

## Urodynamic test and female urinary stress incontinence: An open debate

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### Abstract

In this editorial we discussed the pros and cons of urodynamics in the assessment of female stress urinary incontinence.

**Key words:** Urodynamic; Female urinary incontinence; Stress urinary incontinence

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**Core tip:** In the last few years, the debate on the role of urodynamic tests in the preoperative evaluation of female urinary incontinence is hot. Even in absence of strong evidence, urodynamic investigation (UDI) is used to be considered mandatory before surgery in all female patients affected by stress urinary incontinence, according to several guidelines or recommendations. Nevertheless, a clear demonstration of an improvement of outcomes or change of clinical strategy after UDI was lacking.

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In the last few years, the debate on the role of urodynamic tests in the preoperative evaluation of female urinary incontinence is hot. Even in absence of strong evidence, urodynamic investigation (UDI) is used to be considered mandatory before surgery in all female patients affected by stress urinary incontinence (SUI), according to several guidelines or recommendations<sup>[1,2]</sup>. Nevertheless, a clear demonstration of an improvement

of outcomes or change of clinical strategy after UDI was lacking.

The scenario started to change after the publication of a relevant randomized controlled trial in 2012, aimed to compare outcomes of incontinence surgery after preoperative office evaluation (OE) and urodynamic tests or OE alone. This trial, generally known as Value of Urodynamic Evaluation (ValUE) trial<sup>[3]</sup>, showed that women with OE alone had non-inferior outcomes compared to those undergoing OE plus UDI. In 2012 and 2013, two papers from van Leijsen *et al.*<sup>[4,5]</sup> showed that the omission of urodynamics is not inferior to the inclusion of urodynamics in the preoperative workup in women with (predominant) SUI and that the consequences of discordant findings between symptoms and urodynamics are only of limited frequency. It should be underlined, as correctly done by the Authors, that all these trials enrolled exclusively women with pure SUI or mixed incontinence with prevalent SUI, according to strict inclusion and exclusion criteria. Those patients had been classified as having an “uncomplicated” demonstrable SUI, in the ValUE trial<sup>[3]</sup>.

As a consequence, the contemporary guidelines<sup>[6,7]</sup> are more cautious on the role of preoperative UDI stating that “there is limited evidence that performing urodynamics will alter the outcome of treatment for urinary incontinence” (European Association of Urology guidelines on incontinence<sup>[6]</sup>); whilst, according to the International Consultation on Incontinence the grade of recommendation for urodynamics before surgery is B<sup>[7]</sup>.

A recent Cochrane systematic review by Clement *et al.*<sup>[8]</sup> evaluated published randomized clinical trials with the aim of analyzing if pre-operative UDI could improve the clinical outcomes or alter clinical decision-making. The authors concluded that while urodynamics may change clinical decision-making, there is “some high-quality evidence that this did not result in lower urinary incontinence rates after treatment”. A systematic review and meta-analysis published recently by Rachaneni *et al.*<sup>[9]</sup> evaluated 388 papers (including only four randomized controlled trials) and concluded that UDI do not improve outcomes “in women undergoing primary surgery for SUI or stress-predominant MUI without voiding difficulties”. These two systematic reviews included few papers and the majority of the patients analyzed came from the ValUE study<sup>[3]</sup>.

Thus, the message that could be received (at least by an inattentive reader) is that UDI before surgery for stress incontinence is simply useless in all patients (uncomplicated and complicated). This logical step is absolutely unjustified considering that uncomplicated/simple patients are the minority of the patients as it has been several times demonstrated. Agur *et al.*<sup>[10]</sup> showed in 2009 that only 324 (5.2%) out of 6276 women with urinary incontinence, collected from an electronic database at a tertiary referral center, showed pure stress urinary incontinence, a quarter of which showed some different findings at the urodynamic evaluation. In a more recent trial, collecting data from several referral

centers in Italy, we were able to show that only 36% of more 2053 patients could have been diagnosed as having an “uncomplicated” SUI, according to ValUE trial criteria<sup>[11]</sup>. Furthermore, preoperative UDI led to the diagnosis of different type of urinary incontinence in 74.6% of complicated vs 40% of uncomplicated SUI cases ( $P = 0.0001$ ). Moreover, a voiding dysfunction on UDI was observed in 13.4% of the uncomplicated cases and in 22.5% of the complicated cases ( $P = 0.0001$ ).

In our opinion, some important informations come from these studies: first of all the so-called “uncomplicated” SUI patients are a minority. Also in the ValUE trial the majority of the screened patients (more than 60%) had been excluded from the study because non fitting in inclusion/exclusion criteria<sup>[3]</sup>. This result confirms the observation coming from our recent study<sup>[11]</sup>, in which 64% of patients were considered “complicated”, using the ValUE trial criteria. A second consideration emerging from our study is that in the majority of our “complicated” patients the urodynamic observation varies from the pre-urodynamic diagnosis much more frequently than in the “uncomplicated” patients. In a sub analysis of the ValUE trial<sup>[12]</sup>, Sirls *et al.*<sup>[12]</sup> showed that UDI was able to add some data to the pre-urodynamic information, but that these new informations changed the following surgical management only in around 12% of patients. In our study we confirmed that UDI was able to cancel/change the surgical management in a comparable percentage of “uncomplicated” SUI patients (11%), but much more frequently in the “complicated” ones (23.8%). Thus, it is possible to suppose that UDI effectively changes the surgical management of one quarter of “complicated” patients, and possibly in a 20% of the total patients’ population.

Actually, a tailored treatment is an essential target to obtain. UDI may prevent surgical intervention in women without USI or with prevalent detrusor overactivity incontinence. Recently, Serati *et al.*<sup>[13]</sup> demonstrated that UDI is able to show that several patients with symptoms of pure SUI present an underlying detrusor overactivity and do not require surgery, even one year after UDI. In these patients, antimuscarinic treatment appears to ensure a good rate of cure; thus, UDI could lead to the avoidance of several surgical procedures<sup>[13]</sup>. Furthermore, some urodynamic variables could guide the choice of the operation and potentially the surgical technique (*e.g.*, trans-obturator vs retropubic mid-urethral sling). They may also identify patients at risk of failure and at risk of the development of postoperative urgency, urgency incontinence and voiding dysfunction. This accurate assessment of the risks and benefits of surgery is fundamental to facilitate a correct preoperative counseling directed towards appropriate patient expectations, as well as guide the proactive management of postoperative symptoms<sup>[14]</sup>. In particular, the presence of a pre-existing voiding dysfunction could affect the outcomes: in a reply to a letter to the Editor on the ValUE trial<sup>[15]</sup> published on Neurourology and Urodynamics in 2013, Nager<sup>[16]</sup> affirmed that patients diagnosed with

a voiding dysfunction met a successful outcome in a reduced proportion in comparison to the rest of the population (62.1% vs 78.8%). This difference was not statistically significant ( $P = 0.06$ ), but, considering the huge difference in groups number (29 vs 230 patients) and the lack of power of the study for this outcome, a voiding dysfunction could be considered a negative prognostic factor for success after surgery. This condition, according to the VALUE trial and to our study, may be diagnosed in the majority of patients only after UDI even in "uncomplicated" patients.

In conclusion, we believe that in the majority of patients (the "complicated" ones) the role of UDI has not been fully evaluated. Nevertheless, data coming from literature together with data coming from daily clinical practice show that UDI may provide valuable data to evaluate the best clinical strategy. In uncomplicated cases, pretreatment UDI is probably not mandatory but it could give important informations (voiding dysfunction in about 10% of cases) offering a valuable guide to the surgeon and to the patient. "Primum non nocere" (First, do not harm) is one of the principal precepts of bioethics. A careful patient assessment allows to avoid a negligent practice. Urodynamic investigations is a valuable tool able to help us in counseling our patients with the aim of cure their symptoms, never risking of worsening them or causing further discomfort. In summary UDI help us in trying to "Primum non nocere".

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