



Translation and validation of the Polish version of the Pelvic Floor Impact Questionnaire short form 7

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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 Impact Questionnaire 7 (PFIQ-7) and to validate it in a sample of Polish-speaking women with pelvic floor disorders (PFDs).

Methods The PFIQ-7 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 USA performed a forward translation of the PFIQ-7. Next, a community review process was undertaken consisting of one-on-one cognitive interviews with 20 patients. The translated questionnaire was then back translated into English. The final Polish version of the PFIQ-7 was subsequently administered to Polish-speaking patients presenting with PFDs at university-based urogynecology clinics in Poland and the USA along with a Polish version of the Pelvic Floor Distress Inventory (PFDI-20). Internal consistency and criterion validity were assessed.

Results A total of 225 women with PFDs enrolled in this multicenter study. Complete data from 185 women in Poland and 40 primarily Polish-speaking women in the USA were analyzed. Participants had a mean age of 60.1 ± 11.1 years and mean body mass index (BMI) 27.9 ± 4.9 . The Poland and United States cohorts did not vary significantly in age, BMI, or education level. PFIQ-7 internal consistency as measured by Cronbach's alpha was good (0.93). Criterion validity was adequate between responses on the PFIQ-7 and PFDI-20 prolapse, colorectal, and urinary subscales (0.62 - 0.69 , $p < 0.05$).

Conclusions The Polish version of the PFIQ-7 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

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Introduction

Pelvic floor disorders (PFDs) including urinary incontinence (UI), fecal incontinence (FI), and pelvic organ prolapse (POP), are prevalent conditions that affect millions of women worldwide [1]. Owing to the significant health and economic burden of these conditions on individuals and society, effective therapies are paramount. In turn, as patient-reported outcomes continue to gain increased prominence in medicine, they may be used to assess treatment efficacy and patient satisfaction in women undergoing care for PFDs. Specifically, to evaluate the effectiveness of non-surgical and surgical interventions for PFDs, one should consider using a combination of metrics, including symptom severity from the patient's perspective and evaluating the multifaceted impact that the PFD may have on a woman's life [2].

The Pelvic Floor Impact Questionnaire (PFIQ) is a reliable condition-specific questionnaire that was developed in

English in 2001 by Barber et al. to assess the degree to which bladder, bowel or vaginal symptoms affect the daily activities, relationships and emotions of women with PFDs [3]. The PFIQ consists of three separate subscales, including the Urinary Impact Questionnaire (UIQ), the Colo-Rectal-Anal Impact Questionnaire (CRAIQ) and the Pelvic Organ Prolapse Impact Questionnaire (POPIQ). This initial 93-item PFIQ instrument was subsequently abbreviated to form the Pelvic Floor Impact Questionnaire 7 (PFIQ-7) [4]. Owing to its significant clinical and research utility, the PFIQ-7 has been translated and validated in other languages, including Spanish, French, Swedish, Chinese, Turkish, Korean, Norwegian, Portuguese, Afrikaans and Sesotho, Greek, Tigrigna, Finnish, and Danish [5–17].

Although the Pelvic Floor Distress Inventory short form (PFDI-20) has been translated and validated in Polish, the PFIQ-7 is not currently available in the Polish language [18]. Therefore, the aim of the study was to translate and validate a Polish version of the PFIQ-7 to assess the impact of pelvic floor symptoms on quality of life metrics in Polish women with PFDs.

Materials and methods

The PFIQ-7 consists of three subscales (bladder or urine, bowel or rectum, vagina or pelvis) and seven items: performing household chores, physical activities, entertainment, ability to travel, participation in social activities, emotional health, and frustration. Participants are asked to qualify how each symptom or condition affects their ability to function in these seven domains. Responses are determined on a four-point scale (0, Not at all; 1, Somewhat; 2, Moderately; 3, Quite a bit. Each of the three scales of the PFIQ-7 is scored from 0 (least impact) to 100 (greatest adverse impact). The sum of the scores of these three scales serves as the overall summary score of the PFIQ-7 and ranges from 0 to 300 [4].

Following approval from the Institutional Review Board at both Northwestern University in Chicago, IL, USA, and the Medical University of Gdańsk, Poland, the PFIQ-7 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 USA performed a forward translation of the PFIQ-7. 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 PFIQ-7 was subsequently administered to Polish-speaking women presenting with pelvic floor disorders at university-based urogynecology clinics in Poland and the

USA, along with a Polish version of the short form of the PFDI-20 [18].

When performing psychometrics and scale evaluation, a subject-to-item ratio of at least 5:1 has been recommended [19, 20]. There were 21 items on this version of the PFIQ-7. Therefore, a sample size of at least 105 was required to fulfill the above criteria and to assess the correlation of the PFIQ-7 with the Polish version of the PFDI-20. Patient demographics, medical and surgical history variables, and self-reported reason for visiting were collected. A physical examination, including pelvic organ prolapse quantification (POP-Q), was performed. Descriptive statistics were used to report patient characteristics and between-group comparisons were made using Chi-squared, Fisher's exact, and Mann–Whitney *U* testing, as indicated. Pearson correlations were calculated between responses on the PFIQ-7 and 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 [21]. Internal consistency was determined by Cronbach's alpha. Statistical analysis was carried out using SPSS version 20 (Chicago, IL, USA).

Results

A total of 225 women with pelvic floor disorders completed this multinational study. One hundred and eighty-five women in Poland and 40 primarily Polish-speaking women in the USA were enrolled. Participants had a mean age (\pm standard deviation) of 60.1 ± 11.1 years and mean body mass index (BMI) 27.9 ± 4.9 (Table 1). All participants were white. The Polish and US cohorts did not vary significantly in age, BMI, parity, or medical comorbidities such as hypertension and diabetes. More women in the US cohort had a history of hysterectomy and more women in the Polish cohort were using tobacco at that time. All patients had completed high school. Patient self-reported chief complaints (or primary reasons for the clinical visit) including urinary symptoms, POP, or a combination of urinary symptoms and POP. The majority of all participants (76.4%) reported urinary symptoms and 38.6% of patients reported POP symptoms. Primary reasons for clinical visits did not vary between participants in the Polish or US cohorts ($p < 0.36$).

Mean (\pm standard deviation) PFIQ-7 scores for the entire cohort were 46.4 ± 32.2 , 19.3 ± 26.8 , 36.7 ± 32.3 , and 102.7 ± 69.2 on the UIQ-7, CRAIQ-7, POPIQ-7 subscales, and composite PFIQ-7 respectively. Mean (\pm standard deviation) PFDI-20 scores for the entire cohort were 44.7 ± 25.9 , 48.4 ± 26.3 , 25.2 ± 23.5 , and 118.3 ± 59.7 on the POPDI-6, UDI-6, CRADI-8, and composite PFDI-20 respectively. Large correlations were found between the PFIQ-7 and PFDI-20 urinary, colorectal, and prolapse subscales, as well as composite questionnaire scores, ranging from 0.61 to 0.70 (Table 2).

Table 1 Participant characteristics

	Poland cohort <i>N</i> = 185 (% patients)	USA cohort <i>N</i> = 40 (% patients)	<i>p</i> value
Age (years ± SD)	60.5 ± 10.6	57.8 ± 13.2	0.87
BMI	28.1 ± 5.9	28.0 ± 5.7	0.78
Hypertension	48 (26.0)	12 (30)	0.60
Diabetes	26 (14.1)	2 (5)	0.18
History of cesarean delivery	10 (5.4)	3 (7.5)	0.71
Prior hysterectomy	20 (10.8)	11 (27.5)	0.01
Parity (median [range])	2 [0–6]	2 [0–4]	0.81
Current tobacco use	64 (34.6)	5 (12.5)	<0.01
History of tobacco use	6 (3.2)	12 (30)	<0.01
Highest level of education			
Graduate school	57 (30.8)	12 (30)	0.92
College/university	10 (5.4)	16 (40)	<0.01
Trade school (4)	39 (21.1)	0 (0)	<0.01
High school (3)	79 (42.7)	12 (30)	0.14
Prior treatments for pelvic floor symptoms			
Pelvic floor physical therapy	5 (2.7)	9 (22.5)	<0.01
Pessary	21 (11.4)	13 (32.5)	<0.01
Medications	24 (13)	2 (5)	0.18
Surgery	38 (20.5)	10 (25)	0.33
POP-Q stage (median [range])	3 [1–4]	3 [2–3]	0.31

SD standard deviation, *BMI* body mass index, *POP-Q* Pelvic Organ Prolapse Quantification

Specifically, the strongest correlations were observed between the UIQ-7 and UDI-6 (0.69), CRAIQ-7 and CRADI-8 (0.62), and POPIQ-7 and POPDI-6 (0.61). The weakest correlations were observed between the UIQ-7 and POPDI-6 (0.17), UIQ-

Table 2 Polish Pelvic Floor Impact Questionnaire 7 (PFIQ-7) and Pelvic Floor Distress Inventory 20 short form (PFDI-20) correlations

PFIQ-7 subscales and total	PFDI-20 subscales and total			
	POPDI-6	CRADI-8	UDI-6	PFDI-20
UIQ-7	0.17*	0.23**	0.69**	0.47**
CRAIQ-7	0.43**	0.62**	0.36**	0.59**
POPIQ-7	0.61**	0.38**	0.26**	0.53**
PFIQ-7	0.53**	0.53**	0.59**	0.70**

PFDI Pelvic Floor Distress Inventory, *POPDI* Pelvic Organ Prolapse Distress Inventory, *CRADI* Colorectal–Anal Distress Inventory, *UDI* Urinary Distress Inventory, *UIQ* Urinary Impact Questionnaire, *CRAIQ* Colo-Rectal–Anal Impact Questionnaire, *POPIQ* Pelvic Organ Prolapse Impact Questionnaire

*Correlation significant at 0.05 level

**Correlation significant at 0.01 level

7 and CRADI-8 (0.23), and CRAIQ-7 and UDI-6 (0.36). Additionally, higher POP-Q stage correlated with higher scores on the POPIQ-7 ($r = 0.22$, $p < 0.01$) and POPDI-6 ($r = 0.29$, $p < 0.01$).

Participants with POP, UI, and FI had higher responses on the POPIQ-7 ($r = 0.48$, $p < 0.01$), UIQ-7 ($r = 0.62$, $p < 0.01$), and CRAIQ-7 ($r = 0.42$, $p < 0.01$) respectively. In the entire cohort, most patients were found to either have stage III ($n = 134$, 54.9%) or stage II ($n = 64$, 26.2%) POP as defined by the POP-Q system. Higher POP stage correlated with higher scores on the POPDI-6 ($r = 0.39$, $p < 0.01$), indicating more symptom bother. Finally, internal consistency was demonstrated with Cronbach's alpha (range 0.93–0.95 for subscales and 0.93 for the cumulative PFIQ-7; Table 3).

Discussion

We successfully translated and validated a new Polish version of the PFIQ-7 using rigorous methodology at two university settings in Poland and the USA. This Polish version of the PFIQ-7 had excellent internal consistency in Polish-speaking women in Poland and the USA and correlated well with responses on the Polish PFDI-20.

Validation of an instrument requires several steps, including linguistic, cultural, and psychometric validation. Linguistic and cultural validation was performed during our translation process and through cognitive interviews. Psychometric validation was assessed by confirming the reliability and validity of the Polish version of the PFIQ-7. Internal consistency is a measure of reliability and indicates how well individual items correlate within the same subscale. In our study, internal consistency for all PFIQ-7 subscales was excellent, with values greater or equal to 0.93, which is in line with Spanish, Swedish, and Greek validation studies [5, 7, 14]. Similarly, Kaplan et al. reported Cronbach's alpha values for the Turkish version of the PFIQ-7 subscales ranging, from 0.73 to 0.80 [9]. Zhu et al. presented lower but acceptable Cronbach's alpha values, ranging 0.64 to 0.70, on their Chinese PFIQ-7 subscales [8].

Table 3 Internal consistency of the Polish PFIQ-7

PFIQ-7	Cronbach's alpha
UIQ-7	0.94
CRAIQ-7	0.95
POPIQ-7	0.93
Total	0.93

PFIQ Pelvic Floor Impact Questionnaire, *UIQ* Urinary Impact Questionnaire, *CRAIQ* Colo-Rectal–Anal Impact Questionnaire, *POPIQ* Pelvic Organ Prolapse Impact Questionnaire

Validity refers to the ability of an instrument to measure what it was intended to measure. An instrument should, therefore, be validated through administration to its target population [22]. Our study group consisted of women with a variety of pelvic floor disorders (UI, POP, and FI); thus, it was an appropriate study group for the validation of the PFIQ-7. Criterion validity was evaluated by comparing responses on the PFIQ-7 with responses on an established Polish version of the PFDI-20. The PFDI-20 and PFIQ-7 are two complementary questionnaires intended for women with all forms of pelvic floor disorders. The PFDI-20 is an inventory intended to measure the degree of bother associated with pelvic floor symptoms, whereas the PFIQ-7 focuses on the impact of pelvic floor symptoms on functional status [4]. The detrimental effect and impact of pelvic floor disorders on various aspects of everyday life is often an important reason for seeking medical help by patients. However, the extent to which women are bothered by their symptoms may be related to personal circumstances and attitudes as well as cultural differences [23]. Similar to studies translating and validating the PFIQ-7 into Spanish and Swedish, our study showed high correlations between the urinary, bowel, and prolapse subscales of the PFIQ-7 and PFDI-20 questionnaires, thereby establishing criterion validity [5, 7]. Specifically, our subscale correlations were greater than 0.6, thereby meeting the criteria for large correlations according to Cohen's convention.

In our study group, 133 women (59.1%) had stage 3 or 4 POP, as graded by the POP-Q. In turn, we noted a correlation between POP-Q stage and POP-related subscales ($r = 0.22$ and $r = 0.29$, $p < 0.01$). Similarly, in a Turkish study, a correlation between POP-Q stage and POPIQ-7 and POPDI-6 responses was also presented [9]. These observations add to the existing body of literature supporting the correlation of higher POP-Q stages with symptomatic prolapse [24].

The primary strength of this study is its enrollment of Polish-speaking patients in both Poland and the USA to create a conceptually equivalent and culturally appropriate Polish version of the PFIQ-7. This was performed in a multicenter, prospective fashion using established, rigorous methodology. This study enrolled a diverse group of Polish-speaking women with pelvic floor disorders in an effort to capture many linguistic and cultural nuances. Additionally, care was taken to ensure the condition-specific design of the PFIQ-7 such that all enrolled participants were presenting for treatment of their pelvic floor disorders.

Several limitations to our present work should be considered. First, the translation and validation of the PFIQ-7 in two university settings may not capture all contexts in which the questionnaire can be used. Owing to the preponderance of Polish language speakers in Poland relative to Chicago, more participants were enrolled in Poland, although patient characteristics did not vary significantly and there were no significant differences encountered between the two groups during

one-on-one cognitive interviews. Finally, our study was limited by a lack of test–retest analysis and the fact that there was no evaluation of responsiveness to treatment.

In conclusion, our study confirms that the Polish version of the PFIQ-7 is a reliable tool for evaluating pelvic floor symptoms in Polish-speaking women with pelvic floor disorders.

Contributions All authors contributed to the concept and design, acquisition of data, analysis and interpretation of data, and preparation of the manuscript.

Compliance with ethical standards

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

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