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Reliability and Validity of the Thai Version of the Pelvic Floor Bother Questionnaire

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ABSTRACT

Objectives: To develop a Thai version of the pelvic floor bother questionnaire (PFBQ) and to evaluate its reliability and validity. The correlation with the pelvic floor distress inventory-20 (PFDI-20) questionnaire was evaluated.

Materials and Methods: A Thai version of PFBQ was developed from the original English version by translation and back translation method. The psychometric properties of the questionnaire were evaluated in 100 Thai women with pelvic floor dysfunction (PFD). Internal consistency was measured by Cronbach's alpha coefficient for all items. Test-retest reliability was measured by intraclass correlation coefficient (ICCr). The agreement of each item between two visits (two-week interval) was measured by Kappa coefficient. Concurrent validity of the PFBQ was evaluated by assessing its correlation with the PFDI-20 using the Spearman's correlation coefficient (r).

Results: A total of 100 women who had PFD symptoms (mean age ± standard deviation = 61.89 ± 11.70 years) were enrolled in the study. All women completed the study. The Thai version of PFBQ demonstrated acceptable internal consistency (Cronbach's alpha = 0.76) and excellent test-retest reliability (ICCr = 0.90, 95% confidence interval 0.85-0.93). The agreement of each question between two visits ranged from moderate to substantial (Kappa = 0.43-0.69). There was a positive correlation between the Thai version of PFBQ and the PFDI-20 (r = 0.81).

Conclusion: The Thai version of the PFBQ is valid and reliable. It may be used as a tool to identify the presence of symptoms and assess the severity of bother of various pelvic floor dysfunction in Thai women. PFBQ can be used as a patient reported outcome instrument in both research and clinical practice.

Keywords: Thai version, pelvic floor bother questionnaire, PFBQ, pelvic floor dysfunction.

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การศึกษาความเที่ยงและความตรงของแบบสอบถามการรบกวนในอุ้งเชิงกราน

เบญจมาภรณ์ เสรีนนท์ชัย, ปุริม เรือนภู่, กีรติ เชียงทอง, สุวิทย์ บุณยเวชชีวิน

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาการศึกษาความเที่ยงของแบบสอบถามการรบกวนในอุ้งเชิงกราน (Pelvic Floor Bother Questionnaire) ฉบับภาษาไทย และหาสหสัมพันธ์เทียบกับแบบสอบถาม Pelvic Floor Distress Inventory -20 (PFDI-20)*

วัสดุและวิธีการ: *การศึกษาแบบสอบถามทางจิตวิทยา (Psychometric test) โดยมีการแปลแบบสอบถามการรบกวนในอุ้งเชิงกรานเป็นฉบับภาษาไทย โดยมีการแปลแบบสอบถามโดยนักภาษาศาสตร์เป็นภาษาไทย และแปลฉบับภาษาไทยเป็นภาษาอังกฤษอีกครั้ง (translation-back translation method) เพื่อใช้ในการประเมินเรื่องของการรบกวนในอุ้งเชิงกราน*

ผลการศึกษา: *จากการศึกษาผู้เข้าร่วมวิจัย 100 คน ที่มีอายุเฉลี่ย 61.89 ± 11.70 ปี ค่าสัมประสิทธิ์สหสัมพันธ์ ของความสอดคล้องภายใน (Internal Consistency) อยู่ในเกณฑ์ที่ยอมรับได้ (α = 0.76) และมีค่าสัมประสิทธิ์ของความคงที่ (test-restet reliability) อยู่ในเกณฑ์ดีมาก (ICCr = 0.90 (0.85-0.93) โดยมีค่าสถิติแคปปาที่บ่งบอกถึงความไปด้วยกันของการตอบคำถามแต่ละข้อในการตอบคำถามครั้งแรกและครั้งที่สองเมื่อผ่านไป 2 สัปดาห์ อยู่ในเกณฑ์ปานกลางถึงมาก (k = 0.43-0.69) และมีค่าความสอดคล้องระหว่างแบบสอบถามการรบกวนในอุ้งเชิงกรานเป็นฉบับภาษาไทย และ PFDI-20 ฉบับภาษาไทย ในระดับสูง (r = 0.81)*

สรุป: *แบบสอบถามการรบกวนในอุ้งเชิงกรานฉบับภาษาไทย มีความเที่ยงและความตรง และสามารถใช้เป็นเครื่องมือที่ใช้ในการประเมินการมีอาการของภาวะอุ้งเชิงกรานผิดปกติ รวมทั้งประเมินความรุนแรงของอาการที่เกิดขึ้นจากภาวะอุ้งเชิงกรานผิดปกติ*

คำสำคัญ: *ฉบับภาษาไทย, แบบสอบถามการรบกวนในอุ้งเชิงกรานฉบับภาษาไทย, ภาวะอุ้งเชิงกรานผิดปกติ*

Introduction

Pelvic floor dysfunction (PFD) refers to a variety of conditions, including pelvic organ prolapse, lower urinary tract dysfunction such as urinary incontinence, defecatory dysfunction, and sexual dysfunction[1]. Even though, PFD rarely result in severe morbidity, this problem can significantly have the effect to the patient's quality of life[2]. The patient reported outcome instruments for self-assessment of symptoms by patients are important. As the most effective way is to assess the bother of patients by evaluating at the patient's point of view[3]. A questionnaire is a data collection tool that can provide objective measures of the patient's symptoms and other aspects of health, such as discomfort, bother, satisfaction, and quality of life. It can be used in clinical practice or in a research study. Questionnaire with scoring system is extremely useful to determine the most bothersome symptoms and grasp the impact of treatment. Currently, several questionnaires are used for evaluating pelvic floor dysfunction, of which many have been translated into Thai and validated. These questionnaires are used in both clinical and research settings. For example, the pelvic floor distress inventory-20 (PFDI-20) is a tool that evaluates the distress related to pelvic floor dysfunctions[4]. However, the tools that assess multiple conditions of PFD are mostly multi-item questionnaires which are difficult to use in the clinical setting. There are validated shorter questionnaires for single PFD problem such as the overactive bladder symptom score (OABSS). This four-item questionnaire evaluates four symptoms of overactive bladder, including daytime frequency, nighttime frequency, urgency, and urgency incontinence[5]. It is convenient to use but this questionnaire is specific for only one disorder of PFD.

The pelvic floor bother questionnaire (PFBQ) is a short questionnaire that assesses the presence of multiple common conditions of PFD that can evaluate the severity or bother of these pelvic floor problems. The original PFBQ questionnaire was developed in English language and demonstrated good validity and reliability[6]. The PFBQ has been translated and validated in many languages, including Arabic[7], Turkish[8] Portuguese[9] and Chinese[10]. The PFBQ was used as a tool to evaluate pelvic floor symptoms and level of bother in many research studies[11-15]. It can be used to evaluate prevalence of PFD in various populations[16-17].

In Thailand, the PFBQ was adopted and translated in Thai language in a tertiary care clinic without psychometric test (validity and reliability test) being studied or reported before[18]. The aim of this study was to translate the PFBQ into Thai and to assess the validity and reliability of the Thai version of the PFBQ for further use to assess multiple pelvic floor dysfunctions in clinical practice and for research purposes with one instrument.

Materials and Methods

This study was conducted at the Female Pelvic Medicine and Reconstructive Surgery Clinic, the King Chulalongkorn Memorial Hospital (KCMH), a tertiary care center in Bangkok, Thailand, between July 2020 and July 2021. The study was approved by the Research Ethics Committee, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. Informed consent was obtained from all participants. The participants were invited into the study by convenient sampling technique. The inclusion criteria were: 1) Thai women who had any symptoms of pelvic organ prolapse, urinary incontinence, urinary urgency and frequency, urge incontinence, fecal incontinence, obstructed defecation or dyspareunia, 2) agree to have self-answering questionnaires. The exclusion criteria were: 1) pregnant, 2) age less than 18 years, 3) inability to read Thai language or mental incapacity to complete self-administered questionnaires.

All participants were evaluated by detailed medical history and complete physical examination, including pelvic organ prolapse assessment using pelvic organ prolapse quantification (POP-Q) system[19] during the initial visit. Participant's demographic data were recorded. The final diagnosis, additional investigation, and management of each participant were decided by the attending physicians without any influence from this study.

The participants completed the Thai version of the PFBQ at the initial visit by themselves. The self-answered PFDI-20 was also completed at the initial visit

in order to assess its correlation with the PFBQ. To evaluate test-retest reliability, all participants received a second copy of the Thai version of the PFBQ in a stamped envelope and were instructed to complete and return it by mail, two weeks after the initial visit.

Questionnaires

The pelvic floor bother questionnaire (PFBQ) consisted of nine items to assess the presence of symptoms and their degree of bother related to pelvic floor dysfunctions. Each item had dichotomous options, "yes" and "no", for identification of the presence of symptoms. If the answer of any symptom was "yes", the extent of its bother was reflected by the following options: not at all (1), only a little bit (2), somewhat (3), a moderate amount (4) and a lot (5). Each answer was scored in a range from 0 to 5 with a higher score indicated a more severe bother. The scoring system had the same weight for all questions. The total questionnaire score ranged from 0 to 45. In order to have a summary score ranging from 0 to 100, the total score was transformed by multiplying the mean score of the answered items by 20[20]. This transformed score was used in our study.

Translation of the PFBQ was processed as follows. After permission from the original study's authors, the English version of the PFBQ was translated into Thai by a linguist from the Language Institute, Chulalongkorn University and backward translated by another independent linguist. The final draft was accomplished after a small group interview with patients with PFD and content validation was ensured by two urogynecologists from our department.

The pelvic floor distress inventory-20 (PFDI-20) is a tool to evaluate distress related to pelvic floor dysfunction. The PFDI-20 has a total of 20 questions divided to three scales (urinary dysfunction, pelvic organ prolapse and defecatory dysfunction). The distress associated with each symptom ranges from 0 (not present) to 4 (quite a bit). The score of each subscale was calculated by multiplying the mean score by 25 (range 0-100). The summary score was the sum of the three subscale scores (range 0–300). A higher score indicated more symptom distress[13]. The PFDI-20 has been translated into Thai and validated (Cronbach's alpha coefficient 0.93, intraclass correlation (ICCr) 0.83)[4].

Statistical analysis

For baseline characteristics, the categorical data were presented with number and percentage. The continuous data were presented with mean and standard deviation (SD) or median with interquartile range (IQR) as appropriate.

Rule of thumb's formula was used to estimate the sample size of this psychometric test study[21-22]. Ninety participants were required for the nine-item questionnaire. After adding of 10% for dropouts, 100 participants in total were needed.

The PFBQ was assessed in terms of internal consistency and test-retest reliability. Internal consistency of the questionnaire was measured by Cronbach's alpha coefficient for all items. A Cronbach's alpha coefficient of < 0.50 was classified as 'unacceptable', 0.50-0.60 as 'poor', 0.60-0.70 as 'questionable', 0.70-0.80 as 'acceptable', 0.80-0.90 as 'good' and > 0.90 as 'excellent'[23]. Test-retest reliability was measured by ICCr with 95% confidence interval (CI). An ICCr of < 0.50 was classified as 'poor', 0.50-0.75 as 'moderate', 0.75-0.90 as 'good' and > 0.90 as 'excellent'[24]. The agreement of each item between two visits was measured by the kappa coefficient. A kappa coefficient of < 0 was classified as 'poor', 0-0.20 as 'slight', 0.21-0.40 as 'fair', 0.41-0.60 as 'moderate', 0.61-0.80 as 'substantial' and 0.81-1.00 as 'almost perfect'[25]. Concurrent validity of the PFBQ was evaluated by assessing the correlation between the PFBQ and the PFDI-20 with Spearman's correlation coefficient. The correlation coefficient of 0-0.30 was classify as 'negligible', 0.30-0.50 as 'low', 0.50-0.70 as 'moderate', 0.70-0.90 as 'high' and 0.90-1.00 as 'very high'[26].

All data were managed using the Statistical Package for the Social Sciences for Windows version 22.0 (SPSS, Chicago, IL USA). Statistical significance was considered if a p value was lower than 0.05.

Results

One hundred twenty-two women were invited

to participate in the study, of which 100 were enrolled. Twenty-two women declined to participate. All enrolled participants completed the questionnaires on both visits (Fig. 1). The mean ± SD age was 61.89 ± 11.70 years and mean ± SD body mass index was 25.36 ± 4.05 kg/m^2. The majority of participants were in menopause (84%). The initial complaints were demonstrated in Table 1.

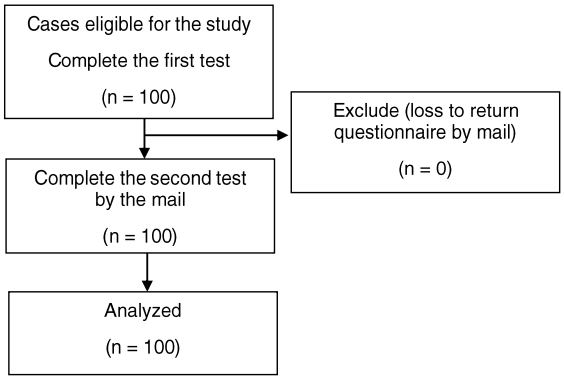

Fig. 1. Flow of participants.

Table 1. Participants' characteristic (n = 100).

Age (mean ± SD)	61.89 ± 11.70
BMI (mean ± SD)	25.36 ± 4.05
Number of children	n (%)
Nulliparous	12 (12%)
1	21 (21%)
2	33 (33%)
3	22 (22%)
> 3	12 (12%)
Education	n (%)
Under primary school	18 (18%)
Primary school	25 (25%)
Secondary school	30 (30%)
Bachelor's degree	23 (23%)
Higher than Bachelor's degree	3 (3%)
Marital status	n (%)
Single	8 (8%)
Married	89 (89%)
Divorced or widowed	3 (3%)
Menopausal status	n (%)
Menopause	84 (84%)
Premenopause	16 (16%)
Initial complaint	n (%)
Genital prolapse	72 (72%)
Stress urinary incontinence	7 (7%)
Urge urinary incontinence	8 (8%)
Mixed urinary incontinence	4 (4%)
Urinary frequency	9 (9%)

SD: standard deviation

The median (IQR) of the total PFBQ score at the first and second visits were 15.56 (7.22-32.78) and 17.78 (8.89-31.11), respectively (Table 2). The internal consistency of total questionnaire was acceptable (Cronbach's alpha = 0.76, Table3). The internal consistency of urinary symptoms was good (Cronbach's alpha = 0.80). The internal consistency of defecatory symptoms was questionable (Cronbach's alpha = 0.67, Table 3). The intraclass correlation coefficient for the total PFBQ score was excellent (ICCr = 0.90, Table 4).

Table 2. Participants' symptoms reported by the PFBQ.

	Frequency, n (%)
Stress urinary incontinence	49 (49)
Urinary frequency	69 (69)
Urinary urgency	51 (51)
Urinary urge incontinence	45 (45)
Voiding difficulty	25 (25)
Genital prolapse	31 (31)
Obstructed defecation	26 (26)
Fecal incontinence	28 (28)
Dyspareunia	17 (17)

PFBQ: pelvic floor bother questionnaire

Table 3. Internal reliability for the Thai version of PFBQ.

	Internal reliability (Cronbach's alpha coefficient)
Global	0.76
Urinary symptoms	0.80
Defecatory symptoms	0.67

PFBQ: pelvic floor bother questionnaire

Table 4. Test-retest reliability of Thai version of PFBQ.

	Estimate	95% Confidence interval
PFBQ total score		
Intraclass correlation	0.90	0.85-0.93
PFBQ items		
Kappa		
1.Stress urinary incontinence	0.61	0.55-0.67
2.Urinary frequency	0.55	0.49-0.61
3.Urinary urgency	0.60	0.54-0.66
4.Urinary urge incontinence	0.57	0.50-0.63
5.Voiding difficulty	0.43	0.35-0.50
6.Genital prolapse	0.59	0.52-0.66
7.Obstructed defecation	0.57	0.49-0.64
8.Fecal incontinence	0.59	0.52-0.67
9.Dyspareunia	0.69	0.60-0.77

PFBQ: pelvic floor bother questionnaire

The kappa statistics of each item ranged from 0.43-0.69 which indicated moderate to substantial agreement between the two visits. The median (IQR) of the total PFDI-20 score was 14.38 (7.50-25.94). The total PFBQ score had a high positive correlation with the total PFDI-20 score (Spearman's correlation coefficient = 0.81, $p < 0.001$).

Discussion

A total of 100 women participated in this study. All participants completed the protocol. The mean age of the participants was 61.89 ± 11.70 years. The reason that might explain this surprisingly young participants was the nature of self-answered questionnaires. Younger women might be more comfortable to complete the questionnaires by themselves than older women. However, we did not have data of the excluded women to confirm this hypothesis.

The PFBQ can identify the bother of all pelvic floor dysfunction problems (pelvic organ prolapse, urinary incontinence, fecal incontinence, and dyspareunia). We found other additional PFD apart from the patients' complaints (voiding difficulty, obstructed defecation, fecal incontinence, and dyspareunia) (Table 1 and 2). This benefit supported the use of this questionnaire as a screening tool for PFD problems in the clinical setting.

The internal consistency of Thai version of the PFBQ was acceptable (Cronbach's alpha = 0.76), similar to the original English version[6], Portuguese-Brazilian version[9] and Chinese version[10]. The PFBQ is a short questionnaire that assesses different symptoms of PFD, so the expected internal consistency is not relatively high. Some language translational versions such as Arabic version and Turkish version did not evaluate internal consistency because they expected that it would be low, due to each question of the PFBQ focused on different conditions[7, 8]. In the Turkish version, the authors performed confirmatory factor analysis to establish the construct validity of the PFBQ. They found that the factor loads of all items in the PFBQ were high, which supported the construct validity of the PFBQ[8]. In Arabic version, the authors calculated the construct validity by comparing scores of an affected population with those of a control population. They found significant differences in the scores of each PFBQ item between the two groups, with the exception of dyspareunia[7].

The Thai version of the PFBQ questionnaire had an excellent test-retest reliability (ICCr = 0.90) which was consistent with the original English version(6), and other language translation versions (Arabic, Turkish, Brazillian-Portuguese, and Chinese)[7-10]. The agreements the Thai version of PFBQ measured within each item ranged from moderate to substantial (kappa coefficient 0.43-0.69) which were lower than the original study[6] and Portuguese-Brazilian version[9]. This may be due to cultural and language difference. These reflected the consistent validity and reliability of the PFBQ after being translated into many languages. We found the good concurrent validity (high positive correlation of Thai version PFBQ and the Thai version of PFDI-20) (Spearman's correlation coefficient = 0.81). This was similar to the Turkish version of PFBQ[8].

Strengths of this study

This study was conducted with strict and validated processes. The questionnaire was translated by experienced linguists and its contents were confirmed by two urogynecologists. There were no dropouts in this study. This excellent cooperation from participants might result from understanding the objective of the study explained by the investigator team. This may reflect the ease of use of the questionnaire. We also assessed the correlation of the PFBQ with the PFDI-20 which was used in our routine clinical practice for concurrent validity.

Limitations of this study

There were no data on the time used for questionnaire completion included in this study. Apart from reliability and validity, the time used to complete the questionnaire is another factor to consider whether the questionnaire should be used in the clinical setting.

As this study was done as hospital based, in one teaching hospital in Bangkok, there might be some limitations for the generalization of our results for other women in different parts of Thailand with different ethnic and culture. There was also possibility of selective bias as we only included women with PFD at our clinic that can come for the treatment at hospital. These women might have better social status and living in the metropolitan city (Bangkok) who can easily access to the hospital service. There was no data on responsiveness because there was no follow up-of the score changes after the treatment compared to the other clinical symptoms. Future study on responsiveness by using the PFBQ before and after medical or surgical treatment and the time used for completion of different questionnaires are advocated.

Conclusion

The Thai version of the PFBQ is valid and reliable. It may be used as a tool to identify the presence of symptoms and assess the severity or bother of various pelvic floor dysfunctions in Thai women. PFBQ can be used as a patient reported outcome instrument in both research and clinical practice.

Potential conflicts of interest

The authors declare no conflicts of interest.

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