

Validity and Reliability of the Thai Version of International Consultation on Incontinence Questionnaire-Male Lower Urinary Tract Symptoms-Long Form (ICIQ-MLUTS-LF)

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Background: Lower Urinary Tract Symptoms (LUTS) affect a person's quality of life significantly and are highly prevalent in aging male. However, appropriate tools for evaluating their severity and progression are lacking. There has been no tool to appropriately and sufficiently evaluate and validate their severity and progression.

Objective: To evaluate the validity and reliability of the Thai version of International Consultation on Incontinence Questionnaire-male lower urinary tract symptoms-long form (ICIQ-MLUTS-LF) questionnaire.

Materials and Methods: Questionnaire translation and validation were conducted according to the ICIQ website protocol. Content validity, internal consistency, and stability were assessed.

Results: Sixty-three men were included in the present study. The mean age of the participants was 68, with a range from 44 to 96 years. For reliability, Cronbach's alpha value was 0.954 and considered to have internal consistency. For test-retest reliability, the questionnaires were again filled by all participants two to four weeks later. The intraclass correlation was 0.974, demonstrating stability. Nocturia was the most prevalent symptom (98%). Urinary frequency was the most bothersome symptom.

Conclusion: The Thai version of ICIQ-MLUTS-LF is a valid and reliable tool for clinical application and research

Keywords: Questionnaire, Lower Urinary Tract Symptoms, LUTS, ICIQ, IPSS, AUASI

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There is an increasing prevalence of aging male around the world, and so are their urinary disorders. According to the 2019 European Association of Urology (EAU) guideline regarding male lower urinary tract symptoms (LUTS) assessment, incorporating questionnaires as a part of patient assessment is strongly recommended⁽¹⁾. There are many proposed and validated self-completed questionnaires. Currently, the American Urological Association (AUA) Symptom Index or the identical International Prostate Symptom Score (IPSS) is

recommended as a baseline assessment of symptom severity in men with LUTS⁽²⁾. However, there has been an increasing debate on the precision and accuracy of the IPSS since it does not entail other urinary symptoms, particularly storage symptoms such as incontinence, and post micturition dribble described by patients⁽³⁾.

In 1998, the ICI committee suggested the application of a standard questionnaire for universal integration and more convenient communication among the scientific subcommittees. The International Consultation on Incontinence Questionnaire (ICIQ) website (ICIQ.net) has collected several questionnaires including male lower urinary tract symptoms-long form (MLUTS-LF), developed by Donovan et al in 1996⁽⁴⁾. The MLUTS questionnaire was awarded grade "A" recommendation by the Symptom and Quality of Life Assessment Committee in the third ICI meeting in 2004⁽⁵⁾. Thus, MLUTS is a valid, reliable, and responsive instrument⁽⁵⁾. It has been translated and culturally adapted to several European and Asian languages⁽⁶⁾.

MLUTS-LF is an extended form of MLUTS that

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consists of 23 items. Twenty of which consist of two sections inquiring the presence of the symptoms and their intensity. Symptoms are scored on a scale of 0 to 4, with 0 being “never” and 4 being “always”. For intensity, the subject will mark on a visual analog scale of 1 to 10, with 0 being “no bother” and 10 being “most annoying”. The remaining three items have different structures and are scored 2 or 4. MLUTS-LF scores between 1 and 84. Higher scores signify worse symptoms. This questionnaire may be considered to cover most symptoms of prostatic hyperplasia, overactive bladder, and urinary incontinence, which is very useful for most patients who often presented with a wide spectrum of the disease. Furthermore, the questionnaire can be used to accurately evaluate pre- and post-treatment symptoms.

Materials and Methods

The following procedure was undertaken to validate the translated questionnaire:

Translation

After obtaining permission from the ICIQ website, courtesy of Dr. Nikki Cotterill, the MLUTS-LF was translated into Thai by native Thai foreign language instructors in the university who were fluent in English. Then, the questionnaire was translated back into English by native Thai foreign language instructors who were unaware of the original questionnaire. The back-translated questionnaires were analyzed in a meeting by a research team and translators. Finally, the questionnaire was sent to ICIQ Committee for Approval.

Content and face validity

The Thai version of the questionnaire was completed by 10 male volunteers who were having LUTS. After completing the task, they were interviewed and asked about the perception in the questionnaire whether they understood the content in each item. The interview was conducted to ask volunteers' perception.

Internal consistency

This was evaluated using Cronbach's alpha coefficient. A value of 0.70 or greater was considered acceptable for internal consistency.

Stability (test-retest reliability)

A test-retest analysis indicated whether the questionnaire measures the same sorts of things in the same person over a period of time. Participants

were asked to finish the questionnaire twice in a two to four weeks interval without any treatment given.

Data collection: Thai male patients aged above 18 years old in the urology clinic at Phramongkutklo Hospital were selected. Those who had intellectual or visual disability, being uncooperative, had abnormal urinalysis such as pyuria and hematuria, and unstable vital signs such as fever and hypotension were excluded. Participants were given the questionnaire for self-completion without a physician's assistance. After two to four weeks without any treatment or intervention, participants were appointed back to the clinic to complete the questionnaire again. Data were analyzed using SPSS version 15.0 statistical program. Internal consistency was determined by calculating Cronbach alpha coefficient. Test-retest reliability was analyzed with intraclass correlation coefficient (ICC). ICC values greater than 0.7 were accepted as satisfactory. The minimum acceptable value for Cronbach alpha coefficient was 0.7. A p-value of less than 0.05 was statistically significant.

According to Pourmomeny and Mazdak, Cronbach's alpha coefficient in their study was 0.819⁽⁷⁾. This is used for sample size calculation. Given $\alpha=0.05$, $Z_{\alpha/2}=1.96$ (two tail), P_u =Upper limit of population correlation=0.900, P_l =Lower limit of population correlation=0.745, $Z_u=1.472$, $Z_l=0.962$, $N=[(2(1.96))/(1.472-0.962)]^2+3=61.94$. As the result, the sample size should be at least 62.

Ethical approval

The present study was approved by the Institutional Review Board of Phramongkutklo Hospital (IRBRTA 518/2561).

Results

The questionnaire was reported easily understood by all 10 volunteers, thus implying content validity. Of the 63 participants ($n=63$), the mean age was 68. Most participants had university degree (53.9%), whereas the remaining (30.3%) had a high school diploma or (15.8%) an elementary school diploma. Every participant agreed that the questionnaire was clear and easy to complete without assistance. Regarding symptom domains, 97% had storage symptoms, 93.7% had voiding symptoms, 58.7% had urinary incontinence, and 73% had post-micturition dribble. Sixteen percent of participants had a history of urinary retention that required urethral catheterization. Nocturia was the most prevalent urinary symptoms with 98% of the participants, whereas urinary frequency was the most bothersome symptom.

Table 1. Correlation between each question and total score of Cronbach's alpha value of each question if item deleted

Symptoms	Corrected item-total correlation	Cronbach's alpha if item deleted
Frequency	0.453	0.954
Nocturia	0.289	0.954
Urgency	0.421	0.954
Urge urinary incontinence	0.439	0.954
Bladder pain	0.423	0.954
Stress urinary incontinence	0.474	0.954
Unexplained urinary incontinence	0.416	0.954
Hesitancy	0.288	0.954
Straining to urinate	0.499	0.954
Straining to continue urination	0.416	0.954
Position while urination	0.178	0.954
Strength of urinary stream	0.435	0.954
History of weak urinary stream	0.477	0.954
Strength of urinary stream, as in picture item	0.123	0.954
Intermittency	0.577	0.953
Dysuria	0.423	0.954
Incomplete emptying	0.541	0.953
Terminal dribbling	0.626	0.953
Post-micturition dribble	0.750	0.953
Nocturnal enuresis	0.444	0.954
Pad use	0.470	0.954
Double voiding	0.605	0.953
Urine retention	0.130	0.954

The Cronbach's alpha value in the present study, as shown in Table 1, was 0.954 (95% CI 0.937 to 0.969), which represented good internal consistency.

For test-retest reliability, the intraclass correlation coefficient was 0.974 (95% CI 0.964 to 0.982), as shown in Figure 1.

Discussion

LUTS, classified by the subcommittee of International Continence Society (ICS), are constellation of symptoms. They are categorized as storage symptoms, which include increased daytime frequency, urgency, nocturia of at least one episode per night, and urge incontinence, voiding symptoms, which include intermittent or slow urinary stream, splitting or spraying of the urine stream, straining, hesitation, and terminal dribble, and post-micturition symptoms, which include feeling of incomplete emptying and post-micturition dribble⁽⁸⁾. Their prevalence is age dependent and increasing recently⁽⁹⁾.

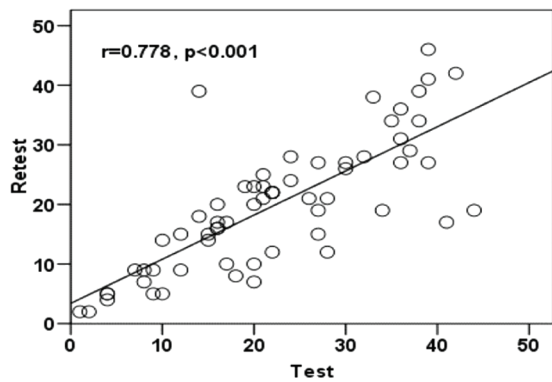


Figure 1. Correlation graph of the test-retest results.

LUTS, although not fatal, are considered bothersome by many patients since they negatively affect the quality of life⁽¹⁰⁾. For instance, LUTS may cause many patients frequent awakening at night leads to sleep deprivation and subsequently a decline in work or study performance. Multiple accesses to a lavatory during the day while working or traveling may also inevitably affect the individual's self-confidence⁽⁷⁾.

In many cultures, including Thai's, discussing about these symptoms is embarrassing for most people and thus history taking can be difficult⁽¹¹⁾. Furthermore, they may not be able to precisely determine which symptoms may annoy or interfere with their social, occupational, psychological, or even sexual aspects of daily routine lives^(11,12).

Given the dilemma described above, the self-administered patient-oriented questionnaires culturally adapted may provide patients with a better perspective about themselves and priorities in goal setting⁽⁷⁾. This also minimizes patient-physician bias⁽¹³⁾, a common scenario seen in clinical practice. Moreover, most patients find it easier to write down their problems than talking to physicians directly. The patient-oriented questionnaires are cheap, safe, easy to use, and focus on core symptoms effectively⁽⁷⁾.

The present study result showed that the Thai version of ICIQ-MLUTS-LF is a valid and reliable questionnaire for accessing urinary symptoms in Thai male patients. More than half of the study population suffered from urinary incontinence and almost three quarter from post-micturition dribble. The most prevalent domain was storage symptoms, which was consistent with other studies⁽¹⁴⁾. The Thai version questionnaire might be considered more thorough than the IPSS questionnaire since it also provides assessment of urinary incontinence, bladder sensation, urethral sensation, pad use, strength of urinary stream,

and history of urinary retention. Moreover, there has been increasing debate on the precision and accuracy of the IPSS⁽¹⁵⁻¹⁷⁾. It does not comprehensively assess all LUTS, particularly storage symptoms such as incontinence, as described by patients⁽¹⁷⁾. In the EpiLUTS study, it emphasized that LUTS should be taken with a more holistic approach beyond an organ-specific focus and the interaction of the whole urinary system in both men and women, and it suggested that all these symptoms should be evaluated completely⁽¹⁴⁾. This emphasizes the importance of MLUTS-LF.

There are limitations in the present study. First, the study was conducted in a military hospital, where most participants obtained a university degree. Therefore, the results might vary when conducted in population with lower education level. Second, the number of the participant was quite low, it might not provide solid evidence to represent a larger population.

Conclusion

Thai version of ICIQ-MLUTS-LF is a valid and reliable tool for assessing male patients with LUTS.

What is already known on this topic?

IPSS and AUA Symptom Index have long recommended the questionnaire for assessing men with LUTS and has been translated into many languages including Thai. However, there are increasing debates regarding its accuracy and efficacy due to a lack of other symptoms' assessments such as post-micturition dribble, bladder and urethral sensation, and incontinence.

What this study adds?

The Thai version of ICIQ-MLUTS-LF is a valid and reliable questionnaire for assessing men with LUTS and can be used in both research and clinical aspects.

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Conflicts of interest

The authors declare no conflict of interest.

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