | Cardozo, 2004[245] | 17/55 | 4/54 | 4.17 (1.50; 11.60) | 19.05 | 0.24 (0.09; 0.38) | 14.43 |
| Improvement in PGI rating: very much better, much better | Pooled estimate | | | 1.68 (0.94; 3.00) | 100 | 0.08 (0.01; 0.14) | 100 |
| I squared | I squared | | | 62.10% | | 69.40% | |
| p value for heterogeneity | p value for heterogeneity | | | 0.048 | | 0.02 | |
| Improvement in UI | Lin, 2008[333] | 42/60 | 28/61 | 1.53 (1.11; 2.10) | 12.7 | 0.24 (0.07; 0.41) | 10.63 |
| Improvement in UI | Yalcin, 2006[399] | 198/433 | 152/425 | 1.28 (1.09; 1.51) | 48.26 | 0.10 (;0.03; 0.17) | 34.27 |
| Improvement in UI | Cardozo, 2004[245] | 4/55 | 1/54 | 3.93 (0.45; 34.02) | 0.28 | 0.05 (-0.02; 0.13) | 29.68 |
| Improvement in UI | Millard, 2004[344] | 135/227 | 100/231 | 1.37 (1.15; 1.65) | 38.76 | 0.16 (0.07; 0.25) | 25.42 |
| Improvement in UI | Cardozo, 2010[243] | 697/1378 | 431/1380 | 1.62 (1.47; 1.78) | 37.29 | 0.19 (0.16; 0.23) | 27.76 |
| Improvement in UI: 50% or more reduction in urinary episode frequency | Pooled estimate | | | 1.46 (1.28; 1.66) | 100 | 0.14 (0.08; 0.21) | 100 |
| p value for heterogeneity | I squared | | | 0.10 | | 0.01 | |
| I squared | | | | 49.20% | | 72.60% | |

**Appendix Table F37. Perceived treatment success after different doses of duloxetine**

| Reference Sample Size | Outcome | Subgroup | Daily Dose | Events in Active/ Randomized | Events in Control/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|
| Norton, 2002[349] 275 | PGI-I score Percent in "very much" or "much better" categories | Baseline IEF ≥14 | 20 vs. 40mg/day | 29/138 | 56/138 | 0.51 (0.35; 0.75) | -0.20 (-0.31; -0.09) | -5 (-11; -3) | -199 (-305; -92) |
| Norton, 2002[349] 275 | Increase in avoidance/limiting domain of I-QOL score from baseline | | 20 vs. 40mg/day | 4/138 | 14/138 | 0.28 (0.10; 0.84) | -0.07 (-0.13; -0.02) | -14 (-65; -8) | -73 (-131; -15) |
| Norton, 2002[349] 275 | Increase in psychosocial domain of I-QOL score from baseline | | 20 vs. 40mg/day | 4/138 | 10/138 | 0.40 (0.13; 1.24) | -0.04 (-0.10; 0.01) | | |
| Norton, 2002[349] 275 | Increase in social embarrassment domain of I-QOL score from baseline | | 20 vs. 40mg/day | 5/138 | 16/138 | 0.31 (0.12; 0.82) | -0.08 (-0.14; -0.02) | -12 (-54; -7) | -81 (-143; -18) |
| Norton, 2002[349] 278 | PGI-I score Percent in "very much" or "much better" categories | | 20 vs. 80mg/day | 29/138 | 70/138 | 0.42 (0.29; 0.60) | -0.29 (-0.40; -0.18) | -3 (-5; -3) | -290 (-397; -183) |
| Norton, 2002[349] 278 | Increase in avoidance/limiting domain of I-QOL score from baseline | | 20 vs. 80mg/day | 4/138 | 20/138 | 0.20 (0.07; 0.58) | -0.11 (-0.18; -0.05) | -9 (-20; -6) | -114 (-178; -50) |
| Norton, 2002[349] 278 | Increase in psychosocial domain of I-QOL score from baseline | | 20 vs. 80mg/day | 4/138 | 16/138 | 0.25 (0.09; 0.74) | -0.09 (-0.14; -0.03) | -12 (-39; -7) | -85 (-145; -26) |
| Norton, 2002[349] 278 | Increase in social embarrassment domain of I-QOL score from baseline | | 20 vs. 80mg/day | 5/138 | 21/138 | 0.24 (0.09; 0.62) | -0.11 (-0.18; -0.05) | -9 (-21; -6) | -114 (-181; -47) |
| Norton, 2002[349] 277 | PGI-I score Percent in "very much" or "much better" categories | | 40 vs. 80mg/day | 56/137 | 70/137 | 0.82 (0.63; 1.06) | -0.09 (-0.21; 0.03) | | |
| Norton, 2002[349] 277 | Increase in avoidance/limiting domain of I-QOL score from baseline | | 40 vs. 80mg/day | 14/137 | 20/137 | 0.72 (0.38; 1.36) | -0.04 (-0.12; 0.04) | | |

**Appendix Table F37. Perceived treatment success after different doses of duloxetine (continued)**

| Reference Sample Size | Outcome | Subgroup | Daily Dose | Events in Active/ Randomized | Events in Control/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|
| Norton, 2002[349] 277 | Increase in psychosocial domain of I-QOL score from baseline | | 40 vs. 80mg/day | 10/137 | 16/137 | 0.64 (0.30; 1.36) | -0.04 (-0.11; 0.03) | | |
| Norton, 2002[349] 277 | Increase in social embarrassment domain of I-QOL score from baseline | | 40 vs. 80mg/day | 16/137 | 21/137 | 0.78 (0.42; 1.43) | -0.03 (-0.11; 0.05) | | |
| Duckett, 2007[278] 222 | PGI-I score: very much better | in stress vs. mixed UI | 60 vs. 40mg twice daily | 10/123 | 8/123 | 1.01 (0.41; 2.45) | 0.00 (-0.07; 0.07) | | |
| Duckett, 2007[278] 222 | PGI-I score: much better | in stress vs. mixed UI | 60 vs. 40mg twice daily | 22/123 | 11/123 | 1.61 (0.82; 3.16) | 0.07 (-0.02; 0.16) | | |
| Duckett, 2007[278] 222 | PGI-I score: a little better | in stress vs. mixed UI | 60 vs. 40mg twice daily | 15/123 | 14/123 | 0.86 (0.44; 1.70) | -0.02 (-0.11; 0.07) | | |
| Duckett, 2007[278] 222 | PGI-I score: no change | in stress vs. mixed UI | 60 vs. 40mg twice daily | 21/123 | 10/123 | 1.69 (0.84; 3.42) | 0.07 (-0.02; 0.16) | | |
| Duckett, 2007[278] 222 | PGI-I score: a little worse | in stress vs. mixed UI | 60 vs. 40mg twice daily | 1/123 | 3/123 | 0.27 (0.03; 2.54) | -0.02 (-0.06; 0.02) | | |
| Duckett, 2007[278] 222 | PGI-I score: much worse | in stress vs. mixed UI | 60 vs. 40mg twice daily | 1/123 | 3/123 | 0.27 (0.03; 2.54) | -0.02 (-0.06; 0.02) | | |
| Duckett, 2007[278] 222 | PGI-I score: very much worse | in stress vs. mixed UI | 60 vs. 40mg twice daily | 0/123 | 1/123 | 0.27 (0.01; 6.53) | -0.01 (-0.04; 0.02) | | |
| Duckett, 2007[278] 222 | PGI-I score: total | in stress vs. mixed UI | 60 vs. 40mg twice daily | 70/123 | 50/123 | 1.13 (0.88; 1.44) | 0.06 (-0.07; 0.20) | | |
| Bump, 2003[108] 277 | Mixed urinary incontinence | | 40 vs. 0mg/day | 85/137 | 88/137 | 0.99 (0.82; 1.18) | -0.01 (-0.12; 0.11) | | |
| Bump, 2003[108] 277 | Stress urinary incontinence | | 40 vs. 80mg twice daily | 79/137 | 91/137 | 0.89 (0.74; 1.07) | -0.07 (-0.19; 0.04) | | |

**Evidence table F38. Treatment failure after duloxetine vs. placebo (random effects model)**

| Change in PGI-I Rating Scale | Reference | Active Events/Randomized | Control Events/Randomized | Relative Risk (95% CI) | Weight | Absolute Risk Difference (95% CI) | Weight |
|---|---|---|---|---|---|---|---|
| Deterioration very much worse | Schagen van Leeuwen, 2008[372] | 0/131 | 1/134 | 0.34 (0.01; 8.29) | 0.99 | -0.01 (-0.03; 0.01) | 30.27 |
| Deterioration very much worse | Bent, 2008[228] | 4/300 | 0/288 | 8.64 (0.47; 159.78) | 1.19 | 0.01 (-0.00; 0.03) | 35.81 |
| Deterioration very much worse | Steers, 2007[375] | 1/153 | 1/153 | 1 (0.06; 15.84) | 1.32 | 0 (-0.02; 0.02) | 32.56 |
| Deterioration very much worse | Cardozo, 2004[245] | 31/55 | 42/54 | 0.73 (0.55; 0.95) | 96.5 | -0.21 (-0.39; -0.04) | 1.36 |
| Deterioration very much worse | Pooled estimate | | | 0.74 (0.54; 1.02) | 100 | 0 (-0.02; 0.02) | 100 |
| Deterioration very much worse | I squared | | | 0.70% | | 67.30% | |
| Deterioration very much worse | p value for heterogeneity | | | 0.39 | | 0.03 | |
| Deterioration much worse | Schagen van Leeuwen, 2008[372] | 1/131 | 1/134 | 1.02 (0.07; 16.18) | 26.1 | 0 (-0.02; 0.02) | 22.7 |
| Deterioration much worse | Bent, 2008[228] | 3/300 | 1/288 | 2.88 (0.30; 27.53) | 39.06 | 0.01 (-0.01; 0.02) | 57.04 |
| Deterioration much worse | Steers, 2007[375] | 1/153 | 2/153 | 0.5 (0.05; 5.46) | 34.84 | -0.01; -0.03; 0.02) | 20.26 |
| Deterioration much worse | Pooled estimate | | | 1.19 (0.29; 4.90) | 100 | 0.00 (-0.01; 0.01) | 100 |
| Deterioration much worse | I squared | | | 0.00% | | 0.00% | |
| Deterioration much worse | p value for heterogeneity | | | 0.575 | | 0.591 | |
| No change | Schagen van Leeuwen, 2008[372] | 26/131 | 35/134 | 0.76 (0.49; 1.19) | 17.76 | -0.06 (-0.16; 0.04) | 25.63 |
| No change | Bent, 2008[228] | 74/300 | 94/288 | 0.76 (0.58; 0.98) | 53.17 | -0.08 (-0.15; -0.01) | 49.21 |
| No change | Steers, 2007[375] | 41/153 | 49/153 | 0.84 (0.59; 1.19) | 29.07 | -0.05 (-0.15; 0.05) | 25.16 |
| No change | Pooled estimate | | | 0.78 (0.65; 0.94) | 100 | -0.07 (-0.12; -0.02) | 100 |
| No change | I squared | | | 0.00% | | 0.00% | |
| No change | p value for heterogeneity | | | 0.89 | | 0.90 | |

**Evidence Table F38. Treatment failure after duloxetine vs. placebo (random effects model) (continued)**

| Change in PGI-I Rating Scale | Reference | Active Events/Randomized | Control Events/Randomized | Relative Risk (95% CI) | Weight | Absolute Risk Difference (95% CI) | Weight |
|---|---|---|---|---|---|---|---|
| Deterioration a little worse | Schagen van Leeuwen, 2008[372] | 4/131 | 14/134 | 0.29 (0.10; 0.87) | 28.82 | -0.07 (-0.13; -0.01) | 22.62 |
| Deterioration a little worse | Bent, 2008[228] | 8/300 | 10/288 | 0.77 (0.31; 1.91) | 39.65 | -0.01 (-0.04; 0.02) | 47.04 |
| Deterioration a little worse | Steers, 2007[375] | 6/153 | 8/153 | 0.75 (0.27; 2.11) | 31.53 | -0.01 (-0.06; 0.03) | 30.34 |
| Deterioration a little worse | Pooled estimate | | | 0.58 (0.32; 1.05) | 100 | -0.03 (-0.06; 0.01) | 100 |
| Deterioration a little worse | I squared | | | 5.80% | | 48.80% | |
| Deterioration a little worse | p value for heterogeneity | | | 0.35 | | 0.14 | |

**Appendix Table F39. Adverse effects after duloxetine vs. placebo, random effects model**

| Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|
| Abnormal elevation in bilirubine | Millard, 2004[344] | 1/227 | 9/231 | 0.11 (0.01; 0.89) | 33.43 | -0.04 (-0.06; -0.01) | 40.86 |
| Total bilirubin above ULN | Hurley, 2006[304] | 4/958 | 8/955 | 0.50 (0.15; 1.65) | 66.57 | -0.00 (-0.01; 0.00) | 59.14 |
| | Pooled | 5/1185 | 17/1186 | 0.30 (0.08 1.20) | 100 | -0.02 (-0.05; 0.01) | 100 |
| | P value/I squared | | | 0.22<br>33.00% | | 0.03<br>78.90% | |
| Abnormal elevation in alanine aminotransferase | Millard, 2004[344] | 4/227 | 2/231 | 2.04 (0.38; 11.00) | 3.38 | 0.01 (-0.01; 0.03) | 56.46 |
| ALT above ULN | Hurley, 2006[304] | 84/958 | 62/955 | 1.35 (0.99; 1.85) | 96.62 | 0.02 (-0.00; 0.05) | 43.54 |
| | Pooled | 88/1185 | 64/1186 | 1.37 (1.00; 1.87) | 100 | 0.02 (-0.00; 0.03) | 100 |
| | P value/I squared | | | 0.64<br>0.00% | | 0.39<br>0.00% | |
| Abnormal elevation in aspartate aminotransferase | Millard, 2004[344] | 3/227 | 6/231 | 0.51 (0.13; 2.01) | 28.62 | -0.01 (-0.04; 0.01) | 46.87 |
| AST above ULN | Hurley, 2006[304] | 60/958 | 42/955 | 1.42 (0.97; 2.09) | 71.38 | 0.02 (-0.00; 0.04) | 53.13 |
| | Pooled | 63/1185 | 48/1186 | 1.06 (0.43; 2.64) | 100 | 0.00 (-0.03; 0.04) | 100 |
| | P value/I squared | | | 0.16<br>50.00% | | 0.06<br>72.40% | |
| Anorexia | Millard, 2004[344] | 15/227 | 0/231 | 31.54 (1.90; 524.06) | 17.1 | 0.07 (0.03; 0.10) | 19.84 |
| Anorexia | Hurley, 2006[304] | 37/958 | 2/955 | 18.44 (4.46; 76.3) | 66.97 | 0.04 (0.02; 0.05) | 59.74 |
| Anorexia | Schagen van Leeuwen, 2008[372] | 4/131 | 0/134 | 9.21 (0.5; 169.28) | 15.93 | 0.03 (-0.00; 0.06) | 20.42 |
| | Pooled | 56/1316 | 2/1320 | 18.10 (5.66; 57.85) | 100 | 0.04 (0.02; 0.06) | 100 |
| | P value/I squared | | | 0.84<br>0.00% | | 0.23<br>32.50% | |
| Anorgasmia | Hurley, 2006[304] | 13/958 | 0/955 | 26.92 (1.60; 452.12) | 51.14 | 0.01 (0.01; 0.02) | 81.44 |
| Anorgasmia | Steers, 2007[375] | 5/153 | 0/153 | 11 (0.61; 197.22) | 48.86 | 0.03 (0.00; 0.06) | 18.56 |
| | Pooled | 18/1111 | 0/1108 | 17.38 (2.31; 130.72) | 100 | 0.02 (0.00; 0.03) | 100 |
| | P value/I squared | | | 0.66<br>0.00% | | 0.24<br>28.90% | |
| Anxiety | Hurley, 2006[304] | 18/958 | 7/955 | 2.56 (1.08; 6.11) | 70.6 | 0.01 (0.00; 0.02) | 61.05 |
| Anxiety | Kinchen, 2005[325] | 9/224 | 2/227 | 4.56 (1.00; 20.87) | 23.01 | 0.03 (0.00; 0.06) | 20.6 |
| Anxiety | Steers, 2007[375] | 5/153 | 0/153 | 11 (0.61; 197.22) | 6.39 | 0.03 (0.00; 0.06) | 18.35 |
| | Pooled | 32/1335 | 9/1335 | 3.21 (1.55; 6.66) | 100 | 0.02 (0.01; 0.03) | 100 |
| | P value/I squared | | | 0.56<br>0.00% | | 0.22<br>33.50% | |
| Appetite decreased | Hurley, 2006[304] | 22/958 | 2/955 | 10.97 (2.59; 46.50) | 34.81 | 0.02 (0.01; 0.03) | 64.18 |
| Appetite decreased | Kinchen, 2005[325] | 10/224 | 2/227 | 5.07 (1.12; 22.87) | 32 | 0.04 (0.01; 0.07) | 7.18 |

**Appendix Table F39. Adverse effects after duloxetine vs. placebo, random effects model (continued)**

| Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|
| Appetite decreased | Lin, 2008[333] | 4/60 | 1/61 | 4.07 (0.47; 35.34) | 15.54 | 0.05 (-0.02; 0.12) | 1.26 |
| Appetite decreased | Bent, 2008[228] | 6/300 | 0/288 | 12.48 (0.71; 220.56) | 8.81 | 0.02 (0.00; 0.04) | 21.58 |
| Appetite decreased | Steers, 2007[375] | 6/153 | 0/153 | 13 (0.74 (23;.77) | 8.84 | 0.04 (0.01; 0.07) | 5.8 |
| | Pooled | 48/1695 | 5/1684 | 7.54 (3.21; 17.68) | 100 | 0.02 (0.02; 0.03) | 100 |
| | P value/I squared | | | 0.90<br>0.00% | | 0.64<br>0.00% | |
| Asthenia | Ghoniem, 2005[285] | 6/104 | 0/97 | 12.13 (0.69; 212.55) | 7.05 | 0.06 (0.10; 0.11) | 4.14 |
| Asthenia | Hurley, 2006[304] | 7/958 | 0/955 | 14.95 (0.86; 261.45) | 7.05 | 0.01 (0.00; 0.01) | 50.11 |
| Asthenia | Lin, 2008[333] | 3/60 | 1/61 | 3.05 (0.33; 28.51) | 11.56 | 0.03 (-0.03; 0.10) | 2.44 |
| Asthenia | Cardozo, 2010[243] | 27/1378 | 6/1380 | 4.51 (1.87; 10.88) | 74.34 | 0.02 (0.01; 0.02) | 43.31 |
| | Pooled | 43/2500 | 7/2493 | 5.03 (2.35; 10.75) | 100 | 0.01 (0.00; 0.02) | 100 |
| | P value/I squared | | | 0.76<br>0.00% | | 0.08<br>55.10% | |
| Constipation | Ghoniem, 2005[285] | 15/104 | 3/97 | 4.66 (1.39; 15.61) | 2.95 | 0.11 (0.04; 0.19) | 2.98 |
| Constipation | Millard, 2004[344] | 29/227 | 4/231 | 7.38 (2.64; 20.65) | 4.07 | 0.11 (0.06; 0.16) | 6.62 |
| Constipation | Hurley, 2006[304] | 105/958 | 22/955 | 4.76 (3.03; 7.47) | 21.2 | 0.09 (0.07; 0.11) | 15.57 |
| Constipation | Kinchen, 2005[325] | 20/224 | 5/227 | 4.05 (1.55; 10.61) | 4.65 | 0.07 (0.03; 0.11) | 7.7 |
| Constipation | van Kerrebroeck, 2004[321] | 35/247 | 10/247 | 3.5 (1.77; 6.91) | 9.31 | 0.10 (0.05; 0.15) | 5.96 |
| Constipation | Norton, 2002[349] | 6/140 | 1/138 | 5.91 (0.72; 48.49) | 0.97 | 0.04 (-0.00; 0.07) | 9.29 |
| Constipation | Castro-Diaz, 2007[247] | 16/136 | 6/120 | 2.35 (0.95; 5.82) | 5.25 | 0.07 (0.00; 0.13) | 3.72 |
| Constipation | Lin, 2008[333] | 10/60 | 0/61 | 21.34 (1.28; 356.28) | 0.54 | 0.17 (0.07; 0.26) | 1.9 |
| Constipation | Schagen van Leeuwen, 2008[372] | 14/131 | 1/134 | 14.32 (1.91; 107.35) | 1.06 | 0.10 (0.05; 0.15) | 5.15 |
| Constipation | Dmochowski, 2003[272] | 33/344 | 7/339 | 4.65 (2.08; 10.36) | 6.7 | 0.08 (0.04; 0.11) | 9.9 |
| Constipation | Bent, 2008[228] | 25/300 | 12/288 | 2 (1.02; 3.91) | 9.62 | 0.04 (0.00; 0.08) | 8.54 |
| Constipation | Steers, 2007[375] | 21/153 | 5/153 | 4.2 (1.63; 10.85) | 4.78 | 0.11 (0.04; 0.17_ | 4.29 |
| Constipation | Cardozo, 2010[243] | 125/1378 | 31/1380 | 4.04 (2.75; 5.94) | 28.89 | 0.07 (0.05; 0.09) | 18.38 |
| | Pooled | 454/4402 | 107/4370 | 4.01 (3.26; 4.93) | 100 | 0.08 (0.06; 0.09) | 100 |
| | P value/I squared | | | 0.55<br>0.00% | | 0.10<br>35.10% | |
| Diarrhea | Hurley, 2006[304] | 49/958 | 26/955 | 1.88 (1.18; 3.00) | 48.74 | 0.02 (0.01; 0.04) | 27.08 |
| Diarrhea | Kinchen, 2005[325] | 19/224 | 8/227 | 2.41 (1.08; 5.38) | 16.4 | 0.05 (0.01; 0.09) | 12.38 |
| Diarrhea | Norton, 2002[349] | 4/140 | 3/138 | 1.31 (0.30; 5.76) | 4.86 | 0.01 (-0.03; 0.04) | 15.23 |
| Diarrhea | Castro-Diaz, 2007[247] | 1/136 | 4/120 | 0.22 (0.03; 1.95) | 2.24 | -0.03 (-0.06; 0.01) | 16 |
| Diarrhea | Dmochowski, 2003[272] | 21/344 | 9/339 | 2.30 (1.07; 4.95) | 18.1 | 0.03 (0.00; 0.07) | 18.46 |
| Diarrhea | Steers, 2007[375] | 10/153 | 5/153 | 2 (0.70; 5.72) | 9.65 | 0.03 (-0.02; 0.08) | 10.84 |
| | Pooled | 104/1955 | 55/1932 | 1.91 (1.38; 2.65) | 100 | 0.02 (0; 0.04) | 100 |

**Appendix Table F39. Adverse effects after duloxetine vs. placebo, random effects model (continued)**

| Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|
| | P value/I squared | | | 0.47<br>0.00% | | 0.07<br>50.70% | |
| Dizziness | Ghoniem, 2005[285] | 19/104 | 5/97 | 3.54 (1.38; 9.12) | 5.03 | 0.13 (0.05; 0.22) | 3.2 |
| Dizziness | Millard, 2004[344] | 25/227 | 6/231 | 4.24 (1.77; 10.14) | 5.92 | 0.08 (0.04; 0.13) | 7.79 |
| Dizziness | Cardozo, 2004[245] | 9/55 | 2/54 | 4.42 (1; 19.52) | 2.04 | 0.13 (0.02; 0.24) | 2.12 |
| Dizziness | Hurley, 2006[304] | 91/958 | 25/955 | 3.63 (2.35; 5.60) | 23.95 | 0.07 0.05; 0.09) | 13.78 |
| Dizziness | Kinchen, 2005[325] | 30/224 | 8/227 | 3.8 (1.78; 8.11) | 7.84 | 0.10 (0.05; 0.15) | 6.9 |
| Dizziness | van Kerrebroeck, 2004[321] | 30/247 | 8/247 | 3.75 (1.75; 8.02) | 7.8 | 0.09 (0.04; 0.14) | 7.65 |
| Dizziness | Norton, 2002[349] | 7/140 | 2/138 | 3.45 (0.73; 16.32) | 1.86 | 0.04 (-0.01; 0.08) | 8.66 |
| Dizziness | Castro-Diaz, 2007[247] | 14/136 | 1/120 | 12.35 (1.65; 92.55) | 1.11 | 0.10 (0.04; 0.15) | 6.43 |
| Dizziness | Lin, 2008[333] | 8/60 | 6/61 | 1.36 (0.50; 3.67) | 4.53 | 0.04 (-0.08; 0.15) | 2 |
| Dizziness | Schagen van Leeuwen, 2008[372] | 12/131 | 6/134 | 2.05 (0.79; 5.29) | 4.99 | 0.05 (-0.01; 0.11) | 5.48 |
| Dizziness | Dmochowski, 2003[272] | 26/344 | 8/339 | 3.20 (1.47; 6.97) | 7.43 | 0.05 (0.02; 0.08) | 10.77 |
| Dizziness | Bent, 2008[228] | 29/300 | 7/288 | 3.98 (1.77; 8.94) | 6.87 | 0.07 (0.03; 0.11) | 9.41 |
| Dizziness | Cardozo, 2010[243] | 68/1378 | 23/1380 | 2.96 (1.86; 4.72) | 20.64 | 0.03 (0.02; 0.05) | 15.8 |
| | Pooled | 368/4304 | 107/4271 | 3.33 (2.69; 4.11) | 100 | 0.07 (0.045; 0.08) | 100 |
| | P value/I squared | | | 0.86<br>0.00% | | 0.01<br>56.20% | |
| Dry mouth | Ghoniem, 2005[285] | 19/104 | 3/97 | 5.91 (1.81; 19.34) | 6.36 | 0.15 (0.07; 0.23) | 5.12 |
| Dry mouth | Millard, 2004[344] | 28/227 | 4/231 | 7.12 (2.54; 19.98) | 7.39 | 0.11 (0.06; 0.15) | 7.97 |
| Dry mouth | Cardozo, 2004[245] | 12/55 | 0/54 | 24.55 (1.49; 404.63) | 1.75 | 0.22 (0.11; 0.33) | 3.53 |
| Dry mouth | Kinchen, 2005[325] | 26/224 | 5/227 | 5.27 (2.06; 13.48) | 8.09 | 0.09 (0.05; 0.14) | 7.95 |
| Dry mouth | van Kerrebroeck, 2004[321] | 48/247 | 6/247 | 8 (3.49; 18.35) | 9 | 0.17 (0.12; 0.22) | 7.35 |
| Dry mouth | Norton, 2002[349] | 7/140 | 1/138 | 6.9 (0.86; 55.35) | 2.89 | 0.04 (0.00; 0.08) | 8.6 |
| Dry mouth | Castro-Diaz, 2007[247] | 22/136 | 5/120 | 3.88 (1.52; 9.93) | 8.09 | 0.12 (0.05; 0.19) | 5.85 |
| Dry mouth | Lin, 2008[333] | 10/60 | 2/61 | 5.08 (1.16; 22.24) | 4.83 | 0.13 (0.03; 0.24) | 3.87 |
| Dry mouth | Schagen van Leeuwen, 2008[372] | 26/131 | 2/134 | 13.30 (3.22; 54.90) | 5.09 | 0.18 (0.11; 0.26) | 5.86 |
| Dry mouth | Dmochowski, 2003[272] | 42/344 | 3/339 | 13.80 (4.32; 44.08) | 6.51 | 0.11 (0.08; 0.15) | 8.84 |
| Dry mouth | Bent, 2008[228] | 36/300 | 8/288 | 4.32 (2.04; 9.14) | 9.72 | 0.09 (0.05; 0.13) | 8.37 |
| Dry mouth | Steers, 2007[375] | 25/153 | 2/153 | 12.5 (3.01; 51.86) | 5.07 | 0.15 (0.09; 0.21) | 6.65 |
| Dry mouth | Cardozo, 2010[243] | 117/1378 | 47/1380 | 2.49 (1.79; 3.47) | 13.56 | 0.05 (0.03; 0.07) | 10.19 |
| Dry mouth | Hurley, 2006[304] | 128/958 | 14/955 | 9.11 (5.29; 15.71) | 11.65 | 0.12 (0.10; 0.14) | 9.86 |
| | Pooled | 546/4457 | 102/4424 | 6.26 (4.22; 9.28) | 100 | 0.12 (0.09; 0.14) | 100 |
| | P value/I squared | | | 0.00<br>58.20% | | 0<br>78.60% | |

**Appendix Table F39. Adverse effects after duloxetine vs. placebo, random effects model (continued)**

| Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|
| Fatigue | Millard, 2004[344] | 23/227 | 8/231 | 2.93 (1.34; 6.40) | 6.04 | 0.07 (0.02; 0.11) | 8.93 |
| Fatigue | Cardozo, 2004[245] | 10/55 | 6/54 | 1.64 (0.64; 4.19) | 4.2 | 0.07 (-0.06; 0.20) | 2.52 |
| Fatigue | Hurley, 2006[304] | 122/958 | 36/955 | 3.38 (2.36; 4.85) | 28.49 | 0.09 (0.07; 0.11) | 11.92 |
| Fatigue | Kinchen, 2005[325] | 45/224 | 12/227 | 3.8 (2.07; 6.99) | 9.98 | 0.15 (0.09; 0.21) | 7.14 |
| Fatigue | van Kerrebroeck, 2004[321] | 34/247 | 11/247 | 3.09 (1.60; 5.96) | 8.6 | 0.09 (0.04; 0.14) | 8.36 |
| Fatigue | Norton, 2002[349] | 10/140 | 3/138 | 3.29 (0.92; 11.68) | 2.3 | 0.05 (0.00; 0.10) | 8.49 |
| Fatigue | Lin, 2008[333] | 5/60 | 0/61 | 11.18 (0.63; 197.86) | 0.45 | 0.08 (0.01; 0.16) | 5.6 |
| Fatigue | Schagen van Leeuwen, 2008[372] | 19/131 | 7/134 | 2.78 (1.21; 6.38) | 5.35 | 0.09 (0.02; 0.160 | 5.98 |
| Fatigue | Dmochowski, 2003[272] | 51/344 | 13/339 | 3.87 (2.14; 6.98) | 10.64 | 0.11 (0.07; 0.15) | 9.35 |
| Fatigue | Bent, 2008[228] | 20/300 | 8/288 | 2.4 (1.07; 5.36) | 5.74 | 0.04 (0.01; 0.07) | 10.59 |
| Fatigue | Steers, 2007[375] | 16/153 | 3/153 | 5.33 (1.59; 17.93) | 2.52 | 0.09 (0.03; 0.14) | 7.96 |
| Fatigue | Cardozo, 2010[243] | 65/1378 | 21/1380 | 3.1 (1.91; 5.04) | 15.68 | 0.03 (0.02; 0.05) | 13.16 |
| | Pooled | 420/4217 | 128/4207 | 3.22 (2.66; 3.90) | 100 | 0.08 (0.05; 0.10) | 100 |
| | P value/I squared | | | 0.94<br>0.00% | | 0<br>73.70% | |
| Headache | Millard, 2004[344] | 33/227 | 20/231 | 1.68 0.99; 2.84) | 9.44 | 0.06 (0; 0.12) | 4.8 |
| Headache | Cardozo, 2004[245] | 15/55 | 5/54 | 2.95 (1.15; 7.54) | 2.94 | 0.18 (0.04; 0.32) | 0.87 |
| Headache | Hurley, 2006[304] | 93/958 | 63/955 | 1.47 (1.08; 2) | 27.54 | 0.03 (0.01; 0.06) | 21.9 |
| Headache | Kinchen, 2005[325] | 28/224 | 14/227 | 2.03 (1.10; 3.75) | 6.87 | 0.06 (0.01; 0.12) | 5.69 |
| Headache | van Kerrebroeck, 2004[321] | 24/247 | 19/247 | 1.26 (0.71; 2.25) | 7.84 | 0.02 (-0.03; 0.07) | 6.51 |
| Headache | Norton, 2002[349] | 8/140 | 9/138 | 0.88 (0.35; 2.21) | 3.05 | -0.01 (-0.06; 0.05) | 5.15 |
| Headache | Castro-Diaz, 2007[247] | 11/136 | 11/120 | 0.88 (0.40; 1.96) | 4.07 | -0.01 (-0.08; 0.06) | 3.5 |
| Headache | Dmochowski, 2003[272] | 25/344 | 12/339 | 2.05 (1.05; 4.02) | 5.75 | 0.04 (0.00; 0.07) | 13.02 |
| Headache | Steers, 2007[375] | 13/153 | 8/153 | 1.63 (0.69; 3.81) | 3.58 | 0.03 (-0.02; 0.09) | 5.11 |
| Headache | Cardozo, 2010[243] | 109/1378 | 64/1380 | 1.71 (1.26; 2.30) | 28.93 | 0.03 (0.02; 0.05) | 33.46 |
| | Pooled | 359/3862 | 225/3844 | 1.58 (1.35; 1.86) | 100 | 0.03 (0.02; 0.05) | 100 |
| | P value/I squared | | | 0.57<br>0.00% | | 0.34<br>10.90% | |
| Hyperhidrosis | Lin, 2008[333] | 5/60 | 0/61 | 11.18 (0.63; 197.86) | 0.94 | 0.08 (0.01; 0.16) | 3.1 |
| Hyperhidrosis | Schagen van Leeuwen, 2008[372] | 7/131 | 0/134 | 15.34 (0.89; 265.91) | 0.95 | 0.05 (0.01; 0.09) | 8.15 |
| Hyperhidrosis | Cardozo, 2010[243] | 45/1378 | 13/1380 | 3.47 (1.88; 6.40) | 20.58 | 0.02 (0.01; 0.03) | 22.23 |
| Hyperhidrosis | Brunton, 2010[233] | 189/10326 | 34/7496 | 4.04 (2.80; 5.81) | 58.33 | 0.01 (0.01; 0.02) | 25.17 |
| Hyperhidrosis | Millard, 2004[344] | 13/227 | 2/231 | 6.62 (1.51; 28.98) | 3.54 | 0.05 (0.02; 0.08) | 10.84 |
| Hyperhidrosis | Kinchen, 2005[325] | 15/224 | 1/227 | 15.20 (2.03; 114.11) | 1.9 | 0.06 (0.03; 0.10) | 10.34 |
| Hyperhidrosis | Hurley, 2006[304] | 43/958 | 8/955 | 5.36 (2.53; 11.34) | 13.76 | 0.04 (0.02; 0.05) | 20.17 |

**Appendix Table F39. Adverse effects after duloxetine vs. placebo, random effects model (continued)**

| Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|
| | Pooled | 317/13304 | 58/10484 | 4.34 (3.29; 5.73) | 100 | 0.04 (0.02; 0.05) | 100 |
| | P value/I squared | | | 0.69<br>0.00% | | 0<br>79.40% | |
| Insomnia | Ghoniem, 2005[285] | 12/104 | 1/97 | 11.19 (1.48;84.47) | 2.85 | 0.11 (0.04; 0.17) | 7.07 |
| Insomnia | Millard, 2004[344] | 31/227 | 6/231 | 5.26 (2.24;12.36) | 9.09 | 0.11 (0.06; 0.16) | 8.3 |
| Insomnia | Cardozo, 2004[245] | 7/55 | 3/54 | 2.29 (0.63; 8.40) | 5.6 | 0.07 (-0.04; 0.18) | 4.37 |
| Insomnia | Hurley, 2006[304] | 121/958 | 18/955 | 6.70 (4.12; 10.91) | 13.41 | 0.11 (0.09; 0.13) | 10.24 |
| Insomnia | Kinchen, 2005[325] | 33/224 | 13/227 | 2.57 (1.39; 4.76) | 11.81 | 0.09 (0.04; 0.15) | 7.8 |
| Insomnia | van Kerrebroeck, 2004[321] | 31/247 | 3/247 | 10.33 (3.20; 33.36) | 6.41 | 0.11 (0.07; 0.16) | 8.76 |
| Insomnia | Norton, 2002[349] | 7/140 | 1/138 | 6.9 (0.86; 55.35) | 2.71 | 0.04 (0.00; 0.08) | 9.13 |
| Insomnia | Castro-Diaz, 2007[247] | 14/136 | 6/120 | 2.06 (0.82;5.19) | 8.41 | 0.05 (-0.01; 0.12) | 7.1 |
| Insomnia | Dmochowski, 2003[272] | 49/344 | 8/339 | 6.04 (2.90; 12.55) | 10.42 | 0.12 (0.08; 0.16) | 9.01 |
| Insomnia | Bent, 2008[228] | 7/300 | 7/288 | 0.96 (0.34; 2.70) | 7.44 | -0.00 (-0.03; 0.02) | 10.13 |
| Insomnia | Steers, 2007[375] | 20/153 | 5/153 | 4 (1.54; 10.38) | 8.14 | 0.10 (0.04; 0.16) | 7.4 |
| Insomnia | Cardozo, 2010[243] | 63/1378 | 24/1380 | 2.63 (1.65; 4.18) | 13.7 | 0.03 (0.02; 0.04) | 10.69 |
| | Pooled | 395/4266 | 95/4229 | 3.76 (2.59; 5.47) | 100 | 0.08 (0.05; 0.11) | 100 |
| | P value/I squared | | | 0.01<br>55.20% | | 0<br>86.90% | |
| Nausea | Ghoniem, 2005[285] | 40/104 | 5/97 | 7.46 (3.07; 18.13) | 6.09 | 0.33 (0.23; 0.44) | 5.49 |
| Nausea | Millard, 2004[344] | 57/227 | 9/231 | 6.45 (3.27; 12.71) | 7.72 | 0.21 (0.15; 0.27) | 7.51 |
| Nausea | Cardozo, 2004[245] | 25/55 | 7/54 | 3.51 (1.66; 7.42) | 7.13 | 0.33 (0.17; 0.48) | 3.48 |
| Nausea | Hurley, 2006[304] | 222/958 | 35/955 | 6.32 (4.48; 8.93) | 10.74 | 0.20 (0.17; 0.22) | 8.92 |
| Nausea | Kinchen, 2005[325] | 70/224 | 13/227 | 5.46 (3.11; 9.58) | 8.76 | 0.26 (0.19; 0.32) | 7.21 |
| Nausea | van Kerrebroeck, 2004[321] | 69/247 | 16/247 | 4.31 (2.58; 7.21) | 9.21 | 0.22 (0.15; 0.28) | 7.41 |
| Nausea | Norton, 2002[349] | 13/140 | 2/138 | 6.41 (1.47; 27.87) | 3.22 | 0.08 (0.03; 0.13) | 7.98 |
| Nausea | Castro-Diaz, 2007[247] | 40/136 | 7/120 | 5.04 (2.35; 10.83) | 7.01 | 0.24 (0.15; 0.32) | 6.23 |
| Nausea | Lin, 2008[333] | 9/60 | 0/61 | 19.31 (1.15; 324.56) | 1.08 | 0.15 (0.06; 0.24) | 5.93 |
| Nausea | Schagen van Leeuwen, 2008[372] | 10/131 | 4/134 | 2.56 (0.82; 7.95) | 4.6 | 0.05 (-0.01; 0.10) | 7.9 |
| Nausea | Dmochowski, 2003[272] | 78/344 | 7/339 | 10.98 (5.14; 23.45) | 7.06 | 0.21 (0.16; 0.25) | 8.23 |
| Nausea | Bent, 2008[228] | 54/300 | 13/288 | 3.99 (2.23; 7.15) | 8.57 | 0.13 (0.09; 0.19) | 8.09 |
| Nausea | Steers, 2007[375] | 47/153 | 7/153 | 6.71 (3.13; 14.38) | 7.03 | 0.26 (0.18; 0.34) | 6.58 |
| Nausea | Cardozo, 2010[243] | 279/1378 | 113/1380 | 2.47 (2.01; 3.04) | 11.78 | 0.12 (0.10; 0.15) | 9.04 |
| | Pooled | 1013/4457 | 238/4424 | 5.02 (3.70; 6.82) | 100 | 0.19 (0.15; 0.22) | 100 |
| | P value/I squared | | | 0<br>70.40% | | 0<br>84.30% | |
| Sleep disorder | Schagen van | 4/131 | 1/134 | 4.09 (0.46; 36.12) | 6.18 | 0.02 (-0.01; 0.06) | 8.58 |

**Appendix Table F39. Adverse effects after duloxetine vs. placebo, random effects model (continued)**

| Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|
| | Leeuwen, 2008[372] | | | | | | |
| Somnolence | Ghoniem, 2005[285] | 11/104 | 1/97 | 10.26 (1.35; 77.99) | 6.84 | 0.10 (0.03; 0.16) | 5.43 |
| Somnolence | Millard, 2004[344] | 19/227 | 0/231 | 39.68 (2.41; 653.35) | 4.17 | 0.08 (0.05; 0.12) | 8.13 |
| Somnolence | Cardozo, 2004[245] | 7/55 | 1/54 | 6.87 (0.88; 54.00) | 6.69 | 0.11 (0.01; 0.20) | 3.25 |
| Somnolence | Hurley, 2006[304] | 65/958 | 1/955 | 64.80 (9.01; 466.01) | 7.12 | 0.07 (0.05; 0.08) | 10.33 |
| Somnolence | Kinchen, 2005[325] | 23/224 | 4/227 | 5.83 (2.05; 16.58) | 14.22 | 0.09 (0.04; 0.13) | 7.38 |
| Somnolence | van Kerrebroeck, 2004[321] | 10/247 | 0/247 | 21 (1.24; 356.41) | 4.1 | 0.04 (0.02; 0.07) | 9.4 |
| Somnolence | Castro-Diaz, 2007[247] | 15/136 | 2/120 | 6.62 (1.55; 28.35) | 10.42 | 0.09 (0.04; 0.15) | 5.89 |
| Somnolence | Lin, 2008[333] | 9/60 | 0/61 | 19.31 (1.15; 324.56) | 4.12 | 0.15 (0.06; 0.24) | 3.32 |
| Somnolence | Dmochowski, 2003[272] | 30/344 | 1/339 | 29.56 (4.06; 215.57) | 7.05 | 0.08 (0.05; 0.12) | 8.87 |
| Somnolence | Bent, 2008[228] | 8/300 | 1/288 | 7.68 (0.97; 61.02) | 6.64 | 0.02 (0.00; 0.04) | 10.03 |
| Somnolence | Steers, 2007[375] | 6/153 | 0/153 | 13 (0.74; 228.77) | 4.01 | 0.04 (0.01; 0.07) | 8.57 |
| Somnolence | Cardozo, 2010[243] | 28/1378 | 12/1380 | 2.34 (1.19; 4.58) | 18.45 | 0.01 (0.00; 0.02) | 10.81 |
| | Pooled | 235/4317 | 24/4286 | 8.61 (4.58; 16.20) | 100 | 0.06 (0.04; 0.08) | 100 |
| | P value/I squared | | | 0.08<br>38.40% | | 0<br>85.20% | |
| Treatment associated adverse effects | Dmochowski, 2003[272] | 255/344 | 170/339 | 1.48 (1.31; 1.68) | 13.35 | 0.24 (0.17; 0.31) | 13.9 |
| Treatment associated adverse effects | Millard, 2004[344] | 173/227 | 137/231 | 1.29 (1.13; 1.46) | 12.63 | 0.169<br>0.085<br>0.253 | 11.46 |
| Treatment associated adverse effects | van Kerrebroeck, 2004[321] | 200/247 | 158/247 | 1.27 (1.13; 1.42) | 14.93 | 0.17 (0.09; 0.25) | 12.61 |
| Treatment associated adverse effects | Cardozo, 2004[245] | 51/55 | 39/54 | 1.28 (1.07; 1.54) | 7.98 | 0.21 (0.07; 0.34) | 5.77 |
| Treatment associated adverse effects | Kinchen, 2005[325] | 198/224 | 159/227 | 1.26 (1.15; 1.39) | 17.06 | 0.18 (0.11; 0.26) | 13.44 |
| Treatment associated adverse effects | Steers, 2007[375] | 121/153 | 85/153 | 1.42 (1.21; 1.68) | 9.27 | 0.24 (0.13; 0.34) | 9.01 |
| Treatment associated adverse effects | Lin, 2008[333] | 48/60 | 27/61 | 1.81 (1.33; 2.46) | 3.29 | 0.36 (0.20; 0.52) | 4.49 |
| Treatment associated adverse effects | Schagen van Leeuwen, 2008[372] | 58/131 | 49/134 | 1.21 (0.90; 1.63) | 3.59 | 0.08 (-0.04; 0.20) | 7.32 |
| Treatment associated adverse effects | Cardozo, 2010[243] | 666/1378 | 460/1380 | 1.45 (1.32; 1.59) | 17.88 | 0.15 (0.11; 0.19) | 21.99 |
| | Pooled | 1769/2819 | 1283/2826 | 1.36 (1.28; 1.44) | 100 | 0.19 (0.15; 0.22) | 100 |
| | P value/I squared | | | 0.12<br>37.70% | | 0.07<br>44.60% | |

**Appendix Table F39. Adverse effects after duloxetine vs. placebo, random effects model (continued)**

| Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|
| Vomiting | Millard, 2004[344] | 14/227 | 4/231 | 3.56 (1.19; 10.66) | 7.65 | 0.04 (0.01; 0.08) | 6.05 |
| Vomiting | Cardozo, 2004[245] | 7/55 | 1/54 | 6.87 (0.88; 54.00) | 2.16 | 0.11 (0.01; 0.20) | 0.85 |
| Vomiting | Hurley, 2006[304] | 46/958 | 15/955 | 3.06 (1.72; 5.44) | 27.71 | 0.03 (0.02; 0.05) | 29.24 |
| Vomiting | Kinchen, 2005[325] | 19/224 | 8/227 | 2.41 (1.08; 5.38) | 14.17 | 0.05 (0.01; 0.09) | 4.02 |
| Vomiting | van Kerrebroeck, 2004[321] | 16/247 | 5/247 | 3.2 (1.19; 8.60) | 9.4 | 0.05 (0.01; 0.08) | 6.1 |
| Vomiting | Steers, 2007[375] | 5/153 | 3/153 | 1.67 (0.41; 6.85) | 4.6 | 0.01 (-0.02; 0.05) | 5.98 |
| Vomiting | Cardozo, 2010[243] | 54/1378 | 19/1380 | 2.85 (1.70; 4.78) | 34.31 | 0.03 (0.01; 0.04) | 47.75 |
| | | 161/3242 | 55/3247 | 2.9 (2.14; 3.93) | 100 | 0.03 (0.02; 0.04) | 100 |
| | | | | 0.95<br>0.00% | | 0.40<br>2.90% | |
| Adverse effects | Bent, 2008[228] | 5/300 | 5/288 | 0.96 (0.28; 3.28) | 61.32 | -0.00 (-0.02; 0.02) | 57.85 |
| | Steers, 2007[375] | 6/153 | 1/153 | 6 (0.73; 49.25) | 38.68 | 0.03 (-0.00; 0.07) | 42.15 |
| | Pooled | 11/453 | 6/441 | 1.95 (0.34; 11.22) | 100 | 0.01 (-0.02; 0.05) | 100 |
| | P value/I squared | | | 0.14<br>53.90% | | 0.10<br>63.90% | |

**Appendix Table F40. Adverse effects after duloxetine treatments compared to placebo (pooled results from RCTs)**

| Outcome | Studies | Patients | Rate Active/ Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) | Bayesian Odds Ratio Median (2.5; 97.5%) | Evidence |
|---|---|---|---|---|---|---|---|---|---|
| Total bilirubin above ULN | 2[304,344] | 2,371 | 0.4/1.4 | 0.30 (0.08; 1.20) | -0.02 (-0.05; 0.00) | | | 0.26 (0.06; 0.90) | Low |
| ALT above ULN/ Abnormal elevation in alanine aminotransferase | 2[304,344] | 2,371 | 7.4/5.4 | 1.37 (1.00; 1.87) | 0.015 (-0.001; 0.000) | | | 1.38 (0.55; 3.34) | Low |
| AST above ULN/ Abnormal elevation in aspartate aminotransferase | 2[304,344] | 2,371 | 5.3/4.0 | 1.06 (0.43; 2.64) | 0.00 (-0.03; 0.00) | | | 1.06 (0.28; 2.76) | Low |
| Anorexia | 3[304,344,372] | 2,636 | 4.3/0.2 | 18.10 (5.66; 57.85) | 0.04 (0.02; 24.39) | 24 (17; 42) | 41 (24; 58) | 36.13 (9.10; 233.30) | Moderate |
| Anorgasmia | 2[304,375] | 2,219 | 1.6/0.0 | 17.38 (2.31; 130.72) | 0.02 (0.00; 58.82) | 59 (31; 333) | 17 (3; 32) | | Low |
| Anxiety | 3[304,325,375] | 2,670 | 2.4/0.7 | 3.21 (1.55; 6.66) | 0.02 (0.01; 52.63) | 53 (29; 200) | 19 (5; 34) | 4.11 (1.65; 11.50) | High |
| Appetite decreased | 5[228,304,325,333,375] | 3,379 | 2.8/0.3 | 7.54 (3.21; 17.68) | 0.02 (0.02; 43.48) | 43 (32; 67) | 23 (15; 31) | 11.44 (4.43; 35.72) | High |
| Asthenia | 4[243,285,304,333] | 4,993 | 1.7/0.3 | 5.03 (2.35; 10.75) | 0.01 (0.00; 76.92) | 77 (42; 333) | 13 (3; 24) | 7.47 (2.90; 23.90) | Moderate |
| Constipation | 13[228,243,247,272,285,304,321,325,333,344,349,372,375] | 8,772 | 10.3/2.4 | 4.01 (3.26; 4.93) | 0.08 (0.06; 12.82) | 13 (11; 16) | 78 (64; 91) | 4.67 (3.55; 6.17) | High |
| Diarrhea | 6[247,272,304,325,349,375] | 3,887 | 5.3/2.9 | 1.91 (1.38; 2.65) | 0.02 (0.00; 52.63) | | | 1.80 (1.01; 2.95) | Moderate |
| Dizziness | 13[228,243,245,247,272,285,304,321,325,333,344,349,372] | 8,575 | 8.6/2.5 | 3.33 (2.69; 4.11) | 0.07 (0.05; 14.93) | 15 (12; 20) | 67 (49; 84) | 3.80 (2.89; 5.06) | High |
| Dry mouth | 14[228,243,245,247,272,285,304,321,325,333,344,349,372,375] | 8,881 | 12.2/2.3 | 6.26 (4.22; 9.28) | 0.12 (0.09; 8.70) | 9 (7; 11) | 115 (89; 141) | 6.94 (5.07; 9.76) | High |
| Fatigue | 12[228,243,245,272,304,321,325,333,344,349,372,375] | 8,424 | 10.0/3.0 | 3.22 (2.66; 3.90) | 0.08 (0.05; 12.99) | 13 (10; 19) | 77 (53; 100) | 3.60 (2.75; 4.73) | High |
| Headache | 10[243,245,247,272,3 | 7,706 | 9.3/5.9 | 1.58 (1.35; 1.86) | 0.03 (0.02; 30.30) | 30 (22; 50) | 33 (20; 46) | 1.67 (1.28; 2.21) | High |

**Appendix Table F40. Adverse effects after duloxetine treatments compared to placebo (pooled results from RCTs) (continued)**

| Outcome | Studies | Patients | Rate Active/ Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) | Bayesian Odds Ratio Median (2.5; 97.5%) | Evidence |
|---|---|---|---|---|---|---|---|---|---|
| | [304,321,325,344,349,375] | | | | | | | | |
| Hyperhidrosis | 7[233,243,304,325,333,344,372] | 23,788 | 2.4/0.6 | 4.34 (3.29; 5.73) | 0.04 (0.02; 28.57) | 29 (20; 48) | 35 (21; 49) | 6.02 (3.85; 10.53) | High |
| Insomnia | 12[228,243,245,247,272,285,304,321,325,344,349,375] | 8,495 | 9.3/2.3 | 3.76 (2.59; 5.47) | 0.08 (0.05; 13.16) | 13 (10; 21) | 76 (47; 105) | 4.35 (3.01; 6.26) | High |
| Nausea | 14[228,243,245,247,272,285,304,321,325,333,344,349,372,375] | 8,881 | 22.7/5.4 | 5.02 (3.70; 6.82) | 0.19 (0.15; 5.35) | 5 (4; 7) | 187 (149; 224) | 6.25 (4.66; 8.50) | High |
| Somnolence | 13[228,243,245,247,272,285,304,321,325,333,344,372,375] | 8,603 | 5.4/0.6 | 8.61 (4.58; 16.20) | 0.06 (0.04; 16.95) | 17 (13; 26) | 59 (39; 80) | 11.84 (6.99; 21.58) | High |
| Treatment associated adverse effects | 9[243,245,272,321,325,333,344,372,375] | 5,646 | 62.7/45.4 | 1.36 (1.28; 1.44) | 0.19 (0.15; 5.35) | 5 (4; 7) | 187 (150; 224) | 2.53 (1.95; 3.44) | High |
| Vomiting | 7[243,245,304,321,325,344,375] | 6,489 | 5.0/1.7 | 2.90 (2.14; 3.93) | 0.03 (0.02; 32.26) | 32 (26; 45) | 31 (22; 39) | 3.21 (2.16; 4.95) | High |
| Adverse effects | 2[228,375] | 894 | 2.4/1.4 | 1.95 (0.34; 11.22) | 0.01 (-0.02; 0.00) | | | 1.94 (0.54; 8.21) | Low |

**Appendix Table F41. Outcomes after different doses of duloxetine**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Any TEAE mild | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 49/136 | 51/133 | 0.94 (0.69; 1.28) | -0.02 (-0.14; 0.09) | | |
| Any TEAE mild | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 49/136 | 65/127 | 0.70 (0.53; 0.93) | -0.15 (-0.27; -0.03) | -6.60 (-30.39; -3.70) | -151.52 (-270.13; -32.91) |
| At least one adverse event | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 62/138 | 68/137 | 0.91 (0.70; 1.16) | -0.05 (-0.16; 0.07) | | |
| At least one adverse event | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 62/138 | 73/140 | 0.86 (0.68; 1.10) | -0.07 (-0.19; 0.05) | | |
| At least one adverse event | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 68/137 | 73/140 | 0.95 (0.76; 1.20) | -0.03 (-0.14; 0.09) | | |
| Constipation | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 4/138 | 4/137 | 0.99 (0.25; 3.89) | 0.00 (-0.04; 0.04) | | |
| Constipation | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 4/138 | 6/140 | 0.68 (0.20; 2.34) | -0.01 (-0.06; 0.03) | | |
| Constipation | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 4/137 | 6/140 | 0.68 (0.20; 2.36) | -0.01 (-0.06; 0.03) | | |
| Constipation | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 16/136 | 18/133 | 0.87 (0.46; 1.63) | -0.02 (-0.10; 0.06) | | |
| Constipation | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 16/136 | 6/127 | 2.49 (1.01; 6.17) | 0.07 (0.00; 0.14) | 14.20 (7.36; 205.04) | 70.40 (4.88; 135.93) |
| Constipation | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 6/127 | 18/133 | 0.35 (0.14; 0.85) | -0.09 (-0.16; -0.02) | -11.35 (-51.99; -6.37) | -88.09 (-156.95; -19.24) |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Constipation | Gahimer, 2007[283] 15,178 | 20-60mg/day vs. 20-120mg once/twice a day | 48/826 | 1149/14352 | 0.73 (0.55; 0.96) | -0.02 (-0.04; -0.01) | -45.56 (-185.66; -25.97) | -21.95 (-38.51; -5.39) |
| Diarrhea | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 5/138 | 4/137 | 1.24 (0.34; 4.52) | 0.01 (-0.03; 0.05) | | |
| Diarrhea | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 5/138 | 4/140 | 1.27 (0.35; 4.62) | 0.01 (-0.03; 0.05) | | |
| Diarrhea | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 4/137 | 4/140 | 1.02 (0.26; 4.00) | 0.00 (-0.04; 0.04) | | |
| Diarrhea | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 1/136 | 0/133 | 2.93 (0.12; 71.39) | 0.01 (-0.01; 0.03) | | |
| Diarrhea | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 1/136 | 4/127 | 0.23 (0.03; 2.06) | -0.02 (-0.06; 0.01) | | |
| Diarrhea | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 4/127 | 0/133 | 9.42 (0.51; 173.25) | 0.03 (0.00; 0.07) | | |
| Diarrhea | Gahimer, 2007[283] 15178 | 20-60mg/day vs. 20-120mg once/twice a day | 11/826 | 502/14352 | 0.38 (0.21; 0.69) | -0.02 (-0.03; -0.01) | -46.17 (-75.27; -33.29) | -21.66 (-30.04; -13.29) |
| Dizziness | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 2/138 | 6/137 | 0.33 (0.07; 1.61) | -0.03 (-0.07; 0.01) | | |
| Dizziness | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 2/138 | 7/140 | 0.29 (0.06; 1.37) | -0.04 (-0.08; 0.01) | | |
| Dizziness | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 6/137 | 7/140 | 0.88 (0.30; 2.54) | -0.01 (-0.06; 0.04) | | |
| Dizziness | Castro-Diaz, 2007[247] 2 69 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 14/136 | 4/133 | 3.42 (1.16; 10.13) | 0.07 (0.01; 0.13) | 13.72 (7.60; 70.81) | 72.87 (14.12; 131.61) |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Dizziness | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 14/136 | 10/127 | 1.31 (0.60; 2.84) | 0.02 (-0.05; 0.09) | | |
| Dizziness | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 10/127 | 4/133 | 2.62 (0.84; 8.14) | 0.05 (-0.01; 0.10) | | |
| Dizziness | Gahimer, 2007[283] 15,178 | 20-60mg/day vs. 20-120mg once/twice a day | 31/826 | 852/14352 | 0.63 (0.44; 0.90) | -0.02 (-0.04; -0.01) | -45.80 (-120.35; -28.28) | -21.83 (-35.36; -8.31) |
| Dry mouth | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 4/138 | 5/137 | 0.79 (0.22; 2.89) | -0.01 (-0.05; 0.03) | | |
| Dry mouth | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 4/138 | 7/140 | 0.58 (0.17; 1.94) | -0.02 (-0.07; 0.02) | | |
| Dry mouth | Norton, 2002[349] 277 | 40mg/day vs.80mg/d | 5/137 | 7/140 | 0.73 (0.24; 2.24) | -0.01 (-0.06; 0.03) | | |
| Dry mouth | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 22/136 | 19/133 | 1.13 (0.64; 1.99) | 0.02 (-0.07; 0.10) | | |
| Dry mouth | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 22/136 | 15/127 | 1.37 (0.74; 2.52) | 0.04 (-0.04; 0.13) | | |
| Dry mouth | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 15/127 | 19/133 | 0.83 (0.44; 1.56) | -0.02 (-0.11; 0.06) | | |
| Dry mouth | Gahimer, 2007[283] 15,178 | 20-60mg/day vs. 20-120mg once/twice a day | 63/826 | 1559/14352 | 0.70 (0.55; 0.89) | -0.03 (-0.05; -0.01) | -30.91 (-73.79; -19.55) | -32.35 (-51.16; -13.55) |
| Fatigue | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 1/138 | 8/137 | 0.12 (0.02; 0.98) | -0.05 (-0.09; -0.01) | -19.55 (-106.26; -10.77) | -51.15 (-92.89; -9.41) |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Fatigue | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 1/138 | 10/140 | 0.10 (0.01; 0.78) | -0.06 (-0.11; -0.02) | -15.58 (-51.99; -9.16) | -64.18 (-109.13; -19.24) |
| Fatigue | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 8/137 | 10/140 | 0.82 (0.33; 2.01) | -0.01 (-0.07; 0.04) | | |
| Fatigue | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 12/136 | 8/133 | 1.47 (0.62; 3.47) | 0.03 (-0.03; 0.09) | | |
| Fatigue | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 12/136 | 6/127 | 1.87 (0.72; 4.83) | 0.04 (-0.02; 0.10) | | |
| Fatigue | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 6/127 | 8/133 | 0.79 (0.28; 2.20) | -0.01 (-0.07; 0.04) | | |
| Fatigue | Gahimer, 2007[283] 15,178 | 20-60mg/day vs. 20-120mg once/twice a day | 41/826 | 1102/14352 | 0.65 (0.48; 0.88) | -0.03 (-0.04; -0.01) | -36.84 (-85.41; -23.48) | -27.15 (-42.59; -11.71) |
| Headache | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 7/138 | 10/137 | 0.69 (0.27; 1.77) | -0.02 (-0.08; 0.03) | | |
| Headache | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 7/138 | 8/140 | 0.89 (0.33; 2.38) | -0.01 (-0.06; 0.05) | | |
| Headache | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 10/137 | 8/140 | 1.28 (0.52; 3.14) | 0.02 (-0.04; 0.07) | | |
| Headache | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 11/136 | 9/133 | 1.20 (0.51; 2.79) | 0.01 (-0.05; 0.08) | | |
| Headache | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 11/136 | 11/127 | 0.93 (0.42; 2.08) | -0.01 (-0.07; 0.06) | | |
| Headache | Castro-Diaz, 2007[247] | 100mg/day vs. 20mg BID for 2 | 11/127 | 9/133 | 1.28 (0.55; 2.98) | 0.02 (-0.05; 0.08) | | |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| | 260 | weeks escalating to 40mg BID for 6 weeks | | | | | | |
| Headache | Gahimer, 2007[283] 15,178 | 20-60mg/day vs. 20-120mg once/twice a day | 68/826 | 1029/14352 | 1.15 (0.91; 1.45) | 0.01 (-0.01; 0.03) | | |
| Hyperhidrosis | Gahimer, 2007[283] 15,178 | 20-60mg/day vs. 20-120mg once/twice a day | 54/826 | 549/14352 | 1.71 (1.30; 2.24) | 0.03 (0.01; 0.04) | 36.87 (22.59; 100.24) | 27.12 (9.98; 44.27) |
| Insomnia | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 2/138 | 7/137 | 0.28 (0.06; 1.34) | -0.04 (-0.08; 0.01) | | |
| Insomnia | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 2/138 | 7/140 | 0.29 (0.06; 1.37) | -0.04 (-0.08; 0.01) | | |
| Insomnia | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 7/137 | 7/140 | 1.02 (0.37; 2.84) | 0.00 (-0.05; 0.05) | | |
| Insomnia | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 14/136 | 8/133 | 1.71 (0.74; 3.94) | 0.04 (-0.02; 0.11) | | |
| Insomnia | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 14/136 | 6/127 | 2.18 (0.86; 5.50) | 0.06 (-0.01; 0.12) | | |
| Insomnia | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 6/127 | 8/133 | 0.79 (0.28; 2.20) | -0.01 (-0.07; 0.04) | | |
| Insomnia | Gahimer, 2007[283] 15,178 | 20-60mg/day vs. 20-120mg once/twice a day | 59/826 | 1179/14352 | 0.87 (0.68; 1.12) | -0.01 (-0.03; 0.01) | | |
| Nasopharyngitis | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 8/138 | 4/137 | 1.99 (0.61; 6.44) | 0.03 (-0.02; 0.08) | | |
| Nasopharyngitis | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 8/138 | 6/140 | 1.35 (0.48; 3.80) | 0.02 (-0.04; 0.07) | | |
| Nasopharyngitis | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 4/137 | 6/140 | 0.68 (0.20; 2.36) | -0.01 (-0.06; 0.03) | | |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Nausea | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 9/138 | 9/137 | 0.99 (0.41; 2.43) | 0.00 (-0.06; 0.06) | | |
| Nausea | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 9/138 | 13/140 | 0.70 (0.31; 1.59) | -0.03 (-0.09; 0.04) | | |
| Nausea | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 9/137 | 13/140 | 0.71 (0.31; 1.60) | -0.03 (-0.09; 0.04) | | |
| Nausea | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 40/136 | 22/133 | 1.78 (1.12; 2.82) | 0.13 (0.03; 0.23) | 7.77 (4.39; 33.96) | 128.70 (29.45; 227.96) |
| Nausea | Castro-Diaz,2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 40/136 | 32/127 | 1.17 (0.78; 1.74) | 0.04 (-0.07; 0.15) | | |
| Nausea | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 32/127 | 22/133 | 1.52 (0.94; 2.47) | 0.09 (-0.01; 0.18) | | |
| Nausea | Gahimer, 2007[283] 15,178 | 20-60mg/day vs. 20-120mg once/twice a day | 19/826 | 2204/14352 | 0.15 (0.10; 0.23) | -0.13 (-0.14; -0.12) | -7.66 (-8.42; -7.02) | -130.57 (-142.37; -118.76) |
| Nausea mild | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 56/136 | 78/133 | 0.70 (0.55; 0.90) | -0.17 (-0.29; -0.06) | -5.72 (-17.53; -3.42) | -174.70 (-292.37; -57.03) |
| Nausea mild | Castro-Diaz, 2007[247] 264 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 56/136 | 64/127 | 0.82 (0.63; 1.07) | -0.09 (-0.21; 0.03) | | |
| Nausea moderate | Castro-Diaz, 2007[247] | 100mg/day vs. 20mg BID for 2 | 48/127 | 43/133 | 1.17 (0.84; 1.63) | 0.05 (-0.06; 0.17) | | |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| | 260 | weeks escalating to 40mg BID for 6 weeks | | | | | | |
| Nausea severe | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 14/136 | 12/133 | 1.14 (0.55; 2.37) | 0.01 (-0.06; 0.08) | | |
| Nausea severe | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 14/136 | 15/127 | 0.87 (0.44; 1.73) | -0.02 (-0.09; 0.06) | | |
| Nausea severe | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 15/127 | 12/133 | 1.31 (0.64; 2.69) | 0.03 (-0.05; 0.10) | | |
| Sinusitis | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 4/138 | 4/137 | 0.99 (0.25; 3.89) | 0.00 (-0.04; 0.04) | | |
| Sinusitis | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 4/138 | 4/140 | 1.01 (0.26; 3.98) | 0.00 (-0.04; 0.04) | | |
| Sinusitis | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 4/137 | 4/140 | 1.02 (0.26; 4.00) | 0.00 (-0.04; 0.04) | | |
| Somnolence | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 15/136 | 11/133 | 1.33 (0.64; 2.80) | 0.03 (-0.04; 0.10) | | |
| Somnolence | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 15/136 | 6/127 | 2.33 (0.93; 5.83) | 0.06 (0.00; 0.13) | | |
| Somnolence | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 6/127 | 11/133 | 0.57 (0.22; 1.50) | -0.04 (-0.10; 0.02) | | |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Somnolence | Gahimer, 2007[283] 15,178 | 20-60mg/day vs. 20-120mg once/twice a day | 60/826 | 990/14352 | 1.05 (0.82; 1.35) | 0.00 (-0.01; 0.02) | | |
| TEAE moderate | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 65/136 | 64/133 | 0.99 (0.77; 1.27) | 0.00 (-0.12; 0.12) | | |
| TEAE moderate | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 42/127 | 64/133 | 0.69 (0.51; 0.93) | -0.15 (-0.27; -0.03) | -6.64 (-30.70; -3.73) | -150.49 (-268.42; -32.57) |
| TEAE severe | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 20/136 | 19/133 | 1.03 (0.58; 1.84) | 0.00 (-0.08; 0.09) | | |
| TEAE severe | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 20/136 | 20/127 | 0.93 (0.53; 1.65) | -0.01 (-0.10; 0.08) | | |
| TEAE severe | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 20/127 | 19/133 | 1.10 (0.62; 1.97) | 0.01 (-0.07; 0.10) | | |
| Upper respiratory tract infection | Norton, 2002[349] 275 | 20mg/day vs.40mg/d | 2/138 | 2/137 | 0.99 (0.14; 6.95) | 0.00 (-0.03; 0.03) | | |
| Upper respiratory tract infection | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 2/138 | 1/140 | 2.03 (0.19; 22.12) | 0.01 (-0.02; 0.03) | | |
| Upper respiratory tract infection | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 2/137 | 1/140 | 2.04 (0.19; 22.28) | 0.01 (-0.02; 0.03) | | |
| Adverse effects leading to discontinuation | Duckett, 2007[278]215 | 60mg/day vs. 40mg twice daily | 21/67 | 74/148 | 0.63 (0.42; 0.93) | -0.19 (-0.32; -0.05) | -5.36 (-20.26; -3.09) | -186.57 (-323.78; -49.36) |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Discontinuation due to any adverse event | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 22/136 | 10/133 | 2.15 (1.06; 4.37) | 0.09 (0.01; 0.16) | 11.55 (6.14; 98.36) | 86.58 (10.17; 162.99) |
| Discontinuation due to any adverse event | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 22/136 | 15/127 | 1.37 (0.74; 2.52) | 0.04 (-0.04; 0.13) | | |
| Discontinuation due to any adverse event | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 15/127 | 10/133 | 1.57 (0.73; 3.37) | 0.04 (-0.03; 0.11) | | |
| Discontinuation due to asthenia | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 2/136 | 1/133 | 1.96 (0.18; 21.31) | 0.01 (-0.02; 0.03) | | |
| Discontinuation due to asthenia | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 2/136 | 0/127 | 4.67 (0.23; 96.38) | 0.01 (-0.01; 0.04) | | |
| Discontinuation due to asthenia | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 0/127 | 1/133 | 0.35 (0.01; 8.49) | -0.01 (-0.03; 0.01) | | |
| Discontinuation | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 13/138 | 17/137 | 0.76 (0.38; 1.50) | -0.03 (-0.10; 0.04) | | |
| Discontinuation | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 13/138 | 21/140 | 0.63 (0.33; 1.20) | -0.06 (-0.13; 0.02) | | |
| Discontinuation | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 17/137 | 21/140 | 0.83 (0.46; 1.50) | -0.03 (-0.11; 0.05) | | |
| Discontinuation due to dizziness | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 0/138 | 2/137 | 0.20 (0.01; 4.10) | -0.01 (-0.04; 0.01) | | |
| Discontinuation due to dizziness | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 0/138 | 1/140 | 0.34 (0.01; 8.23) | -0.01 (-0.03; 0.01) | | |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Discontinuation due to dizziness | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 2/137 | 1/140 | 2.04 (0.19; 22.28) | 0.01 (-0.02; 0.03) | | |
| Discontinuation due to dizziness | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 2/136 | 0/133 | 4.89 (0.24; 100.92) | 0.01 (-0.01; 0.04) | | |
| Discontinuation due to dizziness | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 2/136 | 2/127 | 0.93 (0.13; 6.53) | 0.00 (-0.03; 0.03) | | |
| Discontinuation due to dizziness | Castro-Diaz, 2007[247] | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 2/127 | 0/133 | 5.23 (0.25; 107.98) | 0.02 (-0.01; 0.04) | | |
| Discontinuation due to fatigue | Castro-Diaz, 2007[247] | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 0/136 | 0/133 | 0.00 (0.00; 0.00) | 0.00 (-0.01; 0.01) | | |
| Discontinuation due to fatigue | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 0/136 | 1/127 | 0.31 (0.01; 7.58) | -0.01 (-0.03; 0.01) | | |
| Discontinuation due to fatigue | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 1/127 | 0/133 | 3.14 (0.13; 76.39) | 0.01 (-0.01; 0.03) | | |
| Discontinuation due to headache | Castro-Diaz, 2007[247] 275 | 20mg/day vs. 40mg/d | 1/138 | 1/137 | 0.99 (0.06; 15.71) | 0.00 (-0.02; 0.02) | | |
| Discontinuation due to headache | Castro-Diaz, 2007[247] 278 | 20mg/day vs. 80mg/d | 1/138 | 2/140 | 0.51 (0.05; 5.53) | -0.01 (-0.03; 0.02) | | |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Discontinuation due to headache | Castro-Diaz, 2007[247] 277 | 40mg/day vs. 80mg/d | 1/137 | 2/140 | 0.51 (0.05; 5.57) | -0.01 (-0.03; 0.02) | | |
| Discontinuation due to headache | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 3/136 | 0/133 | 6.85 (0.36; 131.29) | 0.02 (-0.01; 0.05) | | |
| Discontinuation due to headache | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 3/136 | 1/127 | 2.80 (0.30; 26.59) | 0.01 (-0.01; 0.04) | | |
| Discontinuation due to headache | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 1/127 | 0/133 | 3.14 (0.13; 76.39) | 0.01 (-0.01; 0.03) | | |
| Discontinuation due to insomnia | Castro-Diaz, 2007[247] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 2/136 | 1/133 | 1.96 (0.18; 21.31) | 0.01 (-0.02; 0.03) | | |
| Discontinuation due to insomnia | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 2/136 | 1/127 | 1.87 (0.17; 20.35) | 0.01 (-0.02; 0.03) | | |
| Discontinuation due to insomnia | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 1/127 | 1/133 | 1.05 (0.07; 16.56) | 0.00 (-0.02; 0.02) | | |
| Discontinuation due to menorhagia | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 2/138 | 0/137 | 4.96 (0.24; 102.46) | 0.01 (-0.01; 0.04) | | |
| Discontinuation due to menorhagia | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 2/138 | 0/140 | 5.07 (0.25; 104.69) | 0.01 (-0.01; 0.04) | | |

**Appendix Table F41. Outcomes after different doses of duloxetine (continued)**

| Outcome | Reference Sample Size | Daily Dose mg/day | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Discontinuation due to menorhagia | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 0/137 | 0/140 | | 0.00 (-0.01; 0.01) | | |
| Discontinuation due to nausea | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 2/138 | 5/137 | 0.40 (0.08; 2.01) | -0.02 (-0.06; 0.02) | | |
| Discontinuation due to nausea | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 2/138 | 6/140 | 0.34 (0.07; 1.65) | -0.03 (-0.07; 0.01) | | |
| Discontinuation due to nausea | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 5/137 | 6/140 | 0.85 (0.27; 2.73) | -0.01 (-0.05; 0.04) | | |
| Discontinuation due to nausea | Norton, 2002[349] 269 | 80mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 4/136 | 3/133 | 1.30 (0.30; 5.72) | 0.01 (-0.03; 0.04) | | |
| Discontinuation due to nausea | Castro-Diaz, 2007[247] 263 | 80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks | 4/136 | 2/127 | 1.87 (0.35; 10.02) | 0.01 (-0.02; 0.05) | | |
| Discontinuation due to nausea | Castro-Diaz, 2007[247] 260 | 100mg/day vs. 20mg BID for 2 weeks escalating to 40mg BID for 6 weeks | 2/127 | 3/133 | 0.70 (0.12; 4.11) | -0.01 (-0.04; 0.03) | | |
| Discontinuation due to somnolence | Norton, 2002[349] 275 | 20mg/day vs. 40mg/d | 1/138 | 0/137 | 2.98 (0.12; 72.48) | 0.01 (-0.01; 0.03) | | |
| Discontinuation due to somnolence | Norton, 2002[349] 278 | 20mg/day vs. 80mg/d | 1/138 | 2/140 | 0.51 (0.05; 5.53) | -0.01 (-0.03; 0.02) | | |
| Discontinuation due to somnolence | Norton, 2002[349] 277 | 40mg/day vs. 80mg/d | 0/137 | 2/140 | 0.20 (0.01; 4.22) | -0.01 (-0.04; 0.01) | | |
| Discontinuation due to lack of efficacy leading to discontinuation | Duckett, 2007[278] 215 | 60mg/day vs. 40mg twice daily | 14/67 | 37/148 | 0.84 (0.49; 1.44) | -0.04 (-0.16; 0.08) | | |

**Appendix Table F42. Adverse effects that result in discontinuation of the treatment after duloxetine vs. placebo, random effects models**

| Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk | Lower (95% CI) | Upper (95% CI) | Weight | Absolute Risk Difference | Lower (95% CI) | Upper (95% CI) | Weight |
|---|---|---|---|---|---|---|---|---|---|---|
| **Anxiety** | | | | | | | | | | |
| | 0/955 | 0/955 | 9.158 | 0.496 | 169.125 | 49.29 | 0.018 | -0.001 | 0.037 | 16.45 |
| | 0/231 | 0/231 | 12.959 | 0.731 | 229.72 | 50.71 | 0.006 | 0.001 | 0.012 | 83.55 |
| Pooled estimate | | | 10.921 | 1.41 | 84.603 | 100 | 0.008 | 0 | 0.016 | 100 |
| I squared | | | 0.00% | | | | 21.20% | | | |
| p value for heterogeneity | | | 0.868 | | | | 0.26 | | | |
| **Asthenia** | | | | | | | | | | |
| | 0/61 | 0/61 | 2.8 | 0.115 | 67.922 | 23.69 | 0.01 | -0.017 | 0.036 | 12.41 |
| | 0/120 | 0/120 | 4.416 | 0.214 | 91.081 | 26.3 | 0.015 | -0.01 | 0.04 | 14 |
| | 0/288 | 0/288 | 3.049 | 0.127 | 73.398 | 23.81 | 0.017 | -0.028 | 0.061 | 4.42 |
| | 0/97 | 0/97 | 4.801 | 0.231 | 99.566 | 26.2 | 0.007 | -0.005 | 0.018 | 69.18 |
| Pooled estimate | | | 3.71 | 0.786 | 17.516 | 100 | 0.009 | -0.001 | 0.018 | 100 |
| I squared | | | 0.00% | | | | 0.00% | | | |
| p value for heterogeneity | | | 0.994 | | | | 0.926 | | | |
| **Constipation** | | | | | | | | | | |
| Hurley, 2006[304] | 1/955 | 1/955 | 0.311 | 0.013 | 7.547 | 37.16 | -0.01 | -0.038 | 0.017 | 2.14 |
| **Constipation-discontinuation due to adverse event** | | | | | | | | | | |
| Ghoniem, 2005[285] | 1/97 | 1/97 | 2.991 | 0.312 | 28.699 | 62.84 | 0.002 | -0.002 | 0.006 | 97.86 |
| Pooled estimate | | | 1.29 | 0.151 | 11.001 | 100 | 0.002 | -0.002 | 0.006 | 100 |
| I squared | | | 22.30% | | | | 0.00% | | | |
| p value for heterogeneity | | | 0.257 | | | | 0.385 | | | |
| **Dizziness** | | | | | | | | | | |
| Ghoniem, 2005[285] | 0/97 | 0/97 | 4.667 | 0.227 | 95.996 | 6.33 | 0.019 | -0.013 | 0.052 | 3.74 |
| Millard, 2004[344] | 0/231 | 0/231 | 11.193 | 0.623 | 201.255 | 6.93 | 0.022 | 0.001 | 0.043 | 9.08 |
| Hurley, 2006[304] | 2/955 | 2/955 | 9.969 | 2.337 | 42.531 | 27.48 | 0.019 | 0.009 | 0.028 | 43.41 |
| van Kerrebroeck, 2004[321] | 1/247 | 1/247 | 9 | 1.149 | 70.504 | 13.65 | 0.032 | 0.008 | 0.057 | 6.45 |
| Norton, 2002[349] | 0/138 | 0/138 | 2.957 | 0.122 | 71.977 | 5.68 | 0.007 | -0.012 | 0.027 | 10.17 |
| Castro-Diaz, 2007[247] | 0/120 | 0/120 | 4.416 | 0.214 | 91.081 | 6.32 | 0.015 | -0.01 | 0.04 | 6.2 |
| Lin, 2008[333] | 2/61 | 2/61 | 2.033 | 0.387 | 10.689 | 21 | 0.034 | -0.043 | 0.111 | 0.66 |
| Dmochowski, 2003[272] | 1/339 | 1/339 | 4.927 | 0.579 | 41.954 | 12.61 | 0.012 | -0.002 | 0.025 | 20.3 |
| Pooled estimate | | | 5.487 | 2.564 | 11.739 | 100 | 0.017 | 0.011 | 0.023 | 100 |
| I squared | | | 0.00% | | | | 0.00% | | | |
| p value for heterogeneity | | | 0.914 | | | | 0.821 | | | |
| **Fatigue** | | | | | | | | | | |
| Hurley, 2006[304] | 2/955 | 2/955 | 6.48 | 1.466 | 28.636 | 37.22 | 0.011 | 0.004 | 0.019 | 41.12 |

**Appendix Table F42. Adverse effects that result in discontinuation of the treatment after duloxetine vs. placebo, random effects models (continued)**

| Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk | Lower (95% CI) | Upper (95% CI) | Weight | Absolute Risk Difference | Lower (95% CI) | Upper (95% CI) | Weight |
|---|---|---|---|---|---|---|---|---|---|---|
| Castro-Diaz, 2007[247] | 2/120 | 2/120 | 0.177 | 0.009 | 3.643 | 17.1 | -0.017 | -0.044 | 0.011 | 11.54 |
| Bent, 2008[228] | 0/288 | 0/288 | 8.869 | 1.13 | 69.624 | 27.67 | 0.023 | 0.005 | 0.041 | 20.97 |
| Dmochowski, 2003[272] | 1/339 | 1/339 | 8.641 | 0.467 | 159.784 | 18.01 | 0.013 | -0.001 | 0.028 | 26.37 |
| Pooled estimate | | | 4.021 | 0.913 | 17.71 | 100 | 0.011 | 0.001 | 0.022 | 100 |
| I squared | | | 42.60% | | | | 48.30% | | | |
| p value for heterogeneity | | | 0.156 | | | | 0.121 | | | |
| **Insomnia** | | | | | | | | | | |
| Hurley, 2006[304] | 2/955 | 2/955 | 10.267 | 0.575 | 183.248 | 8.47 | 0.048 | 0.003 | 0.093 | 1.91 |
| van Kerrebroeck, 2004[321] | 1/247 | 1/247 | 7.123 | 0.37 | 137.119 | 8.05 | 0.013 | -0.004 | 0.03 | 13.25 |
| Castro-Diaz, 2007[247] | 1/120 | 1/120 | 7.975 | 1.839 | 34.589 | 32.69 | 0.015 | 0.006 | 0.023 | 51.81 |
| Lin, 2008[333] | 0/61 | 0/61 | 5 | 0.588 | 42.488 | 15.37 | 0.016 | -0.003 | 0.035 | 10.37 |
| Dmochowski, 2003[272] | 1/339 | 1/339 | 1.765 | 0.162 | 19.218 | 12.34 | 0.006 | -0.02 | 0.032 | 5.71 |
| Ghoniem, 2005[285] | 0/97 | 0/97 | 3.049 | 0.127 | 73.398 | 6.96 | 0.017 | -0.028 | 0.061 | 1.92 |
| Millard, 2004[344] | 0/231 | 0/231 | 6.898 | 0.853 | 55.767 | 16.11 | 0.017 | 0.001 | 0.033 | 15.03 |
| Pooled estimate | | | 5.7 | 2.463 | 13.189 | 100 | 0.015 | 0.009 | 0.021 | 100 |
| I squared | | | 0.00% | | | | 0.00% | | | |
| p value for heterogeneity | | | 0.959 | | | | 0.85 | | | |
| **Nausea** | | | | | | | | | | |
| Ghoniem, 2005[285] | 0/97 | 0/97 | 14 | 0.81 | 241.894 | 5.74 | 0.067 | 0.016 | 0.119 | 3.31 |
| Millard, 2004[344] | 0/231 | 0/231 | 15.263 | 0.877 | 265.685 | 5.71 | 0.031 | 0.007 | 0.055 | 12.96 |
| Hurley, 2006[304] | 3/955 | 3/955 | 15.95 | 4.985 | 51.03 | 34.44 | 0.047 | 0.033 | 0.061 | 27.18 |
| van Kerrebroeck, 2004 | 2/247 | 2/247 | 6.5 | 1.482 | 28.503 | 21.32 | 0.045 | 0.015 | 0.075 | 8.83 |
| Norton, 2002[349] | 1/138 | 1/138 | 5.914 | 0.721 | 48.486 | 10.52 | 0.036 | -0.001 | 0.072 | 6.26 |
| Castro-Diaz, 2007[247] | 0/120 | 0/120 | 7.949 | 0.432 | 146.134 | 5.5 | 0.029 | -0.003 | 0.061 | 7.91 |
| Lin, 2008[333] | 0/61 | 0/61 | 5.082 | 0.249 | 103.691 | 5.12 | 0.033 | -0.021 | 0.088 | 2.94 |
| Dmochowski, 2003[272] | 0/339 | 0/339 | 44.348 | 2.701 | 728.141 | 5.95 | 0.064 | 0.038 | 0.09 | 11.02 |
| Bent, 2008[228] | 0/288 | 0/288 | 14.402 | 0.826 | 251.018 | 5.7 | 0.023 | 0.005 | 0.042 | 19.61 |
| Pooled estimate | | | 11.267 | 5.693 | 22.295 | 100 | 0.04 | 0.031 | 0.05 | 100 |
| I squared | | | 0.00% | | | | 16.40% | | | |
| p value for heterogeneity | | | 0.958 | | | | 0.297 | | | |
| **Somnolence** | | | | | | | | | | |
| Norton, 2002[349] | 0/138 | 0/138 | 4.667 | 0.227 | 95.996 | 12.04 | 0.019 | -0.013 | 0.052 | 2.74 |

**Appendix Table F42. Adverse effects that result in discontinuation of the treatment after duloxetine vs. placebo, random effects models (continued)**

| Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk | Lower (95% CI) | Upper (95% CI) | Weight | Absolute Risk Difference | Lower (95% CI) | Upper (95% CI) | Weight |
|---|---|---|---|---|---|---|---|---|---|---|
| Bent, 2008[228] | 0/288 | 0/288 | 9.969 | 1.279 | 77.721 | 26.09 | 0.009 | 0.003 | 0.016 | 63.07 |
| Lin, 2008[333] | 0/61 | 0/61 | 4.929 | 0.239 | 101.744 | 12.01 | 0.014 | -0.01 | 0.038 | 5.02 |
| Dmochowski, 2003 | 1/339 | 1/339 | 5.082 | 0.249 | 103.691 | 12.1 | 0.033 | -0.021 | 0.088 | 0.97 |
| Hurley, 2006[304] | 1/955 | 1/955 | 6.898 | 0.853 | 55.767 | 25.19 | 0.017 | 0.001 | 0.033 | 11.24 |
| Ghoniem, 2005[285] | 0/97 | 0/97 | 6.721 | 0.349 | 129.543 | 12.57 | 0.01 | -0.003 | 0.023 | 16.96 |
| Pooled estimate | | | 6.684 | 2.341 | 19.081 | 100 | 0.011 | 0.006 | 0.017 | 100 |
| I squared | | | 0.00% | | | | 0.00% | | | |
| p value for heterogeneity | | | 0.998 | | | | 0.874 | | | |
| **Any adverse event** | | | | | | | | | | |
| Millard, 2004[344] | 4/231 | 4/231 | 9.922 | 3.604 | 27.312 | 9.98 | 0.154 | 0.103 | 0.206 | 11.06 |
| Cardozo, 2004[245] | 3/54 | 3/54 | 5.891 | 1.841 | 18.851 | 9.37 | 0.272 | 0.133 | 0.41 | 7.66 |
| Castro-Diaz, 2007[247] | 7/120 | 7/120 | 5 | 0.241 | 103.616 | 3.8 | 0.008 | -0.006 | 0.022 | 11.87 |
| Bent, 2008[228] | 9/288 | 9/288 | 2.957 | 1.299 | 6.731 | 10.72 | 0.099 | 0.03 | 0.169 | 10.45 |
| Norton, 2002[349] | 7/138 | 7/138 | 2.773 | 1.228 | 6.261 | 10.75 | 0.103 | 0.029 | 0.178 | 10.26 |
| Lin, 2008[333] | 4/61 | 4/61 | 4.067 | 1.443 | 11.46 | 9.88 | 0.201 | 0.073 | 0.329 | 8.07 |
| Schagen van Leeuwen, 2008[372] | 7/134 | 7/134 | 2.192 | 0.924 | 5.202 | 10.56 | 0.062 | -0.004 | 0.129 | 10.57 |
| Dmochowski, 2003[272] | 14/339 | 14/339 | 5.842 | 3.384 | 10.086 | 11.66 | 0.2 | 0.15 | 0.25 | 11.12 |
| Duckett, 2007[278] | 74/148 | 74/148 | 0.627 | 0.425 | 0.925 | 12.08 | -0.187 | -0.324 | -0.049 | 7.7 |
| van Kerrebroeck, 2004[321] | 53/247 | 12/247 | 5.013 | 2.503 | 10.041 | 11.19 | 0.125 | 0.08 | 0.171 | 11.24 |
| Pooled estimate | | | 3.434 | 1.691 | 6.974 | 100 | 0.105 | 0.041 | 0.169 | 100 |
| I squared | | | 87.40% | | | | 92.80% | | | |
| p value for heterogeneity | | | 0.00% | | | | 0.00% | | | |
| **Diarrhea** | | | | | | | | | | |
| Bent, 2008[228] | 1/288 | 1/288 | 1.994 | 0.181 | 21.951 | 46.97 | 0.001 | -0.003 | 0.005 | 93.23 |
| Hurley, 2006[304] | 1/955 | 1/955 | 2.88 | 0.301 | 27.527 | 53.03 | 0.007 | -0.007 | 0.02 | 6.77 |
| Pooled estimate | | | 2.423 | 0.468 | 12.541 | 100 | 0.001 | -0.002 | 0.005 | 100 |
| I squared | | | 0.00% | | | | 0.00% | | | |
| p value for heterogeneity | | | 0.827 | | | | 0.43 | | | |
| **Headache** | | | | | | | | | | |
| Norton, 2002[349] | 0/138 | 0/138 | 4.929 | 0.239 | 101.744 | 25.72 | 0.014 | -0.01 | 0.038 | 22.85 |
| Castro-Diaz, 2007[247] | 1/120 | 1/120 | 2.647 | 0.279 | 25.11 | 46.58 | 0.014 | -0.016 | 0.043 | 15 |
| Bent, 2008[228] | 0/288 | 0/288 | 8.641 | 0.467 | 159.784 | 27.7 | 0.013 | -0.001 | 0.028 | 62.15 |
| Pooled estimate | | | 4.311 | 0.928 | 20.016 | 100 | 0.014 | 0.002 | 0.025 | 100 |
| I squared | | | 0.00% | | | | 0.00% | | | |
| p value for heterogeneity | | | 0.816 | | | | 0.998 | | | |

**Appendix Table F43. Exploring clinical diversity in discontinuation rates due to adverse effects after duloxetine when compared to placebo**

| Reference | Country | Weeks of Treatment | Age | Prior Treatment | Concurrent Medication | % Women | Inclusion of Women with Surgical Risk Factors for UI | Inclusion of those who Failed Prior Treatments | Inclusion of Minorities | Presence of Mixed UI | Daily UI |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Millard, 2004[344] | Poland, South Africa, Australia, Brazil, Argentina and Finland | 12 | 53.7-52.6 | Previous continence surgery including injections, 18.5% in active and 17.3% in control group | No response | 100 | No response | No response | Yes | No response | Yes |
| Cardozo, 2004[245] | Australia, Canada, the Netherlands, and the United Kingdom | 8 | 54.5-52.4 | Prior continence surgery in 16.4% duloxetine and 14.8% placebo women | Hormone replacement therapy in 47.3% duloxetine and 40.7% placebo group | 100 | No response | No response | Yes | No response | Yes |
| Castro-Diaz, 2007[247] | 64 study centers in 8 countries | 8 | 52.7-53.3 | No response | No response | 100 | No response | No response | No response | No response | Yes |
| Bent, 2008[228] | USA | 8 | 53.2-54.2 | Antimuscarinic agents (either tolterodine or oxybutynin) were used by 7.8% of subjects | Antidepressant medications, including other SNRIs and selective serotonin reuptake inhibitors:19.4 % in placebo and 23.0% in active group | 100 | No | No | Yes | Yes | Yes |
| Norton, 2002[349] | USA | 12 | 49.3-53.2 | No response | No response | 100 | No | No response | Yes | No response | Yes |
| Lin, 2008[333] | Taiwan | 8 | 53-56 | Previous surgery had 3 women in duloxetine and 5 in placebo group | Were not permitted | 100 | No response | No response | No response | No response | Yes |

**Appendix Table F43. Exploring clinical diversity in discontinuation rates due to adverse effects after duloxetine when compared to placebo (continued)**

| Reference | Country | Weeks of Treatment | Age | Prior Treatment | Concurrent Medication | % Women | Inclusion of Women with Surgical Risk Factors for UI | Inclusion of those who Failed Prior Treatments | Inclusion of Minorities | Presence of Mixed UI | Daily UI |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Schagen van Leeuwen, 2008[372] | Germany, France, The Netherlands, Spain, Sweden, Switzerland and South-Africa | 12 | 70.63-71.1 | Previous incontinence surgery 15.3% in placebo and 11.9% in duloxetine | Approximately 80% of patients reported concomitant drug therapies before and after randomization. Behavioral therapy 0.8% in placebo and 0.7% in duloxetine; Current PFMT 9.9% in placebo and 9.7% in duloxetine group | 100 | No | No response | Yes | Yes | Yes |
| Dmochowski, 2003[272] | Canada and the United States | 12 | 52.3-53.3 | % prior continence surgery, including injection 12.2% in duloxetine and 13.1% in placebo group % PFMT 16.9% in duloxetine and 18.0% in placebo group | No response | 100 | No response | No response | Yes | No response | Yes |
| van Kerrebroeck, 2004[321] | Belgium, Canada, Denmark, France, Germany, The Netherlands, Sweden and the United Kingdom | 12 | 52-54 | Prior continence surgery in 7.7% in duloxetine and in 7.7% placebo group | No response | 100 | No response | No response | Yes | No response | Yes |

**Appendix Table F44. Exploring heterogeneity in discontinuation rates due to adverse effects after duloxetine compared to placebo (results from meta-regression)**

| Variable | Coefficient | Standard Error | T Statistic | P>t | Lower 95% CI | Upper 95% CI |
|---|---|---|---|---|---|---|
| Daily dose | 0.01 | 0.004 | 1.83 | 0.11 | -0.01 | 0.02 |
| Constant | -.49 | 0.34 | -1.47 | 0.19 | -1.69 | 0.69 |
| Conflict of interest | 0.03 | 0.06 | 0.52 | 0.62 | -0.17 | 0.23 |
| Constant | 0.08 | 0.10 | 0.78 | 0.46 | -0.27 | 0.42 |
| Adequacy of randomization | 0.06 | 0.06 | 1.00 | 0.36 | -0.16 | 0.28 |
| Allocation concealment | 0.08 | 0.07 | 1.20 | 0.28 | -0.17 | 0.33 |
| Constant | -0.12 | 0.18 | -0.64 | 0.55 | -0.80 | 0.57 |
| Presence of mixed UI | -0.04 | 0.14 | -0.26 | 0.81 | -0.70 | 0.63 |
| Inclusion of minorities | 0.00 | 0.09 | 0.00 | 1.00 | -0.43 | 0.43 |
| Presence of those who failed prior treatments | 0.06 | 0.14 | 0.45 | 0.68 | -0.59 | 0.71 |
| Presence of women with surgical risk factors for UI | -0.05 | 0.11 | -0.42 | 0.70 | -0.57 | 0.48 |
| Constant | 0.15 | 0.08 | 1.90 | 0.13 | -0.21 | 0.50 |

**Appendix Table F45. Exploring methodological diversity in discontinuation rates due to adverse effects after duloxetine compared to placebo**

| Reference | Masking | Intention to Treat | Allocation Concealment | Adequacy of Randomization | Justification for Sample Size | Presence of Conflict of Interest |
|---|---|---|---|---|---|---|
| Millard, 2004[344] | Double blind | Yes | Adequate | No | Yes | No response |
| Cardozo, 2004[245] | Double blind | Yes | Adequate | Adequate | Yes | Yes |
| Castro-Diaz, 2007[247] | Double blind | Yes | Unclear | Adequate | Yes | Yes |
| Bent, 2008[228] | Double blind | Yes | Adequate | Adequate | Yes | Yes |
| Norton, 2002[349] | Double blind | Yes | Adequate | Adequate | Yes | No response |
| Lin, 2008[333] | Double blind | Yes | Adequate | No | Yes | Yes |
| Schagen van Leeuwen, 2008[372] | Double blind | Yes | Unclear | Adequate | Yes | No response |
| Dmochowski, 2003[272] | Double blind | Yes | Adequate | Adequate | Yes | Yes |
| van Kerrebroeck, 2004[321] | Double blind | Yes | Adequate | No | Yes | Yes |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Darifenacin | Adverse effects | Chapple, 2007[254] | 99/266 | 24/133 | 2.06 (1.39; 3.06) | 19.71 | 0.192 (0.10; 0.28) | 42.22 |
| Darifenacin | Adverse effects | Hill, 2006[44] | 73/107 | 54/109 | 1.38 (1.10; 1.73) | 35.82 | 0.187 (0.06; 0.32) | 19.46 |
| Darifenacin | Adverse effects | Zinner, 2006[405] | 136/214 | 110/225 | 1.30 (1.10; 1.54) | 44.47 | 0.147 (0.06; 0.24) | 38.32 |
| | Pooled | | | | 1.45 (1.18; 1.80) | 100 | 0.173 (0.12; 0.23) | 100 |
| | P value/I squared | | | | 0.107 | 55.20% | 0.764 | 0.00% |
| Darifenacin | nausea | Lipton, 2005[334] | 1/65 | 1/69 | 1.06 (0.07; 16.62) | 29.5 | 0.001 (-0.04; 0.04) | 19.08 |
| Darifenacin | Nausea | Zinner, 2006[405] | 3/214 | 2/225 | 1.58 (0.27; 9.35) | 70.5 | 0.005 (-0.02; 0.03) | 80.92 |
| | Pooled | | | | 1.40 (0.32; 6.25) | 100 | 0.004 (-0.01; 0.02) | 100 |
| | P value/I squared | | | | 0.813 | 0.00% | 0.856 | 0.00% |
| Darifenacin | Serious adverse effects | Hill, 2006[44] | 2/107 | 2/109 | 1.02 (0.15; 7.10) | 41.31 | 0.000 (-0.04; 0.04) | 29.35 |
| Darifenacin | Serious adverse effects | Zinner, 2006[405] | 2/214 | 5/225 | 0.42 (0.08; 2.15) | 58.69 | -0.013 (-0.04; 0.01) | 70.65 |
| | Pooled | | | | 0.61 (0.17; 2.11) | 100 | -0.009 (-0.03; 0.01) | |
| | P value/I squared | | | | 0.494 | 0.00% | 0.545 | 0.00% |
| Darifenacin | Urinary tract infection | Hill, 2006[44] | 3/107 | 2/109 | 1.53 (0.26; 8.96) | 28.46 | 0.010 (-0.03; 0.05) | 36.63 |
| Darifenacin | Urinary tract infection | Zinner, 2006[405] | 6/214 | 6/225 | 1.05 (0.34; 3.21) | 71.54 | 0.001 (-0.03; 0.03) | 63.37 |
| | Pooled | | | | 1.17 (0.46; 3.01) | 100 | 0.004 (-0.02; 0.03) | 100 |
| | P value/I squared | | | | 0.726 | 0.00% | 0.747 | 0.00% |
| Darifenacin | Constipation | Hill, 2006[44] | 17/108 | 5/109 | 3.43 (1.31; 8.97) | 11.81 | 0.112 (0.03; 0.19) | 12.17 |
| Darifenacin | Constipation | Chapple, 2007[254] | 41/266 | 11/133 | 1.86 (0.99; 3.51) | 16.56 | 0.071 (0.01; 0.14) | 13.21 |
| Darifenacin | Constipation | Chapple, 2004[464] | 2/53 | 11/164 | 0.56 (0.13; 2.46) | 7.01 | -0.029 (-0.09; 0.04) | 13.19 |
| Darifenacin | Constipation | Lipton, 2005[334] | 8/65 | 6/69 | 1.42 (0.52; 3.86) | 11.3 | 0.036 (-0.07; 0.14) | 10.46 |
| Darifenacin | Constipation | Hill, 2006[44] | 27/107 | 5/109 | 5.50 (2.20; 13.75) | 12.38 | 0.206 (0.12; 0.30) | 11.33 |
| Darifenacin | Constipation | Zinner, 2006[405] | 9/214 | 8/225 | 1.18 (0.47; 3.01) | 12.16 | 0.007 (-0.03; 0.04) | 14.81 |
| Darifenacin | Constipation | Chapple, 2004[464] | 33/229 | 11/164 | 2.15 (1.12; 4.13) | 16.24 | 0.077 (0.02; 0.14) | 13.49 |
| Darifenacin | Constipation | Hill, 2006[44] | 32/115 | 5/109 | 6.07 (2.45; 15.00) | 12.52 | 0.232 (0.14; 0.32) | 11.35 |
| | Pooled | | | | 2.29 (1.44; 3.65) | 100 | 0.084 (0.03; 0.14) | 100 |
| | P value/I squared | | | | 0.032 | 54.50% | 0 | 83.20% |
| Darifenacin | Treatment discontinuation | Chapple, 2004[464] | 4/53 | 12/164 | 1.03 (0.35; 3.06) | 14.52 | 0.002 (-0.08; 0.08) | 40.1 |
| Darifenacin | Treatment discontinuation | Zinner, 2006[405] | 29/214 | 37/225 | 0.82 (0.53; 1.29) | 85.48 | -0.029 (-0.10; 0.04) | 59.9 |
| | Pooled | | | | 0.85 (0.56; 1.29) | 100 | -0.016 (-0.07; 0.04) | 100 |
| | P value/I squared | | | | 0.709 | 0.00% | 0.561 | 0.00% |
| Darifenacin | Treatment discontinuation | Steers, 2005[45] | 12/108 | 4/41 | 1.14 (0.39; 3.33) | 11.61 | 0.014 (-0.10; 0.12) | 1.72 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | due to adverse effects | | | | | | | |
| Darifenacin | Treatment discontinuation due to adverse effects | Hill, 2006[44] | 2/108 | 3/109 | 0.67 (0.12; 3.95) | 4.92 | -0.009 (-0.05; 0.03) | 9.74 |
| Darifenacin | Treatment discontinuation due to adverse effects | Chapple, 2007[254] | 12/266 | 9/133 | 0.67 (0.29; 1.54) | 16.75 | -0.023 (-0.07; 0.03) | 6.99 |
| Darifenacin | Treatment discontinuation due to adverse effects | U.S. Food and Drug Administration, 2004 [43] | 3/229 | 3/164 | 0.72 (0.15; 3.50) | 5.98 | -0.005 (-0.03; 0.02) | 17.32 |
| Darifenacin | Treatment discontinuation due to adverse effects | Chapple, 2004[464] | 0/53 | 2/164 | 0.61 (0.03; 12.53) | 1.79 | -0.012 (-0.04; 0.02) | 13.36 |
| Darifenacin | Treatment discontinuation due to adverse effects | Steers, 2005[45] | 6/160 | 4/41 | 0.38 (0.11; 1.30) | 9.46 | -0.060 (-0.16; 0.04) | 2.18 |
| Darifenacin | Treatment discontinuation due to adverse effects | Zinner, 2006[405] | 17/214 | 10/225 | 1.79 (0.84; 3.82) | 19.19 | 0.035 (-0.01; 0.08) | 8.07 |
| Darifenacin | Treatment discontinuation due to adverse effects | U.S. Food and Drug Administration, 2004 [43] | 8/112 | 4/115 | 2.05 (0.64; 6.63) | 10.07 | 0.037 (-0.02; 0.10) | 5.32 |
| Darifenacin | Treatment discontinuation due to adverse effects | U.S. Food and Drug Administration, 2004 [43] | 3/115 | 3/164 | 1.43 (0.29; 6.94) | 6.02 | 0.008 (-0.03; 0.04) | 11.42 |
| Darifenacin | Treatment discontinuation due to adverse effects | Chapple, 2004[464] | 3/229 | 2/164 | 1.07 (0.18; 6.36) | 4.88 | 0.001 (-0.02; 0.02) | 19.54 |
| Darifenacin | Treatment discontinuation due to adverse effects | Hill, 2006[44] | 13/115 | 3/109 | 4.11 (1.20; 14.02) | 9.33 | 0.086 (0.02; 0.15) | 4.34 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | Pooled | | | | 1.16 (0.77; 1.75) | 100 | 0.003 (-0.01; 0.02) | 100 |
| | P value/I squared | | | | 0.283 | 16.90% | 0.184 | 27.30% |
| Darifenacin | Treatment discontinuation due to failure | Hill, 2006[44] | 2/107 | 2/109 | 1.02 (0.15; 7.10) | 26.72 | 0.000 (-0.04; 0.04) | 11.42 |
| Darifenacin | Treatment discontinuation due to failure | Zinner, 2006[405] | 2/214 | 5/225 | 0.42 (0.08; 2.15) | 37.96 | -0.013 (-0.04; 0.01) | 27.5 |
| Darifenacin | Treatment discontinuation due to failure | U.S. Food and Drug Administration, 2004[43] | 1/112 | 2/115 | 0.51 (0.05; 5.58) | 17.69 | -0.008 (-0.04; 0.02) | 16.9 |
| Darifenacin | Treatment discontinuation due to failure | U.S. Food and Drug Administration, 2004[43] | 2/269 | 1/129 | 0.96 (0.09; 10.48) | 17.62 | 0.000 (-0.02; 0.02) | 44.18 |
| | Pooled | | | | 0.64 (0.23; 1.74) | 100 | -0.005 (-0.02; 0.01) | 100 |
| | P value/I squared | | | | 0.892 | 0.00% | 0.842 | 0.00% |
| Darifenacin | Dry mouth | Lipton, 2005[334] | 5/74 | 2/69 | 2.33 (0.47; 11.62) | 6.27 | 0.039 (-0.03; 0.11) | 11.35 |
| Darifenacin | Dry mouth | Hill, 2006[44] | 25/108 | 6/109 | 4.21 (1.80; 9.84) | 11.88 | 0.176 (0.09; 0.27) | 10.89 |
| Darifenacin | Dry mouth | Chapple, 2007[254] | 59/266 | 5/133 | 5.90 (2.43; 14.35) | 11.51 | 0.184 (0.13; 0.24) | 11.55 |
| Darifenacin | Dry mouth | Chapple, 2004[464] | 7/53 | 14/164 | 1.55 (0.66; 3.63) | 11.85 | 0.047 (-0.05; 0.15) | 10.63 |
| Darifenacin | Dry mouth | Lipton, 2005[334] | 6/65 | 2/69 | 3.19 (0.67; 15.22) | 6.49 | 0.063 (-0.02; 0.14) | 11.11 |
| Darifenacin | Dry mouth | Hill, 2006[44] | 43/107 | 6/109 | 7.30 (3.24; 16.44) | 12.26 | 0.347 (0.25; 0.45) | 10.59 |
| Darifenacin | Dry mouth | Zinner, 2006[405] | 15/214 | 10/225 | 1.58 (0.72; 3.43) | 12.59 | 0.026 (-0.02; 0.07) | 11.8 |
| Darifenacin | Dry mouth | Chapple, 2004[464] | 43/229 | 14/164 | 2.20 (1.25; 3.89) | 14.71 | 0.102 (0.04; 0.17) | 11.42 |
| Darifenacin | Dry mouth | Hill, 2006[44] | 68/115 | 6/109 | 10.74 (4.86; 23.73) | 12.45 | 0.536 (0.44; 0.64) | 10.66 |
| | Pooled | | | | 3.55 (2.16; 5.84) | 100 | 0.165 (0.07; 0.26) | 100 |
| | P value/I squared | | | | 0.004 | 64.80% | 0 | 93.30% |
| Darifenacin | Dyspepsia | Lipton, 2005[334] | 1/74 | 1/69 | 0.93 (0.06; 14.62) | 7.8 | -0.001 (-0.04; 0.04) | 15.59 |
| Darifenacin | Dyspepsia | Hill, 2006[44] | 4/108 | 1/109 | 4.04 (0.46; 35.54) | 11.64 | 0.028 (-0.01; 0.07) | 15.15 |
| Darifenacin | Dyspepsia | Lipton, 2005[334] | 4/71 | 1/69 | 3.89 (0.45; 33.91) | 11.72 | 0.042 (-0.02; 0.10) | 9.65 |
| Darifenacin | Dyspepsia | Hill, 2006[44] | 9/107 | 1/109 | 9.17 (1.18; 71.13) | 12.83 | 0.075 (0.02; 0.13) | 10.75 |
| Darifenacin | Dyspepsia | Zinner, 2006[405] | 9/214 | 2/225 | 4.73 (1.03; 21.65) | 20.05 | 0.033 (0.00; 0.06) | 18.85 |
| Darifenacin | Dyspepsia | Chapple, 2004[464] | 4/229 | 4/164 | 0.72 (0.18; 2.82) | 23.02 | -0.007 (-0.04; 0.02) | 19.03 |
| Darifenacin | Dyspepsia | Hill, 2006[44] | 10/115 | 1/109 | 9.48 (1.23; 72.81) | 12.93 | 0.078 (0.02; 0.13) | 10.99 |
| | Pooled | | | | 3.08 (1.36; 7.00) | 100 | 0.030 (0.01; 0.05) | 100 |
| | P value/I squared | | | | 0.26 | 22.20% | 0.034 | 56.10% |
| Darifenacin | Headache | Lipton, 2005[334] | 1/74 | 0/69 | 2.80 (0.12; 67.60) | 6.79 | 0.014 (-0.02; 0.05) | 21.88 |
| Darifenacin | Headache | Hill, 2006[44] | 7/108 | 2/109 | 3.53 (0.75; 16.62) | 28.69 | 0.046 (-0.01; 0.10) | 10.92 |
| Darifenacin | Headache | Lipton, 2005[334] | 2/71 | 0/69 | 4.86 (0.24; 99.46) | 7.55 | 0.028 (-0.02; 0.08) | 14 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Darifenacin | Headache | Hill, 2006[44] | 7/107 | 2/109 | 3.57 (0.76; 16.78) | 28.7 | 0.047 (-0.01; 0.10) | 10.77 |
| Darifenacin | Headache | Zinner, 2006[405] | 7/214 | 2/225 | 3.68 (0.77; 17.52) | 28.27 | 0.024 (0.00; 0.05) | 42.43 |
| | Pooled | | | | 3.61 (1.58; 8.28) | 100 | 0.027 (0.01; 0.05) | 100 |
| | P value/I squared | | | | 1 | 0.00% | 0.804 | 0.00% |
| Darifenacin | Improvement in UI | Hill, 2006[44] | 72/108 | 53/109 | 1.37 (1.08; 1.73) | 12.64 | 0.180 (0.05; 0.31) | 7.05 |
| Darifenacin | Improvement in UI | Hill, 2006[44] | 53/108 | 31/109 | 1.73 (1.21; 2.46) | 5.54 | 0.206 (0.08; 0.33) | 7.33 |
| Darifenacin | Improvement in UI | Hill, 2006[44] | 28/108 | 15/109 | 1.88 (1.07; 3.32) | 2.16 | 0.122 (0.02; 0.23) | 10.69 |
| Darifenacin | Improvement in UI | Hill, 2006[44] | 12/108 | 5/109 | 2.42 (0.88; 6.64) | 0.68 | 0.065 (-0.01; 0.14) | 23.28 |
| Darifenacin | Improvement in UI | Hill, 2006[44] | 62/108 | 54/109 | 1.16 (0.90; 1.49) | 11.16 | 0.079 (-0.05; 0.21) | 6.72 |
| Darifenacin | Improvement in UI | Chapple, 2007[254] | 186/266 | 77/133 | 1.21 (1.02; 1.42) | 25.55 | 0.120 (0.02; 0.22) | 11.68 |
| Darifenacin | Improvement in UI | Chapple, 2007[254] | 154/266 | 63/133 | 1.22 (0.99; 1.50) | 16.32 | 0.105 (0.00; 0.21) | 10.98 |
| Darifenacin | Improvement in UI | Chapple, 2007[254] | 122/266 | 47/133 | 1.30 (1.00; 1.69) | 9.95 | 0.105 (0.00; 0.21) | 11.56 |
| Darifenacin | Improvement in UI | Steers, 2005[45] | 160/268 | 60/127 | 1.26 (1.03; 1.56) | 16 | 0.125 (0.02; 0.23) | 10.71 |
| | Pooled | | | | 1.29 (1.18; 1.40) | 100 | 0.112 (0.08; 0.15) | 100 |
| | P value/I squared | | | | 0.466 | 0.00% | 0.73 | 0.00% |
| Fesoterodine | Abdominal pain | NCT00444925,[58] | 10/685 | 4/337 | 1.23 (0.39; 3.89) | 22.52 | 0.003 (-0.01; 0.02) | 52.38 |
| Fesoterodine | Abdominal pain | Chapple, 2004[259] | 14/173 | 7/183 | 2.12 (0.88; 5.12) | 38.32 | 0.043 (-0.01; 0.09) | 23.45 |
| Fesoterodine | Abdominal pain | Chapple, 2004[259] | 15/186 | 7/183 | 2.11 (0.88; 5.05) | 39.16 | 0.042 (-0.01; 0.09) | 24.17 |
| | Pooled | | | | 1.87 (1.08; 3.23) | 100 | 0.022 (-0.01; 0.05) | 100 |
| | P value/I squared | | | | 0.721 | 0.00% | 0.113 | 54.10% |
| Fesoterodine | Abnormal vision | Chapple, 2004[259] | 0/186 | 2/183 | 0.20 (0.01; 4.07) | 22.65 | -0.011 (-0.03; 0.01) | 36.7 |
| Fesoterodine | Abnormal vision | Chapple, 2004[259] | 0/173 | 2/183 | 0.21 (0.01; 4.37) | 22.65 | -0.011 (-0.03; 0.01) | 35.8 |
| Fesoterodine | Abnormal vision | Chapple, 2004[259] | 2/186 | 2/183 | 0.98 (0.14; 6.91) | 54.7 | 0.000 (-0.02; 0.02) | 27.5 |
| | Pooled | | | | 0.48 (0.11; 2.04) | 100 | -0.008 (-0.02; 0.00) | 100 |
| | P value/I squared | | | | 0.567 | 0.00% | 0.697 | 0.00% |
| Fesoterodine | Adverse effects | Chapple, 2007[252] | 135/272 | 107/285 | 1.32 (1.09; 1.60) | 15.82 | 0.121 (0.04; 0.20) | 14.75 |
| Fesoterodine | Adverse effects | Nitti C, 2007[347] | 171/283 | 149/274 | 1.11 (0.96; 1.28) | 18.07 | 0.060 (-0.02; 0.14) | 14.7 |
| Fesoterodine | Adverse effects | NCT00444925,[58] | 290/685 | 76/337 | 1.88 (1.51; 2.33) | 14.68 | 0.198 (0.14; 0.26) | 20.88 |
| Fesoterodine | Adverse effects | NCT00536484,[59] | 199/438 | 130/445 | 1.56 (1.30; 1.86) | 16.5 | 0.162 (0.10; 0.23) | 19.43 |
| Fesoterodine | Adverse effects | Chapple, 2007[252] | 167/288 | 107/285 | 1.54 (1.29; 1.85) | 16.41 | 0.204 (0.12; 0.28) | 15.12 |
| Fesoterodine | Adverse effects | Nitti C, 2007[347] | 193/279 | 149/274 | 1.27 (1.11; 1.45) | 18.52 | 0.148 (0.07; 0.23) | 15.12 |
| | Pooled | | | | 1.41 (1.22; 1.63) | 100 | 0.153 (0.11; 0.19) | 100 |
| | P value/I squared | | | | 0.001 | 76.50% | 0.094 | 46.80% |
| Fesoterodine | Back pain | Chapple, 2004[259] | 6/186 | 5/183 | 1.18 (0.37; 3.80) | 21.26 | 0.005 (-0.03; 0.04) | 16.67 |
| Fesoterodine | Back pain | NCT00444925,[58] | 10/685 | 10/337 | 0.49 (0.21; 1.17) | 38.69 | -0.015 (-0.04; 0.01) | 49.02 |
| Fesoterodine | Back pain | Chapple, 2004[259] | 7/173 | 5/183 | 1.48 (0.48; 4.58) | 22.82 | 0.013 (-0.03; 0.05) | 14.12 |
| Fesoterodine | Back pain | Chapple, 2004[259] | 4/186 | 5/183 | 0.79 (0.22; 2.89) | 17.23 | -0.006 (-0.04; 0.03) | 20.2 |
| | Pooled | | | | 0.83 (0.48; 1.42) | 100 | -0.006 (-0.02; 0.01) | 100 |
| | P value/I squared | | | | 0.429 | 0.00% | 0.543 | 0.00% |
| Fesoterodine | Constipation | Chapple, 2004[259] | 4/186 | 5/183 | 0.79 (0.22; 2.89) | 5.73 | -0.006 (-0.04; 0.03) | 8.35 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Fesoterodine | Constipation | Chapple, 2007[252] | 9/272 | 4/285 | 2.36 (0.74; 7.57) | 6.42 | 0.019 (-0.01; 0.04) | 8.52 |
| Fesoterodine | Constipation | Nitti C, 2007[347] | 14/283 | 7/274 | 1.94 (0.79; 4.73) | 8.1 | 0.024 (-0.01; 0.06) | 8.35 |
| Fesoterodine | Constipation | Dmochowski, 2010[465] | 48/438 | 25/445 | 1.95 (1.23; 3.11) | 11.08 | 0.053 (0.02; 0.09) | 8.2 |
| Fesoterodine | Constipation | Herschorn, 2010[466] | 37/679 | 10/334 | 1.82 (0.92; 3.62) | 9.54 | 0.025 (0.00; 0.05) | 8.52 |
| Fesoterodine | Constipation | Kaplan, 2010[314] | 270/963 | 10/480 | 13.46 (7.23; 25.06) | 10 | 0.260 (0.23; 0.29) | 8.36 |
| Fesoterodine | Constipation | NCT00444925,[58] | 37/685 | 10/337 | 1.82 (0.92; 3.62) | 9.54 | 0.024 (0.00; 0.05) | 8.53 |
| Fesoterodine | Constipation | NCT00536484,[59] | 48/438 | 25/445 | 1.95 (1.23; 3.11) | 11.08 | 0.053 (0.02; 0.09) | 8.2 |
| Fesoterodine | Constipation | Chapple, 2004[259] | 5/173 | 5/183 | 1.06 (0.31; 3.59) | 6.12 | 0.002 (-0.03; 0.04) | 8.26 |
| Fesoterodine | Constipation | Chapple, 2007[252] | 13/288 | 4/285 | 3.22 (1.06; 9.75) | 6.74 | 0.031 (0.00; 0.06) | 8.46 |
| Fesoterodine | Constipation | Nitti C, 2007[347] | 21/279 | 7/274 | 2.95 (1.27; 6.82) | 8.46 | 0.050 (0.01; 0.09) | 8.21 |
| Fesoterodine | Constipation | Chapple, 2004[259] | 11/186 | 5/183 | 2.17 (0.77; 6.11) | 7.17 | 0.032 (-0.01; 0.07) | 8.03 |
| | Pooled | | | | 2.33 (1.54; 3.54) | 100 | 0.047 (0.01; 0.09) | 100 |
| | P value/I squared | | | | 0 | 70.80% | 0 | 94.80% |
| Fesoterodine | Cough | Chapple, 2004[259] | 6/186 | 7/183 | 0.84 (0.29; 2.46) | 25.64 | -0.006 (-0.04; 0.03) | 8.89 |
| Fesoterodine | Cough | NCT00444925,[58] | 8/685 | 1/337 | 3.94 (0.49; 31.34) | 12.44 | 0.009 (0.00; 0.02) | 40.07 |
| Fesoterodine | Cough | NCT00536484,[59] | 9/438 | 2/445 | 4.57 (0.99; 21.04) | 18.35 | 0.016 (0.00; 0.03) | 30.58 |
| Fesoterodine | Cough | Chapple, 2004[259] | 2/173 | 7/183 | 0.30 (0.06; 1.44) | 17.93 | -0.027 (-0.06; 0.01) | 11.56 |
| Fesoterodine | Cough | Chapple, 2004[259] | 6/186 | 7/183 | 0.84 (0.29; 2.46) | 25.64 | -0.006 (-0.04; 0.03) | 8.89 |
| | Pooled | | | | 1.16 (0.48; 2.78) | 100 | 0.004 (-0.01; 0.02) | 100 |
| | P value/I squared | | | | 0.095 | 49.40% | 0.151 | 40.50% |
| Fesoterodine | Diarrhea | Herschorn, 2010[466] | 14/679 | 4/334 | 1.72 (0.57; 5.19) | 30.45 | 0.009 (-0.01; 0.02) | 36.36 |
| Fesoterodine | Diarrhea | NCT00444925,[58] | 14/685 | 4/337 | 1.72 (0.57; 5.19) | 30.45 | 0.009 (-0.01; 0.02) | 36.56 |
| Fesoterodine | Diarrhea | NCT00536484,[59] | 9/438 | 19/445 | 0.48 (0.22; 1.05) | 39.11 | -0.022 (-0.05; 0.00) | 27.07 |
| | Pooled | | | | 1.05 (0.42; 2.61) | 100 | 0.000 (-0.02; 0.02) | 100 |
| | P value/I squared | | | | 0.078 | 60.90% | 0.062 | 64.00% |
| Fesoterodine | Treatment discontinuation | Chapple, 2007[252] | 41/272 | 33/285 | 1.30 (0.85; 2.00) | 11.01 | 0.035 (-0.02; 0.09) | 5.95 |
| Fesoterodine | Treatment discontinuation | Nitti C, 2007[347] | 58/283 | 41/274 | 1.37 (0.95; 1.97) | 15.18 | 0.055 (-0.01; 0.12) | 4.83 |
| Fesoterodine | Treatment discontinuation | Dmochowski, 2010[465] | 56/438 | 60/445 | 0.95 (0.68; 1.33) | 17.44 | -0.007 (-0.05; 0.04) | 9.12 |
| Fesoterodine | Treatment discontinuation | Herschorn, 2010[466] | 81/679 | 30/334 | 1.33 (0.89; 1.98) | 12.69 | 0.029 (-0.01; 0.07) | 11.38 |
| Fesoterodine | Treatment discontinuation | NCT00444925,[58] | 6/685 | 3/337 | 0.98 (0.25; 3.91) | 1.06 | 0.000 (-0.01; 0.01) | 48.14 |
| Fesoterodine | Treatment discontinuation | NCT00536484,[59] | 56/438 | 60/445 | 0.95 (0.68; 1.33) | 17.44 | -0.007 (-0.05; 0.04) | 9.12 |
| Fesoterodine | Treatment | Chapple, 2007[252] | 36/288 | 33/285 | 1.08 (0.69; 1.68) | 10.24 | 0.009 (-0.04; 0.06) | 6.62 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | discontinuation | | | | | | | |
| Fesoterodine | Treatment discontinuation | Nitti C, 2007[347] | 56/279 | 41/274 | 1.34 (0.93; 1.94) | 14.94 | 0.051 (-0.01; 0.11) | 4.83 |
| | Pooled | | | | 1.16 (1.00; 1.33) | 100 | 0.010 (-0.01; 0.02) | 100 |
| | P value/I squared | | | | 0.661 | 0.00% | 0.306 | 15.70% |
| Fesoterodine | Treatment discontinuation due to adverse effects | Chapple, 2004[259] | 11/186 | 7/183 | 1.55 (0.61; 3.90) | 9.57 | 0.021 (-0.02; 0.07) | 8.42 |
| Fesoterodine | Treatment discontinuation due to adverse effects | Dmochowski, 2010[465] | 34/438 | 21/445 | 1.65 (0.97; 2.79) | 18.74 | 0.030 (0.00; 0.06) | 12.15 |
| Fesoterodine | Treatment discontinuation due to adverse effects | Herschorn, 2010[466] | 44/679 | 6/334 | 3.61 (1.55; 8.38) | 10.92 | 0.047 (0.02; 0.07) | 15.77 |
| Fesoterodine | Treatment discontinuation due to adverse effects | Kaplan, 2010[314] | 48/963 | 10/480 | 2.39 (1.22; 4.69) | 14.55 | 0.029 (0.01; 0.05) | 17.97 |
| Fesoterodine | Treatment discontinuation due to adverse effects | NCT00444925,[58] | 44/685 | 6/337 | 3.61 (1.55; 8.38) | 10.92 | 0.046 (0.02; 0.07) | 15.86 |
| Fesoterodine | Treatment discontinuation due to adverse effects | NCT00536484,[59] | 34/438 | 21/445 | 1.65 (0.97; 2.79) | 18.74 | 0.030 (0.00; 0.06) | 12.15 |
| Fesoterodine | Treatment discontinuation due to adverse effects | Chapple, 2004[259] | 3/173 | 7/183 | 0.45 (0.12; 1.73) | 5.35 | -0.021 (-0.06; 0.01) | 11.4 |
| Fesoterodine | Treatment discontinuation due to adverse effects | Chapple, 2004[259] | 22/186 | 7/183 | 3.09 (1.35; 7.06) | 11.23 | 0.080 (0.03; 0.13) | 6.29 |
| | Pooled | | | | 2.05 (1.47; 2.87) | 100 | 0.032 (0.02; 0.05) | 100 |
| | P value/I squared | | | | 0.131 | 37.40% | 0.027 | 55.60% |
| Fesoterodine | Treatment discontinuation due to failure | Dmochowski, 2010[465] | 5/438 | 16/445 | 0.32 (0.12; 0.86) | 25.28 | -0.025 (-0.04; -0.01) | 23.5 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Fesoterodine | Treatment discontinuation due to failure | Herschorn, 2010[466] | 13/679 | 5/334 | 1.28 (0.46; 3.56) | 24.72 | 0.004 (-0.01; 0.02) | 26.44 |
| Fesoterodine | Treatment discontinuation due to failure | NCT00444925,[58] | 13/685 | 5/337 | 1.28 (0.46; 3.56) | 24.72 | 0.004 (-0.01; 0.02) | 26.57 |
| Fesoterodine | Treatment discontinuation due to failure | NCT00536484,[59] | 5/438 | 16/445 | 0.32 (0.12; 0.86) | 25.28 | -0.025 (-0.04; -0.01) | 23.5 |
| | Pooled | | | | 0.63 (0.29; 1.39) | 100 | -0.009 (-0.03; 0.01) | 100 |
| | P value/I squared | | | | 0.062 | 59.00% | | |
| Fesoterodine | Dizziness | Chapple, 2004[259] | 7/186 | 5/183 | 1.38 (0.45; 4.26) | 33.68 | 0.010 (-0.03; 0.05) | 8.46 |
| Fesoterodine | Dizziness | NCT00444925,[58] | 8/685 | 3/337 | 1.31 (0.35; 4.91) | 24.63 | 0.003 (-0.01; 0.02) | 66.81 |
| Fesoterodine | Dizziness | Chapple, 2004[259] | 2/173 | 5/183 | 0.42 (0.08; 2.15) | 16.23 | -0.016 (-0.04; 0.01) | 13.61 |
| Fesoterodine | Dizziness | Chapple, 2004[259] | 4/186 | 5/183 | 0.79 (0.22; 2.89) | 25.46 | -0.006 (-0.04; 0.03) | 11.13 |
| | Pooled | | | | 0.97 (0.51; 1.88) | 100 | 0.000 (-0.01; 0.01) | 100 |
| | P value/I squared | | | | 0.644 | 0.00% | 0.615 | 0.00% |
| Fesoterodine | Continence | Kaplan, 2010[314] | 609/963 | 258/480 | 1.18 (1.07; 1.30) | 54.44 | 0.095 (0.04; 0.15) | 52.89 |
| Fesoterodine | Continence | NCT00444925,[58] | 396/685 | 138/337 | 1.41 (1.22; 1.63) | 45.56 | 0.169 (0.10; 0.23) | 47.11 |
| | Pooled | | | | 1.28 (1.07; 1.53) | 100 | 0.130 (0.06; 0.20) | 100 |
| | P value/I squared | | | | 0.038 | 76.70% | 0.085 | 66.30% |
| Fesoterodine | Dry eye | Chapple, 2007[252] | 6/272 | 0/285 | 13.62 (0.77; 240.60) | 6.45 | 0.022 (0.00; 0.04) | 14.34 |
| Fesoterodine | Dry eye | Nitti C, 2007[347] | 2/283 | 0/274 | 4.84 (0.23; 100.39) | 5.89 | 0.007 (-0.01; 0.02) | 19.1 |
| Fesoterodine | Dry eye | Dmochowski, 2010[465] | 13/438 | 8/445 | 1.65 (0.69; 3.94) | 25.71 | 0.012 (-0.01; 0.03) | 13.46 |
| Fesoterodine | Dry eye | NCT00444925,[58] | 9/685 | 6/337 | 0.74 (0.27; 2.06) | 23.03 | -0.005 (-0.02; 0.01) | 15.84 |
| Fesoterodine | Dry eye | NCT00536484,[59] | 13/438 | 8/445 | 1.65 (0.69; 3.94) | 25.71 | 0.012 (-0.01; 0.03) | 13.46 |
| Fesoterodine | Dry eye | Chapple, 2007[252] | 12/288 | 0/285 | 24.74 (1.47; 415.89) | 6.64 | 0.042 (0.02; 0.07) | 11.31 |
| Fesoterodine | Dry eye | Nitti C, 2007[347] | 9/279 | 0/274 | 18.66 (1.09; 319.06) | 6.57 | 0.032 (0.01; 0.05) | 12.48 |
| | Pooled | | | | 2.35 (1.05; 5.25) | 100 | 0.016 (0.01; 0.03) | 100 |
| | P value/I squared | | | | 0.082 | 46.50% | 0.022 | 59.40% |
| Fesoterodine | Dry mouth | Chapple, 2004[259] | 47/186 | 16/183 | 2.88 (1.69; 4.88) | 6.48 | 0.164 (0.09; 0.24) | 6.79 |
| Fesoterodine | Dry mouth | Chapple, 2007[252] | 59/272 | 20/285 | 3.09 (1.91; 4.99) | 7.57 | 0.147 (0.09; 0.20) | 8.25 |
| Fesoterodine | Dry mouth | Nitti C, 2007[347] | 45/283 | 19/274 | 2.29 (1.38; 3.82) | 6.88 | 0.090 (0.04; 0.14) | 8.71 |
| Fesoterodine | Dry mouth | Dmochowski, 2010[465] | 113/438 | 34/445 | 3.38 (2.36; 4.84) | 11.32 | 0.182 (0.13; 0.23) | 9.11 |
| Fesoterodine | Dry mouth | Herschorn, 2010[466] | 189/679 | 20/334 | 4.65 (2.99; 7.23) | 8.54 | 0.218 (0.18; 0.26) | 9.62 |
| Fesoterodine | Dry mouth | Kaplan, 2010[314] | 270/963 | 24/480 | 5.61 (3.75; 8.39) | 9.74 | 0.230 (0.20; 0.27) | 10.3 |
| Fesoterodine | Dry mouth | NCT00444925,[58] | 189/685 | 20/337 | 4.65 (2.99; 7.23) | 8.54 | 0.217 (0.18; 0.26) | 9.65 |
| Fesoterodine | Dry mouth | NCT00536484,[59] | 113/438 | 34/445 | 3.38 (2.36; 4.84) | 11.32 | 0.182 (0.13; 0.23) | 9.11 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Fesoterodine | Dry mouth | Chapple, 2004[259] | 45/173 | 16/183 | 2.98 (1.75; 5.06) | 6.45 | 0.173 (0.10; 0.25) | 6.58 |
| Fesoterodine | Dry mouth | Chapple, 2007[252] | 97/288 | 20/285 | 4.80 (3.05; 7.55) | 8.25 | 0.267 (0.21; 0.33) | 7.82 |
| Fesoterodine | Dry mouth | Nitti C, 2007[347] | 99/279 | 19/274 | 5.12 (3.23; 8.12) | 8.01 | 0.285 (0.22; 0.35) | 7.68 |
| Fesoterodine | Dry mouth | Chapple, 2004[259] | 63/186 | 16/183 | 3.87 (2.33; 6.45) | 6.89 | 0.251 (0.17; 0.33) | 6.4 |
| | Pooled | | | | 3.82 (3.29; 4.45) | 100 | 0.200 (0.17; 0.23) | 100 |
| | P value/I squared | | | | 0.183 | 26.60% | 0 | 72.70% |
| Fesoterodine | Failure | Dmochowski, 2010[465] | 14/438 | 29/445 | 0.49 (0.26; 0.92) | 16.31 | -0.033 (-0.06; -0.01) | 31.89 |
| Fesoterodine | Failure | Herschorn, 2010[466] | 32/679 | 34/334 | 0.46 (0.29; 0.74) | 29.42 | -0.055 (-0.09; -0.02) | 19.47 |
| Fesoterodine | Failure | NCT00444925,[58] | 49/685 | 36/337 | 0.67 (0.44; 1.01) | 37.78 | -0.035 (-0.07; 0.00) | 17.41 |
| Fesoterodine | Failure | NCT00536484,[59] | 14/438 | 30/445 | 0.47 (0.26; 0.88) | 16.49 | -0.035 (-0.06; -0.01) | 31.23 |
| | Pooled | | | | 0.54 (0.42; 0.69) | 100 | -0.038 (-0.05; -0.02) | 100 |
| | P value/I squared | | | | 0.628 | 0.00% | 0.807 | 0.00% |
| Fesoterodine | Fatigue | NCT00444925,[58] | 12/685 | 0/337 | 12.32 (0.73; 207.42) | 22.03 | 0.018 (0.01; 0.03) | 68.42 |
| Fesoterodine | Fatigue | NCT00536484,[59] | 11/438 | 2/445 | 5.59 (1.25; 25.07) | 77.97 | 0.021 (0.01; 0.04) | 31.58 |
| | Pooled | | | | 6.65 (1.77; 25.03) | 100 | 0.018 (0.01; 0.03) | |
| | P value/I squared | | | | 0.628 | 0.00% | 0.752 | 0.00% |
| Fesoterodine | Headache | Chapple, 2004[259] | 32/186 | 29/183 | 1.09 (0.69; 1.72) | 15.51 | 0.014 (-0.06; 0.09) | 2.11 |
| Fesoterodine | Headache | Chapple, 2007[252] | 12/272 | 14/285 | 0.90 (0.42; 1.91) | 7.14 | -0.005 (-0.04; 0.03) | 8.22 |
| Fesoterodine | Headache | Nitti C, 2007[347] | 12/283 | 9/274 | 1.29 (0.55; 3.02) | 5.8 | 0.010 (-0.02; 0.04) | 9.63 |
| Fesoterodine | Headache | Dmochowski, 2010[465] | 19/438 | 15/445 | 1.29 (0.66; 2.50) | 8.82 | 0.010 (-0.02; 0.04) | 13.08 |
| Fesoterodine | Headache | Herschorn, 2010[466] | 38/679 | 8/334 | 2.34 (1.10; 4.95) | 7.17 | 0.032 (0.01; 0.06) | 14.19 |
| Fesoterodine | Headache | NCT00444925,[58] | 38/685 | 8/337 | 2.34 (1.10; 4.95) | 7.16 | 0.032 (0.01; 0.06) | 14.35 |
| Fesoterodine | Headache | NCT00536484,[59] | 19/438 | 15/445 | 1.29 (0.66; 2.50) | 8.82 | 0.010 (-0.02; 0.04) | 13.08 |
| Fesoterodine | Headache | Chapple, 2004[259] | 28/173 | 29/183 | 1.02 (0.64; 1.64) | 14.76 | 0.003 (-0.07; 0.08) | 2.09 |
| Fesoterodine | Headache | Chapple, 2007[252] | 7/288 | 14/285 | 0.50 (0.20; 1.21) | 5.29 | -0.025 (-0.06; 0.01) | 10.01 |
| Fesoterodine | Headache | Nitti C, 2007[347] | 8/279 | 9/274 | 0.87 (0.34; 2.23) | 4.84 | -0.004 (-0.03; 0.03) | 11.02 |
| Fesoterodine | Headache | Chapple, 2004[259] | 28/186 | 29/183 | 0.95 (0.59; 1.53) | 14.68 | -0.008 (-0.08; 0.07) | 2.22 |
| | Pooled | | | | 1.15 (0.92; 1.43) | 100 | 0.009 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.271 | 18.20% | 0.205 | 25.10% |
| Fesoterodine | Improvement in UI | Dmochowski, 2010[465] | 182/438 | 137/445 | 1.35 (1.13; 1.61) | 31.57 | 0.108 (0.05; 0.17) | 18.56 |
| Fesoterodine | Improvement in UI | Herschorn, 2010[466] | 293/679 | 113/334 | 1.28 (1.07; 1.52) | 33.47 | 0.093 (0.03; 0.16) | 18.59 |
| Fesoterodine | Improvement in UI | NCT00444925,[58] | 102/685 | 32/337 | 1.57 (1.08; 2.28) | 7.12 | 0.054 (0.01; 0.10) | 43.58 |
| Fesoterodine | Improvement in UI | NCT00536484,[59] | 161/438 | 130/445 | 1.26 (1.04; 1.52) | 27.84 | 0.075 (0.01; 0.14) | 19.27 |
| | Pooled | | | | 1.31 (1.19; 1.45) | 100 | 0.075 (0.05; 0.10) | 100 |
| | P value/I squared | | | | 0.74 | 0.00% | 0.501 | 0.00% |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Fesoterodine | Influenza-like symptoms | Chapple, 2004[259] | 17/186 | 15/183 | 1.12 (0.57; 2.17) | 40.53 | 0.009 (-0.05; 0.07) | 27.49 |
| Fesoterodine | Influenza-like symptoms | Chapple, 2004[259] | 7/173 | 15/183 | 0.49 (0.21; 1.18) | 29.75 | -0.042 (-0.09; 0.01) | 35.53 |
| Fesoterodine | Influenza-like symptoms | Chapple, 2004[259] | 7/186 | 15/183 | 0.46 (0.19; 1.10) | 29.71 | -0.044 (-0.09; 0.00) | 36.98 |
| | Pooled | | | | 0.67 (0.37; 1.22) | 100 | -0.029 (-0.06; 0.00) | 100 |
| | P value/I squared | | | | 0.183 | 41.20% | 0.308 | 15.10% |
| Fesoterodine | Nasopharyngitis | Chapple, 2007[252] | 8/272 | 7/285 | 1.20 (0.44; 3.26) | 12.88 | 0.005 (-0.02; 0.03) | 13.51 |
| Fesoterodine | Nasopharyngitis | Nitti C, 2007[347] | 10/283 | 7/274 | 1.38 (0.53; 3.58) | 14.25 | 0.010 (-0.02; 0.04) | 12.09 |
| Fesoterodine | Nasopharyngitis | NCT00444925,[58] | 13/685 | 10/337 | 0.64 (0.28; 1.44) | 19.47 | -0.011 (-0.03; 0.01) | 22.68 |
| Fesoterodine | Nasopharyngitis | Chapple, 2007[252] | 5/288 | 7/285 | 0.71 (0.23; 2.20) | 10 | -0.007 (-0.03; 0.02) | 17.82 |
| Fesoterodine | Nasopharyngitis | Nitti C, 2007[347] | 2/279 | 7/274 | 0.28 (0.06; 1.34) | 5.28 | -0.018 (-0.04; 0.00) | 21.95 |
| Fesoterodine | Nasopharyngitis | NCT00536484,[59] | 19/438 | 25/445 | 0.77 (0.43; 1.38) | 38.12 | -0.013 (-0.04; 0.02) | 11.94 |
| | Pooled | | | | 0.80 (0.56; 1.15) | 100 | -0.007 (-0.02; 0.00) | 100 |
| | P value/I squared | | | | 0.553 | 0.00% | 0.629 | 0.00% |
| Fesoterodine | Nausea | Chapple, 2004[259] | 9/186 | 13/183 | 0.68 (0.30; 1.55) | 17.86 | -0.023 (-0.07; 0.03) | 3.77 |
| Fesoterodine | Nausea | Chapple, 2007[252] | 1/272 | 1/285 | 1.05 (0.07; 16.67) | 2.03 | 0.000 (-0.01; 0.01) | 21.32 |
| Fesoterodine | Nausea | Nitti C, 2007[347] | 3/283 | 6/274 | 0.48 (0.12; 1.92) | 7.58 | -0.011 (-0.03; 0.01) | 12.43 |
| Fesoterodine | Nausea | NCT00444925,[58] | 12/685 | 6/337 | 0.98 (0.37; 2.60) | 13.8 | 0.000 (-0.02; 0.02) | 15.12 |
| Fesoterodine | Nausea | NCT00536484,[59] | 6/438 | 18/445 | 0.34 (0.14; 0.85) | 15.21 | -0.027 (-0.05; -0.01) | 12.26 |
| Fesoterodine | Nausea | Chapple, 2004[259] | 3/173 | 13/183 | 0.24 (0.07; 0.84) | 9.14 | -0.054 (-0.10; -0.01) | 4.77 |
| Fesoterodine | Nausea | Chapple, 2007[252] | 4/288 | 1/285 | 3.96 (0.45; 35.20) | 3.2 | 0.010 (-0.01; 0.03) | 16.75 |
| Fesoterodine | Nausea | Nitti C, 2007[347] | 7/279 | 6/274 | 1.15 (0.39; 3.37) | 11.61 | 0.003 (-0.02; 0.03) | 10.05 |
| Fesoterodine | Nausea | Chapple, 2004[259] | 11/186 | 13/183 | 0.83 (0.38; 1.81) | 19.57 | -0.012 (-0.06; 0.04) | 3.51 |
| | Pooled | | | | 0.67 (0.45; 1.01) | 100 | -0.006 (-0.02; 0.00) | 100 |
| | P value/I squared | | | | 0.31 | 14.90% | 0.051 | 48.20% |
| Fesoterodine | Serious adverse effects | NCT00444925,[58] | 15/685 | 8/337 | 0.92 (0.40; 2.15) | 64.37 | -0.002 (-0.02; 0.02) | 37.71 |
| Fesoterodine | Serious adverse effects | NCT00536484,[59] | 5/438 | 7/445 | 0.73 (0.23; 2.27) | 35.63 | -0.004 (-0.02; 0.01) | 62.29 |
| | Pooled | | | | 0.85 (0.43; 1.67) | 100 | -0.003 (-0.02; 0.01) | 100 |
| | P value/I squared | | | | 0.741 | 0.00% | 0.845 | 0.00% |
| Fesoterodine | Upper respiratory tract infection | NCT00444925,[58] | 2/685 | 4/337 | 0.25 (0.05; 1.34) | 31.3 | -0.009 (-0.02; 0.00) | 84.59 |
| Fesoterodine | Upper respiratory tract infection | NCT00536484,[59] | 21/438 | 23/445 | 0.93 (0.52; 1.65) | 68.7 | -0.004 (-0.03; 0.03) | 15.41 |
| | Pooled | | | | 0.61 (0.18; 2.05) | 100 | -0.008 (-0.02; 0.00) | 100 |
| | P value/I squared | | | | 0.146 | 52.80% | 0.743 | 0.00% |
| Fesoterodine | Urinary tract infection | Herschorn, 2010[466] | 15/679 | 2/334 | 3.69 (0.85; 16.04) | 29.81 | 0.016 (0.00; 0.03) | 36.48 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Fesoterodine | Urinary tract infection | NCT00444925,[58] | 15/685 | 2/337 | 3.69 (0.85; 16.04) | 29.81 | 0.016 (0.00; 0.03) | 36.7 |
| Fesoterodine | Urinary tract infection | NCT00536484,[59] | 8/438 | 12/445 | 0.68 (0.28; 1.64) | 40.39 | -0.009 (-0.03; 0.01) | 26.82 |
| | Pooled | | | | 1.86 (0.53; 6.50) | 100 | 0.009 (-0.01; 0.02) | 100 |
| | P value/I squared | | | | 0.052 | 66.20% | 0.086 | 59.30% |
| Oxybutynin | Adverse effects | Dmochowski, 2003[271] | 7/121 | 13/117 | 0.52 (0.22; 1.26) | 30.53 | -0.053 (-0.12; 0.02) | 34.84 |
| Oxybutynin | Adverse effects | Homma, 2003[303] | 30/244 | 4/122 | 3.75 (1.35; 10.40) | 27.72 | 0.090 (0.04; 0.14) | 36.04 |
| Oxybutynin | Adverse effects | Madersbacher, 1999[337] | 104/145 | 30/72 | 1.72 (1.29; 2.31) | 41.75 | 0.301 (0.17; 0.44) | 29.12 |
| | Pooled | | | | 1.48 (0.61; 3.60) | 100 | 0.101 (-0.05; 0.26) | 100 |
| | P value/I squared | | | | 0.011 | 78.10% | 0 | 91.40% |
| Oxybutynin | Blurred vision | Szonyi, 1995[377] | 14/28 | 17/29 | 0.85 (0.53; 1.38) | 43.59 | -0.086 (-0.34; 0.17) | 3.4 |
| Oxybutynin | Blurred vision | Homma, 2003[303] | 8/244 | 0/122 | 8.54 (0.50; 146.65) | 7.26 | 0.033 (0.01; 0.06) | 60.42 |
| Oxybutynin | Blurred vision | Burgio, 1998[237] | 10/67 | 6/65 | 1.62 (0.62; 4.19) | 30.46 | 0.057 (-0.05; 0.17) | 15.29 |
| Oxybutynin | Blurred vision | Zinner, 2005[403] | 1/19 | 0/19 | 3.00 (0.13; 69.31) | 6.11 | 0.053 (-0.08; 0.19) | 11.14 |
| Oxybutynin | Blurred vision | Tapp, 1990[379] | 8/37 | 1/33 | 7.14 (0.94; 54.07) | 12.58 | 0.186 (0.04; 0.33) | 9.76 |
| | Pooled | | | | 1.73 (0.76; 3.95) | 100 | 0.050 (0.00; 0.10) | 100 |
| | P value/I squared | | | | 0.118 | 45.60% | 0.266 | 23.20% |
| Oxybutynin | Constipation | Moore, 1990[345] | 6/48 | 0/43 | 11.67 (0.68; 201.30) | 1.45 | 0.125 (0.03; 0.23) | 7.13 |
| Oxybutynin | Constipation | Dmochowski, 2002[269] | 1/125 | 4/132 | 0.26 (0.03; 2.33) | 2.48 | -0.022 (-0.06; 0.01) | 27.48 |
| Oxybutynin | Constipation | Homma, 2003[303] | 15/244 | 6/122 | 1.25 (0.50; 3.14) | 13.66 | 0.012 (-0.04; 0.06) | 19.48 |
| Oxybutynin | Constipation | Staskin, 2009[33] | 5/389 | 4/400 | 1.29 (0.35; 4.75) | 6.84 | 0.003 (-0.01; 0.02) | 38.24 |
| Oxybutynin | Constipation | Burgio, 1998[237] | 26/67 | 24/65 | 1.05 (0.68; 1.63) | 57.22 | 0.019 (-0.15; 0.18) | 2.92 |
| Oxybutynin | Constipation | Zinner, 2005[403] | 2/19 | 1/19 | 2.00 (0.20; 20.24) | 2.2 | 0.053 (-0.12; 0.22) | 2.75 |
| Oxybutynin | Constipation | Tapp, 1990[379] | 13/37 | 6/33 | 1.93 (0.83; 4.50) | 16.15 | 0.170 (-0.03; 0.37) | 1.99 |
| | Pooled | | | | 1.22 (0.87; 1.72) | 100 | 0.012 (-0.02; 0.04) | 100 |
| | P value/I squared | | | | 0.414 | 1.30% | 0.087 | 45.70% |
| Oxybutynin | Treatment discontinuation | Szonyi, 1995[377] | 8/28 | 5/29 | 1.66 (0.62; 4.46) | 9.16 | 0.113 (-0.10; 0.33) | 2.81 |
| Oxybutynin | Treatment discontinuation | Madersbacher, 1999[337] | 16/145 | 7/72 | 1.14 (0.49; 2.63) | 12.65 | 0.013 (-0.07; 0.10) | 18.08 |
| Oxybutynin | Treatment discontinuation | Staskin, 2009[33] | 43/389 | 45/400 | 0.98 (0.66; 1.46) | 57.78 | -0.002 (-0.05; 0.04) | 68.23 |
| Oxybutynin | Treatment discontinuation | Burgio, 1998[237] | 10/67 | 9/65 | 1.08 (0.47; 2.48) | 12.91 | 0.011 (-0.11; 0.13) | 9.19 |
| Oxybutynin | Treatment discontinuation | Zinner, 2005[403] | 6/19 | 4/19 | 1.50 (0.50; 4.48) | 7.5 | 0.105 (-0.17; 0.38) | 1.7 |
| | Pooled | | | | 1.10 (0.81; 1.48) | 100 | 0.007 (-0.03; 0.04) | 100 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | P value/I squared | | | | 0.863 | 0.00% | 0.811 | 0.00% |
| Oxybutynin | Treatment discontinuation due to adverse effects | Homma, 2003[303] | 42/244 | 11/122 | 1.91 (1.02; 3.58) | 42.87 | 0.082 (0.01; 0.15) | 28.89 |
| Oxybutynin | Treatment discontinuation due to adverse effects | Homma, 2004[302] | 21/122 | 5/57 | 1.96 (0.78; 4.94) | 19.79 | 0.084 (-0.02; 0.18) | 20.69 |
| Oxybutynin | Treatment discontinuation due to adverse effects | Staskin, 2009[33] | 19/389 | 13/400 | 1.50 (0.75; 3.00) | 35.27 | 0.016 (-0.01; 0.04) | 42.43 |
| Oxybutynin | Treatment discontinuation due to adverse effects | Zinner, 2005[403] | 4/19 | 0/19 | 9.00 (0.52; 156.41) | 2.07 | 0.211 (0.02; 0.41) | 7.99 |
| Oxybutynin | Treatment discontinuation due to adverse effects | Thuroff, 1991[381] | 2/63 | 0/52 | 4.14 (0.20; 84.38) | 6.59 | 0.032 (-0.02; 0.09) | 80.16 |
| Oxybutynin | Treatment discontinuation due to adverse effects | Abrams, 1998[220] | 20/118 | 7/57 | 1.38 (0.62; 3.07) | 93.41 | 0.047 (-0.06; 0.16) | 19.84 |
| | Pooled | | | | 1.74 (1.21; 2.50) | 100 | 0.046 (0.01; 0.08) | 100 |
| | P value/I squared | | | | 0.816 | 0.00% | 0.182 | 33.90% |
| Oxybutynin | Dizziness | Moore, 1990[345] | 2/48 | 3/43 | 0.60 (0.11; 3.41) | 18.34 | -0.028 (-0.12; 0.07) | 1.62 |
| Oxybutynin | Dizziness | Dmochowski, 2002[269] | 5/125 | 5/132 | 1.06 (0.31; 3.56) | 37.66 | 0.002 (-0.05; 0.05) | 6.51 |
| Oxybutynin | Dizziness | Homma, 2003[303] | 6/244 | 2/122 | 1.50 (0.31; 7.32) | 22.12 | 0.008 (-0.02; 0.04) | 16.49 |
| Oxybutynin | Dizziness | Staskin, 2009[33] | 6/389 | 2/400 | 3.09 (0.63; 15.19) | 21.88 | 0.010 (0.00; 0.02) | 73.82 |
| Oxybutynin | Dizziness | Zinner, 2005[403] | 0/19 | 0/19 | (Excluded) (0.00; 0.00) | | 0.000 (-0.10; 0.10) | 1.56 |
| | Pooled | | | | 1.30 (0.62; 2.74) | 100 | 0.009 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.564 | 0.00% | 0.946 | 0.00% |
| Oxybutynin | Continence | Moore, 1990[345] | 5/28 | 0/25 | 9.86 (0.57; 169.86) | 0.69 | 0.179 (0.03; 0.33) | 9.2 |
| Oxybutynin | Continence | Staskin, 2009[33] | 108/389 | 69/400 | 1.61 (1.23; 2.10) | 78.38 | 0.105 (0.05; 0.16) | 63.55 |
| Oxybutynin | Continence | Burgio, 1998[237] | 15/67 | 8/65 | 1.82 (0.83; 4.00) | 9.07 | 0.101 (-0.03; 0.23) | 13.03 |
| Oxybutynin | Continence | Goode, 2004[287] | 15/67 | 8/65 | 1.82 (0.83; 4.00) | 9.07 | 0.101 (-0.03; 0.23) | 13.03 |
| Oxybutynin | Continence | Lehtoranta, | 4/9 | 2/9 | 2.00 (0.48; 8.31) | 2.77 | 0.222 (-0.20; 0.65) | 1.19 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | | 2002[331] | | | | | | |
| | Pooled | | | | 1.68 (1.32; 2.13) | 100 | 0.112 (0.07; 0.16) | 100 |
| | P value/I squared | | | | 0.787 | 0.00% | 0.893 | 0.00% |
| Oxybutynin | Dry mouth | Dmochowski, 2002[269] | 27/388 | 11/132 | 0.84 (0.43; 1.64) | 9.91 | -0.014 (-0.07; 0.04) | 10.67 |
| Oxybutynin | Dry mouth | Moore, 1990[345] | 42/48 | 14/43 | 2.69 (1.73; 4.19) | 11.56 | 0.549 (0.38; 0.72) | 9.67 |
| Oxybutynin | Dry mouth | Szonyi, 1995[377] | 26/28 | 25/29 | 1.08 (0.90; 1.29) | 12.94 | 0.067 (-0.09; 0.22) | 9.8 |
| Oxybutynin | Dry mouth | Homma, 2003[303] | 131/244 | 12/122 | 5.46 (3.15; 9.46) | 10.81 | 0.439 (0.36; 0.52) | 10.51 |
| Oxybutynin | Dry mouth | Homma, 2004[302] | 75/122 | 3/57 | 11.68 (3.85; 35.45) | 6.9 | 0.562 (0.46; 0.67) | 10.34 |
| Oxybutynin | Dry mouth | Staskin, 2009[33] | 27/389 | 11/400 | 2.52 (1.27; 5.02) | 9.8 | 0.042 (0.01; 0.07) | 10.76 |
| Oxybutynin | Dry mouth | Burgio, 1998[237] | 65/67 | 36/65 | 1.75 (1.40; 2.19) | 12.78 | 0.416 (0.29; 0.54) | 10.12 |
| Oxybutynin | Dry mouth | Abrams, 1998[220] | 102/118 | 12/57 | 4.11 (2.47; 6.82) | 11.11 | 0.654 (0.53; 0.78) | 10.17 |
| Oxybutynin | Dry mouth | Zinner, 2005[403] | 7/19 | 1/19 | 7.00 (0.95; 51.54) | 3.34 | 0.316 (0.08; 0.56) | 8.75 |
| Oxybutynin | Dry mouth | Tapp, 1990[379] | 29/37 | 10/33 | 2.59 (1.50; 4.46) | 10.85 | 0.481 (0.28; 0.69) | 9.21 |
| | Pooled | | | | 2.58 (1.69; 3.93) | 100 | 0.347 (0.19; 0.51) | 100 |
| | P value/I squared | | | | 0 | 88.70% | 0 | 97.10% |
| Oxybutynin | Dry skin | Szonyi, 1995[377] | 14/28 | 17/29 | 0.85 (0.53; 1.38) | 46.25 | -0.086 (-0.34; 0.17) | 26.21 |
| Oxybutynin | Dry skin | Homma, 2003[303] | 4/244 | 1/122 | 2.00 (0.23; 17.70) | 25.72 | 0.008 (-0.01; 0.03) | 40.56 |
| Oxybutynin | Dry skin | Tapp, 1990[379] | 13/37 | 1/33 | 11.60 (1.60; 83.90) | 28.03 | 0.321 (0.16; 0.49) | 33.23 |
| | Pooled | | | | 2.21 (0.44; 11.14) | 100 | 0.087 (-0.13; 0.31) | 100 |
| | P value/I squared | | | | 0.035 | 70.10% | 0.001 | 85.90% |
| Oxybutynin | Dyspepsia | Chancellor, 2001[248] | 1/36 | 0/36 | 3.00 (0.13; 71.28) | 5.66 | 0.028 (-0.05; 0.10) | 32.67 |
| Oxybutynin | Dyspepsia | Homma, 2003[303] | 20/244 | 4/122 | 2.50 (0.87; 7.15) | 51.4 | 0.049 (0.00; 0.10) | 40.58 |
| Oxybutynin | Dyspepsia | Abrams, 1998[220] | 27/118 | 3/57 | 4.35 (1.38; 13.73) | 42.94 | 0.176 (0.08; 0.27) | 26.75 |
| | Pooled | | | | 3.20 (1.51; 6.81) | 100 | 0.076 (0.00; 0.15) | 100 |
| | P value/I squared | | | | 0.784 | 0.00% | 0.037 | 69.80% |
| Oxybutynin | Dysuria | Dmochowski, 2002[269] | 3/125 | 0/132 | 7.39 (0.39; 141.62) | 46.77 | 0.024 (-0.01; 0.06) | 29.95 |
| Oxybutynin | Dysuria | Staskin, 2009[33] | 1/389 | 1/400 | 1.03 (0.07; 16.38) | 53.23 | 0.000 (-0.01; 0.01) | 70.05 |
| | Pooled | | | | 2.59 (0.34; 19.49) | 100 | 0.007 (-0.01; 0.03) | 100 |
| | P value/I squared | | | | 0.34 | 0.00% | 0.134 | 55.40% |
| Oxybutynin | Failure | Wang, 2006[392] | 14/23 | 19/21 | 0.67 (0.47; 0.96) | 47.59 | -0.296 (-0.53; -0.06) | 7.81 |
| Oxybutynin | Failure | Homma, 2003[303] | 12/244 | 10/122 | 0.60 (0.27; 1.35) | 9.17 | -0.033 (-0.09; 0.02) | 30.74 |
| Oxybutynin | Failure | Madersbacher, 1999[337] | 28/145 | 23/72 | 0.60 (0.38; 0.97) | 26.86 | -0.126 (-0.25; 0.00) | 18.01 |
| Oxybutynin | Failure | Burgio, 1998[237] | 1/67 | 3/65 | 0.32 (0.04; 3.03) | 1.2 | -0.031 (-0.09; 0.03) | 30.17 |
| Oxybutynin | Failure | Thuroff, 1991[381] | 11/63 | 21/52 | 0.43 (0.23; 0.81) | 15.17 | -0.229 (-0.39; -0.07) | 13.28 |
| | Pooled | | | | 0.60 (0.47; 0.77) | 100 | -0.096 (-0.17; -0.02) | 100 |
| | P value/I squared | | | | 0.785 | 0.00% | 0.028 | 63.20% |
| Oxybutynin | Headache | Chancellor, | 6/36 | 4/36 | 1.50 (0.46; 4.87) | 19.22 | 0.056 (-0.10; 0.22) | 1.35 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | | 2001[248] | | | | | | |
| Oxybutynin | Headache | Homma, 2003[303] | 11/244 | 8/122 | 0.69 (0.28; 1.67) | 34.08 | -0.020 (-0.07; 0.03) | 13.13 |
| Oxybutynin | Headache | Chancellor, 2001[248] | 6/36 | 4/36 | 1.50 (0.46; 4.87) | 19.22 | 0.056 (-0.10; 0.22) | 1.35 |
| Oxybutynin | Headache | Staskin, 2009[33] | 6/389 | 11/400 | 0.56 (0.21; 1.50) | 27.48 | -0.012 (-0.03; 0.01) | 84.17 |
| | Pooled | | | | 0.88 (0.52; 1.47) | 100 | -0.011 (-0.03; 0.01) | 100 |
| | P value/I squared | | | | 0.444 | 0.00% | 0.686 | 0.00% |
| Oxybutynin | Improvement in UI | Moore, 1990[345] | 10/28 | 1/25 | 8.93 (1.23; 64.90) | 1.9 | 0.317 (0.12; 0.51) | 7.45 |
| Oxybutynin | Improvement in UI | Johnson, 2005[309] | 4/46 | 1/38 | 3.30 (0.39; 28.33) | 1.65 | 0.061 (-0.04; 0.16) | 9.71 |
| Oxybutynin | Improvement in UI | Szonyi, 1995[377] | 22/28 | 16/29 | 1.42 (0.97; 2.08) | 11.39 | 0.234 (0.00; 0.47) | 6.47 |
| Oxybutynin | Improvement in UI | Wang, 2006[392] | 2/23 | 0/21 | 4.58 (0.23; 90.30) | 0.91 | 0.087 (-0.05; 0.22) | 8.8 |
| Oxybutynin | Improvement in UI | Homma, 2003[303] | 129/244 | 31/122 | 2.10 (1.51; 2.91) | 11.99 | 0.277 (0.18; 0.38) | 9.65 |
| Oxybutynin | Improvement in UI | Homma, 2004[302] | 20/122 | 26/57 | 0.36 (0.22; 0.59) | 10.11 | -0.292 (-0.44; -0.15) | 8.62 |
| Oxybutynin | Improvement in UI | Madersbacher, 1999[337] | 116/145 | 43/72 | 1.34 (1.09; 1.65) | 13.16 | 0.203 (0.07; 0.33) | 8.96 |
| Oxybutynin | Improvement in UI | Burgio, 1998[237] | 37/67 | 20/65 | 1.80 (1.18; 2.74) | 10.9 | 0.245 (0.08; 0.41) | 8.17 |
| Oxybutynin | Improvement in UI | Goode, 2002[286] | 7/35 | 7/37 | 1.06 (0.41; 2.71) | 5.78 | 0.011 (-0.17; 0.19) | 7.7 |
| Oxybutynin | Improvement in UI | Goode, 2004[287] | 33/67 | 18/65 | 1.78 (1.12; 2.82) | 10.45 | 0.216 (0.05; 0.38) | 8.22 |
| Oxybutynin | Improvement in UI | Thuroff, 1991[381] | 26/63 | 15/52 | 1.43 (0.85; 2.40) | 9.79 | 0.124 (-0.05; 0.30) | 7.94 |
| Oxybutynin | Improvement in UI | Abrams, 1998[220] | 58/118 | 27/57 | 1.04 (0.75; 1.44) | 11.96 | 0.018 (-0.14; 0.18) | 8.31 |
| | Pooled | | | | 1.36 (1.01; 1.82) | 100 | 0.122 (0.03; 0.22) | 100 |
| | P value/I squared | | | | 0 | 75.90% | 0 | 80.10% |
| Oxybutynin | Nausea | Moore, 1990[345] | 4/48 | 1/43 | 3.58 (0.42; 30.83) | 8.42 | 0.060 (-0.03; 0.15) | 7.91 |
| Oxybutynin | Nausea | Dmochowski, 2002[269] | 2/125 | 7/132 | 0.30 (0.06; 1.43) | 14.52 | -0.037 (-0.08; 0.01) | 18.56 |
| Oxybutynin | Nausea | Chancellor, 2001[248] | 1/36 | 1/36 | 1.00 (0.07; 15.38) | 5.48 | 0.000 (-0.08; 0.08) | 10.14 |
| Oxybutynin | Nausea | Madersbacher, 1999[337] | 14/145 | 6/72 | 1.16 (0.47; 2.89) | 29.83 | 0.013 (-0.07; 0.09) | 9.44 |
| Oxybutynin | Nausea | Chancellor, 2001[248] | 0/36 | 1/36 | 0.33 (0.01; 7.92) | 4.16 | -0.028 (-0.10; 0.05) | 10.57 |
| Oxybutynin | Nausea | Staskin, 2009[33] | 1/389 | 2/400 | 0.51 (0.05; 5.65) | 6.96 | -0.002 (-0.01; 0.01) | 31.29 |
| Oxybutynin | Nausea | Abrams, 1998[220] | 7/118 | 6/57 | 0.56 (0.20; 1.60) | 25.49 | -0.046 (-0.14; 0.04) | 7.89 |
| Oxybutynin | Nausea | Tapp, 1990[379] | 7/37 | 0/33 | 13.42 (0.80; 226.31) | 5.15 | 0.189 (0.06; 0.32) | 4.2 |
| | Pooled | | | | 0.88 (0.45; 1.72) | 100 | 0.000 (-0.03; 0.03) | 100 |
| | P value/I squared | | | | 0.279 | 19.00% | 0.057 | 48.80% |
| Oxybutynin | Retention | Homma, 2003[303] | 8/244 | 0/122 | 8.54 (0.50; 146.65) | 24.79 | 0.033 (0.01; 0.06) | 40.48 |
| Oxybutynin | Retention | Staskin, 2009[33] | 0/389 | 1/400 | 0.34 (0.01; 8.39) | 20.77 | -0.002 (-0.01; 0.00) | 45.15 |
| Oxybutynin | Retention | Burgio, 1998[237] | 14/67 | 2/65 | 6.79 (1.61; 28.71) | 54.44 | 0.178 (0.07; 0.28) | 14.37 |
| | Pooled | | | | 3.87 (0.74; 20.21) | 100 | 0.038 (-0.01; 0.09) | 100 |
| | P value/I squared | | | | 0.224 | 33.20% | 0 | 88.70% |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Oxybutynin | Serious adverse effects | Dmochowski, 2003[271] | 1/121 | 3/117 | 0.32 (0.03; 3.06) | 30.01 | -0.017 (-0.05; 0.02) | 32.74 |
| Oxybutynin | Serious adverse effects | Homma, 2003[303] | 20/244 | 0/122 | 20.58 (1.26; 337.49) | 24.45 | 0.082 (0.05; 0.12) | 31.85 |
| Oxybutynin | Serious adverse effects | Staskin, 2009[33] | 7/389 | 10/400 | 0.72 (0.28; 1.87) | 45.54 | -0.007 (-0.03; 0.01) | 35.41 |
| | Pooled | | | | 1.28 (0.19; 8.67) | 100 | 0.018 (-0.04; 0.07) | 100 |
| | P value/I squared | | | | 0.055 | 65.60% | 0 | 90.10% |
| Oxybutynin | Somnolence | Dmochowski, 2002[269] | 2/125 | 1/132 | 2.11 (0.19; 23.00) | 21.73 | 0.008 (-0.02; 0.04) | 6.37 |
| Oxybutynin | Somnolence | Homma, 2003[303] | 4/244 | 4/122 | 0.50 (0.13; 1.97) | 66.15 | -0.016 (-0.05; 0.02) | 3.57 |
| Oxybutynin | Somnolence | Staskin, 2009[33] | 1/389 | 0/400 | 3.09 (0.13; 75.49) | 12.12 | 0.003 (0.00; 0.01) | 90.06 |
| | Pooled | | | | 0.85 (0.28; 2.60) | 100 | 0.002 (0.00; 0.01) | 100 |
| | P value/I squared | | | | 0.415 | 0.00% | 0.527 | 0.00% |
| Oxybutynin | Vision disorder | Dmochowski, 2002[269] | 0/125 | 2/132 | 0.21 (0.01; 4.35) | 4.51 | -0.015 (-0.04; 0.01) | 68.22 |
| Oxybutynin | Vision disorder | Madersbacher, 1999[337] | 26/145 | 10/72 | 1.29 (0.66; 2.53) | 91.4 | 0.040 (-0.06; 0.14) | 5.64 |
| Oxybutynin | Vision disorder | Thuroff, 1991[381] | 1/63 | 0/52 | 2.48 (0.10; 59.73) | 4.09 | 0.016 (-0.03; 0.06) | 26.13 |
| | Pooled | | | | 1.22 (0.64; 2.32) | 100 | -0.004 (-0.03; 0.02) | 100 |
| | P value/I squared | | | | 0.47 | 0.00% | 0.334 | 8.70% |
| Oxybutynin | Vomiting | Chancellor, 2001[248] | 2/36 | 0/36 | 5.00 (0.25; 100.63) | 23.29 | 0.056 (-0.03; 0.15) | 17.46 |
| Oxybutynin | Vomiting | Madersbacher, 1999[337] | 2/145 | 2/72 | 0.50 (0.07; 3.45) | 55.8 | -0.014 (-0.06; 0.03) | 58.1 |
| Oxybutynin | Vomiting | Chancellor, 2001[248] | 1/36 | 0/36 | 3.00 (0.13; 71.28) | 20.91 | 0.028 (-0.05; 0.10) | 24.45 |
| | Pooled | | | | 1.24 (0.29; 5.27) | 100 | 0.008 (-0.03; 0.05) | 100 |
| | P value/I squared | | | | 0.371 | 0.00% | 0.305 | 15.80% |
| Propiverine | Adverse effects | Abrams, 2006[221] | 30/38 | 12/24 | 1.58 (1.03; 2.43) | 25.82 | 0.289 (0.05; 0.53) | 11.2 |
| Propiverine | Adverse effects | Lee, 2010[330] | 32/176 | 10/88 | 1.60 (0.83; 3.10) | 11.01 | 0.068 (-0.02; 0.16) | 35.65 |
| Propiverine | Adverse effects | Junemann, 2006[311] | 117/391 | 30/202 | 2.02 (1.40; 2.90) | 36.57 | 0.151 (0.08; 0.22) | 41.52 |
| Propiverine | Adverse effects | Abrams, 2006[221] | 34/42 | 12/24 | 1.62 (1.06; 2.48) | 26.6 | 0.310 (0.08; 0.54) | 11.63 |
| | Pooled | | | | 1.74 (1.40; 2.17) | 100 | 0.155 (0.07; 0.25) | 100 |
| | P value/I squared | | | | 0.803 | 0.00% | 0.101 | 51.80% |
| Propiverine | Blurred vision | Yamaguchi, 2007[401] | 15/402 | 8/406 | 1.89 (0.81; 4.42) | 67 | 0.018 (-0.01; 0.04) | 49.98 |
| Propiverine | Blurred vision | Junemann, 2006[311] | 18/391 | 1/202 | 9.30 (1.25; 69.16) | 33 | 0.041 (0.02; 0.06) | 50.02 |
| | Pooled | | | | 3.20 (0.74; 13.88) | 100 | 0.029 (0.01; 0.05) | 100 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | P value/I squared | | | | 0.152 | 51.20% | 0.156 | 50.40% |
| Propiverine | Constipation | Abrams, 2006[221] | 6/38 | 0/24 | 8.33 (0.49; 141.53) | 3.05 | 0.158 (0.03; 0.29) | 7.75 |
| Propiverine | Constipation | Yamaguchi, 2007[401] | 45/402 | 16/406 | 2.84 (1.63; 4.94) | 79.72 | 0.073 (0.04; 0.11) | 26.56 |
| Propiverine | Constipation | Lee, 2010[330] | 5/176 | 0/88 | 5.53 (0.31; 98.91) | 2.94 | 0.028 (0.00; 0.06) | 28.41 |
| Propiverine | Constipation | Junemann, 2006[311] | 13/391 | 2/202 | 3.36 (0.77; 14.74) | 11.17 | 0.023 (0.00; 0.05) | 30.42 |
| Propiverine | Constipation | Abrams, 2006[221] | 10/42 | 0/24 | 12.21 (0.75; 199.55) | 3.13 | 0.238 (0.10; 0.38) | 6.86 |
| | Pooled | | | | 3.19 (1.95; 5.23) | 100 | 0.063 (0.02; 0.10) | 100 |
| | P value/I squared | | | | 0.801 | 0.00% | 0.002 | 76.10% |
| Propiverine | Treatment discontinuation | Yamaguchi, 2007[401] | 36/402 | 34/406 | 1.07 (0.68; 1.67) | 70.84 | 0.006 (-0.03; 0.05) | 50.3 |
| Propiverine | Treatment discontinuation | Junemann, 2006[311] | 23/391 | 11/202 | 1.08 (0.54; 2.17) | 29.16 | 0.004 (-0.04; 0.04) | 49.7 |
| | Pooled | | | | 1.07 (0.74; 1.56) | 100 | 0.005 (-0.02; 0.03) | 100 |
| | P value/I squared | | | | 0.981 | 0.00% | 0.959 | 0.00% |
| Propiverine | Treatment discontinuation due to adverse effects | Yamaguchi, 2007[401] | 26/402 | 11/406 | 2.39 (1.20; 4.77) | 89.7 | 0.038 (0.01; 0.07) | 30.45 |
| Propiverine | Treatment discontinuation due to adverse effects | Junemann, 2006[311] | 11/391 | 1/202 | 5.68 (0.74; 43.71) | 10.3 | 0.023 (0.00; 0.04) | 69.55 |
| | Pooled | | | | 2.61 (1.36; 5.02) | 100 | 0.028 (0.01; 0.04) | 100 |
| | P value/I squared | | | | 0.43 | 0.00% | 0.413 | 0.00% |
| Propiverine | Dizziness | Lee, 2010[330] | 1/176 | 2/88 | 0.25 (0.02; 2.72) | 47.45 | -0.017 (-0.05; 0.02) | 35.29 |
| Propiverine | Dizziness | Junemann, 2006[311] | 6/391 | 1/202 | 3.10 (0.38; 25.57) | 52.55 | 0.010 (-0.01; 0.03) | 64.71 |
| | Pooled | | | | 0.94 (0.08; 11.03) | 100 | 0.001 (-0.03; 0.03) | 100 |
| | P value/I squared | | | | 0.121 | 58.30% | 0.141 | 53.80% |
| Propiverine | Continence | Junemann, 2006[311] | 211/391 | 77/202 | 1.42 (1.16; 1.73) | 86.85 | 0.158 (0.08; 0.24) | 83.96 |
| Propiverine | Continence | Dorschner, 2000[275] | 24/49 | 15/49 | 1.60 (0.96; 2.66) | 13.15 | 0.184 (-0.01; 0.37) | 16.04 |
| | Pooled | | | | 1.44 (1.20; 1.73) | 100 | 0.163 (0.09; 0.24) | 100 |
| | P value/I squared | | | | 0.661 | 0.00% | 0.812 | 0.00% |
| Propiverine | Dry mouth | Abrams, 2006[221] | 13/38 | 4/24 | 2.05 (0.76; 5.57) | 8.97 | 0.175 (-0.04; 0.39) | 9.34 |
| Propiverine | Dry mouth | Yamaguchi, 2007[401] | 103/402 | 23/406 | 4.52 (2.94; 6.96) | 48.14 | 0.200 (0.15; 0.25) | 27.41 |
| Propiverine | Dry mouth | Lee, 2010[330] | 14/176 | 2/88 | 3.50 (0.81; 15.06) | 4.19 | 0.057 (0.01; 0.11) | 27.11 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Propiverine | Dry mouth | Junemann, 2006[311] | 85/391 | 13/202 | 3.38 (1.93; 5.90) | 28.61 | 0.153 (0.10; 0.21) | 26.81 |
| Propiverine | Dry mouth | Abrams, 2006[221] | 22/42 | 4/24 | 3.14 (1.23; 8.05) | 10.1 | 0.357 (0.15; 0.57) | 9.33 |
| | Pooled | | | | 3.70 (2.74; 4.98) | 100 | 0.161 (0.08; 0.24) | 100 |
| | P value/I squared | | | | 0.663 | 0.00% | 0 | 80.50% |
| Propiverine | Failure | Junemann, 2006[311] | 63/391 | 59/202 | 0.55 (0.40; 0.75) | 62.84 | -0.131 (-0.20; -0.06) | 56.33 |
| Propiverine | Failure | Dorschner, 2000[275] | 6/49 | 23/49 | 0.26 (0.12; 0.58) | 37.16 | -0.347 (-0.51; -0.18) | 43.67 |
| | Pooled | | | | 0.42 (0.21; 0.85) | 100 | -0.225 (-0.44; -0.02) | 100 |
| | P value/I squared | | | | 0.09 | 65.30% | 0.02 | 81.50% |
| Propiverine | Headache | Abrams, 2006[221] | 1/38 | 0/24 | 1.92 (0.08; 45.37) | 16.44 | 0.026 (-0.06; 0.11) | 6.64 |
| Propiverine | Headache | Lee, 2010[330] | 1/176 | 2/88 | 0.25 (0.02; 2.72) | 28.4 | -0.017 (-0.05; 0.02) | 28.99 |
| Propiverine | Headache | Junemann, 2006[311] | 6/391 | 1/202 | 3.10 (0.38; 25.57) | 35.99 | 0.010 (-0.01; 0.03) | 59.69 |
| Propiverine | Headache | Abrams, 2006[221] | 3/42 | 0/24 | 4.07 (0.22; 75.60) | 19.17 | 0.071 (-0.03; 0.17) | 4.68 |
| | Pooled | | | | 1.48 (0.41; 5.39) | 100 | 0.006 (-0.02; 0.03) | 100 |
| | P value/I squared | | | | 0.378 | 2.90% | 0.254 | 26.40% |
| Propiverine | Improvement in UI | Lee, 2010[330] | 55/176 | 12/88 | 2.29 (1.30; 4.05) | 14.38 | 0.176 (0.08; 0.28) | 36.6 |
| Propiverine | Improvement in UI | Junemann, 2006[311] | 264/391 | 94/202 | 1.45 (1.23; 1.71) | 73.52 | 0.210 (0.13; 0.29) | 52.25 |
| Propiverine | Improvement in UI | Dorschner, 2000[275] | 19/49 | 11/49 | 1.73 (0.92; 3.24) | 12.09 | 0.163 (-0.02; 0.34) | 11.15 |
| | Pooled | | | | 1.58 (1.26; 1.99) | 100 | 0.192 (0.13; 0.25) | 100 |
| | P value/I squared | | | | 0.292 | 18.90% | 0.829 | 0.00% |
| Solifenacin | Adverse effects | Chapple, 2004[258] | 6/41 | 6/38 | 0.93 (0.33; 2.63) | 5.76 | -0.012 (-0.17; 0.15) | 10.7 |
| Solifenacin | Adverse effects | Chapple, 2004[258] | 12/37 | 6/38 | 2.05 (0.86; 4.90) | 7.55 | 0.166 (-0.02; 0.36) | 8.41 |
| Solifenacin | Adverse effects | Karram, 2009[316] | 160/372 | 88/367 | 1.79 (1.45; 2.23) | 22.68 | 0.190 (0.12; 0.26) | 21.87 |
| Solifenacin | Adverse effects | Toglia, 2009[317] | 160/372 | 88/367 | 1.79 (1.45; 2.23) | 22.68 | 0.190 (0.12; 0.26) | 21.87 |
| Solifenacin | Adverse effects | Chapple, 2004[258] | 12/35 | 6/38 | 2.17 (0.91; 5.16) | 7.59 | 0.185 (-0.01; 0.38) | 8.1 |
| Solifenacin | Adverse effects | Chu, 2009[262] | 236/340 | 197/332 | 1.17 (1.04; 1.31) | 25.09 | 0.101 (0.03; 0.17) | 21.07 |
| Solifenacin | Adverse effects | Chapple, 2004[258] | 21/37 | 6/38 | 3.60 (1.64; 7.89) | 8.67 | 0.410 (0.21; 0.61) | 7.99 |
| | Pooled | | | | 1.69 (1.27; 2.24) | 100 | 0.165 (0.10; 0.23) | 100 |
| | P value/I squared | | | | 0 | 78.20% | 0.021 | 59.60% |
| Solifenacin | Blurred vision | Chapple, 2004[258] | 1/41 | 2/38 | 0.46 (0.04; 4.91) | 0.88 | -0.028 (-0.11; 0.06) | 0.76 |
| Solifenacin | Blurred vision | Chapple, 2004[258] | 1/37 | 2/38 | 0.51 (0.05; 5.42) | 0.88 | -0.026 (-0.11; 0.06) | 0.71 |
| Solifenacin | Blurred vision | Chapple, 2004[54] | 10/279 | 7/267 | 1.37 (0.53; 3.54) | 5.41 | 0.010 (-0.02; 0.04) | 4.69 |
| Solifenacin | Blurred vision | Cardozo, 2006[244] | 13/314 | 14/781 | 2.31 (1.10; 4.86) | 8.86 | 0.023 (0.00; 0.05) | 6 |
| Solifenacin | Blurred vision | Staskin, 2006[39] | 22/578 | 22/1216 | 2.10 (1.18; 3.77) | 14.43 | 0.020 (0.00; 0.04) | 8.36 |
| Solifenacin | Blurred vision | Yamaguchi, 2007[401] | 7/400 | 8/406 | 0.89 (0.33; 2.43) | 4.85 | -0.002 (-0.02; 0.02) | 7.81 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Solifenacin | Blurred vision | Cardozo, 2008[63] | 4/641 | 2/224 | 0.70 (0.13; 3.79) | 1.71 | -0.003 (-0.02; 0.01) | 9.94 |
| Solifenacin | Blurred vision | Karram, 2009[316] | 14/372 | 4/367 | 3.45 (1.15; 10.39) | 4.03 | 0.027 (0.01; 0.05) | 6.58 |
| Solifenacin | Blurred vision | Toglia, 2009[317] | 15/372 | 4/367 | 3.70 (1.24; 11.04) | 4.1 | 0.029 (0.01; 0.05) | 6.4 |
| Solifenacin | Blurred vision | Vardy, 2009[467] | 4/386 | 5/382 | 0.79 (0.21; 2.93) | 2.87 | -0.003 (-0.02; 0.01) | 9.25 |
| Solifenacin | Blurred vision | Chapple, 2004[258] | 5/35 | 2/38 | 2.71 (0.56; 13.10) | 1.98 | 0.090 (-0.05; 0.23) | 0.31 |
| Solifenacin | Blurred vision | Chapple, 2004[54] | 15/269 | 7/267 | 2.13 (0.88; 5.13) | 6.31 | 0.030 (0.00; 0.06) | 3.83 |
| Solifenacin | Blurred vision | Cardozo, 2006[244] | 36/778 | 14/781 | 2.58 (1.40; 4.75) | 13.19 | 0.028 (0.01; 0.05) | 8.29 |
| Solifenacin | Blurred vision | Staskin, 2006[39] | 59/1233 | 22/1216 | 2.65 (1.63; 4.29) | 20.98 | 0.030 (0.02; 0.04) | 9.78 |
| Solifenacin | Blurred vision | Yamaguchi, 2007[401] | 16/385 | 8/406 | 2.11 (0.91; 4.87) | 6.99 | 0.022 (0.00; 0.05) | 5.95 |
| Solifenacin | Blurred vision | Chu, 2009[262] | 3/340 | 0/332 | 6.84 (0.35; 131.83) | 0.56 | 0.009 (0.00; 0.02) | 11.01 |
| Solifenacin | Blurred vision | Chapple, 2004[258] | 5/37 | 2/38 | 2.57 (0.53; 12.42) | 1.97 | 0.083 (-0.05; 0.21) | 0.33 |
| | Pooled | | | | 2.11 (1.70; 2.64) | 100 | 0.015 (0.01; 0.02) | 100 |
| | P value/I squared | | | | 0.578 | 0.00% | 0.014 | 48.10% |
| Solifenacin | Dry mouth | Chapple, 2004[258] | 5/37 | 0/38 | 11.29 (0.65; 197.21) | 0.9 | 0.135 (0.02; 0.25) | 5.68 |
| Solifenacin | Dry mouth | Cardozo, 2006[244] | 35/314 | 35/781 | 2.49 (1.59; 3.90) | 9.74 | 0.067 (0.03; 0.10) | 8.53 |
| Solifenacin | Dry mouth | Staskin, 2006[39] | 63/578 | 51/1216 | 2.60 (1.82; 3.71) | 10.74 | 0.067 (0.04; 0.10) | 8.76 |
| Solifenacin | Dry mouth | Yamaguchi, 2007[401] | 67/400 | 23/406 | 2.96 (1.88; 4.65) | 9.71 | 0.111 (0.07; 0.15) | 8.39 |
| Solifenacin | Dry mouth | Cardozo, 2008[63] | 80/641 | 6/224 | 4.66 (2.06; 10.53) | 6.21 | 0.098 (0.07; 0.13) | 8.64 |
| Solifenacin | Dry mouth | Karram, 2009[316] | 94/372 | 33/367 | 2.81 (1.94; 4.07) | 10.6 | 0.163 (0.11; 0.22) | 8.08 |
| Solifenacin | Dry mouth | Toglia, 2009[317] | 93/372 | 33/367 | 2.78 (1.92; 4.03) | 10.6 | 0.160 (0.11; 0.21) | 8.08 |
| Solifenacin | Dry mouth | Chapple, 2004[258] | 5/35 | 0/38 | 11.92 (0.68; 207.96) | 0.9 | 0.143 (0.02; 0.27) | 5.49 |
| Solifenacin | Dry mouth | Cardozo, 2006[244] | 226/778 | 35/781 | 6.48 (4.61; 9.12) | 10.89 | 0.246 (0.21; 0.28) | 8.6 |
| Solifenacin | Dry mouth | Staskin, 2006[39] | 340/1233 | 51/1216 | 6.58 (4.95; 8.73) | 11.46 | 0.234 (0.21; 0.26) | 8.77 |
| Solifenacin | Dry mouth | Yamaguchi, 2007[401] | 130/385 | 23/406 | 5.96 (3.91; 9.08) | 10.05 | 0.281 (0.23; 0.33) | 8.1 |
| Solifenacin | Dry mouth | Chapple, 2004[258] | 14/37 | 0/38 | 29.76 (1.84; 481.47) | 0.95 | 0.378 (0.22; 0.54) | 4.35 |
| Solifenacin | Dry mouth | Vardy, 2009[467] | 51/386 | 9/382 | 5.61 (2.80; 11.23) | 7.25 | 0.109 (0.07; 0.15) | 8.55 |
| | Pooled | | | | 4.10 (3.09; 5.43) | 100 | 0.161 (0.12; 0.21) | 100 |
| | P value/I squared | | | | 0 | 73.80% | 0 | 92.80% |
| Solifenacin | Dyspepsia | Chapple, 2004[258] | 1/37 | 0/38 | 3.08 (0.13; 73.25) | 8.98 | 0.027 (-0.04; 0.10) | 8.41 |
| Solifenacin | Dyspepsia | Chapple, 2004[258] | 1/35 | 0/38 | 3.25 (0.14; 77.25) | 8.98 | 0.029 (-0.05; 0.10) | 7.85 |
| Solifenacin | Dyspepsia | Chu, 2009[262] | 16/340 | 3/332 | 5.21 (1.53; 17.71) | 60.22 | 0.038 (0.01; 0.06) | 33.06 |
| Solifenacin | Dyspepsia | Chapple, 2004[258] | 5/37 | 0/38 | 11.29 (0.65; 197.21) | 11.02 | 0.135 (0.02; 0.25) | 3.44 |
| Solifenacin | Dyspepsia | Vardy, 2009[467] | 5/386 | 0/382 | 10.89 (0.60; 196.20) | 10.79 | 0.013 (0.00; 0.03) | 47.24 |
| | Pooled | | | | 5.62 (2.17; 14.52) | 100 | 0.028 (0.01; 0.05) | 100 |
| | P value/I squared | | | | 0.952 | 0.00% | 0.132 | 43.50% |
| Solifenacin | Failure | Chapple, 2004[54] | 2/279 | 2/267 | 0.96 (0.14; 6.75) | 1.21 | 0.000 (-0.02; 0.01) | 26.24 |
| Solifenacin | Failure | Cardozo, 2008[63] | 298/641 | 147/224 | 0.71 (0.63; 0.80) | 39.46 | -0.191 (-0.27; -0.12) | 24.27 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Solifenacin | Failure | Toglia, 2009[317] | 112/372 | 191/367 | 0.58 (0.48; 0.70) | 34.39 | -0.219 (-0.29; -0.15) | 24.47 |
| Solifenacin | Failure | Vardy, 2009[467] | 53/386 | 115/382 | 0.46 (0.34; 0.61) | 24.95 | -0.164 (-0.22; -0.11) | 25.02 |
| | Pooled | | | | 0.59 (0.48; 0.74) | 100 | -0.141 (-0.27; -0.01) | 100 |
| | P value/I squared | | | | 0.03 | 66.50% | 0 | 96.40% |
| Solifenacin | Fatigue | Karram, 2009[316] | 10/372 | 4/367 | 2.47 (0.78; 7.79) | 39.63 | 0.016 (0.00; 0.04) | 24.58 |
| Solifenacin | Fatigue | Toglia, 2009[317] | 11/372 | 4/367 | 2.71 (0.87; 8.44) | 40.71 | 0.019 (0.00; 0.04) | 23.01 |
| Solifenacin | Fatigue | Vardy, 2009[467] | 5/386 | 2/382 | 2.47 (0.48; 12.67) | 19.66 | 0.008 (-0.01; 0.02) | 52.41 |
| | Pooled | | | | 2.57 (1.24; 5.29) | 100 | 0.012 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.992 | 0.00% | 0.617 | 0.00% |
| Solifenacin | Headache | Chapple, 2004[258] | 0/41 | 1/38 | 0.31 (0.01; 7.38) | 1.13 | -0.026 (-0.10; 0.04) | 2.57 |
| Solifenacin | Headache | Chapple, 2004[258] | 2/37 | 1/38 | 2.05 (0.19; 21.70) | 2.05 | 0.028 (-0.06; 0.12) | 1.53 |
| Solifenacin | Headache | Karram, 2009[316] | 17/372 | 19/367 | 2.17 (0.21; 22.91) | 2.05 | 0.031 (-0.06; 0.12) | 1.43 |
| Solifenacin | Headache | Toglia, 2009[317] | 19/372 | 18/367 | 2.05 (0.19; 21.70) | 2.05 | 0.028 (-0.06; 0.12) | 1.53 |
| Solifenacin | Headache | Chapple, 2004[258] | 2/35 | 1/38 | 0.88 (0.47; 1.67) | 27.99 | -0.006 (-0.04; 0.03) | 12.57 |
| Solifenacin | Headache | Chu, 2009[262] | 16/340 | 24/332 | 1.04 (0.56; 1.95) | 28.88 | 0.002 (-0.03; 0.03) | 12.26 |
| Solifenacin | Headache | Chapple, 2004[258] | 2/37 | 1/38 | 0.59 (0.14; 2.47) | 5.62 | -0.005 (-0.02; 0.01) | 58.66 |
| Solifenacin | Headache | Vardy, 2009[467] | 3/386 | 5/382 | 0.65 (0.35; 1.20) | 30.22 | -0.025 (-0.06; 0.01) | 9.45 |
| | Pooled | | | | 0.86 (0.61; 1.21) | 100 | -0.005 (-0.02; 0.01) | 100 |
| | P value/I squared | | | | 0.84 | 0.00% | 0.845 | 0.00% |
| Solifenacin | Improvement in UI | Toglia, 2009[317] | 260/372 | 206/367 | 1.25 (1.11; 1.39) | 52.27 | 0.138 (0.07; 0.21) | 49.62 |
| Solifenacin | Improvement in UI | Vardy, 2009[467] | 196/386 | 109/382 | 1.78 (1.48; 2.15) | 47.73 | 0.222 (0.16; 0.29) | 50.38 |
| | Pooled | | | | 1.48 (1.04; 2.09) | 100 | 0.180 (0.10; 0.26) | 100 |
| | P value/I squared | | | | 0.001 | 90.30% | 0.085 | 66.40% |
| Solifenacin | Nausea | Chu, 2009[262] | 19/340 | 13/332 | 0.66 (0.19; 2.32) | 25.82 | -0.005 (-0.02; 0.01) | 70.68 |
| Solifenacin | Nausea | Vardy, 2009[467] | 4/386 | 6/382 | 1.43 (0.72; 2.84) | 74.18 | 0.017 (-0.02; 0.05) | 29.32 |
| | Pooled | | | | 1.17 (0.60; 2.27) | 100 | 0.001 (-0.02; 0.02) | 100 |
| | P value/I squared | | | | 0.292 | 10.10% | 0.228 | 31.10% |
| Solifenacin | Urinary retention | Chu, 2009[262] | 7/340 | 3/332 | 5.13 (0.26; 103.41) | 16.69 | 0.054 (-0.03; 0.14) | 4.25 |
| Solifenacin | Urinary retention | Chapple, 2004[258] | 2/37 | 0/38 | 2.28 (0.59; 8.74) | 83.31 | 0.012 (-0.01; 0.03) | 95.75 |
| | Pooled | | | | 2.61 (0.77; 8.90) | 100 | 0.013 (0.00; 0.03) | 100 |
| | P value/I squared | | | | 0.629 | 0.00% | 0.345 | 0.00% |
| Solifenacin | Constipation | Chapple, 2004[258] | 1/41 | 0/38 | 2.79 (0.12; 66.37) | 0.74 | 0.024 (-0.04; 0.09) | 5.1 |
| Solifenacin | Constipation | Cardozo, 2006[244] | 20/314 | 28/781 | 5.42 (0.27; 109.06) | 0.82 | 0.057 (-0.03; 0.15) | 3.59 |
| Solifenacin | Constipation | Staskin, 2006[39] | 31/578 | 35/1216 | 13.34 (0.78; 228.71) | 0.91 | 0.162 (0.04; 0.29) | 2.26 |
| Solifenacin | Constipation | Yamaguchi, 2007[401] | 42/400 | 16/406 | 1.78 (1.02; 3.11) | 8.81 | 0.028 (0.00; 0.06) | 8.38 |
| Solifenacin | Constipation | Cardozo, 2008[63] | 35/641 | 5/224 | 3.91 (2.61; 5.85) | 10.58 | 0.104 (0.08; 0.13) | 8.59 |
| Solifenacin | Constipation | Karram, 2009[316] | 55/372 | 34/367 | 1.86 (1.16; 2.99) | 9.77 | 0.025 (0.00; 0.05) | 9.18 |
| Solifenacin | Constipation | Toglia, 2009[317] | 56/372 | 33/367 | 4.65 (3.26; 6.64) | 11.11 | 0.105 (0.08; 0.13) | 9.14 |
| Solifenacin | Constipation | Chapple, 2004[258] | 2/35 | 0/38 | 2.66 (1.52; 4.66) | 8.8 | 0.066 (0.03; 0.10) | 7.86 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Solifenacin | Constipation | Cardozo, 2006[244] | 109/778 | 28/781 | 4.75 (2.81; 8.01) | 9.2 | 0.148 (0.10; 0.19) | 7.1 |
| Solifenacin | Constipation | Staskin, 2006[39] | 165/1233 | 35/1216 | 2.45 (0.97; 6.17) | 5.48 | 0.032 (0.01; 0.06) | 8.72 |
| Solifenacin | Constipation | Yamaguchi, 2007[401] | 72/385 | 16/406 | 1.60 (1.07; 2.39) | 10.58 | 0.055 (0.01; 0.10) | 6.78 |
| Solifenacin | Constipation | Chu, 2009[262] | 26/340 | 7/332 | 1.67 (1.12; 2.51) | 10.55 | 0.061 (0.01; 0.11) | 6.78 |
| Solifenacin | Constipation | Chapple, 2004[258] | 6/37 | 0/38 | 4.38 (1.95; 9.83) | 6.38 | 0.062 (0.03; 0.09) | 8.35 |
| Solifenacin | Constipation | Vardy, 2009[467] | 31/386 | 7/382 | 3.63 (1.60; 8.24) | 6.27 | 0.055 (0.02; 0.09) | 8.17 |
| | Pooled | | | | 2.80 (2.11; 3.70) | 100 | 0.066 (0.05; 0.09) | 100 |
| | P value/I squared | | | | 0.001 | 64.20% | 0 | 80.30% |
| Solifenacin | Death | Chapple, 2004[54] | 0/279 | 0/267 | 2.98 (0.12; 72.77) | 50.01 | 0.000 (-0.01; 0.01) | 40.44 |
| Solifenacin | Death | Cardozo, 2008[63] | 1/641 | 0/224 | 1.05 (0.04; 25.72) | 49.99 | 0.004 (-0.01; 0.01) | 19.64 |
| Solifenacin | Death | Chapple, 2004[54] | 1/269 | 0/267 | (Excluded) (0.00; 0.00) | | 0.002 (-0.01; 0.01) | 39.92 |
| | Pooled | | | | 1.77 (0.19; 16.96) | 100 | 0.001 (0.00; 0.01) | 100 |
| | P value/I squared | | | | 0.652 | 0.00% | 0.842 | 0.00% |
| Solifenacin | Treatment discontinuation | Chapple, 2004[258] | 3/37 | 6/38 | 0.51 (0.14; 1.90) | 2.07 | -0.077 (-0.22; 0.07) | 1.09 |
| Solifenacin | Treatment discontinuation | Chapple, 2004[54] | 28/279 | 32/267 | 1.27 (0.47; 3.41) | 3.54 | 0.042 (-0.13; 0.22) | 0.75 |
| Solifenacin | Treatment discontinuation | Yamaguchi, 2007[401] | 34/400 | 34/406 | 0.84 (0.52; 1.35) | 12.91 | -0.019 (-0.07; 0.03) | 8.37 |
| Solifenacin | Treatment discontinuation | Cardozo, 2008[63] | 49/641 | 24/224 | 0.62 (0.36; 1.06) | 10.83 | -0.046 (-0.10; 0.01) | 9.24 |
| Solifenacin | Treatment discontinuation | Toglia, 2009[317] | 9/372 | 18/367 | 1.02 (0.64; 1.60) | 14.01 | 0.001 (-0.04; 0.04) | 15.68 |
| Solifenacin | Treatment discontinuation | Chapple, 2004[258] | 7/35 | 6/38 | 0.99 (0.63; 1.58) | 13.66 | -0.001 (-0.04; 0.04) | 15.54 |
| Solifenacin | Treatment discontinuation | Chapple, 2004[54] | 20/269 | 32/267 | 0.71 (0.45; 1.14) | 13.57 | -0.031 (-0.08; 0.02) | 11.2 |
| Solifenacin | Treatment discontinuation | Yamaguchi, 2007[401] | 32/385 | 34/406 | 0.49 (0.23; 1.08) | 5.43 | -0.025 (-0.05; 0.00) | 31.56 |
| Solifenacin | Treatment discontinuation | Chu, 2009[262] | 70/340 | 58/332 | 1.18 (0.86; 1.61) | 23.98 | 0.031 (-0.03; 0.09) | 6.57 |
| | Pooled | | | | 0.88 (0.73; 1.07) | 100 | -0.015 (-0.03; 0.00) | 100 |
| | P value/I squared | | | | 0.293 | 16.80% | 0.529 | 0.00% |
| Solifenacin | Treatment discontinuation due to adverse effects | Chapple, 2004[54] | 9/279 | 10/267 | 0.86 (0.36; 2.09) | 5.11 | -0.005 (-0.04; 0.03) | 7.82 |
| Solifenacin | Treatment discontinuation | Cardozo, 2006[244] | 14/314 | 40/781 | 0.70 (0.27; 1.80) | 4.5 | -0.011 (-0.04; 0.02) | 8.18 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | due to adverse effects | | | | | | | |
| Solifenacin | Treatment discontinuation due to adverse effects | Staskin, 2006[39] | 4/159 | 19/430 | 0.87 (0.48; 1.58) | 9.88 | -0.007 (-0.03; 0.02) | 8.9 |
| Solifenacin | Treatment discontinuation due to adverse effects | Yamaguchi, 2007[401] | 20/400 | 11/406 | 1.28 (0.86; 1.91) | 16.95 | 0.014 (-0.01; 0.04) | 10.6 |
| Solifenacin | Treatment discontinuation due to adverse effects | Cardozo, 2008[63] | 15/641 | 4/224 | 0.57 (0.20; 1.65) | 3.68 | -0.019 (-0.05; 0.01) | 7.72 |
| Solifenacin | Treatment discontinuation due to adverse effects | Karram, 2009[316] | 24/372 | 17/367 | 1.55 (0.89; 2.71) | 10.94 | 0.024 (-0.01; 0.06) | 7.97 |
| Solifenacin | Treatment discontinuation due to adverse effects | Toglia, 2009[317] | 25/372 | 16/367 | 1.85 (0.90; 3.80) | 7.23 | 0.023 (0.00; 0.05) | 9.27 |
| Solifenacin | Treatment discontinuation due to adverse effects | Chapple, 2004[54] | 7/269 | 10/267 | 2.49 (1.25; 4.98) | 7.78 | 0.040 (0.01; 0.07) | 8.2 |
| Solifenacin | Treatment discontinuation due to adverse effects | Cardozo, 2006[244] | 51/778 | 40/781 | 1.31 (0.44; 3.91) | 3.5 | 0.006 (-0.02; 0.03) | 11.65 |
| Solifenacin | Treatment discontinuation due to adverse effects | Staskin, 2006[39] | 31/452 | 19/430 | 1.39 (0.76; 2.55) | 9.63 | 0.018 (-0.02; 0.05) | 7.19 |
| Solifenacin | Treatment discontinuation due to adverse effects | Yamaguchi, 2007[401] | 26/385 | 11/406 | 1.54 (0.84; 2.84) | 9.48 | 0.024 (-0.01; 0.06) | 7.2 |
| Solifenacin | Treatment discontinuation due to adverse effects | Chu, 2009[262] | 37/340 | 18/332 | 2.01 (1.17; 3.45) | 11.33 | 0.055 (0.01; 0.10) | 5.3 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | Pooled | | | | 1.36 (1.10; 1.68) | 100 | 0.012 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.246 | 20.10% | 0.059 | 42.50% |
| Solifenacin | Treatment discontinuation due to failure | Cardozo, 2008[63] | 11/641 | 6/224 | 0.50 (0.05; 5.44) | 7.05 | -0.004 (-0.02; 0.01) | 41.35 |
| Solifenacin | Treatment discontinuation due to failure | Toglia, 2009[317] | 8/372 | 5/367 | 0.64 (0.24; 1.71) | 41.82 | -0.010 (-0.03; 0.01) | 12.06 |
| Solifenacin | Treatment discontinuation due to failure | Chapple, 2004[54] | 1/269 | 2/267 | 1.58 (0.52; 4.78) | 32.92 | 0.008 (-0.01; 0.03) | 18.46 |
| Solifenacin | Treatment discontinuation due to failure | Chu, 2009[262] | 4/340 | 3/332 | 1.30 (0.29; 5.77) | 18.22 | 0.003 (-0.01; 0.02) | 28.13 |
| | Pooled | | | | 0.96 (0.51; 1.82) | 100 | 0.000 (-0.01; 0.01) | 100 |
| | P value/I squared | | | | 0.598 | 0.00% | 0.623 | 0.00% |
| Solifenacin | Dizziness | Karram, 2009[316] | 12/372 | 7/367 | 1.69 (0.67; 4.25) | 33.62 | 0.013 (-0.01; 0.04) | 34.2 |
| Solifenacin | Dizziness | Toglia, 2009[317] | 11/372 | 7/367 | 1.55 (0.61; 3.96) | 32.5 | 0.010 (-0.01; 0.03) | 36 |
| Solifenacin | Dizziness | Chu, 2009[262] | 10/340 | 8/332 | 1.22 (0.49; 3.06) | 33.88 | 0.005 (-0.02; 0.03) | 29.8 |
| | Pooled | | | | 1.47 (0.86; 2.51) | 100 | 0.010 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.878 | 0.00% | 0.896 | 0.00% |
| Solifenacin | Continence | Cardozo, 2006[244] | 160/314 | 266/781 | 1.50 (1.29; 1.73) | 23.09 | 0.169 (0.10; 0.23) | 14.08 |
| Solifenacin | Continence | Staskin, 2006[39] | 49/159 | 122/430 | 1.53 (1.36; 1.72) | 34.95 | 0.180 (0.13; 0.23) | 15.75 |
| Solifenacin | Continence | Karram, 2009[316] | 133/372 | 93/367 | 1.09 (0.82; 1.43) | 6.4 | 0.024 (-0.06; 0.11) | 12.11 |
| Solifenacin | Continence | Cardozo, 2006[244] | 405/778 | 266/781 | 1.44 (1.19; 1.73) | 14.08 | 0.123 (0.06; 0.19) | 14.32 |
| Solifenacin | Continence | Staskin, 2006[39] | 184/452 | 122/430 | 1.41 (1.13; 1.76) | 9.96 | 0.104 (0.04; 0.17) | 13.92 |
| Solifenacin | Continence | Chu, 2009[262] | 119/340 | 80/332 | 1.32 (0.88; 1.99) | 2.95 | 0.030 (-0.01; 0.07) | 16.16 |
| Solifenacin | Continence | Vardy, 2009[467] | 48/386 | 36/382 | 1.45 (1.14; 1.85) | 8.56 | 0.109 (0.04; 0.18) | 13.66 |
| | Pooled | | | | 1.45 (1.35; 1.56) | 100 | 0.107 (0.06; 0.16) | 100 |
| | P value/I squared | | | | 0.496 | 0.00% | 0 | 78.60% |
| Tolterodine | Abdominal pain | Jacquetin, 2001[308] | 6/97 | 2/51 | 1.58 (0.33; 7.54) | 6.13 | 0.023 (-0.05; 0.09) | 1.69 |
| Tolterodine | Abdominal pain | Van Kerrebroeck, 2001[322] | 19/507 | 8/508 | 2.38 (1.05; 5.39) | 22.47 | 0.022 (0.00; 0.04) | 15.81 |
| Tolterodine | Abdominal pain | Van Kerrebroeck, 2001[322] | 13/514 | 8/508 | 1.61 (0.67; 3.84) | 19.71 | 0.010 (-0.01; 0.03) | 18.74 |
| Tolterodine | Abdominal pain | Malone-Lee, 2001[340] | 6/73 | 5/74 | 1.22 (0.39; 3.81) | 11.5 | 0.015 (-0.07; 0.10) | 1.21 |
| Tolterodine | Abdominal pain | Jacquetin, 2001[308] | 4/103 | 2/51 | 0.99 (0.19; 5.23) | 5.41 | 0.000 (-0.07; 0.07) | 2.04 |
| Tolterodine | Abdominal pain | Swift, 2003[376] | 18/417 | 7/410 | 2.53 (1.07; 5.99) | 20.16 | 0.026 (0.00; 0.05) | 12.56 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Tolterodine | Abdominal pain | Khullar, 2004[323] | 12/569 | 2/285 | 3.01 (0.68; 13.34) | 6.75 | 0.014 (0.00; 0.03) | 21.83 |
| Tolterodine | Abdominal pain | NCT00444925,[58] | 4/690 | 4/337 | 0.49 (0.12; 1.94) | 7.87 | -0.006 (-0.02; 0.01) | 26.11 |
| | Pooled | | | | 1.72 (1.17; 2.54) | 100 | 0.011 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.549 | 0.00% | 0.212 | 27.10% |
| Tolterodine | Abnormal vision | Rentzhog, 1998[356] | 0/21 | 1/13 | 0.21 (0.01; 4.85) | 7.71 | -0.077 (-0.25; 0.10) | 0.18 |
| Tolterodine | Abnormal vision | Rentzhog, 1998[356] | 3/16 | 1/13 | 2.44 (0.29; 20.75) | 16.47 | 0.111 (-0.13; 0.35) | 0.1 |
| Tolterodine | Abnormal vision | Rentzhog, 1998[356] | 1/14 | 1/13 | 0.93 (0.06; 13.37) | 10.62 | -0.005 (-0.20; 0.19) | 0.14 |
| Tolterodine | Abnormal vision | Van Kerrebroeck, 2001[322] | 4/514 | 2/508 | 1.98 (0.36; 10.74) | 26.35 | 0.004 (-0.01; 0.01) | 63.53 |
| Tolterodine | Abnormal vision | Swift, 2003[376] | 5/417 | 2/410 | 2.46 (0.48; 12.60) | 28.28 | 0.007 (-0.01; 0.02) | 35.89 |
| Tolterodine | Abnormal vision | Rentzhog, 1998[356] | 1/16 | 1/13 | 0.81 (0.06; 11.77) | 10.57 | -0.014 (-0.20; 0.17) | 0.16 |
| | Pooled | | | | 1.54 (0.65; 3.67) | 100 | 0.005 (0.00; 0.01) | 100 |
| | P value/I squared | | | | 0.78 | 0.00% | 0.873 | 0.00% |
| Tolterodine | Adverse effects | Rentzhog, 1998[356] | 8/21 | 6/13 | 0.83 (0.37; 1.84) | 1.2 | -0.081 (-0.42; 0.26) | 0.89 |
| Tolterodine | Adverse effects | Jonas, 1997[310] | 31/99 | 17/44 | 0.81 (0.51; 1.30) | 3.16 | -0.073 (-0.24; 0.10) | 3.44 |
| Tolterodine | Adverse effects | Rentzhog, 1998[356] | 6/16 | 6/13 | 0.81 (0.34; 1.93) | 1.04 | -0.087 (-0.45; 0.27) | 0.8 |
| Tolterodine | Adverse effects | Rentzhog, 1998[356] | 10/14 | 10/13 | 0.93 (0.60; 1.45) | 3.5 | -0.055 (-0.38; 0.27) | 0.96 |
| Tolterodine | Adverse effects | Abrams, 1998[220] | 105/118 | 46/57 | 1.10 (0.96; 1.27) | 15.24 | 0.083 (-0.03; 0.20) | 6.88 |
| Tolterodine | Adverse effects | Drutz, 1999[276] | 85/109 | 42/56 | 1.04 (0.87; 1.25) | 12.31 | 0.030 (-0.11; 0.17) | 5.13 |
| Tolterodine | Adverse effects | Jacquetin, 2001[308] | 55/103 | 16/51 | 1.70 (1.09; 2.65) | 3.52 | 0.220 (0.06; 0.38) | 3.89 |
| Tolterodine | Adverse effects | Chapple, 2004[258] | 12/37 | 6/38 | 2.05 (0.86; 4.90) | 1.03 | 0.166 (-0.02; 0.36) | 2.79 |
| Tolterodine | Adverse effects | Khullar, 2004[323] | 221/569 | 96/285 | 1.15 (0.95; 1.40) | 11.55 | 0.052 (-0.02; 0.12) | 16.84 |
| Tolterodine | Adverse effects | Chapple, 2007[252] | 144/290 | 107/285 | 1.32 (1.09; 1.60) | 11.77 | 0.121 (0.04; 0.20) | 12.99 |
| Tolterodine | Adverse effects | Rogers, 2008[361] | 114/202 | 111/211 | 1.07 (0.90; 1.28) | 12.64 | 0.038 (-0.06; 0.13) | 9.71 |
| Tolterodine | Adverse effects | Malone-Lee, 2009[339] | 88/165 | 67/142 | 1.13 (0.90; 1.42) | 9.69 | 0.062 (-0.05; 0.17) | 7.44 |
| Tolterodine | Adverse effects | Junemann, 2000[312] | 25/76 | 12/79 | 2.17 (1.17; 3.99) | 1.99 | 0.177 (0.05; 0.31) | 5.53 |
| Tolterodine | Adverse effects | NCT00444925,[58] | 213/690 | 76/337 | 1.37 (1.09; 1.72) | 9.58 | 0.083 (0.03; 0.14) | 21.83 |
| Tolterodine | Adverse effects | Rentzhog, 1998[356] | 12/16 | 6/13 | 1.63 (0.85; 3.12) | 1.77 | 0.288 (-0.06; 0.63) | 0.88 |
| | Pooled | | | | 1.17 (1.07; 1.28) | 100 | 0.079 (0.05; 0.11) | 100 |
| | P value/I squared | | | | 0.111 | 32.20% | 0.333 | 10.80% |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Tolterodine | Autonomic nervous system | Jonas, 1997[310] | 11/99 | 4/44 | 1.22 (0.41; 3.63) | 7.95 | 0.020 (-0.09; 0.13) | 22.51 |
| Tolterodine | Autonomic nervous system | Jonas, 1997[310] | 16/99 | 4/44 | 1.78 (0.63; 5.01) | 8.76 | 0.071 (-0.04; 0.18) | 21.39 |
| Tolterodine | Autonomic nervous system disorders | Millard, 1999[343] | 37/129 | 11/64 | 1.67 (0.91; 3.05) | 25.92 | 0.115 (-0.01; 0.24) | 19.88 |
| Tolterodine | Autonomic nervous system disorders | Millard, 1999[343] | 53/123 | 11/64 | 2.51 (1.41; 4.46) | 28.49 | 0.259 (0.13; 0.39) | 18.92 |
| Tolterodine | Autonomic nervous system disorders | Drutz, 1999[276] | 35/109 | 12/56 | 1.50 (0.85; 2.65) | 28.88 | 0.107 (-0.03; 0.25) | 17.3 |
| | Pooled | | | | 1.78 (1.31; 2.42) | 100 | 0.110 (0.03; 0.19) | 100 |
| | P value/I squared | | | | 0.696 | 0.00% | 0.074 | 53.00% |
| Tolterodine | Blurred vision | Chapple, 2004[258] | 0/37 | 2/38 | 0.21 (0.01; 4.14) | 14.1 | -0.053 (-0.14; 0.03) | 7.45 |
| Tolterodine | Blurred vision | Chapple, 2004[54] | 4/266 | 7/267 | 0.57 (0.17; 1.94) | 85.9 | -0.011 (-0.04; 0.01) | 92.55 |
| | Pooled | | | | 0.50 (0.16; 1.53) | 100 | -0.014 (-0.04; 0.01) | 100 |
| | P value/I squared | | | | 0.534 | 0.00% | 0.358 | 0.00% |
| Tolterodine | Constipation | Rentzhog, 1998[356] | 1/21 | 0/13 | 1.91 (0.08; 43.65) | 0.46 | 0.048 (-0.10; 0.19) | 0.17 |
| Tolterodine | Constipation | Jonas, 1997[310] | 2/99 | 2/44 | 0.44 (0.07; 3.05) | 1.22 | -0.025 (-0.09; 0.04) | 0.76 |
| Tolterodine | Constipation | Rentzhog, 1998[356] | 3/16 | 0/13 | 5.77 (0.32; 102.44) | 0.55 | 0.188 (-0.03; 0.40) | 0.07 |
| Tolterodine | Constipation | Malone-Lee, 2001[340] | 5/61 | 2/74 | 3.03 (0.61; 15.09) | 1.77 | 0.055 (-0.02; 0.13) | 0.57 |
| Tolterodine | Constipation | Jacquetin, 2001[308] | 4/97 | 2/51 | 1.05 (0.20; 5.55) | 1.64 | 0.002 (-0.06; 0.07) | 0.79 |
| Tolterodine | Constipation | Jonas, 1997[310] | 3/99 | 2/44 | 0.67 (0.12; 3.85) | 1.48 | -0.015 (-0.09; 0.06) | 0.7 |
| Tolterodine | Constipation | Rentzhog, 1998[356] | 1/14 | 0/13 | 2.80 (0.12; 63.20) | 0.47 | 0.071 (-0.11; 0.25) | 0.11 |
| Tolterodine | Constipation | Van Kerrebroeck, 2001[322] | 35/514 | 22/508 | 1.57 (0.94; 2.64) | 16.89 | 0.025 (0.00; 0.05) | 4.4 |
| Tolterodine | Constipation | Van Kerrebroeck, 2001[322] | 30/507 | 22/508 | 1.37 (0.80; 2.34) | 15.82 | 0.016 (-0.01; 0.04) | 4.71 |
| Tolterodine | Constipation | Malone-Lee, 2001[340] | 0/73 | 2/74 | 0.20 (0.01; 4.15) | 0.5 | -0.027 (-0.07; 0.02) | 1.73 |
| Tolterodine | Constipation | Jacquetin, 2001[308] | 2/103 | 2/51 | 0.50 (0.07; 3.42) | 1.22 | -0.020 (-0.08; 0.04) | 0.98 |
| Tolterodine | Constipation | Swift, 2003[376] | 27/417 | 14/410 | 1.90 (1.01; 3.56) | 11.43 | 0.031 (0.00; 0.06) | 4 |
| Tolterodine | Constipation | Chapple, 2004[258] | 1/37 | 0/38 | 3.08 (0.13; 73.25) | 0.45 | 0.027 (-0.04; 0.10) | 0.68 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Tolterodine | Constipation | Khullar, 2004[323] | 9/569 | 2/285 | 2.25 (0.49; 10.36) | 1.95 | 0.009 (-0.01; 0.02) | 17.4 |
| Tolterodine | Constipation | DuBeau, 2005[277] | 6/569 | 3/285 | 1.00 (0.25; 3.98) | 2.39 | 0.000 (-0.02; 0.02) | 16.43 |
| Tolterodine | Constipation | Chapple, 2007[252] | 8/290 | 4/285 | 1.97 (0.60; 6.46) | 3.22 | 0.014 (-0.01; 0.04) | 6.39 |
| Tolterodine | Constipation | Rogers, 2008[361] | 7/202 | 8/211 | 0.91 (0.34; 2.47) | 4.59 | -0.003 (-0.04; 0.03) | 2.66 |
| Tolterodine | Constipation | Herschorn, 2008[297] | 11/410 | 3/207 | 1.85 (0.52; 6.56) | 2.84 | 0.012 (-0.01; 0.04) | 6.8 |
| Tolterodine | Constipation | Herschorn, 2010[466] | 28/684 | 10/334 | 1.37 (0.67; 2.78) | 9.02 | 0.011 (-0.01; 0.04) | 6.25 |
| Tolterodine | Constipation | Kaplan, 2010[314] | 29/974 | 10/480 | 1.43 (0.70; 2.91) | 9.01 | 0.009 (-0.01; 0.03) | 12.5 |
| Tolterodine | Constipation | NCT00444925,[58] | 28/690 | 10/337 | 1.37 (0.67; 2.78) | 9.02 | 0.011 (-0.01; 0.03) | 6.36 |
| Tolterodine | Constipation | Rentzhog, 1998[356] | 2/16 | 0/13 | 4.12 (0.22; 78.89) | 0.52 | 0.125 (-0.07; 0.32) | 0.09 |
| Tolterodine | Constipation | Chapple, 2004[54] | 7/266 | 5/267 | 1.41 (0.45; 4.37) | 3.53 | 0.008 (-0.02; 0.03) | 5.46 |
| | Pooled | | | | 1.45 (1.17; 1.79) | 100 | 0.009 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.982 | 0.00% | 0.767 | 0.00% |
| Tolterodine | Diarrhea | Van Kerrebroeck, 2001[322] | 16/514 | 11/508 | 1.44 (0.67; 3.07) | 23.9 | 0.009 (-0.01; 0.03) | 12.85 |
| Tolterodine | Diarrhea | Van Kerrebroeck, 2001[322] | 10/507 | 11/508 | 0.91 (0.39; 2.13) | 19.11 | -0.002 (-0.02; 0.02) | 16.16 |
| Tolterodine | Diarrhea | Malone-Lee, 2001[340] | 4/73 | 5/74 | 0.81 (0.23; 2.90) | 8.45 | -0.013 (-0.09; 0.07) | 0.83 |
| Tolterodine | Diarrhea | Swift, 2003[376] | 10/417 | 9/410 | 1.09 (0.45; 2.66) | 17.32 | 0.002 (-0.02; 0.02) | 11.89 |
| Tolterodine | Diarrhea | Khullar, 2004[323] | 10/569 | 3/285 | 1.67 (0.46; 6.02) | 8.35 | 0.007 (-0.01; 0.02) | 19.29 |
| Tolterodine | Diarrhea | Herschorn, 2010[466] | 15/684 | 4/334 | 1.83 (0.61; 5.47) | 11.44 | 0.010 (-0.01; 0.03) | 19.32 |
| Tolterodine | Diarrhea | NCT00444925,[58] | 15/690 | 4/337 | 1.83 (0.61; 5.48) | 11.44 | 0.010 (-0.01; 0.03) | 19.66 |
| | Pooled | | | | 1.28 (0.89; 1.86) | 100 | 0.006 (0.00; 0.01) | 100 |
| | P value/I squared | | | | 0.889 | 0.00% | 0.941 | 0.00% |
| Tolterodine | Treatment discontinuation | Drutz, 1999[276] | 14/109 | 8/56 | 0.90 (0.40; 2.01) | 4.95 | -0.014 (-0.13; 0.10) | 0.46 |
| Tolterodine | Treatment discontinuation | Van Kerrebroeck, 2001[322] | 1/507 | 8/508 | 0.13 (0.02; 1.00) | 0.75 | -0.014 (-0.03; 0.00) | 43.35 |
| Tolterodine | Treatment discontinuation | Kelleher, 2002[319] | 57/507 | 68/508 | 0.84 (0.60; 1.17) | 29.63 | -0.021 (-0.06; 0.02) | 3.51 |
| Tolterodine | Treatment discontinuation | Chapple, 2004[258] | 5/37 | 6/38 | 0.86 (0.29; 2.56) | 2.68 | -0.023 (-0.18; 0.14) | 0.22 |
| Tolterodine | Treatment discontinuation | DuBeau, 2005[277] | 29/569 | 18/285 | 0.81 (0.46; 1.43) | 9.89 | -0.012 (-0.05; 0.02) | 5.1 |
| Tolterodine | Treatment discontinuation | Chapple, 2007[252] | 37/290 | 33/285 | 1.10 (0.71; 1.71) | 16.65 | 0.012 (-0.04; 0.07) | 2.01 |
| Tolterodine | Treatment | Robinson, | 8/61 | 2/61 | 4.00 (0.89; 18.08) | 1.42 | 0.098 (0.00; 0.19) | 0.62 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | discontinuation | 2007[359] | | | | | | |
| Tolterodine | Treatment discontinuation | Herschorn, 2010[466] | 56/684 | 30/334 | 0.91 (0.60; 1.39) | 17.95 | -0.008 (-0.05; 0.03) | 4.2 |
| Tolterodine | Treatment discontinuation | NCT00444925,[58] | 6/690 | 3/337 | 0.98 (0.25; 3.88) | 1.69 | 0.000 (-0.01; 0.01) | 38.56 |
| Tolterodine | Treatment discontinuation | Chapple, 2004[54] | 29/266 | 32/267 | 0.91 (0.57; 1.46) | 14.4 | -0.011 (-0.07; 0.04) | 1.96 |
| | Pooled | | | | 0.91 (0.76; 1.09) | 100 | -0.007 (-0.02; 0.00) | 100 |
| | P value/I squared | | | | 0.499 | 0.00% | 0.504 | 0.00% |
| Tolterodine | Treatment discontinuation due to adverse effects | Abrams, 1998[220] | 10/118 | 7/57 | 0.69 (0.28; 1.72) | 8.72 | -0.038 (-0.14; 0.06) | 1.07 |
| Tolterodine | Treatment discontinuation due to adverse effects | Drutz, 1999[276] | 7/109 | 4/56 | 0.90 (0.28; 2.94) | 6.35 | -0.007 (-0.09; 0.07) | 1.54 |
| Tolterodine | Treatment discontinuation due to adverse effects | Malone-Lee, 2001[340] | 7/73 | 1/74 | 7.10 (0.90; 56.25) | 2.68 | 0.082 (0.01; 0.16) | 1.92 |
| Tolterodine | Treatment discontinuation due to adverse effects | Jacquetin, 2001[308] | 3/97 | 1/51 | 1.58 (0.17; 14.78) | 2.35 | 0.011 (-0.04; 0.06) | 3.56 |
| Tolterodine | Treatment discontinuation due to adverse effects | Jacquetin, 2001[308] | 2/103 | 1/51 | 0.99 (0.09; 10.67) | 2.11 | 0.000 (-0.05; 0.05) | 4.22 |
| Tolterodine | Treatment discontinuation due to adverse effects | Chapple, 2004[54] | 5/266 | 10/267 | 0.50 (0.17; 1.45) | 7.33 | -0.019 (-0.05; 0.01) | 8.98 |
| Tolterodine | Treatment discontinuation due to adverse effects | Khullar, 2004[323] | 26/569 | 16/285 | 0.81 (0.44; 1.49) | 12.51 | -0.010 (-0.04; 0.02) | 7.58 |
| Tolterodine | Treatment discontinuation due to adverse effects | DuBeau, 2005[277] | 26/569 | 16/285 | 0.81 (0.44; 1.49) | 12.51 | -0.010 (-0.04; 0.02) | 7.58 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Tolterodine | Treatment discontinuation due to adverse effects | Chapple, 2007[252] | 9/290 | 6/285 | 1.47 (0.53; 4.09) | 7.68 | 0.010 (-0.02; 0.04) | 9.86 |
| Tolterodine | Treatment discontinuation due to adverse effects | Herschorn, 2008[297] | 12/410 | 2/207 | 3.03 (0.68; 13.41) | 4.59 | 0.020 (0.00; 0.04) | 12.46 |
| Tolterodine | Treatment discontinuation due to adverse effects | Herschorn, 2010[466] | 28/684 | 6/334 | 2.28 (0.95; 5.45) | 9.15 | 0.023 (0.00; 0.04) | 12.76 |
| Tolterodine | Treatment discontinuation due to adverse effects | Kaplan, 2010[314] | 29/974 | 10/480 | 1.43 (0.70; 2.91) | 11.09 | 0.009 (-0.01; 0.03) | 15.38 |
| Tolterodine | Treatment discontinuation due to adverse effects | NCT00444925,[58] | 28/690 | 6/337 | 2.28 (0.95; 5.45) | 9.15 | 0.023 (0.00; 0.04) | 12.87 |
| Tolterodine | Treatment discontinuation due to adverse effects | Rentzhog, 1998[356] | 2/67 | 3/13 | 0.13 (0.02; 0.70) | 3.77 | -0.201 (-0.43; 0.03) | 0.2 |
| | Pooled | | | | 1.12 (0.78; 1.62) | 100 | 0.008 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.048 | 42.20% | 0.114 | 32.70% |
| Tolterodine | Treatment discontinuation due to failure | Khullar, 2004[323] | 3/569 | 2/285 | 0.75 (0.13; 4.47) | 12.83 | -0.002 (-0.01; 0.01) | 29.08 |
| Tolterodine | Treatment discontinuation due to failure | Herschorn, 2008[297] | 3/410 | 9/207 | 0.17 (0.05; 0.62) | 23.29 | -0.036 (-0.07; -0.01) | 7.68 |
| Tolterodine | Treatment discontinuation due to failure | Herschorn, 2010[466] | 5/684 | 5/334 | 0.49 (0.14; 1.68) | 25.51 | -0.008 (-0.02; 0.01) | 22.07 |
| Tolterodine | Treatment discontinuation due to failure | NCT00444925,[58] | 5/690 | 5/337 | 0.49 (0.14; 1.68) | 25.5 | -0.008 (-0.02; 0.01) | 22.32 |
| Tolterodine | Treatment discontinuation due to failure | Chapple, 2004[54] | 3/266 | 2/267 | 1.51 (0.25; 8.94) | 12.87 | 0.004 (-0.01; 0.02) | 18.84 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | Pooled | | | | 0.47 (0.24; 0.90) | 100 | -0.006 (-0.02; 0.00) | 100 |
| | P value/I squared | | | | 0.364 | 7.50% | 0.191 | 34.60% |
| Tolterodine | Dizziness | Van Kerrebroeck, 2001[322] | 9/514 | 5/508 | 1.78 (0.60; 5.27) | 15.05 | 0.008 (-0.01; 0.02) | 17.93 |
| Tolterodine | Dizziness | Van Kerrebroeck, 2001[322] | 11/507 | 5/508 | 2.20 (0.77; 6.30) | 16.08 | 0.012 (0.00; 0.03) | 15.47 |
| Tolterodine | Dizziness | Malone-Lee, 2001[340] | 4/73 | 7/74 | 0.58 (0.18; 1.90) | 12.7 | -0.040 (-0.12; 0.05) | 0.51 |
| Tolterodine | Dizziness | Swift, 2003[376] | 7/417 | 4/410 | 1.72 (0.51; 5.83) | 11.98 | 0.007 (-0.01; 0.02) | 14.95 |
| Tolterodine | Dizziness | Khullar, 2004[323] | 6/569 | 3/285 | 1.00 (0.25; 3.98) | 9.44 | 0.000 (-0.02; 0.02) | 17.2 |
| Tolterodine | Dizziness | Chapple, 2007[252] | 4/290 | 7/285 | 0.56 (0.17; 1.90) | 12.05 | -0.011 (-0.03; 0.01) | 7.21 |
| Tolterodine | Dizziness | Herschorn, 2008[297] | 5/410 | 5/207 | 0.51 (0.15; 1.72) | 11.84 | -0.012 (-0.04; 0.01) | 6.59 |
| Tolterodine | Dizziness | NCT00444925,[58] | 10/690 | 3/337 | 1.63 (0.45; 5.88) | 10.86 | 0.006 (-0.01; 0.02) | 20.14 |
| | Pooled | | | | 1.12 (0.73; 1.72) | 100 | 0.004 (0.00; 0.01) | 100 |
| | P value/I squared | | | | 0.412 | 2.30% | 0.515 | 0.00% |
| Tolterodine | Continence | Rogers, 2008[361] | 115/202 | 89/211 | 1.35 (1.11; 1.65) | 22.57 | 0.148 (0.05; 0.24) | |
| Tolterodine | Continence | Malone-Lee, 2009[339] | 41/165 | 26/142 | 1.36 (0.88; 2.10) | 6.99 | 0.065 (-0.03; 0.16) | 17.05 |
| Tolterodine | Continence | Kaplan, 2010[314] | 566/974 | 258/480 | 1.08 (0.98; 1.19) | 39.93 | 0.044 (-0.01; 0.10) | 18.14 |
| Tolterodine | Continence | NCT00444925,[58] | 358/690 | 138/337 | 1.27 (1.09; 1.47) | 30.52 | 0.109 (0.05; 0.17) | 35.49 |
| | Pooled | | | | 1.21 (1.07; 1.37) | 100 | 0.085 (0.04; 0.13) | 29.32 |
| | P value/I squared | | | | 0.11 | 50.20% | 0.209 | 34.00% |
| Tolterodine | Dry mouth | Rentzhog, 1998[356] | 2/21 | 2/13 | 0.62 (0.10; 3.87) | 0.92 | -0.059 (-0.29; 0.17) | 1.27 |
| Tolterodine | Dry mouth | Rentzhog, 1998[356] | 2/16 | 2/13 | 0.81 (0.13; 5.01) | 0.94 | -0.029 (-0.28; 0.23) | 1.08 |
| Tolterodine | Dry mouth | Rentzhog, 1998[356] | 5/14 | 2/13 | 2.32 (0.54; 9.95) | 1.44 | 0.203 (-0.12; 0.52) | 0.71 |
| Tolterodine | Dry mouth | Abrams, 1998[220] | 59/118 | 12/57 | 2.38 (1.39; 4.05) | 8.18 | 0.289 (0.15; 0.43) | 3.01 |
| Tolterodine | Dry mouth | Van Kerrebroeck, 2001[322] | 118/507 | 39/508 | 3.03 (2.16; 4.26) | 14.42 | 0.156 (0.11; 0.20) | 9.47 |
| Tolterodine | Dry mouth | Jacquetin, 2001[308] | 35/103 | 3/51 | 5.78 (1.87; 17.89) | 2.31 | 0.281 (0.17; 0.39) | 4.1 |
| Tolterodine | Dry mouth | Chapple, 2004[258] | 9/37 | 0/38 | 19.50 (1.18; 323.41) | 0.4 | 0.243 (0.10; 0.39) | 2.91 |
| Tolterodine | Dry mouth | Chapple, 2007[252] | 49/290 | 20/285 | 2.41 (1.47; 3.95) | 9.15 | 0.099 (0.05; 0.15) | 8.57 |
| Tolterodine | Dry mouth | Rogers, 2008[361] | 26/202 | 19/211 | 1.43 (0.82; 2.50) | 7.64 | 0.039 (-0.02; 0.10) | 7.8 |
| Tolterodine | Dry mouth | Herschorn, 2008[297] | 89/410 | 21/207 | 2.14 (1.37; 3.34) | 10.52 | 0.116 (0.06; 0.17) | 8.08 |
| Tolterodine | Dry mouth | Malone-Lee, 2009[339] | 20/165 | 0/142 | 35.32 (2.16; 578.77) | 0.4 | 0.121 (0.07; 0.17) | 8.71 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Tolterodine | Dry mouth | Herschorn, 2010[466] | 112/684 | 20/334 | 2.74 (1.73; 4.32) | 10.15 | 0.104 (0.07; 0.14) | 10.06 |
| Tolterodine | Dry mouth | Junemann, 2000[312] | 21/76 | 5/79 | 4.37 (1.74; 10.99) | 3.34 | 0.213 (0.10; 0.33) | 4 |
| Tolterodine | Dry mouth | Kaplan, 2010[314] | 127/974 | 24/480 | 2.61 (1.71; 3.98) | 11.26 | 0.080 (0.05; 0.11) | 10.89 |
| Tolterodine | Dry mouth | NCT00444925,[58] | 112/690 | 20/337 | 2.74 (1.73; 4.32) | 10.15 | 0.103 (0.07; 0.14) | 10.09 |
| Tolterodine | Dry mouth | Rentzhog, 1998[356] | 9/16 | 2/13 | 3.66 (0.95; 14.05) | 1.67 | 0.409 (0.10; 0.72) | 0.74 |
| Tolterodine | Dry mouth | Chapple, 2004[54] | 49/266 | 13/267 | 3.78 (2.10; 6.81) | 7.1 | 0.136 (0.08; 0.19) | 8.48 |
| | Pooled | | | | 2.63 (2.20; 3.15) | 100 | 0.127 (0.10; 0.15) | 100 |
| | P value/I squared | | | | 0.203 | 21.50% | 0 | 63.70% |
| Tolterodine | Dry skin | Van Kerrebroeck, 2001[322] | 2/507 | 1/508 | 2.00 (0.18; 22.03) | 49.99 | 0.002 (-0.01; 0.01) | 59.94 |
| Tolterodine | Dry skin | Swift, 2003[376] | 2/417 | 1/410 | 1.97 (0.18; 21.60) | 50.01 | 0.002 (-0.01; 0.01) | 40.06 |
| | Pooled | | | | 1.99 (0.37; 10.81) | 100 | 0.002 (0.00; 0.01) | 100 |
| | P value/I squared | | | | 0.991 | 0.00% | 0.944 | 0.00% |
| Tolterodine | Dyspepsia | Abrams, 1998[220] | 11/118 | 3/57 | 1.77 (0.51; 6.10) | 11.3 | 0.041 (-0.04; 0.12) | 1.42 |
| Tolterodine | Dyspepsia | Van Kerrebroeck, 2001[322] | 16/514 | 7/508 | 2.26 (0.94; 5.45) | 20.56 | 0.017 (0.00; 0.04) | 15.6 |
| Tolterodine | Dyspepsia | Van Kerrebroeck, 2001[322] | 15/507 | 7/508 | 2.15 (0.88; 5.22) | 20.21 | 0.016 (0.00; 0.03) | 15.82 |
| Tolterodine | Dyspepsia | Malone-Lee, 2001[340] | 6/73 | 9/74 | 0.68 (0.25; 1.80) | 17.07 | -0.039 (-0.14; 0.06) | 0.92 |
| Tolterodine | Dyspepsia | Swift, 2003[376] | 11/417 | 6/410 | 1.80 (0.67; 4.83) | 16.94 | 0.012 (-0.01; 0.03) | 14.51 |
| Tolterodine | Dyspepsia | Khullar, 2004[323] | 7/569 | 2/285 | 1.75 (0.37; 8.39) | 7.31 | 0.005 (-0.01; 0.02) | 21.17 |
| Tolterodine | Dyspepsia | Malone-Lee, 2009[339] | 12/165 | 0/142 | 21.54 (1.29; 360.53) | 2.35 | 0.073 (0.03; 0.11) | 4.61 |
| Tolterodine | Dyspepsia | NCT00444925,[58] | 8/690 | 1/337 | 3.91 (0.49; 31.11) | 4.26 | 0.009 (0.00; 0.02) | 25.95 |
| | Pooled | | | | 1.81 (1.17; 2.79) | 100 | 0.014 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.355 | 9.70% | 0.107 | 40.80% |
| Tolterodine | Failure | Kelleher, 2002[319] | 35/507 | 66/508 | 0.53 (0.36; 0.79) | 18.08 | -0.061 (-0.10; -0.02) | 14.83 |
| Tolterodine | Failure | Freeman, 2003[282] | 88/398 | 168/374 | 0.49 (0.40; 0.61) | 23.2 | -0.228 (-0.29; -0.16) | 11.75 |
| Tolterodine | Failure | Herschorn, 2008[297] | 16/410 | 19/207 | 0.43 (0.22; 0.81) | 11.71 | -0.053 (-0.10; -0.01) | 14.11 |
| Tolterodine | Failure | Rogers, 2009[360] | 16/202 | 12/211 | 1.39 (0.68; 2.87) | 10.22 | 0.022 (-0.03; 0.07) | 13.56 |
| Tolterodine | Failure | Herschorn, 2010[466] | 64/684 | 34/334 | 0.92 (0.62; 1.36) | 17.96 | -0.008 (-0.05; 0.03) | 14.58 |
| Tolterodine | Failure | NCT00444925,[58] | 59/690 | 36/337 | 0.80 (0.54; 1.19) | 18 | -0.021 (-0.06; 0.02) | 14.58 |
| 4.0 | Failure | Rogers, 2008[361] | 0/202 | 1/211 | 0.35 (0.01; 8.50) | 0.83 | -0.005 (-0.02; 0.01) | 16.6 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | Pooled | | | | 0.66 (0.50; 0.89) | 100 | -0.045 (-0.09; -0.01) | 100 |
| | P value/I squared | | | | 0.011 | 63.80% | 0 | |
| Tolterodine | Fatigue | Van Kerrebroeck, 2001[322] | 11/507 | 4/508 | 2.76 (0.88; 8.60) | 40.48 | 0.014 (0.00; 0.03) | 25.66 |
| Tolterodine | Fatigue | Chapple, 2007[252] | 10/290 | 1/285 | 9.83 (1.27; 76.27) | 12.48 | 0.031 (0.01; 0.05) | 14.89 |
| Tolterodine | Fatigue | Herschorn, 2008[297] | 11/410 | 4/207 | 1.39 (0.45; 4.31) | 40.89 | 0.008 (-0.02; 0.03) | 12.74 |
| Tolterodine | Fatigue | NCT00444925,[58] | 4/690 | 0/337 | 4.40 (0.24; 81.53) | 6.15 | 0.006 (0.00; 0.01) | 46.71 |
| | Pooled | | | | 2.51 (1.22; 5.18) | 100 | 0.012 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.404 | 0.00% | 0.174 | 39.60% |
| Tolterodine | Flatulence | Van Kerrebroeck, 2001[322] | 10/507 | 9/508 | 1.11 (0.46; 2.72) | 58.06 | 0.002 (-0.02; 0.02) | 52.59 |
| Tolterodine | Flatulence | Swift, 2003[376] | 8/417 | 6/410 | 1.31 (0.46; 3.75) | 41.94 | 0.005 (-0.01; 0.02) | 47.41 |
| | Pooled | | | | 1.19 (0.60; 2.35) | 100 | 0.003 (-0.01; 0.02) | 100 |
| | P value/I squared | | | | 0.816 | 0.00% | 0.837 | 0.00% |
| Tolterodine | General body disorders | Jonas, 1997[310] | 6/99 | 4/44 | 0.67 (0.20; 2.25) | 19.24 | -0.030 (-0.13; 0.07) | 59.49 |
| Tolterodine | General body disorders | Drutz, 1999[276] | 40/109 | 15/56 | 1.37 (0.83; 2.26) | 80.76 | 0.099 (-0.05; 0.25) | 40.51 |
| | Pooled | | | | 1.19 (0.68; 2.08) | 100 | 0.022 (-0.10; 0.15) | 100 |
| | P value/I squared | | | | 0.282 | 13.60% | 0.15 | 51.70% |
| Tolterodine | Headache | Jonas, 1997[310] | 3/99 | 1/44 | 1.33 (0.14; 12.46) | 0.9 | 0.008 (-0.05; 0.06) | 2.21 |
| Tolterodine | Headache | Malone-Lee, 2001[340] | 5/61 | 2/74 | 3.03 (0.61; 15.09) | 1.74 | 0.055 (-0.02; 0.13) | 1.14 |
| Tolterodine | Headache | Jonas, 1997[310] | 3/99 | 1/44 | 1.33 (0.14; 12.46) | 0.9 | 0.008 (-0.05; 0.06) | 2.21 |
| Tolterodine | Headache | Van Kerrebroeck, 2001[322] | 19/514 | 23/508 | 0.82 (0.45; 1.48) | 12.65 | -0.008 (-0.03; 0.02) | 9.81 |
| Tolterodine | Headache | Van Kerrebroeck, 2001[322] | 32/507 | 23/508 | 1.39 (0.83; 2.35) | 16.47 | 0.018 (-0.01; 0.05) | 7.83 |
| Tolterodine | Headache | Malone-Lee, 2001[340] | 7/73 | 2/74 | 3.55 (0.76; 16.51) | 1.89 | 0.069 (-0.01; 0.15) | 1.17 |
| Tolterodine | Headache | Jacquetin, 2001[308] | 3/97 | 2/51 | 0.79 (0.14; 4.57) | 1.45 | -0.008 (-0.07; 0.06) | 1.71 |
| Tolterodine | Headache | Jacquetin, 2001[308] | 3/103 | 2/51 | 0.74 (0.13; 4.31) | 1.45 | -0.010 (-0.07; 0.05) | 1.76 |
| Tolterodine | Headache | Swift, 2003[376] | 29/417 | 19/410 | 1.50 (0.86; 2.63) | 14.17 | 0.023 (-0.01; 0.06) | 6.22 |
| Tolterodine | Headache | Chapple, 2004[258] | 0/37 | 1/38 | 0.34 (0.01; 8.14) | 0.45 | -0.026 (-0.10; 0.04) | 1.39 |
| Tolterodine | Headache | Khullar, 2004[323] | 22/569 | 8/285 | 1.38 (0.62; 3.06) | 7.06 | 0.011 (-0.01; 0.04) | 9.47 |
| Tolterodine | Headache | DuBeau, 2005[277] | 17/569 | 7/285 | 1.22 (0.51; 2.90) | 5.94 | 0.005 (-0.02; 0.03) | 10.93 |
| Tolterodine | Headache | Chapple, 2007[252] | 14/290 | 14/285 | 0.98 (0.48; 2.02) | 8.58 | -0.001 (-0.04; 0.03) | 5.18 |
| Tolterodine | Headache | Rogers, 2008[361] | 7/202 | 6/211 | 1.22 (0.42; 3.56) | 3.89 | 0.006 (-0.03; 0.04) | 5.58 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Tolterodine | Headache | Herschorn, 2008[297] | 21/410 | 9/207 | 1.18 (0.55; 2.53) | 7.7 | 0.008 (-0.03; 0.04) | 5.22 |
| Tolterodine | Headache | Malone-Lee, 2009[339] | 13/165 | 0/142 | 23.26 (1.40; 387.80) | 0.57 | 0.079 (0.04; 0.12) | 3.63 |
| Tolterodine | Headache | Herschorn, 2010[466] | 23/684 | 8/334 | 1.40 (0.64; 3.11) | 7.11 | 0.010 (-0.01; 0.03) | 12.19 |
| Tolterodine | Headache | NCT00444925,[58] | 23/690 | 8/337 | 1.40 (0.64; 3.11) | 7.11 | 0.010 (-0.01; 0.03) | 12.36 |
| | Pooled | | | | 1.27 (1.03; 1.57) | 100 | 0.011 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.828 | 0.00% | 0.828 | 10.40% |
| Tolterodine | Improvement in UI | Kelleher, 2002[319] | 294/507 | 218/508 | 1.35 (1.19; 1.53) | 15.54 | 0.151 (0.09; 0.21) | 12.9 |
| Tolterodine | Improvement in UI | Freeman, 2003[282] | 171/398 | 90/374 | 1.79 (1.44; 2.21) | 12.12 | 0.189 (0.12; 0.25) | 12.59 |
| Tolterodine | Improvement in UI | Herschorn, 2008[297] | 156/410 | 64/207 | 1.23 (0.97; 1.56) | 11.17 | 0.071 (-0.01; 0.15) | 11.6 |
| Tolterodine | Improvement in UI | Sand, 2009[366] | 140/227 | 167/430 | 1.59 (1.36; 1.86) | 14.31 | 0.228 (0.15; 0.31) | 11.62 |
| Tolterodine | Improvement in UI | Rogers, 2009[360] | 79/202 | 58/211 | 1.42 (1.08; 1.88) | 9.77 | 0.116 (0.03; 0.21) | 10.73 |
| Tolterodine | Improvement in UI | Herschorn, 2010[466] | 256/684 | 113/334 | 1.11 (0.93; 1.32) | 13.45 | 0.036 (-0.03; 0.10) | 12.79 |
| Tolterodine | Improvement in UI | Kaplan, 2010[314] | 654/974 | 287/480 | 1.12 (1.03; 1.22) | 16.86 | 0.074 (0.02; 0.13) | 13.46 |
| Tolterodine | Improvement in UI | NCT00444925,[58] | 79/690 | 32/337 | 1.21 (0.82; 1.78) | 6.77 | 0.020 (-0.02; 0.06) | 14.31 |
| | Pooled | | | | 1.33 (1.17; 1.51) | 100 | 0.108 (0.06; 0.16) | 100 |
| | P value/I squared | | | | 0 | 76.40% | 0 | 82.90% |
| Tolterodine | Insomnia | Van Kerrebroeck, 2001[322] | 7/507 | 9/508 | 0.78 (0.29; 2.08) | 45.27 | -0.004 (-0.02; 0.01) | 38.98 |
| Tolterodine | Insomnia | Swift, 2003[376] | 7/417 | 9/410 | 0.77 (0.29; 2.03) | 45.35 | -0.005 (-0.02; 0.01) | 33.55 |
| Tolterodine | Insomnia | Rogers, 2008[361] | 5/202 | 0/211 | 11.49 (0.64; 206.42) | 9.38 | 0.025 (0.00; 0.05) | 27.47 |
| | Pooled | | | | 0.99 (0.39; 2.53) | 100 | 0.004 (-0.01; 0.02) | 100 |
| | P value/I squared | | | | 0.204 | 37.00% | 0.091 | 58.30% |
| Tolterodine | Nasopharyngitis | Chapple, 2007[252] | 10/290 | 7/285 | 1.40 (0.54; 3.64) | 15.42 | 0.010 (-0.02; 0.04) | 15.71 |
| Tolterodine | Nasopharyngitis | Chapple, 2008[253] | 10/290 | 7/283 | 1.39 (0.54; 3.61) | 15.42 | 0.010 (-0.02; 0.04) | 15.62 |
| Tolterodine | Nasopharyngitis | Rogers, 2008[361] | 9/202 | 10/211 | 0.94 (0.39; 2.27) | 18.06 | -0.003 (-0.04; 0.04) | 7.36 |
| Tolterodine | Nasopharyngitis | Herschorn, 2008[297] | 9/410 | 5/207 | 0.91 (0.31; 2.68) | 11.97 | -0.002 (-0.03; 0.02) | 18.8 |
| Tolterodine | Nasopharyngitis | Sand, 2009[366] | 8/227 | 12/430 | 1.26 (0.52; 3.05) | 18.04 | 0.007 (-0.02; 0.04) | 14.68 |
| Tolterodine | Nasopharyngitis | NCT00444925,[58] | 13/690 | 10/337 | 0.64 (0.28; 1.43) | 21.09 | -0.011 (-0.03; 0.01) | 27.84 |
| | Pooled | | | | 1.03 (0.71; 1.49) | 100 | 0.001 (-0.01; 0.01) | 100 |
| | P value/I squared | | | | 0.784 | 0.00% | 0.805 | 0.00% |
| Tolterodine | Nausea | Abrams, 1998[220] | 4/118 | 6/57 | 0.32 (0.10; 1.10) | 10.58 | -0.071 (-0.16; 0.02) | 0.79 |
| Tolterodine | Nausea | Van Kerrebroeck, 2001[322] | 10/514 | 10/508 | 0.99 (0.42; 2.35) | 21.07 | 0.000 (-0.02; 0.02) | 16.43 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Tolterodine | Nausea | Van Kerrebroeck, 2001[322] | 7/507 | 10/508 | 0.70 (0.27; 1.83) | 17.29 | -0.006 (-0.02; 0.01) | 18.45 |
| Tolterodine | Nausea | Malone-Lee, 2001[340] | 3/73 | 2/74 | 1.52 (0.26; 8.84) | 5.13 | 0.014 (-0.05; 0.07) | 1.68 |
| Tolterodine | Nausea | Swift, 2003[376] | 7/417 | 9/410 | 0.77 (0.29; 2.03) | 16.59 | -0.005 (-0.02; 0.01) | 13.93 |
| Tolterodine | Nausea | Khullar, 2004[323] | 7/569 | 5/285 | 0.70 (0.23; 2.19) | 12.24 | -0.005 (-0.02; 0.01) | 15.33 |
| Tolterodine | Nausea | Chapple, 2007[252] | 6/290 | 1/285 | 5.90 (0.71; 48.67) | 3.56 | 0.017 (0.00; 0.04) | 15.28 |
| Tolterodine | Nausea | NCT00444925,[58] | 7/690 | 6/337 | 0.57 (0.19; 1.68) | 13.54 | -0.008 (-0.02; 0.01) | 18.11 |
| | Pooled | | | | 0.77 (0.52; 1.15) | 100 | -0.002 (-0.01; 0.01) | 100 |
| | P value/I squared | | | | 0.453 | 0.00% | 0.311 | 15.10% |
| Tolterodine | Serious adverse effects | Millard, 1999[343] | 5/129 | 1/64 | 2.48 (0.30; 20.79) | 4.45 | 0.023 (-0.02; 0.07) | 5.35 |
| Tolterodine | Serious adverse effects | Van Kerrebroeck, 2001[322] | 12/507 | 18/508 | 0.67 (0.33; 1.37) | 38.84 | -0.012 (-0.03; 0.01) | 24.85 |
| Tolterodine | Serious adverse effects | Malone-Lee, 2001[340] | 2/61 | 1/74 | 2.43 (0.23; 26.12) | 3.57 | 0.019 (-0.03; 0.07) | 4.05 |
| Tolterodine | Serious adverse effects | Drutz, 1999[276] | 1/109 | 2/56 | 0.26 (0.02; 2.77) | 3.56 | -0.027 (-0.08; 0.03) | 4.06 |
| Tolterodine | Serious adverse effects | Van Kerrebroeck, 2001[322] | 7/507 | 18/508 | 0.39 (0.16; 0.93) | 26.95 | -0.022 (-0.04; 0.00) | 29.72 |
| Tolterodine | Serious adverse effects | NCT00444925,[58] | 9/690 | 8/337 | 0.55 (0.21; 1.41) | 22.62 | -0.011 (-0.03; 0.01) | 31.97 |
| | Pooled | | | | 0.59 (0.38; 0.93) | 100 | -0.012 (-0.02; 0.00) | 100 |
| | P value/I squared | | | | 0.466 | 0.00% | 0.411 | 0.70% |
| Tolterodine | Somnolence | Van Kerrebroeck, 2001[322] | 14/507 | 9/508 | 1.56 (0.68; 3.57) | 49.83 | 0.010 (-0.01; 0.03) | 25.93 |
| Tolterodine | Somnolence | Swift, 2003[376] | 12/417 | 8/410 | 1.48 (0.61; 3.57) | 43.97 | 0.009 (-0.01; 0.03) | 21.15 |
| Tolterodine | Somnolence | Khullar, 2004[323] | 1/569 | 2/285 | 0.25 (0.02; 2.75) | 6.2 | -0.005 (-0.02; 0.01) | 52.91 |
| | Pooled | | | | 1.36 (0.75; 2.47) | 100 | 0.002 (-0.01; 0.01) | 100 |
| | P value/I squared | | | | 0.359 | 2.50% | 0.237 | 30.60% |
| Tolterodine | urinary tract infection | Jonas, 1997[310] | 2/99 | 2/44 | 0.44 (0.07; 3.05) | 4.15 | -0.025 (-0.09; 0.04) | 1.39 |
| Tolterodine | Urinary tract infection | Van Kerrebroeck, 2001[322] | 13/514 | 20/508 | 0.64 (0.32; 1.28) | 21.36 | -0.014 (-0.04; 0.01) | 10.45 |
| Tolterodine | Urinary tract infection | Van Kerrebroeck, 2001[322] | 16/507 | 20/508 | 0.80 (0.42; 1.53) | 22.99 | -0.008 (-0.03; 0.02) | 9.71 |
| Tolterodine | Urinary tract infection | Swift, 2003[376] | 15/417 | 19/410 | 0.78 (0.40; 1.51) | 22.3 | -0.010 (-0.04; 0.02) | 7.35 |
| Tolterodine | Urinary tract infection | Khullar, 2004[323] | 2/569 | 2/285 | 0.50 (0.07; 3.54) | 4.05 | -0.004 (-0.01; 0.01) | 23.99 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Tolterodine | Urinary tract infection | Rogers, 2008[361] | 12/202 | 5/211 | 2.51 (0.90; 6.99) | 12.28 | 0.036 (0.00; 0.07) | 3.98 |
| Tolterodine | Urinary tract infection | Herschorn, 2010[466] | 10/684 | 2/334 | 2.44 (0.54; 11.08) | 6.44 | 0.009 (0.00; 0.02) | 21.48 |
| Tolterodine | Urinary tract infection | NCT00444925,[58] | 10/690 | 2/337 | 2.44 (0.54; 11.08) | 6.44 | 0.009 (0.00; 0.02) | 21.66 |
| | Pooled | | | | 0.97 (0.64; 1.45) | 100 | 0.001 (-0.01; 0.01) | 100 |
| | P value/I squared | | | | 0.234 | 24.50% | 0.166 | 32.90% |
| Tolterodine | Xerophthalmia | Van Kerrebroeck, 2001[322] | 17/507 | 10/508 | 1.70 (0.79; 3.68) | 54.12 | 0.014 (-0.01; 0.03) | 57.01 |
| Tolterodine | Xerophthalmia | Swift, 2003[376] | 16/417 | 8/410 | 1.97 (0.85; 4.54) | 45.88 | 0.019 (0.00; 0.04) | 42.99 |
| | Pooled | | | | 1.82 (1.03; 3.21) | 100 | 0.016 (0.00; 0.03) | 100 |
| | P value/I squared | | | | 0.805 | 0.00% | 0.745 | 0.00% |
| Trospium | Abdominal distension | Sand, 2009[368] | 6/484 | 2/505 | 3.13 (0.64; 15.43) | 66.69 | 0.008 (0.00; 0.02) | 57.23 |
| Trospium | Abdominal distention | Staskin, 2007[47] | 3/298 | 1/303 | 3.05 (0.32; 29.16) | 33.31 | 0.007 (-0.01; 0.02) | 42.77 |
| | Pooled | | | | 3.10 (0.84; 11.42) | 100 | 0.008 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.985 | 0.00% | 0.849 | 0.00% |
| Trospium | Abdominal pain | Zinner, 2004[37] | 8/262 | 3/261 | 2.66 (0.71; 9.90) | 44.43 | 0.019 (-0.01; 0.04) | 12.43 |
| Trospium | Abdominal pain | Staskin, 2007[47] | 3/298 | 2/303 | 1.53 (0.26; 9.06) | 24.22 | 0.003 (-0.01; 0.02) | 35.33 |
| Trospium | Abdominal pain | Sand, 2009[368] | 7/484 | 2/505 | 3.65 (0.76; 17.49) | 31.35 | 0.011 (0.00; 0.02) | 52.23 |
| | Pooled | | | | 2.57 (1.07; 6.17) | 100 | 0.009 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.849 | 0.00% | 0.533 | 0.00% |
| Trospium | Adverse effects | Rudy, 2006[363] | 196/329 | 153/329 | 1.28 (1.11; 1.48) | 29.01 | 0.131 (0.06; 0.21) | 17.77 |
| Trospium | Adverse effects | Junemann, 2000[312] | 26/76 | 12/79 | 2.25 (1.23; 4.13) | 6.29 | 0.190 (0.06; 0.32) | 5.76 |
| Trospium | Adverse effects | Staskin, 2007[47] | 80/298 | 53/303 | 1.54 (1.13; 2.09) | 16.44 | 0.094 (0.03; 0.16) | 23.29 |
| Trospium | Adverse effects | Dmochowski, 2008[48] | 154/280 | 130/284 | 1.20 (1.02; 1.42) | 27.34 | 0.092 (0.01; 0.17) | 15.04 |
| Trospium | Adverse effects | Sand, 2009[368] | 138/484 | 83/505 | 1.74 (1.36; 2.21) | 20.92 | 0.121 (0.07; 0.17) | 38.15 |
| | Pooled | | | | 1.43 (1.21; 1.69) | 100 | 0.116 (0.08; 0.15) | 100 |
| | P value/I squared | | | | 0.042 | 59.70% | 0.71 | 0.00% |
| Trospium | CNS disorders | Staskin, 2004[373] | 19/327 | 17/326 | 1.11 (0.59; 2.11) | 77.34 | 0.006 (-0.03; 0.04) | 29.81 |
| Trospium | CNS disorders | Dmochowski, 2008[48] | 5/280 | 6/284 | 0.85 (0.26; 2.74) | 22.66 | -0.003 (-0.03; 0.02) | 70.19 |
| | Pooled | | | | 1.05 (0.60; 1.83) | 100 | -0.001 (-0.02; 0.02) | 100 |
| | P value/I squared | | | | 0.685 | 0.00% | 0.665 | 0.00% |
| Trospium | Constipation | Zinner, 2004[37] | 25/262 | 10/261 | 2.49 (1.22; 5.08) | 21.9 | 0.057 (0.02; 0.10) | 13.43 |
| Trospium | Constipation | Rudy, 2006[363] | 36/329 | 19/329 | 1.90 (1.11; 3.23) | 25.67 | 0.052 (0.01; 0.09) | 13.69 |
| Trospium | Constipation | Staskin, 2007[47] | 28/298 | 4/303 | 7.12 (2.53; 20.04) | 15.96 | 0.081 (0.05; 0.12) | 19.23 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Trospium | Constipation | Dmochowski, 2008[48] | 21/280 | 5/284 | 4.26 (1.63; 11.14) | 17.19 | 0.057 (0.02; 0.09) | 20.47 |
| Trospium | Constipation | Sand, 2009[368] | 43/484 | 6/505 | 7.48 (3.21; 17.41) | 19.28 | 0.077 (0.05; 0.10) | 33.18 |
| | Pooled | | | | 3.72 (2.09; 6.62) | 100 | 0.068 (0.05; 0.08) | 100 |
| | P value/I squared | | | | 0.03 | 62.50% | 0.716 | 0.00% |
| Trospium | Diarrhea | Zinner, 2004[37] | 8/262 | 14/261 | 0.57 (0.24; 1.33) | 53.1 | -0.023 (-0.06; 0.01) | 36.75 |
| Trospium | Diarrhea | Rudy, 2006[363] | 7/329 | 13/329 | 0.54 (0.22; 1.33) | 46.9 | -0.018 (-0.04; 0.01) | 63.25 |
| | Pooled | | | | 0.56 (0.30; 1.03) | 100 | -0.020 (-0.04; 0.00) | 100 |
| | P value/I squared | | | | 0.93 | 0.00% | 0.825 | 0.00% |
| Trospium | Treatment discontinuation | U.S. Food and Drug Administration, 2007 [40] | 37/280 | 36/284 | 1.04 (0.68; 1.60) | 53.66 | 0.005 (-0.05; 0.06) | 44.55 |
| Trospium | Treatment discontinuation | U.S. Food and Drug Administration, 2007 [40] | 35/298 | 30/303 | 1.19 (0.75; 1.88) | 46.34 | 0.018 (-0.03; 0.07) | 55.45 |
| | Pooled | | | | 1.11 (0.81; 1.51) | 100 | 0.013 (-0.02; 0.05) | 100 |
| | P value/I squared | | | | 0.687 | 0.00% | 0.731 | 0.00% |
| Trospium | Treatment discontinuation due to adverse effects | Zinner, 2004[37] | 23/262 | 15/261 | 1.53 (0.82; 2.86) | 20.34 | 0.030 (-0.01; 0.08) | 8.73 |
| Trospium | Treatment discontinuation due to adverse effects | Rudy, 2006[363] | 24/329 | 15/329 | 1.60 (0.86; 2.99) | 20.39 | 0.027 (-0.01; 0.06) | 13.26 |
| Trospium | Treatment discontinuation due to adverse effects | Staskin, 2007[47] | 12/298 | 11/303 | 1.11 (0.50; 2.47) | 12.44 | 0.004 (-0.03; 0.04) | 18.27 |
| Trospium | Treatment discontinuation due to adverse effects | Sand, 2009[368] | 24/484 | 18/505 | 1.39 (0.77; 2.53) | 22.37 | 0.014 (-0.01; 0.04) | 27.08 |
| Trospium | Treatment discontinuation due to adverse effects | U.S. Food and Drug Administration, 2007 [40] | 18/280 | 8/284 | 2.28 (1.01; 5.16) | 12.02 | 0.036 (0.00; 0.07) | 14.39 |
| Trospium | Treatment discontinuation | U.S. Food and Drug | 12/298 | 11/303 | 1.11 (0.50; 2.47) | 12.44 | 0.004 (-0.03; 0.04) | 18.27 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | due to adverse effects | Administration, 2007 [40] | | | | | | |
| | Pooled | | | | 1.46 (1.10; 1.94) | 100 | 0.017 (0.00; 0.03) | 100 |
| | P value/I squared | | | | 0.824 | 0.00% | 0.657 | 0.00% |
| Trospium | Continence | Zinner, 2004[37] | 55/262 | 29/261 | 1.89 (1.25; 2.86) | 12.28 | 0.099 (0.04; 0.16) | 23.9 |
| Trospium | Continence | Staskin, 2007[47] | 61/298 | 34/303 | 1.82 (1.24; 2.69) | 14.12 | 0.092 (0.04; 0.15) | 27.62 |
| Trospium | Continence | Dmochowski, 2008[48] | 95/280 | 58/284 | 1.66 (1.25; 2.20) | 26.74 | 0.135 (0.06; 0.21) | 17.61 |
| Trospium | Continence | Sand, 2009[368] | 163/484 | 103/505 | 1.65 (1.34; 2.04) | 46.86 | 0.133 (0.08; 0.19) | 30.87 |
| | Pooled | | | | 1.71 (1.47; 1.97) | 100 | 0.114 (0.08; 0.14) | 100 |
| | P value/I squared | | | | 0.925 | 0.00% | 0.675 | 0.00% |
| Trospium | Dry eye | Staskin, 2007[47] | 4/298 | 1/303 | 4.07 (0.46; 36.18) | 47.1 | 0.010 (0.00; 0.03) | 42.94 |
| Trospium | Dry eye | Sand, 2009[368] | 9/484 | 1/505 | 9.39 (1.19; 73.84) | 52.9 | 0.017 (0.00; 0.03) | 57.06 |
| | Pooled | | | | 6.33 (1.41; 28.37) | 100 | 0.014 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.585 | 0.00% | 0.51 | 0.00% |
| Trospium | Dry mouth | Zinner, 2004[37] | 57/262 | 17/261 | 3.34 (2.00; 5.58) | 22.05 | 0.152 (0.09; 0.21) | 15.7 |
| Trospium | Dry mouth | Rudy, 2006[363] | 65/329 | 17/329 | 3.82 (2.29; 6.38) | 22.24 | 0.146 (0.10; 0.20) | 17.54 |
| Trospium | Dry mouth | Junemann, 2000[312] | 22/76 | 5/79 | 4.57 (1.83; 11.46) | 6.9 | 0.226 (0.11; 0.34) | 7.59 |
| Trospium | Dry mouth | Staskin, 2007[47] | 26/298 | 9/303 | 2.94 (1.40; 6.16) | 10.6 | 0.058 (0.02; 0.10) | 20.03 |
| Trospium | Dry mouth | Dmochowski, 2008[48] | 36/280 | 13/284 | 2.81 (1.52; 5.18) | 15.52 | 0.083 (0.04; 0.13) | 18.19 |
| Trospium | Dry mouth | Sand, 2009[368] | 55/484 | 19/505 | 3.02 (1.82; 5.01) | 22.69 | 0.076 (0.04; 0.11) | 20.95 |
| | Pooled | | | | 3.30 (2.59; 4.20) | 100 | 0.109 (0.07; 0.15) | 100 |
| | P value/I squared | | | | 0.937 | 0.00% | 0.003 | 72.60% |
| Trospium | Dry skin | Staskin, 2007[47] | 3/298 | 0/303 | 7.12 (0.37; 137.19) | 34.42 | 0.010 (0.00; 0.02) | 36.22 |
| Trospium | Dry skin | Sand, 2009[368] | 5/484 | 1/505 | 5.22 (0.61; 44.49) | 65.58 | 0.008 (0.00; 0.02) | 63.78 |
| | Pooled | | | | 5.81 (1.02; 32.94) | 100 | 0.009 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.868 | 0.00% | 0.836 | 0.00% |
| Trospium | Dyspepsia | Staskin, 2007[47] | 6/298 | 3/303 | 2.03 (0.51; 8.06) | 45.54 | 0.010 (-0.01; 0.03) | 29.31 |
| Trospium | Dyspepsia | Sand, 2009[368] | 6/484 | 4/505 | 1.57 (0.44; 5.51) | 54.46 | 0.004 (-0.01; 0.02) | 70.69 |
| | Pooled | | | | 1.76 (0.70; 4.47) | 100 | 0.006 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.783 | 0.00% | 0.626 | 0.00% |
| Trospium | Headache | Zinner, 2004[37] | 17/262 | 12/261 | 1.41 (0.69; 2.90) | 30.18 | 0.019 (-0.02; 0.06) | 11.6 |
| Trospium | Headache | Rudy, 2006[363] | 18/329 | 15/329 | 1.20 (0.62; 2.34) | 32.39 | 0.009 (-0.02; 0.04) | 15.46 |
| Trospium | Headache | Staskin, 2007[47] | 3/298 | 8/303 | 0.38 (0.10; 1.42) | 13.87 | -0.016 (-0.04; 0.01) | 31.94 |
| Trospium | Headache | Sand, 2009[368] | 7/484 | 14/505 | 0.52 (0.21; 1.28) | 23.56 | -0.013 (-0.03; 0.01) | 41 |
| | Pooled | | | | 0.88 (0.51; 1.55) | 100 | -0.007 (-0.02; 0.01) | 100 |
| | P value/I squared | | | | 0.159 | 42.20% | 0.291 | 19.90% |
| Trospium | Improvement in UI | Staskin, 2004[373] | 5/327 | 8/326 | 0.62 (0.21; 1.89) | 21.8 | -0.009 (-0.03; 0.01) | 52.53 |
| Trospium | Improvement in UI | Zinner, 2004[37] | 186/262 | 141/261 | 1.31 (1.15; 1.51) | 78.2 | 0.170 (0.09; 0.25) | 47.47 |

**Appendix Table F46. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)**

| Drug | Outcome | Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| | Pooled | | | | 1.12 (0.61; 2.04) | 100 | 0.076 (-0.10; 0.25) | 100 |
| | P value/I squared | | | | 0.19 | 41.90% | 0 | 94.20% |
| Trospium | Nausea | Staskin, 2007[47] | 3/298 | 2/303 | 1.53 (0.26; 9.06) | 56.36 | 0.003 (-0.01; 0.02) | 37.72 |
| Trospium | Nausea | Sand, 2009[368] | 7/484 | 1/505 | 7.30 (0.90; 59.14) | 43.64 | 0.012 (0.00; 0.02) | 62.28 |
| | Pooled | | | | 3.02 (0.66; 13.85) | 100 | 0.009 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.264 | 19.90% | 0.338 | 0.00% |
| Trospium | Urinary tract infection | Rudy, 2006[363] | 16/329 | 8/329 | 2.00 (0.87; 4.61) | 54.52 | 0.024 (0.00; 0.05) | 12.68 |
| Trospium | Urinary tract infection | Staskin, 2007[47] | 6/298 | 3/303 | 2.03 (0.51; 8.06) | 20.05 | 0.010 (-0.01; 0.03) | 27.38 |
| Trospium | Urinary tract infection | Sand, 2009[368] | 7/484 | 4/505 | 1.83 (0.54; 6.20) | 25.44 | 0.007 (-0.01; 0.02) | 59.94 |
| | Pooled | | | | 1.96 (1.06; 3.63) | 100 | 0.010 (0.00; 0.02) | 100 |
| | P value/I squared | | | | 0.991 | 0.00% | 0.541 | 0.00% |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Study | Darifenacin | Constipation | Country | RR | -0.55 | 0.81 | 0.53 |
| Study | Darifenacin | Constipation | Country | ARD | -0.01 | 0.04 | 0.71 |
| Study | Darifenacin | Constipation | Intention to treat | RR | 1.09 | 1.19 | 0.41 |
| Study | Darifenacin | Constipation | Intention to treat | ARD | 0.04 | 0.06 | 0.50 |
| Treatment | Darifenacin | Constipation | Daily dose | RR | 0.08 | 0.09 | 0.42 |
| Treatment | Darifenacin | Constipation | Daily dose | ARD | 0.00 | 0.00 | 0.43 |
| Treatment | Darifenacin | Constipation | Weeks of treatment | RR | 0.16 | 0.23 | 0.52 |
| Treatment | Darifenacin | Constipation | Weeks of treatment | ARD | 0.01 | 0.01 | 0.63 |
| Women | Darifenacin | Constipation | % of women | RR | 0.09 | 0.08 | 0.33 |
| Women | Darifenacin | Constipation | % of women | ARD | 0.00 | 0.00 | 0.47 |
| Women | Darifenacin | Constipation | Daily UI | RR | 2.19 | 2.37 | 0.41 |
| Women | Darifenacin | Constipation | Daily UI | ARD | 0.08 | 0.11 | 0.50 |
| Women | Darifenacin | Constipation | Inclusion of minorities | RR | -2.19 | 2.37 | 0.41 |
| Women | Darifenacin | Constipation | Inclusion of minorities | ARD | -0.08 | 0.11 | 0.50 |
| Women | Darifenacin | Constipation | Inclusion of mixed UI | RR | -2.90 | 1.48 | 0.12 |
| Women | Darifenacin | Constipation | Inclusion of mixed UI | ARD | -0.13 | 0.06 | 0.08 |
| Women | Darifenacin | Constipation | Inclusion of prior failures | RR | 1.20 | 0.83 | 0.22 |
| Women | Darifenacin | Constipation | Inclusion of prior failures | ARD | 0.04 | 0.04 | 0.41 |
| Women | Darifenacin | Constipation | Inclusion of women with surgical risk factors for UI | RR | 2.58 | 1.59 | 0.18 |
| Women | Darifenacin | Constipation | Inclusion of women with surgical risk factors for UI | ARD | 0.11 | 0.06 | 0.15 |
| Women | Darifenacin | Constipation | Rate in placebo group | RR | -52.15 | 37.96 | 0.22 |
| Women | Darifenacin | Constipation | Rate in placebo group | ARD | -1.62 | 1.86 | 0.42 |
| Study | Darifenacin | Dry mouth | Adequate randomization | RR | 1.59 | 1.32 | 0.28 |
| Study | Darifenacin | Dry mouth | Adequate randomization | ARD | 0.10 | 0.07 | 0.23 |
| Study | Darifenacin | Dry mouth | Country | RR | 0.33 | 1.26 | 0.81 |
| Study | Darifenacin | Dry mouth | Country | ARD | 0.00 | 0.07 | 0.96 |
| Study | Darifenacin | Dry mouth | Intention to treat | RR | 1.59 | 1.32 | 0.28 |
| Study | Darifenacin | Dry mouth | Intention to treat | ARD | 0.10 | 0.07 | 0.23 |
| Treatment | Darifenacin | Dry mouth | Daily dose | RR | 0.11 | 0.13 | 0.42 |
| Treatment | Darifenacin | Dry mouth | Daily dose | ARD | 0.01 | 0.01 | 0.24 |
| Treatment | Darifenacin | Dry mouth | Weeks of treatment | RR | 0.20 | 0.26 | 0.47 |
| Treatment | Darifenacin | Dry mouth | Weeks of treatment | ARD | 0.01 | 0.01 | 0.30 |
| Women | Darifenacin | Dry mouth | % of women | RR | 0.11 | 0.10 | 0.34 |
| Women | Darifenacin | Dry mouth | % of women | ARD | 0.01 | 0.01 | 0.24 |
| Women | Darifenacin | Dry mouth | Daily UI | RR | 3.19 | 2.63 | 0.28 |
| Women | Darifenacin | Dry mouth | Daily UI | ARD | 0.20 | 0.15 | 0.23 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Women | Darifenacin | Dry mouth | Inclusion of minorities | RR | -3.19 | 2.63 | 0.28 |
| Women | Darifenacin | Dry mouth | Inclusion of minorities | ARD | -0.20 | 0.15 | 0.23 |
| Women | Darifenacin | Dry mouth | Inclusion of mixed UI* | RR | -4.70 | 1.73 | 0.04 |
| Women | Darifenacin | Dry mouth | Inclusion of mixed UI* | ARD | -0.26 | 0.10 | 0.04 |
| Women | Darifenacin | Dry mouth | Inclusion of prior failures | RR | 1.06 | 1.27 | 0.44 |
| Women | Darifenacin | Dry mouth | Inclusion of prior failures | ARD | 0.09 | 0.07 | 0.26 |
| Women | Darifenacin | Dry mouth | Inclusion of women with surgical risk factors for UI | RR | 1.87 | 2.82 | 0.54 |
| Women | Darifenacin | Dry mouth | Inclusion of women with surgical risk factors for UI | ARD | 0.13 | 0.16 | 0.47 |
| Women | Darifenacin | Dry mouth | Rate in placebo group | RR | -17.57 | 55.39 | 0.76 |
| Women | Darifenacin | Dry mouth | Rate in placebo group | ARD | 0.59 | 3.01 | 0.85 |
| Study | Darifenacin | Dyspepsia | Adequate randomization | ARD | 0.02 | 0.01 | 0.23 |
| Study | Darifenacin | Dyspepsia | Intention to treat | ARD | 0.02 | 0.01 | 0.23 |
| Treatment | Darifenacin | Dyspepsia | Daily dose | ARD | 0.00 | 0.00 | 0.87 |
| Treatment | Darifenacin | Dyspepsia | Weeks of treatment | ARD | 0.00 | 0.00 | 0.54 |
| Women | Darifenacin | Dyspepsia | % of women | ARD | 0.00 | 0.00 | 0.25 |
| Women | Darifenacin | Dyspepsia | Daily UI | ARD | 0.03 | 0.02 | 0.23 |
| Women | Darifenacin | Dyspepsia | Inclusion of minorities | ARD | -0.03 | 0.02 | 0.23 |
| Women | Darifenacin | Dyspepsia | Inclusion of mixed UI | ARD | -0.03 | 0.02 | 0.22 |
| Women | Darifenacin | Dyspepsia | Inclusion of prior failures | ARD | 0.02 | 0.01 | 0.23 |
| Women | Darifenacin | Dyspepsia | Inclusion of women with surgical risk factors for UI | ARD | 0.01 | 0.03 | 0.84 |
| Women | Darifenacin | Dyspepsia | Rate in placebo group* | ARD | -3.54 | 1.30 | 0.04 |
| Study | Darifenacin | Improvement in UI | Country | ARD | 0.00 | 0.01 | 0.98 |
| Study | Darifenacin | Improvement in UI | Intention to treat | ARD | -0.01 | 0.03 | 0.83 |
| Treatment | Darifenacin | Improvement in UI | Daily dose | ARD | 0.00 | 0.01 | 0.82 |
| Women | Darifenacin | Improvement in UI | % of women | ARD | 0.00 | 0.01 | 0.83 |
| Women | Darifenacin | Improvement in UI | Inclusion of women with surgical risk factors for UI | ARD | -0.02 | 0.07 | 0.83 |
| Treatment | Fesoterodine | Adverse effects | Daily dose | RR | 0.05 | 0.07 | 0.54 |
| Women | Fesoterodine | Adverse effects | % of women | RR | 0.01 | 0.02 | 0.56 |
| Women | Fesoterodine | Adverse effects | Inclusion of minorities | RR | -0.40 | 0.17 | 0.08 |
| Women | Fesoterodine | Adverse effects | Inclusion of prior failures | RR | -0.40 | 0.17 | 0.08 |
| Women | Fesoterodine | Adverse effects | Inclusion of women with surgical risk factors for UI | RR | 0.40 | 0.17 | 0.08 |
| Women | Fesoterodine | Adverse effects | Rate in placebo group* | RR | -1.81 | 0.42 | 0.01 |
| Study | Fesoterodine | Adverse effects | Adequate randomization | RR | -0.20 | 0.08 | 0.08 |
| Study | Fesoterodine | Adverse effects | Allocation concealment | RR | -0.20 | 0.08 | 0.08 |
| Study | Fesoterodine | Adverse effects | Conflict of interest | RR | -0.01 | 0.26 | 0.97 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Study | Fesoterodine | Adverse effects | Country | RR | 0.27 | 0.20 | 0.26 |
| Study | Fesoterodine | Adverse effects | Intention to treat | RR | 0.40 | 0.17 | 0.08 |
| Study | Fesoterodine | Adverse effects | Justification of sample size | RR | 0.40 | 0.17 | 0.08 |
| Study | Fesoterodine | Constipation | Adequate randomization | RR | -0.29 | 0.94 | 0.77 |
| Study | Fesoterodine | Constipation | Adequate randomization | ARD | -0.01 | 0.02 | 0.51 |
| Study | Fesoterodine | Constipation | Allocation concealment | RR | -0.60 | 1.01 | 0.57 |
| Study | Fesoterodine | Constipation | Allocation concealment | ARD | -0.01 | 0.02 | 0.52 |
| Study | Fesoterodine | Constipation | Conflict of interest | RR | -0.95 | 2.16 | 0.67 |
| Study | Fesoterodine | Constipation | Conflict of interest | ARD | -0.02 | 0.04 | 0.61 |
| Study | Fesoterodine | Constipation | Country | RR | 0.73 | 1.17 | 0.54 |
| Study | Fesoterodine | Constipation | Country | ARD | 0.01 | 0.02 | 0.73 |
| Study | Fesoterodine | Constipation | Intention to treat | RR | 2.13 | 1.98 | 0.31 |
| Study | Fesoterodine | Constipation | Intention to treat | ARD | 0.06 | 0.04 | 0.14 |
| Study | Fesoterodine | Constipation | Justification of sample size | RR | 1.41 | 1.28 | 0.29 |
| Study | Fesoterodine | Constipation | Justification of sample size | ARD | 0.04 | 0.02 | 0.16 |
| Treatment | Fesoterodine | Constipation | Daily dose | RR | -0.01 | 0.47 | 0.98 |
| Treatment | Fesoterodine | Constipation | Daily dose | ARD | 0.00 | 0.01 | 1.00 |
| Women | Fesoterodine | Constipation | % of women | RR | -0.28 | 0.14 | 0.07 |
| Women | Fesoterodine | Constipation | % of women* | ARD | -0.01 | 0.00 | 0.04 |
| Women | Fesoterodine | Constipation | Inclusion of minorities | RR | -1.20 | 2.02 | 0.57 |
| Women | Fesoterodine | Constipation | Inclusion of minorities | ARD | -.0275674<br>.0411983 | -0.67 | -0.12 |
| Women | Fesoterodine | Constipation | Inclusion of mixed UI | RR | 2.16 | 2.29 | 0.37 |
| Women | Fesoterodine | Constipation | Inclusion of mixed UI | ARD | 0.05 | 0.05 | 0.30 |
| Women | Fesoterodine | Constipation | Inclusion of prior failures | RR | -0.88 | 2.07 | 0.68 |
| Women | Fesoterodine | Constipation | Inclusion of prior failures | ARD | -0.03 | 0.04 | 0.48 |
| Women | Fesoterodine | Constipation | Inclusion of women with surgical risk factors for UI | RR | 0.83 | 2.07 | 0.70 |
| Women | Fesoterodine | Constipation | Inclusion of women with surgical risk factors for UI | ARD | 0.02 | 0.04 | 0.64 |
| Women | Fesoterodine | Constipation | Rate in placebo group | RR | -73.31 | 75.60 | 0.36 |
| Women | Fesoterodine | Constipation | Rate in placebo group | ARD | -0.49 | 1.62 | 0.77 |
| Study | Fesoterodine | Discontinuation due to failure | Adequate randomization | ARD | 0.01 | 0.01 | 0.33 |
| Study | Fesoterodine | Discontinuation due to failure | Allocation concealment | ARD | 0.00 | 0.01 | 1.00 |
| Study | Fesoterodine | Discontinuation due to failure | Conflict of interest | ARD | 0.00 | 0.02 | 1.00 |
| Study | Fesoterodine | Discontinuation due to failure | Country | ARD | 0.00 | 0.01 | 0.78 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Study | Fesoterodine | Discontinuation due to failure | Justification of sample size | ARD | 0.00 | 0.02 | 1.00 |
| Women | Fesoterodine | Discontinuation due to failure | % of women | ARD | -0.01 | 0.00 | 0.20 |
| Women | Fesoterodine | Discontinuation due to failure | Inclusion of minorities | ARD | 0.00 | 0.02 | 1.00 |
| Women | Fesoterodine | Discontinuation due to failure | Inclusion of prior failures | ARD | 0.02 | 0.02 | 0.44 |
| Women | Fesoterodine | Discontinuation due to failure | Inclusion of women with surgical risk factors for UI | ARD | 0.02 | 0.02 | 0.41 |
| Women | Fesoterodine | Discontinuation due to failure | Rate in placebo group | ARD | -1.36 | 0.44 | 0.09 |
| Study | Fesoterodine | Dry eye | Adequate randomization | ARD | 0.01 | 0.00 | 0.22 |
| Study | Fesoterodine | Dry eye | Allocation concealment | ARD | 0.01 | 0.01 | 0.18 |
| Study | Fesoterodine | Dry eye | Conflict of interest | ARD | 0.01 | 0.01 | 0.27 |
| Study | Fesoterodine | Dry eye | Country | ARD | 0.00 | 0.01 | 0.83 |
| Study | Fesoterodine | Dry eye | Intention to treat | ARD | -0.02 | 0.01 | 0.17 |
| Study | Fesoterodine | Dry eye | Justification of sample size | ARD | -0.01 | 0.01 | 0.29 |
| Treatment | Fesoterodine | Dry eye | Daily dose | ARD | 0.01 | 0.00 | 0.22 |
| Women | Fesoterodine | Dry eye | % of women | ARD | 0.00 | 0.00 | 0.35 |
| Women | Fesoterodine | Dry eye | Inclusion of minorities | ARD | 0.02 | 0.01 | 0.18 |
| Women | Fesoterodine | Dry eye | Inclusion of prior failures | ARD | 0.02 | 0.01 | 0.17 |
| Women | Fesoterodine | Dry eye | Inclusion of women with surgical risk factors for UI | ARD | -0.02 | 0.01 | 0.18 |
| Women | Fesoterodine | Dry eye | Rate in placebo group | ARD | -0.96 | 0.60 | 0.17 |
| Study | Fesoterodine | Dry mouth | Adequate randomization | ARD | 0.00 | 0.02 | 0.95 |
| Study | Fesoterodine | Dry mouth | Allocation concealment | ARD | 0.00 | 0.02 | 0.82 |
| Study | Fesoterodine | Dry mouth | Conflict of interest | ARD | 0.00 | 0.03 | 0.91 |
| Study | Fesoterodine | Dry mouth | Country | ARD | 0.00 | 0.02 | 0.95 |
| Study | Fesoterodine | Dry mouth | Intention to treat | ARD | 0.01 | 0.03 | 0.72 |
| Study | Fesoterodine | Dry mouth | Justification of sample size | ARD | 0.01 | 0.02 | 0.70 |
| Treatment | Fesoterodine | Dry mouth | Daily dose | ARD | 0.02 | 0.01 | 0.01 |
| Women | Fesoterodine | Dry mouth | % of women | ARD | 0.00 | 0.00 | 0.87 |
| Women | Fesoterodine | Dry mouth | Inclusion of minorities | ARD | -0.01 | 0.03 | 0.82 |
| Women | Fesoterodine | Dry mouth | Inclusion of mixed UI | ARD | 0.01 | 0.04 | 0.89 |
| Women | Fesoterodine | Dry mouth | Inclusion of prior failures | ARD | 0.00 | 0.03 | 0.97 |
| Women | Fesoterodine | Dry mouth | Inclusion of women with surgical risk factors for UI | ARD | 0.02 | 0.03 | 0.65 |
| Women | Fesoterodine | Dry mouth | Rate in placebo group | ARD | -0.91 | 1.33 | 0.51 |
| Treatment | Oxybutynin | Adverse effects | Daily dose | RR | 0.33 | 0.37 | 0.53 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Treatment | Oxybutynin | Adverse effects | Daily dose | ARD | 0.05 | 0.02 | 0.32 |
| Treatment | Oxybutynin | Adverse effects | Weeks of treatment | RR | 0.05 | 0.34 | 0.91 |
| Treatment | Oxybutynin | Adverse effects | Weeks of treatment | ARD | -0.04 | 0.02 | 0.29 |
| Women | Oxybutynin | Adverse effects | % of women | ARD | 0.00 | 0.01 | 0.91 |
| Women | Oxybutynin | Adverse effects | Daily UI | RR | 0.40 | 2.76 | 0.91 |
| Women | Oxybutynin | Adverse effects | Daily UI | ARD | -0.28 | 0.14 | 0.29 |
| Women | Oxybutynin | Adverse effects | Inclusion of minorities | RR | -2.15 | 1.77 | 0.44 |
| Women | Oxybutynin | Adverse effects | Inclusion of minorities | ARD | -0.24 | 0.18 | 0.41 |
| Women | Oxybutynin | Adverse effects | Inclusion of mixed UI | RR | -1.08 | 0.89 | 0.44 |
| Women | Oxybutynin | Adverse effects | Inclusion of mixed UI | ARD | -0.12 | 0.09 | 0.41 |
| Women | Oxybutynin | Adverse effects | Rate in placebo group | RR | -2.58 | 7.43 | 0.79 |
| Women | Oxybutynin | Adverse effects | Rate in placebo group | ARD | 0.70 | 0.52 | 0.41 |
| Study | Oxybutynin | Adverse effects | Country | RR | -1.28 | 0.56 | 0.26 |
| Study | Oxybutynin | Adverse effects | Country | ARD | 0.01 | 0.15 | 0.94 |
| Study | Oxybutynin | Adverse effects | Justification of sample size | RR | 0.20 | 1.38 | 0.91 |
| Study | Oxybutynin | Adverse effects | Justification of sample size | ARD | -0.14 | 0.07 | 0.29 |
| Study | Oxybutynin | Dry mouth | Adequate randomization | RR | -1.13 | 0.83 | 0.21 |
| Study | Oxybutynin | Dry mouth | Adequate randomization | ARD | -0.06 | 0.06 | 0.38 |
| Study | Oxybutynin | Dry mouth | Allocation concealment | RR | -0.81 | 1.35 | 0.57 |
| Study | Oxybutynin | Dry mouth | Allocation concealment | ARD | 0.10 | 0.10 | 0.33 |
| Study | Oxybutynin | Dry mouth | Conflict of interest | RR | -0.16 | 2.81 | 0.96 |
| Study | Oxybutynin | Dry mouth | Conflict of interest | ARD | -0.27 | 0.19 | 0.19 |
| Study | Oxybutynin | Dry mouth | Country | RR | -0.56 | 0.96 | 0.58 |
| Study | Oxybutynin | Dry mouth | Country | ARD | -0.03 | 0.07 | 0.67 |
| Study | Oxybutynin | Dry mouth | Intention to treat | RR | 1.15 | 1.03 | 0.30 |
| Study | Oxybutynin | Dry mouth | Intention to treat | ARD | 0.07 | 0.08 | 0.37 |
| Study | Oxybutynin | Dry mouth | Justification of sample size | RR | -1.48 | 1.27 | 0.28 |
| Study | Oxybutynin | Dry mouth | Justification of sample size | ARD | -0.12 | 0.09 | 0.24 |
| Treatment | Oxybutynin | Dry mouth | Daily dose | RR | 0.12 | 0.20 | 0.56 |
| Treatment | Oxybutynin | Dry mouth | Daily dose | ARD | 0.02 | 0.01 | 0.21 |
| Treatment | Oxybutynin | Dry mouth | Weeks of treatment | RR | 0.29 | 0.29 | 0.34 |
| Treatment | Oxybutynin | Dry mouth | Weeks of treatment | ARD | -0.01 | 0.02 | 0.67 |
| Women | Oxybutynin | Dry mouth | % of women* | RR | -0.18 | 0.07 | 0.03 |
| Women | Oxybutynin | Dry mouth | % of women | ARD | -0.01 | 0.01 | 0.39 |
| Women | Oxybutynin | Dry mouth | Daily UI | RR | -0.90 | 2.24 | 0.70 |
| Women | Oxybutynin | Dry mouth | Daily UI | ARD | -0.11 | 0.16 | 0.52 |
| Women | Oxybutynin | Dry mouth | Inclusion of minorities | RR | -2.81 | 2.58 | 0.31 |
| Women | Oxybutynin | Dry mouth | Inclusion of minorities* | ARD | -0.43 | 0.12 | 0.01 |
| Women | Oxybutynin | Dry mouth | Inclusion of mixed UI* | RR | -2.53 | 0.86 | 0.02 |
| Women | Oxybutynin | Dry mouth | Inclusion of mixed UI | ARD | -0.14 | 0.08 | 0.09 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Women | Oxybutynin | Dry mouth | Inclusion of prior failures | RR | 0.45 | 1.75 | 0.80 |
| Women | Oxybutynin | Dry mouth | Inclusion of prior failures | ARD | -0.09 | 0.13 | 0.48 |
| Women | Oxybutynin | Dry mouth | Inclusion of women with surgical risk factors for UI | RR | -1.26 | 2.73 | 0.66 |
| Women | Oxybutynin | Dry mouth | Inclusion of women with surgical risk factors for UI | ARD | 0.24 | 0.19 | 0.24 |
| Women | Oxybutynin | Dry mouth | Rate in placebo group | RR | -6.22 | 3.73 | 0.13 |
| Women | Oxybutynin | Dry mouth | Rate in placebo group | ARD | -0.08 | 0.32 | 0.81 |
| Study | Oxybutynin | Dry skin | Allocation concealment | RR | 5.34 | 0.52 | 0.06 |
| Study | Oxybutynin | Dry skin | Allocation concealment | RR | 0.16 | 0.04 | 0.17 |
| Study | Oxybutynin | Dry skin | Intention to treat | RR | -2.09 | 4.67 | 0.73 |
| Study | Oxybutynin | Dry skin | Intention to treat | RR | -0.06 | 0.17 | 0.78 |
| Treatment | Oxybutynin | Dry skin | Daily dose | RR | 0.73 | 0.12 | 0.10 |
| Treatment | Oxybutynin | Dry skin | Daily dose | RR | 0.03 | 0.01 | 0.17 |
| Treatment | Oxybutynin | Dry skin | Weeks of treatment | RR | -0.87 | 0.80 | 0.47 |
| Treatment | Oxybutynin | Dry skin | Weeks of treatment | RR | -0.03 | 0.03 | 0.52 |
| Women | Oxybutynin | Dry skin | % of women | RR | 0.22 | 0.30 | 0.60 |
| Women | Oxybutynin | Dry skin | % of women | RR | 0.01 | 0.01 | 0.64 |
| Women | Oxybutynin | Dry skin | Daily UI | RR | -4.18 | 9.34 | 0.73 |
| Women | Oxybutynin | Dry skin | Daily UI | RR | -0.12 | 0.33 | 0.78 |
| Women | Oxybutynin | Dry skin | Inclusion of mixed UI | RR | 4.81 | 3.48 | 0.40 |
| Women | Oxybutynin | Dry skin | Inclusion of mixed UI | RR | 0.15 | 0.13 | 0.45 |
| Women | Oxybutynin | Dry skin | Inclusion of prior failures | RR | -4.18 | 9.34 | 0.73 |
| Women | Oxybutynin | Dry skin | Inclusion of prior failures | RR | -0.12 | 0.33 | 0.78 |
| Women | Oxybutynin | Dry skin | Rate in placebo group | RR | -9.94 | 14.78 | 0.62 |
| Women | Oxybutynin | Dry skin | Rate in placebo group | RR | -0.40 | 0.53 | 0.59 |
| Study | Oxybutynin | Failure | Adequate randomization | ARD | -0.04 | 0.04 | 0.41 |
| Study | Oxybutynin | Failure | Allocation concealment | ARD | -0.03 | 0.06 | 0.70 |
| Study | Oxybutynin | Failure | Country | ARD | 0.02 | 0.06 | 0.76 |
| Study | Oxybutynin | Failure | Intention to treat | ARD | 0.10 | 0.04 | 0.06 |
| Study | Oxybutynin | Failure | Justification of sample size | ARD | -0.02 | 0.06 | 0.72 |
| Study | Oxybutynin | Failure | Mask1 | ARD | 0.22 | 0.15 | 0.24 |
| Treatment | Oxybutynin | Failure | Daily dose | ARD | -0.01 | 0.02 | 0.81 |
| Treatment | Oxybutynin | Failure | Weeks of treatment | ARD | 0.01 | 0.02 | 0.63 |
| Women | Oxybutynin | Failure | % of women | ARD | 0.00 | 0.00 | 0.47 |
| Women | Oxybutynin | Failure | Daily UI | ARD | 0.13 | 0.07 | 0.19 |
| Women | Oxybutynin | Failure | Inclusion of mixed UI | ARD | 0.03 | 0.06 | 0.68 |
| Women | Oxybutynin | Failure | Inclusion of prior failures | ARD | 0.08 | 0.07 | 0.33 |
| Women | Oxybutynin | Failure | Inclusion of women with surgical risk factors for UI | ARD | 0.11 | 0.07 | 0.22 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Women | Oxybutynin | Failure | Rate in placebo group | ARD | -0.37 | 0.12 | 0.05 |
| Study | Oxybutynin | Improvement in UI | Adequate randomization | RR | 0.48 | 0.53 | 0.38 |
| Study | Oxybutynin | Improvement in UI | Adequate randomization | ARD | 0.04 | 0.04 | 0.30 |
| Study | Oxybutynin | Improvement in UI | Allocation concealment | RR | 1.03 | 0.66 | 0.15 |
| Study | Oxybutynin | Improvement in UI | Allocation concealment | ARD | 0.02 | 0.05 | 0.68 |
| Study | Oxybutynin | Improvement in UI | Conflict of interest | RR | -0.52 | 2.34 | 0.83 |
| Study | Oxybutynin | Improvement in UI | Conflict of interest | ARD | 0.10 | 0.18 | 0.59 |
| Study | Oxybutynin | Improvement in UI | Country | RR | -0.48 | 0.59 | 0.44 |
| Study | Oxybutynin | Improvement in UI | Country | ARD | -0.01 | 0.05 | 0.88 |
| Study | Oxybutynin | Improvement in UI | Intention to treat | RR | -0.79 | 0.64 | 0.25 |
| Study | Oxybutynin | Improvement in UI | Intention to treat | ARD | -0.03 | 0.05 | 0.54 |
| Study | Oxybutynin | Improvement in UI | Justification of sample size | RR | 0.53 | 0.71 | 0.47 |
| Study | Oxybutynin | Improvement in UI | Justification of sample size | ARD | 0.03 | 0.05 | 0.62 |
| Study | Oxybutynin | Improvement in UI | Mask1 | RR | -2.50 | 2.75 | 0.39 |
| Study | Oxybutynin | Improvement in UI | Mask1 | ARD | 0.04 | 0.18 | 0.84 |
| Treatment | Oxybutynin | Improvement in UI | Daily dose* | RR | -0.33 | 0.14 | 0.04 |
| Treatment | Oxybutynin | Improvement in UI | Daily dose | ARD | -0.01 | 0.01 | 0.59 |
| Treatment | Oxybutynin | Improvement in UI | Weeks of treatment | RR | -0.19 | 0.21 | 0.39 |
| Treatment | Oxybutynin | Improvement in UI | Weeks of treatment | ARD | -0.02 | 0.01 | 0.14 |
| Women | Oxybutynin | Improvement in UI | % of women | RR | 0.06 | 0.05 | 0.22 |
| Women | Oxybutynin | Improvement in UI | % of women | ARD | 0.01 | 0.00 | 0.20 |
| Women | Oxybutynin | Improvement in UI | Daily UI | RR | -0.21 | 1.34 | 0.88 |
| Women | Oxybutynin | Improvement in UI | Daily UI | ARD | -0.01 | 0.10 | 0.95 |
| Women | Oxybutynin | Improvement in UI | Inclusion of mixed UI | RR | 0.43 | 0.75 | 0.58 |
| Women | Oxybutynin | Improvement in UI | Inclusion of mixed UI | ARD | 0.03 | 0.06 | 0.58 |
| Women | Oxybutynin | Improvement in UI | Inclusion of prior failures | RR | -1.21 | 1.06 | 0.28 |
| Women | Oxybutynin | Improvement in UI | Inclusion of prior failures | ARD | -0.06 | 0.08 | 0.45 |
| Women | Oxybutynin | Improvement in UI | Inclusion of women with surgical risk factors for UI | RR | -0.98 | 1.14 | 0.41 |
| Women | Oxybutynin | Improvement in UI | Inclusion of women with surgical risk factors for UI | ARD | -0.03 | 0.08 | 0.75 |
| Women | Oxybutynin | Improvement in UI | Rate in placebo group* | RR | -7.06 | 2.63 | 0.02 |
| Women | Oxybutynin | Improvement in UI | Rate in placebo group | ARD | -0.11 | 0.26 | 0.67 |
| Study | Propiverine | Constipation | Adequate randomization | ARD | 0.04 | 0.04 | 0.44 |
| Study | Propiverine | Constipation | Allocation concealment | ARD | 0.07 | 0.09 | 0.48 |
| Study | Propiverine | Constipation | Conflict of interest | ARD | -0.02 | 0.10 | 0.86 |
| Study | Propiverine | Constipation | Country | ARD | -0.01 | 0.04 | 0.82 |
| Study | Propiverine | Constipation | Intention to treat | ARD | 0.08 | 0.03 | 0.06 |
| Study | Propiverine | Constipation | Justification of sample size | ARD | -0.06 | 0.04 | 0.19 |
| Treatment | Propiverine | Constipation | Daily dose | ARD | 0.00 | 0.00 | 0.34 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Treatment | Propiverine | Constipation | Weeks of treatment | ARD | -0.01 | 0.01 | 0.31 |
| Women | Propiverine | Constipation | % of women | ARD | 0.00 | 0.01 | 0.52 |
| Women | Propiverine | Constipation | Daily UI | ARD | -0.07 | 0.08 | 0.42 |
| Women | Propiverine | Constipation | Inclusion of minorities | ARD | -0.08 | 0.09 | 0.44 |
| Women | Propiverine | Constipation | Inclusion of mixed UI | ARD | 0.03 | 0.06 | 0.71 |
| Women | Propiverine | Constipation | Rate in placebo group | ARD | -1.13 | 2.72 | 0.71 |
| Study | Propiverine | Dry mouth | Adequate randomization | ARD | 0.01 | 0.06 | 0.88 |
| Study | Propiverine | Dry mouth | Allocation concealment | ARD | 0.13 | 0.04 | 0.06 |
| Study | Propiverine | Dry mouth | Conflict of interest | ARD | 0.05 | 0.11 | 0.71 |
| Study | Propiverine | Dry mouth | Country | ARD | 0.01 | 0.04 | 0.85 |
| Study | Propiverine | Dry mouth | Intention to treat | ARD | 0.06 | 0.05 | 0.29 |
| Study | Propiverine | Dry mouth | Justification of sample size | ARD | -0.06 | 0.05 | 0.32 |
| Treatment | Propiverine | Dry mouth | Daily dose | ARD | 0.01 | 0.01 | 0.25 |
| Treatment | Propiverine | Dry mouth | Weeks of treatment | ARD | -0.01 | 0.01 | 0.38 |
| Women | Propiverine | Dry mouth | % of women | ARD | 0.00 | 0.01 | 0.75 |
| Women | Propiverine | Dry mouth | Daily UI | ARD | 0.02 | 0.10 | 0.84 |
| Women | Propiverine | Dry mouth | Inclusion of minorities | ARD | -0.02 | 0.12 | 0.88 |
| Women | Propiverine | Dry mouth | Inclusion of mixed UI | ARD | 0.02 | 0.07 | 0.76 |
| Women | Propiverine | Dry mouth | Rate in placebo group | ARD | 1.39 | 0.69 | 0.14 |
| Treatment | Solifenacin | Adverse effects | Daily dose | RR | 0.13 | 0.05 | 0.05 |
| Treatment | Solifenacin | Adverse effects | Daily dose | ARD | 0.02 | 0.01 | 0.07 |
| Treatment | Solifenacin | Adverse effects | Weeks of treatment | RR | -0.08 | 0.08 | 0.34 |
| Treatment | Solifenacin | Adverse effects | Weeks of treatment | ARD | 0.00 | 0.01 | 0.88 |
| Women | Solifenacin | Adverse effects | % of women | RR | -0.03 | 0.03 | 0.36 |
| Women | Solifenacin | Adverse effects | % of women | ARD | 0.00 | 0.00 | 0.91 |
| Women | Solifenacin | Adverse effects | Daily UI | RR | 0.18 | 0.74 | 0.82 |
| Women | Solifenacin | Adverse effects | Daily UI | ARD | -0.04 | 0.09 | 0.69 |
| Women | Solifenacin | Adverse effects | Inclusion of mixed UI | RR | 0.09 | 0.37 | 0.82 |
| Women | Solifenacin | Adverse effects | Inclusion of mixed UI | ARD | -0.02 | 0.05 | 0.69 |
| Women | Solifenacin | Adverse effects | Inclusion of prior failures | RR | -0.89 | 0.82 | 0.33 |
| Women | Solifenacin | Adverse effects | Inclusion of prior failures | ARD | -0.08 | 0.11 | 0.48 |
| Women | Solifenacin | Adverse effects | Inclusion of women with surgical risk factors for UI | RR | 0.89 | 0.82 | 0.33 |
| Women | Solifenacin | Adverse effects | Inclusion of women with surgical risk factors for UI | ARD | 0.08 | 0.11 | 0.48 |
| Women | Solifenacin | Adverse effects | Rate in placebo group | RR | -2.39 | 1.90 | 0.26 |
| Women | Solifenacin | Adverse effects | Rate in placebo group | ARD | -0.19 | 0.27 | 0.52 |
| Study | Solifenacin | Adverse effects | Allocation concealment | RR | -0.44 | 0.41 | 0.33 |
| Study | Solifenacin | Adverse effects | Allocation concealment | ARD | -0.04 | 0.05 | 0.48 |
| Study | Solifenacin | Adverse effects | Conflict of interest | RR | 0.18 | 0.50 | 0.73 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Study | Solifenacin | Adverse effects | Conflict of interest | ARD | 0.04 | 0.06 | 0.51 |
| Study | Solifenacin | Adverse effects | Country | RR | 0.66 | 0.62 | 0.34 |
| Study | Solifenacin | Adverse effects | Country | ARD | 0.01 | 0.09 | 0.88 |
| Study | Solifenacin | Adverse effects | Intention to treat | RR | 0.33 | 0.31 | 0.34 |
| Study | Solifenacin | Adverse effects | Intention to treat | ARD | 0.01 | 0.05 | 0.88 |
| Study | Solifenacin | Blurred vision | Adequate randomization | ARD | -0.01 | 0.00 | 0.22 |
| Study | Solifenacin | Blurred vision | Allocation concealment | ARD | 0.01 | 0.00 | 0.27 |
| Study | Solifenacin | Blurred vision | Conflict of interest | ARD | 0.00 | 0.01 | 0.62 |
| Study | Solifenacin | Blurred vision | Country | ARD | 0.00 | 0.00 | 0.39 |
| Study | Solifenacin | Blurred vision | Intention to treat | ARD | -0.01 | 0.01 | 0.16 |
| Study | Solifenacin | Blurred vision | Justification of sample size* | ARD | -0.02 | 0.01 | 0.02 |
| Treatment | Solifenacin | Blurred vision | Daily dose | ARD | 0.00 | 0.00 | 0.11 |
| Treatment | Solifenacin | Blurred vision | Weeks of treatment | ARD | 0.00 | 0.00 | 0.35 |
| Women | Solifenacin | Blurred vision | % of women | ARD | 0.00 | 0.00 | 0.39 |
| Women | Solifenacin | Blurred vision | Daily UI | ARD | 0.00 | 0.01 | 0.99 |
| Women | Solifenacin | Blurred vision | Inclusion of minorities | ARD | 0.00 | 0.01 | 0.73 |
| Women | Solifenacin | Blurred vision | Inclusion of mixed UI | ARD | 0.00 | 0.01 | 0.98 |
| Women | Solifenacin | Blurred vision | Inclusion of prior failures | ARD | 0.01 | 0.01 | 0.56 |
| Women | Solifenacin | Blurred vision | Inclusion of women with surgical risk factors for UI | ARD | 0.01 | 0.01 | 0.59 |
| Women | Solifenacin | Blurred vision | Rate in placebo group | ARD | 0.25 | 0.44 | 0.58 |
| Study | Solifenacin | Constipation | Adequate randomization | RR | 0.29 | 1.08 | 0.79 |
| Study | Solifenacin | Constipation | Adequate randomization | ARD | 0.00 | 0.01 | 0.96 |
| Study | Solifenacin | Constipation | Allocation concealment | RR | -0.52 | 1.05 | 0.63 |
| Study | Solifenacin | Constipation | Allocation concealment | ARD | 0.00 | 0.01 | 0.85 |
| Study | Solifenacin | Constipation | Conflict of interest | RR | -1.23 | 1.17 | 0.32 |
| Study | Solifenacin | Constipation | Conflict of interest | ARD | 0.01 | 0.02 | 0.75 |
| Study | Solifenacin | Constipation | Country | RR | 0.50 | 0.58 | 0.41 |
| Study | Solifenacin | Constipation | Country | ARD | -0.01 | 0.01 | 0.31 |
| Study | Solifenacin | Constipation | Intention to treat | RR | 1.34 | 0.81 | 0.12 |
| Study | Solifenacin | Constipation | Intention to treat | ARD | -0.01 | 0.01 | 0.45 |
| Study | Solifenacin | Constipation | Justification of sample size | RR | 1.00 | 1.66 | 0.56 |
| Study | Solifenacin | Constipation | Justification of sample size | ARD | 0.00 | 0.02 | 0.97 |
| Treatment | Solifenacin | Constipation | Daily dose* | RR | 0.61 | 0.11 | 0.00 |
| Treatment | Solifenacin | Constipation | Daily dose | ARD | 0.01 | 0.00 | 0.00 |
| Treatment | Solifenacin | Constipation | Weeks of treatment* | RR | -0.48 | 0.19 | 0.03 |
| Treatment | Solifenacin | Constipation | Weeks of treatment | ARD | 0.00 | 0.00 | 0.76 |
| Women | Solifenacin | Constipation | % of women | RR | -0.15 | 0.07 | 0.06 |
| Women | Solifenacin | Constipation | % of women | ARD | 0.00 | 0.00 | 0.97 |
| Women | Solifenacin | Constipation | Daily UI | RR | 1.56 | 1.79 | 0.40 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Women | Solifenacin | Constipation | Daily UI | ARD | 0.01 | 0.03 | 0.75 |
| Women | Solifenacin | Constipation | Inclusion of minorities | RR | 0.70 | 1.54 | 0.66 |
| Women | Solifenacin | Constipation | Inclusion of minorities | ARD | -0.02 | 0.02 | 0.33 |
| Women | Solifenacin | Constipation | Inclusion of mixed UI | RR | 1.24 | 0.96 | 0.22 |
| Women | Solifenacin | Constipation | Inclusion of mixed UI | ARD | 0.01 | 0.01 | 0.49 |
| Women | Solifenacin | Constipation | Inclusion of prior failures | RR | -0.84 | 1.84 | 0.66 |
| Women | Solifenacin | Constipation | Inclusion of prior failures | ARD | 0.00 | 0.03 | 0.87 |
| Women | Solifenacin | Constipation | Inclusion of women with surgical risk factors for UI | RR | 0.14 | 2.96 | 0.96 |
| Women | Solifenacin | Constipation | Inclusion of women with surgical risk factors for UI | ARD | 0.01 | 0.04 | 0.77 |
| Women | Solifenacin | Constipation | Rate in placebo group | RR | -49.51 | 23.42 | 0.06 |
| Women | Solifenacin | Constipation | Rate in placebo group | ARD | 0.05 | 0.44 | 0.92 |
| Study | Solifenacin | Dry mouth | Adequate randomization | RR | 1.60 | 2.90 | 0.59 |
| Study | Solifenacin | Dry mouth | Adequate randomization | ARD | 0.01 | 0.03 | 0.84 |
| Study | Solifenacin | Dry mouth | Allocation concealment | RR | -2.17 | 3.62 | 0.56 |
| Study | Solifenacin | Dry mouth | Allocation concealment | ARD | 0.00 | 0.04 | 0.91 |
| Study | Solifenacin | Dry mouth | Conflict of interest | RR | -7.07 | 3.68 | 0.08 |
| Study | Solifenacin | Dry mouth | Conflict of interest | ARD | -0.01 | 0.05 | 0.88 |
| Study | Solifenacin | Dry mouth | Country | RR | 2.66 | 1.33 | 0.07 |
| Study | Solifenacin | Dry mouth | Country | ARD | 0.00 | 0.02 | 0.88 |
| Study | Solifenacin | Dry mouth | Intention to treat* | RR | 5.01 | 1.74 | 0.02 |
| Study | Solifenacin | Dry mouth | Intention to treat | ARD | 0.00 | 0.03 | 0.88 |
| Study | Solifenacin | Dry mouth | Justification of sample size | RR | 3.99 | 4.43 | 0.39 |
| Study | Solifenacin | Dry mouth | Justification of sample size | ARD | 0.01 | 0.05 | 0.82 |
| Treatment | Solifenacin | Dry mouth | Daily dose* | RR | 1.58 | 0.28 | 0.00 |
| Treatment | Solifenacin | Dry mouth | Daily dose* | ARD | 0.03 | 0.00 | 0.00 |
| Treatment | Solifenacin | Dry mouth | Weeks of treatment* | RR | -1.45 | 0.38 | 0.00 |
| Treatment | Solifenacin | Dry mouth | Weeks of treatment* | ARD | -0.01 | 0.01 | 0.33 |
| Women | Solifenacin | Dry mouth | % of women | RR | -0.49 | 0.16 | 0.01 |
| Women | Solifenacin | Dry mouth | % of women | ARD | 0.00 | 0.00 | 0.56 |
| Women | Solifenacin | Dry mouth | Daily UI | RR | 4.64 | 4.83 | 0.36 |
| Women | Solifenacin | Dry mouth | Daily UI | ARD | 0.02 | 0.06 | 0.68 |
| Women | Solifenacin | Dry mouth | Inclusion of minorities | RR | 5.73 | 3.90 | 0.17 |
| Women | Solifenacin | Dry mouth | Inclusion of minorities | ARD | 0.01 | 0.05 | 0.89 |
| Women | Solifenacin | Dry mouth | Inclusion of mixed UI | RR | 3.09 | 2.68 | 0.27 |
| Women | Solifenacin | Dry mouth | Inclusion of mixed UI | ARD | 0.02 | 0.03 | 0.60 |
| Women | Solifenacin | Dry mouth | Inclusion of prior failures | RR | -3.32 | 5.78 | 0.58 |
| Women | Solifenacin | Dry mouth | Inclusion of prior failures | ARD | -0.01 | 0.07 | 0.93 |
| Women | Solifenacin | Dry mouth | Rate in placebo group* | RR | -160.12 | 55.51 | 0.02 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Women | Solifenacin | Dry mouth | Rate in placebo group | ARD | -0.07 | 0.91 | 0.94 |
| Study | Tolterodine | Dry mouth | Adequate randomization | ARD | -0.01 | 0.02 | 0.46 |
| Study | Tolterodine | Dry mouth | Allocation concealment | ARD | -0.02 | 0.03 | 0.50 |
| Study | Tolterodine | Dry mouth | Conflict of interest | ARD | -0.06 | 0.04 | 0.14 |
| Study | Tolterodine | Dry mouth | Country | ARD | 0.00 | 0.02 | 0.90 |
| Study | Tolterodine | Dry mouth | Intention to treat | ARD | 0.04 | 0.02 | 0.07 |
| Study | Tolterodine | Dry mouth | Justification of sample size | ARD | 0.00 | 0.03 | 0.97 |
| Treatment | Tolterodine | Dry mouth | Daily dose | ARD | 0.01 | 0.01 | 0.52 |
| Treatment | Tolterodine | Dry mouth | Weeks of treatment | ARD | -0.01 | 0.01 | 0.06 |
| Women | Tolterodine | Dry mouth | % of women | ARD | 0.00 | 0.00 | 0.14 |
| Women | Tolterodine | Dry mouth | Daily UI | ARD | -0.05 | 0.05 | 0.31 |
| Women | Tolterodine | Dry mouth | Inclusion of minorities | ARD | -0.04 | 0.04 | 0.36 |
| Women | Tolterodine | Dry mouth | Inclusion of mixed UI | ARD | 0.00 | 0.03 | 0.87 |
| Women | Tolterodine | Dry mouth | Inclusion of prior failures | ARD | 0.01 | 0.03 | 0.65 |
| Women | Tolterodine | Dry mouth | Inclusion of women with surgical risk factors for UI | ARD | 0.07 | 0.05 | 0.21 |
| Women | Tolterodine | Dry mouth | Rate in placebo group | ARD | 0.16 | 0.45 | 0.73 |
| Study | Tolterodine | Failure | Adequate randomization | RR | 0.08 | 0.08 | 0.39 |
| Study | Tolterodine | Failure | Adequate randomization | ARD | 0.05 | 0.02 | 0.07 |
| Study | Tolterodine | Failure | Allocation concealment | RR | -0.03 | 0.13 | 0.81 |
| Study | Tolterodine | Failure | Allocation concealment | ARD | -0.04 | 0.03 | 0.22 |
| Study | Tolterodine | Failure | Conflict of interest | RR | -0.07 | 0.16 | 0.67 |
| Study | Tolterodine | Failure | Conflict of interest | ARD | -0.06 | 0.04 | 0.21 |
| Study | Tolterodine | Failure | Country | RR | -0.12 | 0.09 | 0.23 |
| Study | Tolterodine | Failure | Country | ARD | -0.03 | 0.03 | 0.34 |
| Study | Tolterodine | Failure | Intention to treat | RR | -0.11 | 0.17 | 0.55 |
| Study | Tolterodine | Failure | Intention to treat | ARD | 0.01 | 0.04 | 0.87 |
| Study | Tolterodine | Failure | Justification of sample size | RR | 0.10 | 0.18 | 0.61 |
| Study | Tolterodine | Failure | Justification of sample size | ARD | 0.03 | 0.05 | 0.58 |
| Treatment | Tolterodine | Failure | Daily dose | RR | 0.06 | 0.16 | 0.71 |
| Treatment | Tolterodine | Failure | Daily dose | ARD | 0.02 | 0.05 | 0.75 |
| Women | Tolterodine | Failure | % of women | RR | 0.03 | 0.02 | 0.21 |
| Women | Tolterodine | Failure | % of women | ARD | 0.00 | 0.00 | 0.46 |
| Women | Tolterodine | Failure | Daily UI | RR | -0.15 | 0.29 | 0.63 |
| Women | Tolterodine | Failure | Daily UI | ARD | -0.04 | 0.07 | 0.61 |
| Women | Tolterodine | Failure | Inclusion of minorities | RR | 0.06 | 0.27 | 0.83 |
| Women | Tolterodine | Failure | Inclusion of minorities | ARD | -0.01 | 0.07 | 0.90 |
| Women | Tolterodine | Failure | Inclusion of mixed UI | RR | 0.28 | 0.19 | 0.21 |
| Women | Tolterodine | Failure | Inclusion of mixed UI | ARD | 0.08 | 0.06 | 0.26 |
| Women | Tolterodine | Failure | Inclusion of prior failures | RR | -0.21 | 0.23 | 0.41 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Women | Tolterodine | Failure | Inclusion of prior failures | ARD | -0.08 | 0.06 | 0.22 |
| Women | Tolterodine | Failure | Rate in placebo group | RR | -0.86 | 0.49 | 0.14 |
| Women | Tolterodine | Failure | Rate in placebo group | ARD | -0.51 | 0.09 | 0.00 |
| Study | Tolterodine | Improvement in UI | Adequate randomization | RR | -0.05 | 0.08 | 0.54 |
| Study | Tolterodine | Improvement in UI | Adequate randomization | ARD | 0.00 | 0.02 | 0.92 |
| Study | Tolterodine | Improvement in UI | Allocation concealment | RR | 0.10 | 0.10 | 0.36 |
| Study | Tolterodine | Improvement in UI | Allocation concealment | ARD | 0.02 | 0.03 | 0.53 |
| Study | Tolterodine | Improvement in UI | Conflict of interest | RR | 0.23 | 0.11 | 0.08 |
| Study | Tolterodine | Improvement in UI | Conflict of interest | ARD | 0.05 | 0.04 | 0.24 |
| Study | Tolterodine | Improvement in UI | Country | RR | 0.06 | 0.09 | 0.54 |
| Study | Tolterodine | Improvement in UI | Country | ARD | 0.01 | 0.03 | 0.81 |
| Study | Tolterodine | Improvement in UI | Intention to treat | RR | -0.17 | 0.10 | 0.12 |
| Study | Tolterodine | Improvement in UI | Intention to treat | ARD | -0.04 | 0.03 | 0.28 |
| Study | Tolterodine | Improvement in UI | Justification of sample size | RR | -0.17 | 0.09 | 0.11 |
| Study | Tolterodine | Improvement in UI | Justification of sample size | ARD | -0.06 | 0.03 | 0.07 |
| Treatment | Tolterodine | Improvement in UI | Daily dose | RR | -0.08 | 0.16 | 0.63 |
| Treatment | Tolterodine | Improvement in UI | Daily dose | ARD | -0.05 | 0.03 | 0.18 |
| Women | Tolterodine | Improvement in UI | % of women | RR | 0.01 | 0.01 | 0.11 |
| Women | Tolterodine | Improvement in UI | % of women | ARD | 0.00 | 0.00 | 0.15 |
| Women | Tolterodine | Improvement in UI | Daily UI | RR | -0.17 | 0.18 | 0.39 |
| Women | Tolterodine | Improvement in UI | Daily UI | ARD | -0.09 | 0.05 | 0.10 |
| Women | Tolterodine | Improvement in UI | Inclusion of minorities | RR | 0.20 | 0.18 | 0.30 |
| Women | Tolterodine | Improvement in UI | Inclusion of minorities | ARD | 0.05 | 0.05 | 0.41 |
| Women | Tolterodine | Improvement in UI | Inclusion of mixed UI* | RR | -0.45 | 0.11 | 0.01 |
| Women | Tolterodine | Improvement in UI | Inclusion of mixed UI* | ARD | -0.13 | 0.04 | 0.02 |
| Women | Tolterodine | Improvement in UI | Inclusion of prior failures | RR | -0.02 | 0.14 | 0.88 |
| Women | Tolterodine | Improvement in UI | Inclusion of prior failures | ARD | -0.02 | 0.04 | 0.70 |
| Women | Tolterodine | Improvement in UI | Inclusion of women with surgical risk factors for UI | RR | -0.27 | 0.25 | 0.31 |
| Women | Tolterodine | Improvement in UI | Inclusion of women with surgical risk factors for UI | ARD | -.1372185 .0723651 | -1.90 | |
| Women | Tolterodine | Improvement in UI | Rate in placebo group | RR | -0.53 | 0.65 | 0.45 |
| Women | Tolterodine | Improvement in UI | Rate in placebo group | ARD | 0.10 | 0.20 | 0.62 |
| Treatment | Trospium | Adverse effects | Daily dose | RR | -0.01 | 0.02 | 0.70 |
| Treatment | Trospium | Adverse effects | Weeks of treatment | RR | -0.09 | 0.04 | 0.13 |
| Women | Trospium | Adverse effects | % of women | RR | -0.01 | 0.02 | 0.72 |
| Women | Trospium | Adverse effects | Daily UI | RR | -0.83 | 0.40 | 0.13 |
| Women | Trospium | Adverse effects | Inclusion of minorities | RR | -0.83 | 0.40 | 0.13 |
| Women | Trospium | Adverse effects | Inclusion of mixed UI | RR | 0.10 | 0.22 | 0.68 |
| Women | Trospium | Adverse effects | Inclusion of prior failures | RR | -0.10 | 0.41 | 0.82 |

**Appendix Table F47. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)**

| Diversity Factor | Drug | Outcome | Contributing Variable | Estimate | Coefficient | Standard Error | P Value |
|---|---|---|---|---|---|---|---|
| Women | Trospium | Adverse effects | Rate in placebo group* | RR | -1.59 | 0.45 | 0.04 |
| Study | Trospium | Adverse effects | Adequate randomization | RR | -0.42 | 0.20 | 0.13 |
| Study | Trospium | Adverse effects | Allocation concealment | RR | -0.01 | 0.25 | 0.97 |
| Study | Trospium | Adverse effects | Conflict of interest | RR | -0.41 | 0.34 | 0.31 |
| Study | Trospium | Adverse effects | Country | RR | -0.27 | 0.10 | 0.07 |
| Study | Trospium | Adverse effects | Intention to treat | RR | -0.22 | 0.24 | 0.43 |
| Study | Trospium | Adverse effects | Justification of sample size | RR | 0.02 | 0.26 | 0.93 |
| Study | Trospium | Constipation | Allocation concealment | RR | 1.55 | 1.41 | 0.35 |
| Study | Trospium | Constipation | Conflict of interest | RR | -0.25 | 2.71 | 0.93 |
| Study | Trospium | Constipation | Country | RR | -1.78 | 1.31 | 0.27 |
| Study | Trospium | Constipation | Intention to treat | RR | 0.47 | 3.32 | 0.90 |
| Study | Trospium | Constipation | Justification of sample size | RR | 0.55 | 1.46 | 0.73 |
| Treatment | Trospium | Constipation | Daily dose | RR | 0.21 | 0.07 | 0.05 |
| Women | Trospium | Constipation | % of women | RR | 0.21 | 0.10 | 0.12 |
| Women | Trospium | Constipation | Inclusion of mixed UI | RR | -1.87 | 1.41 | 0.28 |
| Women | Trospium | Constipation | Inclusion of prior failures | RR | 0.47 | 3.32 | 0.90 |
| Women | Trospium | Constipation | Rate in placebo group | RR | -114.78 | 33.25 | 0.04 |
| Study | Trospium | Dry mouth | Adequate randomization | ARD | -0.06 | 0.04 | 0.15 |
| Study | Trospium | Dry mouth | Allocation concealment | ARD | -0.03 | 0.03 | 0.29 |
| Study | Trospium | Dry mouth | Conflict of interest | ARD | -0.03 | 0.05 | 0.62 |
| Study | Trospium | Dry mouth | Country | ARD | -0.01 | 0.03 | 0.77 |
| Study | Trospium | Dry mouth | Intention to treat | ARD | -0.04 | 0.04 | 0.36 |
| Study | Trospium | Dry mouth | Justification of sample size | ARD | -0.01 | 0.03 | 0.80 |
| Treatment | Trospium | Dry mouth | Daily dose* | ARD | 0.00 | 0.00 | 0.02 |
| Treatment | Trospium | Dry mouth | Weeks of treatment | ARD | -0.01 | 0.01 | 0.15 |
| Women | Trospium | Dry mouth | % of women | ARD | 0.00 | 0.00 | 0.12 |
| Women | Trospium | Dry mouth | Daily UI | ARD | -0.13 | 0.07 | 0.15 |
| Women | Trospium | Dry mouth | Inclusion of minorities | ARD | -0.13 | 0.07 | 0.15 |
| Women | Trospium | Dry mouth | Inclusion of mixed UI | ARD | 0.04 | 0.02 | 0.14 |
| Women | Trospium | Dry mouth | Inclusion of prior failures | ARD | -0.03 | 0.06 | 0.66 |
| Women | Trospium | Dry mouth | Rate in placebo group* | ARD | 3.28 | 0.85 | 0.02 |

*Significant at 95% C; ARD-absolute risk difference; RR-relative risk

**Appendix Table F48. Severity and quality of life after oxybutynin (individual RCTs)**

| Reference | Active | Dose | Active N | Control N | Active Mean+/- Standard Deviation | Control Mean+/- Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| **Anxiety** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 44.5+/-12.3 | 45.8+/-12.9 | -1.3 (-6.3; 3.7) |
| **Depression** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 50.6+/-10.7 | 51.4+/-11.2 | -0.8 (-5.2; 3.6) |
| **Emotions** | | | | | | | |
| Homma, 2006[301] | Oxytrol | Transdermal patch 39cm$^2$ | 164 | 161 | 24.9+/-21.6 | 35.2+/-28.4 | -10.3 (-15.8; -4.8) |
| Homma, 2004[302] | Oxybutynin IR | 3mg thrice daily | 122 | 57 | 26.7+/-27.9 | 37.1+/-30.7 | -10.4 (-19.8; -1.0) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 26cm$^2$ | 160 | 161 | 28.2+/-25.8 | 35.2+/-28.4 | -7.0 (-12.9; -1.1) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 52cm$^2$ | 152 | 161 | 29.3+/-26.7 | 35.2+/-28.4 | -5.9 (-12.0; 0.2) |
| **Estimate of percent improvement** | | | | | | | |
| Burgio, 1998[237] | Oxybutynin | 2.5-5mg thrice daily | 67 | 65 | 66.4+/-35.4 | 45.1+/-36.6 | 21.3 (9.0; 33.6) |
| **General health** | | | | | | | |
| Homma, 2006[301] | Oxytrol | Transdermal patch 39cm$^2$ | 164 | 161 | 30.9+/-22.2 | 33.0+/-22.7 | -2.1 (-7.0; 2.8) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 26cm$^2$ | 160 | 161 | 33.4+/-20.3 | 33.0+/-22.7 | 0.4 (-4.3; 5.1) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 52cm$^2$ | 152 | 161 | 33.9+/-21.6 | 33.0+/-22.7 | 0.9 (-4.0; 5.8) |
| **General health perception** | | | | | | | |
| Homma, 2004[302] | Oxybutynin IR | 3mg thrice daily | 122 | 57 | 34.6+/-20.9 | 32.9+/-21.2 | 1.7 (-4.9; 8.3) |
| **Global severity** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 50.4+/-10.0 | 51.4+/-10.9 | -1.0 (-5.2; 3.2) |
| **Hostility** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 44.6+/-10.5 | 47.3+/-11.2 | -2.7 (-7.0; 1.6) |
| **Incontinence impact** | | | | | | | |
| Homma, 2006[301] | Oxytrol | Transdermal patch 39cm$^2$ | 164 | 161 | 32.7+/-23.6 | 39.7+/-26.0 | -7.0 (-12.4; -1.6) |
| Homma, 2004[302] | oxybutynin-IR | 3mg thrice daily | 122 | 57 | 33.9+/-29.4 | 46.2+/-28.0 | -12.3 (-21.2; -3.4) |
| Homma, 2006[301] | Oxytrol | transdermal patch 52cm$^2$ | 152 | 161 | 34.0+/-24.4 | 39.7+/-26.0 | -5.7 (-11.3; -0.1) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 26cm2 | 160 | 161 | 34.6+/-23.2 | 39.7+/-26.0 | -5.1 (-10.5; 0.3) |
| **Interpersonal sensitivity** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 48.9+/-11.2 | 49.2+/-11.3 | -0.3 (-4.8; 4.2) |
| **Mean total UDI score** | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 3.9mg | 125 | 132 | 78.8+/-51.9 | 94.7+/-50.0 | -15.9 (-28.4; -3.4) |
| **Obsessive-compulsive** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 53.9+/-10.9 | 55.4+/-11.0 | -1.5 (-5.8; 2.8) |
| **Paranoid ideation** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 47.2+/-11.6 | 47.2+/-12.0 | 0.0 (-4.7; 4.7) |
| **Personal relationship** | | | | | | | |
| Homma, 2006[301] | Oxytrol | Transdermal patch 39cm$^2$ | 164 | 161 | 8.4+/-16.8 | 12.0+/-20.2 | -3.6 (-7.6; 0.4) |

**Appendix Table F48. Severity and quality of life after oxybutynin (individual RCTs) (continued)**

| Reference | Active | Dose | Active N | Control N | Active Mean+/- Standard Deviation | Control Mean+/- Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Homma, 2006[301] | Oxytrol | Transdermal patch 26cm$^2$ | 160 | 161 | 10.4+/-17.3 | 12.0+/-20.2 | -1.6 (-5.7; 2.5) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 52cm$^2$ | 152 | 161 | 11.6+/-22.1 | 12.0+/-20.2 | -0.4 (-5.1; 4.3) |
| Homma, 2004[302] | oxybutynin-IR | 3mg thrice daily | 122 | 57 | 3.5+/-9.6 | 10.3+/-19.8 | -6.8 (-12.2; -1.4) |
| **Phobia** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 45.0+/-8.3 | 45.1+/-8.5 | -0.1 (-3.4; 3.2) |
| **Physical limitation** | | | | | | | |
| Homma, 2006[301] | Oxytrol | Transdermal patch 39cm$^2$ | 164 | 161 | 26.6+/-22.8 | 36.5+/-27.5 | -9.9 (-15.4; -4.4) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 26cm$^2$ | 160 | 161 | 29.7+/-25.6 | 36.5+/-27.5 | -6.8 (-12.6; -1.0) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 52cm$^2$ | 152 | 161 | 29.7+/-27.3 | 36.5+/-27.5 | -6.8 (-12.9; -0.7) |
| Homma, 2004[302] | oxybutynin-IR | 3mg thrice daily | 122 | 57 | 20.6+/-24.4 | 35.7+/-29.3 | -15.1 (-23.9; -6.3) |
| **Psychoticism** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 50.4+/-9.7 | 49.6+/-10.3 | 0.8 (-3.2; 4.8) |
| **Role limitation** | | | | | | | |
| Homma, 2006[301] | Oxytrol | Transdermal patch 39cm$^2$ | 164 | 161 | 22.0+/-20.3 | 31.9+/-24.1 | -9.9 (-14.7; -5.1) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 26cm$^2$ | 160 | 161 | 24.8+/-22.0 | 31.9+/-24.1 | -7.1 (-12.1; -2.1) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 52cm$^2$ | 152 | 161 | 26.5+/-24.7 | 31.9+/-24.1 | -5.4 (-10.8; 0.0) |
| Homma, 2004[302] | Oxybutynin IR | 3mg thrice daily | 122 | 57 | 18.6+/-21.0 | 28.7+/-26.9 | -10.1 (-18.0; -2.2) |
| **Severity (coping) measure** | | | | | | | |
| Homma, 2004[302] | oxybutynin IR | 3mg thrice daily | 122 | 57 | 19.4+/-18.9 | 29.7+/-21.5 | -10.3 (-16.8; -3.8) |
| **Sleep and energy** | | | | | | | |
| Homma, 2004[302] | oxybutynin IR | 3mg thrice daily | 122 | 57 | 17.2+/-21.4 | 29.2+/-29.4 | -12.0 (-20.5; -3.5) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 39cm$^2$ | 164 | 161 | 17.9+/-18.9 | 26.0+/-25.6 | -8.1 (-13.0; -3.2) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 26cm$^2$ | 160 | 161 | 18.2+/-19.2 | 26.0+/-25.6 | -7.8 (-12.7; -2.9) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 52cm$^2$ | 152 | 161 | 21.1+/-22.8 | 26.0+/-25.6 | -4.9 (-10.3; 0.5) |
| **Social limitation** | | | | | | | |
| Homma, 2006[301] | Oxytrol | Transdermal patch 39cm$^2$ | 164 | 161 | 13.2+/-17.1 | 21.6+/-24.2 | -8.4 (-13.0; -3.8) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 26cm$^2$ | 160 | 161 | 16.3+/-21.3 | 21.6+/-24.2 | -5.3 (-10.3; -0.3) |
| Homma, 2006[301] | Oxytrol | Transdermal patch 52cm$^2$ | 152 | 161 | 18.4+/-22.8 | 21.6+/-24.2 | -3.2 (-8.4; 2.0) |
| Homma, 2004[302] | oxybutynin-IR | 3mg thrice daily | 122 | 57 | 14.0+/-22.1 | 21.0+/-26.3 | -7.0 (-14.9; 0.9) |
| **Summarization** | | | | | | | |
| Burgio, 2001[235] | Oxybutynin | 2.5 to 5mg thrice daily | 52 | 46 | 51.2+/-9.8 | 49.8+/-13.0 | 1.4 (-3.2; 6.0) |
| **Symptom severity** | | | | | | | |
| Homma, 2004[302] | oxybutynin-IR | 3mg thrice daily | 122 | 57 | 16.4+/-13.6 | 26.6+/-16.4 | -10.2 (-15.1; -5.3) |

**Appendix Table F49. Domains of quality of life after oxybutynin treatments (individual RCTs)**

| Reference | Active | Control | Active N | Control N | Active Mean+/- Standard Deviation | Control Mean+/- Standard Deviation | Mean Difference (95%CI) |
|---|---|---|---|---|---|---|---|
| **Personal relationship** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 39cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 164 | 152 | 8.4+/-16.8 | 11.6+/-22.1 | -3.2 (-7.6; 1.2) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 39cm$^2$ | 160 | 164 | 10.4+/-17.3 | 8.4+/-16.8 | 2.0 (-1.7; 5.7) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 160 | 152 | 10.4+/-17.3 | 11.6+/-22.1 | -1.2 (-5.6; 3.2) |
| **Social limitation** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 39cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 164 | 152 | 13.2+/-17.1 | 18.4+/-22.8 | -5.2 (-9.7; -0.7) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 39cm$^2$ | 160 | 164 | 16.3+/-21.3 | 13.2+/-17.1 | 3.1 (-1.1; 7.3) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 160 | 152 | 16.3+/-21.3 | 18.4+/-22.8 | -2.1 (-7.0; 2.8) |
| **Sleep/energy** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 39cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 164 | 152 | 17.9+/-18.9 | 21.1+/-22.8 | -3.2 (-7.8; 1.4) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 39cm$^2$ | 160 | 164 | 18.2+/-19.2 | 17.9+/-18.9 | 0.3 (-3.8; 4.4) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 160 | 152 | 18.2+/-19.2 | 21.1+/-22.8 | -2.9 (-7.6; 1.8) |
| **Role limitation** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 39cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 164 | 152 | 22.0+/-20.3 | 26.5+/-24.7 | -4.5 (-9.5; 0.5) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 39cm$^2$ | 160 | 164 | 24.8+/-22.0 | 22.0+/-20.3 | 2.8 (-1.8; 7.4) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 160 | 152 | 24.8+/-22.0 | 26.5+/-24.7 | -1.7 (-6.9; 3.5) |
| **Emotions** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 39cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 164 | 152 | 24.9+/-21.6 | 29.3+/-26.7 | -4.4 (-9.8; 1.0) |
| **Physical limitation** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 39cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 164 | 152 | 26.6+/-22.8 | 29.7+/-27.3 | -3.1 (-8.7; 2.5) |
| **Emotions** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 39cm$^2$ | 160 | 164 | 28.2+/-25.8 | 24.9+/-21.6 | 3.3 (-1.9; 8.5) |

**Appendix Table F49. Domains of quality of life after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active | Control | Active N | Control N | Active Mean+/- Standard Deviation | Control Mean+/- Standard Deviation | Mean Difference (95%CI) |
|---|---|---|---|---|---|---|---|
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 160 | 152 | 28.2+/-25.8 | 29.3+/-26.7 | -1.1 (-6.9; 4.7) |
| **Physical limitation** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 39cm$^2$ | 160 | 164 | 29.7+/-25.6 | 26.6+/-22.8 | 3.1 (-2.2; 8.4) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 160 | 152 | 29.7+/-25.6 | 29.7+/-27.3 | 0.0 (-5.9; 5.9) |
| **General health** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 39cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 164 | 152 | 30.9+/-22.2 | 33.9+/-21.6 | -3.0 (-7.8; 1.8) |
| **Incontinence impact** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 39cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 164 | 152 | 32.7+/-23.6 | 34.0+/-24.4 | -1.3 (-6.6; 4.0) |
| **General health** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 39cm$^2$ | 160 | 164 | 33.4+/-20.3 | 30.9+/-22.2 | 2.5 (-2.1; 7.1) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 160 | 152 | 33.4+/-20.3 | 33.9+/-21.6 | -0.5 (-5.2; 4.2) |
| **Incontinence impact** | | | | | | | |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 39cm$^2$ | 160 | 164 | 34.6+/-23.2 | 32.7+/-23.6 | 1.9 (-3.2; 7.0) |
| Homma, 2006[301] | Oxytrol-Oxybutynin transdermal patch 26cm$^2$ | Oxybutynin transdermal patch 52cm$^2$ | 160 | 152 | 34.6+/-23.2 | 34.0+/-24.4 | 0.6 (-4.7; 5.9) |
| **Mean reduction in IIQ score** | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS, 2.6mg | Oxybutynin TDS3.9mg | 133 | 125 | -85.1+/-72.7 | -64.2+/-82.9 | -20.9 (-40.0; -1.8) |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Continence** | | | | | | | | | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 8/38 | 10/38 | 0.80 (0.35; 1.81) | -0.05 (-0.24; 0.14) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 4/53 | 7/52 | 0.56 (0.17; 1.80) | -0.06 (-0.18; 0.06) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 4/53 | 5/52 | 0.78 (0.22; 2.76) | -0.02 (-0.13; 0.09) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 2/53 | 3/52 | 0.65 (0.11; 3.76) | -0.02 (-0.10; 0.06) | | |
| **Adverse events** | | | | | | | | | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 22/53 | 21/52 | 1.03 (0.65; 1.63) | 0.01 (-0.18; 0.20) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 22/53 | 21/52 | 1.03 (0.65; 1.63) | 0.01 (-0.18; 0.20) | | |
| **Continence** | | | | | | | | | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 6/53 | 4/52 | 1.47 (0.44; 4.92) | 0.04 (-0.08; 0.15) | | |
| **Efficacy** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 22/77 | 26/77 | 0.85 (0.53; 1.36) | -0.05 (-0.20; 0.09) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 27/77 | 28/77 | 0.96 (0.63; 1.47) | -0.01 (-0.16; 0.14) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 71/77 | 61/77 | 1.16 (1.02; 1.33) | 0.13 (0.02; 0.24) | 8 (4; 47) | 130 (21; 238) |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 22/77 | 42/83 | 0.56 (0.37; 0.85) | -0.22 (-0.37; -0.07) | -5 (-14; -3) | -220 (-368; -73) |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 27/77 | 43/83 | 0.68 (0.47; 0.98) | -0.17 (-0.32; -0.02) | -6 (-62; -3) | -167 (-319; -16) |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 71/77 | 68/83 | 1.13 (1.00; 1.27) | 0.10 (0.00; 0.20) | 10 (5; 1567) | 103 (1; 205) |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 26/77 | 42/83 | 0.67 (0.46; 0.97) | -0.17 (-0.32; -0.02) | -6 (-57; -3) | -168 (-319; -18) |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 28/77 | 43/83 | 0.70 (0.49; 1.01 | -0.15 (-0.31; 0.00 | -6 (-408; -3) | -154 (-306; -2) |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 61/77 | 68/83 | 0.97 (0.83; 1.13) | -0.03 (-0.15; 0.10) | | |
| **Adverse effects** | | | | | | | | | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 25/38 | 13/38 | 1.92 (1.17; 3.16) | 0.32 (0.10; 0.53) | 3 2; 10) | 316 (102; 529) |
| Gupta, 1999[288] | OROS oxybutynin chloride | 5mg once daily | Immediate-release oxybutynin-Ditropan | 5mg thrice daily | 6/13 | 12/13 | 0.50 (0.27; 0.92) | -0.46 (-0.77; -0.15) | -2 (-6; -1) | -462 (-769; -154) |
| **Undefined** | | | | | | | | | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 3/27 | 4/39 | 1.08 (0.26; 4.46) | 0.01 (-0.14; 0.16) | | |
| **Adverse effects** | | | | | | | | | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 14/38 | 2/38 | 7.00 (1.71; 28.72) | 0.32 (0.15; 0.48) | 3( 2; 7) | 316 (147; 485) |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 46/53 | 49/52 | 0.92 (0.81; 1.04) | -0.07 (-0.19; 0.04) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 46/53 | 49/52 | 0.92 (0.81; 1.04) | -0.07 (-0.19; 0.04) | | |
| **Discontinuation** | | | | | | | | | | |
| Preik, 2004[386] | OROS-oxybutynin controlled release | 5-30mg/day | immediate-release oxybutynin | 5-20mg/day | 5/53 | 5/52 | 0.98 (0.30; 3.19) | 0.00 (-0.11; 0.11) | | |
| **Withdrawal** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 3/77 | 11/77 | 0.27 (0.08; 0.94) | -0.10 (-0.19; -0.01) | -10 (-69; -5) | -104 (-193; -15) |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 4/77 | 4/77 | 1.00 (0.26; 3.86) | 0.00 (-0.07; 0.07) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 3/77 | 12/83 | 0.27 (0.08; 0.92) | -0.11 -0.19; -0.02) | -9 (-54; -5) | -106 (-193; -18) |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 11/77 | 12/83 | 0.99 (0.46; 2.11) | 0.00 (-0.11; 0.11) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 4/77 | 2/83 | 2.16 (0.41; 11.44) | 0.03 (-0.03; 0.09) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 4/77 | 2/83 | 2.16 (0.41; 11.44) | 0.03 (-0.03; 0.09) | | |
| **Blurred vision** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 1/77 | 1/77 | 1.00 (0.06; 15.70) | 0.00 (-0.04; 0.04) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 1/77 | 1/83 | 1.08 (0.07; 16.94) | 0.00 (-0.03; 0.04) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 1/77 | 1/83 | 1.08 (0.07; 16.94) | 0.00 (-0.03; 0.04) | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 7/38 | 9/38 | 0.78 (0.32; 1.87) | -0.05 (-0.24; 0.13) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 15/53 | 9/52 | 1.64 (0.79; 3.40) | 0.11 (-0.05; 0.27) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 15/53 | 9/52 | 1.64 (0.79; 3.40) | 0.11 (-0.05; 0.27) | | |
| **Treatment compliance** | | | | | | | | | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 11/27 | 11/39 | 1.44 (0.73; 2.84) | 0.13 (-0.11; 0.36) | | |
| **Constipation** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 7/130 | 3/133 | 2.39 (0.63; 9.03) | 0.03 (-0.01; 0.08) | | |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 3.9mg | 7/130 | 1/125 | 6.73 (0.84; 53.92) | 0.05 (0.00; 0.09) | 22 (11; 249) | 46 (4; 88) |
| Dmochowski, 2002[269] | Oxybutynin TDS | 2.6mg | Oxybutynin TDS | 3.9mg | 3/133 | 1/125 | 2.82 (0.30; 26.75) | 0.01 (-0.02; 0.04) | | |
| Dmochowski, 2002[269] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 4/77 | 3/77 | 1.33 (0.31; 5.76) | 0.01 (-0.05; 0.08) | | |
| Dmochowski, 2002[269] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 4/77 | 4/83 | 1.08 (0.28; 4.16) | 0.00 (-0.06; 0.07) | | |
| Dmochowski, 2002[269] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 3/77 | 4/83 | 0.81 (0.19; 3.50 | -0.01 (-0.07; 0.05 | | |
| Dmochowski, 2002[269] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 8/38 | 19/38 | 0.42 (0.21; 0.84) | -0.29 (-0.49; -0.08) | -3 (-12; -2) | -289 (-495; -84) |
| Dmochowski, 2002[269] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 16/53 | 16/52 | 0.98 (0.55; 1.75) | -0.01 (-0.18; 0.17) | | |
| **Constipation** | | | | | | | | | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 16/53 | 16/52 | 0.98 (0.55; 1.75) | -0.01 (-0.18; 0.17) | | |
| **Dizziness** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 3.9mg | 2/130 | 5/125 | 0.38 (0.08; 1.95) | -0.02 (-0.06; 0.02) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 2.6mg | Oxybutynin TDS | 3.9mg | 4/133 | 5/125 | 0.75 (0.21; 2.74) | -0.01 (-0.05; 0.04) | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 0/27 | 2/39 | 0.29 (0.01; 5.73) | -0.05 (-0.14; 0.04) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 5/77 | 6/77 | 0.83 (0.27; 2.62) | -0.01 (-0.09; 0.07) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 5/77 | 6/83 | 0.90 (0.29; 2.82) | -0.01 (-0.09; 0.07) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 6/77 | 6/83 | 1.08 (0.36; 3.20) | 0.01 (-0.08; 0.09) | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate | 5mg twice/thrice | 6/38 | 10/38 | 0.60 (0.24; 1.49) | -0.11 (-0.29; 0.08) | | |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | release | daily or 7.5mg thrice daily | | | | | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 15/53 | 20/52 | 0.74 (0.42; 1.27) | -0.10 (-0.28; 0.08) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 15/53 | 20/52 | 0.74 (0.42; 1.27) | -0.10 (-0.28; 0.08) | | |
| **Maximum dosage reached** | | | | | | | | | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 26/38 | 12/38 | 2.17 (1.29; 3.63) | 0.37 (0.16; 0.58) | 3( 2; 6) | 368 (159; 577) |
| **Dry eyes** | | | | | | | | | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 0/27 | 1/39 | 0.48 (0.02; 11.27) | -0.03 (-0.10; 0.05) | | |
| **Worse dry mouth on completion of treatment** | | | | | | | | | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 2/38 | 13/38 | 0.15 (0.04; 0.64) | -0.29 (-0.46; -0.12) | -3 (-8; -2) | -289 (-456; -123) |
| **Dry mouth** | | | | | | | | | | |
| Gupta, 1999[288] | OROS oxybutynin chloride | 5mg once daily | Immediate-release oxybutynin-Ditropan | 5mg thrice daily | 6/13 | 10/13 | 0.60 (0.31; 1.16) | -0.31 (-0.66; 0.05) | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 1/27 | 4/39 | 0.36 (0.04; 3.06) | -0.07 (-0.18; 0.05) | | |
| **Moderate to severe dry mouth** | | | | | | | | | | |
| Versi, 2000[42] | CR-Oxybutynin | 5mg/day | IR-Oxybutynin | 5mg/day | 4/111 | 8/115 | 0.52 (0.16; 1.67) | -0.03 (-0.09; 0.02) | | |
| **Dry mouth** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 43/77 | 52/77 | 0.83 (0.64; 1.06) | -0.12 (-0.27; 0.04) | | |
| **Severe dry mouth** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 2/77 | 11/77 | 0.18 (0.04; 0.79) | -0.12 (-0.20; -0.03) | -9 (-32; -5) | -117 (-203; -31) |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Dry mouth** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 43/77 | 58/83 | 0.80 (0.63; 1.02) | -0.14 (-0.29; 0.01) | | |
| **Severe dry mouth** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 2/77 | 4/83 | 0.54 (0.10; 2.86) | -0.02 (-0.08; 0.04) | | |
| **Dry mouth** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 52/77 | 58/83 | 0.97 (0.78; 1.19) | -0.02 (-0.17; 0.12) | | |
| **Severe dry mouth** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 11/77 | 4/83 | 2.96 (0.99; 8.92) | 0.09 (0.00; 0.19) | 11 (5; 254) | 95 (4; 185) |
| **Dry mouth of any severity** | | | | | | | | | | |
| Preik, 2004[386] | OROS-oxybutynin controlled release | 5-30mg/day | immediate-release oxybutynin | 5-20mg/day | 31/53 | 41/52 | 0.74 (0.57; 0.97) | -0.20 (-0.38; -0.03) | -5( -33; -3) | -204 (-377; -31) |
| **Moderate or severe dry mouth** | | | | | | | | | | |
| Preik, 2004[386] | OROS-oxybutynin controlled release | 5-30mg/day | immediate-release oxybutynin | 5-20mg/day | 12/53 | 22/52 | 0.53 (0.29; 0.95) | -0.20 (-0.38; -0.03) | -5 (-37; -3) | -201 (-375; -27) |
| **Dose titration endpoint-MTD-dry mouth** | | | | | | | | | | |
| Preik, 2004[386] | OROS-oxybutynin controlled release | 5-30mg/day | immediate-release oxybutynin | 5-20mg/day | 7/53 | 13/52 | 0.53 (0.23; 1.22) | -0.12 (-0.27; 0.03) | | |
| **Dose titration endpoint-MED-dry mouth** | | | | | | | | | | |
| Preik, 2004[386] | OROS-oxybutynin controlled release | 5-30mg/day | immediate-release oxybutynin | 5-20mg/day | 3/53 | 7/52 | 0.42 (0.11; 1.54) | -0.08 (-0.19; 0.03) | | |
| **Moderate dry mouth** | | | | | | | | | | |
| Preik, 2004[386] | OROS-oxybutynin controlled | 5-30mg/day | immediate-release oxybutynin | 5-20mg/day | 1/53 | 4/52 | 0.25 (0.03; 2.12) | -0.06 (-0.14; 0.02) | | |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| | release | | | | | | | | | |
| **Dose titration endpoint-MAD-dry mouth** | | | | | | | | | | |
| Preik, 2004[386] | OROS-oxybutynin controlled release | 5-30mg/day | immediate-release oxybutynin | 5-20mg/day | 1/53 | 1/52 | 0.98 (0.06; 15.28) | 0.00 (-0.05; 0.05) | | |
| **Moderate to severe dry mouth** | | | | | | | | | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 3/53 | 11/52 | 0.27 (0.08; 0.90) | -0.15 (-0.28; -0.03) | -6 (-36; -4) | -155 (-282; -28) |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 5/53 | 10/52 | 0.49 (0.18; 1.34) | -0.10 (-0.23; 0.03) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 7/53 | 10/52 | 0.69 (0.28; 1.67) | -0.06 (-0.20; 0.08) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 2/53 | 4/52 | 0.49 (0.09; 2.56) | -0.04 (-0.13; 0.05) | | |
| **Dry mouth** | | | | | | | | | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 15/38 | 31/38 | 0.48 (0.32; 0.74) | -0.42 (-0.62; -0.22) | -2 (-4; -2) | -421 (-619; -223) |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 36/53 | 45/52 | 0.78 (0.63; 0.97) | -0.19 (-0.34; -0.03) | -5 (-33; -3) | -186 (-342; -30) |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 36/53 | 45/52 | 0.78 (0.63; 0.97) | -0.19 (-0.34; -0.03) | -5 (-33; -3) | -186 (-342; -30) |
| **Moderate to severe dry mouth** | | | | | | | | | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 13/53 | 24/52 | 0.53 (0.30; 0.93) | -0.22 (-0.39; -0.04) | -5 (-26; -3) | -216 (-395; -38) |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 13/53 | 24/52 | 0.53 (0.30; 0.93) | -0.22 (-0.39; -0.04) | -5 (-26; -3) | -216 (-395; -38) |
| **Dry nose** | | | | | | | | | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 0/27 | 1/39 | 0.48 (0.02; 11.27) | -0.03 (-0.10; 0.05) | | |
| **Dry throat** | | | | | | | | | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 2/27 | 0/39 | 7.14 (0.36; 143.14) | 0.07 (-0.04; 0.19) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 21/77 | 32/77 | 0.66 (0.42; 1.03) | -0.14 (-0.29; 0.01) | | |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 21/77 | 24/83 | 0.94 (0.57; 1.55) | -0.02 (-0.16; 0.12) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 32/77 | 24/83 | 1.44 (0.94; 2.21) | 0.13 (-0.02; 0.27) | | |
| **Dyspepsia** | | | | | | | | | | |
| Chancellor, 2001[248] | ER-oxybutynin | 10mg/day | IR-oxybutynin | 5mg/day | 0/36 | 1/36 | 0.33 (0.01; 7.92) | -0.03 (-0.10; 0.05) | | |
| **Dysuria** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 1/130 | 3/133 | 0.34 (0.04; 3.24) | -0.01 (-0.04; 0.01) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 3.9mg | 1/130 | 3/125 | 0.32 (0.03; 3.04) | -0.02 (-0.05; 0.01) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 2.6mg | Oxybutynin TDS | 3.9mg | 3/133 | 3/125 | 0.94 (0.19; 4.57) | 0.00 (-0.04; 0.04) | | |
| **Erythema absent** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 120/130 | 108/133 | 1.14 (1.03; 1.25) | 0.11 (0.03; 0.19) | 9 (5; 33) | 111 (30; 192) |
| **Erythema-mild** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 79/130 | 92/133 | 0.88 (0.73; 1.05) | -0.08 (-0.20; 0.03) | | |
| **Erythema-moderate** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 46/130 | 46/133 | 1.02 (0.74; 1.42) | 0.01 (-0.11; 0.12) | | |
| **Erythema-severe** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 6/130 | 8/133 | 0.77 (0.27; 2.15) | -0.01 (-0.07; 0.04) | | |
| **Halitosis** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 6/77 | 10/77 | 0.60 (0.23; 1.57) | -0.05 (-0.15; 0.04) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 6/77 | 8/83 | 0.81 (0.29; 2.22) | -0.02 (-0.11; 0.07) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 10/77 | 8/83 | 1.35 (0.56; 3.24) | 0.03 (-0.06; 0.13) | | |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Headache** | | | | | | | | | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 0/27 | 1/39 | 0.48 (0.02; 11.27) | -0.03 (-0.10; 0.05) | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 0/27 | 1/39 | 0.48 (0.02; 11.27) | -0.03 (-0.10; 0.05) | | |
| Chancellor, 2001[248] | ER-oxybutynin | 10mg/day | IR-oxybutynin | 5mg/day | 6/36 | 6/36 | 1.00 (0.36; 2.81) | 0.00 (-0.17; 0.17) | | |
| **Impaired urination** | | | | | | | | | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 13/53 | 15/52 | 0.85 (0.45; 1.61) | -0.04 (-0.21; 0.13) | | |
| **Nausea** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 6/130 | 5/133 | 1.23 (0.38; 3.92) | 0.01 (-0.04; 0.06) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 3.9mg | 6/130 | 2/125 | 2.88 (0.59; 14.02) | 0.03 (-0.01; 0.07) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 2.6mg | Oxybutynin TDS | 3.9mg | 5/133 | 2/125 | 2.35 (0.46; 11.89) | 0.02 (-0.02; 0.06) | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 0/27 | 4/39 | 0.16 (0.01; 2.83) | -0.10 (-0.21; 0.01) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 5/77 | 8/77 | 0.63 (0.21; 1.83) | -0.04 (-0.13; 0.05) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 5/77 | 7/83 | 0.77 (0.26; 2.32) | -0.02 (-0.10; 0.06) | | |
| Chancellor, 2001[248] | ER-oxybutynin | 10mg/day | IR-oxybutynin | 5mg/day | 0/36 | 1/36 | 0.33 (0.01; 7.92) | -0.03 (-0.10; 0.05) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 8/77 | 7/83 | 1.23 (0.47; 3.24) | 0.02 (-0.07; 0.11) | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 3/38 | 10/38 | 0.30 (0.09; 1.01) | -0.18 (-0.35; -0.02) | -5 (-50; -3) | -184 (-348; -20) |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 10/53 | 9/52 | 1.09 (0.48; 2.46) | 0.02 (-0.13; 0.16) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 10/53 | 9/52 | 1.09 (0.48; 2.46) | 0.02 (-0.13; 0.16) | | |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Nervousness** | | | | | | | | | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 13/53 | 12/52 | 1.06 (0.54; 2.11) | 0.01 (-0.15; 0.18) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 13/53 | 12/52 | 1.06 (0.54; 2.11) | 0.01 (-0.15; 0.18) | | |
| **Palpitation** | | | | | | | | | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 3/38 | 5/38 | 0.60 (0.15; 2.34) | -0.05 (-0.19; 0.08) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 1/130 | 0/133 | 3.07 (0.13; 74.65) | 0.01 (-0.01; 0.03) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 3.9mg | 1/130 | 1/125 | 0.96 (0.06; 15.21) | 0.00 (-0.02; 0.02) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 2.6mg | Oxybutynin TDS | 3.9mg | 0/133 | 1/125 | 0.31 (0.01; 7.62) | -0.01 (-0.03; 0.01) | | |
| **Urinary retention** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 2/77 | 8/77 | 0.25 (0.05; 1.14) | -0.08 (-0.15; 0.00) | -13 (-938; -6) | -78 (-155; -1) |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 2/77 | 6/83 | 0.36 (0.07; 1.73) | -0.05 (-0.11; 0.02) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 8/77 | 6/83 | 1.44 (0.52; 3.95) | 0.03 (-0.06; 0.12) | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 9/38 | 13/38 | 0.69 (0.34; 1.42) | -0.11 (-0.31; 0.10) | | |
| **Impaired urination** | | | | | | | | | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 9/38 | 9/38 | 1.00 (0.45; 2.24) | 0.00 (-0.19; 0.19) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 13/53 | 15/52 | 0.85 (0.45; 1.61) | -0.04 (-0.21; 0.13) | | |
| **Somnolence** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 1/130 | 0/133 | 3.07 (0.13; 74.65) | 0.01 (-0.01; 0.03) | | |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 3.9mg | 1/130 | 2/125 | 0.48 (0.04; 5.24) | -0.01 (-0.03; 0.02) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 2.6mg | Oxybutynin TDS | 3.9mg | 0/133 | 2/125 | 0.19 (0.01; 3.88) | -0.02 (-0.04; 0.01) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 4/77 | 3/77 | 1.33 (0.31; 5.76) | 0.01 (-0.05; 0.08) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 4/77 | 2/83 | 2.16 (0.41; 11.44) | 0.03 (-0.03; 0.09) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 3/77 | 2/83 | 1.62 (0.28; 9.42) | 0.01 (-0.04; 0.07) | | |
| Davila, 2001[264] | Oxybutynin transdermal | 1.3mg | Oxybutynin-immediate release | 5mg twice/thrice daily or 7.5mg thrice daily | 7/38 | 14/38 | 0.50 (0.23; 1.10) | -0.18 (-0.38; 0.01) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 20/53 | 21/52 | 0.93 (0.58; 1.51) | -0.03 (-0.21; 0.16) | | |
| Anderson, 1999[385] | CR-oxybutynin | 5 to 30mg once daily | IR-oxybutynin | 5mg 1 to 4 times daily | 20/53 | 21/52 | 0.93 (0.58; 1.51) | -0.03 (-0.21; 0.16) | | |
| **Tachycardia** | | | | | | | | | | |
| Salvatore, 2005[365] | Oxybutynin | 2.5 twice daily | Oxybutynin | 5mg nocte | 0/27 | 1/39 | 0.48 (0.02; 11.27) | -0.03 (-0.10; 0.05) | | |
| **Urinary tract infection** | | | | | | | | | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 10mg/day | 8/77 | 9/77 | 0.89 (0.36; 2.18) | -0.01 (-0.11; 0.09) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 5mg/day | Oxybutynin-controlled release | 15mg/day | 8/77 | 13/83 | 0.66 (0.29; 1.51) | -0.05 (-0.16; 0.05) | | |
| Corcos, 2006[263] | Oxybutynin-controlled release | 10mg/day | Oxybutynin-controlled release | 15mg/day | 9/77 | 13/83 | 0.75 (0.34; 1.65) | -0.04 (-0.15; 0.07) | | |
| **Vasodilatation** | | | | | | | | | | |
| Chancellor, 2001[248] | ER-oxybutynin | 10mg/day | IR-oxybutynin | 5mg/day | 0/36 | 0/36 | 0.00 (0.00; 0.00) | 0.00 (-0.05; 0.05) | | |
| **Vision abnormal** | | | | | | | | | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 2.6mg | 3/130 | 2/133 | 1.53 (0.26; 9.03) | 0.01 (-0.03; 0.04) | | |

**Appendix Table F50. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Dmochowski, 2002[269] | Oxybutynin TDS | 1.3mg | Oxybutynin TDS | 3.9mg | 3/130 | 0/125 | 6.73 (0.35; 129.03) | 0.02 (-0.01; 0.05) | | |
| Dmochowski, 2002[269] | Oxybutynin TDS | 2.6mg | Oxybutynin TDS | 3.9mg | 2/133 | 0/125 | 4.70 (0.23; 96.98) | 0.02 (-0.01; 0.04) | | |
| **Vomiting** | | | | | | | | | | |
| Chancellor, 2001[248] | ER-oxybutynin | 10mg/day | IR-oxybutynin | 5mg/day | 1/36 | 2/36 | 0.50 (0.05; 5.27) | -0.03 (-0.12; 0.06) | | |

**Appendix Table F51. Clinical outcomes after tolterodine vs. placebo in secondary data analyses**

| Outcome | Author, year | Dose | Events /Randomized to duloxetine | Events/Randomized to placebo | Relative risk (95%CI) | Absolute risk difference (95%CI) | Number needed to treat (95%CI) | Attributable events (95%CI) |
|---|---|---|---|---|---|---|---|---|
| **Improvement in incontinence** | | | | | | | | |
| improved perceptions of bladder condition | Appell, 1997[223] | 1mg twice daily | 50/121 | 69/176 | 1.05(0.80; 1.40) | 0.02(-0.09; 0.13) | | |
| improved perceptions of bladder condition | Appell, 1997[223] | 2mg twice daily | 246/474 | 69/176 | 1.32(1.08; 1.62) | 0.13(0.04; 0.21) | 8(5; 24) | 127(42; 212) |
| treatment response (primary and secondary efficacy endpoints) | Sand, 2009[366] | 4mg daily | 140/227 | 167/430 | 1.59(1.36; 1.86) | 0.23(0.15; 0.31) | 4(3; 7) | 228(150; 307) |
| Perceived improvement in bladder symptoms | Freeman, 2003[282] | 4mg once daily | 247/398 | 180/374 | 1.19(1.04; 1.37) | 0.09(0.02; 0.16) | 11(6; 48) | 89(21; 156) |
| Perceived improvement in bladder symptoms in females | Freeman, 2003[282] | 4mg once daily | 250/398 | 181/374 | 1.30(1.14; 1.48) | 0.14(0.07; 0.21) | 7(5; 13) | 144(75; 214) |
| global self-evaluation of treatment: "much benefit" | Freeman, 2003[282] | 4mg once daily | 171/398 | 90/374 | 1.53(1.24; 1.88) | 0.16(0.09; 0.23) | 6(4; 12) | 158(86; 231) |
| global self-evaluation of treatment: much benefit | Freeman, 2003[282] | 4mg once daily | 172/398 | 88/374 | 1.84(1.48; 2.28) | 0.20(0.13; 0.26) | 5(4; 8) | 197(132; 262) |
| **Treatment failure** | | | | | | | | |
| No change in urgency perception scale score | Freeman, 2003[282] | 4mg once daily | 203/398 | 212/374 | 0.90(0.79; 1.03) | -0.06(-0.13; 0.01) | | |
| Decrease in urgency perception scale score | Freeman, 2003[282] | 4mg once daily | 22/398 | 44/374 | 0.47(0.29; 0.77) | -0.06(-0.10; -0.02) | -16(-44; -10) | -62(-102; -23) |
| global self-evaluation of treatment: little benefit | Freeman, 2003[282] | 4mg once daily | 138/398 | 118/374 | 1.10(0.90; 1.34) | 0.03(-0.04; 0.10) | | |
| global self-evaluation of treatment: no benefit | Freeman, 2003[282] | 4mg once daily | 88/398 | 168/374 | 0.49(0.40; 0.61) | -0.23(-0.29; -0.16) | -4(-6; -3) | -228(-293; -163) |
| **Increase in urgency perception scale score** | | | | | | | | |
| Freeman, 2003[282] | 4mg once daily | 173/398 | 118/374 | 1.38(1.14; 1.66) | 0.12(0.05; 0.19) | 8(5; 19) | 119(51; 187) | |

**Appendix Table F51. Clinical outcomes after tolterodine vs. placebo in secondary data analyses (continued)**

| Outcome | Author, year | Dose | Events /Randomized to duloxetine | Events/Randomized to placebo | Relative risk (95%CI) | Absolute risk difference (95%CI) | Number needed to treat (95%CI) | Attributable events (95%CI) |
|---|---|---|---|---|---|---|---|---|
| Appell, 1997[223] | 1mg twice daily | 7/121 | 17/176 | 0.60(0.26; 1.40) | -0.04(-0.10; 0.02) | | | |
| discontinued prematurely | Chapple, 2008 [253] | 4mg daily | 9/290 | 6/283 | 1.46(0.53; 4.06) | 0.01(-0.02; 0.04) | | |
| withdrawal due to AE | Appell, 1997[223] | 1mg twice daily | 2/121 | 9/176 | 0.32(0.07; 1.47) | -0.03(-0.07; 0.01) | | |
| withdrawal due to AE | Appell, 1997[223] | 2mg twice daily | 38/474 | 9/176 | 1.57(0.77; 3.18) | 0.03(-0.01; 0.07) | | |
| **Adverse effects** | | | | | | | | |
| abdominal pain | Freeman, 2003[282] | 4mg once daily | 16/398 | 6/374 | 2.51(0.99; 6.34) | 0.02(0.00; 0.05) | 41(21; 964) | 24(1; 47) |
| adverse events | Appell, 1997[223] | 1mg twice daily | 94/121 | 164/176 | 0.83(0.75; 0.92) | -0.15(-0.24; -0.07) | -6(-14; -4) | -155(-238; -72) |
| adverse events | Appell, 1997[223] | 2mg twice daily | 351/474 | 164/176 | 0.79(0.74; 0.85) | -0.19(-0.25; -0.14) | -5(-7; -4) | -191(-246; -137) |
| autonomic nervous system disorder | Appell, 1997[223] | 1mg twice daily | 35/121 | 37/176 | 1.38(0.92; 2.05) | 0.08(-0.02; 0.18) | | |
| autonomic nervous system disorder | Appell, 1997[223] | 2mg twice daily | 204/474 | 37/176 | 2.05(1.51; 2.78) | 0.22(0.15; 0.30) | 5(3; 7) | 220(145; 295) |
| back pain | Sand, 2009[366] | 4mg daily | 1/227 | 1/430 | 1.89(0.12; 30.14) | 0.00(-0.01; 0.01) | | |
| cardiac dysfunction | Appell, 1997[223] | 2mg twice daily | 4/474 | 3/176 | 0.50(0.11; 2.19) | -0.01(-0.03; 0.01) | | |
| cardiovascular adverse events | Appell, 1997[223] | 1mg twice daily | 15/121 | 14/176 | 1.56(0.78; 3.11) | 0.04(-0.03; 0.12) | | |
| cardiovascular adverse events | Appell, 1997[223] | 2mg twice daily | 20/474 | 14/176 | 0.53(0.27; 1.03) | -0.04(-0.08; 0.01) | | |
| constipation | Chapple, 2008 [253] | 4mg daily | 8/290 | 4/283 | 1.95(0.59; 6.41) | 0.01(-0.01; 0.04) | | |

**Appendix Table F51. Clinical outcomes after tolterodine vs. placebo in secondary data analyses (continued)**

| Outcome | Author, year | Dose | Events /Randomized to duloxetine | Events/Randomized to placebo | Relative risk (95%CI) | Absolute risk difference (95%CI) | Number needed to treat (95%CI) | Attributable events (95%CI) |
|---|---|---|---|---|---|---|---|---|
| constipation | Sand, 2009[366] | 4mg daily | 6/227 | 10/430 | 1.14(0.42; 3.09) | 0.00(-0.02; 0.03) | | |
| constipation | Freeman, 2003[282] | 4mg once daily | 23/398 | 16/374 | 1.35(0.73; 2.52) | 0.02(-0.02; 0.05) | | |
| cough | Sand, 2009[366] | 4mg daily | 5/227 | 3/430 | 3.16(0.76; 13.09) | 0.02(-0.01; 0.04) | | |
| diarrhea | Sand, 2009[366] | 4mg daily | 3/227 | 10/430 | 0.57(0.16; 2.04) | -0.01(-0.03; 0.01) | | |
| diarrhea | Freeman, 2003[282] | 4mg once daily | 8/398 | 7/374 | 1.07(0.39; 2.93) | 0.00(-0.02; 0.02) | | |
| dizziness | Sand, 2009[366] | 4mg daily | 4/227 | 9/430 | 0.84(0.26; 2.70) | 0.00(-0.03; 0.02) | | |
| dose reduction in case of intolerance | Appell, 1997[223] | 2mg twice daily | 43/474 | 7/176 | 2.28(1.05; 4.98) | 0.05(0.01; 0.09) | 20(11; 82) | 51(12; 90) |
| dry eye | Chapple, 2008 [253] | 4mg daily | 1/290 | 0/283 | 2.93(0.12; 71.57) | 0.00(-0.01; 0.01) | | |
| dry eye | Sand, 2009[366] | 4mg daily | 1/227 | 0/430 | 5.67(0.23; 138.65) | 0.00(-0.01; 0.02) | | |
| dry mouth | Chapple, 2008 [253] | 4mg daily | 49/290 | 20/283 | 2.39(1.46; 3.92) | 0.10(0.05; 0.15) | 10(7; 22) | 98(46; 151) |
| dry mouth | Sand, 2009[366] | 4mg daily | 37/227 | 32/430 | 2.19(1.40; 3.42) | 0.09(0.03; 0.14) | 11(7; 29) | 89(35; 143) |
| dry mouth | Freeman, 2003[282] | 4mg once daily | 95/398 | 28/374 | 3.19(2.14; 4.74) | 0.16(0.11; 0.21) | 6(5; 9) | 164(114; 213) |
| dry throat | Chapple, 2008 [253] | 4mg daily | 3/290 | 0/283 | 6.83(0.35; 131.66) | 0.01(0.00; 0.02) | | |
| dry throat | Sand, 2009[366] | 4mg daily | 2/227 | 0/430 | 9.45(0.46; 196.04) | 0.01(-0.01; 0.02) | | |
| fatigue | Chapple, 2008 [253] | 4mg daily | 10/290 | 1/283 | 9.76(1.26; 75.74) | 0.03(0.01; 0.05) | 32(19; 113) | 31(9; 53) |
| fatigue | Sand, 2009[366] | 4mg daily | 7/227 | 2/430 | 6.63(1.39; 31.65) | 0.03(0.00; 0.05) | 38(20; 358) | 26(3; 50) |
| gastrointestinal disorder | Appell, 1997[223] | 1mg twice daily | 27/121 | 48/176 | 0.82(0.54; 1.23) | -0.05(-0.15; 0.05) | | |

**Appendix Table F51. Clinical outcomes after tolterodine vs. placebo in secondary data analyses (continued)**

| Outcome | Author, year | Dose | Events /Randomized to duloxetine | Events/Randomized to placebo | Relative risk (95%CI) | Absolute risk difference (95%CI) | Number needed to treat (95%CI) | Attributable events (95%CI) |
|---|---|---|---|---|---|---|---|---|
| gastrointestinal disorder | Appell, 1997[223] | 2mg twice daily | 123/474 | 48/176 | 0.95(0.72; 1.27) | -0.01(-0.09; 0.06) | | |
| headache | Sand, 2009[366] | 4mg daily | 13/227 | 18/430 | 1.37(0.68; 2.74) | 0.02(-0.02; 0.05) | | |
| headache | Freeman, 2003[282] | 4mg once daily | 23/398 | 14/374 | 1.54(0.81; 2.95) | 0.02(-0.01; 0.05) | | |
| increased alanine aminotransferase | Chapple, 2008 [253] | 4mg daily | 0/290 | 1/283 | 0.33(0.01; 7.95) | 0.00(-0.01; 0.01) | | |
| moderate or severe dry mouth | Appell, 1997[223] | 1mg twice daily | 5/121 | 11/176 | 0.66(0.24; 1.85) | -0.02(-0.07; 0.03) | | |
| moderate or severe dry mouth | [223] | 2mg twice daily | 81/474 | 11/176 | 2.73(1.49; 5.01) | 0.11(0.06; 0.16) | 9(6; 17) | 108(59; 158) |
| nasopharyngitis | Chapple, 2008 [253] | 4mg daily | 10/290 | 7/283 | 1.39(0.54; 3.61) | 0.01(-0.02; 0.04) | | |
| naspharyngitis | Sand, 2009[366] | 4mg daily | 8/227 | 12/430 | 1.26(0.52; 3.04) | 0.01(-0.02; 0.04) | | |
| nausea | Chapple, 2008 [253] | 4mg daily | 6/290 | 1/283 | 5.86(0.71; 48.33) | 0.02(0.00; 0.03) | | |
| nausea | Sand, 2009[366] | 4mg daily | 3/227 | 5/430 | 1.14(0.27; 4.71) | 0.00(-0.02; 0.02) | | |
| nausea | Freeman, 2003[282] | 4mg once daily | 5/398 | 5/374 | 0.94(0.27; 3.22) | 0.00(-0.02; 0.02) | | |
| palpitations | Appell, 1997[223] | 1mg twice daily | 8/121 | 4/176 | 2.91(0.90; 9.45) | 0.04(-0.01; 0.09) | | |
| palpitations | Appell, 1997[223] | 2mg twice daily | 2/474 | 4/176 | 0.19(0.03; 1.00) | -0.02(-0.04; 0.00) | | |
| serious adverse events | Appell, 1997[223] | 2mg twice daily | 19/474 | 5/176 | 1.41(0.53; 3.72) | 0.01(-0.02; 0.04) | | |
| URI | Sand, 2009[366] | 4mg daily | 2/227 | 9/430 | 0.42(0.09; 1.93) | -0.01(-0.03; 0.01) | | |

**Appendix Table F51. Clinical outcomes after tolterodine vs. placebo in secondary data analyses (continued)**

| Outcome | Author, year | Dose | Events /Randomized to duloxetine | Events/Randomized to placebo | Relative risk (95%CI) | Absolute risk difference (95%CI) | Number needed to treat (95%CI) | Attributable events (95%CI) |
|---|---|---|---|---|---|---|---|---|
| urinary tract infection | Freeman, 2003[282] | 4mg once daily | 7/398 | 12/374 | 0.55(0.22; 1.38) | -0.01(-0.04; 0.01) | | |
| UTI | Sand, 2009[366] | 4mg daily | 4/227 | 17/430 | 0.45(0.15; 1.31) | -0.02(-0.05; 0.00) | | |
| Dry mouth | Freeman, 2003[282] | 4mg once daily | 15/398 | 7/374 | 2.01(0.83; 4.88) | 0.02(0.00; 0.04) | | |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Improvement in UI | Appell, 1997[223] Pooled analysis | 1mg twice daily vs. 2mg daily | 50/121 | 246/474 | 0.80 (0.63; 1.00) | -0.11 (-0.20; -0.01) | -9 (-139; -5) | -106 (-204; -7) |
| Completed the study | Malone-Lee, 2006[340] RCT | 1mg twice daily vs. 2mg twice daily | 53/61 | 64/73 | 0.99 (0.87; 1.13) | -0.01 (-0.12; 0.11) | | |
| Withdrew from study | Appell, 1997[223] Pooled analysis | 1mg twice daily vs. 2mg daily | 7/121 | 63/474 | 0.44 (0.20; 0.93) | -0.08 (-0.13; -0.02) | -13 (-43; -8) | -75 (-127; -23) |
| Withdrew from study | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg twice daily | 27/507 | 28/514 | 0.98 (0.58; 1.63) | 0.00 (-0.03; 0.03) | | |
| Withdrew due to adverse events | Appell, 1997[223] Pooled analysis | 1mg twice daily vs. 2mg daily | 2/121 | 38/474 | 0.21 (0.05; 0.84) | -0.06 (-0.10; -0.03) | -16 (-33; -10) | -64 (-97; -30) |
| Withdrew due to adverse events | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 15/193 | 19/399 | 1.63 (0.85; 3.14) | 0.03 (-0.01; 0.07) | | |
| Withdrew due to adverse events | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 4/61 | 7/73 | 0.68 (0.21; 2.23) | -0.03 (-0.12; 0.06) | | |
| Withdrew due to adverse events | Jacquetin, 2001[308] RCT | 1mg twice daily vs. 2mg twice daily | 3/97 | 2/103 | 1.59 (0.27; 9.33) | 0.01 (-0.03; 0.06) | | |
| All adverse events | Jacquetin, 2001[308] RCT | 1mg twice daily vs. 2mg twice daily | 78/97 | 84/103 | 0.99 (0.86; 1.13) | -0.01 (-0.12; 0.10) | | |
| All adverse events | Jacquetin, 2001[308] RCT | 1mg twice daily vs. 2mg twice daily | 39/97 | 55/103 | 0.75 (0.56; 1.02) | -0.13 (-0.27; 0.01) | | |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| All adverse events | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 34/99 | 43/99 | 0.79 (0.56; 1.13) | -0.09 (-0.23; 0.04) | | |
| All adverse events | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 31/99 | 32/99 | 0.97 (0.64; 1.46) | -0.01 (-0.14; 0.12) | | |
| At least one adverse event | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 152/193 | 254/399 | 1.24 (1.11; 1.37) | 0.15 (0.08; 0.23) | 7 (4; 13) | 151 (76; 226) |
| At least one adverse event | Millard, 1999[343] RCT | 1mg twice daily vs. 2mg twice daily | 8/129 | 2/123 | 3.81 (0.83; 17.61) | 0.05 (0.00; 0.09) | | |
| At least one adverse event | Appell, 1997[223] Pooled analysis | 1mg twice daily vs. 2mg daily | 94/121 | 351/474 | 1.05 (0.94; 1.17) | 0.04 (-0.05; 0.12) | | |
| Adverse events of severe intensity | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 5/61 | 6/73 | 1.00 (0.32; 3.11) | 0.00 (-0.09; 0.09) | | |
| Mild adverse events related to study medication | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 81/193 | 123/399 | 1.36 (1.09; 1.70) | 0.11 (0.03; 0.19) | 9 (5; 35) | 111 (28; 194) |
| Mild adverse events not related to study medication | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 57/193 | 117/399 | 1.01 (0.77; 1.31) | 0.00 (-0.08; 0.08) | | |
| Moderate adverse events related to study medication | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 46/193 | 84/399 | 1.13 (0.83; 1.55) | 0.03 (-0.04; 0.10) | | |
| Moderate adverse events not related to study medication | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 35/193 | 40/399 | 1.81 (1.19; 2.75) | 0.08 (0.02; 0.14) | 12 (7; 52) | 81 (19; 143) |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Severe adverse events related to study medication | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 7/193 | 9/399 | 1.61 (0.61; 4.25) | 0.01 (-0.02; 0.04) | | |
| Severe adverse events not related to study medication | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 5/193 | 6/399 | 1.72 (0.53; 5.57) | 0.01 (-0.01; 0.04) | | |
| Serious adverse event | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 2/61 | 1/73 | 2.39 (0.22; 25.76) | 0.02 (-0.03; 0.07) | | |
| Serious adverse event | Millard, 1999[343] RCT | 1mg twice daily vs. 2mg twice daily | 5/129 | 7/123 | 0.68 (0.22; 2.09) | -0.02 (-0.07; 0.03) | | |
| Serious adverse event | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 7/507 | 12/514 | 0.59 (0.23; 1.49) | -0.01 (-0.03; 0.01) | | |
| Abdominal pain | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 18/417 | 12/408 | 1.47 (0.72; 3.01) | 0.01 (-0.01; 0.04) | | |
| Abdominal pain | Jacquetin, 2007[308] RCT | 1mg twice daily vs. 2mg twice daily | 6/97 | 4/103 | 1.59 (0.46; 5.47) | 0.02 (-0.04; 0.08) | | |
| Abdominal pain | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 3/61 | 6/73 | 0.60 (0.16; 2.29) | -0.03 (-0.12; 0.05) | | |
| Abdominal pain | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 19/507 | 13/514 | 1.48 (0.74; 2.97) | 0.01 (-0.01; 0.03) | | |
| Abnormal accommodation | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 0/61 | 3/73 | 0.17 (0.01; 3.24) | -0.04 (-0.09; 0.01) | | |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Abnormal accommodation | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 3/99 | 5/99 | 0.60 (0.15; 2.44) | -0.02 (-0.07; 0.03) | | |
| Abnormal vision | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 5/417 | 4/408 | 1.22 (0.33; 4.52) | 0.00 (-0.01; 0.02) | | |
| Abnormal vision | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 6/507 | 4/514 | 1.52 (0.43; 5.36) | 0.00 (-0.01; 0.02) | | |
| Arthralgia | Takei, 2005[378] RCT | 4mg/day vs. 4mg/day | 1/80 | 11/74 | 0.08 (0.01; 0.64) | -0.14 (-0.22; -0.05) | -7 (-19; -5) | -136 (-221; -52) |
| Arthritis | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 1/417 | 5/408 | 0.20 (0.02; 1.67) | -0.01 (-0.02; 0.00) | | |
| Autonomic nervous system | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 11/99 | 16/99 | 0.69 (0.34; 1.41) | -0.05 (-0.15; 0.04) | | |
| Autonomic nervous system disorder | Appell, 1997[223] Pooled analysis | 1mg twice daily vs. 2mg daily | 35/121 | 204/474 | 0.67 (0.50; 0.91) | -0.14 (-0.23; -0.05) | -7 (-20; -4) | -141 (-233; -49) |
| Autonomic nervous system disorder | Millard, 1999[343] RCT | 1mg twice daily vs. 2mg twice daily | 37/129 | 53/123 | 0.67 (0.47; 0.93) | -0.14 (-0.26; -0.03) | -7 (-37; -4) | -144 (-261; -27) |
| Back pain | Takei, 2005[378] RCT | 4mg/day vs. 4mg/day | 3/80 | 11/74 | 0.25 (0.07; 0.87) | -0.11 (-0.20; -0.02) | -9 (-50; -5) | -111 (-202; -20) |
| Body disorder as a whole | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 61/193 | 85/399 | 1.48 (1.12; 1.96) | 0.10 (0.03; 0.18) | 10 (6; 38) | 103 (26; 180) |
| Cardiovascular adverse events | Appell, 1997[223] Pooled analysis | 1mg twice daily vs. 2mg daily | 15/121 | 20/474 | 2.94 (1.55; 5.57) | 0.08 (0.02; 0.14) | 12 (7; 49) | 82 (20; 143) |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Constipation | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 27/417 | 27/408 | 0.98 (0.58; 1.64) | 0.00 (-0.04; 0.03) | | |
| Constipation | Jacquetin, 2001[308] RCT | 1mg twice daily vs. 2mg twice daily | 4/97 | 2/103 | 2.12 (0.40; 11.33) | 0.02 (-0.03; 0.07) | | |
| Constipation | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 2/99 | 3/99 | 0.67 (0.11; 3.90) | -0.01 (-0.05; 0.03) | | |
| Constipation | Takei, 2005[378] RCT | 4mg/day vs. 4mg/day | 12/80 | 16/74 | 0.69 (0.35; 1.37) | -0.07 (-0.19; 0.06) | | |
| Constipation | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 5/61 | 0/73 | 13.13 (0.74; 232.79) | 0.08 (0.01; 0.16) | 12 (6; 114) | 82 (9; 155) |
| Constipation | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 30/507 | 35/514 | 0.87 (0.54; 1.39) | -0.01 (-0.04; 0.02) | | |
| Constipation | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 12/193 | 31/399 | 0.80 (0.42; 1.52) | -0.02 (-0.06; 0.03) | | |
| Diarrhea | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 8/61 | 4/73 | 2.39 (0.76; 7.57) | 0.08 (-0.02; 0.18) | | |
| Diarrhea | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 10/507 | 16/514 | 0.63 (0.29; 1.38) | -0.01 (-0.03; 0.01) | | |
| Diarrhea | Armstrong, 2007[226] pooled analysis | 2mg qd vs. 4mg qd | 9/193 | 25/399 | 0.74 (0.35; 1.56) | -0.02 (-0.05; 0.02) | | |
| Diarrhea | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 10/417 | 14/408 | 0.70 (0.31; 1.56) | -0.01 (-0.03; 0.01) | | |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Diarrhea | Takei, 2005[378] RCT | 4mg/day vs. 4mg/day | 6/80 | 12/74 | 0.46 (0.18; 1.17) | -0.09 (-0.19; 0.01) | | |
| Digestive system | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 87/193 | 145/399 | 1.24 (1.01; 1.52) | 0.09 (0.00; 0.17) | 11 (6; 360) | 87 (3; 172) |
| Dizziness | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 7/417 | 7/408 | 0.98 (0.35; 2.76) | 0.00 (-0.02; 0.02) | | |
| Dizziness | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 5/61 | 4/73 | 1.50 (0.42; 5.33) | 0.03 (-0.06; 0.11) | | |
| Dizziness | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 11/507 | 9/514 | 1.24 (0.52; 2.96) | 0.00 (-0.01; 0.02) | | |
| Dry mouth | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 105/417 | 127/408 | 0.81 (0.65; 1.01) | -0.06 (-0.12; 0.00) | | |
| Dry mouth | Jacquetin, 2001[308] RCT | 1mg twice daily vs. 2mg twice daily | 20/97 | 35/103 | 0.61 (0.38; 0.97) | -0.13 (-0.26; -0.01) | -7 (-85; -4) | -134 (-255; -12) |
| Dry mouth | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 8/99 | 10/99 | 0.80 (0.33; 1.94) | -0.02 (-0.10; 0.06) | | |
| Dry mouth | Takei, 2005[378] RCT | 4mg/day vs. 4mg/day | 42/80 | 63/74 | 0.62 (0.49; 0.78) | -0.33 (-0.46; -0.19) | -3 (-5; -2) | -326 (-463; -190) |
| Dry mouth | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 30/61 | 48/73 | 0.75 (0.55; 1.01) | -0.17 (-0.33; 0.00) | | |
| Dry mouth | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 118/507 | 156/514 | 0.77 (0.62; 0.94) | -0.07 (-0.12; -0.02) | -14 (-60; -8) | -71 (-125; -17) |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Dry mouth | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 64/193 | 89/399 | 1.49 (1.13; 1.95) | 0.11 (0.03; 0.19) | 9 (5; 33) | 109 (31; 187) |
| Dry skin | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 2/417 | 5/408 | 0.39 (0.08; 2.01) | -0.01 (-0.02; 0.01) | | |
| Dry skin | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 2/507 | 6/514 | 0.34 (0.07; 1.67) | -0.01 (-0.02; 0.00) | | |
| Dyspepsia | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 11/417 | 14/408 | 0.77 (0.35; 1.67) | -0.01 (-0.03; 0.02) | | |
| Dyspepsia | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 2/61 | 6/73 | 0.40 (0.08; 1.91) | -0.05 (-0.13; 0.03) | | |
| Dyspepsia | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 15/507 | 16/514 | 0.95 (0.47; 1.90) | 0.00 (-0.02; 0.02) | | |
| Dyspepsia | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 10/193 | 11/399 | 1.88 (0.81; 4.35) | 0.02 (-0.01; 0.06) | | |
| Dysuria | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 5/507 | 8/514 | 0.63 (0.21; 1.92) | -0.01 (-0.02; 0.01) | | |
| Fatigue | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 11/507 | 6/514 | 1.86 (0.69; 4.99) | 0.01 (-0.01; 0.03) | | |
| Flatulence | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 8/417 | 11/408 | 0.71 (0.29; 1.75) | -0.01 (-0.03; 0.01) | | |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Flatulence | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 10/507 | 14/514 | 0.72 (0.32; 1.62) | -0.01 (-0.03; 0.01) | | |
| Gastrointestinal | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 5/99 | 6/99 | 0.83 (0.26; 2.64) | -0.01 (-0.07; 0.05) | | |
| Gastrointestinal disorder | Appell, 1997[223] Pooled analysis | 1mg twice daily vs. 2mg daily | 27/121 | 123/474 | 0.86 (0.60; 1.24) | -0.04 (-0.12; 0.05) | | |
| General disorders | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 7/99 | 6/99 | 1.17 (0.41; 3.35) | 0.01 (-0.06; 0.08) | | |
| Headache | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 29/417 | 14/408 | 2.03 (1.09; 3.78) | 0.04 (0.01; 0.07) | 28 (15; 196) | 35 (5; 65) |
| Headache | Jacquetin, 2001[308] RCT | 1mg twice daily vs. 2mg twice daily | 3/97 | 3/103 | 1.06 (0.22; 5.14) | 0.00 (-0.05; 0.05) | | |
| Headache | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 3/99 | 3/99 | 1.00 (0.21; 4.83) | 0.00 (-0.05; 0.05) | | |
| Headache | Takei, 2005[378] RCT | 4mg/day vs. 4mg/day | 6/80 | 10/74 | 0.56 (0.21; 1.45) | -0.06 (-0.16; 0.04) | | |
| Headache | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 5/61 | 7/73 | 0.85 (0.29; 2.56) | -0.01 (-0.11; 0.08) | | |
| Headache | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 32/507 | 19/514 | 1.71 (0.98; 2.97) | 0.03 (0.00; 0.05) | | |
| Headache | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 18/193 | 24/399 | 1.55 (0.86; 2.79) | 0.03 (-0.01; 0.08) | | |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Hypertension | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 6/417 | 4/408 | 1.47 (0.42; 5.16) | 0.00 (-0.01; 0.02) | | |
| Insomnia | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 7/417 | 2/408 | 3.42 (0.72; 16.39) | 0.01 (0.00; 0.03) | | |
| Insomnia | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 7/507 | 2/514 | 3.55 (0.74; 17.00) | 0.01 (0.00; 0.02) | | |
| Metabolic and nutritional system | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 17/193 | 21/399 | 1.67 (0.90; 3.10) | 0.04 (-0.01; 0.08) | | |
| Mild to-moderate intensity dry mouth | Jacquetin, 2001[308] RCT | 1mg twice daily vs. 2mg twice daily | 18/97 | 30/103 | 0.64 (0.38; 1.07) | -0.11 (-0.22; 0.01) | | |
| Minor noncholinergic and cholinergic adverse events | Millard, 1999[343] RCT | 1mg twice daily vs. 2mg twice daily | 95/129 | 90/123 | 1.01 (0.87; 1.17) | 0.00 (-0.10; 0.11) | | |
| Moderate or severe dry mouth | Appell, 1997[223] Pooled analysis | 1mg twice daily vs. 2mg daily | 5/121 | 81/474 | 0.24 (0.10; 0.58) | -0.13 (-0.18; -0.08) | -8 (-12; -6) | -130 (-179; -81) |
| Nasopharyngitis | Takei, 2005[378] RCT | 4mg/day vs. 4mg/day | 6/80 | 50/74 | 0.11 (0.05; 0.24) | -0.60 (-0.72; -0.48) | -2 (-2; -1) | -601 (-722; -479) |
| Nausea | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 7/417 | 9/408 | 0.76 (0.29; 2.02) | -0.01 (-0.02; 0.01) | | |
| Nausea | Malone-Lee, 2001[340] RCT | 1mg twice daily vs. 2mg twice daily | 2/61 | 3/73 | 0.80 (0.14; 4.62) | -0.01 (-0.07; 0.06) | | |
| Nausea | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 7/507 | 10/514 | 0.71 (0.27; 1.85) | -0.01 (-0.02; 0.01) | | |
| Pain | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 15/193 | 14/399 | 2.22 (1.09; 4.50) | 0.04 (0.00; 0.08) | 23 (12; 1303) | 43 (1; 84) |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Palpitations | Appell, 1997[223] Pooled analysis | 1mg twice daily vs. 2mg daily | 8/121 | 2/474 | 15.67 (3.37; 72.84) | 0.06 (0.02; 0.11) | 16 (9; 58) | 62 (17; 107) |
| Peripheral edema | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 7/507 | 7/514 | 1.01 (0.36; 2.87) | 0.00 (-0.01; 0.01) | | |
| Peripheral edema | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 11/193 | 13/399 | 1.75 (0.80; 3.83) | 0.02 (-0.01; 0.06) | | |
| Psychiatric adverse events | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 1/99 | 1/99 | 1.00 (0.06; 15.76) | 0.00 (-0.03; 0.03) | | |
| Respiratory adverse events | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 1/99 | 3/99 | 0.33 (0.04; 3.15) | -0.02 (-0.06; 0.02) | | |
| Sinusitis | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 8/417 | 2/408 | 3.91 (0.84; 18.32) | 0.01 (0.00; 0.03) | | |
| Skin and appendages | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 1/99 | 1/99 | 1.00 (0.06; 15.76) | 0.00 (-0.03; 0.03) | | |
| Somnolence | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 12/417 | 11/408 | 1.07 (0.48; 2.39) | 0.00 (-0.02; 0.02) | | |
| Somnolence | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 14/507 | 13/514 | 1.09 (0.52; 2.30) | 0.00 (-0.02; 0.02) | | |
| Urinary AE | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 6/99 | 5/99 | 1.20 (0.38; 3.80) | 0.01 (-0.05; 0.07) | | |
| Urinary tract infection | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 15/417 | 11/408 | 1.33 (0.62; 2.87) | 0.01 (-0.01; 0.03) | | |
| Urinary tract infection | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 16/507 | 13/514 | 1.25 (0.61; 2.57) | 0.01 (-0.01; 0.03) | | |

**Appendix Table F52. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)**

| Outcome | Reference Design | Active vs. Control | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Urinary tract infection | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd | 11/193 | 13/399 | 1.75 (0.80; 3.83) | 0.02 (-0.01; 0.06) | | |
| Urinary tract infection | Jonas, 1997[310] RCT | 1mg twice daily vs. 2mg twice daily | 5/99 | 2/99 | 2.50 (0.50; 12.58) | 0.03 (-0.02; 0.08) | | |
| Urogenital system adverse events | Armstrong, 2007[226] Pooled analysis | 2mg qd vs. 4mg qd campaign | 35/193 | 38/399 | 1.90 (1.24; 2.91) | 0.09 (0.02; 0.15) | 12 (7; 41) | 86 (25; 148) |
| Xerophthalmia | Swift, 2003[376] RCT | 4mg once daily vs. 2mg twice daily | 16/417 | 8/408 | 1.96 (0.85; 4.52) | 0.02 (0.00; 0.04) | | |
| Xerophthalmia | Van Kerrebroeck, 2001[322] RCT | 4mg once daily vs. 2mg once daily | 17/507 | 12/514 | 1.44 (0.69; 2.98) | 0.01 (-0.01; 0.03) | | |

**Appendix Table F53. Clinical outcomes after tolterodine vs. placebo, the results from randomized controlled clinical trials pooled with random effects models**

| Drug | Outcome | Studies | Patients | Rate Active/Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) |
|---|---|---|---|---|---|---|---|
| Tolterodine | Continence | 4[58,314,339,361] | 3,404 | 53.2/43.7 | 1.2 (1.1; 1.4) | 0.09 (0.04; 0.13) | 12 (8; 12) |
| Tolterodine | Improvement in UI | 8[282,297,319,360,366 58,314,466] | 6,783 | 44.7/35.7 | 1.3 (1.2; 1.5) | 0.11 (0.06; 0.16) | 9 (6; 9) |
| Tolterodine | Treatment failure | 7[58,282,297,319,360,361,466] | 5,275 | 9.0/15.4 | 0.7 (0.5; 0.9) | -0.05 (-0.09; -0.01) | |
| Tolterodine | Adverse effects | 12[58,220,252,258,276,308,310,312,323,339,356,361] | 4,162 | 44.7/38.1 | 1.2 (1.1; 1.3) | 0.08 (0.05; 0.11) | 13 (9; 13) |
| Tolterodine | Serious adverse effects | 5[58,276,322,340,343] | 3,550 | 1.8/3.1 | 0.6 (0.4; 0.9) | -0.01 (-0.02; 0.00) | |
| Tolterodine | Discontinuation | 10[54,58,252,258,276,277,319,322,359,466] | 6,399 | 6.5/7.8 | 0.9 (0.8; 1.1) | -0.01 (-0.02; 0.00) | |
| Tolterodine | Discontinuation Adverse effects | 13[54,58,220,252,276,277,297,308,314,323,340,356,466] | 7,801 | 3.9/3.2 | 1.1 (0.8; 1.6) | 0.01 (0.00; 0.02) | |
| Tolterodine | Discontinuation Treatment failure | 5[54,58,297,323,466] | 4,049 | 0.7/1.6 | 0.5 (0.2; 0.9) | -0.01 (-0.02; 0.00) | |
| Tolterodine | autonomic nervous system disorders | 3[276,310,343] | 831 | 27.2/15.5 | 1.8 (1.3; 2.4) | 0.11 (0.03; 0.19) | 9 (5; 9) |
| Tolterodine | Blurred vision | 2[54,258] | 608 | 1.3/3.0 | 0.5 (0.2; 1.5) | -0.01 (-0.04; 0.01) | |
| Tolterodine | Constipation | 15[54,58,252,258,277,297,308,310,314,322,323,340,356,361,376,466] | 11,273 | 3.7/2.8 | 1.4 (1.2; 1.8) | 0.01 (0.00; 0.02) | 111 (67; 111) |
| Tolterodine | Diarrhea | 6[58,322,323,340,376,466] | 5,910 | 2.3/1.9 | 1.3 (0.9; 1.9) | 0.01 (0.00; 0.01) | |
| Tolterodine | Dizziness | 7[58,252,297,322,323,340,376] | 6,084 | 1.6/1.5 | 1.1 (0.7; 1.7) | 0.00 (0.00; 0.01) | |
| Tolterodine | Dry mouth | 14[54,58,220,252,258,297,308,312,314,322,339,356,361,466] | 7,637 | 18.4/6.7 | 2.6 (2.2; 3.2) | 0.13 (0.10; 0.15) | 8 (6; 8) |
| Tolterodine | Dry skin | 2[322,376] | 1,842 | 0.4/0.2 | 2.0 (0.4; 10.8) | 0.00 (0.00; 0.01) | |
| Tolterodine | Dyspepsia | 7[58,220,322,323,339,340,376] | 5,374 | 2.8/1.5 | 1.8 (1.2; 2.8) | 0.01 (0.00; 0.02) | 71 (43; 71) |
| Tolterodine | Fatigue | 4[58,252,297,322] | 3,234 | 1.9/0.7 | 2.5 (1.2; 5.2) | 0.01 (0.00; 0.02) | 83 (45; 83) |
| Tolterodine | Flatulence | 2[322,376] | 1,842 | 1.9/1.6 | 1.2 (0.6; 2.4) | 0.00 (-0.01; 0.02) | |
| Tolterodine | General body disorders | 2[276,310] | 308 | 22.3/18.6 | 1.2 (0.7; 2.1) | 0.02 (-0.10; 0.15) | |
| Tolterodine | Headache | 14[58,252,258,277,297,308,310,322,323,339,340,361,376,466] | 9,474 | 4.4/3.5 | 1.3 (1.0; 1.6) | 0.01 (0.00; 0.02) | 91 (53; 91) |
| Tolterodine | Insomnia | 3[322,361,376] | 2,255 | 1.7/1.6 | 1.0 (0.4; 2.5) | 0.00 (-0.01; 0.02) | |
| Tolterodine | Nasopharyngitis | 6[58,252,253,297,361,366] | 3,862 | 2.8/2.9 | 1.0 (0.7; 1.5) | 0.00 (-0.01; 0.01) | |
| Tolterodine | Nausea | 7[58,220,252,322,323,340,376] | 5,642 | 1.6/2.0 | 0.8 (0.5; 1.1) | 0.00 (-0.01; 0.01) | |
| Tolterodine | Somnolence | 3[322,323,376] | 2,696 | 1.8/1.6 | 1.4 (0.7; 2.5) | 0.00 (-0.01; 0.01) | |
| Tolterodine | Urinary tract infection | 7[58,310,322,323,361,376,466] | 6,319 | 2.2/2.7 | 1.0 (0.6; 1.5) | 0.00 (-0.01; 0.01) | |

**Appendix Table F53. Clinical outcomes after tolterodine vs. placebo, the results from randomized controlled clinical trials pooled with random effects models (continued)**

| Drug | Outcome | Studies | Patients | Rate Active/Control | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) |
|---|---|---|---|---|---|---|---|
| Tolterodine | Xerophthalmia | 2[322,376] | 1,842 | 3.6/2.0 | 1.8 (1.0; 3.2) | 0.02 (0.00; 0.03) | 63 (32; 63) |
| Tolterodine | Abdominal pain | 6[58,308,322,323,340,376] | 5,194 | 2.8/1.7 | 1.7 (1.2; 2.5) | 0.01 (0.00; 0.02) | 91 (50; 91) |
| Tolterodine | Abnormal vision | 3[322,356,376] | 1,968 | 1.4/0.8 | 1.5 (0.6; 3.7) | 0.01 (0.00; 0.01) | |

**Appendix Table F54. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence)**

| Studies, Reference | Dose, mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat 95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|
| **≥7 consecutive dry days** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 19/337 | 15/388 | 1.46 (0.75; 2.82 | 0.018 (-0.013; 0.049) | | |
| Chapple, 2005[255] | 15 | 24/334 | 16/388 | 1.74 (0.94; 3.22 | 0.031 (-0.003; 0.065) | 33 (15; -293) | 31 (-3; 65) |
| **≥3 dry days/week** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 55/337 | 43/388 | 1.47 (1.02; 2.13 | 0.052 (0.002; 0.103) | 19 (10; 486) | 52 (2; 103) |
| Chapple, 2005[255] | 15 | 61/334 | 48/388 | 1.48 (1.04; 2.09 | 0.059 (0.006; 0.112) | 17 (9; 164) | 59 (6; 112) |
| **Reduction in incontinence episodes: ≥50%** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 222/337 | 202/388 | 1.27 (1.12; 1.43 | 0.138 (0.067; 0.209) | 7 (5; 15) | 138 (67; 209) |
| Chapple, 2005[255] | 15 | 234/334 | 217/388 | 1.25 (1.12; 1.40 | 0.141 (0.072; 0.211) | 7 (5; 14) | 141 (72; 211) |
| **Reduction in incontinence episodes: ≥70%** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 162/337 | 128/388 | 1.46 (1.22; 1.74 | 0.151 (0.080; 0.222) | 7 (5; 13) | 151 (80; 222) |
| Chapple, 2005[255] | 15 | 190/334 | 151/388 | 1.46 (1.25; 1.71 | 0.180 (0.108; 0.252) | 6 (4; 9) | 180 (108; 252) |
| **Reduction in incontinence episodes: ≥90%** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 91/337 | 66/388 | 1.59 (1.20; 2.10 | 0.100 (0.040; 0.160) | 10 (6; 25) | 100 (40; 160) |
| Chapple, 2005[255] | 15 | 94/334 | 66/388 | 1.65 (1.25; 2.19 | 0.111 (0.050; 0.172) | 9 (6; 20) | 111 (50; 172) |
| **Incontinence impact** | | | | | | | |
| Abrams, 2008[50] | 7.5 | 52/337 | 30/388 | 2.00 (1.30; 3.05 | 0.077 (0.030; 0.124) | 13 (8; 33) | 77 (30; 124) |
| Abrams, 2008[50] | 15 | 46/334 | 30/388 | 1.78 (1.15; 2.75 | 0.060 (0.015; 0.106) | 17 (9; 67) | 60 (15; 106) |
| **Severity measures** | | | | | | | |
| Abrams, 2008[50] | 7.5 | 47/337 | 27/388 | 2.00 (1.28; 3.14 | 0.070 (0.025; 0.115) | 14 (9; 40) | 70 (25; 115) |
| Abrams, 2008[50] | 15 | 46/334 | 27/388 | 1.98 (1.26; 3.11 | 0.068 (0.023; 0.113) | 15 (9; 43) | 68 (23; 113) |
| **Role limitations** | | | | | | | |
| Abrams, 2008[50] | 7.5 | 65/337 | 46/388 | 1.63 (1.15; 2.30 | 0.074 (0.021; 0.127) | 13 (8; 47) | 74 (21; 127) |
| Abrams, 2008[50] | 15 | 59/334 | 46/388 | 1.49 (1.04; 2.13 | 0.058 (0.006; 0.110) | 17 (9; 165) | 58 (6; 110) |
| **Social limitations** | | | | | | | |
| Abrams, 2008[50] | 7.5 | 57/337 | 42/388 | 1.56 (1.08; 2.26 | 0.061 (0.010; 0.111) | 16 (9; 97) | 61 (10; 111) |
| Abrams, 2008[50] | 15 | 54/334 | 42/388 | 1.49 (1.03; 2.17 | 0.053 0.003; 0.104) | 19 (10; 305) | 53 (3; 104) |
| **Physical limitations** | | | | | | | |
| Abrams, 2008[50] | 7.5 | 58/337 | 49/388 | 1.36 (0.96; 1.94 | 0.046 (-0.006; 0.098) | | |
| Abrams, 2008[50] | 15 | 53/334 | 49/388 | 1.26 (0.88; 1.80 | 0.032 (-0.019; 0.084) | | |
| **Emotions** | | | | | | | |
| Abrams, 2008[50] | 7.5 | 56/337 | 44/388 | 1.47 (1.02; 2.11 | 0.053 (0.002; 0.104) | 19 (10; 493) | 53 (2; 104) |
| Abrams, 2008[50] | 15 | 53/334 | 44/388 | 1.40 (0.96; 2.03 | 0.045 (-0.005; 0.096) | | |
| **Personal relationships** | | | | | | | |
| Abrams, 2008[50] | 7.5 | 24/337 | 20/388 | 1.38 (0.78; 2.46 | 0.020 (-0.016; 0.055) | | |
| Abrams, 2008[50] | 15 | 23/334 | 20/388 | 1.34 (0.75; 2.39 | 0.017 (-0.018; 0.052) | | |

**Appendix Table F54. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)**

| Studies, Reference | Dose, mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat 95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|
| **Sleep/energy** | | | | | | | |
| Abrams, 2008[50] | 7.5 | 46/337 | 37/388 | 1.43 (0.95; 2.15 | 0.041 (-0.006; 0.088) | | |
| Abrams, 2008[50] | 15 | 46/334 | 37/388 | 1.44 (0.96; 2.17 | 0.042 (-0.005; 0.089) | | |
| **General health perception** | | | | | | | |
| Abrams, 2008[50] | 7.5 | 24/337 | 19/388 | 1.45 (0.81; 2.61 | 0.022 (-0.013; 0.057) | | |
| Abrams, 2008[50] | 15 | 21/334 | 19/388 | 1.28 (0.70; 2.35 | 0.014 (-0.020; 0.048) | | |
| **≥1 adverse effect** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 182/337 | 189/388 | 1.11 (0.96; 1.28 | 0.053 (-0.020; 0.126) | | |
| Chapple, 2005[255] | 15 | 219/334 | 189/388 | 1.35 (1.18; 1.53 | 0.169 (0.097; 0.240) | 6 (4; 10) | 169 (97; 240) |
| **Adverse effects of any cause** | | | | | | | |
| Foote, 2005[281] | 15 | 76/110 | 56/110 | 1.36 (1.09; 1.69 | 0.182 (0.055; 0.309) | 5 (3; 18) | 182 (55; 309) |
| Foote, 2005[281] | 7.5 | 52/97 | 56/110 | 1.05 (0.81; 1.37 | 0.027 (-0.109; 0.163) | | |
| **Discontinued** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 19/337 | 31/388 | 0.71 (0.41; 1.23 | -0.024 (-0.060; 0.013) | | |
| Chapple, 2005[255] | 15 | 43/334 | 31/388 | 1.61 (1.04; 2.50 | 0.049 (0.004; 0.094) | 20 (11; 255) | 49 (4; 94) |
| **Adverse effects leading to discontinuation** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 5/337 | 10/388 | 0.58 (0.20; 1.67 | -0.011 (-0.031; 0.009) | | |
| Chapple, 2005[255] | 15 | 17/334 | 10/388 | 1.97 (0.92; 4.25 | 0.025 (-0.003; 0.053) | | |
| Foote, 2005[281] | 15 | 10/110 | 6/110 | 1.67 (0.63; 4.43 | 0.036 (-0.032; 0.105) | | |
| Foote, 2005[281] | 7.5 | 1/97 | 6/110 | 0.19 (0.02; 1.54 | -0.044 (-0.091; 0.003) | | |
| **Reduction in incontinence episodes: ≥30%** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 259/337 | 248/388 | 1.20 (1.09; 1.32 | 0.129 (0.064; 0.195) | 8 (5; 16) | 129 (64; 195) |
| Chapple, 2005[255] | 15 | 274/334 | 264/388 | 1.21 (1.11; 1.31 | 0.140 (0.078; 0.202) | 7 (5; 13) | 140 (78; 202) |
| **Abdominal pain** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 8/337 | 2/388 | 4.61 (0.98; 21.54 | 0.019 (0.001; 0.036) | 54 (28; 1194) | 19 (1; 36) |
| Chapple, 2005[255] | 15 | 13/334 | 2/388 | 7.55 (1.72; 33.22 | 0.034 (0.012; 0.056) | 30 (18; 84) | 34 (12; 56) |
| **Back pain** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 8/337 | 12/388 | 0.77 (0.32; 1.86 | -0.007 (-0.031; 0.016) | | |
| Chapple, 2005[255] | 15 | 5/334 | 12/388 | 0.48 (0.17; 1.36 | -0.016 (-0.038; 0.006) | | |
| **Cardiovascular system (total)** | | | | | | | |
| Foote, 2005[281] | 7.5 | 3/97 | 0/110 | 7.93 (0.41; 151.59 | 0.031 (-0.008; 0.070) | | |
| Foote, 2005[281] | 15 | 1/110 | 0/110 | 3.00 (0.12; 72.85 | 0.009 (-0.016; 0.034) | | |
| **Constipation** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 50/337 | 24/388 | 2.40 (1.51; 3.82 | 0.087 (0.042; 0.131) | 12 (8; 24) | 87 (42; 131) |
| Chapple, 2005[255] | 15 | 71/334 | 24/388 | 3.44 (2.22; 5.33 | 0.151 (0.101; 0.201) | 7 (5; 10) | 151 (101; 201) |
| Foote, 2005[281] | 7.5 | 18/97 | 7/110 | 2.92 (1.27; 6.68 | 0.122 (0.032; 0.212) | 8 (5; 31) | 122 (32; 212) |
| Foote, 2005[281] | 15 | 26/110 | 7/110 | 3.71 (1.68; 8.20 | 0.173 (0.081; 0.264) | 6 (4; 12) | 173 (81; 264) |

**Appendix Table F54. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)**

| Studies, Reference | Dose, mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat 95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|
| **Dry mouth** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 68/337 | 32/388 | 2.45 (1.65; 3.63 | 0.119 (0.068; 0.170) | 8 (6; 15) | 119 (68; 170) |
| Chapple, 2005[255] | 15 | 118/334 | 32/388 | 4.28 (2.98; 6.15 | 0.271 (0.213; 0.329) | 4 (3; 5) | 271 (213; 329) |
| Foote, 2005[281] | 7.5 | 20/97 | 5/110 | 4.54 (1.77; 11.63 | 0.161 (0.071; 0.250) | 6 (4; 14) | 161 (71; 250) |
| Foote, 2005[281] | 15 | 34/110 | 5/110 | 6.80 (2.76; 16.74 | 0.264 (0.169; 0.358) | 4 (3; 6) | 264 (169; 358) |
| **Dyspepsia** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 9/337 | 10/388 | 1.04 (0.43; 2.52 | 0.001 (-0.022; 0.024) | | |
| Chapple, 2005[255] | 15 | 28/334 | 10/388 | 3.25 (1.60; 6.60 | 0.058 (0.024; 0.092) | 17 (11; 41) | 58 (24; 92) |
| Foote, 2005[281] | 7.5 | 2/97 | 1/110 | 2.27 (0.21; 24.63 | 0.012 (-0.022; 0.045) | 0 (0; 0) | 0 (0; 0) |
| Foote, 2005[281] | 15 | 8/110 | 1/110 | 8.00 (1.02; 62.89 | 0.064 (0.012; 0.115) | 16 (9; 84) | 64 (12; 115) |
| **Headache** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15/337 | 21/388 | 0.82 (0.43; 1.57 | -0.010 (-0.041; 0.022) | | |
| Chapple, 2005[255] | 15 | 17/334 | 21/388 | 0.94 (0.50; 1.75 | -0.003 (-0.036; 0.029) | | |
| Foote, 2005[281] | 7.5 | 0/97 | 2/110 | 0.23 (0.01; 4.66 | -0.018 (-0.049; 0.013) | | |
| Foote, 2005[281] | 15 | 0/110 | 2/110 | 0.20 (0.01; 4.12 | -0.018 (-0.048; 0.012) | | |
| **Nervous system (total)** | | | | | | | |
| Foote, 2005[281] | 7.5 | 2/97 | 2/110 | 1.13 (0.16; 7.90 | 0.002 (-0.035; 0.040) | | |
| Foote, 2005[281] | 15 | 2/110 | 2/110 | 1.00 (0.14; 6.97 | 0.000 (-0.035; 0.035) | | |
| **Respiratory tract information** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 9/337 | 26/388 | 0.40 (0.19; 0.84 | -0.040 (-0.071; -0.010) | -25 (-99; -14) | -40 (-71; -10) |
| Chapple, 2005[255] | 15 | 17/334 | 26/388 | 0.76 (0.42; 1.38 | -0.016 (-0.050; 0.018) | | |
| **UTI** | | | | | | | |
| Chapple, 2005[255] | 7.5 | 16/337 | 10/388 | 1.84 (0.85; 4.00 | 0.022 (-0.006; 0.049) | | |
| Chapple, 2005[255] | 15 | 15/334 | 10/388 | 1.74 (0.79; 3.83 | 0.019 (-0.008; 0.046) | | |

**Appendix Table F55. Dose response association between clinical outcomes and darifenacin in pooled analyses of individual patient data from RCTs (high level of evidence)**

| Studies, Reference | Active Dose, mg/day | Control Dose mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat 95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|
| **≥1 adverse effect** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 182/337 | 219/334 | 0.82 (0.73; 0.93 | -0.116 (-0.189; -0.042) | -9 (-24; -5) | -116 (-189; -42) |
| **Adverse effects of any cause** | | | | | | | | |
| Foote, 2005[281] | 7.5 | 15 | 52/97 | 76/110 | 0.78 (0.62; 0.97 | -0.155 (-0.286; -0.023) | -6 (-43; -3) | -155 (-286; -23) |
| **Discontinued** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 19/337 | 43/334 | 0.44 (0.26; 0.74 | -0.072 (-0.116; -0.029) | -14 (-35; -9) | -72 (-116; -29) |
| **Adverse effects leading to discontinuation** | | | | | | | | |
| Foote, 2005[281] | 7.5 | 15 | 1/97 | 10/110 | 0.11 (0.01; 0.87 | -0.081 (-0.138; -0.023) | -12 (-43; -7) | -81 (-138; -23) |
| **Adverse effects leading to discontinuation** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 5/337 | 17/334 | 0.29 (0.11; 0.78 | -0.036 (-0.063; -0.009) | -28 (-109; -16) | -36 (-63; -9) |
| **Incontinence impact** | | | | | | | | |
| Abrams, 2008[50] | 7.5 | 15 | 52/337 | 46/334 | 1.12 (0.78; 1.62 | 0.017 (-0.037; 0.070) | | |
| **Severity measures** | | | | | | | | |
| Abrams, 2008[50] | 7.5 | 15 | 47/337 | 46/334 | 1.01 (0.69; 1.48 | 0.002 (-0.051; 0.054) | | |
| **Role limitations** | | | | | | | | |
| Abrams, 2008[50] | 7.5 | 15 | 65/337 | 59/334 | 1.09 (0.79; 1.50 | 0.016 (-0.042; 0.075) | | |
| **Social limitations** | | | | | | | | |
| Abrams, 2008[50] | 7.5 | 15 | 57/337 | 54/334 | 1.05 (0.74; 1.47 | 0.007 (-0.049; 0.064) | | |
| **Physical limitations** | | | | | | | | |
| Abrams, 2008[50] | 7.5 | 15 | 58/337 | 53/334 | 1.08 (0.77; 1.52 | 0.013 (-0.043; 0.070) | | |
| **Emotions** | | | | | | | | |
| Abrams, 2008[50] | 7.5 | 15 | 56/337 | 53/334 | 1.05 (0.74; 1.48 | 0.007 (-0.048; 0.063) | | |
| **Personal relationships** | | | | | | | | |
| Abrams, 2008[50] | 7.5 | 15 | 24/337 | 23/334 | 1.03 (0.60; 1.80 | 0.002 (-0.036; 0.041) | | |
| **Sleep/energy** | | | | | | | | |
| Abrams, 2008[50] | 7.5 | 15 | 46/337 | 46/334 | 0.99 (0.68; 1.45 | -0.001 (-0.053; 0.051) | | |
| **General health perception** | | | | | | | | |
| Abrams, 2008[50] | 7.5 | 15 | 24/337 | 21/334 | 1.13 (0.64; 1.99 | 0.008 (-0.029; 0.046) | | |
| **Dry mouth** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 68/337 | 118/334 | 0.57 (0.44; 0.74 | -0.152 (-0.218; -0.085) | -7 (-12; -5) | -152 (-218; -85) |
| Foote, 2005[281] | 7.5 | 15 | 20/97 | 34/110 | 0.67 (0.41; 1.08 | -0.103 (-0.221; 0.015) | | |
| **Abdominal pain** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 8/337 | 13/334 | 0.61 (0.26; 1.45 | -0.015 (-0.042; 0.011) | | |
| **Back pain** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 8/337 | 5/334 | 1.59 (0.52; 4.80 | 0.009 (-0.012; 0.030) | | |
| **Cardiovascular system (total)** | | | | | | | | |
| Foote, 2005[281] | 7.5 | 15 | 3/97 | 1/110 | 3.40 (0.36; 32.17 | 0.022 (-0.017; 0.061) | | |

**Appendix Table F55. Dose response association between clinical outcomes and darifenacin in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)**

| Studies, Reference | Active Dose, mg/day | Control Dose mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat 95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|
| **Constipation** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 50/337 | 71/334 | 0.70 (0.50; 0.97 | -0.064 (-0.122; -0.006) | -16 (-161; -8) | -64 (-122; -6) |
| Foote, 2005[281] | 7.5 | 15 | 18/97 | 26/110 | 0.79 (0.46; 1.34 | -0.051 (-0.162; 0.060) | | |
| **Dyspepsia** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 9/337 | 28/334 | 0.32 (0.15; 0.66 | -0.057 (-0.091; -0.023) | -18 (-44; -11) | -57 (-91; -23) |
| Foote, 2005[281] | 7.5 | 15 | 2/97 | 8/110 | 0.28 (0.06; 1.30 | -0.052 (-0.108; 0.004) | | |
| **Headache** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 15/337 | 17/334 | 0.87 (0.44; 1.72 | -0.006 (-0.039; 0.026) | | |
| Foote, 2005[281] | 7.5 | 15 | 0/97 | 0/110 | 0.00 (0.00; 0.00 | 0.000 (-0.019; 0.019) | | |
| **Nervous system (total)** | | | | | | | | |
| Foote, 2005[281] | 7.5 | 15 | 2/97 | 2/110 | 1.13 (0.16; 7.90 | 0.002 (-0.035; 0.040) | | |
| **Respiratory tract information** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 9/337 | 17/334 | 0.52 (0.24; 1.16 | -0.024 (-0.053; 0.005) | | |
| **UTI** | | | | | | | | |
| Chapple, 2005[255] | 7.5 | 15 | 16/337 | 15/334 | 1.06 (0.53; 2.10 | 0.003 (-0.029; 0.034) | | |

**Appendix Table F56. Significant dose response association with clinical outcomes after darifenacin (individual RCTs)**

| Studies, Reference | Active Dose, mg/day | Control Dose mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat 95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|---|
| **Adverse effects** | | | | | | | | |
| Hill, 2006[44] | 7.5 | 30 | 62/108 | 92/115 | 0.72 (0.60; 0.86) | -0.23 (-0.34; -0.11) | -4 (-9; -3) | -226 (-344; -107) |
| **Withdrawals: adverse effects** | | | | | | | | |
| Hill, 2006[44] | 15 | 30 | 73/107 | 92/115 | 0.85 (0.73; 1.00) | -0.12 (-0.23; 0.00) | -8 (-314; -4) | -118 (-232; -3) |
| Hill, 2006[44] | 7.5 | 30 | 2/108 | 13/115 | 0.16 (0.04; 0.71) | -0.09 (-0.16; -0.03) | -11 (-32; -6) | -95 (-158; -31) |
| Chancellor, 2008[249] | 7 | 15 | 21/205 | 6/190 | 3.24(1.34; 7.86) | 0.07(0.02; 0.12) | 14(8; 44) | 71(22; 119) |
| **Withdrawals due to lack of response** | | | | | | | | |
| Hill, 2006[44] | 7.5 | 15 | 1/108 | 2/107 | 0.50 (0.05; 5.38) | -0.01 (-0.04; 0.02) | -106 (46; -25) | -9 (-41; 22) |
| Hill, 2006[44] | 7.5 | 30 | 1/108 | 1/115 | 1.06 (0.07; 16.81) | 0.00 (-0.02; 0.03) | 1774 (39; -41) | 1 (-24; 25) |
| Hill, 2006[44] | 15 | 30 | 2/107 | 1/115 | 2.15 (0.20; 23.36) | 0.01 (-0.02; 0.04) | 100 (25; -48) | 10 (-21; 41) |
| **Constipation** | | | | | | | | |
| Steers, 2005[45] | 7.5 | 15 | 32/108 | 24/160 | 1.98 (1.24; 3.16) | 0.15 (0.04; 0.25) | 7 (4; 23) | 146 (44; 249) |
| Hill, 2006[44] | 7.5 | 30 | 17/108 | 32/115 | 0.57 (0.33; 0.96) | -0.12 (-0.23; -0.01) | -8 -72; -4) | -121 (-228; -14) |
| Chapple, 2004[464] | 15 | 30 | 2/53 | 33/229 | 0.26 (0.06; 1.06) | -0.11 (-0.17; -0.04) | -9 (-26; -6) | -106 (-175; -38) |
| Chapple, 2004[464] | 15 | 60 | 2/53 | 16/115 | 0.27 (0.06; 1.14) | -0.10 (-0.18; -0.02) | -10 (-50; -5) | -101 (-183; -20) |
| **Dry mouth** | | | | | | | | |
| Steers, 2005[45] | 7.5 | 15 | 28/108 | 22/160 | 1.89 (1.14; 3.12) | 0.12 (0.02; 0.22) | 8 (5; 43) | 122 (23; 220) |
| Hill, 2006[44] | 7.5 | 15 | 25/108 | 43/107 | 0.58 (0.38; 0.87) | -0.17 (-0.29; -0.05) | -6 (-21; -3) | -170 (-293; -48) |
| Hill, 2006[44] | 7.5 | 30 | 25/108 | 68/115 | 0.39 (0.27; 0.57) | -0.36 (-0.48; -0.24) | -3 (-4; -2) | -360 (-480; -240) |
| Hill, 2006[44] | 15 | 30 | 43/107 | 68/115 | 0.68 (0.52; 0.90) | -0.19 (-0.32; -0.06) | -5 (-17; -3) | -189 (-319; -60) |
| Chapple, 2004[464] | 15 | 60 | 7/53 | 36/115 | 0.42 (0.20; 0.89) | -0.18 (-0.31; -0.06) | -6 (-18; -3) | -181 (-305; -57) |
| Chapple, 2004[464] | 30 | 60 | 43/229 | 36/115 | 0.60 (0.41; 0.88) | -0.13 (-0.22; -0.03) | -8 (-38; -4) | -125 (-224; -27) |
| **Dyspepsia** | | | | | | | | |
| Chapple, 2004[464] | 30 | 60 | 4/229 | 9/115 | 0.22 (0.07; 0.71) | -0.06 (-0.11; -0.01) | -16 (-113; -9) | -61 (-113; -9) |
| **Headache** | | | | | | | | |
| Steers, 2005[45] | 7.5 | 15 | 13/108 | 5/160 | 3.85 (1.41; 10.49) | 0.09 (0.02; 0.16) | 11 (6; 45) | 89 (22; 156) |
| **Respiratory tract infection** | | | | | | | | |
| Hill, 2006[44] | 15 | 30 | 6/107 | 1/115 | 6.45 (0.79; 52.69) | 0.05 (0.00; 0.09) | 21 (11; 1665) | 47 (1; 94) |
| **Urinary tract disorder** | | | | | | | | |
| Hill, 2006[44] | 7.5 | 15 | 0/108 | 6/107 | 0.08 (0.00; 1.34) | -0.06 (-0.10; -0.01) | -18 (-106; -10) | -56 (-103; -9) |

**Appendix Table F57. Clinical outcomes after solifenacin vs. placebo, pooled individual patient data from RCTs (high level of evidence)**

| Outcome | Reference | Dose, mg/day | Number of Subjects | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|
| Complete continence | Cardozo, 2006[244] | 5.00 | 1,095 | 1.50 (1.29; 1.73) | 0.17 (0.10; 0.23) | 6 (4; 10) | 169 (104; 233) |
| Complete continence | Cardozo, 2006[244] | 10.00 | 1,559 | 1.53 (1.36; 1.72) | 0.18 (0.13; 0.23) | 6 (4; 8) | 180 (132; 228) |
| Complete continence | Staskin, 2006[39] | 5.00 | 589 | 1.09 (0.82; 1.43) | 0.02 (-0.06; 0.11) | | |
| Complete continence | Staskin, 2006[39] | 10.00 | 882 | 1.43 (1.19; 1.73) | 0.12 (0.06; 0.19) | 8 (5; 16) | 123 (61; 186) |
| Discontinued treatment due to adverse effects | Cardozo, 2006[244] | 5.00 | 1,095 | 0.87 (0.48; 1.58) | -0.01 (-0.03; 0.02) | | |
| Discontinued treatment due to adverse effects | Cardozo, 2006[244] | 10.00 | 1,559 | 1.28 (0.86; 1.91) | 0.01 (-0.01; 0.04) | | |
| Discontinued treatment due to adverse effects | Staskin, 2006[39] | 5.00 | 589 | 0.57 (0.20; 1.65) | -0.02 (-0.05; 0.01) | | |
| Discontinued treatment due to adverse effects | Staskin, 2006[39] | 10.00 | 882 | 1.55 (0.89; 2.71) | 0.02 (-0.01; 0.06) | | |
| Blurred vision | Staskin, 2006[39] | 5.00 | 1,794 | 2.10 (1.17; 3.77) | 0.02 (0.00; 0.04) | 50 (27; 375) | 20 (3; 37) |
| Blurred vision | Staskin, 2006[39] | 10.00 | 2,449 | 2.64 (1.63; 4.29) | 0.03 (0.02; 0.04) | 34 (23; 64) | 30 (16; 44) |
| Blurred vision | Cardozo, 2006[244] | 5.00 | 1,095 | 2.31 (1.10; 4.86) | 0.02 (0.00; 0.05) | | |
| Blurred vision | Cardozo, 2006[244] | 10.00 | 1,559 | 2.58 (1.40; 4.75) | 0.03 (0.01; 0.05) | 35 (22; 92) | 28 (11; 46) |
| Mild blurred vision | Cardozo, 2006[244] | 5.00 | 1,150 | 1.94 (0.86; 4.37) | 0.02 (-0.01; 0.04) | | |
| Mild blurred vision | Cardozo, 2006[244] | 10.00 | 1,643 | 2.01 (1.04; 3.88) | 0.02 (0.00; 0.03) | 63 (33; 833) | 16 (1; 31) |
| Moderate blurred vision | Cardozo, 2006[244] | 5.00 | 1,150 | 2.52 (0.36; 17.79) | 0.00 (-0.01; 0.01) | | |
| Moderate blurred vision | Cardozo, 2006[244] | 10.00 | 1,643 | 4.01 (0.86; 18.85) | 0.01 (0.00; 0.02) | | |
| Severe blurred vision | Cardozo, 2006[244] | 5.00 | 1,150 | 7.54 (0.31; 184.53) | 0.00 (-0.00; 0.01) | | |
| Severe blurred vision | Cardozo, 2006[244] | 10.00 | 1,643 | 9.03 (0.49; 167.51) | 0.01 (0.00; 0.01) | | |
| Constipation | Staskin, 2006[39] | 5.00 | 1,794 | 1.86 (1.16; 2.99) | 0.03 (0.00; 0.05) | 40 (22; 237) | 25 (4; 45) |
| Constipation | Staskin, 2006[39] | 10.00 | 2,449 | 4.65 (3.26; 6.64) | 0.11 (0.08; 0.13) | 10 (8; 12) | 105 (84; 126) |
| Constipation | Cardozo, 2006[244] | 5.00 | 1,095 | 1.78 (1.02; 3.11) | 0.03 (-0.00; 0.06) | | |
| Constipation | Cardozo, 2006[244] | 10.00 | 1,559 | 3.91 (2.61; 5.85) | 0.10 (0.08; 0.13) | 10 (8; 13) | 104 (77; 132) |
| Mild constipation | Cardozo, 2006[244] | 5.00 | 1,150 | 1.99 (1.02; 3.86) | 0.02 (-0.00; 0.05) | | |
| Mild constipation | Cardozo, 2006[244] | 10.00 | 1,643 | 2.69 (1.61; 4.52) | 0.039 (0.020; 0.059) | 26 (17; 51) | 39 (20; 59) |
| Moderate constipation | Cardozo, 2006[244] | 5.00 | 1,150 | 1.14 (0.40; 3.27) | 0.00 (-0.01; 0.02) | | |
| Moderate constipation | Cardozo, 2006[244] | 10.00 | 1,643 | 4.84 (2.54; 9.19) | 0.05 (0.03; 0.07) | 20 (14; 31) | 51 (33; 70) |
| Severe constipation | Cardozo, 2006[244] | 5.00 | 1,150 | 7.54 (0.31; 184.53) | 0.00 (-0.00; 0.01) | | |
| Severe constipation | Cardozo, 2006[244] | 10.00 | 1,643 | 23.08 (1.36; 391.08) | 0.01 (0.01; 0.02) | 75 (46; 192) | 13 (5; 22) |
| Dry mouth | Staskin, 2006[39] | 5.00 | 1,794 | 2.60 (1.82; 3.71) | 0.07 (0.04; 0.10) | 15 (11; 25) | 67 (39; 95) |
| Dry mouth | Staskin, 2006[39] | 10.00 | 2,449 | 6.57 (4.95; 8.73) | 0.23 (0.21; 0.26) | 4 (4; 5) | 234 (206; 261) |
| Dry mouth | Cardozo, 2006[244] | 5.00 | 1,095 | 2.49 (1.59; 3.90) | 0.07 (0.03; 0.10) | 15 (10; 35) | 67 (29; 104) |
| Dry mouth | Cardozo, 2006[244] | 10.00 | 1,559 | 6.48 (4.60; 9.12) | 0.25 (0.21; 0.28) | 4 (4; 5) | 246 (211; 281) |
| Mild dry mouth | Cardozo, 2006[244] | 5.00 | 1,150 | 2.92 (1.74; 4.91) | 0.06 (0.03; 0.09) | 17 (11; 39) | 58 (25; 91) |

**Appendix Table F57. Clinical outcomes after solifenacin vs. placebo, pooled individual patient data from RCTs (high level of evidence) (continued)**

| Outcome | Reference | Dose, mg/day | Number of Subjects | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|
| Mild dry mouth | Cardozo, 2006[244] | 10.00 | 1,643 | 6.18 (4.10; 9.33) | 0.16 (0.13; 0.19) | 6 (5; 8) | 157 (128; 187) |
| Moderate dry mouth | Cardozo, 2006[244] | 5.00 | 1,150 | 1.60 (0.63; 4.10) | 0.01 (-0.01; 0.03) | | |
| Moderate dry mouth | Cardozo, 2006[244] | 10.00 | 1,643 | 6.30 (3.36; 11.81) | 0.07 (0.05; 0.09) | 14 (11; 20) | 71 (50; 91) |
| Severe dry mouth | Cardozo, 2006[244] | 5.00 | 1,150 | 0.84 (0.03; 20.50) | -0.00 (-0.01; 0.00) | | |
| Severe dry mouth | Cardozo, 2006[244] | 10.00 | 1,643 | 16.06 (2.13; 120.81) | 0.02 (0.01; 0.03) | 55 (36; 117) | 18 (9; 28) |

**Appendix Table F58. Evidence of dose response association in clinical outcomes after solifenacin 5 vs.10mg/day (pooled individual patient data from RCTs)**

| Outcome | Reference | Number of Subjects | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|
| Continence | Staskin, 2006[39] | 611 | 0.76 (0.58; 0.98) | -0.10 (-0.18; -0.01) | -10 (-71; -5) | -99 (-184; -14) |
| Continence | Cardozo, 2006[244] | 1092 | 0.98 (0.86; 1.11) | | | |
| Discontinued treatment due to adverse effects | Cardozo, 2006[244] | 1092 | 0.68 (0.38; 1.21) | | | |
| Discontinued treatment due to adverse effects | Staskin, 2006[39] | 611 | 0.37 (0.13; 1.02) | -0.04 (-0.08; -0.01) | -23 (-103; -13) | -43 (-77; -10) |
| Dry mouth | Cardozo, 2006[244] | 1092 | 0.38 (0.28; 0.53) | -0.18 (-0.23; -0.13) | -6 (-8; -4) | -179 (-226; -132) |
| Dry mouth | Staskin, 2006[39] | 1811 | 0.40 (0.31; 0.51) | -0.17 (-0.20; -0.13) | -6 (-8; -5) | -167 (-202; -131) |
| Mild dry mouth | Cardozo, 2006[244] | 1147 | 0.47 (0.32; 0.69) | -0.10 (-0.14; -0.06) | -10 (-17; -7) | -99 (-140; -58) |
| Moderate dry mouth | Cardozo, 2006[244] | 1147 | 0.25 (0.12; 0.55) | -0.06 (-0.09; -0.04) | -16 (-26; -11) | -63 (-87; -38) |
| Severe dry mouth | Cardozo, 2006[244] | 1147 | 0.08 (0.00; 1.26) | -0.02 (-0.03; -0.01) | -51 (-111; -33) | -20 (-30; -9) |
| Blurred vision | Cardozo, 2006[244] | 1092 | 0.89 (0.48; 1.66) | | | |
| Blurred vision | Staskin, 2006[39] | 1811 | 0.80 (0.49; 1.28) | | | |
| Mild blurred vision | Cardozo, 2006[244] | 1147 | 0.96 (0.47; 1.98) | | | |
| Moderate blurred vision | Cardozo, 2006[244] | 1147 | 0.63 (0.13; 2.94) | | | |
| Severe blurred vision | Cardozo, 2006[244] | 1147 | 0.63 (0.07; 5.59) | | | |
| Constipation | Cardozo, 2006[244] | 1092 | 0.45 (0.29; 0.72) | -0.08 (-0.11; -0.04) | -13 (-25; -9) | -76 (-113; -40) |
| Constipation | Staskin, 2006[39] | 1811 | 0.40 (0.28; 0.58) | -0.08 (-0.11; -0.05) | -12 (-19; -9) | -80 (-107; -54) |
| Mild constipation | Cardozo, 2006[244] | 1147 | 0.74 (0.42; 1.29) | -0.02 (-0.04; 0.01) | | |
| Moderate constipation | Cardozo, 2006[244] | 1147 | 0.24 (0.10; 0.59) | -0.05 (-0.07; -0.03) | -20 (-36; -14) | -49 (-71; -28) |
| Severe constipation | Cardozo, 2006[244] | 1147 | 0.23 (0.03; 1.76) | -0.01 (-0.02; 0.00) | -97 (-2145; -49) | -10 (-20; 0) |

**Appendix Table F59. Results from VIBRANT trial[467]**

| Outcome | Dose | Relative Risk 95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|
| BSW: benefit-much | 5 -10mg daily | 1.78 (1.48; 2.14) | 0.222 (0.155; 0.290) | 4 (3; 6) | 222 (155; 290) |
| BSW: satisfaction-yes | 5 -10mg daily | 1.42 (1.26; 1.61) | 0.207 (0.139; 0.275) | 5 (4; 7) | 207 (139; 275) |
| BSW: willingness to continue-yes | 5 -10mg daily | 1.39 (1.23; 1.57) | 0.192 (0.123; 0.260) | 5 (4; 8) | 192 (123; 260) |
| PPBC score: None | 5 -10mg daily | 1.32 (0.88; 1.98) | 0.030 (-0.014; 0.074) | | |
| PPBC score: Very minor | 5 -10mg daily | 1.46 (1.10; 1.94) | 0.079 (0.021; 0.136) | 13 (7; 47) | 79 (21; 136) |
| Discontinuation | 10mg daily | 0.84 (0.39; 1.81) | -0.011 (-0.057; 0.036) | | |
| | 5mg daily | 0.63 (0.27; 1.46) | -0.031 (-0.089; 0.027) | | |
| BSW: benefit-little | 5 -10mg daily | 0.88 (0.67; 1.15) | -0.028 (-0.087; 0.030) | | |
| BSW: benefit-none | 5 -10mg daily | 0.46 (0.34; 0.61) | -0.164 (-0.221; -0.106) | -6 (-9; -5) | -164 (-221; -106) |
| BSW: satisfaction-no | 5 -10mg daily | 0.51 (0.39; 0.66) | -0.167 (-0.227; -0.106) | -6 (-9; -4) | -167 (-227; -106) |
| BSW: willingness to continue-no | 5 -10mg daily | 0.55 (0.43; 0.71) | -0.151 (-0.212; -0.090) | -7 (-11; -5) | -151 (-212; -90) |
| PPBC score: Severe | 5 -10mg daily | 0.42 (0.27; 0.64) | -0.095 (-0.140; -0.050) | -11 (-20; -7) | -95 (-140; -50) |
| PPBC score: Many severe | 5 -10mg daily | 0.78 (0.36; 1.69) | -0.008 (-0.033; 0.017) | | |
| Dry mouth | 5 -10mg daily | 5.61 (2.80; 11.23) | 0.109 (0.072; 0.146) | 9 (7; 14) | 109 (72; 146) |
| Constipation | 5 -10mg daily | 4.38 (1.95; 9.83) | 0.062 (0.032; 0.092) | 16 (11; 32) | 62 (32; 92) |
| Dry eye | 5 -10mg daily | 5.94 (0.72; 49.09) | 0.013 (0.000; 0.026) | | |
| Dyspepsia | 5 -10mg daily | 10.89 (0.60; 196.20) | 0.013 (0.001; 0.025) | 77 (40; 1616) | 13 (1; 25) |
| Fatigue | 5 -10mg daily | 2.47 (0.48; 12.67) | 0.008 (-0.006; 0.021) | | |
| Nausea | 5 -10mg daily | 0.66 (0.19; 2.32) | -0.005 (-0.021; 0.011) | | |
| Blurred vision | 5 -10mg daily | 0.79 (0.21; 2.93) | -0.003 (-0.018; 0.013) | | |
| Headache | 5 -10mg daily | 0.59 (0.14; 2.47) | -0.005 (-0.020; 0.009) | | |

**Appendix Table F60. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses**

| Outcome | Reference Daily Dose mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|
| Response to treatment | Sand, 2009[366] 4 mg/day | 251/434 | 167/430 | 1.49 (1.29; 1.72) | 0.190 (0.125; 0.255) | 5 (4; 8) | 190 (125; 255) |
| Response to treatment | Sand, 2009[366] 8 mg/day | 291/452 | 167/430 | 1.66 (1.45; 1.90) | 0.255 (0.192; 0.319) | 4 (3; 5) | 255 (192; 319) |
| Discontinuation | Sand, 2009[366] 8 mg/day | 14/287 | 6/283 | 2.30 (0.90; 5.90) | 0.028 (-0.002; 0.058) | | |
| Discontinuation due to adverse effects | Khullar, 2008[324] 4 mg/day | 27/554 | 19/554 | 1.42 (0.80; 2.53) | 0.014 (-0.009; 0.038) | | |
| Discontinuation due to adverse effects | Khullar, 2008[324] 8 mg/day | 41/566 | 19/554 | 2.11 (1.24; 3.59) | 0.038 (0.012; 0.064) | 26 (16; 84) | 38 (12; 64) |
| Back pain | Sand, 2009[366]mg/day | 9/434 | 1/430 | 8.92 (1.13; 70.08) | 0.018 (0.004; 0.033) | 54 (31; 235) | 18 (4; 33) |
| Back pain | Sand, 2009[366] 8 mg/day | 4/421 | 1/430 | 4.09 (0.46; 36.40) | 0.007 (-0.003; 0.018) | | |
| Constipation | Sand, 2009[366] 4 mg/day | 20/434 | 10/430 | 1.98 (0.94; 4.18) | 0.023 (-0.002; 0.047) | | |
| Constipation | Khullar, 2008[324] 4 mg/day | 23/554 | 11/554 | 2.09 (1.03; 4.25) | 0.022 (0.001; 0.042) | 46 (24; 719) | 22 (1; 42) |
| Constipation | Chapple, 2008[253] 8 mg/day | 13/287 | 4/283 | 3.20 (1.06; 9.71) | 0.031 (0.003; 0.059) | 32 (17; 290) | 31 (3; 59) |
| Constipation | Sand, 2009[366] 4 mg/day | 24/421 | 10/430 | 2.45 (1.19; 5.06) | 0.034 (0.007; 0.060) | 30 (17; 135) | 34 (7; 60) |
| Constipation | Khullar, 2008[324] 8 mg/day | 34/566 | 11/554 | 3.03 (1.55; 5.91) | 0.040 (0.017; 0.063) | 25 (16; 57) | 40 (17; 63) |
| Cough | Sand, 2009[366] 4 mg/day | 7/434 | 3/430 | 2.31 (0.60; 8.88) | 0.009 (-0.005; 0.023) | | |
| Cough | Sand, 2009[366] 4 mg/day | 5/421 | 3/430 | 1.70 (0.41; 7.08) | 0.005 (-0.008; 0.018) | | |
| Diarrhea | Sand, 2009[366] 4 mg/day | 7/434 | 10/430 | 0.69 (0.27; 1.81) | -0.007 (-0.026; 0.011) | | |
| Diarrhea | Sand, 2009[366] 4 mg/day | 6/421 | 10/430 | 0.61 (0.22; 1.67) | -0.009 (-0.027; 0.009) | | |
| Dizziness | Sand, 2009[366] 4 mg/day | 4/434 | 9/430 | 0.44 (0.14; 1.42) | -0.012 (-0.028; 0.005) | | |

**Appendix Table F60. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)**

| Outcome | Reference Daily Dose mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|
| Dizziness | Sand, 2009[366] 4 mg/day | 5/421 | 9/430 | 0.57 (0.19; 1.68) | -0.009 (-0.026; 0.008) | | |
| Dry eye | Sand,2009[366] 4 mg/day | 6/434 | 0/430 | 12.88 (0.73; 227.94) | 0.014 (0.002; 0.026) | | |
| Dry eye | Chapple, 2008[253] 8 mg/day | 12/287 | 0/283 | 24.65 (1.47; 414.40) | 0.042 (0.018; 0.066) | 24 (15; 56) | 42 (18; 66) |
| Dry eye | Sand, 2009[366] 4 mg/day | 10/421 | 0/430 | 21.45 (1.26; 364.85) | 0.024 (0.009; 0.039) | 42 (26; 117) | 24 (9; 39) |
| Dry mouth | Sand, 2009[366] 4 mg/day | 89/434 | 32/430 | 2.76 (1.88; 4.03) | 0.131 (0.085; 0.176) | 8 (6; 12) | 131 (85; 176) |
| Dry mouth | Khullar, 2008[324] 4 mg/day | 104/554 | 39/554 | 2.67 (1.88; 3.78) | 0.117 (0.078; 0.156) | 9 (6; 13) | 117 (78; 156) |
| Dry mouth | Chapple, 2008[253] 8 mg/day | 97/287 | 20/283 | 4.78 (3.04; 7.52) | 0.267 (0.205; 0.330) | 4 (3; 5) | 267 (205; 330) |
| Dry mouth | Sand, 2009[366] 4 mg/day | 155/421 | 32/430 | 4.95 (3.47; 7.06) | 0.294 (0.241; 0.346) | 3 (3; 4) | 294 (241; 346) |
| Dry mouth | Khullar, 2008[324] 8 mg/day | 196/566 | 39/554 | 4.92 (3.56; 6.80) | 0.276 (0.231; 0.321) | 4 (3; 4) | 276 (231; 321) |
| Dry throat | Sand, 2009[366] 4 mg/day | 4/434 | 0/430 | 8.92 (0.48; 165.12) | 0.009 (-0.001; 0.019) | | |
| Dry throat | Khullar, 2008[324] 4 mg/day | 5/554 | 2/554 | 2.50 (0.49; 12.83) | 0.005 (-0.004; 0.015) | | |
| Dry throat | Chapple, 2008[253] 8 mg/day | 8/287 | 0/283 | 16.76 (0.97; 289.07) | 0.028 (0.008; 0.048) | 36 (21; 129) | 28 (8; 48) |
| Dry throat | Sand, 2009[366] 4 mg/day | 10/421 | 0/430 | 21.45 (1.26; 364.85) | 0.024 (0.009; 0.039) | 42 (26; 117) | 24 (9; 39) |
| Dry throat | Khullar, 2008[324] 8 mg/day | 13/566 | 2/554 | 6.36 (1.44; 28.06) | 0.019 (0.006; 0.033) | 52 (31; 165) | 19 (6; 33) |
| Dyspepsia | Khullar, 2008[324] 4 mg/day | 9/554 | 3/554 | 3.00 (0.82; 11.02) | 0.011 (-0.001; 0.023) | | |
| Dyspepsia | Khullar, 2008[324] 8 mg/day | 13/566 | 3/554 | 4.24 (1.22; 14.80) | 0.018 (0.004; 0.031) | | |
| Fatigue | Sand, 2009[366] 4 mg/day | 5/434 | 2/430 | 2.48 (0.48; 12.70) | 0.007 (-0.005; 0.019) | | |
| Fatigue | Chapple, 2008[253] 8 mg/day | 1/287 | 1/283 | 0.99 (0.06; 15.69) | 0.000 (-0.010; 0.010) | | |
| Fatigue | Sand, 2009[366] 4 mg/day | 1/421 | 2/430 | 0.51 (0.05; 5.61) | -0.002 (-0.010; 0.006) | | |

**Appendix Table F60. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)**

| Outcome | Reference Daily Dose mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|
| Headache | Sand, 2009[366] 4 mg/day | 21/434 | 18/430 | 1.16 (0.62; 2.14) | 0.007 (-0.021; 0.034) | | |
| Headache | Khullar, 2008[324] 4 mg/day | 24/554 | 23/554 | 1.04 (0.60; 1.83) | 0.002 (-0.022; 0.026) | | |
| Headache | Sand, 2009[366] 4 mg/day | 13/421 | 18/430 | 0.74 (0.37; 1.49) | -0.011 (-0.036; 0.014) | | |
| Headache | Khullar, 2008[324] 8 mg/day | 15/566 | 23/554 | 0.64 (0.34; 1.21) | -0.015 (-0.036; 0.006) | | |
| Increased alanine aminotransferase | Chapple, 2008[253] 8 mg/day | 6/287 | 1/283 | 5.92 (0.72; 48.83) | 0.017 (-0.001; 0.035) | | |
| Lacrimal disorder | Khullar, 2008[324] 4 mg/day | 8/554 | 0/554 | 17.00 (0.98; 293.82) | 0.014 (0.004; 0.025) | 69 (40; 255) | 14 (4; 25) |
| Lacrimal disorder | Khullar, 2008[324] 8 mg/day | 21/566 | 0/554 | 42.09 (2.56; 693.13) | 0.037 (0.021; 0.053) | 27 (19; 47) | 37 (21; 53) |
| Mild-constipation | Khullar, 2008[324] 4 mg/day | 8/554 | 1/554 | 8.00 (1.00; 63.75) | 0.013 (0.002; 0.023) | 79 (43; 478) | 13 (2; 23) |
| Mild-constipation | Khullar, 2008[324] 4 mg/day | 14/554 | 8/554 | 1.75 (0.74; 4.14) | 0.011 (-0.006; 0.027) | | |
| Mild-constipation | Khullar, 2008[324] 8 mg/day | 14/566 | 1/554 | 13.70 (1.81; 103.86) | 0.023 (0.010; 0.036) | 44 (28; 104) | 23 (10; 36) |
| Mild-constipation | Khullar, 2008[324] 8 mg/day | 18/566 | 8/554 | 2.20 (0.97; 5.02) | 0.017 (0.000; 0.035) | 58 (29; -5599) | 17 (0; 35) |
| Mild-dry mouth | Khullar, 2008[324] 4 mg/day | 16/554 | 11/554 | 1.45 (0.68; 3.11) | 0.009 (-0.009; 0.027) | | |
| Mild-dry mouth | Khullar, 2008[324] 4 mg/day | 84/554 | 27/554 | 3.11 (2.05; 4.72) | 0.103 (0.068; 0.138) | 10 (7; 15) | 103 (68; 138) |
| Mild-dry mouth | Khullar, 2008[324] 8 mg/day | 53/566 | 11/554 | 4.72 (2.49; 8.93) | 0.074 (0.047; 0.100) | 14 (10; 21) | 74 (47; 100) |
| Mild-dry mouth | Khullar, 2008[324] 8 mg/day | 126/566 | 27/554 | 4.57 (3.07; 6.81) | 0.174 (0.135; 0.213) | 6 (5; 7) | 174 (135; 213) |
| Mild-headache | Khullar, 2008[324] 4 mg/day | 6/554 | 3/554 | 2.00 (0.50; 7.96) | 0.005 (-0.005; 0.016) | | |
| Mild-headache | Khullar, 2008[324] 4 mg/day | 15/554 | 19/554 | 0.79 (0.41; 1.54) | -0.007 (-0.028; 0.013) | | |
| Mild-headache | Khullar, 2008[324] 8 mg/day | 5/566 | 3/554 | 1.63 (0.39; 6.79) | 0.003 (-0.006; 0.013) | | |
| Mild-headache | Khullar, 2008[324] 8 mg/day | 9/566 | 19/554 | 0.46 (0.21; 1.02) | -0.018 (-0.037; 0.000) | | |

**Appendix Table F60. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)**

| Outcome | Reference Daily Dose mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|
| Mild-urinary tract infection | Khullar, 2008[324] 4 mg/day | 7/554 | 5/554 | 1.40 (0.45; 4.38) | 0.004 (-0.009; 0.016) | | |
| Mild-urinary tract infection | Khullar, 2008[324] 4 mg/day | 11/554 | 12/554 | 0.92 (0.41; 2.06) | -0.002 (-0.019; 0.015) | | |
| Mild-urinary tract infection | Khullar, 2008[324] 8 mg/day | 8/566 | 5/554 | 1.57 (0.52; 4.76) | 0.005 (-0.007; 0.018) | | |
| Mild-urinary tract infection | Khullar, 2008[324] 8 mg/day | 15/566 | 12/554 | 1.22 (0.58; 2.59) | 0.005 (-0.013; 0.023) | | |
| Naspharyngitis | Sand, Morrow, 2009[366] 4 mg/day | 14/434 | 12/430 | 1.16 (0.54; 2.47) | 0.004 (-0.018; 0.027) | | |
| Naspharyngitis | Khullar, 2008[324] 4 mg/day | 18/554 | 14/554 | 1.29 (0.65; 2.56) | 0.007 (-0.012; 0.027) | | |
| Naspharyngitis | Chapple, 2008[253] 8 mg/day | 5/287 | 7/283 | 0.70 (0.23; 2.19) | -0.007 (-0.031; 0.016) | | |
| Naspharyngitis | Sand, 2009[366] 4 mg/day | 6/421 | 12/430 | 0.51 (0.19; 1.35) | -0.014 (-0.033; 0.006) | | |
| Naspharyngitis | Khullar, 2008[324] 8 mg/day | 7/566 | 14/554 | 0.49 (0.20; 1.20) | -0.013 (-0.029; 0.003) | | |
| Nausea | Sand, 2009[366] 4 mg/day | 4/434 | 5/430 | 0.79 (0.21; 2.93) | -0.002 (-0.016; 0.011) | | |
| Nausea | Chapple, 2008[253] 8 mg/day | 4/287 | 1/283 | 3.94 (0.44; 35.07) | 0.010 (-0.005; 0.026) | | |
| Nausea | Sand, 2009[366] 4 mg/day | 11/421 | 5/430 | 2.25 (0.79; 6.41) | 0.015 (-0.004; 0.033) | | |
| Severe-constipation | Khullar, 2008[324] 4 mg/day | 1/554 | 2/554 | 0.50 (0.05; 5.50) | -0.002 (-0.008; 0.004) | | |
| Severe-constipation | Khullar, 2008[324] 8 mg/day | 2/566 | 2/554 | 0.98 (0.14; 6.92) | 0.000 (-0.007; 0.007) | | |
| Severe-dry mouth | Khullar, 2008[324] 4 mg/day | 4/554 | 1/554 | 4.00 (0.45; 35.67) | 0.005 (-0.002; 0.013) | | |
| Severe-dry mouth | Khullar, 2008[324] 8 mg/day | 17/566 | 1/554 | 16.64 (2.22; 124.61) | 0.028 (0.014; 0.043) | 35 (23; 73) | 28 (14; 43) |
| Severe-headache | Khullar, 2008[324] 4 mg/day | 3/554 | 1/554 | 3.00 (0.31; 28.75) | 0.004 (-0.003; 0.011) | | |
| Severe-headache | Khullar, 2008[324] 8 mg/day | 1/566 | 1/554 | 0.98 (0.06; 15.61) | 0.000 (-0.005; 0.005) | | |

**Appendix Table F60. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)**

| Outcome | Reference Daily Dose mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|
| Severe-urinary tract infection | Khullar, 2008[324] 4 mg/day | 0/554 | 0/554 | 0.00 (0.00; 0.00) | 0.000 (-0.004; 0.004) | | |
| Severe-urinary tract infection | Khullar, 2008[324] 8 mg/day | 1/566 | 0/554 | 2.94 (0.12; 71.93) | 0.002 (-0.003; 0.007) | | |
| Upper respiratory tract infection | Sand, 2009[366] 4 mg/day | 12/434 | 9/430 | 1.32 (0.56; 3.10) | 0.007 (-0.014; 0.027) | | |
| Upper respiratory tract infection | Khullar,2008[324] 4 mg/day | 14/554 | 12/554 | 1.17 (0.54; 2.50) | 0.004 (-0.014; 0.021) | | |
| Upper respiratory tract infection | Sand, 2009[366] 4 mg/day | 8/421 | 9/430 | 0.91 (0.35; 2.33) | -0.002 (-0.021; 0.017) | | |
| Upper respiratory tract infection | Khullar, 2008[324] 8 mg/day | 10/566 | 12/554 | 0.82 (0.36; 1.87) | -0.004 (-0.020; 0.012) | | |
| Urinary tract infection | Sand, 2009[366] 4 mg/day | 18/434 | 17/430 | 1.05 (0.55; 2.01) | 0.002 (-0.024; 0.028) | | |
| Urinary tract infection | Khullar, 2008[324] 4 mg/day | 18/554 | 17/554 | 1.06 (0.55; 2.03) | 0.002 (-0.019; 0.022) | | |
| Urinary tract infection | Sand, 2009[366] 4 mg/day | 24/421 | 17/430 | 1.44 (0.79; 2.64) | 0.017 (-0.011; 0.046) | | |
| Urinary tract infection | Khullar, 2008[324] 8 mg/day | 24/566 | 17/554 | 1.38 (0.75; 2.54) | 0.012 (-0.010; 0.034) | | |

**Appendix Table F61. Significant dose response effects of fesoterodine**

| Reference | Dose, mg/day | Outcome | Relative Risk 95% CI) | Absolute Risk Difference 95%CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|
| Chapple, 2007[252] | 8 vs.4 | Any adverse event | 1.17 (1.00; 1.36) | 0.084 (0.001; 0.166) | 12 (6; 836) | 84 (1; 166) |
| Nitti, 2007[347] | 8 vs.4 | Any adverse event | 1.14 (1.01; 1.29) | 0.088 (0.009; 0.166) | 11 (6; ;112) | 88 (9; 166) |
| Nitti, 2007[347] | 8 vs.4 | Dry eye | 4.56 (1.00; 20.94) | 0.025 (0.002; 0.048) | 40 (21; 439) | 25 (2; 48) |
| Chapple, 2007[252] | 8 vs.4 | Dry mouth | 1.55 (1.18; 2.05) | 0.120 (0.047; 0.193) | 8 (5; 21) | 120 (47; 193) |
| Nitti, 2007[347] | 8 vs.4 | Dry mouth | 2.23 (1.63; 3.05) | 0.196 (0.125; 0.266) | 5 (4; 8) | 196 (125; 266) |
| Chapple, 2007[252] | 8 vs.4 | Dry throat | 7.56 (0.95; 60.01) | 0.024 (0.004; 0.044) | 41 (23; 263) | 24 (4; 44) |
| Nitti, 2007[347] | 8 vs.4 | Hypertension | 0.07 (0.00; 1.18) | -0.025 (-0.044; -0.005) | -40 (-184; -23) | -25 (-44; -5) |
| Chapple, 2007[252] | 8 vs.4 | Influenza | 0.21 (0.05; 0.96) | -0.026 (-0.049; -0.003) | -38 (-354; -20) | -26 (-49; -3) |
| Nitti, 2007[347] | 8 vs.4 | Nasopharyngitis | 0.20 (0.04; 0.92) | -0.028 (-0.052; -0.004) | -36 (-223; -19) | -28 (-52; -4) |
| Sand, 2009[366] 4 mg/day Pooled analysis | 8 vs. 4 | Dry mouth | 1.67 (1.3; 42.09) | 0.138 (0.080; 0.196) | 7 (5; 13) | 138 (80; 196) |
| Khullar, 2008[324] Pooled analysis | 4 vs.8 | Dry mouth-total | 0.54 (0.44; 0.67) | -0.159 (-0.209; -0.108) | -6 (-9; -5) | -159 (-209; -108) |
| Khullar, 2008[324] Pooled analysis | 4 vs.8 | Lacrimal disorder | 0.39 (0.17; 0.87) | -0.023 (-0.041; -0.004) | -44 (-239; -24) | -23 (-41; -4) |
| Khullar, 2008[324] Pooled analysis | 4 vs.8 | Moderate dry mouth | 0.31 (0.18; 0.53) | -0.065 (-0.093; -0.037) | -15 (-27 -11) | -65 (-93; -37) |
| Khullar, 2008[324] Pooled analysis | 4 vs.8 | Mild dry mouth | 0.68 (0.53; 0.87) | -0.071 (-0.116; -0.026) | -14 (-39 -9) | -71 (-116; -26) |
| Khullar, 2008[324] Pooled analysis | 4 vs.8 | Nasopharyngitis | 2.63 (1.11; 6.24) | 0.020 (0.003; 0.037) | 50 (27; ;360) | 20 (3; 37) |
| Khullar, 2008[324] Pooled analysis | 4 vs.8 | Severe dry mouth | 0.24 (0.08; 0.71) | -0.023 (-0.039; -0.007) | -44 (-141; -26) | -23 (-39; -7) |
| Sand, 2009[366] 4 mg/day Pooled analysis | 8 vs. 4 | Treatment response | 1.11 (1.00; 1.24) | 0.065 (0.001; 0.130) | 15 (8; 727) | 65 (1; 130) |

**Appendix Table F62. Clinical outcomes after fesoterodine vs. placebo**

| Reference | Mg/day | Number of Subjects | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable/1000 Events (95% CI) |
|---|---|---|---|---|---|---|
| **Any adverse events** | | | | | | |
| Cardozo, 2010[468]* | 4 | 867 | 1.21 (1.07; 1.38) | 0.100 (0.033; 0.166) | 10 (6; 30) | 100 (33; 166) |
| | 8 | 882 | 1.39 (1.23; 1.57) | 0.181 (0.117; 0.246) | 6 (4; 9) | 181 (117; 246) |
| **Discontinuations** | | | | | | |
| Dmochowski, 2010[465] | 4 to 8 | 883 | 0.95 (0.68; 1.33) | -0.007 (-0.052; 0.038) | | |
| Herschorn, 2010[466] | 4 to 8 | 1013 | 1.33 (0.89; 1.98) | 0.029 (-0.010; 0.069) | | |
| **Adverse events leading to discontinuation** | | | | | | |
| Dmochowski, 2010[465] | 4 to 8 | 883 | 1.64 (0.97; 2.79) | 0.030 (-0.001; 0.062) | | |
| Herschorn, 2010[466] | 4 to 8 | 1013 | 3.61 (1.55; 8.38) | 0.047 (0.023; 0.070) | 21 (14; 43) | 47 (23; 70) |
| **Lack of efficacy leading to discontinuation** | | | | | | |
| Dmochowski, 2010[465] | 4 to 8 | 883 | 0.32 (0.12; 0.86) | -0.025 (-0.044; -0.005) | -41 (-218; -22) | -25 (-44; -5) |
| Herschorn, 2010[466] | 4 to 8 | 1013 | 1.28 (0.46; 3.56) | 0.004 (-0.012; 0.021) | | |
| **Deterioration on the PPBC scale** | | | | | | |
| Dmochowski, 2010[465] | 4 to 8 | 883 | 0.49 (0.26; 0.92) | -0.033 (-0.061; -0.005) | -30 (-201; -16) | -33 (-61; -5) |
| **Deterioration on the UPS scale** | | | | | | |
| Dmochowski, 2010[465] | 4 to 8 | 883 | 0.85 (0.51; 1.42) | -0.010 (-0.042; 0.022) | | |
| **Deterioration on the PPBC scale from baseline** | | | | | | |
| Herschorn, 2010[466] | 4 to 8 | 1013 | 0.46 (0.29; 0.74) | -0.055 (-0.091; -0.019) | -18 (-54; -11) | -55 (-91; -19) |
| **Deterioration on the UPS scale from baseline** | | | | | | |
| Herschorn, 2010[466] | 4 to 8 | 1013 | 0.65 (0.36; 1.16) | -0.020 (-0.049; 0.009) | | 0 (0; 0) |
| **≥2-point improvement on the PPBC scale** | | | | | | |
| Dmochowski, 2010[465] | 4 to 8 | 883 | 1.29 (1.06; 1.57) | 0.080 (0.019; 0.141) | 13 (7; 54) | 80 (19; 141) |
| **improvement on the UPS scale** | | | | | | |
| Dmochowski, 2010[465] | 4 to 8 | 883 | 1.35 (1.13; 1.61) | 0.108 (0.045; 0.171) | 9 (6; 22) | 108 (45; 171) |
| **≥2-point improvement on the PPBC scale from baseline** | | | | | | |
| Herschorn, 2010[466] | 4 to 8 | 1013 | 0.94 (0.80; 1.11) | -0.024 (-0.088; 0.040) | | |
| **improvement on the UPS scale from baseline** | | | | | | |
| Herschorn, 2010[466] | 4 to 8 | 1013 | 1.28 (1.07; 1.52) | 0.093 (0.030; 0.156) | 11 (6; 33) | 93 (30; 156) |
| **UTI** | | | | | | |
| Herschorn, 2010[466] | 4 to 8 | 1013 | 3.69 (0.85; 16.04) | 0.016 (0.002; 0.030) | 62 (33; 436) | 16 (2; 30) |
| Cardozo, 2010[468]* | 4 | 867 | 0.89 (0.43; 1.81) | -0.004 (-0.028; 0.020) | | |
| | 8 | 882 | 1.41 (0.74; 2.66) | 0.014 (-0.012; 0.041) | | |

* pooled analysis

**Appendix Table F63. Clinical outcomes after propiverine vs. placebo, individual RCTs**

| Reference | Dose, mg/day | Outcome | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Dorschner, 2000[275] | 45 | Urgency symptom free | 15/49 | 7/49 | 2.14 (0.96; 4.79) | 0.163 (0.001; 0.325) | 6 (3; 806) | 163 (1; 325) |
| | | Incontinence symptom free | 24/49 | 15/49 | 1.60 (0.96; 2.66) | 0.184 (-0.007; 0.374) | | |
| | | Urgency improved | 29/49 | 19/49 | 1.53 (1.00; 2.33) | 0.204 (0.010; 0.398) | 5 (3; 97) | 204 (10; 398) |
| | | Incontinence improved | 19/49 | 11/49 | 1.73 (0.92; 3.24) | 0.163 (-0.016; 0.343) | | |
| | | Incontinence unchanged | 6/49 | 23/49 | 0.26 (0.12; 0.58) | -0.347 (-0.514; -0.180) | -3 (-6; -2) | -347 (-514; -180) |
| | | Urgency unchanged | 5/49 | 23/49 | 0.22 (0.09; 0.53) | -0.367 (-0.531; -0.204) | -3 (-5; -2) | -367 (-531; -204) |
| Abrams, 2006[221] | 20 | Patients with ≥1 AE | 30/38 | 12/24 | 1.58 (1.02; 2.43) | 0.289 (0.051; 0.528) | 3 (2; 20) | 289 (51; 528) |
| | 45 | Patients with ≥1 AE | 34/42 | 12/24 | 1.62 (1.06; 2.48) | 0.310 (0.077; 0.542) | 3 (2; 13) | 310 (77; 542) |
| | 20 | Patients with ≥1 AE* | 30/38 | 12/24 | 1.58 (1.02; 2.43) | 0.289 (0.051; 0.528) | 3 (2; 20) | 289 (51; 528) |
| | 45 | Patients with ≥1 AE* | 34/42 | 12/24 | 1.62 (1.06; 2.48) | 0.310 (0.077; 0.542) | 3 (2; 13) | 310 (77; 542) |
| | 45 | Abnormal vision | 14/42 | 0/24 | 16.86 (1.05; 270.62) | 0.333 (0.182; 0.485) | 3 (2; 6) | 333 (182; 485) |
| | 20 | Abnormal vision | 9/38 | 0/24 | 12.18 (0.74; 200.11) | 0.237 (0.091; 0.382) | 4 (3; 11) | 237 (91; 382) |
| | 20 | Abnormal vision* | 9/38 | 0/24 | 12.18 (0.74; 200.11) | 0.237 (0.091; 0.382) | 4 (3; 11) | 237 (91; 382) |
| | 45 | Abnormal vision* | 14/42 | 0/24 | 16.86 (1.05; 270.62) | 0.333 (0.182; 0.485) | 3 (2; 6) | 333 (182; 485) |
| | 20 | Constipation | 6/38 | 0/24 | 8.33 (0.49; 141.53) | 0.158 (0.029; 0.287) | 6 (3; 35) | 158 (29; 287) |
| | 45 | Constipation | 10/42 | 0/24 | 12.21 (0.75; 199.55) | 0.238 (0.098; 0.378) | 4 (3; 10) | 238 (98; 378) |
| | 20 | Constipation* | 6/38 | 0/24 | 8.33 (0.49; 141.53) | 0.158 (0.029; 0.287) | 6 (3; 35) | 158 (29; 287) |
| | 45 | Constipation* | 10/42 | 0/24 | 12.21 (0.75; 199.55) | 0.238 (0.098; 0.378) | 4 (3; 10) | 238 (98; 378) |
| | 20 | Dry mouth | 13/38 | 4/24 | 2.05 (0.76; 5.56) | 0.175 (-0.037; 0.388) | | |
| | 45 | Dry mouth | 22/42 | 4/24 | 3.14 (1.23; 8.05) | 0.357 (0.145; 0.569) | 3 (2; 7) | 357 (145; 569) |
| | 20 | Dry mouth* | 13/38 | 4/24 | 2.05 (0.76; 5.56) | 0.175 (-0.037; 0.388) | | |
| | 45 | Dry mouth* | 22/42 | 4/24 | 3.14 (1.23; 8.05) | 0.357 (0.145; 0.569) | 3 (2; 7) | 357 (145; 569) |
| | 20 | Headache | 1/38 | 0/24 | 1.92 (0.08; 45.37) | 0.026 (-0.055; 0.108) | | |
| | 45 | Headache | 3/42 | 0/24 | 4.07 (0.22; 75.60) | 0.071 (-0.027; 0.170) | | |
| | 20 | Headache* | 1/38 | 0/24 | 1.92 (0.08; 45.37) | 0.026 (-0.055; 0.108) | | |
| | 45 | Headache* | 3/42 | 0/24 | 4.07 (0.22; 75.60) | 0.071 (-0.027; 0.170) | | |

* at followup

**Appendix Table F64. Clinical outcomes after botulinum toxin vs. placebo, individual RCTs**

| Reference Sample | Dose | Outcome | Active n/N | Control n/N | Relative Risk | Lower 95% CI | Upper 95% CI | Absolute Risk Difference | Lower 95% CI | Upper 95% CI | Number Needed to Treat | Attributable Events/1000 Treated |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brubaker, 2008[232] 84 | 200U-single dose | >75% decreased number of incontinence episodes | 18/28 | 0/15 | 20.41 | 1.32 | 316.75 | 0.643 | 0.448 | 0.837 | 2 | 643 |
| Brubaker, 2008[232] 84 | 200U-single dose | Serious adverse events | 3/28 | 2/15 | 0.80 | 0.15 | 4.29 | -0.026 | -0.233 | 0.180 | | |
| Brubaker, 2008[232] 84 | 200U-single dose | Unexpected adverse events | 6/28 | 0/15 | 7.17 | 0.43 | 119.24 | 0.214 | 0.040 | 0.388 | 5 | 214 |
| Brubaker, 2008[232] 84 | 200U-single dose | Treatment failure | 6/28 | 11/15 | 0.29 | 0.14 | 0.63 | -0.519 | -0.790 | -0.249 | -2 | -519 |
| Brubaker, 2008[232] 84 | 200U-single dose | Urinary tract infection | 12/28 | 3/15 | 2.14 | 0.71 | 6.43 | 0.229 | -0.045 | 0.502 | | |
| Brubaker, 2008[232] 84 | 200U-single dose | Increase in post-void residual volume | 12/28 | 0/15 | 13.79 | 0.87 | 217.93 | 0.429 | 0.229 | 0.628 | 2 | 429 |
| Brubaker, 2008[232] 84 | 200U-single dose | Urinary tract infection without increased PVR | 3/28 | 3/15 | 0.54 | 0.12 | 2.34 | -0.093 | -0.325 | 0.140 | | |

**Appendix Table F65. Quality of life after botulinum toxin vs. placebo, individual RCTs**

| Reference | Dose | Outcome | Active N | Control N | Active Mean+/- Standard Deviation | Control Mean+/- Standard Deviation | Mean Difference | Lower 95% CI | Upper 95% CI |
|---|---|---|---|---|---|---|---|---|---|
| Ghei, 2005[284] | 5000IU | KHQ score: emotional problems | 10 | 10 | 5.3+/-2.02 | 7.0+/-2.42 | -1.75 | -3.70 | 0.20 |
| Ghei, 2005[284] | 5000IU | KHQ score: impact on life | 10 | 10 | 1.5+/-0.81 | 2.5+/-0.81 | -1 | -1.71 | -0.29 |
| Ghei, 2005[284] | 5000IU | KHQ score: incontinence impact | 10 | 10 | 4.5+/-3.23 | 7.0+/-4.03 | -2.5 | -5.70 | 0.70 |
| Ghei, 2005[284] | 5000IU | KHQ score: incontinence severity measures | 10 | 10 | 8.5+/-3.23 | 12.0+/-4.03 | -3.5 | -6.70 | -0.30 |
| Ghei, 2005[284] | 5000IU | KHQ score: personal relationships | 10 | 10 | 2.0+/-4.03 | 3.5+/-3.23 | -1.5 | -4.70 | 1.70 |
| Ghei, 2005[284] | 5000IU | KHQ score: physical/social limitations | 10 | 10 | 5.0+/-2.42 | 7.5+/-4.03 | -2.5 | -5.42 | 0.42 |
| Ghei, 2005[284] | 5000IU | KHQ score: present health | 10 | 10 | 1.0+/-0.81 | 1.5+/-0.81 | -0.5 | -1.21 | 0.21 |
| Ghei, 2005[284] | 5000IU | KHQ score: role limitations | 10 | 10 | 2.5+/-1.61 | 3.5+/-1.61 | -1 | -2.41 | 0.41 |
| Ghei, 2005[284] | 5000IU | KHQ score: sleep/energy disturbances | 10 | 10 | 3.5+/-1.61 | 5.0+/-0.81 | -1.5 | -2.62 | -0.38 |

**Appendix Table F66. Outcomes after intravesical 100ml of 50nM-single dose injection of resiniferatoxin vs. placebo, individual RCTs**

| Reference | Active N | Control N | Outcome | Active Mean+/- Standard Deviation | Control Mean+/- Standard Deviation | Mean Difference | Lower 95% CI | Upper 95% CI |
|---|---|---|---|---|---|---|---|---|
| Rios, 2007[358] | 34 | 24 | General health perception | 35.3+/-13.92 | 44.8+/-23.29 | -9.50 | -19.93 | 0.93 |
| Rios, 2007[358] | 34 | 24 | Incontinence impact | 61.8+/-33.97 | 66.7+/-36.78 | -4.90 | -23.53 | 13.73 |
| Rios, 2007[358] | 34 | 24 | Role limitations | 50.5+/-35.65 | 51.5+/-35.86 | -0.96 | -19.65 | 17.73 |
| Rios, 2007[358] | 34 | 24 | Physical limitations | 47.1+/-37.03 | 46.5+/-38.06 | 0.53 | -19.14 | 20.20 |
| Rios, 2007[358] | 34 | 24 | Social limitations | 24.2+/-29.27 | 37.9+/-30.83 | -13.74 | -29.52 | 2.04 |
| Rios, 2007[358] | 34 | 24 | Personal relationships | 32.7+/-45.77 | 35.4+/-39.85 | -2.75 | -24.91 | 19.41 |
| Rios, 2007[358] | 34 | 24 | Emotions | 44.4+/-36.60 | 54.6+/-35.12 | -10.19 | -28.87 | 8.49 |
| Rios, 2007[358] | 34 | 24 | Sleep and energy | 28.9+/-23.68 | 38.2+/-31.27 | -9.28 | -24.11 | 5.55 |
| Rios, 2007[358] | 34 | 24 | Symptom severity | 15.5+/-10.05 | 10.1+/-10.98 | 5.39 | -0.15 | 10.93 |

| Reference | Active N | Control N | Outcome | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Rios, 2007[358] | 34 | 24 | Hypogastric pain | 12/34 | 4/24 | 2.12 (0.78;5.78) | 0.19 (-0.03;0.41) |
| Rios, 2007[358] | 34 | 24 | Dysuria | 15/34 | 6/24 | 1.76 (0.80;3.89) | 0.19 (-0.05;0.43) |
| Rios, 2007[358] | 34 | 24 | Minor hematuria | 1/34 | 3/24 | 0.24 (0.03;2.13) | -0.10 (-0.24;0.05) |

**Appendix Table F67. Outcomes after nimodipine, 60mg/day, vs. placebo, individual RCT**

| Reference | Active N | Control N | Outcome | Active Mean+/- Standard Deviation | Control Mean+/- Standard Deviation | Mean Difference | Lower 95% CI | Upper 95% CI |
|---|---|---|---|---|---|---|---|---|
| Naglie, 2002[346] | 42 | 44 | Mean IIQ scores(lower better) | 15.0+/-13.29 | 19.4+/-14.82 | -4.38 | -10.69 | 1.93 |
| Naglie, 2002[346] | 42 | 44 | AUA symptom scores (lower better) | 11.4+/-5.62 | 13.8+/-6.46 | -2.31 | -6.26 | 1.64 |
| Naglie, 2002[346] | 42 | 44 | Incontinent episodes | 11.0+/-10.75 | 18.7+/-20.29 | -7.71 | -14.56 | -0.86 |

| Reference | Active N | Control N | Outcome | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Naglie, 2002[346] | 42 | 44 | Withdrawals | 6/42 | 4/44 | 1.57(0.48;5.18) | 0.05(-0.08;0.19) |

**Appendix Table F68. Comparative effectiveness of local estrogen therapy**

| Active | Control | Reference Studies | Subjects | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1,000 Treated (95% CI) | Evidence |
|---|---|---|---|---|---|---|---|---|
| **Continence** | | | | | | | | |
| Estradiol-releasing ring, 7.5mg/day | Estradiol pessaries 0.5 mg every second day | 1[335] | 251 | Urgency 77.79 (4.84; 1249.40) | 0.33 (0.25; 0.41) | 3 (2; 4) | 328 (248; 409) | Insufficient |
| Estradiol-releasing ring, 7.5mg/day | Estradiol pessaries 0.5 mg every second day | 1[335] | 251 | Stress 0.84 (0.61; 1.15) | -0.07 (-0.19; 0.05) | | | Insufficient |
| **Improved incontinence** | | | | | | | | |
| Estradiol-releasing vaginal ring | Estradiol pessary | 1[335] | 232 | 2.69 1.60; 4.50) | 0.26 (0.15; 0.37) | 4 (3; 6) | 262 (155; 369) | Insufficient |

**Appendix Table F69. Comparative effectiveness of estrogen topical treatments (individual RCTs)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1,000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Continence** | | | | | | | | | | |
| Chompootaweep, 1998[260] 22/0 | Combined contraceptive Intravaginal 1 pill/week at bedtime with 250 mg levonorgestrel +30 microg ethinyl estradiol | Intravaginal conjugated estrogen cream (1g=0.625 mg conjugated equine estrogens) at bedtime | No urinary urgency | 10/10 | 9/85 | 9/85 | 1.00 (0.67; 1.48) | 0.00 (-0.32; 0.32) | | |
| Lose, 2000[335] 251/0 | Estradiol-releasing ring, 7.5 mg estradiol | Estradiolpessaries 0.5 mg every second day | No urge incontinence | 134/117 | 44/33 | 0/34 | 77.79 (4.84; 1249.40) | 0.33 (0.25; 0.41) | 3 (2; 4) | 328 (248; 409) |
| Lose, 2000[335] 251/0 | Estradiol-releasing ring, 7.5 mg estradiol | Estradiolpessaries 0.5 mg every second day | No stress incontinence | 134/117 | 46/34 | 48/41 | 0.84 (0.61; 1.15) | -0.07 (-0.19; 0.05) | | |
| **Improved incontinence** | | | | | | | | | | |
| Lose, 2000[335] 232/0 | Estradiol-releasing vaginal ring | Estradiol pessary | Treatment perception: good | 110/101 | 30/27 | 34/34 | 0.80 (0.52; 1.21) | -0.06 (-0.18; 0.05) | | |
| Lose, 2000[335] 232/0 | Estradiol-releasing vaginal ring | Estradiol Pessary | Treatment perception: excellent | 110/101 | 66/60 | 14/14 | 2.69 (1.60; 4.50) | 0.26 (0.15; 0.37) | 4 (3; 6) | 262 (155;3 69) |
| Lose, 2000[335] 232/0 | Estradiol-releasing vaginal ring | Estradiol Pessary | Treatment perception: bad | 110/101 | 2/2 | 3/3 | 0.61 (0.10; .59) | -0.01 (-0.05; 0.03) | | |
| Lose, 2000[335] 232/0 | Estradiol-releasing vaginal ring | Estradiol Pessary | Treatment perception: unacceptable | 110/101 | 3/3 | 2/2 | 1.38 (0.23; 8.08) | 0.01 (-0.03; 0.05) | | |

**Appendix Table F70. Adverse effects of pharmacological treatments for UI when compared to each other**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Chapple, 2005[251] | darifenacin IR | 2.5 t.i.d. | Oxybutynin IR | 2.5 t.i.d. | 5/8 | 8/8 | 0.6 (0.4; 1.) | -0.38 (-0.73; -0.02) |
| Abrams, 1998[220] | Tolterodine | 2mg twice daily | Oxybutynin | 5mg thrice daily | 105/118 | 114/118 | 0.9 (0.9; 1.) | -0.08 (-0.14; -0.01) |
| Madersbacher, 1999[337] | Propiverine | 15mg thrice daily | Oxybutynin | 5mg twice daily | 95/149 | 104/145 | 0.9 (0.8; 1.) | -0.08 (-0.19; 0.03) |
| Drutz, 1999[276] | Oxybutynin | 5mg thrice a day | Tolterodine | 2mg twice a day | 101/112 | 85/109 | 1.2 (1.0; 1.) | 0.12 (0.03; 0.22) |
| Lee, 2002[329] | Oxybutynin | 5mg twice daily | Tolterodine | 2mg twice daily | 94/116 | 62/112 | 1.5 (1.2; 2.) | 0.26 (0.14; 0.37) |
| Leung, 2002[332] | Oxybutynin | 5mg twice daily | Tolterodine | 2mg twice daily | 26/53 | 32/53 | 0.8 (0.6; 1.) | -0.11 (-0.30; 0.08) |
| Halaska, 2003[294] | Trospium | 40mg/day | Oxybutynin | 10mg/day | 103/267 | 46/90 | 0.8 (0.6; 1.) | -0.13 (-0.24; -0.01) |
| Halaska, 2003[294] | Trospium | 20mg twice daily | Oxybutynin | 5mg twice daily | 173/267 | 69/90 | 0.8 (0.7; 1.) | -0.12 (-0.22; -0.01) |
| Dmochowski, 2003[271] | Oxybutynin | 3.9mg/day | Tolterodine LA | 4mg/day | 23/121 | 29/123 | 0.8 (0.5; 1.) | -0.05 (-0.15; 0.06) |
| Homma, 2003[303] | Oxybutynin | 3mg thrice daily | Tolterodine ER | 4mg/day | 42/244 | 12/239 | 3.4 (1.9; 6.) | 0.12 (0.07; 0.18) |
| Chapple, 2004[258] | Solifenacin | 20mg once daily | Tolterodine | 2mg twice daily | 21/37 | 12/37 | 1.8 (1.0; 3.) | 0.24 (0.02; 0.46) |
| Chapple, 2004[258] | Solifenacin | 2.5mg once daily | Tolterodine | 2mg twice daily | 6/41 | 12/37 | 0.5 (0.2; 1.) | -0.18 (-0.36; 0.01) |
| Chapple, 2004[258] | Solifenacin | 5mg once daily | Tolterodine | 2mg twice daily | 12/37 | 12/37 | 1.0 (0.5; 2.) | 0.00 (-0.21; 0.21) |
| Chapple, 2004[258] | Solifenacin | 10mg once daily | Tolterodine | 2mg twice daily | 12/35 | 12/37 | 1.1 (0.6; 2.) | 0.02 (-0.20; 0.24) |
| Junemann, 2005[313] | Propiverine | 15mg twice daily | Tolterodine | 2mg twice daily | 42/100 | 43/101 | 1.0 (0.7; 1.) | -0.01 (-0.14; 0.13) |
| Armstrong, 2007[226] | Oxybutynin | 10mg qd | Tolterodine ER | 4mg qd | 404/576 | 254/399 | 1.1 (1.0; 1.) | 0.06 (0.00; 0.12) |

**Appendix Table F70. Adverse effects of pharmacological treatments for UI when compared to each other (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Chapple, 2007[252] | Tolterodine | 4mg daily | Fesoterodine | 8mg daily | 144/290 | 167/288 | 0.9 (0.7; 1.) | -0.08 (-0.16; 0.00) |
| Chapple, 2007[252] | Tolterodine | 4mg daily | Fesoterodine | 4mg daily | 144/290 | 135/272 | 1.0 (0.8; 1.) | 0.00 (-0.08; 0.08) |
| Herschorn, 2010[296] | Solifenacin | 5mg once daily | Oxybutynin IR | 5mg 3 times daily | 49/68 | 59/64 | 0.8 (0.7; 1.) | -0.20 (-0.33; -0.08) |
| Junemann, 2000[312] | Trospium | 20mg twice daily | Tolterodine | 2mg twice daily | 26/76 | 25/77 | 1.1 (0.7; 2.) | 0.02 (-0.13; 0.17) |
| U.S. Food and Drug Administration , [60] | Solifenacin | 5mgonce daily/5mg twice daily | Tolterodine ER | 4mg once daily | 282/593 | 265/607 | 1.1 (1.0; 1.) | 0.04 (-0.02; 0.10) |
| NCT00444925, [58] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 to 8mg once daily | 290/685 | 213/690 | 1.4 (1.2; 2.) | 0.11 (0.06; 0.17) |

**Appendix Table F71. Dry mouth after pharmacological treatments for UI when compared to each other**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Zinner, 2005[403] | Darifenacin ER | 15mg/day | Oxybutynin | 5 mg 3 times/day | 0/19 | 7/19 | 0.1 (0.0; 1.) | -0.37 (-0.59; -0.15) |
| Abrams, 1998[220] | Oxybutynin | 5mg thrice daily | Tolterodine | 2mg twice daily | 102/118 | 59/118 | 1.7 (1.4; 2.) | 0.36 (0.26; 0.47) |
| Drutz, 1999[276] | Oxybutynin | 5mg thrice a day | Tolterodine | 2mg twice a day | 77/112 | 33/109 | 2.3 (1.7; 3.) | 0.38 (0.26; 0.51) |
| Appell, 2001[224] | Oxybutynin | 10mg/day | Tolterodine LA | 2mg twice daily | 52/185 | 64/193 | 0.8 (0.6; 1.) | -0.05 (-0.14; 0.04) |
| Lee, 2002[329] | Oxybutynin | 5mg twice daily | Tolterodine | 2mg twice daily | 72/116 | 39/112 | 1.8 (1.3; 2.) | 0.27 (0.15; 0.40) |
| Halaska, 2003[294] | Trospium | 40mg/day | Oxybutynin | 10mg/day | 87/267 | 45/90 | 0.7 (0.5; 1.) | -0.17 (-0.29; -0.06) |
| Halaska, 2003[294] | Trospium | 20mg twice daily | Oxybutynin | 5mg twice daily | 87/267 | 45/90 | 0.7 (0.5; 1.) | -0.17 (-0.29; -0.06) |
| Diokno, 2003[266] | Oxybutynin | 10mg/d | Tolterodine ER | 4mg/d | 116/391 | 89/399 | 1.3 (1.0; 2.) | 0.07 (0.01; 0.13) |
| Homma, 2003[303] | Oxybutynin | 3mg thrice daily | Tolterodine ER | 4mg/day | 131/244 | 80/239 | 1.6 (1.3; 2.) | 0.20 (0.12; 0.29) |
| Chapple, 2004[258] | Solifenacin | 2.5mg once daily | Tolterodine | 2mg twice daily | 0/41 | 9/37 | 0.0 (0.0; 1.) | -0.24 (-0.38; -0.10) |
| Chapple, 2004[258] | Solifenacin | 5mg once daily | Tolterodine | 2mg twice daily | 5/37 | 9/37 | 0.6 (0.2; 2.) | -0.11 (-0.28; 0.07) |
| Chapple, 2004[258] | Solifenacin | 10mg once daily | Tolterodine | 2mg twice daily | 5/35 | 9/37 | 0.6 (0.2; 2.) | -0.10 (-0.28; 0.08) |
| Chapple, 2004[258] | Solifenacin | 20mg once daily | Tolterodine | 2mg twice daily | 14/37 | 9/37 | 1.6 (0.8; 3.) | 0.14 (-0.07; 0.34) |
| Chapple, 2004[54] | Solifenacin | 5mg daily | Tolterodine | 2mg twice daily | 39/279 | 49/266 | 0.8 (0.5; 1.) | -0.04 (-0.11; 0.02) |
| Chapple, 2004[54] | Solifenacin | 10mg daily | Tolterodine | 2mg twice daily | 57/269 | 49/266 | 1.2 (0.8; 2.) | 0.03 (-0.04; 0.10) |
| Homma, 2004[302] | Oxybutynin | 3mg thrice daily | Tolterodine ER | 4mg/day | 75/122 | 42/114 | 1.7 (1.3; 2.) | 0.25 (0.12; 0.37) |

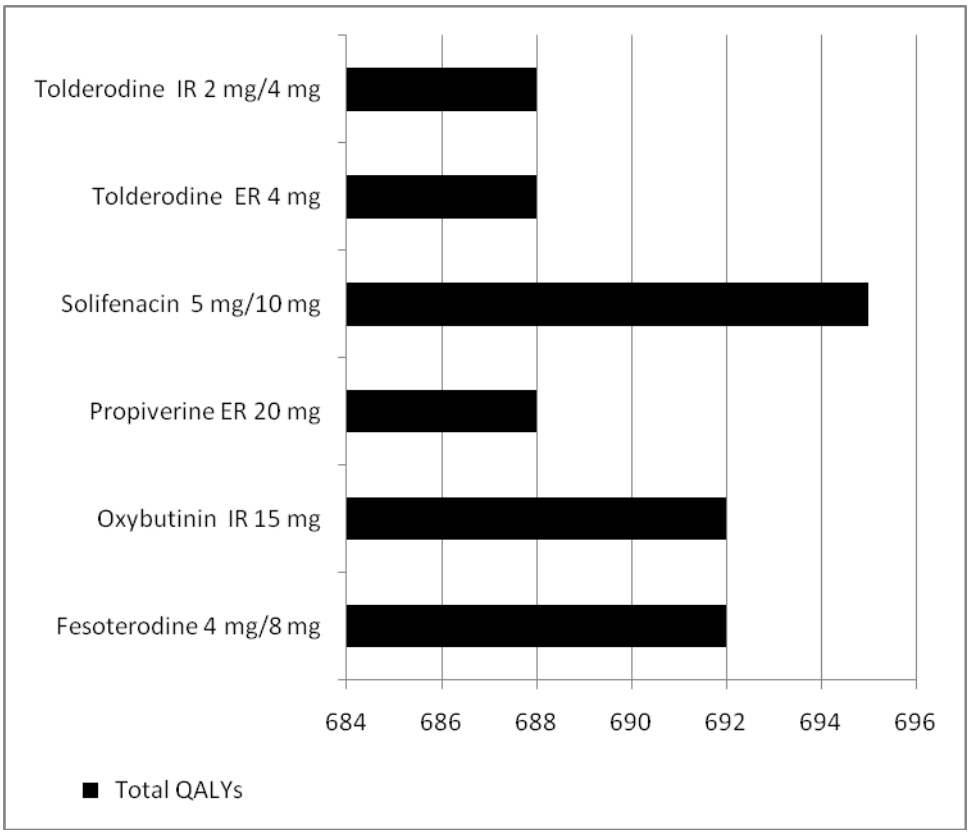
**Appendix Table F71. Dry mouth after pharmacological treatments for UI when compared to each other (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Sand, 2004[367] | Oxybutynin | 10mg/day | Tolterodine | 2mg b.i.d. | 43/152 | 55/163 | 0.8 (0.6; 1.) | -0.05 (-0.16; 0.05) |
| Chapple, 2005[251] | Darifenacin IR | 2.5 t.i.d. | Oxybutynin IR | 2.5 t.i.d. | 4/8 | 8/8 | 0.5 (0.3; 1.) | -0.50 (-0.86; -0.14) |
| Zinner, 2005[403] | Darifenacin ER | 30mg/day | Oxybutynin | 5 mg 3 times/day | 7/19 | 7/19 | 1.0 (0.4; 2.) | 0.00 (-0.31; 0.31) |
| Armstrong, 2005[225] | Oxybutynin | 10mg/day | Tolterodine ER | 4mg daily | 110/391 | 86/399 | 1.3 (1.0; 2.) | 0.07 (0.01; 0.13) |
| Armstrong, 2007[226] | Oxybutynin | 10mg qd | Tolterodine ER | 2mg qd | 169/576 | 64/193 | 0.9 (0.7; 1.) | -0.04 (-0.11; 0.04) |
| Armstrong, 2007[226] | Oxybutynin | 10mg qd | Tolterodine ER | 4mg qd | 169/576 | 89/399 | 1.3 (1.1; 2.) | 0.07 (0.02; 0.13) |
| Chapple, 2007[256] | Solifenacin | 5mg daily | Tolterodine | 4mg daily | 82/578 | 69/599 | 1.2 (0.9; 2.) | 0.03 (-0.01; 0.06) |
| Chapple, 2007[252] | Fesoterodine | 8mg daily | Tolterodine | 4mg daily | 97/288 | 49/290 | 2.0 (1.5; 3.) | 0.17 (0.10; 0.24) |
| Chapple, 2007[252] | Fesoterodine | 4mg daily | Tolterodine | 4mg daily | 59/272 | 49/290 | 1.3 (0.9; 2.) | 0.05 (-0.02; 0.11) |
| Yamaguchi, 2007[401] | Solifenacin | 5mg daily | Propiverine | 20mg daily | 67/400 | 103/402 | 0.7 (0.5; 1.) | -0.09 (-0.14; -0.03) |
| Yamaguchi, 2007[401] | Solifenacin | 10mg daily | Propiverine | 20mg daily | 130/385 | 103/402 | 1.3 (1.1; 2.) | 0.08 (0.02; 0.15) |
| Chapple, 2008[253] | Fesoterodine | 8mg daily | Tolterodine | 4mg daily | 97/287 | 49/290 | 2.0 (1.5; 3.) | 0.17 (0.10; 0.24) |
| Choo, 2008[261] | Solifenacin | 5mg once daily | Tolterodine IR | 2mg twice daily | 9/120 | 22/118 | 0.4 (0.2; 1.) | -0.11 (-0.20; -0.03) |
| Choo, 2008[261] | Solifenacin | 10mg once daily | Tolterodine IR | 2mg twice daily | 23/119 | 22/118 | 1.0 (0.6; 2.) | 0.01 (-0.09; 0.11) |
| Sand, 2009[366] | Fesoterodine | 8mg daily | Tolterodine | 4mg daily | 155/452 | 37/227 | 2.1 (1.5; 3.) | 0.18 (0.11; 0.24) |
| Sand, 2009[366] | Fesoterodine | 4mg daily | Tolterodine | 4mg daily | 89/434 | 37/227 | 1.3 (0.9; 2.) | 0.04 (-0.02; 0.10) |
| Herschorn, 2010[466] | Fesoterodine | 4-8mg once daily | Tolterodine ER | 4mg once daily | 189/679 | 112/684 | 1.7 (1.4; 2.) | 0.11 (0.07; 0.16) |

**Appendix Table F71. Dry mouth after pharmacological treatments for UI when compared to each other (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Herschorn, 2010[296] | Solifenacin | 5mg once daily | Oxybutynin IR | 5mg 3 times daily | 24/68 | 53/64 | 0.4 (0.3; 1.) | -0.48 (-0.62; -0.33) |
| Junemann, 2000[312] | Trospium | 20mg twice daily | Tolterodine | 2mg twice daily | 22/76 | 21/77 | 1.1 (0.6; 2.) | 0.02 (-0.13; 0.16) |
| Kaplan, 2010[314] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 mg once daily | 270/963 | 127/974 | 2.2 (1.8; 3.) | 0.15 (0.11; 0.19) |
| NCT00444925,[58] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 to 8mg once daily | 189/685 | 112/690 | 1.7 (1.4; 2.) | 0.11 (0.07; 0.16) |

**Appendix Figure F26. Gain in quality adjusted life years per 1,000 treated patients[469]**



**Appendix Table F72. Constipation after pharmacological treatments for UI when compared to each other**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Zinner, 2005[403] | Darifenacin ER | 15mg/day | Oxybutynin | 5 mg 3 times/day | 2/19 | 2/19 | 1.0 (0.2; 6.) | 0.00 (-0.20; 0.20) |
| Halaska, 2003[294] | Trospium | 40mg/day | Oxybutynin | 10mg/day | 18/267 | 4/90 | 1.5 (0.5; 4.) | 0.02 (-0.03; 0.08) |
| Halaska, 2003[294] | Trospium | 20mg twice daily | Oxybutynin | 5mg twice daily | 18/267 | 4/90 | 1.5 (0.5; 4.) | 0.02 (-0.03; 0.08) |
| Chapple, 2004[258] | Solifenacin | 2.5mg once daily | Tolterodine | 2mg twice daily | 1/41 | 1/37 | 0.9 (0.1; 14.) | 0.00 (-0.07; 0.07) |
| Chapple, 2004[258] | Solifenacin | 5mg once daily | Tolterodine | 2mg twice daily | 5/37 | 1/37 | 5.0 (0.6; 41.) | 0.11 (-0.01; 0.23) |
| Chapple, 2004[258] | Solifenacin | 10mg once daily | Tolterodine | 2mg twice daily | 2/35 | 1/37 | 2.1 (0.2; 22.) | 0.03 (-0.06; 0.12) |
| Chapple, 2004[258] | Solifenacin | 20mg once daily | Tolterodine | 2mg twice daily | 6/37 | 1/37 | 6.0 (0.8; 47.) | 0.14 (0.01; 0.26) |
| Chapple, 2004[54] | Solifenacin | 5mg daily | Tolterodine | 2mg twice daily | 20/279 | 7/266 | 2.7 (1.2; 6.) | 0.05 (0.01; 0.08) |
| Chapple, 2004[54] | Solifenacin | 10mg daily | Tolterodine | 2mg twice daily | 21/269 | 7/266 | 3.0 (1.3; 7.) | 0.05 (0.01; 0.09) |
| Chapple, 2005[251] | Darifenacin ER | 15mg daily | Oxybutynin IR | 5mg t.i.d. | 8/12 | 6/12 | 1.3 (0.7; 3.) | 0.17 (-0.22; 0.56) |
| Chapple, 2005[251] | Darifenacin ER | 30mg daily | Oxybutynin IR | 5mg t.i.d. | 10/13 | 2/12 | 4.6 (1.3; 17.) | 0.60 (0.29; 0.91) |
| Chapple, 2005[251] | Darifenacin IR | 2.5 t.i.d. | Oxybutynin IR | 2.5 t.i.d. | 1/8 | 1/8 | 1.0 (0.1; 13.) | 0.00 (-0.32; 0.32) |
| Chapple, 2005[61] | Solifenacin | 5-10mg od | Tolterodine | 4mg once daily | 3/578 | 1/599 | 3.1 (0.3; 30.) | 0.00 (0.00; 0.01) |
| Zinner, 2005[403] | Darifenacin ER | 30mg/day | Oxybutynin | 5 mg 3 times/day | 4/19 | 2/19 | 2.0 (0.4; 10.) | 0.11 (-0.12; 0.33) |
| Armstrong, 2007[226] | Oxybutynin | 10mg qd | Tolterodine ER | 4mg qd | 38/576 | 31/399 | 0.8 (0.5; 1.) | -0.01 (-0.04; 0.02) |
| Armstrong, 2007[226] | Oxybutynin | 10mg qd | Tolterodine ER | 2mg qd | 38/576 | 12/193 | 1.1 (0.6; 2.) | 0.00 (-0.04; 0.04) |
| Chapple, 2007[256] | Solifenacin | 5mg daily | Tolterodine | 4mg daily | 12/578 | 7/599 | 1.8 (0.7; 4.) | 0.01 (-0.01; 0.02) |
| Chapple, 2007[252] | Tolterodine | 4mg daily | Fesoterodine | 8mg daily | 8/290 | 13/288 | 0.6 (0.3; 1.) | -0.02 (-0.05; 0.01) |
| Chapple, 2007[252] | Tolterodine | 4mg daily | Fesoterodine | 4mg daily | 8/290 | 9/272 | 0.8 (0.3; 2.) | -0.01 (-0.03; 0.02) |

**Appendix Table F72. Constipation after pharmacological treatments for UI when compared to each other (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Yamaguchi, 2007[401] | Solifenacin | 5mg daily | Propiverine | 20mg daily | 42/400 | 45/402 | 0.9 (0.6; 1.) | -0.01 (-0.05; 0.04) |
| Yamaguchi, 2007[401] | Solifenacin | 10mg daily | Propiverine | 20mg daily | 72/385 | 45/402 | 1.7 (1.2; 2.) | 0.08 (0.03; 0.12) |
| Chapple, 2008[253] | Tolterodine | 4mg daily | Fesoterodine | 8mg daily | 8/290 | 13/287 | 0.6 (0.3; 1.) | -0.02 (-0.05; 0.01) |
| Choo, 2008[261] | Solifenacin | 5mg once daily | Tolterodine IR | 2mg twice daily | 8/120 | 3/118 | 2.6 (0.7; 10.) | 0.04 (-0.01; 0.09) |
| Choo, 2008[261] | Solifenacin | 10mg once daily | Tolterodine IR | 2mg twice daily | 17/119 | 3/118 | 5.6 (1.7; 19.) | 0.12 (0.05; 0.19) |
| Sand, 2009[366] | Tolterodine | 4mg daily | Fesoterodine | 8mg daily | 6/227 | 24/452 | 0.5 (0.2; 1.) | -0.03 (-0.06; 0.00) |
| Sand, 2009[366] | Tolterodine | 4mg daily | Fesoterodine | 4mg daily | 6/227 | 20/434 | 0.6 (0.2; 1.) | -0.02 (-0.05; 0.01) |
| Zellener, 2009[402] | Trospium | 15mg to 30mg thrice daily | Oxybutynin | 2.5mg to 5mg thrice daily | 1/828 | 10/830 | 0.1 (0.0; 1.) | -0.01 (-0.02; 0.00) |
| Herschorn, 2010[466] | Tolterodine ER | 4mg once daily | Fesoterodine | 4-8mg once daily | 28/684 | 37/679 | 0.8 (0.5; 1.) | -0.01 (-0.04; 0.01) |
| Kaplan, 2010[314] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 mg once daily | 270/963 | 29/974 | 9.4 (6.5; 14.) | 0.25 (0.22; 0.28) |
| Milani, 1993[342] | Flavoxate | 1200 | Oxybutynin | 5mg t.i.d. | 1/50 | 2/50 | 0.5 (0.0; 5.) | -0.02 (-0.09; 0.05) |
| NCT00444925,[58] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 to 8mg once daily | 37/685 | 28/690 | 1.3 (0.8; 2.) | 0.01 (-0.01; 0.04) |

**Appendix Table F73. Discontinuation due to adverse effects after pharmacological treatments for UI when compared to each other**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Zinner, 2005[403] | Darifenacin ER | 15mg/day | Oxybutynin | 5 mg 3 times/day | 0/19 | 4/19 | 0.1 (0.0; 2.) | -0.21 (-0.41; -0.02) |
| Appell, 1997[223] | Oxybutynin | 5mg/day | Tolterodine | 1mg/day | 70/349 | 2/121 | 12.1 (3.0; 49.) | 0.18 (0.14; 0.23) |
| Abrams, 1998[220] | Tolterodine | 2mg twice daily | Oxybutynin | 5mg thrice daily | 20/118 | 10/118 | 2.0 (1.0; 4.) | 0.08 (0.00; 0.17) |
| Drutz, 1999[276] | Oxybutynin | 5mg thrice a day | Tolterodine | 2mg twice a day | 23/112 | 7/109 | 3.2 (1.4; 7.) | 0.14 (0.05; 0.23) |
| Appell, 2001[224] | Oxybutynin | 10mg/day | Tolterodine LA | 2mg twice daily | 14/185 | 15/193 | 1.0 (0.5; 2.) | 0.00 (-0.06; 0.05) |
| Lee, 2002[329] | Oxybutynin | 5mg twice daily | Tolterodine | 2mg twice daily | 18/116 | 11/112 | 1.6 (0.8; 3.) | 0.06 (-0.03; 0.14) |
| Halaska, 2003[294] | Trospium | 20mg twice daily | Oxybutynin | 5mg twice daily | 10/267 | 6/90 | 0.6 (0.2; 2.) | -0.03 (-0.09; 0.03) |
| Diokno, 2003[266] | Oxybutynin | 10mg/d | Tolterodine ER | 4mg/d | 20/391 | 19/399 | 1.1 (0.6; 2.) | 0.00 (-0.03; 0.03) |
| Chapple, 2004[54] | Solifenacin | 5mg daily | Tolterodine | 2mg twice daily | 9/279 | 5/266 | 1.7 (0.6; 5.) | 0.01 (-0.01; 0.04) |
| Chapple, 2004[54] | Solifenacin | 10mg daily | Tolterodine | 2mg twice daily | 7/269 | 5/266 | 1.4 (0.4; 4.) | 0.01 (-0.02; 0.03) |
| Homma, 2004[302] | Oxybutynin | 3mg thrice daily | Tolterodine ER | 4mg/day | 21/122 | 6/114 | 3.3 (1.4; 8.) | 0.12 (0.04; 0.20) |
| Sand, 2004[367] | Oxybutynin | 10mg/day | Tolterodine | 2mg b.i.d. | 11/152 | 12/163 | 1.0 (0.4; 2.) | 0.00 (-0.06; 0.06) |
| Chapple, 2005[251] | Darifenacin ER | 15mg daily | Oxybutynin IR | 5mg t.i.d. | 1/12 | 0/12 | 3.0 (0.1; 67.) | 0.08 (-0.12; 0.29) |
| Chapple, 2005[251] | Darifenacin ER | 30mg daily | Oxybutynin IR | 5mg t.i.d. | 1/13 | 2/12 | 0.5 (0.0; 4.) | -0.09 (-0.35; 0.17) |
| Chapple, 2005[251] | Darifenacin IR | 2.5 t.i.d. | Oxybutynin IR | 2.5 t.i.d. | 0/8 | 1/8 | 0.3 (0.0; 7.) | -0.13 (-0.41; 0.16) |
| Zinner, 2005[403] | Darifenacin ER | 30mg/day | Oxybutynin | 5 mg 3 times/day | 1/19 | 4/19 | 0.3 (0.0; 2.) | -0.16 (-0.37; 0.05) |
| Armstrong, 2005[225] | Oxybutynin | 10mg/day | Tolterodine ER | 4mg daily | 20/391 | 19/399 | 1.1 (0.6; 2.) | 0.00 (-0.03; 0.03) |
| Armstrong, 2007[226] | Oxybutynin | 10mg qd | Tolterodine ER | 2mg qd | 155/576 | 61/193 | 0.9 (0.7; 1.) | -0.05 (-0.12; 0.03) |
| Armstrong, 2007[226] | Oxybutynin | 10mg qd | Tolterodine IR | 2mg bid | 35/576 | 15/193 | 0.8 (0.4; 1.) | -0.02 (-0.06; 0.03) |
| Chapple, 2007[256] | Solifenacin | 5mg daily | Tolterodine | 4mg daily | 4/578 | 7/599 | 0.6 (0.2; 2.) | 0.00 (-0.02; 0.01) |
| Chapple, 2007[252] | Tolterodine | 4mg daily | Fesoterodine | 8mg daily | 14/288 | 9/290 | 1.6 (0.7; 4.) | 0.02 (-0.01; 0.05) |
| Chapple, 2007[252] | Tolterodine | 4mg daily | Fesoterodine | 4mg daily | 7/272 | 9/290 | 0.8 (0.3; 2.) | -0.01 (-0.03; 0.02) |

**Appendix Table F73. Discontinuation due to adverse effects after pharmacological treatments for UI when compared to each other (continued)**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Yamaguchi, 2007[401] | Solifenacin | 5mg daily | Propiverine | 20mg daily | 20/400 | 26/402 | 0.8 (0.4; 1.) | -0.01 (-0.05; 0.02) |
| Yamaguchi, 2007[401] | Solifenacin | 10mg daily | Propiverine | 20mg daily | 26/385 | 26/402 | 1.0 (0.6; 2.) | 0.00 (-0.03; 0.04) |
| Choo, 2008[261] | Solifenacin | 5mg once daily | Tolterodine IR | 2mg twice daily | 5/120 | 2/118 | 2.5 (0.5; 12.) | 0.02 (-0.02; 0.07) |
| Choo, 2008[261] | Solifenacin | 10mg once daily | Tolterodine IR | 2mg twice daily | 7/119 | 2/118 | 3.5 (0.7; 16.) | 0.04 (-0.01; 0.09) |
| Zellener, 2009[402] | Trospium | 15mg to 30mg thrice daily | Oxybutynin | 2.5mg to 5mg thrice daily | 61/828 | 47/830 | 1.3 (0.9; 2.) | 0.02 (-0.01; 0.04) |
| Herschorn, 2010[466] | Tolterodine ER | 4mg once daily | Fesoterodine | 4-8mg once daily | 44/679 | 28/684 | 1.6 (1.0; 3.) | 0.02 (0.00; 0.05) |
| Herschorn, 2010[296] | Solifenacin | 5mg once daily | Oxybutynin IR | 5mg 3 times daily | 7/68 | 7/64 | 0.9 (0.3; 3.) | -0.01 (-0.11; 0.10) |
| U.S. Food and Drug Administration, [60] | Solifenacin | 5mgonce daily/5mg twice daily | Tolterodine ER | 4mg once daily | 25/593 | 23/607 | 1.1 (0.6; 2.) | 0.00 (-0.02; 0.03) |
| Kaplan, 2010[314] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 mg once daily | 48/963 | 29/974 | 1.7 (1.1; 3.) | 0.02 (0.00; 0.04) |
| But, 2010[242] | Solifenacin | NR | Darifenacin | NR | 8/40 | 8/37 | 0.9 (0.4; 2.) | -0.02 (-0.20; 0.17) |
| NCT00444925, [58] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 to 8mg once daily | 44/685 | 28/690 | 1.6 (1.0; 3.) | 0.02 (0.00; 0.05) |

**Appendix Table F74. Comparative effectiveness of drugs on continence**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Kaplan, 2010[314] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 mg once daily | 609/963 | 566/974 | 1.1 (1.0; 1.) | 0.05 (0.01; 0.09) |
| NCT00444925[58] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 to 8mg once daily | 396/685 | 358/690 | 1.1 (1.0; 1.) | 0.06 (0.01; 0.11) |
| Milani, 1993[342] | Flavoxate | 1200 | Oxybutynin | 5mg t.i.d. | 14/50 | 21/50 | 0.7 (0.4; 1.) | -0.14 (-0.32; 0.04) |
| Diokno, 2003[266] | Oxybutynin | 10mg/d | Tolterodine | 4mg/d | 90/391 | 67/399 | 1.4(1.0; 2.) | 0.06 (0.01; 0.12) |
| Chapple, 2005[61] | Solifenacin | 5-10mg od | Tolterodine | 4mg once daily | 341/578 | 294/599 | 1.2 (1.1; 1.) | 0.10 (0.04; 0.16) |
| Halaska, 2003[294] | Trospium | 20mg twice daily | Oxybutynin | 5mg twice daily | 60/267 | 11/90 | 1.8 (1.0; 3.) | 0.10 (0.02; 0.19) |

**Appendix Table F75. Comparative effectiveness of oxybutynin vs. tolterodine (secondary data analyses using individual patient data from RCTs)**

| Outcomes | Reference | Oxybutynin Dose | Tolterodine Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Effects/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Improved perceptions of the bladder condition | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 175/349 | 246/474 | 0.96 (0.84; 1.10) | -0.02 (-0.09; 0.05) | | |
| Zero episodes of dry mouth | Armstrong, 2005[225] | 10mg/day | 4mg daily | 281/391 | 313/399 | 0.92 (0.85; 0.99) | -0.07 (-0.13; -0.01) | -15 (-176; -8) | -66 (-126; -6) |
| Adverse events | Armstrong, 2007[226] | 10mg qd | 4mg qd | 404/576 | 254/399 | 1.10 (1.01; 1.21) | 0.07 (0.01; 0.13) | 15 (8; 218) | 65 (5; 125) |
| Adverse events | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 262/349 | 351/474 | 1.01 (0.94; 1.10) | 0.01 (-0.05; 0.07) | | |
| Serious adverse events | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 14/349 | 19/474 | 1.00 (0.51; 1.97) | 0.00 (-0.03; 0.03) | | |
| Serious adverse events | Appell, 1997[223] | 5mg/day | 2mg/day | 14/349 | 19/474 | 1.00 (0.51; 1.97) | 0.00 (-0.027; 0.027) | | |
| Mild adverse events related to treatment | Armstrong, 2007[226] | 10mg qd | 2mg bid | 217/576 | 81/193 | 0.90 (0.74; 1.09) | -0.043 (-0.12; 0.04) | | |
| Moderate adverse events related to treatment | Armstrong, 2007[226] | 10mg qd | 4mg qd | 103/576 | 40/399 | 1.78 (1.27; 2.51) | 0.08 (0.04; 0.12) | 13 (8; 28) | 79 (36; 122) |
| Moderate adverse events related to treatment | Armstrong, 2007[226] | 10mg qd | 2mg bid | 103/576 | 35/193 | 0.99 (0.70; 1.40) | -0.00 (-0.07; 0.06) | | |
| Severe adverse events related to treatment | Armstrong, 2007[226] | 10mg qd | 2mg bid | 25/576 | 5/193 | 1.68 (0.65; 4.32) | 0.02 (-0.01; 0.05) | | |
| Severe adverse events related to treatment | Armstrong, 2007[226] | 10mg qd | 4mg qd | 25/576 | 6/399 | 2.89 (1.20; 6.97) | 0.03 (0.01; 0.05) | 35 (20; 127) | 28 (8; 49) |
| Withdrawal | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 94/349 | 63/474 | 2.03 (1.52; 2.70) | 0.14 (0.08; 0.19) | | |
| Withdrawal | Armstrong, 2005[225] | 10mg/day | 4mg daily | 52/391 | 42/399 | 1.26 (0.86; 1.85) | 0.03 (-0.02; 0.07) | | |
| Patients with at least one adverse event leading to study drug discontinuation | Armstrong, 2007[226] | 10mg qd | 4mg qd | 35/576 | 19/399 | 1.28 (0.74; 2.20) | 0.01 (-0.02; 0.04) | | |
| Patients with at least one adverse event leading to study drug discontinuation | Armstrong, 2007[226] | 10mg qd | 2mg bid | 35/576 | 15/193 | 0.78 (0.44; 1.40) | -0.02 (-0.06; 0.03) | | |

**Appendix Table F75. Comparative effectiveness of oxybutynin vs. tolterodine (secondary data analyses using individual patient data from RCTs) (continued)**

| Outcomes | Reference | Oxybutynin Dose | Tolterodine Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Effects/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Withdrawal due to adverse events | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 70/349 | 38/474 | 2.50 (1.73; 3.62) | 0.12 (0.07; 0.17) | 8 (6; 14) | 120 (72; 169) |
| Withdrawal due to adverse events | Armstrong, 2005[225] | 10mg/day | 4mg daily | 52/391 | 42/399 | 1.26 (0.86; 1.85) | 0.03 (-0.02; 0.07) | | |
| Withdrawal due to adverse events | Armstrong, 2005[225] | 10mg/day | 4mg daily | 20/391 | 19/399 | 1.07 (0.58; 1.98) | 0.00 (-0.03; 0.03) | | |
| Withdrawal due to dry mouth | Armstrong, 2005[225] | 10mg/day | 4mg daily | 110/391 | 86/399 | 1.31 (1.02; 1.67) | 0.07 (0.01; 0.13) | 15 (8; 176) | 66 (6; 126) |
| Dose reduction in case of intolerance | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 112/349 | 43/474 | 3.54 (2.56; 4.89) | 0.23 (0.18; 0.29) | 4 (4; 6) | 230 (175; 286) |
| Asthenia | Armstrong, 2007[226] | 10mg qd | 4mg qd | 17/576 | 0/399 | 24.26 (1.46; 402.30) | 0.03 (0.02; 0.04) | 34 (23; 66) | **30 (15; 44)** |
| Autonomic nervous system disorder | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 283/349 | 204/474 | 1.88 (1.68; 2.11) | 0.38 (0.32; 0.44) | 3 (2; 3) | **381 (320; 441)** |
| Autonomic nervous system disorder | Appell, 1997[223] | 5mg/day | 2mg/day | 283/349 | 204/474 | 1.88 (1.68; 2.11) | 0.38 (0.32; 0.44) | 3 (2; 3) | **381 (320; 441)** |
| Autonomic nervous system disorder | Appell, 1997[223] | 5mg/day | 1mg/day | 283/349 | 35/121 | 2.80 (2.11; 3.72) | 0.52 (0.43; 0.61) | 2 (2; 2) | **52 (431; 612)** |
| Discontinuation due to adverse effect on a body as a whole | Armstrong, 2007[226] | 10mg qd | 4mg qd | 155/576 | 85/399 | 1.26 (1.00; 1.59) | 0.06 (0.01; 0.11) | 18 (9; 507) | **5 6(2; 110)** |
| Gastrointestinal disorders | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 140/349 | 123/474 | 1.55 (1.27; 1.89) | 0.14 (0.08; 0.21) | 7 (5; 13) | **142 (77; 206)** |
| Dry mouth | Armstrong, 2007[226] | 10mg qd | 4mg qd | 169/576 | 92/399 | 1.27 (1.02; 1.58) | 0.06 (0.01; 0.12) | 16 (8; 138) | **63 (7; 118)** |
| Dry mouth | Armstrong, 2007[226] | 10mg qd | 4mg qd | 169/576 | 89/399 | 1.32 (1.05; 1.64) | 0.07 (0.02; 0.13) | 14 (8; 66) | **70 (15; 126)** |
| Dry mouth | Appell, 1997[223] | 5mg/day | 2mg/day | 272/349 | 190/474 | 1.94 (1.72; 2.20) | 0.379 (0.32; 0.44) | 3 (2; 3) | **379 (317; 440)** |
| Dry mouth | Appell, 1997[223] | 5mg/day | 1mg/day | 272/349 | 29/121 | 3.25 (2.36; 4.49) | 0.54 (0.45; 0.63) | 2 (2; 2) | **540 (452; 627)** |
| Dry mouth-onset at 1 month | Armstrong, 2005[225] | 10mg/day | 4mg daily | 101/391 | 74/399 | 1.39 (1.07; 1.82) | 0.07 (0.02; 0.13) | 14 (8; 66) | **73 (15; 131)** |
| Dyspepsia | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 38/349 | 28/474 | 1.84 (1.15; 2.94) | 0.05 (0.01; 0.09) | 20 (11; 92) | **50 (11; 89)** |
| Gastrointestinal disorders | Appell, 1997[223] | 5mg/day | 1mg/day | 140/349 | 27/121 | 1.80 (1.26; 2.57) | 0.178 (0.09; 0.27) | 6 (4; 11) | **178 (88; 268)** |
| Moderate or severe dry mouth | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 209/349 | 81/474 | 3.50 (2.82; 4.35) | 0.428 (0.37; 0.49) | 2 (2; 3) | **428 (366; 490)** |

**Appendix Table F75. Comparative effectiveness of oxybutynin vs. tolterodine (secondary data analyses using individual patient data from RCTs) (continued)**

| Outcomes | Reference | Oxybutynin Dose | Tolterodine Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Effects/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Nausea | Armstrong, 2007[226] | 10mg qd | 4mg qd | 14/576 | 0/399 | 20.10 (1.20; 336.04) | 0.02 (0.01; 0.04) | 41 (27; 90) | **24 (11; 38)** |
| Pain | Armstrong, 2007[226] | 10mg qd | 4mg qd | 22/576 | 0/399 | 31.20 (1.90; 512.77) | 0.04 (0.02; 0.05) | 26 (18; 45) | **38 (22; 54)** |
| Palpitations | Appell, 1997[223] | 5mg three times daily | 2mg twice daily | 8/349 | 2/474 | 5.43 (1.16; 25.43) | 0.02 (0.00; 0.04) | 53 (28; 512) | **19 (2; 35)** |
| Rhinitis | Armstrong, 2007[226] | 10mg qd | 4mg qd | 10/576 | 0/399 | 14.56 (0.86; 247.72) | 0.02 (0.01; 0.03) | 58 (35; 169) | **17 (6; 29)** |
| Severe dry mouth | Appell, 1997[223] | 5mg/day | 2mg/day | 209/349 | 81/474 | 3.50 (2.82; 4.35) | 0.43 (0.37; 0.49) | 2 (2; 3) | **428 (366; 490)** |
| Severe dry mouth | Appell, 1997[223] | 5mg/day | 1mg/day | 209/349 | 5/121 | 14.49 (6.12; 34.33) | 0.56 (0.50; 0.62) | 2 (2; 2) | **558 (495; 620)** |
| Symptoms associated with urinary emptying | Armstrong, 2007[226] | 10mg qd | 4mg qd | 55/576 | 22/399 | 1.73 (1.07; 2.79) | 0.04 (0.01; 0.07) | 25 (14; 133) | **40 (8; 73)** |
| Urinary tract infection | Armstrong, 2007[226] | 10mg qd | 4mg qd | 30/576 | 0/399 | 42.29 (2.59; 689.54) | 0.05 (0.03; 0.07) | 19 (14; 30) | **52 (34; 71)** |
| Urogenital system adverse effects | Armstrong, 2007[226] | 10mg qd | 4mg qd | 92/576 | 38/399 | 1.68 (1.18; 2.39) | 0.06 (0.02; 0.11) | 16 (9; 44) | **64 (23; 106)** |

bold = significant difference at 95% CI

**Appendix Table F76. Comparative effectiveness of drugs on improved UI**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Sand, 2009[366] | Fesoterodine | 8mg daily | Tolterodine | 4mg daily | 291/452 | 140/227 | 1.0 (0.9; 1.) | 0.03 (-0.05; 0.10) |
| Abrams, 1998[220] | Oxybutynin | 5mg thrice daily | Tolterodine | 2mg twice daily | 58/118 | 59/118 | 0.98 (0.76; 1.3) | -0.008 ( -0.136; 0.119;) |
| Madersbacher, 1999[337] | Propiverine | 15mg thrice daily | Oxybutynin | 5mg twice daily | 124/149 | 115/145 | 1.0 (0.9; 1.) | 0.04 (-0.05; 0.13) |
| Lee, 2002[329] | Oxybutynin | 5mg twice daily | Tolterodine | 2mg twice daily | 53/116 | 50/112 | 1.0 (0.8; 1.) | 0.01 (-0.12; 0.14) |
| Homma, 2003[303] | Oxybutynin | 3mg thrice daily | Tolterodine ER | 4mg/day | 129/244 | 100/239 | 1.3 (1.0; 2.) | 0.11 (0.02; 0.20) |
| Chapple, 2005[61] | Solifenacin | 5-10mg od | Tolterodine | 4mg once daily | 428/578 | 401/599 | 1.1 (1.0; 1.) | 0.07 (0.02; 0.12) |
| Sand, 2009[366] | Fesoterodine | 4mg daily | Tolterodine | 4mg daily | 251/434 | 140/227 | 0.9 (0.8; 1.) | -0.04 (-0.12; 0.04) |
| Zellener, 2009[402] | Trospium | 15mg to 30mg thrice daily | Oxybutynin | 2.5mg to 5mg thrice daily | 374/828 | 368/830 | 1.0 (0.9; 1.) | 0.01 (-0.04; 0.06) |
| Herschorn, 2010[466] | Fesoterodine | 4-8mg once daily | Tolterodine ER | 4mg once daily | 293/679 | 256/684 | 1.2 (1.0; 1.) | 0.06 (0.01; 0.11) |
| Kaplan, 2010[314] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 mg once daily | 282/963 | 265/974 | 1.1 (0.9; 1.) | 0.02 (-0.02; 0.06) |
| Milani, 1993[342] | Flavoxate | 1200 | Oxybutynin | 5mg t.i.d. | 17/50 | 9/50 | 1.9 (0.9; 4.) | 0.16 (-0.01; 0.33) |
| NCT00444925, [58] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 to 8mg once daily | 256/685 | 238/690 | 1.1 (0.9; 1.) | 0.03 (-0.02; 0.08) |

**Appendix Table F77. Comparative effectiveness of tolterodine-ER 4mg/day vs. fesoterodine, evidence secondary data analysis**

| Outcome | Reference | Dose of Fesoterodine, mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) | Evidence |
|---|---|---|---|---|---|---|---|---|---|
| Discontinued prematurely | Chapple, 2008[253] | 8 | 9/290 | 14/287 | 0.64 (0.28; 1.45) | -0.018 (-0.050; 0.014) | | | Insufficient |
| Treatment response | Sand, 2009[366] | 8 | 140/227 | 291/452 | 0.96 (0.85; 1.08) | -0.027 (-0.104; 0.050) | | | Low |
| | | 4 | 140/227 | 251/434 | 1.07 (0.94; 1.21) | 0.038 (-0.040; 0.117) | | | Low |
| Back pain | Sand, 2009[366] | 8 | 1/227 | 4/452 | 0.50 (0.06; 4.43) | -0.004 (-0.017; 0.008) | | | Low |
| | | 4 | 1/227 | 9/434 | 0.21 (0.03; 1.67) | -0.016 (-0.032; 0.000) | | | Low |
| Constipation | Chapple, 2008[253] | 8 | 8/290 | 13/287 | 0.61 (0.26; 1.45) | -0.018 (-0.048; 0.013) | | | Insufficient |
| | Sand, 2009[366] | 8 | 6/227 | 24/452 | 0.50 (0.21; 1.20) | -0.027 (-0.056; 0.003) | | | Low |
| | | 4 | 6/227 | 20/434 | 0.57 (0.23; 1.41) | -0.020 (-0.048; 0.009) | | | Low |
| Cough | Sand, 2009[366] | 8 | 5/227 | 5/452 | 1.99 (0.58; 6.81) | 0.011 (-0.010; 0.032) | | | Low |
| | | 4 | 5/227 | 7/434 | 1.37 (0.44; 4.25) | 0.006 (-0.017; 0.028) | | | Low |
| Diarrhea | Sand,2009[366] | 8 | 3/227 | 6/452 | 1.00 (0.25; 3.94) | 0.000 (-0.018; 0.018) | | | Low |
| | | 4 | 3/227 | 7/434 | 0.82 (0.21; 3.14) | -0.003 (-0.022; 0.016) | | | Low |
| Dizziness | Sand, 2009[366] | 8 | 4/227 | 5/452 | 1.59 (0.43; 5.87) | 0.007 (-0.013; 0.026) | | | Low |
| | | 4 | 4/227 | 4/434 | 1.91 (0.48; 7.57) | 0.008 (-0.011; 0.028) | | | Low |
| Dry eye | Chapple, 2008[253] | 8 | 1/290 | 12/287 | 0.08 (0.01; 0.63) | -0.038 (-0.062; -0.014) | -26 (-16; -70) | -38 (-62; -14) | Insufficient |
| | Sand, 2009[366] | 8 | 1/227 | 10/452 | 0.20 (0.03; 1.55) | -0.018 (-0.034; -0.002) | -56 (-30; -605) | -18 (-34; -2) | Low |
| | | 4 | 1/227 | 6/434 | 0.32 (0.04; 2.63) | -0.009 (-0.023; 0.005) | | | Low |

**Appendix Table F77. Comparative effectiveness of tolterodine-ER 4mg/day vs. fesoterodine, evidence secondary data analysis (continued)**

| Outcome | Reference | Dose of Fesoterodine, mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) | Evidence |
|---|---|---|---|---|---|---|---|---|---|
| Dry mouth | Chapple, 2008[253] | 8 | 49/290 | 97/287 | 0.50 (0.37; 0.68) | -0.169 (-0.239; -0.099) | -6 (-4; -10) | -169 (-239; -99) | Insufficient |
| | Sand, 2009[366] | 8 | 37/227 | 155/452 | 0.48 (0.34; 0.66) | -0.180 (-0.245; -0.115) | -6 (-4; -9) | -180 (-245; -115) | Low |
| | | 4 | 37/227 | 89/434 | 0.79 (0.56; 1.13) | -0.042 (-0.103; 0.019) | | | Low |
| Dry throat | Chapple, 2008[253] | 8 | 3/290 | 8/287 | 0.37 (0.10; 1.38) | -0.018 (-0.040; 0.005) | | | Insufficient |
| | Sand, 2009[366] | 8 | 2/227 | 10/452 | 0.40 (0.09; 1.80) | -0.013 (-0.032; 0.005) | | | Low |
| | | 4 | 2/227 | 4/434 | 0.96 (0.18; 5.18) | 0.000 (-0.016; 0.015) | | | Low |
| Fatigue | Chapple, 2008[253] | 8 | 10/290 | 1/287 | 9.90 (1.28; 76.81) | 0.031 (0.009; 0.053) | 32 (112; 19) | 31 (9; 53) | Insufficient |
| | Sand, 2009[366] | 8 | 7/227 | 1/452 | 13.94 (1.73; 112.60) | 0.029 (0.006; 0.052) | 35 (175; 19) | 29 (6; 52) | Low |
| | | 4 | 7/227 | 5/434 | 2.68 (0.86; 8.34) | 0.019 (-0.005; 0.044) | | | Low |
| Headache | Sand, 2009[366] | 8 | 13/227 | 13/452 | 1.99 (0.94; 4.22) | 0.029 (-0.005; 0.062) | | | Low |
| | | 4 | 13/227 | 21/434 | 1.18 (0.60; 2.32) | 0.009 (-0.027; 0.045) | | | Low |
| Increased alanine aminotransferase | Chapple, 2008[253] | 8 | 0/290 | 6/287 | 0.08 (0.00; 1.35) | -0.021 (-0.039; -0.003) | -48 (-26; -322) | -21 (-39; -3) | Insufficient |
| Nasopharyngitis | Chapple, 2008[253] | 8 | 10/290 | 5/287 | 1.98 (0.69; 5.72) | 0.017 (-0.009; 0.043) | | | Insufficient |
| | Sand, 2009[366] | 8 | 8/227 | 6/452 | 2.65 (0.93; 7.56) | 0.022 (-0.004; 0.048) | | | Low |
| | | 4 | 8/227 | 14/434 | 1.09 (0.47; 2.57) | 0.003 (-0.026; 0.032) | | | Low |
| Nausea | Sand, 2009[366] | 8 | 3/227 | 11/452 | 0.54 (0.15; 1.93) | -0.011 (-0.032; 0.009) | | | Low |
| | | 4 | 3/227 | 4/434 | 1.43 (0.32; 6.35) | 0.004 (-0.013; 0.021) | | | Low |
| | Chapple, 2008[253] | 8 | 6/290 | 4/287 | 1.48 (0.42; 5.21) | 0.007 (-0.015; 0.028) | | | Insufficient |

**Appendix Table F77. Comparative effectiveness of tolterodine-ER 4mg/day vs. fesoterodine, evidence secondary data analysis (continued)**

| Outcome | Reference | Dose of Fesoterodine, mg/day | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) | Evidence |
|---|---|---|---|---|---|---|---|---|---|
| URI | Sand, 2009[366] | 8 | 2/227 | 8/452 | 0.50 (0.11; 2.32) | -0.009 (-0.026; 0.008) | | | Low |
| | | 4 | 2/227 | 12/434 | 0.32 (0.07; 1.41) | -0.019 (-0.038; 0.001) | | | Low |
| UTI | Sand, 2009[366] | 8 | 4/227 | 24/452 | 0.33 (0.12; 0.94) | -0.035 (-0.062; -0.009) | -28 (-16; -116) | -35 (-62; -9) | Low |
| | | 4 | 4/227 | 18/434 | 0.42 (0.15; 1.24) | -0.024 (-0.049; 0.002) | | | Low |

**Appendix Table F78. Improvement in UI after pharmacological treatments for UI**

| Active | Dose | Control | Dose | Studies | Patients | Rate in Active Group | Rate in Control Group | Relative Risl (95% CI) | Absolute Risk Difference (95%CI) | Number Needed to Treat (95% CI) | Evidence |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Fesoterodine | 4-8mg once daily | Tolterodine-ER | 4mg daily | 4[58,314,366,466] | 6,015 | 42.6 | 36.1 | 1.08 (0.99; 1.17) | 0.032 (0.002; 0.063) | 31 (500; 16) | High |
| Oxybutynin | 10mg daily | Tolterodine | 4mg/day | 3[220,303,329] | 947 | 50.3 | 44.7 | 1.11 (0.94; 1.31) | 0.050 (-0.028; 0.128) | | Moderate |
| Propiverine | 15mg thrice daily | Oxybutynin | 5mg twice daily | 1[337] | 294 | 83.0 | 79.0 | 1.05 (0.94; 1.17) | 0.039 (-0.050; 0.128) | | Insufficient |
| Solifenacin succinate | 5-10mg once daily | Tolterodine | 4mg once daily | 1[61] | 1,177 | 74.0 | 67.0 | 1.11 (1.03; 1.19) | 0.071 (0.019; 0.123) | 14 (52; 8) | Insufficient |
| Flavoxate hydrochloride | 1200 | Oxybutynin | 5mg t.i.d. | 1[342] | 100 | 34.0 | 18.0 | 1.89 (0.93; 3.83) | 0.160 (-0.009; 0.329) | | Insufficient |
| Trospium Chloride | 15mg to 30mg thrice daily | Oxybutynin Hydrochloride | 2.5mg to 5mg thrice daily | 1[402] | 1,658 | 45.2 | 44.3 | 1.02 (0.92; 1.13) | 0.008 (-0.040; 0.056) | | Insufficient |

**Appendix Table F79. Blurred vision after pharmacological treatments for UI when compared to each other**

| Reference | Active Drug | Dose | Control Drug | Dose | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Zinner, 2005[403] | Darifenacin ER | 15mg/day | Oxybutynin | 5 mg 3 times/day | 0/19 | 1/19 | 0.3 (0.0; 8.) | -0.05 (-0.19; 0.08) |
| Chapple, 2004[258] | Solifenacin | 2.5mg once daily | Tolterodine | 2mg twice daily | 1/41 | 0/37 | 2.7 (0.1; 65.) | 0.02 (-0.04; 0.09) |
| Chapple, 2004[258] | Solifenacin | 5mg once daily | Tolterodine | 2mg twice daily | 1/37 | 0/37 | 3.0 (0.1; 71.) | 0.03 (-0.04; 0.10) |
| Chapple, 2004[258] | Solifenacin | 10mg once daily | Tolterodine | 2mg twice daily | 5/35 | 0/37 | 11.6 (0.7; 203.) | **0.14 (0.02; 0.27)** |
| Chapple, 2004[258] | Solifenacin | 20mg once daily | Tolterodine | 2mg twice daily | 5/37 | 0/37 | 11.0 (0.6; 192.) | **0.14 (0.02; 0.25)** |
| Chapple, 2004[54] | Solifenacin | 5mg daily | Tolterodine | 2mg twice daily | 10/279 | 4/266 | 2.4 (0.8; 8.) | 0.02 (-0.01; 0.05) |
| Chapple, 2004[54] | Solifenacin | 10mg daily | Tolterodine | 2mg twice daily | 15/269 | 4/266 | 3.7 (1.2; 11.) | **0.04 (0.01; 0.07)** |
| Zinner, 2005[403] | Darifenacin ER | 30mg/day | Oxybutynin | 5 mg 3 times/day | 0/19 | 1/19 | 0.3 (0.0; 8.) | -0.05 (-0.19; 0.08) |
| Chapple, 2007[256] | Solifenacin | 5mg daily | Tolterodine | 4mg daily | 1/578 | 7/599 | 0.1 (0.0; 1.) | -0.01 (-0.02; 0.00) |
| Yamaguchi, 2007[401] | Solifenacin | 5mg daily | Propiverine | 20mg daily | 7/400 | 15/402 | 0.5 (0.2; 1.) | -0.02 (-0.04; 0.00) |
| Yamaguchi, 2007[401] | Solifenacin | 10mg daily | Propiverine | 20mg daily | 16/385 | 15/402 | 1.1 (0.6; 2.) | 0.00 (-0.02; 0.03) |
| Milani, 1993[342] | Flavoxate | 1200 | Oxybutynin | 5mg t.i.d. | 1/50 | 2/50 | 0.5 (0.0; 5.) | -0.02 (-0.09; 0.05) |
| NCT00444925,[58] | Fesoterodine | 4 to 8mg once daily | Tolterodine ER | 4 to 8mg once daily | 12/685 | 8/690 | 1.5 (0.6; 4.) | 0.01 (-0.01; 0.02) |
| Armstrong, 2007[226] | Oxybutynin | 10mg qd | Tolterodine ER | 4mg qd | 10/576 | 4/399 | 1.7 (0.5; 5.) | 0.01 (-0.01; 0.02) |

Bold - significant differences at 95%confidence level

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Finazzi Agro, 2005[470]<br>Country: Italy<br>Aim: comparative effectiveness of posterior tibial nerve stimulation performed weekly vs. 3 times per week in men and women with overactive bladder syndrome | Men and women with overactive bladder syndrome not responding to antimuscarinic therapy | Not reported | Posterior tibial nerve stimulation 3 times/week | Posterior tibial nerve stimulation 1 time/week |
| Aksac, 2003[471]<br>Country: Turkey<br>Aim: the effects of pelvic floor muscle exercises or biofeedback on female urinary stress incontinence | 50 postmenopausal women with female urinary stress incontinence taking HRT | Not reported | Pelvic floor muscle exercise (contractions for 10 seconds and relaxation for 20 seconds, 10 times/session, 3 sessions/day) via digital palpation at home; pelvic floor muscle exercise (contractions for 10 seconds and relaxation for 20 seconds) via biofeedback | Usual care, hormone replacement therapy |
| Alewijnse, 2003[472]<br>Country: The Netherlands<br>Aim: the effectiveness of pelvic muscle floor exercise therapy supplemented with a health education program urinary incontinence among women. | 129 community-dwelling women over 17 years old with urinary incontinence, ability to complete questionnaires in Dutch language. | Continence, neurological conditions, venereal disease, viral infections, using medication that may impact incontinence, pregnancy or 3 months after delivery, after surgical treatment for incontinence, and women with physical impairments. Severe prolapse | Bladder training with voiding frequency of ~7 voidings/day and pelvic floor muscle exercise: 10 slow twitch contractions (10-30 seconds) and 10 fast twitch contractions (2-3 seconds), 5 times/day, each contraction being followed by relaxation | Bladder training and pelvic floor muscle exercise |
| Amaro, 2005[473]<br>Country: Brazil<br>Aim: the effect of intravaginal electrical stimulation on pelvic floor muscle strength in women with mixed urinary incontinence. | 40 women with mixed urinary incontinence and predominant urge incontinence. | Anticholinergic and tricyclic antidepressant medications, pelvic floor exercise, bladder training, vaginal prolapse more than II grade, urinary tract infection, metal implants, and neurological diseases | Intravaginal electrical stimulation with 3 20-minute sessions/week using 4Hz frequency. | Sham stimulation with inactive device |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Amaro, 2006[474]<br>Country: Brazil<br>Aim: the effects of intravaginal electrical stimulation in mixed urinary incontinence | 40 women symptoms of predominant urge incontinence not taking anticholinergics or tricyclic antidepressants | Use of pelvic floor exercises or bladder training, vaginal prolapse >grade II, retention complaint or obstruction diagnosis during UDS, urinary infection, changes in cutaneous sensitivity, metal implants, and neurological diseases. | Effective intravaginal electrical stimulation using frequency of 4 Hz with 3 20-minute sessions/week | Sham intravaginal electrical stimulation using frequency of 4Hz with 3 20-minute sessions/week |
| Andersen, 2002[475]<br>Country: USA<br>Aim: the long-term effectiveness of Durasphere vs. Contigen in the treatment of female stress urinary incontinence caused by intrinsic sphincter deficiency | Adult women 21 years of age or older with stress UI caused by intrinsic sphincter deficiency for a period of at least 12 months; positive pad weight test; failure of previous non invasive treatments, post void residual <100 mL and abdominal leak point pressure | Urge primary incontinence, uncontrolled bladder instability, positive urine culture, previous urethral bulking treatments, medication affecting the evaluation of incontinence, pregnancy | Durasphere 4.5 mL injected submucosally between the bladder neck and external sphincter | Contigen 4.2 mL injected submucosally between the bladder neck and external sphincter |
| Appell, 2006[476]<br>Country: USA<br>Aim: the effects of transurethral radiofrequency energy collagen micro-remodeling on female stress urinary incontinence | 173 women with stress urinary incontinence, bladder outlet hypermobility, and leak point pressure >60cm/H2O | Evidence of detrusor overactivity on cystometrogram, post-void residual bladder volumes >50cc, significant pelvic organ prolapse (POP-QStage IV) on physical examination, history of dry or wet overactive bladder, previous surgical or bulking agent therapy | Transurethral radiofrequency energy collagen micro-remodeling | Sham treatment probes lacked needle electrodes and sham treatment of radiofrequency generator |
| Arvonen, 2001[477]<br>Country: Sweden<br>Aim: the effects of pelvic floor muscle training with and without vaginal balls on females stress urinary incontinence | 37 women ages 25-65 with stress urinary incontinence, understanding of spoken Swedish | Pregnancy, cysto/rectocele, prolapse, urinary tract infection, altered vaginal tissue, and medication affecting the functioning of the urinary tract or kidneys | Pelvic floor muscle training program with contractions/ relaxations for 5 seconds 10 times twice a day | Pelvic floor muscle training program with contractions/ relaxations for 20/20 seconds 10 times twice a day using weighted vaginal balls 50-100g. |
| Aukee, 2002[478]<br>Country: Finland<br>Aim: the effects of electromyography-assisted biofeedback training and | 30 women with urodynamically tested stress incontinence ages 31 to 69 years without previous incontinence operations and | Genital protrusion beyond the vaginal hymen, an inability to understand instructions for home training, pregnancy, and any severe disease such | Pelvic floor muscle exercise after verbal and written instructions for home practice of 20 minutes/day 5 times/week and individual | Pelvic floor muscle exercise after verbal and written instructions for home practice of 20 minutes/day 5 times per week |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| pelvic floor muscle training on female stress urinary incontinence | an abdominal leak point pressure >90 | as malignancy in the abdominal region, multiple sclerosis, and insulin-dependent diabetes | EMG-assisted biofeedback device with vaginal probe and verbal control | |
| Aukee, 2004[479]<br>Country: Finland<br>Aim: the effectiveness of pelvic floor training with home biofeedback device among women with stress urinary incontinence | 35 women 21-70 years old with urodynamically confirmed stress incontinent (maximal urethral closure pressure >20cm/H2O and cough leak point pressure >90cm/H2O) | Previous incontinence operations, genital prolapse, inability to understand instructions for home training, pregnancy, severe diseases such as malignancies in the abdominal region, multiple sclerosis and diabetes mellitus requiring insulin | 1. Home program with given verbal and written instructions for home practice and advise to practice for 20 minutes/day, 5 times/week.<br>2. Pelvic floor training by physiotherapist 5 times/12 weeks: 3-5 second contractions with 10 second intervals in supine | Home program with given verbal and written instructions for home practice |
| Bano, 2005[480]<br>Country: UK<br>Aim: the effects of porcine dermal implant (Permacol) and silicone injection (Macroplastique) on urodynamic stress incontinence in females | 50 women with urodynamically proven stress incontinence | Not reported | Peri or transurethral porcine dermal implant injection (Permacol) | Transurethral silicone injection (Macroplastique) |
| Barroso, 2004[481]<br>Country: Brazil<br>Aim: the effects of transvaginal electrical stimulation on urinary incontinence | 36 women (24 patients and 12 controls) with stress, urge, or mixed urinary incontinence | Prolapse or first degree urogenital prolapse, intrinsic sphincter deficiency, cardiac pacemaker; pregnancy, postmenopausal climacteric with symptoms and signs of urogenital atrophy (they could be included after 3 months of treatment with hormone-replacement therapy | Transvaginal electrical stimulation at home twice a day (20-minute sessions) with frequency of 20 (urge) or 50Hz (stress UI), a pulse width of 300ms, with asymmetrical biphasic pulses, an adjustable current intensity (0-100mA) | Placebo |
| Berghmans,1996[482]<br>Country: The Netherlands<br>Aim: the effects of biofeedback and pelvic floor muscle exercise on female genuine stress incontinence. | 40 women 18-70 years with mild or moderate stress incontinence (grade 1). | Use of medicine to counteract functional disabilities of the lower urinary tract, pronounced lesions of the pudendus nerve during clinical neurophysiological examination, positive sediment of urine culture, non-compliance in the | Pelvic floor muscle exercise 12 treatment sessions, 3 times/week with contractions 3-30 seconds 10-30 times beginning with 4 sets of 10 (5 quick and 5 sustained) and increased by 10 per set until 30 times/set. Biofeedback with EMG vaginal probe and | Pelvic floor muscle exercise 12 treatment sessions, 3 times/week with contractions 3-30 seconds 10-30 times beginning with 4 sets of 10 (5 quick and 5 sustained) and increased by 10 per set until 30 times/set |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| | | diagnostic phase, neurogenic urinary incontinence | visualization | |
| Berghmans, 2002[483]<br>Country: The Netherlands<br>Aim: the effects of physiotherapy in women with proven bladder overactivity | 98 patients older than 18 years with proven bladder overactivity defined as Detrusor Activity Index (DAI) ≥0.50, able to understand Dutch | Mechanical intravesical obstruction, urinary calculus, urinary tract infection, colpitis, pacemaker, pregnancy, physiotherapy within 3 months, uncontrolled diabetes mellitus | Pelvic floor exercises with contractions for >20 seconds controlled by physiotherapist palpation with relaxation period of 10 seconds. Bladder training to inhibit the sensation of urgency and to postpone voiding, voiding schedule with an interval >2 hours | Usual care |
| Blowman, 1991[484]<br>Country: UK<br>Aim: To assess the efficacy of neuromuscular stimulation and pelvic floor exercises, compared with pelvic floor exercises only, in the treatment of genuine stress incontinence | Only patients diagnosed from bladder pressure studies as suffering from genuine stress incontinence were recruited. They all had maximum bladder volumes over 500ml and exhibited no detrusor contraction in lying or standing. All patients demonstrated cough-induced leakage when standing. They were referred to the physiotherapy department gynecology unit and gave informed written consent to take part in the trial. | Not reported | Neurotrophic stimulation | Placebo stimulation |
| Bo, 1997[485]<br>Country: Norway<br>Aim: Crossover RCT to examine the effect of voluntary pelvic floor muscle contraction and vaginal electrical stimulation on urethral pressure in women with genuine stress incontinence | 12 women with genuine stress incontinence participated in pelvic floor exercise program with 8-12 contractions | Not reported | 3 voluntary PFM contractions and 2 electrical stimulators Conmax 50Hz – pulse width 0.75ms, 0-90mA Medicon 50Hz - pulse width 0.5ms, 0-100mA | Electrical stimulation with Medicon 50 Hz - pulse width 0.5ms, 0-100mA |
| Bo, 1999[486]<br>Country: Norway<br>Aim: the effects of pelvic floor | 107 women with clinically and urodynamically proved genuine stress incontinence | Urinary incontinence other than genuine stress incontinence, involuntary | 1. Pelvic floor exercise with 8-12 contractions 3 times/day and in groups with skilled | The untreated control group offered the use of a continence guard |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| exercises, electrical stimulation, vaginal cones, and no treatment on females genuine stress incontinence | >4g of leakage measured by pad test with standardized bladder volume. | detrusor contractions >10cm/H2O on cystometry, abnormal bladder function (residual urine >50ml and maximal uroflow <15ml/second), previous surgery for genuine stress incontinence, neurological or psychiatric disease, ongoing urinary tract infections, other diseases that could interfere with participation, use of concomitant treatments during the trial, and inability to understand instructions given in Norwegian | physical therapists 1/week.<br>2. The electrical stimulation using vaginal intermittent stimulation with the MS 106 Twin at 50Hz 30 minutes/day.<br>3. The vaginal cones of 20, 40, and 70g for 20 minutes/day | |
| Bo, 2000[487]<br>Country: Norway<br>Aim: the effects of pelvic floor muscle exercise on female genuine stress incontinence | 59 women with clinically and urodynamically proven genuine stress incontinence .4 grams of leakage measured by the pad test | Urinary incontinence other than GSI, involuntary detrusor contractions exceeding 10cm/H2O on cystometry, residual urine .50ml, maximal uroflow, 15ml/second, previous surgery for GSI, neurological or psychiatric disease, ongoing urinary tract infections | Pelvic floor muscle exercise with 8-12 maximum contractions in 3 series/day and 45 minutes/week group sessions | Untreated control group |
| Bo, 2005[488]<br>Country: Norway<br>Aim: Followup RCT to examine the effects of intensive exercise on stress urinary incontinence. | 52 women with urodynamic stress urinary incontinence participated in the original RCT | Response rate 90.4% | Intensive pelvic floor exercise with 8-12 maximum contractions for 6-8 seconds 3 series/day under the supervision of physical therapist for 6 months | Home exercise groups |
| Borawski, 2007[489]<br>Country: USA<br>Aim: the effects of percutaneous needle electrode technique or a surgical first stage lead placement on implantation of a pulse generator in older urge incontinent women | 30 women >55 years with refractory urge incontinence after failure of medical, behavioral, and pelvic floor reeducation management | Not reported | Electrical stimulation with percutaneous needle electrode (22-G spinal needle) placement | Electrical stimulation with surgical first stage lead placement |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Borello-France, 2006[490]<br>Country: USA<br>Aim: the effects of exercise position during pelvic-floor muscle exercises on females stress urinary incontinence | 44 women 38 to 70 years old, ambulatory, with symptoms of stress urinary incontinence >1/week | Pregnancy, symptoms of urgency or urge urinary incontinence, prior treatments for stress urinary incontinence (collagen injection, medications affecting bladder tone, pessary, or surgery), practicing pelvic-floor muscle exercises, pacemaker, use of intrauterine device, medical history of pelvic cancer, severe endometriosis, neurologic or metabolic disorders likely to impair bladder or sphincter function | Pelvic floor muscle exercises with EMG biofeedback in the supine position only using maximum 30-60 repetitions of 3-12 second contractions twice daily | Pelvic floor muscle exercises with EMG biofeedback in both supine and upright positions, 1 set (3- and 12-second contractions) in each position with maximum 20 repetitions (2 sets of 10) of the 3-12 second contractions twice daily |
| Borello-France, 2008[491]<br>Country: USA<br>Aim: comparative effectiveness of maintenance exercise program either 1 or 4 times per week in women with stress UI | Women 38 to 70 years of age, not pregnant, ambulatory, and recorded at least one SUI episode and no urgency or urge urinary incontinence (UUI) in a 7-day bladder diary | A medical history that included pelvic cancer, severe endometriosis, use of an intrauterine device, or pacemaker; neurologic or metabolic disorders associated with bladder or sphincter dysfunction; previous medical/surgical treatments for SUI; or prior in | High-frequency (4 times per week) maintenance 2 times/day exercise program with 60 repetitions (3 sets of 20 repetitions) of a 3-second PFM contraction and 30 repetitions (3 sets of 10 repetitions) of a 12-second contraction per exercise session | Low-frequency (1 time/week) maintenance 2 times/day exercise program with 60 repetitions (3 sets of 20 repetitions) of a 3-second PFM contraction and 30 repetitions (3 sets of 10 repetitions) of a 12-second contraction per exercise |
| Borrie, 2002[492]<br>Country: Canada<br>Aim: the effects of combined lifestyle and behavioral interventions led by nurses in the management of urinary incontinence | 421 subjects 26 years of age or older with self reported urinary incontinence at least once per week, resided in the community, and communicated in English | Pregnancy, residency of long-term care institutions, dementia | Lifestyle modification sessions every 4 weeks led by trained "nurse continence advisers" with a physician with expertise in continence management | Usual care |
| Bower, 1998[493]<br>Country: Australia<br>Aim: the effects of surface neuromodulation on cystometric pressure and volume parameters in women with detrusor instability or sensory urgency. | 48 women with proved detrusor instability or sensory urgency | Urinary tract infection, pregnancy, cardiac pacemaker, impaired cognition, neurogenic bladder dysfunction or cystocele beyond the introitus | Active transcutaneous electrical nerve stimulation with 10Hz. frequency and 200 microsecond pulse width (sacral placement) | 1. Sham transcutaneous electrical nerve stimulation with sacral or suprapubic placement<br>2. Active transcutaneous electrical nerve stimulation with 150Hz. frequency and 200 microsecond pulse with (suprapubic placement) |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Boyington, 2005[494]<br>Country: USA<br>Aim: the effects of computer-based system for continence health promotion that included self-management techniques for women with symptoms of involuntary urine loss, urinary frequency or urgency, or nocturia | Women 50 years or older who lived independently in the community with symptoms of UI, urinary frequency or urgency, or nocturia; minimum of 30 on the Telephone Interview for Cognitive Status-modified (TICS-m); Self-reported ability to read and write E | Toilet dependently; blood in their urine, recurrent urinary tract infections, persistent difficulty with bladder emptying as evidenced by straining or other efforts to drain the bladder completely, or symptomatic pelvic prolapse | computer-based system to promote continence health using health clinic visit metaphor that provided fact sheets, testimonials from women who improved with the adoption of behavioral techniques; the expert system advice on Bladder training, PFMT, fluid man | Alternate computer-based system simulating women's magazine with information about breast self-examination and tips for women traveling alone |
| Brown, 2006[495]<br>Country: USA<br>Aim: the effects of intensive lifestyle intervention or metformin on prevalence of urinary incontinence among overweight pre-diabetic women | 2,191 women in the Diabetes Prevention Program RCT older than 25 years, body mass index ≥24kg/m2, a fasting plasma glucose level 95-125mg/dl, and a 2-hour post-challenge glucose level 140-199mg/dl | Exclusion criteria: Taking medications that could affect glucose tolerance or serious medical illness | Intensive lifestyle therapy to lose and maintain at least 7% of initial body weight through a low-fat diet and to engage in moderate-intensity physical activity for at least 150 minutes each week | Placebo twice daily. |
| Brubaker, 1997[496]<br>Country: USA<br>Aim: the effects of transvaginal electrical stimulation for treatment of urinary incontinence in women | 121 women >25 years of age with either urinary incontinence due to detrusor instability or genuine stress incontinence, or both (mixed incontinence) diagnosed with filling urethrocystometry | Urinary incontinence other than genuine stress incontinence, detrusor instability, or mixed incontinence; leakage episodes <3/week, inadequate genitourinary estrogen (minimum 3 months HRT), inadequate cognitive ability (investigator judgment), urinary tract infection, anatomic defect that precluded use of device, postvoid residual >100ml, implanted electric device, genitourinary surgery, drug treatment for urinary incontinence, anticipated geographic relocation during study. | The transvaginal electric stimulation for 20 minutes 2 times/day using frequency of 20Hz, a 2-second-4-second work-rest cycle with a range of stimulation intensities, from 0-100mA | Sham inactive device |
| Bryant, 2002[497]<br>Country: Australia<br>Aim: the effects of caffeine | 95 consecutive adult patients with urinary symptoms with routine intake of caffeine | Cognitive impairment, pregnancy, urinary tract infection | Education to reduce caffeine intake to <100mg/day plus bladder training | Bladder training: increasing intervals between voiding; increasing fluid intake to 2 |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| restriction on urinary incontinence symptoms | >100mg every 24 hours | | | L/day; urinary deferment techniques; ceasing "just in case" voiding |
| Burgio, 2002[498]<br>Country: USA<br>Aim: the effects of biofeedback as a part of complex behavioral training program for urge incontinence in community-dwelling older women | 222 ambulatory, nondemented, community-dwelling women ages 55 to 92 years with urge incontinence or mixed incontinence >2 times/week for at least 3 months, and with urodynamic evidence of bladder dysfunction (detrusor instability during filling or provocation or maximal cystometric capacity of ≤400ml) | Continual leakage, postvoid residual urine volume >150ml, severe uterine prolapse past the vaginal introitus, decompensated congestive heart failure, or impaired mental status (Mini-Mental State Examination score <24) | Biofeedback-assisted behavioral training implemented by nurse practitioners. Abdominal pressure and sphincter responses were measured with 3-baloon probe inserted in rectum. Pelvic floor muscle exercise with 10 second contractions/10 second relaxation for 20-30 minutes | Self-administered behavioral treatment using a self-help booklet to advise pelvic floor exercise and bladder control |
| Burns, 1990[499]<br>Country: USA<br>Aim: the effects of pelvic floor exercises or biofeedback on female stress urinary incontinence | 128 women with stress or mixed urinary incontinence >3/week with Mini-Mental scores >23 | Urinary tract infection | Kegel pelvic floor exercises 4 times/day. Biofeedback with vaginal EMG probe and visual control. | Usual care |
| Burns, 1993[500]<br>Country: USA<br>Aim: the effects of biofeedback and pelvic muscle exercise treatment on stress incontinence in older community-dwelling women | 135 community-dwelling women older than 55 years with sphincteric incompetence, >3 urine losses/week, urodynamic incontinence, >23 scores in Mini-Mental State exam | Glycosuira, pyuria, residual urine >50cc, peak urine flow <15cc/second | Biofeedback using vaginal EMG probe, contraction for 10 seconds and relaxations for 10 seconds 10 times in each weekly session. Pelvic muscle exercise with 4 sets of 20 increasing by 10/set until maximum 200 sets/day | Usual care |
| But, 2003[501]<br>Country: Slovenia<br>Aim: the effects of functional magnetic stimulation in the treatment of women with urinary incontinence | 55 women with urinary incontinence older than 18 years, not pregnant, and not physically or mentally disabled | Implanted electronic equipment (pacemakers), urolithiasis, bladder infection, tumor, recent urethral or continence surgery, use of anticholinergic drugs, beta-blocking agents, and diuretics | Functional magnetic stimulation with Pulsegen device, which produced a pulsating magnetic field of B = 10 microT intensity and a frequency of 10Hz | Placebo treatment with sham not active device |
| But, 2005[502]<br>Country: Slovenia<br>Aim: the effects of functional magnetic stimulation for | 39 women with mixed urinary incontinence and predominant urge incontinence | Not reported | Functional magnetic stimulation applied continuously at 18.5Hz day and night | Sham inactive device |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| treating women with mixed urinary incontinence | | | | |
| de Oliveira Camargo, 2009[503]<br>Country: Brazil<br>Aim: comparative effectiveness of individual vs. group pelvic floor muscle training | Women with confirmed urodynamic SUI, positive cough stress test, and less than 3 g of leakage as measured by a pad test with a standardized bladder volume (200 ml) | Detrusor overactivity, chronic neurological or muscular diseases, abnormal genital bleeding, uterine prolapse, advanced genital prolapse, active genitourinary tract infections, pregnancy, or vaginal atrophy, intrinsic sphincter deficiencies, Valsalva leak | Pelvic floor exercises in a group with two weekly sessions of 45 minutes each. In the orthostatic position, patients received oral instructions to perform ten contractions of 5 seconds with 5 seconds of recovery time, 20 contractions of 1 second with 1 second of recovery time | Individual pelvic floor exercises Following PERFECT assessment scheme with contractions in accordance with the endurance, power, and time that the patients could tolerate. |
| Cammu, 1998[504]<br>Country: Belgium<br>Aim: the effects of pelvic floor exercises and vaginal weight cones in the treatment on female genuine stress incontinence | 60 ambulatory and fit white women with urodynamic urinary stress incontinence, and vaginal capacity permitting the use of a vaginal probe-EMG biofeedback-or cones post-partum period, and had neither a genital prolapse nor any other associated pathology | Not in abstract | Weekly session of pelvic floor exercises vaginal probe-EMG biofeedback using perineometer | Vaginal weight cones (20, 32, 45, 57, and 70 g) for 15 minutes, twice daily |
| Castro, 2008[246]<br>Country: Brazil<br>Aim: To compare the effectiveness of pelvic floor exercises, electrical stimulation, vaginal cones, and no active treatment in women with urodynamic stress urinary incontinence. | Women with proven urodynamic stress urinary incontinence were enrolled at the Urogynecology and Reconstructive Pelvic Surgery | Patients with chronic degenerative diseases that would affect muscular and nerve tissues, advanced genital prolapses, pregnancy, active or recurrent urinary tract infections, vulvovaginitis, atrophic vaginitis, continence surgery within one year, and patients with cardiac pacemakers; patients with intrinsic sphincteric deficiencies identified by the Valsalva leak point pressure ≤60cm H20 measurement in the sitting position with a volume of 250 ml in the bladder and/or by the | Pelvic Floor Muscle Training | Electrical stimulation/weighted vaginal cone/no treatment |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| | | measurement of a urethral closure pressure ≤20cm H20 in the sitting position at maximum cystometric capacity. | | |
| Chadha, 2000[505]<br>Country: Australia<br>Aim: the effects of national guidelines and local protocols in improving hospital care for women with UI | 449 women with urinary incontinence from gynecology units in four district general hospitals across Scotland | Not reported | National evidence based guidelines adapted locally to protocols, which were disseminated at specific local educational meetings and implemented by placing a copy of the appropriate protocol in women's hospital case notes prior to consultation | Usual care |
| Coleman,<br>Country: USA<br>Aim: the effect of Chronic Care Clinics on urinary incontinence in frail older adults | Frail older adults were those enrollees at high risk for hospitalization according to the Chronic Disease Score, the patients in the Group Health Cooperative of Puget Sound, a large Health Maintenance Organization located in western Washington State | Severe illness that precluded their participation in the study; moderate to severe dementia; residence in a nursing home, terminal illness | New model of primary care, Chronic Care Clinics:<br>(1) An extended (30 minutes) visit to the patient's physician and team nurse dedicated to developing a shared treatment plan that emphasized the reduction of disability;<br>(2) A session with the pharmacist | Usual care |
| Corcos, 2005[506]<br>Country: Canada<br>Aim: Noninferiority RCT to examine effects of collagen injection or surgery on female stress urinary incontinence | 133 women older than 30 years with stress urinary incontinence lasted for >6 months | Contraindications to surgery or collagen injections (allergic reaction), associated conditions (e.g., severe medical disease or indication for hysterectomy) or pelvic prolapse (vault, cystocele, rectocele), neurogenic bladder or interstitial cystitis | Intraurethral collagen submucosal injection 4 injections at 1-month intervals | Surgery (needle bladder neck suspensions, Burch, and slings). The choice of technique was left to the surgeon |
| Demain, 2001[507]<br>Country: USA<br>Aim: comparative effectiveness of group versus individual management on physical symptoms and | Women over 18 years of age with clinical symptoms of stress and/or urge incontinence (median duration of symptoms 3 years 7 months) presenting to | Pregnancy, recent pelvic surgery (3 months), history of pelvic malignancy, fecal incontinence, current urinary infection, grade III prolapse, diseases of central nervous | Three educational group sessions with 4-12 women. Women attended 3 1-hour sessions with educational and exercise components | One 45-minute individual treatment, instructions in pelvic floor muscle exercise |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| quality of life in female urinary incontinence | physiotherapy | system, acute mental illness and dementia, previous physiotherapy for incontinence | | |
| Demirturk, 2008[508]<br>Country: Turkey<br>Aim: comparative effectiveness of interferential current and biofeedback applications on incontinence severity in patients with urinary stress incontinence | Women with urodynamic stress UI and moderate intensity of incontinence as determined by a one-hour pad test referred Physical Therapy and Rehabilitation, Women's Health Unit | Urinary tract infections, detrusor over activity, cognitive problems and neoplasm | Interferential current with a frequency of 0–00 Hz 5 minutes per session, three times a week for a total of 5 sessions | Kegel exercises with biofeedback 5 minutes per session, three times a week for a total of 5 sessions |
| Diokno, 2004[509]<br>Country: USA<br>Aim: the effects of behavioral modification program on incidence of urinary incontinence in older women | 359 postmenopausal, continent women (0-5 days of incontinent episodes in the previous year) 55 years and older.<br>At baseline 2 groups reported identical 39% absolute continence and zero UI days 61% of participants reported 1 to 5 UI episodes in year | Neurologic diseases, mini-mental scores <24, positive paper towel cough test, grade 4 uterine prolapse | 1 2-hour classroom presentation on behavioral modification program: pelvic floor muscle training, bladder training, and individualized test of knowledge, adherence, and skills to reinforce the technique as needed | Usual care |
| Diokno, 2010[510]<br>USA<br>The effectiveness of behavioral modification program vs. standardized protocol taught to adult incontinent women | Adult incontinent ambulatory females from four Michigan counties in the U.S. | 1) Women currently under incontinence treatment with medications or previous/current behavioral programs, 2) history of bladder cancer, stroke, multiple sclerosis, Parkinsonism, epilepsy or spinal cord tumor or trauma, 3) pregnancy, 4) MESA questionnaire of 725 or higher on urge score, 70% or higher on stress score, or urge percentage higher than stress percentage to eliminate those with total incontinence and those with urge predominant symptoms, respectively. Previously failed anti- | Group intervention | No intervention |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| | | incontinence surgery was not considered for exclusion | | |
| Dougherty, 2002[511]<br>Country: USA<br>Aim: the effects of behavioral management for continence on urinary incontinence in older rural women in their homes | 218 women 55 years and older, who lived in a private residence in rural area; with involuntary urine loss >2/week of 1g/24 hours or more; without urinary tract infection | Bladder cancer or kidney disease, indwelling urinary catheter, residual urine >100cc, needed caregiver | Behavioral management for continence: Self-monitoring and bladder training to reduce caffeinated beverages to <2 cups/glasses, 1,500 <daily fluid intake <4000cc, no fluid consumption after 6 pm, daytime voiding interval <4 hours, and treatment of const | Usual care |
| Dowd, 1996[512]<br>Country: USA<br>Aim: the effects of hydration on the number of urinary incontinence episodes | 58 women 50 years old and older with incontinence more than 6 months, independent in self-care, English speakers with >20 scores on Mini-Mental State | Exclusion criteria: not provided | 1. Increase fluid intake by 500cc<br>2. Maintain fluid intake at baseline level | Decrease daily fluid intake by 300cc |
| Dowd, 2000[513]<br>Country: USA<br>Aim: the effects of cognitive strategies combined with educational programs in urinary incontinence | 40 subjects >40 years of age, independent in self-care, with history of incontinence and/or frequency for at least 6 months, able to read and write English, and having hearing adequate for listening to an audiotape | Presence of urinary tract infections or severe neurological disorders | Education about bladder health, recorded incontinence and frequency episodes in a voiding diary, and listening to the audiotape daily | Education about bladder health and recorded incontinence and frequency episodes in the voiding diary |
| Dumoulin, 2004[514]<br>Country: Canada<br>Aim: the effectiveness of multimodal supervised physiotherapy programs among women with persistent postnatal stress urinary incontinence | 64 premenopausal women younger than 45 years presenting symptoms of stress urinary incontinence at least once per week 3 months or more after their last delivery | Current pregnancy, urinary incontinence before pregnancy, previous surgery for stress incontinence, moderate to severe urogenital prolapse, involuntary detrusor contraction on cystometry neurologic or psychiatric disease, or a major medical condition, taking medication that could interfere with their evaluation or treatment, inability to understand French or English instructions.<br>Loss of followup: 2, plus 2 did not attend the final | 1. Pelvic floor rehabilitation: 15 minute electrical stimulation of the pelvic floor muscle; then 25 minute pelvic floor muscle exercise program with biofeedback, which included strengthening and motor relearning exercises and a home exercise 5 days/week.<br>2. Pelvic floor rehabilitation plus abdominal training: in addition to PFE 30 minutes of deep abdominal muscle training consisting of isolation, reeducation, and functional | Relaxation massage for the back and extremities by physiotherapist. They were asked not to exercise their pelvic floor muscles at home. |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| | | examination and were excluded from the analysis. | retraining of the transversus abdominis | |
| Elser, 1999[515]<br>Country: USA<br>Aim: the effects of pelvic floor muscle training, bladder training, or both, on urodynamic parameters in women with urinary incontinence | 204 women 45 years or older, ambulatory, mentally intact with urodynamic genuine stress incontinence or detrusor instability, with or without stress incontinence, experiencing 1–100 episodes of incontinence per week as recorded on the qualifying 7-day diary | Reversible cause of incontinence, uncontrolled metabolic conditions (e.g., diabetes mellitus), postvoid residual of >100ml, persistent urinary tract infection, urinary tract fistula, or indwelling catheterization | Patient education, self-monitoring with treatment logs, compliance assessment, and positive reinforcement techniques administered by trained research nurses.<br>Pelvic floor muscle training with10 fast (3 second) contractions and 40 sustained (10 second) contractions | Bladder training |
| Emmons, 2005[516]<br>Country: USA<br>Aim: the effects of acupuncture on overactive bladder in women | 85 women older than 18 years, with symptoms of overactive bladder with urge incontinence, >8 voids per day, subjective urgency to void, and urge-associated incontinence at least twice during a 3-day period of time | Pregnancy, taking medications for overactive bladder or receiving acupuncture treatments for any condition, unable to ambulate or unable to complete a 3-day voiding diary, and hematuria or untreated urinary tract infection | Acupuncture treatment expected to improve bladder symptoms | Placebo acupuncture treatment designed to promote relaxation |
| Engberg, 2002[517]<br>Country: USA<br>Aim: Cross-over RCT to examine the effects of prompted voiding in cognitively impaired homebound older adults | 19 adults 60 years and older with urinary incontinence >2 episodes/week for >3 months who met Center for Medicare and Medicaid Services criteria for being homebound, residents in 2 large Medicare-approved home health agencies in a large metropolitan area | Terminal illness; postvoid residual volume >100ml; caregiver was unable or unwilling to provide toileting assistance, complete bladder diaries, or implement the PV protocol | Prompted voiding by caregivers to approach subjects hourly for perceived wet/dry status vs. objective wet checks, feedback and praising for correct response, toilet by request, positive feedback for appropriate toileting | Usual care with attention control (visits by the nurse practitioner every 1-2 weeks to provide social interaction) |
| Fantl, 1991[518]<br>Country: USA<br>Aim: the effects of bladder training on urinary incontinence in older women | 131 noninstitutionalized women 55 years and older with clinical and urodynamic urinary incontinence >1 leakage/week; mentally intact (Mini-Mental State Examination score >23), capable of independent toileting | Uncontrolled diabetes, urinary tract infection, urinary obstruction, reversible cause of incontinence, permanent catheterization | Bladder training using 6 weekly visits included patient education; voiding schedule to have micturition from every 30-60 minutes to every 2.5-3 hours; and positive reinforcement | Usual care |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Felicissimo, 2010[519]<br>Brazil<br>The effectiveness of intensive supervised PFMT to unsupervised PFMT in the treatment of female stress UI | Women with confirmed urodynamic stress urinary incontinence with Valsalva leak point pressure more than 60 cm/h2O and no detrusor overactivity. All subjects had predominant symptoms of SUI with an average of at least three stress continence episodes per week. | Chronic neurological muscular diseases, abnormal genital bleeding, genital prolapse at stage ≥2 of POP-Q (Pelvic Organ Prolapse-Questionnaire), active genitourinary tract infections, pregnancy, and women who preferred surgery. Patients with intrinsic sphincter deficiencies as identified by Valsalva leak point pressure ≤60cm H2O measured in the sitting position with a volume of 250ml in the bladder were also excluded | Supervised Pelvic Floor Muscle Training | Unsupervised Pelvic Floor Muscle Training |
| Fujishiro, 2000[520]<br>Country: Japan<br>Aim: the effects of magnetic stimulation of the sacral roots for the treatment of stress incontinence | 62 women, 37 to 79 years old with stress incontinence, >1 episode of urinary leakage recorded in a 3-day voiding diary, and 2 gm or more urine loss on a 1-hour pad test | Urinary infection, interstitial cystitis and large uterine myoma, and other treatments for stress incontinence, including pelvic floor exercises, medical treatment and electrical stimulation | Magnetic stimulation of sacral roots with 15Hz. frequency, 50% intensity output for 5 seconds per minute for 30 minutes | Sham stimulation with inactive device |
| Fujishiro, 2002[521]<br>Country: Japan<br>Aim: the effects of magnetic stimulation of the sacral roots for treating urinary frequency and urge incontinence | 37 women 43 to 75 years old with the complaint of urinary frequency and/or urge incontinence, >8 voids daily and/or >1 episode of urge incontinence on a 3-day voiding diary, and mean of less than 250 ml. urine volume per void on a 3-day voiding diary | Neurological disorders suggesting neurogenic bladder dysfunction, apparent episode of stress incontinence, urinary infection, interstitial cystitis or large uterine myoma , other treatments for urinary frequency or urge incontinence, including pelvic floor exercises, medical treatment or electrical stimulation | Magnetic stimulation of sacral roots with 15Hz. frequency, 50% intensity output for 5 seconds per minute for 30 minutes | Sham stimulation with inactive device |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Gallo, 1997[522]<br>Country: USA<br>Aim: comparative effectiveness of external cue to action, an audiocassette tape, to improve pelvic floor muscle exercise compliance in women with stress urinary incontinence | Women ages 20–80 with a history of self-reported stress urinary incontinence and objective genuine stress incontinence during a urodynamic evaluation | Pregnancy and psychological disorders that would make it difficult to follow pelvic floor exercise instruction | The audiotape reinforced pelvic floor exercise instruction with counted aloud 25 consecutive pelvic floor muscle exercise contractions for 10 seconds and then relaxing for 10 seconds; 45-minute appointment with the specialized on UI nurse investigator | 45 minute appointment with the specialized on UI nurse investigator with detailed verbal instructions about pelvic floor muscle identification and contraction; proper pelvic floor muscle contraction by the patient measured using a biofeedback computer |
| Gameiro, 2010[523]<br>Country: Brazil<br>Aim: To compare the efficacy of the VWC (Vaginal Weight Cone) and assisted PFMT to treating UI in women. | To be eligible, patients had been referred by a gynecologist as having symptom of predominant SUI, and 50% also presented urge incontinence. None of the patients had a urodynamic diagnosis of SUI. None of the patients had taken anticholinergics or tricyclic antidepressants or had been treated using pelvic floor exercises or bladder training. | Anterior or posterior vaginal prolapse beyond grade II, urinary infection, neurological or demyelinating condition, and poor comprehension. | Assisted Pelvic Muscle Floor Training | Vaginal weight cone |
| Ghoniem, 2009[524]<br>Country: USA, Canada<br>Aim: the effectiveness and safety of Macroplastique® as minimally invasive endoscopic treatment for female stress urinary incontinence primarily due to intrinsic sphincter deficiency | Women with a diagnosis of SUI primarily due to ISD that failed behavior modification (biofeedback) or exercise (Kegel) | Not viable mucosal lining, abnormal bladder capacity, urinary tract infection, uncontrolled detrusor overactivity, high post-void residual urine volume, high grade pelvic organ prolapse, confounding bladder pathology, pregnancy or morbid obesity | Transurethral injection of Macroplastique | Transurethral injection of Contigen® |
| Gilling, 2009[525]<br>Country: New Zealand<br>Aim: the efficacy of extracorporeal electromagnetic stimulation of the pelvic floor for treating female stress urinary | Women >20 years old; symptoms of SUI or mixed UI, genuine SUI confirmed by pad-testing and urodynamics, ambulatory and community-dwelling, neurologically normal, agree not to seek or | Previous incontinence or pelvic floor surgery, Grade 3 or 4 pelvic prolapse (ICS classification), pregnancy, drugs, e.g. diuretics, alfa-adrenergic antagonists or other medication prescribed | Electromagnetic stimulation 3 times/week using the NeoControl chair (Neotonus Inc., Marietta, GA, USA) with 10-minute stimulation at 10 Hz followed by a 3-minute rest and then a further 10- | Sham stimulation with a thin deflective aluminum plate inserted in the chair, which prevented penetration of the magnetic field into the patient, and simulated the noise and sensation produced during |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| incontinence | use any other form of treatment for UI during the study, otherwise healthy | for bladder dysfunction, concurrent use of internal medical device | minute stimulation at 50 Hz. The intensity was adjusted to the maximum level | active treatment sessions. |
| Glavind, 1996[526]<br>Country: Denmark<br>Aim: effects of biofeedback on continence rates in women with stress UI | Women with self reported incontinence when coughing, laughing, lifting and during physical exercise verified by a positive 1-hour pad-weighing test (>2 g) with a bladder volume of three-quarters of the cystometric capacity | Intravesical obstruction and detrusor instability, previous surgery for urinary incontinence | Physiotherapy 2-3 times with individual instruction combined with biofeedback four times. Biofeedback was performed with a vaginal surface electrode (Dantec 21L20, Skovlunde, Denmark) and a rectal catheter. | physiotherapy 2-3 times with individual instruction alone |
| Glavind, 1997[527]<br>Country: Denmark<br>Aim: the effects of vaginal sponge intended to support the urethra during aerobic exercise in women with stress urinary incontinence | Women 44-68 years with stress urinary incontinence lasting from 1 to 11 years, with daily episodes of incontinence. | intravesical obstruction and detrusor instability | half an hour of aerobic exercises on 2 consecutive days with the vaginal sponge intended to support the uretra | Half an hour of aerobic exercises on 2 consecutive days without the vaginal sponge |
| Goode, 2003[286]<br>Country: USA<br>Aim: the effect of biofeedback-assisted behavioral training on urinary incontinence in older women | 105 ambulatory, non demented, community-dwelling women 55 and older with self-reported urge incontinence at least twice per week for >3 months with urodynamic evidence of bladder dysfunction | Continual leakage, postvoid residual urine volume greater than 200ml, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina pectoralis, congestive heart failure, history of malignant arrhythmias, or impaired mental status | Four sessions (over 8 weeks) of biofeedback-assisted behavioral training by nurse practitioners | Placebo control condition, usual care |
| Goode, 2003<br>Country: USA<br>Aim: whether pelvic floor electrical stimulation increases efficacy of behavioral training for community-dwelling women with stress incontinence | 200 ambulatory, nondemented, community-dwelling women ages 40 to 78 years with urinary incontinence (at least 2 stress incontinence episodes per week on the 2-week baseline bladder diary) confirmed during urodynamic testing | Continual leakage, postvoid residual urine volume >150ml, severe uterine prolapse, congestive heart failure, hemoglobin A1C ≥9, or impaired mental status (Mini-Mental State Examination score <24) | Behavioral training (biofeedback-assisted pelvic floor muscle training, home exercises, bladder control strategies, and self-monitoring with bladder diaries). Anorectal biofeedback (~20 minutes) with 3-balloon probe to measure sphincter pressure | Control: self-administered behavioral training administered with a self-help booklet with suggestions for isolating the pelvic floor muscles, progressive home exercise, self monitoring, and bladder control strategies |
| Gorman,1995[528]<br>Country: USA<br>Aim: effectiveness of an expert system for | Ambulatory, alert, community dwelling women with urinary incontinence defined as accidental urine loss at least | Dependence on a urinary catheter; not successful completion of a mental competency test | 1. The expert system-the Urinary Incontinence Consultation System-with the Agency for Health Care Policy | General health video |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| disseminating knowledge to women with urinary incontinence | twice a week | | and Research (AHCPR) patient guideline for urinary incontinence and research literature for behavioral treatments<br>2. The educational printed booklet | |
| Hahn, 1991[529]<br>Country: Sweden<br>Aim: To compare the effect of two conservative methods and evaluate the long -term results | Women not previously operated upon, with pure stress urinary incontinence, consecutively referred for surgery | Not reported | Pelvic floor training | Intravaginal electrical stimulation |
| Harvey, 2002[530]<br>Country: Not reported<br>Aim: To determine the comparative effectiveness of weighted cones versus biofeedback in women with urodynamic incontinence | Consecutive adult clinic patients with symptoms of mainly stress incontinence and confirmed urodynamic stress incontinence on urodynamics were approached | Age >65 year, detrusor overactivity, past treatment with cones/biofeedback/ electrical stimulation/surgery, POPQ >stage 3. | Biofeedback | Weighted vaginal cones |
| Hu, 1989[531]<br>Country: USA<br>Aim: the effects of behavior therapy program for urinary incontinence on women residents of nursing homes | 143 women with confirmed stress incontinence in seven nursing homes with ability to recognize her own name. | Hospitalization, insufficient number of wet episodes per day (an average 0.18) | 13-week behavior therapy program for urinary incontinence which included hourly checking and prompting of individuals to toilet, praising for successful toileting, and social reinforcement (additional personal service). | Control group received usual incontinence-related care |
| Huang, 2009[532]<br>Country: USA<br>Aim: the effects of an intensive behavioral weight reduction intervention on sexual function in overweight and obese women with urinary incontinence | The PRIDE study: at least 30 years old, have a BMI of 25 to 50 kg/m2 and self-report at least 10 episodes of incontinence weekly | Any condition that would prevent safely participating in an intensive diet and exercise program without medical supervision, medical therapy for incontinence, or weight loss in the previous month | Intensive lifestyle and behavior change program modeled after the Diabetes Prevention Program and Look AHEAD (Action for Health in Diabetes) trials designed to produce an average loss of 7% to 9% of initial body weight weekly 1-hour group sessions led by continent nurse | The structured education program: 1-hour group educational sessions at months 1, 2, 3, and 4, providing general information about weight loss, physical activity, healthy eating habits and health promotion |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Hui, 2006[533]<br>Country: China<br>Aim: the effects of telemedicine vs. a conventional outpatient continence service (CS) in community-dwelling older women with urge or stress incontinence | Community-dwelling older women 60 years or over, with symptoms of urge or stress incontinence, and with one or more incontinence episodes in a week | Active urinary tract infection, a post-void residual volume by bladder ultrasound of more than 150 ml, third-degree uterine prolapse and treatment for urinary symptoms | The nurse specialist provided behavioral training to the group via videoconferencing, with the support of a female registered nurse who helped to run the TCP sessions. Each participant was encouraged to share her experiences with the nurse specialist | Face-to-face consultation the nurse specialist to give digital assessment feedback on pelvic floor contraction + booklet on urge and stress incontinence management |
| Hung, 2010[534]<br>Country: Taiwan<br>Aim: To investigate the effect of treating SUI symptoms in women by retraining diaphragmatic, deep abdominal and PFM coordinated function. | Women aged 18-65 years and had at least one episode of SUI symptom during the previous month | Being pregnant or less than three months postpartum, having systemic neuromuscular disease, having had previous surgery or intensive PFMT for UI, having severe low back pain or pelvic pain, having had a radical hysterectomy or having ongoing urinary tract infections | Diaphragmatic, deep abdominal and pelvic floor retraining | Placebo (Self-monitored PFM exercises) |
| Janssen, 2001[535]<br>Country: The Netherlands<br>Aim: the effects of individual and group physiotherapy for urinary incontinence in women | 530 women of all ages (mean 47.8 years) with stress, urge, or mixed incontinence | Neurological cause of incontinence, a tumor or infection in the pelvis, severe vaginal prolapse | Individual pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 11 30-minute sessions | Group pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 9 2-hour sessions |
| Jeyaseelan, 2000[536]<br>Country: UK<br>Aim: effects of electrical stimulation on women stress incontinence | Women with urodynamically proven stress incontinence | Neurological conditions diagnosed by consultant; Previous electrical stimulation for stress incontinence, prolapse; pregnancy; pacemakers and cardiomyopathy; abnormal urological/gynecological findings; urinary tract/vaginal infection; recent pelvic floor surgery | The electrostimulation technique described by Oldham (International Patent Publication WO98/47357)with a background low frequency (to target slow twitch fibers) and intermediate frequency with an initial doublet (to target fast twitch fibers). | Sham electrical stimulation consisted of one 250-μs impulse every minute for 60 minutes |
| Karademir, 2005[315]<br>Country: Turkey<br>Aim: the effects of Stoller | 43 patients with symptoms of detrusor overactivity confirmed urodynamically | Urinary tract obstruction, urinary retention, neurologic or metabolic disorder, other | Stoller afferent neurostimulation with frequency 20Hz and | Stoller afferent neurostimulation with frequency 20Hz and |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| afferent neurostimulation with and without a low-dose anticholinergic (oxybutynin hydrochloride) in patients with detrusor overactivity | | treatments for urinary incontinence | amplitude 0.5-10mA | amplitude 0.5-10mA combined with 5mg of oral oxybutynin hydrochloride |
| Kim, 2009, [537]<br>Country: Japan<br>Aim: To determine the effects of exercise treatment on reducing urine leakage in Japanese elderly women with stress, urge, and mixed UI | Women aged 70 and older who reported urine leakage one or more times per month. | Not reported | Exercise treatment enhancing PFM and functional fitness | Placebo |
| Kim, 2001[538]<br>Country: Korea<br>Aim: the effects of continence efficacy intervention program on stress urinary incontinence in Japanese women | 48 women 20-75 years old with stress or mixed urinary incontinence | Drug or surgery treatment for incontinence | Continence efficacy intervention program: common pelvic floor muscle education, audiovisual tape, calendar, counseling, schedule guideline, assessing self-care methods. | Conventional care |
| Kim, 2007[539]<br>Country: Japan<br>Aim: the effectiveness of pelvic floor muscle and fitness exercises in reducing urine leakage in elderly women with stress urinary incontinence | Women >70 years old with stress UI >1 per month | Stress UI <1/month; urge or mixed incontinence | Fitness exercises and 60-minute pelvic floor muscle exercise sessions two times per week; 10 fast contractions (3 seconds) and 10 sustained contractions (6–8 seconds) with 10-second relaxation periods between the contractions. | Not described (no active intervention) |
| Kim, 2008[540]<br>Country: South Korea<br>Aim: the effect of hand acupuncture treatment on the stress urinary incontinence in women | Women diagnosed with stress UI, never treated for UI including estrogen therapy or surgery | Stroke, dementia, Parkinson's disease, multiple sclerosis, spinal cord injury, communication problems, glycosuria or proteinuria | Active hand acupuncture points, ST27, CV4 or SP15 | Inactive hand acupuncture points |
| Kincade, 2007[541]<br>Country: USA<br>Aim: the efficacy of self-monitoring techniques to reduce urine loss and increase quality of life for women with urinary | Community-dwelling women 18 and older living in Wake, Nash, and surrounding counties in North Carolina with involuntary urine loss of >1 g in 24 hours | Involuntary urine loss of less than 1 g in 24 hours, positive urine test for bacteria, diagnosis of bladder cancer or kidney disease, prior treatment of UI with biofeedback, urinary catheter, | Self-monitoring group with training on self-monitoring techniques at the end of the second visit; individualized counseling about caffeine consumption, amount of and timing of fluid intake, voiding | Wait list group; teaching a simple pelvic floor muscle contraction technique (Quick Kegel) |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| incontinence | | available to participate for less than 1 year, post void residual | frequency, and constipation; teaching a simple pelvic floor exercise | |
| Konstantinidou, 2007[542]<br>Country: Greece<br>Aim: comparative effectiveness of group pelvic floor muscle training under intensive supervision to that of individual home therapy in women with stress UI | Women over 18 years with a clinical and urodynamic diagnosis of SUI for more than 3 months, >7 incontinence episodes per week, daytime frequency of less than 8 micturition episodes, nocturia of less than 3 episodes, positive stress test (urine leakage) | Symptoms of urgency and urge incontinence (excluded by the incontinence-specific history and the absence of detrusor overactivity or increased bladder sensation during standard voiding cystometry), presence of any degree of pelvic organ prolapse | Common weekly session in subgroups of 5, written training instructions for the rest of the week, group instructions for home application of pelvic floor training. Individualized according to the strength and endurance of pelvic floor muscles training program | Group instructions for home application of pelvic floor training and individual followup in hospital every 4 weeks. Individualized according to the strength and endurance of pelvic floor muscles training program included 3 sets of fast contractions. |
| Kumari, 2008[543]<br>Country: India<br>Aim: effects of behavioral therapy for urinary incontinence in women | Adult women with urinary incontinence | Continuous urinary drainage catheter, those taking diuretics, diagnosed vesicovaginal fistula, multiple sclerosis, spinal injury, severe uterine prolapse, mental impairment, pregnant women, and women who had delivered a baby in last 6 months | Behavioral treatment with educational materials, pelvic floor exercises with at least 50 pelvic floor contraction exercises each day, bladder retraining, and maintenance of a voiding diary and exercise record | No active therapy |
| Lagro-Janssen, 1992[544]<br>Country: The Netherlands<br>Aim: the effects of pelvic floor exercises on stress incontinence and bladder training on urge incontinence | 110 women with self-reported urinary incontinence confirmed with urodynamic as stress or urge | Not reported | Pelvic floor exercises alone (stress) or bladder training (urge) or its combination (mixed) | Usual care |
| Lagro-Janssen, 1991[545]<br>Country: The Netherlands<br>Aim: the effects of pelvic floor exercise on urinary incontinence in women | 66 women ages 20-65 years with genuine stress incontinence | Previously undergone an operation for incontinence; if they suffered from underlying neurological causes for incontinence, from diabetes mellitus or from urinary tract infection; or if there was a temporary cause for their incontinence (for example, pregnancy) | Instructions in pelvic floor exercises 5- 10 sessions of 10 pelvic muscle contractions for 6 seconds each day. | No therapy |
| Lamb, 2009[546]<br>Country: UK | Women aged 18 years and over; able and willing to give | Pregnancy; recent pelvic surgery (less than three | Group treatment Pelvic Muscle Floor Training | Individual treatment |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Aim: To compare the effectiveness of group versus individual sessions of physiotherapy in terms of symptoms, quality of life, and costs, and to investigate the effect of patient preference on uptake and outcome of treatment | informed written consent with an interpreter if necessary; clinical symptoms of stress and/or urge incontinence. | months); history of pelvic malignancy; current urinary infection; grade III and IV prolapse; disease of the central nervous system (e.g. multiple sclerosis, cerebrovascular accident) or acute mental illness and dementia; previous physiotherapy for incontinence within the last 12 months. | | |
| Lappin, 2003[547]<br>Country: USA<br>Aim: Crossover, placebo controlled RCT to examine effects of pulsed electromagnetic fields on bladder control in patients with multiple sclerosis | 145 patients 18-65 years old with clinically definite multiple sclerosis and light spasticity (>2 in 6 point scale) and bladder control problems | Changes in medication last 2 months, pregnancy, pacemaker, chronic diseases | Daily simulation with low frequency pulsed electromagnetic fields | Sham inactive device |
| Laycock, 2001[548]<br>Country: UK<br>Aim: the effects of vaginal cones, pressure biofeedback, and pelvic floor exercises on stress urinary incontinence in females | 101 women 20-64 years old with symptoms of stress urinary incontinence | Moderate or severe urge urinary incontinence, moderate or severe genital prolapse, pregnancy or plans to become pregnant, use of medications that can affect the lower urinary tract, HRT for <3 months, neurological diseases | Pelvic floor exercise with maximum contraction for 1 second and rest for 4 seconds, 10 minutes/day combined with home pressure biofeedback using intra-vaginal perineometer | Pelvic floor exercise for 10 minutes/day |
| Lee, 2001[549]<br>Country: Canada<br>Aim: the effects of periurethral autologous fat injection on female stress urinary incontinence | 68 women with stress urinary incontinence determined by history, urinary leakage via the urethra with cough provocation | Detrusor instability on multichannel urodynamic, co-interventions, including hormone replacement, weight reduction, or Kegel exercises, other diagnoses causing incontinence, including bladder instability | Periurethral injections of autologous fat (30cc of fat from the anterior abdominal wall or buttock through a single 2-3mm) with 3 maximum injections depending on outcomes measures | Placebo (saline) |
| Liebergall-Wischnitzer, 2009[550]<br>Country: Israel<br>Aim: comparative | Women at least 1 g urinary leakage in a 1-hour clinic based pad test and with the ability to understand | Pregnancy or breastfeeding; 12 weeks of delivery, 6 weeks of abortion, or 6 months of pelvic surgery; cardiac, | The Paula method of circular muscle exercises. The Paula method was taught by three registered instructors to give | Pelvic floor muscle training taught by ten physiotherapists using a structured exercise program in groups of 1–10 |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| effectiveness of circular muscle exercises (Paula method) or pelvic floor muscle exercise on stress UI in women | instructions in Hebrew or English | respiratory, psychiatric, and neurological illnesses that limit physical activity; no demonstrated leakage of >1 g, grade three or higher uterine prolapse | weekly individual 45-minute sessions + recommendation to practice daily for 45 minutes at home | people for 30 minutes once weekly for 4 weeks, followed by two more lessons 4 weeks apart each (overall six lessons) |
| Liebergall-Wischnitzer, 2005[551]<br>Country: Israel<br>Aim: the effects of circular muscle exercises on female urinary stress incontinence | 59 women, mainly hospital employees with stress or mixed urinary incontinence with urine loss >1gin pad test | Pregnancy, severe cardiac or respiratory diseases, pelvic surgery within 6 months, grade 3 and 4 cystocele, previous pelvic radiation, active mucosal lesion in vagina or perineum | Paula method of circular muscle training 15-45 minutes/day with training sessions of 45 minutes/week | Pelvic floor muscle exercise 15 minutes with 30 minute lesson session/week |
| Lightner, 2001[552]<br>Country: USA<br>Aim: the effects of bulking agents on stress urinary incontinence due to intrinsic sphincter deficiency in women | 355 women diagnosed with stress urinary incontinence due to intrinsic sphincter deficiency, abdominal leak point pressure of less than 90cm/H2O, who failed prior surgical and medical treatment | 355 women diagnosed with stress urinary incontinence due to intrinsic sphincter deficiency, abdominal leak point pressure of less than 90cm/H2O, who failed prior surgical and medical treatment | Injection of bulking agent 1.0ml durasphere maximum 5 times with a minimum 7 day interval | Injection of bulking agent bovine collagen maximum 5 times with a minimum 7 day interval |
| Lightner, 2009[553]<br>Country: USA<br>Aim: Comparative effectiveness of Zuidex using a non-cystoscopy mid-urethral injection technique vs. Contigen injected endoscopically at the bladder neck in the treatment of urinary stress incontinence secondary to intrinsic sphincter deficiency in adult women | Zuidex Study Group: adult women seeking treatment for stress UI with confirmed urodynamic stress incontinence with abdominal leak point pressures <100 cm H2O, positive pad testing (mean urinary leakage of >10 g during screening | Previous treatment with bulking agents of any type, pure predominant symptoms, mean voided volumes <200 ml on bladder diary, detrusor overactivity on filling cystometry, postvoid residual volumes >100 ml on 2 occasions, or stage III or IV pelvic floor prolapse | Non-cystoscopy mid-urethral injection of Zuidex | Endoscopical injection of Contigen |
| Luber, 1997[554]<br>Country: USA<br>Aim: the effects of functional electrical stimulation for stress incontinence in women | 57 women with stress urinary incontinence who could adequately retain the vaginal probe and cooperate with the study protocol | Significant pelvic prolapse and detrusor instability, postvoid residual urine >100cc, extra urethral incontinence, history of vaginal intraepithelial neoplasia, urinary tract | Functional electrical stimulation with 15-minute treatment session/day using pulse-width of 2msec scheduled for 2 seconds with 4 seconds rest, frequency of 50Hz, and power 10-100mA. | Sham stimulation with inactive device |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| | | infection, and a fixed, immobile urethra | | |
| MacDiarmid, 2010[555]<br>Country: USA<br>Aim: To assess the sustained effectiveness of PTNS therapy offered at individualized intervals during 1 year in subjects who finished an initial course of 12 consecutive weekly sessions. | Subjects in the OrBIT trial who finished an initial course of 12 consecutive weekly PTNS treatments were offered ongoing sessions of therapy for an additional 9 months to monitor improvement in frequency, nocturia, urgency, urge incontinence episodes and voided volume. Subjects were required to be OAB drug-free throughout the study. | Not reported | Percutaneous Tibial Nerve Stimulation | Percutaneous Tibial Nerve Stimulation |
| Majumdar, 2010[556]<br>UK<br>To evaluate treatment outcomes based on baseline urodynamics vs. symptoms alone | Patients over 18 years of age referred from a primary care with UI and other lower urinary tract symptoms | Patients who were referred for undergoing surgery for significant prolapse (stage2 or more) or had previous consultation and were then referred for surgery for incontinence, cognitive difficulties (consent issue), neurological disorders, previous treatment for incontinence at tertiary level, recurrent dysuria or infection on urine culture | Urodynamics | Conservative treatment based on symptoms and bladder diary |
| Manganotti, 2007[557]<br>Country: Italy<br>Aim: the short and long-term effects of repetitive magnetic stimulation on the sacral roots | Women with stress UI, >1 episodes of stress UI in 3-day diary, >2g of urine loss in 1 hour pad test | Urinary tract infection, intersticial cystitis, large uterine myoma, severe cardiac or cerebrovascular disorders | Fifteen-Hz repetitive magnetic stimulation of the sacral roots (S2-S4) applied for 15 minutes 3 days a week for 2 weeks (6 times in all) | Sham stimulation |
| Manonai, 2006[558]<br>Country: Thailand<br>Aim: Cross-over RCT to examine the effect of a soy-rich diet on urogenital symptoms in peri- and postmenopausal women | 42 healthy perimenopausal and postmenopausal women between 45-70 years old reported at least one type of urinary incontinence | Exclusion criteria: Presence or history of sex hormone dependent malignancies, liver or renal disorders, and pathology of urogenital tract | Self-selected diet with low-fat and low cholesterol foods and soy protein 25g in various forms of soy foods containing more than 50mg/day of isoflavones | Self-selected diet with low fat and low cholesterol foods |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Mayer, 2007[559]<br>Country: USA<br>Aim: comparative effectiveness of soft-tissue augmentation of the urethral sphincter with calcium hydroxylapatite vs. glutaraldehyde cross-linked bovine collagen in female stress urinary incontinence due to intrinsic sphincter deficiency and without associated urethral hypermobility | Women age 18 years old or older, stress UI due to intrinsic sphincter deficiency without associated urethral hypermobility (straining urethral angle of 35° or less from horizontal), good bladder function and capacity (more than 250 mL without detrusor instability | Morbid obesity (more than 100 lb over ideal body weight) and a urethral length of less than 2.5 cm | Transurethral or periurethral soft-tissue augmentation of the urethral sphincter with calcium hydroxylapatite; up to 5 injections during 6 months | Transurethral or periurethral soft-tissue augmentation of the urethral sphincter with glutaraldehyde cross-linked bovine collagen; up to 5 injections during 6 months |
| McDowell, 2006[560]<br>Country: Northern Ireland<br>Aim: the effects of pelvic floor training and advice, electromyography biofeedback, and neuromuscular electrical stimulation on urinary incontinence in patients with multiple sclerosis | 30 women >18 years with multiple sclerosis stabilized for the previous 3 months. Expanded Disability Status Scale score <7.5 with at least one of the following: any involuntary leakage of urine, voiding frequency >8/24 hours, nocturia, and/or reported voiding dysfunction such as hesitancy, straining, poor stream, and incomplete emptying demonstrated by uro-flowmetry. | MS relapse necessitating hospitalization 3 months prior to or during the study, symptomatic prolapse, presence of urinary tract infection, current or recent diagnosis of a serious medical condition (other than MS), severe cognitive impairment, contraindications to neuromuscular electrical stimulation. | Pelvic Floor Training and Advice: education with booklet about normal bladder control, lifestyle interventions (weight reduction, relieving constipation, cessation of smoking, caffeine reduction, fluid management, clothing, reducing emotional stress) | Pelvic Floor Training and Advice with EMG Biofeedback and neuromuscular electrical stimulation. Stimulation at clinic (weekly) initially for 5 min 30 minutes using pulse rate 40Hz, pulse width 250msec,with 5sec on and10 sec off or 10 Hz, 450msec, 10sec |
| McDowell, 1999[561]<br>Country: USA<br>Aim: Cross-over RCT to examine the effects of behavioral therapies of urinary incontinence in homebound older adults. | 105 adults 60 years and older, homebound (Health Care Financing Administration, cognitively intact (Folstein Mini-Mental State Examination score >24), with urinary incontinence (>2 urinary accidents/week for at least 3 months), who understand and speak English | Folstein MMSE scores <24, severe pelvic prolapse, terminal illness, post-void residual >100ml unable to toilet independently, no caregiver willing and able to assist with toileting, <2 urinary accidents per week, unable to provide satisfactory self-report | Biofeedback-assisted pelvic floor muscle training by nurse practitioners skilled in behavioral therapies for urinary incontinence. Behavioral therapy: 8 weekly sessions at homes with biofeedback-assisted pelvic floor muscle exercises, urge and stress strategies, and bladder training | Usual care with attention control (visits by the nurse practitioner every 1-2 weeks to provide social interaction). |
| McFall, 2000[562]<br>Country: USA | 145 women ages 65 or older with self reported urinary | Severe prolapse of uterus, hematuria, diverticulum, | Community-based intervention with 5 biweekly | Usual care |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Aim: the effects of group educational intervention for urinary incontinence in elderly women | incontinence ≥3 months, residing in Oklahoma. | fistula, unresolved urinary tract infection, two or more urinary tract infections within 3 months, urinary obstruction, overflow incontinence, a postvoid residual volume of urine (PVR) >100ml, and blood | sessions of education and skill-building, for bladder training, managing the urge to urinate, and performing pelvic muscle exercises. Group support by registered nurses; occupational therapist, and public health professional | |
| McFall, 2000[563]<br>Country: USA<br>Aim: To report an assessment of a community-based intervention for UI and to summarize the outcomes of the intervention model related to incontinence and other urinary symptoms. | Most participants attended a community presentation prior to enrollment. Participants lived independently in a four-county region in central Oklahoma. The women were 65 years or older and had urinary incontinence for 3 months or more. | Severe prolapse of uterus, hematuria, diverticulum, fistula, unresolved urinary tract infection, two or more urinary tract infections within 3 months, urinary obstruction, overflow incontinence, a postvoid residual volume of urine (PVR) >100 ml, and blood glucose >300 mg/dl on two or more visits in a 3 month period. Functional or disability exclusions were being homebound because of frailty, severe hearing or vision problems, low literacy, and cognitive impairment. | Small group educational approach | Wait control |
| Miller, 1998[564]<br>Country: USA<br>Aim: the effects of intentionally contracting the pelvic floor muscles before and during a cough on mild and moderate female stress urinary incontinence. | 27 women with self reported stress urinary incontinence and demonstrable urine loss during a deep cough with leakage occurring at least weekly and up to 5 times/day. | History of systemic neuromuscular disease, previous bladder surgery, active urinary tract infection, leakage that was delayed after coughing and categorized as detrusor instability, leakage that saturated a paper towel and/or pooled on the floor when coughing in the standing posture, inability to demonstrate any voluntary contraction of the pelvic floor muscles despite detailed instruction during the pelvic | Immediate intervention group taught intentionally contracting the pelvic floor muscles before and during a cough (Knack) | Wait-listed control group |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| | | exam, and significant coexistent pelvic organ prolapse below the hymenal ring | | |
| Moore, 2003[565]<br>Country: Australia<br>Aim: the effects of nurse continence advisors and urogynecologists in conservative management of urinary incontinence. | 145 consecutive patients with stress and/or urge incontinence with idiopathic detrusor instability, sensory urgency, and mild or moderate leakage (urine loss in 1-hour pad test 2-9.9ml/hour or 10-50ml/hour). | Previous pelvic radiotherapy, proven recurrent bacterial cystitis, prolapse beyond the introitus, uterine enlargement or incomplete bladder emptying (postvoid residual >100ml). | 2 nurse continence advisors/patient and consulting urogynecologist for 25-35 minutes/week provided bladder training, gradual increase in fluid intake, individual deferment techniques, pelvic floor muscle exercise and examination, transvaginal electrostimulation | Outpatient regimen with 15-20 minute consultation with referral to physiotherapist and bladder training. |
| Morkved, 2002[566]<br>Country: Norway<br>Aim: the effects of individual pelvic floor muscle training with and without biofeedback in women with urodynamic stress incontinence. | 103 women with symptoms of stress incontinence and >2g leakage measured by a pad test with standardized bladder volume. | involuntary detrusor contractions on cystometry, abnormal bladder function (residual urine >50ml), previous surgery for stress incontinence, neurologic or psychiatric disease, urinary tract infection, other diseases that could interfere with participation | Pelvic floor muscle training with 3 sets of 10 contractions 3 times/day, individually supervised by a physical therapist. At home, 3 sets of 10 high intensity (close to maximum) contractions per day with a biofeedback apparatus | Pelvic floor muscle training with 3 sets of 10 contractions 3 times/day, individually supervised by a physical therapist. At home, 3 sets of 10 high intensity (close to maximum) contractions per day without biofeedback |
| Du Moulin, 2007[567]<br>Country: Netherlands<br>Aim: effects of a specialized nurse in the care of community-dwelling women with urinary incontinence | Community-dwelling women aged 18 years who attended general practitioner clinic because of urinary incontinence | Urinary tract infection, PVR of 100 mL or more, delivery within 3 months preceding recruitment, bladder cancer, renal disease, or uterine prolapse past the introitus | The continence nurse and multidisciplinary team comprising a GP, urologist, physiotherapist | Standard care provided by the general practitioners |
| Nager, 2009[568]<br>Country: USA<br>Aim: association between successful incontinence pessary fitting or pessary size and specific pelvic organ prolapse measurements in women without advanced pelvic organ prolapse | Pelvic Floor Disorders Network (PFDN): women with stress urinary incontinence (SUI) and POPQ stage ≤2 | Not reported | Incontinence pessary+ behavioral therapy including pelvic floor muscle training and exercise and bladder control strategies | Incontinence pessary |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Ng, 2008[569]<br>Country: Taiwan<br>Aim: the effect of nursing intervention to enhance the efficacy of a home-based pelvic floor muscle exercise (PFME) on mixed urinary incontinence in community-dwelling women | Women with mixed urinary incontinence interested in behavioral training and potentially available for telephone contact | no educational background, dependent in daily activities | A registered nurse monitoring via telephone checkups twice a week home based PFMT. Education about the pelvic anatomy, the function of the pelvic floor muscle, the bladder and urethra, the use of PFMT, and how to perform PFMT: 1 hour per session, twice weekly, for 4 weeks in total. | Home based PFMT. Education about the pelvic anatomy, the function of the pelvic floor muscle, the bladder and urethra, the use of PFMT, and how to perform PFMT:1 hour per session, twice weekly, for 4 weeks in total. |
| Nielsen, 1993[570]<br>Country: Denmark<br>Aim: Cross-over RCT to examine effects of urethral plug on female genuine urinary stress incontinence | 40 women with genuine urinary stress incontinence | Not reported | Urethral plug as oval metal plate, a soft stalk, and 1 sphere along the stalk with fixed distances between the metal plate and the spheres. Inside the stalk is a removable semi-rigid guide pin to ease insertion. | Urethral plug as oval metal plate, a soft stalk, and 2 spheres along the stalk with fixed distances between the metal plate and the spheres. Inside the stalk is a removable semi-rigid guide pin to ease insertion. |
| Nygaard, 1995[571]<br>Country: USA<br>Aim: Crossover RCT to examine the effects of Hodge pessary with support, a super tampon on urinary incontinence during exercise. | 20 female exercisers ages 33-73 with urinary incontinence during exercise and positive coughing test. | Prolapse of the uterus, stenotic vagina, or pelvic mass. | 40-minute standardized aerobics session wearing a Hodge pessary with support 40-minute standardized aerobics sessions wearing a super tampon | 40-minute standardized aerobics sessions with no mechanical device |
| Nygaard, 1996[572]<br>Country: USA<br>Aim: the effects of pelvic floor muscle exercises in combination with specially designed audiotape on stress, urge, and mixed urinary incontinence in women. | 71 women non pregnant women >21 years old with urinary incontinence. | Genital prolapse past the vaginal introitus, parturition within the preceding 6 months, and deafness | Pelvic floor muscle exercises with 2 5-minute daily sessions, beginning with contractions for 4-8 seconds in combination with specially designed audiotape with 270 minutes of music and verbal instructions of technique tips, reminders, and exercise cues. | Pelvic floor muscle exercises with 2 5-minute daily sessions, beginning with contractions for 4-8 seconds. |
| O'Brien, 1991[573]<br>Country: England<br>Aim: the effects of pelvic floor exercises and bladder retraining supervised by non-specialist nurse on urinary | 561 adults ages 35 years and older with regular urinary incontinence (two or more leaks in any one month). | Urinary tract infection. | Four sessions of pelvic floor exercises and bladder retraining supervised by non-specialist nurse. | Usual care |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| incontinence in adults with regular urinary incontinence. | | | | |
| O'Brien, 1996[574]<br>Country: UK<br>Aim: Long term (followup of O'Brien, 1991[573]) effects of behavioral training on urinary incontinence in adult women | Female patients over 35 years from two large Somerset general practices with urinary incontinence two or more leaks in any one month | Reported previously | Nurse-led four sessions of pelvic floor exercises or bladder retraining depending on the dominant symptoms (stress or urge respectively) | Postponed treatment |
| Oldham, 2010[575]<br>Country: Canada<br>Aim: Evaluation of a self-contained, fully automated, disposable device (Femestin), with application similar to that of a tampon | Women with urinary incontinence were recruited via a process of self referral through ads placed in local newspapers and on local radio to reflect future practice | Not reported | Pelvic Floor Exercises obtained from Bladder and Bowel Foundation + Femestin device | Pelvic Floor Exercises obtained from Bladder and Bowel Foundation |
| O'Sullivan, 2003[576]<br>Country: Australia<br>Aim: the effect modification by baseline severity of any urinary incontinence on continence rates after nurse intervention in women with urodynamic UI | Women with urodynamically proven GSI, DI, or Sumild (2-9.9 g) to moderate (10-49.9 g) incontinence (as judged by weight gain on 1-hour pad testing) | Previous pelvic radiotherapy, proven recurrent bacterial cystitis, prolapse beyond the introitus, uterine enlargement of duration more than 12 weeks, or incomplete bladder emptying (residual >100 ml) | Nurse continence adviser with the first visit of 45 minutes with pelvic floor digital testing, verbal biofeedback , bladder training with individual deferment techniques; followup weekly visits of approximately 30 minutes with re-exam of pelvic floor muscle | Routine urogynecology outpatient therapy with a referral note to a physiotherapist (SUI) or educational videotape about bladder training (Urge UI) or anticholinergic therapy (DI) |
| Pages, 2001[577]<br>Country: Germany<br>Aim: the effects of intensive group physical therapy program with individual biofeedback training for female patients with urinary stress incontinence. | 51 women, referred by gynecologists for nonoperative treatment of genuine stress incontinence of mild-to-moderate severity. | Not reported | Specific physical therapy program. Group therapy 5 times/week and home pelvic floor exercise with 50 contractions for 10 minutes 2 times/day. Recommendation of weight loss and aerobic sports. | Biofeedback training daily 90-minutes in group and individually for 15 minutes, 5 times/week; Intra vaginal pressure sensor and visual biofeedback in computer monitor |
| Peters, 2010[578]<br>Country: Canada<br>Aim: To compare the efficacy of PTNS to a validated sham in subjects who have previously used OAB pharmacologic therapy | This analysis includes only those subjects who previously used OAB pharmacologic therapy prior to their participation in the study. Women and men ≥18 years of age; a score of ≥4 on the OAB-q short form for urgency; | Pregnant or planning to become to pregnant during the study; neurogenic bladder; botox use in bladder or pelvic floor muscles within the past one year; pacemakers or implantable defibrillators; current urinary | Percutaneous Tibial nerve stimulation | Placebo |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| | average urinary frequency of ≥10 voids per day; self-reported bladder symptoms ≥3 months; self-reported failed conservative care; discontinued all antimuscarinics for ≥2 weeks; capable of giving informed consent; ambulatory and able to use toilet independently without difficulty; and capable and willing to follow all study-related procedures. | tract infection; current vaginal infection; use of Interstim; use of Bion; current use of TENS in pelvic region, back or legs; previous PTNS treatment; use of investigational drug/device therapy within past 4 weeks; and participation in any clinical investigation involving or impacting gynecologic, urinary or renal function within past 4 weeks | | |
| Ramsay, 1996[579]<br>Country: Scotland<br>Aim: comparative effectiveness of inpatient vs. outpatient behavioral treatment for urinary incontinence in women | Women with urgency, nocturia, urge incontinence and stress incontinence | Previous treatment for their incontinence, symptoms of hematuria, recurrent dysuria or voiding difficulty, or infection on urine culture | Bladder retraining and physiotherapy as an inpatient 5-day hospital stay | Bladder retraining and physiotherapy as an outpatient with two 2-hour sessions, 1 week apart. |
| Richter, 2010[357]<br>Country: USA<br>Aim: To compare the effectiveness of a continence pessary to evidence-based behavioral therapy for stress incontinence and to assess whether combined pessary and behavioral therapy is superior to single modality therapy | ATLAS trial: Women at least 18 years old with symptoms of stress only or stress-predominant mixed-incontinence symptoms | Previously reported in Richter, 2007[580] | Behavioral therapy | Pessary + Behavioral therapy/Pessary alone |
| Robinson, 2003[581]<br>Country: Canada<br>Aim: the effects of new urethral device or the reliance insert on female urinary incontinence. | 24 women 30-75 years old with mixed or stress urinary incontinence >2 episodes/week >2g urine loss on baseline pad weight test, with sound mental condition, willing to use >3 devices/week. | Overflow incontinence or neurogenic bladder, type III incontinence, kidney inflammatory diseases, urinary tract infection, use of anticoagulants or incontinence medications, allergy to antibiotics, diabetes mellitus type II, pregnancy, urethral mucosal | Urethral device (NEAT) – sterile urethral insert with disposable applicator packaged with device. | Reliance insert sterile balloon type device |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| | | abnormalities, prosthetic heart valve, HRT last 3 months, collagen injections or other urethral bulking agents last 3 months, detrusor contraction >20cm/H20. | | |
| Sand, 1995[582]<br>Country: USA<br>Aim: the effects of transvaginal electrical stimulation in treating genuine stress incontinence. | 52 community dwelling women with urodynamically proven genuine stress incontinence, who would comply with visits, not use/seek other treatment for incontinence. | Detrusor instability, pregnancy, pacemaker, prior pelvic floor stimulation, pelvic implanted devices, active vaginal lesions or infections, urinary tract infection, hypermenorrhea or menorrhaghia, urinary retention (>100ml), pelvic surgery in past 6 months | Active pelvic floor stimulator with gradually adjusted 60-80mA from 5 seconds on/1 second off for 15 minutes to 5 seconds on/5 seconds off for 30 minutes. | Sham inactive device |
| Schulz, 2004[583]<br>Country: Canada<br>Aim: the effects of periurethral and transurethral injections of bulking agents on stress urinary incontinence in females. | 40 women ages 18-80 years old, with genuine stress incontinence for >12 months, or mixed incontinence with a minor and controlled urge component, who failed 3 months conservative treatments. | Other treatments for incontinence, urinary tract infection, bladder capacity <250ml or postvoid residual volume >100ml, neurogenic bladder, grade 3 cystoele, uterine prolapse or rectocele, radiation of urethra, pregnancy, life expectancy <15 months. | Periurethral route of injection of bulking agent-dextran copolymer | Transurethral route of injection of bulking agent-dextran copolymer |
| Seo, 2004[584]<br>Country: South Korea<br>Aim: the effects of vaginal cone with conventional FES-biofeedback therapy for female urinary incontinence. | 120 patients, who required a non-surgical treatment for urinary incontinence. | Not reported | Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional electrical stimulation biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week. | Vaginal cone, 150g dumbbell-shaped made of fine ceramic material. |
| Sherman, 1997[585]<br>Country: USA<br>Aim: the effects of pelvic muscle exercises with urethral biofeedback on exercise-induced urinary incontinence in female soldiers. | 39 female active duty soldiers with exercise-induced urinary incontinence (stress or mixed). | Not reported | Pelvic muscle exercises with contractions for 10 seconds and relaxation for 10 seconds 5 times/session, 20 minutes twice/day with urethral biofeedback using vaginal EMG probe. | Pelvic muscle exercises with contractions for 10 seconds and relaxation for 10 seconds 5 times/session 20 minutes twice/day alone. |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Smith, 1996[586]<br>Country: USA<br>Aim: the effects of intravaginal electrical stimulation on genuine stress urinary incontinence and detrusor instability in women. | 57 women with urinary incontinence. | Type 3 stress urinary incontinence, pregnancy, urinary retention, vaginal prolapse, cardiac pacemaker, mixed incontinence with no major and minor components. | 18 women with stress urinary incontinence: Electrical stimulation using frequency 12.5Hz.-50Hz and amplitude 5-10mA-80mA for 15 to 60 minutes 2/day 38 women with detrusor instability Anticholinergic therapy with Propantheline bromide in dose of 7.5 to 4 | Kegel exercise |
| Spruijt, 2003[587]<br>Country: The Netherlands<br>Aim: the effects of intravaginal electrical stimulation of the pelvic floor for urinary incontinence in elderly women. | 51 women ≥65 years of age, with symptoms of stress, urge or mixed urinary incontinence of >3 months' duration, and with urinary leakage >10cc/24hours. | Persistent urinary tract infection (positive urine culture after antibiotic treatment), recurrent urinary tract infection (within 4 weeks after treatment), bladder pathology or dysfunction because of fistula, tumor, pelvic irradiation, neurological or other chronic conditions (diabetes mellitus, Parkinson's disease), genital, pacemaker, and insufficient mental condition. | Intravaginal electrical stimulation of the pelvic floor using stimulator generated biphasic current pulses with duration of 1ms and a frequency of 50Hz (stress urinary incontinence) or 20Hz (urge urinary incontinence). | Kegel exercise program with verbal instructions on how to exercise at home. |
| Strasser, 2007[588]<br>Country: Austria<br>Aim: the effects of ultrasonography-guided injections of autologous cells or endoscopic injections of collagen on stress urinary incontinence. | 63 females 36-84 years old with intrinsic sphincter insufficiency or stress urinary incontinence with only mild hypermobility of the urethra and the urinary bladder; good state of health who failed pelvic floor muscle exercises. | Urge incontinence and pronounced hypermobility of the urethra. | Transurethral ultrasonography-guided injections of autologous myoblasts and fibroblasts; regular training of the rhabdosphincter for 12 weeks and trans vaginal electrical stimulation for 4 weeks. | Conventional endoscopic injections of collagen; regular training of the rhabdosphincter for 12 weeks and trans vaginal electrical stimulation for 4 weeks |
| Subak, 2002[589]<br>Country: USA<br>Aim: the effects of low-intensity behavioral therapy program on urinary incontinence in older women | Women 55 years and older with self reported urinary incontinence, members of health maintenance organization, living independently in the community and functionally capable of independent toileting. | Uncontrolled diabetes mellitus, urinary tract infection, history of urinary obstruction, overflow, functional incontinence, urinary tract anomalies | 6 weekly 20-minute group instructional sessions on bladder training by nurse educators and followed individualized voiding schedules. | Usual care |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Subak, 2005[590]<br>Country: USA<br>Aim: the effect of weight loss on urinary incontinence in overweight and obese women. | 48 women 18 to 80 years old with body mass index between 25 and 45 kg/m2, urinary incontinence for at least 3 months and at least 4 incontinent episodes/week, the stable dose of other incontinence therapy . | Exclusion criteria: pregnancy, urinary tract infection, significant medical condition, pelvic cancer, neurological condition possibly associated with incontinence, interstitial cystitis or potential inability to complete the study. | Weight reduction intervention: 3-month standard low calorie liquid diet (800kcals/day or less), increased physical activity to 60 minutes/day, training by a nutritionist, exercise physiologist or behavioral therapist | Usual care |
| Subak, 2009[591]<br>Country: USA<br>Aim: effectiveness of weight loss on urinary incontinence in obese women | Women at least 30 years of age, a body-mass index of 25 to 50, >10 urinary-incontinence episodes/week, ability to walk unassisted for two blocks (approximately 270 m) without stopping | Pregnancy, urinary tract infection, significant medical condition, pelvic cancer, neurological condition possibly associated with incontinence, interstitial cystitis or potential inability to complete the study. | Intensive 6-month weight-loss program to produce an average loss of 7 to 9% of initial body weight that included diet, exercise, and behavior modification (AHEAD ,Action for Health in Diabetes) trial | Structured education program: four education sessions at months 1, 2, 3, and 4. During these 1-hour group sessions, which included 10 to 15 women, general information was presented about weight loss, physical activity, and healthful eating habits |
| Sung, 2000[592]<br>Country: Korea<br>Aim: the effects of pelvic floor muscle exercises on female genuine stress incontinence. | 90 married women with urinary incontinence. | Not reported. | Functional electrical stimulation-biofeedback for 20 minutes/session with frequency 35Hz-50Hz and contractions of 32 seconds, 2 sessions/week Intensive pelvic floor muscle exercises | Control usual care |
| Sung, 2000[593]<br>Country: South Korea<br>Aim: comparative effectiveness of pelvic floor muscle exercise and the functional electrical stimulation - biofeedback for female urinary incontinence | Married women diagnosed with genuine stress UI | Not reported | Intensive pelvic floor muscle exercise at home, videotape with instructions to perform exercise, weekly examination of accuracy and intensity of contractions | Functional electrical stimulation (FES)-biofeedback for 20 minutes/session, 2 sessions/week and weekly examination of accuracy and intensity of contractions.<br>Pelvic electrical stimulation for 24 seconds at 35 and 50 Hz simultaneously followed by biofeedback |
| Swithinbank, 2005[594]<br>Country: England<br>Aim: Cross-over RCT to examine the effect of caffeine restriction and fluid manipulation in the treatment | 69 women with urodynamically proven stress incontinence naive to surgery. | Urinary tract infection, hepatic, cardiac or renal disease and diabetes mellitus, use of antidepressants, anticholinergics or diuretics. | 1. Increased decaffeinated fluids to 3 liters daily (20 cups) or decreased decaffeinated fluids to 750ml (5 cups) daily<br>2. Caffeine restriction and | Usual care |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| of patients with urodynamic stress incontinence. | | | increased fluid intake to 2, 2,673ml/day<br>3. Caffeine restriction and decreased fluid intake to 872ml/day | |
| Tibaek, 2007[595]<br>Country: Denmark<br>Aim: the long term effect of pelvic floor muscle training in women with urinary incontinence after stroke | Women, diagnosed with first ever ischemic stroke according to the definition of World Health Organization and verified by CAT scan, stroke symptoms in at least one month; normal cognitive function (mini-mental state examination a.m. Folstein >25) | Urinary tract infection; symptoms of descensus urogenitale; chronic respiration diseases; psychiatric diseases; other neurological diseases; and do not speak Danish. | Systematic, controlled, intensive pelvic floor muscle training program by the specialist physiotherapist: group treatment with 6–8 patients/group for 1 hour/week, vaginal palpation 2-3 times and home exercises 1-2 times daily | Standard program of rehabilitation for patients with stroke without any specific treatment of urinary incontinence |
| Theofrastous, 2002[596]<br>Country: USA<br>Aim: the efficacy of bladder training and pelvic muscle exercise with biofeedback-assisted instruction on urinary incontinence in women. | 137 community-dwelling women 45 years and older diagnosed with genuine stress incontinence, (urine loss at least once per week), with urodynamic evidence of genuine stress incontinence, and mentally intact (Mini-Mental State Examination Score >23). | Reversible causes of urinary incontinence, uncontrolled metabolic conditions, residual urine volume after voiding >100ml, urinary tract infection, genitourinary fistula or indwelling catheterization, and inability to correctly perform a pelvic muscle contraction | Pelvic floor muscle training: 4 office biofeedback sessions and home exercise with two sets of 5 quick and 10 sustained contractions with 10-second rest periods increased to 5 quick and 20 sustained contractions 2/day for a total of 50 contractions per day | Bladder training |
| Thornburn, 1997[597]<br>Country: UK<br>Aim: the relationship between pad properties (absorption capacity, strike-through, and wetback) and wet comfort in women with light urinary incontinence | Women with light urinary incontinence who used disposable incontinence pads | Not reported | Pad A with the largest wetback | Pad B with the largest strike-through time; Pad F with the largest absorption capacity |
| Thyssen, 2001[598]<br>Country: Denmark<br>Aim: Crossover RCT to examine the effects of disposable intravaginal device on stress incontinence in women. | 94 women with the predominant symptom of stress incontinence, 39 were recruited in Denmark, 28 in England, and 27 in Australia. | Major uterovaginal prolapse | Conveen Continence Guard, CCG made of hydrophilic polyurethane and requires soaking in water before being placed on a handle like applicator for insertion. | Contrelle Continence Tampon, CCT, Coloplastic made of hydrophobic polyurethane and supplied ready-assembled within an applicator, allowing insertion directly into the vagina with no manual contact |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Tibaek, 2004[599]<br>Country: Denmark<br>Aim: the effect of pelvic floor muscle training in women with urinary incontinence after ischemic stroke | Women diagnosed with first-ever ischemic stroke according to the definition of the World Health Organization and verified by CAT scan; stroke symptoms in at least 1 month; normal cognitive function (Mini-mental state examination a.m. Folstein >25) | Urinary tract infection; symptoms of descensus urogenitale; chronic respiration diseases; psychiatric diseases; other neurological diseases; and do not speak Danish | Systematic, controlled, intensive pelvic floor muscle training program in 12 consecutive weeks by the same specialist physiotherapist. Women received instructions how to perform strength PFM exercise with close to maximum contraction (6 s contraction/6 seconds relaxation | The normal, standard program of rehabilitation without any specific treatment of urinary incontinence |
| Tibaek, 2005[600]<br>Country: Denmark<br>Aim: the effect of pelvic floor muscle training in women with urinary incontinence after ischemic stroke. | 26 women 40 and 85 years old with acute ischemic stroke verified by CAT scan lasting >24 hours; stroke symptoms in at least 1 month; normal cognitive function (mini-mental state examination >25); urinary incontinence related to stroke; independent walking | Urinary tract infection; symptom of vaginal prolapse; chronic respiratory diseases; psychiatric diseases; other neurological diseases; does not speak Danish. | Intensive pelvic floor muscle training 1-2 times/day by specialized physiotherapist: group information on incontinence and instruction in self-palpation of PFM, motivation and instruction in home exercises | Usual care |
| Tsai, 2009[601]<br>Country: Taiwan<br>Aim: comparative effectiveness of interpersonal support and digital vaginal palpation as part of the pelvic floor muscle exercise training compared to pelvic floor muscle exercise training with a printed handout instructions on stress urinary incontinence | Women who presented to the family medicine outpatient clinic without having urine leakage as their chief complaint but with transient UI | Severe uterine prolapse, past the vaginal introitus, heart failure; history of dementia (Mini-Mental State Examination (MMSE) score <24); prior knowledge of PFME prescribed by a physician, a nurse, a physical therapist, or any other health problems | Interpersonal support and digital vaginal palpation as part of the pelvic floor muscle exercise training. The researcher contacted the patients of experimental group by telephone once per week to inquire about any difficulties and/or improvements | Pelvic floor muscle exercise training with a printed handout instruction |
| Wang, 2004[602]<br>Country: Taiwan<br>Aim: the efficacy of pelvic floor muscle training, biofeedback-assisted PFMT, and electrical stimulation in the management of overactive bladder. | 120 women 16-75 years, symptoms of overactive bladder for more than 6 months, frequency of voiding eight times or more per day, and urge incontinence one time or more per day. | Pregnancy, deafness, neurologic disorders, diabetes mellitus, pacemaker or intrauterine device use, genital prolapse greater than Stage II of the International Continence Society grading system, residual urine | 1. Pelvic floor muscle training with submaximal to maximal PFM contractions for 6 seconds 5 times and 10 fast contractions per session at least 3 times/day.<br>2. Biofeedback-assisted pelvic floor muscle training | Electrical stimulation in the management of overactive bladder with intravaginal electrode at the physiotherapy unit. |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| | | >100ml, and urinary tract infection. | with an intravaginal electromyogram probe to contract or relax PFMs following the visual EMG signals. | |
| Wells, 1991[603]<br>Country: USA<br>Aim: the effects of pelvic muscle exercise or pharmacologic treatment of stress urinary incontinence in community-living elderly women | 157 community-living women, ages 55 to 90 years. | Nursing home residency | Pelvic muscle exercises with contractions for 10 seconds and relaxation for 10 seconds, 90-160 times/day. | Phenylpropanolamine hydrochloride in a dose of 50mg /day, increasing to 50mg 2 times/ day |
| Williams, 2005[604]<br>Country: England<br>Aim: the effects of continence service provided by specially trained nurses delivering evidence-based interventions using predetermined care pathways in adults. | 3,746 men and women ages 40 years and over living in private households reporting incontinence several times per month or more, or several times a year and reported significant impact of symptoms on quality of life. | Pregnancy, urinary fistula, pelvic malignancy, treatment for urinary symptoms. | Continence service that included advice on diet and fluids; bladder training; pelvic floor awareness and lifestyle advice. | Existing primary care including GP and continence advisory services in the area |
| Williams, 2006[605]<br>Country:<br>Aim: the efficacy and cost-effectiveness of pelvic floor muscle therapies (PFMT) in women ≥40 years with urodynamic stress incontinence (USI) and mixed UI | Women ≥40 years were randomly sampled by household from the Family Health Service Authority registers of participating GP practices and invited if they had urodynamic diagnosis of USI or mixed UI and DO | Pregnant, had urinary fistula, pelvic malignancy, severe prolapse and those currently receiving treatment for urinary symptoms (e.g. on a waiting list for continence surgery). | Pelvic floor muscle therapies training by specially trained nurses, after an initial digital assessment and perineometry to develop individualized exercise regimen. | Standard care: leaflet with information about pelvic floor muscles and three steps in exercising these muscles |
| Wing, 2010[606]<br>Country: USA<br>Aim: To examine the longer term effects of a weight loss intervention on urinary incontinence. | Being at least 30 years old, having a BMI of 25 to 50 kg/m2, reporting at least 10 UI episodes on a 7-day voiding diary at baseline and agreeing not to initiate new treatments for incontinence or weight reduction during the trial. | Reported Previously in Subak, 2009[591] | Behavioral weight loss program | Structured education program |
| Wong, 2001[607]<br>Country: China<br>Aim: the efficacy of | Chinese women with genuine stress incontinence | Second or third degree uterine prolapse, previous failure of pelvic floor muscle | Biofeedback from the abdominal muscle contractions during pelvic | Biofeedback from pelvic floor muscles during pelvic floor exercises |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| biofeedback in Chinese women with urinary stress incontinence | | exercise, continence surgery, pad test with urine loss <2g, neurologic disease | floor exercises with EMG attached over their abdominal muscles | |
| Wyman, 1997[608]<br>Country: USA<br>Aim: the effects of bladder training on quality of life in older women with urinary incontinence. | 131 women 55 years and older, ambulatory, mentally intact, independent residents in the community with urodynamic stress urinary incontinence >1 episode/week. | Metabolic decompensation, urinary tract infection, outlet obstruction, fistula, reversible cause of urinary incontinence, permanent indwelling catheter. | Bladder training: patient education, progressive scheduled voiding regimen, positive reinforcement. | Usual care |
| Wyman, 1998[609]<br>Country: USA<br>Aim: the efficacy of bladder training, pelvic muscle exercise with biofeedback-assisted instruction, and combination therapy, on urinary incontinence in women. | 204 community-dwelling women age 45 years and older diagnosed with genuine stress incontinence, (urine loss at least once per week), with urodynamic evidence of genuine stress incontinence, and mentally intact (Mini-Mental State Examination Score >23). | Reversible causes of urinary incontinence, uncontrolled metabolic conditions, residual urine volume after voiding >100ml, urinary tract infection, genitourinary fistula or indwelling catheterization, and inability to correctly perform a pelvic muscle contraction | Structured 12-week program of patient education, self-monitoring of voiding behavior with daily treatment logs, compliance assessment, and positive reinforcement administered by trained registered nurses. | Bladder training |
| Yamanishi, 1997[610]<br>Country: Japan<br>Aim: CT to examine the effects of electrical pelvic stimulation in stress incontinence. | 35 patients with stress incontinence. | Persistent urinary infection, uterine or rectal prolapse and cystocele, severe cardiac or cerebrovascular disorders including on-demand heart pacemakers, hepatic disorders and renal dysfunction. Anticholinergics, calcium antagonists, alpha or beta agonist | Electrical pelvic stimulation with 50Hz. square waves of 1msec. pulse duration and vaginal electrode in women and an anal electrode in men for 15 minutes 2 or 3 times daily | Sham electrical pelvic stimulation with inactive device |
| Yamanishi, 2000[611]<br>Country: Japan<br>Aim: the effects of electrical stimulation for urinary incontinence due to detrusor overactivity | 68 patients with urinary incontinence due to detrusor overactivity urodynamically defined as involuntary detrusor contractions of more than 15cm/H2O during the filling phase. | Use of anticholinergics or tricyclic depressants, pelvic floor exercise, bladder training, or pelvic surgery before entry into the study. | Electrical stimulation 15 minutes twice daily for 4 weeks (vaginal electrode in women and an anal or surface electrode in men to provide alternating pulses of 10Hz square waves of 1-ms pulse duration and a maximum output current of 60mA). | Sham inactive device |

**Appendix Table F80. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)**

| Reference<br>Country<br>Aim of the Study | Inclusion Criteria | Exclusion Criteria | Active Treatment | Control Treatment |
|---|---|---|---|---|
| Yoon, 2003[612]<br>Country: South Korea<br>Aim: the effectiveness of bladder training versus pelvic muscle exercises in the treatment of urinary incontinence in women. | 50 parous women 35–55 years old with urine loss of 1.0g or more on a 30 minute pad test and 14 voids or more during a period of 48 hours before the preliminary evaluation. | Urinary tract infection tested by urinalysis and urine culture, previous experience of surgery for urinary incontinence, HRT and other medication for urinary incontinence. | Bladder training with increased interval between voluntary voids ; Pelvic muscle exercise (30 contractions for 15 to 20 minutes/day) with immediate and simultaneous visual feedback of pelvic muscles during a 20 minute weekly biofeedback session | Usual care |
| Zanetti,2007[613]<br>Country: Brazil<br>Aim: comparative effectiveness of pelvic floor muscle exercises with or without physiotherapist supervision on female stress UI | Women with stress urinary incontinence confirmed by means of urodynamic testing | Topical hormone replacement therapy for less than three months, disorder affecting muscle or nerve tissues, or genital bleeding, pregnancy, urinary tract infection, vulvovaginitis, genital prolapse beyond the hymen, atrophic vaginitis or cardiac pacemaker | Supervised perineal exercises repeated in the orthostatic, sitting and supine positions under guidance from a physiotherapist (twice a week, for 45 minutes). | Unsupervised perineal exercises repeated in the orthostatic, sitting and supine positions performed at home with monthly assessment from a physiotherapist. |
| Clarke-O'Neill, 2002[614]<br>Country: UK<br>Aim: The Continence Product Evaluation Network: comparative survey of washable pants with integral pads for women with light incontinence | The Continence Product Evaluation Network: women 18 years of age and normally used an absorbent product (disposable or reusable) for light incontinence | Not reported | 10 pants designed for light incontinence | Cross over evaluation |
| Tomlinson, 1999[615]<br>Country: USA<br>Aim: The effects of dietary caffeine and fluid intake on urinary incontinence in older rural women | The Behavioral Management for Continence (BMC):women 55 or older living in their own home in one of seven rural counties in northern Florida with involuntary urine loss at least twice a week and of 1 g per day or more | Diagnosis of bladder cancer or kidney disease; use of a urinary catheter; retention of 100 ml or more of urine; need for a caregiver but none was available; and availability for less than 6 months | The Behavioral Management for Continence: self-monitoring (2–4 weeks' duration); bladder training (6–8 weeks' duration); and pelvic muscle exercise with biofeedback (12 weeks' duration). The goal was appropriate intake of 1800–2400 ml/day of fluids | No active treatments; alternative resources within the community |

**Appendix Table F81. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI**

| Reference | Sponsorship | Conflict of Interest |
|---|---|---|
| Luber, 1997[554] | Contract grant sponsor: Kaiser Research Foundation; Contract grant number: 01-990-6571. | Not reported |
| Dougherty, 2002[511] | Contract grant sponsor: National Institute of Nursing Research, National Institutes of Health (Nursing model: Urinary incontinence for older, rural women); contract grant number: R01 NR 3139. Johnson & Johnson provided absorbent products for the project | Not reported |
| Hung, 2010[534] | Financial support from the National Science Council of the Republic of China under the grant No. NSC95-2314-B002-226-MY2 | Not reported |
| Tibaek, 2004[599] | Financial support provided by The Foundation of Danish Physiotherapists Research, The Foundation of 1870, and Direktor Jacob Madsen og hustrus Fond. | Not reported |
| Tibaek, 2007[595] | Financial support provided by The Foundation of Danish Physiotherapists Research, The Foundation of 1870, and Direktor Jacob Madsen og hustrus Fond. | Not reported |
| Morkved, 2002[566] | Financial support was given by the Norwegian Industrial and Regional Development Fund, Norwegian National Insurance Administration, and by Trondheim Regional Hospital 2000, SINTEF Unimed, Trondheim and Vitacon, Trondheim, Norway | Not reported |
| Burns, 1993[500] | Funded by a cooperative agreement (UOI AG05260) from the National Institute on Aging and the National Center for Nursing Research | Not reported |
| Mayer, 2007[559] | Funded by BioForm Medical. | R. D. Mayer and K. Jacoby are study investigators partially funded by the sponsor, and are paid consultants to the sponsor. R. Dmochowski, R. A. Appell, P. K. Sand, I. Klimberg, C. W. Graham, J. A. Snyder, V. Nitti, and J. C. Winter are study investigators partially funded by the sponsor. |
| Oldham, 2010[575] | Funded by Femeda | Not reported |
| Kim, 2001[538] | Funded by Sasakawas' Health Science Foundations in Japan and the International Rotarian Scholarship in Japan | Not reported |
| Williams, 2005[604] | Funded by the Medical Research Council (UK) (G9410491). Nicola J Cooper was funded by University Hospitals of Leicester (UHL) NHS Trust. David A Turner was funded by Trent Institute for Health Services Research | None declared |
| Moore, 2003[565] | Funded by the Health Outcomes Unit of the New South Wales Department of Health of Australia. | Not reported |
| Borello-France, 2006[490] | Funded by the National Institutes of Health/National Institute on Aging grant R15AG15488 to Dr.Borello-France | Not reported |
| Bo, 1999[486] | Funded by the Norwegian Fund for Postgraduate studies in Physiotherapy and Norwegian Research Council. Coloplast AS provided the continence guards and Vitacon S provided the electrical stimulators and cones. They also gave financial support to seminars for the research group | None declared |
| Bo, 2000[487] | Funded by The Norwegian Fund for Postgraduate Studies in Physiotherapy and The Norwegian | Not reported |

**Appendix Table F81. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)**

| Reference | Sponsorship | Conflict of Interest |
|---|---|---|
| | Research Council. In addition, Coloplast AS gave financial support to the study | |
| Borrie, 2002[492] | Funded by the Ontario Ministry of Health Assistive Devices Branch (grant no.M695A2), Parkwood Hospital, London, Ont., and the University of Western Ontario, London, Ont. | None |
| Peters, 2010[578] | Funded by Uroplasty, Inc. | Not reported |
| Lightner, 2001[552] | Funded through unrestricted, educational grants by Carbon Medical Technologies. | A. U. Khan and I. Klimberg received research funding from the sponsor of this study. |
| Jeyaseelan, 2000[536] | Funding for this project was provided by University of Manchester Medical Bequest Fund. | Not reported |
| Gorman, 1995[528] | Funding provided by Florida Nurses Foundation, Sigma Theta Tau, Alpha Theta Chapter, and Rural Women's Health Project (NR3139). | Not reported |
| Janssen, 2001[535] | Funding: Ziekenfondsraad; | None |
| Kincade, 2007[541] | Grant from National Institute of Nursing Research; Grant numbers: R01 NR05071, S1 | Not reported |
| Elser, 1999[515] | Grant from National Institute on Aging/National Institutes of Health, Bethesda, MD, grant UO1AG05170-6 | Not reported |
| Chadha, 2000[505] | Grant support for this study was provided by the Chief Scientist Office of the Scottish Office of Home and Health Department, which also funds the Health Services Research Unit, University of Aberdeen, Scotland. | Not reported |
| Williams, 2006[605] | Medical Research Council | None declared |
| Wyman, 1997[608] | National Institute of Aging, National Institute for Nursing Research (formerly National Center for Nursing Research), National Institutes of Health, Bethesda, Maryland, Grant Number AG05170. | |
| Wong, 2001[607] | None | Not reported |
| Zanetti, 2007[613] | None | None |
| Tsai, 2009[601] | None | None |
| Felicissimo, 2010[519] | None | None |
| Harvey, 2002[530] | Not supported by the Industry | Not reported |
| Demain, 2001[507] | Not reported | The physiotherapy clinical trialist is supported by the West Midlands NHS(E) |
| O'Brien, 1991[573] | Not reported | Not reported |
| Lagro-Janssen, 1991[545] | Not reported | Not reported |
| Smith, 1996[586] | Not reported | Not reported |
| Nielsen, 1993[570] | Not reported | Not reported |
| Nygaard, 1996[572] | Not reported | Not reported |
| O'Brien, 1996[574] | Not reported | Not reported |
| Berghmans, 1996[482] | Not reported | Not reported |
| Dowd, 1996[512] | Not reported | Not reported |
| Ramsay, 1996[579] | Not reported | Not reported |
| Glavind, 1996[526] | Not reported | Not reported |
| Bo, 1997[485] | Not reported | Not reported |
| Thornburn, 1997[597] | Not reported | Not reported |
| Brubaker, 1997[496] | Not reported | Not reported |
| Sherman, 1997[585] | Not reported | Not reported |
| Cammu, 1998[504] | Not reported | Not reported |
| Glavind, 1997[527] | Not reported | Not reported |
| Miller, 1998[564] | Not reported | Not reported |
| Bower, 1998[493] | Not reported | Not reported |

**Appendix Table F81. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)**

| Reference | Sponsorship | Conflict of Interest |
|---|---|---|
| Yamanishi, 2000[611] | Not reported | Not reported |
| McFall, 2000[563] | Not reported | Not reported |
| Pages, 2001[577] | Not reported | None |
| Clarke-O'Neill, 2002[614] | Not reported | Not reported |
| Thyseen, 2001[598] | Not reported | Not reported |
| Bryant, 2002[497] | Not reported | Not reported |
| Berghmans, 2002[483] | Not reported | Not reported |
| Aukee, 2002[478] | Not reported | Not reported |
| Yoon, 2003[612] | Not reported | Not reported |
| But, 2003[501] | Not reported | Not reported |
| Aksac, 2003[471] | Not reported | Not reported |
| O'Sullivan, 2003[576] | Not reported | Not reported |
| Robinson, 2003[581] | Not reported | Not reported |
| Diokno, 2004[509] | Not reported | Not reported |
| Bano, 2005[480] | Not reported | Not reported |
| Seo, 2004[584] | Not reported | Not reported |
| Schulz, 2004[583] | Not reported | Not reported |
| Amaro, 2005[473] | Not reported | Not reported |
| Swithinbank, 2005[594] | Not reported | Not reported |
| Finazzi Agro, 2005[470] | Not reported | Not reported |
| Karademir, 2005[315] | Not reported | Not reported |
| Amaro, 2006[474] | Not reported | Not reported |
| Andersen, 2002[475] | Not reported | Not reported |
| Borawski, 2007[489] | Not reported | None |
| Konstantinidou, 2007[542] | Not reported | None |
| Manganotti, 2007[557] | Not reported | Not reported |
| Du Moulin, 2007[567] | Not reported | Not reported |
| Demirturk, 2008[508] | Not reported | None |
| Castro, 2008[246] | Not reported | Not reported |
| Kumari, 2008[543] | Not reported | Not reported |
| Ghoniem, 2009[524] | Not reported | Gamal Ghoniem has financial interest and/or other relationship with Astellas, Coloplast, Uroplasty and Bulkamid; Jacques Corcos has financial interest and/or other relationship with Johnson & Johnson, Astellas, Purdue, Triton and Allergan; Craig Comiter has financial interest and/or other relationship with Coloplast and Astellas; O.Lenaine Westney has financial interest and/or other relationship with American Medical Systems; and Sender Herschorn has financial interest and/or other relationship with Pfizer, Astellas, Johnson & Johnson, Allergan and Lilly. |
| Gilling, 2009[525] | Not reported | None |
| de Oliveira Camargo, 2009[503] | Not reported | None |
| Gameiro, 2010[523] | Not reported | None |
| Blowman, 1991[484] | Not reported | Not reported |
| Majumdar, 2010[556] | Not Reported | None |
| Diokno, 2010[510] | Not Reported | NR |
| Liebergall-Wischnitzer, 2009[550] | Partially funded by The Hadassah Women's Health Research Fund and the Berman Famliy Foundation | None |
| Kim, 2009[537] | Research grant from the Ministry of Health and | Not reported |

**Appendix Table F81. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)**

| Reference | Sponsorship | Conflict of Interest |
|---|---|---|
| | Welfare of Japan and a Grant-in-Aid for the Scientific Research B from the Japan Society for the Promotion of Science and Sanitary Products Research Foundation of the KAO Corporation | |
| Alewijnse, 2003[472] | Sponsored by a grant from Praeventiefonds/ZON (Netherlands Care Research); Grant number: 28-2505. | None |
| Ng, 2008[569] | Sponsored by a grant from The National Science Council in Taiwan (NSC-89-2314-B-040-046) | Not reported |
| Theofrastous, 2002[596] | Sponsored by National Institute on Aging; Contract grant number:UO1-AG-05170. | Not reported |
| Appell, 2006[476] | Sponsored by Novasys Medical, Inc. (Newark, CA) | None |
| McFall, 2000[562] | Supported by a co-operative agreement between the Centers for Disease Control & Prevention and the Oklahoma State Department of Health. | Not reported |
| Goode, 2003[616] | Supported by a grant 1R01DK49472 from the National Institutes of Health | Not reported |
| Sand, 1995[582] | Supported by a grant from Empi, Inc., St.Paul, Minnesota | Not reported |
| Gallo, 1997[522] | Supported by a grant from Incare Medical Products. | Not reported |
| Tibaek, 2005[600] | Supported by a grant from the Foundation of Danish Physiotherapists Research; Grant sponsor: The Foundation of 1870, Direkt r Jacob Madsen og hustrus Fond | Not reported |
| Wang, 2004[602] | Supported by a grant from the National Science Council, Taiwan (NSC90-2314-B-182-111). | Not reported |
| Tomlinson, 1999[615] | Supported by a research grant (R01 NR3139 Nursing Model: Urinary Continence for Older, Rural Women) from the National Institute of Nursing Research, National Institutes of Health (1992–1997). Johnson & Johnson Company (Milltown, NJ) donated the incontinence products | Not reported |
| Kim, 2007[539] | Supported by a Research Grant of the Ministry of Health and Welfare of Japan and a Grant-in-Aid for Scientific Research B of the Japan Society for the Promotion of Science. | None |
| Corcos, 2005[506] | Supported by a University-Industry grant from the Canadian Institute for Health Research (CIHR) in association with Bard Canada. | All authors are study investigators funded by CIHR and Bard. |
| Liebergall-Wischnitzer, 2005[551] | Supported by an Internal Grant for Paramedical Personnel at Hadassah and the Lillian Silverstein Fund | Not reported |
| Fantl, 1991[518] | Supported by Cooperative Agreement AG05170 with the National Institute on Aging and National Center on Nursing Research, Bethesda,Md | Not reported |
| Subak, 2002[589] | Supported by Direct Community Benefit Investment, Kaiser Foundation Research Institute | Not reported |
| Barroso, 2004[481] | Supported by Fundação de Amparo à Pesquisa do Rio Grande do Sul (FAPERGS) and the Fundo de Incentivo à Pesquisa (FIPE) of GPPG/HCPA | Not reported |
| Strasser, 2007[588] | Supported by FWF-grant P-12828 (Fonds zur Foerderung der wissenschaftlichen Forschung, Vienna; Institute for Biochemical Pharmacology, Medical University Innsbruck; Austria). | Michael Mitterberger is co-owner of IGOR, and Hannes Strasser and Rainer Marksteiner are founders and co-owners of Innovacell Biotechnologie. Both companies run certifi ed facilities where the autologous cells were grown. Eva Margreiter, an employee of |

**Appendix Table F81. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)**

| Reference | Sponsorship | Conflict of Interest |
|---|---|---|
| | | Innovacell, did most cell cultures. |
| Burgio, 2002[498] | Supported by grant AG RO1 08010 from the National Institute on Aging, National Institutes of Health, Bethesda, Md. | Not reported |
| Manonai, 2006[558] | Supported by grant from Thai Health Promotion Foundation | Not reported |
| But, 2005[502] | Supported by Grant L3-4476-0334-02/3.08 from the Ministry of Education, Science and Sport of the Republic of Slovenia | Not reported |
| Goode, 2002[286] | Supported by Grants AG 08010 and K04 00431 from the National Institute on Aging to Dr. Burgio. | Not reported |
| Richter, 2010[357] | Supported by grants from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (U10 HD41261, U10 HD 41250, U10 HD54136, U10 HD41249, U10 HD41267, U10 HD41248, U10 HD41268, U10 HD41263, U10 HD54214, U10 HD54241, and U10 HD54215); National Institute of Diabetes and Digestive and Kidney Diseases, and National Institutes of Health Office of Research on Women's Health. | Dr. Burgio is a consultant for Pfizer (New York, NY) and on the advisory board for Astellas (Deerfield, IL). Dr. Brubaker is a Research Consultant for Pfizer (New York, NY) and a Research Investigator for Allergan (Irvine, CA). Dr. Zyczynski has performed contract research for Johnson & Johnson (New Brunswick, NJ). Dr. Lukacz is a consultant for Pfizer (New York, NY), Medtronic (Minneapolis, MN), and Watson Pharmaceuticals (Corona, CA). She has served on the speaker's bureau for Novartis (Basel, Switzerland) and Proctor&Gamble (Cincinnati, OH). She has been a consultant and proctor for Intuitive Surgical Corporation (Sunnyvale, CA) , and she has been an editor First Consult. Dr. Schaffer is on the Speaker's Bureau and National Advisory Board of Astellas/GlaxoSmithKline (Deerfield, IL; Philadelphia, PA) and on the Specialty Surgeons Advisory Board of Cadence Pharmaceuticals (San Diego, CA). The other authors did not report any potential conflicts of interest. |
| Nager, 2009[568] | Supported by grants from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the NIH Office of Research on Women's Health at National Institutes of Health (U10 HD54215, U10 HD41267, U10 HD41250, U10 HD41261, U10 HD54214, U10 HD54241, U10 HD54136, and U01 HD41249). | None |
| Subak, 2009[591] | Supported by grants from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (U01 DK067860, U01 DK067861, and U01 DK067862) and from the Office of Research on Women's Health. | Dr. Subak reports serving on an advisory board for Pfizer and receiving grant support from Pfizer; Dr. Grady, receiving grant support from Bionovo; Dr. Kusek, owning stock in Eli Lilly, Pfizer, and deCODE Genetics; and Dr. Burgio, serving on an advisory board for Pfizer, receiving grant support from Pfizer, and receiving advisory-board fees from Astellas and GlaxoSmithKline. No other potential conflict of interest relevant to this article was reported. |

**Appendix Table F81. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)**

| Reference | Sponsorship | Conflict of Interest |
|---|---|---|
| Wing, 2010[606] | Supported by Grants U01DK067860, U01DK067861 and U01 DK067862 from the National Institute of Diabetes and Digestive and Kidney Diseases, as well as by the Office of Research on Women's Health. | Delia Smith West has financial interest and/or other relationship with Jenny Craig, Inc.; Holly Richter has financial interest and/or other relationship with Xanodyne, University of California, San Francisco, Pfizer and American Geriatrics Society; and Kathryn Burgio has financial interest and/or other relationship with Pfizer, Astellas and Johnson & Johnson. |
| Huang, 2009[532] | Supported by GrantsU01 DK067860, U01 Dk067861 and U01 DK067862, and K24 Dk068389 and K24 Dk080775, from The National Institute of Diabetes and Digestive and Kidney Diseases, and the Office of Research on Women's Health, National Institutes of Health. Alison Huang was supported by Grant KL2RR024130 from the National Center for Research Resources, a component of the National Institutes of Health Clinical Translational Science Award for Medical Research | Alison Huang and Leslee Subak have financial interest and/or other relationship with Pfizer, Inc. |
| Arvonen, 2001[477] | Supported by Ipex Medical AB | Not reported |
| Engberg, 2002[517] | Supported by National Institute for Nursing Research grant No. R01 NR02874. | Not reported |
| Hahn, 1991[529] | Supported by Neurologiskt handikappades Riksförbund and the LIC hygien | Not reported |
| McDowell, 1999[561] | Supported by NINR RO1 NR02874. | Not reported |
| Lee, 2001[549] | Supported by Physicians Sources, Inc. | Not reported |
| Lightner, 2009[553] | Supported by Q-Med Ab, Inc., Uppsala, Sweden | Not reported |
| Subak, 2005[590] | Supported by research awards from Mount Zion Health Services,Inc. and the University of California, San Francisco Academic Senate, Committee on Research. | Leslee Subal is a Women's Reproductive Health Research Scholar supported by the National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland (K12 HD01262–02). Leslee Subak has financial interest and/or other relationship with Yamanouchi. |
| Kim, 2008[540] | Supported by research funds from Chosun Nursing College, 2006 | Not reported |
| Boyington, 2005[494] | Supported by research grant No. 1 K01 NR00125 (A Knowledge-Based System for Continence) from the National Institute for Nursing Research, National Institutes of Health (1999-2003). | Not reported |
| Laycock, 2001[548] | Supported by SSL-International (UK) and Cardio Design (Australia) | Not reported |
| Dumoulin, 2004[514] | Supported by the Canadian Institutes of Health Research and Laborie Medical Technologies Inc. through a Canadian Institutes of Health Research–Industry grant. C. Dumoulin was supported by studentships from the Canadian Institutes of Health Research and from the Fonds de la Recherche en Santé du Québec. | Not reported |
| Brown, 2006[495] | Supported by the following: The Diabetes Prevention Program National Institutes of Health/ National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Child Health and Human Development, the National | Not reported |

**Appendix Table F81. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)**

| Reference | Sponsorship | Conflict of Interest |
|---|---|---|
| | Institute on Aging, the Office of Research on Minority Health and Health Disparities, the Office of Women's Health, the Indian Health Service, the Centers for Disease Control and Prevention, the General Clinical Research Program, the National Center for Research Resources, the American Diabetes Association, Bristol-Myers Squibb, Lipha Pharmaceuticals, and Parke-Davis. LifeScan, Health O Meter, Hoechst Marion Roussel, Merck-Medco Managed Care, Merck, Nike Sports Marketing, Slim Fast Foods, and Quaker Oats donated materials, equipment, or medicines for concomitant conditions. | |
| Sung, 2000[592] | Supported by the Hallym Academy of Science, Hallym University in 1998 | Not reported |
| Sung, 2000[593] | Supported by the Hallym Academy of Sciences, Hallym University in 1998 | |
| Fujishiro, 2002[521] | Supported by the Life Science Foundation of Japan | Not reported |
| Fujishiro, 2000[520] | Supported by the Life Science Foundation of Japan. | Not reported |
| Wyman, 1998[609] | Supported by the National Institute of Aging/National Institutes of Health, Bethesda, Maryland, grant No. UOI AG05170 | Not reported |
| Hu, 1989[531] | Supported by the National Institute on Aging and the National Center for Nursing Research, Bethesda, Md. | Not reported |
| Borello-France, 2008[491] | Supported by the National Institutes of Health, National Institute on Aging (grant R15 AG15488-03), and by a Magee-Women's Health Foundation grant | Not reported |
| Coleman, 1999[617] | Supported by the Robert Wood Johnson Foundation Chronic Care Initiative, Grant No. 024739 | Dr Coleman was a Veteran's Affairs Robert Wood Johnson Clinical Scholar during his participation in this study |
| Dowd, 2000[513] | Supported by The University of Akron Faculty Grant 1355 | Not reported |
| MacDiarmid, 2010[555] | Supported by Uroplasty, Inc. | MacDiarmid Scott has financial interest and/or other relationship with Uroplasty, Pfizer, Watson, Astellas and Allergan; Peters Kenneth has financial interest and/or other relationship with Medtronic, Advanced Bionics, Boston Scientific, Allergan, Pfizer, Celgene and Trillium Therapeutics; Wooldridge Leslie has financial interest and/or other relationship with Uroplasty, Astellas and Watson; Rovner Eric has financial interest and/or other relationship with Astellas; Leong Fah Che has financial interest and/or other relationship with Astellas; Siegel Steven has financial interest and/or other relationship with AMS, Medtronic, Uromedica, Uroplasty and QiG; Tate Susan has financial interest and/or other relationship with C.R. Bard; and Feagins Brian has financial interest and/or other |

**Appendix Table F81. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)**

| Reference | Sponsorship | Conflict of Interest |
|---|---|---|
| | | relationship with Medtronic, AMS, Novartis, Allergan, Astellas, and Boston Scientific |
| Yamanishi, 1997[610] | Supported in part by grants from the National Research and Development for Medical and Welfare Apparatus under Industrial Science and Technology Frontier Program of the Agency of Industrial Science and Technology of the Ministry of International Trade and Industry and the New Energy and Industrial Technology Development Organization of Japan | Not reported |
| Lamb, 2009[546] | The trial was funded by the Physiotherapy Research Foundation | None |
| Hui, 2006[533] | The telemedicine equipment was supported by the SK Yee Medical Foundation | Not reported |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| Pelvic floor muscle training (PFMT) and/or other lifestyle interventions | Aksac, 2003[471]<br>Sample: 50<br>8 weeks | Intention to treat: Intention to treat not stated<br>Allocation concealment not adequate<br>Sample size justified: No | Randomization: Randomization with choosing closed letters (patients had to pick up closed letters) | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Alewijnse, 2003[472]<br>Sample: 129<br>14-22 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Arvonen, 2001[477]<br>Sample: 37<br>16 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Aukee, 2002[478]<br>Sample: 30<br>12 weeks | Intention to treat: Yes<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Randomization with random numbers table with permuted blocks of four | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Aukee, 2004[479]<br>Sample: 35<br>12 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Randomization was performed by a random numbers table, in blocks of four | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Berghmans,1996[482]<br>Sample: 40<br>12 weeks | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: No | Randomization: Computer generated randomization stratified by seriousness of incontinence (grade 1 and 2) and by referral (general practitioner or urologist) with permuted blocks of 4 | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Bo, 2000[487]<br>Sample: 59<br>24 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Computer generated randomization stratified by degree of leakage | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Bo, 2005[488]<br>Sample: 52<br>24 weeks | Intention to treat: Yes<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Borello-France, 2006[490]<br>Sample: 44<br>12 weeks | Intention to treat: Yes<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Block randomization schedule with a random number table | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Borrie, 2002[492]<br>Sample: 421<br>24 weeks | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: No | Randomization: Computer generated randomization with random permuted blocks, block size of 4 | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Boyington, 2005[494]<br>Sample: 71<br>8 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Quasi-experimental trial with random assignment of participants to intervention and control groups. The minimization technique for balancing age (50-59 years, | Randomization: Adequate |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| | | | 60-69 years, and 70 years and older), ethnicity, and presence of the symptom of involuntary urine loss in the 2 groups | |
| PFMT and/or other lifestyle interventions | Brown, 2006[495]<br>Sample: 2191<br>2.9 years | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Randomization was stratified by clinical center | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Bryant, 2002[497]<br>Sample: 95<br>4 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Burgio, 2002[498]<br>Sample: 222<br>8 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: stratified randomization;<br>Randomization stratified by race, type, and severity of incontinence | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Burns,1990[499]<br>Sample: 128<br>8 weeks | Intention to treat: Not stated<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Randomization with permuted blocks of 10. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Burns, 1993[500]<br>Sample: 135<br>24 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate<br>Adjustment for clinical site and study treatment, fluid intake, patient reported diagnosis of congestive heart failure, patient reported diagnosis of diabetes, body mass index, age, urge and stress scores from the medical, epidemiological and social aspects |
| PFMT and/or other lifestyle interventions | de Oliveira Camargo, 2009[503]<br>Sample: 61<br>12 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: computer-generated random number table | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Cammu,1998[504]<br>Sample: 60<br>12 weeks | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: No | Randomization: Computerized randomization with random numbers tables | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Castro, 2008[246]<br>Sample: 118 | Intention to treat: Intention to treat not stated<br>Adequate<br>Sample size justified: No | Randomization: Not reported | Randomization No |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| PFMT and/or other lifestyle interventions | Chadha, 2000[505]<br>Sample: 449<br>48 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Randomization stratified by hospital size and location. 2 x 2 balanced incomplete block controlled before and after study. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Coleman,1999[617]<br>Sample: 169<br>Length of treatment 48 weeks | Intention to treat: Modified intention-to-treat: patients with followup data were included in the followup analysis irrespective of level of exposure to the intervention<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Simple random numbers table;<br>The unit of randomization was the physician practice | Randomization: Adequate<br>Possible because the authors modified intention to treat analysis |
| PFMT and/or other lifestyle interventions | Demain, 2001[507]<br>Sample: 44<br>12 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Stratified randomization using the method of minimization;<br>Stratification by body mass index and age | Randomization: Adequate |
| Group intervention | Diokno, 2010[510]<br>Sample: 44<br>6-8 weeks | Intention to treat: NR<br>Allocation concealment NR<br>Sample size justified: No | Randomization: NR | Randomization: Not adequate |
| PFMT and/or other lifestyle interventions | Diokno, 2004[509]<br>Sample: 359<br>48 weeks | Intention to treat: Not stated<br>Adequate<br>Sample size justified: No | Randomization: Randomizations in blocks of 16 women to provide balanced recruitment between groups | Randomization: Adequate. |
| PFMT and/or other lifestyle interventions | Dougherty, 2002[511]<br>Sample: 218<br>24 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Randomization with minimization to balance by severity, age, bacteriuria ethnicity, and caregiver | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Dowd,1996[512]<br>Sample: 58<br>5 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization Baseline data not provided but some differences at baseline reported. |
| PFMT and/or other lifestyle interventions | Dowd, 2000[513]<br>Sample: 40<br>6 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Elser, 1999[515]<br>Sample: 204<br>Length of treatment 12 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Randomization stratified by severity of urinary incontinence, urodynamic diagnosis, and treatment site randomization. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Engberg, 2002[517]<br>Sample: 19<br>8 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Computer-generated stratified by cognitive ability, toileting skills, and severity of urinary | Randomization: Adequate |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| | | | incontinence randomization. | |
| PFMT and/or other lifestyle interventions | Fantl,1991[518]<br>Sample: 13<br>6 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Randomization stratified by urodynamic incontinence.<br>Randomization stratified by urodynamic incontinence. | Randomization: Adequate |
| Supervised Pelvic Floor Muscle Training | Felicissimo, 2010[519]<br>Sample: 62<br>8 weeks | Intention to treat: No<br>Allocation concealment Adequate<br>Sample size justified: Yes | Randomization: Computer generated random number generator | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Gallo,1997[522]<br>Sample: 86<br>6 weeks | Intention to treat: Intention to treat not stated<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Not reported | Randomization: States as adequate, baseline characteristics not reported. |
| PFMT and/or other lifestyle interventions | Gameiro, 2010[523]<br>Sample: 103 | Intention to treat: Intention to treat not stated<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Patients were systematically allocated, in a single-blind study, into two groups. The odd numbers were included in group 1 (n=51) and submitted to VWC associated to standardized general exercise; the even numbers were included in group G2 (n=52) and treated with assisted PFMT | Randomization Adequate |
| PFMT and/or other lifestyle interventions | Gilling, 2009[525]<br>Sample: 70<br>6 weeks | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Random permuted blocks of 10 | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Glavind,1997[527]<br>Sample: 6<br>0.5 weeks | Intention to treat: Intention to treat not stated<br>Allocation concealment not adequate<br>Sample size justified: No | Randomization: Not reported | Randomization: Cross over trial |
| PFMT and/or other lifestyle interventions | Glavind,1996[526]<br>Sample: 40<br>4 weeks | Intention to treat: No<br>Allocation concealment not adequate<br>Sample size justified: No | Randomization: Not reported | Randomization: Stated as adequate, no data provided |
| PFMT and/or other lifestyle interventions | Goode,2003[616]<br>Sample: 200<br>8 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Computer-generated stratified by types and severity of incontinence and race randomization with block size of 6. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Goode, 2002[286]<br>Sample: 105<br>8 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Gorman,1995[528]<br>Sample: 60<br>6 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or | Hahn, 1991[529] | Intention to treat: Not | Randomization: Not reported | Randomization: |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| other lifestyle interventions | Sample: 20 | reported<br>Allocation concealment Not reported<br>Sample size justified: Not reported | | Adequate |
| PFMT and/or other lifestyle interventions | Harvey, 2002[530]<br>Sample: 44 | Intention to treat: NR<br>Allocation concealment NR<br>Sample size justified: NR | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Hu, 1989[531]<br>Sample: 143<br>12 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Huang, 2009[532]<br>Sample: 338<br>24 weeks | Intention to treat: Not stated<br>Reported previously<br>Sample size justified: No | Randomization: Random permuted blocks;<br>2:1 ratio | Randomization: No, women in control group had slightly higher average Beck Depression Inventory score |
| PFMT and/or other lifestyle interventions | Hui, 2006[533]<br>Sample: 32<br>8 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Randomization with a table of random numbers | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Hung, 2010[534]<br>Sample: 70<br>Length of treatment 16 weeks | Intention to treat: No<br>Allocation concealment Not adequate<br>Sample size justified: Yes | Randomization: Block randomization with a maximum of 6 was used | Randomization Adequate |
| PFMT and/or other lifestyle interventions | Janssen, 2001[535]<br>Sample: 530<br>12 weeks | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: No | Randomization: Randomization stratified by type, severity and duration of incontinence frequency sampling randomization | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Kim, 2009[537]<br>Sample: 147 | Intention to treat: NR<br>Allocation concealment NR<br>Sample size justified: NR | Randomization: NR | Randomization NR |
| PFMT and/or other lifestyle interventions | Kim, 2007[539]<br>Sample: 70<br>12 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Computer-generated random numbers; randomization was repeated until there was no significant difference between the two groups | Randomization: Adequate unclear because the authors stated that "The participants were divided into two groups based on the frequency of urine leakage and functional fitness measurements" |
| PFMT and/or other lifestyle interventions | Kim, 2001[538]<br>Sample: 48<br>12 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Randomization by the order of coming to the clinic. | Randomization: Adequate |
| PFMT and/or other lifestyle | Kincade, 2007[541] | Intention to treat: Yes<br>Allocation concealment | Randomization: The minimization technique; to | Randomization: Adequate |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| interventions | Sample: 224<br>3 weeks | unclear<br>Sample size justified: Yes | balance those in the two study groups on age (18–39, 40–64, 65+), estrogen status (pre menopausal/ hormone replacement versus post menopausal/no hormone replacement), severity of urine loss (<50 g vs. more than 50 g), and race | |
| PFMT and/or other lifestyle interventions | Konstantinidou, 2007[542]<br>Sample: 30<br>12 weeks | Intention to treat: No<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Unclear consecutive order according to women hospital administration sequence; Not reported | Randomization: Adequate<br>Unclear because described methods of treatment assignment was not random |
| PFMT and/or other lifestyle interventions | Kumari, 2008[543]<br>Sample: 198<br>8 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Block randomization; Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Lagro-Janssen,1992[544]<br>Sample: 110<br>12 weeks | Intention to treat: Not stated<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Lagro-Janssen,1991[545]<br>Sample: 66<br>12 weeks | Intention to treat: Not stated<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Lamb, 2009[546]<br>Sample: 174 | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Randomized in a ratio of 2:1 (group: individual) | Randomization Adequate |
| PFMT and/or other lifestyle interventions | Liebergall-Wischnitzer, 2009[550]<br>Sample: 245<br>12 weeks | Intention to treat: Yes<br>Adequate: by a biostatistician and blinded research coordinator<br>Sample size justified: Yes | Randomization: Randomization stratified with a table of random numbers, permuted blocks; block size of 4 and stratified by age (20–50 and 51–65) and place of residence (three towns). | Randomization: No, a significant difference in the prevalence of uterine prolapse |
| PFMT and/or other lifestyle interventions | Liebergall-Wischnitzer, 2005[551]<br>Sample: 59<br>12 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Computer generated randomization with block of 4 stratified by age. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | MacDiarmid, 2010[555]<br>Sample: 33 | Intention to treat: Intention to treat not stated<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: NA |
| Urodynamics | Majumdar, 2010[556]<br>Sample: 99 | Intention to treat: Yes<br>Allocation concealment Adequate | Randomization: Randomization was done with the help of a Clinical | Randomization: NR |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| | 23–26 weeks | Sample size justified: Yes | Trial Simulator, a web-based program | |
| PFMT and/or other lifestyle interventions | Manonai, 2006[558]<br>Sample: 42<br>Two 12-week diet periods and two 4-week washout periods. | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Baseline data provided with no analysis for incontinence rate. |
| PFMT and/or other lifestyle interventions | McDowell, 2006[560]<br>Sample: 30<br>24 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Computer generated randomization list. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | McDowell,1999[561]<br>Sample: 105<br>8 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Computer-generated stratified by cognitive ability, toileting skills, and severity of urinary incontinence randomization with permuted blocks. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | McFall, 2000[562]<br>Sample: 145<br>Length of treatment 12 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Miller,1998[564]<br>Sample: 27<br>1 week | Intention to treat: Not stated<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Baseline data is not reported |
| PFMT and/or other lifestyle interventions | Moore, 2003[565]<br>Sample: 145<br>12 weeks | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Computer-generated randomization stratified with respect to mild and moderate leakage with permuted blocks of 20. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Morkved, 2002[566]<br>Sample: 103<br>24 weeks | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Centralized but no computerized randomization stratified by results of a pad test with standardized bladder volume (20g or less and more than 20g of leakage). | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Du Moulin, 2007[567]<br>Sample: 38<br>24 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Random numbers table; general practitioners were randomized | Randomization No, mixed incontinence was more frequent in the intervention group, whereas stress incontinence was more frequent in the control group. Randomization did not provide balance between treatment groups |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| PFMT and/or other lifestyle interventions | Nager, 2009[568]<br>Sample: 445<br>Not reported | Intention to treat: No<br>Previously reported<br>Sample size justified: No | Randomization: Previously reported;<br>Randomization ignored in the article | Randomization: Adequate<br>The outcome - pessary fitting reported in total sample not by randomization status. |
| PFMT and/or other lifestyle interventions | Ng, 2008[569]<br>Sample: 88<br>12 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Nygaard,1996[572]<br>Sample: 71<br>12 weeks | Intention to treat: Yes<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization:<br>Randomization with random numbers table, in blocks of 4 | Randomization: Baseline data is not reported |
| PFMT and/or other lifestyle interventions | O'Brien, 1991[573]<br>Sample: 561<br>12 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Computer based randomization. | Randomization: Baseline data is not reported |
| PFMT and/or other lifestyle interventions | O'Brien,1996[574]<br>Sample: 292<br>4 years of followup | Intention to treat: No<br>Reported previously<br>Sample size justified: No | Randomization: Not reported | Randomization<br>Not relevant because the authors reported long term outcomes among all treated. The results reported ignoring randomization as non controlled study. |
| PFMT and/or other lifestyle interventions | O'Sullivan, 2003[576]<br>Sample: 150<br>12 weeks | Intention to treat: Yes<br>Adequate<br>Sample size justified: | Randomization: Stratified randomization;<br>randomization was stratified by mild and moderate incontinence | Randomization: Adequate<br>The authors reported outcomes by baseline severity status pooling active and control groups because they did not differ after interventions |
| PFMT and/or other lifestyle interventions | Pages, 2001[577]<br>Sample: 51<br>4 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization<br>Baseline data is not reported |
| PFMT and/or other lifestyle interventions | Richter, 2010[357]<br>Sample: 446 | Intention to treat: Yes<br>Adequate<br>Sample size justified: Yes | Randomization: Previously reported | Randomization<br>Adequate |
| PFMT and/or other lifestyle interventions | Sherman,1997[585]<br>Sample: 39<br>8 weeks | Intention to treat: Not stated<br>Allocation concealment not reported<br>Sample size justified: No | Randomization:<br>Randomization stratified by diagnosis of physical stress incontinence or mixed urge/stress incontinence. | Randomization: Adequate |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| PFMT and/or other lifestyle interventions | Subak, 2005[590]<br>Sample: 48<br>12 weeks | Intention to treat: Yes<br>Adequate<br>Sample size justified: Yes | Randomization: Randomization was stratified by type of incontinence, with randomly permuted blocks of 4. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Subak, 2009[591]<br>Sample: 338<br>24 weeks | Intention to treat: Not stated<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Randomization stratified random permuted blocks; 2:1 ratio with randomly permuted blocks of three or six, stratified according to clinical center | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Subak, 2002[589]<br>Sample: 152<br>6 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Computer based randomization. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Sung, 2000[593]<br>Sample: 60<br>6 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: The authors stated that they randomly selected patients for treatment. Unclear was it invitation for the study or treatment assignment | Randomization: Baseline data is not reported |
| PFMT and/or other lifestyle interventions | Swithinbank, 2005[594]<br>Sample: 69<br>4 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Baseline data is not reported |
| PFMT and/or other lifestyle interventions | Tibaek, 2007[595]<br>Sample: 24<br>12 weeks | Intention to treat: Not stated<br>Reported previously<br>Sample size justified: No | Randomization: Not reported | Randomization: Stated as adequate (no data provided) |
| PFMT and/or other lifestyle interventions | Theofrastous, 2002[596]<br>Sample: 137<br>12 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Thornburn,1997[597]<br>Sample: 20<br>1 week | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization Baseline data is not reported Unclear because baseline characteristics of women were not reported |
| PFMT and/or other lifestyle interventions | Tibaek, 2004[599]<br>Sample: 26<br>12 weeks | Intention to treat: No<br>Allocation concealment not adequate<br>Sample size justified: No | Randomization: Simple random numbers table | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Tibaek, 2005[600]<br>Sample: 26<br>12 weeks | Intention to treat: No<br>Allocation concealment not adequate<br>Sample size justified: No | Randomization: Randomization with a table of random numbers; Randomization with a table of random numbers | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Tsai, 2009[601]<br>Sample: 108<br>12 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Random permuted blocks; block size 2 | Randomization: Adequate |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| PFMT and/or other lifestyle interventions | Wang, 2004[602]<br>Sample: 120<br>12 weeks | Intention to treat: No<br>Adequate<br>Sample size justified: Yes | Randomization: Central computer-generated randomization in blocks of 6. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Wells,1991[603]<br>Sample: 157<br>24 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Williams, 2005[604]<br>Sample: 3746<br>24 weeks | Intention to treat: Yes<br>Adequate<br>Sample size justified: Yes | Randomization: Randomization by household, at a ratio of 4:1 in favor of the continence nurse practitioner. | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Williams, 2006[605]Sample: 238<br>12 weeks | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Wing, 2010[606]<br>Sample: 338 | Intention to treat: Yes<br>Reported previously<br>Sample size justified: Yes | Randomization: Randomly allocated in a 2:1 ratio | Randomization Adequate |
| PFMT and/or other lifestyle interventions | Wong, 2001[607]<br>Sample: 38<br>4 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Permuted block randomization; blocks of 2 | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Wyman,1997[608]<br>Sample: 131<br>6 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Stratified by type of incontinence | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Wyman,1998[609]<br>Sample: 204<br>12 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Stratified on the basis of their urodynamic diagnostic categorization (genuine stress incontinence or detrusor instability with or without genuine stress incontinence), baseline incontinence severity (1 to 9 incontinent episodes, 10 to 25 episodes, or 26 or greater episodes per week), and treatment site | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Yoon, 2003[612]<br>Sample: 50<br>8 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Zanetti, 2007[613]<br>Sample: 44<br>12 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Stratified randomized computer-generated random number table;<br>Stratified by the satisfaction with the previous therapy | Randomization: Adequate |
| PFMT and/or other lifestyle interventions | Tomlinson,1999[615]<br>Sample: 135<br>12 weeks | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate<br>The results are reported after active treatment only |
| PFMT and/or | Clarke-O'Neill, | Intention to treat: Yes | Randomization: | Randomization |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| other lifestyle interventions | 2002[614]<br>Sample: 72<br>1 week | Allocation concealment unclear<br>Sample size justified: Yes | Randomization using Latin squares;<br>Not reported | Cross over trial differences in quality of life were calculated adjusting for baseline level, number of days practiced the intervention or in wait list group, age, hormone status, and race |
| Electrostimulation | Finazzi Agro, 2005[470]<br>Sample: 35<br>2-8 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Baseline data is not reported |
| Electrostimulation | Amaro, 2005[473]<br>Sample: 40<br>4 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Adequate |
| Electrostimulation | Amaro, 2006[474]<br>Sample: 40<br>7 weeks | Intention to treat: Not stated<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Adequate |
| Electrostimulation | Barroso,2004[481]<br>Sample: 36<br>12 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Randomization before the study by drawing lots | Randomization: Adequate |
| Electrostimulation | Berghmans, 2002[483]<br>Sample: 98<br>9 weeks | Intention to treat: Yes<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Randomization using blocks of 4. | Randomization: Adequate |
| Electrostimulation | Blowman, 1991[484]<br>Sample: 14 | Intention to treat: Not reported<br>Sample size justified: Not reported | Randomization: Not reported | Randomization: Not reported |
| Electrostimulation | Bo,1997[485]<br>Sample: 12<br>1 day experiment | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization Baseline data is not reported |
| Electrostimulation | Bo,1999[486]<br>Sample: 122<br>24 weeks | Intention to treat: Yes<br>Unclear<br>Sample size justified: Yes | Randomization: Computer generated random numbers stratified by baseline leakage | Randomization: Adequate |
| Electrostimulation | Borawski, 2007[489]<br>Sample: 30<br>2 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Not reported | Randomization: No |
| Electrostimulation | Borello-France, 2008[491]<br>Sample: 28<br>24 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Randomization stratified random permuted blocks Four blocks with 12 assignments each stratified by age (within 5 years) and incontinence severity minimal | Randomization: Adequate |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| | | | (<5 urine leakage episodes per week), moderate (5–10 urine leakage episodes per week), or severe (>10 urine leakage episodes per week). | |
| Electrostimulation | Bower,1998[493]<br>Sample: 48<br>Unclear | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Not reported | Randomization: Adequate |
| Electrostimulation | Brubaker,1997[496]<br>Sample: 121<br>8 weeks | Intention to treat: No<br>Allocation concealment unclear but centralized data manager blinded for treatment status analyzed the data.<br>Sample size justified: No | Randomization: Computer generated randomization stratified by incontinence type. | Randomization: Adequate |
| Electrostimulation | But, 2003[501]<br>Sample: 55<br>Length of treatment 8 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Electrostimulation | But, 2005[502]<br>Sample: 39<br>8 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Baseline data is not reported |
| Electrostimulation | Demirturk, 2008[508]<br>Sample: 41<br>5 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization by application order;<br>Not reported | Randomization: Adequate |
| Electrostimulation | Dumoulin, 2004[514]<br>Sample: 64<br>8 weeks | Intention to treat: Not stated<br>Adequate<br>Sample size justified: Yes | Randomization: Stratified randomization by the results from pad test using a balanced block randomization schedule generated from a table of random numbers. | Randomization: Adequate |
| Electrostimulation | Emmons, 2005[516]<br>Sample: 85<br>4 weeks | Intention to treat: No<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: Computer-generated randomization with random numbers table. | Randomization: Adequate |
| Electrostimulation | Fujishiro,2000[520]<br>Sample: 62<br>1 week | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Electrostimulation | Fujishiro, 2002[521]<br>Sample: 37<br>1 week | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Electrostimulation | Jeyaseelan, 2000[536]<br>Sample: 27<br>8 weeks | Intention to treat: Not stated<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization: computer-generated table of random numbers | Randomization: Adequate |
| Electrostimula | Karademir, | Intention to treat: Not | Randomization: Not reported | Randomization: |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| tion | 2005[315]<br>Sample: 43<br>8 weeks | stated<br>Allocation concealment not reported<br>Sample size justified: No | | Baseline data reported for age only. |
| Electrostimulation | Kim, 2008[540]<br>Sample: 52<br>12 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Electrostimulation | Lappin, 2003[547]<br>Sample: 145<br>10 weeks, 2 weeks washout period. | Intention to treat: No Adequate<br>Sample size justified: No | Randomization: Central computer generated randomization. | Randomization: Adequate |
| Electrostimulation | Luber,1997[554]<br>Sample: 57<br>12 weeks | Intention to treat: Not stated<br>Allocation concealment not adequate<br>Sample size justified: Yes | Randomization using the table of random numbers | Randomization: Adequate |
| Electrostimulation | Manganotti, 2007[557]<br>Sample: 20<br>2 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Baseline data is not reported |
| Electrostimulation | Oldham, 2010[575]<br>Sample: 128 | Intention to treat: NR<br>Randomly allocated by a computer-generated randomization list<br>Sample size justified: Yes | Randomization: Not reported | Randomization NR |
| Electrostimulation | Peters, 2010[578]<br>Sample: 150 | Intention to treat: Not reported<br>Sample size justified: Yes | Randomization: Subjects were randomized 1:1 at the first intervention visit to PTNS or sham using a random block design stratified by investigational site | Randomization: Adequate |
| Electrostimulation | Ramsay, [579]<br>Sample: 74<br>1 week | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: computer-generated random number | Randomization: Adequate<br>Multiple-imputation with missing data |
| Electrostimulation | Sand, 1995[582]<br>Sample: 52<br>15 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Computer-generated random numbers with blocks at a 2:1 rate favoring active over placebo devices. | Randomization: Adequate |
| Electrostimulation | Smith,1996[586]<br>Sample: 57<br>16 weeks | Intention to treat: Intention to treat not stated<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Electrostimulation | Spruijt, 2003[587]<br>Sample: 51<br>8 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Blocked randomization (Pocock). | Randomization: Adequate |
| Electrostimulation | Sung, 2000[592]<br>Sample: 90 | Intention to treat: Yes<br>Allocation concealment not | Randomization: Not reported | Randomization: Baseline data is |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| | 6 weeks | reported<br>Sample size justified: No | | not reported |
| Electrostimulation | Yamanishi,1997[610]<br>Sample: 35<br>4 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Electrostimulation | Yamanishi, 2000[611]<br>Sample: 68<br>4 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Bulking agents or medical devices | Appell, 2006[476]<br>Sample: 173<br>48 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Computer generated randomization with ratio 2:1 | Randomization: Adequate |
| Bulking agents or medical devices | Bano, 2005[480]<br>Sample: 50<br>Length of treatment 6 months | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Bulking agents or medical devices | Corcos, 2005[506]<br>Sample: 133<br>48 weeks | Intention to treat: Yes<br>Adequate<br>Sample size justified: Yes | Randomization: Centralized randomization stratified by center with randomly distributed blocks 4 and 6 in size. | Randomization: Adequate |
| Bulking agents or medical devices | Ghoniem, 2009[524]<br>Sample: 260<br>24 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: Yes | Randomization: Not reported<br>1:1 ratio | Randomization: Adequate |
| Bulking agents or medical devices | Lee, 2001[549]<br>Sample: 68<br>Duration of followup: 24 months | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: Yes | Randomization: Computerized randomization with random number tables | Randomization: Adequate |
| Bulking agents or medical devices | Lightner, 2001[552]<br>Sample: 355<br>48 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Baseline data is not reported |
| Bulking agents or medical devices | Lightner, 2009[553]<br>Sample: 344<br>12 weeks | Intention to treat: Not stated<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Random permuted blocks;<br>2:1 allocation ratio of Zuidex to Contigen | Randomization: Adequate<br>adjustment for age, race, partner status, parity, hysterectomy, oophorectomy, menopausal status, general health, depression symptoms, systemic estrogen use, SSRI use, clinical severity of incontinence, clinical type of |

**Appendix Table 82. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)**

| Treatment | Reference Sample Length of Treatment | Intention to Treat Allocation Concealment Justification of the Sample Size | Randomization | Bias |
|---|---|---|---|---|
| | | | | incontinence, BMI and clinical site |
| Bulking agents or medical devices | Mayer, 2007[559]<br>Sample: 296<br>24 weeks | Intention to treat: Yes<br>Adequate - central computerized tables generated by Statistical Analysis Systems<br>Sample size justified: Yes | Randomization: Random numbers tables generated by Statistical Analysis Systems | Randomization: Adequate<br>Not relevant |
| Bulking agents or medical devices | Schulz, 2004[583]<br>Sample: 40<br>Duration of followup: 12 months | Intention to treat: Yes<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Computer generated block randomization scheme. | Randomization: Adequate |
| Bulking agents or medical devices | Strasser, 2007[588]<br>Sample: 63<br>48 weeks | Intention to treat: Yes<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Computer-generated randomization list with permuted blocks and ratio of 2:1. | Randomization: Adequate |
| Bulking agents or medical devices | Andersen, 2002[475]<br>Sample: 52<br>Single injection | Intention to treat: No<br>Allocation concealment unclear<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Bulking agents or medical devices | Laycock, 2001[548]<br>Sample: 101<br>12 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Permuted block randomization in ratio 2:2:1 | Randomization: Baseline data is not reported |
| Bulking agents or medical devices | Nielsen, 1993[570]<br>Sample: 40<br>2 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Baseline data is not reported |
| Bulking agents or medical devices | Nygaard, 1995[571]<br>Sample: 20<br>Three exercise sessions | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Block randomization | Randomization: Baseline data is not reported |
| Bulking agents or medical devices | Robinson, 2003[581]<br>Sample: 24<br>Duration of followup: 4 months | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Adequate |
| Bulking agents or medical devices | Seo, 2004[584]<br>Sample: 120<br>6 weeks | Intention to treat: Not stated<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Not reported | Randomization: Baseline data is not reported |
| Bulking agents or medical devices | Thyssen, 2001[598]<br>Sample: 94<br>5 weeks | Intention to treat: No<br>Allocation concealment not reported<br>Sample size justified: No | Randomization: Block randomization; | Randomization: Baseline data is not reported |

**Appendix Table F83. Comparative effectiveness of nonpharmacological treatments on improvement of incontinence**

| Active | Control | Studies Reference | Number of Subjects | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events 95% CI) | Evidence |
|---|---|---|---|---|---|---|---|---|
| Continence service | Bladder training | 1 study[579] | 74 | Not significant | | | | Insufficient |
| Bladder training with audiotape about PFMT | Bladder training | 1 study[513] | 40 | 1.72 (1.10; 2.69) | 0.38 (0.12; 0.64) | 3 (2; 8) | 378 (121; 636) | Insufficient |
| PFMT | Behavioral intervention | 1 study[605] | 238 | Not significant | | | | Insufficient |
| PFMT+ BT | PFMT | 1 study[541] | 224 | Inconsistent across definition benefit | | | | Insufficient |
| Individual PFMT+ bladder training | Group | 1 study[535] | 530 | Not significant | | | | Insufficient |
| Circular muscle exercises (Paula method) | PFMT group | 1 study[550] | 240 | 1.26 (1.02; 1.57) | 0.14 (0.01; 0.26) | 7 (4; 69) | 138 (15; 261) | Insufficient |
| PFMT+ EMG biofeedback | PFMT | 3 studies[482,498,616] | 322 | Inconsistent across definition benefit | | | | Low |
| PFMT | PFMT+ vaginal balls | 1 study[477] | 37 | 1.49 (0.74; 2.98) | 0.19 (-0.13; 0.51) | 5 (2; -8) | 190 (-126; 506) | Insufficient |
| PFMT | Vaginal cone | 1 study[605] | 238 | Not significant | | | | Insufficient |
| Physiotherapy + biofeedback | Physiotherapy | 1 study[526] | 40 | Not significant | | | | Insufficient |
| Group physiotherapy | Biofeedback | 1 study[577] | 40 | Not significant | | | | Insufficient |
| Vaginal cone therapy | Bladder training | 1 study[605] | 238 | Not significant | | | | Insufficient |
| Contrelle Continence Tampon, CCT | Conveen Continence device Guard, CCG | 1 study[598] | 94 | Not significant | | | | Insufficient |
| Durasphere | Contigen | 1 study[475] | 52 | 1.54 (0.99; 2.38) | 0.27 (0.02; 0.52) | 4 (2; 56) | 269 (18; 521) | Insufficient |

**Appendix Table F83. Comparative effectiveness of nonpharmacological treatments on improvement of incontinence (continued)**

| Active | Control | Studies Reference | Number of Subjects | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events 95% CI) | Evidence |
|---|---|---|---|---|---|---|---|---|
| Urethral device (NEAT) packaged with device | Reliance Insert sterile balloon | 1 study[581] | 24 | Not significant | | | | Low |
| Durasphere | Bovine collagen | 1 study[552] | 364 | Not significant | | | | |
| Porcine dermal implant injection (Permacol) | Silicone injection (Macroplastique | 1 study[480] | 50 | Not significant | | | | Insufficient |
| Periurethral dextran copolymer | Transurethral agent-dextran copolymer | 1 study[583] | 40 | Not significant | | | | Insufficient |
| Calcium hydroxylapatite (CaHA | Bovine Dermal Collagen | 1 study[559] | 296 | Not significant | | | | Insufficient |
| Autologous myoblasts and fi broblasts | Collagen | 1 study[588] | 63 | Not significant | | | | Insufficient |
| Transurethral injection of Macroplastique | Transurethral injection of Contigen® | 1 study[524] | 247 | Inconsistent across definition benefit | | | | |
| Zuidex Implacer | Contigen endoscopic guidance | 1 study[553] | 344 | Inconsistent across definition benefit | | | | Insufficient |

**Appendix Table F84. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials**

| Reference | Aim | N | % Women | % With UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|
| Hahn, 1991[618] | To evaluate the function of the pelvic floor and urethral sphincters before and after Contelle device | 20 | 100 | 100 | Pelvic floor training and electrical stimulation with Contelle device (the device was to used for 8-10 hours/night at maximally tolerable intensities) | 6 months | Women with genuine stress incontinence | Very few reliable correlations between symptomatic improvement and urodynamic improvement were found |
| Laycock, 1993[619] | To evaluate the effect of transcutaneous, pre-modulated interferential stimulation on the symptoms of female stress incontinence, by two prospective clinical trials | 46 in first trial and 30 in second trial | 100 | 100 | Interferential pelvic floor therapy using an Endomed 433 (Enraf Nonius, Delft, Holland) for 15 minutes (on average ten sessions). Instructions: Pelvic Floor Exercises. | 6 weeks | Women with urodynamically proven GSI and sterile urine. In the first trial, women were randomized into 2 groups: group 1 received a course of interferential stimulation and group 2 a course of PFMT and weighted vaginal cones therapy. In the second trial, women were randomized into active interferential stimulation and placebo groups. | There was no significant difference in severity of urinary incontinence between the two groups in trial 1 (p=0.4851). In trial 1: 43.5% of patients receiving IFT (n=23) were improved or cured (objectively measured), and 60.9% subjectively classified improved or cured. In trial 2: In the active IFT group: Pad test results showed: 6.7% worse, 6.7% no change, 60% improved, and 13.3% cured, and in the placebo group: 36.4% were worse, 0.7% showed no change, 45.5% improved, and 0% cured. For subjective assessment: in the active IFT group: 6.7% were worse, 60% showed no change, 33.3% improved, and 0% cured and in the placebo group: 54.5% were worse, 18.2% showed no change, 27.3% improved, and 0% cured. For difference in VAS score: in the active IFT group: 26.7% were worse, 0% no change, 73.3% improved, and 0% cured and in the placebo group: 36.4% were |

**Appendix Table F84. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials (continued)**

| Reference | Aim | N | % Women | % With UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | worse, 9.1% showed no change, 54.5% improved, and 0% cured |
| Borello-France, 2010[620] | To describe adherence to PFMT, barriers, and predictors of exercise adherence in women with urge-predominant UI. | 154 | 100 | 100 | Either tolterodine tartrate extended release capsules 4 mg daily or tolterodine tartrate extended release capsules 4 mg daily combined with a behavioral intervention | 10 weeks | BE-DRI trial: Secondary data analysis. Community-dwelling women with pure or predominant UUI , recruited through the investigators' clinical practices, study announcements, advertisements, and referrals, had post-void residual volume of less than 150 mL and the ability to contract their PFMs, had to show 7 or more episodes of UI on a 7-day baseline diary, and had to self-report persistent UI for at least 3 months, no current use of antimuscarinics or other medications that could affect UI, and no history of neurologic diseases or conditions (e.g., Parkinson disease, multiple sclerosis, spina bifida, spinal cord injury) or systemic diseases known to affect bladder function. | At 12 months 42% (41) of total women had difficulty to find time to do all of the exercises; 56% (54) had difficulty remembering to exercise; 30% (28) perceived exercises did not help. During the intervention period: Adjusted regression coefficient: Total number of reported barriers to exercise adherence: -2.0 (95% CI=-3.1, -0.9) p-value=0.0007; Barrier: Difficult to find time to do all of the exercises: -7.7 (95% CI=-11.1, -4.4) p-value=<0.001; Barrier: Difficulty remembering to exercise: -7.5 (95% CI=-10.8, -4.2) p-value <0.001; Barrier: Perceived exercises do not help: 4.2 (95% CI=0.4, 8.0) p-value 0.03; Barrier: Other: -4.0 (95% CI=-8.1, -0.03) p-value=0.048. During the followup period: Adjusted Regression Coefficient: Barrier: Difficult to find time to do all of the exercises: -2.5 (95% CI= -4.7, -0.2) p-value=0.03. (Adjusted for age, education, race/ethnicity, Medical, Epidemiological, and Social Aspects of Aging Questionnaire (MESA) urge index, MESA stress index, volume of fluid intake pretreatment, and clinical site. Regression coefficient is the change in contractions per day per unit increase in total barriers |

**Appendix Table F84. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials (continued)**

| Reference | Aim | N | % Women | % With UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | or for endorsement of individual barrier versus no endorsement of that barrier) |
| Griffiths, 2009[621] | To explore the concerns and expectations of women invited to attend group physiotherapy sessions for the management of female UI and whether the experience changed their views; and to gather recommenda-tions from women attending group sessions on the design and delivery of these sessions | 22 | 100 | 100 | Group treatment | 3 weeks | Women who had participated in a randomized clinical trial comparing individual and group treatment, who had stress, urge or mixed incontinence and were recruited to one of five physiotherapy centers in the West Midlands of the UK. Of these women those who had expressed a preference for individual sessions, but were randomized to group sessions and attended at least one session were recruited for an interview study. | It is necessary to consider reducing embarrassment and uncertainty in women who attend group sessions run in physiotherapy departments for urinary incontinence prior to their attendance |
| Engberg, 2009[622] | To examine the feasibility of recruiting women into a clinical trial designed to examine the efficacy of acupuncture in treating urge and mixed UI and the feasibility of performing the planned study | 11 | 100 | 100 | Acupuncture: 12 treatments over 6 weeks. Control group was given sham acupuncture treatment | 6 weeks | Women, aged 40 to 70 years of age, having urge or mixed urge and stress urinary accidents at least twice a week on average and have been incontinent for at least 3 months | Subjects randomized to true acupuncture group had a mean 67.47% (median=75.76%) reduction in daytime accidents/day at 4 weeks post acupuncture, whereas the mean reduction in daytime accidents was 16.67% (median=0%) at 4 weeks post-sham acupuncture. There were no significant group differences in changes in the scores on the quality-of-life measures. Subjects' perceptions about whether they had received the |

**Appendix Table F84. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials (continued)**

| Reference | Aim | N | % Women | % With UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|
| | procedures | | | | | | | true or sham acupuncture were not significantly better than one would expect by chance. |
| MacDiarmid, 2010[623] | To examine percutaneous tibial nerve stimulation on U I ( ORBIT trial) | 100 | 90% | Not reported | Weekly 30 minute treatment | 12 weeks followed by therapy at tapered intervals for 9 months | Ambulatory adults with AOB symptoms, with or without a history of previous anticholinergic drug use, with at least 8 voids per 24 hours documented by history and physical and voiding diary | Subjects received as low as 1.2 treatments monthly to sustain symptom improvement throughout 12 months. The response to PTNS therapy achieved following 12 weeks of treatment demonstrates excellent durability through 12 months of followup with 94% sustained improvement from 12 weeks. Analysis of number of treatments needed to sustain therapeutic effect appears acceptable |
| Dunn, 2002[624] | To evaluate the short- and medium-term effectiveness of an intraurethral device (FemSoft Insert, Rochester Medical Corporation, Stewartville, Minnesota) in the treatment of exercise-induced incontinence in women | 6 | 100% | 100% | Urethral insert | 3 months+ | Female patients 18 years and older, having stress incontinence during exercise that required pads or clothing changes, being able to perform regular aerobic exercise, and having adequate manual dexterity and intelligence to use the device and complete the subject questionnaires. | This pilot study found that urethral insert is effective and feasible for unsupervised home use. After 3 months, mean satisfaction scores for ease of use were 2.09 for insertion and 1.18 for removal; for comfort, the scores were 2.18 for insertion, 2.05 while wearing, and 1.36 during removal (on a 5-point scale, 1 = very comfortable/satisfied, 5 = very uncomfortable/unsatisfied). |
| Borello-France, 2010[620] | To examine adherence to exercise therapy and barriers for | 154 | 100% | 100% | Behavioral intention: Pelvic floor muscle training, bladder training, and | 10 week study with one-year followup | Adults with OAB | By end of one-year followup period, only 32% of women were exercising at least 5 to 6 days per week.<br>The barriers to exercise |

**Appendix Table F84. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials (continued)**

| Reference | Aim | N | % Women | % With UI | Treatment | Duration | Population | Results |
|---|---|---|---|---|---|---|---|---|
| | adherence | | | | individualized fluid management for those with excessive urine output (>70 oz per day) | | | adherence were: 42% had difficulty finding time to do all of the exercises; 56% had difficulty remembering to exercise, and 30% perceived exercises did not help. |

**Appendix Table F85. Clinical outcomes after bladder training compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CIl) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Continence | Fantl, 1991[518] | 8/65 | 2/66 | 4.06 (0.90; 18.41) | | 0.09 (0.00; 0.18) | | Yes |
| Treatment failure | Fantl, 1991[518] | 5/65 | 28/66 | 0.18 (0.07; 0.44) | | -0.35 (-0.48; -0.21) | | Yes |
| Improved UI | Subak, 2002[589] | 39/77 | 11/75 | 3.41 (1.89; 6.15) | 37 | 0.35 (0.22; 0.49) | 52 | Yes |
| Improved UI | Fantl, 1991[518] | 49/65 | 16/66 | 3.11 (1.99; 4.87) | 63 | 0.51 (0.36; 0.66) | 48 | Yes |
| Pooled | | 87/ | 27/ | 3.22 (2.25; 4.60) | 100 | 0.43 (0.28; 0.59) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.81 | 0.00 | 0.12 | 58 | |

**Appendix Table F86. Improvement in UI after nonpharmacological treatments compared to no active treatment**

| Treatment | Studies/ Patients | Rate in Active/ control | Relative Risk (95% CI) | Absolute Risk Difference 95% CI) | Number needed to Treat (95% CI) | Attributable Events (95% CI) | Bayesian Odds Ratio Median (2.5%; 97.5%) | Level of Evidence |
|---|---|---|---|---|---|---|---|---|
| Continence Service | 2[574,604]/4038 | 62.6/53.5 | 1.33 (1.06; 1.68) | 0.20 (-0.01; 0.41) | | | | Low |
| Bladder Training | 2[518,589]/283 | 61.4/19.2 | 3.22 (2.25; 4.60) | 0.43 (0.28; 0.56) | 2 (2; 4) | 430 (275; 585) | 8 (3; 20) | Low |
| Pelvic Floor Muscle Training | 6[246,471,499,500,534,545]/510 | 56.9/14.7 | 5.44 (1.57; 18.83) | 0.41 (0.17; 0.65) | 2 (2; 6) | 412 (174; 649) | 14 (3; 69) | High |
| Pelvic Floor Muscle Training + Bladder Training | 4[509,544,563,573]/1171 | 53.3/22.5 | 4.13 (1.58; 10.78) | 0.39 (0.17; 0.60) | 3 (2; 6) | 387 (171; 603) | 8 (2; 41) | High |
| Pelvic Floor Muscle Training with Biofeedback | 4[286,471,499,500]/383 | 60.1/18.6 | 3.93 (1.00; 15.49) | 0.39 (0.17; 0.61) | 3 (2; 6) | | | High |
| Electrical Stimulation | 8[246,474,486,496,554,582,610,611]/582 | 31.7/15.1 | 2.01 (1.28; 3.15) | 0.16 (0.04; 0.23) | 6 (4; 12) | 156 (84; 228) | 3 (2; 6) | High |
| Percutaneous Electrical Stimulation | 2[354,578]/370 | 37.3/21.9 | 1.70 (1.22; 2.36) | 0.15 (0.06; 0.24) | 7 (4; 16) | 152 (61; 244) | 2 (1; 5) | Low |
| Magnetic Stimulation | 3[501,502,520]/153 | 46.8/21.2 | 2.30 (1.43; 3.71) | 0.27 (0.11; 0.42) | 4 (2; 9) | 265 (112; 417) | 4 (2; 12) | Moderate |
| Weight Loss | 2[590,591]/386 | 42.8/20.8 | 2.17 (1.26; 3.76) | 0.27 (0.06; 0.49) | 4 (2; 18) | 273 (57; 490) | 3 (1; 10) | Moderate |
| Bulking Agents | 2[476,549]/241 | | Not significant | | | | | Low |

**Appendix Table F87. Clinical outcomes after pelvic floor muscle training compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Continence | Hung, 2010[534] | 5/35 | 1/35 | 5.00 (0.62; 40.64) | 6 | 0.11 (-0.01; 0.24) | 12 | Not reported |
| Continence | Kim, 2009[537] | 34/74 | 10/73 | 3.35 (1.79; 6.28) | 19 | 0.32 (0.18; 0.46) | 12 | Yes |
| Continence | Lagro-Janssen, 1991[545] | 7/33 | 1/33 | 7.00 (0.91; 53.78) | 6 | 0.18 (0.03; 0.33) | 12 | No |
| Continence | Burns, 1993[500] | 7/43 | 1/39 | 6.35 (0.82; 49.32) | 6 | 0.14 (0.02; 0.26) | 13 | Yes |
| Continence | Bo, 1999[486] | 11/29 | 2/32 | 6.07 (1.47; 25.12) | 10 | 0.32 (0.12; 0.51) | 10 | No |
| Continence | Aksac, 2003[471] | 15/20 | 0/10 | 16.24 (1.07; 246.51) | 4 | 0.75 (0.53; 0.97) | 9 | No |
| Continence | Williams, 2006[605] | | | 1.59 (0.43; 5.87) | | | | Yes |
| Continence | Kim, 2007[539] | 19/35 | 3/35 | 6.33 (2.06; 19.49) | 13 | 0.46 (0.27; 0.65) | 10 | No |
| Continence | Castro, 2008[246] | 10/31 | 3/30 | 3.23 (0.98; 10.59) | 12 | 0.22 (0.03; 0.42) | 10 | Not reported |
| Continence | Hung, 2010[534] | 34/35 | 23/35 | 1.48 (1.16; 1.89) | 23 | 0.31 (0.15; 0.48) | 11 | Not reported |
| Pooled | | 142/414 | 45/401 | 4.35 (2.83; 6.7) | 100 | 0.30 (0.17; 0.42) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.90 | 0 | 0 | 79.2 | |
| Improved UI | Aksac, 2003[471] | 5/20 | 2/10 | 1.25 (0.29; 5.35) | 18 | 0.05 (-0.26; 0.36) | 14 | No |
| Improved UI | Castro, 2008[246] | 12/31 | 2/30 | 5.81 (1.42; 23.79) | 18 | 0.32 (0.13; 0.51) | 17 | Not reported |
| Improved UI | Burns, 1990[499] | 21/38 | 0/40 | 45.21 (2.83; 720.96) | 11 | 0.55 (0.39; 0.71) | 17 | Yes |
| Improved UI | Burns, 1993[500] | 23/43 | 2/39 | 10.43 (2.63; 41.39) | 18 | 0.48 (0.32; 0.65) | 17 | Yes |
| Improved UI | Hung, 2010[534] | 25/35 | 21/35 | 1.19 (0.85; 1.68) | 23 | 0.11 (-0.11; 0.34) | 16 | Not reported |
| Improved UI | Lagro-Janssen, 1991[545] | 28/33 | 0/33 | 57.00 (3.62; 896.38) | 11 | 0.85 (0.718; 0.98) | 18 | No |
| Pooled | | 114/200 | 27/187 | 5.44 (1.57; 18.83) | 100 | 0.41 (0.17; 0.65) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.00 | 80.00 | 0.00 | 90.00 | |
| Treatment failure | Hung, 2010[534] | 0/35 | 1/35 | 0.33 (0.01; 7.91) | 12 | -0.03 (-0.10; 0.05) | 39 | Not reported |
| Treatment failure | Bo, 2000[487] | 1/29 | 12/30 | 0.09 (0.01; 0.62) | 24 | -0.37 (-0.55; -0.18) | 32 | |

**Appendix Table F87. Clinical outcomes after pelvic floor muscle training compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Treatment failure | Castro, 2008[246] | 11/31 | 19/30 | 0.56 (0.32; 0.97) | 64 | -0.28 (-0.52; -0.04) | 29 | Not reported |
| Pooled | | 12/95 | 32/95 | 0.33 (0.102; 1.10) | 100 | -0.21 (-0.45; 0.02) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.20 | 39.00 | 0.00 | 84.80 | |

**Appendix Table F88. Clinical outcomes after pelvic floor muscle training combined with bladder training compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Continence | Lagro-Janssen, 1992[544] | 10/54 | 1/56 | 10.37 (1.37; 78.28) | 12 | 0.17 (0.06; 0.28) | 19 | Yes |
| Continence | McFall,2000[563] | 25/72 | 15/73 | 1.69 (0.97; 2.93) | 30 | 0.14 (-0.00; 0.29) | 17 | Yes |
| Continence | Kumari, 2008[543] | 30/78 | 1/86 | 33.08 (4.62; 236.86) | 13 | 0.37 (0.26; 0.48) | 19 | Yes |
| Continence | O'Brien, 1991[573] | 32/378 | 1/183 | 15.49 (2.13; 112.49) | 13 | 0.08 (0.045; 0.11) | 24 | Yes |
| Continence | Diokno, 2004[509] | 61/164 | 55/195 | 1.32 (0.98; 1.78) | 32 | 0.09 (-0.01; 0.19) | 20 | Not reported |
| Pooled | | 158/746 | 72/593 | 3.79 (1.55; 9.27) | 100 | 0.166 (0.06; 0.27) | 100 | |
| Heterogeneity p value<br>I squared | | | <0.05 | 79 | | <0.05 | 85.2 | |
| Improved UI | McFall,2000[563] | 30/49 | 22/59 | 1.64 (1.10; 2.45) | 28 | 0.24 (0.055; 0.42) | 23 | Yes |
| Improved UI | Lagro-Janssen, 1992[544] | 40/54 | 2/56 | 20.74 (5.27; 81.63) | 18 | 0.71 (0.58; 0.83) | 25 | Yes |
| Improved UI | Diokno, 2004[509] | 92/164 | 80/195 | 1.37 (1.10; 1.70) | 29 | 0.15 (0.05; 0.25) | 26 | Not reported |
| Improved UI | O'Brien, 1991[573] | 182/378 | 7/183 | 12.59 (6.04; 26.22) | 25 | 0.44 (0.39; 0.50) | 27 | Yes |
| Pooled | | 344/645 | 111/493 | 4.13 (1.58; 10.78) | 100 | 0.39 (0.17; 0.60) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.00 | 93.00 | 0.00 | 0.94 | |
| Treatment failure | Lagro-Janssen, 1992[544] | 1/54 | 2/56 | 0.52 (0.05; 5.55) | 8 | -0.02 (-0.08; 0.04) | 87 | Yes |
| Treatment failure | McFall, 2000[562] | 10/49 | 15/59 | 0.80 (0.40; 1.62) | 92 | -0.05 (-0.21; 0.11) | 13 | Yes |
| Pooled | | 11/103 | 17/115 | 0.78 (0.39; 1.52) | 100 | -0.02 (-0.78; 0.04) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.7 | 0 | 0.7 | 0 | |
| Treatment discontinuation | McFall, 2000[562] | 7/49 | 5/59 | 1.69 (0.57; 4.98) | 38 | 0.06 (-0.06; 0.18) | 40 | Yes |
| Treatment discontinuation | Kumari, 2008[543] | 9/78 | 10/86 | 0.99 (0.43; 2.31) | 62 | -0.00 (-0.10; 0.10) | 60 | Yes |
| Pooled | | 16/127 | 15/145 | 1.21 (0.62; 2.36) | 100 | 0.02 (-0.05; 0.10) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.45 | 0.00 | 0.46 | 0.00 | |

**Appendix Table F89. Clinical outcomes after pelvic floor muscle training combined with bladder training when compared to no active treatment, individual RCTs**

| Reference Sample/Men | Active | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Lagro-Janssen, 1992[544] 110/0 | PFMT alone (stress) or bladder training (urge) or its combination (mixed) | Self reported severe urinary incontinence | 54/56 | 4/7 | 23/41 | 0.18 (0.07; 0.49) | -0.34 (-0.48; -0.19) | -3 (-5; -2) | -337 (-483; -190) |
| | | Self reported deterioration in urinary incontinence | 54/56 | 1/2 | 2/3 | 0.52 (0.05; 5.55) | -0.02 (-0.08; 0.04) | | |
| McFall, 2000[562] 108/0 | Community based small group educational intervention: PFMT + bladder training | Withdraw | 49/59 | 7/14 | 5/8 | 1.69 (0.57; 4.98) | 0.06 (-0.06; 0.18) | | |
| | | No reduction in number of incontinence episodes | 49/59 | 10/20 | 15/25 | 0.80 (0.40; 1.62) | -0.05 (-0.21; 0.11) | | |
| | | Self reported bothersomeness of urinary incontinence | 72/73 | 42/59 | 62/85 | 0.69 (0.55; 0.85) | -0.27 (-0.41; -0.13) | -4 (-8; -2) | -266 (-406; -126) |
| McFall, 2000[562] 145/0 | Community-based intervention: bladder training, and PFMT | Use absorbent pads for urinary incontinence | 72/73 | 39/54 | 56/77 | 0.71 (0.55; 0.90) | -0.23 (-0.38; -0.07) | -4 (-13; -3) | -225 (-376; -75) |
| Kumari, 2008[543] 164/0 | Behavioral treatment with PFMT + bladder retraining | Death | 78/86 | 2/3 | 1/1 | 2.21 (0.20; 23.85) | 0.01 (-0.03; 0.06) | | |
| | | Stress incontinence 3 months after intervention | 78/86 | 11/14 | 27/31 | 0.45 (0.24; 0.84) | -0.17 (-0.30; -0.05) | -6 (-21; -3) | -173 (-298; -48) |
| | | Stress incontinence 6 months after intervention | 78/86 | 9/12 | 22/26 | 0.45 (0.22; 0.92) | -0.14 (-0.26; -0.02) | -7 (-41; -4) | -140 (-257; -24) |
| | | Stress incontinence | 78/86 | 15/19 | 28/33 | 0.59 (0.34; 1.02) | -0.13 (-0.27; 0.00) | -8 (-873; -4) | -133 (-265; -1) |
| | | Mixed incontinence 6 months after | 78/86 | 17/22 | 28/33 | 0.67 (0.40; 1.12) | -0.11 (-0.24; 0.03) | | |

**Appendix Table F89. Clinical outcomes after pelvic floor muscle training combined with bladder training when compared to no active treatment, individual RCTs (continued)**

| Reference Sample/Men | Active | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| | | intervention | | | | | | | |
| | | Mixed incontinence 3 months after intervention | 78/86 | 23/30 | 32/37 | 0.79 (0.51; 1.23) | -0.08 (-0.22; 0.07) | | |
| | | Mixed incontinence | 78/86 | 25/32 | 34/40 | 0.81 (0.54; 1.23) | -0.07 (-0.22; 0.07) | | |
| | | Urge incontinence 6 months after intervention | 78/86 | 2/3 | 15/17 | 0.15 (0.03; 0.62) | -0.15 (-0.24; -0.06) | -7 (-16; -4) | -149 (-236; -61) |
| | | Urge incontinence 3 months after intervention | 78/86 | 6/8 | 19/22 | 0.35 (0.15; 0.83) | -0.14 (-0.25; -0.04) | -7 (-26; -4) | -144 (-250; -38) |
| | | Urge incontinence | 78/86 | 8/10 | 23/27 | 0.38 (0.18; 0.81) | -0.16 (-0.28; -0.05) | -6 (-20; -4) | -165 (-280; -50) |

**Appendix Table F90. Clinical outcomes after nonpharmacological treatments compared to no active treatment**

| Studies Reference | Number of Subjects | Pooled Relative Risk (95% CI) | Pooled Absolute Risk Difference (95% CI) | Number Needed to Treat (95%CI) | Attributable Events/1000 Treated (95% CI) | Evidence |
|---|---|---|---|---|---|---|
| **SEVERITY OF UI** | | | | | | |
| **Continence service** (1 study)<br>Williams, 2005[604] | 3,746 | 0.94 (0.89; 1.00) | -0.04 (-0.08; 0.00) | -25 (-452; -13) | -40 (-78; -2) | Insufficient |
| **PFMT+BT** (2 studies)<br>Lagro-Janssen, 1992[544]<br>McFall, 2000[562] | 245 | Significant reduction in severity and pad utilization | | | | Low |
| **DISCONTINUATION/ADHERENCE** | | | | | | |
| **PFMT** (1 study)<br>Williams, 2006[605] | 158 | NS differences | | | | Insufficient |
| **PFMT+BT** (1 study)<br>Yang, 1995[625] | 108 | NS differences | | | | Insufficient |
| **Electrical stimulation** (1 study)<br>Jeyaseelan, 2000[536] | 27 | NS differences | | | | Insufficient |
| **Vaginal cones** (1 study)<br>Williams, 2006[605] adherence | 159 | 0.63 (0.49; 0.80) | -0.30 (-0.44; -0.16) | -3 (-6; -2) | -297 (-438; -157) | Insufficient |
| **Weight loss** (1 study)<br>Subak, 2009[591]<br>Huang, 2009[532] | 338 | 0.17 (0.06; 0.44) | -0.11 (-0.18; -0.05) | -9 (-22; -6) | -112 (-178; -46) | Insufficient |
| **PREVALENCE OF UI** | | | | | | |
| **PFMT** (1 study)<br>Williams, 2006[605] | 158<br>NS differences in UI | | | | | Insufficient |
| **PFMT+BT** (1 study)<br>Kumari, 2008[543] | 164<br>Significant reduction in stress, urgency, but not mixed UI | | | | | Insufficient |
| **Acupuncture** (1 study)<br>Emmons, 2005[516] | 85 | NS differences in UUI | | | | Insufficient |
| **Electrical stimulation** (3 studies)<br>Brubaker, 1997[496]<br>Amaro, 2005[473]<br>Amaro, 2006[474] | 201 | NS differences in UUI | | | | Low |
| **Vaginal cones** (1 study)<br>Williams, 2006[605] | 159 | NS differences | | | | Insufficient |

**Appendix Table F90. Clinical outcomes after nonpharmacological treatments compared to no active treatment (continued)**

| Studies Reference | Number of Subjects | Pooled Relative Risk (95% CI) | Pooled Absolute Risk Difference (95% CI) | Number Needed to Treat (95%CI) | Attributable Events/1000 Treated (95% CI) | Evidence |
|---|---|---|---|---|---|---|
| **Weight loss** (1 study)<br>Brown, 2006[495] | 1319<br>NS change in urgency UI | 0.85 (0.73; 0.99) | -0.05 (-0.11; 0.00) | -18 (-329; -10) | -54 (-105; -3) | Insufficient |
| **Diet high in soy protein** (1 study) | 36 | | | | | |
| Manonai, 2006[558] | Significant increase in stress UI, NS changes in urgency UI | | | | | Insufficient |
| **ADVERSE EFFECTS** | | | | | | |
| **Macroplastique** (1 study)<br>Ghoniem, 2009[524] | 240 | NS differences | | | | Insufficient |

NS = Not significant

**Appendix Table F91. Scoring of quality of life after pelvic floor muscle training combined with bladder training compared to no active treatment (individual RCT)**

| Reference | Active | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean/Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Kumari, 2008[543] | Behavioral treatment with PFMT+ bladder training | IIQ score | 78/86 | 4.60/6.80 | 12.03/9.42 | -7.43 (-9.93; -4.93) |
| Kumari, 2008[543] | Behavioral treatment with PFMT+ bladder training | IIQ score 6 month after intervention | 78/86 | 2.57/8.16 | 9.54/10.88 | -6.97 (-9.90; -4.04) |

**Appendix Table F92. Clinical outcomes after pelvic floor muscle training combined with biofeedback compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Continence | Burns, 1993[500] | 9/40 | 1/39 | 8.78 (1.17; 66.04) | 64 | 0.20 (0.06; 0.34) | 51 | Yes |
| Continence | Aksac, 2003[471] | 16/20 | 0/10 | 17.29 (1.14; 261.69) | 36 | 0.80 (0.59; 1.01) | 49 | No |
| Pooled | | 25/60 | 1/49 | 11.17 (2.21; 56.44) | 100 | 0.49 (-0.10; 1.08) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.70 | 0.00 | 0.00 | 95.30 | |
| Improved UI | Aksac, 2003[471] | 4/20 | 2/10 | 1.00 (0.22; 4.56) | 25 | 0.00 (-0.30; 0.30) | 20 | No |
| Improved UI | Burns, 1990[499] | 24/40 | 0/40 | 49.00 (3.08; 779.07) | 15 | 0.60 (0.45; 0.75) | 28 | Yes |
| Improved UI | Burns, 1993[500] | 24/40 | 2/39 | 11.70 (2.96; 46.20) | 26 | 0.55 (0.38; 0.72) | 27 | Yes |
| Improved UI | Goode, 2002[286] | 27/33 | 19/37 | 1.59 (1.12; 2.27) | 35 | 0.31 (0.10; 0.51) | 25 | Yes |
| Pooled | | 80/133 | 23/126 | 3.93 (0.10; 15.49) | 100 | 0.39 (0.17; 0.61) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.00 | 78.00 | 0.00 | 80.30 | |

**Appendix Table F93. Scoring of quality of life after pelvic floor muscle training with biofeedback using vaginal EMG probe compared to no active treatment (individual RCT)**

| Reference | Active | Definition of Quality of Life | Randomized Active/ Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Aksac, 2003[471] | Contractions for 10 seconds and relaxation for 20 seconds) via biofeedback (vaginal probe in EMG) 3 times/ week | Visual analog scale based social activity index: 0=cannot undertake any social activity, 10-does not have any problem | 20/10 | 8.10/0.80 | 3.60/0.60 | 4.50 (3.99; 5.01) |

**Appendix Table F94. Continence after supervised pelvic floor muscle training when compared to no active treatment, individual RCTs**

| Reference Sample/Men | Active | Randomized Active/Control | Active Events/Rate | Control Events/Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Bo, 1999[486] 61/0 | Pelvic floor exercise with 8-12 contractions 3 times/day and in groups with skilled physical therapists 1/week | 29/32 | 12/41 | 1/3 | 13.24 (1.83; 95.63) | 0.38 (0.19; 0.57) | 3 (2; 5) | 383 (193; 572) |

**Appendix Table F95. Scoring of quality of life after supervised pelvic floor muscle training compared to no active treatment (individual RCTs)**

| Reference | Active | Definition of Quality of Life | Randomized Active/ Control | Active Mean/ Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Bo, 1999[486] | Pelvic floor exercise with 8-12 contractions 3 times/day and in groups with skilled physical therapists 1/week | Change from baseline in leakage index | 29/32 | -0.90/0.51 | 0.10/0.58 | -1.00 (-1.27; -0.73) |
| Bo, 1999[486] | Pelvic floor exercise with 8-12 contractions 3 times/day and in groups with skilled physical therapists 1/week | Change from baseline in Social activity index | 29/32 | 0.60/1.02 | -0.20/1.73 | 0.80 (0.09; 1.51) |

**Appendix Table F96. Clinical outcomes after electrical intravaginal stimulation compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Continence | Yamanishi, 1997[610] | 2/20 | 0/13 | 3.33 (0.17; 64.33) | 4 | 0.10 (-0.07; 0.27) | 17 | Yes |
| Continence | Luber, 1997[554] | 3/20 | 3/24 | 1.20 (0.27; 5.30) | 16 | 0.03 (-0.18; 0.23) | 14 | No |
| Continence | [484] | 6/7 | 1/6 | 5.14 (0.84; 31.57) | 11 | 0.69 (0.30; 1.09) | 5 | No |
| Continence | Sand, 1995[582] | 7/35 | 2/17 | 1.70 (0.39; 7.33) | 17 | 0.08 (-0.12; 0.28) | 14 | No |
| Continence | Bo, 1999[486] | 7/32 | 2/32 | 3.50 (0.79; 15.58) | 16 | 0.16 (-0.01; 0.32) | 17 | No |
| Continence | Yamanishi, 2000[611] | 7/37 | 1/31 | 5.86 (0.76; 45.11) | 9 | 0.16 (0.02; 0.30) | 20 | Not reported |
| Continence | Castro, 2008[246] | 11/30 | 3/30 | 3.67 (1.14; 11.84) | 26 | 0.27 (0.04; 0.47) | 14 | Not reported |
| Continence | | | | 4.38 (1.02; 18.84) | | | | No |
| Pooled | | 43/188 | 12/159 | 2.86 (1.57; 5.23) | 100 | 0.16 (0.06; 0.26) | 100 | |
| Heterogeneity p value, I squared | | | | 0.82 | 0.00 | 0.100 | 43.70 | |
| Improved UI | Sand, 1995[582] | 13/35 | 2/17 | 3.16 (0.80; 12.44) | 9 | 0.25 (0.03; 0.48) | 9 | No |
| Improved UI | Brubaker, 1997[496] | 21/60 | 10/61 | 2.14 (1.10; 4.14) | 23 | 0.19 (0.03; 0.34) | 16 | Yes |
| Improved UI | Luber, 1997[554] | 3/20 | 3/24 | 1.20 (0.27; 5.30) | 8 | 0.03 (-0.18; 0.23) | 10 | No |
| Improved UI | Yamanishi, 1997[610] | 3/20 | 0/13 | 4.67 (0.26; 83.55) | 2 | 0.15 (-0.04; 0.34) | 12 | Yes |
| Improved UI | Bo, 1999[486] | 3/32 | 1/32 | 3.00 (0.33; 27.33) | 4 | 0.06 (-0.06; 0.18) | 22 | No |
| Improved UI | Yamanishi, 2000[611] | 8/37 | 2/31 | 3.35 (0.77; 14.64) | 8 | 0.15 (-0.01; 0.31) | 15 | Not reported |
| Improved UI | Amaro, 2006[474] | 17/20 | 14/20 | 1.21 (0.86; 1.71) | 38 | 0.15 (-0.11; 0.40) | 7 | Yes |
| Improved UI | Castro, 2008[246] | 13/30 | 2/30 | 6.50 (1.60; 26.36) | 9 | 0.37 (0.17; 0.57) | 10 | Not reported |
| Pooled | | 81/254 | 34/228 | 2.01 (1.28; 3.15) | 100 | 0.16 (0.08; 0.23) | 100 | |
| Heterogeneity p value, I squared | | | | 0.19 | 30.00 | 0.239 | 23.800 | |
| Treatment discontinuation | Jeyaseelan, 2000[536] | 1/13 | 2/14 | 0.54 (0.06; 5.26) | 46 | -0.07 (-0.30; 0.17) | 43 | |
| Treatment discontinuation | Sand, 1995[582] | 7/35 | 1/17 | 3.40 (0.45; 25.47) | 54 | 0.14 (-0.03; 0.31) | 57 | No |
| Pooled | | 8/48 | 3/31 | 1.47 (0.24; 8.86) | 100 | 0.05 (-0.15; 0.25) | 100 | |
| Heterogeneity p value, I squared | | | | 0.24 | 29.00 | 0.16 | 48.60 | |

**Appendix Table F96. Clinical outcomes after electrical intravaginal stimulation compared to no active treatment (results from RCTs pooled with random effects models) (continued)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Treatment failure | | 2/7 | 1/6 | 1.71 (0.20; 14.55) | 6 | 0.12 (-0.33; 0.57) | 35 | No |
| Treatment failure | Castro, 2008[246] | 12/30 | 19/30 | 0.63 (0.38; 1.06) | 95 | -0.23 (-0.48; 0.01) | 65 | Not reported |
| Pooled | | 14/37 | 20/36 | 0.67 (0.40; 1.10) | 100 | -0.11 (-0.44; 0.22) | 100 | |
| Heterogeneity p value, I squared | | | | 0.37 | 0.00 | 0.18 | 45.20 | |
| Adherence | Sand, 1995[582] | 28/35 | 15/17 | 0.91 (0.71; 1.15) | | -0.08 (-0.29; 0.12) | | No |
| Adverse effects | Sand, 1995[582] | 1/35 | 2/17 | 0.24 (0.02; 2.49) | | -0.09 (-0.25; 0.07) | | No |
| Adverse effects | Sand, 1995[582] | 3/35 | 1/17 | 1.46 (0.16; 12.99) | | 0.03 (-0.12; 0.17) | | No |
| Adverse effects | Sand, 1995[582] | 4/35 | 2/17 | 0.97 (0.20; 4.79) | | -0.00 (-0.19; 0.18) | | No |
| Adverse effects | Sand, 1995[582] | 5/35 | 2/17 | 1.21 (0.26; 5.63) | | 0.03 (-0.17; 0.22) | | No |
| Treatment discontinuation Adverse effects | Sand, 1995[582] | 2/35 | 0/17 | 2.50 (0.13; 49.38) | | 0.06 (-0.06; 0.17) | | No |
| Treatment discontinuation Treatment failure | Castro, 2008[246] | 1/30 | 2/30 | 0.50 (0.05; 5.22) | | -0.03 (-0.14; 0.08) | | Not reported |

**Appendix Table F97. Clinical outcomes after electrical stimulation compared to no active treatments (results from individual RCTs)**

| Reference Sample/Men | Active | Definition of Improvement | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) |
|---|---|---|---|---|---|---|---|
| Amaro, 2006[474] 40/0 | Effective Intravaginal electrical stimulation using frequency of 4 Hz with 3 20-minute sessions/week | Self reported urge incontinence | 20/20 | 3/15 | 6/32 | 0.50 (0.14; 1.73) | -0.15 (-0.40; 0.10) |
| Amaro, 2005[473] 40/0 | Intravaginal electrical stimulation with 3 20 minute sessions/week using 4 Hz frequency | Urge urinary incontinence at 1 month followup | 20/20 | 3/15 | 6/32 | 0.50 (0.14; 1.73) | -0.15 (-0.40; 0.10) |
| Jeyaseelan, 2000[536] 27/0 | New stimulation pattern by Oldham | Withdrawal of the treatment | 13/14 | 1/8 | 2/14 | 0.54 (0.06; 5.26) | -0.07 (-0.30; 0.17) |
| Brubaker, 1997[496] 121/0 | Transvaginal electric stimulation for 20 minutes 2 times/day using frequency of 20 Hz, a 2-second-4-second work-rest cycle with a range of stimulation intensities, from 0 to 100 mA | Final urodynamic diagnosis of Detrusor over activity | 61/60 | 16/27 | 25/41 | 0.63 (0.38; 1.06) | -0.15 (-0.32; 0.01) |

**Appendix Table F98. Clinical outcomes after percutaneuous electrical stimulation compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Improved UI | Peters, 2010[354] | 39/110 | 23/110 | 1.70 (1.09; 2.64) | 55 | 0.15 (0.03; 0.26) | 61 | Not reported |
| Improved UI | Peters, 2010[578] | 29/73 | 18/77 | 1.70 (1.04; 2.78) | 45 | 0.16 (0.02; 0.31) | 39 | |
| Pooled | | 68/183 | 41/187 | | 100 | | 100 | |
| Heterogeneity p value, I squared | | | | | | | | |
| Adverse effects | Peters, 2010[354] | 6/110 | 0/110 | 13.00 (0.74; 228.00) | | 0.06 (0.01; 0.10) | | Not reported |

**Appendix Table F99. Clinical outcomes after continence service compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CIl) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Continence | Kim, 2001[538] | 14/16 | 2/15 | 6.56 (1.78; 24.16) | 8 | 0.72 (0.51; 0.98) | 30 | No |
| Continence | Moore, 2003[565] | 37/74 | 27/71 | 1.31 (0.90; 1.91) | 38 | 0.12 (-0.04; 0.28) | 33 | Yes |
| Continence | Williams, 2005[604] | 828/2958 | 150/788 | 1.47 (1.26; 1.72) | 54 | 0.09 (0.06; 0.12) | 37 | Yes |
| Pooled | | 879/3048 | 179/874 | 1.58 (1.07; 2.34) | 100 | 0.30 (-0.01; 0.60) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.07 | 63 | 0 | 93 | |
| Improved UI | O'Brien, 1996[574] | 56/61 | 102/168 | 3.11 (1.99; 4.87) | 47 | 0.311 (0.21; 0.41) | 47 | Yes |
| Improved UI | Williams, 2005[604] | 1834/2958 | 410/788 | 1.19 (1.11; 1.28) | 53 | 0.100 (0.06; 0.14) | 53 | Yes |
| Pooled | | 1890/3019 | 512/956 | 1.33 (1.06; 1.68) | 100 | 0.2 (-0.01; 0.41) | 100 | |
| Heterogeneity p value<br>I squared | | | | 0.00 | 88.10 | 0.00 | 93.20 | |

**Appendix Table F100. Improvement in urinary incontinence after interventions that were implemented by continence specialists when compared to no active treatment, individual RCTs**

| Reference Sample/Men | Active | Control | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| O'Brien, 1996[574] /0 | Followup after nurse-led continence interventions | Postponed treatment | 146 in cured patients | 19/13 | | | | | |
| | | | in those with improved UI | 124/85 | | | | | |
| | | | in those without improvement in UI | 15/10 | | | | | |
| | Adherence to PFMT for more than year | No adherence | 61/168 | 56/92 | 102/61 | 1.51 (1.31; 1.74) | 0.31 (0.21; 0.41) | 3 (2; 5) | 311 (210; 412) |
| Williams, 2005[604] 3746/1498 | Continence service | Existing primary care | 2958/788 | 1834/62 | 410/52 | 1.19 (1.11; 1.28) | 0.10 (0.06; 0.14) | 10 (7; 16) | 100 (61; 139) |

**Appendix Table F101. Quality of life after interventions that were implemented by continence specialists when compared to no active treatment, individual RCTs**

| Reference Sample/Men | Active | Control | Definition of Quality of Life | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/ 1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Du Moulin, 2007[567] 101/0 | Continence nurse and multi-disciplinary team | Standard care | No problem in pain/discomfort at 1 year of followup | 50/51 | 19/38 | 5/10 | 3.88 (1.57; 9.58) | 0.28 (0.12; 0.44) | 4 (2; 8) | 282 (125; 3547) |
| | | | No problem in usual activities at 1 year of followup | 50/51 | 22/44 | 6/12 | 3.74 (1.66; 8.44) | 0.32 (0.16; 0.49) | 3 (2; 6) | 322 (159; 3102) |
| | | | No problem in mobility at 1 year of followup | 50/51 | 25/50 | 8/16 | 3.19 (1.59; 6.38) | 0.34 (0.17; 0.51) | 3 (2; 6) | 343 (172; 2914) |
| | | | No problem in anxiety/depression at 1 year of followup | 50/51 | 26/52 | 6/12 | 4.42 (1.99; 9.81) | 0.40 (0.24; 0.57) | 2 (2; 4) | 402 (238; 2485) |
| | | | No problem in self-care at 1 year of followup | 50/51 | 31/62 | 10/20 | 3.16 (1.74; 5.74) | 0.42 (0.25; 0.60) | 2 (2; 4) | 424 (251; 2359) |
| Williams, 2005[604] 3746/1498 | Continence service | Existing primary care | % satisfied with current urinary symptoms for rest of life | 2958/788 | 1893/64 | 418/53 | 1.21 (1.12; 1.30) | 0.11 (0.07; 0.15) | 9 (7; 14) | 110 (71; 9132) |
| Williams, 2005[604] 3,746/1,498 | | | % of mild or no problem | 2958/788 | 2337/79 | 552/70 | 1.13 (1.07; 1.18) | 0.09 (0.05; 0.12) | 11 (8; 8) | 90 (54; 11167) |

**Appendix Table F102. Scoring of quality of life after interventions that were implemented by continence specialists when compared to no active treatment (individual RCTs)**

| Reference | Active | Control | Definition of Quality of Life | Randomized Active/ Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Du Moulin, 2007[567] | Continence nurse and multidisciplinary team | Standard care | IIQ (impact) mobility (0 to 100 worse) | 50/51 | 21.00/25.30 | 17.60/20.40 | 3.40 (-5.57; 12.37) |
| | | | IIQ emotional (0 to 100 worse) | 50/51 | 13.90/25.10 | 14.00/17.90 | -0.10 (-8.62; 8.42) |
| | | | IIQ social (0 to 100 worse) | 50/51 | 9.80/18.80 | 3.70/7.90 | **6.10 (0.46; 11.74)** |
| | | | IIQ embarrassment (0 to 100 worse) | 50/51 | 17.90/26.50 | 17.60/23.00 | 0.30 (-9.38; 9.98) |
| | | | IIQ physical (0 to 100 worse) | 50/51 | 13.50/21.60 | 11.70/17.70 | 1.80 (-5.91; 9.51) |
| | | | 1 year of followup IIQ (impact) mobility (0 to 100 worse) | 50/51 | 18.40/25.00 | 14.70/18.40 | 3.70 (-4.87; 12.27) |
| | | | 1 year of followup IIQ emotional (0 to 100 worse) | 50/51 | 12.40/20.70 | 12.90/12.70 | -0.50 (-7.21; 6.21) |
| | | | 1 year of followup IIQ social (0 to 100 worse) | 50/51 | 7.80/21.80 | 5.60/9.40 | 2.20 (-4.37; 8.77) |
| | | | 1 year of followup IIQ embarrassment (0 to 100 worse) | 50/51 | 15.40/26.60 | 13.30/16.30 | 2.10 (-6.52; 10.72) |
| | | | 1 year of followup IIQ physical (0 to 100 worse) | 50/51 | 10.40/19.50 | 9.30/12.40 | 1.10 (-5.29; 7.49) |
| | | | 1 year of followup EQ-5D (0 worse to 100) | 50/51 | 73.50/18.30 | 71.50/8.10 | 2.00 (-3.54; 7.54) |
| | | | Patient satisfaction (1 worse to 10) | 50/51 | 8.20/1.20 | 7.40/1.10 | **0.80 (0.35; 1.25)** |
| | | | Patient satisfaction (1 worse to 10) at 1 year of followup | 50/51 | 8.70/1.00 | 7.50/1.00 | **1.20 (0.81; 1.59)** |
| Chadha, 2000[505] | National evidence based guidelines | Pre-guidelines levels | Self-reported perception of urinary incontinence, scores | 449/449 | 15.50/20.30 | 13.90/20.70 | 1.60 (-1.08; 4.28) |
| Kim, 2001[538] | Continence Efficacy Intervention Program | Conventional care | Improved scores (from 0 to 100) | 16/17 | 37.80/23.90 | 23.60/18.90 | 14.20 (-0.56; 28.96) |
| Moore, 2003[565] | 2 nurse continence advisors/patient and consulting urogynecologist | Outpatient regimen | Incontinence score | 74/71 | 4.00/1.83 | 3.00/2.00 | **1.00 (0.37; 1.63)** |
| | | | Quality of life Urogenital distress inventory | 74/71 | 18.00/6.17 | 15.50/5.00 | **2.50 (0.68; 4.32)** |
| | | | Short Urogenital distress inventory | 74/71 | 8.00/1.50 | 6.00/2.50 | **2.00 (1.33; 2.67)** |
| | | | Quality of life incontinence | 74/71 | 36.00/9.33 | 37.50/3.67 | -1.50 (-3.79; 0.79) |

**Appendix Table F102. Scoring of quality of life after interventions that were implemented by continence specialists when compared to no active treatment, individual RCTs (continued)**

| Reference | Active | Control | Definition of Quality of Life | Randomized Active/ Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| | | | impact questionnaire | | | | |
| | | | Short incontinence impact questionnaire 7 | 74/71 | 11.00/1.33 | 10.00/2.33 | **1.00 (0.38; 1.62)** |
| Kim, 2001[538] | Continence Efficacy Intervention Program | Conventional care | Continence self-efficacy (16 worse 160) | 16/15 | 140.20/14.60 | 107.70/34.70 | **32.50 (13.54; 51.46)** |
| | | | Score of Improvement by subjective evaluation (0 to 100) | 16/15 | 37.80/23.90 | 20.00/17.30 | **17.80 (3.18; 32.42)** |
| Borrie, 2002[492], 120 men | Lifestyle modification by nurse continence advisers | Usual care | Control over urinary incontinence | 210/211 | | | **1.20 (0.70; 1.60)** |
| | | | Acceptance of urinary incontinence | 210/211 | | | **0.50 (0.00; 0.90)** |
| | | | Coping with urinary incontinence | 210/211 | | | **0.60 (0.30; 1.00)** |
| | | | Knowledge about incontinence | 210/211 | | | **2.30 (1.90; 2.70)** |
| | | | IIQ-short form | 210/211 | | | **3.10 (1.90; 4.30)** |
| | | | Change in bladder control | 210/211 | | | **1.70 (1.40; 1.90)** |
| | | | Change in amount leaked | 210/211 | | | **1.70 (1.50; 2.00)** |
| | | | Change in quality of life | 210/211 | | | **1.50 (1.20; 1.70)** |

Bold = Significant differences at 95% confidence level

**Appendix Table F103. Clinical outcomes after magnetic stimulation compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Continence | Fujishiro, 2000[520] | 4/31 | 1/31 | 4.00 (0.47; 33.79) | 4 | 0.10 (-0.04; 0.23) | 51 | No |
| Continence | Gilling, 2009[525] | 6/35 | 3/35 | 2.00 (0.54; 7.37) | 11 | 0.09 (-0.07; 0.24) | 38 | No |
| Continence | But, 2005[502] | 17/23 | 11/16 | 1.08 (0.71; 1.62) | 85 | 0.05 (-0.24; 0.34) | 11 | Yes |
| Pooled | | 27/89 | 15/82 | 1.22 (0.78; 1.88) | 100 | 0.09 (-0.01; 0.18) | 100 | |
| Heterogeneity p value, I squared | | | | 0.35 | 4.00 | 0.96 | 0.00 | |
| Improved UI | But, 2003[501] | 7/30 | 1/22 | 5.13 (0.68; 38.77) | 6 | 0.19 (0.01; 0.36) | 46 | Not reported |
| Improved UI | But, 2005[502] | 11/26 | 3/13 | 1.83 (0.62; 5.45) | 19 | 0.19 (-0.11; 0.49) | 21 | Yes |
| Improved UI | Fujishiro, 2000[520] | 23/31 | 10/31 | 2.30 (1.33; 3.99) | 75 | 0.42 (0.19; 0.64) | 33 | No |
| Pooled | | 41/87 | 14/66 | 2.30 (1.43; 3.71) | 100 | 0.27 (0.11; 0.42) | 100 | |
| Heterogeneity p value, I squared | | | | 0.68 | 0.00 | 0.25 | 27.90 | |

**Appendix Table F104. Pooled analysis of improvement in incontinence after magnetic stimulation when compared to no active treatment, random effects model**

| Reference | Active n/N | Control n/N | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Weight for Relative Risk | Weight for Absolute Risk Differences |
|---|---|---|---|---|---|---|
| Fujishiro, 2000[520] | 23/31 | 10/31 | 2.30 (1.33; 3.99) | 0.42 (0.19; 0.64) | 75.2 | 32.73 |
| But, 2003[501] | 7/30 | 1/22 | 5.13 (0.68; 38.77) | 0.19 (0.01; 0.36) | 5.58 | 45.92 |
| But, 2005[502] | 11/26 | 3/13 | 1.83 (0.62; 5.45) | 0.19 (-0.11; 0.49) | 19.22 | 21.35 |
| Studies: 3 | Patients: 153 | | 2.30 (1.43; 3.71) | 0.27 (0.11; 0.42) | 100 | 100 |
| I-squared (variation attributable to heterogeneity) | | | 0 | 27.9 | | |

**Appendix Table F105. Scoring of quality of life after magnetic stimulation compared to no active treatment (results from RCTs)**

| Reference | Active | Definition of Quality of Life | Randomized Active/ Control | Active Mean/ Standard Deviation | Control Mean/ Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Manganotti, 2007[557] | Active magnetic stimulation | General health perception, 1 week (T2) | 10/10 | 37.50/13.10 | 42.50/16.80 | -5.00 (-18.20; 8.20) |
| Manganotti, 2007[557] | Active magnetic stimulation | Incontinence impact, 1 week (T2) | 10/10 | 39.90/26.20 | 56.60/22.40 | -16.70 (-38.06; 4.66) |
| Manganotti, 2007[557] | Active magnetic stimulation | Role limitation, 1 week (T2) | 10/10 | 33.30/30.40 | 33.30/22.20 | 0.00 (-23.33; 23.33) |
| Manganotti, 2007[557] | Active magnetic stimulation | Physical limitation, 1 week (T2) | 10/10 | 43.20/27.40 | 46.60/24.60 | -3.40 (-26.22; 19.42) |
| Manganotti, 2007[557] | Active magnetic stimulation | Social limitation, 1 week (T2) | 10/10 | 14.90/19.50 | 32.10/21.20 | -17.20 (-35.05; 0.65) |
| Manganotti, 2007[557] | Active magnetic stimulation | Personal relationships, 1 week (T2) | 10/10 | 6.60/11.60 | 31.60/39.60 | -25.00 (-50.58; 0.58) |
| Manganotti, 2007[557] | Active magnetic stimulation | Emotions, 1 week (T2) | 10/10 | 41.00/29.10 | 42.10/29.00 | -1.10 (-26.56; 24.36) |
| Manganotti, 2007[557] | Active magnetic stimulation | Sleep/energy, 1 week (T2) | 10/10 | 29.90/20.40 | 19.90/13.10 | 10.00 (-5.03; 25.03) |
| Manganotti, 2007[557] | Active magnetic stimulation | SEAPI-QMM, 1 week (T2) | 10/10 | 1.70/0.80 | 1.80/0.60 | -0.10 (-0.72; 0.52) |
| Manganotti, 2007[557] | Active magnetic stimulation | General health perception, 1 month (T3) | 10/10 | 52.30/25.90 | 57.50/28.90 | -5.20 (-29.25; 18.85) |
| Manganotti, 2007[557] | Active magnetic stimulation | Incontinence impact, 1 month (T3) | 10/10 | 49.60/22.20 | 64.90/16.50 | -15.30 (-32.44; 1.84) |
| Manganotti, 2007[557] | Active magnetic stimulation | Role limitation, 1 month (T3) | 10/10 | 39.90/29.60 | 53.30/23.30 | -13.40 (-36.75; 9.95) |
| Manganotti, 2007[557] | Active magnetic stimulation | Physical limitation, 1 month (T3) | 10/10 | 47.90/28.80 | 58.20/26.30 | -10.30 (-34.47; 13.87) |
| Manganotti, 2007[557] | Active magnetic stimulation | Social limitation, 1 month (T3) | 10/10 | 27.20/33.00 | 44.40/28.60 | -17.20 (-44.27; 9.87) |
| Manganotti, 2007[557] | Active magnetic stimulation | Personal relationships, 1 month (T3) | 10/10 | 13.80/14.60 | 34.90/34.60 | -21.10 (-44.38; 2.18) |
| Manganotti, 2007[557] | Active magnetic stimulation | Emotions, 1 month (T3) | 10/10 | 46.30/30.90 | 48.80/35.10 | -2.50 (-31.48; 26.48) |
| Manganotti, 2007[557] | Active magnetic stimulation | Sleep/energy, 1 month (T3) | 10/10 | 29.90/17.20 | 33.30/13.60 | -3.40 (-16.99; 10.19) |
| Manganotti, 2007[557] | Active magnetic stimulation | SEAPI-QMM, 1 month (T3) | 10/10 | 2.30/0.80 | 2.10/0.30 | 0.20 (-0.33; 0.73) |
| Gilling, 2009[525] | Electromagnetic stimulation | I-QOL score | 35/35 | 71.20/3.30 | 67.30/4.40 | 3.90 (2.08; 5.72) |
| Gilling, 2009[525] | Electromagnetic stimulation | KHQ score | 35/35 | 6.90/0.70 | 8.60/1.00 | -1.70 (-2.10; -1.30) |

**Appendix Table F105. Scoring of quality of life after magnetic stimulation compared to no active treatment (results from RCTs) (continued)**

| Reference | Active | Definition of Quality of Life | Randomized Active/ Control | Active Mean/ Standard Deviation | Control Mean/ Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Gilling, 2009[525] | Electromagnetic stimulation | I-QOL score at 6 months of followup | 35/35 | 73.60/3.00 | 68.90/4.50 | 4.70 (2.91; 6.49) |
| Gilling, 2009[525] | Electromagnetic stimulation | KHQ score at 6 months of followup | 35/35 | 7.70/0.70 | 8.50/1.00 | -0.80 (-1.20; -0.40) |

**Appendix Table F106. Clinical outcomes after vaginal cones compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Continence | Bo, 1999[486] | 4/29 | 2/32 | 2.21 (0.44; 11.17) | 35 | 0.08 (-0.08; 0.23) | 61 | No |
| Continence | Castro, 2008[246] | 9/27 | 3/30 | 3.33 (1.01; 11.05) | 65 | 0.23 (0.03; 0.44) | 39 | Not reported |
| Pooled | | 13/56 | 5/62 | 2.88 (1.10; 7.55) | 100 | 0.14 (-0.01; 0.29) | 100 | |
| Heterogeneity p value, I squared | | | | 0.69 | 0.00 | 0.23 | 31.20 | |
| Improved UI- negative pad test | Castro, 2008[246] | 11/27 | 2/30 | 6.11 (1.49; 25.13) | | 0.34 (0.14; 0.55) | | Not reported |
| Improved UI- pad weight<2g | Castro, 2008[246] | 11/27 | 3/30 | 4.07 (1.27; 13.07) | | 0.31 (0.09; 0.52) | | Not reported |
| Improved UI- satisfied | Castro, 2008[246] | 13/27 | 5/30 | 2.89 (1.19; 7.04) | | 0.32 (0.08; 0.55) | | Not reported |
| Treatment discontinuation Treatment failure | Castro, 2008[246] | 4/27 | 2/30 | 2.22 (0.44; 11.18) | | 0.08 (-0.08; 0.24) | | Not reported |
| Treatment failure | Castro, 2008[246] | 11/27 | 19/30 | 0.64 (0.38; 1.09) | | -0.23 (-0.48; 0.03) | | Not reported |

**Appendix Table F107. Scoring of quality of life after vaginal cones compared to no active treatment (results from individual RCT)**

| Reference | Active | Definition of Quality of Life | Randomized Active/ Control | Active Mean Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Bo, 1999[486] | Vaginal cones of 20, 40, and 70g worn for 20 minutes/day | Change from baseline in leakage index | 29/32 | -0.30/0.53 | 0.10/0.58 | -0.40 (-0.68; -0.12) |
| Bo, 1999[486] | Vaginal cones of 20, 40, and 70g worn for 20 minutes/day | Change from baseline in social activity index | 29/32 | 0.10/1.06 | -0.20/1.73 | 0.30 (-0.41; 1.01) |

**Appendix Table F108. Clinical outcomes after weight loss program compared to no active treatment (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CII) | Weight, % | Absolute Risk Difference (95% CI) | Weight % | Inclusion of Mixed UI |
|---|---|---|---|---|---|---|---|---|
| Continence | Subak, 2009[591] | 16/226 | 4/112 | 1.98 (0.68; 5.79) | | 0.04 (-0.01; 0.08) | | Yes |
| Improved UI | Subak, 2005[590] | 14/24 | 4/24 | 3.50 (1.35; 9.11) | 26 | 0.42 (0.17; 0.66) | 37 | Yes |
| Improved UI | Subak, 2009[591] | 93/226 | 25/112 | 1.84 (1.26; 2.69) | 74 | 0.19 (0.09; 0.29) | 63 | Yes |
| Pooled | | 107/250 | 28/136 | 2.17 (1.26; 3.76) | 100 | 0.27 (0.06; 0.49) | 100 | |
| Heterogeneity p value, I squared | | | | 0.22 | 33.00 | 0.09 | 64.50 | |
| Treatment discontinuation | Subak, 2009[591] | 5/226 | 15/112 | 0.17 (0.06; 0.44) | | -0.11 (-0.18; -0.05) | | Yes |
| Treatment discontinuation | Huang, 2009[532] | 5/226 | 15/112 | 0.17 (0.06; 0.44) | | -0.11 (-0.18; -0.05) | | Not reported |

**Appendix Table F109. Quality of life after intensive weight loss programs when compared to no active treatment (individual RCTs)**

| Reference Sample | Active | Control | Definition of Improvement | Randomized Active/ Control | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Subak, 2009[591] 313 | Intensive 6-month weight-loss program (7 to 9% of initial body weight) | Structured education program | Incontinence somewhat or much less of a problem | 219/94 | 1.40 (1.14; 1.71) | 0.22 (0.10; 0.33) | 5 (3; 10) | 215 (100; 4642) |
| Huang, 2009[532] | Intensive lifestyle and behavior change program—an average loss of 7% to 9% of initial body weight | Structured education program | Odds ratio of frequency of sexual activity | 226/112 | 1.34 (0.99; 1.81) | | | |
| Huang, 2009[532] | Intensive lifestyle and behavior change program—an average loss of 7% to 9% of initial body weight | Structured education program | Odds ratio of overall sexual satisfaction | 226/112 | 1.28 (0.83; 1.99) | | | |
| Huang, 2009[532] | Intensive lifestyle and behavior change program—an average loss of 7% to 9% of initial body weight | Structured education program | Odds ratio of level of sexual desire | 226/112 | 1.12 (0.79; 1.61) | | | |

**Appendix Table F110. Urinary incontinence, treatment failure and discontinuation after intensive weight loss programs when compared to no active treatment, individual RCTs**

| Reference Sample/Men | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Subak, 2009[591] Huang, 2009[532] 338/0 | Intensive 6-month weight-loss program (7 to 9% of initial body weight) | Structured education program | Discontinued the intervention | 226/112 | 5/2 | 15/13 | 0.17 (0.06; 0.44) | -0.11 (-0.18; -0.05) | -9 (-22; -6) | -112 (-178; -46) |
| Brown, 2006[495] 1319/0 | Intensive lifestyle therapy to lose and maintain at least 7% of initial body weight and physical activity for at least 150 minutes each week | Placebo twice daily. | Prevalence of stress incontinence after the treatment | 659/660 | 206/31 | 242/37 | 0.85 (0.73; 0.99) | -0.05 (-0.11; 0.00) | -18 (-329; -10) | -54 (-105; -3) |
| | | | Prevalence of urge incontinence after the treatment | 659/660 | 156/24 | 169/26 | 0.92 (0.77; 1.12) | -0.02 (-0.07; 0.03) | | |

**Appendix Table F111. Urinary incontinence after the diet high in soy protein (individual RCT)**

| Reference | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Manonai, 2006[558] | Self-selected diet with low-fat and low-cholesterol foods and soy protein 25 g in various forms of soy foods containing more than 50 mg/day of isoflavones | Self-selected diet with low-fat and low-cholesterol foods | % of women reported stress incontinence after treatments | 36/36 | 18/51 | 0/0 | 37.00 (2.31; 591.54) | 0.50 (0.33; 0.67) | 2 (2; 3) | 500 (335; 665) |
| Manonai, 2006[558] | Self-selected diet with low-fat and low-cholesterol foods and soy protein 25 g in various forms of soy foods containing more than 50 mg/day of isoflavones | Self-selected diet with low-fat and low-cholesterol foods | % of women reported urge incontinence after treatments | 36/36 | 6/17 | 8/22 | 0.75 (0.29; 1.94) | -0.06 (-0.24; 0.13) | | |

**Appendix Table F112. UI after acupuncture compared to no active treatment (results from individual RCTs)**

| Reference Sample | Active | Definition of Incontinence | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) |
|---|---|---|---|---|---|---|---|
| Kim, 2005[516] 85 | Acupuncture treatment expected to improve bladder symptoms | Proportion of subjects with detrusor contractions during cystometry | 44/41 | 7/16 | 11/28 | 0.59 (0.25; 1.38) | -0.11 (-0.28; 0.06) |

**Appendix Table F113. Scoring of quality of life after acupuncture compared to no active treatment (results from individual RCTs)**

| Reference | Active | Definition of Quality of Life | Randomized Active/ Control | Active Mean/ Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Emmons, 2005[516] | Acupuncture treatment expected to improve bladder symptoms | Urinary distress inventory score | 44/41 | 3.60/3.20 | 5.80/4.80 | -2.20 (-3.95; -0.45) |
| Emmons, 2005[516] | Acupuncture treatment expected to improve bladder symptoms | Incontinence impact questionnaire score | 44/41 | 4.30/2.70 | 7.00/3.50 | -2.70 (-4.04; -1.36) |
| Kim, 2008[540] | Hand acupuncture | How much inconvenience do you have due to urinary incontinence during daily life? (score 0 worse to 4) | 25/27 | 1.70/0.66 | 1.70/0.08 | 0.00 (-0.26; 0.26) |
| Kim, 2008[540] | Hand acupuncture | for physical hobbies such as exercise and mountain climbing? (score 0 worse to 4) | 25/27 | 1.70/0.59 | 1.80/0.07 | -0.10 (-0.33; 0.13) |
| Kim, 2008[540] | Hand acupuncture | for social communities such as cinema and weddings (score 0 worse to 4) | 25/27 | 1.80/0.70 | 1.30/0.09 | 0.50 (0.22; 0.78) |
| Kim, 2008[540] | Hand acupuncture | for keeping friendships (score 0 worse to 4) | 25/27 | 1.90/0.64 | 1.70/0.08 | 0.20 (-0.05; 0.45) |
| Kim, 2008[540] | Hand acupuncture | for business with colleagues (score 0 worse to 4) | 25/27 | 1.90/0.67 | 1.80/0.09 | 0.10 (-0.16; 0.36) |
| Kim, 2008[540] | Hand acupuncture | for sexual life (score 0 worse to 4) | 25/27 | 1.80/0.70 | 1.40/0.09 | 0.40 (0.12; 0.68) |
| Kim, 2008[540] | Hand acupuncture | for making a new friends (score 0 worse to 4) | 25/27 | 1.90/0.53 | 1.40/0.09 | 0.50 (0.29; 0.71) |
| Kim, 2008[540] | Hand acupuncture | financial loss (score 0 worse to 4) | 25/27 | 1.50/0.51 | 1.60/0.09 | -0.10 (-0.30; 0.10) |
| Kim, 2008[540] | Hand acupuncture | damage to your general health (score 0 worse to 4) | 25/27 | 1.80/0.55 | 1.50/0.09 | 0.30 (0.08; 0.52) |
| Kim, 2008[540] | Hand acupuncture | easily angry or nervous (score 0 worse to 4) | 25/27 | 1.80/0.57 | 1.50/0.09 | 0.30 (0.07; 0.53) |
| Kim, 2008[540] | Hand acupuncture | influence your general activity (score 0 worse to 4) | 25/27 | 1.70/0.45 | 1.50/0.09 | 0.20 (0.02; 0.38) |
| Kim, 2008[540] | Hand acupuncture | useless person than before (score 0 worse to 4) | 25/27 | 1.70/0.52 | 1.50/0.09 | 0.20 (-0.01; 0.41) |

**Appendix Table F114. Improvement in incontinence after injection of bulking agents when compared to no active treatment, results from individual RCTs**

| Reference Sample | Active | Definition of Outcomes | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) |
|---|---|---|---|---|---|---|---|
| Lee, 2001[549] 68 | Periurethral injections of autologous fat with 3 max injections depending on outcomes measures | Cured or improved | 35/33 | 6/17 | 6/18 | 0.94 (0.34; 2.63) | -0.01 (-0.19 ;0.17) |
| Appell, 2006[476] 173 | Transurethral radiofrequency energy collagen micro-remodeling | Improvement >10 point I-QOL score | 110/63 | 53/48 | 28/44 | 1.08 (0.77; 1.52) | 0.04 (-0.12; 0.19) |

**Appendix Table F115. Scoring of quality of life after bulking agent when compared to no active treatment, results from individual RCT**

| Reference | Active | Definition of Quality of Life | Randomized Active/ Control | Active Mean Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Lee, 2001[549] | Periurethral injections of autologous fat (30 cc of fat from the anterior abdominal wall or buttock through a single 2 to 3 mm) with 3 max injections depending on outcomes measures | Mean incontinence score | 35/33 | 10.90/4.50 | 12.20/4.60 | -1.30 (-3.46; 0.86) |

**Appendix Table F116. Clinical outcomes compared after different nonpharmacological treatments (results from individual RCTs)**

| Active | Control | Outcome | Reference | Active n/N | Control n/N | Relative risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Bladder training | PFMT | Continence | Morkved, 2002[566] | 28/53 | 21/50 | 1.26 (0.83; 1.90) | 0.108 (-0.083; 0.300) | |
| Bladder training with audiotape | Bladder training | Improved UI | Dowd, 2000[513] | 19/21 | 10/19 | 1.72 (1.10; 2.69) | 0.378 (0.121; 0.636) | 3 (2; 8) |
| Bladder training with audiotape | Bladder training | Improved UI | Dowd, 2000[513] | 19/21 | 13/19 | 1.32 (0.95; 1.85) | 0.221 (-0.023; 0.464) | |
| Cone | Bladder training | Continence | Williams, 2006[605] | 0/80 | 0/79 | 0.88 (0.28; 2.76) | | |
| Continence service | Bladder training | Continence | Ramsay, 1996[579] | 19/35 | 23/39 | 0.92 (0.62; 1.37) | -0.047 (-0.273; 0.179) | |
| Continence service | Bladder training | Improved UI | Ramsay, 1996[579] | 17/35 | 19/39 | 1.00 (0.62; 1.59) | -0.001 (-0.230; 0.227) | |
| Continence service | PFMT | Continence | Kim, 2001[538] | 14/16 | 2/17 | 7.44 (2.00; 27.70) | 0.757 (0.534; 0.980) | 1 (1; 2) |
| Electrical stimulation | PFMT+ biofeedback | Treatment discontinuation | Demirturk, 208[508] | 0/20 | 1/21 | 0.35 (0.02; 8.10) | -0.048 (-0.171; 0.076) | |
| Electrical stimulation | cone | Treatment discontinuation due to treatment failure | Castro, 2008[246] | 1/30 | 4/27 | 0.23 (0.03; 1.89) | -0.115 (-0.263; 0.034) | |
| Electrical stimulation | cone | Continence | Castro, 2008[246] | 13/30 | 11/27 | 1.06 (0.58; 1.96) | 0.026 (-0.231; 0.282) | |
| Electrical stimulation | cone | Treatment failure | Castro, 2008[246] | 12/30 | 11/27 | 0.98 (0.52; 1.85) | -0.007 (-0.263; 0.248) | |
| Electrical stimulation | cone | Improved UI | Castro, 2008[246] | 13/30 | 11/27 | 1.06 (0.58; 1.96) | 0.026 (-0.231; 0.282) | |
| Pessary | PFMT+ ring | Treatment discontinuation | Richter, 2010[357] | 39/149 | 18/151 | 2.20 (1.32; 3.66) | 0.143 (0.055; 0.230) | 7 (4; 18) |
| Pessary | PFMT+ ring | Treatment discontinuation due to adverse effects | Richter, 2010[357] | 1/149 | 0/151 | 3.04 (0.12; 74.03) | 0.007 (-0.012; 0.025) | |
| Pessary | PFMT+ ring | Treatment discontinuation due to treatment failure | Richter, 2010[357] | 6/149 | 4/151 | 1.52 (0.44; 5.28) | 0.014 (-0.027; 0.054) | |
| Pessary | PFMT+ ring | Improved UI | Richter, 2010[357] | 59/149 | 80/151 | 0.75 (0.58; 0.96) | -0.134 (-0.246; -0.022) | -7 (-45; -4) |
| Pessary | PFMT+ ring | Improved UI | Richter, 2010[357] | 94/149 | 118/151 | 0.81 (0.70; 0.94) | -0.151 (-0.252; -0.049) | -7 (-20; -4) |

**Appendix Table F116. Clinical outcomes compared after different nonpharmacological treatments (results from individual RCTs) (continued)**

| Active | Control | Outcome | Reference | Active n/N | Control n/N | Relative risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) |
|---|---|---|---|---|---|---|---|---|
| PFMT | Balls | Treatment failure | Arvonen, 2001[477] | 1/19 | 1/18 | 0.95 (0.06; 14.04) | -0.003 (-0.149; 0.143) | |
| PFMT | Balls | Improved UI | Arvonen, 2001[477] | 11/19 | 7/18 | 1.49 (0.74; 2.98) | 0.190 (-0.126; 0.506) | |
| PFMT | Bladder training | Improved UI | Williams, 2006[605] | 0/79 | 0/79 | 0.68 (0.35; 1.38) | 0.000 (0.000; 0.000) | |
| PFMT | Bladder training | Improved UI | Williams, 2006[605] | 0/79 | 0/79 | 0.77 (0.40; 1.47) | 0.000 (0.000; 0.000) | |
| PFMT | Pessary | Treatment discontinuation | Richter, 2010[357] | 22/146 | 39/149 | 0.58 (0.36; 0.92) | -0.111 (-0.202; -0.020) | -9 (-51; -5) |
| PFMT | Pessary | Treatment discontinuation due to adverse effects | Richter, 2010[357] | 0/146 | 1/149 | 0.34 (0.01; 8.28) | -0.007 (-0.025; 0.012) | |
| PFMT | Pessary | Treatment discontinuation due to treatment failure | Richter, 2010[357] | 2/146 | 1/149 | 2.04 (0.19; 22.27) | 0.007 (-0.016; 0.030) | |
| PFMT | Pessary | Treatment failure | Richter, 2010[357] | 6/146 | 6/149 | 1.02 (0.34; 3.09) | 0.001 (-0.044; 0.046) | |
| PFMT | Pessary | Improved UI | Richter, 2010[357] | 110/146 | 94/149 | 1.19 (1.02; 1.39) | 0.123 (0.018; 0.227) | 8 (4; 55) |
| PFMT | Pessary | Improved UI | Richter, 2010[357] | 72/146 | 59/149 | 1.25 (0.96; 1.61) | 0.097 (-0.016; 0.210) | |
| PFMT | Pessary | Improved UI | Richter, 2010[357] | 71/146 | 49/149 | 1.48 (1.11; 1.96) | 0.157 (0.047; 0.268) | 6 (4; 21) |
| PFMT | PFMT+ ring | Treatment discontinuation | Richter, 2010[357] | 22/146 | 18/151 | 1.26 (0.71; 2.26) | 0.031 (-0.046; 0.109) | |
| PFMT | PFMT+ ring | Treatment discontinuation due to adverse effects | Richter, 2010[357] | 0/146 | 0/151 | 0.00 (0.00; 0.00) | 0.000 (-0.013; 0.013) | |
| PFMT | PFMT+ ring | Treatment discontinuation Treatment failure | Richter, 2010[357] | 6/146 | 4/151 | 1.55 (0.45; 5.39) | 0.015 (-0.027; 0.056) | |
| PFMT | PFMT+ ring | Improved UI | Richter, 2010[357] | 72/146 | 80/151 | 0.93 (0.74; 1.16) | -0.037 (-0.150; 0.077) | |
| PFMT+ biofeedback | Bladder training | Continence | Wyman, 1998[609] | 8/69 | 12/68 | 0.66 (0.29; 1.51) | -0.061 (-0.178; 0.057) | |
| PFMT+ biofeedback | Bladder training | Continence | Wyman, 1998[609] | 14/69 | 11/68 | 1.25 (0.61; 2.56) | 0.041 (-0.088; 0.170) | |

**Appendix Table F116. Clinical outcomes compared after different nonpharmacological treatments (results from individual RCTs) (continued)**

| Active | Control | Outcome | Reference | Active n/N | Control n/N | Relative risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) |
|---|---|---|---|---|---|---|---|---|
| PFMT+ biofeedback | Bladder training | Continence 3 months | Wyman, 1998[609] | 13/69 | 10/68 | 1.28 (0.60; 2.72) | 0.041 (-0.084; 0.166) | |
| PFMT+ biofeedback | Bladder training | Treatment failure | Wyman, 1998[609] | 13/69 | 14/68 | 0.92 (0.47; 1.80) | -0.017 (-0.151; 0.116) | |
| PFMT+ biofeedback | Bladder training | Improved UI | Wyman, 1998[609] | 8/69 | 11/68 | 0.72 (0.31; 1.67) | -0.046 (-0.161; 0.070) | |
| PFMT+ biofeedback | Cone | Treatment discontinuation | Harvey, 2002[530] | 12/19 | 18/25 | 0.88 (0.58; 1.34) | -0.088 (-0.368; 0.191) | |
| PFMT+ biofeedback | Cone | Continence UD | Harvey, 2002[530] | 1/19 | 1/25 | 1.32 (0.09; 19.71) | 0.013 (-0.114; 0.139) | |
| PFMT+ biofeedback | Cone | Continence (negative pad test) | Harvey, 2002[530] | 2/19 | 2/25 | 1.32 (0.20; 8.51) | 0.025 (-0.149; 0.199) | |
| PFMT+ bladder training | PFMT+ biofeedback | Adherence to treatment | Wyman, 1998[609] | 39/67 | 44/69 | 0.91 (0.70; 1.20) | -0.056 (-0.219; 0.108) | |
| PFMT+ bladder training | PFMT+ biofeedback | Continence 3 months | Wyman, 1998[609] | 16/67 | 13/69 | 1.27 (0.66; 2.43) | 0.050 (-0.087; 0.188) | |
| PFMT+ bladder training | PFMT+ biofeedback | Continence | Wyman, 1998[609] | 19/67 | 8/69 | 2.45 (1.15; 5.20) | 0.168 (0.036; 0.299) | 6 (3; 28) |
| PFMT+ bladder training | PFMT+ biofeedback | Treatment failure | Wyman, 1998[609] | 4/67 | 13/69 | 0.32 (0.11; 0.92) | -0.129 (-0.237; -0.020) | -8 (-49; -4) |
| PFMT+ bladder training | PFMT+ biofeedback | Improved UI | Wyman, 1998[609] | 10/67 | 20/69 | 0.51 (0.26; 1.02) | -0.141 (-0.277; -0.004) | -7 (-270; -4) |
| PFMT+ bladder training | PFMT+ biofeedback | Improved UI 3 months | Wyman, 1998[609] | 6/67 | 9/69 | 0.69 (0.26; 1.82) | -0.041 (-0.146; 0.064) | |
| PFMT+ bladder training | PFMT+ biofeedback | Improved UI | Wyman, 1998[609] | 32/67 | 19/69 | 1.73 (1.10; 2.74) | 0.202 (0.043; 0.362) | 5 (3; 23) |
| PFMT+ bladder training | PFMT+ biofeedback | Improved UI | Wyman, 1998[609] | 14/67 | 8/69 | 1.80 (0.81; 4.01) | 0.093 (-0.030; 0.216) | |
| PFMT+ electrical stimulation | PFMT | Improvement in ICIQ-UI score | Oldham, 2010[575] | 32/64 | 16/64 | 2.00 (1.23; 3.26) | 0.250 (0.088; 0.412) | 4 (2; 11) |
| PFMT+ electrical stimulation | PFMT | Improvement in leak frequency | Oldham, 2010[575] | 43/64 | 21/64 | 2.05 (1.39; 3.02) | 0.344 (0.181; 0.506) | 3 (2; 6) |
| PFMT+ electrical stimulation | PFMT | Improvement in terms of leak interference with life | Oldham, 2010[575] | 32/64 | 21/64 | 1.52 (0.99; 2.34) | 0.172 (0.004; 0.340) | 6 (3; 261) |
| PFMT+ electrical stimulation | PFMT | Reduction in severity of symptoms: Condition mild or normal post treatment | Oldham, 2010[575] | 54/64 | 45/64 | 1.20 (0.99; 1.45) | 0.141 (-0.002; 0.284) | |

**Appendix Table F116. Clinical outcomes compared after different nonpharmacological treatments (results from individual RCTs) (continued)**

| Active | Control | Outcome | Reference | Active n/N | Control n/N | Relative risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) |
|---|---|---|---|---|---|---|---|---|
| PFMT+ reminder | PFMT+ Bladder training | Continence | Alenijnse, 2003[472] | 17/52 | 21/51 | 0.79 (0.48; 1.32) | -0.085 (-0.271; 0.101) | |
| PFMT+ video tape | PFMT | "Routine" pelvic floor exercises, response=yes | Gallo, 1997[522] | 41/43 | 22/43 | 1.86 (1.38; 2.51) | 0.442 (0.280; 0.604) | 2 (2; 4) |
| PFMT+ video tape | PFMT | Number of times per day patient performed pelvic floor exercises, response=two | Gallo, 1997[522] | 34/43 | 4/43 | 8.50 (3.30; 21.89) | 0.698 (0.548; 0.847) | 1 (1; 2) |
| Face to face training | Telemedicine | Urinary incontinence | Hui, 2006[533] | 2/27 | 4/31 | 0.57 (0.11; 2.89) | -0.055 (-0.209; 0.099) | |
| Weight loss | Education | ≥70% improvement in weekly UI episodes: urge: 18 months | Wing, 2010[606] | 106/226 | 38/112 | 1.38 (1.03; 1.85) | 0.130 (0.021; 0.239) | 8 (4; 49) |
| Weight loss | Education | ≥70% improvement in weekly UI episodes: Total: 12 months | Wing, 2010[606] | 104/226 | 35/112 | 1.47 (1.08; 2.01) | 0.148 (0.040; 0.255) | 7 (4; 25) |
| Weight loss | Education | ≥70% improvement in weekly UI episodes: stress:12 months | Wing, 2010[606] | 145/226 | 54/112 | 1.33 (1.07; 1.65) | 0.159 (0.048; 0.271) | 6 (4; 21) |
| Weight loss | Education | ≥70% improvement in weekly UI episodes: urge: 12 months | Wing, 2010[606] | 106/226 | 39/112 | 1.35 (1.01; 1.80) | 0.121 (0.011; 0.230) | 8 (4; 89) |
| Weight loss | Education | Reduction in weekly stress urinary incontinence episodes at 12 months | Wing, 2010[606] | 147/226 | 53/112 | 1.37 (1.11; 1.71) | 0.177 (0.066; 0.289) | 6 (3; 15) |

**Appendix Table F117. Quality of life scoring after continence program vs. PFMT (individual RCT)**

| Reference Sample/Men | Active | Control | Outcome | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Kim, 2001[538] /0 | Continence Efficacy Intervention Program | PFMT | Score of Improvement by subjective evaluation (0 to 100) | 16/17 | 37.80/23.90 | 23.60/18.90 | 14.20 (-0.56;2 8.96) |

**Appendix Table F118. Comparative effectiveness of nonpharmacological treatments on continence (insufficient evidence)**

| Active | Control | Studies Reference | Number of Subjects | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events 95% CI) | Evidence |
|---|---|---|---|---|---|---|---|---|
| Continence service | Bladder training | 1 study[579] | 74 | Not significant | | | | Insufficient |
| Continence service | PFMT | 1 study[538] | 33 | 7.44 (2.00; 27.70) | 0.76 (0.53; 0.98) | 1 (1; 2) | 757 (534; 980) | Insufficient |
| Continence service | Tele continence service | 1 study[533] | 58 | Not significant | | | | Insufficient |
| PFMT+ reminder | PFMT+ bladder training | 1 study[472] | 103 | Not significant | | | | Insufficient |
| PFMT in the supine position | PFMT in both supine and upright positions | 1 study[490] | 44 | Not significant | | | | Insufficient |
| Group physiotherapy | Biofeedback | 1 study[577] | 40 | Not significant | | | | Insufficient |
| Individual PFMT+BT | Group PFMT | 1 study[535] | 530 | 1.58 (1.05; 2.36) | 0.08 (0.00; 0.16) | 12 (6; 1003) | 81 (1; 161) | Insufficient |
| Circular muscle exercises (Paula method) | PFMT | 1 study[550] | 245 | 1.50 (1.11; 2.03) | 0.17 (0.05; 0.29) | 6 (3; 21) | 171 (48; 295) | Insufficient |
| PFMT | PFMT+ Balls | 1 study[477] | 37 | 0.11 (0.01; 1.83) | -0.22 (-0.43; -0.02) | -5 (-52; -2) | -222 (-425; -19) | Insufficient |
| Physiotherapy in combination with biofeedback | Physiotherapy | 1 study[526] | 40 | 3.67 (1.20; 11.19) | 0.40 (0.13; 0.67) | 3 (1; 8) | 400 (132; 668) | Insufficient |
| Weekly posterior tibial nerve simulation | Posterior tibial nerve simulation three times per week | 1 study[470] | 35 | Not significant | | | | Insufficient |
| Vaginal cone | behavioral intervention | 1 study[605] | 238 | Not significant | | | | Insufficient |
| Conveen Continence device Guard, CCG | Contrelle Continence Tampon, CCT | 1 study[598] | 94 | Not significant | | | | Insufficient |
| Hodge pessary with support | Super tampon | 1 study[571] | 40 | Not significant | | | | Insufficient |

**Appendix Table F118. Comparative effectiveness of nonpharmacological treatments on continence (insufficient evidence) (continued)**

| Active | Control | Studies Reference | Number of Subjects | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events 95% CI) | Evidence |
|---|---|---|---|---|---|---|---|---|
| Durasphere | Contigen | 1 study[475] | 52 | 3.33 (1.03; 10.74) | 0.27 (0.05; 0.49) | 4 (2; 22) | 269 (46; 493) | Insufficient |
| Urethral device (NEAT) | Reliance insert sterile balloon | 1 study[581] | 24 | Not significant | | | | Insufficient |
| Calcium hydroxylapatite (CaHA | Bovine Dermal Collagen | 1 study[559] | 296 | Not significant | | | | Insufficient |
| Peri or transurethral porcine dermal implant injection (Permacol) | Transurethral silicone injection (Macroplastique | [480] | | Not significant | | | | Insufficient |
| Periurethral route of injection of bulking agent-dextran copolymer | Transurethral route of injection of bulking agent-dextran copolymer | [583] | | Not significant | | | | Insufficient |
| Macroplastique | Contigen® | 1 study[524] | 247 | 1.49 (1.01; 2.18) NS for self reported continence | 0.12 (0.01; 0.24) | 8 (4; 152) | 121 (7; 235) | Insufficient |
| Autologous myoblasts and fibroblasts | Collagen | 1 study[588] | 63 | 9.50 (2.53; 35.63) | 0.81 (0.66; 0.96) | 1 (1; 2) | 810 (656; 963) | Insufficient |
| Zuidex Implacer | Contigen Endoscopic guidance | 1 study[553] | 344 | Not significant | | | | Insufficient |

**Appendix Table F119. Clinical outcomes after PFMT combined with bladder training compared to PFMT alone (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active n/N | Control n/N | Rate Active/Control | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Continence | Berghmans, 1996[482] | 5/20 | 3/20 | 25/15 | 1.67 (0.46; 6.06) | 7.05 | 0.1 (-0.146; 0.346) | 12.53 |
| Continence | Glavind, 1996[526] | 11/20 | 3/20 | 55/15 | 3.67 (1.20; 11.19) | 8.95 | 0.4 (0.132; 0.668) | 11.19 |
| Continence | Morkved, 2002[566] | 19/53 | 14/50 | 36/28 | 1.28 (0.72; 2.27) | 21.85 | 0.078 (-0.101; 0.258) | 17.73 |
| Continence | Burgio, 2002[498] | 15/73 | 11/75 | 20/15 | 1.40 (0.69; 2.84) | 17.15 | 0.059 (-0.064; 0.181) | 23.68 |
| Continence UD | Goode, 2003[616] | 18/66 | 25/67 | 28/38 | 0.73 (0.44; 1.21) | 24.8 | -0.1 (-0.258; 0.058) | 19.82 |
| Continence | Wang, 2004[602] | 15/38 | 12/40 | 38/30 | 1.32 (0.71; 2.44) | 20.2 | 0.095 (-0.116; 0.305) | 15.05 |
| Pooled | | 82/270 | 68/272 | 30/25 | 1.27 (0.88; 1.85) | 100 | 0.079 (-0.031; 0.189) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.147 | 38.80% | 0.065 | 51.80% |
| Treatment failure | Morkved, 2002[566] | 1/53 | 3/50 | 2/6 | 0.31 (0.03; 2.92) | 66.52 | -0.041 (-0.116; 0.034) | 74.27 |
| Treatment failure | Glavind, 1996[526] | 0/20 | 1/20 | 0/5 | 0.33 (0.01; 7.72) | 33.48 | -0.05 (-0.178; 0.078) | 25.73 |
| Pooled | | 1/73 | 4/70 | 1/6 | 0.32 (0.05; 1.98) | 100 | -0.043 (-0.108; 0.022) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.98 | 0.00% | 0.907 | 0.00% |

**Appendix Table F120. Clinical outcomes after PFMT combined with bladder training compared to bladder training alone (results from RCTs pooled with random effects models**

| Outcome | Reference | Active n/N | Control n/N | Rate Active/Control | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Continence | Wyman, 1998[609] | 16/67 | 10/68 | 24/15 | 1.62 (0.80; 3.32) | 32.71 | 0.092 (-0.041; 0.224) | 33.66 |
| Continence | Elser, 1999[515] | 10/68 | 17/68 | 15/25 | 0.59 (0.29; 1.19) | 33.03 | -0.103 (-0.236; 0.03) | 33.56 |
| Continence | Wyman, 1998[609] | 18/67 | 11/68 | 27/16 | 1.66 (0.85; 3.25) | 34.26 | 0.107 (-0.031; 0.244) | 32.78 |
| | | 44/202 | 38/204 | 22/19 | 1.17 (0.6; 2.28) | | 0.031 (-0.102; 0.164) | |
| | | | | | 0.064 | 63.70% | 0.053 | 66.00% |
| Improved UI | Wyman, 1998[609] | 14/69 | 9/68 | 20/13 | 1.53 (0.71; 3.30) | 46.39 | 0.071 (-0.054; 0.195) | 52.52 |
| Improved UI | Wyman, 1998[609] | 14/67 | 11/68 | 21/16 | 1.29 (0.63; 2.64) | 53.61 | 0.047 (-0.084; 0.178) | 47.48 |
| Pooled | | 28/136 | 20/136 | 21/15 | 1.40 (0.83; 2.36) | 100 | 0.059 (-0.031; 0.15) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.75 | 0.00% | 0.8 | 0.00% |

**Appendix Table F121. Clinical outcomes after supervised PFMT combined with bladder training compared to self administered PFMT (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active n/N | Control n/N | Rate Active/Control | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Continence | Bo, 2005[488] | 13/21 | 4/26 | 60/17 | 4.02 (1.54; 10.53) | 17.48 | 0.465 (0.215; 0.715) | 18.61 |
| Continence | de Oliveira Camargo, 2009[503] | 14/30 | 16/30 | 47/53 | 0.88 (0.53; 1.46) | 22.04 | -0.067 (-0.319; 0.186) | 24.66 |
| Continence | Zanetti, 2007[613] | 11/23 | 2/21 | 48/10 | 5.02 (1.26; 20.07) | 11.75 | 0.383 (0.143; 0.623) | 19.09 |
| Continence | Burgio, 2002[498] | 15/74 | 11/75 | 20/15 | 1.38 (0.68; 2.81) | 25.95 | 0.056 (-0.066; 0.178) | 18.48 |
| Continence | Felicissimo, 2010[519] | 11/31 | 11/31 | 37/35 | 1 (0.5; 1.9) | 22.77 | 0 (-0.24; 0.24) | 19.16 |
| Pooled | | 64/179 | 44/183 | 36/24 | 1.6 (0.88; 2.9) | 100 | 0.16 (-0.03; 0.35) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.018 | 66.4% | 0.003 | 75.1% |
| Improved UI | Zanetti, 2007[613] | 15/23 | 5/21 | 67/24 | 2.74 (1.21; 6.23) | 28.6 | 0.414 (0.147; 0.681) | 24.5 |
| Improved UI | Burgio, 2002[498] | 36/74 | 20/75 | 49/27 | 1.82 (1.17; 2.84) | 17.1 | 0.22 (0.068; 0.371) | 16.59 |
| Improved UI | Konstantinidou, 2007[542] | 1/15 | 1/15 | 7/7 | 1 (0.07; 14.55) | 2.65 | 0 (-0.179; 0.179) | 22.52 |
| Improved UI | de Oliveira Camargo, 2009[503] | 18/30 | 20/30 | 60/67 | 0.9 (0.61; 1.33) | 30.59 | -0.067 (-0.31; 0.177) | 18.03 |
| Improved UI | Felicissimo, 2010[519] | 11/31 | 11/31 | 37/35 | 1(0.51; 1.96) | 21.06 | 0 (-0.24; 0.24) | 18.36 |
| Pooled | | 82/173 | 57/172 | 47/33 | 1.37 ( 0.87; 2.2) | 100 | 0.11 ( -0.05; 0.27) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.05 | 57.9% | 0.023 | 64.6% |
| Treatment failure | Konstantinidou, 2007[542] | 4/15 | 7/15 | 27/47 | 0.86 (0.32; 2.30) | 39.55 | -0.056 (-0.405; 0.294) | 26.35 |
| Treatment failure | Bo, 2005[488] | 1/21 | 7/26 | 5/27 | 0.18 (0.02; 1.33) | 16.43 | -0.222 (-0.415; -0.028) | 44.5 |
| Treatment failure | Aukee, 2004[479] | 9/19 | 5/16 | 47/31 | 1.52 (0.64; 3.61) | 44.03 | 0.161 (-0.158; 0.481) | 29.15 |
| Pooled | | 14/55 | 19/57 | 25/33 | 0.85 (0.34; 2.16) | 100 | -0.066 (-0.3; 0.167) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.15 | 47.60% | 0.126 | 51.70% |
| Treatment discontinuation | Tsai, 2009[601] | 4/54 | 5/54 | 7/9 | 0.8 (0.23; 2.82) | 49.05 | -0.019 (-0.123; 0.086) | 90.15 |
| Treatment discontinuation | Konstantinidou, 2007[542] | 3/15 | 5/15 | 20/33 | 0.79 (0.23; 2.7) | 50.95 | -0.063 (-0.379; 0.252) | 9.85 |
| Pooled | | 7/69 | 10/69 | 10/14 | 0.79 (0.33; 1.91) | 100 | -0.023 (-0.122; 0.076) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.98 | 0.00% | 0.791 | 0.00% |

**Appendix Table F122. Improvement in UI rates compared between nonpharmacological treatments**

| Active Treatment | Control Treatment | Studies | Patients | Rate Active/ Control, % | Relative Risk (95% CI) | Absolute Risk Difference (95%CI) | Level of Evidence |
|---|---|---|---|---|---|---|---|
| Pelvic floor muscle training+ bladder training | Bladder training | 1[609] | 272 | 21/15 | 1.40 (0.83; 2.36) | 0.06 (-0.03; 0.15) | Insufficient |
| Supervised pelvic floor muscle training | Pelvic floor muscle training | 4[498,503,542,613] | 283 | 50/33 | 1.51 (0.85; 2.67) | 0.14 (-0.05; 0.32) | Moderate |
| Pelvic floor muscle training | Electrical stimulation | 4[246,529,586,587] | 136 | 31/45 | 0.97 (0.62; 1.51) | -0.01 (-0.17; 0.16) | Moderate |
| Pelvic floor muscle training | Vaginal cone | 4[246,523,584,605] | 440 | 41/41 | 1.02 (0.91; 1.14) | 0.01 (-0.08; 0.09) | Moderate |

**Appendix Table F123. Failure rates compared between nonpharmacological treatments**

| Active Treatment | Control Treatment | Studies | Patients | Rate Active/ Control, % | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Level of Evidence |
|---|---|---|---|---|---|---|---|
| Pelvic floor muscle training+ biofeedback | Pelvic floor muscle training | 2[526,566] | 143 | 1/6 | 0.32 (0.05; 1.98) | -0.04 (-0.11; 0.02) | Low |
| Supervised pelvic floor muscle training | Pelvic floor muscle training | 3[479,488,542] | 112 | 25/33 | 0.85 (0.34; 2.16) | -0.07 (-0.30; 0.17) | Low |
| Pelvic floor muscle training | Electrical stimulation | 2[246,587] | 98 | 31/43 | 1.41 (0.53; 3.78) | 0.13 (-0.25; 0.51) | Low |

**Appendix Table F124. Quality of life after supervised vs. self-administered PFMT programs (individual RCTs)**

| Reference Sample/Men | Active | Definition of Quality of Life | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|
| Ng, 2008[569] /0 | A registered nurse monitoring via telephone checkups twice a week home based PFMT | Affect on family life | 44/44 | | | 0.96 (0.50; 1.83) | | | |
| Ng, 2008[569] /0 | A registered nurse monitoring via telephone checkups twice a week home based PFMT | Affect on holidays/ recreation | 44/44 | | | 0.92 (0.57; 1.50) | | | |
| Ng, 2008[569] /0 | A registered nurse monitoring via telephone checkups twice a week home based PFMT | Affect on interests/ hobbies | 44/44 | | | 0.85 (0.53; 1.37) | | | |
| Ng, 2008[569] /0 | A registered nurse monitoring via telephone checkups twice a week home based PFMT | Affect on social activities | 44/44 | | | 0.79 (0.48; 1.30) | | | |
| Ng, 2008[569] /0 | A registered nurse monitoring via telephone checkups twice a week home based PFMT | Worried about smell of urine | 44/44 | | | 0.67 (0.44; 1.04) | | | |
| Ng, 2008[569] /0 | A registered nurse monitoring via telephone checkups twice a week home based PFMT | Affect on sexual life | 44/44 | | | 0.62 (0.34; 1.13) | | | |
| Ng, 2008[569] /0 | A registered nurse monitoring via telephone checkups twice a week home based PFMT | Affect on sexual quality | 44/44 | | | 0.52 (0.29; 0.95) | | | |
| Zanetti, 2007[613] 44/0 | Supervised PMFT | Patient satisfaction | 23/21 | 15/67 | 5/24 | 2.74 (1.20; 6.23) | 0.41 (0.15; 0.68) | 2 (1; 7) | 414 (147; 2415) |

**Appendix Table F125. Scoring of quality of life after supervised vs. self-administered PFMT programs (individual RCTs)**

| Reference Sample/Men | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean/Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|
| de Oliveira Camargo, 2009[503] /0 | Final general health (KHQ 0 best to 100) | 30/30 | 39.20/21.50 | 37.50/20.50 | 1.70 (-8.93; 12.33) |
| de Oliveira Camargo, 2009[503] /0 | Final incontinence impact (KHQ 0 best to 100) | 30/30 | 20.00/25.70 | 13.30/24.10 | 6.70 (-5.91; 19.31) |
| de Oliveira Camargo, 2009[503] /0 | Final physical activities limitations (KHQ 0 best to 100) | 30/30 | 3.30/8.10 | 10.60/17.80 | -7.30 (-14.30; -0.30) |
| de Oliveira Camargo, 2009[503] /0 | Final physical limitations (KHQ 0 best to 100) | 30/30 | 4.40/11.50 | 10.60/11.50 | -6.20 (-12.02; -0.38) |
| de Oliveira Camargo, 2009[503] /0 | Final social limitations (KHQ 0 best to 100) | 30/30 | 0.70/2.80 | 3.70/10.20 | -3.00 (-6.78; 0.78) |
| de Oliveira Camargo, 2009[503] /0 | Final personal relationships (KHQ 0 best to 100) | 30/30 | | 2.30/7.80 | |
| de Oliveira Camargo, 2009[503] /0 | Final emotions (KHQ 0 best to 100) | 30/30 | 5.60/19.30 | 4.80/11.60 | 0.80 (-7.26; 8.86) |
| de Oliveira Camargo, 2009[503] /0 | Final sleep/disposition (KHQ 0 best to 100) | 30/30 | 7.20/17.90 | 4.40/10.70 | 2.80 (-4.66; 10.26) |
| de Oliveira Camargo, 2009[503] /0 | Final gravity (KHQ 0 best to 100) | 30/30 | 15.30/20.30 | 14.40/20.30 | 0.90 (-9.37; 11.17) |

**Appendix Table F126. Continence and improvement in incontinence after complex group and individual pelvic floor muscle training programs, individual RCTs.**

| Outcome | Reference | Active | Control | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Continence | Pages, 2001[577] 40/0 | Specific physical therapy program: group therapy 5 times/week and home pelvic floor exercise with 50 contractions for 10 minutes 2 times/day; recommendation of weight loss and aerobic sports. | Biofeedback training daily 90-minutes in group and individually for 15 minutes, 5 times/week Intra vaginal pressure sensor and visual biofeedback in computer monitor | 27/13 | 6/22 | 4/28 | 0.72 (0.25; 2.12) | -0.09 (-0.38; 0.21) | | |
| Continence | Janssen, 2001[535] 530/0 | Individual pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 11 30-minute sessions. | Group pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 9 2-hour sessions | 126/404 | 25/20 | 53/13 | 1.51 (0.98; 2.33) | 0.07 (-0.01; 0.14) | | |
| | | | | 126/404 | 28/22 | 57/14 | 1.58 (1.05; 2.36) | 0.08 (0.00; 0.16) | 12 (6; 1003) | 81 (1; 161) |
| Improvement in incontinence | Janssen, 2001[535] 530/0 | Individual pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 11 30-minute sessions. | Group pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 9 2-hour sessions at 3 months | 126/404 | 118/94 | 347/86 | 1.09 (1.03; 1.16) | 0.08 (0.02; 0.13) | 13 (8; 43) | 78 (23; 132) |
| | | | at 9 months | 126/404 | 107/85 | 315/78 | 1.09 (1.00; 1.19) | 0.07 (0.00; 0.14) | | |
| Improvement in incontinence | Pages, 2001 [577] 40/0 | Specific physical therapy program: group therapy 5 | Biofeedback training daily 90-minutes in | 27/13 | 20/74 | 9/68 | 1.07 (0.70; 1.64) | 0.05 (-0.25; 0.35) | | |

**Appendix Table F126. Continence and improvement in incontinence after complex group and individual pelvic floor muscle training programs, individual RCTs (continued)**

| Outcome | Reference | Active | Control | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | times/week and home pelvic floor exercise with 50 contractions for 10 minutes 2 times/day; recommendation of weight loss and aerobic sports. | group and individually for 15 minutes, 5 times/week Intra vaginal pressure sensor and visual biofeedback in computer monitor | | | | | | | |

**Appendix Table F127. Scoring of quality of life after PFMT with biofeedback using vaginal EMG probe when compared to PFMT (individual RCTs)**

| Reference Sample/Men | Active | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Morkved, 2002[566] /0 | PFMT with biofeedback | Leakage index | 53/50 | 1.90/0.74 | 1.90/0.72 | 0.00 (-0.28; 0.28) |
| Morkved, 2002[566] /0 | PFMT with biofeedback | Social activity index | 53/50 | 9.50/0.74 | 9.40/1.08 | 0.10 (-0.26; 0.46) |
| Aukee, 2002[478] /0 | Pelvic floor muscle exercise of and individual EMG-assisted biofeedback | Leakage index | 15/15 | 34.90/10.40 | 38.10/10.50 | -3.20 (-10.68; 4.28) |
| McDowell, 2006[560] /0 | PFMT and Advice and EMG biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Total score | 10/10 | 62.50/44.20 | 101.60/46.10 | -39.10 (-78.68; 0.48) |
| McDowell, 2006[560] /0 | PFMT and Advice and EMG biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Physical activity | 10/10 | 32.90/37.10 | 35.60/25.70 | -2.70 (-30.67; 25.27) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG Biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Emotional health | 10/10 | 28.70/39.20 | 28.70/26.00 | 0.00 (-29.15; 29.15) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Travel | 10/10 | 32.90/37.10 | 46.40/28.00 | -13.50 (-42.31; 15.31) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Social relationships | 10/10 | 28.80/39.30 | 14.90/12.40 | 13.90 (-11.64;3 9.44) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Urogenital Distress Inventory (UDI) Scores: Total score | 10/10 | 77.90/33.50 | 139.60/66.50 | -61.70 (-107.85; -15.55) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Urogenital Distress Inventory (UDI) Scores: Irritative symptoms | 10/10 | 40.00/18.12 | 56.60/28.80 | -16.60 (-37.69; 4.49) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Urogenital Distress Inventory (UDI) Scores: Obstructive/discomfort | 10/10 | 23.70/18.20 | 49.10/36.10 | -25.40 (-50.46; -0.34) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Urogenital Distress Inventory (UDI) Scores: Stress symptoms | 10/10 | 19.90/23.30 | 47.50/34.70 | -27.60 (-53.51; -1.69) |

**Appendix Table F127. Scoring of quality of life after PFMT with biofeedback using vaginal EMG probe when compared to PFMT (individual RCTs) (continued)**

| Reference Sample/Men | Active | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Total score | 10/10 | 78.90/55.70 | 101.60/46.10 | -22.70 (-67.51; 22.11) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Physical activity | 10/10 | 27.00/30.50 | 35.60/25.70 | -8.60 (-33.32; 16.12) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Emotional health | 10/10 | 28.50/29.50 | 28.70/26.00 | -0.20 (-24.57; 24.17) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Travel | 10/10 | 32.70/30.90 | 46.40/28.00 | -13.70 (-39.54; 12.14) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Incontinence Impact Questionnaire (IIQ) Scores: Social relationships | 10/10 | 25.00/30.60 | 14.90/12.40 | 10.10 (-10.36; 30.56) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Urogenital Distress Inventory (UDI) Scores: Total score | 10/10 | 100.50/43.10 | 139.60/66.50 | -39.10 (-88.22; 10.02) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Urogenital Distress Inventory (UDI) Scores: Irritative symptoms | 10/10 | 47.60/12.00 | 56.60/28.80 | -9.00 (-28.34; 10.34) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Urogenital Distress Inventory (UDI) Scores: Obstructive/discomfort | 10/10 | 31.50/22.80 | 49.10/36.10 | -17.60 (-44.06; 8.86) |
| McDowell, 2006[560] /0 | PFMT and advice and EMG biofeedback | Urogenital Distress Inventory (UDI) Scores: Stress symptoms | 10/10 | 23.20/26.20 | 47.50/34.70 | -24.30 (-51.25; 2.65) |
| Wong, 2001[607] /0 | Pelvic floor exercises with EMG | IIQ-7 (1 to 100 worse) | 19/19 | 14.29/0.00 | 14.29/0.00 | 0.00 (0.00; 0.00) |
| Sung, 2000[593] /0 | Pelvic floor exercises with EMG | Discomfort due to incontinence (0 to 5 worse) | 30/30 | 1.80/0.80 | 2.00/0.70 | -0.20 (-0.58; 0.18) |
| Sung, 2000[593] /0 | Pelvic floor exercises with EMG | Discomfort due to fluid intake restriction (0 to 5 worse) | 30/30 | 1.40/0.70 | 1.10/0.30 | 0.30 (0.03; 0.57) |
| Sung, 2000[593] /0 | Pelvic floor exercises with EMG | Problems on daily tasks (0 to 5 worse) | 30/30 | 1.40/0.70 | 1.10/0.30 | 0.30 (0.03; 0.57) |
| Sung, 2000[593] /0 | Pelvic floor exercises with EMG | Avoidance of places & situations (0 to 5 worse) | 30/30 | 1.40/0.90 | 1.40/0.70 | 0.00 (-0.41; 0.41) |
| Sung, 2000[593] /0 | Pelvic floor exercises with EMG | Discomfort due to avoidance of places & situations (0 to 5 worse) | 30/30 | 1.30/0.70 | 1.20/0.40 | 0.10 (-0.19; 0.39) |

**Appendix Table F127. Scoring of quality of life after PFMT with biofeedback using vaginal EMG probe when compared to PFMT (individual RCTs) (continued)**

| Reference Sample/Men | Active | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|
| Sung, 2000[593] /0 | Pelvic floor exercises with EMG | Interference in physical activity (0 to 5 worse) | 30/30 | 1.60/0.80 | 1.30/0.40 | 0.30 (-0.02; 0.62) |
| Sung, 2000[593] /0 | Pelvic floor exercises with EMG | Interference in relations with other people (0 to 5 worse) | 30/30 | 1.20/0.70 | 1.10/0.30 | 0.10 (-0.17; 0.37) |

**Appendix Table F128. Clinical outcomes after pelvic floor muscle trainings with biofeedback using vaginal EMG probe when compared to pelvic floor muscle trainings, individual RCT**

| Reference Sample | Active | Outcome | Randomized Active/ Control | Active Events /rate, % | Control Events/ Rate, % | Relative Risk (95%CI) | Absolute Risk Differences (95% CI) |
|---|---|---|---|---|---|---|---|
| Morkved, 2002[566] 103 | Pelvic floor muscle training with biofeedback apparatus | Urinary incontinence is problematic | 53/50 | 3/6 | 6/12 | 0.47(0.12;1.79) | -0.06(-0.17;0.05) |
| Morkved, 2002[566] 103 | Pelvic floor muscle training with biofeedback apparatus | Urinary incontinence is minor problem | 53/50 | 17/32 | 18/36 | 0.89(0.52;1.53) | -0.04(-0.22;0.14) |
| Morkved, 2002[566] 103 | Pelvic floor muscle training with biofeedback apparatus | Urinary incontinence is moderate problem | 53/50 | 8/15 | 5/10 | 1.51(0.53;4.31) | 0.05(-0.08;0.18) |

**Appendix Table F129. Clinical outcomes after PFMT compared to electrical stimulation (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active n/N | Control n/N | Rate Active/Control | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Continence | Castro, 2008[246] | 10/31 | 11/30 | 32/37 | 0.88 (0.44; 1.76) | 85.64 | -0.044 (-0.282; 0.194) | 43.26 |
| Continence | Hahn, 1991[529] | 1/10 | 1/10 | 10/10 | 1 (0.07; 13.87) | 5.96 | 0 (-0.263; 0.263) | 35.54 |
| Continence | Smith, 1996[586] | 1/9 | 2/9 | 11/22 | 0.5 (0.06; 4.58) | 8.4 | -0.111 (-0.452; 0.229) | 21.2 |
| Pooled | | 12/50 | 14/49 | 24/29 | 0.85 (0.45; 1.61) | 100 | -0.043 (-0.199; 0.114) | 100 |
| Heterogeneity P value, I squared,% | | | | | | | 0.88 | 0.00% |
| Improved Urinary incontinence | Smith, 1996[586] | 3/9 | 4/9 | 33/44 | 0.75 (0.23; 2.44) | 14.09 | -0.111 (-0.559; 0.336) | 13.49 |
| Improved Urinary incontinence | Spruijt, 2003[587] | 4/25 | 7/12 | 36/29 | 1.19 (0.43; 3.29) | 18.88 | 0.053 (-0.266; 0.373) | 26.46 |
| Improved Urinary incontinence | Castro, 2008[246] | 12/31 | 13/30 | 39/43 | 0.89 (0.49; 1.63) | 53.75 | -0.046 (-0.293; 0.2) | 44.41 |
| Improved Urinary incontinence | Hahn, 1991[529] | 4/10 | 3/10 | 40/30 | 1.33 (0.40; 4.49) | 13.27 | 0.1 (-0.316; 0.516) | 15.63 |
| Pooled | | 23/75 | 27/61 | 31/45 | 0.97 (0.62; 1.51) | 100 | -0.006 (-0.17; 0.159) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.88 | 0.00% | 0.874 | 0.00% |
| Treatment failure | Castro, 2008[246] | 11/31 | 12/30 | 35/40 | 0.89 (0.47; 1.69) | 53.82 | -0.045 (-0.288; 0.198) | 54.03 |
| Treatment failure | Spruijt, 2003[587] | 7/25 | 6/12 | 55/25 | 2.43 (1.04; 5.66) | 46.18 | 0.343 (0.018; 0.669) | 45.97 |
| Pooled | | 18/56 | 18/42 | 31/43 | 1.41 (0.53; 3.78) | 100 | 0.133 (-0.246; 0.513) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.06 | 71.00% | 0.061 | 71.60% |

**Appendix Table F130. Clinical outcomes after PFMT compared to vaginal cones (results from RCTs pooled with random effects models)**

| Outcome | Reference | Active n/N | Control n/N | Rate Active/Control | Relative Risk (95% CI) | Weight, % | Absolute Risk Difference (95% CI) | Weight, % |
|---|---|---|---|---|---|---|---|---|
| Continence | Castro, 2008[246] | 10/31 | 9/27 | 32/33 | 0.97 (0.46; 2.02) | 16.99 | -0.011 (-0.253; 0.232) | 37.49 |
| Continence | Williams, 2006[605] | 0/79 | 0/80 | 0/0 | | | | |
| Continence | Gameiro, 2010[523] | 26/52 | 34/51 | 50/67 | 0.75 (0.54; 1.05) | 83.01 | -0.167 (-0.354; 0.021) | 62.51 |
| Pooled | | 36/162 | 43/158 | 22/27 | 0.78 (0.58; 1.06) | 100 | -0.108 (-0.257; 0.04) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.54 | 0.00% | 0.319 | 0.00% |
| Improved Urinary incontinence | Seo, 2004[584] | 55/60 | 53/60 | 92/88 | 1.04 (0.92; 1.17) | 89.16 | 0.033 (-0.074; 0.141) | 67.1 |
| Improved Urinary incontinence | Castro, 2008[246] | 12/31 | 11/27 | 39/41 | 0.95 (0.50; 1.79) | 3.16 | -0.02 (-0.273; 0.232) | 12.09 |
| Improved Urinary incontinence | Williams, 2006[605] | 0/79 | 0/80 | | | | | |
| Improved Urinary incontinence | Gameiro, 2010[523] | 23/52 | 26/51 | 44/51 | 0.87 (0.58; 1.30) | 7.69 | -0.067 (-0.26; 0.125) | 20.81 |
| Pooled | | 0/222 | 0/218 | 0/0 | 1.02 (0.91; 1.14) | 100 | 0.006 (-0.082; 0.094) | 100 |
| Heterogeneity P value, I squared,% | | | | | 0.69 | 0.00% | 0.653 | 0.00% |

**Appendix Table F131. Scoring of quality of life after PFMT with biofeedback vs. medical devices (individual RCTs)**

| Reference Sample/men | Active | Control | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Seo, 2004[584] /0 | Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week | Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material | Changes in sexual life | 60/60 | -0.19/0.12 | | |
| Seo, 2004[584] /0 | Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week | Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material | Changes in daily life | 60/60 | -0.27/0.11 | | |
| Seo, 2004[584] /0 | Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week | Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material | Changes in difficulty in personal relationships | 60/60 | -0.29/0.14 | | |
| Seo, 2004[584] /0 | Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week | Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material | Changes in quality of life | 60/60 | -0.27/0.13 | | |

**Appendix Table F131. Scoring of quality of life after PFMT with biofeedback vs. medical devices (individual RCTs) (continued)**

| Reference Sample/men | Active | Control | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Cammu, 1998[504] /0 | Weekly session of pelvic floor exercises vaginal probe-EMG biofeedback using perineometer | Vaginal weight cones | Visual analogue scale (0–10) | 30/30 | 2.60/2.10 | 2.90/2.40 | -0.30 (-1.44;0.84) |
| Cammu, 1998[504] /0 | Weekly session of pelvic floor exercises vaginal probe-EMG biofeedback using perineometer | Vaginal weight cones | Visual analogue scale (0–10)Severity of incontinence | 30/30 | 2.10/2.10 | 3.40/3.30 | -1.30 (-2.70;0.10) |

**Appendix Table F132. Comparative effectiveness of circular muscle exercises (Paula method) vs. PFMT (individual RCT)**

| Reference Sample/Men | Outcome | Randomized Active/Control | Active Events/Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Liebergall-Wischnitzer, 2009[550] 241/0 | Improved (pad test <1g) | 117/123 | 76/65 | 62/50 | 1.30 (1.04; 1.62) | 0.15 (0.03; 0.27) | 7 (4; 38) | 150 (26; 273) |
| Liebergall-Wischnitzer, 2009[550] 241/0 | Percent cured | 117/123 | 60/51 | 42/34 | 1.50 (1.11; 2.03) | 0.17 (0.05; 0.29) | 6 (3; 21) | 171 (48; 295) |
| Liebergall-Wischnitzer, 2009[550] 241/0 | No feelings of bladder fullness | 117/123 | 77/66 | 64/52 | 1.26 (1.02; 1.57) | 0.14 (0.01; 0.26) | 7 (4; 69) | 138 (15; 261) |

**Appendix Table F133. Scoring of quality of life after circular muscle exercises (Paula method) vs. PFMT (individual RCTs)**

| Reference Sample/Men | Outcome | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|
| Liebergall-Wischnitzer, 2009[550] /0 | Mean I-QOL improvement | 117/123 | 10.80/18.76 | 9.80/20.37 | 1.00 (-3.95; 5.95) |
| Liebergall-Wischnitzer, 2009[550] /0 | I-QOL overall score | 117/123 | 83.10/5.10 | 78.10/17.60 | 5.00 (1.76; 8.24) |
| Liebergall-Wischnitzer, 2005[551] /0 | Change from baseline in quality of life-avoidance, limiting behaviors scores (8 items) | 31/32 | 9.80/17.30 | 9.50/27.40 | 0.30 (-11.66; 11.06) |
| Liebergall-Wischnitzer, 2005[551] /0 | Change from baseline in quality of life-avoidance, social embarrassment scores (5 items) | 31/32 | 14.00/23.00 | 9.30/13.00 | 4.70 (-13.89; 4.49) |

**Appendix Table F134. Clinical outcomes after circular muscle exercises (Paula method) vs. PFMT (individual RCTs)**

| Reference Sample/Men | Outcome | Randomized Active/Control | Active Events/Rate | Control Events/Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 treated (95%CI) |
|---|---|---|---|---|---|---|---|---|
| Liebergall-Wischnitzer, 2009[550] 240/0 | Leakage annoyance often/very often | 117/123 | 14/12 | 29/24 | 0.51 (0.28; 0.91) | -0.12 (-0.21; -0.02) | -9 (-48; -5) | -116 (-211 ;-21) |
| Liebergall-Wischnitzer, 2009[550] 240/0 | Leakage amount moderate/very large | 117/123 | 17/15 | 25/20 | 0.71 (0.41; 1.25) | -0.06 (-0.15; 0.04) | | |
| Liebergall-Wischnitzer, 2009[550] 240/0 | Feelings of bladder fullness | 117/123 | 16/14 | 22/18 | 0.76 (0.42; 1.38) | -0.04 (-0.13; 0.05) | | |
| Liebergall-Wischnitzer, 2009[550] 240/0 | Leakage frequency monthly or once in several months | 117/123 | 26/22 | 25/20 | 1.0 9 (0.67; 1.78) | 0.02 (-0.08 ;0.12) | | |
| Liebergall-Wischnitzer, 2009[550] 240/0 | Daily-weekly | 117/123 | 65/56 | 61/50 | 1.12 (0.88; 1.43) | 0.06 (-0.07; 0.19) | | |

**Appendix Table F135. Comparative effectiveness on quality of life after PFMT vs. active controls (individual RCTs)**

| Reference Sample/Men | Active | Control | Definitions of the Outcomes | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Liebergall-Wischnitzer, 2009[550] 240/0 | Circular muscle exercises (Paula method) | PFMT group | Leakage annoyance not at all/seldom/ sometime | 117/123 | 81/69 | 59/48 | 1.44 (1.16; 1.80) | 0.21 (0.09; 0.33) | 5 (3; 11) | 213 (91; 4703) |
| Morkved, 2002[566] 103/0 | Pelvic floor muscle training with a biofeedback apparatus | Pelvic floor muscle training without biofeedback | Urinary incontinence is very problematic | 53/50 | 1/2 | 3/6 | 0.31 (0.03; 2.92) | -0.04 (-0.12; 0.03) | | |
| Sherman, 1997[585] 39/0 | Pelvic muscle exercises with vaginal EMG probe. | Pelvic muscle | Best activity level | 23/16 | 4/0 | 5/0 | 0.56 (0.18; 1.76) | -0.14 (-0.41; 0.14) | | |
| Williams, 2006[605] /0 | Pelvic floor muscle therapies | Vaginal cone therapy | Odds ratio of satisfaction with current urinary symptoms for rest of life | 79/80 | | | 1.02 (0.54;1.95) | | | |
| Williams, 2006[605] /0 | Pelvic floor muscle therapies | Behavioral intervention | Odds ratio of satisfaction with current urinary symptoms for rest of life | 79/79 | | | 0.77 (0.40;1.47) | | | |
| Glavind, 1996[526] 40/0 | Physiotherapy in combination with biofeedback | Physiotherapy | Acceptance of degree of incontinence | 20/20 | 15/75 | 10/50 | 1.50 (0.90; 2.49) | 0.25 (-0.04; 0.54) | | |

**Appendix Table F136. Scoring of quality of life after PFMT (individual RCTs)**

| Reference Sample/Men | Active | Control | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean/Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Borello-France, 2008[491] /0 | High-frequency (4 times per week) | Low-frequency (1 time per week) | Change in incontinence impact questionnaire score | 22/22 | -4.00/10.60 | -6.00/27.00 | 2.00 (-10.12; 14.12) |
| Borello-France, 2008[491] /0 | High-frequency (4 times per week) | Low-frequency (1 time per week) | Change in Brink score | 22/22 | 0.00/0.97 | 0.00/1.00 | 0.00 (-0.58; 0.58) |
| Demain, 2001[507] /0 | Three educational group sessions, PFMT | One 45-minute individual instruction in PFMT | Incontinence impact questionnaire score (0 to 100 worse) | 22/22 | 14.30/22.73 | 7.10/28.72 | 7.20 (-8.10; 22.50) |
| Williams, 2006[605] /0 | Pelvic floor muscle therapies | Vaginal cone therapy | Median (interquartile range) impact score | 79/80 | | | -0.46 (-3.09; 2.18) |
| Williams, 2006[605] /0 | Pelvic floor muscle therapies | Primary behavioral intervention | Median (interquartile range) impact score | 79/79 | | | -0.02 (-2.78; 2.75) |
| Kincade, 2007[541] /0 | Self-monitoring group with training on fluid intake, voiding frequency, and PFMT | Quick Kegel | Quality of life using Incontinence impact questionnaire with scores 0-400 (worse) | 117/107 | 99.30/96.60 | 112.10/89.90 | -12.80 (-37.22; 11.62) |

**Appendix Table F137. Continence after PFMT with personal reminders and self-help guides or different positions during exercise (individual RCTs)**

| Reference Sample/Men | Active | Control | Randomized Active/Control | Active Events/Rate | Control Events/Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) |
|---|---|---|---|---|---|---|---|
| Alewijnse, 2003[472] 103/0 | Pelvic floor muscle exercise with reminder and Self-Help Guide | Bladder training and pelvic floor muscle exercise | 52/51 | 17/33 | 21/41 | 0.79 (0.48; 1.32) | -0.08 (-0.27; 0.10) |
| Borello-France, 2006[490] 44/0 | Pelvic-floor muscle exercises with EMG biofeedback in the supine position only using max 30-60 repetitions of 3-12 second contractions twice daily | Pelvic-floor muscle exercises with EMG biofeedback in both supine and upright positions, 1 set (3- and 12-second contractions) in each position with max of 20 repetitions (2 sets of 10) of the 3-12 second contractions twice daily | 22/22 | 13/59 | 13/59 | 1.00 (0.61; 1.64) | 0.00 (-0.29; 0.29) |

**Appendix Table F138. Comparative effectiveness of medical devices (individual RCTs)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/ 1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Williams, 2006[605] /0 | Vaginal cone therapy | Primary behavioral intervention | Odds ratio of no symptoms (cure) | 80/79 | | | 0.88 (0.28; 2.76) | | | |
| Williams, 2006[605] /0 | Vaginal cone therapy | Primary behavioral intervention | Odds ratio of mild or no problem | 80/79 | | | 0.88 (0.44; 1.77) | | | |
| Thyssen, 2001[598] 124/0 | Contrelle Continence Tampon (CCT) | Conveen Continence disposable Intravaginal device guard, (CCG) | Subjectively continent | 62/62 | 30/48 | 22/35 | 1.36 (0.89; 2.08) | 0.13 (-0.04; 0.30) | | |
| Thyssen, 2001[598] 188/0 | Conveen Continence disposable Intravaginal device guard, (CCG) | Contrelle Continence Tampon (CCT) | Cured from stress urinary incontinence | 94/94 | 34/36 | 45/48 | 0.76 (0.54; 1.06) | -0.12 (-0.26; 0.02) | | |
| Nygaard, 1995[571] 40/0 | Hodge pessary with support | 40-minute standardized aerobics sessions wearing a super tampon | Continent during exercise | 20/20 | 7/36 | 12/58 | 0.58 (0.29; 1.17) | -0.25 (-0.55; 0.05) | | |
| Andersen, 2002[475] 52/0 | Durasphere | Contigen® | Dry | 26/26 | 10/38 | 3/12 | 3.33 (1.03; 10.74) | 0.27 (0.05; 0.49) | 4 (2; 22) | 269 (46; 493) |
| Robinson, 2003[581] 24/0 | Urethral device (NEAT) –sterile urethral insert with disposable applicator packaged with device. | Reliance Insert sterile balloon type device | Success as negative pad weight test | 13/11 | 9/73 | 7/62 | 1.09 (0.61; 1.93) | 0.06 (-0.32; 0.44) | | |
| **Improvement in incontinence** | | | | | | | | | | |
| Thyssen, 2001[598] | Contrelle Continence | Conveen Continence | Improvement in UI | 62/62 | 22/35 | 25/40 | 0.88 (0.56; 1.38) | -0.05 (-0.22; 0.12) | | |

**Appendix Table F138. Comparative effectiveness of medical devices (individual RCTs) (continued)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/ 1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| 124/0 | Tampon (CCT) | disposable Intravaginal device guard (CCG) | | | | | | | | |
| Thyssen, 2001[598] 188/0 | Conveen Continence disposable Intravaginal device guard (CCG) | Contrelle Continence Tampon (CCT) | Self reported Improvement in stress urinary incontinence | 94/94 | 38/40 | 34/36 | 1.12 (0.78; 1.61) | 0.04 (-0.10; 0.18) | | |
| Andersen, 2002[475] 52/0 | Durasphere | Contigen® | Improvement of 1 or more continence grades | 26/26 | 20/77 | 13/50 | 1.54 (0.99; 2.38) | 0.27 (0.02; 0.52) | 4 (2; 56) | 269 (18; 521) |
| Seo, 2004[584] 120/0 | Pelvic floor exercise (5 sec contraction and 10 sec relaxation, 3-5 times for >5 min/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 sec); 2 training sessions/week | Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material | Self reported improvement in urinary incontinence | 60/60 | 55/92 | 53/88 | 1.04 (0.92; 1.17) | 0.03 (-0.07; 0.14) | | |
| Robinson, 2003[581] 24/0 | Urethral device (NEAT) –sterile urethral insert with disposable applicator packaged with device. | Reliance Insert sterile balloon type device | Success as a 50% or greater reduction in urine loss | 13/11 | 9/67 | 6/58 | 1.27 (0.66; 2.43) | 0.15 (-0.24; 0.53) | | |

**Appendix Table F139. Scoring of quality of life after medical devices compared to active controls (individual RCTs)**

| Reference Sample | Active | Control | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean/Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Seo, 2004[584] /0 | Pelvic floor exercise with Electrical Stimulation Biofeedback | Vaginal cone | Changes in scores Restriction in exercise due to incontinence | 60/60 | -0.59/0.18 | -0.36/0.17 | -0.23 (-0.29; -0.17) |
| Seo, 2004[584] /0 | Pelvic floor exercise with Electrical Stimulation Biofeedback | Vaginal cone | Changes in scores Avoiding places due to urinary incontinence | 60/60 | -0.29/0.14 | -0.13/0.15 | -0.16 (-0.21; -0.11) |
| Andersen, 2002[475] /0 | Durasphere | Contigen® | Change in continence grade | 26/26 | 1.28/0.84 | 0.86/1.01 | 0.42 (-0.08; 0.92) |
| Williams, 2006[605] /0 | Vaginal cone | Primary behavioral intervention | Median (interquartile range) impact score | 80/79 | 0.00/0.00 | 0.00/0.00 | -0.48 (-2.60; 1.66) |

**Appendix Table F140. Comparative effectiveness of medical devices on quality of life (individual RCT)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Thyssen, 2001[598] 124/0 | CCT | CCG | preference of the device | 62/62 | 39/63 | 16/26 | 2.44 (1.53; 3.87) | 0.37 (0.21; 0.53) | 3 (2; 5) | 371 (209; 2696) |
| Thyssen, 2001[598] 124/0 | CCT | CCG | No bother from UI | 62/62 | 54/87 | 45/72 | 1.20 (1.00; 1.44) | 0.15 (0.01; 0.28) | 7 (4; 160) | 145 (6; 6889) |
| Williams, 2006[605] /0 | Vaginal cone therapy | Behavioral intervention | OR of satisfaction with current urinary symptoms for rest of life | 80/79 | | | 0.75 (0.40; 1.44) | | | |

**Appendix Table F141. Comparative comfort in using different pads for urinary incontinence (individual RCT)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/Control | Active Events/Rate | Control Events/Rate | Relative Risk (95% CI) | Absolute risk Differences (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Thornburn, 1997[597] 514/0 | Pad C | Pad F | Good wet comfort | 258/255 | 116/45 | 128/50 | 0.90 (0.75; 1.08) | -0.05 (-0.14; 0.04) |
| Thornburn, 1997[597] 514/0 | Pad A | Pad C | Good wet comfort | 247/258 | 124/50 | 116/45 | 1.11 (0.93; 1.34) | 0.05 (-0.04; 0.14) |
| Thornburn, 1997[597] 514/0 | Pad A | Pad F | Good wet comfort | 247/255 | 124/50 | 128/50 | 1.00 (0.84; 1.19) | 0.00 (-0.09; 0.09) |
| Thornburn, 1997[597] 514/0 | Pad C | Pad F | Good absorbency | 258/255 | 134/52 | 153/60 | 0.87 (0.74; 1.01) | -0.08 (-0.17; 0.01) |
| Thornburn, 1997[597] 514/0 | Pad A | Pad C | Good leakage performance | 247/258 | 136/55 | 155/60 | 0.92 (0.79; 1.07) | -0.05 (-0.14; 0.04) |
| Thornburn, 1997[597] 514/0 | Pad A | Pad F | Good leakage performance | 247/255 | 136/55 | 153/60 | 0.92 (0.79; 1.07) | -0.05 (-0.14; 0.04) |
| Thornburn, 1997[597] 514/0 | Pad A | Pad C | Good absorbency | 247/258 | 143/58 | 134/52 | 1.11 (0.95; 1.31) | 0.06 (-0.03; 0.15) |
| Thornburn, 1997[597] 514/0 | Pad A | Pad F | Good absorbency | 247/255 | 143/58 | 153/60 | 0.96 (0.83; 1.12) | -0.02 (-0.11; 0.07) |
| Thornburn, 1997[597] 514/0 | Pad C | Pad F | Good leakage performance | 258/255 | 155/60 | 153/60 | 1.00 (0.87; 1.15) | 0.00 (-0.08; 0.09) |

**Appendix Table F142. Comparative effectiveness of bulking agents (individual RCTs)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Continence** | | | | | | | | | | |
| Mayer, 2007[559] 296/0 | Calcium hydroxylapatite (CaHA) | Bovine Dermal Collagen | Cure rate or Stamey grade 0 at 12 months | 158/138 | 51/32 | 37/27 | 1.20 (0.84; 1.72) | 0.05 (-0.05; 0.16) | | |
| Bano, 2005[480] 50/0 | Peri or transurethral porcine dermal implant injection (Permacol) | Transurethral silicone injection (Macroplastique | Urinary continence (negative pad test) | 25/25 | 15/60 | 9/36 | 1.67 (0.90; 3.08) | 0.24 (-0.03; 0.51) | | |
| Schulz, 2004[583] 40/0 | Periurethral route of injection of bulking agent-dextran copolymer | Transurethral route of injection of bulking agent-dextran copolymer | Objective urinary continence (dry in pad test) | 20/20 | 1/5 | 3/15 | 0.33 (0.04; 2.94) | -0.10 (-0.28; 0.08) | | |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Number of Stamey grade dry | 122/125 | 45/37 | 31/25 | 1.49 (1.01; 2.18) | 0.12 (0.01; 0.24) | 8 (4; 152) | 121 (7; 235) |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Patient assessment - dry | 122/125 | 34/28 | 25/20 | 1.39 (0.89; 2.19) | 0.08 (-0.03; 0.18) | | |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Physician assessment - dry | 122/125 | 43/35 | 32/26 | 1.38 (0.94; 2.02) | 0.10 (-0.02; 0.21) | | |
| Strasser, 2007[588] 63/0 | Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts | Conventional endoscopic injections of collagen | Continence | 42/21 | 38/90 | 2/10 | 9.50 (2.53; 35.63) | 0.81 (0.66; 0.96) | 1 (1; 2) | 810 (656; 963) |
| Lightner, 2009[553] 344/0 | Zuidex Implacer | Contigen® endoscopic guidance | Dry rates | 227/117 | 83/37 | 52/44 | 0.82 (0.63; 1.07) | -0.08 (-0.19; 0.03) | | |

**Appendix Table F142. Comparative effectiveness of bulking agents (individual RCTs) (continued)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Improvement in Incontinence** | | | | | | | | | | |
| Lightner, 2001[552] 364/0 | Injection of bulking agent 1.0 mL Durasphere max 5 times with a minimum 7-day interval | Injection of bulking agent bovine collagen max 5 times with a minimum 7-day interval | Improvement of 1 or more continence grades | 176/188 | 76/43 | 79/42 | 1.03 (0.81; 1.30) | 0.01 (-0.09; 0.11) | | |
| Bano, 2005[480] 50/0 | Peri or transurethral porcine dermal implant injection (Permacol) | Transurethral silicone injection (Macroplastique) | Improvement in urinary incontinence (pad test) | 25/25 | 15/60 | 10/40 | 1.50 (0.84; 2.67) | 0.20 (-0.07 ;0.47) | | |
| Bano, 2005[480] 50/0 | Peri or transurethral porcine dermal implant injection (Permacol) | Transurethral silicone injection (Macroplastique) | Improved urinary incontinence scores (Stamey) | 25/25 | 14/56 | 10/40 | 1.40 (0.77; 2.53) | 0.16 (-0.11; 0.43) | | |
| Bano, 2005[480] 50/0 | Peri or transurethral porcine dermal implant injection (Permacol) | Transurethral silicone injection (Macroplastique) | Improved urinary incontinence scores (Kings College Hospital Quality of Health Questionnaire) | 25/25 | 14/56 | 7/28 | 2.00 (0.98; 4.10) | 0.28 (0.02; 0.54) | 4 (2; 57) | 280 (18; 542) |
| Schulz, 2004[583] 40/0 | Periurethral route of injection of bulking agent-dextran copolymer | Transurethral route of injection of bulking agent-dextran copolymer | Subjective improvement in urinary incontinence | 20/20 | 6/30 | 7/35 | 0.86 (0.35; 2.10) | -0.05 (-0.34; 0.24) | | |
| Mayer, 2007[559] 296/0 | Calcium hydroxylapatite (CaHA) | Bovine Dermal Collagen | Improved by one Stamey grade at 6 months | 158/138 | 97/61 | 71/51 | 1.19 (0.97; 1.46) | 0.10 (-0.01; 0.21) | | |

**Appendix Table F142. Comparative effectiveness of bulking agents (individual RCTs) (continued)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Mayer, 2007[559] 296/0 | Calcium hydroxylapatite (CaHA) | Bovine Dermal Collagen | Improved by one Stamey grade at 12 months | 158/138 | 83/53 | 57/41 | 1.27 (0.99; 1.63) | 0.11 (0.00; 0.23) | | |
| Mayer, 2007[559] 296/0 | Calcium hydroxylapatite (CaHA) | Bovine Dermal Collagen | Improvement of two Stamey scale units or being dry | 158/138 | 66/41 | 46/33 | 1.25 (0.92; 1.68) | 0.08 (-0.03; 0.19) | | |
| Mayer, 2007[559] 296/0 | Calcium hydroxylapatite (CaHA) | Bovine Dermal Collagen | 50% or more decline in 24-hour pad weight test at 12 months | 158/138 | 81/51 | 54/39 | 1.31 (1.01; 1.70) | 0.12 (0.01; 0.23) | 8 (4; 116) | 121 (9; 234) |
| Strasser, 2007[588] 63/0 | Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts | Conventional endoscopic injections of collagen | Substantial improvement in urinary incontinence | 42/21 | 3/7 | 1/5 | 1.50 (0.17; 13.56) | 0.02 (-0.10 ;0.14) | | |
| Strasser, 2007[588] 63/0 | Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts | Conventional endoscopic injections of collagen | Slight improvement in urinary incontinence | 42/21 | 1/2 | 6/29 | 0.08 (0.01; 0.65) | -0.26 (-0.46; -0.06) | -4 (-16; -2) | -262 (-461; -63) |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Improvement of at least 1 Stamey grade at 12 months | 122/125 | 75/61 | 60/48 | 1.28 (1.02; 1.61) | 0.13 (0.01; 0.26) | 7 (4; 85) | 135 (12; 258) |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Patient assessment - improved | 122/125 | 45/37 | 39/31 | 1.18 (0.83; 1.68) | 0.06 (-0.06; 0.17) | | |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Physician assessment - marked improvement | 122/125 | 39/32 | 38/30 | 1.05 (0.73; 1.52) | 0.02 (-0.10; 0.13) | | |

**Appendix Table F142. Comparative effectiveness of bulking agents (individual RCTs) (continued)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | With a Stamey grade of 0 or dry outcome | 122/125 | 45/37 | 31/25 | 1.49 (1.01; 2.18) | 0.12 (0.01; 0.24) | 8 (4; 152) | 121 (7; 235) |
| Lightner, 2009[553] 344/0 | Zuidex Implacer | Contigen® Endoscopic guidance | Reduction in urine leakage at least 50% on provocation tests | 227/117 | 148/65 | 98/84 | 0.78 (0.69; 0.88) | -0.19 (-0.28; -0.09) | -5 (-11; -4) | -186 (-277; -94) |
| Lightner, 2009[553] 344/0 | Zuidex Implacer | Contigen® Endoscopic guidance | Responder rate based on >50% reduction in incontinent episodes | 227/117 | 122/54 | 78/67 | 0.81 (0.68 ;0.96) | -0.13 (-0.24; -0.02) | -8 (-46; -4) | -129 (-236; -22) |
| Lightner, 2009[553] 344/0 | Zuidex Implacer | Contigen® Endoscopic guidance | One-grade improvement on Stamey score at 12 months | 227/117 | 116/51 | 64/55 | 0.93 (0.76; 1.15) | -0.04 (-0.15; 0.08) | | |
| Lightner, 2009[553] 344/0 | Zuidex Implacer | Contigen® Endoscopic guidance | 3 treatments needed for clinical effect | 227/117 | 67/30 | 38/33 | 0.91 (0.65; 1.26) | -0.03 (-0.13; 0.07) | | |

**Appendix Table F143. Quality of life scores after bulking agents (individual RCTs)**

| Reference Sample/Men | Active | Control | Definition of Quality of Life | Randomized Active/Control | Active Mean/Standard Deviation | Control Mean/Standard Deviation | Mean Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Ghoniem, 2009[524] /0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | I-QOL improvement | 122/125 | 28.70/20.70 | 26.40/24.00 | 2.30 (-3.29; 7.89) |
| Strasser, 2007[588] /0 | Transurethral ultrasonography-guided injections of autologous myoblasts and fibroblasts | Conventional endoscopic injections of collagen | Quality of life score | 42/21 | 108.00/0.67 | 64.00/17.33 | 44.00 (36.58; 51.42) |

**Appendix Table F144. Clinical outcomes after bulking agents (individual RCTs)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| Lightner, 2009[553] 344/0 | Zuidex Implacer | Contigen® Endoscopic guidance | Withdraw due to adverse events | 227/117 | 8/4 | 2/2 | 2.06 (0.44; 9.55) | 0.02 (-0.02; 0.05) | | |
| Lightner, 2009[553] 344/0 | Zuidex Implacer | Contigen® Endoscopic guidance | Lack of effect | 227/117 | 43/19 | 11/9 | 2.01 (1.08; 3.76) | 0.10 (0.02; 0.17) | 10 (6; 46) | 9 5 (22; 169) |
| Lightner, 2009[553] 344/0 | Zuidex Implacer | Contigen® Endoscopic guidance | Worsened incontinence at 12 months | 227/117 | 32/14 | 8/7 | 2.06 (0.98; 4.33) | 0.07 (0.01; 0.14) | 14 (7; 121) | 73 (8; 137) |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Discontinued due to loss to followup | 122/125 | 20/16 | 31/25 | 0.66 (0.40; 1.09) | -0.08 (-0.18; 0.02) | | |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Withdrew | 122/125 | 8/7 | 4/3 | 2.05 (0.63; 6.63) | 0.03 (-0.02; 0.09) | | |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Physician assessment - unchanged | 122/125 | 6/5 | 10/8 | 0.61 (0.23; 1.64) | -0.03 (-0.09; 0.03) | | |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Patient assessment - unchanged | 122/125 | 8/7 | 11/9 | 0.75 (0.31; 1.79) | -0.02 (-0.09 ;0.04) | | |
| Ghoniem, 2009[524] 247/0 | Transurethral injection of Macroplastique | Transurethral injection of Contigen® | Urge incontinence | 122/125 | 6/5 | 5/4 | 1.23 (0.39; 3.92) | 0.0 (-0.04; 0.06) | | |
| Strasser, 2007[588] 63/0 | Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts | Conventional endoscopic injections of collagen | Number of incontinent patients | 42/21 | 4/10 | 19/90 | 0.11 (0.04; 0.27) | -0.81 (-0.96; -0.66) | -1 (-2; -1) | -810 (-963; -656) |
| Mayer, 2007[559] 296/0 | Calcium hydroxylapatite (CaHA) | Bovine Dermal Collagen | Urge incontinence after treatment | 158/138 | 7/5 | 12/9 | 0.51 (0.21; 1.26) | -0.04 (-0.10; 0.01) | | |
| Lightner, 2001[552] 364/0 | Injection of bulking agent 1.0 mL | Injection of bulking agent bovine | Incidence of urgency | 176/188 | 43/25 | 22/12 | 2.09 (1.30; 3.34) | 0.13 (0.05; 0.21) | 8 (5; 20) | 127 (49; 206) |

**Appendix Table F144. Clinical outcomes after bulking agents (individual RCTs) (continued)**

| Reference Sample | Active | Control | Definition of Outcome | Randomized Active/ Control | Active Events/ Rate | Control Events/ Rate | Relative Risk (95% CI) | Absolute Risk Differences (95% CI) | Number Needed to Treat (95% CI) | Attributable Events/1000 Treated (95% CI) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Durasphere max 5 times with a minimum 7-day interval | collagen max 5 times with a minimum 7-day interval | | | | | | | | |

**Appendix Table F145. Nonsignificant differences in comparative effectiveness of oxybutynin when compared to nonpharmacological treatments (results from individual randomized controlled clinical trials)**

| Reference | Outcome | Active Treatment | Control Treatment | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|---|---|---|
| Karademir, 2005[315] | Cured from urge incontinence | Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA | Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA combined with 5 mg of oral oxybutynin hydrochloride | 3/21 | 3/23 | 1.10 (0.25; 4.84) | 0.01 (-0.19; 0.22) |
| Karademir, 2005[315] | Decrease in symptoms of frequency | Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA | Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA combined with 5 mg of oral oxybutynin hydrochloride | 8/21 | 10/22 | 0.84 (0.41; 1.71) | -0.07 (-0.37;0.22) |
| Karademir, 2005[315] | Decrease in symptoms of urgency | Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA | Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA combined with 5 mg of oral oxybutynin hydrochloride | 10/21 | 13/22 | 0.81 (0.46; 1.42) | -0.12 (-0.41 ;0.18) |
| Karademir, 2005[315] | Decrease in symptoms of urge incontinence | Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA | Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA combined with 5 mg of oral oxybutynin hydrochloride | 15/21 | 20/22 | 0.79 (0.58; 1.06) | -0.20 (-0.42; 0.03) |
| Burgio, 2010[241] | Completely satisfied with treatment progress | Pelvic Floor Muscle training + Urge suppression techniques + Oxybutynin | Oxybutynin | 25/32 | 28/32 | 0.89 (0.71;1.12) | -0.09 (-0.28; 0.10) |
| Burgio, 2010[241] | Perceived improvement: much better | Pelvic Floor Muscle training + Urge suppression techniques + Oxybutynin | Oxybutynin | 25/32 | 29/32 | 0.86 (0.70; 1.07) | -0.13 (-0.30;0.05) |
| Goode, 2002[286] | Self reported improvement in UI | Four sessions (over 8 weeks) of biofeedback-assisted behavioral training by nurse practitioners. | 2.5 mg of oxybutynin chloride 3 times/day, dose adjustments from minimum 2.5 mg/ day to a maximum 5.0 mg 3 times/day | 27/33 | 27/35 | 1.06 (0.83; 1.35) | 0.05 (-0.15; 0.24) |

**Appendix Table F146. Comparative effectiveness of combined therapy with tolterodine ER, 4 mg daily and behavioral intervention with pelvic floor muscle training vs. tolterodine ER, 4 mg daily monotherapy. Urinary Incontinence Treatment Network: behavior enhances drug reduction of incontinence, (BE-DRI) randomized controlled clinical trial**

| Reference | Outcome | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|---|
| Burgio, 2008[238] | Totally dry | 32/154 | 26/153 | 1.22 (0.77; 1.95) | 0.038 (-0.050; 0.125) | | |
| Burgio, 2008[238] | At least 70% reduction in incontinence episodes | 106/154 | 89/153 | 1.18 (1.00; 1.40) | 0.107 (0.000; 0.214) | | |
| Burgio, 2008[238] | Success as not receiving drugs or any other therapy for urge incontinence and a 70% or greater reduction in frequency of incontinence episodes | 43/154 | 41/153 | 1.04 (0.72; 1.50) | 0.011 (-0.088; 0.111) | | |
| Burgio, 2008[238] | Completely satisfied with their progress at the end of stage 1 | 82/154 | 61/153 | 1.34 (1.05; 1.71) | 0.134 (0.023; 0.244) | 7 (43; 4) | 134 (23; 244) |
| Burgio, 2008[238] | Completely satisfied with their progress at 8 months | 51/154 | 31/153 | 1.63 (1.11; 2.41) | 0.129 (0.031 ;0.226) | 8 (33; 4) | 129 (31; 226) |
| Burgio, 2008[238] | Improvement with treatment as "better" or "much better" at stage 1 | 139/154 | 118/153 | 1.17 (1.06; 1.29) | 0.131 (0.050 ;0.213) | 8 (20; 5) | 131 (50; 213) |
| Burgio, 2008[238] | Improvement with treatment as "better" or "much better" at 8 months | 106/154 | 66/153 | 1.60 (1.29; 1.97) | 0.257 (0.150; 0.364) | 4 (7; 3) | 257 (150; 364) |
| Zimmern, 2010[240] | Much better | 63/154 | 46/153 | 1.36 (1.00; 1.85) | 0.108 (0.002; 0.215) | 9 (478; 5) | 108 (2; 215) |
| Zimmern, 2010[240] | Blurriness | 14/154 | 15/153 | 0.93 (0.46; 1.85) | -0.007 (-0.073; 0.058) | | |
| Zimmern, 2010[240] | Confusion | 14/154 | 16/153 | 0.8 (0.44; 1.72) | -0.014 (-0.080 ;0.053) | | |
| Zimmern, 2010[240] | Constipation | 63/154 | 64/153 | 0.98 (0.75; 1.28) | -0.009 (-0.119; 0.101) | | |
| Zimmern, 2010[240] | Dry mouth | 103/154 | 114/153 | 0.90 (0.78; 1.04) | -0.076 (-0.178; 0.025) | | |
| Burgio, 2008[238] | Failure | 75/154 | 49/153 | 1.52 (1.15; 2.02) | 0.167 (0.059; 0.275) | 6 (17; 4) | 167 (59; 275) |
| Zimmern, 2010[240] | Much worse | 0/154 | 0/153 | 0.00 (0.00; 0.00) | 0.000 (-0.013; 0.013) | | |

**Appendix Table F147. Comparative effectiveness of percutaneous tibial nerve stimulation versus extended-release tolterodine (results from overactive bladder innovative therapy trial)[353]**

| Outcome | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|
| Subject assessment: cured | 1/50 | 2/50 | 0.50 (0.05; 5.34) | -0.020 (-0.087; 0.047) | | |
| Investigator assessment : cured | 2/50 | 2/50 | 1.00 (0.15; 6.82) | 0.000 (-0.077; 0.077) | | |
| Subject assessment: improved | 34/50 | 21/50 | 1.62 (1.11; 2.36) | 0.260 (0.072; 0.448) | 4 (2; 14) | 260 (72; 448) |
| Subject assessment: cured or improved | 35/50 | 23/50 | 1.52 (1.07; 2.16) | 0.240 (0.052; 0.428) | 4 (2; 19) | 240 (52; 428) |
| Investigator assessment: improved | 33/50 | 24/50 | 1.38 (0.97; 1.95) | 0.180 (-0.011; 0.371) | | |
| investigator assessment: cured or improved | 35/50 | 26/50 | 1.35 (0.98; 1.86) | 0.180 (-0.008 ;0.368) | | |
| Withdrawn because treatment unsuccessful | 0/50 | 3/50 | 0.14 (0.01; 2.70) | -0.060 (-0.134 ;0.014) | | |
| Subject assessment no improvement/worsening | 9/50 | 19/50 | 0.47 (0.24; 0.94) | -0.200 (-0.372; -0.028) | -5 (-35; -3) | -200 (-372; -28) |
| Investigator assessment no improvement/worsening | 9/50 | 17/50 | 0.53 (0.26; 1.07) | -0.160 (-0.329; 0.009) | | |

**Appendix Table F148. Nonsignificant differences in comparative effectiveness of flexible-dose solifenacin 5/10 mg with and without simplified bladder training in patients with overactive bladder syndrome (results from individual randomized controlled clinical trial)[65]**

| Outcome | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) |
|---|---|---|---|---|
| Mild adverse effects | 66/323 | 71/320 | 0.92 (0.68; 1.24) | -0.018 (-0.081; 0.046) |
| Moderate adverse effects | 68/323 | 66/320 | 1.02 (0.76; 1.38) | 0.004 (-0.059; 0.067) |
| Serious adverse effects | 6/323 | 6/320 | 0.99 (0.32; 3.04) | 0.000 (-0.021; 0.021) |
| Severe adverse effects | 16/323 | 12/320 | 1.32 (0.64; 2.75) | 0.012 (-0.019; 0.044) |
| Treatment-related adverse effects | 83/323 | 81/320 | 1.02 (0.78; 1.32) | 0.004 (-0.064; 0.071) |
| Constipation | 14/323 | 24/320 | 0.58 (0.30; 1.10) | -0.032 (-0.068; 0.005) |
| Dry mouth | 52/323 | 45/320 | 1.14 (0.79; 1.65) | 0.020 (-0.035; 0.076) |
| Dyspepsia | 6/323 | 8/320 | 0.74 (0.26; 2.12) | -0.006 (-0.029; 0.016) |
| Eye disorders | 15/323 | 14/320 | 1.06 (0.52; 2.16) | 0.003 (-0.029; 0.035) |
| Gastrointestinal disorders | 77/323 | 85/320 | 0.90 (0.69; 1.17) | -0.02 7(-0.094; 0.040) |
| General disorders and administration site | 13/323 | 12/320 | 1.07 (0.50; 2.32) | 0.003 (-0.027; 0.033) |
| Influenza and infections | 52/323 | 45/320 | 1.14 (0.79; 1.65) | 0.020 (-0.035; 0.076) |
| Musculoskeletal and connective tissue disorders | 15/323 | 15/320 | 0.99 (0.49; 1.99) | 0.000 (-0.033; 0.032) |
| Nervous system disorders | 19/323 | 15/320 | 1.25 (0.65; 2.43) | 0.012 (-0.023 ;0.047) |
| Psychiatric disorders | 8/323 | 4/320 | 1.98 (0.60; 6.51) | 0.012 (-0.009; 0.033) |
| Renal and urinary disorders | 9/323 | 7/320 | 1.27 (0.48; 3.38) | 0.006 (-0.018; 0.030) |
| Respiratory, thoracic, and mediastinal disorders | 7/323 | 8/320 | 0.87 (0.32; 2.36) | -0.003 (-0.027 ;0.020) |
| Skin/subcutaneous disorders | 11/323 | 5/320 | 2.18 (0.77; 6.20) | 0.018 (-0.006; 0.042) |

**Appendix Table F149. Comparative effectiveness of intravaginal electrical stimulation and trospium hydrochloride in women with overactive bladder syndrome (results from individual randomized controlled clinical trial)[352]**

| Outcome | Active Events/ Randomized | Control Events/ Randomized | Relative Risk (95% CI) | Absolute Risk Difference (95% CI) | Number Needed to Treat (95% CI) | Attributable Events (95% CI) |
|---|---|---|---|---|---|---|
| Very satisfied or satisfied with the treatment | 16/17 | 16/18 | 1.06 (0.87; 1.30) | 0.05 (-0.13; 0.24) | | |
| Experienced side-effects | 8/17 | 5/18 | 1.69 (0.69; 4.16) | 0.19 (-0.12; 0.51) | | |
| Constipation | 1/17 | 0/18 | 3.17 (0.14; 72.80) | 0.06 (-0.09; 0.21) | | |
| Hematuria secondary to nephrolithiasis | 1/17 | 0/18 | 3.17 (0.14; 72.80) | 0.06 (-0.09; 0.21) | | |
| Urinary tract infection | 1/17 | 2/18 | 0.53 (0.05; 5.32) | -0.05 (-0.24; 0.13) | | |
| Vaginal discomfort | 0/17 | 2/18 | 0.21 (0.01; 4.10) | -0.11 (-0.28; 0.06) | | |
| Vaginal hemorrhage | 0/17 | 1/18 | 0.35 (0.02; 8.09) | -0.06 (-0.20; 0.09) | | |
| Xerostomia | 5/17 | 0/18 | 11.61 (0.69; 195.26) | 0.29 (0.07; 0.52) | 3 (14; 2) | 294 (69; 519) |

## References for Appendix F

(Note that this set of references is different from those in the text of the report and the numbers are different.)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