The use of consultation on Incontinence Questioner – Nocturia (ICIQ-N) in Indonesian population: an affirmation study [version 1; peer review: awaiting peer review]

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Abstract

Background: Nocturia is a urological condition in which individuals urinate more frequently than usual at night and it affects both genders. The clinician frequently uses questionnaires to diagnose nocturia however, some validated questions were in English. This study evaluated the validity of the International Consultation on Incontinence Questionnaire – Nocturia (ICIQ-N) in Indonesian patients.

Methods: Two certified bilinguals (English-Indonesian) translated the ICIQ-N questionnaire from English to Indonesian. The reverse translation was done by two certified bilingual (Indonesian-English) translators, and the writers reviewed all of the translations leading to the final Indonesian translation. Instead of a linguistic translation, this technique ensured a thorough and unambiguous intellectual translation. The translated ICIQ-N was presented twice to the subjects, two weeks apart, to verify the questionnaire. The responses' validity and reliability were then investigated. Pearson and Cronbach's alpha analysis were used to determine validity and reliability.

Results: The r-Pearson correlation values ranged from 0.933 to 1 (p:0.001). The translated ICIQ-N questioner items were found to be reliable with a Cronbach’s alpha of 0.994 (>0.6).

Conclusions: The ICIQ-N Indonesian version generated for this study is valid and reliable. As a result, it may be utilized as a diagnostic tool in Indonesian population.

Keywords
Nocturia, International Consultation on Incontinence Questionnaire, Incontinence
Introduction
Nocturia is a urological symptom in which patients wake up to urinate at night with more frequency than usual. Nocturia can affect both men and women. Patients can be said to have symptoms of nocturia if they experience episodes of awakening from sleep more than two times to urinate. According to the International Continence Society (ICS) 2022 definition, nocturia is a common and irritating medical disorder defined by the need to wake up to pass urine throughout the major sleep phase, with each urination followed by sleep or the intention to sleep. According to the International Consultation on Incontinence Research Society’s 2018 definition, waking up two or more times each night to void can also be deemed a clinically relevant definition.

Nocturia has traditionally been considered a male condition but is just as common in women as it is in men. In a population-based survey of 19,165 adults in five European countries, the overall prevalence of male respondents aged 18 years and over was 48.6% and 54.5% in women, when nocturia was defined as one night getting up to urinate. However, when nocturia was defined as 2 urination per night, the prevalence decreased to 20.9% in men and 24.0% in women. Although the prevalence of nocturia is higher in men and women with an older age of more than 70 years, nocturia itself is not only a disease that can be suffered by elderly patients. Two or more episodes of nocturnal urination have been reported in 2%-18% of adults aged 20-39 years. In Indonesia, a prevalence and risk factors study of nocturia involving 1,555 subjects from 7 cities in Indonesia showed that the prevalence of nocturia was 61.4%, of which 61.4% of them were men and 38.6% were women respectively, averaging at 55-65 years old.

Nocturnal polyuria (NP) is the overproduction of urine at night (more than 20%-33% of total 24-hour urine volume depending on age) and is a major contributing factor in nocturia cases. Congestive heart failure (CHF), diabetes, obstructive sleep apnea, peripheral edema, and high overnight fluid intake are all linked to NP. Abnormalities in the anti-diuretic hormone arginine vasopressin (AVP) secretion can also cause nighttime urine output. In the absence of recognized medical conditions, NP is characterized as a “syndrome.” and is likely to be caused by a disruption in the circadian release of AVP, which regulates urine production by increasing water absorption and urine concentration at night.

Nocturia is generally considered to be one of the hallmarks of lower urinary tract symptoms (LUTS), which includes overactive bladder (OAB) and symptoms associated with benign prostatic obstruction (BPO). However, although patients with LUTS frequently report nocturia, reports of previous clinical studies on the treatment of LUTS support the hypothesis that nocturia is not only a symptom of OAB and BPH but is a condition in itself, with multiple etiologies unrelated to the bladder or BPO. Although impaired bladder function or bladder outlet obstruction (BOO) may cause nocturia in some patients, non-urological factors may be the primary cause in most cases. Non-urological causes of nocturia include divergent factors such as hormonal imbalance, uncompensated heart disease, sleep problems, and lifestyle choices (e.g., fluid intake at bedtime). In addition to urological nocturia, bladder-associated bladder storage symptoms such as decreased bladder capacity and BOO may be associated with the kidneys and may manifest as excess urine production.

Patients with nocturia might have a significant reduction in their quality of life due to loss in both mental and physical health, which is predominantly caused by sleep disruption. Patients with nocturia had a higher mortality rate, a higher risk of falls and fractures, and a higher mortality risk as the number of voiding episodes during the night increased. As a result, managing such a troublesome ailment is a major concern for patients as well as a public health issue.

Nocturia is a multifactorial condition that needs to be approached comprehensively, hence needing a multidisciplinary approach for diagnosis and treatment. Some tools are available for clinical assessments, including questionnaires. European Association of Urology (EAU) strongly recommends the use of questionnaires, such as International Consultation on Incontinence Questionnaire Nocturia (ICIQ-N), International Consultation on Incontinence Questionnaire Nocturia Quality of Life Module (ICIQ-Nqol) and Nocturia Impact Diary (NI Diary).

The use of questionnaires as a symptom of nocturia is a common practice in the medical community. However, some of the validated questionnaires are only available in English. The selection of the ICIQ-N questionnaire in this study was based on the form of a questionnaire that was relatively short and easy to understand so that not too many questions were asked to patients, but the form of its validation in Indonesian is not yet available. This study was conducted to assess the validity of the ICIQ-N which was translated into Indonesian to assess the symptoms of nocturia in patients.

Methods
Study design
This is a cross-sectional affirmation study of translated ICIQ-N questionnaire that has been given to the patient with nocturia symptoms at the Urology Department, Cipto Mangunkusumo National General Hospital, Faculty of Medicine,
Universitas Indonesia. Ethical approval was granted by the Ethics Comitee Of The Faculty Of Medicine, Universitas Indonesia – Cipto Mangunkusumo Hospital (KET-901/UN2.F1/ETIK/PPM.00.02/2021). Written informed consent for publication of the participants data was obtained from the participants.

**Study population**
The inclusion criteria were all patients who had symptoms of nocturia who underwent treatment at RSUP Dr. Cipto Mangunkusumo Jakarta for the period September 2021 to January 2022. The exclusion criteria were all patients with a treatment period before September 2021, patients who had been declared cured during the study period and patients who refused to participate in this study.

**Translation and data collection process**
Two separate certified bilinguals (English-Indonesian) translators subsequently translated the ICIQ-N questionnaire from the English to Indonesian language. Two different independent certified bilinguals (Indonesian-English) translators did the backward translation, and then the authors critically assessed all of the translations to create the final Indonesian translated version. This approach was taken to ensure that the written form was a proper and clear intellectual translation rather than a linguistic one.

To avoid bias, the translated ICIQ-N questionnaire was given to each subject individually and separately. Following the test-retest technique for verifying the questionnaire, subjects responded to the translated ICIQ-N twice with a 2-week interval. The validity and reliability of the responses were then assessed and examined.

**Statistical analysis**
According to the cross-sectional study sample size formula, the minimal number of subjects for this study was 196. The sample size was calculated using the Lemeshow formula. The sample size was determined using a 95 percent confidence interval and an 80 percent power level. Using SPSS software version 23, this study assessed the validity and reliability of the translated ICIQ-N (IBM Corp., USA). Questions were declared valid when the p-value was less than 0.05. Based on the Pearson correlation coefficient, the correlation was divided into three groups (r). Cronbach’s alpha was used to estimate consistency among items in the instrument, and test-retest reliability was determined by comparing the pre- and post-tests with a two-week interval. A strong and consistent internal consistency is defined by an Alpha value greater than 0.6.

**Results**
The translated ICIQ-N questionnaire was evaluated in 200 people, with no dropouts, which consists of 99 (49.5%) men and 101 (50.5%) women.

All of the questions in this study attained 100% response rate. There were no complaints regarding the ICIQ-N questioner’s translated version, and all of the subjects understood both the linguistic and the meaning of the questions. The Pearson correlation r-value was used to assess validity statistically. The table’s r-value was then compared to the correlation value (0.1389) and if the correlation value is greater than the table’s r-value, the query was valid. All translated questions from the ICIQ-N questioner were legitimate in this study, with r-Pearson correlation values ranging from 0.933 to 1.0 (p < 0.001). Table 1 shows the Pearson correlation study of the Indonesian version of the ICIQ-N questioner.

With a Cronbach’s alpha score of 0.994 (>0.6), items from the translated ICIQ-N questioner were found to be reliable in this study’s reliability test. The test-retest reliability was assessed in this study by comparing the pre-and post-tests with a two-week interval between them. We also discovered that the correlation between the pre- and post-test was adequately high, with an r-value correlation coefficient of the overall score of 0.988, based on the calculations. Figure 1 illustrates the test-retest reliability result.

**Table 1. Pearson correlation of ICIQ-N.**

| Variable         | Pearson correlation | P-value  | r value (df = 198) | Conclusion               |
|------------------|---------------------|----------|--------------------|--------------------------|
| Question 1 (Test – Retest) | 1.000               | <0.001   | 0.1389             | Valid & Perfect reliability |
| Question 2 (Test – Retest) | 0.980               | <0.001   | 0.1389             | Valid & Excellent reliability |
| Question 3 (Test – Retest) | 0.933               | <0.001   | 0.1389             | Valid & Excellent reliability |
| Question 4 (Test – Retest) | 0.972               | <0.001   | 0.1389             | Valid & Excellent reliability |
Discussion

Nocturia is a common and uncomfortable medical ailment defined by the need to wake up in the middle of the night to pass urine. According to the International Continence Society, each voiding should be followed by sleep or the intention to sleep. Based on the International Consultation on Incontinence Research Society’s 2020, during the primary sleep phase, nocturia is described as the need to wake up to pass urine, with each pee being followed by sleep or the intention to sleep. Overproduction of urine at night (more than 20%-33% of total 24-hour urine volume depending on age) is known as nocturnal polyuria (NP) and has been demonstrated to be a major contributing factor in cases of nocturia.

We validated the ICIQ-N questioner by translating it to Indonesian language. We found that ICIQ-N in the Indonesian version has a distinctive value for its validity and reliability. The p-value of the Pearson correlation analysis for each question was less than 0.05, as shown in the results section. The results also demonstrated a high level of test-retest consistency. The test-retest analysis yielded an R-value of 0.988 and a Cronbach’s alpha score of 0.994 (>0.6), indicating high reliability. The reliability pattern can also be seen in the scatter plot diagram.

To the best of our knowledge, this is the first study of linguistic validation ICIQ-Nocturia questioner in Indonesia. A similar validation study was done by Mock et al. (2008), validating ICIQ-Nocturia in Atlanta. The study reported a similar result with this study, in which ICIQ-N had a strong validity in both men and women with nocturia. Another study that also analyses the validity of ICIQ-N was done by Abraham et al. (2004). The study also showed a good validation and reliability value of ICIQ-N, with Cronbach’s alpha score of 0.84 to 0.90 and r-value 0.74 to 0.82. The study also did questionnaire sampling twice with 1 week separation period.

A study of linguistic validation of all International Consultation on Incontinence including nocturia was carried out by McKown et al. (2010). The study validates the ICIQ in 16 different languages, showed a great comprehension rate, especially for nocturia which is 98.9%. Although a minor change was needed to improve clarity and cultural appropriateness. However, this study did not include Indonesian language as a translation choice.

The clinical impact of this study is significant, as nocturia is a common urologic symptom that can occur at any age in both sexes. The need for tools to evaluate this symptom is also important. Validation of the questionnaire in Indonesian makes it easier for medical personnel, especially physicians, to use the questionnaire because not all are fluent in English. Thus, this study provides a further potential use of translated ICIQ-N in Indonesia. However, limitation of this study is the fact that patients were selected randomly without looking at the primary cause of nocturia.

Conclusion

In conclusion, the Indonesian version of the ICIQ-N developed in response to this study is valid and reliable.

Data availability

Underlying data

Figshare: The use of consultation on incontinence questioner – nocturia (ICIQ-N) in indonesian population: an affirmation study. DOI: https://doi.org/10.6084/m9.figshare.19882393.v1
This project contains the following underlying data:

- Data 1: Raw data
- Data 2: Translated questionnaires

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

**Reporting guidelines**

Figshare. STROBE checklist for ‘The use of consultation on incontinence questioner – nocturia (ICIQ-N) in indonesian population: an affirmation study’. DOI: https://doi.org/10.6084/m9.figshare.19787650

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

**Author contribution**

Miftah Adityagama: Conceptualization, Data curation, Formal analysis, Writing – Original Draft Preparation, Writing – Review & Editing.

Harrina Erlanti Rahardjo: Methodology, Project administration, Supervision, Validation, Writing – Original Draft Preparation, Writing – Review & Editing.

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