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Invasive urodynamic studies for the management of lower urinary tract symptoms (LUTS) in men with voiding dysfunction (Review)

Clement KD, Burden H, Warren K, Lapitan MCM, Omar MI, Drake MJ



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TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
SUMMARY OF FINDINGS FOR THE MAIN COMPARISON	4
BACKGROUND	6
OBJECTIVES	8
METHODS	8
RESULTS	12
Figure 1.	13
Figure 2.	15
Figure 3.	16
DISCUSSION	17
AUTHORS' CONCLUSIONS	18
ACKNOWLEDGEMENTS	18
REFERENCES	19
CHARACTERISTICS OF STUDIES	21
DATA AND ANALYSES	27
CONTRIBUTIONS OF AUTHORS	27
DECLARATIONS OF INTEREST	27
SOURCES OF SUPPORT	27
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	27

[Intervention Review]

Invasive urodynamic studies for the management of lower urinary tract symptoms (LUTS) in men with voiding dysfunction

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ABSTRACT

Background

Invasive urodynamic tests are used to investigate men with lower urinary tract symptoms (LUTS) and voiding dysfunction to determine a definitive objective diagnosis. The aim is to help clinicians select the treatment that is most likely to be successful. These investigations are invasive and time-consuming.

Objectives

To determine whether performing invasive urodynamic investigation, as opposed to other methods of diagnosis such as non-invasive urodynamics or clinical history and examination alone, reduces the number of men with continuing symptoms of voiding dysfunction. This goal will be achieved by critically appraising and summarising current evidence from randomised controlled trials related to clinical outcomes and cost-effectiveness. This review is not intended to consider whether urodynamic tests are reliable for making clinical diagnoses, nor whether one type of urodynamic test is better than another for this purpose.

The following comparisons were made.

- Urodynamics versus clinical management.
- One type of urodynamics versus another.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (2014, issue 10), MEDLINE (1 January 1946 to Week 4 October 2014), MEDLINE In-Process and other non-indexed citations (covering 27 November 2014; all searched on 28 November 2014), EMBASE Classic and EMBASE (1 January 2010 to Week 47 2014, searched on 28 November 2014), ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (searched on 1 December 2014 and 3 December 2014, respectively), as well as the reference lists of relevant articles.

Invasive urodynamic studies for the management of lower urinary tract symptoms (LUTS) in men with voiding dysfunction (Review) |

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Selection criteria

Randomised and quasi-randomised trials comparing clinical outcomes in men who were and were not investigated with the use of invasive urodynamics, or comparing one type of urodynamics against another, were included. Trials were excluded if they did not report clinical outcomes.

Data collection and analysis

Three review authors independently assessed trial quality and extracted data.

Main results

We included two trials, but data were available for only 339 men in one trial, of whom 188 underwent invasive urodynamic studies. We found evidence of risk of bias, such as lack of outcome information for 24 men in one arm of the trial.

Statistically significant evidence suggests that the tests did change clinical decision making. Men in the invasive urodynamics arm were more likely to have their management changed than men in the control arm (proportion with change in management 24/188 (13%) vs 0/151 (0%), risk ratio (RR) 39.41, 95% confidence interval (CI) 2.42 to 642.74). However, the quality of the evidence was low.

Low-quality evidence indicates that men in the invasive urodynamics group were less likely to undergo surgery as treatment for voiding LUTS (164/188 (87%) vs 151/151 (100%), RR 0.87, 95% CI 0.83 to 0.92).

Investigators observed no difference in urine flow rates before and after surgery for LUTS (mean percentage increase in urine flow rate, 140% in invasive urodynamic group vs 149% in immediate surgery group, P value = 0.13). Similarly, they found no differences between groups with regards to International Prostate Symptom Score (IPSS) (mean percentage decrease in IPSS score, 58% in invasive urodynamics group vs 59% in immediate surgery group, P value = 0.22).

No evidence was available to demonstrate whether differences in management equated to improved health outcomes, such as relief of symptoms of voiding dysfunction or improved quality of life.

No evidence from randomised trials revealed the adverse effects associated with invasive urodynamic studies.

Authors' conclusions

Although invasive urodynamic testing did change clinical decision making, we found no evidence to demonstrate whether this led to reduced symptoms of voiding dysfunction after treatment. Larger definitive trials of better quality are needed, in which men are randomly allocated to management based on invasive urodynamic findings or to management based on findings obtained by other diagnostic means. This research will show whether performance of invasive urodynamics results in reduced symptoms of voiding dysfunction after treatment.

PLAIN LANGUAGE SUMMARY

Invasive urodynamic studies for the management of lower urinary tract symptoms (LUTS) in men with voiding dysfunction

Background on the condition

Voiding symptoms - one specific group of lower urinary tract symptoms - are those experienced by men who have difficulty passing urine. Voiding symptoms may include a slow stream of urine, spraying of urine, difficulty in beginning urination and dribbling of urine once the man believes he has finished. These symptoms can be extremely embarrassing and distressing for affected individuals and may dictate or restrict how they live their lives.

Invasive urodynamic tests are used to measure nerve and muscle function, pressure around and in the bladder and other factors that might help to explain why a man may experience these symptoms. Some men find these tests embarrassing or uncomfortable. However, results might reveal the cause of the voiding symptoms, thereby guiding healthcare providers in choosing the most effective treatment. This approach might lead to improvement in the relative success of these treatments and reduce the risk of harm from unnecessary treatment.

Main findings of this review

We found two trials, which included around 350 men, although information was available for only 339 men in one trial. Evidence was not sufficient to show whether invasive urodynamic tests led to better patient outcomes. Some evidence suggests that these tests did

alter management decisions, resulting in fewer men undergoing surgery. No evidence indicates whether this change in management led to fewer symptoms in men after treatment, and it is not known whether patients reported a better quality of life.

Adverse effects

No information obtained from the included trials reveals how common side effects were in those undergoing invasive urodynamic testing.

Limitations of the review

Not enough information from trials is available regarding the benefits of invasive urodynamic testing for men with voiding dysfunction. More research is needed in which people are randomly assigned to treatment decisions based on their symptoms, physical examination findings and results of non-invasive tests alone, or based on the extra information provided by invasive urodynamic tests. Future studies will help healthcare providers determine whether patients benefit from these extra tests, and whether the tests provide good value for healthcare systems.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Patient or population: patients with lower urinary tract symptoms Settings: hospital Intervention: invasive urodynamic studies						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Invasive urodynamic studies				
Number treated with surgery	1000 per 1000	870 per 1000 (830 to 920)	RR 0.87 (0.83 to 0.92)	339 (1 study)	⊕⊕○○ Low ^{a,b}	
Number whose treatment was changed after assessment with or without urodynamics			RR 39.41 (2.42 to 642.74)	339 (1 study)	⊕⊕○○ Low ^{a,b,c}	
Number of men with continuing symptoms of voiding dysfunction after treatment following assessment with and without urodynamic studies - not reported	See comment	See comment	Not estimable	-	See comment	
Incidence of urinary tract infection - not reported	See comment	See comment	Not estimable	-	See comment	

Subjective participant satisfaction with treatment at 3 months after treatment - not reported	See comment	See comment	Not estimable	-	See comment
Need for repeat or alternative treatment within 1 year - not reported	See comment	See comment	Not estimable	-	See comment
Health outcome measures such as quality-adjusted life-years - not reported	See comment	See comment	Not estimable	-	See comment

*The basis for the **assumed risk** (e.g. median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence.

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

^aAll domains of risk of bias assessment (except incomplete outcome data and selective reporting) were judged to be ‘ ‘ unclear’ as information was insufficient. Selective outcome reporting was judged to be at low risk of bias, whereas incomplete outcome data were judged to be at high risk of bias.

^bNot applicable, only 1 trial.

^c95% confidence Interval was very wide (2.42 to 642.74). However, it did not cross the line of no effect.

BACKGROUND

Invasive urodynamic investigations may be performed in the diagnosis of lower urinary tract symptoms (LUTS) in men and in subsequent planning and management. Urodynamic investigations measure bladder pressure and urine flow rate during bladder filling and voiding to assess the function of the lower urinary tract and to identify the cause(s) of urinary storage or voiding symptoms.

In the evaluation of LUTS in men with voiding dysfunction, the aim of urodynamic tests is to measure dysfunction while differentiating between possible causes of symptoms, so that the most likely effective method of treatment can be selected. For men with voiding dysfunction, urodynamics is commonly used to detect the presence of bladder outlet obstruction (BOO) and detrusor underactivity (DU, or weak bladder contraction during voiding), which give rise to similar clinical symptoms (Hosker 2009). Distinguishing between LUTS due to BOO and LUTS due to DU is important, as this approach may influence management decisions specifically related to surgery for BOO. Low-level evidence suggests that making this distinction is important, as clinical outcomes may be affected (Hosker 2009). Detrusor overactivity (DO, or inappropriate bladder contractions during storage) is a storage phase problem that can be associated with urinary urgency symptoms. Prevalence of DO increases with age, and DO can be observed as a feature of urodynamic tests in some men with voiding dysfunction.

Description of the condition

Definitions and terminology

Lower urinary tract symptoms (LUTS)

Lower urinary tract symptoms may be divided into three categories depending on the phase of the micturition cycle affected.

- Storage symptoms, those experienced during the storage phase, include increased daytime frequency, nocturia, urgency and urinary incontinence (Abrams 2002).
- Voiding symptoms, those arising during the voiding phase of the micturition cycle, include slow stream, splitting or spraying, intermittency, hesitancy, straining and terminal dribble (Abrams 2002).
- Postmicturition symptoms, those experienced immediately after micturition, include a feeling of incomplete emptying and postmicturition dribble (Abrams 2002).

Although most men report a combination of the above groups of symptoms, this review focuses on investigation of voiding dysfunction in men and therefore primarily assesses men with voiding and postmicturition symptoms. Storage symptoms are the main focus of another Cochrane review (Clement 2013).

Voiding dysfunction

Voiding LUTS are experienced during the voiding phase (emptying the bladder) of micturition (Abrams 2002). The voiding phase of the micturition cycle alternates with the storage phase and is under voluntary brain control, leading to both contraction of the bladder wall and relaxation of the urethral sphincter. Voiding dysfunction is caused most commonly by poor contractility of the bladder wall in DU, or by enlargement of the prostate gland in benign prostatic hyperplasia (BPH), leading to BOO.

Voiding dysfunction in men may have many different causes; it is important to differentiate between these causes to determine appropriate management.

- Bladder outlet obstruction may be caused by anatomical or functional problems. The most common cause is benign prostatic enlargement (BPE), which compresses the urethral canal, leading to obstruction of the normal flow of urine. Other anatomical causes of BOO include bladder tumour, urethral stricture, prostatitis and foreign body (Oelke 2013). Functional causes of BOO include detrusor-sphincter dyssynergia - inappropriate contraction of the internal urethral sphincter during voiding that occurs as a consequence of neuronal injury such as injury to the spinal cord. Other causes include primary bladder neck obstruction and pelvic floor dysfunction (Dmochowski 2005). Bladder outlet obstruction may be accompanied by DO.

- Detrusor underactivity is defined as “detrusor contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or failure to achieve complete bladder emptying within a normal time span” (Abrams 2002). It is thought to be multi-factorial in origin. “Primary” or “idiopathic” DU is thought to be due to the natural age-related decrease in detrusor contractility. However, not everyone in this group will become clinically symptomatic. Other causes of DU include BOO (secondary to chronic overstretching of the detrusor muscle, leading to muscle damage and hence an inability to contract) and diabetes mellitus (van Koevering 2011).

Voiding LUTS in men are a common problem. It has been reported that among men 50 to 80 years of age, 90% suffer from voiding LUTS at some point (NICE 2010). In one population-based study in the USA, it was reported that 6% of all men (n = 2125) over 40 years of age had isolated voiding dysfunction as defined by the International Prostate Symptom Score (IPSS). Nine percent of all men had mixed voiding and storage LUTS (Glasser 2007). These figures may not reflect the true scope of the problem, as men may not present to a healthcare professional or admit that they are troubled because of embarrassment. Alternatively, some men may be affected but may not find these symptoms to be a problem. Lower urinary tract symptoms in men become more common with increasing age. They are associated with obesity, diabetes mellitus and a genetic susceptibility (Parsons 2010).

Overactive bladder syndrome

Overactive bladder syndrome (OAB) is defined as “urgency, with or without urge incontinence, usually with frequency and nocturia in the absence of an underlying metabolic or pathologic condition.” Detrusor overactivity in the presence or absence of urgency is defined as “a urodynamic observation characterised by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked” (Abrams 2002). Although not strictly a direct cause of voiding dysfunction, OAB is a major cause of LUTS in men. Therefore if present, OAB symptoms or DO on urodynamics may influence a clinician’s management plan for concomitant BOO, for example, by altering the likelihood of proceeding to surgery or counselling the patient about the chance of symptom resolution.

Description of the intervention

The term ‘urodynamics’ is commonly used to refer to a wide variety of physiological measurements of bladder and urethral function that aim to demonstrate a causal abnormality of storage and voiding. The term may also be used to signify multi-channel cystometry, but several tests, including non-invasive free flow rate testing, can be described as urodynamic tests.

Cystometry is an invasive method of investigation. At a minimum, a catheter must be inserted into the bladder. A range of measurements can be taken, including urinary flow rate; pressure within the urethra, bladder and abdomen; and electrical nerve recording (Gorton 1999). A significant number of study participants have reported that undergoing these investigations was embarrassing and painful for them (Gorton 1999; Shaw 2000). Nevertheless, cystometric studies have been invaluable in aiding our understanding of the physiological and pathophysiological processes involved in the development of voiding dysfunction (Chapple 2006).

When urodynamic studies are performed in men, the most important goal is to reproduce symptoms, so that the causes of symptoms of voiding dysfunction and associated storage abnormalities can be determined. This is normally achieved by asking the patient to urinate into a container that is used to measure the volume and rate of urine passed (uroflowmetry) and then measuring the volume of urine contained in the bladder after urination (postvoid residual volume) by performing an external ultrasound scan of the bladder or catheterisation.

Next, a urinary catheter is normally inserted to fill the bladder with water, saline or contrast medium to allow controlled reproduction of symptoms. Bladder sensations during bladder filling are reported by patients, including a sensation of filling, a desire to void, urgency and a sense of discomfort or pain. Concurrently, various pressure measurements are taken during the phases of the micturition cycle by using fluid-filled lines connected to external transducers, or ‘microtip’ transducers, inserted into both the bladder and the abdominal cavity via the rectum. When the bladder is deemed to be “full” (cystometric capacity), the patient is given permission to void, so that urinary flow rates can be related to changes

in pressure during bladder emptying; this is termed a ‘pressure-flow study’. The main pressure measurements taken include:

- intravesical pressure (pressure within the bladder; P_{ves}); and
- abdominal pressure (pressure within the abdominal cavity, normally measured using a rectal catheter; P_{abd}).

Both of these measurements are needed to derive the detrusor pressure (P_{det}), which is the difference between bladder and abdominal pressures ($P_{ves} - P_{abd}$) and is computed throughout the test. Variation in these pressure measurements during phases of the micturition cycle facilitates the diagnosis of various conditions, provided a high-quality study is achieved and everyday symptoms of the patient are reproduced during the test.

Other types of urodynamics

Videourodynamics is another method of assessing the function and anatomy of the lower urinary tract by using synchronous x-ray or ultrasound imaging of the bladder with multi-channel cystometry. This live imaging of the bladder may be recorded for future review. Ambulatory urodynamics involves using portable devices to carry out multi-channel cystometry with natural bladder filling. This allows patients to conduct their normal activities of daily living while they are being urodynamically assessed.

Gas cystometry uses carbon dioxide as the medium for filling the bladder during the study. This approach has been found to be unreliable and is not now recommended (Homma 1999). Surface electromyography may be used as an indirect measure of pelvic floor and sphincter muscle contractility, but it is not commonly used in clinical practice.

Risks of invasive urodynamic tests

The main risks of urodynamic testing are those associated with the process of urethral catheterisation, such as dysuria (painful urination) and urinary tract infection (UTI). A separate Cochrane review addresses interventions to reduce the incidence of infection (Foon 2012). Urodynamic tests require the use of sophisticated machines and technical expertise, both of which have cost implications for the healthcare system. Men may find testing to be an uncomfortable or embarrassing experience.

The reproducibility of cystometry as a diagnostic investigation has been called into question (Kortmann 2000; Sonke 2000), as have its specificity and sensitivity in differentiating between causes of LUTS (Belal 2006). It has been suggested that the correlation between urodynamic findings and symptoms in men with LUTS may be poor (Eckhardt 2001).

How the intervention might work

The National Institute for Health and Care Excellence (NICE) in the UK recommends that men contemplating surgery for the

treatment of LUTS should be offered invasive urodynamic investigations (NICE 2010).

A Committee of the International Consultation on Incontinence (ICI) in 2009 published an overview of the best scientific evidence with regard to the role of cystometry in the treatment of people with urinary incontinence or voiding difficulties (Hosker 2009). This overview reported that evidence demonstrating that invasive urodynamics improves clinical outcomes in men investigated for LUTS related to BOO and DO is limited; nonetheless the ICI advised that the investigation should be performed before surgical intervention is provided (Hosker 2009). The research behind these recommendations is conflicting. Some studies have suggested that preoperative detection of DO facilitated the prediction of postoperative complications such as incontinence (Aboseif 1994; Monoski 2006; Seki 2006). Other evidence supports the contrary assertion that preoperative DO does not predict post-prostatectomy incontinence (Golomb 1999; Kleinhans 1999).

One type of urodynamic investigation may provide more useful information than another. This issue has been addressed by studies comparing the utility of ambulatory urodynamics versus conventional cystometry, particularly in determining the contribution of detrusor overactivity to LUTS in men. In one study, conventional urodynamics was compared with ambulatory urodynamics, and ambulatory urodynamics was found to be more sensitive in detecting DO; however, this finding was not correlated with a better outcome (Robertson 1996).

Why it is important to do this review

The diagnostic accuracy of a test is normally determined by verifying test results against a reference ('gold') standard that defines true disease status. The diagnostic performance of cystometry cannot be assessed in this way, however, because no gold standard has been accepted. In the absence of a gold standard, no alternative may be available for evaluating whether the treatment response after cystometry leads to improved health gains compared with the treatment response after tests that do not include cystometry. Furthermore, these tests are not provided without cost: They are invasive and expensive and may produce adverse effects. For the financial year 2011-2012, in the National Health Service (NHS) in England, urodynamic testing for one patient on an outpatient basis was calculated to cost £147. This cost increased to £340 on a day-case basis. With regard to adverse effects, it is estimated that cystometry results in a 3% or greater incidence of symptomatic UTI (Foon 2012).

The value of accurate diagnosis depends on the availability and effectiveness of appropriate treatments. Accurate diagnosis is of no clinical value unless it is known, for example, that cystometry can distinguish between a group for whom surgery is effective and another group for whom it is neither effective nor contraindicated, or for whom treatment needs to be altered in a specific way.

The value of invasive urodynamic investigation in the diagnosis and management of men with LUTS associated with voiding dysfunction is therefore uncertain.

This review addresses whether the extra information generated by invasive urodynamic testing influences clinical decision making regarding management of voiding LUTS in men, and particularly whether this leads to improvement in clinical and health economic outcomes.

OBJECTIVES

To determine whether performing invasive urodynamic investigation, as opposed to other methods of diagnosis such as non-invasive urodynamics or clinical history and examination alone, reduces the number of men with continuing symptoms of voiding dysfunction. This goal will be achieved by critically appraising and summarising current evidence from randomised controlled trials related to clinical outcomes and cost-effectiveness. This review is not intended to consider whether urodynamic tests are reliable for making clinical diagnoses, nor whether one type of urodynamic test is better than another for this purpose.

The following comparisons were made.

- Urodynamics versus clinical management.
- One type of urodynamics versus another.

METHODS

Criteria for considering studies for this review

Types of studies

We searched for all randomised or quasi-randomised controlled trials on the management of voiding dysfunction in which men with symptoms were randomly assigned to invasive urodynamic testing in at least one arm of the study.

We excluded studies that did not report clinical outcomes of LUTS management nor effects on clinical decision making.

Types of participants

All men with voiding LUTS presenting for investigation and management of their LUTS, as defined by the trial authors.

Types of interventions

The intention was to answer the following clinical questions.

- Do invasive urodynamic investigations improve the clinical outcomes of men with voiding dysfunction?
- Do invasive urodynamic investigations alter clinical decision making?
- Is one type of invasive urodynamics better than another for improving the outcomes of management of LUTS due to voiding dysfunction and/or for influencing clinical decisions?
- Do invasive urodynamic tests identify risk factors for an adverse outcome after surgery?

The intention was to perform the following comparisons.

- Invasive urodynamic tests versus clinical management without invasive urodynamics.
- One type of urodynamic test versus another.

Because a reference ('gold') standard investigation is not available for comparison, this review does not aim to determine whether invasive urodynamic studies are reliable for making a clinical diagnosis, nor whether one type of urodynamic investigation is better than another for this purpose.

Interventions

We searched for invasive urodynamic investigations used as part of a diagnostic workup before management decisions were made. All types of urodynamics were eligible for consideration in this review (AHCPR 1996; Homma 1999), including the following.

- Cystometry (simple, multi-channel or subtracted: study of the pressure/volume relationship of the bladder during urine storage (filling cystometry) and urine expulsion (voiding cystometry)).
 - Pressure-flow studies of voiding (study of the bladder pressure/urine flow rate relationship during voiding).
 - Urethral pressure measurements (profilometry: measurement of pressure within the urethra; urethral closure pressure is defined as the difference between intraluminal pressure in the urethra and intravesical pressure in the bladder at rest or during stress such as coughing or straining).
 - Leak point pressure measurements (pressure within the bladder at which leakage of urine from the urethra occurs: a direct measure of the closure function of the entire urethra).
- Penile cuff test (non-invasive measurement of bladder pressure during voiding, taken by providing intermittent occlusion of the urinary stream with an inflatable cuff placed around the penis).
- Electromyography (direct measurement of the contractility of muscles concerned with continence, i.e. urethral sphincter, anal sphincter or pelvic floor muscles).
- Videourodynamics (radiological (x-ray) imaging and urodynamic measurements of the lower urinary tract performed simultaneously during filling and voiding).

- Ambulatory urodynamic monitoring (urodynamic test performed with natural bladder filling under circumstances in which the patient's mobility is minimally restricted).

Cystoscopy and imaging tests (radiography, ultrasonography) are not usually considered routine urodynamic tests and were not included in this review.

Although the specific management decisions made and the treatments that patients undergo after assessment with or without urodynamics are not included among the interventions assessed in this review, it is important to note that it is the outcome of these by which the usefulness of urodynamics is to be judged. Therefore, to minimise bias associated with systematic differences in care between centres or treatment modalities, we assessed included studies for statements that diagnostic procedures and subsequent interventions had been carried out according to an internationally accepted standard. Furthermore, for trials in which a new intervention was deployed, we sought statements regarding whether training and learning curves were concluded before the start of the trial.

Comparators

We included assessments that do not include invasive tests, such as:

- clinical history;
- physical examination;
- symptoms reported by questionnaire;
- uroflowmetry and residual volume measurement; and
- bladder diaries.

Uroflowmetry and residual urine measurement (recording the volume of fluid expelled via the urethra per unit time during voiding, and the volume of urine left in the bladder after voiding) can be considered as part of urodynamic testing, but alone, they are not by definition invasive and therefore were considered as a comparator in this review unless they were performed in conjunction with other invasive urodynamic tests. This allowed determination of whether urodynamic studies as a whole, or mainly the uroflowmetry and residual urine measurement (non-invasive) portions of the study, influence decisions and outcomes.

Types of outcome measures

We selected outcome measures used in this review on the basis of their relevance to the clinical cure or improvement of LUTS in men with voiding dysfunction, or to management decisions made to address this problem. We regarded the primary outcomes of this review as clinical outcomes, as assessed by symptoms, questionnaire (e.g. IPSS) or urinary diary. In addition, we quantified the influence of invasive urodynamic testing on clinical decisions. We excluded studies that did not report clinical outcomes or effects on clinical decision making.

We adopted the recommendations provided by the Standardisation Committee of the International Continence Society for outcomes of research investigating the effects of therapeutic interventions for people with voiding dysfunction or urinary incontinence. These outcome categories include observations (symptoms) of people investigated for voiding dysfunction, quantification of symptoms, the clinician's observations (anatomical and functional), quality of life and socioeconomic measures (Lose 1998).

Data could be obtained from history and questionnaire assessment, or from urinary diaries (including frequency of micturition and voided volumes).

The review also included adverse events as outcome measures.

The ideal minimum follow-up for our primary outcome and for other relevant clinical outcomes is one year after urodynamics. We analysed separately trials reporting follow-up periods of different lengths for each outcome.

Primary outcomes

- Number of men with continuing symptoms of voiding dysfunction after treatment following assessment with and without urodynamic studies at least one year after assessment.

Secondary outcomes

Clinical decision making

- Number of men receiving conservative, drug or surgical treatment.
- Number of men whose intended treatment was changed after invasive urodynamics.
- Need for repeat or alternative treatment.

Participant observations

- Symptom scores (e.g. IPSS).
- Storage symptoms (urgency, increased daytime frequency, nocturia).
- Urinary incontinence.
- Use of pads.
- Satisfaction with treatment.
- Time to return to normal activity.

Quantification of associated signs and symptoms

- Frequency of micturition as reported through the use of a bladder diary.
- Nocturia.
- Urine flow rate.
- Voided volumes.

Clinician observations (anatomical and functional)

- Clinician-observed urinary incontinence.
- Need for further treatment.

Adverse effects

- Adverse events due to the method of investigation (e.g. UTI after urodynamic investigation).
- Adverse events due to subsequent clinical management.
- Deaths.

Quality of life

- General health status measures (physical, psychological, other).
- Condition-specific health measures (specific instruments designed to assess the effects of voiding dysfunction on quality of life).
- Psychological health status measures (e.g. Hospital Anxiety and Depression Score (HADS)).

Economic outcomes

- Health economic measures.
- Costs of investigations.
- Costs of treatment and re-treatment.

Other outcomes

- Non-prespecified outcomes judged important while the review was conducted.

Quality of evidence

We classified primary and secondary outcomes, as defined above, as 'critical', 'important' or 'not important' for decision making from the participant's perspective. The GRADE Working Group strongly recommends including up to seven outcomes in a systematic review. In this systematic review, we adopted GRADE (Grading of Recommendations, Assessment, Development and Evaluation) methodology to assess the quality of available evidence for the following outcomes.

- Number treated with surgery.
- Number whose treatment was changed after assessment with or without urodynamics.
- Number of men with continuing symptoms of voiding dysfunction after treatment following assessment with and without urodynamic studies.
- Incidence of UTI.
- Subjective participant satisfaction with treatment at three months after treatment.
- Need for repeat or alternative treatment within one year.
- Health economic outcome measures such as quality-adjusted life-years (QALYs).

Search methods for identification of studies

We did not impose language, status of publication or other limits on the searches described below, unless otherwise stated.

Electronic searches

We searched the following electronic bibliographic databases, all on Ovid SP.

- Cochrane Central Register of Controlled Trials (CENTRAL) (2014, issue 10) on 28 November 2014 on Ovid SP. The search strategy is given in Appendix 1.
- MEDLINE (1 January 1946 to October Week 4 2014) and MEDLINE In-Process and other non-indexed citations (covering 27 November 2014) (both searched on 28 November 2014). The search strategy is given in Appendix 2.
- EMBASE Classic and EMBASE (1 January 2010 to Week 47 2014, searched on 28 November 2014). Explanations for the date limitation and the search strategy are given in Appendix 3.

We sought ongoing trials and trial results in the following trial results registers and platforms. The search terms used are given in Appendix 4.

- ClinicalTrials.gov (date of last search: 1 December 2014).
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (date of last search: 3 December 2014).

Search terms tested but rejected (as they did not lead to retrieval of any relevant records during testing) are given in Appendix 5.

Searching other resources

We searched the reference lists of relevant articles.

Data collection and analysis

We excluded studies if they were not randomised or quasi-randomised trials for men with voiding dysfunction. In addition, we excluded studies that did not report clinical outcomes or effects on clinical decision making. We listed excluded studies along with details of the interventions compared and the reasons for their exclusion.

We processed included data as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Selection of studies

Three review authors independently evaluated the reports of all possibly eligible studies for methodological quality and appropriateness for inclusion without prior consideration of the results. We resolved disagreements by discussion. When these were not resolved, arbitration would have rested with a fourth person.

Data extraction and management

At least two review authors extracted data independently and cross-checked them by using a customised data collection form. When data may have been collected but were not reported, we sought clarification from the trialists. We processed included trial data by using RevMan software, as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We contacted authors of original reports to request extra information and data if required.

Assessment of risk of bias in included studies

Each review author independently critically appraised and assessed risk of bias, as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The following were assessed and reported in Cochrane risk of bias tables.

- Was the allocation sequence adequately generated?
- Was allocation adequately concealed?
- Were outcome assessors adequately blinded to intervention allocation?
 - Were incomplete outcome data adequately addressed?
 - Are reports of the study free of the suggestion of selective outcome reporting (or, were all relevant outcomes adequately reported)?
 - Were full details of financial support and funding for the trial provided?
 - Was a sample size calculated before recruitment, and did sample size reflect the required numbers needed to meet a particular statistical power?
 - Was ethical approval sought and received before the trial was begun?
 - Was full informed consent obtained from trial participants?

Studies were considered to be at low risk of bias if the method of blinding was adequate, or if we judged that lack of blinding could not have affected the results or could not be avoided. We assessed each element as having low risk, high risk or unclear risk of bias (the latter usually when no information was supplied).

In this review, we decided to exclude from the risk of bias assessment performance bias as a domain of risk of bias assessment. Blinding of participants undergoing urodynamic testing or of staff carrying out the testing is not possible and would have been judged as introducing 'high risk' across all trials.

Measures of treatment effect

For categorical outcomes, we related the numbers reporting an outcome to the numbers at risk in each group to derive a summary risk ratio (RR). For continuous variables, we would have used means and standard deviations (SDs) to derive a mean difference (MD) if outcomes were measured the same way between trials. However, data for both urine flow rate and the IPSS questionnaire were provided as a percentage change, and so it was not possible

to present these outcomes in forest plot form. Any continuous data that were the product of several different scales (e.g. scales used to assess symptoms such as pain or quality of life) would have been summarised as the standardised mean difference (SMD) by using a fixed-effect model. We used a fixed-effect model for calculation of all summary estimates and 95% confidence intervals (CIs) except when heterogeneity was significant. It was not possible to undertake meta-analysis because of the lack of included trials; however we presented data in forest plot form for ease of graphical representation.

Unit of analysis issues

We would have analysed studies with non-standard design, such as cross-over trials and cluster-randomised trials, as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We would have analysed studies with multiple treatment groups by treating each pair of arms as a separate comparison, as appropriate. All studies in this review were of standard design and were two-armed trials.

Dealing with missing data

We defined an intention-to-treat analysis as analysing all participants in their randomly assigned groups, whether or not they received the allocated intervention. We included data as they were reported by the trialists for each outcome and did not impute missing values. However, we would carry out sensitivity analyses if a differential dropout from the randomly assigned groups occurred, or if systematic bias from missing data was suspected for another reason.

Assessment of heterogeneity

We would have combined trial data only if no clinical heterogeneity was apparent. We would have investigated differences between trials if significant heterogeneity was revealed by the Chi^2 or the I^2 statistic (Higgins 2003), or was obvious from visual inspection of study results and data plots. Visual heterogeneity would be deemed positive when the confidence intervals of studies did not overlap. This would then be confirmed by formal statistical testing. We regarded statistical heterogeneity as substantial if I^2 was greater than 50%, as reported by the *Cochrane Handbook for Systematic Reviews of Interventions* to be the cross-over between moderate and substantial heterogeneity, or if the P value (< 0.10) in the Chi^2 test for heterogeneity was low. For those outcomes, we could have used a random-effects model.

Assessment of reporting biases

It would have been possible to assess publication bias by using a funnel plot if any meta-analysis had included 10 or more studies.

Data synthesis

We used fixed-effect analysis to carry out meta-analyses except when we suspected significant heterogeneity, at which time we could have used a random-effects model.

Subgroup analysis and investigation of heterogeneity

We planned to carry out subgroup analysis on the following groups if the data had allowed.

- Men in the following age groups: younger than 50 years of age, 50 to 80 years of age and older than 80 years of age.
- Men undergoing a primary versus a secondary investigation after failed treatment.
- Men presenting with and without additional storage LUTS.
- Men in urinary retention (i.e. with a catheter in situ) or not.
- Men with different causes of voiding dysfunction (e.g. BPE, other).

Sensitivity analysis

It would have been possible to carry out a sensitivity analysis based on eligibility criteria, such as by including and excluding results from abstract-only publications, if we had identified enough trials (Deeks 2011).

RESULTS

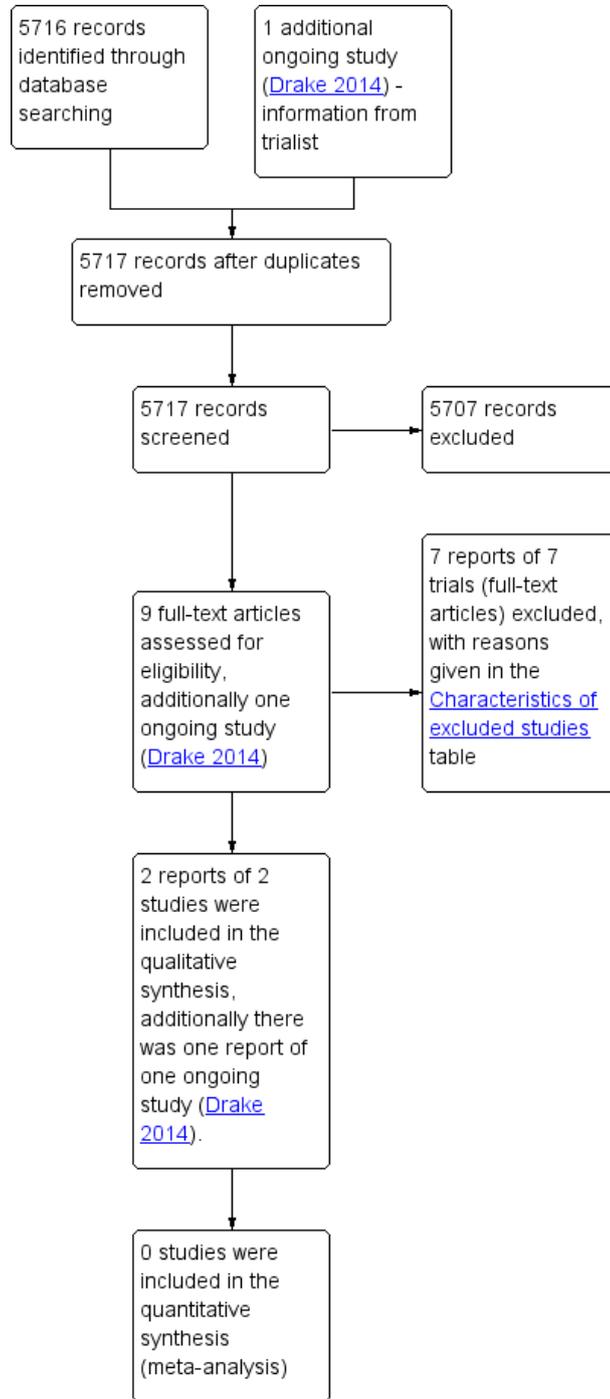
Description of studies

We screened for this review a total of 5716 records, as produced by the literature search. We retrieved the full text of nine studies for further consideration. However, we excluded seven (see below) because they did not randomly assign participants to at least one type of urodynamic investigation or one method of performing a urodynamic investigation.

Additionally we identified one ongoing trial, which is open to recruitment in the UK (Drake 2014; see [Characteristics of ongoing studies](#)).

The flow of literature through the assessment process is shown in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram (Figure 1).

Figure 1. PRISMA study flow diagram.



Included studies

We found two trials that met the inclusion criteria (De Lima 2003; Kristjansson 1999). We approached the authors of these trials to ask for further information, but we received no response. One trial was reported only as a conference abstract and provided no useable data (Kristjansson 1999).

We identified no trials that compared one method of urodynamics versus another and also provided clinical outcome data.

We have provided further details in the [Characteristics of included studies](#) table.

Methods

The two identified studies were two-arm randomised controlled trials with a standard parallel-group design. These studies:

- provided final outcome evaluation at six months (De Lima 2003); and
- reported an unclear duration of follow-up, with sole outcome evaluation detailing future management within an undefined time period (Kristjansson 1999).

Participants

Participant types included:

- men presenting between March 1993 and March 2001 with LUTS (De Lima 2003); and
- men with LUTS (Kristjansson 1999).

Subgroup analysis according to type of participant was not possible, as only one trial provided useable data, which did not specify outcomes according to subgroups (De Lima 2003).

Interventions

In the one included trial that provided useable data (De Lima 2003), participants were randomly assigned to undergoing urodynamic investigations or not before transurethral resection of the prostate (TURP). The following types of urodynamics were used.

- Cystometry and pressure-flow studies (De Lima 2003).
- Pressure-flow urodynamics (Kristjansson 1999).

Comparator or control groups received the following:

- Immediate TURP (De Lima 2003).
- Treatment based on symptoms, history or clinical findings only (Kristjansson 1999).

Outcomes

All outcomes considered in each trial are detailed in the table [Characteristics of included studies](#).

Excluded studies

Of the nine studies considered, seven were excluded because they did not report clinical outcomes (i.e. effect of the trial on urinary outcomes) nor effect on clinical decision making.

Further details are given in the table [Characteristics of excluded studies](#).

Risk of bias in included studies

One trial provided no useable data (Kristjansson 1999); therefore the rest of this section excludes evaluation of this trial. Evidence of high risk of bias was noted in the one remaining trial (De Lima 2003).

[Figure 2](#) and [Figure 3](#) provide a visual summary of the findings.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

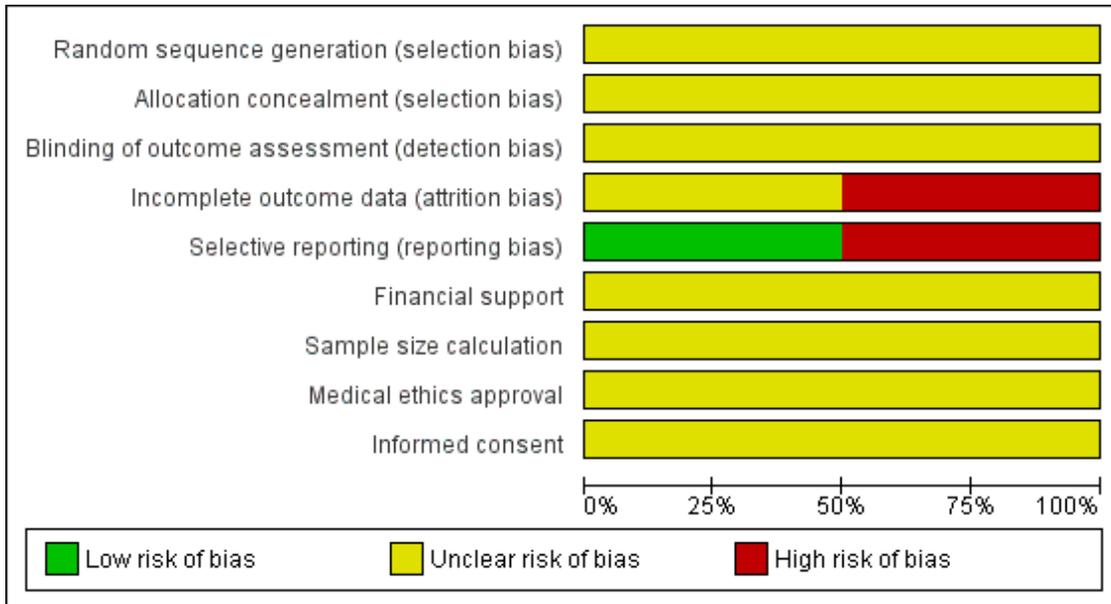


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Financial support	Sample size calculation	Medical ethics approval	Informed consent
De Lima 2003	?	?	?	-	+	?	?	?	?
Kristjansson 1999	?	?	?	?	-	?	?	?	?

Allocation

The one included trial with useable data (De Lima 2003) failed to adequately describe the method of sequence generation implemented and therefore was deemed to be at unclear risk of bias. Similarly, no information regarding the method of allocation concealment was provided; therefore the trial was deemed to be at unclear risk of bias in this domain also.

Incomplete outcome data

Data for outcomes for the pretreatment group include only participants who underwent surgery, not the 24 participants who were not operated on (who may have received some sort of treatment, e.g. drugs). This meant that we were unable to assess the overall difference and effects of immediate surgery versus urodynam-

ics before surgery. For this reason, this trial (De Lima 2003) was deemed to be at high risk of bias in this domain.

Selective reporting

A range of outcomes were reported in the trial (De Lima 2003); therefore it was deemed to be at low risk of bias.

Other potential sources of bias

Details of financial support, an adequate sample size calculation and information on medical ethics approval for the trial and informed consent of participants were not reported in the trial (De Lima 2003); therefore it was deemed to be at unclear risk of bias.

Effects of interventions

See: [Summary of findings for the main comparison Invasive urodynamic studies for the management of lower urinary tract symptoms \(LUTS\) in men with voiding dysfunction](#)

Urodynamics versus clinical management without urodynamics

The one included trial that provided useable data (De Lima 2003) addressed this comparison. This trial included 339 men, of whom 188 were randomly assigned to a urodynamic intervention.

Primary outcome (symptoms of voiding dysfunction after treatment)

No data were available for this outcome.

Secondary outcomes

Clinical decision making

Men in the urodynamic arm of one trial (De Lima 2003) were more likely to have their treatment changed after undergoing invasive urodynamic studies (proportion with change in management 24/188 (13%) vs 0/151 (0%), risk ratio (RR) 39.41, 95% confidence interval (CI) 2.42 to 642.74; Analysis 1.3). The RR for this outcome was derived using Review Manager 5.2, and although it seems high, it is correct. Because any number divided by 0 is infinity, and to work out the RR the equation is $(24/188)/(0/151)$ making the denominator zero, Review Manager has substituted a number in the region of 0.48 to make the calculation work. This results in an RR of 39.41.

Men in the clinical assessment alone group were more likely to undergo surgery as treatment for LUTS (151/151 (100%) vs 164/188 (87%), RR 0.87, 95% CI 0.83 to 0.92; Analysis 1.2).

Participant observations

No difference in IPSS score was noted between groups (mean percentage decrease in IPSS score, 57.64% in invasive urodynamic group vs 59.43% in immediate surgery group, P value = 0.22; Analysis 1.5).

Quantification of associated sign and symptoms

No difference was observed in urine flow rate before and after surgery for LUTS (mean percentage increase in urine flow rate, 140.43% in invasive urodynamic group vs 148.52% in immediate surgery group, P value = 0.13; Analysis 1.4). No data on quantifying storage LUTS or DO were available.

Clinician observations (anatomical and functional)

The number of men still obstructed six months after surgery in the clinical assessment alone group (De Lima 2003) was statistically significantly higher than the number in the group assessed by invasive urodynamic studies (27/151 (18%) vs 16/164 (10%), RR 0.55, 95% CI 0.31 to 0.97; Analysis 1.1).

Adverse effects

No data for these outcomes were available.

Quality of life

No data for these outcomes were available.

Economic outcomes

No data for these outcomes were available.

One type of urodynamics versus another

We identified no trials that compared one method of urodynamics versus another and also provided clinical outcome data.

DISCUSSION

Summary of main results

We found evidence from a single trial to suggest that invasive urodynamic studies changed the management of lower urinary tract symptoms (LUTS) in men with voiding dysfunction (risk ratio (RR) 39.41, 95% confidence interval (CI) 2.42 to 642.74). Men receiving clinical assessment alone were more likely to undergo surgery as treatment for LUTS (RR 0.87, 95% CI 0.83 to 0.92). Men receiving clinical assessment alone were statistically significantly more likely to be obstructed at six months after surgery than were those assessed using invasive urodynamic studies (RR 0.55, 95% CI 0.31 to 0.97), but this information was missing for 24 of 188 men in one arm. No differences were observed between groups in percentage increase of urine flow rate before and after intervention (140% vs 149%, P value = 0.13). Similarly, no difference was noted between groups in the decrease in IPSS score before and after intervention (58% vs 59%, P value = 0.22).

No evidence differentiated between different groups of men with LUTS ([Subgroup analysis and investigation of heterogeneity](#)). Despite the expected incidence of UTI after the procedure (Foon 2012), no data were available from the included randomised trials reporting on whether or not any adverse effects occurred.

Overall completeness and applicability of evidence

We found only two eligible trials, and of these, one did not provide useable data. The excluded studies were mainly non-randomised studies, and the study that randomly assigned participants to two different methods of performing invasive urodynamics reported no clinical outcomes, possibly because it was not designed to assess whether urodynamics should be used and was focused mainly on the best method for carrying out the investigation.

The one included study (De Lima 2003) did not provide what we considered to be important clinical outcomes. Primary outcome data were not reported, and five out of seven prespecified GRADE (Grading of Recommendations, Assessment, Development and Evaluation) outcomes were not reported, as highlighted in [Summary of findings for the main comparison](#).

One large ongoing trial, which began participant recruitment in 2014 (Drake 2014), may produce robust, reliable evidence in the future.

Quality of the evidence

The only trial with useable evidence was classed as having unclear risk of bias in most domains (Figure 3). Evidence of sufficient random sequence generation and allocation concealment was unclear. Furthermore, no data were provided for most outcomes for 24 of 188 participants in one arm of the trial. Five out of seven GRADE-specific outcomes were reported ([Summary of findings for the main comparison](#)).

Agreements and disagreements with other studies or reviews

Recent reviews on the topic of urodynamics have identified the lack of high-quality primary research confirming the clinical utility of carrying out urodynamic investigations (Hosker 2009; NICE 2010). This current review appraised the limited evidence available from one randomised controlled trial, but information gathered regarding the situations in which urodynamic studies are useful was not conclusive.

Some consensus statements and practice recommendations advocate the use of invasive urodynamic studies in cases in which patients and clinicians are contemplating surgery as treatment for LUTS (Hosker 2009; NICE 2010). Conversely, one review (Chapple 2006) recommended a trial of drugs for both benign prostatic hyperplasia (BPH) and overactive bladder syndrome (OAB) in the first instance, with urodynamics reserved for resistant cases. The value of urodynamic studies for the management of LUTS in men with voiding dysfunction requires further evaluation by randomised controlled trials, with reporting of relevant subjective, objective and economic outcomes.

AUTHORS' CONCLUSIONS

Implications for practice

When men with LUTS and voiding dysfunction were assessed by invasive urodynamic studies, they were found to be more likely to have their management changed and less likely to undergo surgery. This may have been result of the fact that urodynamics identified no objectively measurable bladder outlet obstruction (BOO) as a cause of symptoms in some men. However, information was insufficient to demonstrate whether this led to differences in subjective symptom questionnaire scores or objectively observed urine flow rate in those undergoing invasive urodynamic studies. Furthermore, no evidence was available to show whether these differences in management resulted in differences in health outcomes, such as quality of life or economic outcomes after treatment, compared with management of those who did not undergo invasive urodynamic testing.

Implications for research

Evidence regarding the value and risks of invasive urodynamics remains insufficient. Further trials are needed in all subgroups of men with voiding dysfunction whose LUTS could be investigated with urodynamics. In such trials, men would be randomly assigned to treatment based on invasive urodynamic investigations rather than treatment based on clinical history and examination and other non-invasive clinical evaluations such as flow rate testing. Future trials should include all men for whom urodynamics might be indicated to ensure that those considering surgery but who decided not to proceed as a result of urodynamic findings are not missed, and that those for whom surgery is not an option are also evaluated. Furthermore, investigators should take into account the seven specified GRADE outcomes within this review to perform a comprehensive analysis of those outcomes most important to clinical practice, as well as validated health status measures to conduct an assessment of the impact of urodynamic studies and subsequent clinical management on quality of life.

No evidence was found regarding the implications of storage LUTS and filling cystometry findings such as DO for decision making in the management of voiding dysfunction. Further trials are needed to address issues such as whether management of voiding dysfunction can reduce the severity of storage LUTS, or whether it is associated with worse outcomes after surgical management. If so, urodynamic studies might identify men who need supplementary treatment.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

De Lima 2003

Methods	Prospective randomised trial Setting: Division of Urology, University of Campinas Medical Centre, Unicamp, Campinas, São Paulo, Brazil
Participants	452 men were enrolled and 339 were randomly assigned (A, 151; B, 188) Inclusion criteria: patients undergoing transurethral resection of the prostate (TURP), those with International Prostate Symptom Score (IPSS) > 15, urinary flow < 10 mL/s Exclusion criteria: patients exposed to drugs (such as alpha agonists, anticholinergics, cholinergics, diuretic agents, oestrogens, androgens, antihypertensive medications or other agents) within the previous 2 weeks. History or evidence of prostate cancer, pelvic irradiation, urethral stricture, surgery for benign prostatic hyperplasia (BPH), neurogenic bladder dysfunction, hydronephrosis or urinary tract infection within 3 months before the study. Not obstructed or equivocal obstruction found on urodynamics 113 patients were excluded on the basis of initial exclusion criteria. After urodynamic testing, a further 24 patients were excluded, as they were not obstructed or had equivocal obstruction
Interventions	A (n = 151), immediate TURP B (n = 188), urodynamic studies before TURP
Outcomes	Number of men undergoing surgery (number/total number): A, 151/151; B, 164/188 Number of men whose treatment was changed after invasive urodynamics (number/total number): A, 0/151; B, 24/188 Symptom scores (IPSS): A, presurgery score = 21.78 +/- 3.40, postsurgery score = 8.87 +/- 3.27, % decrease = 59.43%. B, presurgery score = 21.99 +/- 3.05, postsurgery score = 9.32 +/- 3.14, % decrease = 57.64%. P value = 0.22 for figures, 0.22 for % Urine flow rate (mL/s): A, presurgery = 6.8 +/- 1.4, postsurgery = 17.0 +/- 2.1, % increase = 148.52%. B, presurgery score = 6.9 +/- 1.3, postsurgery score = 16.6 +/- 2.2, % increase = 140.43%. P value = 0.15 for figures, 0.13 for % Number of men still obstructed at 6 months post surgery as measured using urodynamics (number/total number): A, 27/151, 17.8%; B, 16/164, 9.75%. P value = 0.03
Notes	Data for outcomes for group B (pretreatment) include only participants who underwent surgery, not the 24 participants who were not operated on after urodynamic assessment (who may have had some sort of treatment, i.e. drugs); therefore cannot assess overall difference and effect of immediate surgery versus urodynamics

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Patients were prospectively randomised'

De Lima 2003 (Continued)

Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided
Incomplete outcome data (attrition bias) All outcomes	High risk	Data for outcomes for group B (pretreatment) include only participants who underwent surgery, not the 24 participants who were not operated on (who may have had some sort of treatment, i.e. drugs); therefore cannot assess overall difference and effect of immediate surgery versus urodynamics
Selective reporting (reporting bias)	Low risk	Range of outcomes reported
Financial support	Unclear risk	No information provided
Sample size calculation	Unclear risk	No information provided
Medical ethics approval	Unclear risk	No information provided
Informed consent	Unclear risk	No information provided

Kristjansson 1999

Methods	Randomised controlled trials Setting: Department of Urology, Linköping University, Sweden
Participants	Men with lower urinary tract symptoms (LUTS) and suspected bladder outlet obstruction (BOO) due to prostatic enlargement Pressure-flow studies in group A showed: <ul style="list-style-type: none"> ● 68% moderate to severe obstruction; ● 5% slight obstruction; ● 9% grey zone; ● 11% normal resistance; and ● 7% inconclusive or not done.
Interventions	A (N?): pressure-flow urodynamics with standardised treatment options B (N?): treatment decision directly without urodynamics (control)
Outcomes	Number treated conservatively (non-invasive transurethral microwave therapy (TUMT), drugs): A, 11%; B, 24% Number treated with expectancy: A, 22%; B, 3% Number treated surgically: A, 67%; B, 73%

Kristjansson 1999 (Continued)

Notes	Number of men randomly assigned not given; therefore data cannot be used Abstract format only	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Randomised between A and B'
Allocation concealment (selection bias)	Unclear risk	'Randomised between A and B'
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information provided
Selective reporting (reporting bias)	High risk	No numbers reported
Financial support	Unclear risk	No information provided
Sample size calculation	Unclear risk	No information provided
Medical ethics approval	Unclear risk	No information provided
Informed consent	Unclear risk	No information provided

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Boormans 2007	Not randomly assigned to undergo urodynamics or an alternative
Ding 1998	Non-randomised and no clinical outcomes reported
English 2012	Retrospective case review, non-randomised
Klingler 1996	Non-randomised and no clinical outcomes reported
Losco 2013	Non-randomised
Tanabe 2011	Retrospective analysis of outcomes, non-randomised

(Continued)

Zhao 2006	Compares one type of urodynamics versus another, but no clinical outcomes reported
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Characteristics of ongoing studies [ordered by study ID]

Drake 2014

Trial name or title	Urodynamics for Prostate Surgery Trial; Randomised Evaluation of Assessment Methods (UPSTREAM) for diagnosis and management of bladder outlet obstruction in men
Methods	Randomised controlled parallel-group trial
Participants	<p>Inclusion:</p> <ul style="list-style-type: none">• Men over the age of 18 considering undergoing surgery as a treatment option for their bothersome LUTS.• Willing to be randomly assigned. <p>Exclusion:</p> <ul style="list-style-type: none">• Unable to pass urine without a catheter (urinary retention).• Have a relevant neurological disease.• Undergoing active treatment, or on active surveillance, for prostate or bladder cancer.• Have previously had prostate surgery.• Not medically fit for surgery, or unable to complete outcome assessments.• Do not consent to be randomly assigned.
Interventions	A care pathway based on urodynamic tests with invasive multi-channel cystometry (“Invasive urodynamics” active intervention arm) and a care pathway based on non-invasive tests (i.e. without multi-channel cystometry) (“usual care” control arm)
Outcomes	<p>Primary outcome measure:</p> <ul style="list-style-type: none">• Difference in lower urinary tract symptoms (LUTS) between the 2 arms at 18 months, measured by the International Prostate Symptom Score (IPSS). <p>Secondary outcome measures:</p> <ul style="list-style-type: none">• Surgery rate (the relative proportion of men in each group having surgery up to 18 months after randomisation).• Cost-effectiveness analyses from the perspectives of the NHS, Personal Social Services and patients. Subsequent need for surgery will be recorded.• Adverse events of testing and treatment (e.g. infection, urinary retention).• Measures from the International Consultation on Incontinence Questionnaires (ICIQ) (Abrams et al., 2006) will be used alongside IPSS, allowing sensitive and comprehensive assessment of LUTS severity/bother, sexual function, quality of life and satisfaction with urodynamic testing. The following will be measured at 6, 12 and 18 months:<ul style="list-style-type: none">○ IPSS.○ ICIQ male LUTS (ICIQ-MLUTS).○ ICIQ sexual function in male LUTS (ICIQ-MLUTS-sex).○ ICIQ quality of life (ICIQ-QoL).○ ICIQ urodynamics satisfaction (ICIQ-UDS-S) will be administered at a single time point after urodynamic testing for relevant patients.• Maximum urinary flow rate (Q_{max}) at 18 months. For men in both arms undergoing surgery, an

Drake 2014 (Continued)

	<p>additional Qmax measure at 4 months after operation will be used as a quality measure for surgery.</p> <ul style="list-style-type: none">• EQ-5D-5L will be used to provide the quality of life weights used to calculate quality-adjusted life-years (QALYs).• Qualitative interviewing will explore user acceptability and influences on decisions made by participating men and surgeons.
Starting date	01/10/2014; currently recruiting
Contact information	marcus.drake@bui.ac.uk
Notes	Current Controlled Trials ISRCTN56164274; assigned 08/04/2014

DATA AND ANALYSES

Comparison 1. Urodynamics vs clinical management

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of men still obstructed at 6 months post surgery (objective)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Number treated with surgery	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
3 Number whose treatment was changed after assessment with or without urodynamics	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4 Urine flow rate (objective)			Other data	No numeric data
5 International Prostate Symptom Score (IPSS)			Other data	No numeric data

CONTRIBUTIONS OF AUTHORS

All review authors contributed to the writing of this review.

DECLARATIONS OF INTEREST

One of the authors of this review (MD) is the Chief Investigator of the ongoing trial UPSTREAM ([Drake 2014](#)).

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

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Disclaimer:

The views and opinions expressed therein are those of the review authors and do not necessarily reflect those of the NIHR, the NHS or the Department of Health.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The following outcome was not specified in the protocol.

- Number of men still obstructed at six months post surgery (objective).

We assessed the quality of evidence of the following two additional outcomes, as they were also considered important for clinical decision making for the patient.

- Number treated with surgery.
- Number whose treatment was changed after assessment with or without urodynamics.

We also extracted information about the following.

- Financial support.
- Sample size calculation.
- Medical ethics approval.
- Informed consent.

These domains were not specified in the protocol as part of risk of bias assessment. However, we believe that Information about financial support, sample size calculation, medical ethics approval and informed consent is important and highlights various aspects of how the trial was conducted.