

# EVALUATION OF STRESS URINARY INCONTINENCE: STATE-OF-THE-ART REVIEW

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## ABSTRACT

Stress urinary incontinence (SUI) in women is an endemic and costly problem. It is associated with a significant burden on both a personal and community level. Despite its association with a poor quality of life, many women choose to live with the condition without seeking medical attention. The incidence of SUI, however, is escalating, and it is most evident in women living in residential aged care facilities.

In most instances, diagnosis of SUI patients is straightforward with a demonstrable urinary leak upon coughing or employment of the Valsalva manoeuvre with a relatively full bladder. In these situations, further investigation with formal urodynamics is a matter of debate and there is no standard practice due to a lack of robust data to guide physicians. This review examines the pathophysiology and basic evaluation of SUI, and the current evidence supporting the utility of invasive urodynamic testing.

Keywords: Female stress urinary incontinence (SUI), evaluation, urodynamics.

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## INTRODUCTION

The 2010 joint report by the International Urogynecological Association (IUGA) and International Continence Society (ICS) defined stress urinary incontinence (SUI) as the 'involuntary loss of urine on effort, physical exertion, or on sneezing or coughing'.<sup>1</sup> Urinary incontinence (UI) is an endemic and costly problem, and is associated with a significant burden on both a personal and community level. The prevalence escalates with increasing age; approximately 25% of young women, and up to 75% of older women experience some involuntary urine loss.<sup>2,3</sup> The burden of UI is high in both human and financial terms.<sup>4</sup> UI has a negative impact on health-related quality of life (HRQoL)<sup>5</sup> and contributes to depression<sup>6</sup> and admission to a nursing home.<sup>7</sup> The estimated direct cost of UI care in the USA alone is US\$19.5 billion.<sup>4</sup> Despite the association of UI with a poor quality of life (QoL), many women choose to live with the condition without seeking medical attention.<sup>8</sup>

For those who do seek medical help there has been considerable debate as to whether a basic

office evaluation suffices, or if formal invasive urodynamic studies (UDS) are required before surgical management is considered. In clinical practice, the utilisation of invasive UDSs for the evaluation of UI is not well defined and varies considerably in the community. In addition to the invasive nature of the study, there is also a financial consideration; healthcare spending attributable to UDS has been estimated at approximately \$400 million, at a cost of approximately \$1,000 per study.<sup>9</sup> In 2012, the American Urological Association (AUA) and the Society of Urodynamics and Female Urology (SUFU) produced a document on UDS guidelines to guide physicians with evidence-based clinical recommendations.<sup>10</sup>

SUI in women relates to numerous current controversial topics within urology, and so this review aims to provide an update on the pathophysiology and basic evaluation of SUI, and the role of UDS prior to surgical intervention.

**Table 1: Features of urethral biology contributing to urinary continence in women, and their comprising elements.**

Factor	Elements
Mucous membrane seal	Mucosa and submucosal <sup>11</sup>
Urethral length	-
Urethral sphincter	External - rhabdosphincter <sup>11</sup> Internal - smooth muscle
Integrity of nerve innervations <sup>11</sup>	-
Anatomical support	Petros and Ulmsten integral theory <sup>12,13</sup> DeLancey's hammock theory <sup>12</sup>

**Table 2: Risk factors for stress urinary incontinence.**

Factors
<ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• Route of delivery (vaginal &gt; caesarean delivery &gt; nulliparous)</li> <li>• Menopause</li> <li>• Hysterectomy</li> <li>• Advanced age</li> <li>• Family history</li> <li>• Obesity</li> </ul>

## PATHOPHYSIOLOGY OF STRESS URINARY INCONTINENCE

There are variable contributing factors to the mechanism of continence in females. Static and dynamic components are in constant interplay to prevent urine escaping from the bladder during periods of increased abdominal pressure. These measures are dependent on equal transmission of pressure to the bladder, bladder neck, and the intra-abdominal portion of the urethra arising from optimal anatomical support. Additional contributing factors arise from supportive structures that provide a mucosal seal for optimal urethral coaptation. Such factors include the urothelial lining and the underlying connective tissue layer, the external striated and internal smooth muscle sphincters, and an intact and coordinated neural circuit.<sup>11</sup> Table 1 summarises the elements contributing to urinary continence.

Two significant theories of urinary continence that have improved our understanding of the

structural support of the urogenital diaphragm have emerged within the last three decades. The first is DeLancey's hammock theory, where pelvic floor muscles and fasciae act as a 'hammock' that supports the bladder neck and the upper urethra. Functionally, the urethral closing pressure is dependent upon transmission of pressure to the bladder neck and the proximal urethra against the rigid support of the pelvic floor muscles, fasciae, and anterior vaginal wall.<sup>12</sup> More recently, Petros and Ulmsten proposed the integral theory, in which urinary continence depends upon three factors: 1) the pubococcygeus muscle, which lifts the anterior vaginal wall to compress the urethra; 2) the pelvic floor muscles that draw the hammock upwards closing the bladder neck; and 3) a taut anterior vaginal wall.<sup>13</sup>

## RISK FACTORS

The aetiology of an incontinent urethra is not completely understood. However, some risk factors for SUI have been established, including pregnancy, the mode of delivery, menopause, hysterectomy, advanced age, family history, and obesity.

### Modifiable Factors

#### Pregnancy and mode of delivery

Women who have experienced a vaginal delivery are at a much higher risk of SUI than nulliparous women or those who underwent a caesarean section (Table 2). In a Scandinavian study of more than 15,000 women, the prevalence of UI among nulliparous women was 10%, versus 16% in the caesarean delivery group, and 21% in the vaginal delivery group.<sup>14</sup> This may be the result of pregnancy and labour-induced pelvic floor musculature and connective tissue injury, in addition to nerve damage. Similarly, in a registry based national cohort study by Gyhagen et al.<sup>15</sup> using Swedish Pregnancy, Obesity, and Pelvic Floor (SWEPOP) data, the prevalence of UI 20 years after childbirth in singleton primiparae vaginal delivery was associated with a 67% increased risk of UI, and UI >10 years increased by 275% compared with caesarean section. However, the data indicate that eight or nine caesarean sections were required to avoid one case of UI.<sup>15</sup>

#### Hysterectomy

The role of hysterectomy in the development of SUI is poorly understood but again, may be related to direct damage to the pelvic floor.

## Obesity

Obesity is a pandemic global health issue and has a deleterious effect on the lower urinary tract (LUT) with increased prevalence of both SUI and UUI.<sup>19</sup> Obesity causes chronically high intra-abdominal pressures, leading to weakening of the pelvic floor musculature and innervation. Multiple studies have shown a clear relationship between weight loss from lifestyle modification and improved UI. In a randomised controlled trial (RCT) by Subak et al.<sup>20</sup> 338 obese women randomised to one of two weight-loss programmes with a mean weight loss of 8 kg and 1.6 kg after 6 months had a corresponding reduction in SUI of 58% and 33%, respectively. Auwad et al.<sup>21</sup> also demonstrated the positive effects of weight loss from lifestyle modification, with  $\geq 5\%$  weight loss translating to a statistically significant improvement in both SUI (pad weight) and QoL (King's Health Questionnaire).

### Non-Modifiable Factors

Advanced age is associated with both SUI and UUI.<sup>22</sup> In addition, there is a genetic link as women with a family history of incontinence are more likely to develop UI than those without.<sup>23</sup> Hormonal factors have been implicated as a contributing factor to overall urinary continence, such as oestrogen and vasogenic adrenergic receptors which are found readily in both the urethra and bladder neck. However, the magnitude of their overall influence on the continence mechanism has yet to be fully elucidated, though the higher prevalence of SUI in post-menopausal women at least suggests an indirect causal relationship.<sup>24</sup>

## DIAGNOSIS/INVESTIGATIONS

### Basic Evaluation

Given the high prevalence and personal cost of UI, it is somewhat surprising that no specific screening recommendations have been advocated by major health organisations. As many women experience infrequent leakage and choose to live with the condition, screening is likely to benefit those who are motivated to seek medical attention when their QoL is affected by UI. Each woman affected by SUI should have a comprehensive medical history and physical exam with urinalysis, post-void residual (PVR) measurements, and if appropriate, functional testing with UDS. Bladder diaries and pad usage are important adjunctive assessments (Table 3).

**Table 3: Preoperative evaluation.**

<b>History</b>
<ul style="list-style-type: none"><li>• Onset/duration</li><li>• Severity, pads per day</li><li>• Impact on quality of life</li><li>• Questionnaires - UDI-6, IIQ-7, PFDI-20</li><li>• Prolapse symptoms</li><li>• Obstetrics history</li><li>• Medications</li><li>• Previous surgeries</li></ul>
<b>Physical examination</b>
<ul style="list-style-type: none"><li>• Cough stress test</li><li>• Urethral mobility</li><li>• Vaginal prolapse/atrophy</li><li>• Kegel exercise</li><li>• Neurological symptoms</li></ul>
<b>Urinalysis</b>
<ul style="list-style-type: none"><li>• Haematuria, pyuria</li></ul>
<b>Uroflow/Post-void residual</b>
<ul style="list-style-type: none"><li>• Flow rate/chronic retention</li></ul>
<b>Bladder diary*</b>
<ul style="list-style-type: none"><li>• Input/output</li><li>• Frequency of leakage</li></ul>
<b>Cystoscopy*</b>
<ul style="list-style-type: none"><li>• Urethral stenosis/bladder lesions/haematuria</li></ul>
<b>Urodynamics*</b>
<ul style="list-style-type: none"><li>• Confirmation of SUI</li><li>• Urethral function, leak point pressure</li><li>• Bladder compliance</li><li>• Pressure/flow parametres</li></ul>

\*Optional (physician discretion)

UDI-6: Urogenital Distress Inventory-6; IIQ-7: Incontinence Impact Questionnaire-7; PFDI-20: Pelvic Floor Distress Inventory-short form; SUI: stress urinary incontinence.

Similarly, there is an association with vaginal prolapse, probably due to the common risk factor of pelvic floor muscles weakening.<sup>16,17</sup> Kudish et al.<sup>18</sup> reported on a Women's Health Initiative (WHI) observation study between 1993 and 1996. Post-menopausal women (aged 50-79 years) with (n=53,569) and without (n=38,524) uteri were assessed. Baseline UI incidence rate was 66.5%, with 27.3% of participants demonstrating SUI, 23% urgency urinary incontinence (UUI), and 12.4% mixed urinary incontinence (MUI). Multivariate analysis showed an association between hysterectomy and a higher incidence of an UUI and SUI episode at 3 years.<sup>18</sup>

Recently, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecology Society (AUGS) issued a joint document on the current understanding of UI in women, and outlined guidelines for diagnosis and management that were consistent with the best available scientific evidence. They recommended six basic clinical steps in the evaluation of female UI, which addressed: 1) history; 2) urinalysis; 3) physical examination; 4) demonstration of stress incontinence; 5) assessment of urethral mobility; and 6) PVR.<sup>25</sup>

## History

The onset, severity, and context of UI (stress alone, urgency alone, or both) should be fully explored. Associated urinary symptoms such as frequency, urgency, haematuria, recurrent urinary tract infections, and nocturia should also be elucidated. Symptom severity can be assessed with daily pad usage and the type of pads used (pantiliners, menses pads, incontinence pads, or diapers). Relevant risk factors and gynaecological and obstetric history should be assessed. It is important to enquire about medications and prior surgical history as this can impact on treatment. Symptoms of pelvic organ prolapse (POP) with vaginal bulge are highly associated with SUI and should be explored.<sup>17</sup>

## Questionnaires

Validated questionnaires are helpful to establish the baseline severity of UI and measure condition-specific impact on HRQoL. These can also be utilised for objective outcome measures subsequent to interventions. Numerous validated questionnaires are available to clinicians and some of the most readily used tools include: the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ), especially the short forms (UDI-6, IIQ-7), which are easy to administer even in a busy practice.

Other questionnaires on UI relate to association with pelvic floor dysfunction, such as the Pelvic Floor Distress Inventory short form (PFDI-20) and the Pelvic Floor Impact Questionnaire short form (PFIQ-7),<sup>26,27</sup> which evaluate the relative proportion of stress versus urge (e.g. the MESA questionnaire), or focus on QoL or degree of improvement after intervention (e.g. the Patient Global Impression of Improvement [PGI-I] questionnaire).

## Physical Examination

A comprehensive pelvic examination is important to establish the degree of urethral support and concurrent POP, as well as a woman's ability to perform 'Kegel' exercises. This should be established before initiating pelvic floor muscle training for treatment.<sup>28</sup> The POP quantification system was devised to standardise reporting of vaginal prolapse anatomically at straining in relation to a fixed reference point i.e. vaginal introitus. The classification uses six points along the vagina (two points each on the anterior, middle, and posterior compartments), measured in relation to the vaginal introitus. It is the only prolapse quantification system from the ICS, the AUGS, and the Society of Gynecology Surgeons for the quantification of POP.<sup>29</sup>

Applied with a reasonably full bladder (200–300 mL), a cough stress test (CST) will identify the presence of SUI in most cases. This is performed in the supine or standing position. A positive test is defined as involuntary leakage from the urethra synchronous with effort or physical exertion (straining), or sneezing or coughing. This may be repeated in the standing position if supine CST is negative. If vaginal prolapse is present, the cough test should be repeated following reduction of the prolapse for SUI assessment. Swift et al.<sup>30</sup> have previously reported the test-retest reproducibility of CST in the evaluation of SUI. In a cohort of 50 incontinent women, patients were tested with a CST with a bladder volume of 300 mL or at maximum capacity at the time of cystometry and this was repeated 1–4 weeks later. The conclusion indicated that the CST was most reliable in women with pure SUI (100%) and less so in those with MUI (80%).<sup>30</sup>

Advanced vaginal prolapse can mask SUI as it can kink the urethra resulting in outlet obstruction which protects against UI. It is not uncommon for *de novo* SUI to ensue following prolapse repair; the Colpopexy and Urinary Reduction Efforts (CARE) trial<sup>31</sup> and Outcomes following vaginal Prolapse repair and mid Urethral Sling (OPUS) trial<sup>32</sup> have shown such findings. The optimal methodology for assessing occult SUI in women with vaginal prolapse has not, however, been adequately studied. Most of the studies evaluating this have been in conjunction with prolapse reduction during urodynamics testing and not with clinical testing alone. To date, there is no clear evidence to suggest that assessment of occult SUI on clinical

testing with CST and prolapse reduction alone is comparable to UDSs.

The Q-tip cotton swab test for urethral hypermobility (normal mobility is defined as a resting angle or displacement angle of the urethra-bladder neck with maximum Valsalva of at least 30° from the horizontal) is seldom used as it can cause patient discomfort, and other methods such as point Aa of the POP Quantification system can be used instead.<sup>33</sup> Overall cognitive status should be assessed, along with a neurological examination. Urine analysis should be performed in all patients to assess for microscopic haematuria, glucose, protein, leukocytes, nitrites, and to exclude infection as an acute cause of UI.<sup>34</sup>

### Post-Void Residual Urine Volume

The definition of a high PVR has not been standardised but the cut-off threshold based on the Value of Urodynamic Evaluation (ValUE) trial is generally accepted; a PVR <150 mL measured by bladder ultrasonography or catheter indicates adequate bladder emptying in women seeking to undergo SUI surgery.<sup>34</sup> For any discordant readings, the PVR should be repeated. An elevated PVR in the absence of POP is uncommon and warrants further evaluation of the bladder emptying mechanism with UDS.

### Bladder Diary

A bladder diary can be a useful adjunct for quantifying symptoms with voided times and voided volumes and can act as a record of the number of UI episodes. A 3-day voiding diary is sufficient in most instances for assessment, accounting for daily variation in activities.<sup>35</sup>

### Urodynamics

UDSs are a series of tests that evaluate the function of the LUT. Some components of the testing are invasive (i.e. require catheterisation) and some are non-invasive. The good UDS practice guideline established in 2002 set the benchmark for how this test should be performed. There are two phases to the testing; the cystometry phase (filling) and the pressure-flow (voiding) study. Both of these evaluate the pressure/volume relationships during bladder filling, storage, and emptying in search of a functional diagnosis.<sup>36</sup>

SUI is a condition of urethral dysfunction where the outlet resistance to abdominal pressure has been compromised resulting in urinary leakage.

To this end, invasive urodynamics attempts to evaluate the relative condition of the outlet that may inform clinicians of treatment choices. Urethral dysfunction has been traditionally assessed with two parameters: 1) urethral pressure profile (UPP) and 2) Valsalva leak point pressure (VLPP). Urodynamics data reported by Lemack et al. from the Stress Incontinence Surgical Treatment Efficacy trial (SISTEr) (which evaluated Burch colposuspension and autologous fascial pubovaginal sling) using VLPP as a marker of severity did not find correlations with several indices of SUI severity on physical examination or UDS parameters.<sup>37</sup> Similarly, in the Trial Of Mid-Urethral Slings (TOMUS: a RCT of the retropubic mid-urethral sling versus the transobturator mid-urethral sling), preoperative UDSs in women with low VLPP did not impact on surgical outcome. UDS data from the TOMUS trial also suggested a limited future for the UPP in clinical practice.<sup>38</sup>

Whether to consider UDS testing in patients with UI has been a matter of considerable debate. The AUA/SUFU guidelines have summarised the clinical utility of UDSs for the following situations: '1) to identify factors contributing to LUT dysfunction and assess their relevance; 2) to predict the consequences of LUT dysfunction on the upper tracts; 3) to predict the consequences and outcomes of therapeutic intervention; 4) to confirm and/or understand the effects of interventional techniques; and 5) to investigate the reasons for failure of a treatment or treatments'.<sup>10</sup> However, with the lack of Level 1 evidence supporting routine use, the current position of invasive urodynamic testing in the diagnostic pathway for UI remains controversial and, as stated previously, practices vary considerably. This disconnect between clinicians and evidence-based application of invasive testing has led to several key randomised studies. The first is the Value of Urodynamic Evaluation (ValUE) trial; a non-inferiority RCT undertaken by the Urinary Incontinence Treatment Network with a non-inferiority margin of 11% (equivalent to a standardised difference of <0.8).

In the ValUE study, 630 women with a clinical diagnosis of SUI or stress-predominant MUI, with clinically demonstrable stress leakage, were randomised to either no further assessment or to undergo urodynamic investigation prior to their SUI corrective surgeries. The primary endpoint was treatment success defined as a ≥70% reduction in the baseline score of the urogenital distress inventory, and a PGI-I response of 'much better'

or 'very much better'. At 12 months, treatment success was equivocal in both arms; 76.9% in the urodynamic testing group versus 77.2% in the office evaluation group. Secondary outcomes included cost and utility of performing UDSs in those that had preoperative UDSs with findings of stress predominant incontinence. Again at 12 months, there was no difference between the two groups in Incontinence Severity Index, PGI-I, and global QoL measures, with both groups having similar rates of positive provocative stress tests. The report concluded that UDSs did not improve the rate of treatment success in women with uncomplicated SUI (defined as PVR urine volume <150 mL, negative urinalysis result, a positive CST result, and no POP beyond the hymen), and a well-performed office-based evaluation (including demonstration of SUI) was sufficient.<sup>34</sup>

Almost concurrently, a multicentre study in the Netherlands also evaluated urodynamics in similar patient groups using the Value of Urodynamics prior to Stress Incontinence Surgery (VUSIS-1), but this trial was terminated prematurely due to poor recruitment; an alternative design resulted in the VUSIS-2.<sup>39</sup> In this study, all women underwent invasive urodynamic testing, and only those with discordant clinical and urodynamic findings were randomised between mid-urethral sling (as dictated by their clinical assessment) or 'individual treatment' (dictated by the combination of clinical and urodynamic results). Individual treatment could include pessary, medical treatment, physiotherapy, or surgery at the discretion of the provider. Neither the participants nor healthcare professionals involved were blind to the urodynamic results in either group. The primary outcome in the VUSIS studies was based on the Dutch version of the long form UDI score at 12 months, with a secondary outcome being cost. The conclusion of the study was that in women with uncomplicated SUI, an immediate mid-urethral sling operation is not inferior to individually tailored treatment based on urodynamic findings.<sup>39</sup>

A recent systematic review by Rachaneni et al.<sup>40</sup> on whether preoperative UDSs improved surgical outcomes compared to office evaluation in women with SUI or SUI-predominant MUI (including the aforementioned two trials) reported no benefit with preoperative invasive UDSs overall in women who had a normal bladder capacity and PVR at the time of office evaluation. They further postulated that office evaluation alone may significantly impact on the delivery and cost of continence services, and

has no detriment for health with the avoidance of UDSs, which some women undoubtedly see as an unpleasant and embarrassing procedure. However, this review concluded that more robust RCTs and longer-term outcomes are warranted to assess whether the current outcomes are consistent.<sup>40</sup>

Current guidance from the UK National Institute for Health and Care Excellence (NICE) suggests that invasive cystometry is not required prior to conservative treatments for UI, or prior to surgery where the diagnosis of SUI is clear on clinical grounds (i.e. where there are no symptoms of overactive bladder or voiding dysfunction, no anterior compartment prolapse, and no previous surgery for SUI).<sup>28</sup>

The Cochrane review on urodynamic investigation for the management of UI in adults and children was first reported in 2002, and the latest citations in 2012 report similar findings. The Cochrane review authors' conclusions included the following: "When women with incontinence are assessed using urodynamics in addition to clinical methods, they are more likely to receive different treatment, and to have their management plan changed. However, the evidence was not conclusive in showing whether these differences in management resulted in differences in health outcomes such as incontinence, QoL, or economic outcomes after treatment compared to women who did not have urodynamic tests." Further robust research confirming clinical utility is highly recommended.<sup>41</sup>

As stated, the AUA/SUFU urodynamics guidelines have made the following recommendations for SUI:<sup>10</sup>

1. Clinicians who are making the diagnosis of urodynamic stress incontinence should assess urethral function. (Recommendation; Evidence Strength: Grade C)
2. Surgeons considering invasive therapy in patients with SUI should assess PVR urine volume. (Expert Opinion)
3. Clinicians may perform multichannel urodynamics in patients with both symptoms and physical findings of stress incontinence who are considering invasive, potentially morbid, or irreversible treatments. (Optional; Evidence Strength: Grade C)
4. Clinicians should perform repeat stress testing with the urethral catheter removed in patients suspected of having SUI who do not demonstrate this finding with the catheter in place during urodynamic testing. (Recommendation; Evidence Strength: Grade C)

- Clinicians should perform stress testing with reduction of the prolapse in women with high-grade POP but without the symptom of SUI. Multichannel urodynamics with prolapse reduction may be used to assess for occult stress incontinence and detrusor dysfunction in these women with associated LUTS. (Optional; Evidence Strength: Grade C)

Ambulatory urodynamics have not been particularly favoured for investigation of SUI and hence are not part of the recommendation by the International Consultation on Incontinence (ICI) for routine investigation of SUI. For the most part, it remains a research tool and the procedure is time-consuming, technically challenging, and expensive. The clinical usefulness of ambulatory urodynamics for the detection and treatment of bladder dysfunction has not been studied in detail but studies indicate that it is more sensitive in detecting detrusor muscle overactivity<sup>42</sup> and in those who have already undergone conventional urodynamics, particularly in the case of patients with suspected bladder acontractility and incontinence of unclear origin.<sup>43</sup> NICE states that ambulatory urodynamic monitoring should be used as a second-line investigational modality.<sup>44</sup> Further study is required to determine the clinical implications of these findings and their relationship with treatment outcome.

## CONCLUSION

SUI is an endemic condition that harbours a significant personal and socioeconomic burden.

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The pathophysiology of SUI has evolved over past decades but remains unclear in part. Based on Level 1 evidence, basic office evaluation including a positive CST, a negative or low PVR urine volume, a negative urinalysis, and no significant prolapse was found to be non-inferior to urodynamic testing. Preoperative invasive multichannel urodynamic testing may not be necessary before planning primary anti-incontinence surgery in women with uncomplicated SUI (defined as PVR <150 mL, negative urinalysis result, and positive CST). Progress is needed to develop better tools to assess urethral function and more studies will be necessary to further clarify the role of UDSs in the evaluation of SUI.

## Take-Home Messages

- SUI is a highly prevalent condition in the community and incidence continues to rise
- SUI is associated with substantial morbidity with a high impact on personal and financial cost
- Invasive urodynamic study is not required in the evaluation of women with uncomplicated SUI or SUI predominant MUI
- Invasive urodynamic study does not improve outcomes in women undergoing surgical management compared to those that had office evaluation
- More robust RCTs with longer-term follow-up are required to assess that this current trend is consistent.

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