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ORIGINAL ARTICLE

Turkish version of the Ureteral Stent Symptoms Questionnaire: linguistic and psychometric validation

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Abstract
Purpose Ureteric stents are frequently used in urology practice and can cause significant impairment in quality of life (QoL). The aim of this study was to validate the Ureteral Stent Symptoms Questionnaire (USSQ) to be used in the evaluation of stent-related symptoms and impairment in QoL in Turkish-speaking patients.
Methods After linguistic validation of the original USSQ into Turkish language, the Turkish version of the USSQ (T-USSQ) was self-administered to all participants at week 1 and 4 after stent placement for test–retest reliability and internal consistency and at week 8 (4 weeks after stent removal) for sensitivity to change analysis. Control patients completed the form only once. Additionally male and female patients completed the validated Turkish versions of International Prostate Symptom Score (IPSS) and Marmara Overactive Bladder (mOAB) Symptom Scores, respectively.
Results A total of 68 patients with ureteral stents and 37 controls were available for the final analysis. The Cronbach's alpha value was higher than 0.7 at week 1 for all sub-domains except additional problems domain. The test–retest reliability of the T-USSQ was high for all sub-domains except the additional problems domain. Relatively high correlation coefficients were found for the visual analog scale for pain, IPSS (for males), mOAB score (for females) with the corresponding USSQ domains, suggesting good convergent validity. Also the T-USSQ could effectively differentiate between patients and controls.
Conclusions The T-USSQ is a reliable and robust instrument that can be self-administered to patients of Turkish population with ureteral stent in the clinical applications.

Keywords Ureteral stent · Symptom score · Questionnaire · Validation

Introduction

Since its first introduction in 1978 [1], the double-J ureteral stent has become an indispensable part of the urologist's routine practice. Traditionally, ureteral stents are placed to relieve ureteric obstruction, generally as an adjunct to treatment of urinary stone disease after surgery or shock wave lithotripsy. With advances in stent manufacturing, various designs using different materials with or without different coatings have been produced, resulting in an expansion in the use of stents in clinic despite the absence of robust evidence on patient morbidity and cost-effectiveness [2]. The lack of standardized evaluation of patient experiences with ureteral stents has surely contributed to expansion.

Ureteric stents are safe in most cases; however, they can also cause complications such as migration, fragmentation and

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calcification, the management of which may necessitate further invasive interventions [3, 4]. Ureteral stents may also be associated with significant discomfort, with more than 70 % of patients experiencing voiding symptoms and pain requiring analgesia as well as impairment in quality of life (QoL) resulting from interference with daily activities, work performance, general health and interpersonal relationships [5].

A patient-reported outcome measure has recently been developed by Joshi et al. to evaluate symptom bother/severity and impairment in QoL caused by the ureteral stent [6]. The Ureteral Stent Symptoms Questionnaire (USSQ) designed to define and quantify a range of symptoms experienced by men and women with ureteral stents that involve six domains: urinary symptoms, pain, sexual health, general health, work performance and additional problems. Up until now, validations of cross-cultural adaptations have been performed in French [7], Spanish [8], Italian [9], Korean [10], Arabic [11], Persian [12] and German [13]. These efforts will ensure improved assessment of stent effects in clinical trials, monitoring patient symptoms in clinical practice, patient counseling and clinical decision-making.

The aim of this study is to validate the USSQ to be used in the evaluation of discomfort and impairment in QoL in Turkish-speaking patients with ureteric stents.

Materials

The linguistic validation

Two professional translators translated the original English USSQ into the Turkish language independently of each other. Taking these two translations, the translators and the researchers synthesized a final Turkish version of the questionnaire, giving particular attention to using clear, simple language. Afterward, a bilingual (Turkish and English) researcher who did not have access to the original English version performed a back-translation of the final document. The back-translated version and the original version were then compared, and a final consensus document was agreed upon. Finally, a pilot test was performed with 10 patients to verify the comprehensibility of the questionnaire. With the feedback received from the pilot group, further minor modifications were made and a final version was agreed upon.

The study population

Patients who underwent a ureteral stent placement procedure in a tertiary referral center (Marmara University School of Medicine, Department of Urology) between June 2014 and September 2015 and controls without stents were included in this study. The inclusion criteria were ureteral stent placement for a diagnostic/therapeutic purpose performed for a benign upper urinary tract condition. Illiterate patients and patients with a history of malignancy, any previous lower urinary tract dysfunction, voiding dysfunction or any previous operations in the upper urinary tract that resulted in mucosal damage or perforation were excluded. A standard polyurethane 6 Fr double-J ureteral stent (26 or 30 cm) was inserted in all cases.

The Turkish version of the USSQ was self-administered to all patients at weeks 1 and 4 after stent placement for test–retest reliability and internal consistency and at week 8 (4 weeks after stent removal) for sensitivity to change analysis. In addition, male and female patients completed the validated Turkish version of International Prostate Symptom Score (IPSS) and validated Marmara Overactive Bladder (mOAB) Symptom Score [14], respectively, at weeks 1 and 4. The control group patients completed the Turkish USSQ once only.

This study was approved by the institutional review board. The purpose of the study was explained to each participant, and written informed consent was obtained from each of them. The demographic characteristics of all of the study participants were recorded separately.

Statistical analysis

Statistical analysis was performed using SPSS version 17.0 software. Descriptive statistics were analyzed for statistical significance ($p < 0.05$) using Chi-square test and Student's t test for categorical and continuous variables, respectively. Normal distribution of the data was checked by Kolmogorov–Smirnov test. Mean scores are given with corresponding standard deviations in brackets.

Reliability of the questionnaire was evaluated by two measures: internal consistency (Cronbach's alpha) and rest–retest analysis of week 1 and week 4 scores (Spearman's correlation coefficient). Cronbach alpha and test–retest correlations were calculated for each of the six domains individually, following the methodology of the original article.

Correlations between the Turkish USSQ scores and other validated symptom scores were tested with Spearman's correlation coefficient. Correlation coefficient (CC) values of >0.8, >0.6, >0.4 and >0.2 were designated as very strong, strong, moderately strong and weak correlations, respectively. Sensitivity to change analysis was performed using a paired samples t test.

Results

Demographic characteristics of the study population are shown in Table 1. The mean age of the patients and the controls were 43.23 (13.1) and 41.14 (13.8), respectively ($p = 0.44$). Out of the initial 78 patients and 45 controls, 68 (87.1 %) and 37 (82.2 %) respectively were available for

Table 1 Patient characteristics

	Patients ($n = 68$)	Controls ($n = 37$)	P value
Male-to-female ratio	42/26	23/14	0.96
Mean age (SD)	43.23 (13.1)	41.14 (13.8)	0.44
Employment status			
Employed	31/68	18/37	0.76
Student	13/68	7/37	0.98
Retired	3/68	2/37	0.81
Unemployed and others	21/68	10/37	0.67
Number sexually active	45/68	20/37	0.22

the final analysis. The proportion of sexually active patients in the patient and control groups was 66.1 and 54.0 %, respectively ($p = 0.22$). The patient and control groups were also comparable in terms of employment status and male-to-female ratio (Table 1).

Reliability of Turkish USSQ

The Cronbach's alpha value, a measure of internal consistency, was higher than 0.7 at week 1 for all domains except for the additional problems domain. At week 4, only the work performance domain had a Cronbach's alpha of higher 7 (Table 2).

The test–retest reliability of the Turkish USSQ was demonstrated by strong correlations between the mean scores at weeks 1 and 4 for each domain (Table 2). Correlations between week 1 and week 4 scores were very strong for the work performance domain, strong for the urinary symptoms and body pain domain and moderately strong for the general health and sexual matters domains. The test–retest correlation for the additional problems domain was the lowest (Table 2).

Correlations of individual domain scores with others are shown in Table 3, with the highest correlation observed between urinary symptoms and the general health domains (CC = 0.67), followed by the body pain and additional problems domains (CC = 0.43) at week 1.

Discriminant validity and sensitivity to change

The Turkish USSQ was able to effectively differentiate between patients with and without stents, as demonstrated by the significant differences in all of the domain scores between patients and controls (Table 4). Of 45 sexually active patients in the stent group, 62.2 % reported disturbance in sexual activity, whereas of all patients in the stent group 77.9 % had some amount of body pain due to the stent.

Table 2 Internal consistency and test–retest reliability for each domain of Turkish Ureteral Stent Symptoms Questionnaire

	Internal consistency		Test–retest reliability			
	(Cronbach's alpha)		Mean score (SD)		Spearman's correlation coefficient	P value
	Week 1 with stent ($n = 68$)	Week 4 with stent ($n = 55$)	Week 1 with stent ($n = 68$)	Week 4 with stent ($n = 55$)		
Urinary symptoms	0.819	0.667	24.88 (4.89)	20.30 (3.02)	0.718	0.001
Body pain	0.714	0.693	17.17 (3.17)	11.13 (2.50)	0.666	0.001
General health	0.767	0.586	12.69 (3.25)	9.41 (1.90)	0.570	0.001
Work performance	0.920	0.742	7.90 (1.49)	6.88 (1.57)	0.911	0.001
Sexual matters	0.839	0.637	5.47 (1.88)	2.80 (1.02)	0.612	0.001
Additional problems	0.570	0.691	6.89 (1.57)	5.20 (1.64)	0.353	0.014

Table 3 Correlation of each domain score with other domain scores at week 1/week 4

	Urinary symptoms	Body pain	General health	Work performance	Sexual matters	Additional problems
Urinary symptoms	1.00/1.00					
Body pain	0.42/0.25	1.00/1.00				
General health	0.67/0.40	0.30/0.41	1.00/1.00			
Work performance	0.23/0.11	0.14/0.20	0.41/0.07	1.00/1.00		
Sexual matters	0.15/0.33	0.10/0.14	0.21/0.22	0.22/0.42	1.00/1.00	
Additional problems	0.40/0.07	0.43/0.05	0.13/0.30	0.29/0.17	0.47/0.27	1.00/1.00

Table 4 Ability of the Turkish USSQ to discriminate between patients with and without ureteric stents

	Mean domain score (SD)		*P* value
	Patients with stent ($n = 68$)	Controls ($n = 37$)	
Main domain scores			
Urinary symptoms	24.88 (4.83)	13.51 (2.07)	0.009
Body pain	17.17 (3.17)	–	–
General health	12.69 (3.25)	8.02 (2.68)	0.001
Work performance	7.90 (1.49)	3.31 (0.66)	0.003
Sexual matters	5.47 (1.88)	2.60 (0.81)	0.001
Global QOL	5.29 (0.91)	3.32 (2.01)	0.001
No of patients reporting disturbance in sexual activity	28/45	0/20	–
No of patients reporting body pain	53/68	0/37	–
Number of whole days lost due to stent	2.6 (3.71)	–	–
Number of half days lost due to stent	5.8 (3.54)	–	–

Table 5 Sensitivity to change analysis

	Mean score (SD) $n = 30$			*P* value (week 1 vs. week 8)	*P* value (week 4 vs. week 8)
	With stent		Without stent		
	Week 1	Week 4	Week 8		
Urinary symptoms	24.70 (3.37)	20.60 (2.89)	15.83 (5.07)	0.001	0.001
Body pain	15.0 (1.58)	9.75 (0.0)	0	–	–
General health	12.17 (3.58)	9.13 (1.54)	8.06 (3.58)	0.001	0.013
Work performance	7.71 (1.43)	6.64 (1.82)	3.42 (1.08)	0.001	0.001
Sexual matters	5.40 (1.69)	2.52 (0.60)	2.25 (0.78)	0.001	0.479
QoL	5.41 (0.77)	1.62 (0.67)	0.86 (0.9)	0.001	0.001

Mean domain scores of patients at weeks 1 and 4 were significantly higher than the scores at week 8 (after stent removal), except in the sexual matters domain which was not significantly different at week 8 compared with week 4 (Table 5).

Convergent validity

Among male patients with a stent, the urinary symptoms index at weeks 1 and 4 demonstrated a high correlation with IPSS total score (CC 0.503 [$p = 0.002$] and 0.463 [$p = 0.005$], respectively). Among female patients with a stent, the urinary symptoms index demonstrated a high correlation with mOAB total score only at week 1 (CC 0.558 [$p = 0.01$]). The urinary symptoms index also showed a high correlation with the quality of life domains of the corresponding questionnaires in male and female patients (Table 6). The body pain index showed a strong correlation with the visual analog scale (VAS) score at weeks 1 and 4 (CC 0.603 [$p = 0.001$] and 0.908 [$p = 0.001$], respectively).

Discussion

This study demonstrates the validity and reliability of the Turkish version of the USSQ to characterize the symptoms and quantify the associated impairment in QoL in Turkish-speaking male and female patients with ureteral stents. Overall, our results are in line with those of the previous studies that have validated cross-cultural adaptations of the USSQ. We have demonstrated that all six domains of the Turkish USSQ can effectively differentiate between patients with and patients without stents with good internal consistency, test–retest reliability and responsiveness to change. We hope that our study will contribute to standard reporting of symptoms in Turkish-speaking patient populations, which can then lead to improved assessment of outcomes of ureteral stent insertion.

The internal consistency within each domain of the Turkish USSQ was overall very satisfactory as demonstrated with a Cronbach's alpha value of >0.7 for all domains at week 1 other than additional problems domain. Lower (but closer to 0.7) values were observed at week 4. In terms

Table 6 Correlation of each domain score with IPSS, mOAB and VAS score at weeks 1 and 4

	Spearman's correlation coefficient	*P* value
Urinary symptoms and IPSS total score ($n = 34$)		
Week 1	0.503	0.002
Week 4	0.463	0.005
Urinary symptoms and mOAB total score ($n = 20$)		
Week 1	0.558	0.010
Week 4	0.233	0.320
Urinary symptoms and IPSS QoL question ($n = 34$)		
Week 1	0.720	0.001
Week 4	0.397	0.020
Urinary symptoms and mOAB QoL question ($n = 20$)		
Week 1	0.628	0.003
Week 4	0.116	0.620
Body pain index and VAS score ($n = 38$)		
Week 1	0.603	0.001
Week 4	0.908	0.001

of test–retest reliability, our results show that the Turkish USSQ can consistently quantify the symptoms of patients with ureteral stents, although with slightly lower scores for all domains at week 4 compared with week 1. This can be explained by the developing tolerance to the stent over time [15]. It may also be due to a potential recall bias since the questionnaires were administered 4 weeks apart. Although Park et al. [10] performed the retest at week 2, we chose, like the majority of researchers, to follow the methodology of the original article [8–10].

The Turkish USSQ effectively differentiated between patients with a stent and those, and it was found to be sensitive to stent removal. The exception to this was the sexual domain score, which that did not change after stent removal compared to week 4 with stent. This raises the question whether it is possible that stent-associated bother could persist in some cases despite stent removal.

We have demonstrated moderate to strong correlations between the Turkish USSQ and other validated instruments to evaluate urinary symptoms and their bother. The IPSS in men and the mOAB score in women correlated with the urinary symptoms domain score at weeks 1 and 4, with week 1 correlations being generally higher compared with those of week 4. Also, the QoL items of both questionnaires correlated well with the urinary symptoms score of the USSQ. Not surprisingly, the highest correlation was observed between the body pain domain score and the VAS score of the USSQ.

The USSQ was originally designed as a 38-item questionnaire, with 33 Likert-type questions and 5 more descriptive items organized in six main domains. Although this questionnaire provides a comprehensive assessment of urinary symptoms, general health, pain, sexual health, work performance and other additional problems related to in situ ureteral stents, it does not allow us to calculate a single total USSQ score, as one would expect. Thus, as the creators of the original questionnaire have suggested we recommend that each domain of the Turkish USSQ be used to evaluate a particular construct. Also, it has been argued that the original USSQ could be impractical to use in daily practice for non-research purposes and that a shorter version of the form may be more practical [16]. A similar situation was experienced with the development of different derivatives of the 33-item OAB-q questionnaire (the OAB-q short form and the OAB-V8), which are now frequently used to evaluate symptom bother and QoL of patients with overactive bladder [17]. Thus, we welcome further efforts to find briefer derivatives of the USSQ that can effectively evaluate symptoms and QoL while being more practical in the clinical setting.

A limitation of this study is that the Turkish USSQ is validated for use only in patients with unilateral stents for benign conditions and excludes those patients with malignant conditions or complicated cases, and others.

Conclusion

The Turkish version of the USSQ can be used as a reliable instrument to quantify patient-reported symptoms and the bother associated with use of indwelling ureteral stents. This instrument will help in standardized reporting of patient outcomes in the literature, which can then lead to improved understanding of stent burden.

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Authors' contributions Y. Tanidir was involved in project development, data collection, data analysis, manuscript writing and editing, and supervision. N. Mangir performed data analysis, and manuscript writing and editing. A. Sahan took part in data collection and data analysis. M. Sulukaya carried out data collection.

Compliance with ethical standards

Conflict of interest The authors have no conflict of interest to declare.

Ethical standards This prospective study was conducted after receiving approval from the institutional review board.

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