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# Comprehensive Qualitative Assessment of Urethral Stricture Disease: Toward the Development of a Patient Centered Outcome Measure



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**Purpose:** The primary objective of this study was to report what patients considered to be the most important symptoms, functions and impacts of urethral stricture disease. Patient and physician perspectives were correlated.

**Materials and Methods:** Patients were involved at each step of patient reported outcome measure development. We performed 1) qualitative semistructured concept elicitation interviews, 2) cognitive interviews, 3) prioritization interviews and 4) item prioritization by patients in regard to bother. A total of 22 reconstructive urologists ranked the items in regard to making treatment decisions.

**Results:** Patient qualitative interviews were done until no new information was gained (16 interviews) to reach concept saturation. A total of 40 items were generated from interview data. Urinary items predominated over sexually related content (34 vs 6). A review of published patient reported outcome measures revealed 10 legacy items that were not derived from the qualitative interviews. Two iterative rounds of cognitive interviews were performed in a separate cohort of 5 and 4 patients, respectively, to assess patient comprehension. Item prioritization was done in a separate cohort of 20 patients. The final instrument for validation included 31 items, of which 27 were new and 4 were legacy items. For the top 15 ranked items there was 53% agreement between patients and physicians. Patients were most worried about inability to urinate and urinary dribbling.

**Conclusions:** We found multiple patient generated concepts related to urinary and sexual impact, function and symptoms. Patients and clinicians had a low agreement rate regarding item importance.

**Key Words:** urethral stricture, patient reported outcome measures, urologists, treatment outcome, urination disorders

## Abbreviations and Acronyms

PROM = patient reported outcome measure

USD = urethral stricture disease

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URETHRAL stricture disease results from narrowing of the urethral lumen.<sup>1</sup> USD can lead to pain, infection, bladder calculi and renal failure.<sup>1,2</sup> USD can have a significant impact on the quality of life for the patient and the family of the patient.<sup>1,3,4</sup> There are limited data

regarding the effect of the condition on patient daily experience.

Patient perspective regarding health status and the influence of treatments has been increasingly emphasized in medicine.<sup>5</sup> A PROM is a measurement instrument completed by patients without interpretation by

physicians or others which addresses patient perspective concerning their health condition.<sup>6</sup>

PROMs provide clinicians with structured input from the most important stakeholder, that is the patient. PROMs are expected to serve as a benchmark for physician performance, allowing for reimbursement to be linked to evidence of treatment efficacy. As such, a condition specific PROM that has been comprehensively developed with patient input at each phase is crucial. Producing instrument items in the voice of the patient improves the comprehension and usefulness of PROMs.

The primary objective of this study was to report what patients considered to be the most important symptoms, functions and impacts of USD. This qualitative information was used to develop a new USD specific measure for use in clinical practice and clinical trials. Previous research has shown that physicians and patients disagree regarding the success of USD surgery.<sup>7</sup> We hypothesized that there would be poor agreement of physicians and patients on the PROM items most important for USD treatment and impact.

## METHODS

### Overview

To develop a conceptual framework of the domains to be assessed we chose men with USD who required intervention.<sup>8</sup> Semistructured qualitative interviews were done with individuals to identify important domains and items to assess continence, sexual function, and genital sensation and appearance. We created items for PROM inclusion based on patient interviews and existing outcome measures.

We performed 1) qualitative, semistructured, concept elicitation patient interviews followed by 2) patient cognitive interviews and 3) prioritization interviews with patients, and 4) an item prioritization survey with clinicians expert in USD surgery (fig. 1). Participants met study inclusion criteria if they were 18 years old or older and English speaking, and had USD. Patient participants were given a \$25 gift card in return for study participation.

### Sample

We recruited participants from 2 busy urethral reconstruction practices at University of Washington Medical Center, Seattle, Washington and University of California-San Francisco Medical Center, San Francisco, California. Participants provided consent to participate. Study enrollment was rolling and a convenience sample was obtained from July 2013 to February 2016. The

institutional review board at each study site approved the study procedures.

### Procedures

**Concept Elicitation Interviews, Coding and Thematic Analysis.** We performed concept elicitation interviews in the pre-urethroplasty and post-urethroplasty settings.<sup>9,10</sup> The qualitative interviews included semistructured questions (predetermined questions that were open ended to enable the examiner to explore patient responses further). These questions were created by 2 reconstructive urologists (BNB and BBV) based on their clinical experience. We explored as many USD symptom and life impacts as possible without limiting the participant to an a priori structure. To produce an integrated representation of USD symptomatology certain queries were used to elicit setting specific contexts such as home, work or leisure activities (ie “Describe how your USD impacted participation in leisure activities”).

Qualitative interviews were audio recorded and transcribed by a professional transcriptionist. We interviewed participants with USD until we reached concept saturation (ie no new symptoms or impacts were mentioned). Using the mixed methods, web based Dedoose software platform ([www.dedoose.com](http://www.dedoose.com)) data codes were applied to identify excerpts from the interviews. Coding is the process by which these concepts were identified in the interview transcripts for item development. Teams of 2 group members reviewed and coded each transcript. The research group met collectively to finalize the coding by reconciling inconsistencies and interpreting the results. Data collection and analysis were a rolling iterative process. As interviews were analyzed for themes, emerging themes were further explored in successive interviews.<sup>11</sup>

In keeping with our aim for this PROM to be patient centered items were derived verbatim from the interviews when possible, or modified for clarity while keeping the original meaning. We eliminated items that were redundant, unclear or not directly related to USD symptomatology. We used our clinical experience and examined validated PROMs that focused on sexual health, urinary continence and voiding to ensure that important items were not missed (ie legacy items).

**Cognitive Interviews.** The draft items were pilot tested via cognitive interviews.<sup>12,13</sup> During cognitive interviewing participants assess the relevance, importance and comprehension of the content items. We used the “think aloud” approach since we believed that there would be less bias from the interviewer than with other types of cognitive interviews (ie the verbal probing approach). Interviewees verbally reported (“think aloud”) how they understood the item and why they chose a certain response. The approach helped identify items with poor wording, confusing language or format. Figure 2 shows an



Figure 1. Schematic of steps in process to create USD PROM

example. For this phase of the study a new patient cohort was used.

Cognitive interviews were iterative as additional rounds were done based on patient feedback until there was no constructive feedback. Items were included in successive cognitive interviews if they met certain criteria, that is the item 1) was deemed critically important and relevant to patients with USD, 2) was in the language of the patient and 3) could be related to disease severity and be improved with USD treatment.

**Item Prioritization.** A separate cohort of patients with USD was recruited for item prioritization. Patient participants rated the items in order of personal perceived bother relative to their USD experience. The draft item list was sent to national and international experts in urethral reconstruction. Clinicians were asked to rate the importance of each item for making treatment decisions. The clinician draft item list had subtle wording differences for a few items, which differed from the patient draft item list. This word phrasing difference occurred during the second iterative round of cognitive interviews. As such, patients received the updated draft item list while clinicians received the original draft item list. The item content theme was the same (ie “bothered by dribbling in my underpants” vs “annoyed by dribbling in my pants”).

**RESULTS**

**Interviews**

**Qualitative.** Qualitative interviews were stopped after concept saturation was reached (16 interviews) or no new content was elicited. Median interviewee age was 51 years (range 29 to 70). The

cohort included 13 Caucasian men, and 1 Hispanic, 1 African American and 1 Asian man. Of the men 12 had bulbar strictures and 4 had penile strictures. The etiology of bulbar strictures was idiopathic in 9 cases, external urethral trauma in 2 and iatrogenic in 1. The etiology of penile strictures was lichen sclerosus in 2 cases, hypospadias failure in 1 and iatrogenic in 1.

A total of 40 potential items were generated following patient centered qualitative interviews. Ten additional unique (ie legacy) items were generated after the physician review of existing PROMs. Most of the content pertained to urinary impact (5 legacy and 21 new items), urinary symptom (2 legacy and 8 new items) and function (1 legacy and 5 new items). Eight items were related to sexual content, including sexual impact (2 new and 2 legacy items), symptom (3 new items) and function (1 new item).

Urinary impact included the emotional toll of USD, such as worry, embarrassment and depression. It also included those impacts related to changing daily activities to manage stricture symptoms, such as “I quit doing things I like to do” and “I had to plan everything ahead.” Urinary function included items related to obstruction and trouble with aiming the stream. Urinary symptom included items related to pain, nocturia and urgency. Five of the 8 items related to sexual activity were related to ejaculation.

**Cognitive.** Two iterative rounds of cognitive interviews were performed in separate cohorts of 5

Cognitive Interviews: Round 1

*INTERVIEWER COPY*  
*ID # 65*

3 19. I felt abnormal because it took me so long to pee in public

NOT AT ALL	A LITTLE	MODERATELY	QUITE A BIT	EXTREMELY
<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

*- difficult to answer*  
*° what is abnormal?*

Cognitive Interviews: Round 2

*INTERVIEWER COPY*  
*ID # 10*

2 19. I felt uncomfortable because it took me so long to pee in public

NOT AT ALL	A LITTLE	MODERATELY	QUITE A BIT	EXTREMELY
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input checked="" type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

*° straight forward*  
*° easy to answer*  
*° easy to understand*

Figure 2.

and 4 patients, respectively, to further test patient comprehension. Demographics of the first round of patients were age range 31 to 63 years, 1 Hispanic and 4 Caucasian males, 3 idiopathic bulbar strictures and 2 penile strictures, including 1 due to hypospadias failure and 1 due to lichen sclerosus. Demographics of the second round of patients were age range 33 to 78 years, 4 Caucasian males, 3 idiopathic bulbar strictures and 1 penile stricture due to lichen sclerosus. Changes were made to the existing items based on feedback.

### Item Prioritization

Items were prioritized in a separate cohort of 20 patients who rated the degree of bother related to symptoms and the impact of USD (very much, somewhat or does not bother). Age range was 31 to 78 years. There were 3 Hispanic, 1 Asian, 1 American Indian and 15 Caucasian males. Of the 20 patients 15 (75%) had a bulbar stricture and 5 (25%) had a penile stricture. Bulbar stricture etiology was idiopathic in 8 cases, iatrogenic in 4, due to trauma in 2 and due to infection in 1. Penile stricture etiology was lichen sclerosus in 3, failed hypospadias treatment in 1 and trauma in 1.

Item reduction was necessary to eliminate redundant items such as "I felt pain when I peed" and "I had pain when trying to pee." We also eliminated other items that were consistently ranked as low importance by our patient cohort. After these steps the final item number of items for planned validation was 32.

Urinary issues predominated among the top 15 items that patients rated by bother. There was only 1 sexual item (slow force of ejaculation). On average the patient cohort was most bothered by anxiety about being unable to void, post-void dribbling and trouble aiming the stream.

A total of 22 reconstructive urologists also rated the items in regard to importance for making decisions about treatment. Patients and clinicians agreed on 8 of the 15 items (53%) that they independently rated of highest importance (see Appendix). Patients were most "worried about being unable to pee" and having urinary dribbling "in my underwear after peeing." Clinicians thought that "I had to strain to pee" and "I had a weak stream" were most important for making treatment decisions. Three of the top 5 patient items were not rated highly on the clinician list, including 1) "I had trouble aiming my urine stream," 2) "I sat down to pee" and 3) "I had to plan ahead."

## DISCUSSION

Through concept elicitation, cognitive and prioritization interviews with patients we have produced a

USD specific PROM for planned testing of measurement properties. Multiple themes were derived from the interviews that pertained to urinary and sexual impact, function and symptoms. USD can create a significant emotional impact highlighted by worry, embarrassment and depression as evidenced by the fact that 7 of the 15 highest rated items (47%) pertained to emotional impact.

USD disrupts urinary function and produces symptoms of pain, nocturia and urgency. Sexual themes related to USD were ejaculation pain, weakness and satisfaction. Patients and providers rated item importance differently with patients most focused on dribbling, split stream, sitting and being unable to void.

The importance of patient perception and perspective in urethral surgery has been previously studied. Kessler et al reported differing perceptions of urethroplasty success between patients and clinicians.<sup>7</sup> Interestingly 80% of the 24 men who experienced subjective surgical failure were satisfied or very satisfied with the outcome. This disparity highlights a disconnect between patients and providers.

Others noted a divergence between physician and patient reported outcomes.<sup>14</sup> In a report of 433 patients who underwent urethroplasty patient dissatisfaction correlated with objective outcomes such as postoperative cystoscopy.<sup>15</sup> However, independent of the anatomical diameter of the reconstructed urethra the predictors of patient dissatisfaction were postoperative pain, sexual dysfunction and persistent lower urinary tract symptoms.

In our comparison of patient and physician ratings of USD symptoms before surgical reconstruction the 2 cohorts agreed on 8 of the top 15 rated items (53%). Most disagreement was due to physicians not rating the urinary impact of USD as important as urinary function and symptoms. Physicians did not rate certain impact issues in the top 15, including "I had to plan ahead," "I was frustrated because my activities were reduced," "I worried about my bladder health" and "I did not get enough sleep/rest."

A previous USD PROM was reported.<sup>16</sup> The instrument has multiple strengths, including being condition specific and seeking patient input. However, patient interviews were done to query about important issues at the start of the research but interviews were not performed in further steps until validation. The items were also generated from questionnaires validated for other health conditions and not generated de novo from the words of the patients. This has resulted in a lack of uniformity among items and response choices (ie choices vary from 3 to 5 responses across the included items).



Notably sexual function items are not present. Finally, the PROM uses generic quality of life items and only 1 USD specific quality of life question. Others have validated the instrument in Turkish and German, and added other measures for sexual function and oral mucosa morbidity.<sup>17,18</sup>

Our study has limitations. The respondent racial and ethnic backgrounds reflect our practice settings, which are predominantly Caucasian. We did not assess patient education and literacy, which may influence the patient perceived medical condition and the importance of various attributes. Patients received a \$25 gift card to participate, which may have introduced nonresponse bias.<sup>19</sup> Those motivated to participate by receiving a gift card may differ from participants who were not enticed by the gift card.

Despite these limitations we completed a patient derived PROM specific to USD which included patient feedback at every development level. We are currently working to field test the instrument and determine whether the PROM is sufficiently reproducible, able to detect change with treatment and interpretable.

## CONCLUSIONS

We performed a multipart process to generate a USD specific PROM, including qualitative semistructured concept elicitation interviews, cognitive and prioritization interviews with patients, and an item prioritization survey with clinicians expert in USD surgery. We found multiple constructs related to urinary and sexual impact, function and symptom. Patients and clinicians had a low agreement rate with respect to which items were most important.

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## APPENDIX

### Top 15 Items Rated by Importance to 20 Patients and 22 Clinicians

Patient	Clinician
I worried about being unable to pee	I had to strain to pee
I dribbled in my underwear after peeing	I had a weak stream
I had trouble aiming my urine stream	I worried about being unable to pee
I sat down to pee	It felt like my bladder was always full
I had to plan ahead	I felt abnormal because it took me so long to pee in public
I had a weak urine stream	I felt pain when I peed
I felt bothered by dribbling in my pants	I was annoyed by dribbling in my pants
I felt pain when I peed	I stopped peeing before my bladder was empty
I was frustrated because my activities were reduced	I felt embarrassed because I had to sit to pee
I worried about my bladder health	I had pain in my penis
My semen dribbled out slowly after I ejaculated	I felt embarrassed by my lack of control over peeing
It felt like my bladder was full	I felt stressed because I could not predict when I would have to pee
I did not get enough sleep/rest	I had dribbling at the end of my urine flow
I felt pain in my penis	I worried about not being able to get to the toilet in time
I felt uncomfortable because it took me so long to pee in public	I had pain when I ejaculated

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## EDITORIAL COMMENT

Sadly physician (and surgeon) understanding of the effect of disease and interventions on the daily lives of our patients is poor.<sup>1</sup> As urologists, developing disease specific PROMs is essential to determine whether our surgeries in fact make a difference in patient quality of life and health status. This study by Breyer et al represents continued progress in deciding which factors are important to patients who undergo urethroplasty. The authors embarked on the noble and labor intensive path of performing qualitative and cognitive interviews with subsequent prioritization of this information.

These types of studies are particularly important to patients treated with urethroplasty since most of

these operations are performed for quality of life indications. This study also emphasizes the discrepancy between factors that patients believed were important after urethroplasty and what surgeons believed were important. Clearly further work to develop a robust, disease specific PROM is of the utmost importance for patients with urethral stricture.

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