

# *Draft Comparative Effectiveness Review*

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Number XX

## **Chronic Urinary Retention: Comparative Effectiveness of Treatments and Harms**

Prepared for:

Agency for Healthcare Research and Quality  
U.S. Department of Health and Human Services  
540 Gaither Road  
Rockville, MD 20850  
www.ahrq.gov

**Contract No. HHS-290-2007-10064-I**

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**AHRQ Publication No. xx-EHCxxx**

**<Month Year>**

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None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.
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**Suggested citation:** Brasure M, Fink HA, Risk M, MacDonald R, Shamliyan T, Xu D, Butler M, Kane RL, Ouellette J, Wilt, TJ. Chronic Urinary Retention: Comparative Effectiveness of Treatments and Harms. Comparative Effectiveness Review No. xxx. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2007-10064-I.) AHRQ Publication No. xx-xxxx. Rockville, MD: Agency for Healthcare Research and Quality; date. [www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov).

## 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](http://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](http://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](mailto:epc@ahrq.hhs.gov).

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## Structured Abstract

**Objective.** To determine the effectiveness and comparative effectiveness of treatments for chronic urinary retention in adults.

**Data Sources:** Ovid MEDLINE<sup>®</sup> and the Cochrane Central Register of Controlled Trials bibliographic databases; hand searches of references of relevant studies.

**Review Methods:** Two investigators screened abstracts and full text articles of identified references for eligibility and reviewed randomized controlled trials (RCTs) and prospective cohort studies to describe intervention characteristics and evaluate evidence on primary outcomes of the rate of urinary tract infections, urinary symptom score category, and successful trial without catheter, and intermediate outcomes of post-void residual urine volume and urinary symptom or quality of life scores. We extracted data, assessed risk of bias on individual studies, and evaluated strength of the body of evidence.

**Results:** We identified 11 publications reporting original research and two relevant systematic reviews meeting eligibility criteria. Results are analyzed by etiology: benign prostatic hyperplasia, neurogenic bladder, and other causes. Low strength evidence suggests that TURP and microwave therapy achieve similar improvements in the rates of successful trials without catheter and UTI. Low strength evidence suggests that TURP may improve outcomes more than laser therapy; however adverse events were higher. Low strength evidence suggests that botulinum toxin injections are not effective in reducing in the rates of UTI in neurogenic bladder patients. A previous systematic review provided evidence that neuromodulation improves the rate at which patients with Fowler's syndrome can go without catheters.

**Conclusions:** The body of evidence is limited regarding effectiveness or comparative effectiveness of treatments for chronic urinary retention. Further research should address conceptual issues in studying chronic urinary retention as well as adding to the evidence base for select populations and interventions.

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# Introduction

## Background

Standard diagnostic criteria for chronic urinary retention (CUR), including the duration and volume of post-void residual (PVR) urine necessary for a diagnosis, have not been determined.<sup>1,2</sup> Researchers often define CUR as PVR urine volume greater than 300 ml; however, studies also define it as 100 ml, 400 ml, or 500 ml.<sup>1</sup>

CUR may be either asymptomatic or be associated with lower urinary tract symptoms such as urinary frequency, urgency, or incontinence.<sup>3</sup> The consequences of elevated PVR or CUR include an increased risk for urinary tract infections (UTI) and renal failure.<sup>3</sup> Some studies of men with lower urinary tract symptoms and CUR indicate increased risk of acute urinary retention (AUR), renal failure, and lower likelihood that benign prostatic hypertrophy (BPH) surgery will improve urinary symptoms.<sup>2</sup> The PVR level associated with these effects is unclear, although negative outcomes have been demonstrated in men with PVR volumes over 500 ml.<sup>1</sup> We do not know if these findings are applicable to asymptomatic men with CUR.

CUR typically is caused by another medical condition. The most common causes of CUR are obstructive and neurologic.<sup>3</sup> In men, the most prevalent obstructive cause of CUR is benign prostatic hyperplasia (BPH). As many as 25 percent of men who undergo prostate surgery for BPH have CUR.<sup>2</sup> In women, an obstructive cause of CUR is pelvic organ prolapse. In both sexes, urethral strictures and pelvic masses are obstructive causes.<sup>3</sup> Neurologic conditions that can lead to CUR include spinal cord injury, stroke, multiple sclerosis, Parkinson's disease, and diabetes mellitus.<sup>3</sup> CUR from neurologic causes occurs equally in men and women.<sup>3</sup> Another cause of CUR (neither obstructive nor neurologic) is Fowler's syndrome, which affects mainly young women and is characterized by urinary retention due to a failure of urethral sphincter relaxation.<sup>4</sup>

Treatment aims to cure or ameliorate CUR. Frequently used treatments include catheterization, surgery, minimally invasive procedures, and drugs. Treatment options (Appendix A) depend on etiology. The goal of treatment is to improve function and/or quality of life and reduce complications to an extent meaningful to patients. Our review addresses the following Key Questions:

**Key Question 1:** What are the effectiveness and comparative effectiveness of treatments for chronic urinary retention in adults

- a) with male-specific etiologies?
- b) with female-specific etiologies?
- c) with non sex-specific etiologies
- d) What patient or condition characteristics (e.g., age, severity, etc.) modify the effectiveness of treatment?

**Key Question 2:** What are the harms and comparative harms of treatments for chronic urinary retention in adults

- a) with male-specific etiologies?
- b) with female-specific etiologies?
- c) with non sex-specific etiologies?

- d) What patient or condition characteristics (e.g., age, severity, etc.) modify the harms of treatment?

The PICOTS (Population, Intervention, Comparison, Outcomes, Timing, and Setting) addressed for our key questions are described in Table 1. An analytical framework describing the relationship between the PICOTS elements appears in Appendix B.

**Table 1. PICOTS framework**

<b>PICOTS Element</b>	<b>Inclusion Criteria</b>
Population	Adults 18 or older with CUR (a persistently elevated PVR volume of 100 ml or greater). Patients with acute or transient retention attributed to drug side effects, medical or surgical procedures, or infection/inflammation were excluded.
Intervention	Catheterization Surgical interventions (etiology-specific): prostate surgery (BPH), pelvic organ prolapse repair (pelvic organ prolapse), sacral nerve stimulation (neurologic) Pharmacologic treatments: alpha blockers (AB), 5-alpha reductase inhibitors (5-ARI), AB + 5-ARI combination treatment available in the United States Urinary diversion
Comparator	Placebo or any of above interventions
Outcomes	Primary outcomes: AUR; UTI; TWOC; minimum clinically important change in urinary symptom or quality of life scale scores.
Timing	Any treatment duration
Setting	Any treatment setting

Abbreviations: AUR = acute urinary retention; BPH = benign prostatic hypertrophy; CUR = chronic urinary retention; PICOTS = population, intervention, comparator, outcomes, timing, and setting; PVR = postvoid residual; TWOC = trial without catheterization, UTI = urinary tract infection

## Methods

We registered the protocol for this review with the international prospective registry of systematic reviews, PROSPERO (registration number: CRD42013004639). The final version is available at <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=1539&pageaction=displayproduct>. We conducted bibliographic database searches in MEDLINE and the Cochrane Central Register of Controlled Trials (CENTRAL) to identify previous systematic reviews, randomized controlled trials, and controlled before-and-after studies published from 1946 through May 2013. We searched only for the CUR concept and used relevant medical subject headings and natural language terms to identify studies (Appendix C). We narrowed the search by using filters designed to select experimental designs.<sup>5</sup> Bibliographic database searches were supplemented with backward citation searches of highly relevant systematic reviews. Two investigators reviewed titles and abstracts to identify those potentially meeting inclusion criteria (Appendix D). All controlled studies that addressed the PICOTS described previously were eligible and included. Two investigators worked independently to screen the full text of studies identified as potentially meeting the inclusion criteria. Differences in inclusion decisions were addressed through consultation; a third investigator was consulted when necessary.

We first assessed the relevance of systematic reviews that met inclusion criteria. If certain key questions or comparisons addressed in the previous systematic review were determined relevant to our review, we assessed the quality of the methodology using the modified AMSTAR criteria.<sup>6</sup> When the systematic review was assessed as sufficient quality and when the review assessed strength of evidence, we used the conclusions from that review to replace the *de novo* process. We then abstracted data from trials and controlled prospective cohort studies that addressed comparisons not sufficiently addressed by a previous eligible systematic review. One investigator abstracted the relevant data into the Systematic Review Data Repository tool and/or directly to evidence tables. A second investigator reviewed evidence tables and verified them for accuracy. Based on judgments of selection bias, performance and detection bias (allocation concealment and blinding), attrition bias, reporting bias, and other sources of bias, investigators assessed an overall risk of bias.

We categorized eligible studies into three groups for analysis based on CUR etiology: obstruction, neurogenic disorders, and other conditions. Within these etiology categories, we conducted a qualitative synthesis because of heterogeneity in the populations, interventions, and outcomes studied.

For each treatment comparison addressed by original research, we evaluated the overall strength of evidence for primary outcomes. The primary outcomes we included *a priori* were rates of AUR, UTI, successful trial without catheter, and minimum clinically important differences in urinary symptom or quality of life scales. We added an additional primary outcome *post hoc*. We considered an IPSS categorical outcome (indicating a poor, fair, or good outcome in terms of urinary symptoms after intervention), which was reported in one study as a primary outcome because no study examined for this review reported minimum clinically important differences for this scale, and categorization better measured a clinical difference than changes in mean scores. Additionally, while change in PVR urine volume is not a patient-centered outcome, we discuss the impact treatment had on PVR urine volume to assess whether patients no longer meet CUR diagnostic criteria and to better understand the impact of treatment on BPH symptoms and CUR. Strength of evidence was not assessed for intermediate outcomes or harms.

Strength of evidence assessments (as high, moderate, low, or insufficient) were based on four required domains: (1) study limitations (internal validity); (2) directness (single, direct link between intervention and outcome); (3) consistency (similarity of effect direction and size); and (4) precision (degree of certainty around an estimate).<sup>7</sup> When risk of bias was moderate or low and at least one other strength of evidence domain had a positive assessment, strength of evidence was assessed as low. High or moderate strength of evidence assessments required at least two studies.

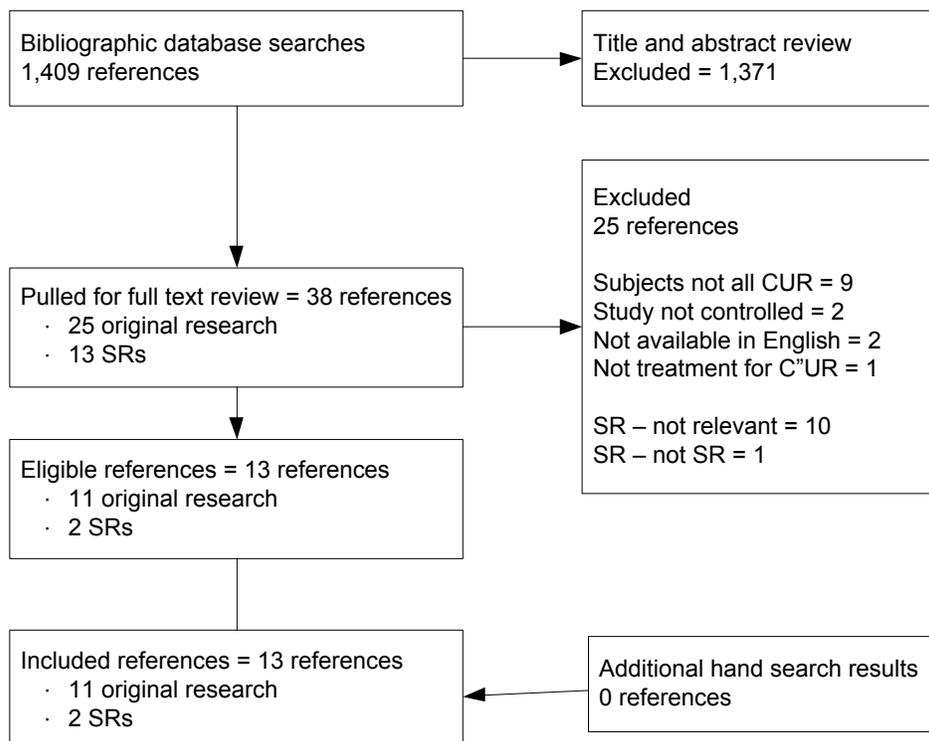
We evaluated the applicability of study results according to the PICOTS framework, paying particular attention to narrow eligibility criteria and patient characteristics that may differ from those of individuals in the community.<sup>8</sup>

# Results

## Search Results

Our search identified 1,409 citations, of which 38 citations required full text review after title and abstract screening (Figure 1). Of the 38 full text articles screened, we identified 11 eligible studies representing 11 unique reports of original research<sup>9-19</sup> and two relevant systematic reviews.<sup>20, 21</sup> Studies excluded after full text review are listed in Appendix E along with exclusion reasons.

**Figure 1. Literature Flow Diagram**



We categorized studies into groups for synthesis based on CUR etiology:

- Men with BPH
- Adults with neurogenic disorders
- Other or mixed etiology

The appendices of this report provide detailed information about the included studies: Characteristics of the individual studies (Appendix F); risk of bias and quality assessments of original research and systematic reviews (Appendix G); summaries of included studies, analysis, and detailed outcomes tables by etiology (Appendix H); detailed strength of evidence assessments (Appendix I).

## Men with BPH

Three eligible RCTs compared treatments for CUR in men with BPH.<sup>11, 12, 18</sup> All three RCTs included men with CUR (defined as persistent PVR >300ml) and other lower urinary tract symptoms. The mean age of the 243 men enrolled was 71 years. Two studies reported mean baseline International Prostate Symptom Scores (IPSS) and PVR volumes with a mean baseline total IPSS of 21.4 (indicating severe symptoms) and mean baseline PVR volume of 626 ml. All three trials compared surgery (transurethral resection of the prostate [TURP] or prostate enucleation) to a less invasive intervention (laser, microwave, clean intermittent sterile catheterization [CISC]). Two trials were conducted in Europe and one in Asia. All three demonstrated methodological problems (i.e., inability to blind patient and provider, allocation concealment) and were assessed as having overall moderate risk of bias. Table 2 provides a summary of primary outcomes and adverse effects.

## Benefits

Two of the three RCTs reported on five primary outcomes (UTI, treatment failure, TWOC, need for surgical intervention, and IPSS category). The third RCT assessed only intermediate outcomes, analysis of which is not included here. Studies reported no significant differences in primary outcomes between men that underwent TURP and men who received microwave therapy; both treatment groups showed similar improvements over baseline. Low-strength evidence suggested no significant difference in the rate of UTI and successful TWOC between TURP and microwave therapy. Adjusted results provided low-strength evidence that, compared to laser therapy, TURP was associated with a lower degree of symptoms (IPSS category) post-intervention.

Only two RCTs provided data on PVR. No other changes in intermediate outcomes (PVR) were statistically significant for either comparison (Appendix H). Mean change from baseline was sufficient to suggest that CUR diagnostic criteria were no longer met after treatment with either TURP or laser therapy. While the mean change from baseline for CISC did not lower mean baseline PVR below 300mL, mean change was not statistically significantly different than the TURP group.

## Harms

Each study measured adverse effects differently, reporting either incidence of specific adverse effects, incidence of serious adverse effects, or postsurgical complication rates. Harms did not differ between surgery versus microwave therapy or between surgery versus clean intermittent self-catheterization, but a larger proportion of patients in the TURP group experienced complications than in the laser group.

**Table 2. Summary outcomes and strength of evidence treatments for chronic urinary retention in men with BPH**

Study (n); Comparison; Inclusion Criteria; Design	Outcomes	Results	Strength of Evidence
Schelin 2006 <sup>11</sup> (n=120)	<b>Primary outcomes</b> Urinary tract infection	NS RR 1.49 [0.82 to 2.71]	Low (moderate risk of bias, imprecise, unclear consistency)
TURP or prostate enucleation surgery vs. microwave therapy	TWOC	NS RR 0.89 [0.76 to 1.05]	Low (moderate risk of bias, unclear consistency)
Men ≥45 years of age with symptomatic BPH and PVR >300mL	<b>Adverse effects</b> Serious adverse events	NS	NA
RCT			
Ghalayini 2005 <sup>12</sup> (n=51)	<b>Primary outcomes</b> None reported	NR	Insufficient (no data)
TURP vs. CISC	<b>Adverse effects</b> Complication rate	NS	NA
Men with LUTS, baseline IPSS >7 and PVR>300 mL			
RCT			
Gujral 2000 <sup>18</sup> (n=82)	<b>Primary outcomes</b> Urinary tract infection	NS RR 1.73 [0.16 to 18.31]	Insufficient (moderate risk of bias, imprecise, unclear consistency)
TURP vs. Laser therapy	Surgical intervention	NS RR 0.12 [0.01 to 2.32]	Insufficient (moderate risk of bias, imprecise, unclear consistency)
Men with LUTS and baseline IPSS ≥8 and PVR >300mL	IPSS Category (Good, Fair, Poor)	NS RR 1.27 [95% CI 0.97 to 1.68]	Insufficient (high risk of bias, unclear consistency)
RCT	IPSS Category (Good, Fair, Poor) <i>adjusted</i> **	TURP ↑ RR 3.9 [95% CI 1.0 to 14.3]	Low (moderate risk of bias, unclear consistency)
	<b>Adverse effects</b> Complication rate	TURP ↑	NA

BPH = benign prostatic hyperplasia; CI= confidence intervals; CISC = clean intermittent self-catheterization; IPSS = International Prostate Symptom Score (range 0 [mild symptoms] to 35 [severe symptoms]); LUTS = lower urinary tract symptoms; MD = mean difference; NA = not assessed; NR = not reported; NS = no statistically significant difference; PVR = post void residual; QoL = quality of life; RCT = randomized controlled trial; RR = risk ratio; TURP = transurethral resection of the prostate; TWOC = trial without catheter

\* Mean difference could not be calculated

\*\* Adjustment for differences between groups at baseline in marital status and prostate volume

## **Comparative Effectiveness of CUR Treatments in Adults with Neurogenic Bladder**

Four small efficacy studies compared treatments for CUR attributed to neurogenic bladder in adults; three were RCTs with moderate risk of bias and one was a controlled before-and-after design. Studies enrolled a total of 139 patients with sample sizes ranging from 13 to 86. The mean age of enrolled patients was 54, with a range from 46 to 66. Fifty-one percent of subjects were men. Baseline mean IPSS score was 21.4 across the two studies that measured IPSS, suggesting a severe level of symptoms. Neurogenic disorders among the patients included multiple sclerosis (64 percent), spinal cord injury (7 percent), and other (29 percent). In the three studies reporting, patients had been living with these neurogenic disorders for an average of 13 years. Trials were conducted in Europe and Asia. Three studies compared injections of botulinum A into the sphincter to an inactive control (placebo, lidocaine, usual care). The fourth study compared bethanechol/prostaglandin (BC/PGE2) to placebo.

### **Benefits**

Most of the evidence was insufficient due to indirect outcomes and imprecise estimates created by the wide confidence intervals of underpowered studies. One study provided low-strength evidence of no difference between botulinum treatment and placebo in rates of UTI at 120 days post intervention (Table 3).

### **Harms**

Neither study found differences in the rates of any adverse effects between treatment groups though studies were not adequately powered to detect these.

**Table 3. Summary outcomes, adverse events, and strength of evidence of treatments for chronic urinary retention in neurogenic bladder patients**

Study (n); Comparison; Inclusion criteria; Design	Outcomes	Results	Strength of Evidence
Gallien 2005 <sup>13</sup> (n=86)	<b>Primary outcomes</b>		
Botulinum A toxin vs. Placebo	Urinary tract infection	NS RR 1.21 [95% CI 0.66 to 2.25]	Low (moderate risk of bias, unclear consistency)
MS patients with DSD. Patients with CUR had PVR of 100 to 500 ml	<b>Adverse effects</b> Serious adverse events	NS	NA
RCT			
Hindley 2004 <sup>14</sup> (n=19)	<b>Primary outcomes</b>		
Bethanechol chloride plus prostaglandin E2 vs. placebo	TWOC	NS	Insufficient (moderate risk of bias, indirect, imprecise, unclear consistency)
Patients with suspected detrusor under-activity, defined as PVR >300 mL in the absence of BPO	<b>Adverse effects</b> Any adverse events	NS	NA
RCT			
de Sèze 2002 <sup>16</sup> (n=13)	<b>Primary outcomes:</b>		
Botulinum A toxin vs. Lidocaine	None reported	NR	Insufficient (no data)
Patients with DSD. CUR defined as PVR >100 ml	<b>Adverse effects:</b> Any adverse events	NS	NA
RCT			
Chen 2004 <sup>15</sup> (n=21)	<b>Primary outcomes:</b>		
Botulinum A toxin vs. Usual care	None reported	NR	Insufficient (no data)
Patients with urethral sphincter pseudo- dyssynergia due to chronic cerebrovascular accidents or intracranial lesions	<b>Adverse effects:</b> Serious adverse events	NS	NA
Prospective study			

CI = confidence intervals; DSD = detrusor sphincter dyssynergia; IPSS = International Prostate Symptom Score (range 0 [mild symptoms] to 35 [severe symptoms]); MD = mean difference; MS = multiple sclerosis; NA = not assessed; NR = not reported; NS = no statistically significant difference; PVR = post void residual ; QoL = quality of life; RCT = randomized controlled trial; RR = risk ratio; TWOC = trial without catheter

\* Mean difference could not be calculated

## Comparative Effectiveness of CUR Treatments in Adults with Other Causes of CUR

Four studies (original research) and two systematic reviews addressed four different comparisons for treatments for CUR from mixed etiologies or etiologies that were not obstructive or neurogenic. Two of these comparisons were adequately addressed by previous systematic reviews.<sup>20, 21</sup> Two systematic reviews were conducted by the Cochrane Incontinence Group and were assessed as being of good quality. We report conclusions from these reviews in lieu of *de novo* abstraction and analysis of the original research addressing those comparisons (Table 4).<sup>17, 19</sup>

The Moore et al. systematic review<sup>21</sup> examined one comparison relevant to our review—the rates of UTI after clean versus sterile catheterization technique. They found the data from three studies insufficient to draw conclusions.<sup>21</sup> Only one of these trials was eligible for our review.<sup>19</sup> Because the results from the three trials eligible for the Cochrane review were consistent and the data were assessed as insufficient, we reiterate their conclusion of insufficient evidence for this comparison.

### Benefits

Herbison et al. reviewed sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults.<sup>20</sup> Herbison et al. addressed one comparison relevant to our review—immediate implant versus a delayed implant in treating CUR from nonobstructive retention. They concluded that sacral neuromodulation with implanted devices is effective in treating nonobstructive CUR.

Two small RCTs also studied efficacy and comparative effectiveness of CUR interventions in women with mixed or other causes of urinary retention (Table 5). One study of 19 women with obstructed voiding or retention associated with Fowler’s syndrome found insufficient evidence about the efficacy of sildenafil on rates of UTI when used for treating CUR. The study reported no significant difference in adverse effects.<sup>9</sup> The other RCT evaluated intermittent versus indwelling catheterization among elderly women with CUR admitted to a geriatric rehabilitation ward. This study provided insufficient information to draw conclusions about the rates of UTI with intermittent versus indwelling catheterization, but provided low-strength evidence that there was no difference between the proportion of patients able to go without catheter after intermittent or indwelling catheter treatment.

### Harms

Adverse effects were measured differently in each RCT. These events were rare, and results did not differ between treatment groups though studies were not adequately powered to detect these.

**Table 4. Description and conclusions from previous systematic reviews treatments for chronic urinary retention in other populations**

Study Information	Literature Through; SR Quality	Population; Relevant Comparison	Results; Conclusion Strength of Evidence
Moore 2009 <sup>21</sup> (Cochrane Incontinence Group)  Long-term bladder management by intermittent catheterization in adults and children	Literature search through June 2007  Good	Adults and children with incomplete bladder emptying  Sterile technique/clean technique (3 trials; only one with only CUR population)	No significant difference in rates of UTI between groups  Insufficient
Herbison 2009 <sup>20</sup> (Cochrane Incontinence Group) Sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults	Literature search through February, 2009  Good	Women with Fowler's syndrome.  Immediate/delayed implant (1 trial with CUR patients)	Catheter free: Implant>Delay PVR: Implant>Delay  Strength of evidence – not reported; Author's conclude 'Continuous stimulation offers benefits for urinary retention without obstruction.'

PVR = post void residual; SR=systematic review; UTI = urinary tract infection

**Table 5. Summary outcomes, adverse events, and strength of evidence of treatments for chronic urinary retention in other populations**

Study (n); Comparison; Inclusion Criteria; Design	Outcomes	Result	Strength of Evidence
Datta 2007 <sup>9</sup> (n=19)  Sildenafil vs. Placebo  Women with obstructed voiding or retention associated with Fowler's Syndrome  RCT	<b>Primary outcomes</b> Urinary tract infection  <b>Adverse effects</b> Death Clinical deterioration (Total not reported)	NS  NS	Insufficient (moderate risk of bias, imprecise, unclear consistency)  NA
Tang 2006 <sup>10</sup> (n=81)  Intermittent urinary catheterization vs. indwelling urinary catheterization  Elderly women admitted to a female geriatric rehabilitation ward. Patients with a PVR >150 ml were regarded as having urinary retention. If PVR remained ≥300 ml, the subjects were then randomized  RCT	<b>Primary outcomes</b> Urinary tract infection  TWOC  <b>Adverse effects</b> Total adverse effects	NS  NS RR 0.86 [95% CI 0.59 to 1.25]  NS	Insufficient (moderate risk of bias, imprecise, unclear consistency) Low (moderate risk of bias, unclear consistency)  NA

CI = confidence interval; NA = not assessed; NR = not reported; NS = no statistically significant difference; PVR = post void residual; RCT = randomized controlled trial; RR = risk ratio; TWOC = trial without catheter

\* Mean difference could not be calculated

## Discussion

Overall, few studies enrolled patients specifically because they had CUR. Those that did enrolled mostly adults with CUR as well as a contributing condition such as BPH or neurologic disorders. Eligible studies were generally small and had moderate risk of bias. Because treatment options depend on etiology, we analyzed data from eligible studies by etiology category. Many possible etiologies were not studied. In those that were, in most cases evidence was insufficient to draw conclusions about efficacy and comparative effectiveness of various interventions.

Only three studies examined the treatment of patients with CUR due to obstructive causes. The population addressed in all three RCTs is men with CUR who have lower urinary tract symptoms believed to be due to BPH.

- Low-strength evidence demonstrated no difference between TURP and microwave therapy in rates of UTI and TWOC.
- Low-strength evidence demonstrated that patients undergoing TURP experienced fewer treatment failures and were more likely to report a “good” level of symptoms than those undergoing laser therapy.

We found no data to assess the impact of treating CUR independent of treating BPH and other lower urinary tract symptoms. The objective in the studies we analyzed was to compare the effectiveness of BPH treatments when BPH is complicated by CUR. The two included RCTs that measured PVR provided insufficient evidence that one treatment was superior to the other in terms of reducing PVR. However, low-strength evidence showed that TURP was superior to laser for one primary outcome (adjusted IPSS category post-intervention). Both treatments reduced mean baseline PVR below the CUR diagnostic threshold used in the study. The clinical significance of this reduction in PVR is not known. Therefore, we could not determine the degree to which improvements in primary outcomes were attributable to PVR volumes no longer meeting CUR diagnostic criteria. Low-strength evidence from single studies suggests that TURP is not more effective than microwave therapy as measured by rate of urinary tract infection and time without catheter but may be more effective than laser therapy in terms of urinary symptoms; however other outcomes were not statistically different and there is an increased incidence of complications. However, treatment decisions would be better informed by additional research to strengthen this evidence and address the long-term outcomes weighed against potential adverse effects.

The second group of patients had CUR due to neurogenic bladder. This population is heterogeneous because the many neurogenic conditions that can lead to CUR are associated with a wide range of neurologic damage. We identified four studies that addressed treatments for CUR in these populations.

- Low-strength evidence suggested that botulinum injections do not decrease rates of UTI in multiple sclerosis patients with detrusor sphincter dyssynergia.

Neurogenic bladder is common; however we found sparse data for this analysis. Primarily, this was because most of the studies we screened did not specify the type of voiding dysfunction(s) (e.g., incontinence, CUR, etc.) within enrolled neurogenic bladder patients and were therefore ineligible for our review.

We identified two eligible effectiveness studies of CUR, not attributable to obstructive or neurologic.

- Evidence synthesized in a previous systematic review demonstrated that sacral neuromodulation is effective in reducing PVR urine and the need for catheterization for urinary retention not attributable to obstructive causes.

## **Applicability**

The applicability of our conclusions is good for patients with conditions similar to those examined. Participants in the studies reflected these populations well. Age and sex of subjects appear similar to that reported in population studies. Recruitment methods varied but were overall judged as likely to represent their respective populations.

## **Limitations**

This review suffers from several limitations. First, few studies were identified that specifically evaluated treatments for chronic urinary retention. Included studies evaluated treatments for the overarching condition, BPH or neurogenic bladder, which likely caused the urinary retention in subpopulations with chronic urinary retention. Treatments were similar to treatments in the broader population with these conditions. Additionally, some primary outcomes would likely change as a result of treating the overarching condition whether CUR was eliminated or not.

Of the studies identified, many suffered from methodological weaknesses and were underpowered.

## **Future Research Needs**

Our review provides low-strength evidence at best on a select few treatments for CUR attributed to a variety of underlying conditions. Research on this topic contains large gaps. Although several ongoing studies may, when completed, help close some of the gaps (Appendix J), additional research is also needed (specific recommendations appear in Appendix K).

Many population groups known to suffer from CUR were not addressed by controlled studies. These include individuals with other obstructive or anatomical causes such as strictures or prolapsed organs, those with neurologic disorders such as diabetes mellitus, diabetic neuropathy, and Parkinson's disease, and women with CUR arising as a complication from surgery for stress urinary incontinence. Additionally, treatments other than those examined in included studies are available and may alleviate CUR. Pharmaceutical interventions are commonly used in men with BPH and the evidence from those trials suggests that alpha-blockers help to reduce PVR volumes in men with BPH.<sup>22</sup> One study addressing this question is registered with ClinicalTrials.gov; however, results are not available.

## Conclusions

Standard clinical diagnostic criteria for CUR have not been established, and CUR is variably defined in research. Because CUR typically is caused by other medical conditions, treatment options differ based on the underlying problem. Of the many possible subgroups of CUR patients (based on underlying conditions), the evidence addresses just three (and only a subset of possible treatments). In men with symptomatic BPH, TURP is as effective as microwave therapy at reducing rates of UTI and increasing ability to go without catheterization and more effective than laser at improving symptoms and reducing rates of treatment failure (composite index), but only as effective as microwave therapy with respect to other outcomes (rates of UTI, necessity for surgical intervention). We could not determine what portion of the improvement in primary outcomes is attributable to treating CUR (above and beyond treatment for the underlying condition). Benefits of treatment likely result from improvements in lower urinary tract symptoms. In patients with neurogenic bladder, botulinum injections may not be effective. In Fowler's syndrome patients, sacral neuromodulation may be effective. We found no data on treatment of "asymptomatic" patients with CUR.

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## Abbreviations

AUR	Acute urinary retention
BPH	Benign prostate hyperplasia
CI	Confidence interval
CISC	Clean intermittent self-catheterization
CUR	Chronic urinary retention
DSD	Detrusor sphincter dyssynergia
IPSS	International Prostate Symptom Score
LUTS	Lower urinary tract symptoms
MD	Mean difference
MS	Multiple sclerosis
NA	Not assessed
NR	Not reported
NS	No statistical difference
PICOTS	Population, interventions, comparison, outcomes, timing, setting
PVR	Post void residual
QoL	Quality of life
RCT	Randomized controlled trial
RR	Risk ratio
SR	Systematic review
TURP	Transurethral resection of the prostate
TWOC	Trial without catheter
UTI	Urinary tract infection

# Appendix A. CUR Treatments

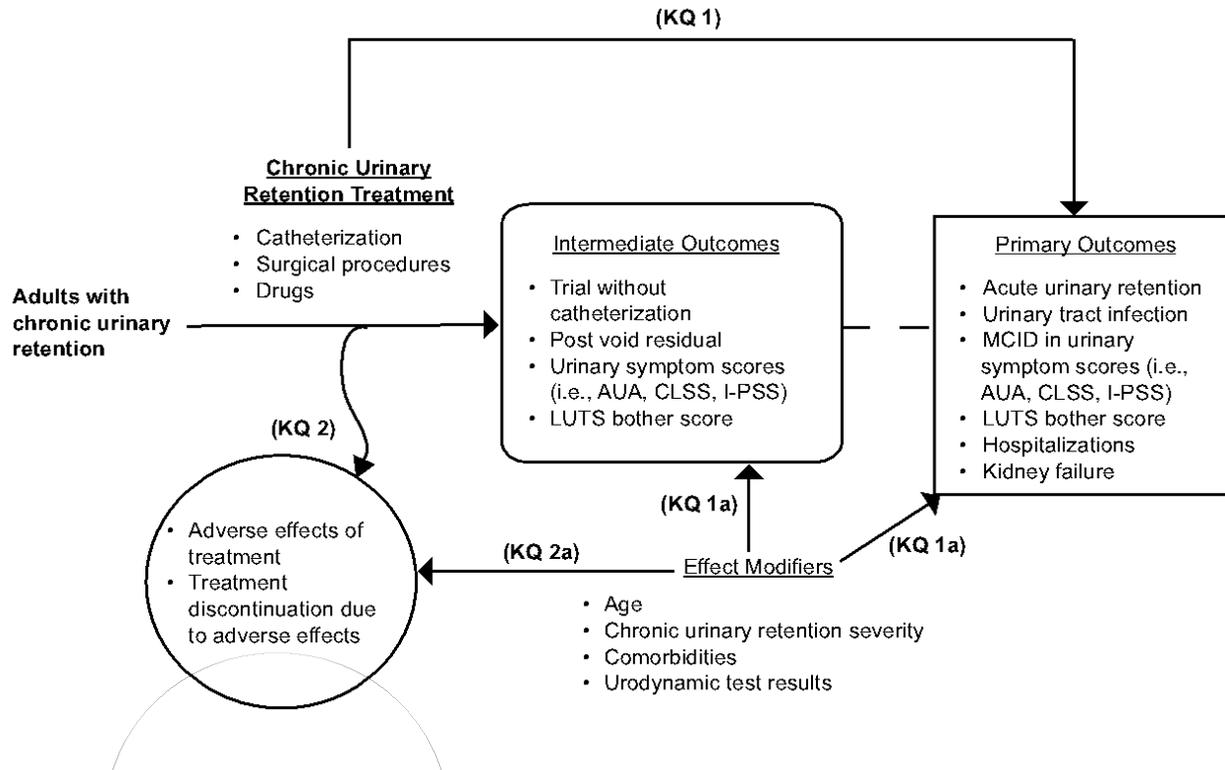
**Table A1. Treatments for chronic urinary retention**

<b>Intervention</b>	<b>Type or Class</b>
Catheterization	In-dwelling catheterization, intermittent catheterization (clean or sterile technique)
Surgical interventions (etiology-specific)	Male-specific etiologies: prostate surgeries Female-specific etiologies: pelvic organ prolapse repair, adjustment to stress urinary incontinence (SUI) procedures Nonsex-specific etiologies: sacral nerve stimulation, urethroplasty Multiple etiologies: urinary diversion procedures
Pharmacological interventions	Alpha blockers (AB) (doxazosin, prazosin, tamsulosin, terazosin, alfuzosin, silodosin); 5-Alpha Reductase Inhibitors (5-ARI): dutasteride, finasteride; AB + 5-ARI combination therapy: tamsulosin/dutasteride Neurogenic etiologies: botulinum toxin

AB = alpha blockers; SUI = stress urinary incontinence; 5-ARI = 5-alpha reductase inhibitors

# Appendix B. Analytical Framework

Figure B1. Analytical Framework



# Appendix C. Search Strategy

## MEDLINE

Database: Ovid MEDLINE(R) <1946 to November Week 3 2012> Search Strategy:

- 1 exp \*Urinary Retention/ (1930)
- 2 "urinary retention".ti,ab. (5318)
- 3 "voiding dysfunction".ti,ab. (1312)
- 4 "incomplete voiding".ti,ab. (50)
- 5 "voiding difficult\*".ti,ab. (423)
- 6 "underactive bladder".ti,ab. (27)
- 7 "incomplete bladder empt\*".ti,ab. (117)
- 8 "elevated post void residual".ti,ab. (13)
- 9 ischuria.ti,ab. (29)
- 10 or/1-9 (7624)
- 11 limit 10 to "all child (0 to 18 years)" (1408)
- 12 limit 11 to "all adult (19 plus years)" (560)
- 13 10 not 11 (6216)
- 14 12 or 13 (6776)
- 15 limit 14 to animals (370)
- 16 14 not 15 (6406)
- 17 Randomized Controlled Trials as Topic/ (84921)
- 18 randomized controlled trial/ (342334)
- 19 Random Allocation/ (76596)
- 20 Double Blind Method/ (118498)
- 21 Single Blind Method/ (17086)
- 22 clinical trial/ (476450)
- 23 clinical trial, phase i.pt. (12809)
- 24 clinical trial, phase ii.pt. (20505)
- 25 clinical trial, phase iii.pt. (7571)
- 26 clinical trial, phase iv.pt. (759)
- 27 controlled clinical trial.pt. (85694)
- 28 randomized controlled trial.pt. (342334)
- 29 multicenter study.pt. (153247)
- 30 clinical trial.pt. (476450)
- 31 exp Clinical Trials as topic/ (264416)
- 32 or/17-31 (949526)
- 33 (clinical adj trial\$.tw. (178736)
- 34 ((singl\$ or doubl\$ or treb\$ or tripl\$) adj (blind\$3 or mask\$3)).tw. (116076)
- 35 PLACEBOS/ (31583)
- 36 placebo\$.tw. (141131)
- 37 randomly allocated.tw. (14209)
- 38 (allocated adj2 random\$.tw. (16559)
- 39 33 or 34 or 35 or 36 or 37 or 38 (363492)
- 40 Epidemiologic studies/ (5579)
- 41 exp case control studies/ (586243)
- 42 exp cohort studies/ (1234174)
- 43 Case control.tw. (63924)
- 44 (cohort adj (study or studies)).tw. (65854)
- 45 Cohort analy\$.tw. (2895)
- 46 (Follow up adj (study or studies)).tw. (33920)
- 47 (observational adj (study or studies)).tw. (33241)
- 48 Longitudinal.tw. (115334)
- 49 Retrospective.tw. (223737)
- 50 Cross sectional.tw. (130903)

- 51 Cross-sectional studies/ (150828)
- 52 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 (1654583)
- 53 Meta-Analysis as Topic/ (12608)
- 54 meta analy\$.tw. (43811)
- 55 metaanaly\$.tw. (1130)
- 56 Meta-Analysis/ (37918)
- 57 (systematic adj (review\$1 or overview\$1)).tw. (35503)
- 58 exp Review Literature as Topic/ (6626)
- 59 or/53-58 (89518)
- 60 32 or 39 or 52 or 59 (2503667)
- 61 16 and 60 (2820)

Note: a search with similar concept terms was used for the Cochrane Central Register of Controlled Trials.

## Appendix D. Inclusion Criteria

**Table D1. Study inclusion criteria**

<b>Category</b>	<b>Criteria for Inclusion</b>
Study enrollment	Studies that enroll adults with CUR and test the effectiveness of treatments for CUR.
Study design	Meta-analyses, systematic reviews, RCTs, and nonrandomized controlled trials for each population and treatment option. Controlled before and after studies for KQs that cannot be answered using trial data alone.
Time of publication	Search all literature from 1946 forward.
Study quality	For all studies meeting inclusion criteria after title and abstract review, the full articles were screened for eligibility; studies of any risk of bias level were included.
Language of publication	Given that literature on this topic published in English best represents interventions available and accessible in the United States, we limited inclusion to studies with full text published in English. However, we did not limit our search based on language so that potential language bias could be assessed.

CUR = chronic urinary retention; KQ = key question; RCT = randomized controlled trial

# Appendix E. Excluded Studies

## Original Research Excluded

Yi WM, Pan AZ, Li JJ, et al. Clinical observation on the acupuncture treatment in patients with urinary retention after radical hysterectomy. *Chinese Journal of Integrative Medicine*. 2011 Nov;17(11):860-3. PMID 21809126. *Not CUR population*

Hakvoort RA, Thijs SD, Bouwmeester FW, et al. Comparing clean intermittent catheterisation and transurethral indwelling catheterisation for incomplete voiding after vaginal prolapse surgery: a multicentre randomised trial. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2011 Aug;118(9):1055-60. PMID 21481147. *Not CUR population*

Chartier-Kastler E, Lauge I, Ruffion A, et al. Safety of a new compact catheter for men with neurogenic bladder dysfunction: a randomised, crossover and open-labelled study. *Spinal Cord*. 2011 Jul;49(7):844-50. PMID 21339763. *Not CUR population*

Autorino R, Damiano R, Di Lorenzo G, et al. Four-year outcome of a prospective randomised trial comparing bipolar plasmakinetic and monopolar transurethral resection of the prostate. *European Urology*. 2009 Apr;55(4):922-9. PMID 19185975. *Not CUR population*

Bjerkklund Johansen T, Hultling C, Madersbacher H, et al. A novel product for intermittent catheterisation: its impact on compliance with daily life--international multicentre study. *European Urology*. 2007 Jul;52(1):213-20. PMID 17166653. *Not eligible study design*

Yamanishi T, Yasuda K, Kamai T, et al. Combination of a cholinergic drug and an alpha-blocker is more effective than monotherapy for the treatment of voiding difficulty in patients with underactive detrusor. *International Journal of Urology*. 2004 Feb;11(2):88-96. PMID 14706012. *Not CUR population*

McNeill SA, Hargreave TB, Geffriaud-Ricouard C, et al. Postvoid residual urine in patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia: pooled analysis of eleven controlled studies with alfuzosin. *Urology*. 2001 Mar;57(3):459-65. PMID 11248620. *Not CUR population*

Bernier F, Davila GW. The treatment of nonobstructive urinary retention with high-frequency transvaginal electrical stimulation. *Urologic Nursing*. 2000 Aug;20(4):261-4. PMID 11998089. *Not eligible study design*

Lukkarinen O, Hellstrom P, Leppilahti M, et al. Antibiotic prophylaxis in patients with urinary retention undergoing transurethral prostatectomy. *Annales Chirurgiae et Gynaecologiae*. 1997;86(3):239-42. PMID 9435936. *Not a treatment for CUR*

Belzner S. [Eucalyptus oil dressings in urinary retention]. *Pflege Aktuell*. 1997 Jun;51(6):386-7. PMID 9287850. *Not available in English*

Mompo Sanchis JA, Paya Navarro JJ, Prosper Rovira F. [Transurethral thermotherapy with microwaves in patients with benign prostatic hypertrophy and urinary retention: comparative study between high energy (25) and standard energy (2.0)]. *Archivos Espanoles de Urologia*. 1996 May;49(4):337-46. PMID 8754190. *Not available in English*

King RB, Carlson CE, Mervine J, et al. Clean and sterile intermittent catheterization methods in hospitalized patients with spinal cord injury. *Archives of Physical Medicine & Rehabilitation*. 1992 Sep;73(9):798-802. PMID 1514886. *Not CUR population*

Abrams PH, Shah PJ, Gaches CG, et al. Role of suprapubic catheterization in retention of urine. *Journal of the Royal Society of Medicine*. 1980 Dec;73(12):845-8. PMID 7005439. *Not CUR population*

## Systematic Reviews Excluded

Barendrecht MM, Oelke M, Laguna MP, et al. Is the use of parasympathomimetics for treating an underactive urinary bladder evidence-based? *BJU International*. 2007 Apr;99(4):749-52. PMID 17233798. *Not Relevant*

Chartier-Kastler E, Denys P. Intermittent catheterization with hydrophilic catheters as a treatment of chronic neurogenic urinary retention. *Neurourology & Urodynamics*. 2011 Jan;30(1):21-31. PMID 20928913. *Not SR*

Getliffe K, Fader M, Allen C, et al. Current evidence on intermittent catheterization: sterile single-use catheters or clean reused catheters and the incidence of UTI. *Journal of Wound, Ostomy, & Continence Nursing*. 2007 May-Jun;34(3):289-96. PMID 17505249. *Not Relevant*

Hagen S, Stark D. Conservative prevention and management of pelvic organ prolapse in women. John Wiley & Sons, Ltd. 2011. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003882.pub4/abstract>. *Not Relevant*

Jahn P, Beutner K, Langer G. Types of indwelling urinary catheters for long-term bladder drainage in adults. John Wiley & Sons, Ltd; 2012. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004997.pub3/abstract>. *Not Relevant*

Jamison J, Maguire S, McCann J. Catheter policies for management of long term voiding problems in adults with neurogenic bladder disorders. John Wiley & Sons, Ltd; 2011. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004375.pub3/abstract>. *Not Relevant*

Lefevre F, Civic D, Aronson N, et al. Percutaneous tibial nerve stimulation for the treatment of voiding dysfunction. Technology Evaluation Center Assessment Program. 2011 Mar;25(8):1-7. PMID 21638944. *Not Relevant*

Mehta S, Hill D, Foley N, et al. A meta-analysis of botulinum toxin sphincteric injections in the treatment of incomplete voiding after spinal cord injury. *Archives of Physical Medicine & Rehabilitation*. 2012 Apr;93(4):597-603. PMID 22365478. *Not Relevant*

Moore Katherine N, Fader M, Getliffe K. Long-term bladder management by intermittent catheterisation in adults and children. John Wiley & Sons, Ltd; 2007. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006008.pub2/abstract>. *Not Relevant*

Moore KN, Burt J, Voaklander DC. Intermittent catheterization in the rehabilitation setting: a comparison of clean and sterile technique. *Clinical rehabilitation*. 2006;20(6):461-8. *Not Relevant*

Utomo E, Blok B. Surgical management of functional bladder outlet obstruction in adults with neurogenic bladder dysfunction. John Wiley & Sons, Ltd; 2011. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004927.pub3/abstract>. *Not Relevant*

## Appendix F. Description and Characteristics of Included Studies

**Table F1. Characteristics of included studies**

Author, Year, Funding, Design	Inclusion/Exclusion Criteria	Patient Characteristics	CUR Characteristics	CUR Urodynamics/ Severity (Expressed in means unless noted)	Risk of Bias
Datta, 2007 <sup>1</sup> UK Grant RCT N=20	Inclusion criteria: women aged 18-65 year suffering with complete or partial retention or obstructive voiding. Exclusion criteria: major hematologic, renal, or hepatic impairment and major psychiatric disorders not well controlled by treatment; significant cardiovascular disease and a history of stroke or myocardial infarction in the previous 6 months; resting blood pressure over 90/50mmHg and 180/110 mmHg; known history of retinitis pigmentosa; uses of nitrates or NO donors	Age, mean: 39 Gender: women 100% Race: NR Comorbidities: NR  Intervention: sildenafil citrate  Control: placebo	Definition/etiology max flow rate <15ml/min, max urethral closure pressure 92-age cmH <sub>2</sub> O, sphincter volume >1.6 cm <sup>3</sup> Fowler's syndrome  Concurrent treatment: NR  Previous treatments: NR	PVRU (ml): 140 IPSS: 21.5 MUCP (cmH <sub>2</sub> O): 106.6 Sphincter volume (cm <sup>3</sup> ): 2.1 Detrusor pressure at qmax (cmH <sub>2</sub> O): 35.2 Voiding time (sec): 90.5	Overall risk of bias: medium
Schelin, 2006 <sup>2</sup> Sweden, Denmark, and Norway Not reported RCT N=120	Inclusion criteria: patients ≥45 years, with symptomatic BPH and persistent urinary retention requiring an indwelling catheter or clean intermittent catheterization for at least 1 month before screening. Prostate size was >30 cm <sup>3</sup> and at least 35 mm in length as measured by TRUS. Exclusion criteria: Patients who were medically and/or psychologically unable to tolerate surgery	Intervention: ProstaLund feedback treatment n=61 Age, mean: 73 Gender: men 100% Race: NR Comorbidities: NR  Control: TURP or prostate enucleation surgery n=59 Age, mean: 73 Gender: men 100% Race: NR Comorbidities: NR	Definition/etiology: PVRU ≥300 ml BPH  Concurrent treatment: NR  Previous treatments: NR	Intervention: PLFT Indwelling catheter: 87% Catheterization  Control: TURP and prostate enucleation surgery Indwelling catheter: 86% Catheterization	Overall risk of bias: medium
Tang, 2006 <sup>3</sup> Hong Kong, China Not reported RCT N=81	Inclusion criteria: female patients ≥65 years of age admitted to a female geriatric rehabilitation ward with PVRU over ≥300 ml on two occasions Exclusion criteria: terminally ill or those who required an indwelling urinary catheter for	Intervention: intermittent urinary catheterization n=36 Age, mean: 80 Gender: women 100% Race: NR	Definition/etiology PVRU persistently ≥300 ml  Concurrent treatment: diuretics: 25%	Intervention: PVRU (ml): 545.9 Past history of urinary retention: 6% Control: PVRU (ml): 539.8	Overall risk of bias: medium

Author, Year, Funding, Design	Inclusion/Exclusion Criteria	Patient Characteristics	CUR Characteristics	CUR Urodynamics/ Severity (Expressed in means unless noted)	Risk of Bias
	urine output monitoring.	<p>Mean Barthel index (baseline disability) (out of 20): 7.8 Comorbidities: NR</p> <p>Control: indwelling urinary catheterization n=45 Age, mean: 81 Gender: women 100% Race: NR Mean Barthel index (baseline disability) (out of 20): 6.2 Comorbidities: NR</p>	<p>calcium channel blockers: 11% anticholinergic agents: 19% alpha-blockers: 3% distigmine bromide: 0%</p> <p>Previous treatments: NR</p>	Past history of urinary retention: 0%	
<p>Gallien, 2005<sup>4</sup> France Not for profit organizations RCT N=86</p>	<p>Inclusion criteria: Patients &gt;18 years of age and suffering from MS with DSD. The diagnosis of MS had to have been made according to Poser criteria at least 6 months before inclusion</p> <p>Exclusion criteria: Urine or prostate febrile infection, perineal skin disorders, or myasthenia, or if they took any treatment which could have altered neuromuscular transmission. Pregnant women or non-menopausal women who did not take effective contraception were also excluded.</p>	<p>Intervention: botulinum A toxin n=45 Age, mean: 50 Gender: men 38% Race: NR Expanded disability status scale: 5.4 Comorbidities: NR Time from onset of urinary disorders (months): 98 Incontinence: 78% Control: placebo n=41 Age, mean: 51 Gender: men 27% Race: NR Expanded disability status scale: 6.0 Comorbidities: NR Time from onset of urinary disorders (months): 111 Incontinence: 83%</p>	<p>Definition/etiology: Patients with CUR were included if they had PVRU between 100 and 500 ml.</p> <p>Concurrent treatment: Patients were prescribed an alpha blocker (5 mg tablet of slow release alfuzosin bid) over 4 months.</p> <p>Previous treatments: Alpha blocker use before inclusion: 56%</p>	<p>Intervention: botulinum A toxin PVRU (ml): 220 Peak urine flow (ml/s): 13 IPSS: 21 Voiding volume (ml): 135 Blaivas's classification of DSD: Type 2: 40% Type 3: 44%</p> <p>Control: placebo PVRU (ml): 217 Peak urine flow (ml/s): 16 IPSS: 20 Voiding volume (ml): 166 Blaivas's classification of DSD: Type 2: 34% Type 3: 44%</p>	Overall risk of bias: medium

Author, Year, Funding, Design	Inclusion/Exclusion Criteria	Patient Characteristics	CUR Characteristics	CUR Urodynamics/ Severity (Expressed in means unless noted)	Risk of Bias
Ghalayini, 2005 <sup>5</sup> Jordan Not reported RCT N=41	<p>Inclusion criteria: men with LUTS and an IPSS of &gt;7, together with CUR, defined as a PVRU of &gt;300 ml measured by ultrasonography on two occasions, with patients and physicians agreeing that the findings justified intervention.</p> <p>Exclusion criteria: clinical evidence of prostate cancer, infection, previous prostatic surgery, uncontrolled renal impairment, a life-expectancy of &lt;6 months, proven neurological bladder dysfunction, or inability to practice CISC.</p>	<p>Intervention: transurethral resection of the prostate (TURP) n=17 Age, mean: 67 Gender: men 100% Race: NR Comorbidities: NR</p> <p>Control: Clean intermittent self-catheterization (CISC) n=24 Age, mean: 69 Gender: men 100% Race: NR Comorbidities: NR</p>	<p>Definition/etiology: PVRU of &gt;300 ml Concurrent treatment: All had a 4-6-week period of indwelling catheterization to stabilize renal function before starting the allocated management</p> <p>Previous treatments: NR</p>	<p>Intervention: IPSS: 25.8 IPSS QoL: 4.4 PVR (ml): 954</p> <p>Control: IPSS: 23.2 IPSS QoL: 4.2 PVRU (ml): 963</p>	Overall risk of bias: medium
Chen, 2004 <sup>6</sup> Taiwan, China Grant Prospective study	<p>Inclusion criteria: Patients with chronic cerebrovascular accidents or intracranial lesions were enrolled. All patients had symptoms of severe difficulty in initiation of urination or urinary retention.</p> <p>Exclusion criteria: NR</p>	<p>N=21</p> <p>Intervention: botulinum A toxin n=11 Age, mean: 67 Gender: men 45% Race: NR Comorbidities: Stroke: 73% Intracranial hemorrhage: 18% Meningitis: 9% Detrusor hyperreflexia: 91% Detrusor underactivity: 9% Urethral sphincter pseudodyssynergia: 100%</p> <p>Control: usual care n=10 Age, mean: 65</p>	<p>Definition/etiology: NR Concurrent treatment: NR Previous treatments: Medications such as <math>\alpha</math>-blockers, skeletal muscle relaxants, or nitric oxide donors without remarkable effect.</p>	<p>Intervention: PVRU (ml): 126 IPSS: 27.3 QoL: 4.7</p> <p>Control: PVRU (ml): NR IPSS: 22.5 QoL: 4.3</p>	Overall risk of bias: medium

Author, Year, Funding, Design	Inclusion/Exclusion Criteria	Patient Characteristics	CUR Characteristics	CUR Urodynamics/ Severity (Expressed in means unless noted)	Risk of Bias
		Gender: men 70% Race: NR Comorbidities: Stroke: 100% Detrusor hyperreflexia: 80% Detrusor underactivity: 20%			
Hindley 2004 <sup>7</sup> UK Not reported RCT N=19	<u>Inclusion criteria:</u> Patients with suspected detrusor underactivity.  <u>Exclusion criteria:</u> Asthma, hyperthyroidism, severe bradycardia, hypotension, recent myocardial infarction, bowel obstruction, active peptic ulcer disease, epilepsy, parkinsonism and evidence of serious concomitant psychiatric disease. Patients who were categorized as obstructed on the nomogram were also excluded from the study (all patients had an Abrams-Griffiths number of <40).	<u>Intervention:</u> bethanechol chloride (BC) plus prostaglandin E2 (PGE2) n=9 Age, mean: 67 Gender: men 89% Race: NR Comorbidities: bladder neck incision: 22% TURP: 33% interstitial radiofrequency therapy to the prostate: 11% chronic retention: 11%  <u>Control:</u> placebo n=10 Age, mean: 64 Gender: men 90% Race: NR Comorbidities: Bladder neck incision: 10% TURP: 30% Chronic retention: 40%	<u>Definition/etiology:</u> PVRU consistently >300ml in the absence of BOO.  <u>Concurrent treatment:</u> NR  <u>Previous treatments:</u> NR	<u>Intervention:</u> Frequency of CISC/day: 2.22 CISC volume drained (ml): 381.25 PVRU (ml), median: 426  <u>Control:</u> Frequency of CISC/day: 2.70 CISC volume drained (ml): 505 PVRU (ml), median: 575.5	Overall risk of bias: medium
de Sèze, 2002 <sup>8</sup> France The Coloplast Foundation for quality of life RCT	<u>Inclusion criteria:</u> presence of DSD in patients affected by upper motor neuron type bladder dysfunction due to medical (MS, myelitis) or traumatic spinal disease which was neurologically stable (i.e., no progression in neurological symptoms in the previous 3	<u>Intervention:</u> botulinum A toxin n=5 Age, mean: 41 Gender: men 80% Race: NR	<u>Definition/etiology:</u> PVRU >100 ml  <u>Concurrent treatment:</u> No concurrent treatments	<u>Intervention:</u> PVRU (ml): 264.4 MUP (cmH <sub>2</sub> O): 109.4 Blaivas's classification of DSD: Type 3: 40%	Overall risk of bias: medium

Author, Year, Funding, Design	Inclusion/Exclusion Criteria	Patient Characteristics	CUR Characteristics	CUR Urodynamics/ Severity (Expressed in means unless noted)	Risk of Bias
N=13	months).  Exclusion criteria: pregnancy, blood coagulation, abnormalities, inflammation or infection of the injection site, myasthenia, aminoglycoside treatment, hypersensitivity to botulinum toxin or lidocaine, lidocaine contraindications and lower motor neuron perineal lesion.	Comorbidities: Spinal cord injury: 80% MS: 20%  Control: lidocaine n=8 Age, mean: 49 Gender: men 100% Race: NR Comorbidities: Spinal cord injury: 63% MS: 25% Dural fistulization: 12.5%	Previous treatments: NR	Type 2: 40% Type 1: 20% DP (cmH <sub>2</sub> O): 74.2  Control: PRUV (ml): 313.1 MUP (cmH <sub>2</sub> O): 83.2 Blaivas's classification of DSD: Type 3: 38% Type 2: 62% DP (cmH <sub>2</sub> O): 88.6	
Gujral, 2000 <sup>9</sup> UK Government (NHS) RCT N=82	Inclusion criteria: LUTS with an IPSS) ≥8 indicating moderate to severe symptoms. Patients had a urinary flow rate of <15, <13, <10 ml/s when voided volume was >200, between 150 and 200, and between 100 and 149 ml, as measured on at least 2 occasions.  Exclusion criteria: Clinically diagnosed prostate cancer, previous prostatic surgery, life expectancy <6 months, neuropathic bladder dysfunction, serum creatinine >250 mmol, abnormal upper tracts on renal tract ultrasonography or a prostate volume >120 cc, men on long-term active medication for the lower urinary tract.	Intervention: Transurethral prostatic resection n=44 Age, mean:71 Gender: men 100% Race: white 100% Comorbidities: NR  Control: Laser therapy n=38 Age, mean: 70 Gender: men 100% Race: white 100% Comorbidities: NR	Definition/etiology: PVRU >300 ml BPH Concurrent treatment: NR  Previous treatments: NR	Intervention: PVRU (ml): 545 IPSS: 19.5 IPSS quality of life score, median: 4.5 Peak urine flow (ml/s): 8.5 Control: Laser therapy PVRU (ml): 438 IPSS: 20.9 IPSS quality of life score, median: 5.0 Peak urine flow (ml/s): 11.2	Overall risk of bias: medium

BOO = bladder outflow obstruction; BPH = benign prostatic hyperplasia; BPO = benign prostatic obstruction; CISC = clean intermittent self-catheterization; CUR = chronic urinary retention; DP = detrusor pressure; DSD = detrusor sphincter dyssynergia; IPSS = International Prostate Symptom Score; LUTS = lower urinary tract symptoms; MS = multiple sclerosis; MUCP = maximal urethral closure pressure; MUP = maximal urethral pressure; NR = not reported; PLFT = ProstaLund Feedback Treatment; PVRU = post-voiding residual urine volume; TURP = transurethral resection of the prostate; UTI = urinary tract infection

## References for Appendix F

1. Datta SN, Kavia RB, Gonzales G, et al. Results of double-blind placebo-controlled crossover study of sildenafil citrate (Viagra) in women suffering from obstructed voiding or retention associated with the primary disorder of sphincter relaxation (Fowler's Syndrome). *European Urology*. 2007 Feb;51(2):489-95; discussion 95-7. PMID 16884844.
2. Schelin S, Geertsen U, Walter S, et al. Feedback microwave thermotherapy versus TURP/prostate enucleation surgery in patients with benign prostatic hyperplasia and persistent urinary retention: a prospective, randomized, controlled, multicenter study. *Urology*. 2006 Oct;68(4):795-9. PMID 17070355.
3. Tang MW, Kwok TC, Hui E, et al. Intermittent versus indwelling urinary catheterization in older female patients. *Maturitas*. 2006 Feb 20;53(3):274-81. PMID 16084677.
4. Gallien P, Reymann JM, Amarenco G, et al. Placebo controlled, randomised, double blind study of the effects of botulinum A toxin on detrusor sphincter dyssynergia in multiple sclerosis patients. *Journal of Neurology, Neurosurgery & Psychiatry*. 2005 Dec;76(12):1670-6. PMID 16291892.
5. Ghalayini IF, Al-Ghazo MA, Pickard RS. A prospective randomized trial comparing transurethral prostatic resection and clean intermittent self-catheterization in men with chronic urinary retention. *BJU International*. 2005 Jul;96(1):93-7. PMID 15963128.
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9. Gujral S, Abrams P, Donovan JL, et al. A prospective randomized trial comparing transurethral resection of the prostate and laser therapy in men with chronic urinary retention: The CLasP study. *Journal of Urology*. 2000 Jul;164(1):59-64. PMID 10840425.

## Appendix G. Risk of Bias and Quality

**Table G1. Risk of bias of included original research**

Study	Outcome	Risk of Selection bias Due to Inadequate Randomization	Risk of Selection Bias Due to Inadequate Allocation	Risk of Performance Bias Due to Inadequate Blinding of Provider and Patient	Risk of Detection Bias Due to Inadequate Blinding	Risk of Attrition Bias	Risk of Reporting Bias Due to Selective Outcome Reporting	Intent to Treat	Groups Similar at Baseline	Other Risks of Bias	Overall Risk of Bias per Study-Outcome
<b>RCTs</b>											
Datta 2007 <sup>1</sup>	UTI	Unclear	Unclear	Low	Unclear	Low	Low	Yes	Yes	No	Moderate
	IPSS	Unclear	Unclear	Low	Unclear	Low	Low	Yes	Yes	No	Moderate
	PVR	Unclear	Unclear	Low	Unclear	Low	Low	Yes	Yes	No	Moderate
Schelin 2006 <sup>2</sup>	UTI	Unclear	High	High	Unclear	Low	Low	Unclear	Yes	No	Moderate
	Cath Free	Unclear	High	High	Unclear	Low	Low	Unclear	Yes	No	Moderate
	IPSS	Unclear	High	High	Unclear	Low	Low	Unclear	Yes	No	Moderate
	IPSS QoL	Unclear	High	High	Unclear	Low	Low	Unclear	Yes	No	Moderate
Tang 2006 <sup>3</sup>	UTI	Low	Unclear	High	High	Low	Low	Yes	Yes	No	Moderate
	TWOC	Low	Unclear	High	High	Low	Low	Yes	Yes	No	Moderate
	PVR	Low	Unclear	High	High	Low	Low	Yes	Yes	No	Moderate
Gallien 2005 <sup>4</sup>	UTI	Low	Low	Low	Unclear	Low	Low	Yes	Yes	Yes	Moderate
	IPSS	Low	Low	Low	Unclear	Low	Low	Yes	Yes	Yes	Moderate
	PVR	Low	Low	Low	Unclear	Low	Low	Yes	Yes	Yes	Moderate
Ghalayini 2005 <sup>5</sup>	IPSS	High	Unclear	High	High	Low	Low	Yes	No	No	Moderate
	PVR	High	Unclear	High	High	Low	Low	Yes	No	No	Moderate
Hindley 2004 <sup>6</sup>	QoL	High	Unclear	Low	Unclear	Low	Low	Yes	No	No	High
	PVR	High	Unclear	Low	Unclear	Low	Low	Yes	No	No	Moderate
de Sèze 2002 <sup>7</sup>	PVR	Low	Unclear	Low	Unclear	Low	Low	Yes	Yes	No	Moderate
Gujral 2000 <sup>8</sup>	UTI	High	Low	High	Unclear	Low	Low	Yes	No	Yes	High
	IPSS Category, adjusted	High	Low	High	Unclear	Low	Low	Yes	No	No	Moderate
	PVR, adjusted	High	Low	High	Unclear	Low	Low	Yes	No	No	Moderate
<b>Observational</b>											
Chen 2004 <sup>9</sup>	IPSS	High	NA	NA	NA	NA	Low	Low	Unclear	Yes <sup>1</sup>	High
	IPSS QoL	High	NA	NA	NA	NA	Low	Low	Unclear	Yes <sup>1</sup>	High
	PVR	High	NA	NA	NA	NA	Low	Low	Unclear	Yes <sup>1</sup>	High

<sup>1</sup>No adjustments for selection bias during analysis.

## References for Table G1

1. Datta SN, Kavia RB, Gonzales G, et al. Results of double-blind placebo-controlled crossover study of sildenafil citrate (Viagra) in women suffering from obstructed voiding or retention associated with the primary disorder of sphincter relaxation (Fowler's Syndrome). *European Urology*. 2007 Feb;51(2):489-95; discussion 95-7. PMID 16884844.
2. Schelin S, Geertsen U, Walter S, et al. Feedback microwave thermotherapy versus TURP/prostate enucleation surgery in patients with benign prostatic hyperplasia and persistent urinary retention: a prospective, randomized, controlled, multicenter study. *Urology*. 2006 Oct;68(4):795-9. PMID 17070355.
3. Tang MW, Kwok TC, Hui E, et al. Intermittent versus indwelling urinary catheterization in older female patients. *Maturitas*. 2006 Feb 20;53(3):274-81. PMID 16084677.
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5. Ghalayini IF, Al-Ghazo MA, Pickard RS. A prospective randomized trial comparing transurethral prostatic resection and clean intermittent self-catheterization in men with chronic urinary retention. *BJU International*. 2005 Jul;96(1):93-7. PMID 15963128.
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**Table G2. Quality of Previous Systematic Reviews**

Study	A priori Study Design	Dual Study Selection and Data Abstraction	Comprehensive literature search	Publication Status	Lists of Included and Excluded Studies Provided?	Scientific Quality of Included Studies Assessed and Documented?	Scientific Quality of Included Studies Used Appropriately in Formulating Conclusions?	Methods of Combining Studies Appropriate?	Likelihood of Publication Bias Assessed?	Conflict of Interest Stated?	Overall Quality
Moore 2007 <sup>1</sup>	yes	yes	yes	yes	yes	yes	yes	yes	Unclear	yes	good
Herbison 2009 <sup>2</sup>	yes	yes	yes	yes	yes	yes	yes	yes	Unclear	yes	good

## References for Table G2

1. Moore Katherine N, Fader M, Getliffe K. Long-term bladder management by intermittent catheterisation in adults and children. John Wiley & Sons, Ltd; 2007.  
<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006008.pub2/abstract>. Accessed on 4.
2. Herbison GP, Arnold EP. Sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults. Cochrane Database of Systematic Reviews. 2009(2):CD004202. PMID 19370596.

# Appendix H. Detailed Results

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## Men with BPH

Three eligible RCTs compared treatments for CUR in men with BPH.<sup>1-3</sup> Each of these studies included men with CUR (defined as persistent PVR >300ml) and other lower urinary tract symptoms. Study and patient characteristics appear in Table H1. The mean age of the 243 men enrolled in these studies was 71. Two studies reported mean baseline IPSS scores and PVR volumes with a mean baseline total IPSS score of 21.4 (severe symptoms) and mean baseline PVR volume of 626 ml. All three trials compared surgery (transurethral resection of the prostate or prostate enucleation) to a less invasive intervention (laser, microwave, clean intermittent sterile catheterization). Two of these trials were conducted in Europe and one in Asia. All three RCTs demonstrated methodological problems (limited ability for blinding and allocation concealment) and each was assessed to have an overall medium risk of bias.

## Primary Outcomes

Two of the three RCTs reported on five primary outcomes (UTI, treatment failure, trial without catheter [TWOC], need for surgical intervention, and IPSS category) (Table H2). The third RCT assessed only intermediate outcomes. We included IPSS category as a primary outcome because no study reported those achieving a minimum clinically important difference as the primary variable and the categorization better measures a clinical difference than changes in mean scores. Overall, the studies reported few differences in primary outcomes between groups, with both treatment groups typically showing improvements over baseline.

No studies reported AUR. Schelin et al. and Gujral et al. reported rates of UTI. More than 30 percent of the microwave therapy patients and 22 percent of the TURP patients experienced a UTI over the 6-month followup period.<sup>3</sup> UTI was recorded only as a postsurgical complication in the other study with nearly 5 percent of the TURP patients and nearly 3 percent of the laser therapy patients experiencing a postsurgical UTI.<sup>2</sup> Neither difference between treatment groups was statistically significant.

Gujral, et al. reported on surgical interventions. Three patients in the laser therapy group required TURP for continuing symptoms. None of the TURP patients needed to return to surgery; the difference was not statistically significant.<sup>2</sup> IPSS category was also measured in this study. Nearly 88 percent of the TURP patients and 69 percent of the laser therapy patients were in the good category after treatment. Once adjusted (groups differed at baseline in marital status and prostate volume), the proportional odds model indicated this difference was statistically significant favoring TURP (OR=3.9; CI: 1.0 to 14.3). Gujral, et al. also reported a composite variable called ‘treatment failure.’ A treatment failure was defined as being in the poor IPSS and maximum urinary flow categories. None of the TURP patients experienced treatment failure, but more than 20 percent of the laser therapy patients did. This difference was significant before adjustment, and effect was larger after adjustment (OR=3.0; CI: 1.1 to 8.2).<sup>2</sup>

## Intermediate Outcomes

Outcomes that we classified as intermediate were more frequently reported and authors may have considered them primary outcomes in their research (Table H3). Mean changes in IPSS scores were reported in two of the three trials. When TURP is compared to clean intermittent self-catheterization, the TURP patients mean IPSS score improved by 20 points whereas the catheter patients mean score improved by 12 points. This level of change would be considered clinically important; however, confidence intervals were too wide for the difference to be

statistically significant and included values that would not represent clinically meaningful change. Schelin, et al., report that after 3 months, the mean IPSS score in the microwave therapy group was 7.3 and 5.1 in the TURP/enucleation group<sup>3</sup>. At 6 months, these scores were 7.3 and 4.1, respectively.<sup>3</sup> This difference did not reach statistical significance nor are the values clinically important. However, the adjusted mean change for the TURP versus laser therapy group was significant after adjustment (adjusted mean difference = -3.6; CI: -7.2 to -0.1).<sup>2</sup> No other changes in intermediate outcomes (IPSS Quality of Life scores, PVR) were statistically significant for either comparison.

## **Harms**

Each study measured adverse effects differently, reporting either the incidence of serious adverse effects or complication rates (Table H4). These harms did not differ between groups in the surgery versus microwave therapy or in surgery versus clean intermittent self-catheterization. However, a larger proportion of the TURP group experienced complications than the laser group. Strength of evidence was not assessed for harms.

**Table H1. Treatment for chronic urinary retention in men with benign prostatic hyperplasia: summary of included studies**

Number of studies	3
Randomized controlled trials	3
Number of patients enrolled (range)	243 (41 to 120)
Age of subjects, mean years (range)	71 (68 to 73)
Gender (range)	Men 100%
Baseline mean IPSS total score (range) (range 0 to 35)*	21.4 (20.0 to 24.3; 2 studies†)
Baseline mean PVR, mL (range)	626 (459 to 959; 2 studies†)
Neurogenic disease etiology	NR
Neurogenic disease duration, mean years	NR
Trials conducted in the United States (% of patients)	None
Trials conducted in Europe (% of patients)	2 (83)
Trials conducted in Asia (% of patients)	1 (17)
Studies reporting primary outcomes	2
Studies reporting secondary outcomes	3

\* IPSS = International Prostate Symptom Score: Scoring criteria are: Mild (score 1-7); Moderate (score 8-19); Severe (score 20-35); NR = not reported; PVR=post-void residual

† Number of studies reporting this variable

**Table H2. Treatment for chronic urinary retention in men with benign prostatic hyperplasia: primary outcomes**

Study Design Followup	Treatment Arms	Acute Urinary Retention n/N (%)	Urinary Tract Infection n/N (%)	Surgical Intervention n/N (%)	IPSS* n/N (%)	Catheter Free n/N (%)
Schelin, 2006 <sup>3</sup> RCT 6 months	TUMT (n=61)	NR	20/61 (32.8)	NR	NR	48/61†† (78.7)
	TURP or enucleation (n=59)	NR	13/59 (22)	NR	NR	52/59†† (88.1)
	<i>RR [95% CI]</i>		1.49 [0.82 to 2.71]			0.89 [0.76 to 1.05]
Ghalanyini, 2005 <sup>1</sup> RCT 6 months	TURP (n=22)	NR	NR	NR	NR	NR
	CISC (n=29)	NR	NR	NR	NR	NR
	<i>RR [95% CI]</i>					
Gujral, 2000 RCT <sup>2</sup> 7.5 months	TURP (n=44)	NR	2/44 (4.5)	0/44	“good”† 29/33 (87.9)	NR
	Laser (n=38)	NR	1/38 (2.6)	3/38 (7.9)**	good† 20/29 (69.0)	NR
	<i>RR [95% CI]</i>		1.73 [0.16 to 18.31]	0.12 [0.01 to 2.32]	1.27 [0.97 to 1.68]	
	<i>Adjusted OR</i>		NR	NR	3.9 [1.0 to 14.3]	

CI = confidence interval; CISC = clean intermittent self-catheterization; IPSS = International Prostate Symptom Score (range 0 (mild symptoms) to 35 (severe symptoms)); NR – not reported; RCT = randomized controlled trial; RR=risk ratio; TUMT = transurethral microwave therapy; TURP = transurethral resection of the prostate

\* Subjects with clinically relevant improvement from baseline

\*\* These patients required a TURP following laser surgery due to “unacceptable levels of symptoms.”

† “Good” defined as postoperative score <8 or ≥50% reduction from baseline

†† All patients required catheterization at baseline

**Table H3. Treatment for chronic urinary retention in men with benign prostatic hyperplasia: intermediate outcomes**

Study; Design; Followup	Treatment Arms	IPSS, Mean (SD) at Baseline	IPSS, Mean (SD) Change from Baseline	IPSS QoL, Mean (SD) at Baseline	IPSS QoL, Mean Change (SD) from Baseline	PVRU (mL), Mean (SD) at Baseline	PVRU (mL), Mean (SD) Change from Baseline
Schelin, 2006 <sup>3</sup> RCT 6 months	TUMT (n=61)	NR	7.3** (7.3) (n=50)	~4.6† [3.2 to 5.9]	~1.5†† [0 to 3.0]	NR	NR
	TURP/enucleation surgery (n=59)	NR	4.4** (4.9) (n=49)	~4.7† [3.5 to 5.9]	~0.9†† [0 to 2.0]	NR	NR
		<i>Mean difference between groups [95% CI]</i>	2.90 [0.46 to 5.34]	<i>Mean difference between groups [95% CI]</i>	NR <sup>a</sup>		
Ghalanyini, 2005 <sup>1</sup> RCT 6 months	TURP (n=17)	25.8 (4.2)	-20.3 (8.9)	4.4 (0.9)	-3.0 (1.5)	954 (531)	-854.4 (437)
	CISC (n=24)	23.2 (6.1)	-12.3 (7.8)	4.2 (1.1)	-2.5 (1.4)	963 (503)	-600.5 (537)
		<i>Mean difference between groups [95% CI]</i>	-8.0 [-13.3 to 2.8]	<i>Mean difference between groups [95% CI]</i>	-0.5 [-1.4 to 0.4]	<i>Mean difference between groups [95% CI]</i>	-253.9 [-552.8 to 45.0]
Gujral, 2000 RCT <sup>2</sup> 7.5 months	TURP (n=44)	19.5 (7.2)	-14.2 (8.4) (n=33)	4.5 (2.6) median	-3.2 (1.8) (n=33)	545 (275)	-464 (280) (n=40)
	Laser (n=38)	20.9 (6.4)	-12.2 (9.2) (n=29)	5 (2.6) median	-2.8 (1.7) (n=30)	438 (151)	-329 (135) (n=33)
		<i>Mean difference between groups [95% CI]</i>	-2.0 [-6.4 to 2.4]	<i>Mean difference between groups [95% CI]</i>	-0.4 [-1.3 to 0.5]	<i>Mean difference between groups [95% CI]</i>	-135.0* [-233.2 to -36.8]
	<i>Adj. mean difference between groups [95% CI]</i>	-3.6 [-7.2 to 0.1]	<i>Adj. mean difference between groups [95% CI]</i>	-0.6 [-1.3 to 0.1]	<i>Adj. mean difference between groups [95% CI]</i>	-27.5 [-68.1 to 13]	

CI= confidence interval; CISC = clean intermittent self-catheterization; IPSS = International Prostate Symptom Score (range 0 [mild symptoms] to 35 [severe symptoms]); NR = not reported; PLFT = ProstaLund Feedback Treatment; PVRU: post-void residual urine volume; QoL = quality of life. IPSS QoL ranges from 1 (delighted) to 6 (terrible); RCT = randomized controlled trial; SD = standard deviation; TURP = transurethral resection of the prostate

<sup>a</sup> could not be calculated.

\* Analysis of covariance, adjusting for center effects and baseline measurements, found no statistically significant difference between groups. Difference in means at followup was -27.5 mL [-68.1 to 13.0].

\*\* Mean at endpoint

† Mean score at baseline (extracted from graph)

†† Mean at endpoint (extracted from graph)

**Table H4. Treatment for chronic urinary retention in men with benign prostatic hyperplasia: adverse events**

Study; Design; Followup	Treatment Arms	Death n/N (%)	Septicemia n/N (%)	Blood Transfusion n/N (%)	Major Bleeding n/N (%)	Complication Rate n/N (%)	Serious Adverse Events n/N (%)	Withdrawals
Schelin, 2006 <sup>3</sup> RCT 6 months	TUMT (n=61)	NR	NR	NR	NR	NR	1/61 (1.6)	2/61 (3.3)
	TURP/enucleation surgery (n=59)	NR	NR	NR	NR	NR	5/59 (8.5)	3/59 (5.1)
	<i>Risk ratio [95% CI]</i>						0.19 [0.02 to 1.61]	
Ghalanyini, 2005 <sup>1</sup> RCT 6 months	TURP (n=22)	NR	NR	NR	NR	2/17* (11.8)	NR	
	CISC (n=29)	NR	NR	NR	NR	8/24* (33.3)	NR	
	<i>Risk ratio [95% CI]</i>					0.35 [0.09 to 1.46]		
Gujral, 2000 RCT <sup>2</sup> 7.5 months	TURP (n=44)	1/44 (2.3)	3 incidences**	3 incidences**	6 incidences**	13/44 (29.5)	NR	
	Laser (n=38)	0/38 (0.0)	1/38 (2.6)	0/38	0/38	3/38 (7.9)	NR	
	<i>Risk ratio [95% CI]</i>	2.60 [0.11 to 62.01]				3.74 [1.15 to 12.15]		

CI = confidence interval; CISC = clean intermittent self-catheterization; IPSS = International Prostate Symptom Score (range 0 [mild symptoms] to 35 [severe symptoms]); NR = not reported; RCT = randomized controlled trial; TUMT = transurethral microwave therapy; TURP = transurethral resection of the prostate

\* Symptomatic infection (6), bleeding (2) or both (2)

\*\* Number of patients unclear

## Adults with Neurogenic Disorders

We identified four studies that compared treatments for CUR attributed to neurogenic disorders in adults. Summary statistics for these studies appear in Table H5. Three of these studies were RCTs with moderate risk of bias, and one was a controlled before-and-after design with a high risk of bias. All four studies were efficacy trials. Studies enrolled a total of 139 patients with sample sizes ranging from 13 to 86. The mean age of enrolled patients was 54 with a range from 46 to 66. Patient sex was fairly evenly distributed with 51 percent men and 49 percent women. Baseline mean IPSS scores were 21.4 across the two studies that measured IPSS, suggesting a severe level of symptoms. Neurogenic disorders among the patients included MS (64 percent), SCI (7 percent), and other (29 percent). Patients had been living with these neurogenic disorders for an average of 13 years in the three studies reporting. Trials were conducted in Europe and Asia. Three studies compared injections of botulinum A into the sphincter to an inactive control (placebo, lidocaine, usual care). The fourth study compared bethanechol/prostaglandin (BC/PGE2) to placebo.

### Primary Outcomes

Only one study reported a primary outcome (Table H6). Gallien, et al. report the rate of UTI at 6 month followup to be 35 percent in the botulinum patients and 29 percent in the placebo patients.<sup>4</sup> This difference was not statistically significant.

### Intermediate Outcomes

All four studies reported on at least one of our prespecified intermediate outcomes. (Table H7). Gallien reports IPSS scores at baseline and at 30 day followup for each treatment group. The mean IPSS score improved by three points in the botulinum group, but the placebo group improved by four points.<sup>4</sup> The difference was not significant. In another study of a similar comparison, the botulinum group improved their IPSS mean score by 13 points and the usual care group by only four points.<sup>5</sup> However, this study was not blinded and patients were allowed to select their treatments. Two studies reported quality of life using the IPSS quality of life scale. Hindley et al. found that the botulinum group improved by one point, but the placebo group remained unchanged.<sup>6</sup> Chen et al. found a significant improvement in the botulinum patients over and above the improvement in the usual care patients.<sup>5</sup> Gallien et al., Hindley et al., and de Seze et al. measured PVR at baseline and again at followup. Patients in Gallien et al. had PVRs at baseline of below 300 ml. Both groups showed minimal decreases with no significant difference between groups<sup>4</sup>. Hindley et al. found PVR decreases in both groups from fairly high baseline levels (over 500ml), but only the botulinum patients showed a significant reduction.<sup>6</sup> De Seze et al. also found a significantly greater change in mean PVR in the botulinum group.<sup>7</sup>

### Harms

Adverse effects were measured differently in each RCT (Table H8). Adverse effects were rare in all treatment arms. No differences between groups were reported; however, the small sample sizes were likely unable to detect differences in rare events. Strength of evidence was not assessed for harms.

**Table H5. Treatment for chronic urinary retention in adults with neurogenic disorders: summary of included studies**

Number of studies	4
Randomized controlled trials	3
Number of patients enrolled (range)	139 (13 to 86)
Age of subjects, mean years (range)	54 (46 to 66)
Gender (range)	Men 51% (35 to 92) Women 49% (8 to 65)
Baseline mean IPSS total score (range) (range 0 to 35)*	21.4 (20.5 to 25.0; 2 <i>studies</i> †)
Baseline mean PVRU, mL (range)	277 (219 to 530; 3 <i>studies</i> †)
Neurogenic disease etiology	Multiple sclerosis 64% Spinal cord injury 7% Other 29% (stroke, detrusor underactivity)
Neurogenic disease duration, mean years	12.8 (1.4 to 16.1; 3 <i>studies</i> †)
Trials conducted in the United States (% of patients)	None
Trials conducted in Europe (% of patients)	3 (85)
Trials conducted in Asia (% of patients)	1 (15)
Studies reporting primary outcomes	1
Studies reporting secondary outcomes	4

\* IPSS = International Prostate Symptom Score: Scoring criteria are: Mild (score 1-7); Moderate (score 8-19); Severe (score 20-35)

† Number of studies reporting this variable

**Table H6. Treatment for chronic urinary retention in adults with neurogenic disorders: primary outcomes**

<b>Study; Design; Followup</b>	<b>Treatment Arms</b>	<b>Acute Urinary Retention n/N (%)</b>	<b>Urinary Tract Infection n/N (%)</b>	<b>Catheter Outcomes n/N (%)</b>
Gallien 2005 <sup>4</sup> RCT 120 days	botulinum A (n=45)	NR	16/45 (35.6)	NR
	placebo (n=41)	NR	12/41 (29.3)	NR
	RR [95% CI]		1.21 [0.66 to 2.25]	
Hindley 2004 <sup>6</sup> RCT 6 weeks	BC/PGE2 (n=9)	NR	NR	NR
	placebo (n=10)	NR	NR	NR
	RR [95% CI]			
De Seze 2002 <sup>7</sup> RCT 30 days	botulinum A (n=5)	NR	NR	NR
	lidocaine (n=8)	NR	NR	NR
	RR [95% CI]			
Chen 2004 <sup>5</sup> Prospective study 6 months	botulinum A (n=11)	NR	NR	NR
	usual care (n=10)	NR	NR	NR
	RR [95% CI]			

BC/ PGE2 = bethanechol chloride/prostaglandin E2; CI = confidence interval; NR = not reported, RR=risk ratio

**Table H7. Treatment for chronic urinary retention in adults with neurogenic disorders: intermediate outcomes**

Study Design Followup	Treatment Arms	TWOC n/N (%)	IPSS, Mean (SD) Value	Quality of Life Measure	PVRU (mL), Mean (SD)
Gallien 2005 <sup>4</sup> RCT 30 days	botulinum A (n=43)	NR	Baseline 21 (7)	NR	Baseline 220 (99)
			Endpoint 18 (7)		Endpoint 186 (158)
	placebo (n=40)	NR	Baseline 20 (7)	NR	Baseline 217 (96)
			Endpoint 16 (7)		Endpoint 206 (145)
	<i>Between group comparison ([95% CI] if applicable)</i>		Mean difference at endpoint 2.00 [-1.01 to 5.01]		Mean difference at endpoint -20.00 [-85.19 to 45.19]
Hindley 2004 <sup>6</sup> RCT 6 weeks	BC/PGE2 (n=9)	-		Baseline* median (range) 4* (3 to 4.5)	Baseline median (range) 426 (405 to 480)
				Endpoint* median (range) 3* (2.5 to 3.5)	Endpoint median (range) 325 (290 to 1,252)
	placebo (n=10)			Baseline* median (range) 3.5* (2 to 4)	Baseline median (range) 575 (539 to 777)
				Endpoint* median (range) 3.5* (2.5 to 4)	Endpoint median (range) 537.5 (350 to 1,775)
		<i>between group comparison ([95% CI] if applicable)</i>		1 point improvement in active arm, unchanged in placebo arm	Significant improvement from baseline in active arm but not placebo arm
de Sèze 2002 <sup>7</sup> RCT 30 days	botulinum A (n=5)	NR	NR	NR	Baseline 264.4 (141.3)
					Endpoint 105.0 (100.6)
	lidocaine (n=8)	NR	NR	NR	Baseline 313.1 (138.1)
					Endpoint 263.3 (115.9)
	<i>Between group comparison ([95% CI] if applicable)</i>				Mean difference at endpoint -158.30 [-277.57 to -39.03]
Chen 2004 <sup>5</sup> Prospective study 6 months	botulinum A (n=11)	NR	Baseline 27.3 (12.1)	IPSS QoL, baseline 4.7 (1.5)	Baseline 125.5 (88.8)
			Mean change from baseline -13.6 (5.7)	Mean change from baseline 2.4 (1.1)	Endpoint 69.1 (61.4)
	usual care (n=10)	NR	Baseline 22.5 (11.7)	IPSS, baseline 4.3 (2.1)	NR

Study Design Followup	Treatment Arms	TWOC n/N (%)	IPSS, Mean (SD) Value	Quality of Life Measure	PVRU (mL), Mean (SD)
			Mean change from baseline - 4.1 (5.5)	Mean change from baseline 1.2 (1.0)	
	Between group comparison ([95% CI] if applicable)		Mean difference at endpoint -9.50 [-14.29 to -4.71]	Mean difference at endpoint -1.20 [-2.10 to -0.30]	

BC/ PGE2 = bethanechol chloride/prostaglandin E2; C I= confidence interval; CISC = clean intermittent self-catheterization; IPSS = International Prostate Symptom Score (range 0 [mild symptoms] to 35 [severe symptoms]); NR = not reported; PVR: post-void residual; RCT = randomized controlled trial; RR=risk ratio; SD = standard deviation

\* Quality of life scale and range not reported

**Table H8. Treatment for chronic urinary retention in adults with neurogenic disorders: adverse events**

Study; Design; Followup	Treatment Arms	Serious Adverse Effects n/N (%)	Urinary Leakage/Incontinence n/N (%)	Any Adverse Event n/N (%)
Gallien, 2005 <sup>4</sup> RCT 120 days	botulinum A (n=45)	3/45 (2.2)*	2/45 (4.4)	NR
	placebo (n=41)	3/41 (2.4)*	2/41 (4.9)	NR
	RR [95% CI]	0.91 [0.19 to 4.26]	0.91 [0.13 to 6.18]	
Hindley, 2004 <sup>6</sup> RCT 6 weeks	BC/PGE2 (n=9)	0/9 (0.0)	NR	3/9 (33.3)**
	placebo (n=10)	0/10 (0.0)	NR	0/10 (0.0)
	RR [95% CI]	-		7.70 [0.45 to 131.36]
De Seze 2002 <sup>7</sup> RCT 30 days	botulinum A (n=5)	0/5 (0.0) <sup>†</sup>	0/5 (20.0)	1/5 (0.0) <sup>†</sup>
	lidocaine (n=8)	0/8 (12.5) <sup>†</sup>	0/8 (0.0) <sup>†</sup>	1/8 (0.0) <sup>†</sup>
	RR [95% CI]	-	-	1.60 [0.13 to 20.22]
Chen 2004 <sup>5</sup> Prospective study 6 months	botulinum A (n=11)	0/11 (0.0)	NR	NR
	usual care (n=10)	0/10 (0.0)	NR	NR
	RR [95% CI]	-		

BC/ PGE2 = bethanechol chloride/prostaglandin E2; CI = confidence interval; NR = not reported; RR=risk ratio

\* Uterine leiomyoma, drug induced confusion, and dyspnoea (one patient in the botulinum A toxin group for each event) and pyelonephritis, lumbar radicular pain, and femoral fracture (one patient in the placebo group for each event)

\*\* Symptomatic adverse effects of BC, including mild lower abdominal cramps, diarrhea and increased perspiration.

† Botulinum - transitory exacerbation of per-existing urine incontinence for 2 weeks, lidocaine -anal incontinence one day after injection

## Comparative Effectiveness of CUR Treatments in Adults with Other Causes of CUR

We identified four studies addressing four different comparisons for treatments for CUR from mixed etiologies or etiologies that were not obstructive or neurogenic. Two of these comparisons were adequately addressed by previous systematic reviews.<sup>8,9</sup> Both reviews were conducted by the Cochrane Incontinence Group. We reviewed the PICOTS and assessed the quality of each review to determine that relevance and quality was sufficient and we identified no new studies comparing the same interventions; therefore, we report conclusions from the relevant systematic review in lieu of *de novo* abstraction and analysis of the original research addressing those comparisons.<sup>10,11</sup> Table H9 summarizes relevant conclusions from previous systematic reviews.

The relevant comparison from the Moore et al. systematic review compared clean versus sterile intermittent catheterization techniques in individuals needing long-term bladder management.<sup>9</sup> Herbison et al. conducted a systematic review evaluating the efficacy of sacral neuromodulation with implanted devices in individuals with voiding dysfunction.<sup>8</sup> They found one RCT that evaluated the efficacy of this intervention in a CUR population. One comparison in the Moore et al., review is relevant to our review. In assessing the data for clean versus sterile catheterization technique, they found the data from three studies insufficient to draw conclusions about the comparative rates of UTI.<sup>9</sup> Only one of these trials was eligible for our review.<sup>10</sup> Because the data from the three trials eligible for the Cochrane review were consistent and this data was assessed insufficient, we reiterate their conclusion of insufficient evidence.

Herbison et al. reviewed sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults.<sup>8</sup> The Cochrane review addressed one comparison relevant to our review, immediate implant versus a delayed implant (i.e., 6-month waitlist control) in treating CUR from nonobstructive retention. We identified one RCT that studied this comparison. At 6 months post-intervention, a greater proportion of the immediate implant group (19/29) no longer needed catheterization compared to the delayed implant group (2/22) with a relative risk of 7.21 [CI: 1.87-27.73]. Those in the immediate implant group also had significantly lower PVR urine volumes. The Cochrane review concludes that sacral neuromodulation with implanted devices is effective in treating nonobstructive CUR. They do not appear to provide strength of evidence for this conclusion.

Two RCTs also studied efficacy and comparative effectiveness of CUR interventions in mixed or other populations. Datta et al. conducted a crossover RCT in Europe evaluating the efficacy of sildenafil in women suffering from obstructed voiding or retention associated with Fowler's syndrome.<sup>12</sup> Tang et al. evaluated intermittent versus indwelling catheterization among elderly women with CUR admitted to a geriatric rehabilitation ward.

### Primary Outcomes

Primary outcomes from the two abstracted studies appear in Table H10. Datta et al. report rates of UTI and successful trial without catheter. Only one patient in either group had a UTI, with no difference between groups.<sup>12</sup> Tang reported only one instance of UTI in either group and TWOC was successful in 59 percent of the intermittent catheter patients and in 69 percent of the indwelling catheter patients.<sup>13</sup> This difference was not statistically significant.

## **Intermediate Outcomes**

Both studies reported several prespecified intermediate outcomes (Table H11). Datta et al. reported before and after data on mean IPSS scores and PVRs. These intermediate outcomes did not improve substantially for either groups and changes from baseline did not differ with statistical significance between sildenafil citrate and placebo patients.<sup>12</sup> Tang et al. report substantial reductions in PVRs after 2 weeks with indwelling versus intermittent catheter; however, the difference was not statistically significant.<sup>13</sup>

## **Harms**

Adverse effects were measured differently in each RCT (Table H12). These events were rare, and results did not differ between treatment groups.

**Table H9. Description and conclusions from previous systematic reviews on treatments for chronic urinary retention in other populations**

Study Information	Literature Through/SR Quality	Population/Relevant Comparison	Results; Conclusion; Strength of Evidence
Moore, 2007 <sup>9</sup> (Cochrane Incontinence Group)  Long-term bladder management by intermittent catheterization in adults and children	Literature search through June 2007  Good	Adults and children with incomplete bladder emptying  Sterile technique/clean technique (3 trials; only one with only CUR population)	No significant difference in rates of UTI between groups.  insufficient
Herbison, 2009 <sup>8</sup> (Cochrane Incontinence Group) Sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults	Literature search through February 2009  Good	Women with Fowler's syndrome.  Immediate/delayed implant (1 trial with CUR patients)	Catheter free: Implant>Delay PVR: Implant>Delay  Strength of evidence – not reported; Author's conclude 'Continuous stimulation offers benefits for urinary retention without obstruction.'

UTI = urinary tract infection; PVR = post void residual urine volume

**Table H10. Treatment for chronic urinary retention in other populations: primary outcomes**

Study; Design; Followup	Treatment Arms	Acute Urinary Retention n/N (%)	Urinary Tract Infection n/N (%)	Surgical Intervention n/N (%)	IPSS n/N (%)	TWOC n/N (%)
Datta, 2007 <sup>12</sup> Randomized crossover trial 10 weeks	sildenafil citrate (n=20)	NR	1/20 (0.05)	NR	NR	NR
Tang, 2006 <sup>13</sup> RCT 2 weeks	placebo (n=20) RR [95% CI]  RR [95% CI]	NR	0/20 (0.0)  No statistically significant difference 3.73 [0.16 to 88.90]	NR	NR	NR  0.86 [0.59 to 1.25]

CI = confidence interval; IDC = indwelling urinary catheterization; IMC = intermittent urinary catheterization; IPSS = International Prostate Symptom Score (range 0 [mild symptoms] to 35 [severe symptoms]); NR = not reported; RCT = randomized controlled trial; TWOC = successful trial without catheter

**Table H11. Treatment for chronic urinary retention in other populations: intermediate outcomes**

Study; Design; Followup	Treatment Arms	IPSS, Mean (SD) Value	Quality of Life Measure	PVRU (mL), Mean (SD)
Datta, 2007 <sup>12</sup> Randomized crossover trial 10 weeks	sildenafil citrate (n=20)	Baseline 21.5* [20 to 23]	NR	Baseline 140* [90 to 180]
		Mean change from baseline - 3.6		Endpoint 90* [70 to 120]
	placebo (n=20)	Baseline 21.5* [20 to 23]	NR	Baseline 140* [90 to 180]
		Endpoint 19* [18 to 20]		Endpoint 99* [70 to 130]
	Between group comparison ([95% CI] if applicable)	Mean difference at endpoint. No statistically significant difference		Mean difference at endpoint: no statistically significant difference
Tang, 2006 <sup>13</sup> RCT 2 weeks	IMC (n=27)	NR	NR	Baseline 539.8 (219.7)
				Endpoint 54.4 (49.1)
	IDC (n=39)	NR	NR	Baseline 545.9 (187.2)
				Endpoint 77.6 (48.2)
	Between group comparison ([95% CI] if applicable)			Mean difference at endpoint -23.20 [-47.03 to 0.63]

IDC = indwelling urinary catheterization; IMC = intermittent urinary catheterization; NR = no response; SD = standard deviation

\* Extracted from graph

**Table H12. Treatment for chronic urinary retention in other populations: adverse events**

Study; Design; Followup	Treatment Arms	Death n/N (%)	Bacteriuria n/N (%)	Clinical Deterioration n/N (%)	Urinary Leakage/ Incontinence n/N (%)	Total Adverse Events n/N (%)
Datta, 2007 <sup>12</sup> Randomized crossover trial 10 weeks	sildenafil citrate (n=20)	0/20 (0.0)	NR	NR	0/20 (0.0)	14/20 (0.7)
	Placebo (n=20)	1/20 (0.05)	NR	NR	1/20 (0.05)	14/20 (0.7)
	RR [95% CI]	No statistically significant difference			No statistically significant difference	No statistically significant difference
Tang, 2006 <sup>13</sup> RCT 2 weeks	IMC (n=36)	0/36 (0.0)	14/22* (63.6)	4/36 (11.1)	NR	NR
	IDC (n=45)	2/45 (4.4)	21/34* (61.8)	1/45 (2.2)	NR	NR
	RR [95% CI]	0.25 [0.01 to 5.02]	1.03 [0.68 to 1.56]	5.00 [0.58 to 42.80]		

IDC = indwelling urinary catheterization; IMC = intermittent urinary catheterization; NR = not reported; RR=risk ratio

\* Based on number of urine cultures sent on day 14.

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## Appendix I. Strength of Evidence

**Appendix Table 11. Strength of evidence assessments for BPH studies**

Comparison; # of Studies; N	Outcomes	Summary Statistics [95% CI]	Risk of Bias	Directness	Precision	Consistency	Evidence Rating
Microwave therapy vs. TURP or prostate enucleation surgery  1 RCT  N=120	<b>Primary Outcomes</b>						
	Urinary tract infection	RR 1.49 [95% CI 0.82 to 2.71]	Moderate	Direct	Imprecise	Unclear	Low
	Catheter-free status	RR 0.89 [95% CI 0.76 to 1.05]	Moderate	Direct	Precise	Unclear	Low
	<b>Intermediate Outcomes</b>						
	IPSS, mean at endpoint	MD 2.9 [95%CI 0.5 to 5.3]	Moderate	Indirect	Imprecise	Unclear	Insufficient
	IPSS QoL, mean change	NS between interventions*	Moderate	Indirect	Unclear	Unclear	Insufficient
	PVRU (ml)	Not reported	-	-	-	-	Insufficient
TURP vs. clean intermittent self-catheterization  1 RCT  N=51	<b>Primary Outcomes</b>						
	Urinary tract infection	Not reported	-	-	-	-	Insufficient
	<b>Intermediate Outcomes</b>						
	IPSS, mean at endpoint	MD -8.0 [95%CI -13.3 to 2.8]	Moderate	Indirect	Imprecise	Unclear	Insufficient
	IPSS QoL, mean change	MD -0.5 [95%CI -1.4 to 0.4]	Moderate	Indirect	Imprecise	Unclear	Insufficient
	PVRU (ml)	MD -254 [95%CI -553 to 45]	Moderate	Indirect	Imprecise	Unclear	Insufficient
TURP vs. laser therapy  1 RCT  N=82	<b>Primary Outcomes</b>						
	Urinary tract infection	RR 1.73 [95% CI 0.16 to 18.31]	High	Direct	Imprecise	Unclear	Insufficient
	IPSS category, adjusted	RR 1.27 [95% CI 0.97 to 1.68]	Moderate	Direct	Imprecise	Unclear	Low
	<b>Intermediate Outcomes</b>						
	IPSS, mean at endpoint	MD -2.0 [95%CI -6.4 to 2.4]	Moderate	Indirect	Imprecise	Unclear	Insufficient
	IPSS QoL, mean change	MD -0.4 [95%CI -1.3 to 0.5]	Moderate	Indirect	Imprecise	Unclear	Insufficient
	PVRU (ml), adjusted	MD -135 [95%CI -233 to -37]	Moderate	Indirect	Precise	Unclear	Low

RR = relative risk [95 percent confidence intervals]; MD = mean difference [95 percent confidence intervals]; TURP = transurethral resection of the prostate; NS = No statistically significant difference.

\* Mean difference could not be calculated

**Table I2. Strength of Evidence assessments for neurogenic bladder studies**

Study; Comparison; N	Outcomes	Summary Statistics [95% CI]	Risk of Bias	Directness	Precision	Consistency	Evidence Rating
Botulinum A toxin vs. placebo 1 RCT N=86	<b>Primary Outcomes</b>						
	Urinary tract infection	RR 1.21 [95% CI 0.66 to 2.25]	Moderate	Direct	Imprecise	NA	Low
	<b>Intermediate Outcomes</b>						
	IPSS, mean at endpoint	MD 2.0 [95%CI -1.0 to 5.0]	Moderate	Indirect	Imprecise	NA	Insufficient
	IPSS QoL, mean change	Not reported	-	-	-	-	Insufficient
Bethanechol chloride plus prostaglandin E2 vs. placebo 1 RCT N=19	<b>Primary Outcomes</b>						
	Urinary tract infection	Not reported	-	-	-	-	Insufficient
	<b>Intermediate Outcomes</b>						
	IPSS, mean at endpoint	Not reported	-	-	-	-	Insufficient
	QoL, mean change	NS between interventions*	High	Indirect	Imprecise	NA	Insufficient
Botulinum A toxin vs. Lidocaine 1 RCT N=13	<b>Primary Outcomes</b>						
	Urinary tract infection	Not reported	-	-	-	-	Insufficient
	<b>Intermediate Outcomes</b>						
	IPSS, mean at endpoint	Not reported	-	-	-	-	Insufficient
	IPSS QoL, mean change	Not reported	-	-	-	-	Insufficient
Botulinum A toxin vs. Lidocaine 1 Prospective study N=21	<b>Primary Outcomes</b>						
	Urinary tract infection	Not reported	-	-	-	-	Insufficient
	<b>Intermediate Outcomes</b>						
	IPSS, mean at endpoint	MD -9.5 [95%CI -14.3 to -4.7]	High	Indirect	Imprecise	NA	Insufficient
	IPSS QoL, mean change	MD -1.2 [95%CI -2.1 to -0.3]	High	Indirect	Imprecise	NA	Insufficient
	PVRU (ml)	MD -135 [95%CI -233 to -37]	High	Indirect	Imprecise	NA	Insufficient

RR = relative risk [95 percent confidence intervals] MD = mean difference [95 percent confidence intervals]; NS = No statistically significant difference.

\* Mean difference could not be calculated

**Appendix Table I3. Strength of evidence assessments for treatments for chronic urinary retention in other populations**

Study; Comparison; N	Outcomes	Summary Statistics [95% CI]	Risk of Bias	Directness	Precision	Consistency	Evidence Rating
Sildenafil vs. placebo 1 RCT N=19	<b>Primary Outcomes</b>						
	Acute urinary retention	Not reported	-	-	-	-	Insufficient
	Urinary tract infection	1 event in sildenafil arm	Moderate	Direct	Imprecise	NA	Insufficient
	Surgical intervention	Not reported	-	-	-	-	Insufficient
	Treatment failure	Not reported	-	-	-	-	Insufficient
	Catheter outcomes	Not reported	-	-	-	-	Insufficient
	<b>Intermediate Outcomes</b>						
	IPSS, mean at endpoint	NS between interventions*	Moderate	Indirect	Imprecise	NA	Insufficient
	QoL, mean change	Not reported	-	-	-	-	Insufficient
PVRU (ml)	NS between interventions*	Moderate	Indirect	Imprecise	NA	Insufficient	
Intermittent urinary catheterization vs. indwelling urinary catheterization 1 RCT N=81	<b>Primary Outcomes</b>						
	Acute urinary retention	Not reported	-	-	-	-	Insufficient
	Urinary tract infection	1 event in IMC arm	Moderate	Direct	Imprecise	NA	Insufficient
	Surgical intervention	Not reported	-	-	-	-	Insufficient
	Treatment failure	Not reported	-	-	-	-	Insufficient
	Catheter outcomes	RR 0.86 [95% CI 0.59 to 1.25]	Moderate	Direct	Imprecise	NA	Low
	<b>Intermediate Outcomes</b>						
	IPSS, mean at endpoint	Not reported	-	-	-	-	Insufficient
	QoL, mean change	Not reported	-	-	-	-	Insufficient
PVRU (ml)	MD -23 [95% CI -47 to 0.63]	Moderate	Indirect	Precise	NA	Low	

NA = not applicable; RR = relative risk [95 percent confidence intervals]; MD = mean difference [95 percent confidence intervals]; NS = No statistically significant difference.

\* Mean difference could not be calculated

## Appendix J. Ongoing Studies

**Table J1. Ongoing studies**

NCT Number	Title	Conditions	Interventions	Study Designs
NCT01460303	Patient-operated Valved Catheter Versus Indwelling Transurethral Catheter	Bladder Dysfunction Urinary Retention	Device: Bladder catheter: OPTION-vf patient controlled catheter vs. indwelling transurethral catheter with leg bag Device: Transurethral catheter with leg bag	Allocation: Randomized Endpoint Classification: Efficacy Study Intervention Model: Parallel Assignment Masking: Open Label Primary Purpose: Treatment
NCT00878176	Sacral Neuromodulation Test With Bilateral First Stage Tined Lead Procedure in Patients with Non-obstructive Urinary Retention: A Pilot Study	Urinary Retention	Procedure: First stage tined lead procedure	Endpoint Classification: Efficacy Study Intervention Model: Crossover Assignment Masking: Open Label Primary Purpose: Screening
NCT00680680	Treatment of Refractory Urinary Retention Secondary to Benign Prostatic Hyperplasia (BPH) with Dual Five Alpha Reductase Inhibition Combined with an Alpha Blocker	Urinary Retention Benign Prostatic Hyperplasia	Drug: Dutasteride	Allocation: Non-Randomized Endpoint Classification: Efficacy Study Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Treatment
NCT00700505	A Study to Determine the Safety and Efficacy of a New Non-invasive Heating Garment to Reduce Urinary Hesitancy	Benign Prostatic Hyperplasia (BPH) Urinary Retention Urinary Hesitancy Intermittent	Device: FlowPants(R) Garment	Endpoint Classification: Safety/Efficacy Study Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Treatment
NCT00441935	InterStim Prospective Database	Urinary Retention Urinary Incontinence Pelvic Pain	Device: InterStim Neuromodulation	Time Perspective: Prospective
NCT00970242	Ambulatory Urodynamic Evaluation of Sacral Neuromodulation for Non-Obstructive Urinary Retention	Acontractile Bladder		Time Perspective: Prospective
NCT01404481	Clean Intermittant Self Catheterisation: A Trial Comparing Single Use vs. Reuse of Nelaton Catheters	Urinary Retention	Device: clean intermittent self catheterisation single use vs. re use	Observational Model: Cohort Time Perspective: Prospective
NCT01771159	Tissue Bonding Cystostomy (TBC)	Spinal Cord Injury (SCI) Chronic Urinary Retention Urinary Incontinence	Device: TBC	Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Treatment

<b>NCT Number</b>	<b>Title</b>	<b>Conditions</b>	<b>Interventions</b>	<b>Study Designs</b>
NCT01164280	Effect of Pulse Rate Changes on Clinical Outcome	Overactive Bladder Syndrome Chronic Urinary Retention	Other: Pulse Rate Change	Intervention Model: Single Group Assignment Primary Purpose: Treatment
NCT00883220	Self Management in Urinary Catheter Users	Urinary Retention Neurogenic Bladder	Behavioral: Self-management of urinary catheter	Allocation: Randomized Endpoint Classification: Safety/Efficacy Study Intervention Model: Parallel Assignment Masking: Single Blind (Investigator) Primary Purpose: Prevention
NCT00225966	Patient Registry to Study the Tined Lead Used with the InterStim System for Urinary Control	Urge Incontinence Urinary Retention	Device: Device Medtronic InterStim Tined Leads Models 3889 and 3093	Allocation: Non-Randomized Endpoint Classification: Safety/Efficacy Study Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Treatment
NCT01284361	Comparison of Two Intermittent Urinary Catheters	Urinary Retention	Device: test and control intermittent urinary catheters	Allocation: Randomized Intervention Model: Crossover Assignment Masking: Open Label
NCT01305681	Bacterial Properties with LoFric® Catheters During Clean Intermittent Catheterization	Neurogenic Bladder Urinary Retention	Device: LoFric® catheters during clean intermittent catheterization	Allocation: Non-Randomized Intervention Model: Parallel Assignment Masking: Open Label Primary Purpose: Treatment
NCT00200031	A Cost Analysis of Interstim Therapy	Urinary Retention and Symptoms of Overactive Bladder (Urge, Frequency)	Device: Interstim therapy	
NCT01130415	Screening Method in Sacral Neuromodulation	Overactive Bladder Urinary Retention		Observational Model: Cohort Time Perspective: Retrospective

# Appendix K: Future Research Needs

Table K1. Future research needs

Key Question	Results of Literature Review	Types of Studies; Needed to Answer Question	Future Research Recommendations
General	<p>Many of the studies on interventions for CUR were uncontrolled</p> <p>Intervention studies enrolling men with CUR and BPH typically also required them to have significant lower urinary tract symptoms, not possible to differentiate whether improvements reflect the treatment for CUR or LUTS when they have overlapping interventions</p> <p>Intervention studies enrolling neurogenic bladder patients rarely described type of voiding dysfunction</p>	<p>Observational</p> <p>Qualitative</p> <p>Consensus development</p>	<p>Research to describe the natural history of CUR</p> <p>Standardized definition of CUR</p> <p>Clearly separate AUR and CUR patients in research studies</p> <p>Studies that evaluate if, when, and who it is beneficial to screen for CUR</p> <p>Make determination whether CUR should be addressed as a separate condition or better addressed as a manifestation of the underlying condition</p> <p>Design intervention studies in the neurogenic bladder population that include adequate numbers of different types of neurogenic bladder (incontinent, retention, both) to determine if outcomes vary by type of voiding dysfunction</p> <p>Conduct controlled studies on CUR interventions</p> <p>Studies with adequately powered subgroups of CUR patients should be conducted to determine whether CUR modifies the effect of treatment</p> <p>Only conduct studies that are adequately powered</p>
1a. What is the effectiveness and comparative effectiveness of treatments for chronic urinary retention in adults, male-specific etiologies?	<p>Only three trials were identified.</p> <p>No two studies compared the same interventions</p> <p>BPH was the only male-specific etiology studied</p> <p>We identified no studies that examined BPH as a subgroup of a larger trial</p> <p>Data was identified for only four interventions</p> <p>No data for long-term outcomes available</p>	<p>RCTs; controlled before and after studies</p>	<p>Additional studies necessary to establish consistency for TURP</p> <p>Efficacy and comparative effectiveness of pharmaceutical interventions such as alpha blockers and 5 alpha reductase inhibitors<sup>a</sup></p> <p>Studies with followup times extending for several years</p>

<b>Key Question</b>	<b>Results of Literature Review</b>	<b>Types of Studies; Needed to Answer Question</b>	<b>Future Research Recommendations</b>
1b. What is the effectiveness and comparative effectiveness of treatments for chronic urinary retention in adults, female-specific etiologies?	<p>Only one study addressed a predominantly female etiology (Fowler's syndrome)</p> <p>Only one patient-centered outcome was evaluated</p> <p>No data for long-term outcomes available</p>	RCTs; controlled before and after studies	<p>Controlled studies of interventions for women with CUR resulting from SUI procedures</p> <p>Intervention studies with nonimplanted devices to treat Fowler's syndrome</p> <p>Controlled studies of neuromodulation interventions with long-term followup to determine duration of effectiveness</p>
1c. What is the effectiveness and comparative effectiveness of treatments for chronic urinary retention in adults, nonsex-specific etiologies?	<p>We identified few studies that addressed nonsex-specific etiologies</p> <p>Neurogenic bladder was the only etiology studied</p> <p>Studies often enrolled populations with heterogeneous underlying conditions</p> <p>Small sample sizes</p> <p>Primarily intermediate outcomes studied</p>	RCTs, controlled before and after studies	Additional patient-centered outcomes should be included
1d. What patient or condition characteristics (e.g., age, severity, etc.) modify the effectiveness of treatment?	One study used a more conservative treatment in men with higher prostate volumes	RCTs, controlled before and after studies	Stratify enrolled CUR patients by severity
2a. What are the harms and comparative harms of treatments for chronic urinary retention in adults with male-specific, female-specific, and nonsex-specific etiologies?	Harms were inconsistently measured and reported		Adequately collect and report data on harms.
2d. What patient or condition characteristics (e.g., age, severity, etc.) modify the harms of treatment?	Not addressed by current literature.		Larger sample sizes will enable this type of analysis

<sup>a</sup> One RCT was identified in Clinicaltrials.gov; completed in 2008, but results are not available