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ORIGINAL ARTICLE

Validity and reliability of the Turkish version of the Pelvic Floor Distress Inventory-20

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Abstract
Introduction and hypothesis The aim of this study was to investigate the reliability and validity of the Turkish version of the Pelvic Floor Distress Inventory-20 (PFDI-20).
Methods One hundred and twenty-eight women with pelvic floor disorders, including pelvic organ prolapse, urinary incontinence, and anal incontinence were enrolled in the study. The Turkish version was developed using forward back translation. Construct validity was examined by correlation of clinical methods. Interclass correlation coefficients (ICC) compared the PFDI-20 and subscale scores. Cronbach's alpha assessed the internal consistency of the Turkish version.
Results The PFDI-20 has three subscales. The test–retest reliability of the PFDI-20 and subscale was excellent (ICC 0.96 to 0.98, $p<0.001$). Cronbach's alpha value (0.79) was moderate for the PFDI-20. Construct validity demonstrated that the PFDI-20 and each subscale displayed significant correlation with other clinical methods used ($p<0.05$).
Conclusions The PFDI-20 is a valid and reliable condition-specific questionnaire for Turkish women with pelvic floor disorders.

Keywords EMG biofeedback · Incontinence · Pelvic floor · Pelvic Floor Distress Inventory-20 · Pelvic organ prolapse

Introduction

Pelvic floor disorders encompass a wide variety of interrelated clinical conditions including urinary incontinence (UI), anal incontinence (AI), pelvic organ prolapse (POP), voiding, and defecatory dysfunction [1]. These symptoms of pelvic floor disorders are common and, although not life-threatening, affect the quality of life of women with these conditions [2]. Therefore, it is quite important to evaluate all symptoms of pelvic floor disorders and to plan appropriate treatment programs for these symptoms.

In 2001, the Pelvic Floor Distress Inventory (PFD) was developed. The PFDI investigates all symptoms related to pelvic floor disorders and the severity of inconvenience they cause [2]. In 2005, the shorter version of the PFDI (PFDI-20) was developed by Barber et al. The PFDI-20 was proven to be a valid and reliable condition-specific questionnaire in the original language, and is now among the most commonly used instruments for measuring symptom severity of prolapse and incontinence [3]. Furthermore, it is sensitive to change, is applicable for epidemiological studies, as well as for evaluating results of treatment. The PFDI-20 has been

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translated and validated into several languages including Swedish [4], Arabic [5], and French [6]. There is currently no validated questionnaire in the Turkish language addressing symptoms of pelvic floor disorders. Therefore, our study aimed to investigate the reliability and validity of the Turkish version of the PFDI-20.

Materials and methods

This study was approved by the Ethics Committee of Hacettepe University, Faculty of Medicine in Ankara, Turkey. The study was carried out in 128 women diagnosed with pelvic floor disorders who were admitted to the Department of Obstetrics and Gynecology of Hacettepe University. Patients were eligible for inclusion in the study if they met the following inclusion criteria: female, 18 years of age and older, with Stage II and higher POP, UI or AI, and who voluntarily participated in the study. Patients were excluded from the study if they had mental incapacity that would preclude completion of the self-administered questionnaires. Before their participation, written informed consent was obtained from all subjects.

Linguistic validation of the questionnaire was undertaken in three steps [7]. First: forward translation consisted of translation of the questionnaire from the original language into the target language to produce a conceptually equivalent translation of the original questionnaire into a language easy to understand. Two local professional English–Turkish translators, native target language speakers, and bilingual in the source language, worked independently to produce two forward translations of the original items and instructions and response choices in the Turkish language (Version 1). Second: the back translation consisted of translation of the first version of the questionnaire back into the source language. Another translator (bilingual in the target language) who did not have access to the original version of the questionnaire translated the first version of the questionnaire back to the source language. Comparison of the back translation version with the original source version was performed. This resulted in changes to the first version, giving rise to the second version. Finally, pretesting of the final draft of the questionnaire was undertaken. The questionnaire was administered by means of face-to-face interviews with 20 women with pelvic floor disorders. During the interviews, women were asked if they had any difficulty in understanding any of the items in the questionnaire, and if so, that item was then corrected, producing the final Turkish version.

After producing the final Turkish version of the PFDI-20, the socio-demographic data of the patients in our study were recorded. Clinically, vaginal support, the presence of POP (cystocele, rectocele, and uterine prolapse) and its stages were measured with the simplified pelvic organ prolapse quantification (POP-Q) system [8]. “Feeling a bulge in the vagina” is the symptom most commonly attributed to prolapse, and previous studies have shown a moderate correlation between this symptom and the severity of the prolapse [9, 10]. Therefore, we evaluated the severity of prolapse with the Visual Analog Scale (VAS). The VAS is a simple, reliable, and reproducible method in urogynecological research [11]. The severity of prolapse was assessed by a range of 0 cm to 10 cm, on which "0" indicated "no bulge or something falling out in your vaginal area" to "10" which indicated "very large bulge or something falling out in your vaginal area". The best score is "0" and the worst score is "10." A higher total score indicates more severe prolapse.

The severity of UI and AI was evaluated by the VAS and Wexner incontinence scales. The severity of UI was assessed by 0 cm to 10 cm, on which "0" indicated "no UI" and "10" indicated "very severe UI." The best score is "0" and the worst score is "10." A higher total score indicates more severe UI.

The Wexner scale is a reliable, consistent, and valid instrument for evaluating anal function in women with AI [12]. The scale consists of five items. The symptoms are graded as "always: 4" if they occurred more than once a day, "usually: 3" if they occurred more than once per week, "sometimes: 2" if they occurred more than once per month, "rarely: 1" if they occurred less than once per month, and "never: 0" if they were never seen. The best score is "0" and the worst score is "20." A higher total score indicates more severe AI.

The PFDI-20 was developed to evaluate all symptoms of pelvic floor disorders and their severity. It consists of 20 items and three subscales including the Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6), the Colo-Rectal-Anal Distress Inventory-8 (CRADI-8), and the Urinary Distress Inventory-6 (UDI-6). The responses for all items are "no: 0" or "yes" in the PFDI-20. If the patient’s response is "yes," the symptom severity is graded as "unimportant: 1," " little: 2," "moderate: 3," and "a lot: 4." Each of the three subscales of the PFDI-20 is scored from 0 (least distress) to 100 (greatest distress). The best total score is "0" and the worst total score is "300." A higher total score indicates more severe pelvic floor disorders [3].

At their initial visit, we requested patients to complete the questionnaire. To measure the test–retest reliability of the PFDI-20, we requested patients returning to the clinic to complete the questionnaire 1 week later. During this process, none of the women was offered any treatment.

The electromyographic (EMG) activity response of pelvic floor muscles is a method used to measure pelvic floor muscle strength and endurance [13]. Women suffering from pelvic floor disorders can have varying symptoms. These symptoms are caused by dysfunction of the ligaments, fascia, and the pelvic floor muscles [14]. Therefore, we preferred to use the EMG activity response of the pelvic floor

muscles for general information related to all symptoms of pelvic floor disorders and to investigate the construct validity of the PFDI-20. The EMG activity response of pelvic floor muscles was evaluated with a Myomed 932 model (ENRAF NONIUS, the Netherlands) EMG Biofeedback device.

We used the G*Power package software program to determine the necessary sample size for this study. We calculated that a sample consisting of at least 111 patients was needed to obtain 95% power with | r |=0.30 effect range, α=0.05 type I error, and β=0.05 type II error. Our study included a larger sample size (n=128) rather than the minimum requirement (n=111). A descriptive statistical analysis of the socio-demographic data (age, body mass index, parity, education level, Stage II and higher POP, UI and AI) was undertaken.

Reliability was evaluated by means of a test–retest analysis and calculation of internal consistency. The Wilcoxon signed rank test or paired samples t test was used depending on normal distribution to compare the test and retest scores. The test–retest reliability was assessed with interclass correlations (ICCs), while internal consistency was measured by means of Cronbach's α [15].

The construct validity was assessed by investigating correlations using the Pearson or Spearman's rank correlation coefficients between the total score of the PFDI-20 and EMG activity response of pelvic floor muscles, between the POPDI-6 score and the VAS score including the severity of prolapse, between the CRADI-8 score and Wexner score, and between the UDI-6 score and the VAS score including the severity of UI.

SPSS for Windows 15.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analyses. The level of significance was set at p <0 .05.

Results

The analysis of socio-demographic findings including age, body mass index, parity, education level, the presence of Stage II and higher POP, UI, and AI is shown in Table 1.

The PFDI-20 total score, which was obtained from 128 patients, was calculated as 108.01±58.77 for the test. The PFDI-20 total score ,which was obtained from 45 patients was calculated as 107.04±57.91 for the retest. There was no statistically significant difference between the test and retest scores for any subscale and the questionnaire (p>0.05). Table 2 shows the test–retest scores.

In the test–retest analysis, all ICCs were significant (p< 0.05) and varied between 0.96 and 0.98, thus indicating good test–retest reliability (Table 3). Internal consistency was measured by means of Cronbach's α, and the values for the PFDI-20 and its subscales ranged between 0.66 and 0.80 (Table 3).

Table 1 Characteristics and pelvic floor diagnoses of participants

Variables	n=128
Age (years, X±SD)	51.91±9.87
Body mass index (kg/m², X±SD)	28.96±4.75
Parity (median [IQR])	3.0 (1.0)
Education (n [%])	
Literate	10 (7.8)
Primary school	73 (57.1)
High school	23 (18.0)
University	22 (17.1)
Pelvic floor disorders (n [%])	
POP (Stage II and higher)	88 (68.7)
UI	108 (84.4)
AI	38 (29.7)

X=mean; SD=standard deviation; IQR=interquartile range; POP=pelvic organ prolapse; UI=urinary incontinence; AI=anal incontinence

Other measurement methods accepted as the gold standard were used to determine the construct validity of the Turkish version of PFDI-20. Some types of POP are usually asymptomatic in the early stages [16]. Therefore, we took patients with Stage II and higher POP to evaluate the construct validity of the POPDI-6. The median VAS score of patients with POP was 5.00 (IQR=3.20), ranging from 0 to 10. This indicates that women in our study had moderate-to-severe prolapse. The POPDI-6 scores varied between 0 and 100.00, with a POPDI-6 score of 33.33 (IQR=44.79). There was a significant relationship between the VAS score, including the severity of the prolapse, and the POPDI-6 scores (ρ=0.75, p<0.001). This demonstrated that more severe prolapse indicates a higher POPDI-6 score.

The median Wexner score in patients with AI was 5.0 (IQR=4.0), ranging from 2 to 12. This indicates that the women in our study had mild AI. The CRADI-8 scores ranged between 0 and 4. The median CRADI-8 score was

Table 2 Comparison of the test–retest scores for PFDI-20, POPDI-6, CRADI-8, and UDI-6

Test	Test score (n=128) X±SD Median (IQR)	Retest score (n=45) X±SD Median (IQR)	p
POPDI-6	37.50 (64.58)	33.33 (58.33)	0.310
CRADI-8	21.88 (43.75)	25.00 (39.06)	0.573
UDI-6	37.50 (41.67)	41.67 (43.75)	0.278
PFDI-20	108.01±58.77	107.04±57.91	0.500

*p<0 .05

POPDI=Pelvic Organ Prolapse Distress Inventory; CRADI=Colorectoanal Distress Inventory; UDI=Urinary Distress Inventory; PFDI=Pelvic Floor Distress Inventory

Table 3 Results of the reliability analyses (test–retest and internal consistency) of the PFDI-20 and subscales

	Internal consistency (Cronbach's α)	Test–retest reliability (ICC)	*p* value for ICC
PFDI-20	0.79	0.98	<0.001
POPDI-6	0.80	0.98	<0.001
CRADI-8	0.73	0.96	<0.001
UDI-6	0.66	0.98	<0.001

ICC=interclass correlation coefficients

1.33 (IQR=1.00). A significant correlation was found between the Wexner score and the CRADI-8 score in patients with AI (ρ=0.73, $p<0.001$). This demonstrated that more severe AI indicates a higher CRADI-8 score.

The median VAS score of patients with UI was 6.00 (IQR=4.00), ranging from 1.2 to 10. This indicates that women in our study had moderate-to-severe UI. The UDI-6 scores varied between 8.33 and 100.00, with a median of 50.00 (IQR=33.33). There was a significant correlation between the VAS score and the UDI-6 scores (ρ=0.75, $p<0.001$). This demonstrated that more severe UI indicates a higher UDI-6 score.

The median EMG activity response of pelvic floor muscles was 1108.5 (IQR=631.0), ranging from 413.0 to 2,854.0. The PFDI-20 total scores ranged between 8.33 and 259.38. The median PFDI-20 total score was 98.95 (IQR=77.86). There was a statistically significant and negative correlation between the PFDI-20 score and the EMG activity response of pelvic floor muscles ρ=0.51, $p<0.001$). This demonstrated that greater pelvic floor muscle strength indicates a lower PFDI-20 total score.

Discussion

Questionnaires developed to evaluate outcomes in clinical trials, and their translations, need to be carefully validated in a target population [17–19]. The validation of patient-reported measures is important, since the questionnaire construct differs cross-culturally.

Our results revealed that the Turkish version of the PFDI-20 is a reliable tool for use in women with pelvic floor disorders, specifically with POP, AI, and UI. The Cronbach's α values preferably range between 0.7 and 0.9, although figures as low as 0.6 may be acceptable [20]. Values of α lower than 0.7–0.6 indicate high heterogeneity and values higher than 0.9 indicate that the items may be too similar. The PFDI-20, POPDI-6. and CRADI-8 were shown to have good reliability with Cronbach's α coefficient above the accepted standard of 0.70 [18]. Only UDI-6 had α values below 0.70, indicating low homogeneity. Moreover, the internal consistency of the Turkish version of the PFDI-20, which was similar to that of the Swedish version [4], may not be compared with the original version [3]. We were unable to find a study showing the internal consistency of the original version in the literature.

Interclass coefficients, a standard method of assessing test–retest reliability, were calculated to compare the PFDI-20 and subscale scores. ICCs of 0.41–0.6 were considered moderate agreement, 0.61–0.8 good agreement, and 0.81 or more excellent agreement [21]. We found that the ICC values of the Turkish version of the PFDI-20 and its subscales were over 0.90. Our results were higher than those of the English and Swedish versions. Portney and Watkins claim that ICC values of most clinical instruments exceed 0.90 and can be easily used in the clinic [22]. These results showed that application of the Turkish version of the questionnaire is quite consistent and reliable.

Linguistic validation does not consist of literal translation of the original questionnaires, but rather in developing conceptually equivalent and culturally appropriate versions adapted to the target country. There are three different studies on the translated PFDI-20 in the literature in Arabic, French, and Swedish. The Arabic and French versions of the PFDI-20 chose forward–back translation methods. The Swedish version used the dual-panel translation method, while our study used the forward–back translation method for linguistic validation. The forward–back translation method is the standard for translation of surveys and is commonly used in version studies [4, 6]; this method specifically indicates the cultural and conceptional adaptation between the original language and the target language. Thus, the translated questionnaire's understandability can increase in the target population.

In studying psychometric properties, validity coefficients within the range 0.30 to 0.40 are commonly considered to be high [23]. The construct validity of the PFDI-20 and its subscales was demonstrated with Spearman's correlation coefficients. As expected, similar scales were more highly correlated than unrelated scales. The construct validity of the Turkish version of the PFDI-20 was demonstrated by a negative correlation between the patient's EMG activity responses and their PFDI-20 scores. Pelvic floor disorders are caused by dysfunction of the ligaments, fascia, and pelvic floor muscles [14]. Therefore, decreased pelvic floor muscle strength causes increased pelvic floor disorders. In addition, the construct validity of its subscales was supported by the positive correlation between the VAS scores assessing the severity of the UI and the UDI-6 scores, the Wexner scores evaluating severity of AI and the CRADI-8 scores, and the VAS scores assessing the severity of the prolapse and the POPDI-6 scores. These correlations demonstrated construct validity of the PFDI-20 and its subscales. Furthermore, the negative correlation between EMG activity response and the PFDI-20 scores indicated that using the PFDI-20 provides a general opinion about

pelvic floor muscle strength. For this reason, using the PFDI-20 in a clinical setting is important.

Our study had some limitations. First, only 45 patients participated in the second (retest) evaluation of the PFDI-20. Some of the patients did not return to the clinic to complete the questionnaire 1 week later, as they live outside the city and under inadequate socio-economic conditions. Another limitation of this study is that the assessment of responsiveness of the Turkish version of the PFDI-20 is not available. The interval between diagnosis and arranging different types of treatment, including surgery, was generally long. It is quite difficult to obtain long-term follow-up in these patients. Therefore, it is difficult to assess the responsiveness of the Turkish version of the PFDI-20. As such, further studies are needed to investigate the responsiveness of the Turkish version of PFDI-20. This is an important criterion as ideally an instrument should be sensitive to changes.

In conclusion, the Turkish version of the PFDI-20 is a valid and reliable condition-specific questionnaire for women with pelvic floor disorders. This Turkish version of the PFDI-20, although it has some limitations, may help health-care providers in exploring symptoms in women with pelvic floor disorders, especially with POP, AI, and UI.

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Conflicts of interest None.

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