ORIGINAL ARTICLE

Validation of the Thai version of the International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS)

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Abstract

Introduction and hypothesis To provide a validated Thai language version of the International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) following a standardized procedure and to evaluate its psychometric properties.

Methods After IRB approval, the English ICIQ-FLUTS was translated into Thai according to the cross-cultural adaptation process for patient-reported outcome measures. The psychometric properties of the final version of the Thai ICIQ-FLUTS were tested for content validity, internal consistency, construct validity, and test-retest reliability. Patients attending an urogynecology clinic and women from two communities were recruited for this study.

Results The final Thai version of the ICIQ-FLUTS was developed and assessed by a panel of clinicians fluent in both languages including the content expert. Women with and without female lower urinary tract symptoms (FLUTS), in whom the translation was pretested, agreed that the final version made sense and was understandable. Among the 288 women who received the questionnaires, 283 (142 attending the clinic and 141 living in the communities) returned the completed questionnaire. The overall internal consistency of the Thai-version questionnaire was high, with a Cronbach's alpha score of 0.849. Symptom scores for filling, voiding, and incontinence in patients attending the clinic were significantly higher than in individuals from the community ($p < 0.001$). The correlation coefficients between the test and retest among 136 participants for symptoms of filling, voiding, and incontinence were 0.925, 0.769, and 0.921, respectively ($p < 0.05$).

Conclusions The Thai ICIQ-FLUTS contained satisfactory content and exhibited construct validity, internal consistency, and test-retest reliability. It is equivalent to the original English version and will be a valuable tool for assessing LUTS in Thai-speaking women.

Keywords Female · ICIQ · Lower urinary tract symptoms · Validation

Introduction

Female lower urinary tract symptoms (FLUTS), such as frequency, urgency, nocturia, incontinence, and sensation of incomplete bladder emptying, are commonly observed [1].

These symptoms can interfere with everyday life activities and often require the affected women to seek professional assistance. According to the International Continence Society (ICS), there are > 20 symptoms of FLUTS, which can be classified into three main groups: storage, voiding, and post micturition symptoms [1, 2]. The prevalence of FLUTS is higher in elderly populations, and the global occurrence of FLUTS is anticipated to rise because of aging populations [3–7]. The incidence of FLUTS reported in different populations varies from 5.62% to 75.3%, with some variability due to the questionnaire used. Population- and hospital-based cross-sectional surveys in Thailand report a high prevalence of FLUTS, including urinary incontinence [8–12]. FLUTS, either generic or symptom-specific, impair patients' quality of life (QoL) and are associated with depression and

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anxiety, also causing healthcare-related financial stress [4, 6, 7]. The substantial impact of FLUTS on QoL highlights the need for treatment and the potential benefits of effective intervention. However, many women with FLUTS do not seek treatment, which is often regarded as a low priority by primary care physicians. A reliable FLUTS screening tool, suitable for use in a primary care setting, would aid in diagnosis and allow patients to be referred to specialists and receive proper management for their condition.

In Thailand, there are currently reliable tools for the assessment of lower urinary tract symptoms; however, these focus primarily on incontinence and storage symptoms. The Urinary Incontinence Quality of Life Scale (I-QOL) [13] and the Questionnaire for Urinary Incontinence Diagnosis (QUID) [14] have been translated and validated for use in the assessment of urinary incontinence. The King's Health Questionnaire [15] and the Overactive Bladder Symptom Scores (OABSS) Questionnaire [16] are also practical and reliable for use in Thai women with overactive bladder symptoms.

In 2003, the International Consultation on Incontinence (ICI) developed a generic questionnaire, the International Consultation on Incontinence Modular Questionnaire on Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) [17, 18]. This questionnaire for evaluating female urinary tract symptoms has applications in both research and clinical practice. It is psychometrically robust, is highly recommended, and has a high rate of patient completion [19]. The English version of the ICIQ-FLUTS has been translated into several European and Asian languages [20–24]. However, a FLUTS questionnaire for Thai-speaking women has not been validated for the three main groups of lower urinary tract symptoms. Therefore, the present study aimed to translate the original English ICIQ-FLUTS questionnaire into the Thai language, cross-culturally adapt it for use in Thailand, and evaluate its psychometric properties.

Materials and methods

The study was conducted in a university hospital in Bangkok, Thailand. The questionnaire was based on the English version of the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Modules (ICIQ-FLUTS), which is derived from the fully validated BFLUTS-SF questionnaire [17, 18]. This instrument is self-completed by patients and effective in assessing female lower urinary tract symptoms in three domains: abnormal bladder filling, abnormal voiding, and urinary incontinence. The questionnaire also demonstrates good psychometric testing results with regard to validity and reliability [17]. The ICIQ-FLUTS consists of 12 items, with two questions in each item. The first question asks about the presence and severity of a symptom and quantifies it based on a Likert scale (0 = never;

4 = all the time). The second question determines the degree to which the symptom affects the patients, with scores from 0 (not at all) to 10 (a great deal). Permission was obtained from the International Consultation on Incontinence (ICI) development group to translate the ICIQ-FLUTS into Thai. The Thai version was validated for use in Thailand in accordance with the group's validation protocol to assure the validity and reliability of the questionnaire. The validation procedure was comprised of two stages: (1) translation; (2) psychometric properties testing.

Stage 1 translation

The original English ICIQ-FLUTS was translated into Thai according to the cross-cultural adaptation process for patient-reported outcomes measures [25]. The validation protocol of the ICI development group was followed and consisted of the following steps [26]:

(1) Forward translation of the questionnaire: two Thai-speaking translators, experienced in translating health questionnaires, independently translated the ICIQ-FLUTS into Thai.

(2) Reconciliation: an expert experienced with the questionnaire validation process compared and merged the two forward translations into a reconciled translation.

(3) Back translation into English: two bilingual native English speakers, who were not involved in the translation stage and blinded to the original version of the questionnaire, individually translated the reconciled translation back into English.

(4) Back translation review: the two back translations were reviewed by the specialists, the questionnaire validation expert, and the Bristol Urological Institute. Any differences in the translated versions that do not accurately reflect the content of the original questionnaire were examined. Discrepancies between the original and the reconciled translation were adjusted to resolve the issues. An expert panel, made up of the participating investigators and translators, gathered to review the final draft and consolidated the Thai version.

(5) Cognitive debriefing: the final draft version of the questionnaire was tested on 20 relevant patients and laypeople to examine the effects of alternative word use, the overall ability of participants to understand the questionnaire, applicability, and cultural relevance of the translation. The principal investigator observed the volunteers completing the questionnaire followed by an interview based on the ICIQ recommendation [26]. The interview was performed using a one-on-one technique. The clarity was evaluated based on the questions recommended by the ICIQ.

Stage 2 psychometric property testing

During the second stage, the validity and reliability of the instrument were assessed in a cross-sectional analytical study. Eligible participants were patients who attended the urogynecology clinic, Faculty of Medicine Ramathibodi Hospital (the clinical population), or women who lived at Saun-ngern or Phetcha-buri Soi 7 communities (the community population). Study subjects communicated fluently in Thai and were willing to participate, with signed informed consent. Participants were excluded from the study if they withdrew or were unable to complete the analysis. The final version of the ICIQ-FLUTS questionnaire was distributed, completed, marked, and scored. No compensation of any type was provided.

The final version of the Thai ICIQ-FLUTS was examined according to the quality criteria for measurement properties of health status questionnaires [27]. The psychometric properties examined were content validity, internal consistency, construct validity, and test-retest reliability.

(1) Content validity: This property was assessed by observing participants completing the questionnaire. Levels of missing data were measured and used as an indicator of inappropriate items.
(2) Internal consistency (reliability): Correlations between different items within the questionnaire were assessed by determining the Cronbach's alpha coefficient and the total score without it (item-total correlations).
(3) Construct validity: This property was examined by comparing symptom scores between urogynecology patients (the clinical population) and women living in the community (the community population). Known-groups validity would also predict lower symptom scores from women in the community compared to those who attended the Urogynecology Clinic.
(4) Test-retest reliability: The stability of this questionnaire was measured by having participants complete the same test twice, with a 2-week interval between the initial and second tests. All participants living in the Suan-ngern and Phetchaburi Soi 7 communities (the community population) were invited to participate in the retest study.

Ethical considerations

The protocol of this study was approved by the Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University (protocol no. MURA 2019/87). Written informed consent was obtained from all the women who participated in the study.

Statistical analyses

Data were analyzed using SPSS version 18. The results were considered statistically significant at $P < 0.05$. Demographic and baseline characteristics were expressed as mean and standard deviation (SD), median and range for continuous data, or number and percentage for categorical data. Baseline characteristics were compared using t-tests and chi-square tests. The content of the Thai version of the ICIQ-FLUTS was evaluated using the missing value, while the internal consistency was determined using Cronbach's alpha, with values > 0.70 indicating good internal consistency. Test-retest reliability was assessed by comparing the mean test-retest scores for each domain using the intraclass correlation coefficients (ICCs). ICC values between 0.75 and 0.90 represent good reliability, and values > 0.90 indicate excellent reliability.

The required sample size was estimated at 288 to allow for a 20% dropout rate. Validation of a questionnaire with 24 items requires a sample size of 240 to satisfy the 10 subjects per item ratio [28].

Results

Stage I: Translation and cross-cultural adaptation

Following the completion of the translation and cross-cultural adaptation process, the Thai version of the ICIQ-FLUTS questionnaire was ready for preliminary assessment with a small group (see Appendix). The pilot test was performed with 20 women with and without lower urinary tract symptoms. After the cognitive debriefing interviews, the respondents did not suggest any changes to the questionnaire and stated that all of the items in the questionnaire were clear.

The panel of clinicians fluent in both English and Thai, the content expert, and the group of women with and without FLUTS in whom the Thai translation was pretested agreed that the final Thai translation was understandable and evaluated the intended conditions. The final Thai ICIQ-FLUTS version was also approved by the ICIQ Development Group to assure the validity and reliability of the questionnaire.

Stage II: Instrument validity and reliability assessment

The prospective validation process was performed between August 2019 and December 2019.

For the clinical population, eligible women who attended the Urogynecology Clinic of Faculty of Medicine Ramathibodi Hospital within the study period were invited to participate. Two participants who agreed to participate

refused to return the questionnaire, while 142 completed the questionnaire. For the community population, the questionnaire was administered to 144 women living in Saun-ngern and Phetchaburi Soi 7 Communities; 141 responses were received. In summary, among 288 women who received the Thai ICIQ-FLUTS questionnaire, 283 returned the completed form, a response rate of 98.26%.

A total of 283 women (142 from the clinical population and 141 from the community population) were included in the analyses. The demographic and clinical characteristics of the respondents are shown in Table 1. The majority of respondents were parous, were postmenopausal, and had high school or above levels of education. Women attending the Urogynecology Clinic were older than those living in the community (mean age $65.08 + 11.65$ vs. $55.25 + 12.76$ years; $p < 0.001$). The occurrence of lower urinary tract symptoms in the clinical population was higher than in the community population (Table 2). Urgency was reported in 83.8% and 43.9% of the clinical and community populations, respectively. Intermittency, a symptom of impaired voiding, was found in 56.3% and 16.3% of clinical and community populations, respectively.

Face and content validity

Cognitive debriefing interviews were performed for the face validity analysis. Respondents indicated that all of the items in the Thai ICIQ-FLUTS questionnaire were clear and no further changes were needed. Content validity was assessed by the level of missing data among the 283 responses; the number of missing items was 0.

Internal consistency (reliability)

The overall Cronbach's alpha coefficient was 0.849 with a 95% confidence interval (CI) from 0.819 to 0.864 (Table 3). This indicates high internal consistency of the Thai ICIQ-FLUTS questionnaire. Cronbach's alpha for each subscale on filling, voiding, and incontinence symptoms was 0.646, 0.709, and 0.792, respectively. The removal of items sequentially did not significantly alter the original alpha magnitude.

Construct validity

Comparison of the scores between the known groups examined in this study, women in the clinical and community populations, showed statistically significant differences in the filling, voiding, and incontinence subscales ($p < 0.001$). The median scores for abnormal filling symptoms of women attending the clinic and those living in the community were 6.00 and 2.00, respectively (Table 4). In addition, the median scores for symptoms of incontinence in the clinical population were higher than in the community population (5.00 vs. 1.00).

Table 1 Respondents' demographic data

	Clinical population (n = 142)	Community population (n = 141)	p value
Age (years), mean (SD)[a]	65.08 (11.68)	55.25 (12.76)	< 0.001
BMI (kg/m^2), mean (SD) [a]	25.42 (4.55)	24.72 (4.08)	0.184
Menopause, frequency (%)[b]	134 (94.3)	96 (68.1)	< 0.05
Parity, frequency (%)[b]			< 0.001
- Nulliparous	13 (9.2%)	53 (37.6%)	
- Parous	129 (90.8%)	88 (62.4%)	
Delivery route, frequency (%)[b]			< 0.001
- Vaginal	113 (87.5%)	74 (84.0%)	
- Cesarean	16 (12.5%)	14 (16.0%)	
History of pelvic surgery, frequency (%)[b]	30 (21.1%)	29 (20.5%)	0.932
Level of literacy, frequency (%)[b]			0.377
- Primary education	43 (30.3%)	33 (23.4%)	
- High school	40 (28.2%)	40 (28.4%)	
- University	59 (41.5%)	68 (48.2%)	
Job, frequency (%)[b]			< 0.001
- Housewife/retired	95 (66.9%)	50 (35.5%)	
- Employed	47 (33.1%)	91 (64.5%)	

[a] t-test

[b] Chi-square test

Table 2 Prevalence of female lower urinary tract symptoms (FLUTS); number (%) (n = 283)

Symptoms	Clinical population n = 142	Community population n = 141
Nocturia	135 (95.1)	114 (80.1)
Urgency	119 (83.8)	62 (43.9)
Bladder pain	65 (45.7)	30 (21.2)
Frequency	51 (35.9)	12 (8.5)
Hesitancy	48 (33.8)	19 (13.4)
Straining	48 (33.8)	17 (12.1)
Intermittency	80 (56.3)	23 (16.3)
Urge urinary incontinence	100 (70.4)	41 (29.1)
Frequency of urinary incontinence	109 (76.7)	25(17.7)
Stress urinary incontinence	110 (77.4)	62 (43.9)
Unexplained urinary incontinence	37 (26.1)	5 (3.5)
Nocturnal enuresis	26 (18.3)	11 (7.8)

Test-retest reliability (stability)

Among 141 women from the community population, 136 completed the questionnaire twice, a response rate of 96.4%. The overall test-retest reliability was > 0.75, indicating that the Thai ICIQ-FLUTS questionnaire was stable (Table 5). The test-retest correlation coefficients for the filling, voiding, and incontinence subscales were 0.925 (95% CI; 0.860–0.990), 0.769 (95% CI; 0.664–0.881), and 0.921 (95% CI; 0.855–0.988), respectively ($p < 0.001$).

The average time required to complete the questionnaire was 7 min (range 4–10) and 4 min (range 3–5) in the clinical and the community populations, respectively.

Table 3 Internal consistency of the Thai version of the International Consultation on Incontinence Modular Questionnaire for Female Lower Urinary Tract Symptoms (n = 283)

Question	Corrected item total correlation (r)	Cronbach's alpha if item deleted
2a	0.408	0.842
3a	0.669	0.817
4a	0.474	0.833
5a	0.441	0.836
6a	0.359	0.841
7a	0.511	0.832
8a	0.519	0.830
9a	0.637	0.820
10a	0.693	0.815
11a	0.558	0.827
12a	0.501	0.834
13a	0.439	0.838

Discussion

Epidemiological studies have revealed a worldwide increase in the prevalence of lower urinary tract symptoms during the last decades. Female patients with LUTS have impaired health-related quality of life as well as a substantial economic burden due to direct and indirect costs of treatment. Early diagnosis of this condition, through the identification of symptomatic patients using simple screening tools, should assist patients in receiving appropriate treatment. The ICIQ-FLUTS questionnaire is a brief comprehensive tool that allows reporting of lower urinary tract symptoms in women and evaluating the impact of the symptoms on their quality of life [17]. The results of our study demonstrate that the Thai Version of the ICIQ-FLUTS had high psychometric properties and good validity and reliability. Analysis of filling, voiding, and incontinence symptoms subscales using this questionnaire was also good between different assessments, occurring within 2 weeks.

The rigorous translation and cross-cultural adaptation process used ensured that the resulting questionnaire was appropriate for speakers of the Thai language [25, 26]. The forward and backward translations were performed by two independent translators. Interestingly, a significant misunderstanding was detected in the initial English-to-Thai translation that was revealed following backward translation. An example of the problem is with the word "bother," which does not have a direct Thai translation. To eliminate possible misunderstandings, the forward translation process was repeated several times to produce the translated version of the questionnaire. After discrepancies were resolved, the members of the expert committee and the ICI development group reached a consensus on all items to produce a final draft version of the translated questionnaire. Content validity assessment from the preliminary testing indicated that the Thai version is equivalent to

Table 4 Construct validity of the Thai version of the International Consultation on Incontinence Modular Questionnaire for Female Lower Urinary Tract Symptoms ($n = 283$)

	Clinical population ($n = 142$)	Community population ($n = 141$)	p value
Filling symptoms subscale			< 0.001
(score 0–16)			
- Mean (SD)	5.75 (2.92)	2.44 (2.01)	
- Median	6.00	2.00	
- IQR	3.00–8.00	1.00–3.00	
- Range (min- max)	1.00–14.00	0.00–12.00	
Voiding symptoms subscale			< 0.001
(score 0–12)			
- Mean (SD)	2.53 (2.35)	0.51 (0.51)	
- Median	2.00	0.00	
- IQR	0.00–4.00	0.00–1.00	
- Range (min- max)	0.00–11.00	0.00–5.00	
Incontinence symptoms subscale (score 0–20)			< 0.001
- Mean (SD)	5.25 (3.89)	1.39 (1.87)	
- Median	5.00	1.00	
- IQR	2.00–7.00	0.00–2.00	
- Range (min- max)	0.00–17.00	0.00–8.00	

the original questionnaire. The missing value which diminished interpretability of the items was not found [27]. It appears that the items were clear enough to be understood by average Thai speaking respondents with age varying from 22 to 84 years old. In addition, the time to complete the Thai version of the ICIQ-FLUTS was between 4 and 10 min for the older clinical group of respondents and 3 and 5 min for the younger community group. That means that the items were short and simple and did not require high-level reading skills [27]. These indicators suggest that the instrument is appropriate and field friendly for screening lower urinary tract symptoms in both clinical settings and epidemiological studies.

The Thai version of the ICIQ-FLUTS questionnaire was found to have high levels of reliability with regard to internal consistency and stability. The correlation coefficient between the test and retest for all three subscales demonstrates the ability of the questionnaire to produce consistent responses from participants. These validation results are similar to those from the English version of the Bristol Female Lower Urinary Tract Symptoms Questionnaire [17] and the Sinhala, Tamil, Persian, Greek, and the Chinese versions [20–24]. The Thai

version of this instrument can be used as a valid and reliable screening tool for female lower urinary tract symptoms. The use of the questionnaire should increase the timely delivery of appropriate treatment for symptomatic women. Early treatment of FLUTS provides the best opportunity for a positive health outcome and better quality of life. When LUTS were divided into filling, voiding, and incontinence subscales, the Cronbach's alpha of the filling subscale was < 0.7 (0.646). This finding suggests moderate correlations between different items on the filling subscale, although the responses vary from item to item. This limitation was also reported in previous studies including those using the original English ICIQ-FLUTS version [17, 20, 22]. This limitation requires that clinical specialists, practicing health care professionals, and researchers consider each symptom individually for LUTS assessment.

The known-groups technique was used to assess the construct validity of the Thai version of the ICIQ-FLUTS. The ability of the present questionnaire to identify women attending the Urogynecology Clinic with a high prevalence of FLUTS and individuals in the community who only

Table 5 Stability of the Thai version of the International Consultation on Incontinence Modular Questionnaire for Female Lower Urinary Tract Symptoms ($n = 136$)

Subscale	Test-retest Correlation coefficient (r)	95% Confidence interval	p value
Filling symptoms	0.925	0.860–0.990	< 0.001
Voiding symptoms	0.769	0.664–0.881	< 0.001
Incontinence symptoms	0.921	0.855–0.988	< 0.001

sporadically experienced symptoms was demonstrated. The construct validity was also represented by the findings from different age, menopausal status, and parity between the two populations based on established risk factors for FLUTS. Women in the clinical population were considerably older than those living in the community, in accordance with the known prevalence of FLUTS. The known-groups analysis produced the expected results demonstrating that the instrument was able to detect differences between the two groups. In Thai-speaking women, the present questionnaire was found to be a valid and reliable measure of FLUTS that was easily administered in both the clinic and research settings. Additionally, the Thai version of the ICIQ-FLUTS questionnaire will be valuable for clinicians when urodynamic assessments are not available, especially for pretreatment evaluations.

The main strength of this work is that a rigorous translation and validation process was carried out in collaboration with the ICIQ development group. The testing of the Thai ICIQ-FLUTS questionnaire utilized a suitable sample size for the respondent-to-item ratios 29 and a satisfactory response rate was obtained. The high rate of responses demonstrates that the participants were willing to return the questionnaire and may mask a selection bias. Besides the strengths mentioned, the present study had some limitations that should be addressed. One possible limitation is that the questionnaire was not designed to detect changes in clinical status over time. Another constraint is that the analysis of the questionnaire was population-specific with clinical and community participants from the central region of Thailand. Future studies investigating the correlation of the questionnaire with the clinical diagnosis and the responsiveness of the Thai version of the ICIQ-FLUTS questionnaire and examining the practicality of this instrument in different regions and populations are warranted. Thus, the questionnaire could be suitable for differentiating patients who will need further specific examinations as well as measuring changes following treatment.

Conclusion

The Thai ICIQ-FLUTS demonstrated satisfactory content and construct validity, internal consistency, and test-retest reliability. It is equivalent to the original English version and will be a valuable tool for assessing LUTS in urology/gynecology clinical practices, primary health care settings, and epidemiological studies in Thailand.

Compliance with ethical standards

Conflict of interest   None.

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