

Evaluation of Generic Versus Condition-Specific Quality of Life Indicators for Successful Urethral Stricture Surgery



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OBJECTIVE	To compare the utility of generic health quality of life (QOL) and condition specific indicators as patient reported outcomes measures for urethral stricture surgery.
MATERIALS AND METHODS	Patient data were obtained from the Trauma and Urologic Reconstructive Network of Surgeons collaborative database. Patients who underwent any successful urethroplasty and completed both pre- and postoperative generic and condition-specific questionnaires were included.
RESULTS	A total of 201 patients met inclusion criteria. Urethral-stricture specific measures improved after surgery: mean LUTS score (13.1-4.0, $p < 0.05$), Peeling curve (3.1-1.7, $p < 0.05$), and overall interference of urinary symptoms on life (3.0-1.6, $p < 0.05$). Mean overall health status visual analog scale (74.2-80.0, $p < 0.05$) and generic health QOL EQ-5D index scores (0.90-0.95, $p < 0.05$) also improved; however, individual EQ-5D measures assessing mobility, self-care, and activity level did not change. EQ-5D measures for pain/discomfort (1.48-1.23, $p < 0.05$) and anxiety/depression (1.33-1.21, $p < 0.05$) improved, but not to the same extent as stricture-specific measures. More patients reported improvement in condition-specific urethra/penis pain and bladder pain compared to improvement in generic EQ-5D pain/discomfort ($p < 0.001$).
CONCLUSION	Generic health QOL indicators are less meaningful in the assessment of urethral stricture surgery and should be replaced with condition-specific outcomes measures. It is important to ensure that appropriate condition-specific outcomes measures are utilized as patient reported outcomes measures become more prevalent in medicine and potentially become utilized to evaluate surgeon outcomes and determine surgeon reimbursement. UROLOGY 126: 222–226, 2019. © 2018 Elsevier Inc.

Success after urethroplasty has most commonly been defined by freedom from secondary procedures and objective patency of the urethra.¹ These classic definitions of success were defined by urologists, lack patient input, and do not account for subjective symptoms. Patient input and subjective symptoms should be considered when defining

success. For example, urethra/bladder pain and a decrease in postoperative sexual activity can negatively impact how a patient views on objective success following urethroplasty.² Patient reported outcomes (PROMs) are questionnaires commonly administered to patients before and after intervention to assess health and quality of life (QOL). PROMs may be used to measure individual components of success and help to characterize the effects of stricture disease and surgery on domains ranging from urinary to sexual function.

Several stricture PROM questionnaires have been developed by combining preexisting surveys, such as the Sexual Health Inventory for Men or Male Sexual Health Questionnaire, which were not developed for patients with urethral stricture disease.^{3,4} The Urethral Stricture Surgery (USS) PROM is the first validated stricture questionnaire and incorporated the EuroQol-5 dimension (EQ-5D) descriptive system to evaluate measurements of generic health status.⁵ The EQ-5D is a standardized instrument developed by the EuroQol Group as a measure of health-related QOL and evaluates 5 dimensions of

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health status including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.⁶ Use of the EQ-5D may be relevant in chronic illnesses or life-altering disease; however, its use may be limited in urethral stricture disease. When developing a PROM, it is important to ensure that relevant questions are being asked to directly assess effects from the disease rather than background noise and to ensure patients are not burdened unnecessarily by questionnaire fatigue. We hypothesized that generic health QOL indicators (EQ-5D) are less meaningful in the assessment of urethral stricture surgery and should be replaced with condition-specific measures.

MATERIALS AND METHODS

Study Population

Patient data were obtained from the Trauma and Urologic Reconstructive Network of Surgeons (TURNS) collaborative registry. Male patients undergoing urethral reconstruction at institutions participating in the TURNS outcomes study were enrolled into a prospective urethroplasty registry. Patients underwent standard preoperative uroflowmetry, retrograde urethrography, and/or cystoscopy to characterize length, location, and severity of stricture disease. We identified patients who underwent urethroplasty between June 2013 and April 2016 and completed pre- and postoperative questionnaires including the Sexual Health Inventory for Men, Male Sexual Health Questionnaire, and USS-PROM questionnaires.^{3,4,7}

All patients included in this study achieved anatomic success, defined as being able to pass a flexible cystoscope through the area of repair and absence of a secondary procedure following stricture recurrence. Patients with anatomic failure ($n = 19$) were not included in this study in an effort to keep the surgical outcome similar across all patients. All types of urethroplasty and stricture locations were included. The TURNS study protocol recommended follow-up at 3-6 months and 12 months. Postoperative evaluation included uroflowmetry, cystoscopy, and repeat questionnaires. For patients who completed multiple postoperative questionnaires, the most recent results were utilized.

Study Outcomes

The USS-PROM is comprised of a 6-item additive lower urinary tract symptoms (LUTS) construct, a Peeling's voiding picture, a Likert-type LUTS-specific QOL question, an EuroQol visual analogue scale (EQ-VAS), and the EQ-5D.⁶⁻⁸ Additional nonvalidated questions addressing urinary urgency and pain in the bladder, urethra, and penis were included. The 6-item additive LUTS construct addresses hesitancy, stream, strain, intermittency, incomplete emptying, and postmicturition dribbling to generate a score between 0 and 24 (least to most symptomatic). The Peeling voiding picture is an illustration of a man with 4 voiding stream trajectories (1: best, 4: worst). The Likert-type LUTS-specific QOL question asks "Overall, how much do your urinary symptoms interfere with your life?" The EQ-VAS is a scale ranging from 0 to 100 (0: "worst imaginable health state", 100: "best imaginable health state"). The EQ-5D was developed by the EuroQol Group as a measure of health-related QOL and addresses mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D score can be converted to a single EQ-5D index score using population preference weights derived from a time trade-off survey to account for differences in health perception between countries.

Statistical Analysis

Patients were grouped into improved, same, or worsened categories based on the change of their pre- and postoperative questionnaire responses for each category of the USS-PROM. Statistical analyses included chi-square, Student *t* test, or ANOVA as required. Significance was considered if $P < .05$.

RESULTS

After applying the inclusion criteria (anatomic success and completion of both pre- and postoperative questionnaires), 201 patients were identified from the TURNS registry (Table 1). Prior to undergoing successful urethroplasty, 163 patients (93%) failed prior treatment with direct visual internal urethrotomy and/or urethral dilation, while 37 patients (19%) had failed prior urethroplasty. The origin of stricture disease was idiopathic ($n = 117$, 61%), iatrogenic ($n = 24$, 13%), traumatic ($n = 19$, 10%), or related to lichen sclerosis ($n = 16$, 9%). All patients underwent cystoscopy to ensure successful urethroplasty with a mean follow-up of 7 months (range 5-25).

Urethral-stricture specific measures improved after surgery: mean LUTS score (13.1-4.0, $P < .05$), Peeling curve (3.1-1.7, $P < .05$), and overall interference of urinary symptoms on life (3.0-1.6, $P < .05$). Generic health QOL measures EQ-VAS (74.2-80.0, $P < .05$) and EQ-5D index scores (0.90-0.95, $P < .05$) also improved; however, individual generic EQ-5D measures assessing mobility, self-care, and activity level did not change. Individual EQ-5D measures for pain/discomfort (1.48-1.23, $P < .05$) and anxiety/depression (1.33-1.21, $P < 0.05$) improved and were the driving factors for the change in EQ-5D index scores; however, these measures did not correspond with a successful urethroplasty to the same extent as stricture-specific measures (Fig. 1).

Table 1. Background characteristics of patients

	N (Range)	%
Age, mean (y)	48 (16-85)	-
Follow-up (mo)	7 (2-25)	-
Prior endoscopic stricture treatment	163	93%
Prior urethroplasty	37	19%
Stricture origin		
Idiopathic	117	61%
Iatrogenic	24	13%
Lichen sclerosis	16	9%
Trauma	19	10%
Failed hypospadias	5	3%
Radiation	6	3%
Infectious	3	2%
Stricture length (cm)	4 (1-17)	-
Stricture location		
Bulbar urethra	150	78%
Posterior urethra	51	26%
Penile urethra	42	22%
Meatus/Fossa	21	11%
Type of urethroplasty		
One-stage buccal graft	122	63%
One-stage EPA	63	32%
Perineal urethrostomy	7	4%
One-stage penile fasciocutaneous flap	5	3%
Stricturoplasty	5	3%
Hypospadias repair	2	1%
Extended meatotomy	1	1%

EPA, excision and primary anastomotic.

Distribution of Patient Reported Outcomes Measures After Successful Urethroplasty

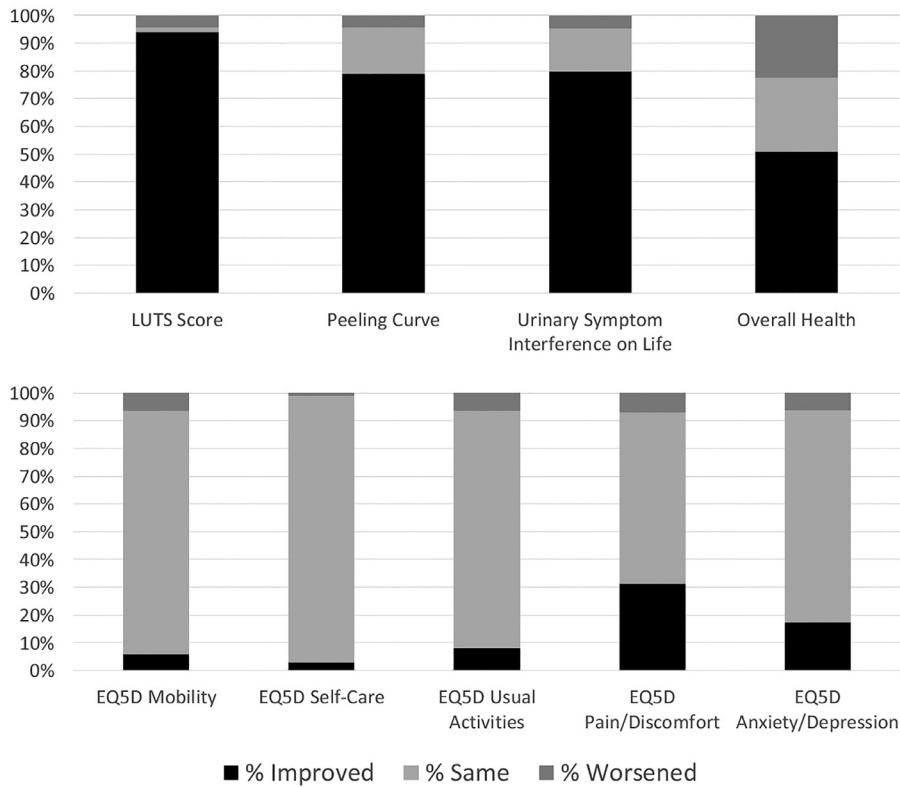


Figure 1. Distribution of patient reported outcome measures after urethroplasty. Patients more frequently reported improvement with condition-specific (top) vs generic overall health (bottom) quality of life measures after successful urethroplasty.

Postoperatively, patients reported EQ-5D pain/discomfort as improved ($n = 57, 31\%$), unchanged ($n = 113, 62\%$), or worsened ($n = 13, 7\%$; Fig. 2). More patients reported improvement in urethra/penis ($n = 87, 61\%$) and bladder pain ($n = 73, 42\%$) than generic EQ-5D pain/discomfort ($n = 57, 31\%$; $P < .001$). Of the 13 patients who reported worse EQ-5D pain/discomfort, only 1 and 3 patients reported worse bladder or urethra/penis pain, respectively.

DISCUSSION

Success after urethral stricture surgery has traditionally been defined by the provider and not by the patient. Many would agree that a successful outcome should be defined in terms of what is meaningful and valuable to the patient in addition to the provider. As medicine transitions to a less paternalistic and a more patient-driven

Generic Versus Condition-Specific Pain Measures After Successful Urethroplasty

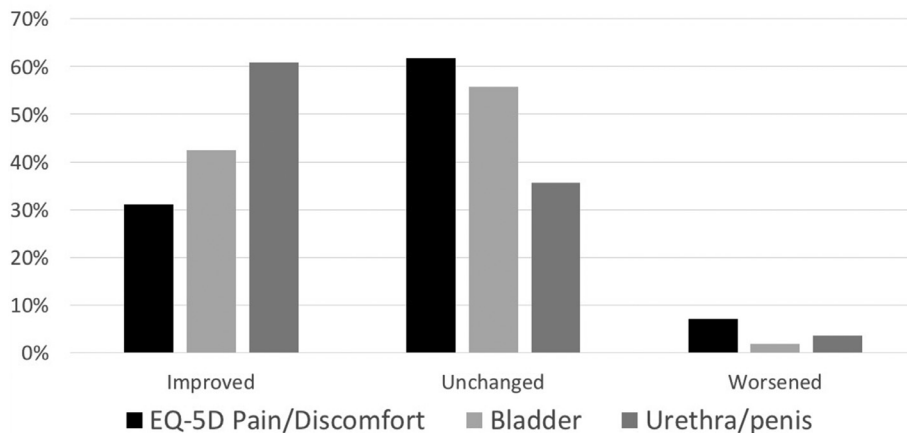


Figure 2. Distribution of changes in generic (EQ-5D) vs condition-specific (bladder, urethra/penis) pain measures after successful urethroplasty.

approach, the patient experience has become an important monitor of quality of care.⁹ Surveys are therefore being developed and utilized to identify areas of improvement based on the input and point of view of the patient. Urethral stricture PROMs may help providers to better understand patients' expectations, facilitate preoperative counseling, better define success, and improve outcomes. Furthermore, as PROMs become more prevalent in medicine and potentially utilized to evaluate surgeon outcomes and determine reimbursements, it is important to ensure that appropriate condition-specific outcomes measures are assessed.

The USS-PROM was created by first identifying symptoms which were expected to improve after urethral surgery and subsequently finding corresponding validated questionnaires. Although the selected constructs were evaluated in semi-structured patient interviews, the application of pre-existing surveys to disease states in which they may not have been created or validated may not always be optimal. As illustrated in the present study, the changes in generic health EQ-5D QOL measures were less meaningful than condition-specific measures in the assessment of urethral stricture surgery. The EQ-5D may be better fit for evaluating more chronic, life-altering illnesses than urethral stricture disease.

Specific criteria exist (content validity, internal consistency, criterion validity, construct validity, reproducibility, responsiveness, floor and ceiling effects, and interpretability) for developing and evaluating PROMs based on recommendations from the Scientific Advisory Committee of the Medical Outcomes Trust.^{10,11} Content validity refers to the adequacy to which questionnaire items address the question of interest. Although patients in the present study demonstrated improvement in generic overall health items EQ-VAS and EQ-5D, a deeper assessment identified that individual EQ-5D measures (mobility, self-care, and activity) did not change after successful urethroplasty.^{5,7} Mobility, self-care, and activity levels are less valid content for patients undergoing urethral stricture surgery and contribute to response burden and questionnaire length. While these items may be pertinent for research purposes, they do not warrant inclusion for clinical purposes.

Although mean generic health EQ-5D pain/discomfort improved for patients after urethroplasty, more patients reported greater improvement when specifically asked about bladder and urethra/penis pain. Furthermore, of the patients who reported worse overall EQ-5D pain/discomfort, few actually reported worse bladder or urethral/penile pain. When responding to the generic health pain/discomfort prompt, nonstricture issues from other musculoskeletal or neuropathic pain may have influenced patients. Patients could have also reported pain secondary to urethroplasty surgery (ie, oral, scrotal, or perineal pain from dissection or upper/lower extremity pain from positioning) that may be of separate, additional value to urologists. It is important to ensure PROM items specifically address the question of interest so the goal objectives may be achieved.

Additional benefit of stricture-specific vs nonstricture-specific items can also be demonstrated by evaluating use of the American Urological Association Symptom Score (AUASS) or International Prostate Symptom Score in urethral stricture PROMs. The AUASS was initially developed for use in patients with LUTS secondary to benign prostatic hypertrophy; patients with urethral stricture were specifically excluded during development.¹² Morey et al. and Heynes et al. evaluated the use of the AUASS and post-operative maximum urine flow in patients who underwent urethroplasty.^{13,14} After successful surgery, the AUASS significantly improved and inversely correlated with the maximum urinary flow rates. Although the AUASS may be helpful in evaluating patients after surgery, it cannot be used as a stand-alone measure for treatment success or disease recurrence. Nuss et al. evaluated the AUASS and identified that 21% who presented for urethroplasty did not have voiding symptoms assessed by the index and that spraying and dysuria were the most commonly reported symptoms that were not assessed.¹⁵ Tam et al. also identified that the International Prostate Symptom Score also had insufficient sensitivity and specificity to be a stand-alone measure for stricture recurrence.¹⁶

The important need for condition-specific measures and patient participation in the development of questionnaires was demonstrated by Kessler et al who developed a urethral stricture PROM based on a literature review and surgeon experience. They identified that patient satisfaction did not correlate with objectively defined success or failure after urethroplasty ($P = .679$).¹⁷ In fact, of the 30 patients whose surgery was considered a failure by the surgeon measures, 24 were subjectively satisfied or very satisfied with the outcome. Sexual function was a strong component to patient satisfaction as patients with marked or severe penile curvature, penile shortening, erection deterioration, and impaired sexual life reported more dissatisfaction. Sexual function is an important patient reported measure and should be considered when evaluating success.

The Urethral Stricture Symptom and Impact Measure is a comprehensive PROM aimed at addressing stricture-specific issues which is currently being validated.^{11,18} During development of the Urethral Stricture Symptom and Impact Measure, researchers compared what reconstructive urologists and patients believed were the most important subjective symptoms attributed to a symptomatic urethral stricture among the 34 items generated from concept-elicitation interviews.¹⁸ For patients, "I worried about being unable to pee" and "I dribbled into my underwear after peeing" were the 2 items of greatest importance. For physicians, "I had to strain to pee" and "I had a weak stream" were the 2 items of greatest importance. There was only a concordance of 53% between patient and physician perspectives when comparing the top 15 ranked items demonstrating an obvious difference of opinion between patients and physicians. Patient involvement in survey development will help to define condition-specific

measures and eliminate the inclusion of noncontributory generic health QOL indicators.

The strengths of this study include a multi-institutional population of patients collected in a prospective manner utilizing a validated PROM. Further, the patient cohort was inclusive and included patients who underwent any type of urethroplasty in any urethral location. A limitation of this study includes lack of patient comorbidities and demographics that may have played a role changes in a patient's general health. Despite these limitations, this study reinforces the need for condition-specific items and patient participation in PROM development.

CONCLUSION

Generic health QOL indicators may capture medical issues not related to urethral stricture disease and are best replaced with condition-specific outcomes measures. PROMs created in collaboration with the patient will help to better understand patients' expectations, facilitate preoperative counseling, and better define success. As PROMs become more prevalent in medicine and potentially utilized to evaluate surgeon outcomes and determine reimbursements, it is crucial to ensure that appropriate condition-specific outcomes measures are assessed.

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