Original Article

Validity and Reliability of Thai version of International Consultation on Incontinence Questionnaire Nocturia Module (ICIQ-N) and International Consultation on Incontinence Questionnaire Nocturia Quality of Life Module (ICIQ-Nqol)

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Abstract

OBJECTIVES: To evaluate the validity and reliability of the Thai version of ICIQ-N and ICIQ-Nqol.

MATERIALS AND METHODS: Descriptive study, the English version of the ICIQ-N and ICIQ-Nqol were translated to Thai, Back-translations, evaluated by Urologist experts and calculated IOC for validity assessment. Then 284 subjects in Vajira hospital were randomly selected for test-retest method, twice, two weeks apart for reliability evaluation.

RESULTS: Completed data were obtained from 249 subjects. Their mean age was 37.7 ± 12 years old and 88 % of subjects were female. Most subjects were hospital personnel accounting for approximately 92.8% that complete questionnaires. The overall validity from index of item-objective congruence (IOC) ranged from 0.67-1.0. The internal consistency was strong in ICIQ-Nqol with Cronbach alpha = 0.937 and 0.938, respectively and moderate in ICIQ-N with Cronbach alpha = 0.677 and 0.653, respectively. The test-retest reliability of ICIQ-N and ICIQ-Nqol with Pearson product-moment correlation showed Coefficient of Stability close to 1 in both (r = 0.81, r = 0.92, respectively, $p < 0.001$) (statistically significant with $p < 0.001$ level and ≥ 0.5 values).

CONCLUSION: ICIQ-N and ICIQ-Nqol have good content validity and convergent validity. There is a strong internal consistency in ICIQ-Nqol but moderate in ICIQ-N. And they have excellent test-retest reliability. Therefore, these questionnaires can be used to evaluate nocturia problems in Thailand patients.

Keywords: nocturia, ICIQ, validation, reliability

Nocturia refers to the condition where a person needs to wake up to urinate during the sleeping hours.[1] This condition can affect anyone of any gender, age, or ethnicity, but it tends to be more common in older individuals.[2]

In individuals aged 30 to 79 years old, it has been found that nocturia in approximately 25.2% of males and 31.3% of females. This proportion tends to increase with age. Additionally, people who have higher body mass index, diabetes, heart disease, or those taking diuretic medications are more likely to experience nocturia.[3]

Currently, nocturia is the 3rd most bothersome problem of lower urinary tract symptoms[4] and the most prevalent symptom with the greatest negative impact on quality of life in men > 50 years old.[5] From the study, it was found that most nocturia patients typically wake up to urinate only 2-3 hours after falling asleep, leading to disturbances in sleep during that period.[6,7] This symptom can lead to inadequate rest, resulting in fatigue, decreased concentration and potential accidents or injuries. Increased risk of falls and significantly statistically associated with hip fractures.[8] Additionally, insufficient sleep can have implications on cardiovascular health, depression, endocrine function, immune response, and metabolic disorders.[9]

Diagnosing and assessing the impact of nocturia on a patient's quality of life can be done through medical history-taking, physical examinations, and specialized tests in some cases.[10] Various assessment tools have been developed, including questionnaires such as the International Consultation on Incontinence Questionnaire Nocturia Module (ICIQ-N)[11] and the International Consultation on Incontinence Questionnaire Nocturia Quality of Life Module (ICIQ-Nqol).[12] These tools have been translated into multiple languages and are widely used globally for their reliability and accessibility. However, there is a need for translation and validation of these assessment tools in Thai, hence the motivation for this research.

Material and Method

This was a single center (Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand), questionnaire validation study. 284 subjects recruited by accidental sampling, as a result of COVID 19 era, which meant it was difficult to enroll by efficiency distribution random method. They were randomly recruited from Vajira Hospital. Bangkok, Thailand in December 2019.

The inclusion criteria were Thai people older than 18 years' old who agreed and could answer the questionnaire. The institutional ethical committee approved the present study, and all subjects provided written informed consent.

Translating ICIQ-N and ICIQ-Nqol

Recommend the following steps for ensure a high level of linguistic validity from ICIQ:[13]

1. Permission from ICIQ Development Group to translate the ICIQ - Nocturia to be the Thai version
2. The original English ICIQ-N and ICIQ-Nqol version were translated into Thai by a standard translation policy, the translation and interpretation service unit, Faculty of Arts, Chulalongkorn University.
3. The maintaining of the original content of the questionnaire was confirmed by backward translation to English by Thai non-medical who did not know the original English version. (ICIQ suggest bilingual native English speaker) in our study made from Faculty of Arts, Mahidol University.
4. Review of back translation by the ICIQ group
5. Cognitive interviews with the target population by bilingual interviewer(s), including review of any unresolved conceptual equivalence issues by the ICIQ group and adjustment as necessary.

Characteristics of the ICIQ-N and ICIQ-Nqol Questionnaire

The ICIQ-N questionnaire (assumed as a questionnaire in the results table) consists of 4 items to evaluate frequent urination at night, how many people suffer from such symptoms and how bothersome they are. The questionnaire requires around 10 to 15 minutes to complete. Item is rated using a 5-point scale for frequency measurement (0–1-6 times, 1– 7-8 times, 2– 9-10 times, 3– 11-12 times, and 4– 13 times or more) and scores for bothersome range from '0' (not bothering at all) to '10' (extremely bothering). The ICIQ-Nqol questionnaire consists (assumed as B questionnaire in the results table) of 13 items to evaluate effects to Quality of Life from having to get up to urinate at night. Each item is rated using a 5-point Likert scale (0–not at all, 1– Once in a while/ Not really, 2– Some days/Sometimes/ Moderate, 3– Almost every day/quite significantly/Quite greatly, and 4– Every night/ Every day/ Very significantly/All the time/ Very greatly) and Scores for bothersome range from '0' (not bothering at all) to '10' (extremely bothering).

Test-retest method

284 subjects completed both questionnaires in 1st test. Then retested with the same questionnaires 2weeks after their first response in the same subjects. 35 subjects were excluded due to missing values and complete data for analysis included 249 subjects.

Statistical analysis

SPSS version 23 (Chicago, Illinois, USA) was used for all analyses.

For subject's characteristics, continuous variables (age) were presented as mean and standard deviation, categorized variables (sex and role) were presented as frequencies and percentages.

Content validity was interpreted from Index of item-objective congruence (IOC) calculated from rating about conformity to the objective or thing to be measured of each question by 21 expert urologists. IOC value is 0.5-1 for good content validity indicates this question is valid and should be selected for use in the questionnaire.

Corrected Item-Total Correlation (CITC) for interpret Discriminating Power which shows the relationship of a question with the total score when eliminating that question. Discriminating Power passed the criteria when CITC > 0.2.[14]

The internal consistency reliability implies about the correlation between the items which calculated from the Cronbach α coefficient that can be interpreted as excellent ($\alpha \geq 0.9$), good ($0.9 > \alpha \geq 0.8$), acceptable ($0.8 > \alpha \geq 0.7$), questionable ($0.7 > \alpha \geq 0.6$), poor ($0.6 > \alpha \geq 0.5$), and unacceptable ($0.5 > \alpha$).[15]

The test-retest reliability for the measure of stability was analyzed using the Pearson Correlation Coefficient (r). The coefficient indicates the relationship between two variables in this project mean 1st test and 2nd test have strong positive linear relationship. Pearson Correlation Coefficient (r) ranges from -1.0 to +1.0. If the value of "r" approaches to -1.0, it means that the two variables have a strong negative linear relationship. Conversely, the value of "r" approaches +1.0, it indicates a strong positive linear relationship between the two variables,

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suggesting high consistency. However, if the correlation coefficient "r" equals 0, it means no relationship between the variables (statistically significant with $p < 0.001$ level and ≥ 0.5 values).

Ethical Considerations

This study was approved by The Institutional Review Board of the Faculty of Medicine Vajira Hospital. All subjects gave written informed consent before participating in answering questionnaires.

Result

A total of 284 subjects in Vajira hospital were randomly selected for test-retest method, twice, two weeks apart but completed data were obtained from 249 subjects. From Table 1, male subjects were 30 (12%), female subjects were 219 (88%) and the mean age of the subjects was 37.7 years old. Most subjects were hospital personnel accounting for approximately 92.8%. Patient and Service recipients were 4% and Other 3.2%

Content validity

All questions in both versions of the questionnaire have passed the predefined criteria for good content validity, with Index of Item-Objective Congruence (IOC) values ranging from 0.67 to 1.00. Therefore, the questions in both versions of the questionnaire align well with the objectives and can be used without the need for modification or removal. When considering the discrimination power of each question based on the Corrected Item-Total Correlation (CITC), which indicates the relationship between each question and the total score in the same direction, it was found that all questions except A3a in the 2nd test of the ICIQ-N questionnaire met all criteria (CITC > 0.2).[14] Question A3a had a CITC value of 0.197. Interpreting this result, it suggests that this question has a weak relationship with the total score when statistically calculated. Then calculating the mean scores of ICIQ-N (Questions A) and ICIQ-Nqol (Questions B) and then analyzing the Test-Retest Reliability between the 1st and 2nd Test using the Pearson Correlation Coefficient (r), the results shown in Table 2 indicate a strong positive correlation between the scores measured at the 1st and 2nd tests for both ICIQ-N and ICIQ-Nqol at a statistically significant level of 0.05. Which (r) for ICIQ-N and ICIQ-Nqol were 0.817 and 0.929, respectively ($p < 0.001$). A correlation coefficient (r) close to +1.0 indicates that both variables have a high positive correlation, suggesting high consistency between the scores obtained in both tests.

Table 1: Subject's characteristics (n = 249)

Characteristics	n (%)
Sex	
Male	30 (12.0)
Female	219 (88.0)
Age (mean, years)	37.7 ± 12.0
Role	
Hospital personnel	231 (92.8)
Doctor	42 (16.8)
Medical student	27 (10.8)
Nurse	95 (38.0)
Officer	15 (6.0)
Stretcher-bearer	18 (7.2)
Cleaning staff	6 (2.4)
Other personnel	28 (11.2)
Patient and Service recipient	10 (4.0)
Other (food seller)	8 (3.2)

Table 2: Overall Statistical Analysis

Question	IOC	1st Test			2nd Test		Test-retest Reliability		
		CITC	αitem-deleted	α	CITC	αitem-deleted	α	r	p value
ICIQ-N									
A3a	0.856	0.221	0.734	**0.677**	0.197	0.707	**0.653**	**0.817**	**< 0.001**
A3b	0.809	0.641	0.468		0.604	0.445			
A4a	0.714	0.454	0.636		0.412	0.619			
A4b	0.810	0.712	0.409		0.684	0.371			
ICIQ-Nqol									
B3	0.905	0.664	0.933	**0.937**	0.636	0.936	**0.938**	**0.929**	**< 0.001**
B4	0.905	0.754	0.931		0.774	0.933			
B5	0.762	0.698	0.933		0.659	0.935			
B6	1.000	0.800	0.930		0.804	0.932			
B7	0.952	0.788	0.932		0.749	0.935			
B8	0.905	0.728	0.931		0.731	0.933			
B9	0.857	0.838	0.928		0.830	0.930			
B10	0.952	0.724	0.932		0.721	0.934			
B11	0.905	0.791	0.930		0.809	0.931			
B12	0.905	0.760	0.930		0.778	0.932			
B13	0.667	0.827	0.930		0.812	0.932			
B14	0.762	0.846	0.928		0.851	0.929			
B15	0.762	0.733	0.949		0.752	0.948			

IOC = Item-Objective Congruence; CITC = Corrected Item-Total Correlation
ICIQ-N = Incontinence Questionnaire Nocturia Module
ICIQ-Nqol = Incontinence Questionnaire Nocturia Quality of Life Module

The Internal Consistency Reliability using Cronbach's Alpha coefficient. From Table 3 it is observed that the consistency of the questions in set A (4 questions in ICIQ-N) fall within the moderate level. The Cronbach's Alpha values are 0.677 and 0.653 for the 1st and 2nd administrations, respectively. ($0.7 > \alpha \geq 0.6$ = questionable).[15] On the other hand, the consistency of the questions in set B (13 questions in ICIQ-Nqol) in both tests have the high level. The Cronbach's Alpha values are 0.937 and 0.938 for the 1st and 2nd test, respectively. ($\alpha \geq 0.9$ = excellent)

Table 3: Internal Consistency Reliability

Questionnaires	Test-Retest	Cronbach α coefficient	n of Items
ICIQ-N (Questions A)	1st Test	0.677	4
	2nd Test	0.653	4
ICIQ-Nqol (Questions B)	1st Test	0.937	13
	2nd Test	0.938	13

Discussion

Our study has the objective to translate the ICIQ-N and ICIQ-Nqol questionnaires into Thai to evaluate the quality about validity and reliability. So that this Thai version of the questionnaire is of international standard and can be used with accurate results for patients.

The analysis of content validity, was derived from ratings regarding the alignment with the intended objectives or constructs of each question given by 21 expert urologists, with Item-Objective Congruence (IOC) ranging from 0.67 to 1.00. This interpretation suggests that the questions in this questionnaire align well with the intended objectives, making them suitable for use. Therefore, the Thai versions of ICIQ-N and ICIQ-Nqol are considered good valid questionnaires. Cronbach's α coefficients are used to analyze Internal Consistency Reliability, aiming to estimate the degree to which all items in a questionnaire measure the same construct. If items measure the same construct, there will be high consistency in measurement, with Cronbach's α coefficients typically interpreted as follows: excellent ($\alpha \geq 0.9$), good ($0.9 > \alpha \geq 0.8$), acceptable ($0.8 > \alpha \geq 0.7$).[15] There is no clear-cut point for the coefficients, but generally, a value of ≥ 0.7 is considered acceptable.[16]

A low α value may stem from various factors such as a small number of items, use of negatively worded items, or use of scale items fewer than 5. [17] To improve Cronbach's α coefficients, adjustments can be made to the questionnaire. This may involve revising items to enhance their interrelatedness or removing some items altogether. It is essential to base these adjustments on theoretical grounds, ensuring that the questionnaire adequately covers the definition of what is being studied and that the items have been validated to meet acceptable standards.

Our study of ICIQ-Nqol has a Cronbach's alpha score 0.937 and 0.938, as an excellent level, see the findings from Funda Gungor Uğurlucan et al.'s study.[18] On the validation of the Turkish version of the ICIQ-LUTS quality-of-life, in their study, they calculated a Cronbach's Alpha value of 0.979, which falls within the category of excellent reliability ($\alpha \geq$ 0.9)15 and has 20 items in questionnaire and ICIQ-Nqol has 13 items in questionnaire. While the ICIQ-N has a lower Cronbach's alpha score 0.677 and 0.653 (questionable) and just has 4 items in the questionnaire. From study of Chattrakulchai K et al.[19] study about the Thai version of the ICIQ-FLUTS about female lower urinary tract symptoms that are high, with a Cronbach's alpha score of 0.849, they have 12 items in the questionnaire. It is shown that the number of items can affect Cronbach's alpha score and the reliability of the questionnaire. But it is not just any one factor that affects the Cronbach's alpha score. From the studyof Sriwat W.et al.[20] on the ICIQ-VS questionnaire in Thai version to assess the severity of pelvic organ prolapse has a vaginal symptom score (VSS) 0.75 and sexual matter score (SMS) 0.75 that is just in the acceptable range. Their questionnaire has 14 items. That is more items than Chattrakulchai K et al.'s study.[19]

From data analysis to determine the discrimination power of questionnaire items using the corrected item-total correlation (CITC), with a criterion of CITC > 0.2, we found that one question from the ICIQ-N questionnaire in 2nd test did not meet the threshold. This question had a CITC value of 0.197, indicating that it is not adequately correlated with the overall scale. This question about "how often have you urinated during the day?" This lack of correlation could be due to the scale of measurement not aligning with the other questions. This issue could be addressed by modifying the tone of the question to better align with the other questions. However, if the question already comprehensively covers the definition and objectives, it may not need modification.

Test-Retest Reliability is a method used to determine the coefficient of stability, which measures the consistency of scores from measurements taken at different time intervals. It involves administering the same questionnaire to the same group twice, with a gap in between. In our study, the 2nd test was conducted approximately 2 weeks after the 1st test. The scores obtained from both tests are then calculated to find the value using the Pearson product-moment correlation coefficient (r). According to our study, in Table 2, r = 0.817 in ICIQ-N and 0.929 in ICIQ-Nqol. A value of r close to +1.0 indicates that the tests conducted twice are positively correlated in the same direction. The interpretation suggests

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that the scores measured between the 1st and 2nd tests are significantly positively related at a high level ($p < 0.001$), indicating excellent reliability. This aligns with the study on ICIQ-FLUTS regarding female lower urinary tract symptoms of Angelo PH.,et al.[21] where the correlation coefficients between the test and retest among 80 participants have values for test-retest were 0.907 and 0.901. The correlation between ICIQ-FLUTS (score I - domain of urinary incontinence) with the ICIQ-SF (final score) was strong and positive (r = 0.836, $p = 0.000$). In the same direction as Hajebrahimi S., et al.[22] study about the Persian version of the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) as a standard questionnaire for assessment of urinary incontinence (UI) that have The Pearson Correlation Coefficient 0.93 indicating good agreement between the questionnaire and the urodynamic study.

In our study, the Pearson correlation coefficients were found to be r = 0.817 for ICIQ-N and 0.929 for ICIQ-Nqol. A correlation coefficient closes to +1.0 indicates that the scores from the two testing occasions are highly positively correlated. This suggests that the measurements taken at both time points are highly consistent and reliable ($p < 0.001$), indicating excellent reliability. Like the ICIQ-FLUTS on female lower urinary tract symptoms, the correlation coefficients between the test and retest among 136 participants for symptoms of filling, voiding, and incontinence were 0.925 ($p < 0.05$).[16]

Limitation

This study's population group, serving as subjects for questionnaire responses, is drawn from a hospital-based sample, including staff, patients, and their relatives, obtained through random sampling. The test and retest method necessitates repeating the questionnaire within another two-week period, leading to missing data, which in our study amounted to 35 individuals. The sample group able to undergo the questionnaire again in the second round mostly comprises hospital staff who are easily traceable and already working within the hospital premises. However, for practical application, we need to extend it to patients, a diverse population group beyond just hospital personnel. Thus, it is advisable to selectively choose a target population more representative of actual patients for future study enhancements. Additionally, data derived from questionnaire responses can be beneficial for gaining insights into nocturia conditions, beyond solely measuring the quality of the tool.

Conclusion

The Thai version of the ICIQ-N and ICIQ-Nqol are valid and reliable questionnaire for screening, evaluating bothersome effects to daily life from nocturia when applied to Thai patients with equivalent efficiency with the English version.

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