Draft Comparative Effectiveness Review

Number XX

Treatments for Fecal Incontinence

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Treatments for Fecal Incontinence

Structured Abstract

Objective. To assess the efficacy and comparative effectiveness of surgical and nonsurgical treatments for fecal incontinence (FI) in adults.

Data sources. Ovid MEDLINE®, Embase®, PEDro®, CINAHL, AMED, and the Cochrane Central Register of Controlled Trials (CENTRAL), hand searches of systematic reviews.

Methods. Two investigators screened abstracts of identified references for eligibility (examined treatments in adults with FI, published 1980 to present, had a control/comparator group; case series were included for surgical interventions). Full-text articles were reviewed to identify patient-reported outcomes (FI episodes, FI severity, quality of life, urgency, pain, other). We extracted data, assessed risk of bias of individual studies, and evaluated strength of evidence for each comparison and outcome.

Results. Sixty-three unique studies met inclusion criteria; an additional 52 surgical case series were examined for surgical adverse effects. Enrolled adults were mostly female with mixed FI etiologies. Most RCTs were nonsurgical (n=37); 13 examined pelvic floor muscle training (PFMT) and PFMT with biofeedback (PFMT-BF). Meta-analysis was not possible because numerous outcomes were used. Low strength evidence suggests that dietary fiber (psyllium) decreases FI episodes (-2.5 per week) at 1 month; clonidine has no effect; and PFMT-BF with electrostimulation is no more effective than PFMT-BF for FI severity and quality of life over 2 to 3 months. Low-strength evidence at 6 months suggests that dextranomer anal bulking injections are more effective than sham injections on FI quality of life, the number of FI-free days, and the percent of adults with at least 50 percent reduction from baseline in FI episodes; but no more effective than PFMT-BF with or without electrostimulation on FI severity (PFMT-BF -5.4 vs. dextranomer -4.6 point Vaizey score improvements) and quality of life; and no more effective than sham injection on FI severity (-2.5 vs. -1.7 point sham improvement in Cleveland Clinic FI score [CCFIS]) or FI episode frequency. Moderate-strength evidence suggests that Durasphere® (off-label) bulking injections reduce FI severity up to 6 months (-4 to -5 points CCFIS) but gains diminish thereafter. Evidence was insufficient for all other comparisons. Surgical improvements varied. Temporary nonsurgical treatments had few minor adverse effects (AEs). Surgical treatments were associated with more frequent and more severe complications than nonsurgical interventions. AEs were most frequent for the artificial bowel sphincter (22-100% of adults). Surgical AEs ranged from minor to major (infection, bowel obstruction, perforation, fistula). Major surgical complications often required reoperation; fewer required permanent colostomy. Only 12 percent of RCTs were high quality.

Conclusion. There is limited evidence to support any FI treatments beyond 3 to 6 months. It is difficult to compare the effectiveness of surgical to nonsurgical FI treatments because nonsurgical approaches generally precede surgery, and adults who undergo surgery have typically failed more nonsurgical treatment. Most current interventions show modest improvements in FI outcomes that meet minimal important differences (MID) in the short-term, where MID is known. Surgical interventions have substantial complications. Numerous outcome

measures and lack of compliance with study reporting standards are modifiable impediments in the field. Future studies should focus on longer-term effects and attempt to identify etiologic subgroups that might benefit from specific interventions.

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Introduction

Background

Fecal incontinence (FI) is the recurrent involuntary loss of fecal material,[1,2] which is defined by the frequency of episodes (such as daily or weekly episode counts) and by the consistency of the fecal material (solid, liquid, or mucus).[1,3] FI severity varies widely and the amount of leakage can vary across episodes. The negative psychological effects, social stigma, and reduced quality of life surrounding FI can be devastating.[3] Severe skin breakdown and ulceration can result from FI, particularly in nursing home residents and immobile adults.

FI prevalence increases with age and varies by sex, but prevalence varies across patient populations and by FI definition used. Among community-dwelling adults, the prevalence of FI is 8.3 percent,[2] with higher prevalence in women (9 percent) than men (7.7 percent).[2] FI affects less than 3 percent of young adults age 20 to 29 but more than 15 percent of adults age 70 and older.[2] Women over age 40 are disproportionately affected due to pelvic floor dysfunction after childbirth and obstetrical trauma. At least half of all nursing home residents and 83 percent of residents with severe cognitive impairment have experienced FI.[4] Monthly FI occurs in 6 percent to 25 percent[4] of adults, with weekly prevalence less than 3 percent.[2] Of the 8.3 percent of affected community-dwelling adults, 6.2 percent experience FI as liquid stool, 1.6 percent as solid stool, and 3.1 percent as mucus.[2]

FI etiologies fall into two broad categories: nonneurological or neurological. Nonneurological causes of FI may be structural (e.g., muscle damage from episiotomy or surgery), functional (e.g., post-radiation or muscle atrophy), due to an underlying gastrointestinal (GI) disorder (e.g., inflammatory bowel disease), from stool consistency problems, or from other factors. Neurological causes of FI include damage to the nervous system or advanced cognitive impairment. Multiple causes of FI in individual adults are common and a dominant etiology may not be determinable. Risk factors for FI include increasing age, female sex, chronic diarrhea, nerve damage (from injury, multiple sclerosis, or chronic diabetes), postsurgical or post radiation complications, cognitive impairment, or other factors such as severe constipation.[4,5]

Treatment goals are to decrease the frequency and severity of FI episodes. Treatments for FI are imperfect and combinations are common. FI treatments typically follow a progression from nonsurgical to surgical, and from easy to implement (dietary fiber, drugs) to more intensive nonsurgical (pelvic floor muscle training with biofeedback [PFMT-BF, electrostimulation]), to permanent nonsurgical or surgical treatments. However, nonsurgical treatments may also be used to complement surgical treatment. As a result, the nature of patients offered different types of FI treatment can vary widely.

Nonsurgical treatments include dietary fiber supplementation,[5] bowel schedules, stool-modifying drugs,[6] PFMT-BF,[7,8] anal plugs, rectal irrigation,[9,10] or combinations thereof.[5,7] A new vaginal bowel control device received Food and Drug Administration (FDA) approval in February 2015.[11] Injections of biocompatible tissue-bulking agents into the anal canal walls are a newer, more invasive nonsurgical procedure.[12] Surgical procedures used to treat FI in the United States include implanted sacral nerve stimulation (SNS), radiofrequency anal sphincter remodeling (SECCA), anal sphincter repair (sphincteroplasty), sphincter replacement (artificial anal sphincter or muscle transposition), surgical correction of conditions that can result in FI (rectal prolapse, hemorrhoids, or rectocele), or, when all other treatments fail, colostomy.[1,5,13,14]

FI etiologies and other patient factors dictate feasible treatment options.[1] For example, the range of treatment approaches used for FI in adults with spinal cord (neurologic) injury would

differ from those used to treat pelvic floor muscle atrophy (structural weakness) or anal sphincter injury (structural damage).

Although many recent systematic reviews have assessed the effectiveness of component treatments for FI,[6-8,12-22] none have yet examined the collective evidence for FI treatment effectiveness, reported overall and subgroup treatment effects (when available), or examined the long-term treatment effects across all FI treatments. Given the heterogeneous population of adults afflicted with FI, information on subgroup treatment outcomes across that range of available FI treatments would advance knowledge and have the potential to improve patient care and outcomes.[3]

This systematic review synthesizes the available evidence on FI treatment outcomes across FI etiologies and treatments to provide current and potentially better information to aid decisionmaking for both patients and physicians and identifies gaps in the evidence base for treatment-subgroup combinations. Additional information on baseline patient factors that could modify treatment effects, such as age, sex, FI severity, comorbidities, and prior FI treatments, will be addressed when available.

Our findings should inform FI treatment guidelines and clinical decisions in general.

Scope and Key Questions

Scope of the Review

This review provides comparative effectiveness (benefits and harms) information on FI treatments for patients and their health care providers and reports it in the context of how FI treatment decisions are commonly made along the spectrum of available interventions, from initial presentation to a primary care provider, to more complex and invasive interventions for persistent and/or severe FI. Adults with FI are rarely offered surgery as an initial approach; even with structural injuries, such as anal sphincter tears, the magnitude of structural defect may not dictate the functional improvements possible from conservative measures alone. Therefore, nonsurgical interventions are often the first-line treatment, and these measures are often continued throughout successive additional treatments if the desired level of fecal continence is not obtained, or sustained, with initial measures.

We report treatments from least to most invasive within each category of nonsurgical and surgical approaches. Nonsurgical interventions are further divided into temporary nonsurgical (such as dietary fiber and PFMT) and permanent nonsurgical, such as injectable bulking agents. We report summary information across all included etiologies, then add etiologic subgroup-specific outcomes whenever the literature permitted.

Key Questions

Key Question 1: What is the comparative effectiveness of treatments to improve quality of life and continence and lessen the severity of fecal incontinence in affected adults?

Key Question 2: What adverse effects are associated with specific treatments for adults with fecal incontinence?

The analytic framework for this review is in Appendix A. The PICOTS elements (Population, Intervention, Comparator, Outcomes, Timing, Setting) that determined study inclusion is identified in Table 1 below.

Table 1. PICOTS framework for fecal incontinence systematic review

Element	Inclusion Criteria
Population	• Adults age 18 and older with patient or investigator reported FI. Included adults per study were classified by FI etiologic subgroups: mixed, geriatric, structural, GI (altered GI motility/stool texture), neurogenic (SCI vs. mixed neurogenic), unknown or not reported. Additional subgroups were included as identified in the literature. • Excluded: Adults with fistulas; adults with structural problems (e.g., rectal prolapse) that may or may not be associated with FI, for which the treatment was designed to correct the structural problem, not treat FI.
Interventions	• Studies that tested the effectiveness FDA-approved treatments for FI and medications used off-label (not specifically approved for the treatment of FI) and available for use in U.S. Both nonsurgical (temporary vs. permanent), surgical and combinations of interventions were included for KQ 1 and KQ 2. • For treatments not FDA-approved but used outside of the U.S., studies were included if a treatment was FDA-approved for some indication and was used off-label in the U.S. and if a device was FDA-approved for FI under a certain brand name (e.g., an anal plug) and there were studies comparing it to other brands approved only in Europe. • Excluded: We excluded colostomy, diarrhea treatments in the absence of FI, laxatives used exclusively for stool impaction
Comparators	All other treatment options, alone or in combination. Where available, trials with placebo or sham controls were included.
Outcomes	Studies reported at least one patient-reported outcome **KQ 1**: Benefits of treatment • FI Severity and Impact: Changes from baseline (such as FI frequency, FI consistency, CCFIS,[23] FISI,[24] Vaizey FI Score,[25] Pescatori FI Score,[26] SMFIS,[27] fecal urgency, change in FI coping behaviors, emotional and psychological outcomes, social activity and sexual function) • Quality of Life: such as FIQL[28] • Health status: such as SF-36[29] • Other: satisfaction with treatment, effectiveness of treatment, improvement **KQ 2**: Adverse effects of treatment(s): Pain (abdominal, other); worsening of FI (frequency, severity); GI symptoms (such as cramping, bloating, difficultly evacuating bowels, constipation); surgical complications (such as infection, revision surgery, colostomy); negative emotional/psychological effects; other adverse effect(s) related to treatment (local dermatitis, skin breakdown, urinary tract infection, headache, nausea etc.)
Timing	Followup more than 1 day. Since FI is a chronic condition, most interest is in studies with at least 3 months of followup after treatment initiation were the main focus of the review Excluded: Studies where the only outcome was assessed the same day as the only treatment
Setting	Any setting (community dwelling, long-term care, other)

F=fecal incontinence; FDA=Food and Drug Administration; GI=gastrointestinal; IBS=irritable bowel syndrome; KQ=key question; CCFIS=Cleveland Clinic Fecal Incontinence Score; FISI=Fecal Incontinence Severity Index; FIQL=Fecal Incontinence Quality of Life Instrument; SMFIS=St. Mark's Fecal Incontinence Score; SF-36=Medical Outcomes Study Short-Form 36-item Health Survey; SCI=spinal cord injury; UC=ulcerative colitis; NR=not reported; PICOTS=Population, Intervention, Comparator, Outcomes, Timing, Setting

Methods

The methods for this comparative effectiveness review (CER) update follow the methods suggested in the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews (available at http://www.effectivehealthcare.ahrq.gov/methodsguide.cfm); some methods map to the PRISMA checklist.[30] We recruited a technical expert panel (TEP) to provide specialized and expert content feedback on the review protocol, which is posted on AHRQ's Effective Healthcare web site. This section summarizes the methods we used.

Literature Search Strategy

Bibliographic database searches identified randomized controlled trials and observational studies published from 1980 to October 2014 on treatments for adults with FI to include early studies of antidiarrheal drugs that are currently used in the treatment of FI. Relevant bibliographic databases for this topic included Ovid MEDLINE®, Embase, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL), Ovid Physiotherapy Evidence Database (PEDro), and Allied and Complementary Medicine (AMED). Our search strategies through October 2014 are in Appendix B. An experienced librarian developed the MEDLINE search strategy, which was modified for other databases. Additionally, we searched reference lists of systematic reviews published since 2007 that evaluated treatments for FI to confirm that our search captured evidence in recent review updates, and to avoid the inclusion of obsolete treatments or interventions that have been replaced with newer approaches.

Grey literature searches were conducted via ClinicalTrials.gov and from Scientific Information Packets (SIP) received from relevant industry stakeholders who submitted published and unpublished information on their product(s) at the request of AHRQ for this review. Grey literature search results were used to identify studies and outcomes not reported in the published literature to assess publication and reporting bias and inform future research needs.

Studies for this comparative effectiveness review of treatments for FI were selected based on the PICOTS framework outlined in the section above, and on the study-specific inclusion criteria described in Table 2 below.

Table 2. Study inclusion criteria for fecal incontinence review

Category	Criteria for Study Inclusion
Study enrollment	• Adults with FI
Study designs	• Randomized clinical trials (RCTs), nonrandomized controlled trials, and prospective or retrospective cohort studies with control groups were included. Surgical observational studies without control groups (case series, n >10) were included if they assessed treatment harms (Key Question 2). Published systematic reviews were used for reference list cross checking only.
Time of publication	• English language RCTs and observational studies published from 1980 forward (to include early studies of drugs that are currently used in the treatment of FI); reference lists from systematic literature reviews were examined from 2007 forward.
Language of publication	• We limited included studies to English language publications because that literature best represents FDA-approved and/or interventions available in the United States. The search strategies were not limited by language.
Study quality	• All studies that met the inclusion criteria were screened for eligibility • Studies that did not adequately report study information to allow the abstraction of patient-important outcomes identified in the key questions, or had indeterminate numerators and denominators for those outcomes and adverse event rates were excluded from the analytic set.

KQ=key question; RCT=randomized controlled trial; FDA=Food and Drug Administration; FI=Fecal Incontinence

Study Selection and Data Extraction

Two independent investigators reviewed titles and abstracts of bibliographic database search results to identify studies that examined interventions for FI and reported at least one patient-reported outcome regarding FI severity, impact, or quality of life. Citations deemed potentially eligible by either investigator underwent full text screening to determine if all inclusion criteria were met. Differences in screening decisions were resolved by consultation between investigators and a third investigator. Studies excluded during full-text screening are listed in Appendix C.

We extracted data from included studies into evidence tables by the type of study design. Extracted data included the relevant population, intervention, baseline, and outcomes data on the adult subgroups of interest. Initial data abstraction was quality checked by a second investigator.

Quality (Risk of Bias) Assessment of Individual Studies

Risk of bias of eligible studies was assessed by at least two independent investigators using instruments specific to each study design (Appendix D). Two investigators consulted to reconcile discrepancies in overall risk-of-bias assessments and, when needed, a third investigator was consulted to reconcile the summary judgment. We assessed randomized control trial (RCT) risk of bias using a modified Cochrane risk-of-bias tool[31] (Appendix D). The risk of bias elements of the tool are sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of bias (i.e., problems not covered by other domains).[31] We developed an instrument to assess risk of bias for observational studies using the RTI Observational Studies Risk of Bias and Precision Item Bank[32] (Appendix D).We selected items most relevant in assessing risk of bias from studies of FI treatments, including subject selection, baseline patient information, attrition, ascertainment of outcomes and analytic tools used to address selection bias in nonrandomized studies. An overall summary risk-of-bias assessment for each study was classified as low, moderate, or high based on the collective risk of bias inherent in each outcome domain and our confidence that the results were believable given the study's limitations.[33] When the two investigators disagreed, a third trained investigator was consulted to reconcile the summary judgment.

Data Synthesis

We summarized the results into evidence tables and qualitatively synthesized evidence by the type of study (RCT, observational, case series) for each treatment comparison and outcome combination within specific followup periods. Studies were grouped by intervention category and then etiologic subgroup. Pooling was planned for measures that assessed the same outcome and had comparable scoring characteristics.

For each Key Question, we will summarize the results into evidence tables and synthesize evidence by the type of study (RCT, observational) for each unique population, comparison, and outcome combination within specific followup time periods.

We emphasized patient-centered outcomes in this review. The primary outcomes were quality of life[28] and FI severity[24] including episode frequency and the type and amount of leakage (Appendix E), as identified in the literature and by Key Informants (consumers, clinical experts and researchers).[34]

We planned to pool data, but pooling was not possible due to heterogeneous treatments and numerous and varied outcome measures that were not comparable on scoring (Appendix F1). Rather, we summarized evidence qualitatively with as much etiologic information as was feasible. In general, RCTs were given priority over observational studies with comparators when risk of bias was low or moderate; high risk of bias studies of either design provided low value information. Case series were used only for postsurgical harms because the harms were unlikely to occur under other circumstances. We report treatment effects using change scores from baseline, when reported.

Strength of the Body of Evidence

We evaluated the overall strength of evidence for selected intervention-outcome pairs based on five domains:[35] (1) study limitations (internal validity); (2) directness (single direct link between the intervention and outcome); (3) consistency (similarity of effect direction and size); (4) precision (degree of certainty around an estimate), with the study limitations domain having considerable importance; and (5) reporting bias, which was evaluated by the potential for bias related to publication, selective outcome reporting, or selective analysis reporting by comparing reported results with those in the methods sections and an assessment of the grey literature to assess potentially unpublished studies. Study limitations were rated as low, moderate, or high according to study design and conduct. Consistency was rated as consistent, inconsistent, or unknown/not applicable (e.g., single study). Directness was rated as direct or indirect. Precision was rated as precise or imprecise. Reporting bias was rated as detected or not detected. Deficiencies in domains lowered the strength of evidence grade.[35] We required at least two moderate risk of bias studies or one sufficiently powered, low risk of bias RCT to assign a low strength of evidence rather than considering it to be insufficient. Moderate or high strength of evidence ratings were based on risk of bias and additional strength of evidence domain criteria. We required at least two low risk of bias studies for moderate strength of evidence, and two sufficiently-powered low risk of bias studies for high strength of evidence, plus intervention-outcome pairs needed a positive response on two out of the three domains other than risk of bias. We graded strength of evidence for treatment—patient-reported outcome combinations that assessed FI severity/impact or quality of life in studies with low or moderate risk of bias as per the above criteria. Based on these factors, the possible strength of evidence (SOE) grades[35] were:

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change the estimates.
- Moderate: Moderate confidence that the estimate reflects the true effect. Further research may change estimates and our confidence in the estimates.
- Low: Limited confidence that the estimate of effect lies close to the true effect. Further research is likely to change the confidence in the effect estimate or change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.

Applicability

Applicability of studies was determined according to the PICOTS framework. Study characteristics that affected applicability included, but were not limited to, enrollment of adults with heterogeneous etiologic factors, narrow (or excessively broad) inclusion criteria, or patient and intervention characteristics that differed from those described by population studies of FI interventions. All treatments are not feasible for all FI etiologies at all time points (early versus

chronic), so sample differentiation and prior treatments are important. Adults in clinical trials of FI treatments may be higher functioning, younger, or less impaired than the FI patient population as a whole. Some comparator interventions are only available outside of the United States and may never be considered for use in the United States. Short followup on interventions may be less applicable to the long-term management of chronic FI for patients and providers.

Results

Overview

This section is organized by type of treatment, following the general sequence of treatments as they occur in clinical practice, from nonsurgical (temporary to permanent) to surgical. We planned to organize this section by etiologic subgroup, which was not possible because FI etiologies were inconsistently defined and reported, and in most articles, etiologies were mixed.

Results of Literature Searches

We identified 2,908 unique citations (Figure 1) from all databases combined. We examined the full text of 188 articles to determine final inclusion. Of those, 115 unique studies were included in the review: 49 RCTs, and 14 observational studies with comparators (OBS), and 52 surgical case series. Thirty-seven randomized controlled trials (75.5 percent) assessed nonsurgical treatments; 12 assessed surgical interventions including sacral nerve stimulation. We found RCT evidence for one off-label tissue bulking agent (Durasphere®) that was not on our initial list of treatments.

Due to variability in followup assessment timing, we aggregated evidence into short-term outcomes (less than 3 months), intermediate-term (3 to 6 months) and long-term (more than 6 months), (Appendix F2). Evidence tables in this report (Tables 3-17) and Appendix F provide detailed information about the included studies.

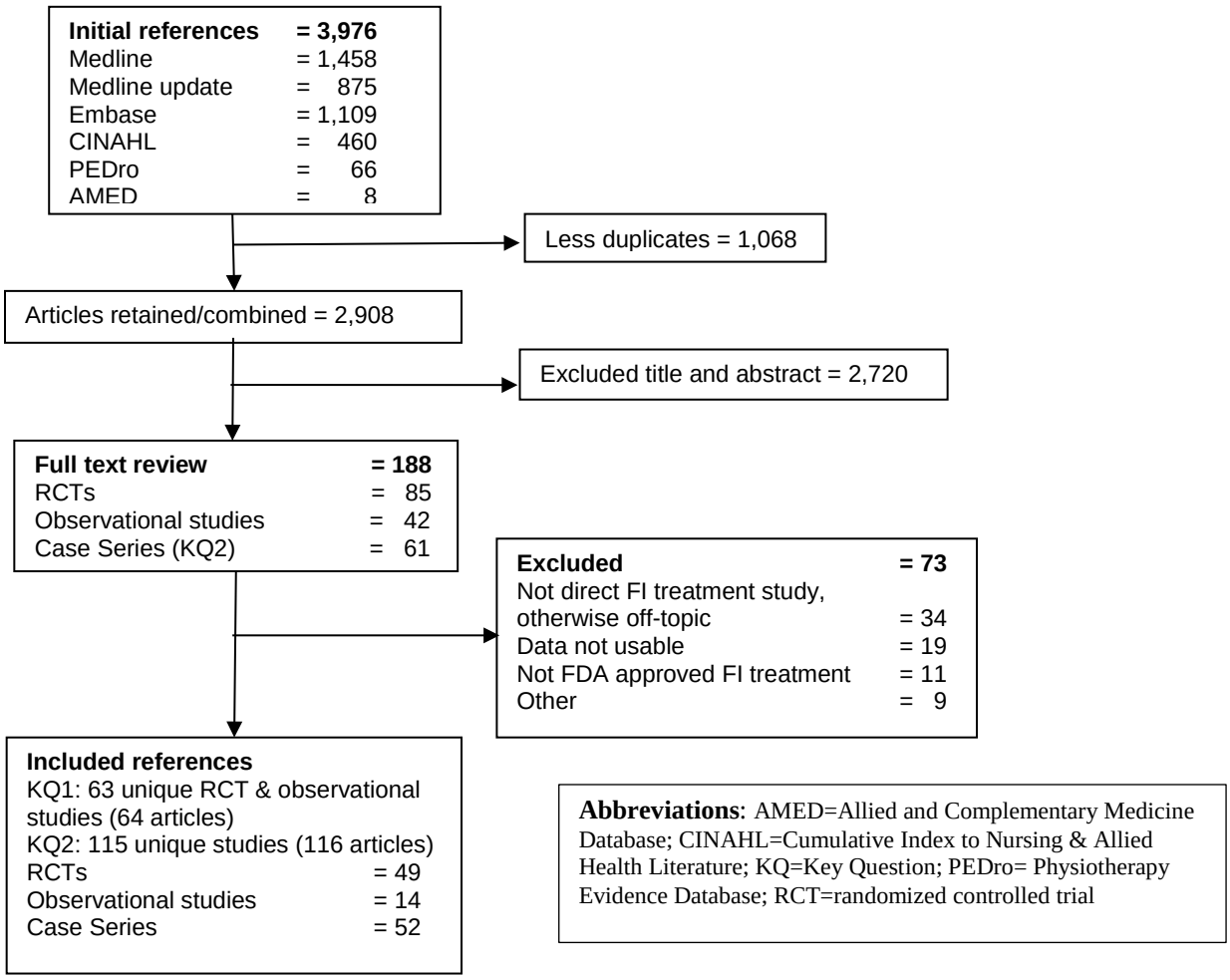
Evidence of publication bias was not identified from the information we reviewed in Scientific Information Packets received from industry, and by examining clinicaltrials.gov.

Key Question 1: What is the comparative effectiveness of treatments to improve quality of life and continence and lessen the severity of fecal incontinence in affected adults?

Included studies are listed under Nonsurgical or Surgical headings below, and subclassified by the type of intervention in the approximate order that they might be used in clinical practice. We did not find RCT or observational studies with comparison groups for anal plugs, antegrade colonic irrigation (ACE), or radiofrequency anal sphincter remodeling (SECCA).

The mean age of enrolled adults was 55 to 65 years in 61 percent of 36 nonsurgical RCTs that reported age, and 75 percent of surgical RCTs. Females comprised 75 percent of adults in 34 nonsurgical RCTs (Tables 3-17) and 95 percent of adults in 11 surgical RCTs (Appendix F3) that reported patient sex, but these proportions varied by FI etiology and the type of intervention. Nearly two-thirds (62 percent) of RCTs enrolled adults with mixed FI etiologies; FI etiology was not reported in 20 percent of RCTs (Appendix F4) FI severity at baseline was inconsistently reported and varied widely per study inclusion criteria.

Figure 1. Disposition of fecal incontinence studies identified for this review



Nonsurgical Treatments (Temporary and Permanent)

Key Points

- Low-strength evidence suggests that dietary fiber supplementation with psyllium decreases FI frequency by 2.5 episodes per week at 1 month; clonidine has no effect; and PFMT-BF with electrostimulation is no more effective than PFMT-BF on FI severity and FI quality of life (FIQL) over 2 to 3 months.
- Low-strength evidence at 6 months suggests that dextranomer tissue-bulking injections are more effective than sham injections on FI quality of life, the number of FI-free days, and the percent of adults with at least 50 percent reduction from baseline in FI episodes; no more effective than PFMT-BF with or without electrostimulation on FI severity (PFMT-BF -5.4 versus dextranomer -4.6 point Vaizey improvements) and quality of life; and no more effective than sham injection on FI severity (-2.5 vs. -1.7 point sham CCFIS improvement) or FI episode frequency.
- Moderate-strength evidence suggests that Durasphere® (off-label) bulking injections reduce FI severity (-4 to -5 points in CCFIS) up to 6 months, but gains diminish thereafter.

- There is insufficient evidence that pelvic floor muscle training with biofeedback (PFMT-BF) offers any advantage over standard care (dietary fiber, stool-modifying drugs); all other PFMT studies assessed refinements in treatment delivery.
- Evidence was insufficient for all other nonsurgical interventions.
- In most cases, short-term outcomes improvements in both treated and active controls met minimal clinically important differences (MID) when those values were known (Appendix E); studies that claimed greater improvements typically excluded nonresponders, noncompleters or those not fully compliant with study protocols.
- Numerous outcome measures were used that limited comparability across studies.
- Most RCTs had moderate or high risk of bias (84 percent [31/37]).
- Incomplete reporting of baseline patient information and FI etiologies were common.
- Most evidence was short-term (less than 6 months of follow-up, Appendix F2)

Nonsurgical Treatments with Temporary Effects

Dietary Fiber

The evidence for dietary fiber and fiber supplementation in FI is exclusively short term (up to 3 months (Table 3). Two RCTs[36,37] assessed the 31 day and 38 day effects of various dietary fiber supplements on FI frequency, and stool frequency and consistency. Low-strength evidence[36] suggests that dietary fiber supplementation with psyllium reduces FI frequency by 2.5 episodes per week and has no effect on FI quality of life.[36]

Evidence was insufficient for other outcomes, including one moderate risk of bias RCT that found no added benefit of dietary fiber in addition to loperamide on FI severity and FI quality of life over 3 months[38] (Table 3). Evidence was insufficient for methylcellulose plus loperamide versus no treatment[39] (Appendix F5).

Pharmacological Treatments

Drug studies were exclusively short term (1 to 6 weeks) and most were 1 month in duration. The effectiveness of oral and topical medications for FI was examined in 11 RCTs: three of topical phenylephrine versus placebo[40-42](Table 4), four of antidiarrheal medications[43-46](three versus placebo, one with active comparators, Table 5) and four studies of other medications[47-50] (all versus placebo, Table 6). Low-strength evidence suggests that oral clonidine has no effect on FI severity as measured by the FI and Constipation Assessment (FICA). Evidence was insufficient for loperamide,[43-46] topical phenylephrine (10 percent[41,42] and 30 percent[40]), zinc-aluminum ointment,[48] estrogen cream,[49] and valproate sodium.[50]

Pelvic Floor Muscle Training and Adjunctive Modalities

Pelvic floor muscle training accomplished with the use of biofeedback (PFMT-BF) was the most frequently studied intervention in the literature we reviewed; 15 studies (13 RCTs and 3 OBS[51-53]) assessed the effects of PFMT-BF with or without electrostimulation on the outcomes of FI frequency and severity, quality of life (general and FI-specific), and perceived improvement (Tables 7-13 and Appendix F5).

We found insufficient evidence that PFMT-BF offers any advantage over standard care (dietary fiber, stool-modifying drugs, Table 7 and Appendix F5). Only two RCTs[54,55] with moderate[55] and high[54] risk of bias assessed the benefit of PFMT-BF versus standard care, and one high risk of bias observational study[53] examined PFMT-BF plus standard care versus

standard care alone. Nonetheless, most of the literature focused on ways to improve or prolong the purported benefits of PFMT for FI, rather than to establish the benefits of it. Accordingly, only two RCTs used PFMT alone as a control;[56,57] all other studies assessed refinements in PFMT delivery, including biofeedback sensor comparisons,[58,59] exercise comparisons,[60] electrostimulation to augment PFMT-BF,[61-63] electrostimulation frequency comparisons,[64,65] assessed care site differences,[66] added FI education,[67] or examined the mode of training delivery (by phone or in-person) on outcomes.[51] Risk of bias was moderate to high in all PFMT studies.

We found low-strength evidence that PFMT-BF with electrostimulation is no more effective than PFMT-BF on FI severity and FI quality of life (FIQL).[62,63] Evidence was insufficient for all other PFMT comparisons.[51,52,56-61,64,65,67]

PFMT-BF was associated with improvements in FI outcomes (usually 2 to 6 points, various scales) in most studies, but improvements were not significantly different than those of the comparison group. Four RCTs reported short-term (less than 3 months) outcomes,[60,62,63,67] eight reported 3 to 6 month outcomes, and only four reported outcomes beyond 6 months.[55,57,60,68]

Anal Electrostimulation

There was insufficient evidence that home-based anal electrostimulation without PFMT offers any outcomes advantage over home-based sham stimulation,[69] or that home-based electrostimulation offers any benefit over hospital-based therapy[66] in the short-term (Table 14). The extremely low compliance with home-based electrostimulation in one RCT[69] (only 25 percent of the treatment group used the stimulator at least 20 of the 34 protocol-recommended hours) suggests that home-based stimulator use for FI may not be an acceptable option to patients, even if it worked.

Rectal Irrigation

Evidence was insufficient for rectal irrigation versus a non-FDA approved injectable bulking agent for mixed FI etiologies (Appendix F5).[70]

Mixed Nonsurgical Interventions

Mixed interventions were primarily assessed for two groups of adults: older adults residing in nursing homes and adults with spinal cord injuries (SCI). Both groups may deal with FI, constipation, or both. The goal of bowel management is to minimize extremes and maintain bowel regularity.

Two RCTs focused on bowel management interventions for adults with SCI[71,72] (Table 15). Females comprised 31 percent of enrolled adults; the overall median age was 48 years. One moderate risk of bias study found that transanal irrigation improved bowel and FI outcomes more than supportive, guidelines-based care over 10 weeks.[71] One high risk of bias study reported that a 6-week step-wise, increasing intensity bowel management program made FI outcomes worse.[72]

In contrast, two high risk of bias RCTs assessed staff-directed interventions for FI and bowel issues in nursing home residents with mixed results (Table 16). Females comprised 83 percent of enrolled residents; the overall mean age was 87 years. Both interventions were focused on multiple aspects of diet, fluids, activity, and care that affect bowel regularity. One RCT found significant reductions in FI frequency with prompted toileting four times per day, exercise and increased fluid offering 5 days per week.[73] The other RCT was a multicomponent intervention for UI and FI, which did not affect FI frequency.[68]

Nonsurgical Treatments with Permanent Effects

Anal Sphincter Tissue-bulking Injections

Four low risk of bias RCTs (Table 17) examined anal sphincter tissue-bulking injections: two RCTs of dextranomer,[74,75] which is FDA-approved for FI, and two of an off-label injectable, Durasphere®[76,77] (FDA-approved for vaginal bulking for urinary incontinence).

Low-strength, evidence at 6 months post-treatment suggests that dextranomer tissue-bulking injections are no more effective than PFMT-BF with or without electrostimulation on FI severity and FI-related quality of life.[74]

Low-strength, evidence at 6 months post-treatment suggests that dextranomer tissue-bulking injections are more effective than sham injections on FI quality of life, the number of FI-free days, and in reducing FI episodes 50 percent or more from baseline over 6 months; but no more effective than sham injection on FI severity and FI episode frequency.[75]

Durasphere® (off-label) anal sphincter injections improved FI severity by several points (CCFIS) shortly after injections, but gains diminished slightly between 6 months and 1 year.[76,77] Both studies used a non-FDA approved comparator (PTQ™).

Table 3: KQ1. RCT evidence for dietary fiber and dietary fiber supplementation for fecal incontinence

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Bliss, 2014[36] *Bliss, 2011[78] used same sample as Bliss, 2014[36], minus 17*	Compare fiber supplements	N=206 n=206 74% F; 58 y Not reported T: 38 d. FU: 38 d.	T_1: carboxymethy-cellulose (CMC) (53) T_2: gum arabic (50) T_3: psyllium (54) C: placebo (49)	**FI frequency/wk**, amount, consistency, severity; FIQL	FI significantly decreased by 2.5 episodes per week with psyllium (vs. placebo) and increased 1.5 episodes per week with CMC. No differences in other outcomes. Sufficient power.	Low
Bliss, 2001[37]	Compare fiber supplements	N=39 n=39 79% F; 61 y Not reported T: 31 d. FU: 31 d.	T_1: psyllium (13) T_2: gum arabic (13) C: placebo (13)	% incontinent, stool frequency, stool consistency, dietary intake	Tested between-group comparison at followup. Proportion of incontinent stools decreased most with gum arabic (48%) and psyllium (32%). No change in stool freq. Power not reported.	Moderate
Lauti, 2008[38]	Does fiber supplement and loperamide improve FI over low residue diet and loperamide	N: 63 n: 47 91% F; 59 y Mixed T: 12 wks (6 + 6) FU: 6 wk, 12 wk	Crossover T: balanced fiber diet + fiber supplement + loperamide (32) C: low residue diet + placebo fiber + loperamide (31)	**FISI**, FIQL	Both groups improved. No significant difference in FISI improvement between treated vs. control (-13 vs. -12.4). FIQL largely unchanged. Sufficient power.	Moderate

*Significant = statistically significant; **Attrition based on the number randomized as calculated by the MN EPC
C=Comparator/control; CMC=carboxymethy-cellulose; d=day; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FISI=Fecal Incontinence Severity Index; FU=Follow up T_1=Treatment group 1 T_2=Treatment group 2 T_3=Treatment group 3; y=years

Table 4: KQ1. RCT evidence for topical phenylephrine (sphincter function enhancement drug) for fecal incontinence

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Park, 2007[40]	Efficacy of 30% phenylephrine gel for FI after low anterior resection for rectal cancer	N=35 n=29 37% F; 60 y Postsurgical T: 4 wks FU: 4 wks	T: 30% topical phenylephrine (17) 2x/day C: placebo 2x/d (12)	FISI, FIQL, Global Efficacy	Phenylephrine did not improve FISI or FIQL scores. Subjective improvement in 29% treated (33% controls). Power not reported. Excluded post-randomization data from those with *poor compliance*.	High
Carapeti, 2000[41]	Effectiveness of 10% topical phenylephrine in FI patients with IAS dysfunction	N=36 n=36 61% F; 58 y Not reported T: 4 wks each FU: 4 wks, 8 wks	Crossover, 1 wk. washout T: topical 10% phenylephrine gel (anus) 2x/d (36) C: placebo gel (36)	**Vaizey score**, subjective improvement	Vaizey improved 2 to 2.9 points from baseline, regardless of treatment period. No significant difference in mean improvement in Vaizey or subjective improvement in treated vs. placebo period by group. Sufficient study power.	Moderate
Carapeti, 2000[42]	Effectiveness of 10% topical phenylephrine in FI patients with ileoanal pouch	N=12 n=12 58% F; 44 y Ileoanal pouch T: 4 wks each FU: 4 wks, 8 wks	Crossover, 1wk. washout T: topical 10% phenylephrine gel (anus) 2x/d (12) C: placebo gel (12)	Vaizey score, overall FI symptom score, self-rated improvement	Results reported for period 1 only due to significant treatment x period interaction. Significant improvement in mean Vaizey in treated vs controls (6 vs. 0 points). FI symptoms lower when treated. Study likely underpowered.	High

* Significant = statistically significant

C=Comparator/control; d=day; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FISI=Fecal Incontinence Severity Index; FU=Followup; IAS=internal anal sphincter; T=Treatment group; Vaizey=Vaizey Fecal Incontinence score; wk=week

Table 5: KQ1. RCT evidence for antidiarrheal drugs for fecal incontinence

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Sun, 1997[43]	Effectiveness of loperamide oxide for chronic diarrhea with FI	N=11 n=11 73% F; 56 y Mixed T: 1 wk each FU: 2 wks, 4 wks	Crossover, 1wk run-in, washout T: loperamide 8mg/d (11) C: placebo (11)	FI episodes, % fully continent, stool freq/consistency, urgency, FI severity, urgency, diarrhea, abdominal pain	Significantly more treated vs. placebo achieved continence & no diarrhea (65% vs. 27%), and had significant reduction urgency and stool frequency. Power not reported.	High
Hallgren, 1994[44]	Effectiveness of loperamide HCl after proctoco-lectomy for ulcerative colitis	N=30 n=28 27% F; 38y Postsurgical T: 8 d each FU: 15 d, 30 d	Crossover, 1wk run-in, washout T: loperamide HCl 12mg/d (30) C: placebo (30)	Defecation freq, need for night evacuation, soling daytime, soiling nighttime, use of pads, flatus release	Tested differences in outcome at followup; no baseline outcomes reported. Loperamide significantly decreased FI and pad use over placebo; no change in defecation freq. Power not reported.	Moderate
Read, 1982[45]	Effectiveness of loperamide for chronic diarrhea with FI and urgency	N=26 n=26 57% F; 45 y Mixed T: 1 wk each FU: 1 wk, 2 wks	Crossover, washout not reported T: loperamide 12mg/d (26) C: placebo (26)	FI episodes/wk; stool freq, weight and consistency; urgency; improvement in FI and urgency	Tested differences in outcome at followup. Loperamide significantly decreased FI and urgency episodes, stool freq. and related outcomes over placebo; more reported improvement on drug. Power not reported.	Moderate
Palmer, 1980[46]	Compare 3 drugs for chronic diarrhea (95% had urgency with FI)	N=30 n=25 % F NR; age NR Mixed T: 4 wks each FU: outcomes every 4 wks up to 12 wks.	Crossover; used 3 wks data per period T_1: loperamide HCl 2mg/d (30) T_2: codeine phosphate 45mg/d (30) T_3: diphenoxylate 5mg/d (30)	FI episodes, # of patients with FI, stool freq. and consistency, urgency episodes, dose/capsule consumption	Baseline data for urgency only. Not all outcomes were reported. Loperamide and codeine decreased number of patients with urgency more than diphenoxylate; all drugs decreased stool freq. Power not reported. Analyzed completers only.	High

*Significant = statistically significant
C=Comparator/control; d=day; FI=Fecal incontinence; FU=Followup; HCl=Hydrochloride; mg=milligrams; T=Treatment group; T_1=Treatment group 1 T_2=Treatment group 2 T_3=Treatment group 3; wk=week

Table 6: KQ1. RCT evidence for other drugs for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; FI Etiology; % Female; Mean Age; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Results (benefits)*	Risk of Bias (inverse of quality)
Bharucha, 2014[47]	Effectiveness of clonidine vs. placebo in women with FI	N=44 n=44 100% F; 58 y Mixed T: 4 wks FU: 4 wks	T: Clonidine 0.2mg/d (22) C: placebo (22)	**FICA**, FI count, days of FI, FIQL, FISI, satisfaction, rectal urgency, loperamide use	No significant difference between groups in FICA improvement (1.6 clonidine vs. 1.5 placebo) or other outcomes. Sufficient power.	Low
Pinedo, 2012[48]	Compare Zinc-Aluminum ointment to anal submucosa vs. placebo for FI	N=50 n=44 % F NR; 61 y Not reported T: 1 mo FU: 1 mo	T: Zinc-aluminum ointment 3x/d (25) C:placebo (25)	**CCFIS**, FIQL	Significant CCFIS between-group improvement from baseline in treated vs. controls (-8.1 vs. -3.6), and all FIQL subscales. Underpowered study. Analyzed completers only.	Moderate
Pinedo, 2009[49]	Compare topical estrogen vs. placebo for FI in postmenopausal women	N=36 n=35 100% F; 69 y Not reported T: 3x/d for 6 wks FU: 6 wks	T: Estrogen cream to anal submucosa (18) C: placebo (18)	**CCFIS,** FIQL	Both groups improved in CCFIS (-5 treated, -3 controls); between-group test not significant. Within-group FIQL improvements minimal in both groups. Sufficient study power.	Moderate
Kusunoki, 1990[50]	Effectiveness of valproate sodium for FI after ileoanal anastomosis	N=17 n=17 24% F; 34 y Postsurgical T: 1 wk FU: 1 wk	Crossover, 3 d. washout T: Valproate sodium 1600mg/d (17) C: placebo (17)	FI count (soiling), stool freq., perianal skin trouble	Tested within-group changes only: Greater reduction in FI soiling (9 vs. 2) and mean stool freq. (4 vs. 0.4) during treatment vs. placebo period. Power not reported.	Moderate

*Significant = statistically significant

CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; d=day; FI=Fecal incontinence; FICA=Fecal Incontinence and Continence Assessment; FIQL=Fecal Incontinence Quality of Life scale; FISI=Fecal Incontinence Severity Index; FU=Followup; freq=frequency; mo=month; mg=milligrams; T=Treatment group; wks=weeks

Table 7: KQ1. Randomized controlled trial evidence for pelvic floor muscle training with biofeedback (PFMT-BF) versus standard care

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Damon, 2014[54]	Does PFMT-BF plus standard care improve FI outcomes over standard care only?	N=157 n=92-142 varied 77% F; 61 y Mixed T: 4 mo. FU: 4 mo.	T: PFMT-BF (20 sessions) plus standard care (77) C: standard care of laxative, oral bulking agent, loperamide (80)	**Treatment effectiveness** (-5 to 5), CCFIS, FIQL, KESS, SF-12, symptom change	Differences between groups in opinion of treatment effectiveness, symptom change, CCFIS, KESS, FIQL, or SF-12 were not significant. Underpowered study. Analyzed completers only.	High
Norton, 2003[55]	Does biofeedback (PFMT-BF, various modes) improve FI over standard care (advice on diet, drugs, bowel evacuation)	N=171 n=171 (ITT) 93% F; 56 y Mixed T: 3-6 mo. FU:6 mo., 1yr	T_1: Hospital & home-based PFMT-BF plus advice (42) T_2: Hospital-based PFMT-BF plus advice (49) T_3: PFMT with DRF plus advice (43) C: advice (37)	**Treatment effectiveness & rating thereof,** Vaizey, Bowel Symptom Questionnaire, SF-36, FI counts/wk), HAD, quality of life (FI-unpublished)	Over half of patients improved; biofeedback was no better than standard care with advice. No differences between groups in functional outcomes. Quality of life, SF- 36, (vitality, mental, social) and HAD significantly improved. Sustained improvement at 1 yr. Sufficient power.	Moderate

*Significant = statistically significant

BF=Biofeedback; C=Comparator/control; CCFIS=Cleveland Clinic Fecal Incontinence Score; DRF=digital rectal feedback; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; HAD=Hospital Anxiety and Depression Scale; ITT=Intention-to-treat analysis; KESS=Knowles-Eccersley-Scott-Symptom Questionnaire for Constipation; mo=month; mg=milligrams; ms=microseconds; PFMT=Pelvic floor muscle training; SF-12=Short-Form-12 health survey; SF-36=Medical Outcomes Study Short-Form 36-item Health Survey; T=Treatment group; T_1=Treatment group 1 T_2=Treatment group 2 T_3=Treatment group 3; Vaizey=Vaizey Fecal Incontinence Score; wk=week; y=year

Table 8: KQ1. Randomized controlled trial evidence for pelvic floor muscle training with biofeedback (PFMT-BF) versus PFMT alone

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Heymen, 2009[56]	Does PFMT-BF with intrarectal balloon improve FI outcomes over PFMT alone?	N=168 before 4 wk. run-in n=108 (3m, ITT) 77% F; 60 y Mixed T: 6 sessions/3mo FU: 3 mo;	T: PFMT-BF with intrarectal balloon (45) C:PFMT (63) Both: PFMT 5x/d at home	**FISI** (3 mo change), FI days/wk, FIQL (3 mo), adequate relief, STAI-1, STAI-2, BDI	Significant difference in between-group improvements in FISI (no data), continence (44% vs. 21% control) and FI relief (76% vs. 41%) at 3 mo. FIQL similar in both groups; psychological scales unchanged. Underpowered study. Only successes followed after 3 mo.	Moderate
Whitehead, 1985[57]	Does PFMT-BF (with rectal balloon) improve FI over PFMT alone?	N=13 n=13 77% F; 73 y Mixed (geriatric) T: 1+ mo (varied) FU: 6m,12m	Crossover: all exercised for 1 mo, then crossover if FI persisted T:PFMT-BF C:PFMT	FI counts/wk	Exercise instruction alone did not decrease FI episodes but there was a significant reduction in FI counts in first 2 wks on biofeedback. Study power not reported	High

*Significant = statistically significant

BDI=Beck Depression Inventory; BF=Biofeedback; C=Comparator/control; d=day; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FISI=Fecal Incontinence Severity Index; FU=Followup; ITT=Intention-to-treat analysis; m/mo=month; mg=milligrams; PFMT=Pelvic floor muscle training; STAI=State-trait Anxiety Inventory; T=Treatment group; wk=week

Table 9: KQ1. Randomized controlled trial evidence for PFMT-BF versus PFMT plus education

Author, Year	**A**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Ilnyckyj, 2005[67]	Does PFMT-BF with rectal balloon improve FI over PFMT plus education?	N=23 n=18 100% F; 59 y Idiopathic T: 5 wks FU: 5 wks	T:BF (RBT) w PFMT + FI education (7) C: PFMT + FI education (11) *Initial n/ group NR*	% without FI	No significant difference in percent of patients without FI (86% treated vs. 45% control); no baseline for FI counts/wk. No sample size calculation. Analyzed completers only.	High

*Significant = statistically significant
BF=Biofeedback; C=Comparator/control; F=Female; FI=Fecal incontinence; FU=Followup; NR=Not Reported; PFMT=Pelvic floor muscle training; RBT=Rectal Balloon Training; T=Treatment group; w=with; wk=week

Table 10: KQ1. Randomized controlled trial evidence for PFMT-BF versus PFMT with digital rectal feedback (DRF)

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Bols, 2012[58]	Does PFMT-BF with rectal balloon improve FI over PFMT (digital rectal feedback)?	N=80 n=80 (ITT)90% F; 59 y Mixed T: 9 wks FU: 4.5 mo. (varied)	12 sessions/9 wks: T: PFMT-BF plus rectal balloon (40) C: PFMT "alone" (with DRF) (40) PFMT 3x/d (home)	**Vaizey** (0-24); FIQL, GPE	No evidence for add-on benefit of RBT in PFMT; both groups improved. Difference in Vaizey not significant (treated -5.5 vs. controls -4.5); small improvement in other RBT outcomes. Underpowered study (106 needed).	Moderate
Solomon, 2003[59]	Are PFMT-BF (TRUS) & PFMT-BF (AM) superior to PFMT-digital rectal feedback?	N=120 n=120 89% F; 62 y Neuropathic T: 4 mo. FU: 4 mo.	T_1: PFMT-BF (TRUS) (40) T_2: PFMT-BF(AM) (39) C: PFMT (DRF) (41)	**SMFIS**(0-13), Pescatori, FI severity (patient, investigator), 0-10 quality of life	All groups had small improvements. No significant difference in mean improvement from baseline between groups for any outcome. Under-powered study. Analysis of completers likely.	High

*Significant = statistically significant
AM=Anal Manometry; BF=Biofeedback; C=Comparator/control ; d=day; DRF=digital rectal feedback; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; GPE=Global Perceived Effect; ITT=Intention-to-treat analysis; mo=month; Pescatori=Pescatori Fecal Incontinence Score; PFMT=Pelvic floor muscle training; RBT=rectal balloon training; SMFIS=St. Mark's Fecal Incontinence Score; s=Seconds; T=Treatment group; T_1=Treatment group 1 T_2=Treatment group 2; TRUS=Trans Rectal Ultrasound; Vaizey=Vaizey Fecal Incontinence Score; wk=week

Table 11: KQ1. Randomized controlled trial evidence for types of exercise used for PFMT-BF for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Results (benefits)*	Risk of Bias (inverse of quality)
Bartlett, 2011[60]	Compare exercises: PFMT-BF (RBT) mixed exercise vs. PFMT-BF (RBT) sustained contraction	N=72 n=69 (2 m); 53 (2 y) 74% F; 62 y Mixed T: 5 sessions/2m FU: 2 m., 2 y.	5 sessions/8 wks: T: PFMT-BF rapid & sustained contraction (35) C: PFMT-BF, sustained contraction (37)	**CCFIS**, FIQL, self-rated improvement	No significant difference between groups in CCFIS improvement at 2 m (-7 vs -6.5), 2y (-8 vs -7), or FIQL scales. Improvements maintained at 2 yrs. Sufficient power at 2 mo.	High

*Significant = statistically significant
BF=Biofeedback; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; m=month; PFMT=Pelvic floor muscle training; RBT=Rectal Balloon Training; T=Treatment group; wk=week; y=year

Table 12: KQ1. Randomized controlled trial evidence for PFMT-BF with electrostimulation for fecal incontinence: compare frequencies

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Results (benefits)*	Risk of Bias (inverse of quality)
Schwandner, 2011[64]	Does PFMT-BF with medium freq estim improve FI over PFMT-BF with low freq estim)?	N=80 n=80 (ITT) 81% F; 63 y Mixed T: 6m. FU: 3m., 6m.	T: Estim (medium freq.) with PFMT-BF (39) C(41): Estim (low freq.) with PFMT-BF	**CCFIS**, adapted Vaizey (0-24), FIQL, ICIQ-SF, % complete responders	Significant improvement from baseline in treated vs. controls in CCFIS at 3m (-4 vs. 0) and 6m (-7 vs. -1); Vaizey, ICIQ-SF and FIQL had similar improvements. 54% complete responders in treated (vs. none). Sufficient power.	Moderate
Schwandner, 2010[65]	Does PFMT-BF with medium freq estim improve FI outcomes over PFMT-BF with low freq estim)?	N=158 n=158 87% F; 63 y Mixed T: 9 mo. FU: 9 mo.	T: PFMT-BF(EMG) plus estim (79) C: PFMT-BF (EMG) (79) 2x/d, 20 min each	**CCFIS** (9 mo), **Vaizey** (9 mo); change in CCFIS, Vaizey at 3 m, 6 m; FIQL; % improved, therapy acceptance	Significantly greater median CCFIS improvement from baseline to 9 mo. in treated vs. controls (mean 2.5 points), 6 mo (2 points) and Vaizey (6 mo). No difference in FIQL between groups. Half of Results tables are per protocol analysis. Adults who deteriorated were analyzed no change group. Attrition 61% at 9 mo.	High

*Significant = statistically significant; **Attrition was calculated by the MN EPC based on the number randomized
BF=Biofeedback; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; d=day; EMG=Electromyographic; estim=Electrostimulation; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; freq=frequency; ICIQ-SF=International Consultation on Incontinence Questionnaire-Short Form; ITT=Intention-to-treat anal; mo=month; PFMT=Pelvic floor muscle training; T=Treatment group; Vaizey=Vaizey Fecal Incontinence Score

Table 13: KQ1. Randomized controlled trial evidence for PFMT-BF with electrostimulation versus PFMT-BF for fecal incontinence

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Naimy, 2007[62]	Does PFMT-BF with estim improve FI over PFMT-BF?	N=49 n=40 100% F; 36 y Obstetric trauma T: 8 wks FU: 8 wks	T: PFMT-BF (EMG) plus estim (25) C: PFMT-BF (EMG) (24)	**CCFIS**, FIQL, reduced quality of life (0-10)	No significant difference between groups in CCFIS improvement (-1 both) or other outcomes. Excluded all data from drop-outs (18.4%)	Moderate
Mahoney, 2004[63]	Does PFMT-BF (EMG) with estim improve FI over PFMT-BF (EMG)?	N=60 n=54 100% F; 34 y Obstetric T: 3 mo. FU: 3 mo.	T: PFMT-BF (EMG) plus estim.(20 min) 1x/w (30) C: PFMT-BF (EMG) 10 min 1x/w k (30) Both PFMT (home)	**CCFIS**, FIQL	Both groups improved. Estim with PFMT-BF did not improve outcomes more than PFMT-BF without estim (CCFIS -2 treated, -2.5 control; or FIQL). Completer analysis.	Moderate
Fynes, 1999[61]	Does estim with PFMT-BF improve FI outcomes over PFMT-BF?	N=40 n=39 100% F; 32 y Obstetric trauma T: 3 mo. FU: 3 mo.	T: PFMT-BF (anal EMG) + estim 25 min/wk (20) C: PFMT-BF (vaginal EMG) 30 min/wk (20) Both PFMT (home)	**Modified Pescatori** (?0-20), % asymptomatic	Significant difference in improvement in modified Pescatori between treated and controls (-10 vs -3). Treatment protocols and therapists differed by group. Power not reported.	Moderate

*Significant = statistically significant; **Attrition was calculated by the MN EPC based on the number randomized
BF=Biofeedback; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; EMG=Electromyographic; Estim=Electrostimulation; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; mo=month; Pescatori=Pescatori Fecal Incontinence Score; PFMT=Pelvic floor muscle training; T=Treatment group; wk=week

Table 14: KQ1. Randomized controlled trial evidence for electrostimulation (without PFMT) for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Results (benefits)*	Risk of Bias (inverse of quality)
Norton, 2006[69]	Does home-based estim without PFMT improve FI over sham home-based estim?	N=90 n=90 (ITT) 90% F; 55 y Idiopathic T: 2 mo. FU: 2 mo.	T: estim 35Hz 20 min/d x 3w, then 40 min/d x 5w (47) C: same protocol but 1Hz estim(43)	Symptom change outcome rating, FI counts/w, 0-10 of bowel control & satisfaction, effectiveness	No significant difference between groups in any outcome measure. Low treatment compliance: only 25% of treated used estim for 20h or more (protocol= 34h). Underpowered study (98 needed)	Moderate
Healy, 2006[66]	Does home-based low-freq. endoanal estim without PFMT improve FI over (hospital-based mixed estim treatment?	N=58 n=38 CCFIS; n=48 other outcomes. 100% F; 54 y Idiopathic T: 3 mo. FU: 3 mo.	T: Estim at home 1h/d (23) C: 30 min. hospital based, 3/wk (25): 1. estim-BF with *muscle contraction* 15min 1x/wk 2. estim 15 min. 2x/wk	**CCFIS**, SF-36	Within-group analysis: Similar CCFIS improvement in treated (-4.4) and controls (-5.5). SF-36 improved in both. Power not reported. Sparse sample data (in text). Aim was a care site comparison but treatments differed in duration & protocol. Analyzed completers only.	High

*Significant = statistically significant; **Attrition was calculated by the MN EPC based on the number randomized
CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; d=day; Estim=Electrostimulation; FI=Fecal incontinence; FU=Followup; h=hour; Hz=Hertz; ITT=Intention-to-treat analysis; min=minute; mo=month; SF-36=Medical Outcomes Study Short-Form 36-item Health Survey; PFMT=Pelvic Floor Muscle Training; T=Treatment group; wk=week

Table 15: KQ1. Randomized controlled trial evidence for interventions to manage fecal incontinence in adults with spinal cord injury

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Christensen, 2006[71]	Compare transanal irrigation to best supportive care	N=87 n=79-87 (ITT) 28% F; 49 y Spinal cord injury T: 10 wks. FU: 10 wks.	T: Transanal irrigation 1x/d then every 2d or less C: bowel care every 2d, diet, exercise, stool modifying drugs	**CCCS**, **Vaizey**, modified FIQL, neurogenic bowel dysfunction score (NBDS); satisfaction, bowel function, daily activities	Tested mean differences between groups at termination; baseline comparability not tested. Irrigation significantly better than control on CCCS, Vaizey, NBDS, most other outcomes. 29% of treated discontinued study (4% controls). Sufficient power.	Moderate
Coggrave, 2010[72]	Does stepwise intervention improve bowel management & reduce FI over usual care?	N: 68 n: 68 (ITT) 34% F; 47 y Spinal cord injury T: 6 wks FU: 6 wks	T: Stepwise intervention (7 steps, least to most invasive) (35) C: Usual bowel management (33)	**Duration and level of intervention**, FI frequency, time to stool, minimum level of effective intervention	Stepwise intervention did not improve outcomes or the need for invasive bowel management interventions. FI was significantly more frequent in the treatment group. Underpowered study.	High

*Significant = statistically significant; **Attrition was calculated by the MN EPC based on the number randomized;
CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; d=day; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; ITT=Intention-to-treat analysis; NBDS=neurogenic bowel dysfunction score; T=Treatment group; Vaizey=Vaizey Fecal Incontinence Score; wk=week

Table 16: KQ1. Randomized controlled trial evidence for interventions to manage fecal incontinence in older adults in nursing homes

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (benefits)***	**Risk of Bias (inverse of quality)**
Schnelle, 2010[68]	Evaluate a multicomponent intervention on UI and FI in nursing home residents	N: 125 n: 112 83% F; 86 y Mixed T: 12 wks FU: 12 wks	T: toileting assistance, exercise, choice of food, fluid & snacks) 5d/wk (65) C: Usual care (60)	FI counts/d, bowel movements/d, fecal toileting percentage	Frequency of FI did not change with intervention but physical activity, freq. of toileting and food and fluid intake significantly improved. FI difficult to analyze; 45% of residents did not have a bowel movement during baseline or 10d post-intervention.	High
Schnelle, 2002[73]	Assess benefits of an exercise and incontinence intervention in NH residents	N: 190 n: 148 (FI outcome) 83% F; 88 y Not reported T: 32 wks. FU: 2 mo, 8 mo.	T: 4x/d prompted toileting, exercise, fluids (5d/wk) (94) C: No intervention (96)	FI freq (% of checks w/ FI), UI freq, fecal & urine toileting ratio, strength & endurance	Significant reduction in FI freq in treated vs. control (4% vs. 1%) at 8mo (2mo not reported); significant improvements in all other measures for treated. Power not reported	High

*Significant = statistically significant

C=Comparator/control; d=day; FI=Fecal incontinence; FU=Followup; freq=frequency; mo=month; NH=nursing home; T=Treatment group; UI=Urinary Incontinence; wk=week

Table 17: KQ1. Randomized controlled trial evidence for injectable tissue bulking agents for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Results (benefits)*	Risk of Bias (inverse of quality)
Dehli, 2013[74]	Determine if tissue bulking injections with dextranomer superior to PFMT-BF (plus estim if needed) for FI	N: 126 n: 119 (6 mo.) 93% F; 57 y Mixed T: 6mo control FU: 6 mo.	T: Dextranomer in hyaluronic acid (4 x 1mL injections to anal submucosa); repeat 1x if needed (64) C: PFMT-BF plus estim if needed x 6 sessions/6mo (62)	**Vaizey** (0-24), FIQL, EQ-5D	No significant difference between groups in Vaizey improvement to 6m (-4.6 points dextranomer vs -5.4 points PFMT-BF); between group change in FIQL at 6 months not significant; EQ-5D not reported. Sufficient power. Dismissed 44% of sample at 6 months for observational study of successes.	Low
Graf, 2011[75]	Does anal canal injection of dextranomer in hyaluronic acid improve FI over sham injection?	N=206 n=197 (6 mo) 89% F; 61 y Mixed T: Injections (1 d); repeat in 1 mo if CCFIS >10 FU: 3mo, 6mo	T: Total of 4-8 ml dextranomer injections in four quadrants of anal submucosa (136) C: Sham injections (nothing injected) (70)	**FI counts/wk (50% or more reduction from baseline**) CCFIS, FIQL, number of FI-free days, decrease in FI episodes	Significant difference in 50% or more reduction in FI episodes/wk in treated (52%) vs. controls (31%) at 6 mo. No differences between groups in CCFIS at 3mo or 6mo. FIQL and FI-free days better in treated at 6 mo. Sufficient power. Only followed treated group after 6 mo.	Low
Morris, 2013[77]	Compare bulking agents: Durasphere® (off-label) vs. PTQ™ (non-FDA approved)	N=35 n=34 % F NR; 66 y Not reported T: 1 d FU: 6wk, 6mo, 1y	T_1: Durasphere®: perianal injection (18) T_2: PTQ™ (not-FDA approved) (17)	**CCFIS**, SF-36	Durasphere® only: Improvement in mean CCFIS was 5.3 points at 6 wks., 4.1 at 6 mo., and 1.8 at 1 y. No significant change in SF-36 at any time. Trial underpowered due to early closure of study (from high cost of PTQ™ per authors)	Low
Tjandra, 2009[76]	Compare bulking agents: Durasphere® (off-label) vs. PTQ™ (non-FDA approved)	N=40 n=40 90% F; 59 y Mixed T: 1 day FU: 2wk, 6wk, 6mo, 1y	T_1: Durasphere®: perianal injection (20) T_2: PTQ™ (not-FDA approved) (20)	**CCFIS**, FIQL, SF-12	Durasphere® only: Improvement in mean CCFIS was 3.2 points at 2 wks, 3.8 at 6 wks, 5.3 at 6 mo, and 4.5 at 1 y. No significant change in SF-12 at any time point. Adequate study power.	Low

*Significant = statistically significant; **Attrition was calculated by the MN EPC based on the number randomized
BF=Biofeedback; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; d=day; EQ-5D=EuroQoL Questionnaire-5 Dimensions; Estim=Electrostimulation; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; FDA=Food and Drug Administration; mo=month; ml=milliliter; PFMT=Pelvic floor muscle training; PTQ™=injectable bulking agent not FDA approved for use in the U.S.; SF-12=Short-Form-12 health survey; SF-36=Medical Outcomes Study Short-Form 36-item Health Survey; T=Treatment group; T_1=Treatment group 1; T_2=Treatment group 2; Vaizey=Vaizey Fecal Incontinence Score; wk=week; y=year

Surgical Treatments

This section includes RCT and OBS studies on surgical treatments for FI including surgically-placed sacral neurostimulation (SNS), and combined surgical and nonsurgical treatments. We found only case series evidence for radiofrequency anal sphincter remodeling (SECCA) and antegrade continence enema (ACE) in adults; those studies are discussed under Key Question 2 only.

Key Points

- There is insufficient evidence for all surgical interventions for FI. Few surgical treatments were examined in RCTs or OBS studies; aims and treatments were highly varied and all studies had moderate to high risk of bias.
- The overwhelming majority of surgical studies are case series (low quality evidence).
- There is insufficient evidence that sacral neurostimulation is better than supportive care for FI up to 1 year; that turning the stimulator on improves FI severity and frequency more than having it off in newly-implanted patients; that stimulation at 75 percent or 50 percent of sensory threshold matters over stimulation at sensory threshold; that high-frequency, low prolonged pulse width stimulation regains efficacy in persons with sustained loss of efficacy after chronic stimulation; and that turning stimulation off at night results in worse FI outcomes.
- Surgical outcomes, in general, were reported for longer term followup than for nonsurgical interventions.
- In most RCTs, outcomes improvements with treatment and control interventions met or slightly exceeded minimal clinically important differences (MID) in intermediate-term outcomes when those values were known (Appendix E); greater improvements were infrequently reported.
- Reporting deficiencies in baseline patient, FI etiologies and outcomes and were common, particularly in SNS studies, which included minimal nonphysiologic patient information.

Surgically-implanted Sacral Neurostimulation

Surgically-placed sacral nerve stimulation (SNS) is used when conservative measures have failed to afford the desired level of fecal continence. There are two main limitations of SNS: (1) the stimulator battery has a limited lifetime and needs to be surgically replaced within the stimulator approximately every 5 years and (2) the nervous system adapts to stimulation over time which may result in the loss of efficacy on FI in some adults. Only one RCT[79] assessed the effectiveness of SNS[79] with the stimulator on versus off in newly-implanted patients; more recent studies focused on the maintenance of SNS battery life while maintaining continence effects,[80,81] measures to regain SNS efficacy that was dwindling,[82] and the comparison of SNS to best supportive care.[83] All SNS RCTs were crossover studies (Appendix F4) that almost exclusively enrolled adult females approximately 60 years old with mixed FI etiologies.

There is insufficient evidence that sacral neurostimulation offers any outcomes advantage over supportive care for FI up to 1 year;[83] that turning the stimulator on improves FI severity and frequency more than having it off in newly-implanted patients;[79] that stimulation at 75 percent or 50 percent of sensory threshold matters versus stimulation at sensory threshold;[80] that high-frequency, low prolonged pulse width stimulation regains efficacy in persons with sustained loss

of efficacy after chronic stimulation;[82] and that turning stimulation off at night results in worse FI outcomes.[81]

Observational studies provided insufficient evidence for SNS versus sphincteroplasty[84] and open versus percutaneous lead placement[85] (Appendix F5).

Anal Sphincter Repair (Sphincteroplasty)

Surgical repair of the anal sphincter is performed for adults with fecal incontinence resulting from anal sphincter tears that have accompanying moderate to severe fecal incontinence and have failed conservative treatment. Only two RCTs[86,87] (Appendix F4) and one observational study[88] (Appendix F5) examined sphincteroplasty.

There was insufficient evidence for sphincter repair with stoma (fecal diversion) versus sphincter repair alone;[86] for the use of adjuvant biofeedback following anal sphincter repair versus sphincter repair alone;[87] for a perineal versus a posterior forchette incision in overlapping anal sphincter repair; [88]for sphincteroplasty with pelvic floor repair versus sphincteroplasty only;[89] for anal sphincter repair versus SNS;[84] for sphincteroplasty versus anterior levatorplasty;[90] and anterior versus direct sphincter repair[91] (Appendices F4 and F5).

Anal Sphincter Replacement

Evidence was insufficient for the artificial bowel sphincter (ABS) versus conservative medical management from one RCT of 14 patients with severe FI[92] (Appendix F4) and for ABS versus a non-FDA approved surgery (magnetic sphincter)[93] (Appendix F5).

Other Surgeries and Mixed Treatment Comparisons

Appendices F4 and F5 include other surgical studies and mixed treatment comparisons. Evidence was insufficient for total pelvic floor repair versus gluteus maximus transposition without electrical stimulation for postobstetric neuropathic FI;[94] for postanal repair versus total pelvic floor repair for neurogenic FI;[95] and for total pelvic floor repair versus anterior levatorplasy versus postanal repair for neurogenic FI.[96]

Evidence was insufficient for levatorplasty surgery versus nonsurgical anal plug electrostimulation[97] and for SNS versus a non-FDA approved surgery (magnetic sphincter).[98]

Evidence was insufficient for what to do after failed sphincter repair surgery.[99] Only one high risk of bias observational study compared outcomes of three surgical treatments that were used in adults who had failed anal sphincter repair surgery[99] (Appendix F5).

Key Question 2: What adverse effects are associated with specific treatments for adults with fecal incontinence?

Key Points

- Few nonsurgical RCTs reported adverse effects (AEs). When reported, temporary nonsurgical treatments had few to no adverse effects that were minor.
- All surgical interventions were associated with more frequent and more severe complications than nonsurgical interventions.
- AEs increased as the treatment invasiveness increased and were highest for surgical interventions, especially the artificial bowel sphincter.
- Most surgical AEs were identified from surgical case series studies.
- Adverse effects from surgical case series had longer followup than other designs.

Nonsurgical Treatments

Adverse effects were reported in 17 of 37 nonsurgical RCTs (Appendix F6) and three OBS studies (Appendix F7); 6 additional RCTs reported no adverse effects (three PFMT, three drug studies). Adverse effects were generally mild and varied by the type of intervention; the frequency of adverse effects was variably reported (overall, by group or only identified in text). Gastrointestinal symptoms occurred with fiber supplements in 5 percent[39] to 20 percent[36] of patients. Oral medications used for FI were most commonly associated with nausea and abdominal pain and were not serious. Adverse effects of abdominal pain, headache, and nausea were reported for 55 percent of adults treated with 8mg of loperamide per day in one RCT;[43] no adverse effects at 12mg/day in another RCT;[44] and abdominal pain, headache, and nausea and vomiting in 69 percent of patients on 12mg in another RCT.[45] No adverse effects occurred in PFMT-BF studies that reported them. PFMT-BF with electrostimulation at low frequency caused pain in 50 percent of patients in the control group but no pain in the high-frequency treatment group.[64] Electrostimulation without PFMT caused discomfort in 9 percent of patients.[69] No AEs occurred with rectal irrigation in adults with passive FI.[70] However, bursts of the rectal balloon during rectal irrigation occurred in one in every three adults with spinal cord injuries;[71] abdominal distention and hospitalization for severe constipation occurred infrequently.[71] Repeated expulsion of the rectal catheter during irrigation was common in adults with SCI.[71]

In general, placebo or comparison group AE rates varied widely but were less frequent (none to half of treatment rates) and less severe than treatment group AEs (Appendices F6 and F7).

Tissue bulking injections had the highest proportion and variety of complications of the nonsurgical treatments (Appendix F6). Reported in aggregate, 25 percent of patients treated with dextranomer in hyaluronic acid experienced leakage of the injected agent, infection, or prolonged defecation over 6 months.[74] A dextranomer versus sham study reported treatment complications of proctalgia (14 percent), rectal hemorrhage (7 percent), diarrhea (5 percent), constipation (2 percent), injection site bleeding (5 percent), rectal discharge (4 percent) anal pruritus (2 percent), proctitis (3 percent), painful defecation (2 percent), fever (8 percent), other (16 percent) versus sham (injection site bleeding (17 percent), and other minor effects in 1-7 percent of patients.

Surgical Treatments

Adverse effects from surgical treatments were reported in 7 RCTs (Appendix F8), 8 OBS (Appendix F7), and 52 case series studies (Appendix F9). Surgical complications were common and ranged from minor (swelling, hematoma) to major (infection, bowel obstruction, perforation, fistula,); major complications often required reoperation; some required a permanent colostomy.

The frequency of surgical complications ranged from 0-32 percent in SECCA;[100-105] 21-74 percent in ACE;[106-109] 5-27 percent with sphincter repair;[86,88-91,99,110-118] 2-85 percent with SNS;[79,83,85,98,99,119-136] 8-64 percent with other surgeries;[94,96,97,137] and 22-100 percent with sphincter replacement.[92,93,99,138-151]

The severity of adverse effects varied by the type of surgery. Adverse effects were least severe for SECCA (pain, bleeding, swelling, mucosal ulceration) and SNS (infection, pain, electrode/lad issues, device malfunction) although SNS often required reoperation for device-related complications. ACE, sphincter repair and sphincter replacement had the most severe complications (wound infection, stenosis, bowel obstruction, sepsis, leak, and fistula). The most frequent and most severe complications occurred with sphincter replacement with an artificial

bowel sphincter: 20-81 percent of recipients had to have the implant removed (explanted) and either replaced (most often) or treated with colostomy (less often).

Discussion

Key Findings and Strength of Evidence

We found low-quality evidence to inform clinical decisionmaking for the range of treatments for FI in adults in the United States. The situation is more dismal when it comes to surgical treatments. Not only is evidence insufficient across the board for surgical treatments, but they are often associated with considerable complications. We were unable to conduct a meta-analysis because few studies examined the same treatment-outcome combination within similar timeframes. We encountered a plethora of outcomes (Appendix F1). Table 18 summarizes the major findings of this review. Details of the overall strength of evidence assessments are provided in Appendix F10; risk of bias ratings for individual studies that informed strength of evidence assessments are provided in Appendixes F11 and F12.

Low-strength evidence suggests that dietary fiber supplementation with psyllium decreases FI episode frequency by 1 month; that clonidine has no effect at 1 month; and that PFMT-BF with electrostimulation is no more effective than PFMT-BF on FI severity and FIQL over 2 to 3 months.

Low-strength evidence at 6 months post-treatment suggests that dextranomer anal tissue-bulking injections are more effective than sham injections on FIQL, the number of FI-free days, and on the percent of patients with FI episode reduction of 50 percent or more from pre-injection levels, but no more effective than PFMT-BF with or without electrostimulation on FI severity and quality of life, and no more effective than sham injection on FI severity (CCFIS) or in reducing the number of FI episodes from baseline. The only anal sphincter tissue bulking agent examined in a randomized trial beyond 6 months was Durasphere® (off-label), which showed improvements in FI severity up to 6 months. However, gains with Durasphere diminished slightly between 6 months and 1 year post-injections in two RCTs.[76,77]

Although PFMT has been successful in addressing urinary incontinence,[152] most of the included PFMT literature for FI focused on treatment delivery refinements to improve or prolong the purported benefits of PFMT for FI, rather than to establish the benefits of it. Various iterations of PFMT produce similar improvements that appear to meet MID when those measures were used (CCFIS,[153] FISI,[154] Vaizey,[153,155] and FIQL subscales[153]). We found insufficient evidence that PFMT-BF offers any advantage over standard care (dietary fiber, stool-modifying drugs) for FI. We found no clear standard protocol for PFMT-BF training for FI; none of the studies we reviewed used the same treatment protocol for timing, intensity, type, and duration of exercise. In some cases, no information was provided on exercise repetitions and duration, despite the presence of intricate details regarding biofeedback sensors, probe placement, and patient positioning.

The evidence for FI treatment benefits was insufficient for all other nonsurgical and surgical interventions. Thus this literature provides little guidance for primary care providers and patients in their selection and sequencing of treatments for FI. Limitations in study conduct were common and avoidable, and the degree of substandard study reporting was unexpected given the longstanding reporting recommendations of CONSORT.[156-158]

Table 18. Strength of evidence summary for nonsurgical treatments for fecal incontinence*

Comparison	Type of FI Measure	Outcome, Study Information	Findings	Strength of Evidence (rationale by domain)
Dietary fiber supplementation with psyllium vs. placebo	Severity	FI episodes per week, 1 RCT[36] N=206	Psyllium significantly decreased FI by 2.5 episodes per week vs. placebo (0.7 fewer episodes/wk) at 1 month	**Low** (low study limitations, direct, imprecise, consistency unknown [single study])
Clonidine (oral) 0.2 mg/day vs. placebo	Severity	Mean weekly FICA 1 RCT[47] N=44	No significant difference between groups in FICA improvement at 1 month (1.6 points clonidine vs. 1.5 placebo)	**Low** (low study limitations, direct, imprecise, consistency unknown [single study])
PFMT-BF plus electrostimulation vs. PFMT-BF	Severity	CCFIS, 2 RCTs[62,63] N=109	No significant difference between groups in mean CCFIS improvement at 3 months: -1 point in both groups[61]; -2 points treated, -2.5 points control[62]	**Low** (medium study limitations, direct, imprecise, consistent)
	Quality of life	FIQL, 2 RCTs[62,63] N=109	No significant difference in FIQL between groups at 2 to 3 months; neither group improved (0 to 0.3 point change from baseline per subscale)	**Low** (medium study limitation , direct, precise, consistent)
Dextranomer tissue bulking injections vs. PFMT-BF +/- electrostimulation	Severity	Vaizey score 1 RCT[74] N=126	No significant difference between groups in Vaizey improvement at 6 months (-4.6 points dextranomer vs. -5.4 points PFMT-BF)	**Low** (medium study limitations, direct, imprecise, consistency unknown [single study], reporting bias detected)
	Quality of life	FIQL 1 RCT[74] N=126	No significant difference between groups in FIQL at 6 months (per text and figures; values NR)	**Low** (medium study limitations, direct, imprecise, consistency unknown [single study], reporting bias detected)
Dextranomer tissue bulking injections vs. sham injections	Severity	CCFIS 1 RCT[75] N=206	No significant difference between treated vs. sham in CCFIS improvement at 3 months (-2.6 points dextranomer vs. -2 sham) and 6 months (-2.5 points dextranomer vs. -1.7 sham)	**Low** (low study limitations, direct, imprecise, consistency unknown [single study])
	Severity	FI severity 1 RCT[75] N=206	Significant difference in percent of patients with ≥50% reduction in FI episodes at 6 months: 52% of dextranomer group vs. 31% sham. Median decrease in number of FI episodes over 2 weeks was not significantly different between groups at 3 months or 6 months (6.0, IQR 0-12.5) vs. 3.0 sham, IQR 0-8.9: p=0.09). Mean increase in number of FI-free days was greater in treated (3.1 days, SD 4.1) vs. sham (1.7 days, SD 3.5) group	**Low** (low study limitations, direct, imprecise; 3 measures gave inconsistent results: 2 better, 1 no different)
	Quality of life	FIQL 1 RCT[75] N=206	Percent change (improvement) from baseline in FIQL coping-behavior subscale favored dextranomer at 6 months: 27% (CI 21%, 34%) vs. sham 11% (CI 3%, 18%). Change scores in 3 other subscales did not differ (per text and figures, values NR)	**Low** (low study limitations, direct, imprecise, consistency unknown [single study])

Comparison	Type of FI Measure	Outcome, Study Information	Findings	Strength of Evidence (rationale by domain)
Durasphere® (off-label) tissue bulking injections vs. non-FDA approved PTQ™ injections	Severity	CCFIS 2 RCTs[76,77] N=75	Durasphere® (FDA-approved) results:** Mean CCFIS improvements were: 5.3 points at 6wk, 4.1 at 6mo,1.8 at 1y [77]; 3.8 points at 6wk, 5.3 at 6mo, 4.5 at 1y[76]	**Moderate** (low study limitations, direct, imprecise, consistent)

*Table shows strength of evidence for treatment-outcomes combinations with at least 2 moderate risk of bias RCTs or 1 RCT with low risk of bias and sufficient power to assign low strength of evidence. Other comparisons with insufficient evidence are not shown. **Non-FDA approved comparator PTQ™ results are not discussed.
+/- = with or without; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; EQ-5D=EuroQoL Questionnaire-5 Dimensions; Estim=Electrostimulation; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FDA=Food and Drug Administration; IQR=interquartile range; mo=month; NR=not reported; PFMT=Pelvic floor muscle training; PTQ™=injectable bulking agent not FDA approved for use in the U.S.; RCT=randomized controlled trial; SD=standard deviation; Vaizey=Vaizey Fecal Incontinence Score; wk=week; y=year

As noted earlier, treatment for FI generally follows a longitudinal sequence. Patients receiving nonsurgical treatment are typically earlier in their FI course, and those who get surgery have typically failed more conservative treatment. This complicates efforts to compare surgery with nonsurgical treatment. Moreover, nonsurgical treatment is often used as an adjunct to surgery. Understanding the effectiveness of the range of FI treatments requires carefully defining the nature of the patients at risk in terms of underlying problems, clinical characteristics, and prior treatment history. Many of the studies we reviewed failed to provide this information. Nonsurgical studies focused on short-term or intermediate-term outcomes in the management of FI, leaving many unanswered questions about the durability and feasibility of interventions over time.

Aside from adults in nursing homes and those with spinal cord injuries, we were unable to report subgroup-specific outcomes due to the heterogeneity of FI etiologies in enrolled adults in the studies that reported it. The majority of enrolled adults were females and their FI etiologies were most often mixed or not reported.

Adverse effects from nonsurgical interventions are uncommon and tend to be minor. Adverse effects from surgical interventions are substantial and common. For some procedures, complications may occur years after the surgery itself. The severity of complications increases along with invasiveness of the treatment. Although most of the surgical adverse effects were identified from case series, harms reporting was more detailed and comprehensive than the adverse effects reported in higher-level studies. We felt confident using case series for surgical complications because these problems were extremely unlikely to arise among controls who did not receive surgery. Complications from ACE, sphincter repair, and sphincter replacement were most severe. SNS complications were less severe, but all of these treatments may require further surgery. Removal of SNS was required in up to one in four recipients. The highest complications of any surgical procedure for FI were reported for sphincter replacement with an ABS. The ABS required surgical removal (explant) in 20–81percent of patients; infections were common and some patients ultimately required permanent colostomy. Significant complications are important to consider when providers are counseling patients with severe FI.

Applicability and Limitations of the Evidence Base

Several important characteristics limit the generalizability and applicability of these review results.

The evidence base would benefit from better compliance with CONSORT[156] and greater efforts to avoid compromising study integrity by omitting post-randomization data (analyzing only completers or those with perfect compliance) or by aggregating data from those whose condition deteriorated with those who remained stable.

The large number of outcome measures in RCTs alone impeded comparability across studies and the ability to conduct meta-analysis that could inform patient care. The field would benefit from reducing the number of outcomes measures used to improve comparability. In cases where a new assessment tool is used, efforts to simultaneously include a validated, commonly used measure would improve the utility of study information. The wide heterogeneity in current measures leaves the field with single, often underpowered studies for a particular intervention and/or subgroup and provides insufficient evidence to even marginally inform clinical decisions.

Common outcome measures need standardized labels across all disciplines that treat adults with FI. Measures that have undergone several iterations, including changes in content and scale, were variably identified and often mislabeled, even in recent literature. The Vaizey FI score (0-24[25]) was sometimes labeled as "St. Mark's" (0-13[27]), yet baseline or outcomes values, or the reference (when cited) for the measure, made it obvious that the Vaizey score had been used.[74,80-82] The Cleveland Clinic Fecal Incontinence Score[23] (CCFIS) was also variably labeled as CCFIS, Wexner or Jorge/Wexner in the articles we reviewed.

Varied definitions of the same outcome would benefit from standardization. Definitions of what constitutes an FI episode were particularly difficult to compare across studies (soiling versus solid stool versus solid plus liquid versus liquid only), as was urgency (can delay finding toilet 1 minute to 15 minutes or longer). Input from adults with FI may suggest ways to identify and quantify aspects of FI that can capture what matters most to patients in outcome measures. Issues with urgency may be just as problematic to patients as actual FI episodes, since the uncertainty and fear of accidental bowel leakage surrounding urgency require the same prompt behavior: finding a toilet.

The value of intermediate physiologic measures is unclear given the lack of a well-established link between physiologic measures and patient-centered outcomes. Manometric and other physiologic measures are overabundant, while far more information is needed about typical patient demographics, clinical features, and status at baseline. The latter data would better contextualize study results and help to inform which treatments work best in which patients.

Although FI is a chronic problem, most evidence is only short or intermediate term; longer term information on both benefits and adverse effects would better inform clinical decisions for chronic FI management.

Multiple etiologies may contribute to FI, and etiologies were variably reported in the literature. No etiologic information was reported in one-third of RCTs, while other authors provided great detail of nonmutually exclusive contributing factors. The term *neurogenic FI* would benefit from standardization. Aside from its use in the presence of significant nervous system pathology, *neurogenic FI* appears to be a catch-all term for any FI etiologies in the absence of identified structural pathology. Nonetheless, such distinctions were unclear.

Well-designed and conducted prospective cohort studies are underused in FI and may better identify baseline patient, FI severity, and etiologic factors that affect outcomes from various approaches over time. Most of the observational studies with comparators that we reviewed had

extensive study limitations that rendered invalid any treatment conclusions about differences between groups.

Finally, a segment of the FI literature we reviewed lacked baseline patient information that would describe enrolled adults in person-centered terms. This was especially true for (but not limited to) most sacral nerve stimulation studies. Aside from limited treatment metrics that were of interest to investigators, baseline information surrounding patients and their FI experience (etiology, duration, and severity) was missing; enrolled adults were identified largely by their physiologic metrics. The lack of baseline patient information in a segment of the FI literature was unexpected, given the longstanding recommendations of CONSORT.[156-158]

Limitations of the Review Process

Although initially planned, we were unable to report potential differences in treatment effectiveness in FI etiologic subgroups, because FI is often multifactorial. Most studies included adults with mixed FI etiologies.

Outcomes assessments were often timed at unusual intervals, which necessitated our aggregation of evidence into short-term (less than 3 months), intermediate-term (3 to 6 months), or long-term (more than 6 months) effects.

This review was limited to English-language publications. The possibility of missing clinical trials for FDA approved treatments in the United States is remote.[159,160]

We did not examine the FDA Adverse Event Reporting System for drug harms.

We did not contact authors for missing data or clarification of ambiguous or indeterminable table and text information.

Research Gaps

The overall strength of evidence for treatments for FI in adults was low or insufficient, suggesting that future studies with higher quality could change the conclusions of this review. Many research gaps are identified above in Applicability and Limitations of the Evidence Base.

The durability of treatments effects over time warrants more attention. Short-term, easy-to-use treatments, such as drugs and fiber supplements, may be important for planning around important social events, but it is unclear whether their beneficial effects are sustained longer term. Little information was available on rectal irrigation for adults with FI unrelated to spinal cord injury, yet rectal irrigation may prove a viable management tool, at least in the short term.

Few if any treatments can entirely cure FI; therefore, information on treatment combinations would benefit the evidence base. This is especially true since many interventions, once initiated, are continued long term. Dietary fiber, intermittent stool modifying drugs, and PFMT-BF may all be used pre- and post-surgery, but patients who would best benefit from combined therapies are not well identified.

Further research is needed to establish whether PFMT-BF works for FI. Intervention specifics including the optimal type of exercise, duration, number of repetitions, frequency, and specific patients and FI etiologies for which PFMT-BF is effective or ineffective are lacking. Long-term exercise compliance with PFMT-BF for FI is unknown.

Since the benefit of surgical interventions, including sacral nerve stimulation, may diminish over time, it is unclear which additional interventions should be undertaken and when they should be initiated to enhance or prolong the durability of surgical benefits.

Whether there is a degree of external sphincter defect that predicts the outcome of sacral nerve stimulation or nonsurgical treatment is not known. Older studies excluded patients with

extensive tears. However, lower-quality observational studies report that even patients with extensive tears improved with SNS up to 1 year.[161,162]

There is very limited information about the results of treatment options chosen after failed surgical treatments.[99]

Better comparison of the benefit-to-harm ratio of FI treatments is needed, especially for invasive and surgical interventions. This information is necessary in order for patients to accurately weigh the potential benefits and risks when faced with deciding whether to undergo a surgical treatment option. Substantial and life-altering adverse events occur post-surgery for FI, and these were under identified in RCTs alone.

The long-term effects of injected anal bulking agents, including their effects on adjacent normal tissues, and the location of the injected substance itself are unclear.

We found little information that could improve outcomes for adults with FI and spinal cord injuries, or for older adults in nursing homes. Interventions for nursing home residents with FI focused on the prevention of fecal impaction though staff-implemented interventions that gave greater attention to fluid, diet, and toileting measures, none of which improved FI outcomes.

Studies of FDA and non-FDA approved interventions in clinicaltrials.gov that may eventually mitigate some of these research gaps include but are not limited to: interventions for older adults (multicomponent [behavioral, education, medication] FI intervention delivered by home health nurses to frail elderly patients, effect of a nursing home staff education program on FI in residents, surgically-placed TOPAS mesh sling [pelvic floor] for women with FI, pelvic floor muscle training, botulinum toxin A injections on FI and urgency, long-term safety and efficacy of Solesta [dextranomer injection], plus several studies of injections of biologics including stem cells). Also, a case series was recently published for a new nonsurgical vaginal bowel control device.[11]

Conclusions

Only a few nonsurgical treatments for FI in adults had sufficient-quality evidence to inform patient care; the surgical evidence is of insufficient quality for clinical decisionmaking. The use of numerous outcome measures is an impediment to the field. Substantial methodological and reporting issues can be rectified by following current study and reporting standards; small improvements could provide higher quality evidence for the field. The overall strength of evidence for treatments for fecal incontinence in adults was low or insufficient, suggesting that future studies with higher quality could change the conclusions of this review.

References

1. (ICS) ICS. Faecal Incontinence - ICS Fact Sheets July 2013. 2013 4/18/14. Available at: http://www.ics.org/Documents/Documents.aspx?FolderID=82.
2. Whitehead WE, Borrud L, Goode PS, et al. Fecal incontinence in US adults: epidemiology and risk factors. Gastroenterology 2009 Aug;137(2):512-7, 7 e1-2. PMID: 19410574.
3. NIH state-of-the-science conference statement on prevention of fecal and urinary incontinence in adults. NIH Consens State Sci Statements 2007 Dec 12-14;24(1):1-37. PMID: 18183046.
4. Shamliyan T, Wyman J, Bliss DZ, et al. Prevention of urinary and fecal incontinence in adults. Evid rep/technol assess 2007 Dec(161):1-379. PMID: 18457475.
5. Clinic M. Fecal Incontinence. Available at: http://www.mayoclinic.org/diseases-conditions/fecal-incontinence/basics/definition/con-20034575. Accessed 4/18/22014.
6. Omar MI, Alexander CE. Drug treatment for faecal incontinence in adults. Cochrane Database of Systematic Reviews 2013 (6). PMID: CD002116.
7. Norton C, Cody June D. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. Cochrane Database of Systematic Reviews 2012. PMID: CD002111.
8. Boyle R, Hay-Smith EJC, Cody June D, et al. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. Cochrane Database of Systematic Reviews 2012. PMID: CD007471.
9. Cazemier M, Felt-Bersma RJ, Mulder CJ. Anal plugs and retrograde colonic irrigation are helpful in fecal incontinence or constipation. World J Gastroenterol 2007 Jun 14;13(22):3101-5. PMID: 17589927.
10. Briel JW, Schouten WR, Vlot EA, et al. Clinical value of colonic irrigation in patients with continence disturbances. Dis Colon Rectum 1997 Jul;40(7):802-5. PMID: 9221856.
11. Richter HE, Matthews CA, Muir T, et al. A vaginal bowel-control system for the treatment of fecal incontinence. Obstet Gynecol 2015 Mar;125(3):540-7. PMID: 25730213.
12. Maeda Y, Laurberg S, Norton C. Perianal injectable bulking agents as treatment for faecal incontinence in adults. Cochrane Database of Systematic Reviews 2013. PMID: CD007959.
13. Brown SR, Wadhawan H, Nelson RL. Surgery for faecal incontinence in adults. Cochrane Database of Systematic Reviews 2013 (7). PMID: CD001757.
14. Fernando RJ, Sultan AH, Kettle C, et al. Methods of repair for obstetric anal sphincter injury. Cochrane Database Syst Rev 2013;12:CD002866. PMID: 24318732.
15. Coggrave M, Norton C, Cody June D. Management of faecal incontinence and constipation in adults with central neurological diseases. Cochrane Database of Systematic Reviews 2014 (1). PMID: CD002115.
16. Deutekom M, Dobben Annette C. Plugs for containing faecal incontinence. Cochrane Database of Systematic Reviews 2012 (4). PMID: CD005086.
17. Thin NN, Horrocks EJ, Hotouras A, et al. Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence. Br J Surg 2013 Oct;100(11):1430-47. PMID: 24037562.
18. Hong KD, Dasilva G, Kalaskar SN, et al. Long-term outcomes of artificial bowel sphincter for fecal incontinence: a systematic review and meta-analysis. J Am Coll Surg 2013 Oct;217(4):718-25. PMID: 23891075.
19. Ratto C, Litta F, Parello A, et al. Sacral nerve stimulation in faecal incontinence associated with an anal sphincter lesion: a systematic review. Colorectal Dis 2012 Jun;14(6):e297-304. PMID: 22356165.
20. Glasgow SC, Lowry AC. Long-term outcomes of anal sphincter repair for fecal incontinence: a systematic review. Dis Colon Rectum 2012 Apr;55(4):482-90. PMID: 22426274.
21. Hussain ZI, Lim M, Stojkovic SG. Systematic review of perianal implants in the treatment of faecal incontinence. Br J Surg 2011 Nov;98(11):1526-36. PMID: 21964680.
22. Luo C, Samaranayake CB, Plank LD, et al. Systematic review on the efficacy and safety of injectable bulking agents for passive faecal incontinence. Colorectal Dis 2010 Apr;12(4):296-303. PMID: 19320664.

23. Jorge JM, Wexner SD. Etiology and management of fecal incontinence. Dis Colon Rectum 1993 Jan;36(1):77-97. PMID: 8416784.

24. Rockwood TH, Church JM, Fleshman JW, et al. Patient and surgeon ranking of the severity of symptoms associated with fecal incontinence: the fecal incontinence severity index. Dis Colon Rectum 1999 Dec;42(12):1525-32. PMID: 10613469.

25. Vaizey CJ, Carapeti E, Cahill JA, et al. Prospective comparison of faecal incontinence grading systems. Gut 1999 Jan;44(1):77-80. PMID: 9862829.

26. Pescatori M, Anastasio G, Bottini C, et al. New grading and scoring for anal incontinence. Evaluation of 335 patients. Dis Colon Rectum 1992 May;35(5):482-7. PMID: 1568401.

27. Lunniss PJ, Kamm MA, Phillips RK. Factors affecting continence after surgery for anal fistula. Br J Surg 1994 Sep;81(9):1382-5. PMID: 7953425.

28. Rockwood TH, Church JM, Fleshman JW, et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. Dis Colon Rectum 2000 Jan;43(1):9-16; discussion -7. PMID: 10813117.

29. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Medical care 1992 Jun;30(6):473-83. PMID: 1593914.

30. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. J Clin Epidemiol 2009 Oct;62(10):1006-12. PMID: 19631508.

31. Higgins JP, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. Bmj 2011;343:d5928. PMID: 22008217.

32. Viswanathan M, Berkman ND. Development of the RTI item bank on risk of bias and precision of observational studies. Journal of Clinical Epidemiology 2011. PMID.

33. Viswanathan M, Ansari MT, Berkman ND, et al. Assessing the Risk of Bias of Individual Studies in Systematic Reviews of Health Care Interventions: Agency for Healthcare Research and Quality Methods Guide for Comparative Effectiveness Reviews. 2012.

34. Whitehead WE, Wald A, Norton NJ. Priorities for treatment research from different professional perspectives. Gastroenterology 2004 Jan;126(1 Suppl 1):S180-5. PMID: 14978659.

35. Berkman ND, Lohr KN, Ansari M, et al. Grading the strength of a body of evidence when assessing health care interventions for the Effective Health Care Program of the Agency for Healthcare Research and Quality: An Update. Rockville, MD. November 2013. http://www.effectivehealthcare.ahrq.gov/ehc/products/457/1752/methods-guidance-grading-evidence-131118.pdf; http://www.ncbi.nlm.nih.gov/pubmed/24404627.

36. Bliss DZ, Savik K, Jung HJ, et al. Dietary fiber supplementation for fecal incontinence: a randomized clinical trial. Res Nurs Health 2014 Oct;37(5):367-78. PMID: 25155992.

37. Bliss DZ, Jung HJ, Savik K, et al. Supplementation with dietary fiber improves fecal incontinence. Nurs Res 2001 Jul-Aug;50(4):203-13. PMID: 11480529.

38. Lauti M, Scott D, Thompson-Fawcett MW. Fibre supplementation in addition to loperamide for faecal incontinence in adults: a randomized trial. Colorectal Dis 2008 Jul;10(6):553-62. PMID: 18190615.

39. Sze EH, Hobbs G. Efficacy of methylcellulose and loperamide in managing fecal incontinence. Acta Obstet Gynecol Scand 2009;88(7):766-71. PMID: 19452328.

40. Park JS, Kang SB, Kim DW, et al. The efficacy and adverse effects of topical phenylephrine for anal incontinence after low anterior resection in patients with rectal cancer. Int J Colorectal Dis 2007 Nov;22(11):1319-24. PMID: 17569063.

41. Carapeti EA, Kamm MA, Phillips RK. Randomized controlled trial of topical phenylephrine in the treatment of faecal incontinence. Br J Surg 2000 Jan;87(1):38-42. PMID: 10606908.

42. Carapeti EA, Kamm MA, Nicholls RJ, et al. Randomized, controlled trial of topical phenylephrine for fecal incontinence in patients after ileoanal pouch construction. Dis Colon Rectum 2000 Aug;43(8):1059-63. PMID: 10950003.

43. Sun WM, Read NW, Verlinden M. Effects of loperamide oxide on gastrointestinal transit time and anorectal function in patients with chronic diarrhoea and faecal incontinence. Scand J Gastroenterol 1997 Jan;32(1):34-8. PMID: 9018764.

44. Hallgren T, Fasth S, Delbro DS, et al. Loperamide improves anal sphincter function and continence after restorative proctocolectomy. Dig Dis Sci 1994 Dec;39(12):2612-8. PMID: 7995187.

45. Read M, Read NW, Barber DC, et al. Effects of loperamide on anal sphincter function in patients complaining of chronic diarrhea with fecal incontinence and urgency. Dig Dis Sci 1982 Sep;27(9):807-14. PMID: 7105952.

46. Palmer KR, Corbett CL, Holdsworth CD. Double-blind cross-over study comparing loperamide, codeine and diphenoxylate in the treatment of chronic diarrhea. Gastroenterology 1980 Dec;79(6):1272-5. PMID: 7002706.

47. Bharucha AE, Fletcher JG, Camilleri M, et al. Effects of clonidine in women with fecal incontinence. Clinical Gastroenterology and Hepatology 2014 May;12(5):843-51.e2. PMID: 2014269726.

48. Pinedo G, Zarate AJ, Inostroza G, et al. New treatment for faecal incontinence using zinc-aluminium ointment: a double-blind randomized trial. Colorectal Dis 2012 May;14(5):596-8. PMID: 21781231.

49. Pinedo G, Garcia E, Zarate AJ, et al. Are topical oestrogens useful in faecal incontinence? Double-blind randomized trial. Colorectal Dis 2009 May;11(4):390-3. PMID: 18637100.

50. Kusunoki M, Shoji Y, Ikeuchi H, et al. Usefulness of valproate sodium for treatment of incontinence after ileoanal anastomosis. Surgery 1990 Mar;107(3):311-5. PMID: 2106731.

51. Byrne CM, Solomon MJ, Rex J, et al. Telephone vs. face-to-face biofeedback for fecal incontinence: comparison of two techniques in 239 patients. Dis Colon Rectum 2005 Dec;48(12):2281-8. PMID: 16258709.

52. Remes-Troche JM, Ozturk R, Philips C, et al. Cholestyramine--a useful adjunct for the treatment of patients with fecal incontinence. Int J Colorectal Dis 2008 Feb;23(2):189-94. PMID: 17938939.

53. Loening-Baucke V. Efficacy of biofeedback training in improving faecal incontinence and anorectal physiologic function. Gut 1990 Dec;31(12):1395-402. PMID: 2265781.

54. Damon H, Siproudhis L, Faucheron JL, et al. Perineal retraining improves conservative treatment for faecal incontinence: A multicentre randomized study. Digestive and Liver Disease 2014 March;46(3):237-42. PMID: 2014108997.

55. Norton C, Chelvanayagam S, Wilson-Barnett J, et al. Randomized controlled trial of biofeedback for fecal incontinence. Gastroenterology 2003 Nov;125(5):1320-9. PMID: 14598248.

56. Heymen S, Scarlett Y, Jones K, et al. Randomized controlled trial shows biofeedback to be superior to pelvic floor exercises for fecal incontinence. Dis Colon Rectum 2009 Oct;52(10):1730-7. PMID: 19966605.

57. Whitehead WE, Burgio KL, Engel BT. Biofeedback treatment of fecal incontinence in geriatric patients. J Am Geriatr Soc 1985 May;33(5):320-4. PMID: 3989196.

58. Bols E, Berghmans B, de Bie R, et al. Rectal balloon training as add-on therapy to pelvic floor muscle training in adults with fecal incontinence: a randomized controlled trial. Neurourol Urodyn 2012 Jan;31(1):132-8. PMID: 22038680.

59. Solomon MJ, Pager CK, Rex J, et al. Randomized, controlled trial of biofeedback with anal manometry, transanal ultrasound, or pelvic floor retraining with digital guidance alone in the treatment of mild to moderate fecal incontinence. Dis Colon Rectum 2003 Jun;46(6):703-10. PMID: 12794569.

60. Bartlett L, Sloots K, Nowak M, et al. Biofeedback for fecal incontinence: a randomized study comparing exercise regimens. Dis Colon Rectum 2011 Jul;54(7):846-56. PMID: 21654252.

61. Fynes MM, Marshall K, Cassidy M, et al. A prospective, randomized study comparing the effect of augmented biofeedback with sensory biofeedback alone on fecal incontinence after obstetric trauma. Dis Colon Rectum 1999 Jun;42(6):753-8; discussion 8-61. PMID: 10378599.

62. Naimy N, Lindam AT, Bakka A, et al. Biofeedback vs. electrostimulation in the treatment of postdelivery anal incontinence: a randomized, clinical trial. Dis Colon Rectum 2007 Dec;50(12):2040-6. PMID: 17914654.

63. Mahony RT, Malone PA, Nalty J, et al. Randomized clinical trial of intra-anal electromyographic biofeedback physiotherapy with intra-anal electromyographic biofeedback augmented with electrical stimulation of the anal sphincter in the early treatment of postpartum fecal incontinence. Am J Obstet Gynecol 2004 Sep;191(3):885-90. PMID: 15467559.

64. Schwandner T, Hemmelmann C, Heimerl T, et al. Triple-target treatment versus low-frequency electrostimulation for anal incontinence: a randomized, controlled trial. Dtsch 2011 Sep;108(39):653-60. PMID: 22013492.

65. Schwandner T, Konig IR, Heimerl T, et al. Triple target treatment (3T) is more effective than biofeedback alone for anal incontinence: the 3T-AI study.[Erratum appears in Dis Colon Rectum. 2011 Nov;54(11):1461]. Dis Colon Rectum 2010 Jul;53(7):1007-16. PMID: 20551752.

66. Healy CF, Brannigan AE, Connolly EM, et al. The effects of low-frequency endo-anal electrical stimulation on faecal incontinence: a prospective study. Int J Colorectal Dis 2006 Dec;21(8):802-6. PMID: 16544149.

67. Ilnyckyj A, Fachnie E, Tougas G. A randomized-controlled trial comparing an educational intervention alone vs education and biofeedback in the management of faecal incontinence in women. Neurogastroenterol Motil 2005 Feb;17(1):58-63. PMID: 15670265.

68. Schnelle JF, Leung FW, Rao SS, et al. A controlled trial of an intervention to improve urinary and fecal incontinence and constipation. J Am Geriatr Soc 2010 Aug;58(8):1504-11. PMID: 20653804.

69. Norton C, Gibbs A, Kamm MA. Randomized, controlled trial of anal electrical stimulation for fecal incontinence. Dis Colon Rectum 2006 Feb;49(2):190-6. PMID: 16362803.

70. van der Hagen SJ, van der Meer W, Soeters PB, et al. A prospective non-randomized two-centre study of patients with passive faecal incontinence after birth trauma and patients with soiling after anal surgery, treated by elastomer implants versus rectal irrigation. Int J Colorectal Dis 2012 Sep;27(9):1191-8. PMID: 22576903.

71. Christensen P, Bazzocchi G, Coggrave M, et al. A randomized, controlled trial of transanal irrigation versus conservative bowel management in spinal cord-injured patients. Gastroenterology 2006 Sep;131(3):738-47. PMID: 16952543.

72. Coggrave MJ, Norton C. The need for manual evacuation and oral laxatives in the management of neurogenic bowel dysfunction after spinal cord injury: a randomized controlled trial of a stepwise protocol. Spinal Cord 2010 Jun;48(6):504-10. PMID: 19949417.

73. Schnelle JF, Alessi CA, Simmons SF, et al. Translating clinical research into practice: a randomized controlled trial of exercise and incontinence care with nursing home residents. J Am Geriatr Soc 2002 Sep;50(9):1476-83. PMID: 12383143.

74. Dehli T, Stordahl A, Vatten LJ, et al. Sphincter training or anal injections of dextranomer for treatment of anal incontinence: a randomized trial. Scand J Gastroenterol 2013 Mar;48(3):302-10. PMID: 23298304.

75. Graf W, Mellgren A, Matzel KE, et al. Efficacy of dextranomer in stabilised hyaluronic acid for treatment of faecal incontinence: a randomised, sham-controlled trial. Lancet 2011 Mar 19;377(9770):997-1003. PMID: 21420555.

76. Tjandra JJ, Chan MK, Yeh HC. Injectable silicone biomaterial (PTQ) is more effective than carbon-coated beads (Durasphere) in treating passive faecal incontinence--a randomized trial. Colorectal Dis 2009 May;11(4):382-9. PMID: 18637935.

77. Morris OJ, Smith S, Draganic B. Comparison of bulking agents in the treatment of fecal incontinence: a prospective randomized clinical trial. Tech Coloproctol 2013 Oct;17(5):517-23. PMID: 23525964.

78. Bliss DZ, Savik K, Jung HJ, et al. Symptoms associated with dietary fiber supplementation over time in individuals with fecal incontinence. Nurs Res 2011 May-Jun;60(3 Suppl):S58-67. PMID: 21543963.

79. Leroi AM, Parc Y, Lehur PA, et al. Efficacy of sacral nerve stimulation for fecal incontinence: results of a multicenter double-blind crossover study. Ann Surg 2005 Nov;242(5):662-9. PMID: 16244539.

80. Duelund-Jakobsen J, Buntzen S, Lundby L, et al. Sacral nerve stimulation at subsensory threshold does not compromise treatment efficacy: results from a randomized, blinded crossover study. Ann Surg 2013 Feb;257(2):219-23. PMID: 23001079.

81. Michelsen HB, Krogh K, Buntzen S, et al. A prospective, randomized study: switch off the sacral nerve stimulator during the night? Dis Colon Rectum 2008 May;51(5):538-40. PMID: 18299927.

82. Duelund-Jakobsen J, Dudding T, Bradshaw E, et al. Randomized double-blind crossover study of alternative stimulator settings in sacral nerve stimulation for faecal incontinence. Br J Surg 2012 Oct;99(10):1445-52. PMID: 22961528.

83. Tjandra JJ, Chan MK, Yeh CH, et al. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. Dis Colon Rectum 2008 May;51(5):494-502. PMID: 18278532.

84. Ratto C, Litta F, Parello A, et al. Sacral nerve stimulation is a valid approach in fecal incontinence due to sphincter lesions when compared to sphincter repair. Dis Colon Rectum 2010 Mar;53(3):264-72. PMID: 20173471.

85. Dudding TC, Pares D, Vaizey CJ, et al. Comparison of clinical outcome between open and percutaneous lead insertion for permanent sacral nerve neurostimulation for the treatment of fecal incontinence. Dis Colon Rectum 2009 Mar;52(3):463-8. PMID: 19333047.

86. Hasegawa H, Yoshioka K, Keighley MR. Randomized trial of fecal diversion for sphincter repair. Dis Colon Rectum 2000 Jul;43(7):961-4; discussion 4-5. PMID: 10910243.

87. Davis KJ, Kumar D, Poloniecki J. Adjuvant biofeedback following anal sphincter repair: a randomized study. Aliment Pharmacol Ther 2004 Sep 1;20(5):539-49. PMID: 15339325.

88. Tan M, O'Hanlon DM, Cassidy M, et al. Advantages of a posterior fourchette incision in anal sphincter repair. Dis Colon Rectum 2001 Nov;44(11):1624-9. PMID: 11711734.

89. Steele SR, Lee P, Mullenix PS, et al. Is there a role for concomitant pelvic floor repair in patients with sphincter defects in the treatment of fecal incontinence? Int J Colorectal Dis 2006 Sep;21(6):508-14. PMID: 16075237.

90. Osterberg A, Edebol Eeg-Olofsson K, Graf W. Results of surgical treatment for faecal incontinence. Br J Surg 2000 Nov;87(11):1546-52. PMID: 11091244.

91. Briel JW, de Boer LM, Hop WC, et al. Clinical outcome of anterior overlapping external anal sphincter repair with internal anal sphincter imbrication. Dis Colon Rectum 1998 Feb;41(2):209-14. PMID: 9556246.

92. O'Brien PE, Dixon JB, Skinner S, et al. A prospective, randomized, controlled clinical trial of placement of the artificial bowel sphincter (Acticon Neosphincter) for the control of fecal incontinence. Dis Colon Rectum 2004 Nov;47(11):1852-60. PMID: 15622577.

93. Wong MT, Meurette G, Stangherlin P, et al. The magnetic anal sphincter versus the artificial bowel sphincter: a comparison of 2 treatments for fecal incontinence. Dis Colon Rectum 2011 Jul;54(7):773-9. PMID: 21654242.

94. Yoshioka K, Ogunbiyi OA, Keighley MR. A pilot study of total pelvic floor repair or gluteus maximus transposition for postobstetric neuropathic fecal incontinence. Dis Colon Rectum 1999 Feb;42(2):252-7. PMID: 10211504.

95. van Tets WF, Kuijpers JH. Pelvic floor procedures produce no consistent changes in anatomy or physiology. Dis Colon Rectum 1998 Mar;41(3):365-9. PMID: 9514434.

96. Deen KI, Oya M, Ortiz J, et al. Randomized trial comparing three forms of pelvic floor repair for neuropathic faecal incontinence. Br J Surg 1993 Jun;80(6):794-8. PMID: 8330179.

97. Osterberg A, Edebol Eeg-Olofsson K, Hallden M, et al. Randomized clinical trial comparing conservative and surgical treatment of neurogenic faecal incontinence. Br J Surg 2004 Sep;91(9):1131-7. PMID: 15449263.

98. Wong MT, Meurette G, Wyart V, et al. Does the magnetic anal sphincter device compare favourably with sacral nerve stimulation in the management of faecal incontinence? Colorectal Dis 2012 Jun;14(6):e323-9. PMID: 22339789.

99. Hong KD, da Silva G, Wexner SD. What is the best option for failed sphincter repair? Colorectal Dis 2014 April;16(4):298-303. PMID: 2014180374.

100. Abbas MA, Tam MS, Chun LJ. Radiofrequency treatment for fecal incontinence: is it effective long-term? Dis Colon Rectum 2012 May;55(5):605-10. PMID: 22513440.

101. Ruiz D, Pinto RA, Hull TL, et al. Does the radiofrequency procedure for fecal incontinence improve quality of life and incontinence at 1-year follow-up? Dis Colon Rectum 2010 Jul;53(7):1041-6. PMID: 20551757.

102. Takahashi-Monroy T, Morales M, Garcia-Osogobio S, et al. SECCA procedure for the treatment of fecal incontinence: results of five-year follow-up. Dis Colon Rectum 2008 Mar;51(3):355-9. PMID: 18204954.

103. Lefebure B, Tuech JJ, Bridoux V, et al. Temperature-controlled radio frequency energy delivery (Secca procedure) for the treatment of fecal incontinence: results of a prospective study. Int J Colorectal Dis 2008 Oct;23(10):993-7. PMID: 18594840.

104. Felt-Bersma RJ, Szojda MM, Mulder CJ. Temperature-controlled radiofrequency energy (SECCA) to the anal canal for the treatment of faecal incontinence offers moderate improvement. Eur J Gastroenterol Hepatol 2007 Jul;19(7):575-80. PMID: 17556904.

105. Efron JE, Corman ML, Fleshman J, et al. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. Dis Colon Rectum 2003 Dec;46(12):1606-16; discussion 16-8. PMID: 14668584.

106. Chereau N, Lefevre JH, Shields C, et al. Antegrade colonic enema for faecal incontinence in adults: long-term results of 75 patients. Colorectal Dis 2011 Aug;13(8):e238-42. PMID: 21689331.

107. Worsoe J, Christensen P, Krogh K, et al. Long-term results of antegrade colonic enema in adult patients: assessment of functional results. Dis Colon Rectum 2008 Oct;51(10):1523-8. PMID: 18622642.

108. Koivusalo AI, Pakarinen MP, Pauniaho SL, et al. Antegrade continence enema in the treatment of congenital fecal incontinence beyond childhood. Dis Colon Rectum 2008 Nov;51(11):1605-10. PMID: 18629588.

109. Krogh K, Laurberg S. Malone antegrade continence enema for faecal incontinence and constipation in adults. Br J Surg 1998 Jul;85(7):974-7. PMID: 9692576.

110. Oom DM, Gosselink MP, Schouten WR. Anterior sphincteroplasty for fecal incontinence: a single center experience in the era of sacral neuromodulation. Dis Colon Rectum 2009 Oct;52(10):1681-7. PMID: 19966598.

111. Kaiser AM. Cloaca-like deformity with faecal incontinence after severe obstetric injury--technique and functional outcome of ano-vaginal and perineal reconstruction with X-flaps and sphincteroplasty. Colorectal Dis 2008 Oct;10(8):827-32. PMID: 18205849.

112. Grey BR, Sheldon RR, Telford KJ, et al. Anterior anal sphincter repair can be of long term benefit: a 12-year case cohort from a single surgeon. BMC surg 2007;7:1. PMID: 17217528.

113. Ha HT, Fleshman JW, Smith M, et al. Manometric squeeze pressure difference parallels functional outcome after overlapping sphincter reconstruction. Dis Colon Rectum 2001 May;44(5):655-60. PMID: 11357023.

114. Ho YK, Tan M, Seow-Choen F. Anterior anal sphincter repair for faecal incontinence: Anorectal manometric and endoanal ultrasound assessment. Asian J 1999;22(1):89-92. PMID: 1999066795.

115. Sitzler PJ, Thomson JP. Overlap repair of damaged anal sphincter. A single surgeon's series. Dis Colon Rectum 1996 Dec;39(12):1356-60. PMID: 8969660.

116. Nikiteas N, Korsgen S, Kumar D, et al. Audit of sphincter repair. Factors associated with poor outcome. Dis Colon Rectum 1996 Oct;39(10):1164-70. PMID: 8831535.

117. Gibbs DH, Hooks VH, 3rd. Overlapping sphincteroplasty for acquired anal incontinence. South Med J 1993 Dec;86(12):1376-80. PMID: 8272915.

118. Keighley MR. Postanal repair for faecal incontinence. J R Soc Med 1984 Apr;77(4):285-8. PMID: 6716379.

119. Moya P, Arroyo A, Lacueva J, et al. Sacral nerve stimulation in the treatment of severe faecal incontinence: Long-term clinical, manometric and quality of life results. Tech Coloproctol 2014 February;18(2):179-85. PMID: 2014080274.

120. McNevin MS, Moore M, Bax T. Outcomes associated with Interstim therapy for medically refractory fecal incontinence. Am J Surg 2014 May;207(5):735-7. PMID: 2014307622.

121. Maeda Y, Lundby L, Buntzen S, et al. Outcome of sacral nerve stimulation for fecal incontinence at 5 years. Ann Surg 2014;259(6):1126-31. PMID: 2014340452.

122. Feretis M, Karandikar S, Chapman M. Medium-term results with sacral nerve stimulation for management of faecal incontinence, a single centre experience. Journal of Interventional Gastroenterology 2013;3(3):82-8. PMID: 2013738867.

123. Damon H, Barth X, Roman S, et al. Sacral nerve stimulation for fecal incontinence improves symptoms, quality of life and patients' satisfaction: results of a monocentric series of 119 patients. Int J Colorectal Dis 2013 Feb;28(2):227-33. PMID: 22885883.

124. Faucheron JL, Chodez M, Boillot B. Neuromodulation for fecal and urinary incontinence: Functional results in 57 consecutive patients from a single institution. Diseases of the Colon and Rectum 2012 December;55(12):1278-83. PMID: 2013032242.

125. Pascual I, Gomez Cde C, Ortega R, et al. Sacral nerve stimulation for fecal incontinence. Rev Esp Enferm Dig 2011 Jul;103(7):355-9. PMID: 21770681.

126. Mellgren A, Wexner SD, Coller JA, et al. Long-term efficacy and safety of sacral nerve stimulation for fecal incontinence. Dis Colon Rectum 2011 Sep;54(9):1065-75. PMID: 21825885.

127. Maeda Y, Lundby L, Buntzen S, et al. Suboptimal outcome following sacral nerve stimulation for faecal incontinence. Br J Surg 2011 Jan;98(1):140-7. PMID: 21136568.

128. Wexner SD, Coller JA, Devroede G, et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. Ann Surg 2010 Mar;251(3):441-9. PMID: 20160636.

129. Michelsen HB, Thompson-Fawcett M, Lundby L, et al. Six years of experience with sacral nerve stimulation for fecal incontinence. Dis Colon Rectum 2010 Apr;53(4):414-21. PMID: 20305440.

130. Faucheron JL, Voirin D, Badic B. Sacral nerve stimulation for fecal incontinence: causes of surgical revision from a series of 87 consecutive patients operated on in a single institution. Dis Colon Rectum 2010 Nov;53(11):1501-7. PMID: 20940598.

131. El-Gazzaz G, Zutshi M, Salcedo L, et al. Sacral neuromodulation for the treatment of fecal incontinence and urinary incontinence in female patients: long-term follow-up. Int J Colorectal Dis 2009 Dec;24(12):1377-81. PMID: 19488765.

132. Hetzer FH, Hahnloser D, Clavien PA, et al. Quality of life and morbidity after permanent sacral nerve stimulation for fecal incontinence. Arch Surg 2007;142(1):8-13. PMID: 2007036266.

133. Rasmussen OO, Buntzen S, Sorensen M, et al. Sacral nerve stimulation in fecal incontinence. Diseases of the Colon and Rectum 2004 July;47(7):1158-62. PMID: 2004282596.

134. Jarrett ME, Varma JS, Duthie GS, et al. Sacral nerve stimulation for faecal incontinence in the UK. Br J Surg 2004 Jun;91(6):755-61. PMID: 15164447.

135. Kenefick NJ, Vaizey CJ, Cohen RCG, et al. Medium-term results of permanent sacral nerve stimulation for faecal incontinence. Br J Surg 2002;89(7):896-901. PMID: 2002259771.

136. Boenicke L, Kim M, Reibetanz J, et al. Stapled transanal rectal resection and sacral nerve stimulation - impact on faecal incontinence and quality of life. Colorectal Dis 2012 Apr;14(4):480-9. PMID: 21689328.

137. Hultman CS, Zenn MR, Agarwal T, et al. Restoration of fecal continence after functional gluteoplasty: Long-term results, technical refinements, and donor-site morbidity. Ann Plast Surg 2006 January;56(1):65-71. PMID: 2006013845.

138. Darnis B, Faucheron JL, Damon H, et al. Technical and functional results of the artificial bowel sphincter for treatment of severe fecal incontinence: is there any benefit for the patient? Dis Colon Rectum 2013 Apr;56(4):505-10. PMID: 23478619.

139. Wong MT, Meurette G, Wyart V, et al. The artificial bowel sphincter: a single institution experience over a decade. Ann Surg 2011 Dec;254(6):951-6. PMID: 22107742.

140. Michot F, Lefebure B, Bridoux V, et al. Artificial anal sphincter for severe fecal incontinence implanted by a transvaginal approach: experience with 32 patients treated at one institution. Dis Colon Rectum 2010 Aug;53(8):1155-60. PMID: 20628279.

141. Ruiz Carmona MD, Alos Company R, Roig Vila JV, et al. Long-term results of artificial bowel sphincter for the treatment of severe faecal incontinence. Are they what we hoped for? Colorectal Dis 2009 Oct;11(8):831-7. PMID: 18662237.

142. Melenhorst J, Koch SM, van Gemert WG, et al. The artificial bowel sphincter for faecal incontinence: a single centre study. Int J Colorectal Dis 2008 Jan;23(1):107-11. PMID: 17929038.

143. Casal E, San Ildefonso A, Carracedo R, et al. Artificial bowel sphincter in severe anal incontinence. Colorectal Dis 2004 May;6(3):180-4. PMID: 15109383.

144. Parker SC, Spencer MP, Madoff RD, et al. Artificial bowel sphincter: long-term experience at a single institution. Dis Colon Rectum 2003 Jun;46(6):722-9. PMID: 12794572.

145. Wong WD, Congliosi SM, Spencer MP, et al. The safety and efficacy of the artificial bowel sphincter for fecal incontinence: results from a multicenter cohort study. Dis Colon Rectum 2002 Sep;45(9):1139-53. PMID: 12352228.

146. Ortiz H, Armendariz P, DeMiguel M, et al. Complications and functional outcome following artificial anal sphincter implantation. Br J Surg 2002 Jul;89(7):877-81. PMID: 12081737.

147. Devesa JM, Rey A, Hervas PL, et al. Artificial anal sphincter: complications and functional results of a large personal series. Dis Colon Rectum 2002 Sep;45(9):1154-63. PMID: 12352229.

148. Altomare DF, Dodi G, La Torre F, et al. Multicentre retrospective analysis of the outcome of artificial anal sphincter implantation for severe faecal incontinence. Br J Surg 2001 Nov;88(11):1481-6. PMID: 11683745.

149. O'Brien PE, Skinner S. Restoring control: The Acticon Neosphincter artificial bowel sphincter in the treatment of anal incontinence. Diseases of the Colon and Rectum 2000;43(9):1213-6. PMID: 2000330823.

150. Lehur PA, Roig JV, Duinslaeger M. Artificial anal sphincter: prospective clinical and manometric evaluation. Dis Colon Rectum 2000 Aug;43(8):1100-6. PMID: 10950008.

151. Christiansen J, Rasmussen OO, Lindorff-Larsen K. Long-term results of artificial anal sphincter implantation for severe anal incontinence. Ann Surg 1999 Jul;230(1):45-8. PMID: 10400035.

152. Dumoulin C, Hay-Smith J, Habee-Seguin GM, et al. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women: A short version Cochrane systematic review with meta-analysis. Neurourol Urodyn 2015 Apr;34(4):300-8. PMID: 25408383.

153. Bols EM, Hendriks HJ, Berghmans LC, et al. Responsiveness and interpretability of incontinence severity scores and FIQL in patients with fecal incontinence: a secondary analysis from a randomized controlled trial. Int Urogynecol J Pelvic Floor Dysfunct 2013 Mar;24(3):469-78. PMID: 22806487.

154. Jelovsek JE, Chen Z, Markland AD, et al. Minimum Important Differences for Scales Assessing Symptom Severity and Quality of Life in Patients with Fecal Incontinence. Female Pelvic Med Reconstr Surg 2014 Sep 1. PMID: 25185630.

155. Bols EM, Hendriks EJ, Deutekom M, et al. Inconclusive psychometric properties of the Vaizey score in fecally incontinent patients: a prospective cohort study. Neurourol Urodyn 2010 Mar;29(3):370-7. PMID: 19634170.

156. Calvert M, Blazeby J, Altman DG, et al. Reporting of patient-reported outcomes in randomized trials: the CONSORT PRO extension. Jama 2013 Feb 27;309(8):814-22. PMID: 23443445.

157. Moher D, Schulz KF, Altman D, et al. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. Jama 2001 Apr 18;285(15):1987-91. PMID: 11308435.

158. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol 2010 Aug;63(8):e1-37. PMID: 20346624.

159. Moher D, Pham B, Klassen TP, et al. What contributions do languages other than English make on the results of meta-analyses? J Clin Epidemiol 2000 Sep;53(9):964-72. PMID: 11004423.

160. Morrison A, Polisena J, Husereau D, et al. The effect of English-language restriction on systematic review-based meta-analyses: a systematic review of empirical studies. International journal of technology assessment in health care 2012 Apr;28(2):138-44. PMID: 22559755.

161. Melenhorst J, Koch SM, Uludag O, et al. Is a morphologically intact anal sphincter necessary for success with sacral nerve modulation in patients with faecal incontinence? Colorectal Dis 2008 Mar;10(3):257-62. PMID: 17949447.

162. Chan MK, Tjandra JJ. Sacral nerve stimulation for fecal incontinence: external anal sphincter defect vs. intact anal sphincter. Dis Colon Rectum 2008 Jul;51(7):1015-24; discussion 24-5. PMID: 18484136.

Abbreviations

ABS	Artificial bowel sphincter
ACE	Antegrade colonic irrigation
AE	Adverse effects
AM	Anal manometry
AMED	Allied and Complementary Medicine
BDI	Beck Depression Inventory
CENTRAL	Cochrane Central Register of Controlled Trials
CER	Comparative effectiveness review
CCFIS	Cleveland Clinic Fecal Incontinence Score
DRF	Digital rectal feedback
DYS	Dysfunctional
Estim	Intra-anal electrostimulation
FDA	Food and Drug Administration
FI	Fecal incontinence
FICA	Fecal Incontinence and Continence Assessment
FIQL	Fecal Incontinence Quality of Life Instrument
FISI	Fecal Incontinence Severity Index
GI	Gastrointestinal
ITT	Intention-to-treat analysis
KQ	Key Question
MeSH	Medical Subject Headings
MID	Minimal clinically important difference
OBS	Observational Studies
PEDro	Physiotherapy Evidence Database
PFMT	Pelvic floor muscle training
PFMT-BF	Pelvic floor muscle training with biofeedback
PICOTS	Population, Intervention, Comparator, Outcomes, Timing, Setting
RBT	Rectal balloon training
RCT	Randomized controlled trial
SCI	Spinal cord injuries
SECCA	Radiofrequency anal sphincter remodeling
SF-12	MOS Short-Form 12-item Health Survey
SF-36	MOS Short-Form 36-item Health Survey
SIP	Scientific Information Packet
SNS	Sacral nerve stimulation
SOE	Strength of evidence
SMFIS	St. Mark’s Fecal Incontinence Score
STAI	Spielberger State-Trait Anxiety Inventory
TEP	Technical expert panel
UI	Urinary incontinence
Vaizey	Vaizey Fecal Incontinence Score