Further Validation of the short form versions of the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ)

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The PFDI-20 and PFIQ-7 scales correlate well with the PFDI and PFIQ long form and have similar overall responsiveness in three studies with different populations.

Abstract

Objective: To evaluate validity and responsiveness of PFDI and PFIQ short forms across 3 multi-center studies and develop conversion formulas between short and long versions.

Methods: 942 participants in 3 prospective studies completed long versions of the PFDI, PFIQ and SF-36 at baseline and 3 and 12 months after treatment. Responses were used to calculate scores for the short versions. We calculated correlations between scale versions using Pearson's correlation coefficient and compared their relative responsiveness using the standardized response mean.

Results: PFDI and PFIQ short form scale scores demonstrated excellent correlations with long versions and similar responsiveness. Responsiveness was excellent for PFDI-20 urinary and prolapse scales, moderate for PFDI-20 colorectal scale and each of the PFIQ-7 scales, and poor for SF-36 summary scores. Conversion formulas demonstrated excellent goodness of fit.

Conclusions: The long and short forms of the PFDI and PFIQ correlate well and have similar overall responsiveness.

Key Words: quality of life, pelvic organ prolapse, urinary incontinence, pelvic floor, questionnaires, responsiveness

Introduction

The Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ) are two complementary condition-specific health-related quality of life questionnaires for women with pelvic floor disorders.[1] These two instruments are based on the structure and content of two widely-used condition-specific quality of life questionnaires for women with lower urinary tract dysfunction, the Urinary Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ), which were originally described by Shumaker et al.[2] The PFDI and PFIQ together can be used by clinicians and researchers to measure the extent to which lower urinary tract, lower gastrointestinal tract and pelvic organ prolapse symptoms affect the quality of life of women who suffer from disorders of the pelvic floor. Each measure has three scales: urinary, colo-rectal anal and prolapse. The PFDI and PFIQ have each been shown to be psychometrically valid, reliable and responsive to change.[1, 3, 4] The 46-item PFDI assesses symptom distress in women with pelvic floor disorders and has three scales: the Urinary Distress Inventory (UDI; range 0-300), the Pelvic Organ Prolapse Distress Inventory (POPDI: range 0-300), and the Colorectal-Anal Distress Inventory (CRADI; range 0-400).[1] Similarly, the PFIQ measuring the impact of bladder, bowel, and vaginal symptoms on a woman's daily activities, relationships and emotions is composed of 3 scales of 31 questions each: the Urinary Impact Questionnaire (UIQ; range 0-400), the Pelvic Organ Prolapse Impact Questionnaire (POPIQ; range 0-400), and the Colorectal-Anal Impact Questionnaire (CRAIQ; range 0-400). [1]

In spite of the strengths of the PFDI and PFIQ, including their comprehensive coverage of symptom distress and impact on quality of life, their relative length may be inefficient or impractical for some clinical or research situations. Table 1 displays the item reduction used to develop the short forms of the PFDI (PFDI-20) and PFIQ (PFIQ-7).[5] The PFDI-20 and PFIQ-7 demonstrated excellent correlation with their long-form counterparts in the original validation population (n=100) and in a second independent sample of 45 women undergoing pelvic

reconstructive surgery (r=.88-.94 for scales of PFDI-20; r=.95-96 for scales of PFIQ-7, p<.0001 for all). The test-retest reliability of each scale in the short forms was good to excellent (ICC .70-.93, p<.001 for all scales). Moreover, the scales and summary scores of the PFDI-20 and PFIQ-7 demonstrated moderate to excellent responsiveness 3 to 6 months after surgery.[5]

In this analysis, we planned to: (1) further evaluate the validity and responsiveness of the PFDI-20 and PFIQ-7 (short versions of the PFDI and PFIQ) across 3 multi-center studies using diverse patient samples and treatment approaches for pelvic floor disorders and (2) propose formulas for the conversion of scores between short and long versions of the PFDI and PFIQ.

Methods

We analyzed 942 subjects who enrolled in one of three prospective studies (two surgical trials for pelvic organ prolapse and one non-surgical urinary incontinence trial) conducted by the Pelvic Floor Disorders Network (PFDN) and completed at least one of scales of the long-form version of PFDI and PFIQ at baseline; 81% and 73% of which were evaluated at 3 and 12 months post-treatment follow-up. The specifics of each trial including methods and primary outcomes have been reported previously.[6-10] In brief, 316 subjects from the CARE trial, a randomized trial designed to evaluate whether a standardized modified Burch colposuspension, when added to abdominal sacrocolpopexy to treat pelvic organ prolapse, improves urinary stress continence in subjects without preoperative symptoms of stress urinary incontinence;[6, 7] 140 from the colpocleisis trial, a cohort study studying the effect of colpocleisis, a surgical procedure, on pelvic support, symptoms, quality of life, report-associated morbidity, and postoperative satisfaction;[8] 486 from the ATLAS trial, a randomized trial comparing behavioral therapy, incontinence pessary, and a combination of the two for treatment of stress urinary incontinence.[9, 10] Each clinical site and the data coordinating center in PFDN

received institutional review board approval for each of the three trials, and all subjects provided written informed consent.

Data from all study participants from these 3 studies were used for this ancillary analysis. In each study, the instruments were administered either by telephone or in person at baseline and 3 and12 months after the intervention. Participant responses to the PFDI and PFIQ individual items that are included in the short form versions were used to calculate the scores for PFDI-20 and PFIQ-7 scales including urinary, prolapse, and colo-rectal/anal. The scales of PFDI-20 and PFIQ-7 (UDI-6, POPDI-6, CRADI-8; UIQ-7, POPIQ-7, CRAIQ-7) all have a range of 0-100, which is different than the scales of their long-form counterparts.[5]

In addition, participants completed the SF-36, a generic health-related quality of life questionnaire.[11] The scales of the SF-36 considered a priori for this analysis include: physical functioning, social functioning, role-emotional, role-physical, mental health and the mental and physical component summary scores. For the scales of the PFDI and the PFIQ, long-form or short-form versions, a higher score indicates worse symptom bother or greater impact of symptoms on daily functioning. For the scales of the SF-36, a higher score indicates better health-related quality of life.[1, 11]

For all analyses, study participants across the three studies were pooled and considered as a single combined group, as well as analyzed within each separate study. The correlations between the corresponding scales of the long- and short- form versions of the PFDI and PFIQ at baseline were estimated using Pearson's correlation coefficients. In order to evaluate the relative responsiveness of the scales of PFDI, PFIQ, PFDI-20, PFIQ-7, and SF-36, the standardized response mean (SRM) of the change in scores from baseline to 3 months and baseline to 12 months after intervention for each scale was assessed; the SRMs were compared between the corresponding scales of the long and short forms of PFDI and PFIQ, between the condition-specific HRQOL (long- and short-form version of PFDI and PFIQ) and the generic HRQOL (SF-

36) in a descriptive and exploratory fashion. SRM, a commonly used statistic of responsiveness, is equivalent to the change in score over a time period divided by the standard deviation of the change.[12] A higher SRM (in absolute value) indicates better responsiveness. A value of 0.5 is a cutoff for a moderate responsiveness, 0.8 a good responsiveness, and 1.0 an excellent one.[12]

We also used linear regression modeling to develop conversion formulas to calculate the scale scores of the PFDI and PFIQ long form from the short versions of the questionnaires. The proposed formulas were computed from the full sample across the three studies and in each simple linear regression model the scale of the PFDI and PFIQ short form was considered as the single predictor. Only the statistically significant slopes and intercepts remained in the derived equations. The model assumptions were reasonably good when examined by graphical plots, (e.g., linearity, normality) and influence cases and R^2 values were consistent with goodness of fit. All reported p-values were based on the two-sided statistical tests. The analyses were performed in SAS 9.1.3 for Windows (SAS Inc., Cary, NC).

Results

Analyses were performed using data from 942 study participants (CARE = 316 subjects, Colpocleisis = 140 subjects, and ATLAS =486 subjects). All participants provided responses to at least one of the long-version scales of the PFDI, PFIQ and SF-36 (a generic health related quality of life measure) at baseline, with 81% (763/942) available at 3 months and 73% (691/942) available at 12 months.

Baseline demographic data for the studies included in this analysis can be found elsewhere.[6-10] Table 2 displays the overall pooled correlation coefficients between the long forms and selected questions representing the short form version of the PFDI and PFIQ at baseline. Overall, the correlation coefficients between the short and long version scores across

each of the three populations was excellent, with all subscales having Pearson's correlations of greater than 0.82 (all $p < 0.001$).

Responsiveness to change of the PFDI and PFIQ short form scales was similar to that of the long versions across all three study populations.(Table 3) In the pooled sample, the urinary and prolapse scales of the PFDI-20 demonstrated good to excellent responsiveness at 3 and 12 months (SRM .73 - .95). The highest SRM values were found in the POPDI responses collected from women enrolled in the surgical trials for treatment of prolapse (CARE = -1.35 and Colpocleisis = -1.68) while the lowest SRM values (0.42 at 12 months to 0.47 at 3 months) were identified in the POPDI responses from the population of women enrolled in the ATLAS trial (women seeking conservative therapy for stress incontinence). The PFDI-20 colorectal scale demonstrated fair to moderate responsiveness across all three populations. Each of the scales of the PFIQ-7 demonstrated a broad range of SRM from 0.32 to 0.74, with higher SRMs in the UIQ and the lowest values in the POPIQ scores from the ATLAS group (SRM = 0.23 at 3 months and 0.21 at 12 months), however these values were markedly better in the population of women undergoing prolapse surgery (0.60 at 3 months and 0.65 at 12 months for the CARE and Colpocleisis groups). In contrast, the SF-36 summary scores were relatively unresponsive to change (Table 3).

Conversion formulas to estimate long form scale scores were developed from PFDI-20 and PFIQ-7 questions within the baseline questionnaires. Each equation demonstrated goodness of fit ranging from R^2 values of 0.80 - 0.95. (Table 4) For instance, the formula to convert the urinary scale of the PFDI-20 to the long form score is UDI score = 1.8 * UDI-6 score + 13.

Discussion

We found excellent correlation between the long and short forms of the Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ), allowing scientifically

sound use of these short forms for clinical or research purposes. Barber et al reported that it took an average (± SD) of 23 ± 11 minutes to administer both the 46-item PFDI and 93-item PFIQ.[1] The use of short forms instead can reduce participant burden in research settings, as the PFDI and PFIQ are often used in combination with other self-reported measures of interest.

Findings regarding the responsiveness of the short forms over time were generally very positive, although somewhat more varied. The PFDI-20 urinary and prolapse scales demonstrated good to excellent responsiveness, while the colorectal scale was fair to moderate across populations. The responsiveness of the PFIQ-7 showed greater variability across patient populations and treatments, with better responsiveness in studies involving prolapse surgery. Of potential concern was the low responsiveness observed for the colo-rectal subscales of these instruments.[3] In the original validation for the PFDI-20 and the PFIQ-7, the responsiveness for the CRADI-8 and the CRAIQ-7 were lower than the other subscales, with SRMs of 0.70 and 0.51, respectively.[3] Our findings here using a larger cohort of women undergoing specific treatment for pelvic organ prolapse and urinary incontinence also suggest a lower responsiveness of the colorectal scales in comparison to the other subscales (i.e., SRM for CRADI-8 = 0.43 and CRAIQ-7 = 0.33. These lower levels of responsiveness may be accounted for by an overall lower burden of colorectal disease among women presenting for treatment for pelvic organ prolapse and/or urinary incontinence. The women in these multi-center studies were participating in specific intervention studies for pelvic organ prolapse, with and without stress urinary incontinence. No specific treatments for colorectal disorders such as fecal incontinence were provided in these studies, although some women may have experienced some improvement in colo-rectal symptoms with the treatments under study. Future intervention trials for fecal incontinence and other colo-rectal conditions are needed to further evaluate the responsiveness of the colorectal subscales of the PFDI-20 and PFIQ-7.

As anticipated, we found that both the long and short forms of the FPDI and PFIQ were more responsive to change than the SF-36 subscales. In the initial validation of the PFDI-20 and PFIQ-7, low responsiveness was reported for the mental and physical component scores on the SF-36 (SRM range 0.12 and 0.28, respectively).[3] Our findings across three studies found similarly low responsiveness for the SF-36 mental and physical component scores (SRM range 0.08 to 0.16, respectively). These findings are consistent with previous studies showing limited responsiveness of generic QOL measures such as the SF-36 compared to condition-specific measures for women treated for pelvic floor disorders.[13-16] The responsiveness of the SF-36 in studies involving other chronic diseases are somewhat mixed[17-19], but in large part they are less responsive than condition-specific measures.[20]

The conversion score reported in our study are intended for use in clinical and research settings for comparing outcomes measured with the PFDI-20 and PFIQ-7 to the more comprehensive instruments. The conversion formulas were developed for use in well-described patient populations, such as women with specific degrees of pelvic organ prolapse with and without stress urinary incontinence, and may not apply to general clinical populations. [7-10] Therefore, extrapolation of these formulas to other populations should be made with caution.

Our use of three multi-center studies with varying patient demographics, disease characteristics, and treatments is a strength and allows more generalizability of our findings. Another major strength of the study is the use of multiple modalities via self-reported and telephone interviews for administration of the PFDI and PFIQ long forms. Although we derived scores for the short forms from responses to the long form rather than comparing subject responses from the short form itself, we believe this is a minor limitation.

In conclusion, the PFDI-20 and PFIQ-7 scales are well-correlated with the PFDI and PFIQ long forms and have similar overall responsiveness in three different prospective studies. Our findings provide further evidence that these short forms can be applied to studies that vary in

intervention focus and type of pelvic floor disease. These short forms are excellent alternatives to PFDI and PFIQ when decreased response burden is desired in research and clinical settings. We caution that there may be circumstances where the long versions of the PFIQ and PFDI are preferable, such as when a more comprehensive inventory of symptom distress and impact of pelvic floor disorders on daily activities is a primary study aim. In such cases, the long version could provide better characterization across the full spectrum of the disorder. A generic QOL measure such as the SF-36 or SF-12 may also be desirable if comparability of findings across populations is warranted.

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Table 1. Comparison between short and long versions of the PFDI and PFIQ.

Original Questionnaire	Original Scales	No. of items	Short Form	Scales	No. of items
PFDI		46	PFDI-20		20
	Urinary Distress Inventory (UDI)	28		UDI-6	6
	Pelvic Organ Prolapse Distress Inventory (POPDI)	16		POPDI-6	6
	Colorectal-Anal Distress Inventory (CRADI)	17		CRADI-8	8
PFIQ		93	PFIQ-7		21
	Urinary Impact Questionnaire (UIQ)	31		UIQ-7	7
	Pelvic Organ Prolapse Impact Questionnaire (POPIQ)	31		POPIQ-7	7
	Colorectal-Anal Impact Questionnaire (CRAIQ)	31		CRAIQ-7	7

Table 2. Pearson correlation between long and short form versions of PFDI and PFIQ at baseline

Scale	Subscale	N	Coefficient	Coefficient Range#	P-value
PFDI	UDI	942	0.87	(0.82, 0.90)	<.0001
	POPDI	942	0.90	(0.86, 0.89)	<.0001
	CRADI	925	0.92	(0.92, 0.94)	<.0001
PFIQ	UIQ	939	0.96	(0.95, 0.96)	<.0001
	POPIQ	938	0.98	(0.97, 0.98)	<.0001
	CRAIQ	938	0.98	(0.97, 0.98)	<.0001

The range of Pearson correlation across 3 multicenter studies
N, Pearson coefficient and P-value are from pooled sample across 3 multicenter studies

Table 3. Standardized response mean (SRM) from baseline to 3 months and to 12 months

Scale	Subscale	3 month						12 month					
		Long Form			Short Form			Long Form			Short Form		
		N	SRM	Range#	N	SRM	Range#	N	SRM	Range#	N	SRM	Range#
PFDI	UDI	760	-0.859	(-0.730, -1.281)	767	-0.732	(-0.574, -1.091)	690	-0.898	(-0.847, -1.265)	695	-0.764	(-0.641, -1.124)
	POPDI	763	-0.859	(-0.490, -1.450)	767	-0.903	(-0.470, -1.679)	691	-0.889	(-0.433, -1.473)	695	-0.951	(-0.420, -1.682)
	CRADI	741	-0.507	(-0.424, -0.592)	767	-0.433	(-0.361, -0.568)	675	-0.510	(-0.398, -0.614)	695	-0.422	(-0.294, -0.558)
PFIQ	UIQ	758	-0.583	(-0.397, -0.751)	770	-0.606	(-0.425, -0.841)	689	-0.700	(-0.610, -0.807)	697	-0.714	(-0.635, -0.797)
	POPIQ	757	-0.446	(-0.193, -0.663)	769	-0.461	(-0.229, -0.618)	688	-0.471	(-0.213, -0.618)	697	-0.484	(-0.211, -0.645)
	CRAIQ	757	-0.345	(-0.322, -0.410)	769	-0.327	(-0.321, -0.356)	689	-0.340	(-0.292, -0.417)	697	-0.326	(-0.268, -0.403)
SF-36	Physical Summary	760	0.162	(0.122, 0.277)		NA		684	0.265	(0.084, 0.401)		NA	
	Mental Summary	760	0.079	(0.041, 0.091)		NA		684	0.122	(0.106, 0.145)		NA	

The range of standardized response mean (SRM) across 3 multicenter studies
N and standardized response mean (SRM) are from pooled sample across 3 multicenter studies
For the PFDI and PFIQ (long and short forms), a negative change in score indicates improvement. For the SF-36, a positive change in score indicates improvement

Table 4. Linear conversion from short form score to long form score of PFDI and PFIQ at baseline

Scale	**Subscale**	**N**	**Conversion formula#** (long form = slope*short form + intercept)	**R^2**
PFDI	UDI	942	UDI score = 1.8 * UDI-6 score + 13	0.76
	POPDI	942	POPDI score = 2.5 * POPDI-6 score + 12	0.81
	CRADI	925	CRADI score = 3.3 * CRADI-8 score + 10	0.85
PFIQ	UIQ	939	UIQ score = 3.3 * UIQ-7 score	0.91
	POPIQ	938	POPIQ score = 3.3 * POPIQ-7 score	0.95
	CRAIQ	938	CRAIQ score = 3.3 * CRAIQ-7 score + 1	0.95

only statistically significant slope and intercept are kept in the formulas. P = 0.03 for the intercept of CRAIQ, P < .0001 for all other slopes and intercepts

N, slope and intercept in conversion formula, and p-value are from pooled sample across 3 multicenter studies