Cochrane
Library

Cochrane Database of Systematic Reviews

Urodynamic studies for management of urinary incontinence in children and adults (Review)

Clement KD, Lapitan MCM, Omar MI, Glazener CMA

Clement KD, Lapitan MCM, Omar MI, Glazener CMA.

Urodynamic studies for management of urinary incontinence in children and adults.

Cochrane Database of Systematic Reviews 2013, Issue 10. Art. No.: CD003195.

DOI: 10.1002/14651858.CD003195.pub3.

www.cochranelibrary.com

TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
SUMMARY OF FINDINGS FOR THE MAIN COMPARISON	3
BACKGROUND	6
OBJECTIVES	9
METHODS	9
RESULTS	12
Figure 1.	14
Figure 2.	16
Figure 3.	17
DISCUSSION	20
AUTHORS' CONCLUSIONS	21
ACKNOWLEDGEMENTS	22
REFERENCES	22
CHARACTERISTICS OF STUDIES	30
DATA AND ANALYSES	51
Analysis 1.1. Comparison 1 Urodynamics versus clinical management, Outcome 1 Number with incontinence within first year (subjective).	53
Analysis 1.2. Comparison 1 Urodynamics versus clinical management, Outcome 2 Number with incontinence after first year (subjective).	54
Analysis 1.3. Comparison 1 Urodynamics versus clinical management, Outcome 3 Number with incontinence or not improved within first year (subjective).	54
Analysis 1.4. Comparison 1 Urodynamics versus clinical management, Outcome 4 Number with incontinence or not improved after first year (subjective).	55
Analysis 1.5. Comparison 1 Urodynamics versus clinical management, Outcome 5 Number treated conservatively.	55
Analysis 1.6. Comparison 1 Urodynamics versus clinical management, Outcome 6 Number treated with drugs.	56
Analysis 1.7. Comparison 1 Urodynamics versus clinical management, Outcome 7 Number treated with surgery.	57
Analysis 1.8. Comparison 1 Urodynamics versus clinical management, Outcome 8 Number whose treatment was changed after urodynamics.	58
Analysis 1.9. Comparison 1 Urodynamics versus clinical management, Outcome 9 Number not returning for further treatment.	58
Analysis 1.10. Comparison 1 Urodynamics versus clinical management, Outcome 10 Number not satisfied with treatment.	59
Analysis 1.11. Comparison 1 Urodynamics versus clinical management, Outcome 11 Number with urgency symptoms or urgency incontinence after treatment.	59
Analysis 1.12. Comparison 1 Urodynamics versus clinical management, Outcome 12 Volume/weight of urine lost on pad test.	60
Analysis 1.13. Comparison 1 Urodynamics versus clinical management, Outcome 13 Number of incontinence episodes in 24 hours.	60
Analysis 1.14. Comparison 1 Urodynamics versus clinical management, Outcome 14 Number with incontinence within first year (objective).	61
Analysis 1.15. Comparison 1 Urodynamics versus clinical management, Outcome 15 Number with incontinence after first year (objective).	61
Analysis 1.16. Comparison 1 Urodynamics versus clinical management, Outcome 16 Number with adverse events / complications.	62
Analysis 1.17. Comparison 1 Urodynamics versus clinical management, Outcome 17 Number with voiding dysfunction after treatment.	62
Analysis 1.18. Comparison 1 Urodynamics versus clinical management, Outcome 18 Deaths.	63
Analysis 1.19. Comparison 1 Urodynamics versus clinical management, Outcome 19 Health status measures.	64
WHAT'S NEW	67

HISTORY	67
CONTRIBUTIONS OF AUTHORS	67
DECLARATIONS OF INTEREST	68
SOURCES OF SUPPORT	68
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	68
INDEX TERMS	68

Urodynamic studies for management of urinary incontinence in children and adults

Keiran David Clement¹, Marie Carmela M Lapitan², Muhammad Imran Omar³, Cathryn MA Glazener⁴

¹ Cochrane Incontinence Group, University of Aberdeen, Aberdeen, UK. ² Division of Urology, Philippine General Hospital, Manila, Philippines. ³ Academic Urology Unit, University of Aberdeen, Aberdeen, UK. ⁴ Health Services Research Unit, University of Aberdeen, Aberdeen, UK

Contact address: Cathryn MA Glazener, Health Services Research Unit, University of Aberdeen, 3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, Scotland, AB25 2ZD, UK. c.glazener@abdn.ac.uk.

Editorial group: Cochrane Incontinence Group.

Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 10, 2013.

Citation: Clement KD, Lapitan MCM, Omar MI, Glazener CMA. Urodynamic studies for management of urinary incontinence in children and adults. *Cochrane Database of Systematic Reviews* 2013, Issue 10. Art. No.: CD003195. DOI: 10.1002/14651858.CD003195.pub3.

Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Urodynamic tests are used to investigate people who have urinary incontinence or other urinary symptoms in order to make a definitive, objective diagnosis. The aim is to help select the treatment most likely to be successful. The investigations are invasive and time consuming.

Objectives

The objective of this review was to determine if treatment according to a urodynamic-based diagnosis, compared to treatment based on history and examination, led to more effective clinical care of people with urinary incontinence and better clinical outcomes.

The intention was to test the following hypotheses in predefined subgroups of people with incontinence:

- (i) urodynamic investigations improve the clinical outcomes;
- (ii) urodynamic investigations alter clinical decision making;
- (iii) one type of urodynamic test is better than another in improving the outcomes of management of incontinence or influencing clinical decisions, or both.

Search methods

We searched the Cochrane Incontinence Group Specialised Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and MEDLINE In-Process, handsearching of journals and conference proceedings (searched 19 February 2013), and the reference lists of relevant articles.

Selection criteria

Randomised and quasi-randomised trials comparing clinical outcomes in groups of people who were and were not investigated using urodynamics, or comparing one type of urodynamic test against another were included. Trials were excluded if they did not report clinical outcomes.

Data collection and analysis

Two review authors independently assessed trial quality and extracted data.

Main results

Eight trials involving around 1100 people were included but data were only available for 1036 women in seven trials, of whom 526 received urodynamics. There was some evidence of risk of bias. The four deaths and 12 dropouts in the control arm of one trial were unexplained.

There was significant evidence that the tests did change clinical decision making. Women in the urodynamic arms of three trials were more likely to have their management changed (proportion with change in management compared with the control arm 17% versus 3%, risk ratio (RR) 5.07, 95% CI 1.87 to 13.74), although there was statistical heterogeneity. There was evidence from two trials that women treated after urodynamic investigations were more likely to receive drugs (RR 2.09, 95% CI 1.32 to 3.31). On the other hand, in five trials women undergoing treatment following urodynamic investigation were not more likely to undergo surgery (RR 0.99, 95% CI 0.88 to 1.12).

There was no statistically significant difference however in the number of women with urinary incontinence if they received treatment guided by urodynamics (37%) compared with those whose treatment was based on history and clinical findings alone (36%) (for example, RR for the number with incontinence after the first year 1.02, 95% CI 0.86 to 1.21). It was calculated that the number of women needed to treat was 100 women (95% CI 86 to 114 women) undergoing urodynamics to prevent one extra individual being incontinent at one year.

One trial reported adverse effects and no significant difference was found (RR 1.10, 95% CI 0.81 to 1.50).

Authors' conclusions

While urodynamic tests did change clinical decision making, there was some evidence that this did not result in better outcomes in terms of a difference in urinary incontinence rates after treatment. There was no evidence about their use in men, children, or people with neurological diseases. Larger definitive trials are needed in which people are randomly allocated to management according to urodynamic findings or to management based on history and clinical examination to determine if performance of urodynamics results in higher continence rates after treatment.

PLAIN LANGUAGE SUMMARY

Urodynamic studies (tests) for the management of urinary incontinence in children and adults

Urinary incontinence is defined as the involuntary loss of urine and is the inability to retain urine in the bladder between voluntary acts of urination. It has a number of different causes. Urodynamic tests are used to measure nerve and muscle function, pressure around and in the bladder, flow rates, and other factors which might help to explain why someone leaks urine or what type of leakage they have. Some people find these tests embarrassing and uncomfortable. However, they might show what the cause of the incontinence is, or what sort of incontinence the person has, so that the correct treatment can be chosen. This might improve the success of the treatment.

Eight trials were found, which included around 1100 people, although information was only available for 1036 women. There was not enough evidence to determine whether the urodynamic tests led to better outcomes. There was some evidence that urodynamic testing increased the number of people given drugs but not the number of people undergoing surgery. This did not result in any difference in the number of people who leaked urine, and it was not known whether they had a better quality of life.

More research is needed in which people are randomised to having treatment decisions based on either their symptoms and examination alone or after taking into account the extra information provided by urodynamic tests.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [\[Explanation\]](#)

Urodynamics compared to clinical management for management of urinary incontinence in children and adults							
Patient or population: patients with management of urinary incontinence in children and adults							
Settings:							
Intervention: urodynamics							
Comparison: clinical management							
Outcomes	Illustrative comparative risks* (95% CI)			Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk		Corresponding risk				
	CLINICAL MANAGEMENT	MANAGE- URODYNAMICS					
Number with incontinence after first year (subjective)	Study population			RR 1.02 (0.86 to 1.21)	802 (4 studies)	⊕⊕⊕⊕ high ¹	
	362 per 1000		370 per 1000 (312 to 439)				
	Moderate						
	302 per 1000		308 per 1000 (260 to 365)				
Number treated with surgery	Study population			RR 0.99 (0.88 to 1.12)	982 (5 studies)	⊕⊕⊕○ moderate ^{1,2,3}	
	786 per 1000		779 per 1000 (692 to 881)				
	Moderate						
	914 per 1000		905 per 1000 (804 to 1000)				

Number not satisfied with treatment	Study population		RR 0.9 (0.55 to 1.49)	644 (2 studies)	⊕⊕○○ low ^{1,4}
	91 per 1000	82 per 1000 (50 to 136)			
	Moderate				
	91 per 1000	82 per 1000 (50 to 136)			
Number whose treatment was changed after urodynamics	Study population		RR 5.07 (1.87 to 13.74)	272 (3 studies)	⊕⊕○○ low ^{1,3,5}
	30 per 1000	151 per 1000 (56 to 410)			
	Moderate				
	30 per 1000	152 per 1000 (56 to 412)			
Incidence of urinary tract infection associated with urodynamics - not reported	See comment	See comment	Not estimable	-	See comment
Quality of life measures following treatment after urodynamics Health status measures - General health King's QoL scores at 6 months		The mean quality of life measures following treatment after urodynamics in the intervention groups was 6.4 lower (16.61 lower to 3.81 higher)		75 (1 study)	⊕⊕⊕○ moderate ^{1,6,7}
Health economics measure - not reported	See comment	See comment	Not estimable	-	See comment

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) 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.

¹ Not applicable as there are fewer than 10 trials

² 4/5 trials included in the meta-analysis had low risk of bias and it was unclear in the fifth trial

³ Results are inconsistent

⁴ Crosses line of no effect and the CI is very wide (0.55 to 1.49)

⁵ No explanation was provided

⁶ Not applicable

⁷ Imprecise result

BACKGROUND

Urodynamic tests are used in the diagnostic investigation of people complaining of urinary incontinence or bothersome lower urinary tract symptoms (LUTS) during bladder filling or voiding, or both. Urodynamic investigations measure bladder pressure and urine flow rate during bladder filling and voiding in order to assess the neuromuscular function and dysfunction of the urinary tract, and identify the cause(s) of urine storage and voiding dysfunction.

In the evaluation of urinary incontinence, the aim of urodynamic tests is to demonstrate incontinence objectively and differentiate between types of incontinence so that the most effective method of treatment can be selected. However, there is as yet no evidence that this approach improves clinical outcomes or that urodynamic tests can predict who will be cured of or develop overactive bladder (OAB) or voiding dysfunction after surgery for stress incontinence (Hosker 2009).

In the evaluation of urinary incontinence in men, urodynamics are commonly used in the diagnosis of stress urinary incontinence (SUI), OAB and LUTS such as voiding dysfunction (Hosker 2009). In the evaluation of voiding dysfunction in men, it is thought to be important to distinguish between LUTS due to bladder outlet obstruction (BOO) or due to detrusor underactivity as management decisions can be altered depending on the findings; there is some low level evidence that making this distinction is important as clinical outcomes are affected (Hosker 2009). However, this review is confined to the use of urodynamics to help in the diagnosis of stress and urgency incontinence only. Urodynamic studies amongst people with LUTS and voiding dysfunction will be addressed in a separate Cochrane review. Finally, there is strong expert opinion amongst clinicians that the management of certain types of neurogenic bladder requires urodynamic evaluation (Hosker 2009).

Description of the condition

Definitions and terminology

Urinary incontinence

Urinary incontinence is defined as 'a symptom or sign of any involuntary loss of urine' (Abrams 2002) and 'the involuntary loss of urine' (Haylen 2010). Continence (storage of urine) is maintained when the pressure in the outlet from the bladder (urethral pressure) is greater than the pressure inside the bladder itself (intravesical pressure). The principal lower urinary tract storage symptoms are due either to urethral sphincter weakness causing stress urinary incontinence or detrusor overactivity resulting in overactive bladder symptoms (OAB) with or without urgency urinary incontinence.

Urinary incontinence is a common problem. Estimates from a variety of sources present a picture of increasing prevalence during young adult life (prevalence 20% to 30%), a broad peak around middle age (prevalence 30% to 40%) and then a steady increase in the elderly (prevalence 30% to 50%) (Hunnskaar 2002). The presence of severe or 'significant' incontinence (defined by a high frequency or amount of leakage, soakage of clothes, usage of pads, etc) is fairly consistent and ranges between 3% and 17%, with most studies reporting between 6% and 10%. These figures may not reflect the true scope of the problem because embarrassment and other factors may lead to under-reporting, or alternatively because some people may have incontinence without finding it bothersome. Incontinence is more frequent amongst women, increases with age and is particularly common amongst those in residential care.

Urinary incontinence is commonly divided into two types based on the symptoms of stress and urgency.

- Stress urinary incontinence (SUI) is the complaint of involuntary loss of urine on effort or physical exertion (e.g., sporting activities) or on sneezing or coughing (Haylen 2010). This is usually due to anatomical defects in the structures that support the bladder and urethra, or dysfunction of the neuromuscular components that help control urethral pressure, or both. It is less common in men than women. The diagnosis 'stress incontinence' is based on the assumption that the bladder (intravesical) pressure exceeds the urethral pressure (such as when the abdominal pressure rises during coughing or laughing), in the absence of detrusor muscle (bladder smooth muscle) contraction.
- Urgency urinary incontinence (UII) is the involuntary leakage of urine accompanied by or immediately preceded by urgency (Haylen 2010). It usually results from involuntary increases in the bladder pressure due to detrusor overactivity (bladder smooth muscle contractions).
- When symptoms of stress and urgency incontinence are present together, this is called mixed urinary incontinence (MUI) (Haylen 2010).

When symptoms of stress or urgency incontinence are confirmed objectively using urodynamic investigations, the two main types of incontinence are called urodynamic stress incontinence (USI), implying the sign of stress incontinence in the absence of detrusor muscle contraction, and detrusor overactivity (DO) incontinence (DOI), incontinence triggered by a detrusor muscle contraction, respectively (Haylen 2010).

Overactive bladder syndrome (OAB) is diagnosed when urinary urgency occurs in the absence of urinary tract infection; other urinary symptoms such as urgency urinary incontinence, detrusor overactivity, frequency and nocturia may also be present.

Voiding dysfunction

Voiding symptoms are experienced during the voiding phase (emptying the bladder). Voiding dysfunction can include slow stream,

intermittent stream, splitting or spraying, hesitancy, straining or terminal dribble (Haylen 2010). Bladder outlet obstruction (BOO) and detrusor underactivity are the two most common causes of voiding dysfunction but they cannot be distinguished by patient report of symptoms such as slow stream. Voiding difficulties and other LUTS due to BOO are more common in men but the use of urodynamics in their diagnosis and management is not covered in the scope of the current review.

Description of the intervention

The term 'urodynamics' encompasses a number of varied physiological tests of bladder and urethral function that aim to demonstrate an underlying abnormality of storage or voiding (NCCWCH 2006). The term is often used loosely to mean multichannel cystometry.

Urodynamic studies are invasive, usually involving at least the insertion of a catheter into the urethra. A range of parameters may be measured, including pressure in the urethra, bladder and abdomen, electrical nerve function and urinary flow rates. A significant number of people who are tested find the procedures embarrassing, painful or distressing (Gorton 1999). However, urodynamics has been invaluable in increasing our understanding of the different processes involved in both continence and incontinence (Homma 1999).

During urodynamic studies in women, the most important aim is to reproduce the symptoms of incontinence. This is usually achieved by using a urinary catheter to fill the bladder with water, physiological saline or contrast medium (or the normal urine output during time of testing) in order to provoke the conditions resulting in incontinence (mediated by coughing, standing up or with other manoeuvres). The bladder sensations are reported by the patients as desire to void, discomfort or pain.

Another aspect of urodynamic investigation is the measure of pressures during the phases of the micturition cycle, that is, during filling or voiding, or both. The principal pressures are:

- the intravesical pressure (within the bladder); and
- the abdominal pressure (within the abdominal cavity, usually measured in the vagina or rectum).

Intravesical pressure (P_{ves}) is a summation of pressures generated by bladder contraction (P_{det}) and the abdominal pressure transmitted to the bladder wall (P_{abd}). The difference between the intravesical and abdominal pressure is called the detrusor pressure (P_{det}). Pressure is usually measured by a strain gauge outside the body: the pressures generated inside the body must be transmitted to it by fluid-filled catheters. Alternatively, transducers to measure pressure can be mounted on a 'microtip' catheter that can be inserted into a body cavity. The variation in pressure pattern changes (rather than absolute values) are usually used to diagnose various conditions.

Urine flow rate measurement and residual volume measurement

Aside from pressure measurements, urodynamic investigation may also involve the measurement of urine flow rates. Uroflowmetry is a measure of the rate of flow of urine, and may be followed by the measurement of the residual volume either by ultrasonographic scanning of the bladder or by catheterisation. Pressure-flow studies relate flow rates to changes in pressure during bladder emptying.

Other types of urodynamics

Surface electromyography is an indirect measure of pelvic floor and sphincter muscle contractility. Videourodynamics involves synchronous X-ray or ultrasound imaging of the bladder with multichannel cystometry and is so called because originally the information was recorded on a videotape. Ambulatory urodynamics involves multichannel cystometry carried out with physiological bladder filling rates and using portable recording devices that enable the patients to perform their usual activities during the test. Gas cystometry uses carbon dioxide as the medium to fill the bladder during the study. It has been found to be unreliable and is now not recommended (Homma 1999).

Risks of urodynamics

The main risks of urodynamic tests are those associated with urethral catheterisation, such as dysuria (painful urination) and urinary tract infection (UTI). A separate Cochrane review addresses interventions to reduce the risk of infection (Lathe 2012). Urodynamic tests also require the use of sophisticated machines and technical expertise, which may result in considerable expense to the patient or the healthcare system. Many women also find them an uncomfortable or embarrassing experience.

Furthermore, the reliability of urodynamics in diagnosing some forms of incontinence may lead to false-positive or false-negative results. For example, a false-positive result for DO due to artefactual detrusor contractions (for example, due to the insertion of a catheter) may lead to the inappropriate prescription of drugs for this condition and hence the postponement of surgery. Conversely, a false-negative result for DO may lead to conservative or surgical therapy instead, and therefore failure to treat the symptoms correctly.

How the intervention might work

Although urodynamic tests are widely used, their place in the investigation and management of incontinence is controversial. It has been questioned whether urodynamic findings are reproducible (Lose 1996; Sorensen 1988) and whether urodynamics are sufficiently sensitive and specific to identify the underlying pathology reliably (Lose 1998a). It has long been recognised that there is considerable discrepancy between patients' symptoms and the

urodynamic diagnosis (Cardozo 1980; Gorton 2000; Jarvis 1980). Despite this, the Royal College of Obstetricians and Gynaecologists in the UK recommends that women undergoing surgery for stress incontinence should have urodynamic investigations prior to treatment (RCOG 2003). This is not necessarily common practice in the UK (Black 1997) or internationally (Duggan 2003), however.

There is currently no consensus about whether or not urodynamic investigations need to be performed to guide management. Indeed, no published research supports a need for cystometric testing in routine or basic evaluation of urinary incontinence (AHCPR 1996). For example, in a survey of 442 women treated surgically for stress incontinence, Black and colleagues found that the likelihood of improvement was similar regardless of whether or not urodynamic pressure studies had been conducted before surgery (Black 1997). Although this study did not conclusively show that urodynamics had little or no prognostic value, it suggested that the role of urodynamic testing needed reappraisal.

The need for preoperative urodynamics is often justified by the consideration that pre-existing DO may be either a contra-indication for surgery or at least carry a worse prognosis. However, in one study women who suffered from urgency before operation actually reported a reduction in urgency after surgery (Ward 2002). Similarly in a report of the success of tension-free vaginal tape surgery in elderly women (all of whom had preoperative urodynamics), 46% had preoperative urgency cured after surgery and 21% developed it de novo (Sevestre 2003). This symptom is commonly believed to worsen after surgery for stress incontinence, is often considered to be a contra-indication and is thought to result in worse outcomes, but the reverse may be the case in practice as preoperative urgency symptoms resolve in a substantial proportion (50% to 65%) of women after surgery (Hosker 2009). It seems likely that this finding would also apply to DO, and therefore its preoperative diagnosis would seem to be unnecessary as it would not influence management. Similarly, the value of distinguishing between intrinsic sphincter deficiency and bladder neck or urethral mobility has also not been established, and the official position of the International Continence Society (ICS) is that these are simplistic and arbitrary terms and not to be used until further research has been done (Abrams 2002).

A Committee of the International Consultation on Incontinence (ICI) has published a recent overview of the best scientific evidence with regard to the role of urodynamics in the management of people with urinary incontinence or voiding difficulties (Hosker 2009). In contrast to the conclusions of the previous consultation (Griffiths 2005), the new Committee concluded that “urodynamic studies should be carried out in all women prior to surgery for stress urinary incontinence” (Hosker 2009). Nevertheless, they also found that the chance of developing overactive bladder syndrome or urinary urgency after surgery was largely unpredictable (by urodynamics or any other method) (). Nor was urodynamics clearly useful as a predictor of surgical failure (Hosker 2009) or

of postoperative voiding dysfunction (Hosker 2009). Nor was it useful to predict which women would develop SUI after prolapse surgery (Hosker 2009).

They did suggest that “a well-designed multicentre study should address the question as to whether women with symptoms of pure stress urinary incontinence are more at risk of failure from surgical treatment of their incontinence without pre-operative urodynamics or have more adverse events following surgery without pre-operative urodynamics” than women who do have these investigations.

The committee also felt that the cost effectiveness of urodynamic testing should be taken into account when discussing the necessity of urodynamic investigation. For example, it was not considered to be cost effective to carry out urodynamic studies in a primary healthcare setting for women with predominant stress symptoms. It is possible that one type of urodynamic investigation may provide more useful information than another. This is the issue addressed by studies comparing the utility of ambulatory urodynamics and conventional urodynamics, particularly in diagnosing DO and UUI. In one study conventional urodynamic tests were normal but an alternative method (ambulatory urodynamics) provided a pathological diagnosis. However, in this study subsequent management did not appear to be influenced by the new test results as only two thirds of those diagnosed with DO were treated with anticholinergic drugs, of whom less than half improved, and a quarter of those who did not have DO were treated with drugs anyway (Gorton 2000).

The place for drug treatment of urinary incontinence is the subject of other Cochrane Reviews (Alhasso 2006; Campbell 2007; Madhuvrata 2012; Mariappan 2005) and one on anticholinergic drugs (Nabi 2006) and another on adrenergic agonists (Alhasso 2005) have been published.

Why it is important to do this review

Urinary incontinence is an increasingly common problem. In 2008, the ICI (International Consultation on Incontinence) estimated that, globally, there were 250 million adult females and 98 million adult men with some form of incontinence, with these figures expected to rise to 275 and 109 million respectively by 2013 (Abrams 2009).

The diagnostic accuracy of a test is normally determined by verifying the test results against a reference (gold) standard which defines true disease status. The diagnostic performance of urodynamics cannot be assessed in this way, however, because there is no accepted gold standard. In the absence of a gold standard, there may be no alternative to evaluating whether the treatment response after urodynamics leads to more health gain than where the treatment response is based on tests which do not include urodynamics.

Furthermore, the tests are not without cost. They are invasive, expensive and may have adverse effects. For the financial year 2011

to 2012, in the National Health Service (NHS) in England urodynamic testing of one patient on an outpatient basis was calculated to cost GBP 147. This increased to GBP 340 on a day-case basis. With regards to adverse effects, it is estimated that a single urodynamic episode results in a 3% to 20% incidence of symptomatic UTI (Lathe 2012). The use of prophylactic antibiotics to reduce this rate is addressed in another Cochrane review (Lathe 2012). The value of accurate diagnosis depends on the availability and effectiveness of appropriate treatments. It is of no clinical value unless it is known, for example, that urodynamics distinguishes between a group for whom surgery is effective and another group for whom it is not effective or is contra-indicated, or where management needs to be altered in a specific way.

The value of urodynamic investigation in the diagnosis and management of people complaining of incontinence is therefore open to question (Ramsay 1995). Urodynamic studies amongst people with voiding dysfunction will be addressed in a future update of this review.

This review addresses whether the extra information generated by urodynamics influences clinical decision making for people with incontinence, and particularly whether it leads to an improvement in clinical and economic outcomes.

OBJECTIVES

The objective of this review was to determine if treatment according to a urodynamic-based diagnosis, compared to treatment based on history and examination, led to more effective clinical care of people with urinary incontinence and better clinical outcomes.

The intention was to test the following hypotheses in predefined subgroups of people with incontinence:

- (i) urodynamic investigations improve the clinical outcomes;
- (ii) urodynamic investigations alter clinical decision making;
- (iii) one type of urodynamic test is better than another in improving the outcomes of management of incontinence or influencing clinical decisions, or both.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised or quasi-randomised controlled trials on the management of urinary incontinence in which people with symptoms

were randomised to having urodynamics in at least one arm of the study.

Studies which did not report the clinical outcomes of incontinence management or effects on clinical decision making were excluded.

Types of participants

All people presenting for the investigation and management of their urinary incontinence, as defined by the trialists.

It was intended to examine urodynamic tests in the following subgroups of people: women, men, people with neurological diseases, and children. Studies with participants who had primary incontinence or recurrent incontinence after failed treatment were included.

Types of interventions

1. Urodynamic investigations as part of the diagnostic work-up prior to management decisions compared with work-up without recourse to urodynamics (including clinical history, examination, symptoms reported on enquiry or by questionnaire, urinary diaries, pad tests, etc).

2. Comparison of different types of urodynamics programmes prior to management decisions.

All types of urodynamics were eligible for consideration in this review (AHCPR 1996; Homma 1999). These include:

- cystometry (simple, multichannel or subtracted: study of the pressure-volume relationship of the bladder during urine storage (filling cystometry) and urine expulsion (voiding cystometry));
 - urethral pressure measurements (profilometry: measurement of the pressure within the urethra; the urethral closure pressure is the difference between the intraluminal pressure in the urethra and the intravesical pressure in the bladder at rest or during stress such as coughing or straining);
 - leak point pressure measurements (the pressure within the bladder at which leakage of urine from the urethra occurs: a direct measure of the closure function of the entire urethra);
 - uroflowmetry, and residual urine measurement (recording of the volume of fluid expelled via the urethra per unit time during voiding, and the volume of urine left in the bladder after voiding);
 - pressure-flow studies of voiding (study of the bladder pressure-urine flow rate relationship during voiding);
 - electromyography (direct measurement of the contractility of the muscles concerned with continence, i.e., urethral sphincter, anal sphincter, or pelvic floor muscles);
 - video urodynamics (radiologic (X-ray) imaging and urodynamic measurements of the lower urinary tract performed simultaneously during filling and voiding); and
 - ambulatory urodynamic monitoring (urodynamic test performed under physiologic bladder filling and circumstances where the patient is free to move around).

The following comparisons were made:

1. urodynamics versus clinical management without urodynamics;
2. one type of urodynamics versus another.

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

Types of outcome measures

Outcome measures used in this review were selected on the basis of their relevance to the clinical cure or improvement of incontinence. We regarded the principal measures of effectiveness as the proportion of people still incontinent (wet) following a therapeutic intervention, and the proportion of people whose condition was not improved. In addition, the effect of urodynamics in influencing clinical decisions was quantified. Studies which did not report clinical outcomes or effects on clinical decision making were excluded.

We adopted the recommendations made by the Standardisation Committee of the International Continence Society (ICS) for outcomes of research investigating the effect of therapeutic interventions for people with urinary incontinence or voiding dysfunction. These outcome categories include: observations (symptoms) of people being investigated for incontinence; quantification of symptoms; the clinician's observations (anatomical and functional); quality of life; and socioeconomic measures (Lose 1998a). Data could be obtained from both history and questionnaire assessment, or from urinary diaries (including time and type of incontinence, frequency of micturition, and voided volumes) and pad tests (a quantitative estimate of weight of urine lost under standard conditions).

The review also included adverse events as outcome measures.

Primary outcomes

The proportion of people with persistent urinary incontinence after treatment following assessment with and without urodynamic studies.

Secondary outcomes

A. Clinical decision making

- Number of people receiving conservative, drug or surgical treatments
- Number of people whose treatment was changed after urodynamics
- Need for repeat or alternative treatment

B. Observations of people being investigated for incontinence

- Persistent incontinence or lack of improvement in the short term (< 12 months) and longer term (> 12 months)
- Voiding dysfunction (subjective)
- Urgency symptoms or urgency incontinence (post-intervention, clinical diagnosis without urodynamics)
- Satisfaction with treatment

C. Quantification of people's symptoms

- Pad changes over 24 hours (from self-reported number of pads used)
- Pad tests of quantified leakage (mean volume or weight of urine loss on pad)
- Incontinent episodes over 24 hours (from self-completed bladder chart or diary)

D. Clinician's observations

- Objective assessment of incontinence cure or improvement at post-intervention urodynamics testing
- Detrusor overactivity (post-intervention urodynamic diagnosis)
- New or recurrent urogenital prolapse (in women)

E. Adverse effects

- Adverse events (side effects of the urodynamic investigation, or of treatment selected as a result of the investigation)
- Deaths

F. Quality of life

- Time to return to normal activity
- General health status measures (physical, psychological, other)
- Condition-specific health measures (specific instruments designed to assess incontinence or voiding dysfunction)

G. Economic outcomes

- Health economic measures
- Costs of investigations
- Costs of treatments

H. Other outcomes

- Non-prespecified outcomes judged important when performing the review

Primary and secondary outcomes, as defined above, were classified by the review authors as 'critical', 'important', or 'not important' for decision making from the patient's perspective. The GRADE working group strongly recommends including up to seven critical outcomes in a systematic review.

In this systematic review, GRADE methodology was adopted for assessing the quality of the evidence for the following outcomes.

- Number of people whose treatment plan was altered following urodynamics.
- Incidence of urinary tract infection associated with urodynamics.
- Number of women having surgery for incontinence following urodynamics.
- Number of people with incontinence after 12 months (subjective).
- Subjective patient satisfaction with treatment.
- Quality of life measures following treatment after urodynamics.
- Health outcome measures such as quality-adjusted life years (QALYs).

Search methods for identification of studies

We did not impose any language, status of publication or other limits on the searches.

Electronic searches

This review has drawn on the search strategy developed for the Incontinence Review Group. Relevant trials were identified from the Group's Specialised Register of controlled trials which is described, along with the Group's search strategy, under the Incontinence Group's [module](#) in *The Cochrane Library*. The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, CINAHL, and handsearching of journals and conference proceedings. The Incontinence Group Specialised Register was searched using the Group's own keyword system, and the search terms used were:

{design.cct*} OR {design.rct*}

AND

{topic.urine*}

AND

{intervent.invest*}

(All searches were of the keyword field of Reference Manager 12, Thomson Reuters).

The date of the most recent search of the register for this review was 19 February 2013. The trials in the Incontinence Group Specialised Register are also contained in CENTRAL.

Searching other resources

We searched the reference lists of relevant articles.

Data collection and analysis

Studies were excluded if they were not randomised or quasi-randomised trials involving people or children with urinary incontinence. In addition, studies which did not report clinical outcomes or an effect on clinical decision making were excluded. Excluded studies were listed, with details of the interventions compared and the reasons for their exclusion.

Included data were processed as described in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)).

Selection of studies

The reports of all possibly eligible studies were evaluated by two review authors for methodological quality and appropriateness for inclusion without prior consideration of the results. Any disagreements were resolved by discussion. Where these were not resolved, arbitration would rest with a third person.

For this review, no disagreements arose regarding the assessment of the review authors on the methodological quality nor appropriateness for inclusion of the studies selected.

Data extraction and management

Data extraction was undertaken independently by the review authors and cross checked using a customised data collection form. Where data may have been collected but not reported, clarification was sought from the trialists. Included trial data were processed using RevMan software as described in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). Authors of original reports were contacted for extra information and data if required.

Assessment of risk of bias in included studies

Critical appraisal and assessment of risk of bias were undertaken by each review author independently as described in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). The following were assessed and reported in the Cochrane risk of bias tables.

- Was the allocation sequence adequately generated?
- Was allocation adequately concealed?
- Were incomplete outcome data adequately addressed?
- Are reports of the study free of suggestion of selective outcome reporting (or, were all relevant outcomes adequately reported)?
- Were full details of financial support and funding provided for the trial?
- Was a sample size calculated prior to recruitment and did it take in to consideration the required numbers needed to meet a particular statistical power?
- Was ethical approval sought and gained prior to the beginning of the trial?

- Was the study apparently free of other problems that could put it at a high risk of bias?

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

In this review update, we decided to exclude performance bias as a domain of risk of bias assessment from the risk of bias assessment table. Blinding of participants undergoing urodynamic testing or the staff carrying out the test is not possible and would have been judged as 'high risk' across all the 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 used means and standard deviations to derive a mean difference (MD) if the outcomes were measured in the same way between trials. Any continuous data that were the product of a number of different scales (for example, scales used to assess symptoms such as pain or quality of life) were summarised as the standardised mean difference (SMD) using a fixed-effect model. A fixed-effect model was used for calculation of all summary estimates and 95% confidence intervals (CIs) except if there was significant heterogeneity. When appropriate, meta-analysis was undertaken.

Unit of analysis issues

Analysis of studies with non-standard designs, such as crossover trials and cluster-randomised trials, would have been undertaken as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Studies with multiple treatment groups would be analysed 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 to mean that all participants were analysed in their randomised groups whether or not they received the allocated intervention. We included data as they were reported for each outcome and did not impute missing values but used the data as presented by the trialists. However, we would carry out sensitivity analyses if there was a differential dropout from the randomised groups or another reason to suspect systematic bias from missing data.

Assessment of heterogeneity

Trial data were only combined if there was no clinical heterogeneity. Differences between trials were investigated if significant heterogeneity was found from the Chi² test or the I² statistic (Higgins

2003), or was obvious from visual inspection of the results and data plots. Visual heterogeneity was deemed positive when the confidence intervals of studies did not overlap. This was then confirmed by formal statistical testing. Statistical heterogeneity was regarded as substantial if either the I² was greater than 50%, as reported by the *Cochrane Handbook for Systematic Reviews of Interventions*, or there was a low P value ($P < 0.10$) in the Chi² test for heterogeneity. In those outcomes, a random-effects model was used.

Assessment of reporting biases

Publication bias would have been examined by a funnel plot if there were 10 or more studies in a meta-analysis, but this did not occur.

Data synthesis

Fixed-effect model analysis was used to carry out the meta-analyses, except if significant heterogeneity was suspected when a random-effects model was used.

Subgroup analysis and investigation of heterogeneity

We planned to carry out subgroup analysis amongst: different groups of people (women, men, people with neurological diseases, and children); and amongst groups having a primary versus a secondary investigation after failed treatment, if the data allowed. When significant heterogeneity was found, we used a random-effects rather than a fixed-effect model.

Sensitivity analysis

We could carry out sensitivity analysis based on eligibility criteria such as including and excluding results from abstract-only publications if there were enough trials (Deeks 2011).

RESULTS

Description of studies

Ninety-one studies were considered. However, 83 were excluded (see below) because they did not randomise patients to at least one type of urodynamic investigation or one method of performing a urodynamic investigation. One study (Kristjansson 1999), which was included in the second update of the review, was excluded as the study was about the comparison of treatment based on urodynamic findings versus a direct treatment decision in men with presumed bladder outflow obstruction (voiding dysfunction). The updated objective of this review therefore now classed this study as excluded.

One other trial is ongoing (Hilton 2011) (Characteristics of ongoing studies).
The flow of literature through the assessment process is shown in Figure 1.

Figure 1. PRISMA study flow diagram.

Included studies

We found eight trials which met the inclusion criteria, of which two are new in this update (Nager 2009; van Leijsen 2012). The authors of the trials have been approached for further information. One trial was only reported as a conference abstract (Khullar 2000).

Information about another was provided in a report to a grant awarding body (O'Connell 2003) but no useable data relating to the randomised groups were available, although the method of randomisation was classed as secure (A).

No trials were identified which compared one method of urodynamics with another and also provided clinical outcome data. Further details are provided in the table 'Characteristics of Included studies'.

Methods

All included studies were two-armed randomised controlled trials with a standard parallel group design. The duration of the studies included:

- final outcome evaluation at 12 months (Holtedahl 2000; Nager 2009; van Leijsen 2012);
- questionnaire follow up three years after initial presentation and investigation (Khullar 2000);
- questionnaire follow at six months (Majumdar 2009);
- three months following assessment and treatment (Ramsay 1995);
- primary outcome assessed at 12 months but follow up in questionnaire format continued to 24 months (van Leijsen 2011).

No randomised data were available for one trial (O'Connell 2003).

Participants

Participant types included:

- community dwelling women with urinary incontinence (Holtedahl 2000);
- women recruited from the urodynamic clinic with urinary incontinence (Khullar 2000);
- women with urinary incontinence and lower urinary tract symptoms who chose to be randomised (no preference group) (Majumdar 2009);
- men and women with multiple sclerosis and urinary incontinence (O'Connell 2003);
- women with mixed urinary incontinence and lower urinary tract symptoms (Ramsay 1995);
- women with predominant stress urinary incontinence (SUI) (Nager 2009; van Leijsen 2011; van Leijsen 2012).

Subgroup analysis according to type of participant was not possible as each trial included different types of populations.

For the trials measuring subjective (woman-reported) urinary incontinence (UI), the definitions were as follows:

- cure rate determined by asking participants "are you cured?" (Holtedahl 2000);
- pure statement of number of people with any new or continuing evidence of recurrent SUI in the supplementary appendix of the trial (Nager 2009);
- questionnaire use (Urogenital Distress Inventory) to detail the number of women subjectively confident of a cure of SUI, defined as no leakage during physical activity (van Leijsen 2011);
- questionnaire use (Urogenital Distress Inventory) defining cure as no leakage at all on the overall UI section of the questionnaire (van Leijsen 2012).

Interventions

In seven out of eight trials (Holtedahl 2000; Khullar 2000; Majumdar 2009; Nager 2009; O'Connell 2003; Ramsay 1995; van Leijsen 2011), participants were randomised to having urodynamic investigations or not, although in one trial urodynamic investigation could be performed later (delayed group) (Holtedahl 2000). In the eighth trial (van Leijsen 2012), all patients underwent urodynamics but in one arm of the trial the patients were randomised to immediate surgery regardless of the urodynamic results. The following types of urodynamics were used:

- cystometry and cystoflowmetry (Holtedahl 2000);
- ambulatory urodynamics (Khullar 2000);
- non-instrumented uroflowmetry, filling cystometry and pressure-flow studies with urethral pressure profilometry and videourodynamics permitted if routinely performed as preoperative assessment at each centre (Nager 2009);
- urodynamics (unspecified) (Majumdar 2009; O'Connell 2003; van Leijsen 2011; van Leijsen 2012);
- uroflowmetry and filling and voiding cystometry (Ramsay 1995).

It is likely that some of these descriptions (cystometry, cystoflowmetry, pressure flow urodynamics, uroflowmetry, and filling and voiding cystometry) are similar enough to be described as 'standard urodynamics'.

The comparator or control groups were:

- delayed urodynamics (after 12 months, if required) (Holtedahl 2000);
- treatment based on symptoms, history or clinical findings only (Khullar 2000; Kristjansson 1999a; Majumdar 2009; Nager 2009; Ramsay 1995; van Leijsen 2011);

- participants all had urodynamics but treatment was based on history only by a nurse blinded to the results of the urodynamics (O'Connell 2003);
- participants all had urodynamics but treatment was designated as immediate surgery regardless of urodynamic findings (van Leijsen 2012).

Outcomes

All the outcomes considered in each trial are detailed in the table 'Characteristics of included studies'.

Excluded studies

Of the 91 studies, 81 were excluded because they did not report clinical outcomes (that is, effect of the trial on urinary outcomes) or

effect on clinical decision making, or because they were concerned with antibiotic prophylaxis cover for the urodynamic procedure. Another two were possible randomised controlled trials with clinical outcomes but the conference abstracts did not provide enough detail for this to be confirmed (Benson 1991; Choe 2001). The authors have been approached for more information but this outreach has not been successful. Further details are given in the table 'Characteristics of excluded studies'.

Risk of bias in included studies

One trial provided no useable data (O'Connell 2003) and therefore the rest of this section excludes evaluation of this trial.

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	Other bias
Holte Dahl 2000	+	+	?	+	+	+	?	?	+	+
Khullar 2000	?	?	?	-	-	?	?	?	?	-
Majumdar 2009	+	+	+	-	-	?	-	+	+	-
Nager 2009	+	+	?	+	+	+	+	+	+	+
O'Connell 2003	+	+	?	-	-	?	+	+	+	-
Ramsay 1995	+	?	+	+	+	?	?	?	?	-
van Leijssen 2011	+	+	-	+	+	+	+	+	+	?
van Leijssen 2012	+	+	+	?	+	+	+	+	+	+

Allocation

One of the seven trials failed to provide details of the method of sequence generation (Khullar 2000) while six provided adequate information. The adequate methods of sequence generation included a sequence derived from a random numbers table (Holtedahl 2000), a web-based trial simulator programme (Majumdar 2009), an automated randomisation system stratified according to surgeon (Nager 2009), a balanced randomisation schedule based upon permuted blocks and stratified according to multiple sclerosis and urological status (O'Connell 2003), a computer-generated random numbers sequence (Ramsay 1995), and a computer-generated block randomisation with variable block sizes and stratified by centre (van Leijssen 2011; van Leijssen 2012).

Two trials did not describe the method of allocation concealment (Khullar 2000; Ramsay 1995) whereas the other five provided full and adequate information. Adequate methods of allocation concealment included phoning a third party who opened the top sealed opaque envelope from a pile (Holtedahl 2000), sealed opaque envelopes opened in front of the patients (Majumdar 2009), an automated randomisation system (Nager 2009), and a computer-controlled system (O'Connell 2003; van Leijssen 2011; van Leijssen 2012).

Incomplete outcome data

There was differential dropout from the control groups in two trials (Khullar 2000; Majumdar 2009), which was judged likely to introduce bias. Options for analysis may have included presuming all dropouts still had the disease at the defined endpoints, presuming all were cured or using the data available for each participant up to the latest timepoint in the trials. However, in this instance, it was not judged appropriate to compensate for differential dropout by imputation of results for the women lost to follow up and therefore analysis was based upon the results for the women which were available.

However, in one of these trials (Majumdar 2009) the authors interpreted this loss as demonstrating that women who did have urodynamics were more motivated to attend and might therefore have had better compliance with treatment (Analysis 1.9). It may be of relevance that the two randomised groups reported in this review were amongst women who had no preference about whether they had urodynamics or not; the remaining non-randomised women in the study chose to have urodynamics (N = 153) or chose to have conservative treatment without urodynamics (N = 57).

In two trials (Ramsay 1995; van Leijssen 2012), 12 out of 60 women (seven from the intervention group and five from the control group due to failure to complete treatment) and 11 out of 126 women (four plus 1 deceased from the intervention group and 6 from the control group) dropped out. However, we judged that this would

not introduce bias as the numbers were comparable.

Selective reporting

Two trials did not report the primary outcome of this review (number of women with incontinence) (Khullar 2000; Majumdar 2009).

Other potential sources of bias

One trial was only reported in an abstract, and no further data were available (Khullar 2000). Another trial did not provide measures of dispersion (SDs) for an important outcome (incontinence episode frequency) (Majumdar 2009), although it was possible to calculate the SDs for change in incontinence episode frequency using assumptions.

Follow up was short (three months) in one trial (Ramsay 1995). Recruitment was stopped prematurely in one trial because of delays in recruitment (van Leijssen 2011).

Details of medical ethics approval were not fully detailed in three trials (Holtedahl 2000; Khullar 2000; Ramsay 1995), as well as the provision of informed consent not being clear in two trials (Khullar 2000; Ramsay 1995).

Effects of interventions

See: [Summary of findings for the main comparison Urodynamics compared to clinical management for management of urinary incontinence in children and adults](#)

I. Urodynamics versus clinical management without urodynamics

All eight included trials addressed this comparison. However, one trial provided no useable data and therefore it will not be discussed further in this section (O'Connell 2003). This was the only trial which included men or people with neurological disease. No trials included children. The remaining seven trials included 1036 women, of whom 526 were randomised to a urodynamic intervention.

Primary outcome (urinary incontinence)

Five trials addressed this outcome (Holtedahl 2000; Nager 2009; Ramsay 1995; van Leijssen 2011; van Leijssen 2012). There was no statistically significant evidence that the women who received treatment guided by urodynamics were better or worse off than those who did not (for example, proportion of women with incontinence after first year 150/402 (37%) versus 145/400 (36%), RR 1.02, 95% CI 0.86 to 1.21; the GRADE quality of evidence for

this outcome was 'high'). It was calculated using the risk difference that in order to prevent one woman having incontinence after the first year 100 (95% CI 86 to 114) women would have to undergo urodynamic testing ([Analysis 1.2](#)).

Secondary outcomes

Clinical decision making

There was evidence from two trials ([Khullar 2000](#); [van Leijsen 2011](#)) that women treated after urodynamic investigations were more likely to receive drugs (45% versus 21% in no-urodynamic group, RR 2.09, 95% CI 1.32 to 3.31, [Analysis 1.6](#)). Women treated after urodynamic investigation were not, in five trials ([Holtedahl 2000](#); [Khullar 2000](#); [Nager 2009](#); [van Leijsen 2011](#); [van Leijsen 2012](#)), more likely to undergo surgery (401/495 (81%) versus 383/487 (79%), RR 0.99, 95% CI 0.88 to 1.12, [Analysis 1.7](#); a random-effects model was used because of significant heterogeneity). As one of the seven pre-specified GRADE outcomes, the evidence behind the number of women undergoing surgery after urodynamics was seen to be of 'moderate' quality. There was no evidence of a difference in the number treated conservatively after urodynamics but the numbers were small ([Analysis 1.5](#)).

Women in the urodynamic group of another trial ([Majumdar 2009](#)) were more likely to return for further treatment (RR 0.28, 95% CI 0.10 to 0.79, [Analysis 1.9](#)); the authors argued that this would result in better compliance with treatment. Finally, with regards to another of the seven GRADE outcomes, women in the urodynamic arms of three trials ([Holtedahl 2000](#); [van Leijsen 2011](#); [van Leijsen 2012](#)) were more likely to have their management changed (proportion with change in management 17% versus 3%, RR 5.07, 95% CI 1.87 to 13.74, [Analysis 1.8](#)). All three trials showed that more women had their management changed after urodynamics although there was statistical heterogeneity and its importance was unclear. However, the GRADE quality of evidence for this outcome was seen to be 'low'.

Observations of people being investigated for incontinence

One trial reported that more women had urgency symptoms in the urodynamic group ([van Leijsen 2011](#)) but this did not reach statistical significance (RR 5.42, 95% CI 0.69 to 42.28, [Analysis 1.11](#)).

The number of women not satisfied with treatment (another pre-specified outcome, with the quality of evidence being described as 'low') was detailed in two trials ([Nager 2009](#); [van Leijsen 2012](#)) but was not found to be statistically significant (RR 0.90, 95% CI 0.55 to 1.49, [Analysis 1.10](#)).

Quantification of people's symptoms

The evidence from pad weights and incontinence episodes was too scant to be conclusive ([Analysis 1.12](#); [Analysis 1.13](#)).

Clinicians' observations

Although more women had clinician-observed incontinence with urodynamics (39/286 (14%) versus 29/286 (10%) without urodynamics) this did not reach statistical significance (RR 1.33, 95% CI 0.85 to 2.08, [Analysis 1.15](#)).

Adverse effects

One trial ([Nager 2009](#)) found no statistically significant difference in the number of women with adverse effects (RR 1.10, 95% CI 0.81 to 1.50, [Analysis 1.16](#)). Two trials ([Nager 2009](#); [van Leijsen 2011](#)) reported data on the number of women with voiding dysfunction between arms and found no statistically significant difference (RR 0.66, 95% CI 0.29 to 1.49, [Analysis 1.17](#)). There were four deaths in the control group of one trial with none in the urodynamic group ([Khullar 2000](#)), while there was one death in the urodynamic group in another trial ([van Leijsen 2012](#)) ([Analysis 1.18](#)).

One of the seven pre-specified GRADE outcomes, 'incidence of urinary tract infection associated with urodynamics', was not measured in any of the included studies and therefore could not be detailed.

Quality of life

The data for effect on quality of life, evaluated using a variety of health status measures, were largely inconclusive although two trials reported a statistically significant change in the Urogenital Distress Inventory (UDI) questionnaire subscale for UI at 12 months in favour of clinical assessment alone (RR 14.70, 95% CI 7.21 to 22.19, [Analysis 1.19](#)).

Furthermore, a GRADE outcome regarding the quality of life in people following urodynamics was measured using the general health of patients as recorded by the mean difference of the King's Quality of Life (QoL) score at six months. The quality of evidence was described as 'moderate' and the results were inconclusive (MD -6.40, 95% CI -16.61 to 3.81, [Analysis 1.19](#)).

Socioeconomic measures

To date no trials have reported any costs of investigations or treatments and as a result the last of the seven GRADE outcomes, 'health economics measures', could not be assessed.

2. One type of urodynamics versus another

No trials were identified which compared one method of urodynamics with another and also provided clinical outcome data.

DISCUSSION

Summary of main results

There was statistically significant evidence to support the hypothesis that urodynamic testing changed clinical decision making in women treated for urinary incontinence (RR 5.07, 95% CI 1.87 to 13.74) but the GRADE quality of evidence for this outcome was low. However, no evidence was available showing a difference in the number of women with incontinence after one year between those undergoing testing and those not (number with incontinence after first year (subjective) RR 1.02, 95% CI 0.86 to 1.21) and the GRADE quality of evidence for this outcome was high. There was no evidence related to the use of urodynamics in men, children, or people with neurological diseases with UI. Despite the expected incidence of UTI after the procedure (Latthe 2012), only one trial (Nager 2009) reported whether or not there were any adverse effects (RR 1.10, 95% CI 0.81 to 1.50).

Overall completeness and applicability of evidence

Although we found 91 potential trials, only eight proved to be eligible. Of these, one did not provide useable data; this was also the only one which included men (O'Connell 2003). Therefore, no trial data were available about the clinical consequences of urodynamics in men, in people with a neurological cause for their incontinence, or in children, therefore no comment can be made about these population groups. The excluded studies, which generally compared different approaches to urodynamics, were excluded because they did not address clinical outcomes; even if they were randomised controlled trials. This may have been because they were not designed to assess whether to use urodynamics or not and were mainly focused on the best method to carry out the investigation.

The included studies also failed to provide relevant outcome data. Only five reported primary outcome data (Holtedahl 2000; Nager 2009; Ramsay 1995; van Leijssen 2011; van Leijssen 2012) and only four of these could be combined in any one meta-analysis. Furthermore, of the seven pre-specified GRADE outcomes, only five were reported and no evidence was available for two of the outcomes.

There is, however, one other large ongoing trial, of similar design to the two new included trials in this update of the review (Nager 2009; van Leijssen 2012), which may produce robust, reliable evidence (Hilton 2011). However, again it only includes women.

In the light of the findings of this review, the question of whether clinicians will continue to perform urodynamics on their patients is an interesting one. It seems intuitive that if clinicians have more information available to counsel their patients, care and outcomes should be improved. However, this depends on whether the clinician and the patient feel that the extra information provided by the investigation translates into better outcomes and so would be worth the associated risks and costs of urodynamics.

An issue affecting generalisability is that urodynamics are a relatively sophisticated and expensive investigation. The relevant equipment and resources may not be of an equivalent level of sophistication or even available in countries with limited healthcare resources, and the level of technical expertise to perform and interpret the studies may not be the same in different countries.

There are countries which do not have access to urodynamics, and the results of this review may be particularly important for them in making decisions about which resources to source. Where resources are more limited, the policymakers, funders of healthcare services and clinicians must decide whether or not there are important health gains from the use of sophisticated investigations such as urodynamics, and therefore further research providing more definitive answers will aid in these decisions.

Quality of the evidence

Most of the trials were small and all had one or more factors which increased the risk of bias (Figure 2; Figure 3). Seven of eight trials undertook adequate random sequence generation (Holtedahl 2000; Majumdar 2009; Nager 2009; O'Connell 2003; Ramsay 1995; van Leijssen 2011; van Leijssen 2012) while six of eight provided evidence of secure allocation concealment (Holtedahl 2000; Majumdar 2009; Nager 2009; O'Connell 2003; van Leijssen 2011; van Leijssen 2012), but one of these did not provide useable data (O'Connell 2003). The four deaths and 12 dropouts from the control arm of one trial were unexplained (Khullar 2000) and may indicate high risk of bias in this trial.

GRADE quality of evidence

By adopting the GRADE approach to the assessment of risk of bias, the quality of evidence of the GRADE specified outcomes was found to vary from high to low GRADE ('Summary of findings' table 1). The number with incontinence after the first year (subjective), which was the primary outcome of this systematic review, was graded as high. The body of evidence for two outcomes (number treated with surgery, quality of life measures following treatment after urodynamics) were graded as moderate. The quality of evidence of two outcomes (number not satisfied with treatment, number whose treatment was not changed after urodynamics) were deemed to have low quality of evidence. Lastly, two out of seven outcomes were not reported and therefore GRADE could not be applied (incidence of UTI associated with urodynamics, health economics measures).

Agreements and disagreements with other studies or reviews

Recent systematic reviews on the subject of urodynamics have identified the lack of high quality primary research confirming the clinical utility of carrying out urodynamic investigations (Hosker 2009; LUTS Guideline 2010; NCCWCH 2006). The current review incorporates the newer evidence available but is still not conclusive regarding when and in which situations urodynamics are useful.

Some consensus statements and practice recommendations do not advocate initial urodynamic tests prior to conservative treatment of stress incontinence, whereas they do recommend them prior to continence surgery (AHCPR 1996; Homma 1999; Hosker 2009; RCOG 2003) but not before conservative treatment or if there is a clear history of SUI alone (NCCWCH 2006). The NCCWCH 2006 group concluded that: "It has not been shown that carrying out urodynamic investigations before initial treatment improves outcome. Complex reconstructive urological procedures were developed for use for specific urodynamic abnormalities. Hence, the guideline group concluded that urodynamic investigations should be used to demonstrate the presence of specific abnormalities before undertaking these procedures. The guideline group considered that urodynamic investigations were also of value when the clinical diagnosis is unclear prior to surgery or if initial surgical treatment has failed". Some clinicians find the use of urodynamics reassuring to prevent them missing specific abnormalities such as DO, even if the overall management of patients does not change. However, the findings of these abnormalities are not actually predictive of outcome and therefore the use of the investigation in these circumstances may be unwarranted.

The role of urodynamic studies before prolapse surgery is also controversial (Fowler 2006). An ICI Committee found no evidence to suggest whether or not women with occult UI (revealed by prolapse reduction) in fact manifest the problem after surgery, nor whether urodynamics was helpful in predicting this outcome (Hosker 2009 page 448). Their role in men with regards to the diagnosis of UI (that is, storage LUTS secondary to conditions of the bladder and not voiding LUTS due to bladder outlet obstruction, as is the case in prostatic disease) is controversial but one review recommended a trial of drugs for both conditions, in the first instance with urodynamics being reserved for resistant cases (Chapple 2006). The situation in children is also unclear, but the ICI recommend urodynamic testing when there are congenital abnormalities and in children with incontinence or nocturnal enuresis if invasive treatments are contemplated (Hosker 2009).

Finally, there are concerns about the reproducibility, accuracy, standardisation and safety of the tests (Hosker 2009).

Future research

Despite the recent publication of two large trials, larger definitive randomised trials are still needed to determine the place for urodynamics in both the routine and specialised clinical care of people with incontinence. This was first suggested by Black et al

in their survey of clinical practice (Black 1997) and supported by Black and others in subsequent correspondence (Black 1998; Lose 1998b). Further support was provided by the ICI Committee on Dynamic Testing that such a trial "may provide objective documentation of the utility of soundly based tests" (Griffiths 2005, page 630). Cost effectiveness was also identified as an important consideration (Hosker 2009).

One new trial amongst women is in progress and has completed recruitment (attaining 222 participants of a targeted 240) in January 2013 (Hilton 2011). It is possible, when results are available, that the findings of this trial may inform practice.

AUTHORS' CONCLUSIONS

Implications for practice

When women with incontinence are assessed using urodynamics in addition to clinical methods, they are more likely to receive different treatment and to have their management plan changed. However, the evidence was not conclusive in showing whether these differences in management resulted in differences in health outcomes, such as incontinence, quality of life or economic outcomes after treatment, compared to women who did not have urodynamic tests.

No data were available to evaluate the use of urodynamics in men, children, or people with neurological diseases.

Implications for research

There remains insufficient evidence about the value and risks of urodynamic tests. Further trials are needed in all types of patients whose incontinence could be investigated with urodynamics. In such trials, people would be randomised to treatment based on urodynamic investigations compared with treatment based on clinical history and examination. They should include all people for whom urodynamics might be indicated to ensure that those considering surgery but who decided not to proceed due to urodynamic findings are not missed, and that those for whom surgery is not an option are also evaluated. The trial(s) should if possible be designed so that the role of urodynamic testing in different populations (women, men, children, and people with neurological disease) can be assessed separately. Furthermore, they should take into account the seven specified GRADE outcomes within this review to allow a comprehensive analysis of those outcomes most important to clinical practice.

In order to give a definitive answer to the question of whether urodynamic studies are no better than clinical assessment in treating urinary incontinence in adults, a trial of 3222 participants would be required. Assuming the incontinence event rate is similar to that of the four trials already included in this analysis, 1611 patients

per arm would reduce the confidence interval of the risk ratio to plus or minus 10% (RR would be 1.02, 95% CI 0.94 to 1.10).

Thus currently there is insufficient evidence to indicate that one method of management is better than another. Any other additional studies could be highly informative.

ACKNOWLEDGEMENTS

We thank the external referees and the Editors of the Incontinence Review Group who made helpful comments on the content and text of the review. Phil Tooze-Hobson provided extra information about one trial, and Sanne van Leijssen about one completed trial. We also thank Andrew Elders who calculated the number needed for further research.

REFERENCES

References to studies included in this review

Holte Dahl 2000 {published data only}

Holte Dahl K, Verelst M, Schiefeloe A, Hunskaar S. Usefulness of urodynamic examination in female urinary incontinence--lessons from a population-based, randomized, controlled study of conservative treatment. *Scandinavian Journal of Urology and Nephrology* 2000;**34**(3):169-74. [SR-INCONT11839]

Khullar 2000 {published data only}

Khullar V, Salvatore S, Cardozo L, Howland E, Digesu A, Kelleher C, et al. Randomised study of ambulatory urodynamics versus symptomatic treatment of symptomatic women without a urodynamic diagnosis. Proceedings of the International Continence Society (ICS), 30th Annual Meeting; 2000 Aug 28-31; Tampere, Finland. 2000.

Majumdar 2009 {published data only}

Majumdar A, Hassan I, Robb K, Tooze-Hobson P. Urodynamics and patient preference (Abstract number 366). Proceedings of the 35th Annual International Continence Society (ICS), 2005 Aug 28 - Sept 2; Montreal. 2005. [21078]

* Majumdar A, Latthe P, Tooze-Hobson P. Urodynamics prior to treatment as an intervention: A pilot study. *Neurourology and Urodynamics* 2010;**29**(4):522-6. [SR-INCONT34191]

Majumdar A, Tooze-Hobson P. Why women prefer to have urodynamics (Abstract number 11). *Neurourology and Urodynamics* 2007;**26**(5):615-6. [26653]

Tooze-Hobson P, Majumdar A, Robb K, Powles K. How does urodynamics affect subsequent patient behaviour? (Abstract number 159). *International Urogynecology Journal and Pelvic Floor Dysfunction* 2007;**18** Suppl 1:S94-5. [26604]

Nager 2009 {published data only}

Nager CW, Brubaker L, Daneshgari F, Litman HJ, Dandreo KJ, Sirls L, et al. Design of the Value of Urodynamic Evaluation (ValUE) trial: A non-inferiority randomized trial of preoperative urodynamic investigations. *Contemporary Clinical Trials* 2009;**30**(6):531-9. [SR-INCONT34338]
Nager CW, Brubaker L, Litman HJ, Zyczynski HM, Varner RE, Amundsen C, et al. A randomized trial of urodynamic testing before stress-incontinence surgery.

New England Journal of Medicine 2012;**366**(21):1987-97. [SR-INCONT44511]

Norton P, Nager C, Brubaker L, Lemack G, Lowder J, Chai T, et al. The cost of preoperative urodynamics: a secondary analysis of the ValUE trial (Abstract number 29). *Neurourology and Urodynamics* 2012;**31**(6):762. [SR-INCONT45977]

Sirls L, Richter H, Litman H, Kenton K, Lemack G, Lukacz E, et al. The effect of urodynamic testing on clinical diagnosis, treatment plan and outcomes in women undergoing stress urinary incontinence surgery (Abstract number 251). *Neurourology and Urodynamics* 2012;**31**(6):1051-2. [SR-INCONT45980]

O'Connell 2003 {published data only}

Dowling CR, O'Connell HE, Kurczyki L, Myles K, Poole K, Sanjeevan KV. Randomised control trial of bladder pressure management versus management based on symptoms and residual volumes in patients with established multiple sclerosis (Abstract). *BJU International* 2005;**95** Suppl 1:5. [21317]

O'Connell HE, Costello AJ, King J, Kilpatrick T, Whishaw M, Samali R, et al. *Extension study: Randomised control trial bladder pressure management vs management based on symptoms and residual volumes in patients with established multiple sclerosis*. Canberra, Australia: National Continence Management Strategy, Department of Health and Ageing, Australian Government, 2005. Available from: <http://www.bladderbowel.gov.au/ncms/projects/intervention/msurinarnprob.htm>. [31113]

* O'Connell HE, Costello AJ, King J, Kilpatrick T, Whishaw M, Samali R, et al. *Randomised control trial bladder pressure management vs management based on symptoms and residual volumes in patients with established multiple sclerosis*. Canberra, Australia: National Continence Management Strategy, Department of Health and Ageing, Australian Government, 2003. Available from: <http://www.bladderbowel.gov.au/ncms/projects/phases/bladder%20pressure.htm>. [31112]

Ramsay 1995 {published data only}

Ramsay I, Hassan A, Hunter M, Donaldson K. A randomised controlled trial of urodynamic investigation prior to conservative treatment of urinary incontinence in the female (Abstract). *Neurourology and Urodynamics* 1994;

13(4):455–6.

* Ramsay IN, Ali HM, Hunter M, Stark D, Donaldson K. A randomized controlled trial of urodynamic investigations prior to conservative treatment of urinary incontinence in the female. *International Urogynecology Journal* 1995;6: 277–81.

van Leijsen 2011 {published and unpublished data}

van Leijsen SA, Kluivers KB, Mol BW, Broekhuis SR, Milani AL, Bongers MY, et al. A randomized controlled trial on the value of preoperative urodynamic investigation in women with stress incontinence (Abstract number 165) [nb use version sent by first author as published version has wrong RRs]. *International Urogynaecology Journal* 2011;22 (1 Suppl):S158–60. [SR-INCONT45788]
van Leijsen SA, Kluivers KB, Mol BW, Broekhuis SR, Milani AL, Bongers MY, et al. Can preoperative urodynamic investigation be omitted in women with stress urinary incontinence? A non-inferiority randomized controlled trial. *Neurourology and Urodynamics* 2012;31(7):1118–23. [SR-INCONT45113]
van Leijsen SAL, Kluivers KB, Mol BWJ, Broekhuis SR, Milani AL, Bongers MY, et al. A randomised controlled trial on the value of preoperative urodynamics in women with stress incontinence: VUSIS 1 [Abstract 165]. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2011;22 Suppl 1:S159–61.

van Leijsen 2012 {published data only}

van Leijsen S, Kluivers KB, Mol BW, Milani A, Roovers J, den Boon J, et al. A randomised controlled trial on the value of urodynamics prior to stress incontinence surgery (Abstract number 248). *Neurourology and Urodynamics* 2012;31(6):1046–7. [SR-INCONT45979]
van Leijsen SA, Kluivers KB, Mol BW, Broekhuis SR, Milani FL, van der Vaart CH, et al. Protocol for the value of urodynamics prior to stress incontinence surgery (VUSIS) study: a multicenter randomized controlled trial to assess the cost effectiveness of urodynamics in women with symptoms of stress urinary incontinence in whom surgical treatment is considered. *BMC Women's Health* 2009;9:22. [SR-INCONT32078]
van Leijsen SAL, Kluivers KB, Mol BWJ, in 't Hout J, Milani AL, Roovers JPWR, et al. Value of urodynamics before stress urinary incontinence surgery: a randomized controlled trial. *Obstetrics and Gynecology* 2013;121(5): 999–1008.

References to studies excluded from this review

Akil 2005 {published data only}

Akil I, Ozkol M, Ikizoglu OY, Polat M, Tuncyurek OY, Taskin O, et al. Premedication during micturating cystourethrogram to achieve sedation and anxiolysis. *Pediatric Nephrology (Berlin, Germany)* 2005;20(8): 1106–10.

Bael 2008 {published data only}

Bael A, Lax H, Hoebeke P, de Jong TPVM, Nijman RJM, Sixt R, et al. The relevance of urodynamic studies in urge syndrome and dysfunctional voiding: a multi-center

controlled trial in children. *Journal of Urology* 2008;180(4): 1486–93.

Bajpai 1982 {published data only}

Bajpai M, Sutherst J, Brown M. Comparison of cystomat and multichannel cystometry in the diagnosis of bladder instability (Abstract). Proceedings of the International Continence Society (ICS), 12th Annual Meeting; 1982; Leiden, Germany. 1982:203–4.

Baker 1991 {published data only}

Baker KR, Drutz HP, Barnes MD. Effectiveness of antibiotic prophylaxis in preventing bacteriuria after multichannel urodynamic investigations: a blind, randomized study in 124 female patients. *American Journal of Obstetrics and Gynecology* 1991;165(3):679–81.

Batista 1998 {published data only}

Batista JE, Arano P, Granda M, Puigpelat T, Garat JM, Bauer S. Filling rate during cystometry: its effect on detrusor instability and compliance in children (Abstract). Proceedings of the International Continence Society (ICS), Annual Meeting. 1998:144.

Baumann 2007 {published data only}

Baumann BM, McCans K, Stahmer SA, Leonard MB, Shults J, Holmes WC. Caregiver and health care provider satisfaction with volumetric bladder ultrasound. *Academic Emergency Medicine* 2007;14(10):903–7. [26374]

Benson 1991 {published data only}

Benson JT. Anatomic vs urodynamic evaluation of women with urinary incontinence (Abstract). Proceedings of the American Urogynecology Society, 12th Annual Meeting; 1991 Oct 23–26; Newport Beach, California, USA. 1991.

Bhatia 1985 {published data only}

Bhatia NN, Bergman A. Antibiotic prophylaxis following instrumentation of the urinary tract (Abstract). Proceedings of the American Urogynecology Society, 6th Annual Meeting; 1985 Nov 6–9; San Diego, California. 1985.

Blaivas 2001 {published data only}

Blaivas JG, Groutz A, Verhaaren M. Does the method of cystometry affect the incidence of involuntary detrusor contractions? A prospective randomized urodynamic study. *Neurourology and Urodynamics* 2001;20(2):141–5.

Bo 2003 {published data only}

Bo K, Borstad E. Urodynamic assessment during pelvic floor muscle and transversus abdominis contraction (Abstract). Proceedings of the International Continence Society (ICS), 33rd Annual Meeting; 2003 Oct 5–9; Florence. 2003: 484–5.

Byrne 1991 {published data only}

Byrne P. A comparison of rectal and vaginal placement of abdominal pressure catheters during cystometry - patient preference (Abstract). Proceedings of the International Continence Society (ICS), 21st Annual Meeting; 1991; Hannover, Federal Republic of Germany. 1991:49–50.

Chin-Peuckert 2004 {published data only}

Chin-Peuckert L, Rennick JE, Jednak R, Capolicchio JP, Salle JL. Should warm infusion solution be used for

- urodynamic studies in children? A prospective randomized study. *Journal of Urology* 2004;**172**(4 Pt 2):1657–61. [SR–INCONT19217]
- Choe 2001** {published data only}
Choe JM. Sling surgery performed with and without preoperative urodynamics: a comparative outcomes analysis (Abstract). Proceedings of the International Continence Society (ICS), 31st Annual Meeting; 2001 Sept 18–21; Seoul, Korea. 2001:Abstract 175.
- Chung 2010** {published data only}
Chung S, Lim R, Goldman RD. Intranasal fentanyl versus placebo for pain in children during catheterization for voiding cystourethrography. *Pediatric Radiology* 2010 Jul; **40**(7):1236–40.
- Colstrup 1982** {published data only}
Colstrup H, Andersen JT, Walter S. Detrusor reflex instability in the male. Fact or artefact? The influence of investigative technique on the frequency of detrusor instability in CO2-cystometry (Abstract). Proceedings of the International Continence Society (ICS), 12th Annual Meeting; 1992; Leiden, Germany. 1982:201–2.
- Constantini 20148** {published data only}
Constantini E, Mearini L, Biscotto S, Giannantoni A, Bini V, Porena M. Impact of different sized catheters on pressure-flow studies in women with lower urinary tract symptoms. *Neurourology and Urodynamics* 2005;**24**(2): 106–10. [SR–INCONT20148]
- Culligan 2001** {published data only}
Culligan PJ, Goldberg RP, Blackhurst DW, Sasso K, Koduri S, Sand PK. Comparison of microtransducer and fiberoptic catheters for urodynamic studies. *Obstetrics and Gynecology* 2001;**98**(2):253–7.
- Cundiff 1999** {published data only}
Cundiff GW, McLennan MT, Bent AE. Randomized trial of antibiotic prophylaxis for combined urodynamics and cystourethroscopy. *Obstetrics and Gynecology* 1999 May;**93** (5 Pt 1):749–52.
- Darouiche 1994** {published data only}
Darouiche RO, Smith MS, Markowski J. Antibiotic prophylaxis for urodynamic testing in patients with spinal cord injury: a preliminary study. *Journal of Hospital Infection* 1994;**28**(1):57–61.
- Dolan 2005** {published data only}
Dolan LM, Dixon WE, Brown K, Ord T, Hilton P. Randomized comparison of vaginal and rectal measurement of intra-abdominal pressure during subtracted dual-channel cystometry. *Urology* 2005;**65**(6):1059–63.
- Dompeyre 2007** {published data only}
Dompeyre P, Fritel X, Bader G, Delmas V, Fauconnier A. Bladder sensitivity testing using a visual analogue scale: comparative cystometric study on women. *Neurourology and Urodynamics* 2007;**26**(3):350–5. [SR–INCONT23235]
- Eggersmann 1996** {published data only}
Eggersmann C, Wienhold D, Dahms S, Schultz-Lampel D, Thuroff JW. Influence of different lubricants to urodynamic evaluations. Proceedings of the International Continence Society, 26th Annual Meeting; 1996 Aug 27–30; Athens, Greece. 1996:440–1.
- Gehrich 2012** {published data only}
Gehrich AP, Hill MJ, McWilliams GD, Larsen W, McCartin T. Comparison of urodynamic volume measurements using room and body temperature saline: a double-blinded randomized crossover study design. *Female Pelvic Medicine & Reconstructive Surgery* 2012 May;**18**(3):170–4.
- Gluck 2002** {published data only}
Gluck T, Wagg A, Fry C, Malone-Lee J. The effects of biochemical changes to filling media during urodynamic testing in women with lower urinary tract symptoms (Abstract). *Neurourology and Urodynamics* 2002;**21**(4):355.
- Goodman 2003** {published data only}
Goodman TR, Kilborn T, Pearce R. Warm or cold contrast medium in the micturating cystourethrogram (MCUG): which is best?. *Clinical Radiology* 2003;**58**(7):551–4.
- Groutz 2000** {published data only}
Groutz A, Blaivas JG, Verhaaren M. Does the method of cystometry affect the incidence of involuntary detrusor contractions? A prospective randomized urodynamic study (Abstract number 1169). *Journal of Urology* 2000;**163**(4 Suppl):263. [SR–INCONT29635]
- Gurbuz 2011** {published data only}
Gurbuz C, Guner B, Atis G, Canat L, Caskrulu T. The effectiveness of fosfomycin tromethamine and ciprofloxacin prophylaxis in preventing bacteriuria caused by urodynamic study, do patients need prophylaxis (Abstract number 894). Proceedings of the 41st Annual Meeting of the International Continence Society (ICS), 2011 Aug 29 to Sept 2, Glasgow, Scotland. 2011.
- Handa 1994** {published data only}
Handa VL, Jensen JK, Ostergard DR. The effect of patient position on urethral mobility (Abstract). Proceedings of the American Urogynecology Society, 15th Annual Scientific Meeting; 1994 Sept 21–24; Toronto, Ontario. 1994: Abstract P10.
- Heslington 1996** {published data only}
Heslington K, Hilton P. Ambulatory monitoring and conventional cystometry in asymptomatic female volunteers [see comments]. *British Journal of Obstetrics and Gynaecology* 1996;**103**(5):434–41. MEDLINE: 96216877
- Hirakauva 2010** {published data only}
Hirakauva E, Kajikawa M, de Falco K, Zucchi E, De Castro R, Sartori MGF, et al. The prophylactic antibiotic therapy prevents lower urinary tract infection after the urodynamic test? (Abstract number 819). Proceedings of the Joint Meeting of the International Continence Society (ICS) and the International Urogynecological Association, 2010 Aug 23–27, Toronto, Canada. 2010.
- Hosker 1999** {published data only}
Hosker GL, Bryant AM, Wright G, Kilcoyne PM, Lord JC, Smith ARB. A comparison of normal saline and urografin 150 for cystometry in women (Abstract). Proceedings of

- the International Continence Society (ICS), 29th Annual Meeting; 1999; Denver, Colorado. 1999:420–1.
- Hougardy 2009** *{published data only}*
Hougardy V, Vandeweerdt JM, Reda AA, Foidart JM. The impact of detailed explanatory leaflets on patient satisfaction with urodynamic consultation: a double-blind randomized controlled trial. *Neurourology and Urodynamics* 2009;**28**(5): 374–9. [SR-INCONT32112]
- Hundley 2006** *{published data only}*
Hundley AF, Brown MB, Brubaker L, Cundiff GW, Kreder K, Lotze P, et al. A multicentered comparison of measurements obtained with microtip and external water pressure transducers. *International Urogynecology Journal* 2006;**17**(4):400–6. [SR-INCONT22307]
- Jolic 1997** *{published data only}*
Jolic V, Gilja I. Vaginal vs. transabdominal ultrasonography in the evaluation of female urinary tract anatomy, stress urinary incontinence and pelvic organs static disturbances. *Zentralblatt für Gynäkologie* 1997;**119**(10):483–91.
- Kartal 2002** *{published data only}*
Klausner AP, Galea J, Vapnek JM. Effect of catheter size on urodynamic assessment of bladder outlet obstruction. *Urology* 2002;**60**(5):875–80. [SR-INCONT15592]
- Keidan 2005** *{published data only}*
Keidan I, Zaslansky R, Weinberg M, Ben Shlush A, Jacobson JM, Augarten A, et al. Sedation during voiding cystourethrography: comparison of the efficacy and safety of using oral midazolam and continuous flow nitrous oxide. *The Journal of Urology* 2005;**174**(4 Pt 2):1598–1600, discussion 1601. [SR-INCONT21987]
- Khan 2004** *{published data only}*
Khan MS, Chaliha C, Leskova L, Khullar V. The relationship between urinary symptom questionnaires and urodynamic diagnoses: an analysis of two methods of questionnaire administration. *BJOG* 2004 May;**111**(5): 468–74.
- Khullar 1996** *{published data only}*
Khullar V, Cardozo LD, Salvatore S, Hill S. Ultrasound: a noninvasive screening test for detrusor instability. *British Journal of Obstetrics and Gynaecology* 1996;**103**(9):904–8.
- Khullar 2002** *{published data only}*
Khullar V, Soligo M, Salvatore S. Does rectal distension alter bladder function? (Abstract). *Neurourology and Urodynamics* 2002;**21**(4):354. [14543]
- Klarskov 2009** *{published data only}*
Klarskov N, Scholfield D, Soma K, Darekar A, Mills I, Lose G. Measurement of urethral closure function in women with stress urinary incontinence. *Journal of Urology* 2009 Jun;**181**(6):2628–33.
- Kristjansson 1999** *{published data only}*
Kristjansson B. A randomised evaluation of routine urodynamics in patients with LUTS [abstract]. *Scandinavian Journal of Urology and Nephrology Supplementum* 1999;**33** Suppl 200:9. [23728]
- Kuhn 2007** *{published data only}*
Kuhn A, Nager CW, Hawkins E, Schulz J, Stanton SL. A comparative study of water perfusion catheters and microtip transducer catheters for urethral pressure measurements. *International Urogynecology Journal* 18;**8**: 931–5. [SR-INCONT23895]
- Kulseng 1995** *{published data only}*
Kulseng-Hanssen S, Kristoffersen M, Larsen E. Physiological bladder filling with 2 and 4 hours recording versus 45 minutes recording with 300 ml saline bladder prefilling using ambulatory urodynamic equipment (Abstract). Proceedings of the International Continence Society (ICS), 25th Annual Meeting; 1995; Sydney, Australia. 1995: 151–2.
- Lee 2002** *{published data only}*
Lee F, Susser J, Mundy A, Foxall P, Craggs M. Does urinary sodium affect bladder sensations in patients with an overactive bladder during urodynamics? (Abstract). Proceedings of the International Continence Society (ICS), 32nd Annual Meeting; 2002 Aug 28–30; Heidelberg, Germany. 2002:102–3 (Abstract 181).
- Lucas 2009** *{published data only}*
Lucas M, Moore K, Borkowski T, Pantuck A, Heesakkers J, Radziszewski P. Accuracy of CaptiFlow portable home flow measuring device and its use as a diagnostic tool in the management of LUTS - a randomised cross over study (Abstract number 400). Proceedings of the 39th Annual Meeting of the International Continence Society (ICS), 2009 Sep 29 - Oct 3, San Francisco, CA. 2009. [SR-INCONT35613]
- Malone-Lee 2009** *{published data only}*
Malone-Lee JG, Al Buheissi S. Does urodynamic verification of overactive bladder determine treatment success? Results from a randomized placebo-controlled study. *BJU International* 2009 Apr;**103**(7):931–7.
- Massey 1987** *{published data only}*
Massey A, Howell S, Lewis P, Tribe B. Urethral profilometry by different methods (Abstract). Proceedings of the International Continence Society (ICS), 17th Annual Meeting; 1987 Sept; Bristol, UK. 1987:122–3.
- Medina 2002** *{published data only}*
Medina C, Fynes M, Gold R, Wang K, Stanton S. Does the order of patient position for sequential bladder filling at cystometry influence observed detrusor activity? (Abstract). Proceedings of the International Continence Society (ICS), 32nd Annual Meeting; 2002 Aug 28–30; Heidelberg, Germany. 2002:87–8 (Abstract 162).
- Medina 2005** *{published data only}*
Medina CA, Takacs P. Shortening the process of determining postvoid residual. *International Journal of Gynaecology and Obstetrics* 2005;**91**(3):266–7. [21868]
- Minardi 2010** *{published data only}*
Minardi D, d'Anzeo G, Parri G, Polito M Jr, Piergallina M, El Asmar Z. The role of uroflowmetry biofeedback and biofeedback training of the pelvic floor muscles in the treatment of recurrent urinary tract infections in women

- with dysfunctional voiding: a randomized controlled prospective study. *Urology* 2010;**75**(6):1299–304. [SR-INCONT39965]
- Mouritsen 1999** {published data only}
Mouritsen L, Sander P, Bernstein I, Bach A. Comparison of palpation, ultrasonography and perineometry for examination of the pelvic floor. *International Urogynecology Journal and Pelvic Floor Dysfunction* 1999;**10** Suppl 1: S16–7.
- Mueller 2007** {published data only}
Mueller ER, Kenton K, Mahajan S, FitzGerald MP, Brubaker L. Urodynamic prolapse reduction alters urethral pressure but not filling or pressure flow parameters. *Journal of Urology* 2007;**177**(2):600–3. [SR-INCONT22546]
- Neal 1987** {published data only}
Neal DE, Rao CV, Styles RA, Ng T, Ramsden PD. Effects of catheter size on urodynamic measurements in men undergoing elective prostatectomy. *British Journal of Urology* 1987;**60**(1):64–8. [544]
- Panayi 2008** {published data only}
Panayi D, Khullar V, Spiteri M, Hendricken C, Fernando R. Randomised study to determine if rectal distension alters urodynamic findings? (Abstract number 57). *Neurourology and Urodynamics* 2008;**27**(7):636.
- Payne 2001** {published data only}
Payne CK, Sirinian E, Azevedo K. Effect of physiologic levels of urinary potassium on interstitial cystitis symptoms. *Urology* 2001;**57** Suppl 6A:124.
- Peschers 2001** {published data only}
Peschers UMK. Antibiotic treatment to prevent urinary tract infections after urodynamic evaluation. *International Urogynecology Journal* 2001;**12**(4):254–7.
- Peters-Gee 2003** {published data only}
Peters-Gee J, McKinney T, Rezapour M, Mastropietro M, Lucente V, Slack M, et al. Multicenter study of gynecare MoniTor urethral resistance pressure versus standard urodynamic MEA. *Obstetrics and Gynecology* 2003;**101**(4 Suppl):114S. [17196]
- Philip 2007** {published data only}
Philip J, Irwin P. A double-blind, randomised controlled trial of cystometry using normal saline versus 3M potassium chloride infusion (Abstract). Proceedings of the International Continence Society (34th Annual Meeting) and the International Urogynecological Association; 2004 Aug 23–27; Paris. 2004:Abstract number 739. [19085]
* Philip J, Willmott S, Irwin P. Interstitial cystitis versus detrusor overactivity: a comparative, randomized, controlled study of cystometry using saline and 0.3 M potassium chloride. *Journal of Urology* 2006;**175**(2):566–570, discussion 570–1. [21625]
Philip J, Willmott S, Owen D, Samsudin C, Irwin PP. A double-blind, randomized controlled trial of cystometry using saline versus 0.3 M potassium chloride infusion in women with overactive bladder syndrome. *Neurourology and Urodynamics* 2007;**26**(1):110–4. [22576]
- Radley 2001** {published data only}
Radley SC, Rosario DJ, Chapple CR. Inter-observer agreement in interpreting ambulatory urodynamics in women. Proceedings of the International Continence Society (ICS), 30th Annual Meeting; 2000 Aug; Tampere, Finland. 2000:Abstract 265.
* Radley SC, Rosario DJ, Chapple CR, Farkas AG. Conventional and ambulatory urodynamic findings in women with symptoms suggestive of bladder overactivity. *Journal of Urology* 2001;**166**(6):2253–8. MEDLINE: 11696746
Rosario DJ, Chapple CR, Radley SC. Inter-observer agreement in interpreting ambulatory urodynamics in women. Proceedings of the International Continence Society (ICS), 30th Annual Meeting; 2002 Aug; Tampere, Finland. 2000:Abstract 359.
- Realfonso 2005** {published data only}
Realfonso T, Di Mauro U, Campitelli A, Angrisani R, Sanseverino R. Influence of the bladder filling speed over the voiding phase in the pressure flow study in the woman (Abstract number 680). Proceedings of the 35th Annual International Continence Society (ICS); 2005 Aug 28–Sept 2; Montreal. 2005. [21088]
- Rehme 2009** {published data only}
Rehme C, Niedworok C, Rubben H, Stohrer M. A technically reduced urodynamic measuring method compared with a conventional urodynamic study (Abstract number 876). Proceedings of the 39th Annual Meeting of the International Continence Society (ICS), 2009 Sep 29 – Oct 3, San Francisco, CA. 2009. [35362]
- Robinson 2002** {published data only}
Robinson D, Anders K, Cardozo L, Bidmead J, Tooze-Hobson P, Khullar V. Can ultrasound replace ambulatory urodynamics when investigating women with irritative urinary symptoms?. *BJOG: an International Journal of Obstetrics and Gynaecology* 2002;**109**(2):145–8. MEDLINE: 21884932
- Rovner 2005** {published data only}
Rovner E, Payne C, Yalla S, Nitti V. Response to fesoterodine in overactive bladder (OAB) patients is independent of the urodynamic finding of detrusor overactivity (Abstract number 147). Proceedings of the International Continence Society (ICS), 35th Annual Meeting. 2005 Aug 28 – Sep 2, Montreal, Canada, 2005.
- Sand 1985** {published data only}
Sand PK, Bowen LW, Ostergard DR. The effect of a filling catheter during urodynamics (Abstract). Proceedings of the American Urogynecology Society, 6th Annual Meeting; 1985 Nov 6–9; San Diego, California. 1985.
* Sand PK, Bowen LW, Ostergard DR. The effect of a filling catheter during urodynamics (Abstract). Proceedings of the International Urogynecology Association, 9th Annual Meeting; 1985 Sept 9–11; Budapest, Hungary. 1985.
- Scaldazza 2005** {published data only}
Scaldazza CV, Morosetti C. Effect of different sized transurethral catheters on pressure-flow studies in women

- with lower urinary tract symptoms. *Urologia Internationalis* 2005;**75**(1):21–5. [20808]
- Schmidt 2001** {published data only}
Schmidt F, Jorgensen TM, Djurhuus JC. Ambulatory urodynamics and home flowmetry, are there differences in the recorded data (Abstract). Proceedings of the International Continence Society (ICS), 31st Annual Meeting; 2001 Sept 18-21; Seoul, Korea. 2001:Abstract 13.
- Shukla 2006** {published data only}
Shukla A, Johnson D, Bibby J. Impact of patient position on filling phase of urodynamics in women. *International Urogynecology Journal* 2006;**17**(3):231–3. [21915]
- Siracusano 2004** {published data only}
Siracusano S, Knez R, Tiberio A, Alfano V, Giannantoni A, Pappagallo G. The usefulness of antibiotic prophylaxis in invasive urodynamics in postmenopausal female subjects. *International Urogynecology Journal* 2008;**19**(7):939–42. [27793]
* Siracusano S, Tiberio A, Cucchi A, Simonazzi M, Facchini M, Alfano V, et al. Usefulness of antibiotic prophylaxis in invasive urodynamics in fertile and in post menopausal female subjects (Abstract). Proceedings of the International Continence Society (34th Annual Meeting) and the International Urogynecological Association; 2004 Aug 23-27; Paris. 2004:Abstract number 753.
- Sirls 2013** {published data only}
Sirls L, Richter H, Litman H, Kenton K, Lemack G, Lukacz E, et al. The effect of urodynamic testing on clinical diagnosis, treatment plan and outcomes in women undergoing stress urinary incontinence surgery (Abstract number 251). *Neurourology and Urodynamics* 2012;**31**(6): 1051–2.
Sirls LT, Richter HE, Litman HJ, Kenton K, Lemack GE, Lukacz ES, et al. The effect of urodynamic testing on clinical diagnosis, treatment plan and outcomes in women undergoing stress urinary incontinence surgery. *Journal of Urology* 2013 Jan;**189**(1):204–9.
- Slack 2004** {published data only}
Culligan PJ, Lewis-Priestley J, Blackwell L, Tate SB. Can urethral retroresistance pressures predict midurethral sling outcomes?. *Journal of Reproductive Medicine* 2010;**55**(3-4): 103–7. [39947]
* Slack M, Culligan P, Tracey M, Hunsicker K, Patel B, Sumeray M. Relationship of urethral retro-resistance pressure to urodynamic measurements and incontinence severity. *Neurourology and Urodynamics* 2004;**23**(2): 109–14. [17437]
- Slack 2004a** {published data only}
Slack M, Hunsicker K, Patel B, Godwin A, Owens C. Comparison of multichannel cystometrogram (PVES, PABD, PDET) to single channel cystometrogram (PVES) (Abstract number 72). *Progres en Urologie* 2004;**14**(3 Suppl 3):23. [31089]
- Soligo 2002** {published data only}
Soligo M, Salvatore S, Arcari V, Citterio S, Malberti S, Lalia M, et al. Cough stress test and urodynamics: do they correlate? (Abstract). Proceedings of the International Continence Society (ICS), 32nd Annual Meeting; 2002 Aug 28-30; Heidelberg, Germany. 2002:90-1 (Abstract 166).
- Sullivan 1999** {published data only}
Sullivan J, Lewis P, Howell S, Shepherd A, Abrams P. Does contrast medium affect the results of urodynamics? (Abstract). Proceedings of the International Continence Society (ICS), 29th Annual Meeting; 1999 Aug; Denver, Colorado. 1999:98-9 (Abstract 331).
- Sullivan 2001** {published data only}
Sullivan J, Bulmer P, Lewis P, Howell S, Shepherd A, Swithinbank L, et al. Small changes in filling medium temperature and filling rate affect urodynamic results. *Neurourology and Urodynamics* 2001; Vol. 20, issue 4: 567-8 (Abstract 121).
- Sutherst 1984** {published data only}
Sutherst JR, Brown MC. Comparison of single and multichannel cystometry in diagnosing bladder instability. *British Medical Journal* 1984;**288**(6432):1720–2. MEDLINE: 84232969
- Swift 1997** {published data only}
Swift SE. The reliability of performing a screening cystometrogram using a fetal monitoring device for the detection of detrusor instability. *Obstetrics and Gynecology* 1997;**89**(5 Pt 1):708–12. MEDLINE: 97309115
- Swithinbank 1995** {published data only}
Swithinbank LV, Lewis PA, Abrams P. Low detrusor compliance in neurologically normal women - the need for a working definition (Abstract). Proceedings of the International Continence Society (ICS), 25th Annual Meeting; 1995 Oct; Sydney, Australia. 1995:426-7 (Abstract 326).
- Truzzi 1999** {published data only}
Truzzi JC, Bruschini H, Srougi M. Interferences of fluid osmolality in vesical parameters during urodynamic examination (Abstract). Proceedings of the International Continence Society (ICS), 29th Annual Meeting; 1999 Aug 22-26; Denver, Colorado. 1999:92.
- Visco 2004** {published data only}
Visco A. Comparison of measurements obtained with microtip and external water pressure transducers (Abstract). *Neurourology and Urodynamics* 2004;**23**(5/6):588–9. [19019]
- Visco 2008** {published data only}
Visco AG, Brubaker L, Nygaard I, Richter HE, Cundiff G, Fine P, et al. The role of preoperative urodynamic testing in stress-continent women undergoing sacrocolpopexy: the Colpopexy and Urinary Reduction Efforts (CARE) randomized surgical trial. *International Urogynecology Journal* 2008;**19**(5):607–14.
- Voorham-Van 2007** {published data only}
Voorham-Van Der Zalm PJ, Pelger RCM, Ouwkerk TJ, Elzevier HW, Lycklama a Nijeholt GAB. Impact of intra vaginal electrostimulation on urodynamic parameters in the overactive bladder syndrome (Abstract number ?90164). Proceedings of the Annual Meeting of the American

Urological Association (AUA), 2007 May 19-24, Anaheim CA. 2007. [23768]

Wadie 2009 {published data only}

Wadie BS, El Hefnawy AS. Urethral pressure measurement in stress incontinence: does it help?. *International Urology and Nephrology* 2009;**41**(3):491-5.

Yip 2006 {published data only}

Yip S, Cheon C, Wong T, Pang M, Lee L, Yuen C, et al. A randomised double-blind placebo-controlled trial of prophylactic antibiotics in preventing female urinary tract infection after urodynamic study (Abstract number 99). *Neurourology and Urodynamics* 2006;**25**(6):627-8. [26628]
Yip SK, Cheon C, Wong T, Pang MW, Lee L, Yuen C, et al. Preventing female urinary tract infection caused by urodynamic study: a randomised double-blind placebo-controlled trial of prophylactic Augmentin (Abstract number 47). *International Urogynecology Journal and Pelvic Floor Dysfunction* 2006;**17** Suppl 2:S85-6. [34184]

Zehnder 2008 {published data only}

Zehnder P, Roth B, Burkhard FC, Kessler TM. Air charged and microtip catheters cannot be used interchangeably for urethral pressure measurement: a prospective, single-blind, randomized trial. *Journal of Urology* 2008;**180**(3):1013-7. [27508]

Zerin 1993 {published data only}

Zerin JM. Impact of contrast medium temperature on bladder capacity and cystographic diagnosis of vesicoureteral reflux in children. *Radiology* 1993;**187**(1):161-4.

References to studies awaiting assessment

Romero Maroto 2010 {published data only}

Romero Maroto J, Ortiz Gorraiz MA, Gomez Perez L, Lopez Lopez A, Sanchez A, Pacheco Bru JJ. Does pressure flow study improve the outcome of surgery in women with SUI?. *European Urology Supplements* 2010;**9**(2):228.

References to ongoing studies

Hilton 2011 {published data only}

Murdoch M, McColl E, Howel D, Deverill M, Buckley BS, Lucas M, et al. INVESTIGATE-I (INVasive Evaluation before Surgical Treatment of Incontinence Gives Added Therapeutic Effect?): study protocol for a mixed methods study to assess the feasibility of a future randomised controlled trial of the clinical utility of invasive urodynamic testing. *Trials [Electronic Resource]* 2011;**12**: 169. [SR-INCONTid41694]

Additional references

Abrams 2002

Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, et al. The standardisation of terminology of lower urinary tract function: Report from the standardisation sub-committee of the International Continence Society. *Neurourology and Urodynamics* 2002;**21**(2):167-78.

Abrams 2009

Abrams P, Cardozo L, Khoury S, Wein A. *Incontinence, 4th International Consultation on Incontinence*. 4. Paris: Editions 21, 2009.

AHCPR 1996

Fantl JA, Newman DK, Colling J, DeLancey JOL, Keelys C, Loughery R, et al. Chapter 2: Identifying and evaluating urinary incontinence. In: Agency for Health Care Policy and Research, editor(s). *Urinary Incontinence in Adults: Acute and Chronic Management*. 2. Washington, DC: US Government Printing Office, 1996.

Alhasso 2005

Alhasso A, Glazener CMA, Pickard R, N'Dow J. Adrenergic drugs for urinary incontinence in adults. *Cochrane Database of Systematic Reviews* 2005, Issue 3. DOI: 10.1002/14651858.CD001842.pub2

Alhasso 2006

Alhasso AA, McKinlay J, Patrick K, Stewart L. Anticholinergic drugs versus non-drug active therapies for overactive bladder syndrome in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 4. DOI: 10.1002/14651858.CD003193.pub3

Black 1997

Black N, Griffiths J, Pope C, Bowling A, Abel P. Impact of surgery for stress incontinence on morbidity: cohort study. *BMJ* 1997;**315**:1493-8. MEDLINE: 98082059

Black 1998

Black N. Impact of surgery for stress incontinence on morbidity. Author's reply [letter]. *BMJ* 1998;**317**(7151): 144.

Campbell 2007

Campbell R, Cook J, Dublin N. Anticholinergic drugs versus other medications for overactive bladder syndrome in adults. *Cochrane Database of Systematic Reviews* 2007, Issue 4. DOI: 10.1002/14651858.CD003190.pub4

Cardozo 1980

Cardozo LD, Stanton SL. Genuine stress incontinence and detrusor instability--a review of 200 patients. *British Journal of Obstetrics and Gynaecology* 1980;**87**(3):184-90. MEDLINE: 80220963

Chapple 2006

Chapple CR, Roehrborn CG. A shifted paradigm for the further understanding, evaluation, and treatment of lower urinary tract symptoms in men: Focus on the bladder. *European Urology* April 2006;**49**(4):651-9.

Deeks 2011

Deeks JJ, Higgins JPT, Altman DG (editors). Chapter 9: Analysing data and undertaking meta-analyses. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions*. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Duggan 2003

Duggan PM, Wilson PD, Norton P, Brown AD, Drutz HP, Herbison P. Utilization of preoperative urodynamic

- investigations by gynecologists who frequently operate for female urinary incontinence. *International Urogynecology Journal* 2003;**14**(4):282–7.
- Fowler 2006**
Fowler G, Richmond D. Urodynamics: a mandatory preoperative investigation?. *The Obstetrician and Gynaecologist* 2006;**8**:86–90.
- Gorton 1999**
Gorton E, Stanton S. Women's attitudes to urodynamics: a questionnaire survey. *British Journal of Obstetrics and Gynaecology* 1999;**106**(8):851–6. MEDLINE: 99381640
- Gorton 2000**
Gorton E, Stanton S. Ambulatory urodynamics: do they help clinical management?. *British Journal of Obstetrics and Gynaecology* 2000;**107**(3):316–9. MEDLINE: 20201607
- Griffiths 2005**
Griffiths D, Kondo A, Bauer S, Diamant N, Liao L, Lose G, et al. Dynamic testing. *Incontinence: 3rd International Consultation on Incontinence*. 3rd. Paris, France: Health Publication Ltd, 2005.
- Haylen 2010**
Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Report on the Terminology for Female Pelvic Floor Dysfunction. *Neurourology and Urodynamics* 2010; **29**:4–20.
- Higgins 2003**
Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**: 557–60.
- Higgins 2011**
Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.
- Homma 1999**
Homma Y, Batista JE, Bauer SB, Griffiths DJ, Hilton P, Kramer G, et al. Urodynamics. In: Abrams P, Wein A, Schussler B, Kawabi K, Bump R, Melchior H, et al. editor(s). *Incontinence. First International Consultation on Incontinence. Recommendations of the International Scientific Committee: the evaluation and treatment of urinary incontinence*. Plymouth, UK: Health Publication Ltd, 1999: Chapter 9.
- Hosker 2009**
Hosker G, Rosier P, Gajewski J, Sand P. Dynamic Testing. In: Abrams P, Cardozo L, Khoury S, Wein A editor(s). *Incontinence: 4th International Consultation on Incontinence*. Paris: Health Publication Ltd, 2009:413–522.
- Hunnskaar 2002**
Hunnskaar S, Burgio K, Diokno AC, Herzog AR, Hjalmas K, Lapitan M. Epidemiology and natural history of urinary incontinence. *Incontinence: 2nd International Consultation on Incontinence*. Plymouth, UK: Health Publication Ltd, 2002:165–202.
- Jarvis 1980**
Jarvis GJ, Hall S, Stamp S, Millar DR, Johnson A. An assessment of urodynamic examination in incontinent women. *British Journal of Obstetrics and Gynaecology* 1980; **87**(10):893–6. MEDLINE: 81039795
- Latthe 2012**
Foon R, Tooze-Hobson P, Latthe P. Prophylactic antibiotics to reduce the risk of urinary tract infections after urodynamic studies. *Cochrane Database of Systematic Reviews* 2012, Issue 10. DOI: 10.1002/14651858.CD008224.pub2
- Lose 1996**
Lose G, Thyssen H. Reproducibility of cystometry and pressure-flow parameters in female patients. *Neurourology and Urodynamics* 1996;**15**:302–3.
- Lose 1998a**
Lose G, Fantl JA, Victor A, Walter S, Wells TL, Wyman J, et al. Outcome measures for research in adult women with symptoms of lower urinary tract dysfunction. *Neurourology and Urodynamics* 1998;**17**(3):255–62.
- LUTS Guideline 2010**
National Clinical Guideline Centre, National Institute for Health & Clinical Excellence (NICE). The management of lower urinary tract symptoms in men. <http://www.nice.org.uk/nicemedia/live/12984/48554/48554.pdf> 2010 (last accessed 5 December 2011).
- Madhuvrata 2012**
Madhuvrata P, Cody JD, Ellis G, Herbison GP, Hay-Smith EJC. Which anticholinergic drug for overactive bladder symptoms in adults. *Cochrane Database of Systematic Reviews* 2012, Issue 1. DOI: 10.1002/14651858.CD005429.pub2
- Mariappan 2005**
Mariappan P, Alhasso AA, Grant A, N'Dow JMO. Serotonin and noradrenaline reuptake inhibitors (SNRI) for stress urinary incontinence in adults. *Cochrane Database of Systematic Reviews* 2005, Issue 3. DOI: 10.1002/14651858.CD004742.pub2
- Nabi 2006**
Nabi G, Cody JD, Ellis G, Hay-Smith J, Herbison GP. Anticholinergic drugs versus placebo for overactive bladder syndrome in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 4. DOI: 10.1002/14651858.CD003781.pub2
- NCCWCH 2006**
National Collaborating Centre for Women's & Children's Health. Urinary Incontinence - the management of urinary incontinence in women. *Commissioned by the National Institute for Health & Clinical Excellence*. London: RCOG Press, 2006.
- RCOG 2003**
RCOG. *Guideline No. 35. Surgical management of urodynamic stress incontinence*. Royal College of Obstetricians and Gynaecologists, UK, 2006.

Sevestre 2003

Sevestre S, Ciofu C, Deval B, Traxer O, Amarenco G, Haab F. Results of the tension-free vaginal tape technique in the elderly. *European Urology* 2003;**44**(1):128–31.

Sorensen 1988

Sorensen S, Gregersen H, Sorensen SM. Long term reproducibility of urodynamic investigations in healthy fertile females. *Scandinavian Journal of Urology and Nephrology Supplementum* 1988;**114**:35–41.

Ward 2002

Ward K, Hilton P. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. *BMJ* 13 July 2002;**325** (7355):67.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Holte Dahl 2000

Methods	<p>RCT.</p> <p>Setting: women recruited from the community in North-Norwegian municipalities, and treated by GPs and gynaecologists at Norwegian hospitals (Tromsø, Bodø), between 1994-95</p>
Participants	<p>Women invited from random sample of community-dwelling women to attend GP to have gynaecological examination (N = 507, of whom 240 had some UI). A subset with incontinence were randomised to early (6 months) or delayed (12 months) urodynamic studies (87/155 who leaked >1x/month)</p> <p>Inclusion: women with UI that is a social or hygienic problem; UI at least twice per month; objective UI diagnosed by GP (visible leakage; or > 2 g urine on 48-hour pad test; or record of 'wet' on 48-hour frequency/volume chart)</p> <p>Exclusion: cardiac pacemaker, dementia, inability to comply with treatment, conditions requiring early gynaecological referral</p> <p>Age range: 50 to 74 years</p> <p>Comparability at baseline: age: A, 60; B, 61 years; parity: A, 3.2; B, 3; BMI: A, 26.8; B, 26.4</p>
Interventions	<p>A (45) EARLY URODYNAMICS: no treatment by GP for 6 months, then urodynamic investigation and treatment by gynaecologist at 6 and 12 months (diagnosis or treatment could be changed at 6 or 12 months)</p> <p>B (42) DELAYED URODYNAMICS: conservative treatment by GP for 12 months, then urodynamic investigation by gynaecologist at 12 months if still required (diagnosis or treatment could be changed at 12 months)</p> <p>Urodynamics: measurement of residual urine; bladder filling; urethral pressure profile; stress test with pad weighing; cystometry, cystoflowmetry; cystoscopy (first examination only); and gynaecological examination</p> <p>Conservative treatment: all women had oestriol and pelvic floor exercises, and advice about pads or pants; women with urgency also had bladder training and maximal electrical stimulation; women with stress had vaginal long-term electrical stimulation; women with mixed UI had all treatments</p> <p>Surgical treatment: women with persistent UI after 12 months had the option of surgery (but every woman had the option of urodynamics by then either at 6 or 12 months)</p>
Outcomes	<p>Data at 6 months not relevant to randomisation to urodynamics or not, as group A were not treated (but their incontinence outcomes did not improve, while those in group B did)</p> <p>Not cured within 12 months: A, 41/44; B, 37/41</p> <p>Not improved within 12 months: A, 19/44; B, 17/41</p> <p>Change in severity index at 12 months (mean, (95% CI) SD): A, 1.4 (0.7 to 2.2) 2.3; B, 1.6 (0.8 to 2.4) 2.5</p> <p>Change in impact index at 12 months (mean, (95% CI) SD): A, 0.6 (0.4 to 0.9) 0.99; B, 0.7 (0.4 to 1) 0.95</p> <p>Wet episodes at 12 months (mean/24 hours): A, 0.9; B, 0.4 (no SDs)</p>

	Pad test weight (mean g): A, 10; B, 10 (no SDs) Number having urodynamics at 12 months: A, 37/45; B, 12/42 Number whose treatment was changed after urodynamics: A (at 6 months), 11/45 plus (at 12 months) 4/45; B (at 12 months): 1/42 Number having surgery after 12 months: A, 4/45 (3 cured); B, 1/42 (assumed 1 cured) Number failed after 12 months (including results of surgery): A, 38/44; B, 36/41	
Notes	While some women had different diagnoses resulting in different treatments after uro-dynamics, there were no apparent differences in UI outcomes. However, only 12/42 women in the delayed-urodynamics group (B) elected to have urodynamics at 12 months because they were still bothered by their incontinence. The meaning of this finding is unclear	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sequence derived from random numbers table
Allocation concealment (selection bias)	Low risk	GP telephoned third party who opened top sealed, opaque envelope to reveal allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Gynaecologists were blinded to GP diagnosis when reviewing the patient with uro-dynamics, but method of measurement of cure outcomes not specified
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for all women
Selective reporting (reporting bias)	Low risk	Range of outcomes reported, including primary outcome
Financial support	Low risk	Comprehensive details provided
Sample size calculation	Unclear risk	Not specified
Medical ethics approval	Unclear risk	Not specified
Informed consent	Low risk	Written and informed consent given
Other bias	Low risk	None identified

Khullar 2000

Methods	RCT, method of allocation unknown: 'randomised' Follow up for 3 years
Participants	105 80 women followed up by case records 64 women followed up at 3 years Inclusion: women with urinary symptoms and no previous urodynamic diagnosis, recruited from urodynamic clinic Groups comparable at baseline: age (year, SD) A: 50 (16); B: 56 (17) Hospital urogynaecology unit, London, England
Interventions	A (42): Ambulatory urodynamics (4-hour ambulatory urodynamic test with a set fluid intake and provocative manoeuvres with a full bladder) B (38): Symptomatic treatment (12 women lost from this group at 3 years and a further 4 died)
Outcomes	Number treated with drugs: A: 30/42; B: 14/38 Number treated surgically: A: 16/42; B: 6/38 Stress Incontinence Score (n, mean, (SD)): A: 42, 0.7 (0.9); B: 22, 1.2 (1.7) Death: A: 0/42; B: 4/38
Notes	No mention of power calculation or blinding Analysis excluding dropouts Authors contacted for more information Abstract only

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not specified
Allocation concealment (selection bias)	Unclear risk	'Randomised'
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No data (postal questionnaires and case note review)
Incomplete outcome data (attrition bias) All outcomes	High risk	4 women died and 12 were lost to follow up from control group, none from intervention group
Selective reporting (reporting bias)	High risk	No primary outcome data (number of women with incontinence)
Financial support	Unclear risk	No details provided
Sample size calculation	Unclear risk	Not specified

Khullar 2000 (Continued)

Medical ethics approval	Unclear risk	Not specified
Informed consent	Unclear risk	Not Specified
Other bias	High risk	Abstract only, no further information provided by authors when contacted

Majumdar 2009

Methods	RCT: 'randomised' to treatment or investigation using web-based generation of random sequence, and sealed opaque envelopes for allocation Women who did not wish to be randomised were included as extra cohorts in a patient preference design and given treatment of choice (urodynamics or not) Setting: tertiary referral centre	
Participants	309 women with UI and lower urinary tract symptoms, of whom 99 agreed to be randomised: the rest chose whether or not to have urodynamics before treatment, 153 chose to have urodynamics, 57 chose not according to their own preference Inclusion: age >18 years; urinary incontinence; lower urinary tract symptoms (frequency, urgency, nocturia, voiding difficulties) Exclusion: planned surgery for prolapse stage 2 or more; neurological problems; cognitive problems; previous tertiary treatment for UI; recurrent dysuria or UTI Incontinence Episode Frequency at baseline: A 5.2, B 5.5 (NS)	
Interventions	Randomised women only: A (52): urodynamic assessment before conservative treatment B (47): conservative treatment without urodynamic assessment	
Outcomes	Failure to attend next appointment: A 4/52, B 13/47 Incontinence Episode Frequency after treatment (mean, N): A 4.34, 42; B: 5.51, 33 Change in Incontinence Episode Frequency from before to after treatment (mean change (SD*) N): A -0.29 (1.03) 42, B: -0.7 (1.11) 33 Quality of life (incontinence impact on King's QoL questionnaire) mean (SD) N: A 82.1 (24.6), 42; B 76.3 (24.2) 33 Also 8 other King's Health questionnaire outcomes	
Notes	*SDs for change in incontinence episode frequency calculated from 95% CI for change from baseline	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Web-based Trial Simulator programme

Majumdar 2009 (Continued)

Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes opened in front of patients
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes analysed blinded to randomised groups
Incomplete outcome data (attrition bias) All outcomes	High risk	Higher dropout from control group (4 versus 13)
Selective reporting (reporting bias)	High risk	No primary outcome (number of women with incontinence)
Financial support	Unclear risk	Not specified
Sample size calculation	High risk	Not calculated. Authors give reason for this being the lack of background data in the scientific literature
Medical ethics approval	Low risk	Details provided
Informed consent	Low risk	Provided
Other bias	High risk	SDs not available for incontinence episode frequency

Nager 2009

Methods	Randomised non-inferiority trial Setting: 11 centres of reproductive medicine, urology and obstetrics and gynaecology, USA
Participants	683 participants were enrolled and 630 were randomized (315 per arm) Inclusion: Women presenting with UI, aged over 21, history of symptoms of SUI of at least 3 months, MESA score for SUI greater than for UI on same scale, post-voiding residual bladder volume less than 150 ml, negative urinalysis or culture, clinical assessment of urethral mobility, desire for surgery for SUI and a positive provocative stress test Exclusion: Aged < 21 years, previous surgery for incontinence, history of pelvic irradiation, pelvic surgery within previous 3 months, anterior or apical POP of 1cm or more distal to the hymen, within 1 year post partum, pregnant or not completed family, cancer, radiotherapy, urological surgery, recent gynaecological surgery, any mesh surgery, previous botox treatment, previous urodynamics in last 12 months or knowledge about early urodynamics
Interventions	A: (n = 315) basic office evaluation (history and examination without urodynamic studies) B: (n=315) As above plus urodynamic studies (non-instrumented flowmetry, filling cys-

	tometry with Valsalva leak point pressures, pressure flow study)	
Outcomes	Maximum number of people with outcome data per arm: A: 272 and B: 266 Persistent SUI at 12 months after treatment following assessment with and without UDS (number/total number): A 81/274, B 85/273 Success defined as 70% decrease in UDI score or “better/much better” on PGI: A 203/264, B 200/259 Number of people having surgery: A 298/315, B 288/315 Number of women satisfied with treatment (PGI-I score classed as ‘very much better’ or ‘much better’): A 248/270, B 238/262 Objective assessment of incontinence cure or improvement at post-intervention urodynamics testing (positive provocative stress test at 12 months): A 36/225, B 26/222 Adverse events: total number of adverse events: A 80/315, B 79/315; Number of women with adverse events: A 67/315, B 61/315 General health status measures: Change in SF-12 from baseline to 12 months (mean (SD) N): A 5.0 (10.8) 267, B 7.3 (12.0) 261 Condition specific health status measures: Urgency symptoms or urgency incontinence (change in MESA score from baseline to 12 months for UUI, mean (SD) N): A -19.7 (21.4) 272, B -22.2 (22.4) 266 Change in Incontinence Impact Questionnaire score from baseline to 12 months (mean (SD) N): A -35.9 (23.2) 272, B -37.3 (23.7) 266	
Notes	ClinicalTrials.gov identifier: NCT00803959 Powere calculations were used to estimate participant numbers. A sample of 300 women per group was required assuming a 10% dropout rate Reported per protocol and also intention-to-treat (ITT) analysis	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used “randomly assigned ... use of an automated randomization system stratified according to surgeon”
Allocation concealment (selection bias)	Low risk	“automated randomization system” was used
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessor at baseline for urodynamics group may or may not have remembered which diagnosis they came to before and after the intervention. Moreover, at 3 and 12 months, it is unclear whether the outcome assessor was the same as baseline or not and if so they may remember the initial diagnosis

Nager 2009 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Well documented data of small dropouts, numbers were equally balanced and reasons were well documented. Found to be statistically insignificant ($P = 0.12$)
Selective reporting (reporting bias)	Low risk	Reported all pre-specified outcomes from the study protocol
Financial support	Low risk	Financial support details provided
Sample size calculation	Low risk	Calculated needing 300 women per arm for statistical significance. Recruitment achieved these numbers
Medical ethics approval	Low risk	Protocol approved at each site
Informed consent	Low risk	Written and informed consent gained from participants
Other bias	Low risk	No other sources of bias

O'Connell 2003

Methods	RCT, using balanced randomisation schedule based on permuted blocks, stratified on MS and urological status Setting: Neurourology and Continence Outpatient Clinic, Royal Melbourne Hospital, Australia
Participants	19 (4 male, 15 female) Inclusion: Multiple sclerosis, informed consent, bladder problems or urgency or difficulty starting to urinate or urinary incontinence Exclusion: Asymptomatic, recent urodynamic investigation, unable to attend clinic, unwilling to be catheterised, prostate problems, pregnancy, urinary diversion
Interventions	A (9): Treatment based on history and urodynamic investigation B (10): Treatment based on history only (participants did have urodynamics, but the nurse who provided treatment was blinded to the results) Fluoroscopic urodynamic testing included assessment of bladder sensation, detrusor reflex function, detrusor compliance, presence of obstruction and location, activity of the external urethral sphincter by direct measurement and indirect measurement using bladder leak point pressures
Outcomes	Incontinence outcomes measured using UGDI-6, IIQ-7, AVA-SS, Urol QoL No outcome data presented according to the randomised groups
Notes	Information from Grant Report only, no response from author when requesting more data Power calculation suggested 25 participants needed per arm

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Balanced randomisation schedule based on permuted blocks, stratified on MS and urological status
Allocation concealment (selection bias)	Low risk	Computer-controlled
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No data
Incomplete outcome data (attrition bias) All outcomes	High risk	No useable data reported
Selective reporting (reporting bias)	High risk	No useable data reported
Financial support	Unclear risk	Not specified
Sample size calculation	Low risk	Both sample size and power calculation carried out. Required number of 17 patients per arm was not met, however still deemed 'low risk' as sample size was calculated
Medical ethics approval	Low risk	Received from the local hospital ethics committee
Informed consent	Low risk	Written and informed consent gained from participants
Other bias	High risk	No useable data reported

Ramsay 1995

Methods	RCT, computer-generated random numbers but method of allocation unknown Follow up for 3 months
Participants	60, of whom 12 withdrawn due to not completing treatment (A,7; B,5) Inclusion: women with urinary frequency, urgency, nocturia, urge incontinence or stress incontinence Exclusion: previous incontinence treatment, hematuria, recurrent dysuria, voiding difficulty or UTI Groups stated to be comparable at baseline but data not given Hospital outpatient clinic, Glasgow, Scotland

Interventions	A (27): Urodynamics (uroflowmetry, filling and voiding cystometry, perineal pad test) and treatment tailored according to diagnosis (pelvic floor muscle training for stress urinary incontinence, bladder training for urgency urinary incontinence, clean intermittent self-catheterisation for voiding dysfunction) B (33): Conservative treatment as inpatient (5 day stay, dietary advice, monitoring fluid intake, psychological support, psychotherapy if necessary, pelvic floor muscle training by physiotherapists for stress urinary incontinence, bladder training for urgency urinary incontinence)	
Outcomes	Subjective questionnaire, urinary diary, pad test Subjective failure rate (patient report): A: 8/20; B: 8/28 Subjective failure rate (diary record): A: 10/20; B: 12/28 Incontinence episodes/week (mean (SD) N): A: 3.6 (3.1) 20; B: 3.0 (2.8) 28 Pad test, weight urine lost: A: 6.0 (19.3); B: 3.9 (11.1) Objective failure rate (wet pad test): A: 7/20; B: 7/28 Visual analogue scale: A: 20, 4.1 (3.0); B: 28, 3.4 (2.4) Urinary frequency per day (mean (SD) N): A: 6.9 (1.3) 20, B: 6 (1.4) 28 Nocturia voids per night (mean (SD) N): A: 0.9 (1.2) 20, B: 0.8 (0.9) 28	
Notes	Pad test = short test, bladder filled with 200 ml fluid No mention of power calculation or blinding Analysis excluding dropouts Method of urodynamics described Authors contacted for more information	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number
Allocation concealment (selection bias)	Unclear risk	'Randomly allocated'
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes (questionnaires, diaries, pad test, VAS) were participant-reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropouts similar in each group
Selective reporting (reporting bias)	Low risk	Range of outcomes reported
Financial support	Unclear risk	No details given
Sample size calculation	Unclear risk	No details provided
Medical ethics approval	Unclear risk	Not specified

Ramsay 1995 (Continued)

Informed consent	Unclear risk	Not specified
Other bias	High risk	Short follow up

van Leijsen 2011

Methods	RCT VUSiS 1 Computer generated, stratified by centre Setting: University and other hospitals in Holland Follow up: 6 weeks, 6 12 and 24 months: mean 22 months (SD 7) VUSiS 1
Participants	Inclusion criteria: stress urinary incontinence or mixed urinary incontinence with pre-dominant symptoms of stress urinary incontinence, failed conservative management, patients eligible for and opting for surgical management, incontinence suggestive of stress urinary incontinence must have been demonstrated on physical examination and/or micturition diary Exclusion criteria: previous incontinence surgery, pelvic organ prolapse over 1cm beyond the level of the hymen, postvoid residual urine volume of more than 150ml on ultrasound or catheterization
Interventions	A (31): Urodynamics before treatment B (28): no urodynamics, treatment based on symptoms only
Outcomes	Clinical examination, voiding diary, self-completed questionnaires (UDI, IIQ and PGI-I) Number treated surgically: A, 26/31; B, 27/28 Number with management changed to drugs due to urodynamics: A, 3/31; B, 0/28 Subjective incontinence (22 months, SD 7): A, 13/29, B, 7/28 Subjective stress incontinence (from UDI) A: 10/29, B 6/28 Incontinence on voiding diary (objective): A, 8/31; B, 3/27 Incontinence on stress test (objective): A, 2/27; B 2/26 Voiding dysfunction: A, 3/31, B: 7/28 De novo urgency or OAB: A, 6/31; B, 1/28 Quality of life (Urogenital Distress Inventory, mean improvement (SD) N) at 1 year: A, -34 (22) 19; B, -48 (22) 21 Quality of life (UDI, mean improvement (SD) N) at 2 years: A, -33 (23) 29; B, -41 (23) 28
Notes	Trial stopped prematurely because of a hesitating inclusion rate

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated using block randomisation with variable block sizes, stratified by centre

van Leijsen 2011 (Continued)

Allocation concealment (selection bias)	Low risk	Computer-generated
Blinding of outcome assessment (detection bias) All outcomes	High risk	Gynaecologist or urologist was not blinded to allocation when performing stress test. Nurses were not blinded when recording data
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data identified (3%), data entered as reported, excluding missing information
Selective reporting (reporting bias)	Low risk	Objective and subjective cure and global improvement/impairment reported
Financial support	Low risk	Full details provided and no commercial partner involved
Sample size calculation	Low risk	Sample of 130 in each group required to reach a power of 70%. Only 31 patients in arm A were recruited and 28 in arm B. Low risk however as appropriate calculations were performed
Medical ethics approval	Low risk	Ethical approval sought and gained from local institutional review board
Informed consent	Low risk	Written, informed consent provided by all participants
Other bias	Unclear risk	Underpowered due to lack of recruitment

van Leijsen 2012

Methods	VUSIS 2 - Multicentre RCT embedded within a cohort study Participants with discordant urodynamic and clinical assessment findings entered into RCT Web-based block randomisation based upon a computer-generated random number list Setting: 6 academic and 24 non-academic hospitals in the Netherlands Follow up: 6 weeks, 6 and 12 months after randomisation (outcomes measured at 12 months)
Participants	Inclusion: Women with SUI demonstrated on clinical assessment or micturition diary, eligible for surgery for SUI, failed conservative therapy for SUI - particularly PFMT, discordant urodynamic findings, able to comply with intervention and study procedures Exclusion: Previous incontinence surgery, mixed urinary incontinence with predominant urgency, pelvic organ prolapse with leading edge of prolapse 1cm beyond the level of the hymen on valsava, post void residual volume of bladder >150 ml on USS or catheterisation, other prolapse surgery or hysterectomy planned, radiotherapy, family not finished

Interventions	Women whose urodynamic findings are discordant with clinical assessment findings will be randomised to: A (64): immediate surgery (midurethral sling) versus B (62): individual treatment based on urodynamic diagnosis (medical, physiotherapy, pessary, surgery) Dropout rates: A, 6; B, 4 + 1 deceased	
Outcomes	Outcome data available for A: 58 and B: 57 Number of women with no UI at 12 months (UDI questionnaire): A 17/58, B 18/55 Number of women with no SUI at 12 months (UDI questionnaire): A 15/58, B 14/56 Number of people treated conservatively: A 3/64, B 5/62 Number of people having surgery: A 61/64, B 57/62 Number of people whose treatment was changed after urodynamics: A 3/64, B 5/62 Need for repeat or alternative treatment (surgery but reason unclear): A 1/62, B 0/64 Voiding dysfunction (subjective) (UDI questionnaire measuring for obstructive symptoms, mean (SD) N): A 11 (22) 58, B 14 (22) 57 Urgency symptoms or urgency incontinence post-intervention (UDI questionnaire measuring for overactive bladder symptoms, mean (SD) N): A 11(17) 58, B 9(13) 57 Satisfaction with treatment (PGI-I score classed as 'Improvement'): A 50/55, B 52/57 Objective assessment of incontinence cure (no leakage of 48-hour micturition diary): A 45/53, B 41/50 Objective assessment of incontinence cure (negative stress test) A 37/38, B 33/34 Deaths: A 0/64, B 1/62 Condition-specific health measures (UDI questionnaire demonstrating mean improvement of UI, mean (SD) N): A 44 (24) 58, B 29 (25) 57	
Notes	Gynaecologists unwilling to randomise women to having urodynamics or not, hence more complicated design used One protocolviolation occurred in immediate surgery group where one participant was postponed and the patient received treatment for DOA in the abscence of urodynamic SUI	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated using block randomisation with variable block sizes, stratified by centre
Allocation concealment (selection bias)	Low risk	Generated by computer
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Subjective outcome assessors extracting data from questionnaires were blinded. Not possible in clinicians performing stress test
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Missing data accounted for (11 participants): 6 subjects lost to follow up in arm

		A and 4 lost in arm B, 1 patient deceased in arm B
Selective reporting (reporting bias)	Low risk	Objective and subjective cure data reported and compared
Financial support	Low risk	Full details given
Sample size calculation	Low risk	51 women per arm required for 80% power. Recruitment numbers met this
Medical ethics approval	Low risk	Approval obtained from local institutional review board
Informed consent	Low risk	Written and informed consent provided by all participants before enrolment
Other bias	Low risk	None identified

OAB = overactive bladder

RCT = randomised controlled trial

RR = risk ratio

UTI = urinary tract infection

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Akil 2005	RCT but of sedation during micturating cystogram in children (midazolam, chloral hydrate or control) and no clinical outcomes reported
Bael 2008	RCT. Participants randomised to treatment regimen (placebo, oxybutynin, bladder training). Compares clinical patterns and urodynamic patterns in urgency syndrome and dysfunctional voiding
Bajpai 1982	RCT. Comparison of Cystomat versus standard multichannel cystometry, but no clinical outcomes reported
Baker 1991	RCT but of placebo versus prophylactic antibiotic in preventing bacteriuria after urodynamic investigation
Batista 1998	RCT. Cystometry comparing saline filling at two different filling rates in children, but no clinical outcomes reported
Baumann 2007	RCT. Compariosn of urine collection success in children with and without bladder ultrasonography

(Continued)

Benson 1991	Possible RCT. Comparison of women randomised to a dynamic ultrasound adjunctive study or urodynamics. However, reference incomplete and author contacted for more information
Bhatia 1985	RCT. Comparison of antibiotic (cefadroxil) versus placebo before lower urinary tract instrumentation, including urethrocystometry as prophylaxis for UTI. No clinical outcomes related to incontinence
Blaivas 2001	RCT. Two different methods of patient instruction compared, but no clinical outcomes reported
Bo 2003	RCT. Urodynamics used to demonstrate differential effects on urethral pressure when contracting different muscle groups (pelvic floor muscles or abdominal transversus abdominis) but no effect on incontinence reported
Byrne 1991	RCT. Comparison of rectal versus vaginal placement of pressure catheter, but no clinical outcomes reported
Chin-Peuckert 2004	RCT. Comparison of different filing solutions but no clinical incontinence outcomes or effect on clinical decisions
Choe 2001	Possible RCT. Comparison of preoperative multichannel urodynamics or preoperative urethroscopy before suburethral myomesh sling surgery for stress urinary incontinence. However, method of allocation to groups unclear, author contacted for more information
Chung 2010	RCT. Comparison of fentanyl versus placebo in pain reduction in paediatric patients undergoing catheterisation
Colstrup 1982	RCT. Comparison of cystometry with balloon inflated versus not inflated, but no clinical outcomes reported
Constatini 20148	RCT. Comparison of different catheter sizes, but no clinical incontinence outcomes or effect on clinical decisions
Culligan 2001	RCT. Comparison of microtransducer and fiberoptic catheters for urodynamic studies, but no clinical outcomes reported
Cundiff 1999	RCT. Assessing effectiveness of antibiotic prophylaxis for combined urodynamics and cystoscopy. No clinical outcomes related to incontinence
Darouiche 1994	RCT. Comparison of antibiotic (ciprofloxacin versus placebo) before urodynamics
Dolan 2005	RCT of different ways of measuring intra-abdominal pressure but no clinical outcomes
Dompeyre 2007	RCT but in normal women. Two types of cystometry compared (standard and VAS-based) and no clinical outcomes reported
Eggersmann 1996	RCT. Comparison of two different lubricants to aid urodynamic study in healthy male volunteers. Subjects not incontinent and no clinical outcomes reported
Gehrich 2012	RCT. Comparison of room and body temperature saline used during cystometry. No clinical outcomes

(Continued)

Gluck 2002	RCT. Comparison of two different filling solutions used during urodynamics (hyperosmolar solution, an extracellular alkalosis solution, two solutions designed to influence intracellular and extracellular pH, and a high-potassium solution, each versus normal saline in random order. No clinical outcomes reported
Goodman 2003	RCT. Comparison of warm or cold contrast medium in micturating cystourethrogram in children, but no clinical outcomes reported
Groutz 2000	RCT. Crossover of order of having two types of cystometry (ICS method, trying to inhibit micturition versus avoiding inhibition) but no clinical outcomes reported
Gurbuz 2011	RCT of antibiotic prophylaxis prior to urodynamic studies
Handa 1994	RCT. Comparison of supine and standing Q-tip tests in random order to diagnose urethral hypermobility. No clinical outcomes
Heslington 1996	RCT. Comparison of conventional versus ambulatory cystometry, but no clinical outcomes reported
Hirakauva 2010	?RCT. Antibiotics to prevent infection after urodynamics
Hosker 1999	RCT. Comparison (in incontinent women) of urodynamics using normal saline versus Urografin 150, but no clinical outcomes reported
Hougardy 2009	RCT. Comparisn of explanatory leaflet or not for women having urodynamics
Hundley 2006	RCT. Comparison of two different microtip catheters or one of each type, but no clinical outcomes reported
Jolic 1997	Not RCT. Comparison of modified transabdominal ultrasonographic method of diagnosing pelvic organ static disturbance (cystocele) and/or stress urinary incontinence with transvaginal endosonography applied to the vaginal introitus. Not in randomised order. Some women were not incontinent, and so did not have urodynamics. No clinical outcomes
Kartal 2002	RCT. Comparison of ciprofloxacin versus nothing
Keidan 2005	RCT but of sedation during micturating cystogram in children (midazolam versus 50% nitrous oxide) and no clinical outcomes reported
Khan 2004	RCT. Comparison of two methods of administration of a standard urinary symptom questionnaire
Khullar 1996	Not RCT. Comparison of transvaginal ultrasound scan to measure vaginal wall thickness with videocystourethrography (urodynamics). Some women also had ambulatory urodynamics. No clinical outcomes reported
Khullar 2002	RCT. Comparison of urodynamics with rectum empty or full, but no clinical incontinence outcomes or effect on clinical decisions
Klarskov 2009	RCT with crossover design assessing usefulness of urethral pressure reflectometry in detecting pressure increases in the urethra. Patients randomised according to treatment to increase urethral closure pressure

(Continued)

Kristjansson 1999	RCT. Comparison of treatment based on urodynamic findings versus treatment decision directly in men with presumed bladder outflow obstruction (voiding dysfunction)
Kuhn 2007	Not RCT. Comparison of tow different techniques, water perfused catheter and microtip transducer catheter
Kulseng 1995	RCT. Comparison of two different methods of ambulatory urodynamics, 2 and 4 hour recording versus 45 minute recording, but no clinical outcomes reported
Lee 2002	RCT. Comparison of two saline filling solutions (20 mM and 200 mM) in double-blind random order. Some differences in bladder sensation found, but no relation to clinical outcomes
Lucas 2009	RCT. Crossover trial about the accuracy of CaptiFlow portable home flow measuring device and its use as a diagnostic tool in the management of LUTS
Malone-Lee 2009	RCT assessing whether urodynamically assessed patients with detrusor overactivity respond differently to treatments. Patients randomised according to placebo or tolterodine
Massey 1987	RCT. Trial 1: Comparison of two methods of obtaining the static profile, Brown and Wickham versus Gaeltec. Trial 2: Comparison of two methods of obtaining a microtransducer cough stress profile, using the rectal line as reference for subtraction versus vesical pressure measured using an epidural catheter. No clinical outcomes reported
Medina 2002	RCT. Comparison of order of position (sit-stand or stand-sit) on urodynamic findings, but no clinical outcomes related to incontinence
Medina 2005	RCT. Comparison of physiological or retrograde fill for urodynamics performed after pelvic surgery. No clinical outcomes and 10 participants from one group excluded due to incorrect or incomplete recording of data
Minardi 2010	RCT but of PFMT and biofeedback for storage and emptying symptoms, and avoiding UTI, using uroflowmetry biofeedback
Mouritsen 1999	RCT. Comparison of 4 different methods of measuring pelvic floor function. Outcome was quality of the pelvic floor muscle contractions. No urodynamics, no incontinence, no clinical outcomes
Mueller 2007	RCT. Crossover comparison of urodynamics + quantitative urethral electromyography with prolapse reduced and not reduced, but not related to urinary incontinence or LUTS outcomes
Neal 1987	RCT. Comparison of different catheter sizes used for urodynamics, but no clinical incontinence outcomes or effect on clinical decisions
Panayi 2008	RCT. Women randmised to have rectal balloon inflated or not during first or second filling phase of filling cystometry. No clinical outcomes
Payne 2001	RCT. Comparison of effect of two filling solutions (normal saline and normal saline + 115 mEq/litre potassium chloride added) on bladder capacity in patients with interstitial cystitis. No clinical outcomes but 2 of 6 patients identified the potassium chloride solution as 'worse' when it was first, and 9 of 10 when it was second

(Continued)

Peschers 2001	RCT. Comparison of cotrimoxazole (antibiotic) administration with matching placebo after urodynamics. No clinical outcomes related to incontinence reported
Peters-Gee 2003	RCT. Crossover comparison of 2 different urodynamics systems, but no clinical incontinence outcomes or effect on clinical decisions
Philip 2007	RCT. Comparison of different filling solutions (0.9% saline versus 0.3M potassium chloride). No clinical outcomes reported
Radley 2001	RCT, double blind crossover. Comparison of ambulatory urodynamic monitoring versus videocystometry performed in random order and assessed double-blind in order to assess inter-observer agreement. No clinical outcomes reported
Realfonso 2005	?RCT (unclear). Comparison of 2 different filling speeds, but no clinical incontinence outcomes or effect on clinical decisions
Rehme 2009	RCT. Comparison of 2 methods of urodynamics, but no clinical outcomes
Robinson 2002	Not RCT. Comparison of ambulatory urodynamics versus ultrasound assessment of bladder wall thickness
Rovner 2005	RCT. Patients randomised to fesoterodine or placebo for treatment of overactive bladder syndrome
Sand 1985	Prospective crossover study, randomisation not mentioned. Comparison of presence or absence of a filling catheter (6F paediatric feeding tube) upon urethral closure pressure. No clinical outcomes
Scaldazza 2005	RCT. Comparison of 2 different catheter sizes, but no clinical incontinence outcomes or effect on clinical decisions
Schmidt 2001	RCT. Comparison of ambulatory urodynamics with higher or lower fluid intake. Participants not incontinent, and no clinical outcomes
Shukla 2006	RCT. Comparison of different positions (sitting versus standing) while having urodynamic investigation. No clinical outcomes reported
Siracusano 2004	RCT. Comparison of antibiotic prophylaxis or not (norfloxacin vs placebo) to prevent post-intervention UTI, but no clinical incontinence outcomes or effect on clinical decisions
Sirls 2013	Not RCT. Secondary analysis with extra data of Nager 2009 trial but only gives new data on intervention arm of trial and therefore not useable for comparisons
Slack 2004	RCT. Crossover comparison of urodynamics versus urethral retro-resistance pressure measurement, but no clinical incontinence outcomes or effect on clinical decisions
Slack 2004a	RCT. Comparison of multichannel versus single channel cystometrogram. No clinical outcomes reported
Soligo 2002	RCT. Comparison in random order of cough stress test and complete urodynamic test for diagnosis of stress urinary incontinence. No effect on decision making described, and no clinical outcomes

(Continued)

Sullivan 1999	RCT, crossover. Comparison (in incontinent men) of urodynamics using normal saline versus Urografin 150, but no clinical outcomes reported
Sullivan 2001	RCT, two trials: Trial I: crossover. Comparison (in incontinent but neurologically normal people) of urodynamics using room temperature or body temperature saline filling solution Trial II: crossover. Comparison (in incontinent but neurologically normal people) of urodynamics using 50 ml saline on first examination, followed by randomisation to 50 ml or 100 ml Both temperature and filling rate affected results of urodynamic test, but no clinical outcomes were provided
Sutherst 1984	RCT, single blind crossover. Comparison of single channel cystometry versus standard multichannel cystometry, but no clinical outcomes reported
Swift 1997	RCT. Comparison of multichannel electronic cystometer versus intrauterine pressure channel of a fetal monitor, but no clinical outcomes reported
Swithinbank 1995	RCT, single blind crossover. Comparison of two different filling speeds (50 ml/m versus 100 ml/m) to measure bladder compliance, but no clinical outcomes reported
Truzzi 1999	RCT ('by chance'). Comparison of hypotonic (100 mOsm/litre) and hypertonic (1000 mOsm/litre) sodium chloride filling solutions. No clinical outcomes
Visco 2004	RCT. Comparison of 2 different transducers, but no clinical incontinence outcomes or effect on clinical decisions
Visco 2008	RCT. Comparison of surgical treatments of prolapse. All patients received urodynamic investigation
Voorham-Van 2007	Unclear whether RCT. No clinical outcomes reported
Wadie 2009	RCT. Comparison of surgical treatments of stress urinary incontinence. All patients received urodynamic investigation
Yip 2006	RCT. Comparison of antibiotic (Augmentin) versus placebo as prophylaxis to prevent UTI after urodynamics
Zehnder 2008	RCT. Comparison of microtip or air charged catheters for urodynamics, crossover design. No clinical outcomes reported
Zerin 1993	RCT. Comparison of room temperature or warmed cystographic contrast material in children, but no clinical outcomes reported

RCT = randomised controlled trial

UTI = urinary tract infection

Characteristics of studies awaiting assessment *[ordered by study ID]*

Romero Maroto 2010

Methods	RCT
Participants	Inclusion: patients with stress or mixed urinary incontinence agreeing to be randomised in the trial Exclusion: patients younger than 18 years of age; previous radiotherapy; any anti-incontinence procedure previously
Interventions	A (44): basic office evaluation only prior to stress urinary incontinence surgery B (42): basic office evaluation as well as urodynamic studies prior to stress urinary incontinence surgery
Outcomes	Urinary incontinence grade on cough stress test: Dry (A 36/44, B 38/42); Improved (A 7/44, B 3/42); Failure (A 1/44, B 1/42) ICIQ-SF 'How often leak': Never (A 24/44, B 24/42); Once/week (A 10/44, B 6/42); 2-3 times/week (A 2/44, B 3/42); Once a day (A 2/44, B 6/42); Several/day (A 5/44, B 3/42); All the time (A 0/44, B 0/42) ICIQ-SF 'UI type': SUI (A 3/44, B 5/42); MUI (A 16/44, B 10/42); UUI (A 4/44, B 3/42) I-QOL Points: (A 84.9 ± 20.1, B 88 ± 17.6) Qmax ml/s: (A 21.7 ± 7.9, B 22.7 ± 8.3) Urgency (clinical history): 'de novo' (A 3/44, B 1/44); Disappears (A 11/44, B 16/42); Persists (A 17/44, B 17/42)
Notes	Unclear as to whether randomisation to urodynamic studies could affect the decision making of the clinician with regards to the treatment the patients would receive or not

Characteristics of ongoing studies *[ordered by study ID]*

Hilton 2011

Trial name or title	INVESTIGATE-1
Methods	RCT (pilot)
Participants	Inclusion: women with a clinical diagnosis of SUI or stress predominant MUI; failed conservative treatment (e.g. PFMT); requiring surgery for UI Exclusion: symptomatic pelvic organ prolapse; previous incontinence or prolapse surgery; neurological disease causing UI
Interventions	A: Urodynamics B: Basic clinical assessment with non-invasive tests before continence surgery Urodynamics includes multi-channel cystometry; videourodynamics; long-term ambulatory bladder pressure monitoring
Outcomes	Non-invasive and invasive investigations; operative and inpatient procedures including postoperative complications; non-surgical treatments; and resource utilisation ICIQ-FLUTS; three day bladder diary and ICIQ-UI Short Form; the prevalence of symptomatic 'de novo' functional abnormalities including voiding dysfunction and detrusor overactivity (subscales of ICIQ-FLUTS, with cystometry in symptomatic patients), the impact of urinary symptoms on quality of life (ICIQ-LUTSqol and

Hilton 2011 (Continued)

	Urogenital Distress Inventory (UDI)) and utility values from the EQ-5D questionnaire and SF-6D (utility score generated from SF-12 questionnaire)
Starting date	June 2011
Contact information	paul.hilton@ncl.ac.uk
Notes	Current Controlled Trials ISRCTN71327395 assigned 7th June 2010 Feasibility study to determine practicality of definitive trial INVESTIGATE-2

DATA AND ANALYSES

Comparison 1. Urodynamics versus clinical management

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number with incontinence within first year (subjective)	2	133	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.92, 1.29]
2 Number with incontinence after first year (subjective)	4	802	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.86, 1.21]
3 Number with incontinence or not improved within first year (subjective)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4 Number with incontinence or not improved after first year (subjective)	2	649	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.77, 1.38]
5 Number treated conservatively	2	185	Risk Ratio (M-H, Fixed, 95% CI)	1.74 [0.53, 5.76]
6 Number treated with drugs	2	139	Risk Ratio (M-H, Fixed, 95% CI)	2.09 [1.32, 3.31]
7 Number treated with surgery	5	982	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.88, 1.12]
8 Number whose treatment was changed after urodynamics	3	272	Risk Ratio (M-H, Fixed, 95% CI)	5.07 [1.87, 13.74]
9 Number not returning for further treatment	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
10 Number not satisfied with treatment	2	644	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.55, 1.49]
11 Number with urgency symptoms or urgency incontinence after treatment	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
12 Volume/weight of urine lost on pad test	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
13 Number of incontinence episodes in 24 hours	1	48	Mean Difference (IV, Fixed, 95% CI)	0.08 [-0.16, 0.32]
14 Number with incontinence within first year (objective)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
15 Number with incontinence after first year (objective)	3	572	Risk Ratio (M-H, Fixed, 95% CI)	1.33 [0.85, 2.08]
16 Number with adverse events / complications	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
17 Number with voiding dysfunction after treatment	2	689	Risk Ratio (M-H, Fixed, 95% CI)	0.66 [0.29, 1.49]
18 Deaths	2	206	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.08, 1.88]
19 Health status measures	7		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
19.1 General health King's QoL scores at 6 months	1	75	Mean Difference (IV, Fixed, 95% CI)	-6.40 [-16.61, 3.81]
19.2 Incontinence impact from King's QoL questionnaire	1	75	Mean Difference (IV, Fixed, 95% CI)	5.80 [-5.31, 16.91]
19.3 Role limitations King's QoL scores at 6 months	1	75	Mean Difference (IV, Fixed, 95% CI)	-2.40 [-16.38, 11.58]

19.4 Physical limitations King's QoL scores at 6 months	1	75	Mean Difference (IV, Fixed, 95% CI)	-2.80 [-16.97, 11.37]
19.5 Severity measures King's QoL scores at 6 months	1	75	Mean Difference (IV, Fixed, 95% CI)	-7.80 [-22.19, 6.59]
19.6 Social limitations King's QoL scores at 6 months	1	75	Mean Difference (IV, Fixed, 95% CI)	-6.10 [-20.23, 8.03]
19.7 Personal relationships King's QoL scores at 6 months	1	75	Mean Difference (IV, Fixed, 95% CI)	-0.60 [-16.83, 15.63]
19.8 Emotions King's QoL scores at 6 months	1	75	Mean Difference (IV, Fixed, 95% CI)	-3.50 [-16.62, 9.62]
19.9 Sleep energy King's QoL scores at 6 months	1	75	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-12.41, 12.21]
19.10 Severity measures King's QoL scores at 6 months	1	75	Mean Difference (IV, Fixed, 95% CI)	-7.80 [-22.19, 6.59]
19.11 Stress Incontinence Score (King's QoL)	1	64	Mean Difference (IV, Fixed, 95% CI)	-0.5 [-1.26, 0.26]
19.12 Visual Analogue Scale	1	48	Mean Difference (IV, Fixed, 95% CI)	0.70 [-0.89, 2.29]
19.13 Change in severity index	1	85	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-1.28, 0.88]
19.14 Change in incontinence impact index	1	85	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.51, 0.31]
19.15 Change in UI (UDI subscale score for UI) at 12 months	2	155	Mean Difference (IV, Fixed, 95% CI)	14.70 [7.21, 22.19]
19.16 Change in UI (UDI subscale score for UI) at 24 months	1	57	Mean Difference (IV, Fixed, 95% CI)	8.0 [-3.94, 19.94]
19.17 Voiding dysfunction (UDI subscale score)	1	115	Mean Difference (IV, Fixed, 95% CI)	3.00 [-5.04, 11.04]
19.18 Overactive bladder symptoms (UDI subscale score)	1	115	Mean Difference (IV, Fixed, 95% CI)	-2.0 [-7.53, 3.53]
19.19 Urgency score (change in MESA score from baseline for UUI)	1	538	Mean Difference (IV, Fixed, 95% CI)	2.5 [-1.20, 6.20]
19.20 Change in IIQ score from baseline to 12 months	1	538	Mean Difference (IV, Fixed, 95% CI)	1.40 [-2.56, 5.36]
19.21 Change in SF-12 score from baseline to 12 months	1	528	Mean Difference (IV, Fixed, 95% CI)	-2.3 [-4.25, -0.35]

Analysis 1.1. Comparison 1 Urodynamics versus clinical management, Outcome 1 Number with incontinence within first year (subjective).

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 1 Number with incontinence within first year (subjective)

Analysis 1.2. Comparison 1 Urodynamics versus clinical management, Outcome 2 Number with incontinence after first year (subjective).

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 2 Number with incontinence after first year (subjective)

Analysis 1.3. Comparison 1 Urodynamics versus clinical management, Outcome 3 Number with incontinence or not improved within first year (subjective).

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 3 Number with incontinence or not improved within first year (subjective)

Analysis 1.4. Comparison 1 Urodynamics versus clinical management, Outcome 4 Number with incontinence or not improved after first year (subjective).

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 4 Number with incontinence or not improved after first year (subjective)

Analysis 1.5. Comparison 1 Urodynamics versus clinical management, Outcome 5 Number treated conservatively.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 5 Number treated conservatively

Analysis 1.6. Comparison 1 Urodynamics versus clinical management, Outcome 6 Number treated with drugs.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 6 Number treated with drugs

Analysis 1.7. Comparison 1 Urodynamics versus clinical management, Outcome 7 Number treated with surgery.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 7 Number treated with surgery

Analysis 1.8. Comparison 1 Urodynamics versus clinical management, Outcome 8 Number whose treatment was changed after urodynamics.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 8 Number whose treatment was changed after urodynamics

Analysis 1.9. Comparison 1 Urodynamics versus clinical management, Outcome 9 Number not returning for further treatment.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 9 Number not returning for further treatment

Analysis 1.10. Comparison 1 Urodynamics versus clinical management, Outcome 10 Number not satisfied with treatment.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 10 Number not satisfied with treatment

Analysis 1.11. Comparison 1 Urodynamics versus clinical management, Outcome 11 Number with urgency symptoms or urgency incontinence after treatment.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 11 Number with urgency symptoms or urgency incontinence after treatment

Analysis 1.12. Comparison 1 Urodynamics versus clinical management, Outcome 12 Volume/weight of urine lost on pad test.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 12 Volume/weight of urine lost on pad test

Analysis 1.13. Comparison 1 Urodynamics versus clinical management, Outcome 13 Number of incontinence episodes in 24 hours.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 13 Number of incontinence episodes in 24 hours

Analysis 1.14. Comparison 1 Urodynamics versus clinical management, Outcome 14 Number with incontinence within first year (objective).

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 14 Number with incontinence within first year (objective)

Analysis 1.15. Comparison 1 Urodynamics versus clinical management, Outcome 15 Number with incontinence after first year (objective).

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 15 Number with incontinence after first year (objective)

Analysis 1.16. Comparison 1 Urodynamics versus clinical management, Outcome 16 Number with adverse events / complications.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 16 Number with adverse events / complications

Analysis 1.17. Comparison 1 Urodynamics versus clinical management, Outcome 17 Number with voiding dysfunction after treatment.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 17 Number with voiding dysfunction after treatment

Analysis 1.18. Comparison 1 Urodynamics versus clinical management, Outcome 18 Deaths.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 18 Deaths

Analysis 1.19. Comparison 1 Urodynamics versus clinical management, Outcome 19 Health status measures.

Review: Urodynamic studies for management of urinary incontinence in children and adults

Comparison: 1 Urodynamics versus clinical management

Outcome: 19 Health status measures

(Continued ...)

(... Continued)

(Continued ...)

(... Continued)

WHAT'S NEW

Date	Event	Description
21 October 2013	New citation required but conclusions have not changed	Added two new trials (Nager 2009 ; van Leijsen 2012) and excluded one trial which was included in the previous update (Kristjansson 1999) as participants included men with LUTS
21 October 2013	New search has been performed	Added two new trials (Nager 2009 ; van Leijsen 2012) and excluded one trial which was included in the previous update (Kristjansson 1999) as participants included men with lower urinary tract symptoms (LUTS)

HISTORY

Protocol first published: Issue 3, 2001

Review first published: Issue 3, 2002

Date	Event	Description
7 December 2011	New citation required and conclusions have changed	Four new trials added, but data only available from 5 of the 7 included trials
24 March 2011	New search has been performed	Four new trials added, but data only available from 5 of the 7 included trials
10 October 2008	Amended	Converted to new review format.
11 September 2006	New search has been performed	Minor Update Issue 1 2007. 12 new trials were excluded, and one new trial was added (O'Connell 2004). However, the trialists provided no data, so the conclusions of the review are unchanged
11 March 2004	New search has been performed	Minor Update Issue 3 2004. 18 new studies were excluded. Two of these may have been relevant RCTs but we were unable to confirm this with the trialists or obtain extra data
28 May 2002	New citation required and conclusions have changed	Review first published

CONTRIBUTIONS OF AUTHORS

All review authors independently assessed the studies for inclusion, extracted data and wrote the text.

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- The National Institute for Health Research (NIHR), UK.

The National Institute for Health Research (NIHR) is the largest single funder of the Cochrane Incontinence Group.

Disclaimer:

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

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This review update focuses on the use of urodynamics in the diagnosis of stress and urgency incontinence only. This review therefore now excludes trials in which urodynamics were used in the diagnosis of voiding LUTS, voiding dysfunction, and BOO. These conditions will be the focus of a further Cochrane review.

INDEX TERMS

Medical Subject Headings (MeSH)

Randomized Controlled Trials as Topic; Treatment Outcome; Urinary Incontinence [*physiopathology; therapy]; Urination [physiology]; Urodynamics

MeSH check words

Adult; Female; Humans