Mini-Review

The role of noninvasive testing and questionnaires in urethroplasty follow-up

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Abstract: Urethroplasty is the preferred surgical approach for the management of urethral stricture disease. To date, no standard has been established to evaluate stricture recurrence after urethral reconstruction, though both invasive and non-invasive methods are used widely. In this article we review the role of noninvasive testing and questionnaires in urethral monitoring after urethroplasty.

Keywords: Urethral stricture disease; urethroplasty; uroflowmetry (UF); outcomes; questionnaire

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Introduction

Open surgical urethral reconstruction is the gold standard treatment for urethral stricture disease. Despite a greater understanding of how to manage urethral strictures, the many advancements in surgical technique, and reported surgical success following urethral reconstruction (1), extreme variations exist among urologic reconstructive surgeons regarding appropriate postoperative follow-up (2). Currently there is no standardized surveillance protocol after open urethral reconstruction, however, most surgeons will use a combination of questionnaires, noninvasive testing such as uroflowmetry (UF), and invasive procedures such as retrograde urethrogram (RUG) and cystoscopy. While the burden to the patient who is compliant with these protocols can be great (i.e., stress, physical discomfort, loss of work and transportation costs), the usefulness of these protocols to the patient has been openly questioned (3).

A major barrier in developing standarized protocols for urethral monitoring after urethroplasty is that there is also no consensus regarding the definition of urethroplasty success or failure (4-6). Such significant gaps regarding the management of urethral stricture disease after open urethral reconstruction limits our ability to engage in meaningful comparison of surgical outcomes, assessing patient quality of life metrics, and ultimately the advancement of the field.

In a healthcare system that is increasingly driven to deliver cost-effective medicine with a minimally invasive approach while maximizing quality of care and patient satisfaction, noninvasive evaluation for long-term disease surveillance is ideal. Therefore, noninvasive methods to assess urethral stricture recurrence after open urethral reconstruction are critical to the overall management paradigm of urethral stricture disease. While exploring the reconstructive urologic literature identifying both objective and subjective metrics, we report the role of noninvasive testing and use of questionnaires after urethral reconstruction.

Noninvasive testing

Uroflowmetry (UF)

UF is a very common procedure performed in urologic clinics (7,8). UF is relatively simple to conduct and provides quantitative data such as maximum and average flow rates in mL/second, voiding curves, and voided volume in mL (9). Although most commonly performed for men with benign prostatic hyperplasia (BPH) (10,11), UF is also heavily utilized as a primary screen for urethral stricture recurrence after urethroplasty (4).

Erickson *et al.* demonstrated that UF was an adequate test to screen for postoperative stricture recurrence but only when the voiding curve and urinary symptoms were

also evaluated. In the study, the maximum flow rate alone, a commonly used metric that is known to be extremely age and individual dependent, did not prove to be a reliably sensitive metric to evaluate stricture recurrence (12). Erickson *et al.* further expanded upon the use of UF to screen for stricture recurrence looking at patient specific changes in UF maximum flow rates after urethral reconstructive surgery. Setting a change (improvement) in maximum flow rate of less than 10 mL per second as a screen for stricture recurrence resulted in a sensitivity and specificity of 92% and 78%, respectively, and achieved reasonable test reproducibility (r=0.52). It was concluded that change in flow rate after urethroplasty may be a promising noninvasive metric to screen for stricture recurrence (13).

Although ideal for its non-invasiveness and widespread use in general urology clinics, limitations with UF include operator error, the impact of bladder dysfunction, obstruction from BPH, inadequate voiding volumes (<150 cc), and the collective effort needed by clinical staff and patient to complete an adequate study to reliably appreciate an abnormality (14). Both Erickson UF studies excluded a significant number of men from their retrospective analyses due to inadequate and uninterpretable UF (12,13). Due to such inherent limitations and confounding factors influencing UF, they hypothesized that while UF can reliably function as a screener for urethral stricture recurrence, the tests require a concerted effort from both patient and provider and need to be patient specific for them to be useful.

Ultrasound post-void residual (PVR)

PVR urine measurement using ultrasound is also a very common noninvasive test used in the urologic clinic. Through sonographic estimation, ultrasound PVR provides objective data regarding bladder emptying. Although never tested as a means to monitor the urethra after urethroplasty, it is often presumed that an elevated PVR correlates with obstructive voiding, especially in the setting of a known urethral stricture and in younger patients. Use of PVR to monitor micturition efficiency has mainly been studied in BPH management with inconsistent correlation with urinary obstruction. Patient factors such as abdominal ascites, bladder diverticulae, and poor bladder function limit the predictive value of PVR (4). Consequently, increased PVR can be a poor predictor for requiring bladder outlet procedures (15).

Seibold *et al.* is one of many examples which highlights the correlation of PVR and urethral stricture recurrence. They looked at the use of PVR that was included in an algorithm along with urethral ultrasound, UF, and the International Prostate Symptom Score (IPSS) values to assess recurrence after oral mucosa graft urethroplasty. With a PVR mean value of 41 mL (range, 0-300 mL) in patients without recurrent stricture and 133 mL (range, 45-300 mL) in patients with recurrent strictures (P<0.05), it was concluded that PVR can be used as a tool to predict stricture recurrence (16). A major limitation to the use of ultrasound PVR is that it is user dependent with high inter-test variability (17). Currently there is no literature to support its primary or solo use to assess urethral stricture recurrence, but is often used in practice by urologists in conjunction with other screening tools to monitor for recurrence. Additionally, it is appropriate to use the PVR to non-invasively assess for potential upper tract damage from the stricture, with higher PVRs correlating with an increase risk (18).

Questionnaires

Lower urinary tract symptoms (LUTS) instruments

The American Urological Association symptom score (AUA-SS), now often referred to as IPSS was introduced in 1992 to assess treatment outcomes in men with BPH (19). Morey *et al.* first studied the use of the AUA-SS to determine the validity of this instrument as a tool to assess urethroplasty outcomes compared to RUG and urinary flow rates (20). Mean preoperative AUA-SS in the cohort of fifty men, was 26.9, indicating severely bothersome voiding symptoms. After surgery with radiographic evidence of successful reconstruction, the average postoperative score was 5.1 (P<0.0001). A statistically significant inverse correlation (r=–0.712, P<0.0001) was found between AUA-SS and maximum urinary flow rates. Heyns and Marias had similar findings using the AUA-SS and postoperative urine flow rates to predict stricture recurrence after urethroplasty. An inverse correlation was noted between AUS-SS and maximum urine flow (r=–0.47, P<0.0001). Using a AUA-SS of greater than ten or maximum urine flow of less than 15 mL per second as a cutoff would have prevented further invasive studies in 34% of patients while a clinically significant stricture would have been missed in only 4.3% (21). Lastly, the use of AUA-SS was also demonstrated in the work of Belsante *et al.* The AUA-SS was incorporated in a risk stratified, symptom based approach to urethroplasty follow-up and produced reductions in healthcare costs and need for invasive testing,

unnecessary follow-up visits and radiation exposure (3).

Although AUA-SS lacks specificity for urethral stricture disease, it is a simple noninvasive tool that can easily be administered in the outpatient setting. The quantitative data of subjective urinary symptoms obtained through its use can aid decision making on further invasive studies and treatment needs (21). However, it is likely that with further refinement, only a few of the questions that make up the AUA-SS will be important for monitoring the recurrence of urethral stricture disease after reconstruction (e.g., slow urinary flow).

Urethral stricture specific questionnaires

To determine the effect that urethral stricture disease and subsequent reconstructive procedures have on health related quality of life (HRQoL), subjective assessments via patient-reported outcome measures (PROM) are instrumental. However, these tools are lacking in the field of reconstructive urology (22). PROMs are validated questionnaires completed by patients to measure their perceptions of their own functional status and well-being (23). Several studies have explored the use of questionnaires to detect stricture recurrence after urethroplasty. However, to date only two instruments, the Urethral Stricture Surgery PROM (USS PROM) and a male sexual performance questionnaire, have been validated for the purpose of assessing men with anterior urethral strictures (24,25).

The work by Jackson *et al.* in 2011 was the first step in developing a urethroplasty specific instrument (24). The USS PROM is a validated standardized patient-centered evaluation of interventions performed for urethral stricture disease. The USS PROM comprises a LUTS domain consisting of six summative questions derived from the International Consultation on Incontinence Questionnaire Male LUTS (ICIQ MUTS) module, a LUTS-specific QOL question, and Peelings voiding picture from the ICIQ MLUTS. HRQoL is captured by EQ-5D. Lastly, two further questions addressing overall patient satisfaction are included. A total of 85 men completed the preoperative USS PROM and 45 also completing the postoperative PROM. Expert opinion and patient feedback supported content validity. Excellent correlation between voiding symptom scores and maximum flow rate ($r=-0.75$), supported by parallel improvements in the EQ-5D visual analogue scale, establishing criterion validity. Test-retest intraclass correlation coefficients ranged from 0.83 to 0.91 and Cronbach's α was 0.80. Significant improvements in condition-specific and HRQoL components following urethroplasty demonstrated responsiveness to change ($P<0.0001$). Jackson *et al.* continued their work and prospectively evaluated urethral reconstruction using the validated USS PROM in forty six men. Men reported continued relief from symptoms with related improvements in overall health status two years after urethroplasty. The USS PROM, being the first of its kind for urethral stricture disease, is likely to gain widespread use with its ability to report outcome data and benchmark surgeon performance (26). At this point, however, its use in routine practice is mostly for research purposes, as its ability to determine stricture recurrence has yet to be determined.

The 4-question version of the visual prostate symptom score (VPSS), first described by van der Walt *et al.* uses pictograms to assess the force of urinary stream, daytime urinary frequency, nocturia, and the patent's overall quality of life (27). The 4-question version of the VPSS has been validated against the IPSS and the maximum (Qmax) and average urinary flow rates (28) on UF. Although the IPSS is widely used to assess LUTS and has been validated for translation in over 30 languages worldwide, the educational level of the patient plays a major factor with its use in the clinical setting (29). A sixth grade reading level is considered necessary to understand the questions asked in the IPSS (30). Several studies have demonstrated that men with limited education find it difficult to understand and properly complete the IPSS (30-32). Therefore, the VPSS was developed to address the issue with educational level with the IPSS. Recently, Wessels *et al.* evaluated the 4-question version of the VPSS in men with urethral stricture disease (33). Data was collected from men with urethral stricture disease treated through a teaching hospital serving a largely indigent population. There were significant correlations between the VPSS and IPSS ($r=0.845$, $P<0.001$), maximum urinary flow rate (Qmax $r=0.681$, $P<0.001$) and urethral diameter ($r=0.552$, $P<0.001$). A combination of VPSS >8 and Qmax <15 mL per second had a positive and negative predictive value of 87% and 89%, respectively for the presence of urethral strictures. Although VPSS is limited as it was not originally designed nor validated for use with urethral stricture disease, its use is ideal for healthcare providers working in areas with low literacy rates or diverse cultures and languages.

Sexual function instruments

Coursey *et al.* was the first group to assess the impact of

anterior urethroplasty on male sexual function (25). The male sexual performance questionnaire was formulated to assess perceived changes in satisfaction with erection, erect penile length and angle, alterations in frequency of intercourse and changes in patient erection noted by their partners. The questionnaire was validated for content and each question achieved a relevance score of greater than 90% with the Content Validity Index Scale. The outcomes were compared to a non-matched cohort of men undergoing circumcision. There was no significant difference between the two cohorts. Penile skin flap urethroplasty was associated with a slightly higher incidence of impaired sexual function than other forms of reconstruction. Men with longer stricture were most likely to report major changes in erectile function and penile length ($P<0.05$) but improvement was evident with time in 61.8%. Erickson *et al.* also evaluated the effect of urethral reconstruction on sexual drive, erectile function, and ejaculation (34). With a study group of 52 men who underwent reconstructive procedures for anterior urethral stricture disease, sexual function was assessed using the O'Leary Brief Male Sexual Function Inventory (BMSFI) before and after surgery (35). Overall, the men did not report a decline in erectile function or sexual drive after surgery. The common theme or limitation within the literature regarding the assessment of sexual function after urethral reconstruction is that these instruments do not actually measure or determine urethral stricture recurrence (34). Although it may be useful to potentially capture HRQoL after urethroplasty, sexual function instruments provide no objective or subjective value as it relates to the surgical repair and outcome of open urethral reconstruction. Furthermore, the debate remains regarding whether sexual function is truly affected in a clinically significant way among men after urethroplasty and therefore such instruments are not routinely used to screen men for stricture recurrence and generally used for academic purposes only.

Use of non-invasive monitoring in research and clinical practice

The primary goal of open urethral surgery is to restore normal voiding function and improve HRQoL in men with urethral stricture disease. How we assess such goals after surgery remains a debate, but this review provides evidence that both non-invasive testing and symptom questionnaires can be implemented into general clinical practice with relative ease and with potential benefit to both the patient (by recognizing early stricture recurrence) and provider (by providing objective feedback of surgical outcomes).

Published surveillance protocols following open urethral reconstruction vary widely and include both invasive and noninvasive testing and/or questionnaires (4). While cystoscopy and RUG certainly provide more objective evidence of the surgery's success or failure, the use of noninvasive testing modalities and various types of questionnaires add value and as described above, can reliably and accurately assess urethral stricture recurrence. However, a critical limitation to developing a standardized follow-up using any modality is the lack of a standardized definition of success after such surgery.

Success after urethroplasty can be determined using both functional and anatomic definitions (6). Historically, most urethroplasty outcomes studies use a functional definition of success, generally defined as freedom from secondary procedures (i.e., no urethral dilations or repeated open urethral reconstructive surgeries during a follow-up period) and/or a lack of bothersome patient-reported voiding symptoms. A stricter anatomic definition of success, which is less often employed but is potentially more useful and important when describing a new surgical technique (especially when comparing the new technique to an older, established technique), is defined as the ability to demonstrate a normal urethral lumen during RUG or cystoscopy regardless of patient symptoms (6). Erickson *et al.* evaluated multi-institutional outcomes of bulbar urethroplasty utilizing a standardized, cystoscopic follow-up protocol using functional and anatomic definitions of surgical success (6). Expectedly, rates of success were lower when using the anatomic versus functional definition of surgical success after urethroplasty. Interestingly, of the recurrences found by cystoscopy only 65% were symptomatic, which alone calls into question the ability for symptom assessment alone to screen for recurrence. However, this study also reported low (54%) one-year patient compliance with the studies cystoscopic protocol, thereby simultaneously questioning the ability of routine cystoscopic screening or any other invasive testing to be used as the gold standard methodology for diagnosing post-operative stricture recurrences. Additional concerns with invasive testing include radiation exposure, patient discomfort, and risk of urinary tract infection (36-39).

Despite limitations with both invasive and non-invasive monitoring of the urethra, we believe that using both types of follow-up in the initial post-operative period is optimal for both clinical and academic purposes. At our institution, a cystoscopy or RUG at the 3-6-month mark establishes that

no immediate post-operative failure has occurred, which will occur more often with substitution urethroplasties (6). At the time of the invasive monitoring, if the urethra is found to be patent, the corresponding non-invasive UF and/or urethral stricture specific questionnaire results will effectively become the new "baseline" for the individual patient. Thereafter, subsequent non-invasive testing can be compared to patient specific baseline values, as opposed to using generic max flow values which lack both specificity and sensitivity (13). Notably, as UF changes will generally precede symptom changes, significant decreases in max flow rates (5-10 mL/second) or a change in the shape of the voiding curve (from bell-shaped to flat/bread-loafed) should prompt cystoscopic evaluation of the urethra. It must be noted, however, that it is still unknown what advantage early detection of recurrence may have on the overall health of the urethra. We presume that earlier detection of recurrence may allow for the strictured segment to respond more favorably to a salvage endoscopic procedure, though this will need to be studied further in a prospective manner.

Conclusions

Various testing modalities and surveillance algorithms have been described and currently in clinical use for follow-up after open urethral reconstruction. Although a standardized surveillance protocol after urethroplasty has yet to be defined, noninvasive testing and questionnaires play a critical role in assessing stricture recurrence. Coupled with invasive testing in the immediate postoperative period and primarily used as a screening method in subsequent follow-up, noninvasive monitoring of the urethra after urethroplasty is effective and demonstrates great benefit in both clinical practice and academic pursuits.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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