



Review – Female Urology - Incontinence

Urodynamics Useless in Female Stress Urinary Incontinence? Time for Some Sense—A European Expert Consensus

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Abstract

Background: Routine use of urodynamics (UDS) for the assessment of female stress urinary incontinence (SUI) appears to be in decline across Europe. The reasons for this trend appear multifactorial, but the implications are of significant concern.

Objectives: To achieve an expert consensus viewpoint on the value of UDS in female SUI and current barriers to its use.

Methodology: A multidisciplinary group of UDS experts from six European countries was convened, and a modified version of the Delphi method was utilised to reach a consensus viewpoint structured around five key questions.

Results: Consensus was achieved on all five questions. The group was unanimous that the decline in routine use of UDS is unjustified and misguided, driven by restrictions in funding and accelerated by the publication—and subsequent influence—of two trials that had major limitations.

Limitations: The authors comprised a selected group of UDS experts and the analysis is not a formal systematic review.

Conclusions: Extensive experience and observational studies have demonstrated the value of UDS for the assessment of female SUI and the dangers of empiric management. This evidence base should not be eclipsed by the findings of two randomised controlled trials that had numerous shortcomings.

Patient summary: A group of experts were worried that, even though the cause of incontinence varies, doctors seem to be skipping a diagnostic test called urodynamics (UDS) in some patients and just providing treatment—even surgery—without knowing exactly what is wrong. These experts analysed the situation in detail and reached agreement that UDS testing should not be skipped.

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1. Introduction

When assessing urinary incontinence, the patient's subjective perception is often an unreliable reflection of the underlying clinical problem. An objective demonstration of lower urinary tract function can only be achieved by carrying out urodynamic investigations (UDS) [1,2]. The original impetus for developing UDS over a century ago was the observation that the procedures of transurethral resection of the prostate failed in a substantial proportion of seemingly eligible patients. After the first clinical cystometer was designed by Dalton K. Rose in 1927, early UDS pioneers elevated the cystometrogram to its current status within modern urology. Although UDS can be technically challenging for nonexperts and is not without pitfalls, many years of experience and observational studies have demonstrated its value in patients with lower urinary tract symptoms (LUTS). However, except in tertiary referral centres, many of the authors of this paper have been aware of a recent decline in routine use of UDS, partly driven by cost. A shared concern about this trend prompted us to convene with the aim of identifying drivers for the decline, reviewing the available evidence on the value of UDS, and formulating a consensus viewpoint. Our primary objective was to consider the role and value of UDS in female patients who are potential candidates for surgery for stress urinary incontinence (SUI).

2. Methodology

To reach a consensus, we followed a modified version of the Delphi method [3], an iterative process used when evidence is unreliable or conflicting and where opinion is important. The process involved five phases, which took place between March 2017 and April 2018:

1. Our multidisciplinary, pan-European working group was convened in March 2017 at the time of the European Association of Urology (EAU) annual congress in London. The working group included two heads of department of neurourology, a chief of unit for functional urology, a clinical engineer and scientist in a urological institute, two heads of department of urology, a consultant urologist expert in functional urology, and a head of a urogynaecology unit.

The discussion centred around five main questions:

- (a) What do you consider to be the reasons for the decline in use of UDS in routine practice?
- (b) What is your opinion of published evidence that suggests that UDS is unhelpful in female SUI?
- (c) What evidence exists in support of UDS in female SUI?
- (d) Why do you personally consider UDS to be of value within your practice?
- (e) What concerns do you have about the decline of UDS?

2. As a next step, a literature review was undertaken from 2008 to present, using Medline, Embase, and the Cochrane Central Register of Controlled Trials. The keywords and medical subject heading (MeSH) terms; used alone or in combination were “urodynamics”; “cystometry”; “uroflowmetry”; “stress urinary incontinence”; “SUI”; “midurethral sling”; and

“surgery”. All pertinent articles were carefully evaluated and their reference lists examined in order to identify other manuscripts that could be included in this article. Studies included in our analysis met the following criteria: (a) articles evaluating the role and value of UDS in female SUI; (b) randomised clinical trials (RCTs); prospective controlled studies; prospective cohort studies; or retrospective studies; and (c) articles published in English. We also included opinion-based articles and letters to editors on the role of UDS in female SUI. Papers focusing on male LUTS and neurogenic lower urinary tract dysfunction (LUTD) were not included; and information on patients with mixed incontinence was reviewed only in terms of complicated cases where surgery might be considered for the stress component.

3. A second meeting of the group was held in Florence in September 2017 at the time of the International Continence Society annual congress. At this meeting, views of participants were revisited in the light of the literature review.

4. A draft manuscript was produced, and participants convened for the third time in March 2018 at the EAU congress in Copenhagen to share feedback and comments.

5. The manuscript was refined and circulated for final input and alignment.

3. Results

Outputs of the consultation process resulted in a consensus viewpoint on all five questions.

3.1. What do you consider to be the reasons for the decline in use of UDS in routine practice?

Firstly, UDS has drawbacks. In unskilled hands, it is perceived as technically challenging, burdensome, and prone to methodological errors. It is also sometimes uncomfortable and embarrassing for patients, and carries a small risk of introducing infection (<5%) [4]. Secondly, there is a lack of opportunity for staff training and, so far, no formal requirement for trained, certified practitioners. Lack of staff capacity can also mean that UDS is restricted to patients for whom it is essential, rather than just desirable. Thirdly, there is a move towards nonspecialist physicians (eg, in primary care) being responsible for specifying the tests required. Fourthly, securing reimbursement for UDS can be problematic, and this issue seems to be getting worse. Lastly, introduction of interventions such as midurethral sling surgery, neuromodulation, and botulinum toxin, which are less invasive than previous options, has made empiric management seem “easier” and “safer”. These issues have all undermined the usage of UDS, but in our opinion, a turning point came in 2012 with the publication of two randomised controlled trials (RCTs), the VALUE study (US) and the VUSIS-II study (Netherlands), which appeared to indicate that UDS is of questionable value in female SUI [5–8]. The VALUE study in particular, which was published in one of the most prestigious international journals, *The New England Journal of Medicine* [5], has had an apparently polarising effect: some clinicians have viewed it as

providing conclusive evidence about the limitations of UDS, justifying a change to routine practice, while others have voiced major criticisms of the study design, conclusions, and interpretation, provoking an intense debate.

The authors of the VALUE study—the first major RCT set up specifically to test whether UDS makes a difference to diagnosis, management, and outcomes in uncomplicated female SUI ($n = 630$)—reported that “preoperative office evaluation alone is non-inferior to evaluation with UDS in terms of outcomes at one year” and concluded that UDS is “not justified” in this setting [5,6]. A small and underpowered RCT (the VUSIS-I study) conducted in The Netherlands ($n = 59$) reached a similar conclusion [7]. Given its small size, this study was then redesigned as the VUSIS-II study in which patients whose UDS findings did not align with clinical assessment ($n = 109$) were randomly assigned to receive either immediate surgery (a midurethral sling) or individually tailored therapy based on UDS findings. The research team reported that immediate surgery, irrespective of the result of UDS tests, did not result in inferior outcomes [8]. Since RCTs are consistently valued above other forms of evidence, the VALUE and VUSIS-II studies have had a far-reaching impact. The VALUE study in particular appears to have acquired “landmark” status and has led to the following:

1. Inclusion of the findings as the main source of data in two systematic reviews: In the first one, a Cochrane meta-analysis [9], it was concluded that, although UDS may change clinical decision making, there is “some high-quality evidence that this does not result in lower rates of urinary incontinence after treatment”. This meta-analysis failed to mention the fact that the VALUE study (the “high quality evidence” referred to) applied only to uncomplicated cases. The second systematic review [10] reached a similar conclusion. In both cases, only a handful of studies were included and most of the patients analyzed came from the VALUE study [11].

2. Modification of influential incontinence guidelines:

- (a) The 2017 EAU guidelines [12] refer to the “conundrum of the true utility of UDS” but cite only the VALUE and VUSIS studies as their evidence base. They state that, in uncomplicated female SUI, “a good history and clinical evaluation should be all that are required to help decide the best treatment”. The fact that uncomplicated cases represent only a small minority (5–36%) [13–15] is not pointed out.
- (b) The National Institute for Health and Care Excellence—UK’s influential cost-effectiveness assessor—also revised its guidelines along these lines in light of the VALUE study [16].
- (c) In the USA, 2017 guidelines of the AUA/SUFU [17] state that “physicians may omit urodynamic testing for the index patient desiring treatment when SUI is clearly demonstrated”. While a definition of “index” patients is included (ie, patients with no complicating factors or comorbidities), the guidelines again do not make it clear that these individuals represent only a small minority of the overall SUI population.

3. Calls for the “official” abandonment of UDS: In the wake of the VALUE and VUSIS studies, some specialists [18–20] have called for UDS to be formally abandoned in female SUI in order to “act on the evidence”, spare patient discomfort and embarrassment, and save money. A research team at the Cleveland Center in the USA [20], who reported a sharp decline in the use of UDS from 70% in 2008–2009 to only 41% in 2014–2016 ($p < 0.0001$), attributed this decline directly to the publication of the VALUE study in 2012 and recommended that other practitioners follow suit. Of even more concern is that there is a sense across the literature of casual extrapolation of the VALUE and VUSIS study findings beyond female SUI, which may be jeopardising the use of UDS in unrelated areas such as male LUTS and neurogenic LUTD.

4. Apparent justification to abandon UDS in the eyes of nonexperts: Among nonexpert practitioners, UDS is already unpopular due to its technical challenges and difficulty in securing reimbursement, so the VALUE and VUSIS studies have provided a welcome excuse to dispense with it altogether.

5. Influence on payers: For some time, UDS has been under scrutiny by payers looking for cost-cutting opportunities. The VALUE and VUSIS studies have armed them with additional ammunition.

3.2. What is your opinion of published evidence that suggests UDS is unhelpful in female SUI?

Robustly designed RCTs must always be welcomed, and if their findings challenge accepted clinical practice, they must be taken very seriously. However, no fewer than six major criticisms of the VALUE and VUSIS studies have been highlighted [14,15,21–35], including the fact that the narrow participant cohort was unrepresentative of the SUI population. These criticisms are explained in full in Table 1.

3.3. What evidence exists in support of UDS in female SUI?

Between 2009 and 2017, several retrospective and prospective studies [13,14,36–43] and one small RCT [44] have demonstrated that UDS can guide appropriate decision making in female SUI (Table 2). These studies have confirmed the following:

- (a) The rarity of uncomplicated SUI (which ranges from 5% to 36% in studies that have assessed its prevalence) [13–15].
- (b) The greater value of UDS in complicated versus uncomplicated patients (a multicentre database study [$n = 2053$] demonstrated that UDS changed the diagnosis in 74.6% of complicated SUI cases vs 40% of uncomplicated cases [$p = 0.0001$]) [14].
- (c) The fact that, even in pure SUI, UDS can identify additional issues such as underlying detrusor overactivity in approximately 20% of patients [13,37], for whom surgery may be inadvisable.
- (d) The ability of UDS to identify unsuspected voiding dysfunction—as suggested in the VALUE study itself [5,28] and demonstrated in other studies [14,38,39].

Table 1 – Criticisms of the VALUE and VUSIS studies.

Key criticisms	Rationale and basis for criticisms
Patients in both studies comprised a highly selected “index” population: (1) only women, (2) only cases of SUI, and (3) only cases deemed to be “uncomplicated”. The significance of this minor subset of the patient population has apparently been amplified in the eyes of many clinicians who appear to have overlooked the study limitations.	<p>1. In the VALUE study, 66.3% of patients screened were excluded because they did not meet the strict inclusion criteria [21].</p> <p>2. A related health economic analysis [22] made the assumption that uncomplicated patients account for approximately one-half of women with SUI, whereas according to the screen failure rate in the VALUE study itself, such patients account for only one-third [23].</p> <p>3. Recent observational research has confirmed the rarity of uncomplicated SUI. A retrospective UK study of women with urinary incontinence ($n = 6276$) reported that only 5.2% had “pure” SUI [15], while an Italian multicentre database ($n = 2053$) showed that only about one-third of female SUI patients were “uncomplicated” according to VALUE trial criteria [14].</p>
Evidence has shown that UDS is of intrinsically greater value in complicated patients than in uncomplicated populations.	<p>1. Authors of the VUSIS studies argue that the strength of their research was its focus on a “homogenous group of women with predominant SUI” [24]. Del Popolo et al [25] countered that, by excluding women with conditions such as low leak point pressure, low maximum urethral closure pressure, pelvic organ prolapse, previous failed surgery, or voiding dysfunction, the VUSIS (and VALUE) studies focused on the subpopulation least likely to benefit from UDS.</p> <p>2. The Italian multicentre database study ($n = 2053$) [14] demonstrated that UDS led to the diagnosis of a different type of urinary incontinence in as many as 74.6% of complicated SUI cases versus 40% of uncomplicated cases ($p = 0.0001$).</p>
Even in the restricted VALUE study population, there was a clear sign that UDS had highlighted the existence of voiding dysfunction in 10% of patients [4], which was not diagnosed with history and physical examination alone.	<p>1. Although this finding narrowly failed to reach statistical significance ($p = 0.06$) [5], it was nonetheless a clear trend, which the VALUE study was not statistically powered to demonstrate conclusively.</p> <p>2. The presence of voiding dysfunction, which can usually only be identified by UDS, is significant as it predicts a higher failure rate of surgery [26,27]. The VALUE study authors themselves confirmed that the success of surgery within this 10% subgroup was lower than that in the remaining study population (62.1% vs 78.3%) [28]. Thus, UDS is important for decision making in this subgroup, and, even if a decision to operate is taken in such patients, they will benefit from preoperative counselling to manage their expectations [26,27].</p>
Doubt also exists about the robustness of the randomisation process in the VALUE study. Questions have been raised about the quality of UDS practice undertaken in both the VALUE and VUSIS studies and the possibility of subjective interpretation of findings at contributing study sites.	<p>1. Finazzi-Agro et al [29] have pointed out that the two study arms in the VALUE trial appeared to be imbalanced in terms of many relevant variables.</p> <p>1. Lose and Klarskov [30] point out that none of the study centres seemed to be UDS certified by the ICS (or another organisation) and that, in both studies, UDS quality and the level of urodynamic expertise are unclear.</p> <p>2. They also highlight that no clear definitions were provided for detrusor overactivity, overactive bladder, hypoactive detrusor function, obstruction, voiding dysfunction, intrinsic sphincter deficiency, weak flow, postvoid residual, and small cystometric capacity. These terms require clear cut-off values, and it appears that interpretation and urodynamic categorisation were based on individual, subjective judgement by the study physician at each centre [30].</p>
Several authors point out a fundamental conceptual flaw in both the VALUE and VUSIS studies, which contravenes good urodynamic practice (GUP) [30], ie, the lack of a specific urodynamic “question” and a plan for how its answer should guide management decisions.	<p>1. Giarenis and Cardozo [32], and Lose and Klarskov [33,34] both point out that in these studies, invasive UDS was performed with no apparent strategy for interpretation or decision making. Management decisions taken at individual sites appeared to be subjective and inconsistent.</p> <p>2. Attention has also been drawn to the fact that some study physicians simply chose not to act on the findings suggested by UDS. In the VALUE study, 93% of the patients in both arms ended up having a midurethral sling procedure (with similar figures in the VUSIS-II study). Critics of the studies assert: “You cannot test the value of invasive UDS if you don’t use it in your decision-making” [33,34].</p> <p>3. It is noteworthy that, within their instructions to authors, the editors of the <i>International Urogynecology Journal</i> recently called for all original articles on UDS to demonstrate compliance with GUP, including stating clearly the urodynamic question that was initially posed and how the study was designed to answer this question [35].</p>

Table 2 – Published studies in women with SUI that are supportive of UDS.

Ref	Authors	Year	Country	No. of patients	Study design	Journal	Study aims	Key findings
[13]	Digesu et al	2009	UK	3428	Retrospective (single centre)	<i>Urology</i>	<ol style="list-style-type: none"> To assess the prevalence of pure SUI in a database of female SUI patients To assess the value of UDS in women with pure SUI 	<ol style="list-style-type: none"> Only 308 women out of 3428 (9%) qualified as having “pure” SUI UDS showed that 20% of these 308 patients had detrusor overactivity instead of (or as well as) SUI, indicating that, in these cases, surgery may be inappropriate first line
[36]	Kawasaki et al	2012	USA	47 studies of ≥ 30 participants	Systematic review	<i>International Urogynecology Journal</i>	<ol style="list-style-type: none"> To systematically review multiple databases to correlate UDS data with postoperative outcomes after midurethral sling procedures 	<ol style="list-style-type: none"> MUCP and VLPP values gained from UDS may add insight into postoperative outcomes after surgical treatment for SUI
[37]	Serati et al	2013	Italy	2143	Prospective (single centre)	<i>British Journal of Urology International</i>	<ol style="list-style-type: none"> To identify how many patients with pure SUI symptoms do not require surgery based on UDS findings To assess the clinical outcomes of these patients at 12 mo 	<ol style="list-style-type: none"> UDS showed that 15–20% of patients with symptoms of pure SUI had underlying detrusor overactivity, so surgery was not appropriate At 12 mo, 50% of these patients were considered cured from taking antimuscarinics
[38]	Topazio et al	2015	Italy	244	Retrospective (single centre)	<i>International Urogynecology</i>	<ol style="list-style-type: none"> To determine the % of “uncomplicated” female SUI cases To assess how frequently UDS adds new information 	<ol style="list-style-type: none"> Only 22% of patients reviewed were considered to have pure SUI UDS and pre-UDS observations differed in 63.5% of patients UDS identified voiding dysfunction in 25.6% of cases
[39]	Yande et al	2016	India	100	Prospective (single centre)	<i>Journal of Midlife Health</i>	<ol style="list-style-type: none"> To assess the value of UDS as part of preoperative evaluation of SUI 	<ol style="list-style-type: none"> In this broad SUI population, UDS detected a significant % of detrusor overactivity, voiding dysfunction, and bladder outlet obstruction that were not suggested by symptoms alone
[14]	Serati et al	2016	Italy	2053	Retrospective (multicentre; 6 hospitals)	<i>Neurourology & Urodynamics</i>	<ol style="list-style-type: none"> To assess the % of ‘uncomplicated’ female SUI patients To assess how frequently UDS adds new information To assess how often UDS findings impact patient management 	<ol style="list-style-type: none"> Only 36% of patients reviewed were defined as “uncomplicated” UDS findings changed the initial diagnosis in 62.2% of patients UDS identified voiding dysfunction in 19% of patients, and led to cancellation or modification of planned surgery in 15% of patients UDS findings changed the therapeutic strategy in twice as many complicated patients as uncomplicated patients
[40]	Suskind et al	2017	USA	285	Prospective (at three specialist urology divisions)	<i>Urology</i>	<ol style="list-style-type: none"> To assess the clinical value of UDS in tertiary practice Pre- and post-UDS questionnaires were completed for each patient 	<ol style="list-style-type: none"> UDS findings changed the management plan in 42.5% of cases
[41]	Choudhury et al	2017	India	100	Prospective (single centre)	<i>Urology Annals</i>	<ol style="list-style-type: none"> To evaluate the causes of LUTS in postmenopausal women, and assess the correlation between symptoms and UDS findings 	<ol style="list-style-type: none"> UDS was instrumental in reaching accurate diagnoses in all categories of LUTS including voiding dysfunction, storage symptoms and stress, urge or mixed urinary incontinence

Table 2 (Continued)

Ref	Authors	Year	Country	No. of patients	Study design	Journal	Study aims	Key findings
[42]	Rubliotta et al	2017	Italy	323	Retrospective (single centre)	Abstract at International Continence Society 2017	<p>1. To assess the prevalence of pure SUI in a database of female SUI patients</p> <p>2. To compare symptom-based and UDS findings, and estimate the number of surgeries avoided via UDS</p> <p>3. To calculate the cost of UDS procedures and the total cost saved by avoidance of surgery</p>	<p>1. Only 20% of women were considered to have pure SUI</p> <p>2. UDS findings avoided a midurethral sling operation in only six patients, but avoidance of those six surgical procedures achieved an overall cost saving of €10 800</p>
[44]	Agarwal et al	2014	India	60	Randomised controlled study	<i>Korean Journal of Urology</i>	<p>1. To assess the extent to which urodynamic parameters influence postoperative outcomes in female SUI</p>	<p>1. Significantly better postoperative outcomes were seen in the urodynamic group (after excluding those with poor prognostic indicators such as DO, low VLPP, and MUCP) than in the office evaluation only group</p>

DO = detrusor overactivity; LUTS = lower urinary tract symptoms; MUCP = maximum urethral closure pressure; SUI = stress urinary incontinence; UDS = urodynamics; VLPP = Valsalva leak point pressure.

(e) The clear difference in pre- and post-UDS diagnostic observations—which led in some cases to cancellation or modification of surgery [14,40,42].

An additional study published in 2017 [43] is also noteworthy because it compared the long-term clinical outcomes of making management decisions based on UDS with those that followed empiric management. This was a prospective, longitudinal, observational study of 647 women with overactive bladder (OAB) symptoms seen in urogynaecology clinics in 22 UK hospitals. Since the study focused on OAB rather than on SUI, we have not included it in Table 2, but its findings are worth mentioning since OAB symptoms may coexist in patients with SUI and it is particularly important to understand the pathophysiology in patients with mixed UI [32]. The authors state that women who received treatment concordant with their UDS findings were more likely to report an improvement in bladder symptoms after 20 mo (57% vs 45%; $p = 0.02$) [43].

Finally, it is worth emphasising that all the studies mentioned so far include women only and chiefly deal with SUI. We have not included the evidence that exists to support the use of UDS in patients with neurogenic LUTD [45], nor the fact that, while there is a relative lack of studies in male LUTS, two recent meta-analyses focusing on the use of UDS in identifying detrusor underactivity and bladder outlet obstruction in men came to favourable conclusions [46,47]. We await with interest the results of two ongoing UK RCTs investigating the value of UDS in guiding management decisions: the FUTURE study in women (which was prompted by the INVESTIGATE-1 study [48]) and the UPSTREAM study in men [49].

3.4. Why do you personally consider UDS to be of value within your practice?

In our specialist practices, we frequently see patients who have failed surgery. There are strong reasons to suspect that such failures often occur because the surgery was done empirically, and the patient was an inappropriate candidate for it [15,50]. We also see patients—many of whom are already overmedicated—suffering troublesome side effects from drugs that they should probably never have been prescribed. In addition, we see undertreatment of neurological patients, for whom reliance on patient perception is even more inappropriate than usual. UDS provides objective information about what is wrong with the lower urinary tract. It helps us understand underlying mechanisms, not only for the filling, but also for the voiding phase. Patients appreciate this information too. Overall, UDS plays a vital role in identifying candidates for surgery accurately and in determining an appropriate management plan. It also increases the accuracy of prognosis and enables us to counsel patients effectively about their likely clinical outcomes.

3.5. What concerns do you have about the decline of UDS?

It is understandable to wish to spare our patients the discomfort, embarrassment, and small infection risk associated with

UDS, and to save the costs of these tests, especially when it is becoming harder to secure reimbursement. However, while it may be true that we can forego UDS in certain specific cases, doing so on a broader scale is a regressive and misguided trend. It is counterintuitive to implement “blind” treatment without knowing the underlying pathogenesis, and it is unlikely that patients would wish to be spared an uncomfortable diagnostic procedure if they knew that it could help establish the cause of their problem and potentially avoid inappropriate or unnecessary treatment, especially surgery. Even for patients managed conservatively, long-term polypharmacy is not without harm. The side effects of inappropriate or unnecessary medications have significant implications for quality of life and patient nonadherence. Moreover, if patients’ conditions are no longer properly characterised, the large sums currently spent on devising individualised treatment plans will go to waste. Ultimately, we fear that the abandonment of UDS risks contravening the fundamental principle of “primum non nocere” (“first, do no harm”). Empiric decision making is considered bad practice in most other areas of medicine, with good reason.

4. Discussion

Since our multidisciplinary group consisted of experts in functional urology and/or neurourology, for many of us, urodynamic evaluation is a fundamental tool for the management of female LUTS. We acknowledge that our specialist perspective might have influenced our point of view. However, we believe that our opinions are validated by those of many other authors in the field, whose views were revealed by our literature search, and by the list of supportive UDS studies conducted in a range of different clinical settings, which are summarised in [Table 2](#).

Our panel discussions identified many factors that may have contributed to the increasing underuse of UDS in female SUI. We especially noted the likely impact of the VALUE and VUSIS studies and their incorporation into authoritative guidelines. Although the authors of the VALUE trial themselves stated that their findings related only to uncomplicated cases [5], this limitation—and the fact that uncomplicated cases are relatively uncommon—appears to have been overlooked by the community of professionals involved in the management of female UDS. In addition, whilst we recognise the need for evidence-based medicine and acknowledge that RCTs are the gold standard when assessing the value of therapies, they are considered less necessary—and less appropriate—when assessing the value of diagnostics. According to the widely used Oxford Classification of Evidence [51], evidence rated as “1b” calls for an RCT for therapies but requires only a cohort study for diagnostics. This reflects the fact that, in many diagnostic scenarios, RCTs may be (1) impractical, (2) unethical, and (3) not the best way to demonstrate potential benefits. With regard to the potential benefits of UDS in women with SUI, it is regrettable that influential guideline committees have seen fit to cite only RCTs as the justification for their recommendations, even though the two RCTs available so

far have numerous limitations. It is also worth noting that the value of UDS in patients with neurogenic LUTD remains undisputed by guideline committees, even though the evidence underpinning this [45,52,53] does not include RCTs, which would be impossible to conduct in this setting.

In our view, observational research—and even anecdotal expert opinion—should not be undervalued in diagnostics. For example, despite the lack of formal published evidence for digital rectal examinations [54], urologists routinely perform them because accepted wisdom has proved their value. Radiologists often generate sophisticated images using expensive machinery and complex techniques, without randomised prospective evidence of their usefulness. A traumatologist will rarely treat a fracture without an x-ray. Similarly, a substantial body of observational evidence ([Table 2](#)) and expert endorsement exists to support the use of UDS in female SUI. Unless the underuse of UDS in this area is rectified, we predict adverse long-term consequences for patients and greater expense for healthcare providers.

5. Conclusions

Current evidence from RCTs has indicated that UDS may not be a necessary step in a small subset of women with SUI, that is, uncomplicated “index” patients. These RCTs specifically excluded more complicated cases despite the fact that they represent the great majority. Many other sources of evidence suggest that, in these more complicated cases, UDS can provide valuable information that may clarify diagnoses, aid clinical decision making, and enable appropriate patient counselling. The more information we can access for such patients, the greater chance we have of providing clinical benefit. For this reason, we call for guideline committees and those in positions of influence to publicly acknowledge the limitations of the two RCTs [5–8] ([Table 1](#)) on which they have based their recommendations for female SUI. It is time to officially recognise the existing evidence base for the value of high-quality UDS in this patient population ([Table 2](#)) and to reinstate its reputation as an important part of the diagnostic workup for the majority of women with stress incontinence.

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Study concept and design: Finazzi-Agro.

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Analysis and interpretation of data: None.

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