



Responsiveness of the Spanish Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaires Short Forms (PFDI-20 and PFIQ-7) in women with pelvic floor disorders



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ABSTRACT

Objective: To evaluate the responsiveness of the Spanish versions of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire Short Forms (PFDI-20 and PFIQ-7), in order to assess symptoms and quality of life in Spanish women with pelvic floor disorders.

Study design: Prospective observational study to assess the responsiveness in 85 women with pelvic floor disorders. PFDI-20 and PFIQ-7 were completed before and after Physiotherapy intervention. The responsiveness was assessed with the *p* values using the Wilcoxon signed-rank test, the standardized response means of the change (SRM) and the effect size (ES).

Results: The Spanish PFDI-20 and PFIQ-7 and the subscales demonstrated small to good responsiveness. The responsiveness was higher for PFDI-20 than for PFIQ-7. The statistic for PFDI-20 was moderate to good (ES 0.68 and SRM 0.84; $p < 0.0001$), and small to moderate for PFIQ-7 (ES 0.48 and SRM 0.57; $p < 0.0001$). Regarding the subscales, the responsiveness was better for Pelvic Organ Prolapse Distress Inventory (POPDI) than Pelvic Organ Prolapse Impact Questionnaire (POPIQ) (ES 0.70 and SRM 0.78; ES 0.42 and SRM 0.47 respectively; $p < 0.0001$). Moderate responsiveness was found for Urinary Distress Inventory (UDI) and Urinary Impact Questionnaire (UIQ) (ES 0.54 and SRM 0.67; ES 0.52 and SRM 0.61 respectively; $p < 0.0001$). Colo-Rectal-Anal Distress Inventory (CRADI) and Colo-Rectal-Anal Impact Questionnaire (CRAIQ) showed poor responsiveness, small in both (ES 0.42, SRM 0.50 and $p < 0.0001$; ES 0.34, SRM 0.39 respectively; $p < 0.001$). All responsiveness was significant.

Conclusions: PFDI-20 and PFIQ-7 Spanish versions showed good responsiveness to evaluate the symptoms and the quality of life in Spanish women with PFD undergoing Physiotherapy treatment.

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Introduction

Female pelvic floor disorders (PFD) include a wide variety of conditions, such as pelvic organ prolapse (POP), anal incontinence, urinary incontinence (UI), voiding and defecations dysfunction, sexual disorders and several chronic pain syndromes of the perineal area [1]. Although these conditions do not carry any risk to life, the women who undergo PFD usually report they have a negative impact on their quality of life (QoL).

Assessment of QoL in women who suffer PFD is essential for making a diagnosis and designating an adequate treatment.

Therefore, it is necessary to evaluate women's subjective perception. A valid way to measure the patients' perspectives is through psychometrically-validated and self-administered questionnaires that can address the presence and severity of PFD symptoms, and their impact in daily activities and QoL. Symptom severity and QoL in women with PFD can be assessed by two specific questionnaires, the Pelvic Floor Distress Inventory (PFDI-20) and the Pelvic Floor Impact Questionnaire (PFIQ-7) [2].

PFDI-20 and PFIQ-7 are the short versions of two questionnaires developed in 2001 by Barber in the United States of America [3]. Both questionnaires have been validated in different languages such as French, Swedish, Chinese, Arabic, Turkish, Spanish in Hispanic speakers from USA, Spanish for speakers in Spain and, recently, Japanese, Danish, Greek and Dutch [4–15]. The cultural adaptation and validation questionnaire is cheaper than creating

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new questionnaires and it allows researchers to carry out comparisons among countries. It also permits to compare different populations and design multinational studies [16].

It is widely argued that outcome measures in clinical trials should be valid, reliable and responsive or sensitive to change [17]. The validity of a questionnaire is simply whether it measures what it is intended to; the reliability is the ability of an instrument to measure consistently in a reproducible way; and the responsiveness is the ability to detect changes that occur as a result of therapy or disease progression [18].

Adequate responsiveness is an essential psychometric property for any questionnaire. Assessment of responsiveness is of particular value to the clinician, since it can be an indicator of the value of a therapeutic intervention, the need for treatment change and, in general, the degree of satisfaction of the subject to treatment.

In the Spanish validation of PFDI-20 and PFIQ-7 [15], the psychometric properties of feasibility, validity, reliability and ceiling and floor effects were tested, although the responsiveness has not yet been published. Responsiveness is a very important psychometric property that is often forgotten in the studies. For this reason, the aim of the present study was to evaluate the responsiveness of the Spanish PFDI-20 and PFIQ-7 in women with PFD who were undergoing Physiotherapy treatment.

Materials and methods

Consecutive women diagnosed with non-surgery PFD were recruited from the Gynecology Department of Príncipe de Asturias University Hospital in Alcalá de Henares, Spain, between March 2011 and June 2014. They were subjected to clinical and urogynaecological examination, including physical examination, cough stress test, pelvic prolapse anatomical assessment with the Pelvic Organ Prolapse Quantification system (POP-Q) and post-void residual volume. Women over 18 years old, diagnosed with at least one symptom of PFD (UI, POP, AI) existing for at least three months, were included in the study sample. UI was classified according to the type of urinary incontinence as stress urinary incontinence (SUI), where the urinary loss occurs before an increase in abdominal pressure; urge urinary incontinence (UUI) when urinary incontinence is associated to urging to urinate; and mixed urinary incontinence (MUI) which is the combination of both. On the other hand, anal incontinence was classified in two types of incontinence, as fecal incontinence (FI); flat incontinence; or anal incontinence (AI) that is the combination of both. POP scale was classified according the Pelvic Organ Prolapse Quantification (POP-Q), in grades 0–4. Women with previous pelvic surgery within the last 5 years before the study starts, PFD surgery,

pregnant, less than 12 months postpartum or mental incapacity to fill in the questionnaires were excluded. The participants received a Physiotherapy intervention consisting of pelvic-perineal techniques and behavioral training by the Physiotherapy in Women’s Health Research Group of Alcala University. They completed the PFDI-20 and PFIQ-7 Spanish versions twice: the first time after giving their informed consent, and the second time in a review six months after the Physiotherapy intervention. Women’s socio-demographic and urogynaecologic clinical history data were recorded. The written informed consent was obtained from all the participants. The study was approved by the Príncipe de Asturias University Hospital Clinical Research Ethics Committee in Alcalá de Henares (Madrid), Spain.

PFDI-20 reflects different perspectives, so it includes 20 questions divided into three symptom scales: genital prolapse symptoms (POPDI) (questions 1–6); colorectal-anal symptoms (CRADI) (questions 7–14); and urinary symptoms (UDI) (questions 15–20). CRADI scale questions are about FI, except for question 11 that is about flat incontinence; while UDI scale the specific question about UUI is number 16 and about SUI is number 17. Each of the questions can be answered on four levels of dysfunction: none, a little, moderately or a lot. The minimum score for each block is 0 points (minimal dysfunction) and the maximum 100 points (maximum dysfunction). The total score is the sum of the three blocks and the maximum score is 300 (Table 1).

PFIQ-7 includes seven questions concerning the general impact on activities, relationships or feelings of each symptom: urinary (UIQ), colorectal-anal (CRAIQ) and genital prolapse (POPIQ). Each of the questions can be answered on four levels of involvement: none, a little, moderately or a lot. 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 (Table 2).

In order to evaluate the responsiveness of the scales, three distribution based methods were used: the *p* values generated using the Wilcoxon signed-rank test, the effect size (ES) and the standardized response means of the change (SRM) in scores from baseline to six months for each scale and dimension were assessed. The baseline scores were compared with scores after six months using the paired *t* test. The ES is equal to the mean change in score divided by the standard deviation of individual’s baseline. The SRM is equivalent to the change in score over a time period divided by the standard deviation of the change. For SRM and ES a value of 0.2–0.5 was regarded as small, 0.5–0.8 as moderate, above 0.8–1.0 as good and more than 1.0 as excellent [2,19,20].

The data were statistically analyzed using the SPSS® version 15 for Windows®; a *p*-value of <0.05 was considered statistically significant.

Table 1
Scoring PFDI-20.

Pelvic Organ Prolapse Distress Inventory Scale (POPDI-6)		Colorectal-Anal Distress Inventory Scale (CRADI-8)	Urinary Distress Inventory Scale (UDI-6)		
Questions 1–6		Questions 7–14	Questions 15–20		
1.		7.	15.		
2.		8.	16.		
3.		9.	17.		
4.		10.	18.		
5.		11.	19.		
6.		12.	20.		
		13.			
		14.			
Total:	/6	Total:	/8	Total:	/6
Average score:	×25	Average score:	×25	Average score:	×25
Scale:	(range 0–100)	Scale:	(range 0–100)	Scale:	(range 0–100)

None: 1; A little: 2; Moderately: 3; A lot: 4.

Table 2
Scoring PFIQ-7.

Urinary Impact Questionnaire Scale (UIQ-7)	Colorectal-Anal Impact Questionnaire Scale (CRAIQ-7)	Pelvic Organ Prolapse Impact Questionnaire Scale (POPIQ-7)
1.	1.	1.
2.	2.	2.
3.	3.	3.
4.	4.	4.
5.	5.	5.
6.	6.	6.
7.	7.	7.
Total:	/7	Total: /7
Average score:	×(100/3)	Average score: ×(100/3)
Scale:	(range 0–100)	Scale: (range 0–100)

None: 0; A little: 1; Moderately: 2; A lot: 3.

Results

A total of 89 women with PFD were recruited for the responsiveness assessment. Data were collected from March 2011 to June 2014. The baseline socio-demography and clinical characteristics of the subjects are listed in Table 3. Mean age was 53.7(9.7). A POP-Q grade I was found in 27.1% and grade II in 72.9%. The more frequent UI was stress urinary incontinence (SUI) (68.2%), and the most common symptom of ano-rectal dysfunction was the flat incontinence, with 29.4%.

Table 3
Socio-demographics and clinical characteristics of study sample.

Age (years, X(SD))	53.7(9.7)
Parity (Md(IQR))	2(1)
Body mass index (X(SD))	27.5(5.6)
Education (n(%))	
Literate	9(10.6%)
Primary School	49(57.6%)
High School	15(17.6%)
University	12(14.1%)
Menopausia (n(%))	
Yes	45(52.9%)
No	40(47.1%)
Episiotomy (n(%))	
Yes	63(77.8%)
No	18(22.2%)
Instrumental delivery (n(%))	
Yes	26(30.6%)
No	59(69.4%)
Cesarean (n(%))	
Yes	9(11.1%)
No	72(88.9%)
Clinic diagnosis (n(%))	
POP-Q grade(n(%))	
Grade I	23(27.1%)
Grade II	62(72.9%)
Urinary incontinence(n(%))	
SUI	58(68.2%)
UUI	35(41.2%)
MUI	29(34.1%)
Anal incontinence (n(%))	
FI	12(14.1%)
Flat I	25(29.4%)
AI	13(15.3%)
Number of pelvic floor disorders per woman (n(%))	
1	11(12.9%)
2	57(67%)
3+	17(20%)

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

Table 4 shows the responsiveness of the PFDI-20 and PFIQ-7 questionnaires and subscales between baseline and six months after the Physiotherapy intervention.

The responsiveness for PFDI-20 was better than for PFIQ-7; for PFDI-20 it was moderate to good (ES 0.68 and SRM 0.84; $p < 0.0001$), and small to moderate for PFIQ-7 (ES 0.48 and SRM 0.57; $p < 0.0001$). Regarding the prolapse scales, the responsiveness was better for POPDI than for POPIQ; it was moderate in the first case and small in the second (ES 0.70 and SRM 0.78; ES 0.42 and SRM 0.47 respectively; $p < 0.0001$). Moderate responsiveness was found for the urinary scales of PFDI-20 and PFIQ-7 (ES 0.54 and SRM 0.67; ES 0.52 and SRM 0.61 respectively; $p < 0.0001$). The colorectal scales showed poor responsiveness; small in CRADI and CRAIQ (ES 0.42, SRM 0.50 and $p < 0.0001$; ES 0.34, SRM 0.39 respectively; $p < 0.001$). All responsiveness was significant.

Comment

The clinician must try to make the best choice among the different instruments to evaluate woman's perception on her health change. In addition to selecting the most appropriate measurement instruments, they must be sensible, reliable, valid and responsive. The responsiveness has been suggested as one criterion to choose among scales used to evaluate the efficacy of a therapeutic intervention. Responsiveness is an important psychometric property of a questionnaire, because a low responsiveness can increase the risk of a type II error, accepting no difference when a real difference in fact exists, and so underestimating the effect of treatment [18]. Thus, responsiveness or sensitivity to change is considered as a fundamental characteristic of the evaluation instruments. There is no consensus in the literature on the concept of responsiveness of an instrument or the form in which it should be measured [21]. There are different methodologies to assess responsiveness and no single one has proven to be better than others [19]. Guyatt defined the responsiveness as the ability of a questionnaire to detect clinically important changes over time, even if there are small changes [22]. The statistic usually used to quantify it is the ES statistic or an SRM, and, in several respects, the interpretation of responsiveness statistics is analogous to the interpretation of p -values used in treatment trials [17,23–25]. Therefore, in the present study the responsiveness of Spanish PFDI-20 and PFIQ-7 was evaluated with the ES, the SRM and the p -value.

Disease-specific scales have generally been reported to be more responsive than generic scales [24]. The PFDI-20 and the PFIQ-7 are two specific questionnaires that are recommended to measure the symptoms and QoL in women with PFD [26–28]. Both questionnaires have been adapted and validated in their original language and later translated and validated in several languages [4–15]. However, only the original, Turkish, Greek, Danish and

Table 4
Mean change in scores and responsiveness of the Spanish PFDI-20 and PFIQ-7 questionnaires.

n = 85	Pretreatment mean (SD) score	Posttreatment mean (SD) score	p value	Mean change in score (SD)	Effect size (ES)	Standardized response mean (SRM)
PFDI-20	76.41(50.94)	41.93(39.79)	<0.001	34.48(41.04)	0.68	0.84
POPDI	29.64(20.97)	15.04(17.44)	<0.001	14.6(18.65)	0.70	0.78
CRADI	16.17(14.32)	10.22(11.81)	<0.001	5.95(11.91)	0.42	0.50
UDI	30.59(25.94)	16.66(19.73)	<0.001	13.93(20.92)	0.54	0.67
PFIQ-7	60.26(74.79)	24.03(38.46)	<0.001	36.23(63.15)	0.48	0.57
UIQ	26.81(30.41)	11.14(17.96)	<0.001	15.67(25.65)	0.52	0.61
CRAIQ	16.04(26.63)	7.0 (16.44)	=0.001	8.93(22.94)	0.34	0.39
POPIQ	17.4(27.58)	5.77(14.04)	<0.001	11.63(24.81)	0.42	0.47

PFDI: Pelvic Floor Distress Inventory; POPDI: Pelvic Organ Prolapse Distress Inventory; CRADI: Colorectal-Anal Distress Inventory; UDI: Urinary Distress Inventory; PFIQ: Pelvic Floor Impact Questionnaire; UIQ: Urinary Impact Questionnaire; CRAIQ: Colorectal-Anal Impact Questionnaire; POPIQ: Pelvic Organ Prolapse Impact Questionnaire; SD: standard deviation; ES: effect size; SRM: standardized response means.

Dutch have studied the responsiveness of PFDI-20 and PFIQ-7 [2,9,11,13,14].

In the present study many similar results were found when compared to the other responsiveness studies. The responsiveness in this study was moderate to good in PFDI-20 and small to moderate in PFIQ-7, as well as in the other responsiveness studies (original, Greek, Danish and Turkish) which was higher in PFDI-20 than in the PFIQ-7. This fact suggests that the PFDI-20 is more responsive than PFIQ-7 [2]. This fact was also reported in the original and Chinese long versions of PFDI and PFIQ [18,29].

In the Spanish PFDI-20 the subscale that demonstrated more responsiveness was the POPDI, followed by the UDI. In the PFIQ-7, the subscale with more responsiveness was the UIQ, followed by the POPIQ. This fact might suggest that the POP clinic is more symptomatic than the urinary clinic, but that the urinary symptoms affect more the QoL than the POP symptoms. Barber et al. [2,18] also had these results in the original PFDI-20 and PFIQ-7 versions and their long versions (PFDI and PFIQ). Regarding these findings, the experience shows that women often indicate that the urinary symptoms have more impact than POP symptoms, which is consistent with the results found in the present study.

Table 5
Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire Short Forms Responsiveness Studies.

Author (year-lenguaje)	Dysfunction (n)	Assessment	Questionnaire and subscales	Pretreatment mean (SD) score	Posttreatment mean (SD) score	ES	SRM	p value*
Barber M. (2004-English)	PFD (45)	3–6 months after surgery	PFDI-20	121.6 (48.2)	50.2 (38.9)	1.48	1.09	<0.0001
			POPDI	46.6 (26.9)	12.3 (13.7)	1.28	1.15	<0.0001
			CRADI	30.9 (19.0)	16.3 (14.7)	0.78	0.70	<0.0001
			UDI	44 (23.3)	21.6 (21.7)	0.96	0.73	<0.0001
			PFIQ-7	62.9 (58.3)	23.8 (39.4)	0.67	0.63	<0.001
			UIQ	28.1 (22.1)	13.0 (18.1)	0.68	0.55	<0.001
			CRAIQ	17.2 (24.6)	5.7 (12.2)	0.47	0.51	<0.002
			POPIQ	17.7 (23.9)	5.1 (16.7)	0.52	0.50	<0.002
Kaplan P. (2012-Turkish)	POP (103)	6 months after surgery	PFDI-20	145.0 (35.4)	95.9 (20.0)	1.38	1.42	<0.001
			POPDI	55.7 (18.2)	28.6 (7.6)	1.48	1.39	<0.001
			CRADI	35.5 (9.9)	29.4 (6.4)	0.61	0.54	<0.001
			UDI	53.7 (18.0)	37.8 (13.0)	0.88	0.91	<0.001
			PFIQ-7	78.9 (55.7)	9.1 (19.6)	1.25	1.23	<0.001
			UIQ	25.5 (31.7)	6.6 (17.8)	0.59	0.58	<0.001
			CRAIQ	6.6 (18.2)	1.8 (8.7)	0.26	0.25	<0.001
			POPIQ	46.7 (31.8)	0.6 (3.4)	1.45	1.45	<0.001
Due U. (2013-Danish)	POP (43)	3 months after surgery	PFDI-20	104.6 (60.7)	40.4 (46.1)	1.0	1.2	<0.001
			POPDI	44.7 (24.1)	9.9 (13.5)	1.4	1.5	<0.001
			CRADI	20.1 (20.6)	12.5 (16.1)	0.4	0.5	0.002
			UDI	37.8 (28.3)	18.7 (23.2)	0.7	0.7	<0.001
			PFIQ-7	56.7 (59.1)	15.0 (30.7)	0.7	0.8	<0.001
			UIQ	21.4 (26.5)	7.1 (14.1)	0.5	0.5	0.002
			CRAIQ	11.0 (15.7)	4.6 (10.7)	0.4	0.5	0.014
			POPIQ	26.3 (26.9)	3.8 (8.9)	0.8	0.8	<0.001
Grigoriadis T. (2013-Greek)	PFD (85)	6 months after surgery	PFDI-20	100 (46)	25 (30)	1.61	1.49	<0.001
			POPDI	49 (23)	5 (8)	1.92	1.99	<0.001
			CRADI	17 (16)	13 (14)	0.27	0.26	0.022
			UDI	33 (22)	9 (16)	1.06	0.94	<0.001
			PFIQ-7	73 (54)	11 (24)	1.15	1.18	<0.001
			UIQ	25 (31)	4 (12)	0.60	0.64	<0.001
			CRAIQ	5 (15)	7 (17)	-0.11	-0.09	0.544
			POPIQ	43 (31)	0.3 (2)	1.39	1.40	<0.001

PFD: pelvic floor disorders; POP: pelvic organ prolapse; PFDI: Pelvic Floor Distress Inventory; POPDI: Pelvic Organ Prolapse Distress Inventory; CRADI: Colorectal-Anal Distress Inventory; UDI: Urinary Distress Inventory; PFIQ: Pelvic Floor Impact Questionnaire; UIQ: Urinary Impact Questionnaire; CRAIQ: Colorectal-Anal Impact Questionnaire; POPIQ: Pelvic Organ Prolapse Impact Questionnaire; ES: effect size; SRM: standardized response means.

* Paired t test.

Furthermore, in both questionnaires, the subscales that demonstrated less responsiveness were the colorectal-anal subscales; in the other validation studies the urinary and POP subscales also demonstrated more responsiveness than the colo-rectal scales [2,9,11,13,14]. This may be because in the sample of this study the smallest clinic percentage was for women with colorectal-anal symptoms, and a specific clinic has the largest changes in the subscales that assess this clinic was accepted (for example, the UI have more changes in UDI and UIQ) [30]. Also, the bowel symptoms are attributed mainly to an abnormal ano-rectal function [31], so Physiotherapy would involve the smallest changes in these subscales.

In the PFDI-20 and PFIQ-7 original, Turkish, Greek and Danish versions responsiveness was calculated in terms of SRM and ES (Table 5), and showed higher responsiveness than in the present study. This may be for different reasons. Firstly, the samples were different. In the original and in the Greek versions the samples were women with PFD, while the Turkish and the Danish versions they used surgical POP. The participants of the present study were also women with PFD, which included UI, AI and non-surgical POP grades I and II. The literature indicates the relation between the POP stage and symptoms, where more severe POP reports more symptoms [32,33], and some authors report worse QoL in patients with more severe POP [34,35]. These relations could explain that the baseline scores in the others validation studies were higher than in the Spanish version, and our experience indicates that higher symptoms involve more possibilities of improvement.

Secondly, the type of treatment was different in the studies. In all the others validations the treatments were surgical, with an assessment between three and six months after surgery. In the present study, participants received a Physiotherapy intervention with pelvic-perineal techniques and behavioral training, with an assessment after six months of intervention. Despite the fact that Physiotherapy demonstrated effectiveness for PFD treatment [36], the change was not enough to show a large responsiveness statistic, because it varies as a function of effectiveness of treatment. The nature of change of the study must be considered before interpreting the magnitude, and to know what the patients consider “change” in their health [23]. In these terms, in the long PFDI and PFIQ original versions [18], Barber et al. found that the women in the conservative treatment (pessary group) had higher post-treatment scores compared with women in the surgery group. Therefore, the responsiveness was higher in the surgery treatment than in the conservative one.

The objective of this study was to prove the responsiveness of Spanish PFDI-20 and PFIQ-7 questionnaires, and the results indicate that these instruments are adequate to assess symptom and QoL changes in women with PFD.

In conclusion, PFDI-20 Spanish version showed moderate to good responsiveness, while PFIQ-7 Spanish version showed small to moderate responsiveness in women with pelvic floor disorders undergoing Physiotherapy treatment.

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Conflicts of interest

The authors indicate no potential conflicts of interest.

Authors contribution

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