

Persian version of Patient-Reported Outcome Measure for Urethral Stricture Surgery (USS-PROM) Questionnaire, Validation and Adaptation Study

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Purpose: The aim of the present study was translation, cross cultural adaptation and face validity evaluation of the Persian version of Patient-Reported Outcome Measure for Urethral Stricture Surgery (USS-PROM) Questionnaire.

Materials and Methods: This study was assessed: translation, translation quality, reverse translation and comparison of the English version, content validity, internal consistency and stability. Content validity presents by index of content validity (CVI) and the content validity ratio (CVR). Internal consistency reliability was tested by Cronbach's α , and test-retest reliability was evaluated by Intraclass Correlation Coefficient (ICC) assessed by Guttman two way mixed absolute agreements.

Result: Forty males with history of urethroplasty and mean age of 41.4 ± 9.08 (range of 19 to 52) years old were enrolled. In the case of mean scores of difficulty from the 16 translated items, 80% had easy translation. In terms of translation quality, 92% were the satisfactorily clear. In terms of similar concept, 92% were satisfactory. The overall quality of the translation was satisfactory at 88%. The translated questionnaire has a good internal consistency (Cronbach's alpha as 0.84). CVI and the CVR, test-retest ICC evaluation were appropriate/acceptable in all questions. The questionnaire ICC was .791(CI 95%, .678-.876). Two main different aspects of the questionnaire consisted of urinary symptoms (question 1-10) and Quality of life (question 11-15). Cronbach's alpha were .800 and .671 respectively.

Conclusion: The Persian version of the questionnaire has acceptable cultural adaptation and face validity. Further studies should be done using this translated tool to determine its applicability in the urethroplasty patients.

Keywords: adaptation; patient-reported outcomes measures; USS-PROM questionnaire; face validity; urethroplasty; urethral stricture

INTRODUCTION

Urethral Stricture Disease (USD) is a common and challenging problem for urologists⁽¹⁻³⁾. It has an estimated prevalence rate of 0.6%⁽⁴⁻⁶⁾. Many Valid option modalities are accessible for the management of USD^(7,8). The success criteria for urethroplasty are based on clinical and objective examinations, such as uroflowmetry parameters, retrograde-voiding cyst urethrogram (RUG-VCUG), urethroscopy and post void residue⁽⁹⁻¹¹⁾. Recent studies emphasize the need for using a questionnaire that presents surgical outcomes based on subjective perspective^(12,13). Thus, the British scientist Jackson et al. for the first time, developed and validated a questionnaire with mental characteristics for patients undergoing urethroplasty named patient-reported outcome measure for urethral stricture surgery (USS-PROM)⁽¹⁴⁾.

This is a questionnaire developed for early identification of the patients at risk of developing symptoms and complications of urethral stricture, and also a good instrument for assessing need to intervention. The USS-PROM consists of four main constructs: lower urinary tract symptoms (LUTS) and LUTS-related quality-of-life (QoL) domain, Peeling's voiding picture, EuroQoL dimensional scale (EQ-5D), and post-operative overall patient satisfaction questions^(14,15). Due to the ethnic, linguistic, cultural and geographical differences in the countries, the questionnaire should be developed in accordance with the social norms of target community. This study aims to translate and validate the Persian version of USS-PROM questionnaire to investigate psychometric properties and determine its appropriateness for use in clinics in Persian-speaking countries.

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MATERIALS AND METHODS

First Step: Translating the original version into Persian language

In the first stage, two native Persian translators who were unfamiliar with USS-PROM questionnaire (**Supplementary Table 1**) translated it independently from English into Persian and then, one translation was selected for the questionnaire in a meeting with the presence of scholars and translators. One of the translators had a history of translating medical texts and was familiar with medical terms. Furthermore, each translator scored the items in terms of difficulty using a 100-point visual scale (0 = completely easy; 100 = completely difficult). During a meeting with the presence of translators and authors of the present study, the first translated copy of the questionnaire was discussed and, finally, with regard to the items with difficult translation and their equivalences, a common Persian translation version was selected. In order to assess the quality of translation in terms of four concepts of clarity (using plain and intelligible words), usage in common language (avoiding the use of technical, specialized, and artificial words), conceptual equivalence (having the conceptual content of the main version of questionnaire) and the overall quality of translation, the third translator whose mother tongue was Persian and fluent in English, rated the quality of translation forward. So, this translator scored four points for each item of the USS-PROM questionnaire based on a 100-point visual scale (0 = completely bad/unsatisfactory quality; 100 = completely good/satisfactory quality). The criterion for deciding on the satisfactory quality of translations was the average quality scores more than 90. For phrases and sentences with unsatisfactory translations, the proper equivalences suggested by translators one and two were used and the translation quality score was again calculated. This process continued to gain a desirable level. At the end of this stage, a Persian version was obtained that was satisfactory in terms of quality according to translators of one to three.

Second step: Translating the Persian version into English language

At this stage, the original version translated into Persian was reverse-translated into English by the fourth native English translator with sufficient knowledge and experience of texts from Persian into English. The new English version was compared with the original version of the questionnaire in terms of identical concepts and was discussed during two sessions with the presence of the translator and the authors to confirm the identical translation. Eventually, a Persian version of good translation quality was available. For verifying the face validity, the obtained version was distributed to 40 patients with urethral stricture and, with the presence of one of the researchers in the form of an interview, the subjects completed the questionnaire. The face validity of each item of the Persian version of the USS-PROM questionnaire was determined by a survey of 40 people with urethral stricture and urethroplasty in terms of clarity of the items, ability to answer questions, from and arrangement of items in the questionnaire. Participants completed the questionnaire based on a four-point Likert scale (4 = completely disagree; 3 = disagree; 2 = Agree; 1 = completely agree).

Third step: Face validity

With the Lot Quality Assurance Sampling model with an upper limit of .95 and lower limit of .90 with a sample size of 40 patients, up to 5 people could announce that questions, which is not understandable. This was not the case with the current questionnaires.

Forth step: Content validity

Content validity was assessed by two ways: first, in rounds of expert consensus meetings (six reconstructive urologists, four general urologists, one epidemiologist, one Methodologist, one psychologist, one sociologist and one spiritualist), document circulation, and patient interviews. The result of these meetings was no need to add or omit a question to the questionnaire.

Second, index of content validity (CVI/averages the item-level; the sum of CVIs is divided by the total number of items)⁽¹⁶⁾ and the content validity ratio (CVR) was evaluated. The numeric value of CVR is determined by Lawshe (**Supplementary Table 1**). In our investigation that is number of panelists 15, if CVR is > 0.49, the item with an acceptable level of significance will be accepted⁽¹⁷⁾.

Fifth step: Internal consistency (reliability)

Internal consistency characterizes the extent to which question items within the same construct measure the same conceptual domain and demonstrates whether it is valid to sum those item scores. This was statistically evaluated using Cronbach's alpha coefficient. A Cronbach's value of ≥ 0.70 was considered acceptable for internal consistency. Internal consistency for each question (Cronbach's Alpha if Item Deleted) value assessed for all item.

Sixth step: Stability (test-retest reliability)

A test-retest analysis indicates the extent to which a questionnaire, test, or measuring procedure will yield the same results over a period of time. It is assessed after an interval of four weeks.

The intraclass correlation coefficient (ICC) assessed by Guttman two way mixed absolute agreements. An ICC > 0.70 was the predefined threshold for inclusion.

Statistical analysis

The final statistical analysis was performed using SPSS 19 (SPSS Inc, Chicago, Illinois, USA) using suitable methods for assessment of multi-steps. The level of significance was set at $p < 0.05$. Internal consistency reliability was tested by Cronbach's α , and test-retest reliability was evaluated by ICC test. Content validity present by CVI and the CVR.

Ethics

After Shohada-e-Tajrish Hospital review board approval was obtained the study conducted in reconstructive urology clinics (referral center of reconstructive urology in Iran), Shahid Beheshti Medical University, Tehran, Iran, Between May 2017 to September 2018. Written informed consent was taken for all participation in the study.

RESULTS

Forty patients with history of bulbar (32 cases), one- or two-stage (six and two respectively) penile urethroplasty, with mean age of 41.4 ± 9.08 (range of 19 to 52) years; preoperatively, six and seven month following urethroplasty, without history of neurologic, psychic and mental disease, educational status higher than di-

ploma without communications barrier (hearing/speaking, accent) were enrolled in the study. USD etiology was traumatic, idiopathic and iatrogenic in 29, seven and four patients, respectively. Twenty-four subjects had undergone at least one endoscopic intervention before the urethroplasty. Objective success of urethroplasty was defined as demonstration of urethral patency on post-operative RU/VCUG at 6th month.

Furthermore, Patients with diabetes mellitus, pelvic radiation history and previous history of any kind of urethroplasty were excluded from our study as well.

The localization process was followed by translation steps, translation quality measurement and reverse translation. In the case of mean scores in terms of difficulty from the 16 translated items, 80% had easy translation, 16% had relatively easy translation, and 4% had difficult translation. In terms of translation quality, the results also showed that 92% were the satisfactorily clear and 8% were relatively clear. Also, in terms of common language usage, 100% had a good translation. In terms of similar concept, 92% were satisfactory and 4% were unsatisfactory. In other cases, (4%), the similarity was relatively favorable. Finally, the overall quality of the translation was also satisfactory at 88% and relatively satisfactory at 12%. So, overall, the satisfactory quality of translation was provided. The results showed that the translation and equivalence process of the USS-PROM questionnaire was of a satisfactory and desirable quality. The internal consistency of the translated instrument was calculated using Cronbach's alpha as 0.84. Cronbach's Alpha if "Item Deleted" for any item is presented in (**Supplementary Table 1**). Two main different aspects of the questionnaire consisted of urinary symptoms (question 1-10) and quality of life (question 11-15) Cronbach's alpha were .800 and .671 respectively. This results indicating that the translation of the questionnaire has a good internal consistency and supported the content validity of the Persian version of USS-PROM questionnaire according to Iranian socio-cultural and religious features by contemporary literature review, expert opinion, consensus meetings of the study coworker and subject interviews. The translated Persian form of the tool, CVI and CVR content validity and stability ICC evaluation is provided in the (**Supplementary Table 1**). The questionnaire ICC was .791(CI 95%, .678-.876). (**Supplementary Table 1**). English questions, translation into Persian, test-retest reliability and internal consistency results

DISCUSSION

One of the most important features that should always be considered when choosing an instrument is the easy translation and optimal quality of the translated version into a second language. This issue is primarily addressed by the original designers of such instruments. It means that these designers always seek to avoid obscure, intangible, non-transparent, and polysomic terms when using words, phrases and sentences, thereby facilitating the process of translating and finding the equivalence for the text from one language into another⁽¹⁸⁾.

The present study, such a score is clearly seen. In other words, three translators in this project confirmed the easiness and satisfactory quality of translation in a quantitative, measurable and reportable manner. The available texts on the second versions of the USS-PROM questionnaire also confirm this. As mentioned before,

the original version of the USS-PROM questionnaire has been translated into several languages, including German, Italian, Spanish, Turkish and Dutch⁽¹⁹⁻²³⁾.

According to our results, in the case of mean scores in terms of difficulty from the 16 translated items, 80% had easy translation. In terms of translation quality, the results also showed that 92% were the satisfactorily clear. Also, in terms of common language usage, 100% had a good translation. In terms of similar concept, 92% were satisfactory. Finally, the overall quality of the translation was also satisfactory at 88%. The translated questionnaire has a good internal consistency (Cronbach's alpha as 0.84). CVI and the CVR evaluation were appropriate/acceptable in all questions (**Supplementary Table 1**). Two main different aspects of the questionnaire consisted of urinary symptoms (question 1-10) and Quality of life (question 11-15) Cronbach's alpha were .800 and .671 respectively. Intraclass Correlation Coefficient was .791.

Guido Barbagli and coworkers⁽¹⁹⁾ in 2011 published Italian validation of the USS-PROME Questionnaire in patients undergoing anterior urethroplasty. Test-retest reliability and internal consistency statistics demonstrating criterion validity; intra-class correlation coefficients ranged from 0.81 to 0.90 for the individual voiding questions. Cronbach's alpha was 0.79 for the overall score and ranged between 0.74 and 0.81.

Psychometric validation of a German language version of a PROM was conducted on ninety-three men before and 3 months after surgery, with 40 (43 %) also completing the USS-PROM 6 months after surgery to assess reliability. Internal consistency: Cronbach's α was 0.83 for the LUTS. The test-retest ICC was 0.94⁽²⁰⁾.

For internal consistency in Spanish version of USS-PROM(22), the Cronbach's alpha was 0.701. For the test-retest reliability, the overall ICC was 0.974, and the ICC for each item separately ranged from 0.799 to 0.980.

In Turkish research⁽²¹⁾ 42 men had complete pre and postoperative 6th month data for analysis. The test-retest ICC was 0.79. Cronbach's α for internal consistency of the LUTS construct was 0.79.

According to present study the Persian language USS-PROM adaption and validation shows similar properties to the original English, Italian, German, Spanish and Turkish language version.

Therefore, the easy and high quality Persian translation of this scale as well as the relatively large number of international translations can be considered as one of the advantages of this validation.

A further study is recommended with greater sample size cohorts to increase the accuracy of the results in urethroplasty patients.

CONCLUSIONS

During the translation process and cultural adaptation, the questionnaire was changed. It seems that the Persian version of the USS-PROM questionnaire with these changes is ready for evaluating its validity and reliability in subsequent studies and is comparable in psychometric properties with the original version. Moreover, further studies should be done using this translated tool to determine its applicability in the urethroplasty patients.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Supplementary Table. English questions, translation into Persian, test-retest reliability and internal consistency results

No.	Eng Q	Eng A	Per Q	Per A	CVR	CVI	ICC	Cronbach's Alpha if Item Deleted	Cronbach's Alpha
1	Is there a delay before urinating?	<input type="radio"/> never <input type="radio"/> sometimes <input type="radio"/> occasionally <input type="radio"/> often <input type="radio"/> always <input type="radio"/> is normal	آیا پیش از شروع به ادرار کردن شما تاخیری وجود دارد؟	<input type="radio"/> هرگز <input type="radio"/> برخی اوقات <input type="radio"/> گه گاهی <input type="radio"/> اغلب اوقات <input type="radio"/> همیشه	.56	1	.889	.825	.800
2	The power of your urine output	<input type="radio"/> is normal <input type="radio"/> sometimes it is decreased <input type="radio"/> occasionally it is decreased <input type="radio"/> often it is decreased <input type="radio"/> always it is decreased	قدرت جریان خروج ادرار شما	<input type="radio"/> عادی است <input type="radio"/> برخی اوقات کاهش می یابد <input type="radio"/> گه گاهی کاهش می یابد <input type="radio"/> اغلب اوقات کاهش می یابد <input type="radio"/> همیشه کاهش می یابد	.73	1	.708	.825	
3	Do you have to push to continue your urine?	<input type="radio"/> never <input type="radio"/> sometimes <input type="radio"/> occasionally <input type="radio"/> often <input type="radio"/> always	آیا برای ادامه خروج ادرارتان باید زور بزنید؟	<input type="radio"/> هرگز <input type="radio"/> برخی اوقات <input type="radio"/> گه گاهی <input type="radio"/> اغلب اوقات <input type="radio"/> همیشه	.6	1	.695	.826	
4	Is your urine interrupted more than once during urination?	<input type="radio"/> never <input type="radio"/> sometimes <input type="radio"/> occasionally <input type="radio"/> often <input type="radio"/> always	آیا در هنگام ادرار کردن بیش از یکبار ادرارتان قطع و وصل می شود؟	<input type="radio"/> هرگز <input type="radio"/> برخی اوقات <input type="radio"/> گه گاهی <input type="radio"/> اغلب اوقات <input type="radio"/> همیشه	.53	1	.787	.827	
5	How often do you feel after your urination that your urine is not completely drained?	<input type="radio"/> never <input type="radio"/> sometimes <input type="radio"/> occasionally <input type="radio"/> often <input type="radio"/> always	چقدر پیش می آید که پس از ادرار کردن احساس کنید که ادرارتان کامل تخلیه نشده است؟	<input type="radio"/> هرگز <input type="radio"/> برخی اوقات <input type="radio"/> گه گاهی <input type="radio"/> اغلب اوقات <input type="radio"/> همیشه	.6	1	.937	.837	
6	How often do you feel that your pants are soaked after you urinate and wear clothes?	<input type="radio"/> never <input type="radio"/> sometimes <input type="radio"/> occasionally <input type="radio"/> often <input type="radio"/> always	چقدر پیش می آید که پس از ادرار کردن و پوشیدن لباس احساس کنید که شلوارتان خیس شده است؟	<input type="radio"/> هرگز <input type="radio"/> برخی اوقات <input type="radio"/> گه گاهی <input type="radio"/> اغلب اوقات <input type="radio"/> همیشه	.61	1	.931	.832	
7	In general, how much does your urination issues affect your everyday life?	<input type="radio"/> never <input type="radio"/> little <input type="radio"/> somewhat <input type="radio"/> so much	در مجموع، مسائل مربوط به ادرار کردن شما چقدر روی زندگی روزمره شما تاثیرگذار است؟	<input type="radio"/> هیچ وقت <input type="radio"/> کمی <input type="radio"/> تا حدودی <input type="radio"/> خیلی	.73	1	.688	.826	
8	Please mark the number that shows your urine flow capacity in the last month.		لطفاً روی شماره ای که قدرت جریان ادراری شما گذشته نشان می دهد علامت بزنید.		1	1	1	.818	
9	Are you satisfied with the outcome of your surgery?	<input type="radio"/> I'm completely satisfied. <input type="radio"/> I'm satisfied.	آیا از نتیجه عمل جراحی خود رضایت دارید؟	<input type="radio"/> بله ، کاملاً راضی هستم <input type="radio"/> بله ، راضی هستم <input type="radio"/> نه ، ناراضی هستم <input type="radio"/> نه ، کاملاً ناراضی هستم		.86	.974	.835	

		<input type="radio"/> I'm dissatisfied. <input type="radio"/> I'm completely dissatisfied.							
10	I am dissatisfied or completely dissatisfied because	<input type="radio"/> My urination is not good. <input type="radio"/> My urination is good, but there are other problems. <input type="radio"/> My urination is not good and there are other problems	ناراضی و یا کاملاً ناراضی هستیم به دلیل اینکه	<input type="radio"/> وضعیت ادرار کردنم خوب نشده است <input type="radio"/> وضعیت ادرار کردنم خوب شده است ولی مشکلات دیگری پیش آمده است. <input type="radio"/> وضعیت ادرار کردنم خوب نشده است و مشکلات دیگری هم پیش آمده است.	.5	1	β	*	*
Which following options is the best description of your health situation today?									
11	Mobility	<input type="radio"/> I have no trouble in walking <input type="radio"/> There are a few problems in walking <input type="radio"/> I got stuck	تحرك	<input type="radio"/> مشکلی در راه رفتن ندارم <input type="radio"/> در راه رفتن کمی مشکل دارم <input type="radio"/> زمین گیر شده ام	.5	.93	۱		.835
12	Self-care	<input type="radio"/> I have no problem in self-care <input type="radio"/> I have trouble in washing myself and wearing clothes <input type="radio"/> I cannot wash myself and wear clothes	خود مراقبتی	<input type="radio"/> مشکلی در مراقبت از خود ندارم <input type="radio"/> با شستن خود و پوشیدن لباس مشکل دارم <input type="radio"/> قادر به شستنوی خود و پوشیدن لباس نیستم	.5	1	β		.845
13	Daily activities (such as work, study, home, family or leisure)	<input type="radio"/> I have no problems doing my daily activities <input type="radio"/> I have a problem doing my daily activities <input type="radio"/> I cannot do my daily activities	فعالیت های روزانه (مانند کار، تحصیل، امور منزل، خانواده یا اوقات فراغت)	<input type="radio"/> هیچ مشکلی در انجام فعالیت های روزانه ام ندارم <input type="radio"/> کمی با انجام فعالیت های روزانه ام مشکل دارم <input type="radio"/> قادر به انجام فعالیت های روزانه ام نیستم	1	1	۱		.838
14	Pain / discomfort	<input type="radio"/> I have no pain and discomfort <input type="radio"/> I have some pain and discomfort <input type="radio"/> I strongly feel pain and discomfort	درد/ناراحتی	<input type="radio"/> هیچگونه احساس درد و ناراحتی ندارم <input type="radio"/> تا حدودی درد و ناراحتی دارم <input type="radio"/> شدیداً احساس درد و ناراحتی دارم	.06	1	.9۷۶		.820
15	Anxiety / Depression	<input type="radio"/> I'm not anxious or depressed <input type="radio"/> I'm somewhat anxious or depressed <input type="radio"/> I'm very anxious or depressed	اضطراب/افسردگی	<input type="radio"/> مضطرب یا افسرده نیستم <input type="radio"/> تا حدودی مضطرب یا افسرده هستم <input type="radio"/> شدیداً مضطرب یا افسرده هستم	.06	.86	.9۷۲		.821
16	In order to help people to know what good or bad health conditions is, we designed a scale (similar to a thermometer) in which the best imaginary health conditions are represented by 100 and the worst imaginary health conditions are	the best imaginary health conditions 	برای کمک به مردم که بگوییم شرایط سلامتی خوب و بد چگونه است، مقیاسی طراحی کردیم (که به یک دماسنج شبیه است) که در آن بهترین شرایط قابل تصور با عدد ۱۰۰ و بدترین شرایط قابل تصور با عدد ۰ نشان داده شده است. ما می خواهیم که شما روی این مقیاس مشخص کنید که شرایط سلامتی امروز شما خوب یا بد است. لطفاً این کار را با کشیدن یک خط از پایین تا هر نقطه ای روی	بهترین تصور از وضعیت سلامت  بدترین تصور از وضعیت سلامت	.76	1	۹۰۱.		

	<p>represented by zero. We ask you to determine on this scale that your health conditions are good or bad today. Please show this by dragging a line from below to any point on the scale that indicates your good or bad health status.</p>	<p>the worst imaginary health conditions</p>	<p>این مقیاس که وضعیت خوب یا بد بودن سلامت شما را نشان می دهد، نشان دهید.</p>					
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*Question 10 has no answers; β Question10 and 12 Scale has zero variance items.