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European Association of Urology



Platinum Priority

Urodynamic Testing for Men with Voiding Symptoms Considering Interventional Therapy: The Merits of a Properly Constructed Randomised Trial

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Urodynamics is well established in functional urologic assessment, but its contribution is often questioned. Uncertainty stems from modern-day focus on evidence-based medicine, in which well-constructed research is essential justification for an intervention. A recent Cochrane analysis found that urodynamics changes clinical decision-making, but there was no evidence to demonstrate whether this led to reductions in voiding dysfunction symptoms after treatment [1]. Where such evidence is lacking, other factors come into play, such as opinion, service delivery, cost, and convenience. In the European Association of Urology guidelines on non-neurogenic male lower urinary tract symptoms (LUTS) [2], the research evaluated in urodynamics was only rated as level of evidence C. Consequently, the Delphi process was used to derive a consensus based on expert opinion. Only partial agreement was obtained, and there was even discrepancy between age groups (that pressure flow studies “may” be performed for men aged >80 yr, and “should” be performed for men aged <50 yr).

Assessment of men referred for LUTS aims to exclude “red flag” diagnoses, avoid complications of disease or therapy, focus on bothersome symptoms, and use interventional therapy selectively. Routinely, all men with persisting bothersome voiding LUTS are expected to undergo history and examination, with symptom scores, urinalysis, flow rate testing, and postvoid residual urine measurement [2]. Multichannel urodynamics in modern care pathways is for those men who remain bothered by voiding LUTS despite initial treatment, and therefore may be under consideration for interventional care. The aim is to decide whether an individual would realistically benefit

from relief of bladder outlet obstruction (BOO), and whether there are risk factors for adverse outcome, such as detrusor underactivity during voiding (DUA) or detrusor overactivity (DO) during storage. However, there is a dichotomous situation:

- Advocates for routine use of urodynamics suggest that surgery should only be undertaken if BOO is present, arguing that any man undergoing surgery who does not have BOO cannot benefit symptomatically, and will be at risk of adverse effects of intervention (eg, retrograde ejaculation induced by transurethral resection of the prostate).
- Advocates for restricted use of urodynamics (selective or none) point to a perceived unpleasant experience, the lack of evidence of better outcomes, and the associated costs. A survey found that only 34% of men having surgery underwent prior urodynamic testing [3].

Routine use of urodynamics should ensure suitable indications for surgery, but imposes cost to the health economy and patients during assessment. Restricted use of urodynamics generally means that BOO is presumed, though DUA may actually be causative, so a higher proportion of men with voiding LUTS will undergo surgery; additional costs consequently fall later in the care pathway, with a higher demand for surgery, and potential lifelong impact among the minority of men who underwent surgery that turned out to be unnecessary and those who suffered complications. In either case, clinical outcomes and health economic costs are substantial issues.

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<http://dx.doi.org/10.1016/j.eururo.2016.01.035>

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In a review of the care for male LUTS, the UK National Health Institute of Health Research (NIHR) [4] recognised the need for evidence-based understanding of urodynamics. In 2014, they funded the UPSTREAM study (NIHR project number 12/140/01) [5]. UPSTREAM is a two-arm randomised controlled trial set in 26 hospitals. Men ($n = 800$, ≥ 18 yr of age) seeking further treatment for bothersome LUTS for whom surgeons would consider offering surgery are randomised to either an assessment pathway including invasive urodynamics (plus routine noninvasive tests; intervention group) or a control group with routine noninvasive tests). The aim of the study is to determine whether the control arm is noninferior in terms of symptom outcome (International Prostate Symptom Score) at 18 mo after randomisation. It will also establish whether inclusion of invasive urodynamics reduces rates of bladder outlet surgery. Full details are published elsewhere [5].

Noninferiority of symptom outcome was chosen rather than symptom superiority for urodynamics because of several uncertainties:

1. The lower surgery rate anticipated in the urodynamics group means a larger proportion of men would effectively get minimal additional treatment.
2. The quality of urodynamic testing is a confounding variable, so the urodynamic pathway would be affected adversely if the test is not carried out to necessary standards. Central reading of records against International Continence Society standards [6] is undertaken to gauge the potential impact of service quality.
3. Does surgery actually achieve relief of BOO? Flow tests at 4 mo after surgery are used to gauge the likelihood that BOO was relieved (repeat urodynamic testing was not considered feasible). If the maximum flow rate is actually not improved, this would indicate that the quality of surgery is a confounding variable, as differing surgery rates between the pathways is anticipated.
4. Treatment is not randomised nor stipulated by the trial, but selected by the patient on discussion with the urologist. Accordingly, patients may choose not to receive the treatment suggested by the investigations, and the surgeon may also follow individual practice preference.
5. Treatment effects are incompletely understood. For example, it is not clear whether men with DUA gain a sustained improvement as a result of surgery to relieve BOO using modern methods. Outcomes for men undergoing management of voiding LUTS who also have storage LUTS is hard to anticipate, particularly for nocturia [7].

The strongly held views that urologists sometimes express regarding urodynamics do not preclude equipoise in randomising men between care pathways that include or

exclude urodynamic testing. In particular, the range of tests in the non-urodynamic pathway enables clinicians to surmise BOO correctly in the majority of cases. For men with storage LUTS, it is not clear on current evidence whether symptoms are the critical factor for adverse treatment outcome, or the presence of DO. After UPSTREAM reports in 2018, there will be a strong evidence basis for the various tests conventionally used in the assessment of male LUTS in terms of therapeutic choice and outcome, and insight into patient perceptions of the diagnostic pathway. UPSTREAM will provide high-quality randomised scientific evidence to understand the actual importance, or lack thereof, of the diagnostic observations made in urodynamic testing. The study will be greatly beneficial to patients, carers, and health economies in providing a solid basis for guiding diagnostic testing and the use of urodynamics in male LUTS.

Conflicts of interest: Marcus J. Drake has received advisory board and speaker bureau fees and research funding from Allergan, Astellas, and Ferring, and research funding from Vysera. The remaining authors have nothing to disclose.

Department of Health Disclaimer: The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS, or the Department of Health.

Acknowledgments: This project was funded by the National Institute for Health Research HTA programme (project number 12/140/01). The study was designed and delivered in collaboration with the Bristol Randomised Trials Collaboration (BRTC), a UK CRC Registered Clinical Trials Unit in receipt of National Institute for Health Research CTU support funding.

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