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Validation, cultural adaptation and responsiveness of two pelvic-floor-specific quality-of-life questionnaires, PFDI-20 and PFIQ-7, in a Turkish population

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ABSTRACT

Objectives: The aim of the study was cultural adaptation, validation, and test for responsiveness of the short forms of the Pelvic Floor Distress Inventory (PFDI-20) and the Pelvic Floor Impact Questionnaire (PFIQ-7) in a Turkish population.
Study design: To evaluate their validity, questionnaires were applied to 248 women. The questionnaires were compared with prolapse stage according to the Pelvic Organ Prolapse Quantification (POP-Q) system. The responsiveness of the questionnaires was assessed in 103 women with prolapse who also completed the questionnaires after reconstructive surgical treatment, with standardized response mean (SRM), effect size (ES), and the Wilcoxon signed-rank test.
Results: Cronbach alpha coefficients of the Turkish PFDI-20 and PFIQ-7 questionnaires were 0.908 and 0.830, respectively. Significant correlations were observed between the scores of the questionnaires with the vaginal examination findings. The PFDI-20 and PFIQ-7 scores were significantly improved after vaginal reconstructive surgery.
Conclusions: Turkish translated versions of the PFDI-20 and PFIQ-7 are reliable, valid and responsive instruments for assessing symptom severity, impact on QoL in women with pelvic organ prolapse. They can be easily administered and self-completed by Turkish women.

1. Introduction

Clinical history-taking is an important method of assessing a patient's symptoms and their effect on daily life. In a situation, however, in which a standardized, reproducible assessment is desired, the most valid way of measuring the presence, severity and impact of a symptom or condition on a patient's activities and well-being is through the use of psychometrically robust self-administered questionnaires [1]. There has been an increasing need among clinicians for disease-specific quality-of-life (QoL) scales in recent years.

Pelvic organ prolapse, like other female pelvic floor disorders such as urinary and fecal incontinence, causes symptoms that can impact a woman's daily activities and negatively affect her quality of life [2]. In 2001, two condition-specific health-related quality-of-life (HRQoL) instruments were developed for women with pelvic floor disorders, the Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ) [3]. One advantage that the PFDI and PFIQ have over instruments that are specific to a single organ system is that their comprehensive nature allows measurement of these complex interactions. Because they contain urinary, prolapse, and colorectal scales, the PFDI and PFIQ can be used in women with urinary incontinence, pelvic organ prolapse, fecal incontinence, or several other pelvic floor disorders, alone or in combination. Each questionnaire has been shown to be psychometrically valid and reliable [4,5]. These two scales have been used in a number of studies investigating treatment for urinary incontinence in women and each has demonstrated adequate levels of responsiveness [3,6,7]. Barber et al. [8] recently introduced short versions of the PFDI and PFIQ, the PFDI-20, and the PFIQ-7.

While HRQoL is extremely important to the clinical practice of clinicians, a pelvic floor disease-related QoL instrument which analyzes urinary, prolapse-related and colorectal symptoms synchronously was not available in Turkey. Quality-of-life instruments must be culturally specific to the relevant country in order to accurately document the health status of patients.

For a questionnaire to be useful in research or in practice, it must demonstrate three important psychometric properties: validity, reliability, and responsiveness [9]. The validity of a

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questionnaire is simply whether it measures what is intended, whereas reliability is the ability of a questionnaire to measure consistently in a reproducible fashion. Face validity is a subjective assessment by an expert panel and/or patient focus group as to whether the instrument appears to measure what it intends to measure. Content validity is subjective assessment by an expert panel and/or patient focus group as to the extent that the domain of interest is comprehensively sampled by the questions in the instrument.

Construct validity is an assessment as to whether the instrument has appropriate relationships with other variables or measures. That is, the instrument correlates or agrees with other tests or measures of the same construct (convergent validity) and has little or no correlation or agreement with measures of different constructs (divergent validity). Criterion validity is when an instrument correlates with an established criterion standard or gold standard [10].

Responsiveness, or sensitivity to change, refers to an instrument's ability to detect change that occurs as the result of therapy or disease progression. Adequate responsiveness is an essential property for any questionnaire intended to evaluate the effect of a treatment, yet this is the property of a questionnaire that is least often evaluated in the medical literature [3].

Therefore, the aim of this study was to adapt and validate the PFDI-20 and PFIQ-7 measures to the Turkish language so that they can be effectively used in clinical practice settings. This article presents the results of the translation, cultural adaptation, reliability, validation and responsiveness of both questionaires into the Turkish language.

2. Materials and methods

Linguistic validation is the first step of the cultural adaptation of a questionnaire. The second step is psychometric validation, the process by which an instrument is assessed for reliability, validity, and responsiveness through the mounting of a series of defined tests on the population group for whom the instrument is intended.

2.1. Linguistic validation process

The adaptation and validation of an instrument involves several stages: (1) translation of the original instrument, (2) field testing of the translated instrument, and (3) establishment of the reliability and validity of the translated instrument.

2.2. Translation

The translation process followed Brislin's guidelines for translation and cross-cultural adaptation of HRQoL measures [11]. The questionnaires were forward translated into Turkish by three professional Turkish-English translators unfamiliar with the questionnaires, independently, to produce the Turkish version of the questionnaire and then translated back into English by two different native English-speaking people independently. All the translators were blinded to the aim of the study. A common draft of the Turkish version was produced with a list of alternatives for the controversial items and response choices. A review committee formed by the authors with experience of "health and QOL terminology" and the translators examined the translation and produced some revisions that were culturally applicable and reflected the intent of the original instrument. The final version was pre-tested by two bilingual medical professionals who assessed the equivalence between the original source and the final version. For field testing of the final version, the newly translated questionnaire was administered to 30 Turkish women in order to ascertain any difficulties with regard to language or conceptual issues.

2.3. Data source

The study was conducted between December 2006 and May 2010. Interview questionnaires for socio-demographic/clinical data, the PFDI-20 and the PFIQ-7 measures were applied to 248 patients with and without POP from the outpatient clinics of Trakya University Education and Research Hospital, a tertiary referral practice.

One of the questionnaires measures the symptom bother of pelvic floor diseases (PFDI-20), and the other questionaire is QoL measurement for pelvic floor (PFIQ-7). The PFDI-20 is a 20-item symptom inventory that measures the degree of bother caused by a broad array of pelvic symptoms. It has three scales: the pelvic organ prolapse distress inventory (POPDI-6) the urinary distress inventory (UDI-6) and the colo-rectal-anal distress inventory (CRADI-8). The PFIQ-7 is a functional status measure that assesses the degree to which a subject's bowel, bladder, and/or pelvic symptoms impact on different activities of daily living, social relationships, or emotions. It also has three scales: the pelvic organ prolapse impact questionnaire (POPIQ-7); the urinary impact questionnaire (UIQ-7); and the colo-rectal-anal impact questionnaire (CRAIQ-7). The PFDI and PFIQ contain two widely used condition-specific QoL questionnaires for women with lower urinary tract dysfunction, the Urinary Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ) [7]. In fact, the UDI and IIQ serve as the urinary scales for the PFDI and PFIQ, respectively. These questionnaire short forms (UDI-6 and IIQ-7) were validated in the Turkish language by Cam et al. [12].

2.4. Scoring for the PFDI-20

The response to each item of satisfaction, impact and worry was rated from 4 (quite a bit) to 0 (not at all) for the PFDI-20. The mean value of all of the answered items within the corresponding scale (possible value 0–4) was then multiplied by 25 to estimate the scale scores of the PFDI-20 (range 0–100). The three scales were summed as well, resulting in PFDI-20 summary score, which ranged from 0 to 300.

2.5. Scoring for the PFIQ-7

The PFIQ 7 has 7 questions and each question has 3 separate responses. The response to each item of satisfaction, impact and worry was rated from 3 (quite a bit) to 0 (not at all) for the PFIQ-7. The mean value for all the answered items within the corresponding scale (possible value 0–3) was estimated, then multiplied by (100/3) to obtain the scale score, range 0–100. We added the scores from the 3 scales together to obtain the PFIQ 7 summary score (range 0–300).

For the scales of both the PFDI and the PFIQ, a higher score indicates worse health status or poorer HRQOL.

After completing both oquestionnaires, all participants underwent a gynecological examination in the supine position using the Pelvic Organ Prolapse Quantification System (POP-Q), as approved by the International Continence Society (ICS) [13] by the principal investigators (PBK, HS) who were blinded to the questionnaire score of the particular patient. According to the POP-Q scores at the time of the study, the patients were divided into two clinical subgroups: (i) POP-Q score > 2 was classified as prolapse ($n = 103$) and (ii) POP-Q score ≤ 2 was classified as non-prolapse ($n = 145$). To describe the symptoms and signs associated with pelvic floor dysfunction, the definitions of the International Continence Society were used [14].

Exclusion criteria included age less than 18 years, current pregnancy, delivery or surgery in the past 6 months, women who had a history of pelvic reconstructive and/or anti-incontinence surgery, women who could not self-complete the questionnaire and those who presented cognitive impairments that would preclude completion of the questionnaires. Verbal informed consent was obtained from all the participants for use of their personal data for research purposes.

2.6. Pychometric validation process

2.6.1. Reliability

A key measure of reliability is internal consistency, which is determined by the extent to which all items in a scale measure the same thing. The reliability of the Turkish PFDI-20 and PFIQ-7 was tested by internal consistency. To assess the internal consistency, which evaluates the overall correlation between the items within a scale, the Cronbach's alpha method was used.

2.6.2. Criterion validity

Validity refers to the extent to which a measure actually measures what it is supposed to measure; strength of the relationship between a concept and its empirical indicator. Criterion validity, which describes how well the questionnaire correlates with an existing gold standard [15], was assessed by comparing the questionnaire's scores with the POP-Q scores. Based on the prolapse scores according to the POP-Q, participants were categorized into two groups: women with prolapse (POP-Q prolapse stages 3 and 4) and women without prolapse, who had a POP-Q prolapse stage 2 or less. Validity was assessed by two different statistical tests (Mann–Whitney *U* test and receiver-operating characteristic curve, ROC).

2.6.3. Responsiveness

Responsiveness, or sensitivity to change, refers to an instrument's ability to detect change that occurs as the result of therapy or disease progression. Adequate responsiveness is an essential property for any questionnaire intended to evaluate the effect of a treatment. Responsiveness was determined by examining the *P* values generated using the Wilcoxon signed-rank test comparing pre- and post-treatment scores. We also examined the effect size (ES) and standardized response means (SRM) [16]. The ES is equal to the mean change in score divided by the standard deviation of individuals' baseline score. The SRM is equal to the mean change in score divided by the standard deviation of individuals' changes in score. A value of 0.2–0.5 was regarded as "small", 0.5–0.8 as "medium", and those above 0.8 as "large".

2.7. Statistical analysis

Results are expressed as mean ± standard deviation. Normality distribution of the variables was tested by the One Sample Kolmogorov–Smirnov test. The Spearman rank correlation coefficients among the POP-Q, PFDI and PFIQ scores were calculated. Internal consistency reliability of the scales was assessed by calculating Cronbach's alpha coefficient.

Validity of the instrument was assessed two different statistical tests, Mann–Whitney *U* test and receiver-operating characteristic curve (ROC). Differences between groups were assessed using the Mann–Whitney *U* test due to the non-normal distributed data. The ROC was used to discriminate prolapse or non-prolapse cases and area under the curve (AUC) was computed. The AUC is a measure of the overall discriminatory power of the prognostic variable. A value of 1.0 indicates perfect discrimination; a value of 0.5 equals random prediction and a value lower than 0.5 indicates no discriminative power.

Responsiveness of the instrument was assessed by comparing pre- and post-treatment scores in the prolapse group using Wilcoxon signed-rank test, standardized response mean (SRM), and effect size (ES).

A *P*-value of <0.05 was considered statistically significant.

The Turkish version of the full questionnaire is available from the first author on request.

3. Results

Two hundred and forty-eight consecutive female patients seen in the clinic were evaluated. The mean age of the participants was 56.3 ± 10.7 and the mean parity was 3.4 ± 1.9. Demographics and clinical characteristics of the participants with and without pelvic organ prolapse are shown in Table 1. Of the 248 women whose prolapse stage was examined according to POP-Q system, 145 had stage 2 or less pelvic organ prolapse, and 103 were classified as having pelvic organ prolapse.

3.1. Assessment of reliability

Internal consistency reliability of the scales was assessed by calculating Cronbach's alpha coefficient. Cronbach-α coefficients of PFDI-20 and PFIQ-7 scales are shown in Table 2. The internal consistency Cronbach alpha coefficient values obtained from the Turkish versions of the PFDI-20 and PFIQ-7 were 0.908 and 0.830, respectively. The Cronbach alpha coefficient for the subscales of the PFDI-20 ranged from 0.952 for POPDI-6; 0.965 for UDI-6; and 0.964 for CRADI-8. PFIQ-7 subscales Cronbach alpha coefficient value sranged from 0.763 for POPIQ-7; 0.800 for UIQ-7; and 0.734 for CRAIQ-7. The minimal Cronbach alpha value of 0.734, which indicates that the measure has acceptable reliability for comparisons, was achieved for all subscales.

3.2. Assessment of criterion validity

The mean scores of the PFDI-20 and PFIQ-7 scales by prolapse vs. non-prolapse are shown in Table 3. The total and the domain scores for questionnaires of women with prolapse were found to be significantly higher compared to non-prolapse women ($P < 0.05$)

Table 1
Demographics and clinical characteristics of the prolapse vs. non-prolapse participants.

	Prolapse participants ($n=103$)	Non-prolapse participants ($n=145$)
Age (mean ± SD)*	59.9 ± 11.4	53.9 ± 9.5
Parity (mean ± SD)*	3.9 ± 2.1	3.0 ± 9.5
Previous hysterectomy, *n* (%)	31 (30.0)	42(28.9)
Menopause, yes, *n* (%)	70(67.9)	90(62.0)
Systemic disorders, yes, *n* (%) (e.g. hypertension, DM.)	47(44.6)	55(37.9)
POP-Q findings, *n* (%)		
Stage 0	–	23 (15.9)
Stage I	–	32 (22.1)
Stage II	–	90 (62.1)
Stage III	75 (72.8)	
Stage IV	28 (27.2)	
Surgical procedures, *n* (%)		
Vaginal hysterectomy	38 (36.9)	
Anterior colporrhaphy[a]	62 (60.2)	
Posterior colporrhaphy	65 (63.1)	
Vaginal vault suspension[b]	54 (52.4)	
Sling procedure	25 (24.3)	
Colpocleisis	6 (5.8)	

[a] Of the 62 procedures, in 7 of them, mesh was used.
[b] Total mesh was used in 5 of them for vaginal vault suspension.
* $P=0.001$.

Table 2
Cronbach-α coefficient values of PFDI-20 and PFIQ-7 scales.

	Cronbach alpha (α) coefficient[a]
PFDI-20	0.908
UDI-6	0.965
POPDI-6	0.952
CRADI-8	0.964
PFIQ-7	0.830
UIQ-7	0.800
CRAIQ-7	0.734
POPIQ-7	0.763

PFDI: Pelvic Floor Distress Inventory. PFIQ: Pelvic Floor Impact Questionnaire.
[a] Reliability analysis.

except for CRADI-8 ($P = 0.858$) and UIQ-7 ($P = 0.109$) domain scores.

The Spearman rank correlation matrix of POP-Q, PFDI-20 and PFIQ-7 are shown in Table 4. The POP-Q significantly correlated with PFDI-20 score ($r = 0.368$; $P < 0.001$) and with PFIQ-7 score ($r = 0.451$; $P < 0.001$). The PFDI-20 and PFIQ-7 scores increased as the POP-Q increased. Spearman's rank correlation analysis confirmed that the questionnaire items correlated with the objective vaginal examination findings (Table 4). Furthermore, the PFIQ-7 score was significantly correlated with PFDI-20 score ($r = 0.721$; $P < 0.001$).

The ROC analysis was performed to discriminate for prolapse by using PFIQ-7 and PFDI-20 scores and we tested validity of the PFIQ-7 and PFDI-20 by using area under the ROC curves (Fig. 1). Area under ROC curve, cut-off and sensitivity/specificity values to discriminate prolapse are shown in Table 5. As a result of ROC analysis AUCs were found as 0.737 for PFIQ-7 ($P < 0.001$), as 0.705 for PFDI-20 ($P < 0.001$). Cut-off values of the PFDI-20 and PFIQ-7 questionnaires to discriminate prolapse from non-prolapse women were found as >0.14 and >1.75, respectively.

Table 3
The mean scores of the PFDI-20 and PFIQ-7 scales by prolapse vs. non-prolapse.

	Prolapse ($n = 103$)	Non-prolapse ($n = 145$)	P[a]
PFDI-20 summary score	149.0 ± 35.1	124.4 ± 33.6	**<0.001**
UDI-6	53.6 ± 18.0	49.3 ± 17.3	**0.046**
POPDI-6	59.4 ± 18.2	38.2 ± 15.0	**<0.001**
CRADI-8	35.9 ± 9.8	36.8 ± 11.1	0.813
PFIQ-7 summary score	78.2 ± 57.0	38.7 ± 45.7	**<0.001**
UIQ-7	23.0 ± 31.2	16.9 ± 27.0	0.173
CRAIQ-7	6.1 ± 18.6	8.4 ± 16.3	**0.009**
POPIQ-7	49.7 ± 31.7	13.3 ± 25.7	**<0.001**

Mean ± std. deviation.
[a] Mann–Whitney U test.

Table 4
The Spearman rank correlation matrix of POP-Q, PFDI-20 and PFIQ-7.

	POP-Q	PFDI-20
PFDI-20	0.387†	–
UDI-6	0.134*	–
POPDI-6	0.608†	–
CRADI-8	−0.043	–
PFIQ-7	0.433†	0.765†
UIQ-7	0.098	0.551†
CRAIQ-7	−0.196‡	0.214†
POPIQ-7	0.433†	0.548†

* $P < 0.05$.
† $P < 0.001$.
‡ $P < 0.01$.

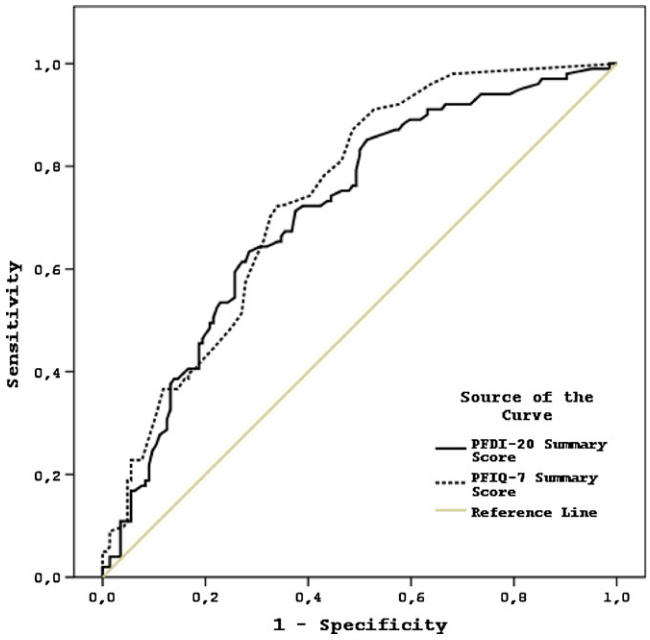

Fig. 1. ROC curves to discriminate women with and without POP.

3.3. Assessment of responsiveness

Responsiveness of the instruments was assessed by using the Wilcoxon signed-rank test, effect size and standardized response mean. Mean change in pre- and post-treatment scores, effect sizes and standardized response means of the scales are shown in Table 6. The POP-Q, PFDI-20 and PFIQ-7 scores and domains were significantly improved 6 months after vaginal reconstructive surgery ($P < 0.05$ for each). All three instruments demonstrated excellent responsiveness (ES = 2.97; SRM = 2.62 for POP-Q), (ES = 1.27; SRM = 1.27 for PFDI-20), and (ES = 1.25; SRM = 1.27 for PFIQ-7).

4. Comment

HRQoL is best measured by using a psychometrically robust self-administered questionnaire [3,6]. Although more than 14 instruments have been developed and validated for assessing the impact of urinary incontinence on the QoL in women, far fewer condition-specific QoL instruments have been developed for fecal incontinence or pelvic organ prolapse [6]. The PFDI and PFIQ represent two HRQoL questionnaires for women with all forms of pelvic floor disorders [4]. These questionnaires were designed to provide a comprehensive evaluation of the extent to which lower urinary tract, lower gastrointestinal tract, and pelvic organ prolapse symptoms affect the quality of life of women who have disorders of the pelvic floor. The validity and reliability of these questionnaires have been established [4,5]. Assessing responsiveness is considered the final step in validating a questionnaire. This is best accomplished through a study comparing an

Table 5
Area under ROC curve, cut-off and sensitivity/specificity values to discriminate pelvic organ prolapse.

	Cut-off	AUC	P	Sensitivity (%)	Specificity (%)
PFDI-20 summary score	>135.4	0.713	<0.001	62.7	71.5
PFIQ-7 summary score	>19.0	0.741	<0.001	86.3	51.0

Table 6
Mean change in pre- and post-treatment scores of the PFDI-20 and PFIQ-7 in patients with POP.

	Pre-treatment score	Post-treatment score	Mean change score	ES	SRM	*P*
POP-Q	2.85 ± 0.74	0.65 ± 0.78	2.20 ± 0.84	2.97	2.62	<0.001
PFDI-20	145.0 ± 35.4	95.9 ± 20.0	49.1 ± 34.5	1.38	1.42	<0.001
UDI-6	53.7 ± 18.0	37.8 ± 13.0	15.9 ± 17.3	0.88	0.91	<0.001
POPDI-6	55.7 ± 18.2	28.6 ± 7.6	27.1 ± 19.5	1.48	1.39	<0.001
CRADI-8	35.5 ± 9.9	29.4 ± 6.4	6.1 ± 11.1	0.61	0.54	<0.001
PFIQ-7	78.9 ± 55.7	9.1 ± 19.6	69.8 ± 56.7	1.25	1.23	<0.001
UIQ-7	25.5 ± 31.7	6.6 ± 17.8	18.9 ± 32.2	0.59	0.58	<0.001
CRAIQ-7	6.6 ± 18.2	1.8 ± 8.7	4.8 ± 18.9	0.26	0.25	0.016
POPIQ-7	46.7 ± 31.8	0.6 ± 3.4	46.1 ± 31.8	1.45	1.45	<0.001

Mean ± std. deviation.
POP-Q: Pelvic Organ Prolapse Quantification.
ES: effect size is equal to the mean change in scores divided by the standart deviation of the baseline score.
SRM: standardized response mean is equal to the mean change in scores divided by the standart deviation of the change in scores.

intervention and a control group. Barber et al. [17] have confirmed that the PFDI and PFIQ are responsive to change in women undergoing both surgical and nonsurgical treatment for pelvic organ prolapse.

Unfortunately their use is limited to English-speaking countries. To allow their utilization in different countries, translation and validation of the translated versions are needed. Overall, the psychometric performance of the Turkish version of the questionnaires of PFDI-20 and PFIQ-7 were quite good. The adaptation of these questionnaires into Turkish was successful. The mean score of the UIQ-7 scale of the women without prolapse was lower than the women with pelvic organ prolapse, but this difference was not statistically significant. There was no difference in the mean CRADI-8 score between the patients with and without prolapse. Although there was a lack of difference between these two domain scales of the questionnaires, we thought that colorectal symptoms are the symptoms that may be influenced from many co-factors in life.

Like the original English questionnaire, the Turkish translated versions of the PFDI-20 and PFIQ-7 are reliable, consistent and a valid instruments for assessing symptom severity and impact on quality of life among women with uterovaginal prolapse. They are easily understood, administered and self-completed by the women. The adapted instruments are likely to be suitable for use in clinical studies of pelvic floor-related diseases in Turkey.

Our study revealed that the Turkish versions of both questionnaires, PFDI-20 and PFIQ-7, correlated well with the POP-Q findings among Turkish women. Furthermore, the total and domain scores were found to be significantly higher in women with prolapse compared to participants who have a normal pelvic support system. The Turkish versions of the PFDI-20 and PFIQ-7 will be instrumental in improving patient–physician communication in both in-patient and out-patient settings.

Conflicts of interest

None.

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