National Institute for Health and Care Excellence

Final

Urinary incontinence and pelvic organ prolapse in women: management

[A] Evidence review for urodynamic assessment prior to primary surgery for stress urinary incontinence

NICE guideline NG123

Evidence reviews

April 2019

Final

These evidence reviews were developed by the National Guideline Alliance hosted by the Royal College of Obstetricians and Gynaecologists

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Urodynamic assessment prior to primary surgery for stress urinary incontinence

Review question

What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence (SUI)?

Introduction

Current clinical practice in the assessment of women before stress urinary incontinence (SUI) surgery varies. Urodynamic assessment might add additional useful information to the clinical assessment to confirm the diagnosis or plan management of SUI.

It was noted in the previous NICE guideline on urinary incontinence in women (CG171) that urodynamic investigation was not essential in every woman before primary surgery for stress urinary incontinence and so a recommendation was made that it should not be performed routinely (as a diagnostic tool) for women with a clearly defined clinical diagnosis of pure SUI. This recommendation only applied to a relatively small proportion of women, who have SUI but no symptoms of OAB and no recommendation was made about the use of urodynamic assessment before primary surgery in women who do not have pure SUI.

This review aims to clarify previous recommendations by determining whether the addition of urodynamic assessment prior to SUI surgery improves outcomes for women.

Summary of the protocol

Please see Table 1: Summary of the protocol (PICO Table) for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO Table)

Population	• Women with SUI who may be eligible for surgery. • All women with SUI who have failed to respond to conservative interventions (lifestyle, behavioural or bladder retraining)
Intervention	SUI surgery following: Multichannel urodynamic assessment
Comparison	SUI surgery following: No urodynamic assessment

Outcomes	**Critical**
	• Continence status (improvement e.g. number of incontinent episodes per day in first 3 months after treatment)
	• Adverse effects of urodynamic testing
	  ○ urinary infection
	  ○ dysuria
	  ○ haematuria
	• Continence specific health-related quality of life (ICIQ, BFLUTS, I-QOL, SUIQQ, UISS, SEAPI-QMM, ISI and KHQ (all from previous guideline) and e-PAQ (new))
	
	Important
	• Adverse effects of SUI surgery
	  ○ urgency
	  ○ urgency incontinence
	  ○ voiding difficulties
	• Satisfaction
	  ○ PGI-I
	• Change of management

BFLUTS: Bristol Female Lower Urinary Tract Symptoms; ICIQ: International Consultation Incontinence Questionnaire; IQOL: Urinary Incontinence Quality of Life Scale; ISI: Incontinence Severity Index; KHQ: Kings Health Questionnaire; PGI-I: Patient Global Impression of Improvement; SEAPI-QMM: Stress-Related Leak, Emptying, Anatomy, Protection, Inhibition, Quality of Life, Mobility and Mental Status Incontinence Classification System; SUI: Stress Urinary Incontinence; SUIQQ: Stress and Urgency Incontinence and Quality of Life Questionnaire; UISS: Urinary Incontinence Severity Score.

For further details see the full review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual 2014. Methods specific to this review question are described in the review protocol in appendix A and for a full description of the methods see supplementary material C.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy until 31 March 2018. From 1 April 2018, declarations of interest were recorded according to NICE's 2018 conflicts of interest policy. Those interests declared until April 2018 were reclassified according to NICE's 2018 conflicts of interest policy (see Register of Interests).

Clinical evidence

Included studies

Four studies were identified for inclusion (van Leijsen 2012, Nager 2012, Sirls 2013, and Hilton 2016), the included studies are summarised in Table 2.

Two studies were multicentre RCT, one conducted in the Netherlands (van Leijsen 2012) and the other in the US (Nager 2012). One study (Sirls 2013) was a secondary analysis of the ValUE RCT, reported in Nager 2012, and the fourth (Hilton 2016) was a multicentre randomised pilot trial performed in the UK.

See also literature search strategies in appendix B, study selection flow chart in appendix C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in appendix F.

Excluded studies

Studies excluded from the review and reasons for their exclusion are provided in appendix K.

Summary of clinical studies included in the evidence review

Table 2: Summary of included studies

Study	Population	Intervention	Comparison	Outcomes
Hilton 2016 Multicentre RCT UK	Women with stress UI (SUI) or stress predominant mixed UI (MUI).	Intensive Urodynamic Treatment (IUT): basic clinical and non-invasive tests as directed by the clinician; these included frequency/volume charting or bladder diary, mid-stream urine culture, urine flow rate and residual urine volume measurement (by ultrasound), plus invasive urodynamic testing.	No IUT: basic clinical assessment supplemented by non-invasive tests as directed by the clinician; these included frequency/volume charting or bladder diary, mid-stream urine culture, urine flow rate and residual urine volume measurement (by ultrasound).	*Continence status* Quantification of urinary leakage (3-day bladder diary and ICIQ-UI short form) *Adverse effects of urodynamic testing* Not applicable, Adverse events related to invasive urodynamic testing. *Continence specific health-related quality of life* Combined symptom score of the ICIQ-FLUTS questionnaire at 6 months after treatment General health questionnaire (Short Form 12) at 6 months after treatment Impact of urinary symptoms on quality of life: ICIQ-LUTSqol and UDI
Nager 2012 Multicentre RCT USA	Women with uncomplicated, stress-predominant urinary incontinence	Physician-performed comprehensive checklist of clinical diagnoses plus urodynamic testing (non-instrumented uroflowmetry with a comfortably full bladder, post void residual obtained with catheter, filling cystometry with Valsalva leak-point pressures and a	Physician-performed comprehensive checklist of clinical diagnoses alone	*Quality of life* Change in ISI score *Adverse outcomes of SUI surgery* Any new or continuing treatment for urge incontinence Any new or continuing evidence of recurrent stress urinary incontinence Any new or continuing treatment for

Study	Population	Intervention	Comparison	Outcomes
		pressure-flow study)		recurrent stress urinary incontinence Voiding dysfunction at 6 weeks or beyond *Patient satisfaction* "Very much better" or "much better" using Patient Global Impression of Improvement Change in PGI-S .
Sirls 2013 Secondary analysis of Nager 2012 UK	Women with uncomplicated stress predominant urinary incontinence	See Nager 2012	See Nager 2012	*Change in management plan* Change to surgical plan based on urodynamic testing results Unsuccessful treatment outcome following change in global treatment plan based on urodynamic testing Self-voiding at discharge following a global treatment plan change Treatment for voiding dysfunction following a global treatment plan change at 3 or 12-month post-operatively Treatment for urgency UI following global treatment plan change at 3 or 12-months postoperatively Urodynamic study events that changed global treatment plan
van Leijsen 2012	Women with uncomplicated SUI	Standard workup (based on history, physical	Standard workup only	*Continence status* Subjective cure: UDI-6 No leakage on

Study	Population	Intervention	Comparison	Outcomes
Multicentre RCT Netherlands	considered as symptoms of pure SUI or mixed urinary incontinence with predominant stress incontinence symptoms	examination, and a voiding diary) plus urodynamic testing		physical activity, coughing, or sneezing at 2 years Objective cure : Stress test negative at 2 years Objective cure: 48-hour voiding diary at 2 years Complete cure : subjectively and objectively at 2 years *Adverse outcomes of SUI surgery* Occurrence of de novo OAB complaints at 2 years Voiding dysfunction after treatment at 2 years *Patient satisfaction* Improvement on PSI-I at 2 years Women's experience of urodynamic testing *Change in management* Initial treatment not surgery

ICIQ-FLUTS: Bristol Female Lower Urinary Tract Symptoms Module; ICIQ-LUTSqol: Lower Urinary Tract Symptoms Quality of Life; ICIQ-UI: International Consultation Incontinence Questionnaire-Urinary Incontinence; IUT: Intensive Urodynamic Treatment; MUI: Mixed Urinary Incontinence; OAB: Overactive Bladder; PGI-I: Patient Global Impression of Improvement; PGI-S: Patient Global Impression of Severity; SUI: Stress Urinary Incontinence; UI: Urinary Incontinence.

See also the clinical evidence tables in appendix D.

Quality assessment of clinical studies included in the evidence review

GRADE analysis was conducted for critical and important outcomes, the clinical evidence profiles are presented in appendix G.

Economic evidence

Included studies

The systematic search of the economic literature conducted for the guideline identified two studies on the cost effectiveness of preoperative urodynamic testing in women with SUI or stress predominant urinary incontinence:

- One UK study on the cost-utility of urodynamic testing before surgery in women with SUI (Homer 2018);
- One USA study on the cost-effectiveness of urodynamic testing before surgery in women with uncomplicated stress predominant urinary incontinence (Norton 2016).

Evidence tables are provided in appendix H. Completed methodology checklists are provided in appendix M. Economic evidence profiles are presented in appendix I.

Excluded studies

No economic evidence was identified for this review question.

Summary of studies included in the economic evidence review

Homer (2018) evaluated the cost-effectiveness of invasive urodynamic testing (IUT) before surgery for SUI in women compared with no urodynamic testing (that is, basic clinical assessment and non-invasive tests).

This economic evaluation was conducted alongside a randomised controlled pilot trial (Hilton 2016, n=222) that was undertaken in seven centres across the UK. The study population comprised women with a clinical diagnosis of SUI or stress-predominant mixed urinary incontinence and were about to undergo a surgical treatment. In this study conventional dual-channel subtracted cystometry with simultaneous pressure/flow voiding studies (that is, cystometry), video urodynamics and ambulatory urodynamics were all permitted. However, cystometry was performed in 92% of women randomised to IUT arm.

The analysis was conducted from the NHS perspective and considered a range of direct healthcare costs including IUT, surgical treatments (vaginal tape operations for urinary incontinence), non-surgical treatments (behaviour modification, bladder training, and pelvic floor muscle training), containment products, visits to the general practitioner, practice nurse, continence nurse, community physiotherapist and prescriptions, inpatient and outpatient visits. The resource use estimates were based on the RCT (n=218). The unit costs were obtained from national sources. The measures of outcome for the economic analysis were QALYs calculated using Short Form-12 (SF-12) and EQ-5D-3L preference-based measures. The time horizon of the analysis was 6 months. Bootstrapping was undertaken to capture uncertainty about estimates of costs and QALYs. The results are presented using adjusted and non-adjusted costs and QALYs. In the adjusted analyses adjusting for randomised allocation in the cost equation and for randomised allocation, baseline utility (estimated from both the SF-12 and EQ-5D-3L respectively), and age in the HRQoL equation was undertaken. Results are further stratified according to whether QALYs were derived using SF-12 or EQ-5D-3L preference-based measure.

Using SF-12 derived QALYs IUT resulted in greater QALYs compared with no IUT (0.385 versus 0.377, respectively; difference 0.008). Similarly, using adjusted QALYs IUT resulted in greater QALYs compared with no IUT (difference 0.004). Using EQ-5D-3L derived QALYs IUT resulted in lower QALYs compared with no IUT (0.395 versus 0.413, respectively; difference 0.018). Similarly, using adjusted QALYs IUT resulted in greater QALYs compared with no IUT (difference 0.004).

The mean total costs per woman were £1,351 for the IUT and £1,489 for no IUT, a difference of £138 in favour of IUT in 2015 prices. The cost difference was the same when using adjusted costs. However, it has to be noted that differences in costs and QALYs were not statistically significant.

When using SF-12 derived QALYs IUT was dominant when compared with no IUT (that is, it resulted in lower costs and also greater QALYs) using both adjusted and non-adjusted costs

and QALYs. Using non-adjusted costs and QALYs at a £20,000 threshold of willingness-to-pay for QALY gained the probability of IUT and no IUT being cost-effective was 0.95 and 0.05, respectively. Using adjusted costs and QALYs at a £20,000 threshold of willingness-to-pay for QALY gained the probability of IUT and no IUT being cost-effective was 0.96 and 0.04, respectively.

However, when using EQ-5D-3L derived QALYs the ICER of no IUT (versus IUT) was £7,667 per QALY which is below NICE lower cost-effectiveness threshold of £20,000 per QALY and when using adjusted EQ-5D-3L derived QALYs the ICER of no IUT (versus IUT) was £34,500 per QALY which is above NICE upper cost-effectiveness threshold of £30,000 per QALY. Using non-adjusted costs and QALYs at a £20,000 threshold of willingness-to-pay for QALY gained the probability of IUT and no IUT being cost-effective was 0.40 and 0.60, respectively. Using adjusted costs and QALYs at a £20,000 threshold of willingness-to-pay for QALY gained the probability of IUT and no IUT being cost-effective was 0.36 and 0.64, respectively.

Overall the results are uncertain. Although, using both adjusted EQ-5D-3L QALYs (as recommended by NICE) and costs the ICER of no IUT (versus IUT) was above NICE upper cost-effectiveness threshold of £30,000 per QALY suggesting that the use of IUT before SUI surgery is the preferred strategy. However, this is based on non-significant differences in costs and outcomes. The analysis was directly applicable to the NICE decision-making context and had minor methodological limitations.

Norton (2016) evaluated the cost-effectiveness of preoperative urodynamic testing in addition to standard office evaluation compared with standard office evaluation only in women with uncomplicated stress predominant urinary incontinence planning surgery alongside an RCT (Nager 2012) (n=539) conducted in the USA. All women underwent an office evaluation. Office evaluation included the MESA questionnaire, provocative stress test, post-void residual (PVR), dipstick urinalysis, assessment of urethral mobility, and a standing, straining prolapse exam. Women randomised to supplementary urodynamic testing underwent non-instrumented uroflowmetry, filling cystometry, and a pressure flow study. The analysis was conducted from a narrow healthcare payer perspective and included only the additional costs associated with urodynamic testing. The resource use estimates were based on the RCT. The unit costs were obtained from national sources. Costs associated with urodynamic testing were estimated assuming that 70% of women randomised to office evaluation plus urodynamic testing underwent complex uroflowmetry with pressure flow study and 30% had a complex cystometry with pressure flow study and urethral pressure profiles. The primary measure of outcome was success defined as 70% reduction in Urogenital Distress Inventory Score and a percent of women responding “very much better” or “much better” on Patient Global Impression of Improvement index. The primary outcome data was available for 539 women. The time horizon of the analysis was 12 months. However, it was assumed that there is no difference in health care costs during the follow-up (that is, only the incremental costs of performing urodynamic testing were considered).

Office evaluation supplemented with urodynamic testing resulted in 1.7% fewer women achieving success defined as 70% reduction in Urogenital Inventory Score (77.2% and 78.9% for urodynamic testing and office evaluation, and office evaluation only groups, respectively; p = ns). Office evaluation supplemented with urodynamic testing resulted in 1.1% more women being “very much better” or “much better” on Patient Global Impression of Improvement index (91.9% and 90.8% for urodynamic testing and office evaluation, and office evaluation only groups, respectively; p = ns).

From a narrow health care payer perspective, urodynamic testing was associated with the mean incremental cost of $338.3 per woman. Statistical significance was not reported.

Based on the above costs and outcomes offering urodynamic testing in addition to office evaluation (versus office evaluation only) was dominant when using success defined as 70%

reduction in Urogenital Inventory Score as an outcome measure. When using success defined as being "very much better" or "much better" on Patient Global Impression of Improvement index urodynamic testing in addition to office evaluation (versus office evaluation only) resulted in an incremental cost-effectiveness ratio of $30,755 per additional women successfully treated. However, this is based on non-significant differences in outcomes.

The analysis was partially applicable to the NICE decision-making context and had potentially serious methodological limitations.

Economic model

No economic modelling was conducted for this review because the committee agreed that other topics were higher priorities for economic evaluation.

Clinical evidence statements

Continence Status

Subjective cure: UDI-6 No leakage on physical activity, coughing, or sneezing

- Low quality evidence from one RCT (n=59) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for subjective cure at 2 years after surgery in women with SUI or mixed urinary incontinence (with symptoms predominantly of SUI): RR 0.82 (95% CI 0.59 to 1.14).

***Objective cure*: Stress test negative**

- Very low quality evidence from one RCT (n=59) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for objective cure at 2 years after surgery in women with SUI or mixed urinary incontinence (with symptoms predominantly of SUI): RR 0.98 (95% CI 0.77 to 1.25).

Objective cure: 48-hour voiding diary

- Low quality evidence from one RCT (n=59) showed that there may be a clinically important difference favouring standard work-up alone over standard work-up plus urodynamic assessment for objective cure assessed at 2 years with a 48-hour voiding diary in women with SUI or mixed urinary incontinence (with symptoms predominantly of SUI) (RR 0.79 [95% CI 0.59 to 1.05]), but there is uncertainty around the estimate.

Complete cure: subjectively (UDI-6 no leakage on physical activity, coughing or sneezing) and objectively (negative stress test)

- Low quality evidence from one RCT (n=59) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for complete cure at 2 years after surgery in women with SUI or mixed urinary incontinence (with symptoms predominantly of SUI): RR 0.77 (95% CI 0.52 to 1.14).

Subjective improvement: UDI overall score

- Very low quality evidence from one pilot RCT (n=222) showed no clinically important difference between standard work-up alone and standard work-up plus

urodynamic assessment for change in UDI overall scores at 6 months in women with SUI or mixed urinary incontinence: MD -14.60 (95% CI -34.83 to 5.63).

Subjective improvement: 3-day bladder diary

- Very low quality evidence from one pilot RCT (n=222) showed that there was a clinically important difference favouring standard work-up alone over standard work-up plus urodynamic assessment for reduction in daytime bathroom visits at 6 months in women with SUI or mixed urinary incontinence: MD 0.80 (95% CI 0.21 to 1.39).
- Very low quality evidence from the same RCT (n=222) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for reduction in night-time bathroom visits at 6 months in women with SUI or mixed urinary incontinence: MD 0.10 (95% CI -0.09 to 0.29).
- Very low quality evidence from one pilot RCT (n=222) showed that there was a clinically important difference favouring standard work-up alone over standard work-up plus urodynamic assessment for reduction in pads used in 24 hours at 6 months in women with SUI or mixed urinary incontinence: MD 1.10 (95% CI 0.43 to 1.77).

Quality of Life (continence specific)

Change in Incontinence Severity Index

- Low quality evidence from one RCT (n=630) showed no clinically important difference between physician evaluated clinical diagnosis plus urodynamic assessment and physician evaluated clinical diagnosis alone for complete cure at 1 year after surgery in women with uncomplicated, stress-predominant urinary incontinence: MD -0.30 (95% CI -0.82 to 0.22).

Change in ICIQ-FLUTS – overall score

- Very low quality evidence from one RCT (n=222) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for improvement in overall scores for ICIQ-FLUTS: MD -1.50 (95% CI -4.43 to 1.43).

Change in ICIQ-UI SF

- Very low quality evidence from one RCT (n=222) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for improvement in scores for ICIQ-UI SF: MD -1.30 (95% CI -3.89 to 1.29).

Change in ICIQ-LUTSqol

- Very low quality evidence from one RCT (n=222) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for improvement in scores for ICIQ-LUTSqol: MD -3.70 (95% CI -9.45 to 2.05).

Adverse outcomes associated with SUI surgery

Any new or continuing treatment for recurrent SUI or urge incontinence

- Low and very low quality evidence from one RCT (n=630) showed no clinically important differences between physician evaluated clinical diagnosis plus urodynamic assessment and physician evaluated clinical diagnosis alone at 1 year after surgery for new or continuing evidence of recurrent SUI (RR 0.95 [95% CI 0.74 to 1.22]) or

treatment for recurrent SUI (RR 1.46 [95% CI 0.53 to 4.05]) or treatment for urge incontinence (RR 1.13 [95% CI 0.76 to 1.68]) in women with uncomplicated, stress-predominant urinary incontinence.

Occurrence of de novo OAB: complaints

- Very low quality evidence from one RCT (n=59) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for occurrence of de novo OAB at 2 years after surgery in women with SUI or mixed urinary incontinence (with symptoms predominantly of SUI): RR 5.42 (95% CI 0.69 to 42.28).

Voiding dysfunction

- Very low quality evidence from one RCT (n=630) showed no clinically important difference between physician evaluated clinical diagnosis plus urodynamic assessment and physician evaluated clinical diagnosis alone for voiding dysfunction at 6 weeks or beyond after surgery in women with uncomplicated, stress-predominant urinary incontinence: RR 1.00 (95% CI 0.33 to 3.07).
- Very low quality evidence from one RCT (n=59) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for voiding dysfunction at 2 years after surgery in women with SUI or mixed urinary incontinence (with symptoms predominantly of SUI): RR 0.39 (95% CI 0.11 to 1.35).

Patient Satisfaction

Improvement on Patient Global Impression of Improvement scale

- Moderate quality evidence from one RCT (n=630) showed no clinically important difference between physician-evaluated clinical diagnosis plus urodynamic assessment and physician -evaluated clinical diagnosis alone for patient satisfaction assessed using PGI-I at 1 year after surgery in women with uncomplicated, stress-predominant urinary incontinence: RR 1.01 (95% CI 0.96 to 1.07).
- Low quality evidence from one RCT (n=59) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for patient satisfaction assessed using PGI-I at 2 years after surgery in women with SUI or mixed urinary incontinence (with symptoms predominantly of SUI): RR 0.90 (95% CI 0.78 to 1.05).

Change in Patient Global Impression

- Low quality evidence from one RCT (n=630) showed no clinically important difference between physician-evaluated clinical diagnosis plus urodynamic assessment and physician-evaluated clinical diagnosis alone for patient satisfaction assessed using change in Patient Global Impression of Severity score at 1 year after surgery in women with uncomplicated, stress-predominant urinary incontinence: MD 0.00 (95% CI -0.15 to 0.15).

Women's experience of urodynamic testing: Unpleasant =<3 score (with scores ranging from 1- very unpleasant to 6 - totally not unpleasant)

- Low quality descriptive evidence from one RCT (n=31) showed that a quarter of women with SUI or mixed urinary incontinence (with symptoms predominantly of SUI) who underwent urodynamic assessment before surgery reported it to be unpleasant.

Change in management

Initial treatment not surgery

- Very low quality evidence from one RCT (n= 59) showed no clinically important difference between standard work-up plus urodynamic assessment and standard work-up alone for a change to non-surgical management after surgery in women with SUI or mixed urinary incontinence (with symptoms predominantly of SUI): RR 4.52 (95% CI 0.56 to 36.34).

Change to surgical plan based on urodynamic testing results

- Very low quality descriptive evidence from one observational study (n = 294) showed that 1.4% of women had surgery cancelled and 5.4% had a change in surgical procedure as a result of specific finding of urodynamic assessment, in women with uncomplicated, stress-predominant urinary incontinence who underwent physician evaluated clinical diagnosis plus urodynamic assessment before surgery (effect not estimable).

Successful treatment outcome following change in global treatment plan based on urodynamic testing

- Very low quality evidence from one observational study (n= 294) showed no clinically important association between a change in global treatment plan after urodynamic studies with successful treatment outcome in women with uncomplicated, stress-predominant urinary incontinence who underwent physician evaluated clinical diagnosis plus urodynamic assessment before surgery: OR 0.96 (95% CI 0.41 to 2.25).

Self-voiding at discharge following a global treatment plan change

- Very low quality evidence from one observational study (n= 294) showed no clinically important association between a change in global treatment plan after urodynamic studies with self-voiding at discharge in women with uncomplicated, stress-predominant urinary incontinence who underwent physician evaluated clinical diagnosis plus urodynamic assessment before surgery: OR 0.89 (95% CI 0.41 to 1.94).

Treatment for voiding dysfunction following a global treatment plan change at 3 or 12 months post-operatively

- Very low quality evidence from one observational study (n= 294) showed no clinically important association between a change in global treatment plan after urodynamic studies with receiving treatment for voiding dysfunction at 3 or 12 months post-operatively in women with uncomplicated, stress-predominant urinary incontinence who underwent physician evaluated clinical diagnosis plus urodynamic assessment before surgery: OR 1.39 (95% CI 0.59 to 3.31).

Treatment for urgency UI following a global treatment plan change at 3 or 12 months post-operatively

- Very low quality evidence from one observational study (n = 294) showed clinically important increased odds of receiving treatment for urgency UI at 3 or 12 months post-operatively in women with uncomplicated, stress-predominant urinary incontinence who underwent physician evaluated clinical diagnosis plus urodynamic assessment before surgery and had a change in global treatment plan after urodynamic studies: OR 3.23 (95% CI 1.46 to 7.14).

Urodynamic study events that changed global treatment plan

- Very low quality descriptive evidence from one observational study (n = 294) showed that there were 75 study events that contributed to changes in global treatment plans in women with uncomplicated, stress-predominant urinary incontinence who underwent physician evaluated clinical diagnosis plus urodynamic assessment before surgery (effect not estimable).

Economic evidence statements

- There was evidence from UK study conducted alongside an RCT (n=222) showing that urodynamic testing before SUI surgery was potentially cost-effective option when compared with no urodynamic testing (that is, basic clinical assessment and non-invasive tests) in women with SUI. However, the results were sensitive to the measure of health status used and whether adjusted for randomised allocation, baseline utility and age health status scores were used. This evidence came from a directly applicable study that was characterised by minor methodological limitations.
- There was evidence from one USA study (n=539) showing that offering urodynamic testing was a dominant strategy when compared with clinical assessment only using success defined as 70% reduction in Urogenital Inventory Score as an outcome measure. When using success defined as a percent of women responding “very much better” or “much better” on Patient Global Impression of Improvement index urodynamic testing in addition to clinical assessment resulted in an incremental cost-effectiveness ratio of $30,755 per additional women successfully treated. However, this is based on non-significant differences in outcomes. This evidence came from a partially applicable study that was characterised by potentially serious methodological limitations.

The committee’s discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The outcomes of continence status, adverse effects of urodynamic testing, urinary infection, dysuria, haematuria and continence specific health-related quality of life were selected as critical, because they have the biggest impact on the women’s quality of life overall.

The other outcomes were important to include because urodynamic testing may have a role in predicting the adverse effects of surgery and the findings from urodynamics may result in changed management. Therefore important outcomes included were: 1) adverse effects of SUI surgery (including urgency, urgency incontinence, and voiding difficulties), 2) satisfaction (patient global impression of improvement) and 3) change in management.

The quality of the evidence

The evidence presented in this review was assessed for quality using the Cochrane risk of bias tool; in addition, the evidence included in pairwise analysis was assessed using the GRADE methodology. The evidence included in this review ranged from moderate to very low quality. Critical outcomes were downgraded as studies were not blinded, both participants and health care professionals were aware of the treatment allocation. The outcomes were further downgraded because of high levels of imprecision. Important outcomes were downgraded because studies were not blinded, both participants and health care professionals were aware of treatment allocation, allocation methods were unclear, and there were high levels of imprecision.

The evidence was limited to a specific group of women, the majority of whom had mid-urethral sling surgery, and so the extent to which this can be extrapolated to other surgical

procedures is uncertain. Furthermore, the studies were underpowered for the outcomes of interest in this review.

Benefits and harms

The evidence presented did not show any clear benefits of urodynamic testing before primary surgery for stress urinary incontinence in women with symptoms of stress incontinence or stress predominant mixed incontinence and the committee agreed that it should not be performed. Nonetheless, the committee decided it was important to illustrate that in some circumstances urodynamic testing may be beneficial and drafted recommendations based on their expertise and experience and by consensus. The committee noted that urodynamic testing is most likely to be of benefit in situations where the diagnosis was unclear from detailed clinical assessment. This includes when there is urge-predominant mixed UI or UI in which the type is unclear; symptoms suggestive of voiding dysfunction; anterior or apical prolapse; and a history of previous surgery for stress UI. In these cases, the committee considered that urodynamic testing may lead to more precise diagnosis, and the benefits may outweigh the intrusive nature of the test.

Cost effectiveness and resource use

The committee acknowledged evidence from a UK pilot study which showed that urodynamic testing before SUI surgery in this group was potentially cost-effective option when compared with no urodynamic testing (that is, basic clinical assessment and non-invasive tests). However, the committee noted that the results were sensitive to the measure of health status used and whether adjusted or non-adjusted costs and QALYs were used. In the adjusted analyses adjusting for randomised allocation in the cost equation and for randomised allocation, baseline utility (estimated from both the SF-12 and EQ-5D-3L respectively), and age in the HRQoL equation was undertaken. Moreover, this economic evaluation was based on a pilot study and was not powered sufficiently. The committee also recognised that the USA study showed that urodynamic testing may potentially result in an increase in intervention costs but no change in outcomes.

The committee were aware that urodynamic testing before SUI surgery in addition to basic office evaluation can add substantial staff costs and patient time. Additional testing with costly equipment and clinician time can add a considerable burden to the care of incontinent women. Given that urodynamic testing is undertaken before each SUI procedure and that there is a high volume of SUI surgical procedures performed in the NHS, urodynamic testing in addition to a basic clinical evaluation could result in a substantial increase in NHS costs.

The committee also noted that in most cases urodynamic information rarely changes the primary diagnosis of SUI and only occasionally changes treatment plans and so no treatment benefit is realised. Urodynamic testing does not influence clinicians to cancel, change or modify their planned surgery.

Overall, given the current state of the evidence the committee were of a view that the NHS could potentially realise substantial cost savings without any adverse impact on patient care by forgoing urodynamic testing before primary surgery in the general SUI population (i.e. in women who have demonstrable SUI). However, the committee noted that there may be value in performing urodynamic in more complex situations e.g. if the diagnosis is unclear or if the woman has symptoms of voiding dysfunction, anterior or apical prolapse, or a history of surgery for SUI.

Other factors the committee took into account

Older women have a higher rate of voiding difficulty and overactive bladder and urinary infections after surgery for SUI. Clinicians may choose to perform voiding studies before surgery in asymptomatic older women. This does not affect the recommendations about urodynamic assessment for this group.

References

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Nager,C.W., Brubaker,L., Litman,H.J., Zyczynski,H.M., Varner,R.E., Amundsen,C., Sirls,L.T., Norton,P.A., Arisco,A.M., Chai,T.C., Zimmern,P., Barber,M.D., Dandreo,K.J., Menefee,S.A., Kenton,K., Lowder,J., Richter,H.E., Khandwala,S., Nygaard,I., Kraus,S.R., Johnson,H.W., Lemack,G.E., Mihova,M., Albo,M.E., Mueller,E., Sutkin,G., Wilson,T.S., Hsu,Y., Rozanski,T.A., Rickey,L.M., Rahn,D., Tennstedt,S., Kusek,J.W., Gormley,E.A., A randomized trial of urodynamic testing before stress-incontinence surgery, New England Journal of Medicine, 366, 1987-1997, 2012

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Sirls, L. T., Richter, H. E., Litman, H. J., Kenton, K., Lemack, G. E., Lukacz, E. S., Kraus, S. R., Goldman, H. B., Weidner, A., Rickey, L., Norton, P., Zyczynski, H. M., Kusek, J. W., The effect of urodynamic testing on clinical diagnosis, treatment plan and outcomes in women undergoing stress urinary incontinence surgery, Journal of Urology, 189, 204-209, 2013

Van Leijsen 2012

Van Leijsen, S. A. L., Kluivers, K. B., Mol, B. W. J., Broekhuis, S. R., Milani, A. L., Bongers, M. Y., Aalders, C. I. M., Dietz, V., Malmberg, G. G. A., Vierhout, M. E., Heesakkers, J. P. F. A., Can preoperative urodynamic investigation be omitted in women with stress urinary incontinence? A non-inferiority randomized controlled trial, Neurology and Urodynamics, 31, 1118-1123, 2012

Appendices

Appendix A – Review protocols

Review protocol for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

Table 3: Review protocol for urodynamic assessment of women with SUI

Field (based on PRISMA-P	Content
Review question	What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?
Type of review question	Intervention
Objective of the review	Clinical assessment prior to stress urinary incontinence (SUI) surgery varies in current practice. Urodynamic assessment might add additional useful information to the clinical assessment to confirm the diagnosis or plan management of SUI. It was noted in the previous CG171 guideline that urodynamic investigation was not essential in every woman before primary surgery for stress urinary incontinence and hence a recommendation was made that it should not be performed routinely (as a diagnostic tool) for women with a clearly defined clinical diagnosis of pure SUI. However, no specific recommendation was made about the use of urodynamic assessment before primary surgery. This review aims to strengthen and clarify recommendations in this area by examining new evidence to determine if there is any added value in performing urodynamic assessment to clarify why the difficulties are present and to inform targeted subsequent interventions.
Eligibility criteria – population/disease/condition/issue/domain	Inclusions: Women with stress UI who may be eligible for surgery. All women with SUI who have failed to respond to conservative interventions (lifestyle, behavioural or bladder retraining)

Field (based on PRISMA-P	Content
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	Primary SUI surgery following: Multichannel urodynamic assessment
Eligibility criteria – comparator(s)/control or reference (gold) standard	Primary SUI surgery following: No urodynamic assessment
Outcomes and prioritisation	**Critical** Continence status (improvement e.g. number of incontinent episodes per day in first 3 months after treatment) Adverse effects of urodynamic testing: urinary infection dysuria haematuria Continence specific health-related quality of life (ICIQ, BFLUTS, I-QOL, SUIQQ, UISS, SEAPI-QMM, ISI and KHQ (all from previous guideline) and E-PAQ (new)) **Important** Adverse effects of SUI surgery: Urgency, urgency incontinence, voiding difficulties Satisfaction Patient Global Impression of Improvement (PGI-I) Change of management
Eligibility criteria – study design	Systematic reviews of RCT RCT Comparative cohort studies will be included if no RCT evidence is retrieved.
Other inclusion exclusion criteria	Exclusions: Women with neurological disease will be excluded as per the scope.

Field (based on PRISMA-P	Content
Proposed sensitivity/sub-group analysis, or meta-regression	Special consideration will be given to the following groups for which data will be reviewed and analysed separately if available: older women women with physical disabilities Special consideration of women with cognitive impairment or who are considering future pregnancy was not prioritised for this question.
Selection process – duplicate screening/selection/analysis	Formal duplicate screening will not be undertaken for this question, although there will be senior supervision of the selection process. Hard copies of retrieved papers will be read by two reviewers and any disputes will be resolved in discussion with the Topic Advisor if necessary. Data extraction will be supervised by a senior reviewer. Draft excluded studies and evidence tables will be discussed with the Topic Advisor, before circulation to the Topic Group for their comments. Resolution of disputes will be by discussion between the senior reviewer, Topic Advisor and Chair.
Data management (software)	Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5). 'GRADEpro' will be used to assess the quality of evidence for each outcome. NGA STAR software will be used for generating bibliographies/citations, study sifting, data extraction and recording quality assessment using checklists
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase Limits (e.g. date, study design): Apply standard animal/non-English language exclusion Limit to RCTs and systematic reviews in first instance but download all results Dates from 1995. Studies published post 1995 will be considered for this review question as the committee believed that this was an appropriate threshold for studies representing current practice For details see appendix B of the full guideline.
Identify if an update	This is a new review question in the guideline that will add to current recommendations in CG171 on urodynamic testing: 1.1.19 Do not perform multi-channel cystometry, ambulatory urodynamics or videourodynamics before starting conservative management. [2006, amended 2013]

Field (based on PRISMA-P	Content
	1.1.20 After undertaking a detailed clinical history and examination, perform multi-channel filling and voiding cystometry before surgery in women who have: symptoms of OAB leading to a clinical suspicion of detrusor overactivity, or symptoms suggestive of voiding dysfunction or anterior compartment prolapse, or had previous surgery for stress incontinence. [2006, amended 2013] 1.1.21 Do not perform multi-channel filling and voiding cystometry in the small group of women where pure SUI is diagnosed based on a detailed clinical history and examination. [2006, amended 2013] 1.1.22 Consider ambulatory urodynamics or videourodynamics if the diagnosis is unclear after conventional urodynamics. [2006, amended 2013]
Author contacts	Developer: The National Guideline Alliance https://www.nice.org.uk/guidance/indevelopment/gid-ng10035.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual 2014.
Search strategy – for one database	For details please see appendix B of the full guideline.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables) of the full guideline.
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables) of the full guideline.
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual 2014 The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual 2014
Methods for analysis – combining studies and exploring (in)consistency	For details please see the methods chapter of the full guideline.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual 2014. If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots.

Field (based on PRISMA-P	Content
	Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway
Assessment of confidence in cumulative evidence	The GRADE approach was used. For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual
Rationale/context – Current management	For details please see the introduction to the evidence review in the full guideline.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Dr Fergus Macbeth in line with section 3 of Developing NICE guidelines: the manual. Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see the methods chapter.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.
PROSPERO registration number	Not registered with PROSPERO.

1

Appendix B – Literature search strategies

Literature search strategies for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

Database: Medline & Embase (Multifile)
Last searched on Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present, Embase Classic+Embase 1947 to 2017 May 05

Date of last search: 8th May 2017

#	Searches
1	URINARY INCONTINENCE/ use ppez
2	URINARY INCONTINENCE, STRESS/ use ppez
3	URINE INCONTINENCE/ use emczd
4	STRESS INCONTINENCE/ use emczd
5	MIXED INCONTINENCE/ use emczd
6	((stress$ or mix$ or effort$ or urin$) adj5 incontinen$).tw.
7	UI.tw.
8	SUI.tw.
9	(urine adj2 (loss or leak$)).tw.
10	or/1-9
11	URODYNAMICS/ use ppez
12	*URODYNAMICS/ use emczd
13	*CYSTOMETRY/ use emczd
14	*URETHRA PRESSURE/ use emczd
15	*UROFLOWMETRY/ use emczd
16	(urodynamic$ or cystometr$ or uroflowmet$).tw.
17	(urethr$ adj3 pressure$ adj3 (study or studies or profile$)).tw.
18	(void$ adj3 pressure$ adj3 (study or studies or profile$)).tw.
19	(pressure$ adj3 flow).tw.
20	(videourodynamic$ or video urodynamic$).tw.
21	(ambulatory adj3 urodynamic$).tw.
22	(videocystometr$ or video cystometr$).tw.
23	(ambulatory adj3 cystometr$).tw.
24	((video$ or void$) adj3 cystourethrogra$).tw.
25	VCUG.tw.
26	profilometr$.tw.
27	leak point pressure$.tw.
28	or/11-27
29	PREOPERATIVE CARE/ use ppez
30	*PREOPERATIVE EVALUATION/ use emczd
31	((preoperati$ or presurgery or presurgical$ or preprocedur$) adj7 (assess$ or test$ or diagnos$ or evaluat$ or investigat$)).tw.
32	((pre or prior or before) adj3 (operat$ or surgery or surgical$ or procedur$) adj7 (assess$ or test$ or diagnos$ or evaluat$ or investigat$)).tw.
33	((pre or prior or before) adj7 ((bulk$ adj3 agent?) or biocompatible material? or collagen or contigen or (silicone adj3 (particle? or implant? or microimplant?)) or macroplastique$ or (carbon$ adj3 (bead? or particle?)) or calcium hydroxylapatite or ethylene vinyl alcohol copolymer? or (hyaluron$ adj3 (acid? or therap$)) or ((urethra$ or suburethra$ or midurethra$ or mid urethra$ or transurethra$ or trans urethra$ or periurethra$ or peri urethra$ or endourethra$ or endo urethra$) adj3 (inject$ or agent$ or bulk$)))).tw.
34	((pre or prior or before) adj7 (retropubic$ or (tension adj3 vagina$) or TVT or transobturator$ or TOT or minisling$ or mini sling$ or miniarc or monarc or plication or (adjustable adj2 tape$) or ((bladder$ or surgical$ or synthetic$ or biologic$ or autologous$) adj3 (sling$ or tape$ or mesh$)) or ((urethra$ or suburethra$ or midurethra$ or mid urethra$ or transurethra$ or trans urethra$ or pubovesical$ or pubo vesical$ or retropubic$ or retro pubic$ or suprapubic$ or supra pubic$ or pubovagina$ or transvagina$ or intravagina$ or vagina$ or transobturator$ or trans obturator$ or tension$ or lyodura$ or rosti$) adj3 (sling$ or tape$ or mesh$ or implant$)) or MUS or SPARC or slingplast$ or sling plast$)).tw.
35	((pre or prior or before) adj7 (colposuspension$ or colpo suspension$ or vesicosuspension$ or urethrosuspension$ or vesicourethra$ suspension$ or urethrovesica$ suspension$ or colpourethrosuspension$ or corner$ suspension$ or urethropex$ or urethrocystopex$ or cystourethropex$ or urethrocervicopex$ or (bladder$ adj3 buttress$) or colpofixation$ or burch$ or ((paravagina$ or pubococcygeal$) adj3 repair$) or (obturator$ adj3 (shelf$ or shelv$)) or ((bladder$ or neck$ or needle$) adj3 suspen$) or ((pereyra$ or stamey$ or raz$ or gittes$) adj3 (suspen$ or procedure$)) or ((anterior$ or vagina$) adj3 repair$) or colporraph$ or colpopex$ or sacrocolpopex$ or sacropex$ or colposacropex$ or (artific$ adj3 (urin$ or genitourin$) adj3 sphincter?))).tw.
36	or/29-35
37	DECISION MAKING/ use ppez

#	Searches
38	CLINICAL DECISION MAKING/ use ppez
39	*DECISION MAKING/ use emczd
40	*CLINICAL DECISION MAKING/ use emczd
41	((make or making) adj3 decision?).tw.
42	or/37-41
43	URINARY INCONTINENCE/di use ppez
44	URINARY INCONTINENCE, STRESS/di use ppez
45	*URINE INCONTINENCE/di use emczd
46	*STRESS INCONTINENCE/di use emczd
47	*MIXED INCONTINENCE/di use emczd
48	or/43-47
49	(preoperati$ or presurgery or presurgical$ or preprocedur$ or ((pre or prior or before) adj3 (operat$ or surgery or surgical$ or procedur$))).tw.
50	10 and 28 and 36
51	10 and 28 and 42
52	28 and 48 and 49
53	or/50-52
54	limit 53 to english language
55	remove duplicates from 54
56	letter.pt. use emczd
57	LETTER/ use emczd
58	Letter/ use ppez
59	EDITORIAL/ use ppez
60	editorial.pt. use emczd
61	NEWS/ use ppez
62	exp HISTORICAL ARTICLE/ use ppez
63	note.pt. use emczd
64	ANECDOTES AS TOPIC/ use ppez
65	COMMENT/ use ppez
66	CASE REPORT/ use ppez
67	CASE REPORT/ use emczd
68	CASE STUDY/ use emczd
69	(letter or comment*).ti.
70	or/56-69
71	RANDOMIZED CONTROLLED TRIAL/ use ppez
72	RANDOMIZED CONTROLLED TRIAL/ use emczd
73	random*.ti,ab.
74	or/71-73
75	70 not 74
76	ANIMALS/ not HUMANS/ use ppez
77	ANIMAL/ not HUMAN/ use emczd
78	exp ANIMALS, LABORATORY/ use ppez
79	exp ANIMAL EXPERIMENTATION/ use ppez
80	exp MODELS, ANIMAL/ use ppez
81	exp RODENTIA/ use ppez
82	NONHUMAN/ use emczd
83	exp ANIMAL EXPERIMENT/ use emczd
84	exp EXPERIMENTAL ANIMAL/ use emczd
85	ANIMAL MODEL/ use emczd
86	exp RODENT/ use emczd
87	(rat or rats or mouse or mice).ti.
88	or/75-87
89	55 not 88
90	limit 89 to yr="1995 -Current"

Database: Cochrane Library via Wiley Online

Date of last search: 8th May 2017

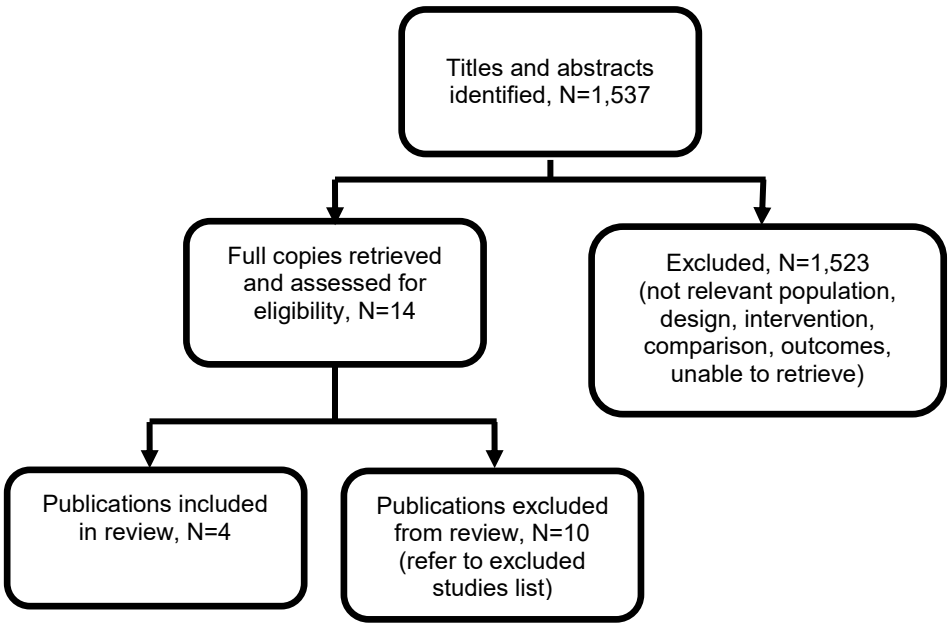
#	Searches
#1	MeSH descriptor: [Urinary Incontinence] this term only
#2	MeSH descriptor: [Urinary Incontinence, Stress] explode all trees
#3	((stress* or mix* or effort* or urin*) near/5 incontinen*):ti,ab,kw
#4	UI:ti,ab,kw
#5	SUI:ti,ab,kw
#6	(urine near/2 (loss or leak*)):ti,ab,kw
#7	#1 or #2 or #3 or #4 or #5 or #6
#8	MeSH descriptor: [Urodynamics] this term only
#9	(urodynamic* or cystometr* or uroflowmet*):ti,ab,kw
#10	(urethr* near/3 pressure* near/3 (study or studies or profile*)):ti,ab,kw
#11	(void* near/3 pressure* near/3 (study or studies or profile*)):ti,ab,kw

#	Searches
#12	(pressure* near/3 flow):ti,ab,kw
#13	(videourodynamic* or video urodynamic*):ti,ab,kw
#14	(ambulatory near/3 urodynamic*):ti,ab,kw
#15	(ambulatory near/3 cystometr*):ti,ab,kw
#16	((video* or void*) near/3 cystourethrogra*):ti,ab,kw
#17	VCUG:ti,ab,kw
#18	profilometr*:ti,ab,kw
#19	leak point pressure*:ti,ab,kw
#20	#8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19
#21	MeSH descriptor: [Preoperative Care] this term only
#22	((preoperati* or presurgery or presurgical* or preprocedur*) near/7 (assess* or test* or diagnos* or evaluat* or investigat*)):ti,ab,kw
#23	((pre or prior or before) near/3 (operat* or surgery or surgical* or procedur*) near/7 (assess* or test* or diagnos* or evaluat* or investigat*)):ti,ab,kw
#24	((pre or prior or before) near/7 ((bulk* near/3 agent*) or biocompatible material* or collagen or contigen or (silicone near/3 (particle* or implant* or microimplant*)) or macroplastique* or (carbon* near/3 (bead* or particle*)) or calcium hydroxylapatite or ethylene vinyl alcohol copolymer* or (hyaluron* near/3 (acid* or therap*)) or ((urethra* or suburethra* or midurethra* or mid urethra* or transurethra* or trans urethra* or periurethra* or peri urethra* or endourethra* or endo urethra*) near/3 (inject* or agent* or bulk*)))):ti,ab,kw
#25	((pre or prior or before) near/7 (retropubic* or (tension near/3 vagina*) or TVT or transobturator* or TOT or minisling* or mini sling* or miniarc or monarc or plication or (adjustable near/2 tape*) or ((bladder* or surgical* or synthetic* or biologic* or autologous*) near/3 (sling* or tape* or mesh*)) or ((urethra* or suburethra* or midurethra* or mid urethra* or transurethra* or trans urethra* or pubovesical* or pubo vesical* or retropubic* or retro pubic* or suprapubic* or supra pubic* or pubovagina* or transvagina* or intravagina* or vagina* or transobturator* or trans obturator* or tension* or lyodura* or rosti*) near/3 (sling* or tape* or mesh* or implant*)) or MUS or SPARC or slingplast* or sling plast*)):ti,ab,kw
#26	((pre or prior or before) near/7 (colposuspension* or colpo suspension* or vesicosuspension* or urethrosuspension* or vesicourethra* suspension* or urethrovesica* suspension* or colpourethrosuspension* or corner* suspension* or urethropex* or urethrocystopex* or cystourethropex* or urethrocervicopex* or (bladder* near/3 buttress*) or colpofixation* or burch* or ((paravagina* or pubococcygeal*) near/3 repair*) or (obturator* near/3 (shelf* or shelv*)) or ((bladder* or neck* or needle*) near/3 suspen*) or ((pereyra* or stamey* or raz* or gittes*) near/3 (suspen* or procedure*)) or ((anterior* or vagina*) near/3 repair*) or colporraph* or colpopex* or sacrocolpopex* or sacropex* or colposacropex* or (artific* near/3 (urin* or genitourin*) near/3 sphincter*))):ti,ab,kw
#27	#21 or #22 or #23 or #24 or #25 or #26
#28	MeSH descriptor: [Decision Making] this term only
#29	MeSH descriptor: [Clinical Decision-Making] this term only
#30	((make or making) near/3 decision*):ti,ab,kw
#31	#28 or #29 or #30
#32	MeSH descriptor: [Urinary Incontinence] this term only and with qualifier(s): [Diagnosis - DI]
#33	MeSH descriptor: [Urinary Incontinence, Stress] this term only and with qualifier(s): [Diagnosis - DI]
#34	#32 or #33
#35	(preoperati* or presurgery or presurgical* or preprocedur* or ((pre or prior or before) near/3 (operat* or surgery or surgical* or procedur*))):ti,ab,kw
#36	#7 and #20 and #27

Appendix C – Clinical evidence study selection

Clinical evidence study selection for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

Figure 1: PRISMA flow chart for review question: what is the value of urodynamic assessment in addition to clinical assessment before primary surgery for SUI



Appendix D - Clinical evidence tables

Clinical evidence tables for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

Table 4: Clinical evidence table for what is the value of urodynamic assessment in addition to clinical assessment before primary surgery for SUI?

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Hilton, P, Armstrong, N, Brennand, C, Howel, D, Shen, J, Bryant, A, Tincello, Dg, Lucas, Mg, Buckley, Bs, Chapple, Cr, Homer, T, Vale, L, McColl, E, A mixed methods study to assess the feasibility of a randomised controlled trial of invasive urodynamic testing versus clinical assessment and non-invasive tests prior to surgery for stress urinary incontinence in women: the INVESTIGATE-I study, Trials, 16, 400, 2016	**Sample size** N = 222 Intensive Urodynamic Treatment (IUT): N = 112 No IUT: N = 110 **Characteristics** Gender - Female/N (%) N = 222 (100%) Age - Mean ± SD IUT: 47.1 (9.5) years No IUT: 46.8 (10.0) years BMI - Mean ± SD IUT: 29.3 (6.5) kg/m2 No IUT: 27.4 (5.0) kg/m2 3-day bladder diary (average visits to bathroom - daytime) - mean ± SD	**Interventions** IUT: basic clinical and non-invasive tests as directed by the clinician; these included frequency/volume charting or bladder diary, mid-stream urine culture, urine flow rate and residual urine volume measurement (by ultrasound), plus invasive urodynamic testing. No IUT: basic clinical assessment supplemented by non-invasive tests as directed by the clinician; these included frequency/volume charting or bladder diary, mid-stream urine culture, urine	**Details** Dual-channel subtracted cystometry with simultaneous pressure/flow voiding studies is the most commonly applied technique in the evaluation of patients prior to surgery for SUI in most centres. Videourodynamics and ambulatory bladder pressure monitoring are used as alternative or additional invasive tests in some units; these tests were also permissible within the pilot trial, at the discretion of the clinician. Further investigation was undertaken, where appropriate, at the same visit or a later one, as per local custom, and the treatment plan formulated.	**Results** 3-day bladder diary (average visits to bathroom - daytime) at 6 months after treatment - mean ± SD IUT (n=44): 6.8 (24.5) No IUT (n=61): 6.2 (1.3) 3-day bladder diary (average visits to bathroom – night time) at 6 months after treatment - mean ± SD IUT (n=32): 1.3 (1.0) No IUT (n=41): 1.1 (0.6) 3-day bladder diary (average pads used in 24 hours) at 6 months after treatment - mean ± SD IUT (n=21): 1.7 (4.9) No IUT (n=26): 0.5 (1.0) Adverse effects of urodynamic testing - n (%)	**Limitations** Random sequence generation: Low risk of bias (internet-accessed computer randomisation on 1:1 basis and stratified by centre using random block length). Allocation concealment: High risk of bias (neither patients nor surgeons blinded to group assignment). Blinding: High risk of bias (it was considered neither feasible nor appropriate to blind participants or clinicians).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 618655 **Country/ies where the study was carried out** UK Study type Pragmatic multicentre randomised pilot trial **Aim of the study** To inform the decision whether or not to proceed to a definitive randomised trial of invasive urodynamic testing compared with clinical assessment with non-invasive tests, prior to surgery in women with stress UI (SUI) or stress predominant mixed UI (MUI) **Study dates** April 2011 to January 2013 **Source of funding**	IUT (n=69): 7.4 (2.2) No IUT (n=79): 7.6 (3.0) 3-day bladder diary (average visits to bathroom – night time) - mean ± SD IUT (n=69): 0.9 (0.7) No IUT (n=79): 0.8 (0.7) 3-day bladder diary (average pads used in 24 hours) - mean ± SD IUT (n=45): 2.8 (2.0) No IUT (n=59): 2.7 (1.9) ICIQ-FLUTS overall score - mean ± SD IUT (n=77): 16.9 (5.7) No IUT (n=85): 16.4 (6.3) Subscales (Filling) - mean ± SD IUT (n=78): 4.4 (2.3) No IUT (n=85): 4.0 (2.6) Subscales (Voiding) - mean ± SD IUT (n=79): 1.8 (2.0) No IUT (n=86): 1.5 (1.7) Subscales (Incontinence) - mean ± SD	flow rate and residual urine volume measurement (by ultrasound).	Randomisation Patients were randomly assigned to a study group using an internet-accessed computer randomisation system held by the Newcastle Clinical Trials Unit; randomisation between intervention and control was 1:1 and stratified by centre using random block length. Statistical analysis Categorical variables were summarised as percentages per category by treatment arm. Questionnaire scale and subscale totals and continuous variables were summarised by mean and standard deviation (SD) and 5-number summaries [median, interquartile range (IQR) and range] by treatment arm and time point. The burden of missing data were summarised by response rates for each variable. No data imputation was attempted for any outcome. The summary statistics for the primary outcome measure were combined with the target/minimum clinically important difference (MCID) and recruitment, retention	No adverse events categorised as related to invasive urodynamic testing. ICIQ-FLUTS overall score at 6 months after treatment - mean ± SD IUT (n=47): 9.2 (7.5) No IUT (n=66): 6.9 (5.0) Change in scale scores: IUT (n=31): 7.8 (5.9) No IUT (n=48): 9.3 (7.3) Subscales (Filling) at 6 months after treatment - mean ± SD IUT (48): 3.0 (2.3) No IUT (n=66): 2.4 (1.8) Subscales (Voiding) at 6 months after treatment - mean ± SD IUT (n=49): 2.0 (2.0) No IUT (n=68): 2.3 (2.1) Subscales (Incontinence) at 6 months after treatment - mean ± SD IUT (n=49): 4.9) No IUT (n=68): 2.3 (3.1) ICIQ-UI SF at 6 months after treatment - mean ± SD	Incomplete outcome data: High risk of bias (More than 15% of patients lost to follow-up. 31 patients were lost to follow-up in the IUT group, and 41 in the no IUT group). Selective reporting: Low risk of bias (All outcomes reported). Other bias: High risk of bias (The recruitment total (N=222) represented 93% of the planned sample size (N=240).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
The National Institute for Health Research Health Technology Assessment programme.	IUT (n=78): 10.8 (3.3) No IUT (n=86): 10.8 (3.6) ICIQ-UI SF - mean ± SD IUT (n=78): 14.0 (3.7) No IUT (n=85): 14.1 (3.8) ICIQ-LUTSqol - mean ± SD IUT (n=73): 46.8 (10.9) No IUT (n=84): 48.5 (11.7) UDI overall score - mean ± SD IUT (n=64): 133.3 (43.5) No IUT (n=74): 130.1 (43.8) Subscales (Stress) - mean ± SD IUT (n=76): 82.9 (21.0) No IUT (n=80): 80.2 (21.2) Subscales (Irritative) - mean ± SD IUT (n=71): 38.4 (25.4) No IUT (n=80): 33.7 (24.3)		and response rates to inform the sample size for a future definitive trial. Power calculation The sample size for the external pilot trial was determined pragmatically, using the recommended minimum of 30 participants per arm. Estimated total of 240 eligible patients to allow for 50% overall attrition. Intention to treat analysis Primary analysis: intention-to-treat.	IUT (n=49): 5.3 (6.0) No IUT (n=65): 3.3 (4.5) Change in scores: IUT (n=34): 8.9 (6.0) No IUT (n=49): 10.2 (5.8) ICIQ-LUTSqol at 6 months after treatment - mean ± SD IUT (n=44): 26.7 (12.3) No IUT (n=65): 25.3 (9.6) Change in scores: IUT (n=29): 20.0 (11.4) No IUT (n=47): 23.7 (13.9) UDI overall score at 6 months after treatment - mean ± SD IUT (n=42): 49.1 (44.1) No IUT (n=59): 33.9 (39.7) Change in scores: IUT (n=27): 79.5 (45.5) No IUT (n=41): 94.1 (55.3) Subscales (Stress) at 6 months after treatment - mean ± SD IUT (n=50): 24.5 (26.1) No IUT (n=65): 18.1 (27.0) Subscales (Irritative) at 6 months after treatment - mean ± SD	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Subscales (Obstructive/discomfort) - mean ± SD IUT (n=68): 17.6 (17.6) No IUT (n=80): 14.8 (14.2) **Inclusion criteria** Women were required to fulfil ALL criteria to be eligible: • Clinical diagnosis of SUI or stress predominant MUI • Women must state that their family is complete • Women should have undergone a course of PFMT (± other non-surgical treatments for their urge symptoms) with inadequate resolution of their symptoms • Both the woman herself and her treating clinician			IUT (n=48): 16.5 (20.5) No IUT (n=64): 10.0 (13.3) Subscales (Obstructive/discomfort) at 6 months after treatment - mean ± SD IUT (n=43): 10.9 (15.1) No IUT (n=64): 8.9 (12.4)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	should agree that surgery is an appropriate and acceptable next line of treatment **Exclusion criteria** • Symptomatic uterovaginal prolapse requiring treatment • Previous surgery for UI or pelvic organ prolapse (POP) • Urodynamic investigation within the last 3 years • Neurological disease causing UI • Current involvement in competing research studies (e.g. studies of investigation or treatment of UI) Unable to give competent				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	informed consent				
Full citation Nager,C.W., Brubaker,L., Litman,H.J., Zyczynski,H.M., Varner,R.E., Amundsen,C., Sirls,L.T., Norton,P.A., Arisco,A.M., Chai,T.C., Zimmern,P., Barber,M.D., Dandreo,K.J., Menefee,S.A., Kenton,K., Lowder,J., Richter,H.E., Khandwala,S., Nygaard,I., Kraus,S.R., Johnson,H.W., Lemack,G.E., Mihova,M., Albo,M.E., Mueller,E., Sutkin,G., Wilson,T.S., Hsu,Y., Rozanski,T.A., Rickey,L.M., Rahn,D., Tennstedt,S., Kusek,J.W., Gormley,E.A., A randomized trial of	**Sample size** N = 630 women Urodynamic testing group: N = 315 Office evaluation only: N = 315 **Characteristics** Gender - Female/N (%) N = 630 (100%) Age - Mean ± SD Urodynamic testing group: 51.9 (10.4) years Office evaluation only: 51.6 (10.0) years Score of moderate or severe on PGIS-no./total no. (%) Urodynamic testing group: 225/262 (85.9%) Office evaluation only: 227/259 (87.6%) Duration of incontinence (months) - Mean ± SD Urodynamic testing: 107.4 (100.3)	**Interventions** Urodynamic testing group: Non-instrumented uroflowmetry with a comfortably full bladder, postvoid residual obtained with catheter, filling cystometry with Valsalva leak-point pressures, and a pressure-flow study. In addition, physicians completed comprehensive checklist of clinical diagnoses, with office visits at 3 and 12 months after treatment (provocative stress test, postvoid residual and urine dipstick). Office evaluation only: Physicians completed comprehensive checklist of clinical diagnoses, with	**Details** Urodynamic testing group: Urethral pressure profilometry or urodynamic testing with the use of video was permitted if it was routinely performed as part of the preoperative investigation at the study site. Testing followed the Good Urodynamic Practice guidelines of the International Continence Society, and interpretation conformed to International Continence Society nomenclature. Outcome data were obtained by study personnel (who were unaware of the group assignments) at office visits 3 and 12 months after treatment. Randomisation Patients were randomly assigned to a study group using an automated randomisation system stratified according to surgeon. Statistical analysis Non-parametric statistics for non-normally distributed	**Results** Voiding dysfunction at 6 weeks or beyond – n/total n (%) Urodynamics testing group: 6/315 (1.9%) Office evaluation only: 6/315 (1.9%); p>0.99 Change in ISI score - means ±SD Urodynamic testing group: -6.0 (3.3) n=272 Office evaluation only: -5.7 (3.4) n=266 ; p=0.40 "Very much better" or "much better" on Patient Global Impression of Improvement - n/N (%) Urodynamic testing group: 248/270 (91.9%) Office evaluation only: 238/262 (90.8%); p=0.68 Change in Patient Global Impression of Severity score - mean ±SD Urodynamic testing group: -1.8 (0.9) n=272 Office evaluation only: -1.8 (0.9) n=266; p=0.68	**Limitations** Random sequence generation: Low risk of bias (automated randomisation system stratified according to surgeon) Allocation concealment: High risk of bias (neither patients nor surgeons blinded to group assignment) Blinding: Low risk of bias (study personnel were unaware of the group assignments) Incomplete outcome data: High risk of bias (More than 15% of patients lost to follow-up. 27 patients were lost to follow-up in the urodynamic testing group, and 26 in the office

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
urodynamic testing before stress-incontinence surgery, New England Journal of Medicine, 366, 1987-1997, 2012 **Ref Id** 188052 Country/ies where the study was carried out USA **Study type** Randomised, non-inferiority trial (11 participating sites) **Aim of the study** To determine whether outcomes at 1 year among women with uncomplicated, stress-predominant urinary incontinence who underwent only an office evaluation (no urodynamic studies) were inferior to women who also underwent pre-operative urodynamic studies.	Office evaluation only: 90.7 (79.9) Postvoiding residual urine volume (ml) - median (interquartile range; IQR) Urodynamic testing: 10 (5-30) Office evaluation only: 18 (5-35) **Inclusion criteria** • Women aged 21 years of age or older • History of symptoms of stress urinary incontinence for at least 3 months • Score on the MESA questionnaire for stress urinary incontinence that was greater than the score on the Value of Urodynamic Evaluation (VALUE)	office visits at 3 and 12 months after treatment.	variables. Wilcoxon rank-sum tests and t-tests used for comparison of continuous variables; chi-square tests and Fisher's exact tests used to compare categorical variables. Linear regression and logistic-regression models were fit to assess whether outcomes differed by treatment group with adjustment for unbalanced baseline variables. For measures collected at two time points, paired t-tests and McNemar's tests were used, as appropriate. Sensitivity analyses were performed by classifying missing data for primary outcome measures as all treatment successes and as all treatment failures in order to examine the consistency of our findings. Planned subgroup analysis: to compare surgical outcomes only among women in study who underwent surgery, to determine whether urodynamic studies might improve outcomes only among women undergoing surgery. Power calculation	Score of moderate or severe on the Patient Global Impression of Severity at 12 mo — no./total no. (%) Urodyanamic testing group: 19/271 (7.0%) Office evaluation only: 15/266 (5.6%); p=0.51 Any new or continuing treatment for urge incontinence – n/total n (%) Urodynamic testing group: 44/273 (16.1%) Office evaluation only: 38/266 (14.3%); p=0.55 Any new or continuing evidence of recurrent stress urinary incontinence – n/total n (%) Urodynamic testing group: 81/274 (29.6%) Office evaluation only: 85/273 (31.1%); p-0.69 Any new or continuing treatment for recurrent stress urinary incontinence – n/total n (%) Urodynamic testing group: 9/269 (3.4%) Office evaluation only: 6/262 (2.3%); p=0.60	evaluation only group) Selective reporting: Low risk of bias (All outcomes reported) Other bias: Low risk of bias (no other potential source of bias identified) **Other information** Voiding dysfunction defined as a complication if one of the following criteria was met: • Uses a catheter to facilitate bladder emptying at or beyond 6 weeks post-surgery • Undergone medical therapy to facilitate bladder emptying

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates November 2008 to June 2010 **Source of funding** Supported by cooperative agreements from the National Institute of Diabetes and Digestive and Kidney Diseases and by the Eunice Kennedy Shriver National Institute of Child Health and Human Development.	questionnaire for urgency incontinence • A postvoiding residual urine volume of less than 150 ml • A negative urinanalysis or urine culture • A clinical assessment of urethral mobility • A desire for surgery for stress urinary incontinence, and • A positive provocative stress test (defined as an observed transurethral loss of urine that was simultaneous with a cough or Valsalva manoeuver at any bladder volume) **Exclusion criteria**		For 80% power, N=270 women required in each study group to determine whether the results in the evaluation-only group were non-inferior to those in the urodynamic testing group. Intention to treat analysis Primary analysis: Per protocol. Secondary analysis: intention-to-treat.	Adverse Events - n/N (%)** Voiding dysfunction Urodynamic testing group: 6/315 (1.90%) Office evaluation only: 6/315 (1.90%)	at or beyond 6 weeks post-surgery, or • Undergone surgical therapy to facilitate bladder emptying at any time after study/index surgery

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Previous surgery for incontinence • History of pelvic irradiation • Pelvic surgery within the previous 3 months, and Anterior or apical pelvic-organ prolapse of 1 cm or more distal to the hymen				
Full citation Sirls, L. T., Richter, H. E., Litman, H. J., Kenton, K., Lemack, G. E., Lukacz, E. S., Kraus, S. R., Goldman, H. B., Weidner, A., Rickey, L., Norton, P., Zyczynski, H. M., Kusek, J. W., The effect of urodynamic testing on clinical diagnosis, treatment plan and outcomes in women undergoing stress urinary incontinence surgery, Journal of	**Sample size** N = 315 women randomised to urodynamic studies underwent office evaluation; N = 307 completed urodynamic studies; N = 294 had complete data available on clinical diagnosis and treatment plan. **Characteristics** See Nager (2012) **Inclusion criteria** **See Nager (2012)** **Exclusion criteria** See Nager (2012)	**Interventions** Urodynamic testing group: Non-instrumented uroflowmetry with a comfortably full bladder, filling cystometry with Valsalva leak-point pressures, and a pressure-flow study. In addition, physicians completed comprehensive checklist of clinical diagnoses, with office visits at 3 and 12 months after treatment (provocative stress	**Details** Randomisation Secondary analysis of a randomised trial (see Nager, 2012). Statistical analysis McNemar test used to compare differences between pre- and post-urodynamic testing. Multivariate logistic regression models. Odds ratios (ORs) and 95% confidence intervals (CIs) calculated for associations between clinical parameters and outcomes. Power calculation See Nager (2012)	**Results** Change in management plan Specific urodynamic studies driven changes to surgical plan Surgery cancelled: 4/294 (1.4%) Surgical procedure changed: 16/294 (5.4%) Retropubic mid urethral sling (RMUS) to transobturator mid urethral sling (TMUS): 8 TMUS to RMUS: 5 RMUS to fascial pubovaginal sling: 1 Fascial pubovaginal sling to RMUS: 1 Retropubic urethropexy to RMUS: 1	**Limitations** Random sequence generation: High risk of bias (secondary analysis) Allocation concealment: High risk of bias (secondary analysis) Blinding: High risk of bias (secondary analysis) Incomplete outcome data: High risk of bias (More than 15% of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Urology, 189, 204-209, 2013 **Ref Id** 619105 **Country/ies where the study was carried out** USA **Study type** Secondary analysis of Nager (2012) **Aim of the study** Secondary analysis of the ValUE trial; subroup analysis of women randomised to urodynamic studies after office evaluation to evaluate the effect of urodynamic studies on clinical diagnoses, global treatment plans and patient outcomes. **Study dates** See Nager (2012) **Source of funding** See Nager (2012)		test, postvoid residual and urine dipstick).	Intention-to-treat analysis See Nager (2012)	Change in global treatment plan after urodynamic studies not associated with a successful treatment outcome (OR 0.96, 95% CI 0.41 to 2.25; p=0.92). Women with a global treatment plan change did not have increased odds of self-voiding at discharge (OR 0.89, 95% CI 0.41 to 1.94; p=0.76) or decreased odds of treatment for voiding dysfunction at the 3 or 12-month visit (OR 1.39, 95% CI 0.59 to 3.31, p=0.45). Fewer women with urodynamic studies voiding dysfunction met primary outcome (18/29, 2.1%) versus women without urodynamic studies voiding dysfunction (180/230, 78.3%); p=0.064. Women with global treatment plan had increased odds of treatment for urgency UI 3 or 12 months post-operatively (OR 3.23, 95 %CI 1.46 to 7.14; p=0.004).	patients lost to follow-up) Selective reporting: High risk of bias (secondary analysis of selected outcomes) Other bias: High risk of bias (secondary analysis) Other information The authors acknowledged the following limitation: 1] Failure to understand outcomes in patients who did not have their procedures altered by urodynamic studies.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Urodynamic study events that changed global treatment plan - n/N (%) Total: 75 events Voiding phase events: 44/75 (59%): Free uroflowmetry pattern: 8/28 Free uroflowmetry numerical values: 5/29 Pressure flow study voiding pattern: 16/28 Voiding phase diagnosis: 15/28 Filling phase events: 17/75 (23%): Sensation: 6/29 Max. cystometric capacity: 7/29 Detrusor function during filling: 4/29 Urethral function measures: 14/75 (19%) Urethral closure mechanism: 3/29 Valsalva leak point pressure: 10/29 Max. urethral closure pressure: 1 (yes), 24 (no), 4 (not applicable).	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Van Leijsen, S. A. L., Kluivers, K. B., Mol, B. W. J., Broekhuis, S. R., Milani, A. L., Bongers, M. Y., Aalders, C. I. M., Dietz, V., Malmberg, G. G. A., Vierhout, M. E., Heesakkers, J. P. F. A., Can preoperative urodynamic investigation be omitted in women with stress urinary incontinence? A non-inferiority randomized controlled trial, Neurourology and Urodynamics, 31, 1118-1123, 2012 **Ref Id** 619187 **Country/ies where the study was carried out** The Netherlands **Study type** Multicentre, non-inferiority randomised controlled trial; 1 academic and 9	**Sample size** N = 59 women Urodynamic testing: N = 31 No urodynamic testing: N = 28 **Characteristics** Gender - Female/N (%) N = 59 (100%) Age - Median (range) With urodynamics: 44 (31-77) years Without urodynamics: 43 (34-65) years Type of incontinence - no./total no. (%) With urodynamics: SUI 26 (84%); MUI 5 (16%) Without urodynamics: SUI 20 (71%); MUI 8 (29%) Daily micturition frequency With urodynamics: 7 (4-14) Without urodynamics: 7 (4-14) Nightly micturition frequency	**Interventions** With urodynamics Standard work-up including urodynamics testing. Without urodynamics Management based on history, physical examination and a voiding diary only.	**Details** Treatment decisions were based on history, voiding diary, and physical examination in combination with urodynamic testing results. If findings of urodynamics were in concordance with symptoms and signs, a surgical treatment was the eligible therapy. When urodynamic findings were disconcordant, a more individual treatment strategy could be tailored, including medical treatment, prolonged physiotherapy, pessary treatment, or surgical treatment. Urodynamic investigation was performed according to ICS standards. It consisted of free flow and PVR measurement, filling cystometry with abdominal leak point pressure measurement and pressure flow. Randomisation Patients were randomly assigned to a study group using a computer generated random number list and stratification by	Results Subjective Cure Global improvement using PGI-I Scale - n/N (%) Improvement With urodynamics: 27/31 (87%) Without urodynamics: 27/28 (96%) RR: 0.90 (95% CI 0.78-1.1) Equal With urodynamics: 1/31 (3%) Without urodynamics: 0 Impairment With urodynamics: 1/31 (3%) Without urodynamics: 1/28 (4%) RR: 0.90 (95% CI 0.06-14) Missing With urodynamics: 2/31 (6%) Without urodynamics: 0 Negative response to UDI-6 question "Do you usually experience urine leakage related to coughing, sneezing, or laughing?" With urodynamics: 20/31 (3%) Without urodynamics: 22/28 (4%) RR: 0.82 (95% CI 0.59-1.1)	**Limitations** Random sequence generation: Low risk of bias (computer generated randomisation system stratified according to centre) Allocation concealment: Low risk of bias (block sizes blinded for researchers and health professionals) Blinding: High risk of bias (patients and health professionals not blinded to allocated work-up) Incomplete outcome data: Low risk of bias (Less than 15% of patients lost to follow-up. 2 patients were lost to follow-up in the urodynamics group, and 0 from

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
non-academic hospitals. **Aim of the study** To assess the value of urodynamics prior to treatment in women with stress urinary incontinence (SUI) **Study dates** August 2007 to September 2008 **Source of funding** **Funded by** ZonMw, the Dutch Organization for Health, Research and Development, project number 945-07203	With urodynamics: 0 (0-2) Without urodynamics: 1 (0-2) Nocturia - N (%) With urodynamics: 14 (45%) Without urodynamics: 15 (54%) Incontinence episodes per day With urodynamics: 3 (0-9) Without urodynamics: 3 (0-8) Number of incontinence pads per day With urodynamics: 2 (0-9) Without urodynamics: 3 (0-7) **Inclusion criteria** • Women with SUI or mixed urinary incontinence wit h symptoms predominantly of SUI • Failure of conservative		centre with a 1:1 allocation using variable block sizes. Statistical analysis Primary outcome (UDI) was analysed using the unpaired t-test. When the upper limit of the 95% confidence interval (CI) was less than 8, non-inferiority was supported. For dichotomous outcomes, the relative risk (RR) with 95% CI was determined. Power calculation 310 women were needed in each treatment group to reach a power of 70% using less than 5% difference between patients with or without urodynamics. Intention to treat analysis Yes. Assessment time points and follow-up Evaluations were made at 6 weeks and at 6 months, 1 year and 2 years after treatment onset. The mean duration of follow up was 22 (±7) months. Where values were missing at 2 years, the observation at 1 year was carried forward	Missing With urodynamics: 2/31 (6%) Without urodynamics: 0 Objective cure 48-hour voiding diary - n/N (%) With urodynamics: 21/31 (81%); missing: 5/31 (16%) Without urodynamics: 24/28 (86%); missing 1/28 (4%) RR: 0.79 (95% CI 0.59-1.1) Negative stress test With urodynamics: 25/31 (81%); missing: 4/31 (13%) Without urodynamics: 23/28 (82%); missing 3/28 (11%) RR: 0.98 (95% CI 0.77-1.3) Complete cure of SUI - n/N (%) Subjectively (UDI-6 negative response) and objectively (negative stress test) cured With urodynamics: 17/31 (55%) Without urodynamics: 20/28 (71%) RR: 0.77 (95% CI 0.52-1.1)	the no urodynamics group) Selective reporting: Low risk of bias (All outcomes reported) Other bias: High risk of bias (underpowered) Other information The trial was stopped prematurely because of slow inclusion. To avoid bias due to loss to follow-up, patients who did not respond were contacted by telephone to increase the response rate. In case of missing values at 2 years, the observation at 1 year after start of treatment was carried forward.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	therapy, and patients opting for surgery • Demonstration of incontinence suggestive of SUI by physical examination and/or micturition diary **Exclusion criteria** • Women with previous incontinence surgery; • Pelvic organ prolapse >1 cm beyond the level of the hymen (POP-Q stage 3 or more) and/or • Post-void residual urine (PVR) >150 ml on ultrasound or catheterisation			Subjectively cured only (defined as no leakage reported during physical activity) With urodynamics: 1/31 (3%) Without urodynamics: 0 Objectively cured only (defined as a negative stress test by physical examination) With urodynamics: 8/31 (26%) Without urodynamics: 3/28 (11%) No cure (defined as objective and subjective leakage) With urodynamics: 1/31 (3%) Without urodynamics: 2/28 (7%) RR: 0.45 (95% CI 0.04-4.7) Missing With urodynamics: 4/31 (13%) Without urodynamics: 3/28 (11%) Change in management With urodynamics (N=31) Initial surgical treatment (n=26; MUS=25; burch=1)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Surgical treated (N=29; MUS=28; burch=1) Conservative treatment (N=5; detrusor overactivity=3; obesity and mild symptoms=1; patient's request=1) Conservative treated (N=2; detrusor overactivity=2) Without urodynamics (N=28 initially randomised to immediate surgery) Surgical treatment (n=27; MUS=25; burch=1) Conservative treatment (N=1; patient's request to change treatment=1) Adverse events - n/N (%) Occurrence of de novo OAB complaints occurred more in urodynamics group, but not statistically significant (6/31 vs 1/28; RR 5.4, 95% CI 0.70-42). Voiding dysfunction after treatment occurred less in urodynamics group (3/31 vs 7/28; RR: 0.39, 95% CI 0.11-1.4; p=0.12). Tape exposures: 2/54 (4%) who received MUS, without differences between treatment groups.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

BMI: Body Mass Index; CI: Confidence Intervals; ICIQ-FLUTS: Bristol Female Lower Urinary Tract Symptoms Module; ICIQ-LUTSqol: Lower Urinary Tract Symptoms Quality of Life; ICIQ-UI: International Consultation Incontinence Questionnaire-Urinary Incontinence; ICS: International Continence Society; IQR: Interquartile Range; IUT: Intensive Urodynamic Treatment; MCID: Minimum Clinically Important Difference; MUI: Mixed Urinary Incontinence; MUS: Midurethral Sling; N: Number; OAB: Overactive Bladder; OR: Odds Ratio; PGI-I: Patient Global Impression of Improvement; PGI-S: Patient Global Impression of Severity; POP: Pelvic Organ Prolapse; POP-Q: Pelvic Organ Prolapse-Questionnaire; PVR: Post-Void Residual; RMUS: Retropubic Mid Urethral Sling; RR: Risk Ratio; SD: Standard Deviation; SUI: Stress Urinary Incontinence; TMUS: Transobturator Mid Urethral Sling; UI: Urinary Incontinence; UDI: Urogenital Distress Inventory; VALUE: Value of Urodynamic Evaluation.

Appendix E – Forest plots

Forest plots for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

No meta-analysis was conducted for this review question, and so there are no forest plots

Appendix F – GRADE tables

GRADE tables for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

Table 5: Clinical profile for comparison urodynamics versus no urodynamics

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Urodynamics	No urodynamics	Relative (95% CI)	Absolute	Quality	Importance
Subjective cure: UDI-6 No leakage on physical activity, coughing, or sneezing at 2 years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	20/31 (64.5%)	22/28 (78.6%)	RR 0.82 (0.59 to 1.14)	141 fewer per 1000 (from 322 fewer to 110 more)	⊕⊕OO LOW	CRITICAL
Objective cure : Stress test negative at 2 years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	25/31 (80.6%)	23/28 (82.1%)	RR 0.98 (0.77 to 1.25)	16 fewer per 1000 (from 189 fewer to 205 more)	⊕OOO VERY LOW	CRITICAL
Objective cure: 48-hour voiding diary at 2 years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	21/31 (67.7%)	24/28 (85.7%)	RR 0.79 (0.59 to 1.05)	180 fewer per 1000 (from 351 fewer to 43 more)	⊕⊕OO LOW	CRITICAL
Complete cure : subjectively (UDI-6 no leakage on physical activity, coughing or sneezing) and objectively (negative stress test) at 2 years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	17/31 (54.8%)	20/28 (71.4%)	RR 0.77 (0.52 to 1.14)	164 fewer per 1000 (from 343 fewer to 100 more)	⊕⊕OO LOW	CRITICAL

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Urodynamics**	**No urodynamics**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Change in Incontinence Severity Index (with scores ranging from 1 to 12 and higher scores indicating greater severity) at 1 year (Better indicated by lower values)												
1	randomised trials	serious[4]	no serious inconsistency	no serious indirectness	serious[2]	none	315	315	-	MD 0.3 lower (0.82 lower to 0.22 higher)	⊕⊕OO LOW	CRITICAL
Any new or continuing evidence of recurrent SUI at 1 year												
1	randomised trials	serious[4]	no serious inconsistency	no serious indirectness	serious[2]	none	81/274 (29.6%)	85/273 (31.1%)	RR 0.95 (0.74 to 1.22)	16 fewer per 1000 (from 81 fewer to 68 more)	⊕⊕OO LOW	IMPORTANT
Any new or continuing treatment for recurrent SUI at 1 year												
1	randomised trials	very serious[4,5]	no serious inconsistency	no serious indirectness	very serious[6]	none	9/269 (3.3%)	6/262 (2.3%)	RR 1.46 (0.53 to 4.05)	11 more per 1000 (from 11 fewer to 70 more)	⊕OOO VERY LOW	IMPORTANT
Any new or continuing treatment for urge incontinence at 1 year												
1	randomised trials	serious[4]	no serious inconsistency	no serious indirectness	very serious[6]	none	44/273 (16.1%)	38/266 (14.3%)	RR 1.13 (0.76 to 1.68)	19 more per 1000 (from 34 fewer to 97 more)	⊕OOO VERY LOW	IMPORTANT
Occurrence of de novo OAB complaints at 2 years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[6]	none	6/31 (19.4%)	1/28 (3.6%)	RR 5.42 (0.69 to 42.28)	158 more per 1000 (from 11 fewer to 1000 more)	⊕OOO VERY LOW	IMPORTANT
Voiding dysfunction at 6 weeks after treatment or beyond												
1	randomised trials	serious[4]	no serious inconsistency	no serious indirectness	very serious[6]	none	6/315 (1.9%)	6/315 (1.9%)	RR 1.00 (0.33 to 3.07)	0 fewer per 1000 (from 13 fewer to 39 more)	⊕OOO VERY LOW	IMPORTANT
Voiding dysfunction after treatment at 2 years												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Urodynamics	No urodynamics	Relative (95% CI)	Absolute	Quality	Importance
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[6]	none	3/31 (9.7%)	7/28 (25%)	RR 0.39 (0.11 to 1.35)	153 fewer per 1000 (from 222 fewer to 88 more)	⊕OOO VERY LOW	IMPORTANT
Improvement on Patient Global Impression of Improvement scale: 'Very much better' or 'much better' on PGI-I at 1 year												
1	randomised trials	serious[4]	no serious inconsistency	no serious indirectness	no serious imprecision	none	248/270 (91.9%)	238/262 (90.8%)	RR 1.01 (0.96 to 1.07)	9 more per 1000 (from 36 fewer to 64 more)	⊕⊕⊕O MODERATE	IMPORTANT
Improvement on Patient Global Impression of Improvement scale: PGI-I Improvement at 2 years												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	27/31 (87.1%)	27/28 (96.4%)	RR 0.9 (0.78 to 1.05)	96 fewer per 1000 (from 212 fewer to 48 more)	⊕⊕OO LOW	IMPORTANT
Change in Patient Global Impression of Severity score at 1 year (Better indicated by lower values)												
1	randomised trials	very serious[4,5]	no serious inconsistency	no serious indirectness	no serious imprecision	none	272	266	-	MD 0.00 higher (0.15 lower to 0.15 higher)	⊕⊕OO LOW	IMPORTANT
Women's experience of urodynamic testing: Unpleasant =<3 score (with scores ranging from 1- very unpleasant to 6 - totally not unpleasant)												
1	randomised trials	very serious[1,8]	no serious inconsistency	no serious indirectness	NC	none	8/31 (25.8%)	-	-	-	⊕⊕OO LOW	IMPORTANT
Change in management: Initial treatment not surgery												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[6]	none	5/31 (16.1%)	1/28 (3.6%)	RR 4.52 (0.56 to 36.34)	126 more per 1000 (from 16 fewer to 1000 more)	⊕OOO VERY LOW	IMPORTANT
Change to surgical plan based on urodynamic testing results: Surgery cancelled												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Urodynamics**	**No urodynamics**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
1	observational studies7	serious[8]	no serious inconsistency	no serious indirectness	NC	none	4/294 (1.4%)	-	-	-	⊕OOO VERY LOW	IMPORTANT
Change to surgical plan based on urodynamic testing results: Surgical procedure changed												
1	observational studies7	serious[8]	no serious inconsistency	no serious indirectness	NC	none	16/294 (5.4%)9	-	-	-	⊕OOO VERY LOW	IMPORTANT
Success of treatment outcome following change in global treatment plan based on urodynamic testing												
1	observational studies[7]	serious[8]	no serious inconsistency	no serious indirectness	Very serious[6]	none	-	-	OR 0.96 (0.41 to 2.25)[10]	-	⊕OOO VERY LOW	IMPORTANT
Self-voiding at discharge following a global treatment plan change												
1	observational studies[7]	serious[8]	no serious inconsistency	no serious indirectness	very serious[6]	none	-	-	OR 0.89 (0.41 to 1.94)[10]	-	⊕OOO VERY LOW	IMPORTANT
Treatment for voiding dysfunction following a global treatment plan change at 3 or 12 months post-operatively												
1	observational studies[7]	serious[8]	no serious inconsistency	no serious indirectness	very serious[6]	none	-	-	OR 1.39 (0.59 to 3.31)[10]	-	⊕OOO VERY LOW	IMPORTANT
Treatment for urgency UI following a global treatment plan change at 3 or 12 months post-operatively												
1	observational studies[7]	serious[8]	no serious inconsistency	no serious indirectness	Serious[14]	none	-	-	OR 3.23 (1.46 to 7.14)[10]	-	⊕OOO VERY LOW	IMPORTANT
Urodynamic study events that changed global treatment plan												
1	observational studies[7]	serious[8]	no serious inconsistency	no serious indirectness	NC	none	75 events[11]	-	-	-	⊕OOO VERY LOW	IMPORTANT
Change in ICIQ-FLUTS – overall score												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Urodynamics**	**No urodynamics**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
1	randomised trials	very serious [12]	no serious inconsistency	no serious indirectness	Serious[13]	none	31	48	-	MD 1.5 lower (4.43 lower to 1.43 higher)	VERY LOW	CRITICAL
Change in ICIQ-UI SF (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious [12]	no serious inconsistency	no serious indirectness	Serious[13]	none	34	49	-	MD 1.3 lower (3.89 lower to 1.29 higher)	⊕OOO VERY LOW	CRITICAL
Change in ICIQ-LUTSqol (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious [12]	no serious inconsistency	no serious indirectness	Serious[13]	none	29	47	-	MD 3.7 lower (9.45 lower to 2.05 higher)	⊕OOO VERY LOW	CRITICAL
Change in UDI - overall score (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious [12]	no serious inconsistency	no serious indirectness	Very serious[13, 14]	none	27	41	-	MD 14.6 lower (38.71 lower to 9.51 higher)	⊕OOO VERY LOW	CRITICAL
Change in daytime bathroom visits (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious [12]	no serious inconsistency	no serious indirectness	Serious[14]	none	44	61	-	MD 0.80 higher (0.10 to 1.50 higher)	⊕OOO VERY LOW	CRITICAL
Change in nighttime bathroom visits (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious [12]	no serious inconsistency	no serious indirectness	No serious imprecision	none	32	41	-	MD 0.10 higher (0.13 lower to 0.33 higher)	⊕OOO VERY LOW	CRITICAL
Change in pads used in 24 hours (follow-up 6 months; Better indicated by lower values)												

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Urodynamics**	**No urodynamics**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
1	randomised trials	very serious [12]	no serious inconsistency	no serious indirectness	Serious[14]	none	21	26	-	MD 1.10 higher (0.31 to 1.89 higher)	⊕OOO VERY LOW	CRITICAL

[1] High risk of bias from lack of blinding of women and health professionals to pre-surgical treatment group.
[2] 95% Confidence Interval crosses the lower default threshold (0.8)
[3] 95% Confidence Interval crosses the lower default threshold and equals the higher default threshold (0.8 to 1.25)
[4] High risk of bias from lack of allocation concealment as neither women nor surgeons blinded to pre-surgical treatment group.
[5] High risk of bias from incomplete outcome data reporting as >15% of patients lost to follow up.
[6] 95% Confidence Interval crosses the lower and higher default thresholds (0.8 to 1.25)
[7] Secondary analysis providing descriptive data for the subgroup of women in the ValUE trial who were randomised to urodynamic testing prior to treatment.
[8] No comparative data are available for women randomised to physician evaluated clinical diagnosis or standard work-up only prior to treatment
[9] Retropubic mid urethral sling (RMUS) to transobturator mid urethral sling (TMUS): 8, TMUS to RMUS: 5, RMUS to fascial pubovaginal sling: 1, Fascial pubovaginal sling to RMUS: 1, Retropubic urethropexy to RMUS: 1
[10] Multivariate logistic regression model used
[11] Voiding phase events: 44/75 (59%): Free uroflowmetry pattern: 8/28, Free uroflowmetry numerical values: 5/29, Pressure flow study voiding pattern: 16/28, Voiding phase diagnosis: 15/28. Filling phase events: 17/75 (23%):Sensation: 6/29, Max. cystometric capacity: 7/29, Detrusor function during filling: 4/29. Urethral function measures: 14/75 (19%): Urethral closure mechanism: 3/29, Valsalva leak point pressure: 10/29, Max. urethral closure pressure: 1 (yes), 24 (no), 4 (not applicable).
[12] Allocation concealment: High risk of bias (neither patients nor surgeons blinded to group assignment); Blinding: High risk of bias (it was considered neither feasible nor appropriate to blind participants or clinicians); Incomplete outcome data: High risk of bias (More than 15% of patients lost to follow-up. 31 patients were lost to follow-up in the UIT group, and 41 in the no UIT group); Other bias: High risk of bias (The recruitment total (N=222) represented 93% of the planned sample size (N=240).
[13] 95% Confidence interval crosses the lower default threshold
[14] 95% Confidence interval crosses the upper default threshold

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

One global search was conducted for this review question. See supplementary material D for further information.

Appendix H – Economic evidence tables

Economic evidence tables for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

Table 6: Economic evidence tables

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Homer, T., Shen, J., Vale, L., McColl, E., Tincello, D. G., Hilton, P., Invasive urodynamic testing prior to surgical treatment for stress urinary incontinence in women: cost-effectiveness and value of information analyses in the context of a mixed methods feasibility study, Pilot and feasibility studies, 4, 1-11, 2018 UK	Interventions: Urodynamics (UDS) vs. no UDS (basic clinical assessment and non-invasive tests)	Adult women with stress urinary incontinence (SUI) planning to undergo surgery RCT (Hilton 2016) Source of clinical effectiveness data: RCT (N=222) Source of resource use data: RCT (N=218) Source of unit costs: national sources	Costs: urodynamic testing, surgical treatments (vaginal tape operations for urinary incontinence), non-surgical treatments (behaviour modification, bladder training, and pelvic floor muscle training), containment products, visits to the general practitioner, practice nurse, continence nurse, community physiotherapist and prescriptions, inpatient and outpatient visits. Mean costs per woman: UDS: £1,351 No UDS: £1,489 Difference: -£138 Primary outcome measure: QALYs (SF-12 and EQ-5D-3L): Mean QALYs per women (EQ-5D-3L): UDS: 0.395 No UDS: 0.413 The difference: -0.018 Adjusted difference[1]: -0.004	The ICER of no UDS (vs. UDS): £7,667/QALY using ED-5D-3L unadjusted QALYs The ICER of no UDS (vs. UDS): £34,500/QALY using ED-5D-3L adjusted QALYs The probability of UDS being cost effective was 0.40 and 0.36 using adjusted and non-adjusted EQ-5D-3L scores, respectively Using SF-12 derived QALYs UDS was dominant The probability of UDS being cost	Perspective: NHS Currency: UK£ Cost year: 2015 Time horizon: 6 months Discounting: NA Applicability: directly applicable Quality: minor limitations Bootstrapping was undertaken to capture uncertainty in costs and outcomes

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Cost-utility analysis Conflict of interest: none Funding: National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme			Mean QALYs per woman (SF-12): UDS: 0.385 No UDS: 0.377 The difference: 0.008 Adjusted difference[1]: 0.004	effective was 0.95 and 0.96 using adjusted and non-adjusted SF-12 scores, respectively	
Norton, P. A., Nager, C. W., Brubaker, L., Lemack, G. E., Sirls, L. T., Holley, R., et al. The cost of preoperative urodynamics: a secondary analysis of the ValUE trial, Neurourology and urodynamics, 35, 81-84, 2016	Interventions: Urodynamics (UDS) (including non-instrumented unflowmetry, filling cyctometry, and a pressure flow study) plus basic office evaluation vs. basic office evaluation (OE) only	Adult women with uncomplicated stress urinary incontinence (SUI) planning to undergo surgery RCT (Nager 2012 - ValUE) Source of clinical effectiveness data: RCT (N=539) Source of resource use data: RCT Source of unit costs: national sources (Medicare	Costs: intervention cost (complex cystometry with pressure flow study, and urethral pressure) Mean incremental cost per participant: $338.3 Primary outcome measure: proportion of women achieving 70% reduction in Urogenital Distress Inventory score; proportion of women rating “very much better“ or “much better“ on Patient Global Impression of Improvement scale Proportion of women achieving 70% reduction in Urogenital Distress Inventory score: UDS and OE: 77.2% OE: 78.9%	OE is dominant using proportion of women achieving 70% reduction in Urogenital Distress Inventory score as an outcome measure The ICER of UDS and OE (vs. OE only): $30,754.55 per additional women rating very much better“ or “much better“ on Patient Global Impression of Improvement scale	Perspective: health care payer Currency: USD Cost year: 2014 Time horizon: 1 year Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

[1] Health scores adjusted for randomised allocation, baseline utility, and age

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
USA Cost-effectiveness analysis Conflict of interest: not reported. Funding: the National Institute of Diabetes and Digestive and Kidney Diseases, and the Eunice Kennedy Shriver National Institute of Child Health and Human Development.		allowable payments)	The difference: -1.7%, p = 0.63 Proportion of women rating “very much better“ or “much better“ on Patient Global Impression of Improvement scale: UDS and OE: 91.9% OE: 90.8% The difference: 1.1%, p = 0.68		

Appendix I – Economic evidence profiles

Economic evidence profiles for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

Table 7: Economic evidence profiles for urodynamic assessment versus no urodynamic assessment prior to primary surgery for SUI

Study and country	Limitations	Applicability	Other comments	Incremental cost (£)	Incremental effect	ICER (£/effect)	Uncertainty
Homer 2018 UK	Minor Limitations[1]	Directly applicable[2]	Cost-effectiveness analysis Outcomes: QALYs using SF-12 and EQ-5D-3L utility weights. Results reported using adjusted and non-adjusted utility scores. Scores were adjusted for randomised allocation, baseline utility and age.	-£138	SF-12 non-adjusted: 0.008 SF-12 adjusted: 0.004 EQ-5D-3L non-adjusted: 0.018 EQ-5D-3L adjusted: 0.004	Using SF-12 QALYs UDS dominant Using EQ-5D-3L non-adjusted QALYS the ICER of no UDS (versus UDS) £7,667 per QALY Using EQ-5D-3L adjusted QALYS the ICER of no UDS (versus UDS) £34,500 per QALY	Using SF-12 QALYs the probability of UDS being cost effective was 0.95 and 0.96 using adjusted and non-adjusted utility scores, respectively. Using EQ-5D-3L QALYs the probability of UDS being cost-effective was 0.36 and 0.64 using adjusted and non-adjusted utility scores, respectively. The differences in costs and outcomes were not significant.
Norton 2016 USA	Potentially serious limitations[3]	Partially applicable[4]	Cost-effectiveness analysis Time horizon: 1 year Outcomes: proportion of women achieving 70% reduction in Urogenital Distress Inventory score; proportion of women rating “very much	$338.3	-1.7% (proportion achieving 70% reduction in Urogenital Distress Inventory)	UDS dominant using proportion achieving 70% reduction in Urogenital Distress Inventory $30,754.55 per additional women rating very much better“ or “much	The difference between the outcomes was statistically not significant. Statistical significance was not reported for costs.

			better“ or “much better“ on Patient Global Impression of Improvement scale		1.1% (proportion rating ‘very much better’ or ‘much better’ on Patient Global Impression of Improvement scale	better“ on Patient Global Impression of Improvement scale	

1. Short time horizon
2. UK study; QALYs with EQ-5D-3L weights, UK population norms
3. Intervention costs only; effectiveness from 1 RCT
4. US study; no QALYs

Appendix J – Economic analysis

Economic analysis for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

No economic analysis was conducted for this review question.

Appendix K – Excluded studies

Excluded studies for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

Clinical studies

Table 8: Excluded clinical studies with reasons for exclusion

Excluded studies: What is the value of urodynamic assessment before botulinum toxin type A treatment?	
Study	**Reason for Exclusion**
Agarwal, A, Rathi, S, Patnaik, P, Shaw, D, Jain, M, Trivedi, S, Dwivedi, Us, Does Preoperative Urodynamic Testing Improve Surgical Outcomes in Patients Undergoing the Transobturator Tape Procedure for Stress Urinary Incontinence? A Prospective Randomized Trial, Korean Journal of Urology, 55, 821-827, 2017	Outcomes not relevant to protocol
Clement, K. D., Lapitan, M. C. M., Omar, M. I., Glazener, C. M. A., Urodynamic studies for management of urinary incontinence in children and adults: A short version Cochrane systematic review and meta-analysis, Neurology and Urodynamics, 34, 407-412, 2015	Systematic review (additional publication based Clement 2013) - references checked for inclusion
Clement, K. D., Lapitan, M. C., Omar, M. I., Glazener, C. M., Urodynamic studies for management of urinary incontinence in children and adults, The Cochrane database of systematic reviews, 10, CD003195, 2013	Systematic review - references checked for inclusion
Glazener, C. M., Lapitan, M. C., Urodynamic studies for management of urinary incontinence in children and adults, Cochrane database of systematic reviews (Online), 1, CD003195, 2012	Populations not relevant to protocol - women were not eligible for SUI surgery
Holtedahl, K., Verelst, M., Schiefloe, 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, 34, 169-174, 2000	Population not relevant to protocol - the majority of women did not have SUI and were not eligible for surgery
Nager, C, Brubaker, L, Litman, H, Zyczynski, H, Varner, Re, Amundsen, C, Sirls, L, Norton, P, Arisco, A, Chai, T, Zimmern, P, Barber, M, Kusek, J, Gormley, Ea, A randomized trial on the effect of urodynamic testing versus office evaluation only before stress urinary incontinence surgery on outcomes, Journal of Urology, 187, e930, 2012	Conference abstract

Excluded studies: What is the value of urodynamic assessment before botulinum toxin type A treatment?	
Nct,, Gormley, A, A Randomized Trial of Urodynamic Testing Before Stress-Incontinence Surgery, Http://clinicaltrials.gov/show/NCT00803959, 2008	Economic evaluation of an included study (Nager 2012)
Rachaneni, S., Latthe, P., Does preoperative urodynamics improve outcomes for women undergoing surgery for stress urinary incontinence? A systematic review and meta-analysis, BJOG: An International Journal of Obstetrics & Gynaecology, 122, 8-16, 2015	Systematic review - references checked for inclusion
Thompson,P.K., Duff,D.S., Thayer,P.S., Stress incontinence in women under 50: Does urodynamics improve surgical outcome?, International urogynecology journal and pelvic floor dysfunction, 11, 285-289, 2000	Retrospective study
van Leijsen, S. A., Kluivers, K. B., Mol, B. W., Hout, Ji, Milani, A. L., Roovers, J. P., Boon, Jd, van der Vaart, C. H., Langen, P. H., Hartog, F. E., Dietz, V., Tiersma, E. S., Hovius, M. C., Bongers, M. Y., Spaans, W., Heesakkers, J. P., Vierhout, M. E., Dutch Urogynecology, Consortium, Value of urodynamics before stress urinary incontinence surgery: a randomized controlled trial, Obstetrics & Gynecology, 121, 999-1008, 2013	Intervention not relevant - all women underwent urodynamics; however, only one group had surgery

Economic studies

No economic evidence was identified for this review question. See supplementary document D for further information.

Appendix L – Research recommendations

Research recommendations for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

No research recommendation was made for this review question.

Appendix M – Economic evidence methodology checklists

Economic evidence methodology checklists for review question: What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

Table 9: Economic evidence methodology checklist for Homer 2018

Study identification: **Homer, T., Shen, J., Vale, L., McColl, E., Tincello, D. G., Hilton, P., Invasive urodynamic testing prior to surgical treatment for stress urinary incontinence in women: cost-effectiveness and value of information analyses in the context of a mixed methods feasibility study, Pilot and feasibility studies, 4, 1-12, 2018**		
Guidance topic: urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence		Review question no: 1.1
Checklist completed by: Eric Slade		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	Yes/partly/no/unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	Adult women with SUI planning to undergo surgery
1.2 Are the interventions appropriate for the review question?	Yes	Urodynamics (UDS), no UDS
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Yes	UK study
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	NHS
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	
1.6 Are all future costs and outcomes discounted appropriately?	NA	Time horizon: 6 months
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	SF-12 and EQ-5D-3L
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Directly applicable		
Other comments:		
Section 2: Study limitations (the level of methodological quality)	Yes/partly/no/unclear/NA	Comments
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	Economic analysis alongside an RCT
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Partly	Time horizon: 6 months
2.3 Are all important and relevant outcomes included?	Yes	QALYs

Study identification: **Homer, T., Shen, J., Vale, L., McColl, E., Tincello, D. G., Hilton, P., Invasive urodynamic testing prior to surgical treatment for stress urinary incontinence in women: cost-effectiveness and value of information analyses in the context of a mixed methods feasibility study, Pilot and feasibility studies, 4, 1-12, 2018**		
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	From a single RCT
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	From RCT
2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Partly	From RCT
2.8 Are the unit costs of resources from the best available source?	Yes	National sources
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	Statistical analysis including bootstrapping
2.11 Is there any potential conflict of interest?	No	Conflict of interest: none Funding: National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme
2.12 Overall assessment: Minor limitations		
Other comments:		

Table 10: Economic evidence methodology checklist for Norton 2016

Study identification: **Norton, P. A., Nager, C. W., Brubaker, L., Lemack, G. E., Sirls, L. T., Holley, R., Chai, T. C., Kraus, S. R., Zyczynski, H., Smith, B., Stoddard, A., The cost of preoperative urodynamics: a secondary analysis of the ValUE trial, Neurourology and urodynamics, 35, 81-84, 2016**		
Guidance topic: urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence		Review question no: 1.1
Checklist completed by: Eric Slade		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	Yes/partly/no/unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	Adult women with uncomplicated stress urinary incontinence (SUI) planning to undergo surgery
1.2 Are the interventions appropriate for the review question?	Yes	Urodynamics (UDS) (including non-instrumented unflowmetry, filling cyctometry, and a pressure flow study) plus basic office evaluation vs. basic office evaluation (OE) only
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	US study

Study identification: **Norton, P. A., Nager, C. W., Brubaker, L., Lemack, G. E., Sirls, L. T., Holley, R., Chai, T. C., Kraus, S. R., Zyczynski, H., Smith, B., Stoddard, A., The cost of preoperative urodynamics: a secondary analysis of the ValUE trial, Neurourology and urodynamics, 35, 81-84, 2016**		
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	Health care payer
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	Condition specific symptoms and HRQoL
1.6 Are all future costs and outcomes discounted appropriately?	NA	Time horizon: 1 year
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	No	Outcome measures were improvement on the Urogenital Distress Inventory; and HRQoL
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
Other comments:		
Section 2: Study limitations (the level of methodological quality)	Yes/partly/no/unclear/NA	Comments
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	Economic analysis alongside an RCT
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	Time horizon: 1 year
2.3 Are all important and relevant outcomes included?	Yes	Outcome measures included Urogenital Distress Inventory and HRQoL
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	From a single RCT
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	From RCT
2.6 Are all important and relevant costs included?	Partly	Intervention costs only
2.7 Are the estimates of resource use from the best available source?	Partly	From RCT
2.8 Are the unit costs of resources from the best available source?	Yes	National sources (Medicare allowable payments)
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Partly	Statistical analysis
2.11 Is there any potential conflict of interest?	Unclear	Conflict of interest is not reported. Funded by the National Institute of Diabetes and Digestive and Kidney Diseases, and the Eunice Kennedy Shriver National Institute of Child Health and Human Development.
2.12 Overall assessment: Potentially serious limitations		
Other comments:		