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Urodynamic assessment of lower urinary tract function for women with symptoms of stress urinary incontinence. ICS Educational Module

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ABSTRACT

Aims: To present the body of evidence about the practice of objective assessment of lower urinary tract (LUT) function and dysfunction of female patients with stress urinary incontinence symptoms It serves as a scientific background review and evidence base for a presentation made available on the International Continence Society (ICS) website.

Methods: This narrative review has been prepared by a working group instituted by the ICS Urodynamics Committee. The method to develop the educational module used included narrative literature review, consensus formation by the members of the Working Group, and review by members of the ICS Urodynamics Committee core panel.

Results: On the basis of the available guidelines and articles, we addressed the following topics: Indications for comprehensive urodynamic study (UDS); the best way to inform and prepare the patient; the urodynamic study protocol in women with SUI; the practice of the different tests (cystometry with pressure flow study, leak point pressure and urethral pressure profile).

Conclusions: This ICS teaching module includes an expert-based profile of patients with signs and symptoms of SUI that can be considered complicated and includes specific recommendations for the practice of testing. UDS helps diagnosing the dysfunction that leads to the symptoms. Most of the testing for women with stress urinary incontinence can be performed in the already standardized manner; some adaptions of practice and evaluation are mentioned.

1. Introduction

Contemporary clinical guidelines regarding patients with symptoms of stress urinary incontinence (SUI) recommend 'to consider' comprehensive urodynamic studies (UDS) in complicated patients. These guidelines do however not provide any further recommendations about diagnosing the dysfunction(s) in these patients. A useful definition of which patients are complicated, not-index or complex, is not available and, recommendations about the practice of UDS are absent.

This ICS educational module is meant to fill these gaps and adds recommendations for the practice as is recommended in the guidelines. We have produced an educational module, based on expert review of the best available evidence for the practice of diagnosing the cause of UI in women. (ICSEducation(3-Part)Module: [www.ics.org/education/icsstandardoperatingprocedures/videosops/icseducation3partmodule]. Since practice is depending on guideline recommendations we wanted to base this teaching module on reliable evidence regarding the here

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above mentioned selection of patients and the recommended diagnostic tests. A systematic search (“stress urinary incontinence” AND “diagnosis” AND urodynam* AND (“sensitivity” OR “specificity” OR “accuracy”) gave 119 results predominantly about ‘promising’, ‘new’ or operator dependent techniques, about questionnaires or, developed for not standard care management. None of the articles was considered relevant for our teaching module regarding diagnosis with standard techniques as was observed earlier.[1]

We added (Oxford) levels of evidence (LoE) for diagnostic tests in our module where recommendations are made and where evidence was not available we added LoE ‘5’ which refers to ‘first principle’ or ‘expert opinion’.

2. Principles of diagnosis of urinary incontinence

Objective assessment of lower urinary tract (LUT) function is done with a urodynamic study (UDS). UDS can help diagnose the dysfunction that leads to the symptoms (LoE 1).[2] Before conservative therapy for stress urinary incontinence (SUI)-predominant symptoms in the *primary* health care setting, i.e. life style adjustment and pelvic floor physiotherapy, invasive UDS is not required and, is not cost-effective (LoE 4) [3] but uroflowmetry with postvoid residual (PVR) assessment are recommended when primary care is in the hands of a medical specialist[2]. If initial conservative and medical treatment fails, then patients will be recommended a *secondary* care workup, and possibly invasive treatment [4] (LoE 1). Failure of initial treatment may, in general, be an indication that the diagnosis was incorrect, imprecise, or incomplete, and shifting to second-line management usually requires further objective assessment. The ‘VALUE’ trial (LoE 3) concluded that UDS does not influence the outcomes of SUI treatment in patients with ‘pure’ or ‘SUI-predominant symptoms’ when all patients with symptoms were subjected to surgery, regardless of the specialist diagnosis (=UDS) [5,6]. However, we highlight that the VALUE study had several drawbacks that prevent generalization [7], and the predictive value for SUI treatment outcome of a diagnosis based on signs and symptoms alone is currently unknown (LoE 5 -absence of evidence). Indeed, as shown by Serati et al. [8], a significant proportion of patients assumed to have uncomplicated-SUI by the definition used earlier [5], present with coexisting abnormalities, relevant for management, once assessed with UDS.

UDS are, in expert consensus, regarded as the gold standard investigation for LUT dysfunction (LUTD) diagnosis [8] (LoE 1). Therefore the relevance of UDS, as the gold standard test, in the clinical workup of patients with symptoms of SUI, can only be disputed (or discarded) when prospectively compared to its potential alternative, e.g. a reproducible, systematically derived clinical assessment and/or a well-defined ‘stress urinary incontinence’ syndrome [9]. In such a prospective comparison, the management would be selected only on the basis of one of two distinct diagnostic -management strategies. Outcome assessment should include all elements of LUT function over a sufficient time span. Such type of study has not been published yet.

Expert consensus in practice guidelines and standards exists for the premise that patients with ‘uncomplicated SUI’ can be recommended anti-incontinence surgery [9] without a UDS diagnosis, to cure their SUI, with a 75% chance of success/cure [4,10,11]. Expert consensus also highlights the fact that there is insufficient evidence to know if UDS before anti-incontinence surgery can predict the incidence or type of any new LUT dysfunction or can predict the failure to cure SUI [3] or the risk for requiring additional management.

A diagnostic test should be conducted only when it can potentially impact decision on management, taking into account both, cost and risks of both the management approach and the diagnostic tests. In patients with uncomplicated pure SUI, the risk and cost of UDS seem (LoE 4) not to outweigh the benefits of a more precise complete and objective diagnosis leading to the above-mentioned consensus, although specific studies regarding this are lacking. Current guidelines do agree that UDS diagnosis is relevant for complicated non-index patients, although the concept of ‘complicated patients’ versus uncomplicated, ‘pure’ or ‘index’ -SUI patients [12], has been poorly defined, leading to over-generalization of published results for clinical practice [13]. To this end we have added a paragraph ‘indications’ to this practice Educational Module.

3. Indications for comprehensive UDS

In this Educational Module we describe the practice comprehensive invasive UDS for patients with symptoms of SUI who can be considered complicated or non-index so that it becomes possible to follow the guidelines in a better standardized manner. To this aim, we regard patients as “complicated” when presenting with SUI symptoms and one or more of the following (LoE 5): 1. frequent small voided volume on bladder diary; 2. postvoid residual (PVR) and/or representative but abnormal uroflowmetry; 3. a history of recurrent urinary tract infections; 4. pain attributed to the LUT dysfunction; 5. using medications potentially affecting LUT function; 6. pelvic organ prolapse (POP) stage 2 and above; 7. failed earlier surgery for SUI or previous POP surgery. We suggest that also patients with a negative ICS-standard uniform cough stress test (ICS-UCST), as well as a negative accessory-upright CST[14] (see below) may be considered complicated (LoE 5).

It probably goes without saying that also patients with neurogenic dysfunction, collagen disease and or anatomical abnormalities of the pelvic floor or LUT do not belong to the pure-SUI group (LoE 1). In this module, we do not discuss UDS for this latter group of patients, nor does the module include diagnostic practice for patients with pelvic organ prolapse more advanced than stage 2 and concomitant SUI [15].

Although we have, similar to the recent American Urological Association (AUA) document [16] (LoE 1), defined complicated SUI for this module, it is our opinion that despite the contemporary guidelines, UDS is of relevance in patients with ‘uncomplicated’ SUI as well (LOE 5), since consistent (LoE 3-4) evidence has shown that these women may have relevant coexisting LUT dysfunction [8,17–19]. UDS in patients with complicated SUI can show other, coexisting dysfunctions or can refute SUI. This module gives no recommendations regarding further management in these situations and does also not include the diagnoses that can be made based on the testing, nor their consequence for management. We refer to textbooks that discuss urodynamic studies and urodynamic diagnoses for this. We have not discussed the role of fluoroscopy in combination with urodynamics in women with primary and recurrent SUI as it is not specifically recommended in the guidelines and thus beyond the scope of this document.

4. The practice of comprehensive urodynamic studies for women with complicated signs in their medical history and symptoms of stress urinary incontinence

The guidelines agree about the fact that UDS should be considered for patients who can be considered complicated. This educational module includes a section on the definition of these patients and the graph shows the expert based list of patients that can be considered not index. This list is based on a collation of the usual exclusion criteria for the SUI- surgery trials including e.g. the VALUE study [5].

Graph: Patients with symptoms of (S)UI who can, according to the opinion of the Educational Module working group, be considered ‘complicated’ or ‘non-index’ have also:

- *Frequent (small volume) and or night-time voiding on bladder diary (with normal fluid intake)*
- *Representative but abnormal uroflowmetry and/or post-void residual (PVR)*
- *History of recurrent urinary tract infections*
- *Pain attributed to LUT dysfunction*
- *Relevant for LUT function -medication use (not only 'urological' medication)*
- *Failed earlier surgery for UI*
- *Previous surgery for pelvic organ prolapse*
- *Pelvic organ prolapse stage 2 and above*

for consideration:

A negative ICS-UCST plus negative accessory CST

Similar criteria used to define women with SUI as complicated were recently listed by the European Urological Association [20].

5. Instructing and preparing the patient

Once the UDS is scheduled, the patient should receive instructions on how to prepare for the test.[2]The preferred elements of written patient information about the test are given in the International Continence Society (ICS) Standard.[2] Example patient leaflets can be found as an appendix to the "United Kingdom continence society: minimum standards for urodynamic studies", published in 2018 [21], or on the website of the International Urogynecological Association (IUGA) [22].

It is well demonstrated that good counseling and information before and during the procedure may be able to reduce patient discomfort and embarrassment [23]. However, even after providing reassuring information, UDS, as any clinical test, may induce significant anxiety in women expecting to undergo the test. As has been emphasized by previous ICS modules [24] and national guidelines [25], it is of paramount importance to allow maximum privacy during voiding, chaperoning during intimate examinations and procedures, adequate draping of the patient, and continuous verbal communication. Universal implementation of a trauma-informed approach will guarantee the patient's emotional safety, prevent panic reaction, improve trust, and ultimately allow UDS testing to proceed smoothly and anxiety-free [26].

Upon referral, the patient should provide evidence of a recent sterile urine culture or dipstick test. The value of universal antibiotic prophylaxis before UDS is questionable: a recent Delphi consensus by the Italian Society of Urodynamics [27] aligned with ICS standard and module recommendations [28], concluded that such routine is not recommended. If a UTI is present it should be treated effectively prior to the UDS test [29,30].

Instruction and preparation for uroflowmetry can be done according to the ICS standard [30], as well as the instructions during catheterization. Any new information regarding pelvic floor or genital anatomy or neurology should be communicated to the patient and reported, e.g. unusually painful catheter insertion. Explanations during cystometry and the establishing diagnosis of filling sensation is done according to the ICS standards [31,32], as well as (urodynamic quality -control) cough tests[2]. Certainly, it should be explained to the patients that these cough-tests are also of diagnostic relevance. Patients may furthermore be able to mimic the situation that causes SUI, e.g. while standing up or going to sit, which can usually be performed during cystometry if patient safety is guarded. Instructions for pressure/flow studies (PFS) after a strong desire to void and, post-void residual analysis [2], do not need adaptions for women with SUI.

6. The ICS -uniform cough stress test

The ICS-uniform cough stress test is introduced in another teaching module [14] and we very briefly explain it here. The test is however designed for primary care (initial) diagnosis of patients with uncomplicated signs and symptoms and its relevance for patients with complicated SUI is never specifically studied. For the ICS-UCST it is recommended that the patient be in a supine/lithotomy position with 200–400 mL of fluid in the bladder. She coughs forcefully 1–4 times in up to 2 series and the examiner directly visualizes the urethral meatus for the presence of leakage. Leakage of fluid from the urethral meatus coincident with/simultaneous to the cough(s) is considered a positive test. If this test is 'negative' an accessory 4 coughs are recommended in standing position.

7. Urodynamic study protocol in women with SUI

UDS testing for women with complicated symptoms of SUI consists of an ICS standard urodynamic test (ICS-SUT) as the element of a full ICS standard urodynamics protocol (ICS-SUP). An ICS-SUT consists of a uroflowmetry and post-void residual (PVR) plus cystometry and pressure-flow studies (PFS) (and PVR again PFR-PVR): all tests are performed in the patient's preferred or most usual position, which is comfortably seated for women [2]. Clinical examinations, including neuro-urological assessment, pelvic floor muscle function evaluation and pelvic organ prolapse staging according to the Pelvic Organ Prolapse Quantification System (POP-Q) [33], as well as ICS-UCST are usually performed and reported before UDS. Please note that ICS-UCST should be done with a comfortably full bladder which precludes UCST when the patient is positioned for insertion of the urodynamic catheters after uroflowmetry and PVR measurement.

7.1. Cystometry and PFS

For women with (complicated) symptoms of SUI, a standard cystometry with PFS and PFS-PVR is done, after uroflowmetry and PVR measurement, all according to ICS Good Urodynamic Practices (ICS-GUP 2002 and 2016) [1,34] and the ICS-SUFU-PFS Standards [35,36]. If the patient is unable to perform uroflowmetry the amount of urine in the bladder should be recorded as well as the presumed reason for this.

The practice of cystometry and PFS including, urodynamic catheter type, fill rate, filling medium and -temperature and positioning is explained in an earlier teaching module [32]. Pretest explanation to the patient as well as assessing filling sensation are explained in the ICS Good Urodynamic Practices [2]. The ICS-GUP and ICS-SUFU-PFS standards require some detailing, adaption and or specification for female patients with symptoms of SUI. Pelvic floor muscle surface electromyography (EMG) may be added to the ICS-SUT but evidence that this adds more insight into the pathophysiology of the dysfunction that leads to the diagnosis is not available (LoE 5) [37]. Also, a urethral pressure profilometry (UPP) may be added to the ICS-SUP (see below). EMG and UPP are not specifically recommended in the guidelines but we nevertheless include these in our teaching because of their very frequent use (LoE 5).

Extra attention should be paid to standard reporting of filling sensation, e.g. to prevent overfilling or, to uncover pharmacogenic reduction of awareness of filling or of the ability to void (LoE 5). Unquestionably detrusor pressure pattern during filling should be observed; detrusor overactivity (DO) as well as reduced compliance are relevant observations. Urodynamic capacity and permission to void should relate more or less to the diary volumes [2]. Fill rate will be standard (10% of maximum voided volume, as measured on a bladder diary, per minute) as well as position of filling (upright) [2]. Cough tests during cystometry are most relevant (to check pressure quality as per standard [2] but also) when a uniform cough stress test (UCST) has been negative. UCST are also relevant to uncover cough-induced DO and leakage [2]. The exclusion of other dysfunction(s) is also important to obtain a comprehensive and complete diagnosis of LUT function. Once capacity (strong desire to void) is achieved, the patient should be allowed to void in privacy in their normal position of voiding (usually

seated) without further interruptions, to achieve the greatest chance of a representative void. In the case that stress testing with a volume 'near capacity' or with a strong desire to urinate is deemed necessary and the subsequent urination is not 'as usual', it is probably better to repeat the cystometry without that testing to ensure a smooth transition from storage to emptying and have a better chance to obtain a representative voiding [35]. No guideline recommends provocations as fast filling or much - larger -than -usual capacity filling thus we do not include these in our education. Cystometry and PFS are analyzed as per (ICS-) standards.

7.2. Leak point pressure

Leak point pressure (LPP) is described as 'the lowest pressure of the intentionally increased intravesical pressure that provokes urinary leakage in the absence of a detrusor contraction' [37,38], based on earlier detailed explanation and description [39]. A cough or Valsalva leak point pressure can be performed during UDS. Just to note, a Valsalva or cough LPP is different from the assessment of detrusor LPP, which is also performed during UDS but relevant in patients with neurogenic LUT dysfunction [4]. For women with signs and symptoms of SUI, coughs may provoke UI during the cystometry. Slowly increasing Valsalva pressure may give an impression of the force that leads to UI. Cut-off values for LPP, based on historical data, are still being used by some centers with patients having relatively low 'urethral pressures' (<60 cmH_2O) being diagnosed with 'intrinsic sphincter deficiency', although some would argue that this has lost its relevance [40,41]. In earlier studies, urethral pressures and LPPs have been shown non-predictive for outcome if identical treatment is applied irrespective of their measured value [42,43]. Possibly, a patient with SUI may not leak during UDS due to the effect of the transurethral UDS catheter [2,44], this artifact can be unmasked by repeating the cystometry and by removing the transurethral catheter at e.g. normal desire to void [45,46] or using a smaller catheter as is the case with the two-catheter technique where pressure is measured with a 16G epidural catheter which causes minimal obstruction. It is therefore recommended not to use a catheter bigger than 6Fr [2]. When the clinical history and the ICS-UCST have been congruent with SUI, a negative UDS should not exclude a diagnosis of SUI in the absence of other dysfunctions, and ambulatory urodynamics can be considered. Also, if the assessment is unclear, the possibility of a false-negative UDS for detrusor overactivity should be considered. This module does not discuss further consequences of this situation.

7.3. Urethral pressure profile (UPP)

Although evidence shows that average urethral pressure is somewhat lower in women with SUI than in patients with other dysfunction or without symptoms of SUI, the overlap of values is too large to allow UPP as a single diagnostic test [4]. There is scanty evidence that if a cystometry excluded other functional abnormalities that may complicate the UI (i.e., filling and voiding are normal), an UPP may provide extra information to select further management (LoE 5) [4]. No (ICS) standards exist for UPP measurement nor a (positive) recommendation. We nevertheless briefly discuss its practice.

UPP is possible with a liquid-filled single lumen catheter with two-eye holes according to the Brown and Wickam technique [47] or with a microtip or an air-filled (charged) sensor. It is important to note that pressures measured with an air-charged catheter will be different to those recorded by liquid-filled catheters and that there are no standardized values for in air-charged catheters. UPP is technically unfeasible with the double-lumen, liquid-filled catheter that is ICS recommended for cystometry, but rather requires a single-lumen catheter (also ICS recommended) with two-eye-holes [48]. Slowly pulling the (appropriate) catheter from the bladder will show a profile. Various parameters have been reported, including the maximum urethral closure pressure and urethral length. The pulling velocity of 1 mm/s is usually utilized. The patient is placed in the lithotomy or supine positions and asked not to contract their pelvic floor. Cough transmission urethral pressures have been reported in the literature [47] but there is no evidence that these add new information that is relevant for currently available management options (LoE 5) [4].

8. Conclusion

This ICS Educational Module has explained the practice of comprehensive urodynamic studies for women with complicated signs and symptoms of SUI. Most of the testing for women with SUI can be performed in the already standardized manner; some adaptions of practice and evaluation are mentioned. The module has also included an expert-based profile of patients with signs and symptoms of SUI that can be considered complicated to allow better applicability of the contemporary guidelines.

Ethics approval

Nothing declared

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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