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The evidence for urodynamic investigation of patients with symptoms of urinary incontinence

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Abstract

Urodynamic studies are the gold standard to objectively diagnose dysfunction of the lower urinary tract. The widely available evidence for the clinical relevance is, however, fragmented. This article summarizes the published knowledge supporting the use of urodynamic studies in urinary incontinence in female, male and frail patients, as well as patients with relevant neurological disease. Five technological innovations are discussed briefly. Standard urodynamic cystometry can, on the basis of a solid body of evidence, objectively unveil the entire function of the lower urinary tract in all patients with urinary incontinence, regardless of the patients' perception of (ab-)normality of signs and or symptoms.

Introduction

Lower urinary tract function and dysfunction can be measured objectively with urodynamic investigation. Urodynamic investigation requires a catheter to be inserted in the urinary bladder to measure intravesical pressure (i.e. in the urinary bladder) and a catheter in the rectum or vagina that measures the intra-abdominal pressure surrounding the bladder. Bladder muscle function can be deduced from the pressure difference between intravesical and intra-abdominal pressures. While the bladder fills, via a filling lumen in the transurethral or suprapubical intravesical catheter, the adaptation of the bladder muscle to the volume increment can be observed. Likewise, during emptying (alongside the pressure-recording catheter) the intravesical pressure can be measured together with the expelled fluid flow. This flow can be measured in a beaker that records the volume increment, and integrated to deduce the flowrate in mL/s. Urodynamic investigation and the terms used in functional (neuro-) urology and urodynamics are standardized [1,2]. As well as abnormalities of emptying, storage function can also be observed.

Urinary incontinence is a prevalent storage dysfunction. Urodynamic investigation is applied to differentiate stress urinary incontinence from urgency urinary incontinence. The urethral closure function is insufficient in stress urinary incontinence and the volume adaptation is insufficient in urgency urinary incontinence. Usually, the detrusor contracts too early in urgency urinary incontinence, and this is termed detrusor overactivity. Detrusor overactivity may cause frequent and urgent voiding (with or without urinary incontinence); a combination of symptoms that is usually referred to as overactive bladder syndrome – a syndrome that is, however, neither specific nor sensitve to the urodynamic diagnosis of detrusor overactivity.

Urodynamic studies

As with many diagnostic tests in medicine, the technique used for urodynamic investigation has developed over the years and has gradually been implemented in clinical practice from its first clinical applications in the late 1950s until now. Technical developments, as well as increasing knowledge about lower urinary tract neurology, physiology and pathophysiology have refined our insight into the diagnostic possibilities of urodynamic investigation. The invasiveness of urodynamic investigation remains a drawback and raises the threshold for its use, although the true morbidity is modest. Alternatives

have been sought in precise and/or standardized clinical evaluation and grading of the patients' perceived symptoms, but have consistently failed to achieve a predictive value that is reliable in clinical practice [3,4]. More recently, alternative methods to evaluate the function of the lower urinary tract have been developed, most of them with the aim of avoiding the need for transurethral catheterization [5,6].

The general consensus is that the "definitive level 1 study" to show the clinical value of urodynamic investigation for urinary incontinence has never been published, and that the overall level of evidence for the clinical value of urodynamic investigation is low [7]. There is, however, a large body of evidence for urodynamic investigation of patients with urinary incontinence, but this evidence is rather scattered throughout the literature. This work intends to give an overview of the current state of the art of urodynamic investigation for patients with urinary incontinence.

Normal values, reliability and diagnostic performance

There is a great variety of literature about inter-observer variation, test-retest, and practice variation and short-term (i.e. within the session), intermediate-, and long-term reproducibility of urodynamic investigation. A number of reports describe what can be summarized as a test-retest variation of ±10-15% for various parameters (volume, pressure or flow). Basically, this variation can be regarded as the physiological variation of lower urinary tract function [8]. Diverse studies have, however, also demonstrated clinically relevant inter-practice variation, and inter-rater/observer variation, so applying standard techniques and continuous quality control is of the utmost importance [9,10].

There have also been studies that provided values for volume, compliance and filling sensation(s) during cystometry that can be regarded to be "normal" [11-13]. These studies have been helpful in understanding lower urinary tract function, but there is also some evidence that the evaluation of filling sensation and of "capacity" may be different between laboratories, and thus "may be observer-dependent". This makes data exchange, as well as generalization and interpretation of published data, difficult. It is important, while judging the result of urodynamic investigation, to bear in mind neuroanatomy and -physiology, including test-retest variation and the sensations that can be expected in healthy persons [9]. Also, the laboratory situation may cause a variation in the patient's usual "lower urinary tract behaviour". This means that volumes and urodynamic filling sensations and capacity have to be weighed against the information from the patients' voiding diary [14].

Urodynamic testing for (bladder storage phase) urinary incontinence is incomplete without evaluation of the voiding phase. Flow rate during voiding may also be less with a catheter in the urethra and, to some degree, this can be caused by the size of the catheter [1]. Such "mechanical" effects are, however, usually larger in male than in female patients [15]. Possibly, the test situation – being stressful for the patient – together with the catheter, influence the voiding. Dual catheter cystometry methods seem disadvantageous in this regard, because removal of a separate filling catheter just before (attempted) micturition interferes with lower urinary tract function and may also displace the intravesical pressure-sensing catheter [1,16]. As thin as possible (e.g. 5-7F), double-lumen catheters for filling and pressure recording during urodynamic investigation are regarded as the gold standard [1], and the majority of patients are able to void relatively well with these in place. Nevertheless, investigators should interpret pressure-flow voiding parameters and the subsequent post-void residual urine together with the catheter-free voiding parameters, preferably of multiple flows.

Urodynamic testing

Female patients with signs of urinary incontinence

The majority of studies to date demonstrate a weak correlation between symptoms and the results of urodynamic investigation, especially cystometry, in patients with urinary incontinence [3,4,17,18]. This indicates that symptom assessment does not give very sensitive, nor very specific, results with which to define the precise dysfunction of the lower urinary tract. Recruitment of data from a recent large study demonstrates that only a very small proportion of patients referred with urinary incontinence could be diagnosed as "uncomplicated stress-predominant urinary incontinence" on the basis of symptoms and the sign of urinary loss during stress testing [19,20]. Nevertheless, the correlation of the symptom "stress urinary incontinence" (expressed by the patient or concluded after questioning by the physician) with the result of urodynamic investigation is somewhat better than the correlation of urgency urinary incontinence (expressed, or questioned) with urodynamic investigation [21]. When frequent voiding, urgency and/or urgency urinary incontinence is part of the symptom complex of patients with urinary incontinence, urodynamic investigation is of value to obtain an objective diagnosis [12-24]. Objective diagnosis is warranted when signs and symptoms do not exclusively direct one to stress urinary incontinence.

Patients with initial presentation of urinary incontinence, which is a sometimes devastating but usually not life-threatening dysfunction, can, however, be treated conservatively on the basis of specific clinical examination and a drinking-voiding diary, preferably over three days and determination of post void residual urine, preferably after flowmetry [25]. In cases of all types of urinary incontinence, where conservative measures have not been successful, and particularly if relevant (neurological) co-morbidity exists on relevant previous surgery that has been performed, urodynamic investigation is usually necessary before initiating a specific and/or more invasive treatment [26].

The results of urodynamic investigation must always be compared with the patients' signs and symptoms, and interpreted in the context of the expressed symptoms, voiding diary and clinical (or other) examinations in order to obtain a sound diagnosis.

There have not been any studies to show differences in patterns of neurogenic or idiopathic detrusor overactivity. Existing studies have been unable to reliably quantify the severity of detrusor overactivity, in a clinically or scientifically useful way [23,24]. No evidence that the cause, neurogenic or idiopathic, or the severity as perceived by the patient, of detrusor overactivity can be diagnosed from urodynamic investigation (cystometry). A recent review [29] concluded that the incidence of detrusor overactivity is higher when the patient is in the sitting position during cystometry, rather than the supine position [27], and furthermore, there is some evidence that moving to a toilet, the sound of water and hand washing can cause detrusor overactivity.

No publications have shed light on the sensitivity and specificity of imaging and electromyograph adjunct to cystometry, nor are there studies that allow extrapolation to the added value of ambulatory urodynamics [26].

Various publications have shown that values of urethral pressure (profile) parameters in women with, or without, incontinence are largely overlapping and that urethral pressure(s) is affected by the volume of fluid in the bladder, the position of the patient and the orientation of the pressure sensor within the urethra [28]. The poor sensitivity and specificity of urethral pressure measurements and their large test-retest variation limits their value in patients with urinary incontinence. Furthermore, reliable "sub-typing" of urinary incontinence between stress urinary incontinence and detrusor overactivity on the basis of urethral pressures has never been possible. Various studies have shown conflicting results of urethral function tests, such as urethral profiles and closure pressures or leak point pressures in relation to urinary incontinence severity [17,18,29,30]. Contemporary urethral function tests are only very modestly suited to further "sub-categorize" patients with stress (predominant) urinary incontinence for treatment, or to judge the severity of incontinence [34]. If performed, urethral pressure measurements should be judged while taking other urodynamic investigation (such as cystometry) and clinical examination into account. Parameters from abdominal leak point pressures measurements are not reliably helpful as single predictors of success for sub-urethral sling or tape treatment of patients with stress urinary incontinence [30,31]. Abdominal leak point pressures measurement cannot be used as a single urodynamic investigation to predict treatment success for patients with urinary incontinence.

Several studies have shown that the results of urodynamic investigation alone do not perfectly predict the treatment response in all patients: neither in patients with urinary incontinence (with or without overactive bladder syndrome or urodynamically confirmed detrusor overactivity) nor in patients with stress urinary incontinence (with or without detrusor overactivity) [22,32-34]. The urodynamic diagnosis or diagnoses should therefore be interpreted in combination with the individual patient's signs, symptoms and other tests to select the optimal treatment strategy. It should be kept in mind, however, that the urodynamic investigation is the most objective element of the diagnostic strategy.

It was concluded in a model study, based on a selected retrospective cohort, that urodynamic investigations are not cost effective in the primary healthcare setting for women initially presenting with predominantly stress urinary incontinence symptoms [35,36]. It was, however, also shown that in the referred population, urodynamic investigation is the most accurate way to obtain an objective diagnosis in patients with predominantly stress urinary incontinence symptoms [35,37]. Evidence shows that "symptomatically genuine" stress urinary incontinence does not exclude diagnosis of other abnormalities of lower urinary tract dysfunction [30,22].

There is conflicting evidence that low urethral closure pressures and voiding dysfunction or an underactive detrusor are associated with poorer success rates of retropubic and transobturator midurethral, vaginal wall and transvaginal bone-anchored slings [38-42]. Leak point pressures and urethral pressures are not recommended routine tests [25]. Evidence for voiding dysfunction is regarded as useful for the individual, although in female patients both bladder outlet obstruction and underactive detrusor are not unambiguously defined

[25,43]. It has also not been possible to predict very well, with contemporary urodynamic tests and analysis methods, which patients will develop voiding difficulties after surgery for stress urinary incontinence [44]. There is, however, some evidence that average and maximum flow rates may be useful in predicting post-operative voiding dysfunction and retention following retropubic and transobturator midurethral slings [45-47]. Post-hoc evidence suggests, on the other hand, that surgical procedures for stress urinary incontinence that are more "obstructive" increase the risk of *de novo* overactive bladder syndrome [47,48].

Signs and symptoms of stress urinary incontinence can also appear after surgery for pelvic organ prolapse in women and there are several methods to uncover "occult stress urinary incontinence" in this context. However, all these methods have relatively low specificity and observer-dependent sensitivity. Concomitant procedures (with or without urodynamic investigation) to address possible *de novo* stress urinary incontinence after pelvic organ prolapse surgery are unreliable and the "number needed to treat" for the surgical prevention of new onset stress urinary incontinence after prolapse surgery is unfavourable [49,50].

Various studies have consistently concluded that the association between symptom severity of overactive bladder syndrome and detrusor overactivity during urodynamic investigation is weak. Several studies have shown that predicting the success of pharmacological treatment for overactive bladder on the basis of the characterization of detrusor overactivity during urodynamic investigation is, as yet, impossible [51].

Comprehensive urodynamic investigation is an essential part of the evaluation of all new therapies in patients with signs and symptoms of lower urinary tract dysfunction.

Male patients with symptoms of urinary incontinence

Male patients with symptoms of lower urinary tract dysfunction based "only" on prostate enlargement, without evidence for complicating factors, and especially without incontinence, need prostate size assessment, urinary flow studies, post-void residual urine measurements, symptom scores and a frequency-volume chart prior to treatment, but do not always need to be investigated with further urodynamic investigations [25,52].

Men (of any age) with urinary incontinence as the predominant symptom and/or with signs or symptoms of "other" lower urinary tract dysfunction, form a group where urodynamic investigation might be considered. In some of these men, urinary incontinence may be an initial symptom – in others it may follow treatment, be associated with neurological disease or non-urologic (e.g. pelvic or spine) disease, trauma or (surgical) treatment. Terminal dribbling is a prevalent urinary incontinence symptom in male patients and urodynamic investigation can be considered when this symptom is objectively and consistently identified in the urinary flow curve [53].

A significant number of patients suffer from urinary incontinence after radical prostatectomy (for malignancy of the prostate) and this can be related to surgical technique [54]. Recovery from urinary incontinence, in the patients that do suffer from this side-effect, occurs predominantly in the first year following surgery, with or without physiotherapy. No urodynamic investigation diagnosis is necessary in this period unless invasive therapy is considered within that year. Studies have suggested that the most common aetiology in patients with persisting urinary incontinence symptoms was urinary sphincter incompetence that causes stress urinary incontinence [55]. There is also evidence, however, that this stress urinary incontinence can occur in conjunction with detrusor overactivity, and also that detrusor overactivity with adequate sphincter function, low compliance and urethral stricture are possible causes of urinary incontinence and/or other lower urinary tract symptoms or dysfunction after radical prostatectomy [56,57]. There is no specific evidence for the value of frequency voiding charts and or flowmetry in this patient group. Complete urodynamic investigation including cystometry, pressure flow analysis and post void residual urine is preferable in patients with persisting incontinence or other lower urinary tract dysfunction following radical prostatectomy [57].

Retrospective studies have shown that urodynamic investigation cannot predict (stress) urinary incontinence or detrusor overactivity after surgical treatment for benign prostatic obstruction [58], although preoperative detrusor overactivity tends to persist in the postoperative period, at least temporarily [59]. Studies have shown that urodynamic investigation identifies the aetiology of lower urinary tract dysfunction in these patients; however, the value in predicting the effects of subsequent treatment is unknown [60].

Prostate size measurement, as well as the assessment of lower urinary tract symptoms, is relevant to predict urinary retention after radiotherapy for prostate cancer [61]. The evidence to support urodynamic investigation

before radiotherapy for prostate cancer is not conclusive, but studies have shown that urodynamic investigation can identify the aetiology of lower urinary tract dysfunction after radiotherapy in this context [62,63].

Patients with relevant neurological abnormalities and lower urinary tract dysfunction

New onset nocturnal enuresis or urinary incontinence in adult males is associated with many aetiologies, i.e. it can be related to ankle oedema or to prostate enlargement and ineffective voiding. It can also be an early sign of Parkinsonism [64]. Lower urinary tract dysfunction in patients with Parkinsonism can be the result of detrusor overactivity, benign prostatic obstruction (BPO), dyssynergic voiding, underactive detrusor and post-void residual urine, or any combination thereof [65]. Urodynamic investigation should be considered in all adult patients with nocturnal enuresis in whom conservative measures have failed and in whom lower urinary tract function may be considered to be affected on the basis of post-void residual urine, prostate size and or flowmetry.

Urodynamic investigation is helpul to initiate a rational treatment for the majority of patients with relevant neurological abnormalities and symptoms or "pathophysiologically suspected" lower urinary tract dysfunction [66,67]. Clinical outcome for patients with neurogenic dysfunction of the lower urinary tract can be improved on the basis of adequate objective-diagnosis [66-71]. Especially, urodynamic investigation can demonstrate prolonged or continuously elevated detrusor pressures during the storage phase, which is the consequence of reduced bladder compliance (or of overactive detrusor), which endangers renal function [69]. Relatively extensive evidence exists to suggest urodynamic investigation in patients with meningomyelocele and those with spinal cord lesions [66-69]. Studies to show the relevance of urodynamic investigation for neurological conditions in the elderly, are lacking, and consequently, guidelines do not provide specific recommendations for these patients [71]. Many types of lower urinary tract dysfunction are a result of, or associated with, neurological disease, and specific treatment is impossible without the knowledge that invasive urodynamic investigation provides. Flowmetry and post-void residual urine assessment are recommended in all patients with lower urinary tract dysfunction and Parkinsonism and further urodynamic investigation may be relevant for all patients that show abnormalities in these assessments [71], but evidence-based recommendations for the lower urinary tract assessment of patients with other relevant neurological abnormalities cannot be given.

Frail elderly patients, with symptoms of lower urinary tract dysfunction

Frail elderly patients are, in general, very poorly represented in all studies of urinary incontinence or lower urinary tract dysfunction, especially in those that entail invasive interventions or medications. This is because frail older patients often suffer from multiple and simultaneous impairments (e.g. poor mobility, cognitive impairment, renal failure) or conditions (heart failure, polypharmacy), which tend to exclude them from research.

Age- and gender-relevant changes in "normality" of urodynamic investigation are important in assessing the (frail) elderly [72,73]. Urinary incontinence in frail elderly people may be the result of a number of contributory factors, many of which are reversible by conservative and non-invasive measures. Frail elderly patients should first be evaluated by a clinician skilled in the care of older people before any invasive investigations, treatments or medications are advised to the patient. This allows easily reversible causes or contributory factors for urinary incontinence to be eliminated first, using conservative measures and therapies [74,75].

The invasive nature of urodynamic investigation becomes a more important factor in the very old or frail elderly and there is no evidence for any specific urodynamic investigation or urodynamic investigation method in this patient group.

Only a few studies have investigated whether urodynamic investigation improves clinical outcomes in the geriatric population with urinary incontinence, and there is a shortage of (positive) evidence that urodynamic investigation can predict the outcome of treatment in this context. A substantial proportion of frail older patients with overactive bladder syndrome will have urodynamic investigation confirmation of detrusor overactivity; however, this is not the case with patients with other abnormalities such as terminal detrusor overactivity with an impaired filling sensation or underactive detrusor and incomplete emptying, which are relatively prevalent [76].

Post-void residual urine is a frequent cause of urinary incontinence in frail elderly patients and "clinical observation" suggests that faecal loading can be a cause of ineffective emptying [77]. Post-void residual urine measurement by a non-invasive method, and attention to rectal filling and defecation, before any specific treatment of urinary incontinence in the frail elderly is a reasonable first step in management. Uroflowmetry (if possible) to screen for voiding abnormalities prior to

treatment for urinary incontinence will be helpful, especially in male patients, but there is some evidence that filling cystometry as a single test has limited value in diagnosing lower urinary tract dysfunction in this patient population. Filling cystometry without pressure flow study and also one channel "simple" cystometry have unknown predictive value towards diagnosis and treatment.

If stress urinary incontinence is suspected, extra tests of urethral function and/or pelvic floor mobility may be useful. Stress urinary incontinence is not only rarer in older patients but may also be more difficult to prove, or rule out, in comparison with other cause(s) of urinary incontinence in this population [78].

Mechanisms of continence and urinary incontinence in the frail elderly, especially those related to supraspinal control or lack thereof, are increasingly better understood [79,80]. Establishment of the reproducibility and reliability of urodynamic investigation in the frail elderly and development of treatments for urinary incontinence in this group is desirable.

Technological innovations

There have been five technological innovations in urodynamic investigation in the last few years. Air-charged catheters may be useful for measuring the female urethra closing pressure, but there have been no clinical studies, however, to show whether they provide a reliable and acceptable alternative to the external (intrarectal and or intravesical) pressure transducer water-filled system that is considered standard technique [1]. Furthermore, data for the comparison with fluid-filled lines for measuring intravesical and intra-abdominal pressure in urodynamic investigation is lacking [81]. Comparative studies would be useful in this regard [25].

Some reports on the development of an objective method to assess bladder filling sensation during cystometry have been published [82], but it has yet to be determined that this improves the reliability, sensitivity or specificity of urodynamic investigation.

Non-invasive measurements of pressure, in combination with flow rate, in men by the penile cuff or condom catheter have been tested to diagnose bladder outlet obstruction and compared with traditional invasive measurement of pressure and flow [83-85] but not for the diagnosis or sub-classification of urinary incontinence, to date. Urethral retro-resistance pressure measurements do not give any better, or more clinically relevant, information about closure function than the urethral profiles and closure pressures or valsalva leak point pressures and are still experimental [86]. Some studies show that measurement of opening pressure from urethral pressure reflectometry can separate women with stress urinary incontinence from those with normal urinary control, but applicability, sensitivity and specificity for the clinical sub-classification of patients with symptoms of urinary incontinence are, as yet, unknown [87].

Transabdominal near-infrared spectroscopy of the detrusor muscle seems applicable in selected patients, but might be prone to artefacts and is still experimental in the clinical diagnosis of patients with urinary incontinence [88,89].

Conclusion

The evidence for urodynamic testing of patients with signs and or symptoms of urinary incontinence, with or without relevant neurological abnormalities or frailty, is extensive and solid. Although pragmatic treatment of the presented symptoms is possible as a first approach, only urodynamic testing can unveil the function of the lower urinary tract, regardless of the patients' perception of (ab-)normality of signs or symptoms. Newer techniques to measure lower urinary tract function and dysfunction are in development, with the aim of reducing invasiveness whilst maintaining reliability. In the meantime, however, "traditional" urodynamic testing remains the gold standard to objectively evaluate lower urinary tract function.

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