

Critical Review of Existing Patient Reported Outcome Measures After Male Anterior Urethroplasty

Bryan B. Voelzke*

From the Department of Urology, Harborview Medical Center, University of Washington Medical Center, Seattle, Washington

Abbreviations and Acronyms

ICC = intraclass correlation

LOA = limits of agreement

LUTS = lower urinary tract symptoms

MIC = minimal important change

QoL = quality of life

SDC = smallest detectable change

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* Correspondence: Harborview Medical Center, 325 9th Ave., Box 359868, Seattle, Washington 98104 (telephone: 206-744-6384; e-mail: voelzke@uw.edu).

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Purpose: Male urethral stricture disease can be recurrent and debilitating. The aim of any intervention is to allow men to return to a normal state of voiding while maintaining a strong quality of life. A systematic review of the literature was conducted to assess for the use of patient reported outcome instruments after male anterior urethroplasty.

Materials and Methods: A review of PubMed® was conducted to identify studies that used a patient reported outcome measure to assess patient outcome after open surgical correction of male strictures. Preference was given to studies that used an instrument in the preoperative and postoperative setting. However, use of an outcome measure solely in the postoperative setting was also accepted. After article selection, the 8 attributes recommended by the Scientific Advisory Committee were used to analyze the measurement properties of each patient reported outcome measure.

Results: A total of 15 studies were identified that included an instrument to assess patients with anterior urethral strictures. The studies used differing instruments to assess anterior urethral strictures in a nonuniform manner. Four studies used a lower urinary tract symptoms instrument, 8 used a sexual/ejaculatory dysfunction instrument, and 3 used a lower urinary tract symptoms and sexual/ejaculatory function instrument. There was only 1 report that described the development of a urethroplasty specific patient reported outcome instrument.

Conclusions: Continued effort is necessary to develop a powerful instrument to assess patient reported outcomes after male urethroplasty. The importance of patient perspective is vital to understanding the success of open urethral reconstruction.

Key Words: self report; treatment outcome; urethral stricture; ejaculation; sexual dysfunction, physiological

MALE urethral stricture disease is a medical issue that can be recurrent and debilitating. Correction of male urethral strictures includes urethral dilation, internal urethrotomy or open surgical reconstruction. The aim of any intervention is to allow men to return to a normal state of voiding while maintaining QoL. After an intervention, objective and subjective assessment is im-

portant. Objective measures exist to assess the success of urethroplasty, and include fluoroscopic imaging, uroflowmetry and cystoscopy. Unfortunately, condition specific health status instruments (ie subjective measures) are lacking in the field of male urethral reconstruction.¹ Of the existing LUTS and sexual instruments, there is no consensus on their use after

urethroplasty. As such, a urethroplasty specific instrument is necessary.

Health status questionnaires, or instruments, are patient assessments of their health condition and subsequent treatment. The health status questionnaire contains 1 or more self-reported items related to the underlying health concept. Instrument development is an iterative process that should involve the patient during each developmental step. These steps include 1) identifying the conceptual model, 2) adjusting the conceptual model/drafting a preliminary instrument, 3) confirming the conceptual model/assessing other measurement properties, 4) collecting/analyzing/interpreting data and 5) modifying the instrument.²

The Scientific Advisory Committee of the Medical Outcomes Trust was initiated in 1994 to review health status questionnaires, or instruments, for clinical application.³ Further refinement has been recommended by the Scientific Advisory Committee to determine how to best define the 8 attributes for clinical interpretation. Terwee et al provide explicit criteria that achieve this goal.⁴ These criteria include 1) content validity, 2) internal consistency, 3) criterion validity, 4) construct validity, 5) reproducibility, 6) responsiveness, 7) floor and ceiling effects, and 8) interpretability.

In this study we review reports on instruments used to assess anterior urethral strictures. The hypothesis was that instruments after urethroplasty have been inadequately used. The study aim of each report was not uniform and, thus, a description of each study was performed. The attributes for instrument interpretation described by Terwee et al were also applied to articles on an instrument that has undergone formal validation.⁴

MATERIALS AND METHODS

A search of PubMed was performed to locate anterior urethral stricture reports that used an instrument in the preoperative and/or postoperative setting. Using the term "urethroplasty" with additional filters (English journal, publication from 1998 to 2011 and male gender), 654 articles were identified. Inclusion criteria were an original publication that assessed LUTS and/or sexual outcome with a validated or nonvalidated instrument after anterior urethroplasty. An effort was made to include only articles that assessed anterior urethral strictures. However, some articles included a minority of patients with posterior urethral stenosis or pelvic fracture associated urethral injuries. Studies that focused primarily on posterior urethral stenosis or pelvic fracture associated urethral injuries were excluded from analysis. The articles were grouped into 3 categories based on the respective health status questionnaire primary focus, namely LUTS, sexual function, and LUTS and sexual function. LUTS

included voiding, storage and post-micturition symptoms. Sexual function included erectile and ejaculatory function. Each article was then analyzed for the criteria of number of subjects, preoperative health status questionnaire use, postoperative health status questionnaire use, timing of questionnaire delivery and instrument delivery method.

Only those studies that specifically validated a questionnaire for patients with anterior urethral stricture were assessed for the quality criteria of instrument items. Content validity, internal consistency, criterion validity, construct validity, reproducibility, responsiveness, floor/ceiling effects and interpretability were assessed for these selected articles (Appendix 1).

RESULTS

A total of 15 articles were identified that included an instrument to assess patients with anterior urethral strictures. The studies used differing instruments to assess anterior urethral strictures in a nonuniform manner. Four articles used a LUTS instrument,⁵⁻⁸ 8 used a sexual/ejaculatory dysfunction instrument⁹⁻¹⁶ and 3 used a LUTS and sexual/ejaculatory dysfunction instrument (see table).¹⁷⁻¹⁹ In addition to author created instruments, the AUA-SS (American Urological Association symptom score), IIEF (International Index of Erectile Function), IIEF-5 (5-item score), BMSFI (brief male sexual function inventory), MSHQ (Male Sexual Health Questionnaire), Incontinence Symptom Index, SLQQ (sexual life quality questionnaire) and QoL questionnaire were used. All studies except for 2 assessed penile and bulbar strictures of the anterior urethra. Of the 2 exceptions one assessed bulbar anastomotic urethroplasty¹⁴ and the other assessed dorsal onlay buccal/penile graft urethroplasty outcomes.¹⁹

Studies on LUTS Instruments

Four articles used an instrument to assess LUTS (see table).⁵⁻⁸ Three articles used the AUA-SS instrument, which was originally developed for men with benign prostatic hyperplasia,⁵⁻⁷ and the other article contained an instrument that was developed specifically for men with anterior urethral strictures.⁸

The LUTS instrument was used in a different manner for each of the 4 studies. Morey et al were the first group to use the AUA-SS.⁶ Their primary focus was to assess how well this instrument captured the therapeutic response after anterior urethroplasty. Failure of urethroplasty was determined by fluoroscopy or cystoscopy. Linear regression was then used to correlate maximum urine flow rate after urethroplasty to postoperative AUA-SS. A significant inverse correlation was noted ($r = -0.712$, $p < 0.0001$). Heyns and Marais had a similar research aim, also using the AUA-SS and postopera-

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