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Cultural adaptation and validation of the Pelvic Floor Distress Inventory Short Form (PFDI-20) and Pelvic Floor Impact Questionnaire Short Form (PFIQ-7) Spanish versions

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ABSTRACT

Objective: To develop a linguistically adapted and psychometrically validated Spanish version of the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire Short Forms (PFDI-20 and PFIQ-7) to assess symptoms and quality of life in Spanish women with pelvic floor disorders.
Study design: Cross-cultural linguistic adaptation was performed following the translation–back-translation method in 30 native Spanish-speaking women with pelvic floor disorders to obtain PFDI-20 and PFIQ-7 Spanish versions. The psychometric properties were evaluated in 114 women with pelvic floor disorders. We calculated the reliability with the intraclass correlation coefficient and Cronbach's alpha coefficient, the validity with Spearman coefficient, the feasibility with the response rate and the filling time, and the ceiling and floor effects.
Results: Spanish versions of the PFDI-20 and PFIQ-7 achieved good semantic, conceptual, idiomatic and content equivalence. Concerning the psychometric validation, internal consistency was high with Cronbach's alpha coefficient of 0.837 ($p < 0.001$) for PFDI-20 and 0.967 ($p < 0.001$) for PFIQ-7. The test–retest reliability was 0.644 ($p < 0.001$) for the PFDI-20 and 0.786 ($p < 0.001$) for the PFIQ-7. Good construct validity was found with questionnaires: SF-12, EPIQ and ICIQ-SF. The average administration time was 10.1 (5.8) min for the PFDI-20, and 7.5 (4.7) min for the PFIQ-7. A ceiling effect was detected in the PFIQ-7 (25.4%).
Conclusions: The PFDI-20 and PFIQ-7 Spanish versions showed semantic, conceptual, idiomatic and content equivalence with the original versions. Both instruments are reliable, valid and feasible to evaluate symptoms and quality of life in Spanish women with pelvic floor disorders.

1. Introduction

Female pelvic floor disorders (PFD) include a wide variety of clinical conditions, such as urinary incontinence (UI), fecal incontinence (FI), pelvic organ prolapse (POP), alterations in perception and emptying disorders of the lower urinary tract, defecation disorders, sexual disorders, and several chronic pain syndromes of the perineal area. The most common problems affect women from 3 to 7 times more than men [1]. Some epidemiological studies have shown that 23.7% of women suffer at least one of PFD symptoms. Up to 15.7% experience urinary incontinence, 9.0% anal incontinence and 2.9% POP [2].

Although PFD do not carry any risk to life, they certainly affect different aspects such as social, physical, psychological, occupational or sexual functioning and so involve a great impact on women's quality of life (QoL).

In order to quantify, classify and design adequate treatment for PFD, it is necessary to perform clinical assessment and also evaluate patients' subjective perceptions. A valid way to measure the subjective aspects of patients' health and wellbeing perception is through psychometrically validated and self-administered questionnaires. Because the creation of new assessment tools is

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expensive and time consuming, it is recommended to adapt and validate existing questionnaires in different populations where they will be administered. Cultural adaptation and validation involve a first phase of cross-cultural adaptation of a questionnaire, followed by validation of its psychometric properties. This methodology, besides being cheaper than creating new questionnaires, allows researchers to carry out comparisons among countries. The goal of questionnaire cross-cultural adaptation is to ensure semantic, conceptual, idiomatic and content equivalence with the original, which requires a systematic approach.

The Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) are two specific QoL questionnaires for women with PFD [3]. Both instruments were developed in 2001 by Barber et al. [4]. Later, in 2005 the author adapted the short versions: PFDI Short Form (PFDI-20) and PDIQ Short Form (PFIQ-7) [5]. Both questionnaires were adapted and validated to other languages such as French, Swedish, Chinese, Arabic, Turkish and, recently, Spanish in Hispanic speakers from the USA [6–12]. In order to consider these questionnaires as a reference in PFD assessment in Spain, it was necessary to develop a cross-cultural adaptation and posterior psychometric validation of PFDI-20 and PFIQ-7.

2. Materials and methods

Of all the women who attended the Gynecology Department of Príncipe de Asturias University Hospital in Alcala de Henares, Spain, for gynecological reasons, only women diagnosed with PDF were included in the study. For this diagnosis, women were submitted to clinic and gynecological assessment including physical examination, cough stress test, focused neurological examination, pelvic prolapse anatomical assessment using the Pelvic Organ Prolapse Quantification system (POP-Q), and post-void residual volume. After being diagnosed, women were sent consecutively to the Physiotherapy in Women's Health Research Group of Alcalá University. Women over 18 years old, who had symptoms of at least one PFD, including UI, POP and FI, were included as study sample. Women with previous pelvic surgery, current pregnancy or less than 12 months postpartum or mental incapacity to fill in the questionnaires were excluded. Written informed consent was obtained from all the participants. The data were collected from March 2010 to May 2012.

This study was approved by Príncipe de Asturias University Hospital Clinical Research Ethics Committee in Alcalá de Henares (Madrid), Spain. It was developed in three phases [13].

2.1. Phase I: translation

In order to obtain semantic, conceptual, idiomatic and content equivalence, this was undertaken in different stages. First was the forward translation, where PFDI-20 and PFIQ-7 original versions in English were translated into Spanish by two English–Spanish translators: they were native Spanish-speaking and worked independently to get two Spanish versions conceptually equivalent to the original questionnaires. Both translations were reviewed by these translators and the research team agreeing the Spanish translation synthesis. Afterwards, to get the back-translated versions, two bilingual professional Spanish–English translators, who were native English-speaking, worked independently to produce two English versions from the Spanish questionnaires obtained in the forward translation. With these back-translated versions, and with the translated versions, an Expert Committee agreed the preliminary PFDI-20 and PFIQ-7 Spanish versions equivalent to the original instruments.

2.2. Phase II: analysis of the comprehensibility of preliminary PFDI-20 and PFIQ-7 Spanish versions

Both preliminary Spanish versions (PFDI-20 and PFIQ-7) were administered to 30 native Spanish-speaking women who fulfilled the inclusion criteria. The women self-filled in the questionnaires, and after they were interviewed face-to-face in order to identify and correct potential understanding difficulties of the items and the quality of cultural adjustment. Finally, PFDI-20 and PFIQ-7 Spanish versions were obtained.

2.3. Phase III: psychometric validation of PFDI-20 and PFIQ-7 Spanish versions

Women with PFD were recruited to complete the questionnaires and thus evaluate their reliability, validity and feasibility. Women's sociodemographic and urogynecologic clinical history data were recorded. The POP stage was measured with the POP-Q. After giving their informed consent, women filled in the PFDI-20 and PFIQ-7 Spanish versions. In order to analyze the test–retest reliability, the first 25 women recruited filled in both questionnaires again two weeks later, and during this time no treatment was delivered. The SF-12 Health Survey (SF-12), International Consultation on Incontinence Short Form (ICIQ-SF) and Epidemiology of Prolapse and Incontinence Questionnaire (EPIQ) Spanish versions were also filled in by the subjects, in order to study the construct validity through the results' correlation with PFDI-20 and PFIQ-7 Spanish versions.

The PFDI-20 has twenty questions divided into three symptom scales: questions 1–6 are about genital prolapse symptoms (POPDI); questions 7–14 are on colorectal-anal symptoms (CRADI); and questions 15–20 are on urinary symptoms (UDI). The PFIQ-7 has seven questions covering the effect on activities, relationships or feelings of each symptom: urinary (UIQ), colorectal-anal (CRAIQ) and genital prolapse (POPIQ). In both the PFDI-20 and PFIQ-7 the minimum score for each block is 0 points (low involvement) and the maximum 100 points (maximum effect). The total score is the sum of the three blocks and the maximum score is 300.

The SF-12 Health Survey [14] is a self-administered questionnaire developed from the SF-36 Health Survey. It is a generic questionnaire that provides a profile of health status. Both versions have been validated in the Spanish population [15,16]. The SF-12 Health Survey results are expressed in Physical Component Summary (PCS) and Mental Component Summary (MCS) scores.

The ICIQ-SF is the short version of the Consultation on Incontinence Questionnaire Urinary Incontinence (ICIQ) questionnaire validated to Spanish [17]. It measures symptoms and urinary incontinence QoL.

The EPIQ questionnaire is an instrument that assesses the presence and severity of pelvic floor pathology [18] and it is validated in Spanish [19].

2.4. Psychometric validation process

The PFDI-20 and PFIQ-7 Spanish versions were tested for reliability, validity and feasibility.

Reliability was assessed by the test–retest reliability and internal consistency. The test–retest reliability was evaluated by the intraclass correlation coefficient (ICC), considering good values greater than 0.7 [9]. Internal consistency was measured by means of Cronbach's alpha (α), in which values greater than 0.7 show good reliability, although 0.6 may be acceptable. The higher the value is, the greater the internal consistency [8,10,20,21].

Validity was assessed by the content and convergent construct validity. Although content validity for assessing the ability of items

to collect health status was guaranteed by the validation of the original scale, in this study the Expert Committee opinion was also taken into account to judge the ability of questionnaires to assess all dimensions, in the pilot study of 30 women who reported completing the questionnaires [6,9]. The convergent construct validity was measured with a multiple comparison with questionnaires that are mainly used for PFD evaluation, assuming that correlations and mean comparisons between groups of patients with versions of validated questionnaires would go, in all cases, in the right direction. For that, the result correlations of the PFDI-20 and PFIQ-7 Spanish versions with the SF-12, ICIQ-SF and EPIQ Spanish versions were calculated. The convergent construct validity was evaluated using the Spearman correlation (r). It was considered to have high validity when the range was between 0.30 and 0.40 [10].

To evaluate feasibility, the percentage of unanswered individual items and the percentage of patients who did not answer any of the items were analyzed. Also, the average administration time was calculated. The ceiling and floor effects were analyzed to measure the percentage of subjects with the best and worst possible score obtained, respectively. Ceiling or floor effects are given when more than 15% of the responses get the best or worst possible score respectively.

SPSS® version 15 for Windows® was used for statistical analysis of the data obtained. A p-value of <0.05 was considered statistically significant for all evaluations.

3. Results

The cross-cultural adaptation of PFDI-20 and PFIQ-7 Spanish versions achieved a good semantic, conceptual, idiomatic and content equivalence.

A total of 114 women with PFD were recruited from September 2010 till May 2012 for the psychometric validation. Table 1 shows baseline socio-demographic and clinical characteristics of the subjects of the study.

Results concerning reliability, internal consistency and test–retest reproducibility are shown in Table 2. The PFIQ-20 and PFDI-7 Spanish versions showed high internal consistency with a Cronbach's α coefficient of 0.837 for PFDI-20 (range between 0.630 and 0.787 for subscales) and 0.976 for PFIQ-7 (range between 0.928 and 0.954 for subscales). In both cases all the ICCs were statistically significant ($p < 0.001$). The ICC was 0.644 for PFDI-20, and 0.786 for PFIQ-7. Therefore, test–retest reliability is acceptable for PFDI-20 and high for PFIQ-7. All the values were statistically significant ($p < 0.001$).

The revisions of experts and the subjects in the pilot study guaranteed the content validity. Spearman rank correlation matrix of PFDI-20 and PFIQ-7 with SF-12, ICIQ-SF and EPIQ is shown in Table 3. Convergent construct validity was high. PFDI-20 and PFIQ-7 Spanish versions were negatively correlated with SF-12 PCS and MCS scores, which indicate high impact in PFD with low QoL. The Spearman's rank of SF-12 Health Survey PCS was $r = -0.340$ ($p < 0.01$) in relation to PFDI-20 Spanish version; and $r = -0.394$ ($p < 0.01$) with PFIQ-7 Spanish version. The higher Spearman coefficients were related to POP dimensions, either in PFDI-20 (POPDI = −0.415) and PFIQ-7 (POPIQ = −0.480) Spanish versions. The Spearman's rank of ICIQ-SF was $r = 0.462$ ($p < 0.01$) and $r = 0.534$ ($p < 0.01$); EPIQ (US) $r = 0.594$ ($p < 0.01$) and $r = 0.567$ ($p < 0.01$); EPIQ (QoL) $r = 0.518$ ($p < 0.01$) and $r = 0.651$ ($p < 0.01$); EPIQ (POP) $r = 0.492$ ($p < 0.01$) and $r = 0.356$ ($p < 0.01$); EPIQ (CRS) $r = 0.282$ ($p < 0.01$) and $r = 0.137$ ($p < 0.01$) in relation to PFDI-20 and PFIQ-7, respectively.

Concerning feasibility, the average time for questionnaire administration was 10.1 (5.8) min for PFDI-20 Spanish version and 7.5 (4.7) min for PFIQ-7 Spanish version. A very low non-response rate was obtained in all items. The non-response maximum rates in PFDI-20 were 2/114 (4 and 17 questions). In this questionnaire the filling rates were 99.5% for complete PFDI-20 Spanish version; 99.7% for POPDI dimension; 99.9% for CRADI dimension and 99.9% for UDI dimension. On the other hand, the non-response maximum rate in PFIQ-7 was 1/114. In PFIQ-7 the filling rate for the complete PFIQ-7 Spanish version was 99%; regarding its dimensions, it was 99.6% for UIQ dimension, 99.7% for CRAIQ dimension and 99.6% for POPIQ. Besides, 10 participants did not answer one question (8.8%) of the 114 women included in the study for PFDI-20, and 2 of them did not answer two questions (0.9%). For PFIQ-7, only 6 participants did not answer one question (5.3%). Only a 25.4% of floor effect was detected in PFIQ-7 Spanish version.

Table 1
Socio-demographics and clinical characteristics of participants.

Age (years, X(SD))	56(11)
Parity (Md(IQR))	2(1)
Body mass index (X(SD))	26.6(5.1)
Education (n(%))	
Literate	19(16.6%)
Primary school	51(44.8%)
High school	17(14.9%)
University	27(23.7%)
Episiotomy (n(%))	
Yes	78(68.4%)
No	36(31.6%)
Instrumental delivery (n(%))	
Yes	27(23.9%)
No	86(76.1%)
Vaginal delivery (n(%))	
0	5(4.4%)
1	29(25.4%)
2	43(37.7%)
≥3	37(32.6%)
Clinic diagnosis (n(%))	
POP (POP-Q)	
Stage 0	29(25.4%)
Stage I	15(13.2%)
Stage II	39(34.2%)
Stage III	29(25.4%)
Stage IV	2(1.8%)
Urinary incontinence	
SUI	35(30.7%)
UUI	17(14.9%)
MUI	42(36.8%)
Anal incontinence	
FI	4(3.5%)
Flat	37(32.4%)
FI and flat	12(10.5%)

Normal distribution: X(SD): mean (deviation standard); no normal distribution: Md (IQR): median (interquartile range). SUI, stress urinary incontinence; UUI, urgency urinary incontinence; MUI, mixed urinary incontinence; FI, fecal incontinence; Flat, flat incontinence.

Table 2
Results from the analyses for internal consistency and test–retest reliability for PFDI-20 and PFIQ-7 and subscales.

	Test–retest (n = 25)		Internal consistency (n = 114)	
	ICC	P-value (for ICC)	Cronbach's α	p-Value (for Cronbach's α)
PFDI-20	0.644	<0.001	0.837	<0.001
POPDI	0.711	<0.001	0.787	<0.001
CRADI	0.771	<0.001	0.630	<0.001
UDI	0.428	=0.011	0.699	<0.001
PFIQ-7	0.786	<0.001	0.967	<0.001
UIQ	0.734	<0.001	0.928	<0.001
CRAIQ	0.797	<0.001	0.953	<0.001
POPIQ	0.875	<0.001	0.954	<0.001

ICC: interclass correlation coefficients.

Table 3
Results from the analysis of convergent construct validity (Spearman's Coefficient (*r*)) for each instrument and subscale (PFDI-20, PFIQ-7, SF-12, ICIQ-SF and EPIQ).

	PFDI-20	POPDI	CRADI	UDI	PFIQ-7	UIQ	CRAIQ	POPIQ	SF-12 (PCS)	SF-12 (MCS)	ICIQ-SF	EPIQ (US)	EPIQ (QoL)	EPIQ (POP)	EPIQ (CRS)
PFDI-20	–														
POPDI	0.787**	–													
CRADI	0.710**	0.397**	–												
UDI	0.847**	0.518**	0.439**	–											
PFIQ−7	0.433**	0.340**	0.220*	0.468**	–										
UIQ	0.393**	0.261**	0.181	0.489**	0.866**	–									
CRAIQ	0.377**	0.212*	0.397**	0.356**	0.691**	0.501**	–								
POPIQ	0.406**	0.453**	0.222*	0.343**	0.773**	0.560**	0.495**	–							
SF-12(PCS)	−0.340**	−0.415**	−0.215*	−0.219*	−0.394**	−0.293**	−0.312**	−0.480**	–						
SF-12(MCS)	−0.078	0.010	−0.188*	−0.077	−0.288**	−0.214*	−0.352**	−0.173	−0.172	–					
ICIQ-SF	0.462**	0.267**	0.207*	0.589**	0.534**	0.567**	0.317**	0.361**	−0.248**	−0.130	–				
EPIQ(US)	0.594**	0.382**	0.346**	0.625**	0.567**	0.564**	0.443**	0.427**	−0.173	−0.214*	0.637**	–			
EPIQ(QoL)	0.518**	0.333**	0.249**	0.594**	0.651**	0.694**	0.504**	0.456**	−0.246**	−0.261**	0.769**	0.737**	–		
EPIQ(POP)	0.492**	0.641**	0.264**	0.314**	0.356**	0.294**	0.219*	0.451**	−0.336**	−0.035	0.074	0.283**	0.230*	–	
EPIQ(CRS)	0.282**	0.136	0.449**	0.112	0.137	0.005	0.314**	0.134	−0.148	−0.175	0.078	0.185*	0.087	0.113	–

PCS, physical component summary; MCS, mental component summary; US, urinary symptoms; QoL, quality of life; POP, pelvic organ prolapse; CRS, colorrectal symptoms.
* $p < 0.05$.
** $p < 0.01$.

4. Discussion

The PFDI-20 and PFIQ-7 are recommended questionnaires to assess PFD symptoms and measure their impact on women's QoL [3,22,23]. Both questionnaires have been adapted and validated to other languages such as French, Swedish, Chinese, Arabic, Turkish and Spanish for Hispanic women in USA [6–12].

The translation/back-translation method was used for the cultural adaptation of PFDI-20 and PFIQ-7 Spanish versions, similar to that performed in the PFDI-20 and PFIQ-7 Turkish, Chinese, Arabic and French versions [6,7,9–11]. In contrast, the Swedish version used a dual translation method, and the Spanish version in Hispanic used the Translation, Review, Adjudication, Pretesting, and Documentation method (TRAP) [12].

The linguistic adaptation process showed that women easily understand PFDI-20 and PFIQ-7 Spanish versions.

Baseline data showed that the sample was similar to other validations of these questionnaires. Regarding clinical factors, women included in this study presented with urinary and anal incontinence and POP, as in the original, French, Turkish and Hispanic validation studies.

The results of convergent construct validity indicated a good relationship between the SF-12 Health Survey PCS dimension and the PFDI-20 and PFIQ-7 Spanish versions. On the other hand, the SF-12 Health Survey MCS only showed good correlation with CRAIQ. That may suggest PFD symptoms primarily affect women's physical component perception, and not so much the mental one, although colorectal symptoms affect either physical or emotional perception. When comparing PFDI-20 and PFIQ-7 with EPIQ and ICIQ-SF, the scores for the dimensions that measure the same symptoms showed a high correlation, which may seem logical. For example, urinary incontinence symptoms have a good correlation between the UDI dimension and the ICIQ-SF, EPIQ (US) and UIQ.

Both questionnaires, PFIQ-7 and PFDI-20 Spanish versions, showed a good reliability, assessed through internal consistency and test–retest reliability. These results are very similar to the original versions and the validations in other languages, such as Chinese, Swedish or Turkish [6–11]. The ICC values were lower in both questionnaires in the subscales that assessed urinary symptoms and impact (UDI and UIQ). This might be because in this study women with urological symptoms often considered these symptoms as normal, due to aging or delivery. Only when asked about them, they often became conscious of them and suggested that maybe they were not normal. Perhaps, for this reason, in the questionnaires second compliance (retest), the assessment of symptoms and impact were not the same, despite having no clinical changes.

The feasibility of both questionnaires was good, because the rates of "no response" were very low. These rates were comparable to the Swedish and French validations [7,8]. The average time of filling in was 10.1 (5.8) min for the PFDI-20 Spanish version, very similar to the French version (9.2 min). Regarding the PFIQ-7 Spanish version, it was 7.5 (4.7) min, higher than in the French version (3.4 min), which is the only validation that includes the filling time [7]. The PFIQ-7 Spanish version showed a floor effect (25.4%). That can only be compared with the Swedish validation which studied this effect and found no ceiling or floor effects [6].

While this work was in progress, PFDI-20 and PFIQ-7 Spanish versions in the USA in Hispanic women were published [12]. Although both questionnaires are in Spanish, the questionnaires developed in USA should be validated in Spanish population to be used in Spain, because linguistic adaptation does not consist of literal translation, but rather in developing conceptually equivalent and culturally appropriate versions adapted to the target country. So, the validation of an instrument is necessary in order to be used in different countries with the same language to check the linguistic validation [24].

The PFDI-20 and PFIQ-7 Spanish versions validations demonstrated psychometric properties of validity, reliability and feasibility for women with PFD, especially in women with POP, urinary incontinence and anal incontinence. That means developing PFD evaluation from the patient's point of view, which is a requirement according to the recommendations of the fourth International Consultation on Incontinence [25]. Validated questionnaires' cultural adaptations provide a widely used tool, as well as the possibility of international multicenter studies and comparing results of studies from different countries.

A limitation of this study is that the responsiveness of the Spanish versions of PFDI-20 and PFIQ-7 is not available. We need to study this psychometric propriety in the future.

5. Conclusion

The validated Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire short forms Spanish versions (PFDI-20 and PFIQ-7) showed semantic, conceptual, idiomatic and content equivalence with the original versions. Both instruments are reliable, valid and feasible to evaluate symptoms and quality of life in Spanish women with pelvic floor disorders.

Conflict of interest

No conflict of interest reported.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ejogrb.2013.07.006.

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