

# Validation of the Short Forms of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) in a Turkish Population

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**Aim:** To validate the Turkish versions of the IIQ-7 and UDI-6 for use in Turkish-speaking populations. **Methods:** After establishing the test-retest reliability and internal consistency in a pilot study, 302 patients were enrolled in the study and general and subscale scores of the questionnaires were calculated. All participants underwent an urodynamic assessment. **Results:** Both instruments showed a high internal consistency (Cronbach's alpha for the IIQ-7 and UDI-6 was 0.87 and 0.74, respectively) and test-retest reliability (Spearman's rho was 0.99 for both of the scales ( $P < 0.001$ )). 55.6% of the participants showed urodynamic abnormality and/or leakage. 39.7% had urodynamic stress incontinence (USI) and 15.9% had detrusor overactivity (DOA)  $\pm$  USI. The mean scores of each IIQ-7 and UDI-6 were significantly higher in the USI, and DOA  $\pm$  USI groups compared with normal women. Women with DOA  $\pm$  USI scored highest in the IIQ-7 and UDI-6. The irritative subscale scores of the 1st and 2nd items of the UDI-6 were significantly higher in the DOA  $\pm$  USI group. The stress subscale scores of 3rd and 4th items of UDI-6 were significantly higher in the USI group. Women with postvoid residual (PVR) urine values greater than 50 ml had significantly higher obstructive subscale scores compared to the ones who had less residual volumes. **Conclusions:** The Turkish translated versions of the IIQ-7 and UDI-6 are reliable, consistent and valid instruments for assessing symptom severity and the impact on QOL in Turkish speaking women with urinary incontinence. *Neurourol. Urodynam.* 26:129–133, 2007. © 2006 Wiley-Liss, Inc.

**Key words:** urinary incontinence; quality of life; urodynamics

## INTRODUCTION

Quality of life (QOL) is a subjective concept, mediated by social and cultural values [Kelleher et al., 1995]. Questionnaires aiming to measure the perception of QOL of an individual patient are usually self-completed and self-completion carries the risk that the questionnaire may be interpreted differently in different populations and cultures. Therefore it is recommended that these questionnaires should always be pre-tested and validated in the population in which they are to be used before clinical trials [Khullar, 2003].

The incontinence impact questionnaire (IIQ) and the urogenital distress inventory (UDI) were both developed and combined to assess the impact of urinary incontinence on QOL [Shumaker et al., 1994]. Both questionnaires are recommended by the Second International Consultation on Incontinence [Khullar, 2003]. These instruments are composed of 30 and 19 questions, respectively, and although validated and shown to be effective in evaluating treatment efficacy, they have been shown to be impractical due to the length of time required to complete them [Shumaker et al., 1994]. Therefore short versions of the IIQ and UDI, composed of 7 and 6 questions, respectively, were developed. These validated question-

naires were shown to have a high degree of correlation with the longer forms [Uebersax et al., 1995].

In the Turkish language, there is no validated QOL instrument, which measures the impact of urinary incontinence. Therefore, the aim of our study was to validate the Turkish translated versions of the IIQ-7 and UDI-6 questionnaires for the use in Turkish-speaking populations.

## MATERIALS AND METHODS

### Questionnaires

The IIQ-7 and UDI-6, consisting of 7 and 6 questions respectively, were developed in combination to measure the

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life impact of incontinence in women. The UDI-6 can also be divided into three subscales: the first, second and the third subscales evaluate irritative symptoms (urgency, frequency, and pain) (questions 1 and 2), stress symptoms (questions 3 and 4) and obstructive/discomfort or voiding difficulty symptoms (questions 5 and 6), respectively [Vassalo et al., 2002].

Two professional English–Turkish translators, not familiar with the IIQ-7 and UDI-6, worked independently to produce two Turkish versions of the questionnaires. After the first meeting, a common draft of the Turkish questionnaire was produced with a list of alternatives for the controversial items and response choices.

Next, after the second meeting between the two translators and Turkish physicians with experience of “health and QOL terminology,” some revisions were made and a second draft was produced. Ten symptomatic women were asked to self-complete the second draft version and then they were interviewed for possible ambiguous questions. After the third meeting, the final Turkish version was completed.

#### Study Population and Data Collection

Initially, a pilot study was carried out in order to evaluate the internal consistency and the test-retest reliability of the Turkish version. Thirty women completed the final version at the beginning of their visit to the urogynecology outpatient clinic at Zeynep Kamil Women’s Hospital, (a tertiary referral teaching institution, Istanbul, Turkey), before being seen by a physician. Questionnaires were printed in large fonts (minimum 16 points) so that women with poor eyesight could read and self-complete them. If a particular woman could not read or write, a relative or accompanist helped to complete the questionnaire, when available. If not, support personnel, not familiar with the concepts of urogynecology and QOL, provided nondirective assistance to those patients.

To measure the test-retest reliability of the final version, a ‘2-weeks’ test-retest analysis’ was used. Therefore, patients were asked to complete the questionnaire at their initial visit and repeat the procedure 2 weeks later in the same clinic.

After the pilot study, 302 patients with at least one urinary incontinence episode in past 12 months, regardless of their primary complaint, were enrolled in the study between March 2004 and October 2004. The participants completed the questionnaires as described above. General scores were calculated for the IIQ-7 and UDI-6 and additional subscale scores were calculated for the three subscales of the UDI-6, as explained above. The total and the subscale scores were transformed to a range between 0 and 100.

After completing both of the questionnaires, all participants underwent urodynamic assessment. Urodynamic assessment was performed by the principle investigator (CC) who was blinded to the questionnaire score of the particular patient. Urodynamic studies consisted primarily of filling cystometry, and uroflowmetric and pressure/flow studies

were added when clinically indicated. In women with irritative complaints but no positive findings on initial urodynamics, the investigation was repeated on the next day.

**Cystometric method.** Each participant with negative urine culture, after self-emptying her bladder, was placed on a birthing chair. The urethral orifice was cleaned and the postvoid residual (PVR) urine was measured using the filling part of the multilumen catheter. An intrabdominal pressure catheter was inserted into her rectum and both catheters were secured to the thigh with tape. Saline at room temperature was used as the filling medium and the external fluid column was zeroed to the symphysis pubis. Pressures were recorded via external pressure transducers and intravesical, intrabdominal and calculated detrusor pressure was displayed simultaneously on a computer screen. The EMG and filling volume were also recorded. Bladder filling was started in a sitting position usually with a filling speed of 50–80 ml/min. The volumes at the first sensation of bladder filling, and the first, normal and strong desires to void were recorded. At a bladder volume of 200 ml all patients were asked to Valsalva with progressively greater effort. The lowest intravesical pressure during this effort which produced incontinence was recorded as the Valsalva leak point pressure (VLLP). The presence of involuntary detrusor contractions, spontaneous or provoked (cough, change in posture), was considered as detrusor overactivity. Filling was stopped when the participant could hold no more fluid or could not delay her micturition, and bladder compliance was recorded.

To describe the symptoms, signs, urodynamic observations and conditions associated with lower urinary tract dysfunction, the definitions of the International Continence Society were used [Abrams et al., 2003].

Mentally incapacitated patients were excluded from the study. The institutional research board approved the study and a written informed consent was obtained from all of the participants.

#### Analysis

The test-retest reliability was assessed using Spearman’s rho. A value of greater than 0.8 was considered as highly reliable [Khullar, 2003]. To assess the internal consistency, which evaluates the overall correlation between the items within a scale, Cronbach’s alpha was used.

The content/face validity, which indicates whether the questionnaire makes sense to the patients and experts and whether all the important and relevant domains are included, was assessed by an expert panel that included two urogynecologists and one psychometrician. Levels of missing data were used as an indicator of inappropriate questions [Khullar, 2003].

Criterion validity, which describes how well the questionnaire correlates with an existing gold standard [Khullar, 2003], was assessed by comparing the general and subscale scores with urodynamic diagnoses. Based on the urodynamic

investigation, participants were categorized in three groups as no urodynamic abnormality, urodynamic stress incontinence (USI) and detrusor overactivity (DOA) with or without USI (DOA  $\pm$  USI). The raw scores obtained from the questionnaires and the subscales were transformed into a range between 0 and 100. The comparison of urodynamic results with the general and subscale scores were performed using nonparametric tests. The Kruskal–Wallis Analysis of Variance test was conducted in order to detect differences between the general and sub scores of the IIQ-7 and UDI-6 among the participants who had no urodynamic abnormality, USI and DOA  $\pm$  USI. Post hoc comparisons were carried out by the Mann-Whitney U test after the Bonferroni adjustment.

Also, the obstructive discomfort subscale score of the UDI-6 was compared by PVR urine values which were categorized as  $\leq 49$  ml and  $\geq 50$  ml by using the Mann–Whitney U test. A  $P$ -value  $< 0.05$  was considered as the statistical significance level.

The full questionnaire is available from the author on request.

## RESULTS

Among 314 participants, a total of 302 women (96%) were available to validate the questionnaire since four questionnaires were incorrectly completed, and of the 12 patients whose urodynamic studies had to be deferred because of technical difficulties only 4 returned to the clinic to complete the procedure.

The characteristics of the women and the results of urodynamic analysis are summarized on Table I. The mean age  $\pm$  SD of the participants was  $47.9 \pm 11.0$  (minimum age was 16 and maximum was 76). Twenty-eight (9.3%) of the women were illiterate, 197 (65.2%) were primary school, 63 (20.9%) were high school and 14 (4.6%) were university graduates.

**TABLE I. Characteristics and Urodynamic Diagnosis of the Participants (n = 302)**

Characteristics and diagnosis of the participants	n	(%)
Age groups (years) <sup>a</sup>		
$\leq 29$	17	(5.6)
30–39	37	(12.3)
40–49	117	(38.9)
50–59	86	(28.6)
60–69	32	(10.6)
$\geq 70$	12	(4.0)
Education		
Illiterate	28	(9.3)
Primary school	197	(65.2)
High school	63	(20.9)
University	14	(4.6)
Uro dynamic diagnosis		
No urodynamic abnormality	134	(44.4)
USI	120	(39.7)
DOA $\pm$ USI	48	(15.9)

<sup>a</sup>Age was missing for one of the participants.

In 168 (55.6%) participants urodynamic abnormality and/or leakage could be objectively assessed and in 134 (44.4%) women neither urinary leakage nor detrusor instability could be demonstrated after two consecutive cystometric evaluations. One hundred twenty patients (39.7%) had a diagnosis of USI, and 48 (15.9%) had a diagnosis of DOA  $\pm$  USI. Among 120 USI cases, 22 (18.3%) had VLLP less than 90 cm H<sub>2</sub>O and 98 (81.7%) had more than or equal to 90 cm H<sub>2</sub>O. Two hundred twenty-seven participants (75.2%) had PVR urine values less than 50 ml, 75 women (24.8%) had residual urine values greater than or equal to 50 ml.

The number of missing items was nil (0%). For the test retest reliability, Spearman's rho was 0.99 for both of the scales ( $P < 0.001$ ). The mean test and retest scores were similar for both the IIQ-7 ( $46.8 \pm 28.4$  vs.  $46.6 \pm 28.2$ ) and the UDI-6 ( $64.8 \pm 24.7$  vs.  $64.8 \pm 24.0$ ) ( $P > 0.05$ ). The Cronbach's alpha for the IIQ-7 and the UDI-6 was 0.87 and 0.74, respectively showing a good to high degree of internal consistency.

Table II presents the transformed scores of the general and subscales on the IIQ-7 and UDI-6 by urodynamic diagnosis. The mean total score on the IIQ-7 and UDI-6 was significantly higher in the DOA  $\pm$  USI and USI groups compared with the women with no urodynamic abnormalities. The mean score on the IIQ-7 was found to be significantly higher in the DOA  $\pm$  USI and USI groups compared with the women with no urodynamic abnormalities. This difference was more significant between the women with DOA  $\pm$  USI and the women with no urodynamic abnormalities. Although the women with DOA  $\pm$  USI had the highest mean total score on the IIQ-7 in general, a subset of patients with USI with VLLP less than 90 cm H<sub>2</sub>O, (not shown on the table), had the highest mean score on the IIQ-7. But when compared with USI patients with VLLP higher than or equal to 90 cm H<sub>2</sub>O and with DOA  $\pm$  USI, the differences were found statistically not significant ( $P = 0.089$  and  $P = 0.69$  respectively). The mean score on the UDI-6 was significantly higher in the DOA  $\pm$  USI and USI groups compared with the women with no urodynamic abnormalities. This difference was more significant between the women with the DOA  $\pm$  USI and the women with no urodynamic abnormalities. Women with DOA  $\pm$  USI had the highest mean total score on the UDI-6.

The subscale scores of the 1st and 2nd items of the UDI-6, which evaluate irritative symptoms, were highest in the DOA  $\pm$  USI group. This group showed significant difference with the USI group and the women with no urodynamic abnormalities. There was no difference between the USI group and the women with any urodynamic abnormalities. The subscale scores of the 3rd and 4th items of the UDI-6, which evaluate stress symptoms, were highest in the USI group. This group showed significant difference from the DOA  $\pm$  USI group and from the women with no urodynamic abnormalities. There was no difference between the DOA  $\pm$  USI group and the women with any urodynamic abnormalities. The subscale scores of the 5th and 6th items of the UDI-6, which

**TABLE II. Short Form Total and Subscale Scores (Transformed to a Range Between 0 and 100) of IIQ-7 and UDI-6 by Urodynamic Diagnosis**

Total and subscale scores	Urodynamic diagnosis median (25th–75th percentiles)			P-value*
	USI (n = 120)	DOA ± USI (n = 48)	No urodynamic abnormality (n = 134)	
IIQ-7 total	47.6 (33.3–66.6)	54.8 (29.8–94.0)	23.8 (4.7–48.8)	<0.001
Physical activity	50.0 (20.8–66.7)	58.3 (33.3–83.3)	16.7 (0–50.0)	<0.001
Travel	33.3 (16.7–66.7)	50.0 (16.7–100.)	16.7 (0–50.0)	<0.001
Social/relationships	66.7 (33.3–66.7)	66.7 (33.3–100)	33.3 (0–66.7)	<0.001
Emotional health	50.0 (33.3–83.3)	83.3 (50.0–100)	33.3 (0–66.7)	<0.001
UDI-6 total	47.2 (38.9–66.7)	52.8 (40.3–65.3)	44.4 (16.7–61.1)	0.005
Irritative symptoms	50.0 (16.7–95.8)	83.3 (66.7–100)	50.0 (16.7–83.3)	<0.001
Stress symptoms	83.3 (66.7–100)	50 (16.7–83.3)	50.0 (16.7–66.7)	<0.001
Obstructive discomfort	16.7 (0–50.0)	33.3 (0–50.0)	33.3 (16.7–54.2)	>0.05

\*P-value represents the difference among the medians of the three groups obtained by the Kruskal–Wallis test.

evaluate obstructive/discomfort or voiding difficulty symptoms, were highest in the women with no urodynamic abnormalities and lowest in the USI group. But no statistical difference was found between the three groups.

The participants who had PVR values  $\leq 49$  ml scored lower compared to the ones who had residual urine values  $\geq 50$  ml on the obstructive discomfort scale of the UDI-6. The median (25th–75th percentiles) of the participants having PVR values  $\leq 49$  ml and  $\geq 50$  ml were 16.7 (0–50.0) and 50.0 (16.7–83.3), respectively. This difference was statistically significant ( $P < 0.001$ ).

## DISCUSSION

Our study shows that the Turkish version of the UDI-6 and IIQ-7 correlates well with urodynamic diagnoses in Turkish women. Among these women, the highest score was achieved by the DOA ± USI group, consistent with the published data revealing the more devastating effect of overactive bladder on the QOL of women. Some women without any urodynamic findings also had a high score for the irritative subscale of the UDI-6 compared with their other total and subscale scores of the questionnaires. This might be due to the limitation of cystometric testing in recording just a short window of the bladder's day that may not reveal intermittent DOA [Katz and Blaivas, 1983; Nager and Albo, 2004] and in five of these women overactive bladder was only diagnosed after second evaluation. It should also be kept in mind that subjects with rare episodes of incontinence or symptoms other than incontinence itself (such as frequency and pain) may not have low scores [Vassallo et al., 2002]. In this study PVR values were used as a proxy measure of obstruction [AHCPR, 1996] and women with lower PVR values scored lower and women with higher residual volumes tended to score higher, regardless of any cut off value. This difference was more significant in the first item of this subscale but it was not surprising finding a less significant difference in the 2nd item which measures the impact of pain or discomfort in

the lower abdominal or genital area, because these symptoms, although associated with obstruction, can have other sources in any woman.

The results of our study are consistent with the study comparing the English version of the UDI-6 with urodynamic findings in women, in which the questionnaire was found to be predictive for urodynamic diagnoses, particularly with regard to USI, DOA and obstruction but not for the severity of incontinence as determined by VLLP measurement [Lemack and Zimmern, 1999].

Assessing responsiveness is considered the final step in validating a questionnaire. This is somewhat controversial because there is no agreement about the best method of determining whether a questionnaire has the optimum measurement of change. This is best done in a study comparing an intervention and control group [Kullar, 2003]. In this study, results on responsiveness are lacking because of the limited number of women who returned to complete the questionnaire after their medical or surgical treatment, and the responsiveness of the Turkish version remains to be demonstrated.

## CONCLUSION

The Turkish translated versions of the IIQ-7 and UDI-6 are easily administered and self-completed by women. The general and subscale scores correlate well with urodynamically proven underlying pathophysiologic conditions. They seem to be reliable, consistent and valid instruments for assessing symptom severity and the impact on QOL in Turkish speaking women with urinary incontinence.

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