Opinion

Do we need new patient reported measures to evaluate lower urinary tract dysfunction?

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With our current knowledge, lower urinary tract symptoms (LUTS) are thought to be caused by a dysfunction of one or more urological organs such as prostate or bladder. As such, the evaluation of these patients has largely been driven by clinical measures. Recently, there has been a major shift in the understanding and evaluation of lower urinary tract dysfunction (LUTD). More emphasis is given to the patient's self-report of their symptom severity, and the subsequent impact on their quality of life (QoL). Accurate assessment of the patient's perspective of their own symptoms becomes paramount, and as such the means by which this is measured must itself be precise.

LUTD is a significant health problem, and it encompasses a range of disease entities and symptom processes complexes. LUTD generally causes a negative impact on QoL, with the incidence and prevalence increasing with advancing age.[1] The underlying causes for LUTD appear more complex than previously appreciated, likely involving both organ-specific factors and systemic contributions. With multifactorial etiologies and varying presentations, a comprehensive assessment strategy that integrates both clinical markers and patient-reported measures is required.[2] The incorporation of patient-reported outcomes (PRO) instruments is invaluable in the clinical assessment of LUTD and in outcomes-based research.

In a series of reports from the International Continence Society (ICS), Mattiasson *et al.*[3] proposed general guidelines in the approach to standardizing outcomes measures, discussing the importance of well-defined measures and endpoints in clinical trials. Development of a PRO questionnaire is a complex process, and Coyne *et al.* describe how cognitive psychology, psychometric theory and input from physicians and patients must be coordinated to create an instrument that is statistically sound.[4] There are multiple well-designed measurement tools aimed at evaluating bladder outlet obstruction in men, incontinence in women, and overactive bladder in both genders; for example the International Prostate Symptom Score (IPSS)[5] for men, and Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI) for women.[6,7] The IPSS is a widely-used questionnaire employed to measure LUTS in men with benign prostatic hyperplasia (BPH). It was not constructed to diagnose BPH, nor was it initially intended to be applied for evaluation of women. The IIQ and the UDI were, however, specifically designed for evaluation of women. The first International Consultation on Incontinence (ICI) in 1998 recognized the multitude of tools available, and thus developed the ICI Modular Questionnaires (ICIQ)[8] which generalize urinary incontinence and its impact on QoL in both women and men. The ICIQ, the UDI-6, and the IIQ-7 all carry Grade A recommendations from the 4th ICI.[9]

There are limitations, however, in the application of PRO questionnaires, which can impede progression in both clinical and research realms. The initial psychometric development of these tools is tailored to a very specific indication and patient population. If they are applied outside of the intended parameters, the data gathered may be invalid, especially when used in research.[10] Furthermore, failure to

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incompletely analyze the results may lead to a rudimentary understanding of the patient's symptom complex. A large limitation stems from the difficulty with fully understanding the patient's description of their symptoms. In a study by Rodríguez *et al*.[11] in which patients completed the UDI-6, as did their treating physician after an interview, physicians underestimated the degree of bother reported by the patient at least 25–37% of the time. There is often weak relationship at best between PROs and clinically objective definitions. Use of the IPSS does not allow for a comprehensive assessment of male LUTD as there are several domains that it does not evaluate, such as urgency, storage and voiding, pain, and most importantly urinary incontinence. Furthermore, although it quantifies the overall symptom complex, it lacks qualitative assessment. For example, a score of 7 is considered low, but if it is comprised of an urgency score of 4 and a nocturia score of 3, it can be a sign of significant bother.

Other setbacks with these questionnaires arise when there is discord among outcomes reported by patients versus outcomes measured by objective clinical parameters. For example, Lemack and Zimmern[12] could not prove a correlation between severity of symptoms assessed by the UDI-6 compared with leakage demonstrated by valsalva leak point pressure during urodynamics. The lack of correlation between questionnaires and laboratory measures is due to these measurement approaches measuring different aspects of LUTD (e.g., emotional bother of symptoms versus the amount of urine leaked). Thus, one cannot necessarily supplant the other, and they must be used in conjunction. Taken by themselves out of the clinical context, these questionnaires cannot discriminate between related conditions. For example, two individual patients with very different symptom complexes may generate a similar score. When treatments are then applied to a group of patients who have different pathophysiologies, responses to both medical and surgical treatments will undoubtedly vary.

The need for characterizing patient groups before implementing treatment modalities is the goal of the LURN (LUTD Research Network) project. A recent NIH-based meeting (Meeting on Measurement of Urinary Symptoms in 2011)[13] looked critically at the subject in order to establish the need for further research, which instigated the design of the LURN project. Novel approaches are needed to better categorize different LUTD complexes and identify their underlying cause(s), as well as their proportional contribution to overlapping symptom profiles seen in numerous urologic conditions. PRO questionnaires are invaluable components in both research setting and clinical assessment of LUTS; although there is need to improve current questionnaires to better discriminate among various pathophysiologies of these symptoms. Using multiple therapies or subjecting patient to invasive diagnostic testing is not cost-effective. Further work is needed to improve the ability of current PROs to provide symptom discrimination for the multitude of etiologies causing LUTD, which will improve insight into disease management.

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