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Evaluation of outcomes of Urethral Stricture Surgery: psychometric validation of a Polish language version of the Patient-Reported Outcome Measure for urethral stricture surgery

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Introduction The aim of this study is to validate the Polish version of the Urethral Stricture Surgery – Patient-Reported Outcome Measure (USS-PROM) by evaluating its psychometric properties.
Material and methods Patients with urethral stricture scheduled for urethroplasty between 2014 and 2018 were prospectively enrolled. The results of the USS-PROM were obtained before the operation, and during follow-up visits. The original USS-PROM was translated into Polish and re-translated into English in accordance with the guidelines by Dawson et al. regarding the adaptation process. Psychometric assessment included internal consistency, test-retest reliability, criterion validity and responsiveness.
Results One hundred twelve patients were included. 54 patients completed the USS-PROM both before and 3 months after the surgery and 39 of them completed the questionnaire 6 months after the surgery to evaluate the test-retest reliability. Cronbach's α for internal consistency of the lower urinary tract symptoms (LUTS) domain score was 0.87. The test-retest intraclass correlation coefficient was 0.82. Spearman's coefficients showed no correlation between USS-PROM's result and maximal urinary flow (Qmax) result before the surgery (rs = 0.13; p >0.05) and a positive correlation between USS-PROM's result and Qmax result at follow up: 3 months after (rs =- 0.56; p <0.05), 6 months after (rs-0.64; p <0.05), and 12 months after (rs =-0.85; p <0.05). There were statistically significant strong and positive correlations between LUTS score and International Prostate Symptom Score (IPSS). Responsiveness of the test was confirmed with non-parametric Friedman's analysis of variance (ANOVA) with Kendall's coefficient of concordance ($\chi2$ ANOVA = 8.95, p = 0.03).
Conclusions The Polish version of the USS-PROM questionnaire has appropriate psychometric properties and can be used in the assessment of patients with urethral stricture undergoing urethroplasty.

INTRODUCTION

Urethral stricture disease is a common condition that affects approximately 300 per 100 000 men [1]. It is associated with high recurrence rates and sig- nificantly affects quality of life. Numerous surgical methods including urethral dilatation, endoscopic urethrotomy, and urethroplasty, aim to return pa- tients to a state of normal voiding. Reported suc- cess rates after urethral reconstruction vary widely

depending on the location, length of the stricture and type of procedure used. In general, the recurrence rates range between 50% and 100% with urethroplasty recognized as the gold standard due to the best long-term effects [2].

Most studies use a functional definition of successful treatment – considering freedom from repeated surgery and no recurrence as an equivalent of a satisfied patient. In clinical practice, treatment results are assessed using objective methods, such as uroflowmetry and urethrography, or subjectively by evaluating the results from the patient's perspective. Numerous papers indicated a need for creating a validated tool designed to measure patient-reported benefit from urethral stricture surgery.

Patient-reported outcome measures (PROMs) are health questionnaires that aim to capture a patient's self-assessment of health and of the quality of care delivered before and after the treatment. A reliable PROM may be used by a urologist to directly measure the benefit that patients derive from the chosen method of treatment. It is also a tool that enables designing comparative studies on the effectiveness of different surgical techniques. By taking into account the patient's assessment, one may achieve powerful patient-centered evidence of relative effectiveness. The first PROM designed for patients undergoing urethral stricture surgery – Patient-Reported Outcome Measure for Urethral Stricture Surgery (USS-PROM) was validated in 2011 by Jackson et al. [3].

The objective of this study is to validate the Polish version of the USS-PROM by evaluating its psychometric properties in a different population, different environment, and a different health care system.

MATERIAL AND METHODS

The local Bioethics Committee approved the study. Written informed consent was obtained from every patient included in the study. Patients with urethral stricture scheduled for urethroplasty in the University Clinical Centre in Gdańsk, Poland between 2014 and 2018 were prospectively enrolled in this study. The results of the PROM were obtained during four consecutive measurements – before the operation (n = 112), and during post-operative follow-up at 3 months (n = 54), 6 months (n = 39) and 12 months or more after the surgery (up to 24 months, n = 31). Table 1 presents the description (socio-demographic and clinical aspects) of the studied group. Every patient completed the paper questionnaire unaided in conditions that ensured complete privacy. Responses were anonymized and collated in an online database.

USS-PROM

The analyzed USS-PROM consists of three domains: The first domain contains six questions taken from the International Consultation on Incontinence Questionnaire. Male Lower Urinary Tract Symptoms Questionnaire (ICIQ-MLUTS) [4]. Each question is scored from 0 to 4, which gives a total score from 0 points (least symptoms) to 24 points (most symptoms). The domain also includes one question about the LUTS-dependent quality of life ("Overall, how much do your urinary symptoms interfere with your life?"), and a visual scale to assess the urine stream (Peeling's voiding picture) [5].

The second domain contains two questions about patient satisfaction with the results of the operation.

The third domain contains five questions about overall health status and quality of life, taken from the EuroQol-5D questionnaire (EQ-5D) along with the analog quality scale of EuroQol-Visual Analogue Score (EQ-VAS) [6].

Translation procedure

Following the guidelines by Dawson et al. regarding the adaptation process, forward and backward translation methods were used [7]. The original USS-PROM was translated into Polish and re-translated into English. Psychometric criteria for the evaluation of the Polish version of the PROM are described in detail below.

Psychometric criteria for evaluation of the Polish version of the USS-PROM and statistical analyses We evaluated the following psychometric criteria: internal consistency, test-retest reliability, criterion validity, and responsiveness.

Reliability

Reliability of the scale was checked with an internal consistency measure. Internal consistency is the extent to which questions within the same domain cover the same concept. Cronbach's α statistics and item-total correlations were used for quantifying the interrelationship between question items within the LUTS domain. Specific data are presented in Table 2. Test-retest reliability is connected with the degree to which a PROM result remains stable over time. To evaluate the test-retest reliability, we asked some patients to complete the PROM at three and six months after surgery.

Criterion validity

To assess criterion validity – Spearman's coefficient of rank correlation ($p < 0.05$) was used between LUTS

scores (Question 1–6) and International Prostate Symptom Scores (IPSS) and between LUTS scores (question 1–6) and maximum flow rates (Qmax).

Responsiveness

The results of the LUTS domains obtained during four consecutive measurements were compared with non-parametric Friedman's Analysis of Variance (ANOVA) with Kendall's coefficient of concordance to check for responsiveness of the Polish version of PROM.
All statistical analyses were performed with STA-TISTICA v.12 (StatSoft Inc).

RESULTS

The study included 112 Polish-speaking men with urethral stricture who completed a PROM before surgery and during postoperative follow-up. The average age of patients was 51 years. The youngest patient was 19 and oldest 84 years old. The socio-demographic and clinical characteristics of the study group are presented in Table 1.

Psychometric evaluation

Reliability

The reliability of the scale was checked with the internal consistency measure. Cronbach's α for the LUTS domain score was 0.87 and with deletion of any item ranged from 0.84 to 0.88. Item total correlations ranged from 0.4 to 0.8 (Table 2).

Test-retest reliability

Three months after the surgery, the questionnaire was completed by 54 patients. Six months after the operation, 72% of the group filled in the questionnaire again (n = 39). The median test-retest was three months, which was expected to be an adequate time interval given the similar clinical status of patients at that stage of treatment. Spearman's correlation was used as a test-retest reliability coefficient. General scores of the two tests (3 months after and six months after) were strongly correlated (rs = 0.82; p >0.05), which shows good reliability of the polish version of a PROM for urethral stricture surgery.

Criterion validity

There were statistically significant strong and positive correlations between LUTS scores and IPSS at each stage of the treatment. The results are presented in Table 3. The Spearman's coefficients

Table 1. *Socio-demographic and clinical characteristics of the study group*

Age (years); M ±SD	50.66 ±16.83
Etiology; N (%)	
trauma	26 (23%)
idiopathic	46 (41%)
hypospadias	14 (12.5%)
TURP	14 (12.5%)
catheterization	12 (11%)
Location; N (%)	
bulbar	59 (53%)
penile	40 (36%)
membranous	13 (11%)
Type of operation; N (%)	
End-to-end	51 (45%)
Oral mucosa graft	22 (20%)
Penile skin	19 (17%)
Johansen	17 (15%)
Mesh-graft	3 (3%)

Table 2. *Internal consistency of the Polish version of patient-reported outcome measure for urethral stricture surgery within the LUTS domain*

Item	Item – total correlation	Cronbach's α with item deleted
Question 1	0.65	0.86
Question 2	0.69	0.85
Question 3	0.73	0.85
Question 4	0.65	0.86
Question 5	0.78	0.84
Question 6	0.55	0.87
Question 7	0.65	0.86
Question 8	0.37	0.88

Table 3. *Spearman's coefficients of correlation for LUTS score of the PROM and IPSS*

		IPSS			
		Pre-op (n = 112)	Post-op 3 months (n = 54)	Post-op 6 months (n = 39)	Post-op 12 months (n = 31)
PROM	Pre-op	0.71*			
	Post-op 3 months		0.83*		
	Post-op 6 months			0.83*	
	Post-op 12 months				0.90*

*p <0.05

showed no statistically significant correlation between the preoperative PROM results and the preoperative Qmax results (rs = 0.13; p >0.05). There

was a positive correlation between PROM results and Qmax results at follow up: 3 months after (rs = -0.56; p <0.05) 6 months after (rs -0.64; p <0.05), and 12 months after (rs =-0.85; p <0.05).

Responsiveness

The LUTS score improved significantly from a median of 21 before the surgery to 7 postoperatively (χ^2 ANOVA = 8.95, p = 0.03). Figure 1 presents the results of four consecutive measurements of the Polish version of the PROM for the entire group of patients with statistically significant differences between them. The general result was worse at the time of admission to the hospital with significant improvement in time. This result shows that the Polish version of the PROM can detect clinically important changes over time.

DISCUSSION

Urethroplasty is currently the gold standard treatment method for urethral stricture. Because urethral stricture is a disease with high recurrence rates, patients require systematic follow-up. The basic tool used in the follow-up is the measurement of Qmax [8]. However, the limit value of Qmax has not been set. Treatment failure is usually defined as the need for surgical re-treatment. In our clinical practice, patients with Qmax <15 ml/s during follow-up are diagnosed as patients with potential restenosis.

The second important aspect in the assessment of surgical treatment results, apart from the improvement of urinary flow, is the change in the quality of life and subjective evaluation of the results by the patient. Created by Jackson et al. in 2011, the USS-PROM is the first validated tool dedicated to patients with urethral stricture [3]. Before its development, due to the lack of dedicated questionnaires, attempts were made to adapt existing questionnaires, such as IPSS. However, they are not entirely appropriate for the assessment of men with urethral stricture [9]. The use of PROM provides more information about the outcome of treatment than uroflowmetry alone. Qmax is a parameter describing only the flow of urine through the urethra. The questionnaire indicates the presence of additional symptoms, such as straining to urinate, urinary urgency or a feeling of incomplete emptying. It defines the subjective feelings of the patient, the level of his satisfaction with the results of the treatment and the impact of symptoms on the quality of life. The PROM result enables comparison of treatment results of different groups of patients and provides comparable
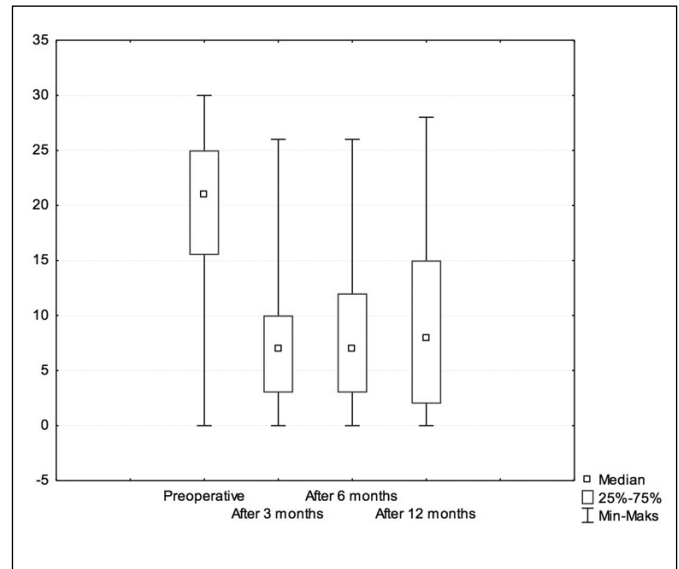
Figure 1. *Patient-Reported Outcome Measure general result before the surgery and during the follow-up.*

data about the outcomes of treatment within different centers. There is no other validated tool available in Polish, evaluating urethroplasty results from the patient's perspective. For these reasons, we validated the Polish version of the questionnaire created by Jackson et al.

The study confirmed good psychometric properties of the questionnaire. Similarly to the authors of other language adaptations, we have demonstrated the high responsiveness of the PROM. The results of the LUTS domain significantly improved after the surgical treatment. We also showed a strong correlation between the postoperative result of the questionnaire and the Qmax result. However, we did not observe such a correlation in the preoperative evaluation. A similar lack of correlation between the LUTS score and Qmax, but both before and after the operation, was found by the Dutch researchers [10]. We agree with the opinion of the authors of the aforementioned paper that this only confirms the need for the existence and use of PROM in patients with urethral stricture. Uroflowmetry is an imperfect tool that evaluates micturition in a simple way and provides little information about it. Its result is not fully reproducible and obtaining a volume of 150 ml of micturition for a patient with significant urethral stricture is often troublesome.

We conducted our study on a relatively heterogeneous group of patients with stricture located in the bulbar, penile or membranous urethra, subjected to various urethroplasty techniques. However, we do not consider it as a limitation. It is not a selected group of patients, but a real population. Since the

aim of the study was to assess the questionnaire, and not to evaluate the results of the treatment as such, it has no negative impact on the results. What's more, the study indicates the versatility of the questionnaire and the possibility of its widespread use in patients with urethral strictures.

Due to the lack of a Polish version of the validated questionnaire dedicated to patients with urethral stricture, we used IPSS to assess the LUTS in our patients. It is a validated and widely used questionnaire. However, it is not dedicated to patients with urethral strictures and does not allow for a full evaluation of the urethroplasty result. As demonstrated by Nuss, up to 21% of patients show symptoms that are not detected by IPSS before the urethroplasty [11]. Being aware of that, we used the results of the IPSS as an external criterion in the validity assessment. In our analysis, we correlated the results of the LUTS domain with the IPSS results. We showed a correlation, both before and after the surgery. This correlation confirms the reliability of the Polish version of the USS-PROM.

One of the essential weaknesses of the questionnaire is the lack of questions addressing the aesthetic changes of the genitals and the impact on sexual life and relationships as mentioned by Verla et al. [10]. It should be pointed out that urethral stricture is the leading cause of difficulty in voiding in younger and middle-aged men. For this group, sexual dysfunction is a concern of particular importance. Transient erectile dysfunction has been reported to be as high as 40% at three months, with most studies showing improvement to baseline by 6 to 12 months [12]. Nonetheless, a systematic review has shown that rates of permanent, de novo sexual dysfunction are likely around 1% [13].

The possible occurrence of sexual dysfunction after surgical treatment significantly affects the quality of life of the patient and his evaluation of the results of the operation. Hence, the risk of sexual dysfunction should always be taken into account preoperatively, and the patient should be informed about potential complications. For this reason, in our clinical practice, we use the International Index of Erectile Function Questionnaire (IIEF-5) in the pre-operative and post-operative assessment. IIEF5 consists of 5 questions regarding erectile function and intercourse satisfaction. A result below 22 points was considered as a marker of erectile dysfunction [14].

The USS-PROM also does not evaluate ejaculation disorders that affect up to 85% of patients with urethral strictures and may persist after the procedure, despite a successful reconstruction of the urethra [15]. A specific limitation of our study is the relatively long, three month periods between tests in the test-retest analysis and the difference in the size of the study groups. Like Kluth et al. who have also used such a time interval, we believe that this is not important in this group of patients [16]. As observed in clinical practice, if the result of the treatment three months afte surgery is satisfying, it rarely significantly changes in the relatively short time of the next three months. In the studied group of patients, we did not report any recurrence of the stricture during the follow-up period.

We also agree with the authors of the German validation that, as the analysis focuses on the properties of the questionnaire and not on the results of treatment, different sizes of the groups does not negatively affect the results.

CONCLUSIONS

The results of our study indicate that the Polish version of the USS-PROM has appropriate psychometric properties, comparable to the original USS-PROM and other language versions. It confirms the versatility of the questionnaire and the possibility of its application in different patient populations, regardless of cultural differences. The questionnaire enables reliable assessment of men with urethral stricture, both before and after surgery, and may be a valuable tool for researchers and clinicians.

CONFLICTS OF INTEREST
The authors declare no conflicts of interest.

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