The National Institute for Clinical Excellence (NICE) is a special health authority of the National Health Service in England and Wales. It is an independent organization responsible for providing national guidance on promoting good health, preventing and treating ill health, and publishing clinical appraisals of whether particular treatments should be considered worthwhile by the National Health Service. However, its role in rationing treatment has led to NICE becoming a controversial body, and it has gained a high profile internationally as a potential role model for the explicit prioritization of health services.

According to NICE and the International Consultation on Incontinence (ICI), urodynamic evaluation still represents a useful diagnostic tool for the assessment and management of incontinent women, and it is recommended before undergoing a surgical procedure if there is clinical suspicion of detrusor overactivity, there has been previous surgery for stress incontinence or anterior compartment prolapse, or there are symptoms suggestive of voiding dysfunction.1,2 Nevertheless, it has been recently reported that multichannel cystometry might be unnecessary for women who complain only of stress urinary incontinence (SUI).2-4 Therefore, the aim of our study was to assess the clinical value of performing multichannel cystometry in women with a history of pure SUI.

MATERIAL AND METHODS

Consecutive women with lower urinary tract symptoms referred to the urodynamic clinic of a teaching hospital between January 2000 and January 2007 were studied retrospectively. On referral, all women were sent a quality of life questionnaire (King’s Health Questionnaire [KHQ])5 and a 3-day frequency-volume chart, which they completed before their urodynamic appointment. The lower urinary tract symptoms were assessed by analyzing the bladder diary and the symptoms section of the KHQ.

Women with active urinary tract infections at the time of their appointments did not proceed to urodynamic investigation. They were first treated and examined to confirm that they were infection free before urodynamic examinations.

All women underwent urodynamic studies according to a standardized protocol.6-7 Each woman was asked to attend for urodynamic studies with a comfortably full bladder. Uroflowmetry was performed, with the woman voiding in private and recorded on a gravimetric flowmeter. The postmicturition urinary residual was measured through the filling catheter used for cystometry.

Dual channel cystometry was performed with each woman supine and the bladder filled through a 10F filling catheter; a fluid-filled 4.5F catheter was used to measure the intravesical and abdominal pressures. The bladder was filled with room-temperature saline at 100 mL/min. Provocative maneuvers were used with each woman in a standing position. Women were asked to cough 1, 3, and 5 times with maximal effort and then to listen to running water and wash their hands in cold water. Finally, they were seated for a pressure-flow study that
was performed in private. Urinary symptoms and urodynamic reports were analyzed retrospectively.

The women's symptoms were determined from the frequency-volume chart and the symptom section of the KHQ that each woman completed before the urodynamic testing. Women who had symptoms of increased daytime frequency, nocturia, urgency, and urge urinary incontinence were excluded; thus, only women who had pure SUI were included in the study. All terms and definitions are in accordance with the International Continence Society terminology.4 Urodynamic stress incontinence was classified as mild, moderate, and severe depending on whether leakage of urine occurred after 1, 3, or 5 coughs, respectively.8 This classification is based on the fact that previous studies demonstrated that the severity of incontinence, as judged on video cystometrogram, correlates with an increased mean 1-hour pad weight of 3, 5, and 12 g, respectively.6 Women with prolapse symptoms, pelvic organ prolapse ≥stage II,9 or history of previous continence surgery were excluded from the study. Ethical approval was not needed, because this study was an audit of our standard of care.

The frequency of the different urodynamic diagnoses was calculated. The Spearman rho coefficient was used to evaluate the correlation between severity of urinary incontinence, based on the bladder diary, and the severity of urodynamic stress incontinence, assessed by urodynamic investigation. A version 14.0 Statistical Package for the Social Sciences database (SPSS Inc., Chicago, IL) was used for the statistical analysis.

RESULTS
A total of 3428 women aged 24-81 years were studied. Of these, 52% (1784/3428) of women complained of urinary incontinence, whereas 48% (1644/3428) self-reported to be dry. Only 308 women (8.9%) could be classified as having pure SUI. The frequency of urinary symptoms is shown in Figure 1.

Of the women who complained of only SUI, 78.2% (241/308) had urodynamic stress incontinence, 7.5% (23/308) had detrusor overactivity, 2.9% (9/308) had urodynamic stress incontinence and detrusor overactivity, and 11.4% (35/308) had inconclusive urodynamics (no urodynamic abnormality). The women with inconclusive urodynamics were investigated further with urethrocystoscopy and/or ambulatory urodynamics. Ambulatory urodynamic evaluations revealed that all of these women had detrusor overactivity.

Of the women with pure SUI, 46.8% (144/308) had mild urodynamic stress incontinence, 19.5% (60/308) had moderate urodynamic stress incontinence, and 12% (37/308) had severe urodynamic stress incontinence. A postvoid residual (PVR) >100 mL was noted in 24 (7.8%) women. The uroflowmetry parameters of women with a high PVR are shown in Table 1. The correlation between severity of urinary incontinence based on the bladder diary, and the severity of urodynamic stress incontinence (mild, moderate, and severe) assessed by urodynamic investigation was very weak (Spearman rho 0.186; P = .001).

COMMENT
The assessment of incontinent women, especially before a surgical treatment, still remains controversial. Some authors believe that urodynamic evaluations are mandatory before embarking on continence surgery, supporting the concept that the “bladder is an unreliable witness,” because symptoms are not predictive of diagnosis and urodynamic investigations might provide useful information about the urethral sphincter and detrusor function. According to these authors, such investigations will help the clinician’s preoperative counseling and management of incontinent women. Cundiff and colleagues studied 535 incontinent women and concluded that pure symptoms identified less than half of the patients with urodynamic stress incontinence, therefore recommending urodynamic evaluations for all patients considering surgical intervention.10-14 By contrast, other authorities recognize that multichannel urodynamic testing is an imperfect diagnostic method and an invasive, expensive, time consuming, and not perfectly reproducible tool for both patients and clinicians, in addition to not being universally available.15-17

Health insurance companies are also questioning the medical necessity for full urodynamic testing.18 However, it is unclear whether this lack of endorsement is motivated by cost saving or the belief that the tests do not add value.19 Therefore, multiple studies in the recent litera-
ture have attempted to identify reliable and inexpensive methods for the assessment of patients with urinary incontinence.\textsuperscript{15,16,20}

The cough stress test has been used for several years by physicians worldwide as a screening and diagnostic test for incontinent women.\textsuperscript{21} Several studies have compared the cough stress test with multichannel urodynamic investigations. These studies demonstrated that the stress test had a good sensitivity and specificity in the diagnosis of urodynamic stress incontinence when compared with sophisticated multichannel cystometry, making it a standard tool commonly used by physicians to evaluate incontinent women before surgery and to measure the surgical outcome.\textsuperscript{21-23} Thompson et al retrospectively studied 212 women with SUI aged 50 years or younger and suggested that for those women, a careful minimal evaluation including only a symptom questionnaire, a cough stress test, and a PVR was needed. The authors finally concluded that at this stage of our knowledge, and especially in this era of managed care and cost containment, urodynamic investigations might be avoided in women under 50 unless there is a complex of symptoms like significant stress incontinence, marked prolapse, or history of prior retropubic urethropexy. They also concluded that urodynamics have no effect on preventing or predicting postoperative voiding problems.\textsuperscript{19}

In light of the reported data, urodynamic studies should be considered a useful tool to demonstrate different causes of urinary symptoms that are not specific and are poor indicators of the underlying diseases. They are important to guide the clinician in the accurate management of patients; this will lead to the selection of women who will benefit from anticholinergic treatment or anti-incontinence surgery and who will need to be investigated further before commencing any therapy that may be inappropriate. Therefore, urodynamic studies are mandatory in the assessment and counseling of incontinent women to obtain a more accurate preoperative diagnosis. This may aid the clinician in the detection of preoperative detrusor overactivity, preoperative abnormal voiding patterns (high postmicturition residual, obstructed flow), and de novo detrusor overactivity.

However, guidelines on assessment of incontinent women undergoing surgery are still controversial among international societies. The 1996 clinical practice guidelines published by the Agency for Health Care Policy and Research recommended considering surgery without referral for urodynamic testing only for patients with symptoms of pure stress urinary loss, because the symptom of pure SUI has been shown to have a positive predictive value for urodynamic stress incontinence of 85.7% (C statistic of 0.807).\textsuperscript{24}

The guideline on surgical treatment of SUI by the Royal College of Obstetricians and Gynaecologists (ACOG) criteria do not mention cystometrography or recommend any specific urodynamic studies in the evaluation of women with SUI.\textsuperscript{26}

Recently, the ICI and the NICE have reported that urodynamic investigations are unnecessary for women who complain only of SUI.\textsuperscript{1,2} The Guideline Development Group (GDG), confirming the Agency for Health Care Policy and Research recommendations, reported that urodynamic investigation is not routinely recommended and is not essential in every woman before primary surgery for SUI because there is no evidence that pretreatment multichannel cystometry will improve the outcomes of treatments for incontinence (available at http://www.nice.org.uk/guidance/CG40/guidance/pdf/English/download.aspx). In summary, GDG concluded that preoperative urodynamic evaluations are not necessary for women with a clearly defined clinical diagnosis of pure SUI, because in these women a simple clinical stress test may be as accurate as multichannel cystometry in the diagnosis of SUI.\textsuperscript{3}

In light of our data, we can conclude that a simple and accurate evaluation of symptoms using self-completed, standardized, and validated questionnaires represents an adequate diagnostic and screening tool in the assessment and management of incontinent women. In spite of the high predictive value of a stress test in diagnosing urodynamic stress incontinence, urodynamic investigations have to be regarded as necessary before continence surgery for women who complain of pure SUI because as much as 20% of these women will have a diagnosis of detrusor overactivity. As a consequence, this latter group of women will need different counseling and management. Finally, preoperative urodynamic examination is recognized to contribute to improved patient counseling and predict surgical outcomes as well as postoperative complications such as voiding difficulty and de novo detrusor overactivity.\textsuperscript{27,28}

**CONCLUSIONS**

The results of our study involving a large dataset disagree with the NICE and GDG recommendation and should lead to a careful revision of the guidelines for the management of pure SUI. Although women with a history of pure SUI are very few, representing only 8.9% of those who attend urodynamic clinics for lower urinary tract symptoms, we demonstrated that the use of urodynamic examinations before undergoing continence surgery should be recommended in these patients. In the absence of urodynamic examinations, accurate counseling of women undergoing continence surgery remains mandatory, because preoperative detrusor overactivity and postoperative voiding difficulties, which might affect the surgical outcome, cannot be excluded. However, to address the issue in more detail, a large prospective trial in which patients are randomly assigned to management according to urodynamic findings vs. management based on history and clinical examination is still needed.
References


EDITORIAL COMMENT

The authors present an extensive review of a large number of urodynamic assessments, representative of a single institutional experience, and the role of those urodynamic evaluations in assessment of stress incontinent women. Other groups have found less value in the outcome predictive capability of urodynamic testing. However, the value of urodynamic assessment for better characterizing initial symptoms, especially in an individual considering invasive intervention, has, heretofore, been less well characterized. What is thought-provoking in this report is that only patients adjudged to manifest pure symptomatic stress incontinence were subsequently reported. Twenty percent of the study population had findings possibly influencing treatment choice or outcome of intervention.

Surgical intervention for a quality of life condition should be founded upon a thorough evaluation of the symptoms affecting the individual seeking therapy (to create reasonable expectations), blended with objective documentation of signs of the condition (that being sphincteric incontinence). The authors of the current study blend their urodynamic evaluation with a symptomatic assessment, using the subjective symptoms as a method to further qualify their patients. In reality, this combined use of subjective and objective assessment is the current “Snapshot” of the best evaluative paradigm, reflecting our increased understanding of the importance of objectifying the type and degree of symptoms on the foundations of symptomatic appraisal.

The trend toward evaluative nihilism is posited upon concerns including cost effectiveness thereof (the concept of least expensive alternative), patient safety and solicitude (instrumentation-related issues and patient modesty), and the purported lack of sensitivity of more exhaustive techniques, such as urodynamic evaluation, to add any discreet additional outcome predictive value. Although all of these concerns are valid and supported by evidence, the evolving science of outcomes reporting would suggest that the blended use of appropriate tools to ascertain type, magnitude of the symptom as well as associated bother, represents the current state of the science.

The authors are leaders in their field internationally, and reflect upon standards and criteria established by an organization entity (NICE) advisory to the National Health Service. NICE guidance positions are used by the NHS to establish