



## Validity and reliability of the ureteral stent symptoms questionnaire to Persian language

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### Abstract

**Introduction:** Ureteral stenting is a common urological procedure. However, morbidity associated with ureteral stents has been identified as a potential health problem. A comprehensive, reliable and valid measure to evaluate health-related quality of life in patients undergoing this procedure is the Ureteral Stent Symptoms Questionnaire (USSQ). In this paper, we validate the Persian version of the USSQ in patients with a ureteral stent.

**Methods:** Linguistic validation of the USSQ was performed through a standard process that included forward and backward translation by two translators and pilot testing. Six clinical specialists scored translated questionnaires to examine content validity. Thirty patients who underwent the ureteroscopy surgery and 20 control participants completed the Persian USSQ as well as the International Prostate Symptom Score (IPSS). Patients completed the questionnaires 1 week after stent placement and again 4 weeks after stent placement while controls completed questionnaires 2 times 3 weeks apart.

**Results:** To assess content validity, content validity index for items and modified Kappa was  $> 0.81$  for the entire scale. Internal consistency using Cronbach's alpha was  $> 0.78$ . Test-retest reliability (Kendall's tau coefficient  $> 0.7$ ) was satisfactory for urinary symptoms, general health, sexual matters, work performance and additional problem domains. Convergent validity was 0.71 for urinary symptoms and IPSS. Discriminant validity between cases and controls was meaningful.

**Conclusion:** The Persian version of the USSQ is a reliable and valid instrument that can be self-administered by patients with indwelling ureteral stent in clinical and research settings.

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### Introduction

Ureteral stenting is a common procedure in urological surgery. However, the side effects and patient morbidity associated with ureteral stents have been identified as a potential health problem.<sup>1-4</sup> Lower urinary tract symptoms (LUTS) were reported in as many as 80% of patients with double-J stents.<sup>5</sup> Flank, abdominal, inguinal and genitalia pain, sexual problems and altering work performance in association with ureteral stents were detected

in several studies; these symptoms have bothersome and unpleasant impact on health-related quality of life.<sup>6-8</sup>

To assess how discomfort and associated problems impact quality of life and to evaluate treatment effectiveness, the use of validated instruments to objectively examine these issues is necessary. Joshi et al. developed and validated the Ureteral Stent Symptoms Questionnaire (USSQ), a self-administered, multidimensional instrument comprised of six

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sections including urinary symptoms, body pain, general health, work performance, sexual matters and additional problems.<sup>9</sup>

Each section contains several questions, of which the answers are summed to provide an index score. Urinary symptoms domain (11-56 scores), body pain (2-43 scores), general health (4-28 scores), work performance (5-25 scores), sexual matters (1-12 scores) and additional problems (5-17 scores). There is a great clinical importance of these symptoms, considering prevalence and impact on patients' quality of life.<sup>10</sup> We translated and validated urologic questionnaires including ICIO-UI (International consultation on incontinence questionnaire-Urinary incontinence) and ICIQ-OAB (International consultation on incontinence questionnaire-Overactive Bladder) in Persian previously<sup>11,12</sup> and due to the lack of proper tools to evaluate patients and perform research projects in Iran and other Persian (Farsi) spoken countries provided the impetus for this study. The goal of this study was to translate and validate a comprehensive multidimensional tool to be used in clinics and research. We also determined the correlation of its domains with another valid questionnaire, the International Prostate Symptom Score (IPSS), for LUTS in men.

## Methods

Linguistic validation of the USSQ was performed through a standard multistep process that included forward and backward translation to Persian by two translators and a pilot study. The questionnaire was initially translated from English to Persian by two independent, bilingual and native Persian speaking professional translators. They utilized a common simple language that could be understandable by individuals with a low literacy level. A third translator compared the two versions and solved small differences, yielding a unique consensus Persian version. Back-translation to the original English version was done by fourth professional translator. This back translation was then compared to the English original questionnaire. The translated questionnaire was submitted to three urology and three other clinical professors who were

native English speakers. These clinical professionals provided scores from one to four for each question to assess the ability of the question to reach the main concept in order to evaluate content validity.

Thirty consecutive male patients (cases) referred to the Department of Urology at Tabriz University of Medical Sciences, Iran, during a 2 months period that underwent Double-J ureteral stent placement due to transurethral lithotripsy were enrolled. Twenty healthy participants were also asked to complete the Persian version of the USSQ. Inclusion criteria for cases were unilateral retrograde stent insertion after ureteroscopic stone surgery.

Exclusion criteria for all participants included a history of, or current treatment for, LUTS, chronic bacterial prostatitis, chronic pelvic pain syndrome, prostate cancer, chronic ureteral obstruction, obstruction due to malignancy, iatrogenic trauma, situations predisposing bleeding, history of bladder cancer, recurrent urinary tract infections, overactive bladder syndrome, neurological and psychiatric diseases and concomitant medication with alpha blockers, anticholinergics, analgesics and other drugs, possibly interfering with lower urinary tract function or pain assessment. The same type of 4.8 F, polyurethane double-J ureteral stent (urotech®) inserted in all cases by expert urologists. Stent length according to patients' height ranged 26-30 cm. Stented patients received prophylactic antibiotics as our department routine policy. All subjects were fully informed about the purpose of the study. All provided written informed consent.

The Persian version of the USSQ was self-administered to all cases at weeks 1 and 4 post stent placement. In all cases after administering the questionnaire at 4<sup>th</sup> week, the stent was removed. In addition, all cases were asked to complete the previously validated Persian version of the IPSS at the same time.<sup>13</sup> The Persian version of USSQ was administered to healthy participants without ureteral stent as controls twice at 3 weeks intervals. To evaluate content validity, we utilized an alternative modified measure

to assess the translated questionnaire. This modified measure takes into account the consistency of agreements.<sup>14,15</sup>

Internal consistency was evaluated in both first and second questionnaires by the calculation of Cronbach's alpha correlation coefficient for each section. Test-retest reliability was evaluated by comparing the scores using Kendall's tau coefficient and Pearson's correlation coefficient. Convergent validity was assessed by correlating the scores of urinary symptoms domain of USSQ to its corresponding Persian validated measure (IPSS). To evaluate the discriminant validity, first and 4<sup>th</sup> week questionnaires of the study group were compared with the corresponding questionnaires of the control group. Convergent validity was evaluated using intraclass correlation coefficients (ICCs) derived assuming a two-way mixed effects model. The ICC was calculated based on an individual unit of analysis (individual ICC) rather than average ICC. An independent T-test was used to assess discriminant validity between cases and the control group, with  $P < 0.05$  considered significant. Analysis was performed using STATA® (version 11, StataCorp LP, Texas 77845, USA) statistical software package.

## Results

A total of 30 cases and 20 controls were enrolled in this study. Mean age of the participants with a ureteral stent was  $33.7 \pm 8.2$  years and the mean age of control group participants was  $30.2 \pm 10.7$  years. The calculated content validity index for items for all questions from one to thirty-eight was above 0.83 (0.83-1) and the modified Kappa was  $> 0.81$  (0.81-1) which was confirmatory of the questionnaire's content validity.

Internal consistency of the Persian version of USSQ using Cronbach's alpha coefficient for all fifty completed questionnaires were recorded to be good including urinary symptoms, body pain, general health, sexual matters and additional problems domains, and was lower for work performance domain. Details are listed in table 1.

Test-retest reliability was satisfactory for the Persian version of the USSQ. Domains scores at weeks one and four were assessed using Kendall's Tau and Pearson's correlation coefficient statistics. Details of these reliability statistics are given in table 2. The lowest correlation coefficients were for body pain and general health domains (0.66 and 0.71, respectively).

**Table 1. Internal consistency using Cronbach's alpha for all domains in case and control groups**

Domain	Week 1	Week 4	Total
Urinary symptoms	0.77	0.78	0.77
Body pain	0.63	0.68	0.60
General health	0.61	0.66	0.63
Work performance	0.48	0.50	0.49
Sexual matters	0.62	0.63	0.63
Additional problems	0.81	0.79	0.80
Total	0.69	0.78	0.74

**Table 2. Test-retest reliability of Persian in case and control groups**

Domain	Kendall's tau coefficient	P	Pearson's coefficient	P
Urinary symptoms	0.7755	$< 0.001$	0.9791	$< 0.001$
Body pain	0.6686	$< 0.001$	0.9978	$< 0.001$
General health	0.7127	$< 0.001$	0.9522	$< 0.001$
Work performance	0.8841	$< 0.001$	0.9915	$< 0.001$
Sexual matters	0.8163	$< 0.001$	0.9990	$< 0.001$
Additional problems	0.7959	$< 0.001$	0.9946	$< 0.001$

USSQ: Ureteral stent symptoms questionnaire

**Table 3. Mean scores in cases and controls for discriminant validity assess**

Domain	Cases scores	Controls scores	P
Urinary symptoms	24.30	16.70	< 0.001
Body pain	15.26	3.55	< 0.001
General health	11.70	9.70	0.002
Work performance	15.00	10.55	< 0.001
Sexual matters	5.40	3.30	0.011
Additional problems	13.13	5.05	< 0.001

Convergent validity was confirmed by the convergence of the urinary symptoms score and IPSS ICC between the two measures of urinary symptoms score and IPSS was estimated to be equal to 0.71 [95% CI (Confidence interval): 0.4-0.87]. Although demographic data for the two groups of participants were similar, all domain scores were significantly different (Table 3), indicating good discriminant validity of the questionnaire.

**Discussion**

It has been nearly five decades since the first application of temporary ureteral stent and indications, and uses are expanding. However, stent associated side effects and morbidities have been reported as major health problems for those who undergo the procedure.<sup>1-4</sup> These stents produce a spectrum of symptoms and in order to assess symptoms and the impact on quality of life, a comprehensive, reliable and psychometrically multidimensional questionnaire (USSQ) developed by Joshi et al. has typically been used. This questionnaire contains various domains of health (6 sections and 42 items) affected by stents including urinary symptoms, body pain, general health, work performance, sexual matters and additional problems.<sup>5</sup>

The USSQ has been validated in several languages including French, Italian, Spanish, and Korean.<sup>16-19</sup> We validated the USSQ in the Persian language by administering the questionnaire both to patients with a ureteral stent and healthy participants. Content validity of the Persian version of the USSQ was promising according to the modified kappa value of 0.81 for all items. These results are assigned to the fine psychometric properties of the original English questionnaire and an accurate linguistic approach.

According to current results the Persian version of the USSQ has a good internal consistency, high test-retest reliability and is a reliable and valid instrument for the evaluation and measurement of quality of life in patients with indwelling ureteral stent. With respect to reliability, the internal consistency of this questionnaire was good. The internal consistency existed for all domains except work performance. We think that it's due to cultural differences.

The good internal consistency recorded for the Persian versions was consistent with previous studies on English, Spanish, Korean and Italian versions, which reported Cronbach's alphas to be in the range of 0.60-0.96, 0.73-0.85, 0.73-0.83 and 0.37-0.92 respectively.<sup>9,16,17,19</sup> Test-retest reliability in our study was good (Pearson's Coefficient > 0.95 and Kendall's tau Coefficient > 0.66) and higher than the Spanish,<sup>18</sup> Korean<sup>19</sup> and Italian<sup>17</sup> versions with Spearman correlation coefficients above 0.6 for Spanish<sup>18</sup> and Korean<sup>19</sup> versions and 0.35-0.72 for Italian<sup>17</sup> version, also it is better correlation than English version with Pearson's Coefficient of 0.82-0.97.<sup>9</sup>

Park et al. reported that internal consistency and test-retest reliability were satisfactory for domains of urinary symptoms, body pain, general health and work performance.<sup>19</sup> Sanguedolce et al. revealed satisfactory results for internal consistency and test-retest reliability for urinary symptoms, body pain, and general health domains.<sup>18</sup> Giannarini et al. detected that internal consistency was good for domains of urinary symptoms, general health and work performance, and intermediate for the body pain and sexual matters domains.<sup>17</sup> In their study test-retest reliability was good except for the sexual matters and additional



problems domain that only sexual matters domain was significantly unreliable. These results indicate this questionnaire is dependent on patients' cultural differences in domains of work performance, sexual matters, and additional problems.

English, Italian, Spanish and Korean versions of this questionnaire have good discriminant validity and significance. The Persian version of USSQ can be differentiated between patients with ureteral stents and healthy participants due to good discriminant validity.

Giannarini et al. have assessed the convergent validity through investigating relationships of IPSS with urinary symptoms and visual analog scale with body pain domain.<sup>17</sup> In the present study, however, the authors only assessed the relationship between IPSS and urinary symptoms. Concurrent validity was generally confirmed with ICC of 0.71, which is comparable with other studies.<sup>9,17-19</sup>

The Persian version of the USSQ was correlated with the Persian version of IPSS, already validated for symptom measure in men. Stent associated symptoms mimic the LUTS due to benign prostate hyperplasia, and in some studies IPSS was applied for stent symptoms evaluation.<sup>8,10,20-23</sup> Indeed, medications for alleviating BPH symptoms like alpha-blockers had a positive impact on stent-related symptoms.<sup>24</sup>

Overall, the results of this study demonstrated the spectrum of the unpleasant impact on urinary symptoms, body pain, general health, work performance and sexual life and decreased health-related quality of life.

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One of the limitations of our study was enrolling healthy patients as a control group instead of patients after an endoscopic urological surgery without stent insertion as more appropriate control group. In addition, to assess convergence there were no more questionnaires formally validated into Persian such as UDI-6 (Urinary distress inventory-6) and IIQ-7 (Incontinence impact questionnaire-7) at the time of this study, therefore, we assess only the convergence of IPSS with urinary symptoms domain of USSQ in male participants.

## Conclusion

The current Persian male version of the USSQ is a valid and reliable instrument that can be applied to measure the severity of the symptom complex in patients with an indwelling ureteral stent in routine clinical practice and research settings in Iran and other Persian spoken countries like Tajikistan, Uzbekistan and Afghanistan.

## Conflict of Interests

Authors have no conflict of interest.

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