Lower Urinary Tract

The first paper in this section is a review by several highly respected authors of diagnostic criteria for evaluating patients with symptomatic stress urinary incontinence, and is followed by a review of the role of urgency and its measurement in the overactive bladder symptom syndrome, with emphasis on current concepts and future prospects. These are two important papers, which point the reader in the direction of a greater understanding of these conditions.

The concept of α-blockade before a trial without catheter after acute urinary retention is revisited by authors from the UK, who used tamsulosin in a randomized controlled trial. They found that it is appropriate to recommend tamsulosin for such use in this condition.

A critical review of diagnostic criteria for evaluating patients with symptomatic stress urinary incontinence

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Accepted for publication 20 September 2004

KEYWORDS

urinary incontinence, stress, female, diagnosis, urodynamics, test

INTRODUCTION

The minimum evaluation criteria necessary to diagnose stress urinary incontinence (SUI) have recently been the subject of debate, especially for the use of urodynamics and the type of treatment contemplated (e.g. conservative or surgical management). The concept of minimum evaluation is important, given that some tests are expensive, unavailable in certain countries, inconvenient for the patient and possibly of doubtful usefulness in indicating therapeutic strategy.

Currently, there is no adequate consensus on how to diagnose SUI or categorize the disorder in terms of the two principal postulated pathophysiological mechanisms; intrinsic sphincter deficiency (ISD) and urethral hypermobility. These represent extremes of a spectrum, and coexist in the vast majority of patients. An inherent problem in current practice is the poor understanding of the pathophysiological basis for female continence.

In August 2003, an international panel met to discuss the different diagnostic tests for SUI and to reach a consensus on (i) the individual diagnostic tests, evaluating their use in clinical practice vs clinical trials or research, and (ii) the minimum diagnostic assessment needed before initiating conservative, noninvasive therapy (behavioural therapy, pharmacotherapy, pelvic floor training, vaginal devices and injectable agents). Injectable agents may not be deemed by some to be noninvasive, instead being described as minimally invasive, but they clearly do not alter further treatment, or unless significant complications arise, produce new problems. A further aim was to discuss the classification of SUI. The outcome of this meeting is presented in this review.

DATA SELECTION

Experts reviewed the published reports on diagnostic methods for SUI and presented

their findings for discussion. Data were obtained from various sources including the ICS [1], the 2nd International Consultation on Incontinence (ICI) [2], and by searches of Medline for articles published between 1966 and 2003. The main Medline search used the term 'stress urinary incontinence' and the following: 'diagnosis', 'urodynamic', 'urodynamics', 'history', 'urethral pressure', 'leak-point pressure', 'Q-tip', 'pad', 'residual', 'cystometry', 'cystography', 'cysto-urethrography', 'video', 'ultrasound' and 'sonography'; 'frequency volume chart' or 'frequency volume charts'; 'incontinence' and 'test'. The ICS website was searched for abstracts published at the Annual meetings between 1999 and 2002 in the 'urodynamics', 'stress incontinence' and 'diagnostic techniques' categories. In all, 2554 references/abstracts were identified, of which 502 met the search criteria of relevance to diagnostic methods, and form the basis of this review. Supplementary references were identified.

DIAGNOSTIC TESTS FOR SUI

SYMPTOMS, HISTORY AND QUESTIONNAIRES

Involuntary leakage of urine on effort or exertion, or on sneezing or coughing, is the most commonly used definition in clinical practice on which to select a treatment [3]. Epidemiological studies, most using this definition, show that SUI occurs in a mean (range) of 49 (24–75)% of patients with UI, while mixed incontinence occurs in 29 (11–61)% [4].

SUI is easily recognized by assessing the patient's history, but there is no practical, validated tool to quantify symptom severity. The Stamey classification [5], used in many publications, is simplistic and of limited use, while alternative symptom/quality-of-life scoring systems (e.g. Bristol Female Urinary Tract Symptom questionnaire [6], Contilife™ scale [7], King's Health Questionnaire [8]), all good research tools, are perceived by many to be too complicated for clinical practice.

Although a careful review of the patient history is essential, it may underestimate the true prevalence of SUI, as shown in the study by Sandvik *et al.* [9], in which patient history was validated using a urodynamic evaluation. The validation altered the apparent prevalence of SUI from 51% to 77%, mainly attributable to fewer patients with mixed incontinence. Conversely, a classification based on urodynamics rather than symptoms may not accurately reflect what bothers the patient. Clearly, a combination of these approaches may provide optimum accuracy.

The relationship between SUI and the overactive bladder (OAB) syndrome is important. It is artificial to differentiate between the urethra and bladder, with experimental evidence suggesting a link between the structures (e.g. urethral perfusion of saline provokes bladder contraction in animal models [10,11]). Moreover, clinical evidence suggests some overlap between SUI and OAB, albeit that current definitions would support the possibility that OAB needs to be considered when urinary frequency is a bothersome complaint. Cardozo and Stanton [12] reported that many women with urodynamic SUI also had urgency/frequency symptoms (e.g. urge incontinence, 55%). This proposed overlap may mean that certain patients with OAB could benefit from treatments directed at the urethra, and that prevalent SUI associated with OAB is not a contraindication to surgery. Indeed, improvements in OAB have been reported when concurrent SUI is treated, i.e. those cases in which detrusor overactivity is precipitated by acutely increased intra-abdominal pressure (e.g. Valsalva manoeuvre) [13].

CLINICAL EXAMINATION

This is the most commonly used method for diagnosing SUI. A general physical examination comprises an assessment of patient cognition, dexterity and ambulation (especially in the elderly), and a targeted neuro-urological examination to detect systemic neurological disease and local neuro-urological problems. The utility of neuro-urological examination has never been formally investigated in ambulatory women with pure/predominant SUI, but common sense supports its routine use.

A directed pelvic examination is of critical importance. Gluteo-sacral region abnormalities and discrete fascial defects can be detected, while examination with a speculum can identify abnormalities such as cancer and urethral diverticula; a bimanual examination can identify pelvic masses. Pelvic muscle strength and integrity can be assessed, with the Brinks scale being commonly used [14]. However, there is scant published evidence validating the use of muscle-strength scores. Pelvic support assessment is another option, with recognized scales being used; Baden-Walker [15]; and pelvic organ prolapse-quantified (POP-Q), in which the stages have been arbitrarily designated [16]. The Baden-Walker system is generally easier to use, although there are concerns over its utility in assessing anterior and posterior wall support, while the reproducibility of the POP-Q system has been more extensively validated. The Q-tip test, which has not been validated, aims to evaluate urethrovesical junction (bladder neck) mobility [17], although it is widely considered to be too inaccurate to be clinically useful.

Provocative measures to produce SUI during examination are essential, with cough-stress tests to produce meatal-based urinary leakage, including several variants [18–21]. In general, this test has a high sensitivity for the diagnosis of SUI, but variable specificity.

Clearly, a clinical examination is a vital component of SUI diagnosis, although it is often not feasible to replicate the position and circumstances in which the patient actually leaks. The utility of specific aspects is generally not well studied, especially in patients with POP.

OBJECTIVE LEAKAGE MEASURES

Frequency/volume charts, or voiding/bladder diaries, are used to record voided volumes, urgency, incontinence episodes, pad usage and fluid intake where appropriate. The Larsson nomogram was proposed as an aid when using chart information to distinguish between SUI and detrusor overactivity [22], but its specificity and sensitivity appear to be too low for this purpose [23]. For differentiating between urge incontinence and SUI, the frequency of night-time micturition has been shown to be the most discriminating chart variable [24].

Pad tests are another diagnostic measure, with many variations in use. The resulting lack of standardization is a major disadvantage, and makes reports using the pad test difficult to interpret [25]. Abnormal results have been interpreted as a leakage of >1.4 g/h (analysis of 90 'normal' women [26]) and 8 g/24 h (analysis of 23 asymptomatic women [27]).

Pad tests cannot distinguish between the type or pathophysiology of incontinence, although leakage may be greater with detrusor overactivity than SUI [28]. It has been proposed that short-term tests (1–2 h) are a measure of function, whereas long-term tests (12–48 h) assess symptoms [29]. Although short-term pad tests have lower reproducibility and sensitivity [29], they are easier to perform and the ICS have defined suggested criteria for a 1-h assessment [30]. Pad tests have not been validated in women with POP.

UROFLOWMETRY, RESIDUAL URINE AND PRESSURE–FLOW STUDIES

Peak flow rate has been investigated as a screening tool, while residual urine is important in excluding incomplete voiding and overflow incontinence (i.e. leakage of urine at a greater than normal bladder capacity because of detrusor underactivity). These are rare conditions in women without POP or previous incontinence procedures. However, the results of a 'minimal' care programme community study suggest that urinary flow rate and residual urine cannot be justified as routine measurements [31]. Pressure-flow studies involve the simultaneous recording of bladder pressure and urinary flow rate, and can, by showing detrusor dysfunction, help to unmask or delineate possible neurogenic dysfunction [32]. It must be recognized that detrusor overactivity may not be evident in symptomatic patients with urge incontinence, and conversely may be seen in asymptomatic patients. Although there is evidently a good correlation between urodynamic findings during the filling phase and symptoms, it is not absolute.

IMAGING METHODS

Cysto-urethrography, pelvic floor ultrasonography and MRI for urinary incontinence were recently reviewed during the 2nd ICI [33].

Cysto-urethrography is the most extensively studied imaging method; it can be used to evaluate both qualitative (e.g. funnelling of the proximal urethra) and quantitative variables (e.g. posterior urethrovesical angle). The degree of change of posterior urethrovesical angle forms the basis of a urethral hypermobility classification system proposed by Green in 1962 [34].

The role of cysto-urethrography alone in female urinary incontinence is yet to be established, and it cannot be recommended for the diagnosis or classification of this condition. Nevertheless, it may be a reasonable option in the preoperative evaluation of complicated/recurrent female UI.

Pelvic floor ultrasonography allows a morphological and functional evaluation of urinary incontinence, although the technique needs to be standardized [33]. Qualitatively, ultrasonography can measure variables such as bladder neck funnelling and position; quantitative variables measured are the retrovesical angle β and internal urethral orifice position. This technique is developing rapidly and, theoretically, allows dynamic visualization of urethral and bladder behaviour, and imaging of pelvic floor muscle contraction. It cannot provide a diagnosis of SUI or urge incontinence, and should be considered as investigational [33], although it may assist in diagnosing urethral hypermobility.

Several MRI variations are available to investigate urinary incontinence [33,35], including endovaginal and dynamic techniques. Advantages of MRI include lack of irradiation, speed and the ability to manipulate images after testing, with the major disadvantages being the high cost and lack of universal facilities. To be of maximum value, MRI should be used in the position of leakage. MRI is indicated in assessing female UI and pelvic floor disorders only in very selected cases, and should be considered an investigational technique [33].

Videocystometry/video-urodynamics: cystometry evaluates the pressure-volume relationship of the bladder, with subtracted cystometry used to measure 'true' bladder pressure. Videocystometry, first described in the late 1960s [36], involves fluoroscopic visualization of the bladder and urethra in conjunction with simultaneous measurement of vesical and urethral pressures and contrast imaging. It allows visualization of the moment of leakage during cough and straining tests, as well as providing information on variables such as urethral hypermobility and bladder base descent.

Video-urodynamics has been considered the reference standard diagnostic technique for UI, but few studies have investigated its use in comparison and correlation with 'simple' urodynamics, or with symptoms of lower urinary tract dysfunction. This technique exposes the patient to radiation and is expensive, but is widely accepted to be effective, and provides comprehensive functional and anatomical information.

Current opinion supports the use of video-urodynamics for patients with complex pathology, when the diagnosis is unclear or when previous treatment has failed. It can also help to ensure the correct positioning of pessaries during preoperative screening of certain patients with POP for 'occult' SUI [37].

Abdominal leak point pressure (ALPP) is the vesical pressure at leakage during abdominal stress in the absence of detrusor contraction. Abdominal stress may be induced by a cough (CLPP) or a Valsalva manoeuvre (VLPP), with the two stressors differing physiologically, particularly in the rate and nature of the observed pressure rise. Whilst higher abdominal pressures can be achieved with CLPP, the VLPP is better controlled and less variable [32]. Generally, CLPP is used for patients with SUI who do not leak during a VLPP measurement.

For an ALPP to be valid, it is assumed that; the transurethral catheter used does not obstruct the urethra or alter coaptation; straining or coughing does not distort the urethra; and no pelvic relaxation or contraction occurs. However, it is difficult to know whether these criteria hold during the test.

Although the concept of ALPP is empirically sound, its value is limited by a lack of standardized methods. Variations occur in the type of catheter, catheter calibre, bladder volume and patient position. The exact baseline used during the test varies among clinicians, which can make a dramatic difference to the derived ALPP value. A large cystocele will make the LPP appear artificially high, and should be reduced and held in place before testing. LPP tests have not been validated in women with POP.

In theory, a successfully treated patient should not have a measurable ALPP, as they do not leak. Few data are available on the actual magnitude of the change in ALPP after treatment for SUI, and how this correlates with treatment outcome. One general finding is that VLPP does not change significantly if the treatment fails. For example, after a

suburethral sling operation in 30 women, the VLPP increased significantly after a successful operation (mean change 61.1 cmH_2O; $P < 0.001$) but not after failure (mean change 9.7 cmH_2O, $P = 0.226$) [38]. Moreover, it is not possible to assign a numerical LPP value that will equate to the cure of patients.

Urethral pressure can be measured either using a catheter-mounted transducer or a fluid-fill system where urethral pressure is equated to the fluid pressure needed to just open a closed (collapsed) urethra [39]. Urethral pressure profilometry (UPP) can be used to measure the maximum urethral pressure, maximum urethral closure pressure, functional urethral length (FUL) and pressure transmission ratio, with urethrocystometry a variant. When reporting UPP data it is important to state the exact method and materials used [40].

Although UPP can potentially be highly informative, it has many problems, the most significant being the large overlap in values between normal and symptomatic patients [41]. UPP does not discriminate SUI from other urinary disorders, or measure severity or return to normal after a successful intervention [42]. Various methods have been developed to improve UPP, including vesico-urethral pressuregrams [43], and cross-sectional area extrapolations [44], but these are research tools unsuitable for clinical practice.

Major factors affecting UPP are the inherently artefactual patient position (not usually upright, the position in which patients normally leak), the transducer position, bladder volume, extent of patient provocation during stress UPP and movement of the transducer during the stress UPP manoeuvre. There are several secondary problems, including the urethral pressure variability during bladder filling and lack of normative values. Lack of reproducibility can also be a problem [45], although not necessarily in specialized and experienced urodynamic laboratories. There is a lack of validation in women with POP.

Other urethral measurements, such as FUL and stress urethral profiles, have been reported to reduce the diagnostic and predictive errors of urethral function, but suffer from similar difficulties; overlap between normal, incontinent and postoperatively continent women, and lack of reproducibility among urodynamic centres.

Overall, UPP is an investigative tool that may provide information about the characteristics of the urethra. The clinical value of UPP, including pressure transmission ratio measurements, is largely unconfirmed, and although prognostic value has been shown in some studies, its actual importance is debatable.

UNDERLINING THE PATHOPHYSIOLOGY IN SUI

Many tests have been used to try and differentiate between urethral hypermobility and ISD. However, such a rigid classification of patients has proven to be controversial, and generated much debate, as it is likely there is a combination of both pathophysiologies in many patients. It was originally proposed that a low ALPP (<60 cmH_2O) or a low MUCP (<20 cmH_2O) is indicative of ISD, but neither of these criteria have a strong evidence base. There is a low concordance between a low ALPP and low MUCP, so the most appropriate method to diagnose ISD is controversial [32]. Attempts have been made to use the supine stress test as a screening tool for ISD [18,20,46], but overall this technique is apparently not sufficiently reliable to be diagnostic in the specific classification of SUI pathophysiology.

The dichotomous classification of SUI into hypermobility and ISD is an over-simplification. In reality, it appears that the two pathophysiologies coexist, as suggested on video-urodynamic studies [47], and form a continuous spectrum. As combined hypermobility and ISD occurs in the vast majority of patients, the challenge is to determine the position of a given patient within the spectrum. The uncertainty over this categorization is recognized by the ICS, which has called for further research in this area [3].

The separation of hypermobility and ISD is important where it may influence treatment outcome. Several studies suggest that a low MUCP or ALPP, indicative of ISD, is predictive of a poorer surgical outcome with a suspension procedure, but overall the data are contradictory, and need clarification [32]. For studies investigating injectable agents, the US Food and Drug Administration (FDA) states that females must have an ALPP of <50–60 cmH_2O [48] (i.e. what the FDA considers indicative of ISD), although a recent registration trial used a value of <90 cmH_2O [49]. However, data show that injectable agents produce similar success rates in patients with ISD or hypermobile SUI [50]. Indeed, in the study by Herschorn and Radomski [51], there was no significant difference in outcome between patients with or without hypermobility.

SUI DIAGNOSIS – A CONSENSUS

EVALUATION OF DIAGNOSTIC TESTS

This review is the first to examine diagnostic techniques for UI in the context of one condition (i.e. SUI). The different techniques are evaluated in Table 1, where the index patient has pure/predominant uncomplicated SUI, no POP, no previous surgery for SUI, and is ambulatory and cognitively intact.

Symptomatic evaluation is of fundamental importance in diagnosing SUI, with diaries being recommended for use in all patients. Interpreting the information is key to an adequate diagnosis (e.g. frequent voiding at night is generally not common in patients with pure/predominant SUI). Diaries are useful tools for educating patients, and reduce the need for questionnaires. Compliance can be a problem, but recent work suggests that a 3-day diary may be as informative as a longer-term assessment [52]. Moreover, a 4-day chart has been shown to be as reliable as a 7-day chart [53]. A comprehensive physical examination is mandatory to assess POP, and neurological evaluation, the use of a speculum and bimanual examination are recommended.

When using observational stress or cough tests, if a patient does not leak when supine, the test should be repeated with the patient upright. Pelvic floor assessments are recommended for routine, clinical study and research use, although they can only provide reliable qualitative rather than quantitative information.

Some opinion supports the routine use of an estimate of postvoid residual volume to exclude large residual volumes as a potential source of leakage or as a potential risk factor for retention after surgery, but this is not unanimously agreed upon.

TABLE 1 The evaluation of the different diagnostic tests for SUI, indicating whether they assess structure or function, or are of use in research (i.e. studies into the pathophysiology of SUI), the routine setting (i.e. before instituting conservative or noninvasive therapy) or clinical studies (specifically with injectable agents). The tests are classified into those that may form part of the simple evaluation adequate to initiate conservative, noninvasive therapy in the index patient, and additional investigations as necessary

Test	Evaluates structure	Evaluates function	Research use‡	Routine use	Use in studies of injectable agents
Simple evaluation (for conservative, noninvasive therapy)					
Symptoms	–	✓	✓	✓	✓
History	–	✓	✓	✓	✓
Questionnaires	–	✓	✓	✓	✓
Diaries	–	✓	✓	✓	✓
Quality of life/bother	–	–	✓	✓	✓
Physical examination (POP), including speculum and bimanual	✓	–	✓	✓	✓
Physical examination (neurological)	–	+–	✓	✓	✓
Stress or cough test	–	✓	✓	✓	✓
Pelvic floor assessment	–	+–	✓	✓	✓
Post-void residual volume	–	✓	✓	✓*	✓
Additional investigations					
Pad test	–	+–	✓	–	+–
ALPP	–	✓	✓	–	✓
UPP	–	✓	✓	–	✓
Non-invasive uroflowmetry	–	✓	✓	✓*	✓
Ultrasonography	✓	–	✓	–	–
Cysto-urethrography	+–	+–	–	–	–
MRI	✓	✓	✓	–	✓
Pressure-flow urodynamics	–	✓	+–	✓ †	+–
Videocystometry	✓	✓	+–	✓ †	+–
Cysto-urethroscopy	+–	–	–	–	–
Electromyography	–	+–	✓	–	–
Five-level improvement scale (subjective)	–	+–	✓	✓	✓

*+–, Limited information/use; *Not a unanimous recommendation; †Only recommended in routine use to answer a specific question; ‡This assessment represents the views of the authors, as any test should be permitted for research use. Urine analysis and assessment of oestrogen status were not evaluated.*

Pad tests are considered of little benefit in the routine setting. In clinical studies, the lack of standardization is problematical, but they may be useful if patients with POP are excluded, or as a secondary outcome.

ALPP is not recommended for routine use because there is no standardization; it is of benefit when using clearly defined criteria in the research and clinical study setting, but a clear need exists to standardize this test for the future. UPP is standardized in theory but not in practice, and it was agreed that the use of a microtip or fibre-optic catheter was the preferred method.

MRI can give information about anatomical structure (and function if dynamic scanning is used). It is inappropriate for routine use at present and is recommended only in studies to provide an insight into a particular problem.

Pressure-flow urodynamic studies and videocystometry are only advocated in routine practice where it is appropriate to find the exact pathophysiology, particularly before invasive and potentially irreversible procedures. Medicolegal issues may dictate the routine use of cystometry/videocystometry in certain countries.

Subjective 5-level Likert scales (e.g. rating symptoms as worse, unchanged, small improvement, improved or much improved) are of particular relevance in monitoring the success of interventions.

CONCLUSIONS

The Second ICI recommended a flow chart for the initial assessment of UI in women [2]; considering the available evidence as reviewed here, we provide additional guidance by proposing an amended flow chart for managing SUI in the index patient (i.e. uncomplicated SUI; Fig. 1).

A clinical examination and assessment of patient history form the basis of SUI diagnosis, with the use of many urodynamic techniques in clinical practice often limited by lack of standardization, complexity and cost. On the basis of current publications, a simple preoperative evaluation is adequate to allow the initiation of conservative, noninvasive therapy. More extensive analysis (i.e.

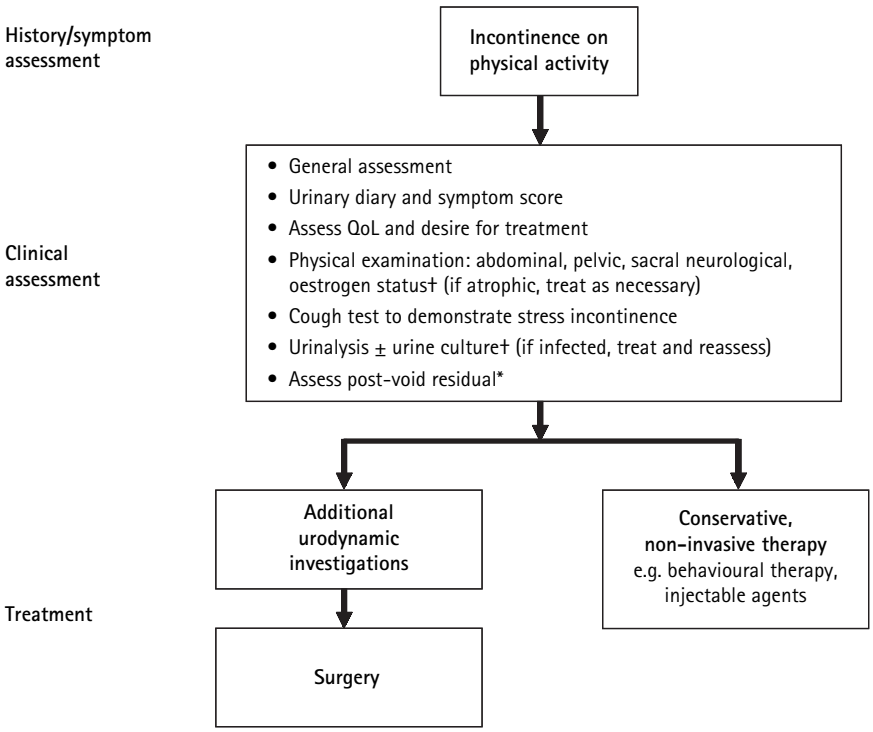
urodynamics) is needed in patients with POP and SUI who require more invasive and complex surgical treatment. Furthermore, some index patients may require surgery, or the clinician may deem it appropriate, particularly after failed surgery, in a complex or a critical situation or where neurological disease is evident.

It is clear from existing reports that the appropriate diagnosis of SUI poses many challenges, both in the need to clarify the role of the relative components of ISD and hypermobility, which appear to exist across a spectrum, and to determine their influence on treatment outcome. The availability of newer dynamic and anatomical investigative techniques, such as functional MRI, is anticipated to facilitate an increased understanding of SUI.

CONFLICT OF INTEREST

None declared.

*FIG. 1. Flow chart for managing SUI in the index patient (i.e. uncomplicated SUI with a clear history of incontinence associated with physical activity). *Not a unanimous recommendation; †not evaluated in this review.*



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Abbreviations: **SUI**, stress urinary incontinence; **ISD**, intrinsic sphincter deficiency; **ICI**, International Consultation on Incontinence; **OAB**, overactive bladder syndrome; **POP**, pelvic organ prolapse; **A(C)(V)LPP**, abdominal (cough) (Valsalva) leak-point pressure; **UPP**, urethral pressure profilometry; **FUL**, functional urethral length; **MUCP**, maximum urethral closure pressure; **FDA**, Food and Drug Administration.