

# Urodynamics in review: stress urinary incontinence in women produced by the Urodynamics Committee of the ICS

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Urodynamic studies (UDS) are the best tools to objectively assess the lower urinary tract dysfunction (LUTD) of various aetiologies [1]. According to the general understanding and consensus of the medical community UDS should be performed only when they will change the patient's management if they are not a part of a surveillance or a research programme [1]. In that sense, the value of preoperative UDS in the surgical management of stress urinary incontinence (SUI) has been a major topic of debate. Two different randomised investigations, namely the VaLUE and VISUS 2 studies, have claimed that preoperative UDS do not improve the outcome of a mid-urethral sling (MUS) surgery in patients with uncomplicated SUI [2,3].

Based on the evidence provided by VaLUE and VISUS 2 studies, systematic reviews followed the same conclusion [4,5] but also stated the strong need for better-planned randomised controlled trials (RCT's). Relying on the same available data, the European Association of Urology (EAU) and American Urological Association / Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (AUA/SUFU) guidelines have suggested that preoperative UDS in women with uncomplicated, clinically demonstrable SUI do not improve the outcome of surgery for SUI [6,7]. These publications and the guideline adherence have unsurprisingly affected the urodynamic practice in North America and Europe by significantly lowering UDS prior to MUS surgery [8,9].

It is worth noting that the level of evidence of the available data is rated with '1b' by EAU guidelines, but the relied studies have important limitations that need to be highlighted [6]. Actually, as also shown by Sirls et al. preoperative UDS do significantly change clinical diagnoses and global treatment plans in patients with SUI [10]. Surprisingly, in the era of MUS, this fact rarely affects the surgical choice because surgeons prefer a MUS first for their so-called 'index' SUI patients and then deal with postoperative urgency or emptying difficulty if they unluckily occur [10]. This approach is being considered as cost-effective or feasible without convincing evidence,

especially when the principles of 'good clinical practice' and the lack of long-term evidence are respected.

The purpose of the present review is to express the view of the ICS Urodynamics Committee on the need for preoperative UDS in patients with SUI prior to MUS surgery by revealing the limitations of the existing data and specifying the questions that still need to be answered.

## A second look to the RCTs: what do they really say?

In the VaLUE study [4] by Nager et al., 630 women with clinical demonstrable SUI about to undergo surgery for SUI were randomised to office evaluation alone (n=315) or to office evaluation and UDS (n=315). Uncomplicated SUI in this study meant a positive stress test, a normal post-voiding residual volume (<150ml), urethral mobility, and absence of bladder infection, significant prolapse and prior pelvic surgery or radiation. Patients with mixed incontinence were not excluded unless urgency incontinence was predominant.

This multicentric study with 11 participating sites and 53 participating surgeons had a non-inferiority design with a margin of 11%. The primary outcome was treatment success at 12 months, defined as a reduction in the score on the Urogenital Distress Inventory of 70% or more and a response of 'much better' or 'very much better' on the Patient Global Impression of Improvement. The outcome data was available for 264 women in the urodynamic-testing group and 259 in the evaluation-only group. More than 90% of surgeries were retropubic or transobturator MUS whereas the rest included mini-slings, traditional slings, retropubic urethropexy, and urethral-bulking injection. The treatment was successful in 76.9% in the urodynamic-testing group versus 77.2% in the evaluation-only group, consistent with non-inferiority.

It was shown that 18 patients had the choice of surgery changed based on UDS, although the protocol design intended to omit the UDS results. Overall, the clinical diagnosis was altered by UDS in 56% of patients but this was not reflected in the outcome of surgery at 12 months. According to initial

clinical assessment, there were only seven (2.2%) patients with the diagnosis of voiding dysfunction in the urodynamic assessment group whereas this number increased to 35 after the urodynamic testing, corresponding to 12% of the arm. This finding clearly revealed that the majority of patients with voiding dysfunction would be missed without UDS. In contrary to voiding dysfunction, pre-urodynamic clinical assessment in the VaLUE study overestimated the presence of overactive bladder with or without incontinence so that approximately one third of clinical diagnosis of overactive bladder was changed by the primary physician after UDS. The latter two findings need further clarification because both overactive bladder and voiding dysfunction are clinical diagnoses whereas UDS should reveal detrusor overactivity or detrusor underactivity. The details of urodynamic studies were not given. It was also not reported how the change of clinical diagnosis affected the preoperative patient counselling by the physician.

In summary, the VaLUE study revealed that UDS alter the preoperative clinical diagnosis in at least half of women with uncomplicated SUI but this did not affect the choice of surgery and the outcome at 12 months whereas many questions remained unanswered. Further research should address the necessity for additional treatments and the long-term outcome of surgery and answer why the UDS only change the clinical diagnosis but not the surgical choice.

In the VISUS 2 RCT by van Leijssen et al., all women with pure SUI or mixed urinary incontinence (MUI) with predominant SUI underwent UDS [3]. Only those women with a disagreement between the findings of UDS and the medical history were randomised in order to focus only on women who might benefit from UDS. This multicentre study recruited patients from 30 centres in the Netherlands and had again a non-inferiority design. The study included 578 patients of which 268 were discordant where 126 were randomised to direct surgery (n=64) or to individual tailored therapy based on the findings of UDS (n=62). After one year follow-up, the outcome of an immediate MUS operation was not found to be inferior

to outcome of individually tailored treatment based on urodynamic findings. Still, detrusor overactivity (n=7) and dysfunctional voiding (n=2) were the findings that led the authors to initially abandon surgical treatment; however, after one year, only three women (0.5%) did not undergo surgery based on discordant urodynamic findings.

One limitation of the study was that the attending specialist was not blinded to the allocated arm and to the urodynamic results. Thus, the authors declared that treatment selection could be influenced by urodynamic findings. Another weakness was that only one woman in the surgery arm had a maximum urethral closure pressure below 20cmH<sub>2</sub>O whereas a higher prevalence in this regard could affect the type of sling selection in the surgery group.

The VISUS 2 study revealed detrusor overactivity to be the only urodynamic parameter that was associated with a compromised cure of symptoms of SUI. Stating that, the authors proposed that the detection of detrusor overactivity preoperatively does not naturally lead to deviation of the intended surgery because the majority (81%) of UI complaints in women with detrusor overactivity improved, postoperatively. However, it should be noted that no urodynamic assessment was done postoperatively to judge on the outcome of detrusor overactivity and we do not know the prognosis in this patient group in a longer follow-up. On the contrary, several studies have demonstrated that the presence of MUI is an important factor decreasing surgical success after MUS [11,12]. Likewise, persistent overactive bladder symptoms after 10 years are further shown to be the main causes of patient dissatisfaction [13]. Therefore, detrusor overactivity may affect the pre-surgery patient counselling and its impact on the quality of life should be assessed in the long-term studies.

### Planning the future research and the importance of study power

The INVESTIGATE 1 study intended to show the feasibility of an RCT into the role of UDS for patients with SUI or stress-predominant MUI [14]. The authors concluded that such a trial was feasible and their pilot data indicated that there was a change in practice based on UDS with 80% versus 95% undergoing surgery. This study was not powered to show significance and the authors concluded that 450 patients would be needed in each arm to answer the question, which is more than the two RCTs (ValUE and VISUS 2) combined, which have been discussed above.

A recent review has highlighted the importance of study power in the assessment of whether a pre-existing voiding dysfunction could affect the outcomes in the ValUE Study [15]. The authors confirmed that patients diagnosed with a voiding dysfunction by UDS had a less successful outcome when compared to the rest of the population (62.1% vs. 78.8%)

[16]. This difference was not statistically significant ( $P=0.06$ ), but, considering the huge difference in group number (29 vs. 230 patients) and the lack of power of the study for this outcome, a voiding dysfunction could be reflected as a negative prognostic factor for surgical success [15].

The International Consultation on Incontinence (ICI) 2017 indicated that it is impossible to establish the need for UDS in a reliable manner unless a simplified accurate and reproducible system is developed to assess the anatomic changes and establishing the likelihood or presence of SUI [1]. Accordingly, the UDS can only be disputed as the gold standard when prospectively compared to its alternative; a (reproducible) systematically derived clinical assessment or a well-defined 'SUI syndrome', and / or a precisely defined 'urgency UI syndrome' (or 'overactive bladder – wet syndrome').

### The uncomplicated SUI or the 'index' patient

An important controversy involves the definition of 'index' patient who is proposed to have 'uncomplicated' SUI. In the recent AUA/SUFU guideline, the index patient is defined as an otherwise healthy female who is considering surgical therapy for the correction of pure SUI or stress-predominant MUI who has not undergone previous SUI surgery. According to EAU and AUA/SUFU guidelines, in uncomplicated patients, UDS may be omitted; still, noninvasive urodynamics (bladder diaries, uroflowmetry and post-void residual urine evaluation) should be used in all patients. It is possible that, even in this group of patients, invasive UDS may be considered when the exact pathophysiology of the LUTD should be better clarified or when an associated dysfunction may be suspected.

Strikingly, the majority of our patients with SUI may not fit to the definition of an index patient. Indeed, a retrospective analysis of 6276 women with UI has shown that only 5.2% had pure SUI [17]. A multicentre database study on 2053 patients has further indicated that only one third could have been diagnosed as having an 'uncomplicated' SUI according to ValUE trial inclusion criteria [18]. Interestingly, different types of UI were diagnosed by preoperative UDS in 74.6% and 40% of complicated and uncomplicated cases, respectively. Preoperative UDS have also revealed voiding dysfunction in 13.4% and 22.5% of the uncomplicated and complicated cases, respectively [18].

This observation seems to indicate that in complicated patients (the majority of the patients seen), urodynamics may be particularly helpful in unmasking unforeseen conditions and therefore possibly leading to a change in the following therapeutic strategy.

### Conclusions

The ICS Urodynamics Committee agrees

that a clinically unequivocal SUI, otherwise symptomless, with no post-void residuals and a reasonable bladder volume and flow, may have an indication for surgery and the risk for failure is minimal, not requiring further invasive studies like urodynamics. Unfortunately, those patients represent a minority of the total.

UDS may not alter the outcome of surgery in a minority of patients whereas the majority of patients with complicated SUI will probably benefit from preoperative UDS.

Rather than provide a fine-tuned diagnosis, UDS can provide a measure of the possible and unsuspected accompanying conditions, such as preoperative voiding dysfunction. Pressure-flow curves gauge the bladder ability to cope with the mechanical influence of various surgeries and the risk of iatrogenic de novo dysfunction.

The current guidelines [6,7] rely mainly on two RCTs [2,3] with short-term follow-up and which are powered according to a non-inferiority design. These two studies have shown that UDS alters the preoperative clinical diagnosis and overall treatment plan, but not the decision for surgery. Especially, voiding dysfunction appears to be underestimated when we only rely on an office-based evaluation. Consequently, UDS does not only provide information on the problem of SUI but also on unexpected different types of dysfunction that may interfere with planned treatment, thus conditioning the final therapeutic strategy or, at least, modifying the counselling of the patients before surgery. This should also be taken in the light of present concerns about possible litigations due to postoperative complications. Unfortunately, these issues have not been addressed so far by any RCT. Further research and new RCTs in this field should be conducted according to recommendations of the recent ICI [1].

The value of preoperative UDS for patients requires further clarification by future research. The perfect surgical solution for female SUI is still being sought after, and research for better surgical options continues. Detailed patient registry in national databases may become obligatory in the near future in many countries. Preoperative UDS are certainly a valuable part of this research. Besides, UDS help us in better understanding the LUTD, in more precise patient counselling and improve our approach to postoperative complications and so, decreases the medicolegal pressure on urologists and urogynaecologists.

We invite you to join us at ICS 2019 in Gothenburg, which will undeniably be an unequalled scientific meeting. The ICS is a multidisciplinary association pertaining to the highest scientific standards and bringing a spectrum of the very best incontinence and pelvic floor disorder research from basic science to large clinical trials. Workshop Submission deadline 3 January 2019. Abstract submission opens 1 April 2019.

## References

1. Rosier PFWM, Kuo H-C, Finazzi Agro E, et al. Urodynamic testing (Committee 6). In: Abrams P, Cardozo L, Wagg A, Wein A (Eds.). *Incontinence, 6th International Consultation on Incontinence* 2017;599-670.
2. Nager CW, Brubaker L, Litman HJ, et al. A randomized trial of urodynamic testing before stress-incontinence surgery. *N Engl J Med* 2012;**366**(21):1987-97.
3. van Leijssen SA, Kluivers KB, Mol BW, et al. Value of urodynamics before stress urinary incontinence surgery: a randomized controlled trial. *Obstet Gynecol* 2013;**121**:999-1008.
4. Rachaneni S, Latthe P. Does preoperative urodynamics improve outcomes for women undergoing surgery for stress urinary incontinence? A systematic review and meta-analysis. *BJOG* 2015;**122**(1):8-16.
5. Clement KD, Lapitan MC, Omar MI, Glazener CM. Urodynamic studies for management of urinary incontinence in children and adults. *Cochrane Database Syst Rev* 2013;**10**:CD003195.
6. Burkhard FC, Bosch JLHR, Cruz F, et al. *EAU guidelines: Urinary Incontinence*. 2018.
7. Kobashi KC, Albo ME, Dmochowski RR, et al. Surgical treatment of female stress urinary incontinence: AUA/SUFU Guideline. *J Urol* 2017;**198**(4):875-83.
8. Lloyd JC, Dielubanza E, Goldman HB. Trends in urodynamic testing prior to midurethral sling placement-what was the value of the VALUE trial? *Neurourol Urodyn* 2018;**37**(3):1046-52.
9. Mengerink BB, Nelen WLDM, van Leijssen SAL, et al. De-implementation of urodynamics in The Netherlands after the VALUE/VUSIS-2 results: a nationwide survey. *Int Urogynecol J* 2018;**29**(9):1261-77.
10. Sirls LT, Richter HE, Litman HJ, et al. The effect of urodynamic testing on clinical diagnosis, treatment plan and outcomes in women undergoing stress urinary incontinence surgery. *J Urol* 2013;**189**:204.
11. Bing MH, Gimbel H, Greisen S, et al. Clinical risk factors and urodynamic predictors prior to surgical treatment for stress urinary incontinence: a narrative review. *Int Urogynecol J* 2015;**26**(2):175-85.
12. Serati M, Bauer R, Cornu JN, et al. TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year followup. *Eur Urol* 2013;**63**(5):872-8.
13. Aigmueller T, Bjelic-Radicic V, Kargl J, et al. Reasons for dissatisfaction ten years after TVT procedure. *Int Urogynecol J* 2014;**25**(2):213-7.
14. Hilton P, Armstrong N, Brennand C, et al.; INVESTIGATE studies group. INVESTIGATE-I (INvasive Evaluation before Surgical Treatment of Incontinence Gives Added Therapeutic Effect?): a mixed-methods study to assess the feasibility of a future randomised controlled trial of invasive urodynamic testing prior to surgery for stress urinary incontinence in women. *Health Technol Assess* 2015;**19**(15):1-273.
15. Finazzi Agro E, Iacovelli V, Iliano E, Costantini E. Urodynamics before surgery for stress urinary incontinence in female patients: An open debate. *Arch Esp Urol* 2017;**70**(8):691-4.
16. Nager CW. Re: Comments on 'A randomized trial of urodynamic testing before stress-incontinence surgery' (*N Engl J Med* 2012;**366**(21):1987-97) from the Italian Society of Urodynamics. *Neurourol Urodyn* 2013;**32**:303-4.
17. Agur W, Housami F, Drake M, Abrams P. Could the National Institute for Health and Clinical Excellence guidelines on urodynamics in urinary incontinence put some women at risk of a bad outcome from stress incontinence surgery? *BJU Int* 2009;**103**(5):635-9.
18. Serati M, Topazio L, Bogani G, et al. Urodynamics useless before surgery for female stress urinary incontinence: Are you sure? Results from a multicenter single nation database. *Neurourol Urodyn* 2016;**35**(7):809-12.



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