

ORIGINAL PAPER

Reliability and validity analysis of Turkish version of the Symptoms of Lower Urinary Tract Dysfunction Research Network Symptom Index-10 questionnaire

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Summary

Introduction: To evaluate the validity and reliability of the Turkish version of the

Symptoms of Lower Urinary Tract Dysfunction Research Network Symptom Index-10 (LURN SI-10).

Materials and methods: In this, single-centre study, patients between 18 and 65 years old, who were suffering from lower urinary tract symptoms (LUTS) without any known urinary tract disease and on no medication, were enrolled. The control group consisted of participants, who were admitted to our clinic suffering from any complaint except LUTS and met all of the other inclusion and exclusion criteria. Participants' demographics such as age, sex, and level of education were recorded.

The Turkish version of the LURN SI-10, International Prostate Symptom Score (IPSS) and Overactive Bladder Questionnaire (OAB-V8) were administered to all participants. Construct validity was evaluated by confirmatory factor analysis and concurrent validity was evaluated with correlations to similar measures. Internal consistency (Cronbach's alpha) was used to establish the scale's internal consistency reliability.

Results: A total of 164 participants were included in the final analysis. Of those, 57% were male. The individuals were identified as being in the "patient group" (n = 86) and a "control group" (n = 78). The mean age was 48.24 ± 14.30 years.

The median total LURN SI-10 scores of patient group and control group were 12.0 (9-18.25) and 4.0 (2.75-6), respectively. The LURN SI-10 questionnaire showed a high correlation with the IPSS and the OAB-V8 questionnaires (r: 0.761; p: 0.001; r: 0.737; p: 0.001, respectively) in concurrent validity analysis. Cronbach's alpha coefficient of the LURN SI-10 was 0.850.

Conclusions: This promising measurement tool can be used to evaluate LUTS in Turkish women and men. Further studies should be conducted to assess the clinical usefulness of this questionnaire.

KEY WORDS: LURN SI-10; LUTS; Patient reported outcomes; Questionnaires; Turkish.

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INTRODUCTION

Lower urinary tract symptoms (LUTS), which include storage, voiding, and post-micturition symptoms, are related with lower urinary tract dysfunction. Above 40 years of

age, LUTS are common in both females and males with similar incidences. Rates of storage, voiding, and post-micturition symptoms in females and males are 51.3% vs 59.2%, 25.7% vs 19.5%, and 16.9% vs 14.2%, respectively (1).

These patients admit to clinic suffering from usually more than one symptom. Therefore, symptom scores obtained from questionnaires are often used for evaluation of these patients (2).

The *International Prostate Symptom Score* (IPSS) has been a well-known and frequently used symptom index for many years. Despite its prevalent utilization, there are some drawbacks of the IPSS. It was devised for males and does not interrogate symptoms such as incontinence and post-void dribbling. On the other hand, *Overactive Bladder Questionnaire V8* (OAB-V8), which is also commonly used, inquires about frequency, urgency, urge or stress incontinence, and nocturia. It was conceived for both males and females, but it covers predominantly storage symptoms and does not question voiding difficulty. As a result, a questionnaire which evaluates both males and females and involves all the important lower urinary tract symptoms will be of benefit for clinicians.

"*Comprehensive Assessment of Self-Reported Urinary Symptoms* (CASUS)" questionnaire, which consists of 93 questions covering a wider spectrum of symptoms when compared with other questionnaires, was developed to enhance phenotypical analyses of the patients with LUTS by The *Lower Urinary Tract Dysfunction Research Network* (LURN) (3). Based upon CASUS, which is impractical in clinical use because of its length, Cella and colleagues devised and reported first the LURN symptom index of 29 items (LURN SI-29) and thereafter LURN symptom index of 10 items (LURN SI-10) by abridging the former (4).

In these studies, it is stated that a shorter and successful measure (LURN SI-10) in correlation with the clinical presentation is obtained, which is also more comprehensive than present LUTS questionnaires and applicable to both males and females (5).

In this study, we aimed to investigate the validity and reliability of the LURN SI-10 questionnaire, which was translated into Turkish before, in patients with LUTS.

MATERIALS AND METHODS

We obtained a written approval of the developers of the LURN SI-10 index for validating it in Turkish language. The local ethics committee endorsed the study with decision number 2022/70 in accordance with the Helsinki Declaration. A written informed consent was signed by all individuals.

Patient population

We planned to enrol a minimum of 70 patients, who admit to our clinic suffering from LUTS, and a minimum of 70 participants for control group between September 2022 and October 2023 prospectively. Our inclusion criteria were: [1] admission to our clinic with clinically significant LUTS, [2] age between 18 and 65 years, [3] answering all the questions in each questionnaire, [4] signing the written informed consent. Our exclusion criteria were: [1] using medications such as alpha blockers, antimuscarinic agents, beta-mimetics, pain killers or drugs potentially impairing lower urinary tract functions, [2] a history of overactive bladder, bladder cancer, chronic pelvic pain syndrome, chronic prostatitis, prostate cancer, and a neurological disorder potentially causing lower urinary tract dysfunction, [3] presence of temporary or permanent urethral or ureteral catheter, [4] presence of a debilitating disorder, [5] being unable to communicate. The control group consisted of participants, who admitted to our clinic suffering from any complaint expect LUTS and met all the other inclusion and exclusion criteria.

Tools for data collection

Demographic data of the participants such as age, sex, education level were collected. All individuals took The Turkish version of the LURN SI-10 and validated Turkish versions of the IPSS and OAB-V8 questionnaires (6, 7). They were requested to complete the questionnaires on their own without professional aid at first application.

LURN SI-10

The LURN SI-10, first published in 2020, was conceived as a self-reported outcome questionnaire for clinical use with patients to assess LUTS 2020 (5). It includes 10 questions about frequency, nocturia, urgency, incontinence, bladder pain, voiding, and post-micturition symptoms as well as an additional question measuring dissatisfaction with LUTS. Each question scores between zero and four according to frequency of the symptom (Ninth and tenth questions between zero and three). The total score is calculated as “*the total score of ten questions x 10/number of the questions answered*” (maximum score 38). Last question about dissatisfaction with LUTS is about quality of life and does not affect the total score.

IPSS

The IPSS consists of eight questions and is usually used for screening, diagnosing and treatment planning of *benign prostate obstruction* (BPO). Seven questions investigate incomplete emptying of the bladder, frequency, intermittency, urgency, weak stream, straining, and nocturia. The eighth question is about overall quality of life. A score between zero and seven means mild, between eight and 19 means moderate, and between 20 and 35

means severe symptoms. Although IPSS is generally used in males with the diagnosis of BPO, it is not specific for males or prostate diseases (8).

OAB-V8

The *Overactive Bladder Questionnaire* (OAB-Q) was developed in 2002 by *Coyne and colleagues* as a questionnaire for OAB symptoms and quality of life (9). It can be used in patients with a provisional diagnosis of both wet and dry OAB. The OAB-V8 consists of the first eight questions of the OAB-q and is recommended as a screening and awareness test for OAB (10). A score between zero and seven indicates mild symptoms and eight and 40 indicates severe symptoms. *Tarcan and colleagues* validated OAB-V8 in Turkish language in 2012 (11).

Linguistic validation

We obtained a written approval of the developers of the LURN SI-10 index for validating it in Turkish language. The Turkish LURN SI-10 questionnaire, which was not validated in Turkish language but developed based upon Turkish LURN SI-29 questionnaire (12), which was validated in Turkish and published in 2021, was sent to the corresponding author by developers of LURN SI-10 and used in this study.

Statistical analysis

For statistical analyses, IBM SPSS Statistics 22 and AMOS 22 computer programs were used. Normally distribution of the data was controlled by Kolmogorov-Smirnov test. Findings were represented with descriptive statistical methods (minimum, maximum, mean, standard deviation, median, frequency). In comparison of quantitative data, normally distributed groups were compared by using Student t test and non-normally distributed groups were compared by using Mann Whitney U test. Qualitative data were compared by using Chi-square test. *Exploratory factor analysis* (EFA) was performed to test the construct validity of the LURN SI-10. *Kaiser-Meyer-Olkin* (KMO) test was used to assess the sufficiency of the sample for the factor analysis. Bartlett test demonstrated the correlation among variables. For evaluating the construct validity, *confirmatory factor analysis* (CFA) test was applied. Model fit was tested by using the χ^2 goodness of fit test (χ^2 , $\chi^2/\text{degree of freedom [df]}$), the goodness of fit index (GFI), *root mean square error of approximation* (RMSEA), the *comparative fit index* (CFI), and the *non-normed fit index* (NNFI). Cronbach's alpha coefficient was calculated for reliability of the scale.

Association between non-normally distributed parameters was controlled by using Spearman's rho correlation test. Partial correlation analysis was performed for evaluating the correlation between scores after adjustment for age. A p value less than 0.05 was considered statistically significant.

RESULTS

Due to incomplete questionnaires, nine participants were excluded. A total of 164 individuals between the age of 18 and 65 years were enrolled in the study. Of those, 71 (43.3%) were female, 93 (56.7%) were male, 86 were in

the patient group, and 78 were in the control group. The ratio of the females in the patient group was significantly higher than that in the control group (55.8% vs 29.5%, $p < 0.05$). The mean age of all participants was 48.24 ± 14.30 years. In the patient and control groups, the mean ages were 50.95 ± 11.79 and 45.24 ± 16.20 years, respec-

tively. The mean age of the patient group was higher than that of the control group significantly ($p < 0.05$). The median total LURN SI-10 scores were 12.0 (9-18.25) vs 4.0 (2.75-6) in patient group and control group, respectively ($p < 0.001$). The median total IPSS scores were 14.0 (9-21.25) vs 4.5 (2-7) in patient group and control group, respectively ($p < 0.001$). The median total OAB-V8 scores were 20.5 (12-28) vs 7.0 (4.75-9.25) in patient group and control group, respectively ($p < 0.001$). Table 1 and Figure 1 demonstrate the LURN SI-10, IPSS and OAB-V8 scores and scale graphs of the groups, respectively.

Table 1.
Comparison of total scores of the LURN SI-10, IPSS, and OAB-V8 between groups.

		Total	Patient	Control
AGE Mean (SD)		50.95 (12)	45.24 (16)	¹ 0.012*
SEX n (%)	Female	48 (%55.8)	23 (%29.5)	² 0.001*
	Male	38 (%44.2)	55 (%70.5)	
		Median (IQR)	Median (IQR)	
LURN SI-10		12 (9-18.25)	4 (2.75-6)	³ 0.001*
IPSS		14 (9-21.25)	5 (2-7)	³ 0.001*
OAB-V8		21 (12-28)	7 (4.75-9.25)	³ 0.001*

¹ Student t test; ² Ki-kare test; ³ Mann Whitney U test; * $p < 0.05$

Table 2.
Correlation of the LURN SI-10 with the IPSS and OAB-V8.

		Total	Patient	Control
IPSS	r	0.761	0.628	0.472
	p	0.001*	0.001*	0.001*
OAB-V8	r	0.737	0.597	0.490
	p	0.001*	0.001*	0.001*

Spearman's correlation; * $p < 0.05$.

The validity of the scale

Exploratory factor analysis (EFA) was performed to test the construct validity of the scale. Principal component analysis and varimax rotation were used in the factor analysis. Associations of LURN SI-10 total score with IPSS and OAB-V8 were assessed for concurrent validity. The LURN SI-10 total score demonstrated a high correlation with those of IPSS and OAB-V8 ($r = 0.761$, $p < 0.001$ and $r = 0.737$, $p < 0.001$, respectively). Figure 2 shows the correlations of LURN SI-10 with IPSS and OAB-V8.

When all individuals were assessed, a high, positive, and statistically significant correlation between both LURN SI-10 vs IPSS (0.76) and LURN SI-10 vs OAB-V8 (0.73) were observed ($p < 0.001$). The correlation analyses in patient and control groups are shown in Table 2.

In addition, the correlations of the LURN SI-10 total score with the IPSS and the OAB-V8 were investigated in male and female participants separately. In all females, a high, positive, and statistically significant correlation between

Figure 1.
Total scores of the LURN SI-10, IPSS and OAB-V8 in groups.

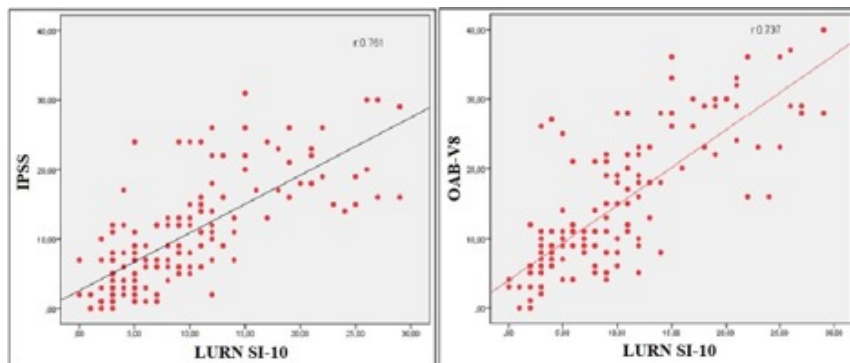
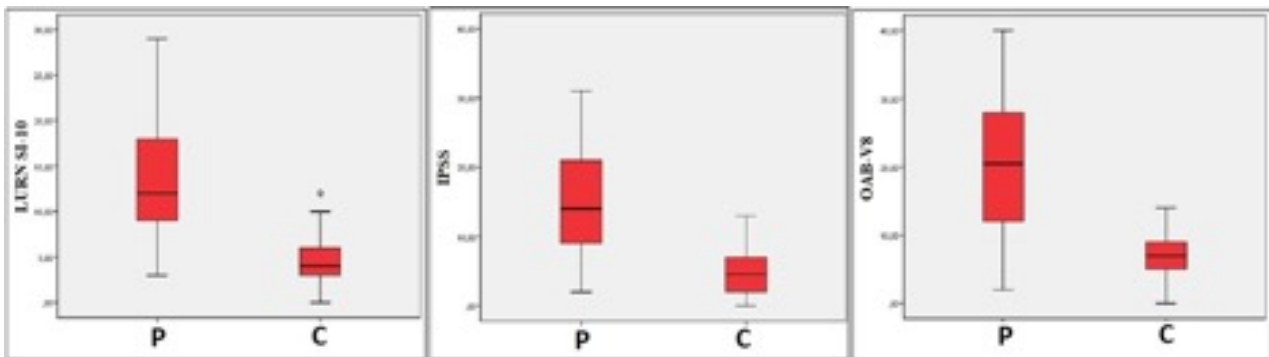


Figure 2.
Correlation of the LURN SI-10 with the IPSS and OAB-V8.

both LURN SI-10 vs IPSS (0.75) and LURN SI-10 vs OAB-V8 (0.79) were observed ($p < 0.001$). Besides, a high, positive, and statistically significant correlation was found between the LURN SI-10 total score and both IPSS and OAB-V8 in the female patient group ($p < 0.001$). In the female control group, a high, positive, and statistically significant correlation was found between LURN SI-10 total score and OAB-V8 ($p < 0.001$). In all males, a high, positive, and statistically significant correlation was found between the LURN SI-10 total score and both IPSS and OAB-V8 (78% and 67%, respectively) ($p < 0.001$). Besides, a high, positive, and statistically significant correlation was found between the LURN SI-10 total score and both IPSS and OAB-V8 in the male patient group ($p < 0.001$). In the male control group, a high, positive, and statistically significant correlation was found between LURN SI-10 total score and IPSS ($p < 0.001$). In the male control group, a low, positive, and statistically significant correlation was found between the LURN SI-10 total score and OAB-V8 ($p = 0.031$) (Table 3).

The reliability of the scale

Cronbach's coefficient of the LURN SI-10 for the internal consistency of the scale was 0.850. Descriptive data and Cronbach's coefficients of the LURN SI-10, IPSS and OAB-V8 questionnaires are shown in Table 4.

Table 3.
The correlations of LURN-10 with IPSS and OAB-V8 in females and males.

			LURN SI-10		
			Total	Patient	Control
Female	IPSS	r	0.754	0.603	0.201
		p	0.001*	0.001*	0.358
	OAB-V8	r	0.789	0.603	0.648
		p	0.001*	0.001*	0.001*
Male	IPSS	r	0.780	0.700	0.572
		p	0.001*	0.001*	0.001*
	OAB-V8	r	0.668	0.580	0.291
		p	0.001*	0.001*	0.031*

Spearman's correlation; * $p < 0.05$.

Table 4.
Descriptive statistics and Cronbach's alpha coefficients of the LURN SI-10, IPSS and OAB-V8.

		n	Minimum	Maximum	Mean \pm SD	Median	Cronbach's alpha
Total	LURN SI-10	164	0	29	9.27 \pm 6.94	8	0.850
	IPSS	164	0	31	10.27 \pm 7.74	8	0.847
	OAB-V8	164	0	40	13.93 \pm 9.64	11	0.921
Patient	LURN SI-10	86	3	29	13.56 \pm 6.80	12	0.782
	IPSS	86	2	31	14.94 \pm 7.43	14	0.780
	OAB-V8	86	2	40	20.23 \pm 0.10	20	0.877
Control	LURN SI-10	78	0	12	4.54 \pm 2.80	4	0.529
	IPSS	78	0	13	5.13 \pm 3.83	5	0.616
	OAB-V8	78	0	14	6.97 \pm 3.47	7	0.613

DISCUSSION

In this study, the validity and reliability assessment of the LURN SI-10 questionnaire in Turkish was performed to make it applicable in patients with LUTS. According to results of our study, version of the LURN SI-10 demonstrated good internal consistency reliability and concurrent validity, consistent with the results of the original study conducted by LURN group (5). We hope that our study will contribute to standard reporting of symptoms in Turkish-speaking patients and lead to improved evaluation of male and female patients with LUTS.

Male patients with LUTS usually admit to clinic suffering from differing types of involuntary loss of urine, which are not adequately caught by the IPSS (13). Thus, by using the IPSS solely, these symptoms, which substantially impair the quality of life, could be overlooked and the patient could miss the appropriate counselling opportunity. On the other hand, OAB-V8 is an excellent questionnaire for evaluating various types of involuntary loss of urine but cannot assess voiding symptoms if used solely. When compared with other questionnaires, LURN SI-10, which was validated in Turkish, has several advantages. First, it can be applied to both male and female patients with LUTS successfully. In addition, LURN SI-10 completely interrogates incontinence and post-void dribbling/pain, which are not included in the IPSS, and LUTS such as voiding difficulty, which are not included in the OAB-V8. It can prevent waste of time and effort, for both clinicians and patients, to be able to interrogate all LUTS by application of this questionnaire of only 10 questions without using other scales. In this study, regarding criterion-related validity was assessed with associations of LURN SI-10 with IPSS and OAB-V8. It was found that LURN SI-10 was highly correlated with IPSS and OAB-V8 questionnaires ($r = .761$ and $r = .737$, respectively).

In our results, Cronbach's alpha internal consistency coefficients of the LURN SI-10, IPSS and OAB-V8 were consistently high (0.850, 0.847, and 0.921, respectively). However, in the control group, internal consistency coefficients were notably lower (0.529, 0.616, and 0.613, respectively). These tools clearly perform better as single total scores in clinical samples, an important consideration when planning future studies.

To the best of our knowledge, this is the first study that assesses the validity and reliability of the LURN SI-10 in a non-English language. Recently, the validity of the

LURN SI-10 has been tested by comparing with the IPSS and its significant correlation has been reported (14). However, that study included only male patients with LUTS. In our study, comparisons with the control group were made for both male and female patients and a significant correlation was demonstrated. A statistically significant, positive correlation was found between the LURN SI-10 and the IPSS in both groups ($p: 0.001$).

In 2021, the LURN SI-29 was translated into Turkish and its validation was completed by comparing with the IPSS and *Urogenital Distress Inventory* (UDI-

6) (12). However, it was developed for use in clinical studies and outcomes research. Conversely, the LURN SI-10 was designed as a concise (single-page) form for simple administration in clinical practice. To the best of our knowledge, there is no study investigating the correlation between the LURN SI-10 and OAB-V8 in English literature. In this study, we opted for the OAB-V8, which covers rather storage symptoms, because it was validated in Turkish language in 2012 and has been used for more than ten years in our country. A statistically significant, positive correlation was found between the LURN SI-10 and the OAB-V8 in both patient and control groups ($p: 0.001$).

There are some limitations of this study. We designed the study as a quality improvement initiative to compare the IPSS and OAB-V8 with the LURN SI-10 and for that reason main clinical data such as comorbidities, race/ethnicity, and body mass index are not included in the present analyses. Moreover, we were not able to attain the age and sex similarity between the patient and control group since this was a pilot study. Further prospective studies, evaluating test-retest reliability, the effects of comorbidities, and any changes in answers in LURN SI-10 questionnaire after medical treatment are needed.

CONCLUSIONS

In this study, the validity and reliability of the LURN SI-10 questionnaire in Turkish language and its use in patients with LUTS were assessed. This promising measurement tool is concise and simple, with initial evidence for reliability and validity in clinical samples and can be used to evaluate LUTS in Turkish women and men. Further studies should be conducted to assess the clinical usefulness of this questionnaire.

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