A Prospective Patient-centred Evaluation of Urethroplasty for Anterior Urethral Stricture Using a Validated Patient-reported Outcome Measure

Matthew J. Jacksona,*, Ishaan Chaudhuryc, Altaf Mangera, Andrew Brettd, Nick Watkin, Christopher R. Chapplec, Daniela E. Andrichb, Robert S. Pickarde, Anthony R. Mundyb

aDepartment of Urology, Freeman Hospital, Newcastle upon Tyne, UK; bInstitute of Urology, University College London Hospital, London, UK; cDepartment of Urology, Royal Hallamshire Hospital, Sheffield, UK; dDepartment of Urology, St. George’s Hospital, London, UK; eInstitute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, UK

Abstract

Background: Studies of interventions for urethral stricture have inferred patient benefit from clinician-driven outcomes or questionnaires lacking scientifically robust evidence of their measurement properties for men with this disease.

Objective: To evaluate urethral reconstruction from the patients’ perspective using a validated patient-reported outcome measure (PROM).

Design, setting, and participants: Forty-six men with anterior urethral stricture at four UK urology centres completed the PROM before (baseline) and 2 yr after urethroplasty.

Intervention: A psychometrically robust PROM for men with urethral stricture disease.

Outcome measurements and statistical analysis: Lower urinary tract symptoms (LUTS), health status, and treatment satisfaction were measured, and paired $t$ and Wilcoxon matched-pairs tests were used for comparative analysis.

Results and limitations: Thirty-eight men underwent urethroplasty for bulbar stricture and eight for penile stricture. The median (range) follow-up was 25 (20–30) mo. Total LUTS scores (0 = least symptomatic, 24 = most symptomatic) improved from a median of 12 at baseline to 4 at 2 yr (mean [95% confidence interval (CI)] of differences 6.6 [4.2–9.1], $p < 0.0001$). A total of 33 men (72%) felt their urinary symptoms interfered less with their overall quality of life, 8 (17%) reported no change, and 5 (11%) were worse 2 yr after urethroplasty. Overall, 40 men (87%) remained “satisfied” or “very satisfied” with the outcome of their operation. Health status visual analogue scale scores (100 = best imaginable health, 0 = worst) 2 yr after urethroplasty improved from a mean of 69 at baseline to 79 (mean [95% CI] of differences 10 [2–18], $p = 0.018$). Health state index scores (1 = full health, 0 = dead) improved from 0.79 at baseline to 0.89 at 2 yr (mean [95% CI] of differences 0.10 [0.02–0.18], $p = 0.012$).

Conclusions: This is the first study to prospectively evaluate urethral reconstruction using a validated PROM. Men reported continued relief from symptoms with related improvements in overall health status 2 yr after urethroplasty. These data can be used as a provisional reference point against which urethral surgeons can benchmark their performance.
1. Introduction

Anterior urethral stricture disease is characterised by fibrosis of the urethral mucosa and underlying spongiosum. The detrimental impact of this condition on the lives of affected men is mediated by progressive symptoms of lower urinary tract obstruction; morbidity from urinary sepsis, acute urinary retention, and kidney injury; a high rate of recurrence after treatment; and the need for repeated surgical intervention. It is the leading cause of difficulty passing urine in younger and middle-age men with an estimated prevalence of 200 per 100 000 men in their 20s rising steadily to 900 per 100 000 men in their 70s [1]. In the National Health Service in the United Kingdom, this equates to 17 000 hospital admissions annually at a cost of £10 million [2].

Urethroplasty is one of a number of competing interventions for urethral stricture that appears to offer the best chance of long-term cure. The outcome measures used in studies of clinical effectiveness of urethroplasty are predominantly clinician-driven indicators of technical success (eg, maximum flow rate, urethrography) [3,4] that are not always aligned with the fundamental aims of the operation, which are to minimise symptoms, reduce disability, and improve health-related quality of life (HRQoL) in men with the condition by restoring normal urinary function. Only patients can assess these outcomes [5], but in the absence of a validated patient-reported outcome measure (PROM), urethral surgeons have adopted questionnaires designed for other conditions of the lower urinary tract, without scientifically robust evidence of their measurement properties for men with urethral stricture [6].

PROMs are validated questionnaires completed by patients to measure their perceptions of their own functional status and well-being [7]. The magnitude of change in patients’ symptoms or overall health status is a marker of quality in health care and can be used to decide whether a particular intervention is worthwhile from both an individual patient’s perspective and more widely in terms of health care resource allocation.

We developed the Urethral Stricture Surgery PROM (USS PROM) in 2011 [8] to standardise patient-centred evaluations of interventions for urethral stricture. The questionnaire is a composite instrument comprising a lower urinary tract symptoms (LUTS) domain, a generic health status domain, and a treatment satisfaction question. LUTS are captured by an additive six-item construct derived from the International Consultation on Incontinence Questionnaire male LUTS modules [9], a LUTS-specific quality-of-life (QoL) question, and Peeling’s voiding picture [10]. HRQoL is captured by EQ-5D (three-level version) [11].

The objective of the present study was to use the validated USS PROM to evaluate urethroplasty for anterior urethral stricture from the patients’ perspective at 2 yr, and thereby determine its medium-term worth.

2. Patients and methods

2.1. Setting and participants

Of 85 men with urethral stricture disease who participated in the USS PROM validation study, 46 men agreed to contribute to 2-yr data collection for the purpose of this study (Fig. 1). Those men were identified from urology outpatient clinics at four specialist centres in the United Kingdom (London [2], Newcastle, and Sheffield) and underwent urethroplasty for anterior urethral stricture between September 2009 and July 2010. They were invited to complete the PROM preoperatively (at baseline) and at 2 yr postoperatively, together with a baseline characteristics questionnaire to elicit the duration of urethral stricture disease and details of previous interventions. All men completed the PROM unaided on paper. Responses were collected by post or by telephone and collated in an anonymised database.

2.2. Scoring the patient-reported outcome measure

The USS PROM incorporates LUTS and HRQoL domains, and a treatment satisfaction question.

The LUTS domain comprises:

- A six-item additive LUTS construct addressing hesitancy, stream, strain, intermittency, incomplete emptying, and postmicturition dribble to generate a total score between 0 (least symptomatic) and 24 (most symptomatic).
- Peeling’s voiding picture: an illustration of a man voiding invites respondents to circle an integer between 1 (best) and 4 (worst) corresponding to their own flow pattern.
- A Likert-type LUTS-specific QoL question asks, “Overall, how much do your urinary symptoms interfere with your life?”
HRQoL is assessed by EQ-5D:

- The EQ visual analogue scale (EQVAS) elicits respondents’ global health rating on a vertical scale anchored on 100 for “best imaginable health state” and 0 for “worst imaginable health state.”
- The EQ-5D descriptive system generates a health profile encompassing mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Profiles can be summarised to a single EQ-5D index score on a scale where full health equals 1 and 0 is equivalent to death. Health profiles were converted to EQ-5D index scores using UK population preference weights derived from a time trade-off survey [12].

Finally, a global treatment satisfaction question asks respondents whether are they are satisfied with the outcome of their operation.

2.3. Data analysis

The primary analysis was a comparison of LUTS construct scores, EQVAS, and EQ-5D index scores, between the baseline and 2-yr postoperative time points using paired \( t \) and Wilcoxon matched-pairs tests to assess statistical significance. A subset of participants had previously supplied PROM data at 6 mo after urethroplasty to determine the responsiveness characteristics of the questionnaire in the validation study. These data are presented here as an illustrative secondary comparison with the novel 2-yr data, delineating trends in score. Limited subgroup analysis was performed with men who were unsatisfied with urethroplasty and with men who underwent reintervention during the follow-up period.

2.4. Ethics

This study was classed as a service evaluation and improvement exercise that did not require research ethics committee approval. The project was registered with audit departments at participating units; all study participants gave informed verbal consent.

3. Results

A total of 46 men completed the PROM just before and at a median of 25 mo (range: 20–30 mo) after urethroplasty, 33 of whom (72%) had also completed the PROM 6 mo after surgery for our initial PROM development study. Table 1 summarises the patient group characteristics.

3.1. Lower urinary tract symptoms

3.1.1. Six-item lower urinary tract symptoms score

For the group, total LUTS score was a median (mean, range, standard deviation [SD]) of 12 (12.0, 0–23, 6.3) at baseline, 1 (3.4, 0–17, 4.3) 6 mo after urethroplasty, and 4 (5.4, 0–17, 4.8) 2 yr after urethroplasty. The LUTS score for individual patients showed a mean decrease of 6.6 scale points (95% confidence interval [95% CI], 4.2–9.1; paired \( t \) test \( p < 0.0001 \), Wilcoxon matched-pairs test \( p < 0.0001 \); Fig. 2) at 2 yr. There was a trend towards worsening of LUTS scores between the 6-mo and 2-yr time points with a mean (95% CI) increase of 1.4 scale points (0.2 to +3.1; paired \( t \) test \( p = 0.09 \); Wilcoxon matched-pairs test \( p = 0.011 \); Fig. 3).

3.1.2. Peeling’s voiding picture and quality of life specific to lower urinary tract symptoms

The median (range) voiding picture score improved from 4 (1–4) at baseline to 2 (1–4) 2 yr after urethroplasty (Wilcoxon matched-pairs test \( p < 0.0001 \)). Scores at the 6-mo and 2-yr time points did not differ ( \( p = 0.79 \)). The LUTS-specific QoL question revealed that 33 men (72%) felt their urinary symptoms interfered less with their overall QoL 2 yr after urethroplasty; 8 (17%) reported no change, and 5 (11%) felt they were worse. The 13 men who did not report a QoL improvement had a lesser reduction in LUTS score compared with those whose QoL improved (median [mean, SD] reduction 1 [2.3, 7.0] vs 10.5 [8.3, 8.0], respectively; unpaired \( t \) test \( p = 0.026 \); Mann-Whitney test \( p = 0.023 \)). Clinical evaluation did not reveal a coexistent alternative cause of lower urinary tract obstruction such as...

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### Table 1 – Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Completed 2-yr PROM</th>
<th>Did not complete 2-yr PROM</th>
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<tbody>
<tr>
<td>( n ) (%)</td>
<td>46 (24)</td>
<td>39 (22)</td>
</tr>
<tr>
<td>Age, yr, median (mean; range)</td>
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<td>43 (43; 23–72)</td>
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#### Subgroup analysis

<table>
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<tbody>
<tr>
<td>Penile</td>
<td>8 (17)</td>
<td>9 (23)</td>
</tr>
<tr>
<td>Bulbar</td>
<td>38 (83)</td>
<td>30 (77)</td>
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</table>

<table>
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<th>Disease duration, yr</th>
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<th>Did not complete 2-yr PROM</th>
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<tbody>
<tr>
<td>&lt;1</td>
<td>10 (22)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>1–5</td>
<td>18 (39)</td>
<td>14 (36)</td>
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<tr>
<td>6–10</td>
<td>7 (15)</td>
<td>13 (33)</td>
</tr>
<tr>
<td>&gt;10</td>
<td>11 (24)</td>
<td>10 (26)</td>
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</table>

#### Previous intervention

<table>
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<th>Urethroplasty</th>
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<tbody>
<tr>
<td>0</td>
<td>13 (28)</td>
<td>9 (23)</td>
</tr>
<tr>
<td>1</td>
<td>18 (39)</td>
<td>19 (49)</td>
</tr>
<tr>
<td>2–5</td>
<td>11 (24)</td>
<td>10 (26)</td>
</tr>
<tr>
<td>&gt;5</td>
<td>4 (9)</td>
<td>1 (3)</td>
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</table>

<table>
<thead>
<tr>
<th>ISD</th>
<th>Completed 2-yr PROM</th>
<th>Did not complete 2-yr PROM</th>
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<tbody>
<tr>
<td>0</td>
<td>28 (61)</td>
<td>26 (67)</td>
</tr>
<tr>
<td>1</td>
<td>10 (22)</td>
<td>12 (31)</td>
</tr>
<tr>
<td>&gt;1</td>
<td>8 (17)</td>
<td>1 (3)</td>
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</table>

#### Non-previous intervention

<table>
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<th>Completed 2-yr PROM</th>
<th>Did not complete 2-yr PROM</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 (24)</td>
<td>12 (31)</td>
<td>5 (13)</td>
</tr>
</tbody>
</table>

**PROM** = patient-reported outcome measure; **DVU** = direct vision internal urethrotomy; **ISD** = intermittent self-dilatation.

The characteristics of men who completed a baseline questionnaire in the PROM development study but did not take part in this follow-up study are given for comparison.

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**Fig. 2** – Individual six-item lower urinary tract symptoms (LUTS) scores before and after urethroplasty (bars indicate mean and 95% confidence interval).
prostatic enlargement to account for their marginal reduction in LUTS.

3.2. Health status: EQ-5D

3.2.1. Visual analogue scale

EQVAS scores were mean (median, range, SD) 69 (80, 0–100, 24) at baseline, 81 (80, 20–100, 16) 6 mo after urethroplasty, and 79 (80, 30–100, 17) 2 yr after urethroplasty, equating to a mean 10-point EQVAS improvement at 2 yr over baseline (95% CI, 2–18; paired t test \( p = 0.018 \); Wilcoxon matched-pairs test \( p = 0.028 \); Fig. 4). Scores at 6 mo and 2 yr after urethroplasty were similar (mean of differences \( -0.05 \) to 0.13; paired t test \( p = 0.35 \); Wilcoxon matched-pairs test \( p = 0.16 \)).

3.2.2. Descriptive system and index score

Twenty-two men (48%) described themselves as being in full health (ie, no problems with mobility, self-care, usual activities, pain/discomfort, or anxiety/depression; index score: 1.0) in the EQ-5D descriptive system preoperatively. EQ-5D index scores showed a mean of 0.79 (median: 0.85; range: −0.02 to 1.0; standard deviation [SD]: 0.29) at baseline, 0.85 (median: 1.0; range: 0.16–1.0; SD: 0.22) at 6 mo, and 0.89 (median: 1.0; range: 0.09–1.0; SD: 0.21) at 2 yr after urethroplasty, equating to a mean 0.10 improvement in self-reported overall health status at 2 yr over baseline (95% CI, 0.02–0.18; paired t test \( p = 0.012 \); Wilcoxon matched-pairs test \( p = 0.0039 \); Fig. 5). Mean 6-mo and 2-yr scores were similar (mean of differences: \( -0.05 \) to 0.13; paired t test \( p = 0.35 \); Wilcoxon matched-pairs test \( p = 0.16 \)).

3.2.3. Treatment satisfaction

Overall, 40 of 46 men (87%) were “satisfied” (33%) or “very satisfied” (54%) with the outcome of their urethroplasty at 2 yr. Six men (13%) who were unsatisfied appeared to report more bother with postmicturition dribble postoperatively than those who were satisfied (median rating “most of the time” vs “occasionally,” respectively).

3.2.4. Unplanned reintervention

Of the total group of 46, 7 men (15%) required surgical reintervention at a median of 5 mo (mean: 8 mo) after urethroplasty: 6 underwent simple urethral dilatation and 1 a first-stage revision. This subgroup’s self-reported improvement appeared to be less, specifically a median improvement in LUTS score 2 yr after urethroplasty of 6 (mean: 5.6; SD: 6.1) versus 9 (mean: 6.8; SD: 8.5) for men who did not undergo reintervention; a median deterioration in EQVAS 2 yr after urethroplasty of 3 (median: 0; SD: 22) versus an improvement of 12 (median: 10; SD: 28) for men who did not undergo reintervention; and a median improvement in EQ-5D index score 2 yr after urethroplasty of 0.02 (median: 0; SD: 0.15) versus 0.12 (median: 0; SD: 0.28) for men who did not undergo reintervention. Three of the seven men who underwent unplanned reintervention were unsatisfied with urethroplasty at 2 yr.

4. Discussion

This study documents patient-reported outcomes after urethroplasty for anterior urethral stricture using an instrument specifically validated for that purpose. Reductions in self-reported LUTS, approaching those seen at 6 mo, were apparent 2 yr after urethroplasty. Condition-specific improvements mirrored self-reported overall health gains.
evidenced by clinically and statistically significant increases in EQVAS and EQ-5D index scores of 10 and 0.10, respectively, at 2 yr over baseline values. For reference, knee replacement surgery has been reported to confer improvements of 9.4 and 0.10 in EQVAS and EQ-5D index scores, respectively, for patients with osteoarthritis [13]. Nearly three-quarters of our patient group felt that their urinary symptoms interfered less with their overall QoL, and most of them were satisfied with urethroplasty 2 yr after the operation, indicating sustained global benefit. Men who underwent reintervention reported a lesser improvement than those who did not and expressed a higher rate of dissatisfaction with urethroplasty, which is perhaps unsurprising because its principal selling point over minimally invasive options is the prospect of long-term cure.

This study has certain limitations. First, reliability of the comparisons between the 6-mo and 2-yr data was limited by the restricted subgroup of men who completed the PROM at both postoperative time points. Second, we did not collect PROM data immediately prior to reintervention for the seven men who encountered the need for further surgery, and their outcomes cannot be attributed to urethroplasty alone. A pragmatic approach to data analysis was taken and their 2-yr scores aggregated with those of the men who did not undergo reintervention to reflect the overall effectiveness of urethroplasty as a treatment strategy for urethral stricture disease. Finally, the men who took part in this study represented a subset of the purposely varied sample we recruited from four of the five centres that participated in the PROM development study to ensure generalizability. Although this allowed us to capture a spectrum of patients’ experiences, there were insufficient men in specific clinical subgroups to make inferences about the superiority of one operative technique over another. This will require further work with a focused cohort.

When selecting a health questionnaire for use as a PROM, it is important to be sure it is supported by peer-reviewed evidence of acceptability, validity, reliability, and responsiveness for the patient group in question [7]. A key strength of the present study is the use of an instrument that, although derived from existing measures, has proven robust psychometric properties for men undergoing urethroplasty. A recent systematic review examining the implementation of PROMs in anterior urethroplasty revealed that to date the most widely used instrument is the American Urological Association (AUA)-7 [6], which was developed in a group of men with benign prostatic enlargement (BPE) but has not been validated for men with urethral stricture. Evidently there is an overlap between patients’ experience of LUTS secondary to BPE and those secondary to urethral stricture, but equally Nuss et al. [14] found that 21% of men with urethral stricture presented with symptoms that were not addressed by the instrument. In addition, many studies overlooked incorporating a measure of overall health status like EQ-5D that has become a key variable in the economically constrained arena of health care resource allocation.

Health economists use generic health status measures like EQ-5D to estimate quality-adjusted life years (QALYs) gained, the favoured dominator in cost-effectiveness analyses of health care interventions. An incidental finding of this study was the self-rated “full health” of about half of our cohort preoperatively, restricting the quantification of their outcome to deterioration only. This limitation with EQ-5D has been noted elsewhere [15]. The fact that men self-described in full health elected to undergo open surgery for urethral stricture would indicate the condition had a personally significant negative impact on their QoL but that the domains of the EQ-5D lacked content validity for health problems they experience. This raises the question of whether generic health status measures like EQ-5D are in fact appropriate for measuring the individual and societal health benefits of interventions for urethral stricture. When tested, they have been found to be problematic for patients with macular degeneration, hearing loss, leg ulcers, and schizophrenia [16]. In certain cases condition-specific instruments offering superior coverage for the QoL outcomes of importance to specific patient groups that are analogous to EQ-5D and amenable to preference elicitation by the general population, have been developed as an alternative means for estimating QALYs [17,18]. A condition-specific preference-based measure may be a more appropriate tool for gathering data for economic evaluations of interventions for urethral stricture disease and is a direction for future research.

5. Conclusions

The results of this study indicate that urethroplasty is worthwhile from the patients’ perspective. They may also serve as a provisional reference point against which individual reconstructive urethral surgeons and institutions can benchmark their performance. The USS PROM appears fit for this purpose, and if deployed in robust comparative trials of competing interventions, it has the potential to generate powerful patient-centred evidence of relative effectiveness. Beyond this, the PROM is a step towards much needed harmonisation of outcome reporting practices in urethral stricture disease [19]. The last decade has witnessed a rapid evolution in operative approaches to urethral reconstruction. Most of these incremental improvements in surgical technique will never be tested within the context of a controlled clinical trial. International consensus on an outcome reporting standard in this field would greatly facilitate the meta-analytical techniques required to demonstrate their worth. We believe the USS PROM should be part of that standard.

Author contributions: Matthew J. Jackson had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Mundy, Pickard, Andrich, Chapple, Watkin, Jackson.

Acquisition of data: Chaudhury, Mangera, Brett, Jackson.

Analysis and interpretation of data: Jackson, Pickard, Mundy, Andrich.

Drafting of the manuscript: Jackson, Pickard.

Critical revision of the manuscript for important intellectual content: Jackson, Pickard, Mundy, Andrich, Chapple, Watkin, Mangera.

Statistical analysis: Jackson.
Obtaining funding: None.
Administrative, technical, or material support: None.
Supervision: Pickard, Andrich, Mundy.
Other (specify): None.

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References