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Iranian Version of Overactive Bladder Symptom Scale: A Methodological Study

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Abstract

Objectives: This study was conducted aiming at evaluating the translation as well as psychometric properties of Persian version of overactive bladder syndrome score (OABSS).

Materials and Methods: To this end, 100 menopausal women aged 45 years or older, who had at least one urgency episode lasting at least 3 months, were recruited in the study and asked to complete the OABSS and international consultation on incontinence questionnaire overactive bladder (ICIQ-OAB) questionnaire. The validity of OABSS was assessed using concurrent validity. In addition, the reliability of the questionnaire was calculated using test-retest reliability as well as Cronbach α .

Results: Generally, the results of the study showed that there were significant correlations between the total score as well as single scores of the Persian version of OABSS and ICIQOAB sum score. Cronbach α , based on current samples, was 0.79 for the whole questionnaire. Moreover, the level of reliability calculated between the OABSS total scores at first and second time of administration enjoyed a good degree.

Conclusions: Persian version of OABSS had an acceptable validity and reliability. According to the findings, the application of such questionnaires is beneficial in developing countries which are faced with resource scarcity.

Keywords: Overactive bladder, Validity, Reliability, Questionnaire

Introduction

The International Continence Society (ICS) defined overactive bladder (OAB) as a syndrome with urgency, with/without urge incontinence, often with frequency and nocturia in the absence of infection or other pathologic features (1). The OAB symptoms can be the origin of many diseases including peripheral or central nervous system disorder, neuromuscular dysfunction, urothelial disorders, and systemic medical problems such as diabetes or congestive heart diseases, bladder outlet obstruction, depression, inflammation or disability symptoms caused by the aging (2). The OAB is mainly accompanied by incontinence, affects people's lifestyle, and impairs the quality of life (QOL) (3,4); it also interferes with daily activities, ability of travel, and sleep (5). The prevalence of OAB varies between different population and depends on age, gender, race, and ethnic group (6). Meanwhile, it is highly prevalent in the world (7) and is more frequent among women and elders. Milsom et al in a systematic review, summarized the results of 50 eligible papers and estimated the prevalence of OAB as follows: between 1.8%

to 30.5% in Europe, 1.7% to 36.4% among US populations, and 1.5%–15.2% in Asia. In addition, they insisted on the effect of age group and gender (7).

Original Article

Since OAB is diagnosed based on subjective symptoms, reports provided by the patients are used in the evaluation and treatment of patients with OAB. However, an objective diagnostic tool is required in order to assess the severity of OAB and also to evaluate the management outcomes (8). Accordingly, several specific questionnaires exist and are currently used including urgency, severity, and impact questionnaire (USIQ) (9), overactive bladder questionnaire (OAB-Q) (8), and Primary OAB Symptom questionnaire (POSQ) (8). However, these measures do not evaluate OAB symptoms themselves, but rather, the questionnaires evaluate the inconvenience resulting from the symptoms (10). A bladder diary provides valid information regarding OAB symptoms (11). However, it is difficult for the patients to keep a diary everywhere and take a note for it continuously (10).

The OABSS was designed and then validated in English literature in 2006 by Homma et al in Japan (11,12). It

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is a valid questionnaire because it can survey all the complexities of OAB symptoms and has a ranked response for severity score (13). This questionnaire is practical and user-friendly both for the patients to complete and for the clinicians to interpret; it is also sensitive to treatment-related changes in OAB symptoms (10).

Using an English questionnaire for those patients who are not native speakers of English leads to a misunderstanding and failure in treatment. Therefore, for using the OABSS in each country of the world, it is crucial to translate the OABSS questionnaire into the native language of that country and to validate it using the local data (14). For this reason, the researchers translated and validated the OABSS in Persian language using the backward-forward method (See online Supplementary data). The aim of this study was to assess the translation and psychometric properties of Persian version of OABSS questionnaire.

Materials and Methods

Patients and Study Design

Purposeful sampling technique was used to meet the aims of the study. One hundred menopausal women aged 45 years or older, who had at least 1 urgency episode with or without urge incontinence throughout the last 3 days, lasting at least 3 months were recruited from 2 university affiliated outpatient gynecology clinics in Tabriz. Patients were excluded if they had the following criteria: significant stress incontinence or mixed stress/urge incontinence, indwelling catheter, urinary tract infection (UTI), and pharmaceutical or non-pharmaceutical treatment for OAB during the last 4 weeks.

Three days before the first visit, all the participants were asked and directed to complete a bladder diary. The diary was recorded as episodes of urgency, incontinence, nocturia, and the number of incontinence pads. To diagnose UTI, a urine analysis (UA) was taken from each of the participants at the same time. Patients excluded if they could not correctly complete their 3-day urinary diary at visit 1 (week 0), according to the instructions, or had more than 3 white blood cells (WBC) in their UA.

All eligible patients who signed informed consent completed a socio-demographic questionnaire. The socio-demographic questionnaire consisted of 12 items and was used to assess medical and obstetrical history of the patients.

Out of demographic questionnaire, Persian version of OABSS and ICIQ-OAB were filled by the participants at the second visit. At the same time, 30 participants were asked to attend the third visit, that is, 10 ± 2 days after the second visit. The OABSS was completed for the third time in order to calculate test re-test reliability.

The OABSS contains 4 items and evaluates 4 subdomains. Calculation of OABSS total score includes the sum of scores of multi items such as daytime and nighttime frequencies, , and also urgency and urgency

incontinence.

The first item is rated 1-2 while the second one is rated 0-3. In addition, the third and fourth items are scored between 0-5. Finally, the sum score of OABSS is ranged between 0-15. The higher score indicates the more severe OAB (12). There are 3 cutoffs in the OABSS. A total score of 5 or less is defined as mild, a score between 6-11 as moderate and the total score and 12 or more are considered as severe OAB (15).

ICIQ-OAB

This is a questionnaire which evaluates the existence and degree of bother of OAB. The ICIQ-OAB was developed by ICS and is of comprised of 4 questionnaires which assess the frequency, nocturia, urgency and incontinency. It was translated in Persian by Sari Motlagh et al. The Persian version of the questionnaire was found to have an acceptable validity and reliability (16).

Sample Size

Owing to Intraclass correlation coefficient (ICC) which is at least 0.40 between each question of OABSS and ICIQ-OAB with regard to $\alpha = 0.01$ and $\beta = 0.1$ (power of study 90%), an also considering 15% dropout rate (17), the required sample size was estimated 100 individuals.

Translation and Cultural Adaptation

The authors obtained permission from professor Homma, the designer of OABSS questionnaire, in order to translate it into Persian and also to adapt and use it for the research purpose. The translation and adaptation process was conducted using forward-backward translation approach as follows: Two translators, with high proficiency in both languages, translated the original version of the questionnaire into Persian separately. The two versions of the translated questionnaire were compared to identify any discrepancy and ambiguity. After clarifying controversial statements and providing one version, consensus version was back translated into English by 2 native translators who did not involve in the study process. A committee composed of 4 translators and the first author of the study was developed. Back translated version of OABSS was compared with the original one by the committee members and the semantic problems were resolved by them. Primary draft of Persian version of OABSS was piloted on a group of 20 women suffering from OAB diagnosed by the urogynecologist.

Validity

The validity of OABSS was evaluated by concurrent related validity. It means that each participant filled ICIQ- OAB along with OABSS.

Reliability

The reliability of OABSS was also assessed by internal consistency and reproducibility. For assessment of internal

consistency, Cronbach α was calculated. To determine the reproducibility, test re-test method was used. The questionnaire was completed 2 times during the 10 days by 30 individuals.

Statistical Analysis

Data analysis was conducted using SPSS software, version 20. Continuous variables were presented by the mean (standard deviation). For categorical variables, frequency including the numbers and percentage were used. Test-retest reliability was evaluated by calculating ICC between the first and second time of questionnaire application. As the items of OABSS have an ordinal nature, Spearman rho correlation was used to assess convergent validity. All the tests were two-tailed. The *P* value <0.05 was indicated meaningful.

Results

This study was carried out during April to July, 2016. The flow diagram of the study is shown in Figure 1 and participants' characteristics are summarized in Table 1.

Reliability

Internal Consistency

Internal consistency was considered as an acceptable value for every question if the item deleted was more than 0.7 (18) or if the corrected item total correlation for each question of OABSS was higher than 0.4. Cronbach α , based on current samples, was 0.79 for the whole questionnaire (Table 2). It means that, no question needed to be removed for the increased Cronbach α coefficient of the Persian version of OABSS.



Figure 1. Flow diagram of the study.

Test Re-test Reliability

Good level of reliability was calculated between the OABSS total scores at the first and second time of the administration (Table 2).

Convergent Validity

The result of convergent validity is presented in Table 2. Each score and also the total score of the Persian version of OABSS had generally significant correlations with ICIQOAB sum of score.

Discussion

The aim of this study was to evaluate the psychometric properties of the Persian version of OABSS for having a sound instrument and comparing our results with the other ones conducted in the OAB field. Regarding the translation of OABSS to Persian, the translated version had no problem. All the statements had simplicity and clarity for the target group and were confirmed in the pilot assessment.

Each statement was acceptable and consistent with Iranian culture; hence, there was no need for cultural adaptation.

The results of this study showed a good internal consistency using Cronbach α and were similar to the results of Homma (0.74) in the original Japanese version (12) and Jeong (0.73) in Korean version (14). Meanwhile, although the Chinese version of OABSS demonstrated a lower Cronbach α (0.67) (19) in the Spanish (0.92) and Thai (0.80) versions, the Cronbach α was appeared to be higher as compared to its level obtained in the present study and Homma and colleagues' (13, 20).

Table 1. Demographic	Characteristics of the	Participants (N =	100)
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Characteristics	No. (%)				
Age					
40-44	9 (9)				
45-49	31 (31)				
50-55	60 (60)				
Education					
Illiterate	14 (14)				
Primary education (<9 years)	49 (49)				
Secondary education (\geq 9 years)	25 (25)				
College diploma & university	12 (12)				
Employment					
Housewife	88 (88)				
Employee/retired	12 (12)				
Marital Status					
Married	71 (71)				
Single	7 (7)				
Widow/Divorced	22 (22)				
Body mass index (BMI), kg/m ²					
<25	34 (34)				
≥25	66 (66)				
OABSS Total Score	3.7 (3.0)				

OABSS	Mean (SD)	Cronbach α if Item Deleted	Spearman rho Correlation Coefficient	Test Re-test Reliability (95% Cl)
Q1 (Frequency)	1.19 (0.41)	0.77	0.83	0.78 (0.61-0.82)
Q2 (Nocturia)	1.04 (0.86)	0.74	0.84	0.81 (0.68-0.90)
Q3 (Urgency)	1.12 (0.85)	0.76	0.79	0.70 (0.56-0.82)
Q4 (Urgency incontinence)	1.11 (0.67)	0.78	0.71	0.73 (0.55-0.80)

Table 2. Results of Internal Consistency, Concurrent Validity, and Test-Retest Reliability

Results of test-retest reliability showed an acceptable ICC between the answers received in the first and second time of the questionnaire administration. A number of previous studies also demonstrated similar results (13,14,20,21). The results of the present study indicated that Spearman rho correlation coefficient was higher than 0.7 between each question of OABSS and ICIQ-OAB and that the convergent validity was significant (r<0.05). Hence, construct validity of the Persian version of OABSS was in a good level. There was no epidemiological study with large sample size regarding OAB in Iran. As the urinary problems were under report and misreport, the existence of a simple, practical, and clear instrument was necessary. It seems that the translated version of OABSS in Persian can be an applicable tool for detecting OAB cases.

Limitation and Strength of the study

The most important limitation of this study is that the samples of the study were only selected from menopausal women population and one clinic through on purpose sampling. Accordingly, generalization of the results of this study should be conducted with precaution. In addition, similar studies focusing on larger sample sizes from a variety of contexts are subject to further investigation.

The strength of this study is the use of urine analysis for detecting urine infection and bladder diary and therefore, to diagnose OAB.

Conclusions

Persian version of OABSS was found to be a simple, valid, and self-administered rate questionnaire which can help health care providers for quick screening and assessment of OAB. The application of such questionnaires is beneficial in developing countries which are encountered with resources scarcity.

Conflict of Interests

The authors declare that there is no conflict of interests.

Ethical Issues

This cross sectional study was approved by Ethics Committee of Tabriz University of Medical Sciences (ethical No. IR.TBZMED.REC.1397.860).

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Supplementary Materials

Supplementary data contains the OABSS in English and Persian versions.

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