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## **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 urological assessment, but its contribution is often questioned. Uncertainty stems from modern-day focus on evidence based medicine, where 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 reduced symptoms of voiding dysfunction 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 consensus based on expert opinion. Only partial agreement was gained and there was even discrepancy between age groups (that pressure flow studies “may” be performed in men aged over 80 years, and “should” be if aged under 50 years).

Assessment of men referred with 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 post void residual 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 dichotomised situation;

- Advocates for routine use of urodynamics suggest 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 (e.g. retrograde ejaculation induced by transurethral resection of the prostate).
- Advocates for restricted (selective or non-) use of urodynamics point to perceived unpleasant experience, the lack of evidence of better outcomes, and the associated costs. A survey found only 34% of men having surgery underwent prior urodynamics 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 life-long impact on the minority of men who underwent surgery that turned out to be “unnecessary”, or suffered complications. In either case, clinical outcomes and health economic costs are substantial issues.

The UK National Health Institute of Health Research (NIHR) reviewing the care of Male LUTS [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 years) seeking further treatment for their bothersome

LUTS for whom surgeons would consider offering surgery, are randomised to either an assessment pathway including invasive urodynamics (plus routine non-invasive tests (intervention)), or only with routine non-invasive tests (control). The study aims to determine whether the control arm is non-inferior in terms of symptom outcome (International Prostate Symptom Score) at 18-months after randomisation. It will also establish whether inclusion of invasive urodynamics reduces rates of bladder outlet surgery. Full details are published elsewhere [5].

Non-inferiority of symptom outcome was chosen, rather than looking whether urodynamics achieves symptom superiority, due to several uncertainties, including;

1. The lower surgery rate anticipated in the urodynamic group means a larger proportion of men would effectively get minimal additional treatment.
2. Quality of urodynamic testing is a confounding variable, so that the urodynamics pathway would be affected adversely where the test is not done 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 4-months after surgery are used to gauge likelihood that BOO was relieved (repeat urodynamic testing was not considered feasible). If maximum flow rate is actually not improved, it would indicate 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, and particularly for nocturia [7].

The strongly-held views urologists sometimes express towards urodynamics do not preclude equipoise in randomising men between care pathways which 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 the 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.

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Department of Health Disclaimer

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

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**Conflict of interest**

MJD; advisory boards, speaker bureaux and research for Allergan, Astellas and Ferring. Research for Vysera.

ALL; no conflict of interest to declare.

JAL; no conflict of interest to declare.

**Take home message;** (separate file):

Insufficient evidence exists regarding the role of invasive urodynamics in routine practice in the clinical assessment of male LUTS. UPSTREAM, a multicentre randomised trial, will inform patients, clinicians and policy makers about whether urodynamics should be more widely used for such patients.