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Reliability and validity of the Turkish language version of the Core Lower Urinary Tract Symptom Score

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Abstract

Objectives: The purpose of this study was to develop the Turkish version of the Core Lower Urinary Tract Symptom Score (CLSS) and determine its psychometric properties in Turkish subjects.

Methods: A total of 428 subjects, 259 with lower urinary tract symptoms (LUTS) and 169 without any complaints, were included in the study. In addition, 40 subjects were included in the study for test-retest analysis. After the Turkish version of the CLSS was created, all patients underwent medical history, physical examination, complete urinalysis, urinary ultrasonography, and filled out a CLSS. In addition, men were asked to fill in International Prostate Symptom Score (IPSS), International Consultation on Incontinence Questionnaire-Male LUTS and National Institutes of Health Chronic Prostatitis Symptom Index. Women completed the Bristol Female LUTS-Short Form and IPSS. The patients from the test-retest group were asked to fill out the CLSS two times at 2-week intervals.

Results: CLSS showed high internal consistency (Cronbach's α for men and women was 0.909 and 0.767, respectively). The test-retest reliability of CLSS was high for subdomains (intraclass correlation coefficient was 0.739-0.962). Scores of CLSS were significantly higher in the study group than the control group ($P < 0.001$). In men and women, it showed very strong convergent validity ($P < 0.0001$) with subdomain related to other questionnaires. In our confirmatory factor analysis, the original model of CLSS was found to be compatible.

Conclusions: The Turkish version of CLSS is a valid and reliable questionnaire to evaluate the symptoms and disorders of patients with LUTS.

KEYWORDS
Core Lower Urinary Tract Symptom Score, lower urinary tract symptoms, questionnaire, reliability, validation

1 | INTRODUCTION

Lower urinary tract symptoms (LUTS) include storage (frequency, urgency, incontinence, and nocturia), voiding (slow stream, splitting or spraying, intermittency, hesitancy, straining to void, and terminal dribble), and post-micturition (feeling of incomplete emptying and post-void dribble) symptoms.[1]

In population-based studies, the prevalence of patients with at least one LUTS ranged from 64.3% to 74.4%. It was observed that the incidence of storage symptoms was higher in women than in men and increased with age.[2,3] In our country, the presence of any LUTS was found to be 83% in adult men and 87% in adult women.[4] Although LUTS is a frequently encountered clinical problem in urology practice, it can easily be overlooked if the patient's complaints are not properly

questioned. In addition, patients do not express their complaints about this issue unless they are specifically questioned. In the same study, it was determined that only 27% of patients with LUTS in our country received health care.[4]

Evaluation of LUTS in men and women is essential both for diagnosis and for evaluating response to treatment of lower urinary tract disorders.[5,6] There is a need for validated questionnaires that can allow the assessment of a broad spectrum of LUTS and question both sexes, and that can also be used in primary care.

Core Lower Urinary Tract Symptom Score (CLSS) questionnaire was developed by Homma et al., in 2008.[7] There are 10 questions in total, including five questions about storage symptoms (urinary frequency, nocturia, urgency, urge and stress urinary incontinence), three questions about voiding symptoms (slow stream, straining and feeling of incomplete emptying), and two questions about lower urinary tract pain. In addition, it includes three questions, two of which are about bothersome symptoms and one about quality of life, added in the English version.[8,9]

The clinical validity and reliability of the CLSS questionnaire has been validated in both men and women with LUTS.[9] However, the Turkish version of this questionnaire is not available. Therefore, in our study, we aimed to develop a Turkish version of the CLSS questionnaire and to determine its validity and reliability.

2 | METHODS

The author of CLSS was contacted and permission was obtained to translate the English version of CLSS into Turkish.[8] Later, its back translation into English was approved by the author. Our study was approved by the local ethics committee (2020/514/186/1) and informed written consent was obtained from all patients before participating in the study. The study was designed in accordance with the Declaration of Helsinki.

2.1 | Questionnaire

The English version of the CLSS questionnaire form consists of a total of 13 questions. The first 10 questions included five questions about storage, following three questions about voiding symptoms, and two questions (questions 9 and 10) about lower urinary tract pain. These questions have Likert type answers ranging 0–3. The CLSS questionnaire also includes a question (question 11) asking participants to list three core symptoms and a question (question 12) about the primary core symptom. In addition, a quality of life index (question 13) was also used: 0 (delighted) to 6 (terrible).[7-9]

2.2 | Language validation

First, the Turkish version of the CLSS was conducted from the English version of the CLSS with a standard, multi-stage process recommended by Hutchinson et al.[10] Briefly, this process consisted of the following steps: translation, back translation, pilot study, final version.

Two professional English-Turkish translators unfamiliar with CLSS independently translated the original English questionnaire into Turkish language. Translators and researchers synthesized a joint draft of the Turkish versions of the questionnaire. Later, another professional translator, unfamiliar with the original English forms of the instruments, back-translated the drafts. The back-translated versions were compared with the original versions, and the final versions of the indices were agreed upon. Next, a pilot test was performed on 10 patients with LUTS to assess the content validity. Patients were invited for face-to-face interviews and were asked to fill out the questionnaires. Content, comprehensibility, and readability of instruments were discussed with patients (ie, face validity). Minor changes were made after the pilot test based on suggestions and feedback from patients.

2.3 | Study population and data collection

Three hundred and twenty-four patients with LUTS who applied to the urology outpatient clinic between January 2021 and August 2021 were assessed for participation in the study group; 65 patients were excluded because they did not meet the inclusion criteria (n = 48) and refused to participate (n = 17). A total of 259 patients (127 men and 132 women) with LUTS over the age of 18 who were literate and had no cognitive problems were included in the study. At the same time period, 260 individuals who applied to the internal medicine outpatient clinic for health screening were evaluated for participation in the control group of the study. Ninety-one subjects were excluded as they did not fulfill the inclusion criteria (n = 63) and did not approve to participate (n = 28).

As the control group, 169 healthy individuals (84 male and 85 female) over the age of 18 who were literate, had no cognitive problems, and did not have any disease that could affect LUTS and lower urinary tract functions were included in the study. In addition, 40 subjects were included in the study for test-retest analysis.

In the study group, patients with active urinary tract infection, who use drugs that affect the urinary system, who have neurogenic LUTS (spinal cord trauma, neurospinal dysraphism, multiple sclerosis, Parkinson's, etc), who have undergone pelvic surgery (last 6 months), who have received pelvic radiotherapy and have undergone permanent or temporary urinary catheterization, who have undergone cystectomy or suprapubic diversion, and patients with pregnancy and mental disorders were excluded. In the control group, those with LUTS and any disease that could affect lower urinary tract functions such as diabetes, atherosclerotic diseases, and neurological diseases were excluded.

After the Turkish version of CLSS was created, all patients underwent medical history, physical examination, complete urinalysis and urinary ultrasonography. In addition, prostate specific antigen levels and residual urine were evaluated in the male group. The CLSS form was filled by the subjects in the control group and patient group.

In addition, men completed the International Prostate Symptom Score (IPSS),[11] International Consultation on Incontinence Questionnaire - Male Lower Urinary Tract Symptoms (ICIQ-MLUTS),[12] National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI),[13] and women completed the Bristol Female Lower Urinary Tract Symptom-Short Form (BFLUTS-SF)[14] and IPSS. The patients from the test-retest group were asked to fill out the Turkish CLSS questionnaire twice at 2-week intervals.

2.4 | Statistical analysis

Consistent with the recommendations, an item subject ratio of 10:1 was used to determine the sample size.[15] Patients' data are presented as ratios for categorical variables, and mean ± SEM for numerical variables. D'Agostino and Pearson test was used to determine whether the data fit a normal distribution. Student's *t* test or Mann-Whitney *U* test was used to compare the mean values of the parameters.

Internal consistency and test-retest reliability tests were performed to evaluate the reliability of the CLSS. Internal consistency was evaluated with the Cronbach alpha value, and test-retest reliability was evaluated with the intraclass correlation coefficient (ICC). The Wilcoxon test was used to examine statistically significant differences between test and retest results. Cohen's Kappa test was used to investigate the fit in test-retest analysis of the questions from the CLSS questionnaire asking them to list at most three and one bothersome symptom. Construct validity was evaluated using discriminant and convergent validity. The correlation between the CLSS and the sub-items of the IPSS, ICIQ-MLUTS, NIH-CPSI and BFLUTS-SF

TABLE 1 Demographic data for the patient and the control groups

	No.		Mean age ± SEM	
	Female	Male	Female	Male
Controls	85	84	41.35 ± 1.12	48.02 ± 1.62
Patients	132	127	52.67 ± 1.42	46.40 ± 1.83
Overactive bladder	43	23	46.31 ± 2.29	34.50 ± 3.05
Underactive bladder	1	12	45.00 ± 0.0	38.33 ± 5.66
Stress urinary incontinence	49	4	51.30 ± 1.89	67.33 ± 1.45
Mixed urinary incontinence	33	-	63.44 ± 2.90	-
Chronic prostatitis/chronic pelvic pain syndrome	-	15	-	34.25 ± 2.82
Bladder pain syndrome/interstitial cystitis	3	-	54.50 ± 7.50	-
Benign prostatic hyperplasia	-	60	-	63.31 ± 1.44
Urethral stricture/bladder neck stenosis	3	13	48.00 ± 13.00	30.33 ± 2.01

TABLE 2 The distribution of symptoms and the mean (±SEM) of item scores in the patient and control groups

	Female			Male		
Item	Patients	Controls	*P*[a]	Patients	Controls	*P*[a]
DF	1.25 ± 0.10	0.31 ± 0.06	<0.0001	1.21 ± 0.15	0.12 ± 0.05	<0.0001
Nocturia	1.82 ± 0.08	0.55 ± 0.07	<0.0001	2.03 ± 0.15	0.57 ± 0.08	<0.0001
Urgency	1.98 ± 0.09	0.13 ± 0.04	<0.0001	1.73 ± 0.16	0.10 ± 0.05	<0.0001
UUI	1.95 ± 0.11	0.04 ± 0.02	<0.0001	0.45 ± 0.15	0.00 ± 0.00	<0.0001
SUI	2.01 ± 0.11	0.13 ± 0.04	<0.0001	0.33 ± 0.17	0.00 ± 0.00	<0.0001
SS	0.88 ± 0.11	0.06 ± 0.03	<0.0001	2.27 ± 0.12	0.10 ± 0.05	<0.0001
Straining	0.81 ± 0.11	0.02 ± 0.02	<0.0001	2.06 ± 0.14	0.05 ± 0.03	<0.0001
IE	1.59 ± 0.11	0.13 ± 0.05	<0.0001	2.58 ± 0.12	0.19 ± 0.06	<0.0001
BP	1.52 ± 0.10	0.36 ± 0.06	<0.0001	1.21 ± 0.17	0.02 ± 0.02	<0.0001
UP	1.54 ± 0.10	0.31 ± 0.05	<0.0001	1.33 ± 0.18	0.02 ± 0.02	<0.0001
Bother	4.82 ± 0.12	0.33 ± 0.05	<0.0001	4.73 ± 0.23	0.19 ± 0.06	<0.0001

Abbreviations: BP, pain in the bladder; DF, daytime frequency; IE, feeling of incomplete emptying; SUI, stress urinary incontinence; SS, slow urinary stream; UP, pain in the urethra; UUI, urgency urinary incontinence.

[a]Mann-Whitney test.

questionnaires was evaluated with Spearman correlation coefficient to determine convergent validity. The discriminant validity was evaluated by comparing the CLSS sub-item scores of the patients with the Mann-Whitney *U* test with the control group. In addition, construct validity of CLSS was investigated using confirmatory factor analysis. These psychometric analyses were performed according to gender. Statistical analysis was performed using a free trial version of the IBM SPSS software program version 28.0 (https://www.ibm.com/tr-tr/analytics/spss-trials). Confirmatory factor analysis was performed with a free trial version of IBM SPSS Amos computer package program version 26.0 (https://www.ibm.com/resources/mrs/assets/packageList?source=SWG-AMOS_TRIAL&lang=en_US). $P < 0.05$ was considered statistically significant.

3 | RESULTS

The demographic data for the subjects are given in Table 1.

The distribution of symptoms and the mean of item scores in the patient and the control groups are given in Table 2. The mean scores for all symptoms of both genders were higher in the patient group than the control group, and the difference was significant ($P < 0.001$) for all symptoms. (Table 2).

Cronbach's alpha value was 0.909 for men and 0.767 for women. The Turkish version of CLSS showed good internal consistency. Test-retest reliability was demonstrated for each item with ICC. All items showed good repeatability. There was no statistical difference between test-retest data ($P > 0.05$). Kappa values for questions

TABLE 3 The distribution of symptoms and the mean (±SEM) of item scores in the test-retest group

Item	Test score	Retest score	P[a]	ICC	95% CI	F test
DF	0.93 ± 0.15	0.90 ± 0.13	0.790	0.859	0.749-0.923	0.0001
Nocturia	1.95 ± 0.11	1.90 ± 0.11	0.565	0.739	0.558-0.853	0.0001
Urgency	2.00 ± 0.15	2.03 ± 0.15	0.790	0.872	0.772-0.930	0.0001
UUI	1.73 ± 0.20	1.78 ± 0.19	0.565	0.915	0.846-0.954	0.0001
SUI	1.58 ± 0.19	1.68 ± 0.20	0.182	0.933	0.878-0.964	0.0001
SS	0.75 ± 0.17	0.65 ± 0.15	0.129	0.929	0.870-0.962	0.0001
Straining	0.85 ± 0.17	0.95 ± 0.17	0.182	0.913	0.841-0.953	0.0001
IE	1.60 ± 0.17	1.70 ± 0.17	0.301	0.852	0.738-0.919	0.0001
BP	1.43 ± 0.12	1.40 ± 0.13	0.790	0.829	0.699-0.906	0.0001
UP	1.63 ± 0.11	1.70 ± 0.10	0.149	0.919	0.850-0.956	0.0001
Bother	4.83 ± 0.16	4.90 ± 0.16	0.149	0.962	0.929-0.980	0.0001

Abbreviations: BP, pain in the bladder; DF, daytime frequency; ICC, intraclass correlation coefficient; IE, feeling of incomplete emptying; SUI, stress urinary incontinence; SS, slow urinary stream; UP, pain in the urethra; UUI, urgency urinary incontinence.
[a]Wilcoxon signed rank test.

TABLE 4 Correlation with other questionnaires in patients group

Male	r	P[a]	Female	r	P[a]
DF vs ICIQ-MLUTS Q13	0.974	<0.0001	DF vs BFLUTS-SF QF4	0.880	<0.0001
Nocturia vs ICIQ-MLUTS Q14	0,987	<0.0001	Nocturia vs BFLUTS-SF QF1	0.968	<0.0001
Urgency vs ICIQ-MLUTS Q7	0.988	<0.0001	Urgency vs BFLUTS-SF QF2	0.927	<0.0001
UUI vs ICIQ-MLUTS Q8	0.910	<0.0001	UUI vs BFLUTS-SF QI1	0.982	<0.0001
SUI vs ICIQ-MLUTS Q9	0.936	<0.0001	SUI vs BFLUTS-SF QI3	0.930	<0.0001
SS vs ICIQ-MLUTS Q4	0.989	<0.0001	SS vs IPSS Q5	0.979	<0.0001
Straining vs ICIQ-MLUTS Q3	0.995	<0.0001	Straining vs BFLUTS-SF QV2	0.909	<0.0001
IE vs ICIQ-MLUTS Q6	0.988	<0.0001	IE vs IPSS Q1	0.981	<0.0001
BP vs NIH-CPSI Q3	0.945	<0.0001	BP vs BFLUTS-SF QF3	0.869	<0.0001
UP vs NIH-CPSI Q3	0.932	<0.0001	UP vs -	-	-
Bother vs IPSS Qol	0.978	<0.0001	Bother vs IPSS Qol	0.829	<0.0001

Abbreviations: BFLUTS-SF, Bristol Female Lower Urinary Tract Symptoms; BP, pain in the bladder; CLSS, Core Lower Urinary Symptom Score; DF, daytime frequency; ICIQ-MLUTS, International Consultation on Incontinence Questionnaire - Male Lower Urinary Tract Symptoms; IE, feeling of incomplete emptying; IPSS, International Prostate Symptom Score; NIH-CPSI, National Institutes of Health Chronic Prostatitis Symptom Index; Q, question; Qol, quality of life; SS, slow urinary stream; SUI, stress urinary incontinence; UP, pain in the urethra; UUI, urgency urinary incontinence.
[a]Spearman correlation coefficients.

11 and 12 were found to be 0.820 and 0.902, respectively ($P = 0.0001$). In the test-retest group, no difference was found with the Wilcoxon test for questions 11 and 12 ($P = .340$ and $P = .102$, respectively). Test-retest reliability results are given in Table 3.

Convergent validity analyses with M-LUTS, IPSS and NIH-CPSI in men showed strong convergent validity with the relevant subdomain ($r = 0.910$-0.989, $P < 0.0001$). Convergent validity analyses with BFLUTS-SF and IPSS in women showed strong convergent validity with the relevant subdomain (0.829-0.982, $P < 0.0001$). Convergent validity results in men and women are given in Table 4.

CLSS was successful in distinguishing the patient and control groups. There was a statistically significant difference in the scores of the patient and control groups ($P < 0.001$).

In the 11th question, which asked the participants to list at most three disturbing symptoms out of 10, 12% of males and 25% of females could not choose three options.

Confirmatory factor analysis of CLSS was performed using the maximum likelihood estimation method. In males, the following values of the model were found: $\chi^2 = 74.453$, $P = 0.0001$, $\chi^2/SD = 3.127$, root mean square error of approximation (RMSEA) value = 0.065 and comparative fit index (CFI) value = 0.920. In females, the following values of the model were found: $\chi^2 = 90.686$, $P = 0.0001$, $\chi^2/SD = 2.864$, RMSEA value = 0.055, CFI value = 0.940. In this case, it was seen that the model found in the original factor analysis results of CLSS was also compatible in our confirmatory factor analysis.

4 | DISCUSSION

In our study, the Turkish version of the CLSS questionnaire was standardized and conducted in accordance with the rules of the multistage process.[10] In our study, the psychometric analysis of the Turkish version of the CLSS questionnaire was conducted with respect to the COSMIN guideline.[16] In this study, the internal consistency of the CLSS questionnaire for both men and women was found to be reliable (Cronbach's $\alpha > 0.7$). Test-retest reproducibility was also found to be high. The ICC for this study was >0.8 (0.8-0.9), providing a sufficient condition for clinical trials. The Kappa value for the 11th and 12th questions was found as >0.8 ($P = 0.0001$). Our results are consistent with previous reliability studies.[7,9]

Construct validity was tested using the convergent validity and discriminant validity. For convergent validity in men and women, more than one questionnaire was used as there was no similar, previously validated questionnaire. In the analysis for convergent validity in men, the items related to storage, emptying and urinary incontinence, quality of life item and pain items of CLSS showed strong convergent validity with ICIQ-MLUTS, IPSS and NIH-CPSI, respectively. In women, the items related to storage, emptying, urinary incontinence and pain of CLSS showed strong convergent validity with the related items of BFLUTS-SF and slow urinary stream, feeling of incomplete emptying and quality of life items showed very strong convergent validity with the related items of IPSS.

Although IPSS was developed for LUTS in men, it has also been validated for women.[17] Fujimura et al. compared CLSS with IPSS and Overactive Bladder Symptom Score (OABSS) in women and found a correlation between CLSS with IPSS and OABSS.[18] In another study, Fujimura et al. also found a correlation between CLSS and IPSS in men.[19] In both studies, it was stated that CLSS was more comprehensive in symptom assessment than the compared questionnaires.

Discriminant validity was assessed by comparing the CLSS subitem scores between the patient and the control groups. The symptoms that did not show any statistical difference between the LUTS and the control groups had not been included in the CLSS questionnaire by Homma et al. in the CLSS development study.[7] In our study, similar to previous validation studies of CLSS, patients without any LUTS were included in the control group. Our data showed that Turkish versions of CLSS can successfully differentiate patients with LUTS from asymptomatic controls for both genders. Therefore, we can say that the content of CLSS reflects LUTS.

In the exploratory factor analysis in the original study, four structural components were identified in all genders. It has been concluded that the first was associated with storage, the second with voiding symptoms, the third with pain, and the fourth with urinary incontinence.[9] In our study, it was thought that confirmatory factor analysis showed the structural validity of the CLSS questionnaire in both genders.

In the 11th question, which asked the participants to list at most three disturbing symptoms out of 10, 12% of males and 25% of females could not choose three options. A similar finding was also detected by Okomura et al.

Results regarding responsiveness are lacking in our study and this can be considered as a limitation of our study. It is necessary to investigate whether CLSS can detect change with treatment or follow-up in patients with different LUTS.

In conclusion, the Turkish version of the CLSS is a valid and reliable tool for assessing the symptoms of patients with LUTS of all genders. The CLSS questionnaire can be used in primary health care and epidemiological studies.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions. “cd_value_code=”text

DISCLOSURE

The authors declare no conflict of interest.

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