

# **REVIEW ARTICLE**

# Executive Summary: The International Consultation on Incontinence 2008—Committee on: "Dynamic Testing"; for Urinary Incontinence and for Fecal Incontinence. Part 1: Innovations in Urodynamic Techniques and Urodynamic Testing for Signs and Symptoms of Urinary Incontinence in Female Patients

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Aims: The members of "The International Consultation on Incontinence 2008 (Paris) Committee on Dynamic Testing' provide an executive summary of the chapter 'Dynamic Testing' that discusses (urodynamic) testing methods for patients with signs and or symptoms of urinary incontinence. Testing of patients with signs and or symptoms of faecal incontinence is also discussed. **Methods:** Evidence based and consensus committee report. **Results:** The chapter 'Dynamic Testing' is a continuation of previous Consultation-reports added with a new systematic literature search and expert discussion. Conclusions, based on the published evidence and recommendations, based on the integration of evidence with expert experience and discussion are provided separately, for transparency. **Conclusion:** This first part of a series of three articles summarizes the committees recommendations about the innovations in urodynamic study techniques 'in general', about the test characteristics and normal values of urodynamic studies as well as the assessment of female with signs and or symptoms of incontinence and includes only the most recent and relevant literature references. *Neurourol. Urodynam.* 29:140–145, 2010. © 2009 Wiley-Liss, Inc.

Key words: consensus report; fecal incontinence; incontinence (female); urinary incontinence; urodynamics

# INTRODUCTION

Subsequent to the first two "Urodynamic Testing" chapters of the International Consultation on Incontinence (ICI) reports,<sup>1,2</sup> the third report expanded from "urinary incontinence," to the inclusion of recommendations for the (diagnostic) management of fecal incontinence, additionally to recommendations considering urinary incontinence (UI).<sup>3</sup> Consequently, the chapter was renamed "Dynamic Testing" at that time and this is remained in the fourth report of which we (members of "The ICI 2008 Committee on Dynamic Testing": ICI-CDT) provide an executive summary.<sup>4</sup>

The ICI-report, with the ICI-CDT chapter discussed here, has the intention to provide recommendations on the basis of the most reliable evidence for the current state of assessment of the patient with urinary or fecal incontinence. To this aim, dedicated and systematic literature searches were performed on the basis of keywords and on the basis of articles related to references in the previous ICI-reports. Throughout the chapters' text "conclusion(s)": solely and entirely based on the published scientific evidence, and "recommendation(s)" are highlighted. The "recommendations" are the integration of scientific evidence with the expert group consensus, together with the discussion with the attendees during the ICI meeting. Conclusions are separated from recommendations to produce maximum transparency about the "evidence base" of the recommendations. Likewise obtained "topics(s) for research" are also highlighted in the text of the ICI-report.

Conflicts of interest: none. Christopher Chapple led the review process. \*Correspondence to: Peter F.W.M. Rosier, MD, PhD, Department of Urology, C 04.236, University Medical Centre Utrecht, P.O. Box 85500, 3580GA Utrecht, The Netherlands. E-mail: p.f.w.m.rosier@umcutrecht.nl Received 6 May 2009; Accepted 12 May 2009 Published online 19 August 2009 in Wiley InterScience (www.interscience.wiley.com) DOI 10.1002/nau.20764



The term "Urodynamic studies" (UDS) was defined by the International Continence Society (ICS) in 1988 and ... involves the assessment of the function and dysfunction of the urinary tract by any appropriate method."  $^{5}$  A more recent report in 2002 did not alter the definition of "urodynamic studies" or "urodynamics" but added definitions of "urodynamic observations."6 The conventional viewimplicitly adopted in the previous standardizations and consultations-is that urodynamics is a series of more or less agreed-upon clinical tests, such as flow studies, filling cystometry, pressure-flow studies and/or assessments of urethral closure function. These can be combined with simultaneous electromyography recording and/or imaging by either X-rays or ultrasound. Also agreed upon is that UDS are the objective way to determine why people have lower urinary tract symptoms (LUTS) and the way to gain understanding of an individuals lower urinary tract (LUT) behavior in relation to what is known about normal-or expected abnormal-physiology.7

In this executive summary we discuss the chapter "Dynamic Testing" from the ICI-report in three parts: "Testing of male patients with symptoms of incontinence, of patients with relevant neurological abnormalities and testing of children and in frail elderly with symptoms of incontinence," in the second part and "Testing in patients with fecal incontinence" in the third part. The innovations in UDS techniques "in general," the test characteristics and normal values of UDS as well as the assessment of female with signs and or symptoms of incontinence are discussed in this, first, part.

The original ICI-report provides a very extensive literature references list. For this summary we have only included the most recent (publication year > 2000) and relevant literature references.

### CONVENTIONAL URODYNAMIC STUDIES

Following a general introduction of the chapter, the ICI-CDT discusses, in the first paragraphs of the fourth report, the "fundamental" and technical aspects of conventional UDS; uroflowmetry; filling cystometry; pressure-flow studies (void-ing cystometry); urethral pressure profilometry; and the assessment of leak point pressure (LPP). The ICI-CDT has not found any evidence for fundamental or technical changes of these tests, and the report provided no (renewed) conclusions or recommendations for these.

### **TECHNOLOGICAL INNOVATIONS**

Five technological innovations are discussed on the basis of new studies. The ICI-CDT concluded that: However air-charged catheters may provide an acceptable alternative to other techniques for measuring the pressure closing the female urethra, there have been no studies to show whether these catheters provide an acceptable alternative to fluid-filled lines for measuring intravesical and intra-abdominal pressure in UDS.<sup>8</sup> The ICI-CDT recommends investigators, planning to use air-charged catheters for intravesical and intra-abdominal pressure in UDS, to check that they have an equivalent performance to their current system. Comparative studies are suggested for research in this regard. Some reports on the development of an objective method to assess bladder filling sensation during cystometry have been published.<sup>9</sup> The ICI-CDT concludes that these developments are desirable. However, whether this improves the reproducibility and sensitivity or specificity of UDS has yet to be determined. The third innovation: manuscripts regarding non-invasive measure-

ments of pressure and flow in men by the penile cuff or condom catheter report these to be as clinically useful as the traditional invasive measurement of pressure and flow.10-12 The ICI-CDT recommends that non-invasive measurements of pressure and flow should be considered when the-further appropriate-patient is not required to undergo an invasive assessment of the storage function of the LUT. ICI-CDT has not found evidence that urethral retro-resistance pressure measurements give any better information about urethral closure function than the urethral pressure profile (UPP) or Valsalva LPP and recommends that these measurements should be discouraged for clinical practice.<sup>13,14</sup> Some evidence shows that measurement of opening pressure from urethral pressure reflectometry can have more power to separate women with stress urinary incontinence (SUI) from those with normal urinary control.<sup>15,16</sup> The ICI-CDT recommends that further studies are undertaken to investigate the clinical usefulness of urethral pressure reflectometry.

## URODYNAMIC TECHNIQUES; NORMAL VALUES, RELIABILITY, AND DIAGNOSTIC PERFORMANCE

Considering the literature about inter-observer variation, test-retest, and practice variation; short-term (withinsession)-, intermediate-, and long-term reproducibility of UDS, the ICI-CDT concludes that a number of reports describe a test retest variation of  $\pm 10-15\%$  for various parameters (volume, pressure, or flow), which can be regarded as the physiological variation of UDS.<sup>17</sup> Various studies have, however also, demonstrated clinically relevant inter-practice variation and inter-rater/observer variation.<sup>18,19</sup> The committee recommends that investigators and clinicians take into account the inherent physiological variability of UDS and, with this in mind, recommends evaluation of the "representativity" of the individual tests (which is an evaluation based on the patient's perception as to how well the tests have reproduced their usual LUT function). The ICI-CDT recommends that examiners strive towards maximal representativity of the test. To reduce inter-practice and interobserver variation the ICI-CDT strongly recommends constant attention to the standardization of techniques and interpretation as well as intensive dissemination of up-to-date standards and careful training of investigators. Evaluation of the effect of these standards and training on health care quality is also recommended.

There have been studies that provide normal values of volume, compliance and sensation(s) during filling cystometry and the ICI-CDT concluded that these studies have been helpful.<sup>20–22</sup> There is however also some evidence that evaluation of filling sensation may be different between laboratories, (thus: "may be observer dependent"), making data exchange as well as generalization and interpretation of published data difficult. The ICI-CDT recommends that investigators and clinicians bear in mind the results of UDS in healthy persons and to recognize "normal" test-retest variation as well as the differences and/or variations between "usual LUT behavior," ambulatory monitoring and office UDS. The ICI-CDT recommends further standardization and (further) development of a practical objective means of recognizing and recording the parameters relevant to sensation(s) during bladder filling.

The ICI-CDT has not found new evidence about ambulatory urodynamics with regard to normal values, reliability, and diagnostic performance.

There is, in general, evidence that flow is reduced with a catheter in the urethra and that this reduction is partially

caused by the size of the catheter.<sup>23</sup> It is the opinion of the committee, but there is no "real" evidence, that dual catheter cystometry methods are disadvantageous because removal of a separate filling catheter just before voiding may displace the pressure sensor and very likely interferes with the representativity of LUT function during (attempted) micturition. The ICI-CDT suggests the standard use of, as thin as possible (e.g., 5–7F), double-lumen catheters for filling and pressure recording during UDS and recommends that investigators interpret pressure-flow voiding parameters and the subsequent postvoid residual urine (PVR) together with the uncatheterized (and as representative as possible) voiding parameters, preferably of multiple flows.

Various studies have shown considerable test-retest variation of all urethral pressure measurements or parameters. Various studies have also shown that normal and pathological values of urethral pressure parameters are largely overlapping and that urethral pressure(s) (parameters) are affected by age, by volume of fluid in the bladder and by the position of the patient and on orientation of the pressure sensor within the urethra.<sup>24</sup> The committee recommends that investigators and clinicians recognize the poor sensitivity and specificity of urethral pressure measurements and their "usual" test retest variation and consequently does not recommend urethral pressure measurement as the only ("single and isolated") UDS in patients with UI. The ICI-CDT additionally recommends that the clinical relevance of urethral pressure measurements, when performed, is judged in relation to other UDS (such as cystometry) and to the clinical examination.

The ICI-CDT has observed that various definitions and techniques to determine (urine) LPP exist and has concluded that there is a weak association of "all" (abdominal) LPPs and the patient experienced or measured severity of UI. Furthermore the ICI-CDT concluded that "isolated" parameters from abdominal LPP measurements are not reliably helpful as predictors of success for tension-free vaginal tape (TVT), transobturator tape (TOT) or suburethral sling-treatment of patients with SUI.<sup>25–27</sup> The committee recommended that the result of (abdominal) LPP measurements, when performed on patients with UI, should be judged in relation to other UDS such as cystometry and to the clinical examination. The ICI-CDT does **not** recommend (abdominal) LPP measurement as a single ("diagnostic-conclusive of LUT function") UDS in patients with UI, without relevant neurological abnormalities.

Considering the diagnostic performance of filling cystometry and ambulatory monitoring the ICI-CDT has concluded that many studies have demonstrated the weak correlation between symptoms and the result of UDS, especially cystometry, in patients with UI.<sup>25,26</sup> The correlation of the symptom "SUI" (expressed or questioned) with the result of UDS is somewhat better than the correlation of urgency or urgency urinary incontinence (UUI; expressed or questioned) with UDS.<sup>28</sup> The ICI-CDT concludes that when frequent voiding, urgency and/or UUI is part of the symptom complex of patients with UI, UDS is of value to obtain an objective diagnosis.<sup>29–31</sup> The ICI-CDT recommends UDS in patients with UI when an objective diagnosis is warranted. This is commonly the case when symptoms do not exclusively direct to SUI, when (for all types of UI) conservative measures have not been successful, when relevant co morbidity exists or, when relevant previous surgery is performed. The committee considers it important that investigators and clinicians judge the individual representativity of the results of the performed tests by comparison with the patients' symptoms and recommends interpretation of the results of all elements of

the testing in relation with ("complementary to") the symptoms, with the voiding diary and the clinical (or other) examinations.

Studies have not been able to show relevant differences in patterns or characteristics of detrusor overactivity (DO) when the cause of DO is neurogenic or idiopathic. Various studies have been unable to reliably quantify the severity of DO, in a clinically or scientifically applicable way.<sup>32,33</sup> The ICI-CDT recommends that neither the cause (neurogenic or idiopathic) nor the severity of DO is diagnosed on the basis of parameters from UDS (cystometry). The committee recommends further evaluation and development of objective parameters for assessing the outcome of DO treatment and preferably the development of an objective and cystometry-based DO severity scale.

A systematic review concluded that more DO is seen when the patient is in the sitting position during cystometry, when compared to the supine position.<sup>34</sup> Furthermore, there is some evidence that moving to a toilet, and hand washing, are strong provocatives of DO. Ice water cystometry can be applied to elicit detrusor activity in patients with LUT dysfunction and relevant neurological abnormalities.<sup>35,36</sup> In that case a detrusor contraction during filling with ice water can be interpreted as a sign of pathologic (existing only in patients with relevant neurology) C-fiber reflex activity, false-negative tests, however, do occur. The ICI-CDT recommends that the position of the patient during filling cystometry is taken into account because it can influence the demonstration of DO. Repetition of the cystometry in a different position can be considered when this is deemed clinically relevant. The ICI-CDT recommends that the results of provocative cystometry are interpretated in view of patients' symptoms and the representativity of the results obtained.

There have not been studies that shed light on the sensitivity and specificity of ambulatory urodynamics nor on the use of imaging and EMG adjunct to cystometry. The conclusion of the previous ICI-CDT remains that there is no (independently comparative) quantitative and only poor qualitative data on the additional value of these supplementary tests.<sup>3</sup>

#### URODYNAMIC TESTING IN FEMALE PATIENTS WITH SIGNS OR SYMPTOMS OF URINARY INCONTINENCE

Various studies have shown that the result of UDS does not perfectly predict the treatment response in all patients; neither in patients with UI with or without overactive bladder (OAB) syndrome with or without "urodynamic" DO nor in patients with "urodynamic" SUI and also not in patients with a "double" urodynamic diagnosis; combined SUI and DO.<sup>31,37–39</sup> The ICI-CDT recommends that the result of UDS is applied to "optimize" treatment strategy without attributing perfect specificity to the result of treatment, in an individual patient.

Various studies have shown conflicting results regarding the association of UI severity and urethral function tests (LPP and urethral closure pressures).<sup>24–27</sup> It is the opinion of the ICI-CDT that contemporary urethral function tests are only modestly suited to judge the severity of incontinence or to further "subcategorize" patients with stress (predominant) UI. The committee recommends that urethral "competence" measurements LPP and urethral closure pressures are not used as a single factor to grade the severity of UI and recommends caution with the prediction of the outcome of any surgical treatment on the basis of contemporary urethral function tests. The ICI-CDT suggests further studies with the aim to better understand urethral closure dysfunction, in relation to treatment for SUI or SUI predominant symptoms.

It is concluded in a model study, based on a selected retrospective cohort that UDS are not cost-effective in the primary health care setting for women with predominant SUI symptoms<sup>40</sup>. It is also shown that in the referred population, UDS is the most accurate way to obtain an objective diagnosis in patients with predominant SUI symptoms.<sup>41,42</sup> Evidence shows that symptoms of "pure SUI" do not exclude other abnormalities of LUT function.<sup>30,31</sup> The ICI-CDT recommends that the cost-effectiveness of UDS is kept in mind when discussing "cost and gain" of the various methods of diagnosis for UI, in relation to the method of treatment. The ICI-CDT suggests that large multicenter (nationwide) prospective studies might be of help to better understand the cost-effectiveness UDS in health care quality for patients with UI.

The ICI-CDT recommends that UDS are carried out in all women prior to surgical intervention for SUI and suggests that a well-designed, prospective multicenter study should address the question as to whether women with symptoms of pure SUI are more at risk of failure from treatment without UDS.

LPPs do not appear to correlate with success rates of colposuspensions, transobturator and retropubic midurethral, bone-anchored suburethral slings. There is some evidence that low urethral (closure) pressures are associated with poorer success rates of retropubic and transobturator midurethral, vaginal wall and transvaginal bone-anchored slings.<sup>43,44</sup> However the ICI-CDT acknowledges some evidence that the values of urethral closure pressure may provide guidance in this respect, the committee recommends that measurements of urethral function (LPPs and urethral pressures) are not used to exactly predict the likelihood of success after surgical treatment for SUI.

Current test methods have not been able to reliably predict patients who will develop voiding difficulties after surgery for SUI. However, the ICI-CDT has found some evidence that average and maximum flow rates may be useful in predicting postoperative voiding dysfunction and retention following retropubic and transobturator midurethral slings.<sup>45–47</sup> The committee recommends that patients are informed that it is difficult to predict who will develop voiding difficulty following surgery for SUI.

Current test methods have been unable to reliably predict which patients will develop voiding difficulties or de novo urinary urgency (or OAB syndrome) after surgery for SUI. Post hoc evidence suggests that procedures which are more "obstructive" produce a higher chance of de novo OAB syndrome.<sup>47,48</sup> The ICI-CDT recommends that patients with SUI are informed that the chance of developing OAB syndrome following surgery is largely unpredictable and suggests further work to establish predictors of voiding difficulties or

Neurourology and Urodynamics DOI 10.1002/nau

OAB after contemporary (moderately invasive) treatments of SUI (e.g., transobturator or transvaginal tapes).

Studies have shown that signs and symptoms of SUI can appear after surgery for vaginal prolapse and there is a variety of methods to uncover "occult SUI" in women with vaginal prolapse. However, all methods have different sensitivities making comparison of results difficult and the ICI-CDT concluded that concomitant procedures (with or without UDS) to address possible SUI developing after prolapse surgery are unreliable.<sup>49,50</sup> The ICI-CDT recommends that patients with vaginal prolapse are informed about the relative unpredictable chance of developing SUI after surgery for that prolapse.

Various studies have consistently concluded that the association between symptoms of OAB syndrome and DO during UDS is weak. Various studies have shown that the prediction of treatment—for OAB—response on the basis of the characterization or quantification of DO during UDS is yet impossible.<sup>51</sup> The committee recommends that investigators and clinicians discuss with patients with DO that neither UDS "quantity" nor specific characteristics of DO predicts the response of any of the therapeutic approaches. The ICI-CDT suggests further studies to find predictors of response on treatment for patients with OAB syndrome and further studies to find (UDS) predictors of response for patients with OAB without DO.

It is also the view of the ICI-CDT that comprehensive UDS should form an essential part of the evaluation of new treatment modalities and therapies in patients with signs and symptoms of LUT dysfunction, and more specific to ICI-goals; patients with UI.

### CONCLUSION

In this first part of the executive summary of the chapter "Dynamic Testing" from the fourth International Consultation on Incontinence 2008 the committee summarizes the conclusions and recommendations, on the basis of the best available evidence, of technological innovations of urodynamic studies, test characteristics, and urodynamic assessment of female patients with UI.

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#### APPENDIX A

Summary table with ICI-CDT recommendations referring to: Innovations in urodynamic techniques and urodynamic testing for signs and symptoms of urinary incontinence in female patients.

Recommendation:
To remain unchanged for clinical setting
To be standardized To study 'objective' measurements
To consider these as possible alternative to fluid filled catheters To consider the lack of studies of air charged catheters in comparision with fluid filled or microtiptransducer catheters

## 144 Rosier et al.

(Continued)

#### APPENDIX A

Urethral pressure reflectometry	To consider the in general unknown reliability to measure urethral, intravesical and or intrarectal pressure To test physical reliability in 'own' laboratory setting when applied To be further studied
Performance of urodynamics	Recommendation
Practice variation, test-retest variation, data quality of UDI-tests	To further standardize UDI and to teach examiners and to continually evaluate quality
Clinical representativity, predictive value and relevance of UDI	To evaluate UDI results in relation to individual clinical signs, symptoms (inc. diary and 'scores'), and patient history To further group wise evaluate UDI results in relation to outcome
Patient position and 'provocative' UDI	To consider effects of position and provocation in relation To relevance and representativity of UDI result
Urinary incontinence	Recommendation
Indication for UDI testing	To be done before invasive treatment To be done after failed treatment To be done (before and) after experimental treatments
Detrusor overactivity	Not to quantify DO Not to use quantification of DO as outcome of treatment Not to use DO as only (or 'discriminating') sign of neurological abnormality To further study DO in relation to burden of disease and response to treatment
UDI testing in female incontinent patients	Recommendation
Reliability, predictive value and relevance of UDI	To discuss with patients the imperfective predictive value towards 'chance to cure' on the basis or UDI To base the individual diagnosis on the <i>supplementary combination</i> of signs, symptoms and UDI-results.
UDI to predict subgroups with relevance to outcome of various treatments of stress urinary incontinence	To consider the limited ability of UDI to discriminate subgroups of stress incontinence To further evaluate potential tests to select patients for the various
UDI to predict subgroups with relevance to inadvertent outcome and risks of various treatments of stress incontinence	To consider the limited ability of UDI to predict inadvertent outcome of treatment To discuss this with the patient

The grade of these recommendations is not always identical to the level of the evidence that supports the recommendation. See introduction and ICI-CDT chapter for grading of recommendations and levels of evidence.<sup>4</sup>

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