Original Article

Reliability and Validity of the Persian Language Version of the Female Lower Urinary Tract Symptoms' Long form Questionnaire

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Abstract

Background: Lower urinary tract symptoms (LUTS) are important and prevalent health problems that seriously affect many women and their quality of life (QOL). The female LUTS long form (FLUTS-LF) is a robust measure to assess the QOL of women. This study aimed at translating FLUTS-LF and assessing the reliability and validity of this questionnaire among Iranian patients with LUTS. **Materials and Methods:** Forward and backward translations of FLUTS-LF questionnaire were carried out by the research team. Data collection was conducted from November 2015 to March 2016 in Isfahan, Iran. A total of 237 women completed the Persian version of FLUTS-LF, incontinence QOL, and International Prostate Symptom Score (IPSS) questionnaires. We evaluated Cronbach's alpha coefficient, intraclass correlation coefficient (ICC), stability (reliability), and confirmatory factor analysis (CFA) of the questionnaire. **Results:** The mean (standard deviation) age of the participants was 45.4 (12.50) years (range 20–70 years). Face and content validities were acceptable and missing data comprise 2% of the total data. Internal consistency (Cronbach's alpha) of the urinary symptoms was 0.78. ICC of the total score in urinary symptoms section was 0.95. Indexes of factor analysis were assessed and found to be acceptable. A high correlation was observed between the total scores of FLUTS-LF and IPSS. **Conclusions:** It seems that FLUTS-LF questionnaire can be a suitable instrument for assessing LUTS and their impacts on Iranian women's QOL.

Keywords: *Female, Iran, lower urinary tract symptoms, psychometrics, questionnaire*

Introduction

Lower urinary tract symptoms (LUTS) are very common among women and affect their quality of life (QQL).[1] According to the International Continence Society (ICS), LUTS involve storage, voiding, and post voiding.[2] The prevalence of at least one LUTS was 45.2% in individuals aged 20 years and more of the 4.3 billion population in 2008.[3] These symptoms negatively affect different aspects of a patient's life.[4] Due to the failure of therapeutical assessments based on physician diagnosis in providing reliable results, implementing some instruments has been suggested for determining and assessing LUTS.[5] In addition, performing invasive paraclinical procedures, such as urodynamic procedures several times and responding to patients' complaints are almost impossible. An alternative method is to apply questionnaires as a supplementary method to assess patients.[6] For this purpose, questionnaires with international acceptability are needed to compare the studies' findings in different clinical settings.

In this connection, International Consultation on Incontinence (ICI) presented some questionnaires for assessing dysfunctions of pelvic floor muscles.[7] This committee provided two self-administrated questionnaires in English including short form (FLUTS) and long form (FLUTS-LF). These instruments assess LUTS among women and their effects on QOL of women. Although FLUTS has been translated and validated in Persian,[6] FLUTS-LF provides more in-depth assessment and is preferred when more detailed information is needed.[7] FLUTS-LF has been translated into at least 10 Asian and European languages.[8-10]

FLUTS-LF questionnaire has 18 items, each with two sections. All items, except questions 9, 15, and 18, have two parts including urinary symptoms and their bothering rate. The most important benefit of this type of combination is to

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simultaneously assess the severity of symptoms as well as the bothering rate. The questionnaire contains 16 items that have a 5-point Likert scale and the remaining two items have 3- and 4-point Likert scales. The minimum and maximum scores of the symptoms are 0 and 87, respectively. A higher score represents more severity of symptoms and vice versa. In the second section, there is a scale including scores 0–10 that represent the lowest and highest levels of bothering caused by each symptom.

Because clinician and researchers need a standardized Persian language version for assessing these symptoms,[11] translating it would provide a valuable tool. The findings of this research can be helpful in evaluating different interventions in clinical practice and research.

Materials and Methods

This study was cross-sectional in design and was conducted from November 2015 to March 2016. The recommended sample size for a psychometric analysis is at least 10 cases per questionnaire, with a 10% attrition.[12] FLUTS-LF, International Prostate Symptom Score (IPSS), and incontinence QOL (I-QOL) questionnaires were used for data collection. Both IPSS and I-QOL questionnaires have been translated into Persian and their internal consistency reliability were reported to be 0.7 and 0.96, respectively.[13,14] As suggested by the protocol on the International Consultation Incontinence Questionnaire (ICIQ) website,[7] the below-mentioned procedure was followed to validate the translated questionnaire.

After obtaining instructions and permission from the ICIQ website, FLUTS-LF was translated into Persian by native Persian translators. The quality of translation was checked by a panel consisting of six experts (psychologist, gastroenterologist, translator, linguist, and two urologists) and researchers and then harmonized. The panel controlled the process of modifying content/face validity. Then, the Persian version was back-translated into English by two bilingual translators. Finally, the back-translated copy was sent to the ICIQ group for assessment.

Because this 18-item questionnaire has no scoring system, the questions were classified into storage, voiding, and incontinence subscales according to short and long forms.[5] Both questionnaires have 12 and 18 questions. A comparison between the two forms shows that 12 questions are common and are classified into storage, voiding, and incontinence subscales. The other six questions fall into one of these classifications based on the symptoms that were asked.[7]

The studied population consisted of women diagnosed with LUTS by a urologist (at least one of sign or symptoms of storage, voiding, or incontinence). The inclusion criteria included being 18–80 years old[5] and having LUTS for at least 1 month. The exclusion criteria consisted of having malignant tumors, myopathy, and neuropathy, history of inflammatory disease in their organs during 3 recent months, mental problems, pregnancy, and breastfeeding.[3,15,16] The study was conducted in two hospital clinics (Alzahra and Noor) located in Isfahan, Iran. The controls were women who had no LUTS at least during the last month.

Content/face validity was assessed through interviews with patients and by observations of patients completing versions of the questionnaire. A pilot study (on 20% of the cases) was performed to assess whether the questionnaire was understandable. All ambiguity and changes were reported to the panel by the researcher for correction and clarification of phrases in a standard form. Internal consistency refers to the extent to which items within the questionnaire are related to each other or the degree of correlation between the items. Cronbach's alpha coefficient was used for measuring internal consistency.

Stability or reproducibility (test–retest reliability) indicates whether the questionnaire measures the same types of things in the same person over a period of time or not.[17] The questionnaire was completed by the cases 2–3 weeks after the first measurement.[10] The stability of FLUTS-LF questionnaire was determined by intraclass correlation coefficient (ICC) test.

Construct validity explains the relationships between the questionnaire and underlying theories. Construct validity can be assessed by hypothesized patterns of associations with other validated instruments.[18] Therefore, to assess convergent validity, a questionnaire with a similar construct was used, whereas for discrimination the capability to distinguish healthy people from patients was used. In addition, a confirmatory factor analysis (CFA) was carried out to evaluate whether the questions are representative of the dimensions or not and how items within the questionnaire are related to each other. The fitness of the model was checked using indicators such as goodness-of-fit index (GFI), comparative fit index (CFI), normed fit index (NFI), and root mean square error of approximation (RMSEA).

The data were analyzed in SPSS and Amos (SPSS Inc., Chicago, IL, USA; version 16; IBM SPSS Amos version 20; IBM Corp.) using two-tail test at 0.01 and 0.05 levels of significance. Both Cronbach's alpha and ICC values greater than 0.7 were considered satisfactory.[16]

Ethical considerations

This study was approved by the Ethics Committee of Isfahan University of Medical Sciences (no. IR.MUI.REC. 13943.575). All participants submitted written informed consents.

Results

The results showed that 237 (88.10%) of 269 participants answered the questions (187 cases and 50 controls). The

mean (standard deviation) age of the attendees (cases and controls) was 46.5 (12.00) and 41.1 (12.00) years (range 20–70 years), respectively. No statistically significant difference was seen in the mean age of the studied groups ($t = -2.76$, $p = 0.52$). Sociodemographic characteristics of the study group are shown in Table 1.

Table 1: Sociodemographic characteristics

Group variable	Patient (*n*=187) *n* (%)	Control (*n*=50) *n* (%)
Marital status		
Married	176 (93.80)	45 (91.00)
Single	11 (6.20)	5 (9.00)
Type of delivery		
Caesarean	63 (33.70)	19 (38.00)
Vaginal	124 (66.30)	31 (62.00)
Menopause		
Yes	89 (48.20)	40 (80.00)
No	98 (51.80)	10 (20.00)
Level of literacy		
Primary education	64 (34.20)	3 (6.00)
High school	60 (32.10)	10 (20.00)
University degree	63 (33.70)	37 (74.00)
Job		
Housewife	129 (69.00)	12 (24.00)
Employed	11 (6.20)	6 (12.00)
Retired	47 (24.80)	32 (6 4.00)

Content/face validity

The content and face validity of the Persian version of the questionnaire were studied by interviewing 40 cases. It was seen that 22 of them had a problem in understanding the meaning of question 14, which was related to the strength of urinary stream. To solve this problem, the phrase "intensity of urinary stream" was replaced by "pressure of urinary stream." In addition, 15 cases with a low level of education had a problem in understanding the second part of questions, which is about the bothering level of symptoms. Besides, six participants could not understand question 18, which was due to the ability to stop urine flow. After necessary revisions in the panel, the participants were provided with the final Persian version the Cronbach's alpha. Missing data comprise 2% (179 items) of the total data for FLUTS-LF, I-QOL, and IPSS questionnaires.

Internal consistency

Cronbach's alpha of urinary symptoms and their bothering was, respectively, 0.78 and 0.85 considering 18 questions and regardless of their subscales, which show a high level of homogeneity among all questions in both sections. Cronbach's alpha of each subscale was also calculated regarding these 12 questions, which was between 0.70 and 0.90 for all subscales except for storage symptoms (0.63). Therefore, the questions in each subscale were highly consistent with each other in addition to the high consistency among all questions without regarding subscales. However, after adding six questions, Cronbach's alpha of all questions was increased at the highest rate compared with other subscales [Table 3]. After adding the questions of bothering caused by "strength of stream," "urinary retention," "dysuria," and "incomplete emptying" to the bothering of voiding symptoms subscales, Cronbach's alpha was increased from 0.84 to 0.85 in the subscale and from 0.82 to 0.85 in the bothering of urinary symptoms section [Table 2].

Table 2: Internal consistency of female lower urinary tract symptoms-long form (12 and 18 Q*)

Symptoms	Subscale	12 questions α**	18 questions α**
Urinary	Storage	0.62	0.63
	Voiding	0.79	0.81
	Incontinence	0.82	0.85
	Total	0.73	0.78
Bothering	Storage	0.77	0.77
	Voiding	0.84	0.85
	Incontinence	0.82	0.82
	Total	0.82	0.85

*Question, **Cronbach's alpha

Stability (test–retest reliability)

Forty-one cases of the 187 ones completed the questionnaire for the first time and filled it out again after 2–3 weeks. The ICC of the total scores in urinary symptoms and bothering of them was 0.95 and 0.94, respectively.

Convergent validity

This analysis was done between related subscales and the total scores of questionnaires. Regarding 12 questions, the subscales of storage and voiding symptoms in FLUTS-LF were correlated strongly with subscales in IPSS questionnaire ($r = 0.79$ and 0.77). In addition, a high correlation was seen between total scores of urinary symptoms section in FLUTS-LF and IPSS (0.66). By adding the questions of urine flow strength, urinary retention, dysuria, and incomplete emptying to the voiding subscale, the correlation between them in two questionnaires was increased from 0.79 to 0.88. Moreover, after adding 6 questions of urinary symptoms to 12, the correlation of the total scores was decreased from 0.71 to 0.64 [Table 3].

Regarding these 12 questions, bothering of urinary incontinence subscale was correlated inversely and highly with subscales and the total score of I-QOL questionnaire. The total score correlation in FLUTS-LF and I-QOL questionnaires was decreased from 0.71 to 0.64 after adding three questions [Table 3].

Discriminant validity

To assess this type of validity, 50 cases selected of 187 and 50 from controls filled out Persian version of

Table 3: Correlation between IPSS*, I-QOL, and subscales of ICIQ-FLUTS LF*** (12 and 18 Q****)**

Variable	12 questions (*r*)	18 questions (*r*)
IPSS and subscales of ICIQ-FLUTS LF		
Storage	0.77	0.77
Voiding	0.79	0.88
Total	0.66	0.75
Bothering subscales of ICIQ-FLUTS LF and total score of I-QOL		
Bothering of storage symptoms and total score	−0.57	−0.57
Bothering of incontinence and total score	−0.73	−0.73
Total	−0.71	−0.64

*International Prostate Symptom Score, **Incontinence QOL, ***female lower urinary tract symptoms, ****question

FLUTS-LF. Since the data were not normally distributed, Mann–Whitney *U*-test was used to analyze the total score of urinary symptoms section. The results of this test showed a statistically significant difference between the mean total score of urinary symptoms section in both groups ($p < 001$). As a result, this questionnaire can discriminate between the cases and controls.

CFA was performed to determine the construct validity of FLUTS questionnaire. First, a diagram of dimensions and the related questions were prepared. Then, indicators including GFI, CFI, NFI, and RMSEA were applied to assess the fitness model. The measured rates were, respectively, 0.84, 0.89, 0.72, and 0.08 for these indicators, which show the relevance of questions with dimensions.

Discussion

In this study, for the first time, FLUTS questionnaire was classified into three subscales and CFA was performed to confirm questions goodness of fit in each subscale. The acceptable range of NFI, CFI, and GFI is between 0 and 1, however, the most suitable amount is between 0.90 and 1. However, in this study, it was estimated to be less than this (0.84, 0.89, and 0.72, respectively). The acceptable amount of RMSEA is between 0 and 1, however, the most suitable one is between 0 and 0.1, which was also within this range in this study (0.085). Although the achieved rates were acceptable, it is necessary to perform more studies. Some important points related to questions were found in studying face validity assessment. All options of question 14 (would you say that the strength of your urinary stream is....?) indicated a decrease in the urine stream, except that some patients reported an increase and intermittent increase in the urine stream. The complexity involved in this question made the patients confused to answer it. In addition, most patients did not consider or respond to question 18 (“can you stop the flow of urine if you try while you are urinating?”) as they could not understand it. In convergent validity, the total score correlation of bothering section of FLUTS-LF with a total score of I-QOL was decreased from 0.71 to 0.64 after adding three questions related to bothering of urinary symptoms. This decrease might be because this score is the total score of storage, voiding, and incontinence symptoms, whereas I-QOL questionnaire concerns the QOL of individuals bothering from urinary incontinence. As a higher number of questions are related to bothering of voiding symptoms, the correlation between total scores of these two questionnaires becomes lower. Moreover, four of six questions added to the questionnaire were related to voiding symptoms. As a result, the correlation between voiding symptom subscales increased from 0.79 to 0.88 in FLUTS-LF and IPSS.

Cronbach’s alpha of Persian version (0.78) was similar to that of the original version FLUTS-LF,[5] reflecting good levels of internal consistency. Test–retest reliability in urinary symptoms section of Persian, Chinese,[9] and Greek versions[10] was achieved as 0.79–1, 0.61–0.86, and 0.72–0.93, respectively. Therefore, Persian rates were higher than those of Greek and Chinese versions. There are some limitations in the studies conducted on Greek and Chinese populations. First, they translated different modules of ICIQ questionnaires. Second, their sample size was small; that is, 61 patients (43 women and 18 men) in Chinese study and only 122 women in Greek population. However, it is suggested to study the responsiveness of this questionnaire in future, which was not done in this study due to time limitation. The questionnaire used in this work can be used in different groups such as patients having only one of these three symptoms.

Conclusion

Considering that 110,000,000 Persian-speaking people live around the world, and FLUTS has been translated into different languages, using the tool developed in this work, it is now possible for the Persian therapists and researchers to publish their studies about lower urinary tract dysfunctions by a common and standard language. In this study, the Persian version of FLUTS-LF questionnaire was designed as a self-completed, high-validity, easy-to-complete, and robust instrument that can be used in clinical settings and in research.

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Conflicts of interest

Nothing to declare.

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