Evaluation of the effect of urethroplasty for anterior urethral strictures by a validated disease-specific patient-reported outcome measure

Akio Horiguchi[1] · Masayuki Shinchi[1] · Kenichiro Ojima[1] · Ayako Masunaga[1] · Keiichi Ito[1] · Tomohiko Asano[1] · Eiji Takahashi[2] · Fumihiro Kimura[2] · Ryuichi Azuma[3]

Abstract

Purpose To better understand our urethroplasty outcome, we translated the English version of a urethral stricture surgery patient-reported outcome measure (USS-PROM) into Japanese and used it to evaluate the effect of urethroplasty for anterior urethral strictures.

Methods The PROM quantifies lower urinary tract symptoms (LUTS) and health-related quality of life (EQ-5D), and it evaluates overall satisfaction by asking patients to choose "very satisfied", "satisfied", "unsatisfied", or "very unsatisfied". 93 Japanese-speaking male patients with anterior urethral stricture who underwent urethroplasty completed it before (baseline) and 6 months after urethroplasty. The psychometric criteria evaluated in the present study were the PROM's internal consistency, test–retest reliability, criterion validity, and responsiveness.

Results Q_{max} was negatively correlated with the LUTS-total scores ($r = -0.61$). Cronbach's alpha was 0.80 and the test–retest intraclass correlation coefficient for the LUTS-total score was 0.82. 83 patients (89.2%) achieved stricture-free, which was defined as no re-stricture on cystoscopy and no need for additional treatment. The mean total LUTS-score improved from 12.4 at baseline to 3.7 postoperatively ($p < 0.0001$). The mean EQ-5D visual analogue scores and EQ-5D index improved from 61.2 and 0.76, respectively, at baseline to 77.9 and 0.89 postoperatively ($p < 0.0001$, $p < 0.0001$). 55 patients (59.1%) were "very satisfied" with the outcome of their urethroplasty and 33 (35.5%) were "satisfied".

Conclusions The Japanese version of the USS-PROM has adequate psychometric properties. Urethroplasty improved not only objective data but also voiding symptoms and health-related QOL, and it resulted in a high rate of patient satisfaction.

Keywords Urethroplasty · Quality of life · Patient-reported outcome · Validation

Introduction

Urethral stricture is one of the oldest documented urological conditions and is still relatively common [1]. Despite the widespread but futile use of urethrotomy and dilation, urethroplasty is the gold standard management for the repair of anterior urethral stricture in most cases [2–4]. It is intended to allow men to return to a normal state of voiding free from any instrumentation while maintaining quality of life. There is therefore a need for patient-reported outcome measures (PROMs) accurately evaluating treatment outcome from the patient's standpoint. Investigators in the UK have tried to fill this need by designing and validating a PROM questionnaire specifically for urethral stricture surgery (USS-PROM) [5]. It has been translated into several languages and the translated versions have been validated [6–8]. The objective of this study was to translate the original version into Japanese and validate the translated version, evaluating its psychometric properties in a different population, environment, and health care system. Furthermore, we evaluated the effect of urethroplasty for anterior urethral strictures using it to better understand our urethroplasty outcome.

✉ Akio Horiguchi
impreza@ndmc.ac.jp

1 Department of Urology, National Defense Medical College, 3-2 Namiki, Tokorozawa, Saitama 359-8513, Japan

2 Department of Urology, Nishisaitama-chuo National Hospital, Saitama, Japan

3 Department of Plastic Surgery, National Defense Medical College, Saitama, Japan

Patients and methods

Patients

Of 351 Japanese-speaking male patients with anterior urethral stricture who underwent urethroplasty between August 2011 and April 2017 by a single surgeon (AH), 93 who could void preoperatively and whose clinical data including maximum flow rate (Q_{max}) and postvoid residual (PVR) bladder volume were available and who completed the following USS-PROM before (baseline) and 6 months after urethroplasty were retrospectively reviewed. Patients who could not void preoperatively and those who underwent perineal urethrostomy or meatoplasty were excluded. Stricture-free status was assigned to patients not needing additional treatment and having a urethral caliber adequate for passage of a 17Fr flexible cystoscope.

USS-PROM

The constructs of the Japanese USS-PROM are exactly same as those of the original UK-version [5]. In brief, the USS-PROM comprises a LUTS construct consisting of six questions from the International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms (ICIQ-MLUTS) module [9, 10] to generate a total score between 0 (asymptomatic) and 24 (most symptomatic), a separate LUTS-related QOL question from the ICIQ-MLUTS (score 0 = not at all, 1 = a little, 2 = somewhat, 3 = a lot), and Peeling's voiding picture score (1 = best, 4 = worst) [11]. The Japanese version of EQ-5D score (1 = full health, 0 = dead) and EQ-5D visual analogue scores (EQ-VAS, 100 = best imaginable health, 0 = worst) were included to assess overall health-related QOL (HRQOL) [12, 13]. Overall satisfaction is evaluated by asking patients to choose "very satisfied", "satisfied", "unsatisfied", or "very unsatisfied".

Psychometric evaluation

The USS-PROM was translated into Japanese by the authors and proofread by patients with anterior urethral strictures. The following psychometric criteria were evaluated as proposed previously [5]. Criterion validity was assessed using the Pearson correlation coefficient to measure the strength of the relationship between LUTS construct score and maximum flow rate (Q_{max}) [5]. Internal consistency is the extent to which questions within the same construct actually cover the same concept: Cronbach' alpha and item–total correlations were quantified for the LUTS-score (questions 1–6). Threshold values were between > 0.70 and 0.20, respectively, as previously reported [5]. The test–retest

reliability represents a PROM's results to be reproducible over time and was assessed and by asking patients to complete the USS-PROM at both 3 and 6 months after surgery as reported previously [7]. Reliability and agreement were assessed using intraclass correlation coefficients (ICCs) and Bland–Altman plots, respectively. A threshold of > 0.70 was predefined for the ICCs. Responsiveness was addressed by examining LUTS and HRQOL construct scores before and after urethroplasty.

Statistical analysis

Paired *t* tests were used to compare preoperative and postoperative continuous variables. The Mann–Whitney *U* test and Wilcoxon signed-rank tests were used to evaluate the relations between continuous data, and a Chi-square test was used to assess the association between categorized data. All statistical analyses were performed using the JMP Pro 13 (SAS Institute Inc.®, Cary, NC, USA). *p* values less than 0.05 were considered to indicate statistical significance.

Results

Patient characteristics

Patient characteristics are listed in Table 1. Stricture location was penile urethra in 25 (26.9%), bulbar urethra in 65 (69.9%) and pan-anterior urethra in 3 (3.2%). Stricture etiology was iatrogenic in 45 (48.4%), unknown in 29 (31.2%), trauma in 13 (14.0%), failed hypospadias repair in 4 (4.3%), lichen sclerosus in 1 (1.1%), and urethral amyloidosis in 1 (1.1%). Median stricture length was 13.6 mm (interquartile range, IQR 7.2–25.1). 74 patients (79.6%) had history of prior transurethral procedures, and 14 patients (15.1%) had history of prior urethroplasty. 49 of the 93 patients (52.7%) received excision and primary anastomosis, 30 (32.3%) received buccal mucosa graft (BMG) one-stage urethroplasty, and 14 (15.0%) received BMG-staged urethroplasty. 83 (89.2%) achieved stricture-free status in the sixth postoperative month.

Psychometric evaluation

Regarding content validity, the questions were translated into Japanese by the authors, and we found no patients to have difficulty understanding them. Regarding criterion validity, there was a negative correlation between LUTS construct total score and Q_{max} in overall variables and stratified by pre- and post-urethroplasty ($r = -0.61$, $p < 0.0001$, 95% CI -0.61 to -0.51 in overall LUTS vs. Q_{max}, $r = -0.40$, $p = 0.0002$, 95% CI -0.57 to -0.20 in preoperative LUTS vs. Q_{max}, $r = -0.43$, $p < 0.0001$, 95% CI -0.58 to -0.24 in

Table 1 Patient characteristics

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Number of patients	93
Age, median (IQR)	54 (37–69)
BMI, median (IQR)	23.4 (21.0–25.2)
Disease duration (months), median (IQR)	39 (16–129)
Stricture location (%)	
Penile	25 (26.9)
Bulbar	65 (69.9)
Pan-anterior	3 (3.2)
Stricture etiology (%)	
Iatrogenic	45 (48.4)
Unknown	29 (31.2)
Trauma	13 (14.0)
Others	6 (6.5)
Stricture length (mm), median (IQR)	13.6 (7.2–25.1)
Prior failed urethrotomy/dilation	74 (79.6)
Prior failed urethroplasty	14 (15.1)
Urethroplasty type (%)	
Excision and primary anastomosis	49 (52.7)
Buccal mucosal onlay	30 (32.3)
Buccal mucosal staged	14 (15.0)
Surgical outcome (%)	
Successful	83 (89.2)
Failed	10 (10.8)

postoperative LUTS vs. Q_{max}, Fig. 1). Regarding internal consistency, Cronbach's alpha for the LUTS-score was 0.80 and with any item deleted ranged from 0.74 to 0.76. The item–total correlations ranged from 0.58 to 0.82. Regarding test–retest reliability, 83 patients completed the USS-PROM at both 3 and 6 months after surgery. The median test–retest interval was 98 days (IQR 91–105 days). The intraclass correlation coefficient was 0.82 for LUTS-total score and ranged from 0.67 to 0.78 for each item. For the summative LUTS-score (scored 0–24), 95% limits of agreement were between −4.22 and 3.62 with a bias of 0.29 and 0.21 as the standard deviation of bias.

Responsiveness

The mean Q_{max} and PVR improved from 6.2 ml/s and 107.3 ml at baseline to 21.0 ml/s and 53.6 ml postoperatively ($p < 0.0001$ and $p = 0.001$, respectively, Table 2). The mean total LUTS-score and mean QOL score improved from 12.4 and 2.6 at baseline to 3.7 and 0.6 postoperatively ($p < 0.0001$ and $p < 0.0001$, respectively, Table 2). The mean Peeling's stream picture score fell from 3.4 at baseline to 2.1 postoperatively ($p < 0.0001$, Table 2). The mean EQ-VAS and EQ-5D index scores improved from 61.2 and 0.76 at baseline to 77.9 and 0.89 postoperatively ($p < 0.0001$ and $p < 0.0001$, respectively, Table 2). When patients were stratified by surgical outcome, the Q_{max}, PVR, LUTS-total score, LUTS-related QOL score, Peeling's picture score, EQ-VAS score, and EQ-5D score were all significantly improved after urethroplasty in patients who achieved stricture-free status ($p < 0.0001$, $p = 0.001$, $p < 0.0001$, $p < 0.0001$, $p < 0.0001$, $p < 0.0001$, $p < 0.0001$, respectively). In patients with

Fig. 1 Scatter plot of lower urinary tract symptoms (LUTS) score vs. maximum flow rate (Q_{max}). Open circles indicate preoperative status and closed circles indicate postoperative status
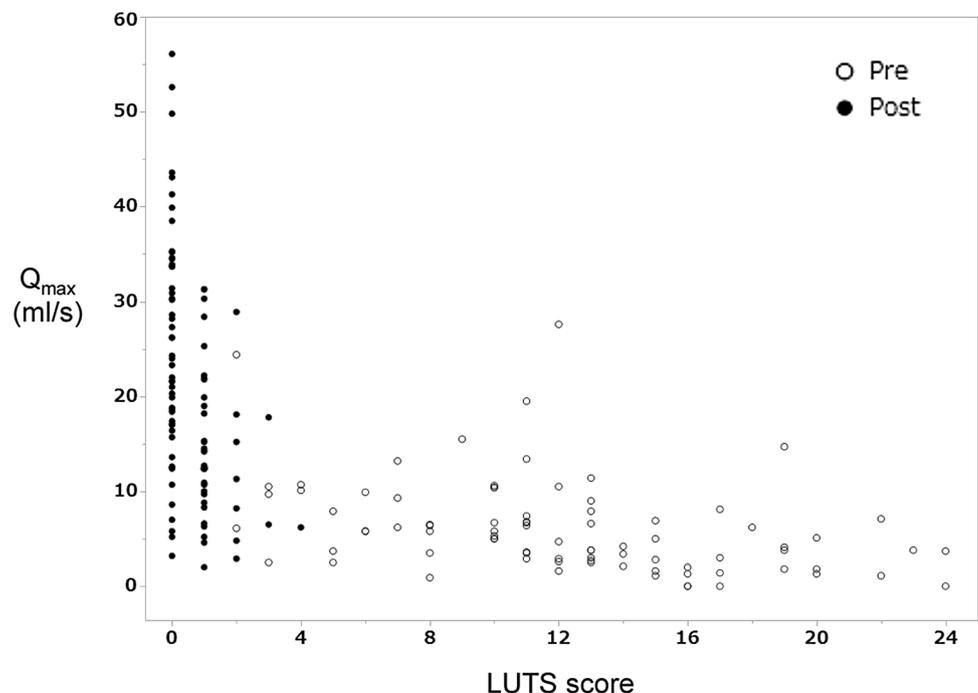
Table 2 Pre- and postoperative parameters in overall patients

	Preoperative mean	Postoperative mean	p	Mean of differences	95% CI of mean of differences
Q_{max} (ml/s)	6.2	21.0	< 0.0001	14.8	12.1–17.6
PVR (ml)	107.3	53.6	0.001	53.7	22.4–84.9
LUTS-score	12.4	3.7	< 0.0001	8.7	7.4–9.9
LUTS-QOL	2.6	0.6	< 0.0001	2.0	1.8–2.3
Peeling's picture score	3.4	2.1	< 0.0001	1.3	1.2–1.5
EQ-VAS	61.2	77.9	< 0.0001	16.7	11.6–21.7
EQ-5D score	0.76	0.89	< 0.0001	0.13	0.07–0.18

re-stricture, however, significant improvement after urethroplasty was found only in LUTS-related QOL score and Peeling's picture score ($p = 0.009$ and $p = 0.002$, respectively).

Patient satisfaction

Fifty-five patients (59.1%) were "very satisfied" with the outcome of their urethroplasty and 33 (35.5%) were "satisfied", while five (5.4%) were "unsatisfied" or "very unsatisfied" (Table 3). All of the stricture-free patients were satisfied, but only five of ten patients (50%) with re-stricture were satisfied ($p < 0.0001$, Table 3). The mean difference of Q_{max} and Peeling's picture score in "very satisfied" or "satisfied" patients were significantly greater than those in "unsatisfied" or "very unsatisfied" patients ($p = 0.03$ and $p = 0.01$, respectively, Table 3).

Discussion

Patients suffering from urethral stricture and undergoing urethroplasty have long been evaluated from a clinician-oriented viewpoint and patient-reported benefit from USS has been lacking. The American Urological Association symptom index has proven useful in assessing men with LUTS related to urethral stricture [14]. However, the inability of this instrument to capture the full range of voiding symptoms in men with urethral stricture limits its usefulness. The first USS-PROM was designed and validated in 2011 by a group of UK urethral surgeons [5] and has been translated into non-English languages [6–8]. Our institute is a tertiary referral center for USS, but we had no USS-PROM in Japanese. We therefore translated the UK-version into Japanese and have been using it without validation as a pre- and postoperative monitoring tool for personal use. To validate its usefulness and to make the Japanese version one

Table 3 Relation of patient satisfaction and clinical parameters

	Very satisfied or satisfied	Very unsatisfied or unsatisfied	p
Number of patients	88	5	
Age, mean (SD)	52.2 (18.3)	56.4 (16.0)	0.65
BMI, mean (SD)	23.6 (3.8)	22.2 (1.4)	0.44
Stricture site (%)			
Penile/pan-anterior	26 (92.9)	2 (7.1)	0.64
Bulbar	62 (95.4)	3 (4.6)	
Stricture length (mm), mean (SD)	19.5 (16.7)	26.6 (27.8)	0.88
Urethroplasty type (%)			
Excision and primary anastomosis	47 (95.9)	2 (4.1)	0.56
Buccal mucosa graft	41 (93.2)	3 (6.8)	
Urethroplasty outcome (%)			
Stricture-free	83 (100)	0 (0)	< 0.0001
Re-strictured	5 (50.0)	5 (50.0)	
Mean difference of Q_{max} (ml/s) (SD)	15.5 (12.6)	4.1 (7.8)	0.03
Mean difference of PVR (ml) (SD)	56.3 (119.4)	7.7 (92.2)	0.59
Mean difference of LUTS-score (SD)	8.8 (5.9)	6.2 (7.1)	0.22
Mean difference of Peeling's picture score (SD)	1.4 (0.9)	0.4 (0.5)	0.01

for official use, we conducted this retrospective study. Our results clearly demonstrate that the psychometric properties of the Japanese version are comparable to those of the versions in other languages and that the Japanese version is clinically reliable and effective.

We achieved a high stricture-free rate, and both clinical data (Q_{max} and PVR) and subjective data were significantly improved after urethroplasty. We further stratified the patients according to stricture-free status and found that all of the parameters were improved after urethroplasty in patients with stricture-free status. Even in patients with re-stricture, LUTS-related QOL score and Peeling's picture score were significantly improved, which might be due to our strict definition of re-stricture (inability to pass the cystoscope). With regard to patient satisfaction, satisfied patients tend to have greater improvement of clinical data such as Q_{max} and PVR. Our study confirms the hypothesis that traditional objective measures of success, such as improvement of Q_{max} and/or PVR, correlate strongly with patient satisfaction. With regard to subjective measures, satisfied patients tend to have greater improvement of LUTS-score and Peeling's picture score. In future studies we should assess the most significant parameters predicting patient's satisfaction by including parameters other than voiding symptoms.

The original UK-version of USS-PROMs does not include any questionnaires on sexual function or storage LUTS because it has been suggested that anterior urethroplasty rarely creates de novo erectile dysfunction and questions targeting storage LUTS are not of specific importance in describing the benefits expected of USS [5]. Although the incidence of de novo erectile dysfunction after anterior urethroplasty is low at 1% and in most cases resolves within 6–12 months [15], it has also been reported that postoperative decrease in sexual activity is an independent predictor of patient dissatisfaction [16]. Patients with anterior urethral stricture frequently have storage LUTS and majority of men experienced symptom stability or improvement after urethroplasty [17, 18], suggesting the changes in storage LUTS after urethroplasty could have positive impact on LUTS-related QOL. In addition, a recent study demonstrated that patient satisfaction after urethroplasty is affected more by erectile function, storage LUTS, and postoperative cosmetic issues such as chordee status and perceived penile shortening than by improvement of voiding function [19]. In our series, two of five patients (40%) reported they were unsatisfied with the outcome of their urethroplasty because their urinary condition had not improved. Interestingly, three of five (60%) reported they were unsatisfied because although their urinary condition had improved there was some other problem (ejaculatory dysfunction in one, decreased glans sensitivity in one, and persistent urinary urgency in one). These findings suggest the necessity of inclusion of constructs of

sexual function and storage LUTS in USS-PROMs, and we are now updating the Japanese USS-PROM questionnaires by including questions for those constructs.

Our study has some limitations. Firstly, our study is not a prospective study and is based on a single center and single surgeon series with heterogeneous stricture etiology. Secondly, patients were asked to complete the paper questionnaires at the clinic, not anonymously, which might have prevented them from being honest. Thirdly, we excluded patients who could not void preoperatively from the analysis. In our cohort, 206 of 315 (65.4%) patients were excluded because they could not void preoperatively and our results reflect the experience of only about two-thirds of our cohort. Fourth, the official WHO protocol for linguistic validation was not strictly adhered to while translating the score. Our study will nonetheless not only facilitate meaningful direct comparisons with other centers in foreign countries and health care systems that use the English version of PROM questionnaires but will also enable us to evaluate our performance compared to other surgeons and thereby improve the quality of the care we provide.

Conclusions

The Japanese version of the USS-PROM has adequate psychometric properties and is a valid instrument for assessing patient-reported outcome measures in men undergoing urethroplasty. Urethroplasty improved not only clinical data but also voiding symptoms and health-related QOL and yielded a high rate of patient satisfaction. Objective urethroplasty success and improvement of the urinary stream are the keys to the patient's satisfaction.

Compliance with ethical standards

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