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Original Article

Obstetrics and Gynaecology Section

Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6): Translation and Psychometric Validation of the Iranian Version

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ABSTRACT

Introduction: Urinary incontinence is a common health, physical, and social problem in the world. There is an urgent need of effective questionnaires for its evaluation in Iranian women.

Aim: The present study aimed to assess validity and reliability of the adapted and translated version of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) in the Persian language.

Materials and Methods: This cross-sectional study was conducted from April to October 2015. A sample of 200 consecutive women who participated in this study filled the final version of the questionnaires. Eligible samples were divided into two groups (with and without UI). Standard forward-backward procedure was applied for translating the questionnaires into Persian. Reliability was assessed using test/retest reliability and internal consistency. In addition, validity was evaluated using face and content validity, comparison with known groups, and convergent validity.

Results: Two hundred women participated in this study and filled both the questionnaires. Both the normal and incontinent groups had 100 subjects. Mean age of the respondents was 47.52±9.84 years. The content validity analysis produced favourable results. IIQ and UDI successfully discriminated the two groups. There was a significant negative correlation between the two questionnaires and all subscales of the Short Form Health Survey (SF-36). The Cronbach's alpha coefficient for UDI-6 and IIQ-7 was 0.88 and 0.95, respectively. The Intraclass Correlations (ICC) scores for the Persian language versions were 0.96 for UDI-6 and 0.97 for IIQ-7.

Conclusion: This study demonstrated that the newly developed Persian language version of IIQ-7 and UDI-6 are short, valid, and reliable methods for assessing the quality of life of women with UI.

Keywords: Health-related quality of life, Iran, Reliability, Validity

INTRODUCTION

Urinary Incontinence (UI) is a common health, physical, and social problem in the world, which affects all ages, groups, and communities with high prevalence [1,2]. Although not life threatening, UI affects psychological, social, familial, occupational, physical, and sexual aspects of life, often leading to anxiety, shame, and isolation [3-7]. Epidemiological studies have shown that UI significantly affects the quality of life [8-11]. Health-related quality of life is a broad and multidimensional concept that cites the overall health of a person, including physical, social, and emotional health and can be assessed from both an objective and a subjective view [12]. Disorders of the quality of life can lead to anxiety problems. However, UI may affect individuals in different ways. Quality of life is one of the most important outcome measures while assessing the burden of the disease and response to therapy. A valid and reliable questionnaire is key to any investigation of the association between UI and the quality of life [13].

Today, measuring the impacts of symptoms severity on the quality of life has become widespread, and the use of questionnaires by researchers and clinicians continues to increase. Several useful questionnaires have been used to assess the quality of life of patients with UI. Although these are valuable for assessing the quality of life, such general questionnaires may not be sensitive enough to fully assess the effects of various aspects of the disease [14]. Because UI is common among Iranian women [15,16], there is an urgent need of such effective questionnaires in Iran. Thus, assessment of the quality of life in Iranian women with UI is very important. IIQ and UDI, which are recommended by the International Consultation on Incontinence, are brief, valid, and widely used questionnaires that assess the effect of symptom severity and subjective aspects of UI on the quality of life of patients [17]. Both IIQ and UDI are available in many languages except Persian [18-20] and other language versions cannot be used in Persian women. Impact of incontinence may vary significantly between countries and amongst different ethnic groups, and even in cultural and religious groups within the same countries, therefore the tools should be native to this aspect, because of this the present study was conducted with an aim to assess validity and reliability of the adapted and translated versions of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) in the Persian language.

MATERIALS AND METHODS

This cross-sectional study was conducted in patients who were referred to the Urogynecology clinic of Imam Khomeini Hospital, a tertiary referral center affiliated to the Tehran University of Medical Sciences from April to October 2015. The ethics committee of the Tehran University of Medical Sciences approved the study with number code 2726. All participants provided written informed consent. Each participant completed the questionnaire in a private environment. Personally, identifiable information regarding the participants were kept confidential. The number of samples needed to conduct a validation study is usually based on a rule of thumb (5-10 participants should be recruited for every item of the instrument) [21]; so 200 people were enough to cover this criterion. A sample of 200 consecutive women who participated in this study filled the final version of the questionnaires.

Eligible samples were divided into two groups. Those who complained of UI were assessed with urodynamics. Of these patients, those with confirmed UI entered the UI group. Those subjects who had no complaints of UI entered the normal group. The inclusion criteria were Iranian women, 20 years of age or older, able to read and write, and not pregnant. Those with reversible causes of UI, functional disability, mental disorders, and comorbidities were excluded.

Questionnaires and Scoring

IIQ is a widely accepted, contextual, self-reported quality of life questionnaire for women with UI. This questionnaire contains 30 items and four different domains. A shorter version of this questionnaire is available, which is an alternative to the IIQ-30 that consists of 7 questions. IIQ-7 includes four domains: physical activity (items 1–2), travel (items 3–4), social relationships (item 5), and emotional health (items 6–7). Internal consistency was high for all domains of questionnaires. Test- retest reliability was not assessed. Whereas the long version of UDI contains 19 items and 3 domains that assess the impact of UI on individuals, the shorter version consists of six items and three different domains, namely irritative symptoms (items 1–2), stress symptoms (items 3–4), and obstructive/discomfort symptoms (item 5–6). Each item of both these questionnaires is scored on a four-point scale. Higher scores indicate more severe symptoms and lower quality of life. Raw scores for each item are then transformed, which gives a score ranging from 0 to 100 for each item [22].

Translation

Permission for developing the Iranian version of IIQ and UDI was taken from the main author (Shumaker). Standard forward-backward procedure was applied for translating the questionnaires into Persian (the language spoken in Iran). Two independent qualified translators who were fluent in English translated the questionnaires from English to Persian. After thorough evaluation, two forward versions were prepared. The differences between the two versions were identified and unit forward versions of the questionnaires were created. Then two translators, native in English and fluent in Persian (different from the first two translators), translated the forward version into English. These translations were compared with the original version. Finally, a panel of experts consisting of gynecologists, midwives, psychometric experts, researchers, and translators reevaluated the questionnaire for cultural adaptation, wording, and grammar. After careful review, few changes were made and interim versions of the questionnaires were created. The translation process was generally error-free.

The Content Validity Ratio (CVR) and Content Validity Index (CVI) were used to quantitatively assess content validity. For assessing CVR, questionnaire was given to 10 experts who were asked to grade each item on a three-point Likert scale: (i) essential; (ii) useful but not essential; (iii) not necessary. According to Lawshe CH, each item with a CVR above 0.62 was selected [23]. For calculating CVI, the same panel of experts was asked to comment on the relevance, clarity, and simplicity using a four-point scale.

To evaluate the linguistic pattern of the questionnaires, the interim versions of both the questionnaires were distributed to 20 women with UI. The mean time to complete both questionnaires was 8.5 minutes (SD = 1.3), and 93% of the patients did not have any difficulty in completing these questionnaires and stated that the questionnaires were easily understood. The patients' comments were collected and minor corrections were made.

STATISTICAL ANALYSIS

Validity

Known group comparison was used to assess how well the questionnaires differentiated between subgroups of women who differed in continence as confirmed by the urodynamic study. For independent comparisons, the *t*-test was used. It was expected that the normal group would have a better score than those who were suffering from UI.

Convergent Validity

Convergent validity was performed between IIQ-7, UDI-6, and the Iranian version of SF-36 [24]. SF-36 contains 36 items and eight subscales, namely physical functioning, role limitation due to physical problems, role limitation due to emotional functioning, social functioning, mental health, vitality, pain, and general health. The Pearson's correlation coefficient (r) between the questionnaires was computed (r= 0.7–1.0, excellent; 0.61–0.80, very good; 0.21–0.40, fair; and 0.20 poor).

Reliability

Internal consistency: Internal consistency was computed by the Cronbach's alpha coefficient ranged from 0 to 1. Alpha equal to or greater than 0.70 was considered satisfactory.

Test-retest: Test-retest reliability was assessed using the ICC. For this, 20 patients completed the questionnaire two weeks apart and the ICC was calculated. The following criteria were used for interpretation: 0.0–0.20, small; 0.2–0.40, fair; 0.41–0.6, moderate; 0.61–0.80, substantial; 0.81–1.0, perfect.

RESULTS

Demographic Characteristics of the Study Sample

All, 200 women participated in this study and filled both questionnaires. Both the normal and incontinent groups had 100 subjects. There were no missing items (0%) and no participant was excluded. Demographic characteristics of the study sample are shown in [Table/Fig-1].

Age	Total	Urinary incontinence	Normal	p
	No (%)	No (%)	No (%)	
Mean(SD)	47.52(9.84)	47.77(9.12)	47.28(10.55)	0.23
Education				
Elementary	71(35.5)	44(44)	27(27)	0.99
Secondary	115(57.5)	50(50)	65(65)	
Higher	14(7)	6(6)	8(8)	
Employment				
Employed	42(21)	10(10)	32(32)	<0.001
Housewife	158(79)	90(90)	68(68)	
BMI				
<18.50	-	-	-	<0.001
18.50-24.99	77(38.5)	32(32)	45(45)	
25-29.99	101(50.5)	64(64)	37(37)	
≥30	22(11)	4(4)	18(18)	
Menopause				
Yes	82(41)	43(43)	39(39)	0.26
No	118(59)	57(57)	61(61)	
Mode of delivery				
No delivery	2(1)	-	2(2)	0.44
NVD*	153(76.5)	79(79)	74(74)	
C/S**	30(15)	14(14)	16(16)	
Both of them	15(7.5)	7(7)	8(8)	
Multiple Pregnancy				
Yes	3(1.5)	1(1)	2(2)	<0.001
No	197(98.5)	99(99)	98(98)	

[Table/Fig-1]: Demographic characteristics of the study sample.
*NVD- Normal Vaginal Delivery, **C/S- Caesarean Section

Questionnaire	Urinary incontinence	Normal	p
	Mean (SD)	Mean (SD)	
IIQ-7	50.14(17.87)	0.52(2.01)	<0.001
UDI-6	46.33(15.73)	8.27(5.98)	<0.001

[Table/Fig-2]: Known group comparison.

Content Validity

The content validity analysis produced favourable results. The CVR score was 0.74, indicating a satisfactory result. The CVI score was 0.88, which indicated an acceptable level of agreement.

Known Group Comparison

[Table/Fig-2] shows the results of the comparisons of IIQ and UDI scores of the normal and incontinent groups. IIQ and UDI successfully discriminated the two groups that differed in continence (p< 0.001).

Convergent Validity

The convergent validity of Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) is shown in [Table/Fig-3]. As expected, there was a significant negative correlation between the two questionnaires and all subscales of SF-36. The Pearson's correlation coefficient for IIQ-7 and UDI-6 varied between 0.02–0.74 and 0.27–0.74, respectively.

Reliability

The Cronbach's alpha coefficient for UDI-6 and IIQ-7 was 0.88 and 0.95, respectively, indicating satisfactory internal consistency. The alpha values for all subscales are shown in [Table/Fig-4]. The ICC scores for the Iranian versions were 0.96 for UDI-6 and 0.97 for IIQ-7, indicating good test re-test reliability. The ICC scores for all subscales are shown in [Table/Fig-4].

DISCUSSION

In this study, we performed psychometric validation of the Iranian versions of IIQ-7 and UDI-6. These questionnaires are condition specific instruments and have greater sensitivity to change and so have a deeper assessment of the quality of life [17]. Our results showed that the Iranian version of both the questionnaires are psychometrically strong and can be used to reliably and accurately measure the quality of life of women with UI and that the questionnaires can be used in clinical settings as well as for research purposes.

The CVI and CVR scores of both the questionnaires revealed acceptable content validity. These questionnaires were easy to read and understand. In many other studies content validity has not been measured [19,20,25]. Cam C et al., assessed content validity by an expert panel and level of missing data were considered as a characteristic for inappropriate questions [18]. The reliability of the newly developed Persian version of the method was comparable to that of the original method. The Cronbach's alpha coefficient for UDI-6 and IIQ-7 was 0.88 and 0.95, respectively. The ICC scores for the Iranian versions were 0.96 for UDI-6 and 0.97 for IIQ-7. In the original version, Shumaker SA et al., assessed Cronbach's alpha coefficient, but did not assess test retest reliability [17]. In a study by Utomo E et al., Cronbach's alpha was 0.49 for UDI-6 and 0.87 for IIQ-7 [25] which is lower than our study. In their study ICC was 0.84 for UDI and 0.76 for IIQ [25]. In another study in China, Cronbach's alpha for UDI-6 and IIQ-7 was 0.80 and 0.93 and ICC was 0.72 and 0.75 [19] which is similar to our study. In this study, significant negative correlation was found between IIQ-7, UDI-6, and SF-36, indicating convergent validity, which means higher scores of IIQ and UDI represent more liberating symptoms, and is therefore associated with lower quality of life scores. The results of this study suggested that the quality of life of those who had severe symptoms was poor. This is consistent with the report of Cam C et al., who found that higher UDI and IIQ scores were correlated with poor general health of the affected women [18]. These results were also found in another study by Chan SS et al., [19].

	Cronbach's alpha	ICC
UDI-6	0.88	0.96
Irritative	0.60	0.90
Stress	0.80	0.96
Obstructive/discomfort	0.78	0.90
IIQ-7	0.95	0.97
Physical activity	0.77	0.91
Travel	0.93	0.98
Social/ relationship	-	0.91
Emotional health	0.89	0.90

[Table/Fig-4]: Reliability of Iranian version of pelvic organ prolapse/urinary incontinence sexual Questionnaire.

Discriminant validity as assessed with known group comparison analysis showed that the Iranian versions of IIQ-7 and UDI-6 are valid methods for measuring the symptom severity. Since these methods are able to clearly discriminate between women who differed in continence, the questionnaires can be used in clinical practice. El-Azab AS in Arabic validation of IIQ and UDI showed that women in normal group have lower scores in both questionnaires and this difference was statistically significant (p< 0.05) [20].

LIMITATION

This study has several limitations that need to be addressed. First, in this study the assessment of responsiveness has not been measured. Second, this study was conducted only in the women's group. Finally, this study was conducted in a referral center and the symptoms of the group of patients may be more severe in this study, Therefore, the results of this study may be limited in generalization elsewhere. However, this study has several strengths such as the design involving two groups of patients confirmed by valid diagnostic test and control groups.

CONCLUSION

The present study aimed to prepare the Persian version of the IIQ and the UDI and to provide evidence for psychometric properties to enable their use in clinical settings and for research purposes. It can help researchers and health professionals to provide data for clinical practice, research and optimal treatment. The results of this study demonstrated that the newly developed Persian version of IIQ-7 and UDI-6 are short, valid, and reliable methods for assessing the quality of life of women with UI.

	SF-36								
	Physical functioning	Role- physical	Bodily pain	General health	Vitality	Social functioning	Role-emotional	Mental health	SF- 36
IIQ-7	-0.40	-0.18	-0.74	-0.42	-0.53	-0.52	-0.02	-0.60	-0.49
UDI-6	-0.49	-0.27	-0.73	-0.52	-0.53	-0. 52	-0.27	-0.60	-0.57
p	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

[Table/Fig-3]: Convergent validity.

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