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The Turkish Language and Psychometric Validation of the "Bladder Control Self-assessment Questionnaire" Evaluating the Lower Urinary Tract Dysfunction

Alt Üriner Sistem Disfonksiyonunu Değerlendiren "Bladder Control Self-assessment Questionnaire"in Türkçe Dil ve Psikometrik Validasyonu

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What's known on the subject? and What does the study add?

B-SAQ has not yet been validated in Turkish. The aim of this study was to develop and validate the Turkish version of the B-SAQ.

Abstract

Objective: The aim of this study was to develop and validate the Turkish version of the Bladder Control Self-assessment Questionnaire (B-SAQ).
Materials and Methods: B-SAQ that comprises two parts and four questions in each section was translated into Turkish, followed by a back-translation into English. The study included 79 and 49 women who were admitted to the urology outpatient clinic with and without complaints of lower urinary tract symptom (LUTS), respectively. Turkish B-SAQ questionnaire was filled for the second time by 67 patients after a two week interval for test-retest correlation. All patients filled the Turkish B-SAQ form, "International Consultation on Incontinence Questionnaire Short Form" (ICIQ-SF) and "Overactive Bladder Screener" (OAB-V8) questionnaire.
Results: The Cronbach alpha value for B-SAQ was 0.868. Reliability of the test/retest was found to be 0.860 ($p<0.001$). There were statistically significant differences in B-SAQ scores between the controls and patients ($p<0.001$). Convergent validity analyzes with ICIQ-SF and OAB-V8 (respectively $r=0.61$ and $r=0.44$, $p<0.001$). The total B-SAQ cut-off score was determined as 7. The sensitivity and specificity of B-SAQ were 96% in women with LUTS.
Conclusion: Turkish version of B-SAQ is a valid and reliable questionnaire to evaluate the symptoms and disorders of patients with LUTS.
Keywords: Lower urinary tract symptoms, Validation, B-SAQ

Öz

Amaç: Bu çalışmada "Bladder Control Self-assessment Questionnaire" (B-SAQ) Türkçe versiyonunun geliştirilmesi ve valide edilmesi amaçlandı.
Gereç ve Yöntem: İki bölüm ve her bölümde dört sorudan oluşan B-SAQ Türkçe'ye çevrildi ve daha sonra tekrar İngilizce'ye çevrildi. Üroloji polikliniğimize alt üriner sistem yakınmaları ile başvuran 79 kadın hasta ve herhangi bir alt üriner sistem şikayeti olmayan 49 kadın hasta çalışmaya dahil edildi. Test-retest uyumluluğu için, ayrıca 67 hastaya iki hafta ara ile Türkçe B-SAQ sorgulama formu ikinci kez doldurtuldu. Tüm hastalara Türkçe B-SAQ, "International Consultation on Incontinence Questionnaire Short Form" (ICIQ-SF) ve "Overactive Bladder Screener" (OAB-V8) formları doldurtuldu.
Bulgular: B-SAQ için Cronbach alfa değeri 0,868 idi. Test/retest güvenilirliği 0,860 ($p<0,001$) olarak bulundu. Kontrol ve hasta grupları arasında B-SAQ skorları açısından istatistiksel anlamlı farklılık bulundu ($p<0,001$). ICIQ-SF ve OABQ ile convergant geçerlilik analizleri yapıldı (sırasıyla

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r=0,61 ve r=0,44, p<0,001). B-SAQ için toplam eşik değer 7 puan olarak belirlenmiştir. Alt üriner sistem semptomları olan kadın hastalarda hastalığı tanımlamadaki sensitivite ve spesifitesi %96 olarak bulundu.
Sonuç: B-SAQ'nun Türkçe versiyonu, alt üriner sistem semptomlu hastaların semptomlarını ve rahatsızlıklarını değerlendiren geçerli ve güvenilir bir sorgulama formudur.
Anahtar Kelimeler: Alt üriner sistem semptomları, Validasyon, BSAQ

Introduction

Lower urinary tract symptoms (LUTS) include voiding (slow stream, splitting or spraying, intermittency, hesitancy, straining to void and terminal dribble), storage (urgency, frequency, urinary incontinence and nocturia), and post-mictional (feeling of incomplete emptying and post micturition dribble) symptoms (1). The incidence and severity of LUTS increases with age and negatively affects the quality of life (1,2). The popular belief that LUTS are a natural consequence of life can prevent patients from seeking help in this regard. Storage symptoms of the lower urinary tract consist of complaints of urgent urination sensation and/or urgent urination, incontinence, frequent urination, and nocturnal urination (nocturia) (3). The quality of life of the patients with LUTS that is especially accompanied by urinary incontinence is highly negatively affected. In community-based studies, the prevalence of patients with at least one of the LUTS varied from 64.3% to 74.4%. The incidence of storage symptoms was observed to be higher in women than in men, and it increased with older age (4,5). A prevalence study of 2730 men over 40 years of age from 19 different provinces in Turkey reported that 3 out of 4 men aged ≥40 years exhibited some degree of LUTS (6).

Although, LUTS is a clinical problem that is frequently encountered in urology practice, it can easily be overlooked if the patient's complaints are not properly questioned. Particularly, patients in our country do not express their complaints on this issue unless questioned. In one study, it was predicted that people with LUTS will wait for an average of 4 years before asking for help (7). It was observed that women seek medical assistance for uncomfortable LUTS lesser than men (8). Questionnaires are needed to diagnose such patients and to monitor their response to treatment. The severity of the complaints should be clearly revealed by the questionnaire forms and the questions should be clear.

Bladder Control Self-assessment Questionnaire (B-SAQ), developed by an expert panel on LUTS, comprises eight items that determine LUTS and related disorders (9). Our study aimed to determine the validity and reliability of the Turkish version of B-SAQ.

Materials and Methods

The study included 79 and 49 women who were admitted to the urology outpatient clinic with and without complaints of LUTS, between February 2016 and June 2016, respectively. Sixty-seven women reported for evaluating the test-retest compliance. Patients with history of trauma, diabetes mellitus, neurogenic lower urinary tract dysfunction, pelvic surgery, cancer, and radiotherapy; and those with active urinary tract infection and those who used medications affecting the lower urinary tract, were excluded from the study. Additionally, patients who were illiterate or had mental problems and could not give consent, were excluded from the study. Our study was approved by the Ethics Committee (08/04/2014-13) of our institution and informed written consent was obtained from all patients before participating in the study.

The validation of the B-SAQ, comprising two parts as symptoms and disorders and with four questions in each part, was carried out in a gradual manner by the method suggested by Hutchinson et al. (10). Firstly, it was translated from English to Turkish by two independent Turkish translators who were not familiar with the B-SAQ, followed by a meeting of the research group with the translators to evaluate the Turkish versions of B-SAQ, and first consensus was reached for the Turkish version. The consensual Turkish form was translated into English by another two translators who were not familiar with the original questionnaire. A second consensus meeting was held in which the original and back-translated versions were evaluated and the final version of the B-SAQ was obtained as a result of the necessary corrections performed by the established committee. Finally, in a pilot study on 10 women, it was found that the B-SAQ was easily implemented in a short time and no further changes were made in the last Turkish version of the B-SAQ.

In this questionnaire, patients' total scores ranging from 0 to 12 for each part were obtained with a scale ranging from 0 to 3 points for each question.

All patients filled in the Turkish B-SAQ form (Appendix 1), "International Consultation on Incontinence Questionnaire Short Form" (ICIQ-SF), and "Overactive Bladder Screener" (OAB-V8) (11) questionnaire. After two weeks, the test-retest compatibility group was asked to fill the Turkish B-SAQ questionnaire again. Three-day voiding diary, complete urine analysis, urine culture, blood creatinine measurement, urinary

tract ultrasonography, direct urinary tract X-ray examinations, and physical examinations were performed for all patients.

Statistical Analysis

The characteristics of the study group and controls were analyzed using descriptive statistics. Psychometric analyses of the B-SAQ were performed by the following procedures. Reliability was evaluated by test-retest reliability and internal consistency. Cronbach's α coefficient was used to test the internal consistency of the Turkish B-SAQ. Test-retest reliability was also evaluated with Spearman correlation. B-SAQ scores of patients were compared between two visits (test-retest) by using Wilcoxon signed-rank test. The correlation between Turkish versions of B-SAQ, OAB-V8, and ICIQ-SF questionnaires were evaluated by Spearmen correlation coefficient to determine the convergent validity. Discriminant validity was assessed by comparing the B-SAQ scores of patients with those of controls. The Mann-Whitney U test was used to explore the mean differences between the controls and patients. The experts assessed the content validity that indicated whether the questionnaire made sense to the patients and experts and whether the items covered all important aspects or if there were any missing components. Receiver operating characteristic (ROC) plots were used to define the detection cut-off or threshold score that best reflected optimal sensitivity and specificity. The data analyses were conducted using SPSS version 22.0 (IBM, USA) and were two-sided with $p<0.05$ defined as statistically significant.

Results

The study included 79 women with LUTS and 49 healthy women controls with mean ages of 40.3 and 42.1 years, respectively. There were no significant differences between the groups ($p=0.42$). Demographic data of the patients included in the study and the results of the questionnaires are given in Table 1. A statistical difference between the study and control groups was detected for all questions ($p<0.05$) (Table 1).

The Cronbach alpha values for Turkish B-SAQ total, B-SAQ-symptom, and B-SAQ-bother were 0.868, 0.753, and 0.749 respectively. Individual items in the B-SAQ scored values of 0.835-0.870, reflecting high levels of internal consistency. Test-retest reliability was performed on 67 LUTS patients. A high correlation was observed between test-retest scores ($r=0.860$, $p<0.01$). B-SAQ symptom, bother, and total test-retest scores did not show a significant difference ($p>0.05$) (Table 2). The domains of the Turkish B-SAQ correlated well with each other according to the Spearman correlation test and showed a high correlation with ICIQ-SF and OAB-V8 ($r=0.61$, $p=0.01$; $r=0.44$, $p=0.01$; respectively). All other correlation scores were significant at the 0.01 level (Table 3).

The ROC curve for the B-SAQ Turkish version is given in Figure 1. When total B-SAQ score of 7 score was used as the predictive value, the sensitivity and specificity of B-SAQ were calculated as 96% and 96% in patients with LUTS symptoms,

Table 1. Basic characteristics: Age, B-SAQ, ICIQ-SF, OAB-V8 scores in study groups

	LUTS	Control	p*
Number of patients	79	49	
Age (year)	40.3±15.5 (24-62)	42.1±15.6 (25-64)	0.420
B-SAQ score Symptom	9.2±2.7	0.8±1.0	<0.001
Bother	9.6±2.5	0.7±1.1	<0.001
Total	18.8±4.9	1.5±2.1	<0.001
ICIQ-SF	14.0±5.0	0	<0.001
OAB-V8	22.8±9.1	3.1±2.4	<0.001

*Mann-Whitney U test. B-SAQ: Bladder control self-assessment questionnaire, ICIQ-SF: International consultation on incontinence questionnaire short form, OAB-V8: Overactive bladder screener, LUTS: Lower urinary tract symptom

Table 2. Internal consistency of the study (Cronbach's alpha coefficient)* and test-retests (Spearman)**

	Cronbach's alpha (n=128)	Test-retest (n=67)		
	p*	Test Mean	Retest Mean	p**
B-SAQ-total	0.868	18.8±5.0	18.3±4.1	0.860
B-SAQ-symptom	0.713	8.9±2.7	9.0±2.3	0.764
B-SAQ-bother	0.738	9.9±2.6	9.3±2.2	0.846

*Cronbach's alpha, **Wilcoxon Signed Ranks test, B-SAQ: Bladder control self-assessment questionnaine

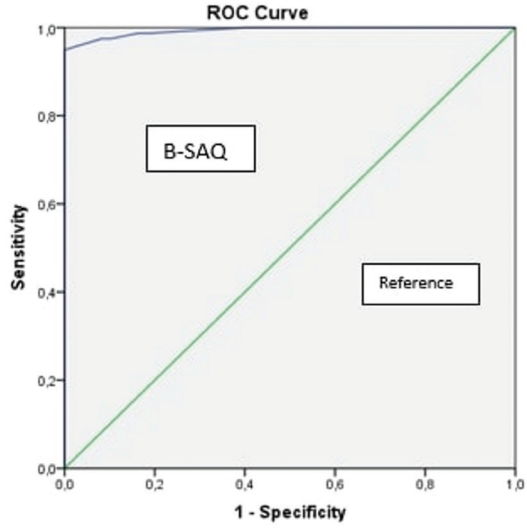

Figure 1. Area under the ROC curve for BSAQ Turkish versions

ROC: Receiver operating characteristic, BSAQ: Bladder control self-assessment questionnaire

Table 3. Correlations (Spearman) of B-SAQ-symptom and bother score, ICIQ-SF (questions 3 + 4 + 5) and OAB-V8 among 79 patients with overactive bladder symptoms

	B-SAQ-total	B-SAQ-symptom	B-SAQ-bother	ICIQ-SF	OAB-V8
B-SAQ-Total	1				
B-SAQ-symptom	0.95*	1			
B-SAQ-bother	0.92*	0.77*	1		
ICIQ-SF	0.61*	0.61*	0.56*	1	
OAB-V8	0.44*	0.5*	0.34*	0.39*	1

*Correlation is significant at the 0.01 level, B-SAQ: Bladder control self-assessment questionnaine, ICIQ-SF: International consultation on incontinence questionnaire short form, OAB-V8: Overactive bladder screener

respectively, and the area beneath the ROC curve was 0.994±0.005 (p<0.001). A symptom score threshold of 4 showed that the B-SAQ had a sensitivity and specificity of 95% and 96% for the detection of LUTS, respectively. For a bother score threshold of 4, the sensitivity and specificity were 98 and 96%, respectively. Here, ROC curves showed high accuracy of B-SAQ, represented by the large area below curve 0.994 that identified patients with LUTS.

Discussion

Although, LUTS is a common clinical condition in our country, there are limited questionnaires pertaining to it that have been translated into Turkish and validated. One of them, ICIQ-SF form, was first translated into Turkish and validated by Çetinel et al. (12) in 2004. In this study, we aimed to validate the Turkish version of B-SAQ, a questionnaire that can be filled in a very short time by a majority of patients. The B-SAQ form is a short and easy-to-understand questionnaire developed by Basra et al. (9) in 2006 to determine LUTS.

In 2014, Sahai et al. (13) performed the validation study of the B-SAQ form in men with LUTS and showed it to have a good correlation with the Kings Health Questionnaire (KHQ). In the same study, B-SAQ was shown to be less specific in men than in women, and 98% of patients were observed to fill the form in less than 5 minutes. In the study of Cidre et al. (14), 3-day voiding diary and B-SAQ to evaluate patients with overactive bladder were reported to be the tests with the best diagnostic performance.

The Cronbach's alpha value that shows the internal consistency for the B-SAQ test was 0.91 in the study conducted by Basra et al. (9), while it was 0.87 in our study. A correlation between test-retest scores was presented. The reliability of the test was thus established to be quite high.

The total score of B-SAQ and the symptom and discomfort scores individually were observed to show correlation with ICIQ-SF and OAB-V8 scores in the patient group. In the study by Basra et al. (9), symptom scores of the B-SAQ correlated highly with that of the KHQ (Pearson's correlation values of 0.46-0.54). In our study, symptom scores of the B-SAQ correlated highly with that of the ICIQ-SF (questions 3 + 4 + 5) (Spearman correlation value: 0.61). In our study and the one by Sahai et al. (13), B-SAQ symptom and discomfort scores correlated well (Spearman r=0.77, p<0.01; Pearson's r=0.94, p<0.01; respectively). Espuña et al. (15), reported the Spearman's correlation coefficient between "discomfort" scale and the ICIQ-SF (question 3 + 4 + 5) as 0.65 (p<0.001), and in our study, this coefficient was 0.56 (p<0.001). The total B-SAQ score correlated moderately with the OAB-V8 score, while it showed a high correlation with ICIQ-SF (Table 3).

While, Espuña et al. (15) in their Spanish validation study of B-SAQ had considered point 6 as the cut-off point for B-SAQ subscales, we considered point 7 as the cut-off point in the ROC curve. When B-SAQ score of 7 was used as the predictive value, the sensitivity and specificity of B-SAQ in patients with LUTS was found to be 96% and 96%, respectively. In the study of Sahai et al. (13), a symptom score threshold of 4 showed that the B-SAQ had the sensitivity and specificity of 75% and 87% for the detection of LUTS, respectively. When the same threshold was taken as a reference in our study, B-SAQ had the sensitivity and specificity of 95% and 96% for the detection of LUTS, respectively. Higher sensitivity and specificity in our study was due to the fact that the study was performed only in women. This showed that the sensitivity and specificity of B-SAQ are higher in women than in men for the detection of LUTS. In a study comparing the questionnaires conducted by Angulo et al. (16) in 2007 on Spanish community, the area under the curve (AUC) for B-SAQ was 0.799; in another study of Basra et al. (17), it was 0.83; in the study by Sahai et al. (13), it was 0.88; while in our study, this area was 0.994 (16,17). The high AUC value in our study showed the high accuracy of B-SAQ in patients with LUTS.

Two patients who noted their hematuria complaint with a warning statement under the B-SAQ form were examined in this respect. Renal calculus was detected in one patient. Therefore, it was thought that this warning statement also added significant value to the test due to enabling the detection of other underlying urological diseases.

Study Limitations

There are some limitations in this study. Firstly, we did not compare B-SAQ questionnaire with a female LUTS survey such as the Bristol LUTS questionnaire. Another limitation was that the design of the B-SAQ was changed due to the poor understanding of text by our patients during translation phase of the study.

Conclusion

The obtained Turkish version of B-SAQ questionnaire whose validity and reliability related to overactive bladder disease has been shown previously, can be filled in a short time, is easy to apply, and was proven to be a valid and reliable test for Turkish population. Thus, it will be possible to use one more questionnaire pertaining to the lower urinary system, for which a validation study has not been previously conducted, in clinical practice in our country.

Ethics

Ethics Committee Approval: Ethics committee approval was received for this study from the Kartal Dr. Lütfi Kırdar Training and Research Hospital Scientific Research Evaluation Board (approval no: 89513307/1009/278, date: 08.04.2014)

Informed Consent: Informed written consent was obtained from all patients before participating in the study.

Author Contributions

Concept: M.B.H., F.T., E.S., Design: M.B.H., F.T., U.C., E.S., P.A., Supervision: M.B.H., F.T., U.C., Resources: F.T., P.A., Materials: M.B.H., U.C., E.S., Data Collection and/or Processing: M.B.H., U.C., E.S., Analysis and/or Interpretation: M.B.H., F.T., P.A., Literature Search: M.B.H., U.C., Writing: M.B.H., F.T., U.C., Critical Review: M.B.H., F.T., E.S., P.A.

Conflict of Interest: The authors have no conflicts of interest to declare.

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