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Platinum Opinion

From Clinical Trials to Routine Practice: Are Urodynamics Still Useful?

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1. Introduction

Two large randomised controlled trials (RCTs) in the UK have compared comprehensive clinical assessment (CCA) to CCA + urodynamics (UDS; filling cystometry and a pressure-flow study of voiding): the UPSTREAM [1,2] and FUTURE [3] studies. The diagnostic uncertainties in both trial populations provided a prima facie argument that UDS might be useful or even essential before invasive surgery. This Platinum Opinion editorial explores whether there are confounders that may have obscured the value of UDS in these RCTs.

2. History of UDS

UDS, without and with the use of contrast (video UDS), was first developed when filling the bladder. The bladder has been described as an "unreliable witness" [4]; as symptoms are not condition- or disease-specific, many patients can be inaccurate observers, and clinicians vary in their interpretation of clinical function. Support for this statement is provided by the EPIC study [5], which showed that the three components of lower urinary tract symptoms (LUTS) have a similar distribution in both sexes. This evidence was based on self-reporting by individuals, with the inherent inaccuracy of a symptom-based diagnosis. Symptom assessment via direct questioning and the use of validated symptom scores represents an objective measure of subjectively reported symptoms, which are neither disease- nor condition-specific, and the naming of questionnaires such as the International Prostate Symptom Score (IPSS) has perpetuated the myth of disease specificity [6].

3. UDS in contemporary clinical practice

UDS has been used extensively in contemporary practice to confirm the presumed cause of LUTS, such as benign prostatic obstruction (BPO) in men and the cause of urinary frequency and incontinence in both sexes related to a diagnosis of overactive bladder (OAB) and its potential association with detrusor overactivity (DO), urodynamic stress incontinence (USI), or a combination of both. In both examples, many patients have characteristics that make a diagnosis following CCA unclear, and UDS has been regarded as essential for these patients before surgical treatment. In the context of the lack of diagnostic specificity of LUTS, UDS provides a subjective assessment of objective parameters that integrates UDS measurements and the clinician's interpretation of the patient's symptoms. CCA uses structured symptom assessment and noninvasive "urodynamic"

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measures, including a bladder diary and measurement of the flow rate and postvoid residual volume.

The majority of male patients in this setting present with the troublesome storage symptoms of an OAB symptom syndrome, usually due to underlying DO. In studies, 90% of men versus 58% of women with urgency urinary incontinence (OAB wet) had DO [7], but OAB can also be present in those with detrusor underactivity (DU). However, the voiding symptoms seen in men with either proven BPO or proven DU are so similar that they give indication of whether a man has BPO, which has an impact on the success of subsequent surgery. Both the European Association of Urology (EAU) and American Urological Association (AUA) guidelines caution that men with DU and not BPO do less well from prostate surgery, and emphasise the poor predictive ability of uroflowmetry in diagnosing BPO. Analysis of a very large urodynamic database of women emphasised that most women had mixed stress and urgency incontinence [8]. For optimal success in women with mixed urinary incontinence (MUI), it is important to differentiate the contribution of the individual components of DO and stress urinary incontinence (SUI). Contemporary EAU and AUA guidelines suggest that UDS is not clinically indicated in women with uncomplicated, demonstrable SUI, which is not a common clinical presentation. In the VALUE study, 630 women with stress-predominant urinary incontinence (UI) were randomly assigned 1:1 to CCA + UDS or CCA alone [9]. The treatment success rate was 76.9% in the UDS + CCA arm versus 77.2% in the CCA arm (difference −0.3 percentage points, 95% confidence interval −7.5 to 6.9), which was consistent with noninferiority. There were no significant between-arm differences in secondary outcome measures. Women who underwent UDS were significantly less likely to receive a diagnosis of DO and more likely to receive a diagnosis of voiding-phase dysfunction, which did not significantly impact the overall outcomes or adverse events. In the FUTURE study, 13% of patients in the UDS + CCA arm were given a urodynamic diagnosis of USI despite symptom assessment suggesting OAB or urgency-predominant MUI [3]. A literature review suggested that contemporary evidence is based on studies in selected populations that were not powered to evaluate subgroups of more "complex" cases.

4. UPSTREAM and FUTURE results

The hypothesis tested in UPSTREAM was whether clear categorisation of lower urinary tract dysfunction would reduce the number of men undergoing prostate surgery to relieve BPO, while achieving the same symptom outcomes (noninferiority). The study randomised 393 men to CCA and 427 to CCA + UDS. Noninferiority was confirmed, and while overall treatment decisions were informed by UDS, there was no reduction in the surgery rate. Data from 5-yr follow-up did not support routine use of UDS in evaluating LUTS or the rates and overall outcomes of prostate surgery [2].

The FUTURE study evaluated women with refractory OAB and/or "urgency-predominant MUI". Previous studies on the efficacy of Botulinum toxin-A (BTXA) and sacral nerve stimulation had suggested that OAB symptoms improved following treatments irrespective of the presence of DO on UDS. This study included 1099 participants who were randomly assigned to UDS + CCA (n = 550) or CCA alone (n = 549). At final follow-up, the participant-reported rate of success after treatment according to the Patient Global Impression of Improvement ("very much improved" and "much improved") was not superior in the UDS + CCA group. The conclusion was that the routine UDS use was neither clinically effective in achieving superior patient outcomes at 15–24 mo after treatment, nor cost-effective according to the threshold of £20 000 per quality-adjusted life-year gained recommended by the UK National Institute for Health and Care Excellence (NICE). A recently published long-term economic model from the FUTURE study emphasised the importance of longer follow-up, taking relevant subsequent treatments into account, as this may affect the long-term cost-effectiveness of UDS. Obviously, cost effectiveness becomes relevant only if a certain invention has demonstrated clinical effectiveness [10].

5. Relevance for routine clinical practice

While the additional value of UDS over CCA alone was evaluated in UPSTREAM and FUTURE using a population-based approach [1,3], a fundamental question is the value of routine diagnostic UDS use in populations versus selective use in individual patients. There is intrinsic variability between individuals that is compounded by coexisting medical conditions, in particular where there is nervous system pathology and factors relating to ageing. UDS is considered to be of greatest value when used for more complex patients, so the question is how we should evaluate well-conducted robust clinical trials such as UPSTREAM and FUTURE that provide high-quality evidence but that are not powered to detect benefit in subgroups. A further question is what is an "improved outcome" after treatment in an individual patient, taking account of the impact of factors such as older age, coexisting medical morbidity and the impact of adverse events following treatment.

We suggest consideration of the following points in interpreting the UPSTREAM and FUTURE evidence.

- **UDS quality:** If the quality of UDS studies is inadequate, this will inevitably reduce clinical utility. UDS is an outlier among physiological measurements in not mandating personnel who are formally trained, which seems to be the case worldwide. It is crucial when assessing the clinical utility of UDS to critically evaluate the quality of UDS studies. This was evaluated in both studies. In UPSTREAM, an initial survey before the start of the study identified one in 20 BPO diagnoses as erroneous and numerous other technical issues [11], so quality control measures were introduced for the full study. The FUTURE study had a robust quality control protocol for UDS. The quality control continued throughout the RCT with a random check of 20% of all UDS traces performed by each centre. Central reading of a sample of studies showed a similar rate of five erroneous diagnoses from the 125 randomly assessed in the data submitted.

- **Patient factors:** Individual patient characteristics will always have an impact on the results of any study, and both studies very carefully optimised the random allocation of patients to both arms [1,3], but were not powered to evaluate individual subgroups for which UDS might be particularly helpful.
- **Patient selection**: Both trials were "pragmatic" with as few exclusion criteria as possible to ensure that they were representative of standard clinical practice; so could positive benefits in subgroups have been masked? If UDS studies are best applied to more complex patients, would a robust clinical trial of such cases have yielded different results than those from UPSTREAM and FUTURE? A secondary analysis of UPSTREAM [12] identified men who would benefit if CCA + UDS were used to identify specific subgroups at risk of an unfavourable outcome from BPO surgery, underlining the importance of fully evaluating the recommended assessments when considering surgery to treat LUTS. Anyone with overall symptom severity below a specific threshold (IPSS $\leq$16 or International Consultation on Incontinence Questionnaire Male LUTS [ICIQ-MLUTS] $\leq$18), low severity of voiding symptoms (ICIQ-MLUTS voiding subscore $\leq$8), and maximum flow rate of >13 ml/s was at risk of a poor symptom outcome after surgery. Use of UDS to confirm the presence of bladder outlet obstruction (BOO) and good bladder contractility was able to mitigate against this risk in those patients (BOO Index >48 and bladder contractility index >123). This underpins the study recommendation of selective UDS use via categorisation of patients for whom UDS evaluation should be considered according to risks identified on CCA. Likewise, despite generally low subgroup numbers in FUTURE, more participants in the CCA + UDS arm received surgery for SUI (16 vs 5), sacral neuromodulation (11 vs 8), and hydrodistension with or without urethral dilatation (22 vs 3) versus the CCA alone arm. Fewer participants in the UDS + CCA arm received BTXA. However, despite receiving more tailored diagnoses according to UDS, women in the UDS + CCA arm did not show superior patient-reported outcomes or fewer adverse events in comparison to the CCA alone arm. The authors noted the poor outcomes following surgery for SUI among women diagnosed with USI in FUTURE. However, they emphasised that the study was not powered to investigate effectiveness in these subgroups.

6. Conclusions

Results from the UPSTREAM and FUTURE trials have clearly demonstrated that there is no overall clinical or health economic advantage associated with routine unselected use of UDS for men with suspected BPO or women with OAB and/or urgency-predominant MUI, and these tests should only be used in appropriately selected patients after considering CCA findings.

The lack of benefit at the population level does not mean that individuals will not benefit from more detailed assessments before surgery. The role of UDS is to increase the degree of certainty of a diagnosis for cases in which CCA is thought to have identified factors that may mitigate against a successful and meaningful treatment outcome. Ultimately, the information that both patients and clinicians need to know is the likely outcome for each individual patient. In other words, does an individual have characteristics that are likely to mitigate against a good outcome? Such a discussion represents truly informed consent. Many clinicians will continue to believe that UDS studies are essential to fully inform certain groups of patients about probable outcomes. We believe that routine UDS before invasive treatment is not required, but that there is an important and continuing indication for UDS use in appropriately selected patients. UDS should ideally reproduce the patient's symptomatic complaint and investigate lower urinary tract function during the whole micturition cycle. This can provide a pathophysiological answer to explain the patient's complaints when other aspects of CCA have failed to adequately do so. Undoubtedly, appropriate UDS use will need to balance cost-effective health care with the ability to improve patient treatment as measured via patient satisfaction scores and patient-reported outcome measures [13].

Conflicts of interest: The authors have nothing to disclose.

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