



Validation of the Polish version of the Pelvic Floor Distress Inventory

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Abstract

Introduction and hypothesis The aim of this study was to develop a Polish language version of the short form of the Pelvic Floor Distress Inventory (PFDI-20) and to validate it in a sample of Polish-speaking women with pelvic floor disorders (PFDs).

Methods The PFDI-20 was initially translated in a stepwise fashion as guided by the International Urogynecological Association (IUGA) Translation Protocol. After initial forward translation from English to Polish, a community review process consisting of cognitive interviews and confirmation via back translation was performed. The final Polish version of the PFDI-20 was administered to Polish-speaking patients presenting with PFDs at university-based urogynecology clinics in Poland and the United States, along with a Polish version of the King's Health Questionnaire (KHQ). Internal consistency and criterion validity were assessed. Test–retest reliability was assessed in 100 patients after 2 weeks.

Results A total of 254 women with PFDs enrolled in this multicenter study. Complete data from 44 Polish-speaking women in the United States and 200 women in Poland were analyzed. Participants had a mean age of 60.3 ± 11.2 years and mean body mass index (BMI) 27.6 ± 4.7 . Internal consistency as measured by Cronbach's alpha was good (0.89). Criterion validity was adequate between responses on the KHQ and PFDI-20 with Pearson correlations in particular domains (0.27–0.50, $P < 0.05$). Excellent test–retest reliability was demonstrated by intraclass correlation using a two-way mixed-effects model with absolute agreement (0.87).

Conclusions The Polish version of the PFDI is a reliable tool for evaluating pelvic floor symptoms in Polish-speaking women with PFDs.

Keywords Pelvic organ prolapse · Urinary incontinence · Pelvic floor disorders · Quality of life

Introduction

Pelvic floor disorders (PFDs), including urinary incontinence (UI), fecal incontinence (FI), and pelvic organ prolapse (POP),

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are prevalent conditions that affect 25% of women in the United States [1, 2]. Co-occurrence of PFDs is high, and many women suffer from more than one PFD [3]. Based on data from a US claims and encounters database between 2007 and 2011, the estimated lifetime risk of surgery for either stress urinary incontinence (SUI) or POP in women is 20% by the age of 80 years [4]. Similarly, the global burden and prevalence of PFDs remains high [5]. In a population-based study, 22 million people in six European countries (France, Germany, Italy, Spain, Sweden, and UK) reported overactive bladder (OAB) symptoms, with 36% reporting urgency UI [6]. Rates of SUI have also been reported as high as 29% [7]. Similarly, review of the literature on the prevalence of PFDs in 16 developing countries has shown that the mean prevalence of POP is 19.7% (range 3.4–56.4%), UI 28.7% (range 5.2–70.8%), and FI 6.9% (range 5.3–41.0%) [8].

The Pelvic Floor Distress Inventory (PFDI) is a reliable condition-specific questionnaire developed in English in 2001 by Barber et al. and consists of three separate subscales, including the Pelvic Organ Prolapse Distress Inventory (POPDI), the Colorectal–Anal Distress Inventory (CRADI),

and the Urinary Distress Inventory (UDI) [9]. Although it has been validated in women with PFDs, the PFDI is not currently available in Polish. Due to its significant clinical and research utility, the PFDI has been translated in Spanish and validated [10, 11]. Abbreviated versions of the PFDI have also been translated and validated in Chinese, Turkish, Greek, Japanese, Portuguese, Korean, Swedish, and Danish [12–19]. These validated patient-oriented symptom measures provide a means to compare symptoms and treatment outcomes across different studies and populations, improving healthcare for women as well as advancing knowledge of pathophysiology and risk factors for disease development.

Our objective was to develop and validate a Polish version of the PFDI to assess pelvic floor symptoms in Polish women with PFDs.

Materials and methods

The PFDI-20 consists of 20 condition-specific questions examining pelvic symptoms. Each question relates to the presence of an individual symptom and, if present, how bothersome it is on a 4-point scale. It contains three subscales: the Pelvic Organ Prolapse Distress Inventory (POPDI), the Colorectal–Anal Distress Inventory (CRADI), and the Urinary Distress Inventory (UDI). Each subscale is scored from 0 (least distress) to 100 (greatest distress). The sum of these three scores serves as the overall summary score of the PFDI-20 and ranges from 0 to 300.

Following approval from the Northwestern University Institutional Review Board and the Medical University of Gdansk, the PFDI-20 was initially translated in a stepwise fashion, as guided by the International Urogynecological Association (IUGA) Translation Protocol. First, two bilingual physicians in Poland and the United States performed a forward translation of the PFDI-20. Next, a community review process was undertaken consisting of one-on-one cognitive interviews with 20 patients (10 in Poland and 10 in the USA). The translated questionnaire was then back translated into English by a bilingual, independent, professional translator.

The final Polish version of the PFDI-20 was subsequently administered to Polish-speaking women presenting with PFDs at university-based urogynecology clinics in Poland and the United States, along with a Polish version of the King's Health Questionnaire (KHQ) to evaluate criterion validity of the Polish PFDI-20. The KHQ is a disease-specific questionnaire for assessing quality of life (QoL) among patients with UI. This questionnaire consists of 21 items divided into eight domains addressing General Health Perception, Incontinence Impact, Role Limitation, Physical Limitations, Social Limitations, Personal Relationships, Emotions, and Sleep and Energy [20]. Scores for each domain and results

range from 0 to 100, with higher scores indicating a more impaired QoL.

When performing psychometrics and scale evaluation, a subject-to-item ratio of at least 5:1 has been recommended [21, 22]. There were 20 items on this version on the PFDI. Therefore, a sample size of at least 100 was required to fulfill the above criteria and assess the correlation of the scales with the KHQ and objective measures of different PFDs. Assuming an effect size of .30 and an $\alpha < 0.05$, a sample size of 100 would enable the study to achieve a power > 0.90 [23, 24].

Patient self-reported primary reason for visit, demographics, medical, and surgical history variables were collected. A physical exam including the Pelvic Organ Prolapse Quantification (POP-Q) was performed. Pearson correlations were calculated between responses on the KHQ domains and the PFDI-20. Correlations were defined as small, moderate, or large (correlation coefficient thresholds of 0.1, 0.3, or 0.5, respectively), consistent with Cohen's conventions [25]. Internal consistency was determined by Cronbach's alpha. Test–retest reliability was assessed in 100 consecutive patients at the start of the study after 2 weeks by intraclass correlation coefficient (ICC) using a two-way mixed-effects model with absolute agreement. Statistical analysis was carried out using SPSS version 20 (Chicago, IL, USA).

Results

A total of 254 women with PFDs enrolled in this multicenter study and completed the questionnaires. Ten participants were excluded from the final analysis due to incomplete demographic or clinical data. Complete data from 44 Polish-speaking women in the United States and 200 women in Poland were analyzed. Mean age [\pm standard deviation (SD)] was 60.7 ± 10.4 and 58.8 ± 14.4 years for the Poland and USA cohorts, respectively. All participants were Caucasian. Both groups were similar in most demographic variables except the Poland group had a higher mean body mass index (BMI). Patient self-reported chief complaints (or primary reasons for clinical visit) included urinary symptoms, POP, or a combination. Most participants (77.9%) reported urinary symptoms; primary reasons for clinical visits did not vary between cohorts (Table 1). More women in the USA cohort completed graduate school or obtained university degrees than the Poland cohort, but the majority of all participants completed high school.

Mean (\pm SD) PFDI-20 scores for the entire cohort were 36.7 ± 27.3 , 23.5 ± 23.6 , 44.1 ± 27.4 , and 109.5 ± 64.6 for the POPDI-6, CRADI-8, UDI-6, and total PFDI-20 score, respectively. Participants with POP, UI, and FI had higher responses on the POPDI-6 ($r = 0.46$, $P < 0.01$), UDI-6 ($r = 0.46$, $P < 0.01$), and CRADI-8 ($r = 0.49$, $P < 0.01$), respectively. In the entire cohort, most patients either had stage III ($n = 134$, 54.9%) or II ($n = 64$, 26.2%) POP as defined

Table 1 Participant characteristics

	Poland cohort <i>N</i> = 200 (%)	US cohort <i>N</i> = 44 (%)	<i>P</i> value
Demographics			
Age, years (\pm SD)	60.7 \pm 10.4	58.8 \pm 14.4	0.31
BMI	28.0 \pm 4.7	25.9 \pm 4.4	<0.01
Parity, median (range)	2 (0–5)	2 (0–6)	0.35
Highest level of education			
Graduate school	56 (28%)	10 (22.7%)	0.47
College/university	5 (2.5%)	21 (46.7%)	<0.01
High school/trade school	118 (59%)	13 (29.5%)	<0.01
Primary school	12 (6%)	0	0.13
Self-reported Primary reason for visit			
Urinary symptoms	51 (25.5%)	12 (27.3%)	0.81
POP	47 (23.5%)	7 (15.9%)	0.27
Urinary symptoms and POP	102 (51%)	25 (56.8%)	0.48

Bolded data indicate statistical significance

SD standard deviation, BMI body mass index, POP pelvic organ prolapse

by the POP-Q system. Higher POP stage was correlated with higher scores on the POPDI-6 ($r = 0.39$, $P < 0.01$), indicating more symptom bother.

Moderate correlations were found between KHQ domains and the PFDI-20 (Table 2). Observed correlations ranged from 0.17 to 0.31, 0.08 to 0.31, 0.41 to 0.69, and 0.27 to 0.50 for the POPDI-6, CRADI-8, UDI-6, and total PFDI-20, respectively. Additionally, higher responses on the first question of the KHQ indicating worse self-assessment of general state of health were correlated with higher scores on the PFDI ($r = 0.40$, $P < 0.01$). Strongest correlations were observed between the UDI-6 and KHQ and weakest between all subscales of the

PFDI and the Relationships domain of the KHQ. Finally, internal consistency was demonstrated with Cronbach's alpha (range 0.8–0.85 for subscales and 0.89 for cumulative PFDI-20), and test–retest reliability was determined by ICC range from 0.8 to 0.87 (Table 3).

Discussion

We successfully translated and validated a new Polish version of the PFDI-20 using rigorous methodology at two university settings in Poland and the United States. The Polish PFDI-20 had excellent internal consistency and test–retest reliability in Polish-speaking women in Poland and the United States, which will allow for inclusion of Polish-speaking women in future studies of PFDs.

Consistent with prior studies, our analysis supports the observation that as UI, FI, and POP symptoms increase in severity, health-related QoL (HR-QoL) metrics worsen [26–28]. Additionally, PFDs are often conditions that create

Table 2 Polish PFDI-20 and KHQ correlations

	PFDI-20 subscales and total			
	POPDI-6	CRADI-8	UDI-6	PFDI-20
KHQ domains				
General health	0.31**	0.25**	0.42**	0.40**
Impact on life	0.27**	0.26**	0.63**	0.48**
Role limitations	0.28**	0.29**	0.64**	0.50**
Physical limitations	0.19**	0.20**	0.66**	0.44**
Social limitations	0.24**	0.20**	0.59**	0.43**
Relationships	0.17*	0.08**	0.41**	0.27**
Emotions	0.27**	0.25**	0.60**	0.46**
Sleep/energy	0.29**	0.31**	0.56**	0.47**
Symptom severity	0.17*	0.26**	0.69**	0.46**

PFDI Pelvic Floor Distress Inventory, POPDI Pelvic Organ Prolapse Distress Inventory, CRADI Colorectal-Anal Distress Inventory, UDI Urinary Distress Inventory

*Correlation is significant at the 0.05 level

**Correlation significant at 0.01 level

Table 3 Polish PFDI-20 internal consistency and test–retest reliability

Questionnaire	Internal consistency Cronbach's alpha	Test–retest reliability ICC
PFDI-20		
POPDI-6	0.81	0.80
CRADI-8	0.85	0.87
UDI-6	0.80	0.86
Total	0.89	0.87

PFDI Pelvic Floor Distress Inventory, POPDI Pelvic Organ Prolapse Distress Inventory, CRADI Colorectal-Anal Distress Inventory, UDI Urinary Distress Inventory, ICC intraclass correlation coefficient

shame and silence. As a result, delays in treatment are common. Barriers to seeking care include lack of knowledge regarding disorder prevalence, feelings of shame regarding the condition, fear related to symptoms, and emotional stress from coping—all of which are further exacerbated by language barriers. By providing a translated and validated version of the PFDI-20 to Polish-speaking women, we aim to provide patients with the opportunity to characterize their PFDs and a means to compare symptoms and treatment outcomes across different studies and populations, thereby improving their healthcare and advancing our knowledge of pathophysiology and risk factors for disease development.

The primary strength of this study is its enrollment of Polish-speaking patients in both the United States and Poland to create a conceptually equivalent and culturally appropriate Polish version of the PFDI. This was performed in a multicenter, prospective fashion using established, rigorous methodology. This study enrolled a diverse group of Polish-speaking women with PFDs in an effort to capture many linguistic and cultural nuances. Additionally, care was taken to ensure the condition-specific design of the PFDI-20 so all enrolled participants were presenting for treatment of their PFDs.

Several limitations to our work should be considered. First, translation and validation of the PFDI-20 in two university settings may not capture all contexts in which the questionnaire can be used, and as the PFDI is a condition-specific questionnaire, we did not enroll patients without PFDs. Due to the preponderance of Polish speakers in Poland relative to Chicago, USA, more participants were enrolled in Poland, although patient characteristics did not vary significantly. Our study was also limited by a paucity of existing Polish-language condition-specific surveys to use in reference during validation of the Polish version of the PFDI. As a result, we chose to use the KHQ, which assesses general perception of HR-QoL and symptoms related to UI. Thus, it is not surprising that the strongest correlations noted in our manuscript are in relation to urinary symptoms. Future studies are needed to increase the availability of Polish-language PFD questionnaires. Finally, although we assessed test–retest reliability of the Polish version of the PFDI, we did not evaluate it to sensitivity to change, which remains an avenue for future study.

In conclusion, our study confirms that the Polish version of the PFDI is a reliable tool for evaluating pelvic floor symptoms in Polish-speaking women with PFDs.

Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflicts of interest, except Dr. Kenton, who receives grant funding from Boston Scientific and is an expert witness for Ethicon.

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