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Validity and Reliability of Thai Version of the Overactive Bladder Questionnaire Short Form in Women with Overactive Bladder

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ABSTRACT

Objectives: To study the validity and reliability of Thai version of the overactive bladder questionnaire short form (OAB-q SF) and the correlation of Thai version OAB-q SF to Thai version overactive bladder questionnaire (OAB-q).

Materials and Methods: During December 2017 to February 2018, after Institutional Review Board (IRB) approval, 46 Thai patients diagnosed as having overactive bladder (OAB) attending a Female Pelvic Medicine and Reconstructive Surgery clinic at King Chulalongkorn Memorial hospital were recruited. Patients' characteristics were recorded. The self-answered, Thai version of the OAB-q SF was administered on two occasions, at the day of recruitment and at 2 weeks apart (by mail). Thai version of OAB-q was administered only at the first visit.

Results: Mean \pm standard deviation of age was 65.63 ± 11.64 years, and their mean body mass index (BMI) was 26.25 ± 8.13 kg/m². Most women were treated for OAB more than 6 months (47.9%). Behavioral modification was used to treat in all patients. Oral medication was administered in 54.35% of patients. Cronbach's alpha of the OAB-q SF was 0.80 and 0.93 for symptom-bother and health related quality of life (HRQL) domains, respectively. The intra-class correlation (ICCr) of symptom bother scale and HRQL were 0.90 and 0.94. The content validity index was equal to 1. Pearson correlation of the total score of the OAB-q SF and OAB-q was 0.95 for the first visit questionnaire.

Conclusion: Thai version of the OAB-q SF showed good psychometric properties (reliability and validity) for measuring the OAB symptom severity and HRQL. There was very strong correlation between Thai version of OAB-q SF and OAB-q.

Keywords: OAB-q SF, Overactive bladder, questionnaire.

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ความตรงและความเที่ยงของแบบสอบถามกระเพาะปัสสาวะไวเกินฉบับสั้น (OAB-q SF) ในสตรีที่มีภาวะกระเพาะปัสสาวะไวเกิน

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บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาความตรงและความเที่ยงของแบบสอบถาม overactive bladder questionnaire short form (OAB-q SF) ฉบับภาษาไทยและความสัมพันธ์ของแบบสอบถาม OAB-q SF ฉบับภาษาไทยกับแบบสอบถาม overactive bladder questionnaire (OAB-q) ฉบับภาษาไทย

วัสดุและวิธีการ: ระหว่างเดือนธันวาคม พ.ศ.2560 ถึง เดือนกุมภาพันธ์ พ.ศ.2561 หลังได้รับการอนุมัติจากกรรมการจริยธรรมแล้ว ทำการคัดเลือกผู้ป่วย 46 ราย ที่ได้รับการวินิจฉัยว่ามีภาวะกระเพาะปัสสาวะไวเกินที่มารับการรักษาที่คลินิกเวชศาสตร์เชิงกรานสตรีและศัลยกรรมช่องคลอดที่โรงพยาบาลจุฬาลงกรณ์ ทำการบันทึกลักษณะประชากร และให้ผู้ป่วยตอบแบบสอบถาม OAB-q SF ฉบับภาษาไทยด้วยตนเองสองครั้ง ในวันที่รับการคัดเลือกเข้าการศึกษา และอีกครั้งที่สองสัปดาห์โดยส่งกลับทางไปรษณีย์ และทำการตอบแบบสอบถาม OAB-q ฉบับภาษาไทยเฉพาะวันที่รับการตรวจครั้งแรก

ผลการศึกษา: ค่าเฉลี่ย \pm ส่วนเบี่ยงเบนมาตรฐานของอายุ คือ 65.63 ± 11.64 ปี และค่าเฉลี่ย \pm ส่วนเบี่ยงเบนมาตรฐานของดัชนีมวลกายคือ 26.25 ± 8.13 กิโลกรัมต่อตารางเมตร สตรีส่วนใหญ่ได้รับการรักษาภาวะกระเพาะปัสสาวะไวเกินมากกว่า 6 เดือน (ร้อยละ 47.9) ผู้ป่วยทุกคนได้รับการรักษาด้วยพฤติกรรมบำบัด และร้อยละ 54.35 ได้รับการรักษาด้วยยา ค่า Cronbach's alpha ของแบบสอบถาม OAB-q SF คือ 0.80 และ 0.93 ในโดเมน ความถี่หรือความถี่ทางอาการและคุณภาพชีวิตที่เกี่ยวข้องกับสุขภาพ ค่า intra-class correlation (ICCr) ของโดเมน ความถี่หรือความถี่ทางอาการและคุณภาพชีวิตที่เกี่ยวข้องกับสุขภาพ 0.90 and 0.94 ตามลำดับ ค่า Pearson correlation ของคะแนนรวมของแบบสอบถาม OAB-q SF และแบบสอบถาม OAB-q คือ 0.95 ในการตอบแบบสอบถามครั้งแรก

สรุป: แบบสอบถาม OB-q SF ฉบับภาษาไทยมีผลทดสอบทางจิตวิทยา (ความเที่ยงและความตรง) อยู่ในเกณฑ์ดีในการวัดความรุนแรงของอาการภาวะกระเพาะปัสสาวะไวเกิน และคุณภาพชีวิตที่เกี่ยวข้องกับสุขภาพ แบบสอบถาม OAB-q SF ฉบับภาษาไทยมีความสัมพันธ์กับแบบสอบถาม OAB-q ฉบับภาษาไทยอย่างมาก

คำสำคัญ: OAB-q SF, กระเพาะปัสสาวะไวเกิน, แบบสอบถาม

Introduction

Overactive Bladder (OAB) is a common problem that impact health related quality of life (HRQL)⁽¹⁾. OAB relates to embarrassment, depression, sleep disturbance and decreased sexual activity^(2, 3). The current definition of OAB is symptom complex consisting of urinary urgency, with or without urgency incontinence, usually with increased daytime frequency and nocturia, in the absence of infection or other obvious pathology⁽⁴⁾. Female gender is associated with a higher prevalence of OAB than male, particularly in younger people⁽⁵⁾. From study in 11 countries in Asia, the overall prevalence of OAB was 53.1% among adult women⁽⁶⁾.

OAB is a symptoms-based condition. Patient-reported outcome (PRO) measurement is critical to provide more understanding of the condition's impact. To be appropriate for evaluation of patients' condition, PROs must be supported by evidence of reliability, validity, and responsiveness. Moreover, PROs should be easy and practical to administer^(7, 8). The overactive bladder qQuestionnaire (OAB-q) is a multi-dimension instrument designed to assess patient perception of symptom bother and impact on HRQL among patients with OAB. The OAB-q consists of an 8-item symptom bother scale and a 25-item HRQL scale covering 4 domains: coping, concern, sleep and social interaction⁽⁹⁾. The OAB-q has been shown to be reliability, validity and responsiveness to change among OAB patients⁽⁹⁻¹¹⁾. The OAB-q was originally developed in United States in English and has been translated into Thai language⁽¹²⁾. However, the 33-item OAB-q is not usually practical due to clinician and patient burden. A shorter version of instrument should be used to reduce respondent burden. The overactive bladder questionnaire-short form (OAB-q SF) is a brief, self-administered PRO tool with two scales assessing symptom bother and HRQL in patients with OAB⁽¹³⁾. The OAB-q SF captures the full spectrum of OAB symptom bother and HRQL impact with good reliability, validity and responsiveness, while being less time-consuming for patients to complete⁽³⁾.

The aims of this study were to test the validity

and reliability of Thai version of the OAB-q SF and to test the correlation of Thai version of the OAB-q SF to Thai version of the OAB-q.

Materials and Methods

This prospective study was conducted at the Female Pelvic Medicine and Reconstructive Surgery Unit, Department of Obstetrics and Gynecology, King Chulalongkorn Memorial hospital during the December 2017 to February 2018 study period. The study protocol was approved by the Institutional Review Board of the university (COA 962/2017). Fifty women who were diagnosed as having OAB were recruited. The inclusion criteria were women who were ≥ 18 years of age, diagnosed as having the symptoms of OAB (diagnosis criteria for OAB: having urinary frequency, urgency with or without urge urinary incontinence for ≥ 3 months and at least one episode of urgency with or without incontinence in the last 3 days), and able to complete the 3-days bladder diary correctly (for the evidence of the urgency episodes and rule out other causes of urinary frequency such as polydipsia). Exclusion criteria were stress urinary incontinence or mixed-type urinary incontinence, patient with indwelling catheters or practicing intermittent self-catheterization, evidence of symptomatic urinary tract infection, previous pelvic radiation therapy, previous or current malignant disease of the pelvic organs, diabetic neuropathy, and bladder stones. Informed consents were obtained in all cases.

OAB-q⁽⁹⁾

The OAB-q consists of 33 questions, which are grouped into two parts. The first part consists of eight questions which construct the symptom bother subscale and concern the severity of the patient's symptoms (frequency, urgency, nocturia and urgency incontinence). This subscale score varies from 0 and 100. The higher the symptom bother score is, the greater the bother from the overactive bladder symptoms. The second OAB-q part consists of 25 questions and measures HRQL with four subscales

(scores from 0 to 100). The higher the HRQL score, the better the HRQL level is. For these four subscales, the higher the score is, the less the subscale is affected by the disease. The OAB-q had been translated into Thai⁽¹²⁾. The Thai version of OAB-q had the good reliability and consistency with intraclass correlation (ICCr) of 0.97 and Cronbach's Alpha coefficient of 0.95⁽¹²⁾.

OAB-q SF⁽¹³⁾

The OAB-q SF is a 19-item, self-administered, and disease specific instrument derived from the OAB-q⁽¹²⁾. The OAB-q SF contains two main subscales: symptom bother (6 items) and health-related quality of life (HRQL, 13 items). Each item is rated on a six-point likert scale. The symptom bother scale ranges from 0 (not at all) to 6 (a very great deal) and the HRQL scale ranges from 0 (none of the time) to 6 (all of the time). The two subscales are separately summed and transformed into scores ranging from 0 to 100. A higher score on the symptom bother scale indicates a greater symptom severity and a higher score on the HRQL scale indicates a better HRQL, so they are inversely related to each other. These two scores are mentioned separately (the OAB-q SF has no total score).

Translation process

After permission from the original study's authors, the English version of OAB-q SF was forward translated into Thai language by a linguist from Language institute of a Thai university and backward translated by another linguist. To confirm the content validity of the Thai version, the questionnaire was evaluated face-to-face with five patients who diagnosed with OAB visiting the Female Pelvic Medicine and Reconstructive Surgery outpatient clinic with another content validation by the 2 urogynecologists. Both urogynecologists read all 19 item questions and check whether the questions were valid (Thai version questions had the same meaning corresponding to the original English version, Thai version measured what the original questionnaire

intended to measure). If any question were not agreed by any urogynecologists. That questions were sent back for re-translation and repeated the questionnaire development process again. All 19 items had to be agreed (valid) by both urogynecologists. So, the content validity index was equal to 1.

The Thai version of the OAB-q SF and Thai version of the OAB-q questionnaires were distributed to all participants by the research nurse. The questionnaires were self-answered twice (at 0 and 2 weeks). Test-retest reliability was examined using the intra-class correlation (ICCr) and Cronbach's alpha between first and second applications of the questionnaires. Pearson correlation coefficients (*r*) was used to test the correlation of Thai version of the OAB-q SF and Thai version of the OAB-q. The sample size was calculated from a pilot study (10 women who diagnosed with OAB, answering the questionnaires two time with 2 weeks interval), using the intra-class correlation of Thai version of the OAB-q SF from the pilot study (ICCr = 0.88, acceptable error: 10% of *p* value = 0.05)⁽¹⁴⁾. The sample size required was 41 cases. Nine cases (20%) were added to account for the lost to follow-up cases. The total sample size required was 50 cases.

Statistical analysis was performed using SPSS software version 22.0 (SPSS science, Chicago, IL, USA). Cronbach's Alpha coefficient was used to measure the internal consistency of Thai version of the OAB-q SF. An intraclass correlation (ICCr) was used to measure the test-retest reliability of Thai version of the OAB-q SF and the correlation with Thai version of the OAB-q.

Results

Fifty participants were recruited, all accepted to participate in the study and provided their written informed consent to participant in the study. Four participants were excluded because they did not send back the questionnaires. The mean \pm standard deviation for age, body mass index (BMI) and parity were 65.63 \pm 11.64 years, 26.25 \pm 8.13 kg/m² and 2.0 \pm 1.35, respectively (Table 1). Almost half of participants

(22 cases (47.83%)) were treated more than 6 months. Behavioral therapy was used in all patients whereas only 25 cases (54.35%) were treated with medication. For Thai version of the OAB-q SF, Cronbach's alpha internal consistency index attained a value of 0.80 in symptom bother scale and 0.931 in HRQL scale. The mean \pm standard deviation for first and second visit

score were 37.63 ± 19.24 , 37.25 ± 20.33 in symptom bother scale and 72.82 ± 19.73 , 73.0 ± 20.93 in HRQL scale. The ICCr of symptom bother scale and HRQL were 0.90 and 0.94 (Table 2.)

Pearson correlation of the total score in Thai version of the OAB-q SF and Thai version of the OAB-q was 0.95 for the first visit questionnaire (Fig. 1).

Table 1. Demographic data (n = 46 participants).

Characteristics	mean \pm SD
Age (years)	65.63 \pm 11.64
BMI (kg/m ²)	26.25 \pm 8.13
Parity	2.0 \pm 1.35
	n (%)
Underlying disease	
Diabetes mellitus	7 (15.21)
Essential hypertension	25 (54.35)
Neurological disease	3 (6.52)
Education	
Less than high school	11 (23.91)
High school	15 (32.61)
Bachelor degree	16 (34.78)
Master degree and higher	4 (8.69)
Duration of OAB treatment	
Less than 1 months	10 (21.74)
1-3 months	11 (23.91)
3-6 months	3 (6.52)
More than 6 months	22 (47.83)
Type of treatment	
Behavioral therapy	46 (100)
Bladder training	42 (91.30)
Medication	25 (54.35)

SD: standard deviation, BMI: body mass index

Table 2. Demographic data (n = 46 participants).

Subscale	Cronbach's alpha	First visit score (mean \pm SD)	Second visit score (mean \pm SD)	Intra-class correlation
Symptom bother	0.80	37.63 \pm 19.24	37.25 \pm 20.32	0.90
HRQL	0.93	72.82 \pm 19.73	73.02 \pm 20.93	0.94

SD: standard deviation, HRQL: health related quality of life

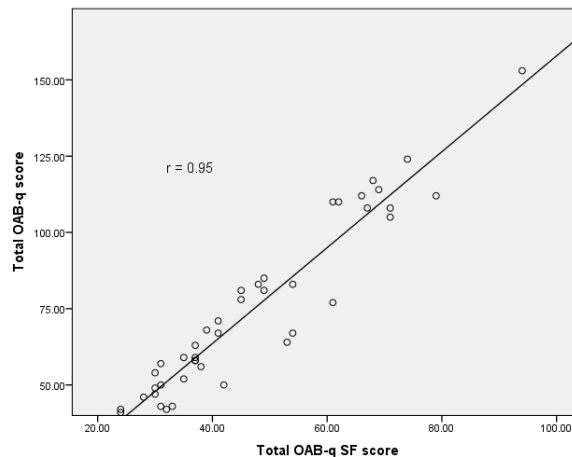


Fig. 1. Pearson correlation (r) between Thai version OAB-q SF and Thai version OAB-q score.

Discussion

OAB is chronic medical condition and complex symptoms. To evaluate the severity of symptoms may need a long time. A good questionnaire can decrease the time in clinical setting. The questionnaire must brief, easy to complete, precise and reliable. The OAB-q SF fulfills these criteria⁽¹³⁾. This study reported on psychometric properties of Thai version of the OAB-q SF. The internal consistency (Cronbach's alpha) was in the acceptable range (more than 0.7)⁽¹⁵⁾ and the test-retest reliability was in the excellent range (more than 0.9)⁽¹⁶⁾. In addition, Pearson correlation between the total score of Thai version of the OAB-q SF and Thai version of the OAB-q was in the very strong correlation range⁽¹⁷⁾.

The primary objective of this study was to translate and validate the OAB-q SF in the Thai language. The results of this study showed that this Thai version was valid, reliable. This enables the use of the OAB-q SF in daily practice in Thailand. This valid tool can be used to measure symptom bother and quality of life in patients with OAB with less items than the original OAB-q.

The results of this study were used to compare the psychometric study of the OAB-q SF in English⁽¹³⁾ and Spanish versions⁽¹⁸⁾. Cronbach's alphas of English and Spanish version attained 0.81 and 0.81 in symptom bother scale and 0.92 and 0.92 in HRQL.

Intra-class correlation was 0.92 and 0.86^(13,18). The psychometric properties of Thai version of the OAB-q SF were similar to original and Spanish version. Concerning the criterion validity, the present study used the Thai version OAB-q to correlate with the Thai OAB-q SF because we would like to compare the Thai OAB-q SF to the original version (gold standard). Because the original version has many questions that take long time to complete the questionnaires. Shorter version with similar reliability and validity can increase the use of this questionnaire in clinical and research setting.

For clinical application, Thai version of the OAB-q SF is shorter than the original version (OAB-q) to use in an outpatient department. It may alert the physician to closely evaluate symptoms in the patient who has severe symptoms with the high impact on quality of life. This Thai version of OAB-q SF can also be used in research to compare with other studies in OAB treatment for Thai women in the future.

Strengths of this study

This study was conducted with the strict validation process with the development process fully compatible with standard protocol suggested by the ISPOR (international Society for Pharmacoeconomics and Outcome Research) task force for translation and cultural adaptation⁽¹⁹⁾. The questionnaire translation

was done by experienced linguists. The inclusion criteria of this study were strict and clear. All participants must complete 3-day bladder diary for diagnosis OAB.

Limitation of this study

The study of responsiveness was not included in our study. Therefore, further studies of Thai version of OAB-q SF in women before and after the treatment comparing to clinical symptoms such as voiding diary are advocated.

Conclusion

Thai version of the OAB-q SF showed good psychometric properties (reliability and validity) for measuring the OAB symptom severity and HRQL. Thai version of the OAB-q SF had very strong correlation to Thai version of the OAB-q. We recommend the use of this questionnaire in both research and clinical practice.

Potential conflicts of interest

The authors declare no conflicts of interest.

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