Validity and Reliability of the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form and Its Correlation With Urodynamic Findings

Sakineh Hajebrahimi,[1] Davoud Nourizadeh,[2] Roghayeh Hamedani,[2] Mohammad Zakaria Pezeshki[3]

[1]Department of Urology, Iranian Center for Evidence-Based Medicine, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran
[2]Department of Urology, Imam Reza Hospital, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran
[3]Department of Community Medicine, Iranian Center for Evidence-Based Medicine, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

Corresponding Author:

Davoud Nourizadeh, MD
Department of Urology, Imam Reza Hospital;
Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

Tel: +98 411 335 7328
Fax: +98 411 335 7328
E-mail: davoudnourizadeh
@yahoo.com

Purpose: To validate 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).

Materials and Methods: After translation and back translation of the questionnaire, the harmonized translation was pre-tested in a pilot study on 28 patients. The final Persian version of the ICIQ-UI SF was administered to 123 consecutive patients aged ≥ 16 years complaining of UI. The psychometric aspects of the questionnaire, such as reliability and construct validity, were assessed and compared with full urodynamics study's findings as the gold standard diagnostic test.

Results: Mean age of the participants was 46.30 ± 13.14 years (range, 16 to 72 years). Based on ICIQ-UI SF, the prevalence of mixed urinary incontinence, stress urinary incontinence and urgency urinary incontinence was 35%, 34.1%, and 30.9%, respectively. Cronbach's alpha coefficient was calculated 0.75, which indicates the high reliability of this questionnaire in determination of UI. The obtained Weighted Kappa Index in determining the value of the test-retest was 0.70, and Pearson Correlation Coefficient was calculated 0.93 and intra-class correlation coefficient was 0.84.

Conclusion: Persian version of ICIQ-UI SF is a simple, valid, and reliable method for evaluation of patients with UI. Significant correlation exists between ICIQ-UI SF score and urodynamics parameters.

Keywords: urinary incontinence, validation studies, questionnaires, translating, diagnosis

INTRODUCTION

Urinary incontinence (UI) is a major health problem worldwide, with a 5% to 72% prevalence rate, depending on the study.[1] Age, vaginal delivery, obesity, menopause, smoking, chronic cough, constipation, and previous pelvic surgery are among its primary risk factors.[1,2] Appropriate diagnosis and assessment of UI is crucial for its treatment. To cure or improve the symptoms of UI, a standard definition is necessary. This is due to growing interest in clinical evaluation with subjective methods. Various different questionnaires have been used to assess and diagnose UI, each with advantages and disadvantages. Few diseases-related quality of life (QOL) questionnaires have been developed for clinical practice, and most are too long and unclear.

The International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) consists of 6 questions developed by the International Consultation on Incontinence. The original version is in English and has been translated into 26 other languages, including Spanish,[3] Chinese,[4] Turkish,[5] Arabic,[6] Portuguese,[7] Japanese,[8] and Taiwanese.[9] A valid and reliable questionnaire may prevent the need for unnecessary UI studies.[10] In prior reports, the ICIQ-UI SF has been translated and validated for initial diagnosis, management, and patient's follow-up.[11-15] It can be used as a self-administrated questionnaire or can be administered by the physician.[14] The ICIQ-UI SF has not yet been translated into Persian; therefore, its reliability and validity have not been assessed in Iran, which has a UI prevalence of 23.5%.[2] Urodynamic studies are performed to investigate the function of the lower urinary tract and are relatively expensive, time-consuming, and invasive. A less complicated method for determining this urodynamic information would therefore benefit the patient.

For this cross-sectional study, the ICIQ-UI SF was translated into Persian according to the ICIQ and reliability protocols. The questionnaire was filled out for patients with UI, and the results were compared with the clinical urodynamic findings of the same patients. The aims of our study were to translate the ICIQ-UI SF into Persian with appropriate cultural adaptations, validate it for clinical and research practices in Persian-speaking countries, and evaluate its correlation with urodynamic studies.

MATERIALS AND METHODS

Using the ICIQ-UI SF (Appendix), the data were obtained from 123 consecutive patients with UI referred to the Female Urology Clinic at Tabriz University of Medical Sciences from May 2008 to June 2009. A written informed consent was obtained from each participant. The patients were excluded if they were pregnant, breast-feeding, or younger than 16 years.

The original ICIQ-UI SF was translated into Persian by 2 bilingual experts. In the case of disagreement between the translators, we asked for a third opinion from another expert. The English and Persian versions were reviewed by 2 physicians who were aware of the research aims. The Persian translation was then back-translated into English by 2 native English speakers (fluent in Persian), who were unaware of the research objectives of this study. After the grammatical corrections, the Persian version was evaluated by a committee of 5 bilingual health workers. To observe the appropriate translation methodology, the back-translation of the questionnaire was sent to the ICI advisory board for review in England. This was to ensure that the content of the translation remained consistent with the original version.

A pilot test was conducted on 28 patients with pretested UI using the Persian translated ICIQ-UI SF to assess reliability and validity. The questionnaire was read to the patient and filled out by the physician for this study. To determine content validity, the patient responses were analyzed based on previously validated results from the pre-translated original ICIQ-UI SF. Concurrent validity, a core criterion of this study, was investigated by cross-validating the results of the ICIQ-UI SF with the urodynamic results. Because urodynamic studies are considered to have high validity, they were used here as a criterion standard, making it possible to estimate the sensitivity and specificity of the questionnaire assessment. The purpose of this study was not to assess the diagnostic value of the ICIQ-UI SF. For this reason, sensitivity and specificity were estimated as a measurement of concurrent validity. The questionnaire was administered at

2 separate times with an interval of 1 week to ensure lack of recall-induced agreement.

According to the results of the pilot study, some of the patients did not understand question 4 regarding QOL. We attributed this to cultural reasons. Therefore, we made a second pretest to improve the cultural implications of this question.

The results of the pilot and main studies were separately analyzed. For the pilot study, the Cronbach alpha coefficient was calculated to assess the reliability of the questions, and the Weighted Kappa Index and Pearson correlation coefficient were calculated to determine the test-retest value. To evaluate the correlation between the results of the questionnaire and the urodynamic, the Pearson coefficient was calculated, with $P < .05$ considered statistically significant.

The construct validity was evaluated by comparison of the Persian version of the ICIQ-UI SF with the urodynamic studies. Validity of the Persian ICIQ-UI SF was determined by its ability to distinguish between different types of UI, including stress (SUI), urgency (UUI), and mixed (MUI). To assess the predictive ability of the questionnaire, true positives, false positives, true negatives, false negatives, sensitivity, and specificity were calculated for each of these UI disorders. A full urodynamic study, including filling and voiding cystometry and Valsalva leak point pressure, was performed using a Laborie Delphis B urodynamic system, with the patient in a sitting position according to International Continence Society standards.

RESULTS

One hundred and twenty-three women with some degree of UI in the previous 4 weeks were enrolled in this study. The mean patients' age was 46.30 ± 13.14 years (range, 16 to 72 years). More than 68% of the participants had low levels of literacy.

The mean questionnaire scores of the patients are shown in Table 1. According to the ICIQ-UI SF, 43 (35.0%) patients had MUI, 42 (34.1%) had SUI, and 38 (30.9%) had UUI. Based on the urodynamic and stress test results, 6 (4.9%) patients had MUI, 38 (30.9%) had SUI, and 63 (51.2%) had UUI. Overflow incontinence was reported in 11.3% of the patients, including 9 (7.3%) with underactive detrusor, 2

Table 1. Average questionnaire scores.

Number of question	Mean score	Standard deviation
1st	3.52	1.27
2nd	3.9	1.81
3rd	7.85	2.35
Total score	16.6	4.07

(1.6%) with acontractile detrusor, and 2 (1.6%) with bladder outlet obstruction. Three (2.4%) subjects had normal urodynamics study. Patients who had more severe symptoms of UI tended to exhibit higher ICIQ-UI SF scores.

The Cronbach alpha coefficient was 0.75, indicating a high level of reliability of this questionnaire in determining UI. The Weighted Kappa Index between the results of the initial questionnaire and the translated version was 0.70. The Pearson correlation coefficient was 0.93, and the intraclass correlation coefficient was 0.84, indicating good agreement between the questionnaire and the urodynamic study. The sensitivity, specificity, and confidence intervals are presented in Table 2.

DISCUSSION

The Persian version of the ICIQ-UI SF demonstrated good diagnostic capabilities for patients with UI. No floor or ceiling effects were observed, suggesting that it enabled discrimination among an adequate range of UI conditions. As expected, the patients with more severe symptoms of UI tended to score higher than those with less severe symptoms. The Persian version showed good internal consistency and test-retest reliability, suggesting that it can be effectively and efficiently used for patients with UI.

The construct validity was analyzed by measuring the correlations between the final ICIQ-UI SF score and a clinical urodynamic study. There was generally a moderate association between the two approaches. This was not entirely expected, as they do not evaluate identical issues, but related issues instead. We observed a significant correlation between the final ICIQ-UI SF score and the urodynamic study ($P < .01$).

The questionnaire measured an MUI with a sensitivity of 0.84 (95% confidence interval: 0.65 to 0.94) and a UUI with

Table 2. Comparison of questionnaire results with urodynamics study.*

Type of incontinence	Sensitivity (95% CI)	Specificity (95% CI)
MUI	0.84 (0.653 to 0.936)	0.78 (0.689 to 0.85)
UUI	0.525(0.402 to 0.645)	0.953 (0.871 to 0.984)
SUI	0.636 (0.466 to 0.778)	0.826 (0.736 to 0.89)

*CI indicates confidence interval; MUI, mixed urinary incontinence; UUI, urgency urinary incontinence; SUI, stress urinary incontinence.

a sensivity of 0.53 (95% confidence interval: 0.40 to 0.65). One possible explanation for this discrepancy may be that women with UI may adapt their lifestyles to avoid situations of physical exertion, and a total QOL scale may be sufficient due to the comparison of the questionnaire with a criterion standard.

Definition of QOL seems to be different in various cultures. Patients with low levels of literacy had problems understanding the QOL scale in the pilot study. For this reason, we changed the number scale for these patients to a visual scale, but the results were not completely satisfactory and we sometimes had to explain the questions.

The ICIQ-UI SF has been translated into more than 26 languages and is used worldwide as a common instrument for assessing the symptoms and QOL of patients with UI.[11] Our work represents the first valid and reliable incontinence questionnaire in Persian-speaking countries. Using this method, the outcomes of studies on UI conducted worldwide can be compared on the basis of a common index. The ICIQ-UI SF consists of only 3 scored questions and is therefore not time-consuming for the patient. The simplicity of this method renders it especially useful for clinical practice, where time and resources are limited. However, because a short questionnaire cannot always provide detailed information about symptoms and QOL,[12,13] other assessment measures may be necessary.

CONCLUSION

The Persian version of the ICIQ-UI SF is a reliable and valid tool for the assessment of patients with UI.

ACKNOWLEDGEMENTS

CONFLICT OF INTEREST

None declared.

REFERENCES

1. Nitti VW. The prevalence of urinary incontinence. Rev Urol. 2001;3 Suppl 1:S2-6.

2. Hajebrahimi S, Madaen SK. Prevalence of urinary incontinence in Tabrizian women. Iranian J Urol. 2001;61-4.

3. Espuna Pons M, Rebollo Alvarez P, Puig Clota M. [Validation of the Spanish version of the International Consultation on Incontinence Questionnaire-Short Form. A questionnaire for assessing the urinary incontinence]. Med Clin (Barc). 2004;122:288-92.

4. Huang L, Zhang SW, Wu SL, Ma L, Deng XH. The Chinese version of ICIQ: a useful tool in clinical practice and research on urinary incontinence. Neurourol Urodyn. 2008;27:522-4.

5. Cetinel B, Ozkan B, Can G. The validation study of ICIQ-SF Turkish version. Turkish J Urol. 2004;30:332–8.

6. Hashim H, Avery K, Mourad MS, Chamssuddin A, Ghoniem G, Abrams P. The Arabic ICIQ-UI SF: an alternative language version of the English ICIQ-UI SF. Neurourol Urodyn. 2006;25:277-82.

7. Tamanini JT, Dambros M, D'Ancona CA, Palma PC, Rodrigues Netto N, Jr. [Validation of the "International Consultation on Incontinence Questionnaire -- Short Form" (ICIQ-SF) for Portuguese]. Rev Saude Publica. 2004;38:438-44.

8. Gotoh M, Homma Y, Funahashi Y, Matsukawa Y, Kato M. Psychometric validation of the Japanese version of the International Consultation on Incontinence Questionnaire-Short Form. Int J Urol. 2009;16:303-6.

9. Chang SR, Chen KH, Chang TC, Lin HH. A Taiwanese version of the International Consultation on Incontinence Questionnaire--Urinary Incontinence Short Form for pregnant women: instrument validation. J Clin Nurs. 2011;20:714-22.

10. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn. 2004;23:322-30.

11. Espuna-Pons M, Dilla T, Castro D, Carbonell C, Casariego J, Puig-Clota M. Analysis of the value of the ICIQ-UI SF questionnaire and stress test in the differential diagnosis of the type of urinary incontinence. Neurourol Urodyn. 2007;26:836-41.

12. Seckiner I, Yesilli C, Mungan NA, Aykanat A, Akduman B. Correlations between the ICIQ-SF score and urodynamic findings. Neurourol Urodyn. 2007;26:492-4.

13. Tamanini JT, Dambros M, D'Ancona CA, Palma PC, Rodrigues-Netto N, Jr. Responsiveness to the Portuguese version of the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) after stress urinary incontinence surgery. Int Braz J Urol. 2005;31:482-9; discussion 90.

14. Klovning A, Avery K, Sandvik H, Hunskaar S. Comparison of two questionnaires for assessing the severity of urinary incontinence: The ICIQ-UI SF versus the incontinence severity index. Neurourol Urodyn. 2009;28:411-5.

15. Kieres P, Rokita W, Stanislawska M, Rechberger T, Galezia M. [The diagnostic value of chosen questionnaires (UDI 6SF, Gaudenz, MESA, ICIQ-SF and King's Health Questionnaire) in diagnosis of different types of women's urinary incontinence]. Ginekol Pol. 2008;79:338-41.

پرسشنامه   ICIQ-UI SF

بسیاری از مردم گاهی وقتها دچار نشت ادراری می شوند.ما سعی می کنیم تا بدانیم چه تعداد از مردم نشت ادراری دارند وچقدر این مسئله برای آنها ناراحت کننده است.ما خوشحال می شویم که شما بتوانید با یادآوری وضعیت خود در چهار هفته گذشته، به سوالات زیر پاسخ دهید.

| ۱ | تاریخ تولد:

| ۲ | مرد ☐   زن☐

| ۳ | هر چندوقت یکبار نشت ادراری دارید؟
- ۰- هرگز ☐
- ۱- حدود یک بار در هفته ☐
- ۲- ۲-۳ بار در هفته ☐
- ۳- یکبار در روز ☐
- ۴- چندین بار در روز ☐
- ۵- همیشه ☐

| ۴ | میزان نشت ادراری شما چقدر است؟ آیا از پوشک و... استفاده می کنید؟
- ۰- نه ☐
- ۱- مقدارکم ☐
- ۴- مقدار متوسط ☐
- ۶- مقدار زیاد ☐

| ۵ | نشت ادراری چقدر کیفیت زندگی شما را تحت تاثیر قرار داده است؟

هیچ | ۰ ۱ ۲ ۳ ۴ ۵ ۶ ۷ ۸ ۹ ۱۰ | فوق العاده

| ۶ | نشت ادراری شما در چه زمانی اتفاق می افتد؟
- ☐ هرگز
- ☐ درست قبل از اینکه خود را به توالت برسانید
- ☐ وقتی سرفه یا عطسه می کنید
- ☐ وقتی خواب هستید
- ☐ وقتی فعالیت بدنی یا ورزش می کنید
- ☐ نشت وقتی که دفع ادرار تمام شده ومی خواهید لباس زیرتان را بپوشید. بلافاصله بعد از تمام شدن دفع ادراری
- ☐ بدون دلیل مشخص
- ☐ همیشه

مجموع امتیازات: ۵ + ۴ + ۳ = ...