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Sikirica V[1], Zyczynski H[2], Subramanian D[1], Slack M[3], Hinoul P[1], Robinson D[1], Gauld J[1], Urquhart C[1], Ilie B[1], Carey M[4]
***1.** Ethicon, Inc, **2.** University of Pittsburgh Magee-Women's Research Institute, **3.** Addenbrooke's Hosp., Univ. of Cambridge Teaching Hosp. Trust, **4.** Royal Women's Hosp*

RESPONSIVENESS OF THE PFDI-20 AND PFIQ-7, 12 MONTHS FOLLOWING VAGINAL PROLAPSE REPAIR AUGMENTED BY MESH AND A VAGINAL SUPPORT DEVICE

Hypothesis / aims of study

To evaluate the responsiveness of the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) in women treated for pelvic organ prolapse (POP) using the GYNECARE PROSIMA™ Pelvic Floor Repair System (Ethicon, Somerville, NJ) that employs polypropylene mesh implants and a vaginal support device.

Study design, materials and methods

The PFDI-20 and PFIQ-7 were administered at baseline, 6 and 12 months postoperatively during a prospective, international, IRB-approved study of 136 women with symptomatic stage II and III prolapse treated using the GYNECARE PROSIMA System. Responsiveness of total and domain scores for each instrument was measured in the entire cohort and separately for POP-Q stages II and III using 3 methods:

a) Mean and standard deviation (SD) were calculated for all total and domain scores. A paired t-test was used to test for significance of the score change from baseline to 12-months.

b) Distribution-based metrics: Effect size (ES; mean score change divided by the SD of baseline score) and standardized response mean (SRM; mean score change divided by SD of that change). ES and SRM >0.8 were considered large, 0.5-0.8 medium and 0.2-0.5 small.[2]

c) Minimal-clinically important differences (MCID) derived from an anchor-based approach. The proportion of women meeting published MCID thresholds (decrease of 45 and 36 points on the PFDI-20 and PFIQ-7 total scores, respectively) were calculated.[3] In the absence of MCID thresholds for use in surgery with mesh augmentation, MCIDs from conventional non-mesh based surgical repairs were used.

Results

Significant improvements (*P*<.001) were seen in all PFDI-20 and PFIQ-7 total and domain scores for stages II, III and the entire group at 12 months (Table 1). The ES and SRM for the PFDI-20 total score and the POPDI-6 and UDI-6 domain scores all demonstrated large responsiveness (>0.8). The CRADI-8 was less responsive, showing moderate to large response (0.60-0.88). PFIQ-7 total and domain scores were less responsive than respective PFDI-20 scores. Most ES and SRM values showed moderate responsiveness (0.50-0.81). When compared to stage III women, stage II women had a higher responsiveness on the POPIQ and UIQ and lower responsiveness on the CRAIQ domains. 76% and 46% of the entire cohort met MCID thresholds for PFDI-20 and PFIQ-7, respectively. For the PFDI-20, 74.6% of women with stage II and 77.6% with stage III prolapse met the MCID (Table 2). A smaller proportion met the PFIQ-7 MCID (51.4% and 39.3% of stage II and III, respectively).

Interpretation of results

Use of the GYNECARE PROSIMA System showed statistically significant symptom and quality of life (QoL) improvement scores in overall and all 3 subscales via the PFDI-20 and PFIQ-7, respectively. Likewise, distribution-based metrics found that both instruments are highly responsive to surgical intervention using the GYNECARE PROSIMA System. Comparatively, symptom responsiveness on the PFDI-20 was greater than QoL responsiveness PFIQ-7, QoL index overall, implying greater patient improvement in POP symptoms than QoL. In both questionnaires, the colorectal-anal subscale was the least responsive of the 3 respective subscales, but maintained moderate-level responsiveness. Thresholds for minimal clinically important differences showed that 76% of patients achieved previously set minimal thresholds of symptom improvement. Similarly, roughly half (46%) of women reached minimally clinically important QoL improvement thresholds. Applying non-mesh intervention MCID thresholds may be a limitation due to inherent differences of baseline disease severity or intervention types between studies (positive or negative).

Concluding message

This is the first study of PFDI-20 and PFIQ-7 responsiveness in mesh augmented vaginal prolapse surgery. We demonstrated significant improvement in total and individual domain scores 12 months after surgery using the GYNECARE PROSIMA™ Pelvic Floor Repair System. Distribution-based metrics found both instruments were quite responsive to prolapse surgery. The PFDI-20 was more responsive than the PFIQ-7, implying greater patient symptom improvement than QoL. Of the 3 domains, colorectal-anal domains were least responsive. MCID assessment found 76% and 46% of women reached minimal POP symptom and QoL improvement, respectively.

Table 1. Effect Size and Standardized Response Mean of the PFDI-20 and PFIQ-7 at 12 Months

PFDI-20 Results at 12 Months

Group	Instrument	Baseline (SD)	Mean Postoperative Mean (SD)	Mean Change (SD)	Effect Size	SRM
Overall (n=136)	PFDI-20	118.9 (57.5)	43.1 (41.1)	-74.2 (50.6)*	1.29	1.47
	POPDI-6	48.0 (23.5)	12.1 (15.6)	-35.2 (23.3)*	1.50	1.51
	CRADI-8	29.8 (22.6)	13.1 (14.2)	-16.3 (20.1)*	0.72	0.81
	UDI-6	41.1 (24.7)	17.8 (19.6)	-22.7 (22.6)*	0.92	1.00
Stage II (n=73)	PFDI-20	114.7 (53.1)	45.0 (44.9)	-69.8 (44.5)*	1.31	1.57
	POPDI-6	45.1 (21.2)	11.8 (16.4)	-33.4 (21.8)*	1.58	1.53

	CRADI-8	26.3 (20.7)	13.9 (15.9)	-12.4 (15.4)*	0.60	0.81
	UDI-6	43.3 (23.5)	19.3 (20.6)	-24.0 (22.6)*	1.02	1.06
	PFDI-20	123.8 (62.3)	40.8 (36.3)	-79.5 (57.1)*	1.28	1.39
Stage III (n=63)	POPDI-6	51.4 (25.8)	12.6 (14.9)	-37.4 (25.1)*	1.45	1.49
	CRADI-8	33.9 (24.1)	12.2 (12.0)	-21.1 (24.1)*	0.88	0.88
	UDI-6	38.5 (26.1)	16.0 (18.3)	-21.0 (22.5)*	0.80	0.93

PFIQ-7 Results at 12 Months

Group	Instrument	Baseline (SD)	Mean Postoperative Mean (SD)	Mean Change (SD)	Effect Size	SRM
	PFIQ-7	65.3 (64.7)	14.8 (26.3)	-47.6 (62.8)*	0.74	0.76
Overall (n=136)	POPIQ-7	21.0 (25.3)	2.8 (8.3)	-17.0 (25.5)*	0.67	0.67
	CRAIQ-7	16.5 (23.4)	3.7 (8.8)	-12.2 (22.0)*	0.52	0.55
	UIQ-7	27.7 (26.0)	9.2 (17.4)	-18.3 (25.9)*	0.70	0.71
	PFIQ-7	64.9 (60.1)	15.6 (27.6)	-48.9 (62.4)*	0.81	0.78
Stage II (n=73)	POPIQ-7	21.5 (23.5)	2.7 (8.3)	-18.6 (25.8)*	0.79	0.72
	CRAIQ-7	15.2 (21.6)	4.2 (9.4)	-10.7 (20.9)*	0.50	0.51
	UIQ-7	28.1 (25.4)	8.6 (17.4)	-19.6 (27.7)*	0.77	0.71
	PFIQ-7	65.8 (70.2)	13.9 (24.8)	-46.0 (63.8)*	0.66	0.72
Stage III (n=63)	POPIQ-7	20.6 (27.4)	2.9 (8.3)	-15.1 (25.3)*	0.55	0.60
	CRAIQ-7	17.9 (25.5)	3.0 (7.9)	-14.1 (23.3)*	0.55	0.61
	UIQ-7	27.3 (27.0)	10.0 (17.5)	-16.7 (23.7)*	0.62	0.70

***P*-value <.001 based on t-test**

Table 2: MCID Results for PFDI-20 and PFIQ-7 at 1 year

PFDI-20 MCID Scores >45[*]

Visit	Stage II (n=71)	Stage III (n=58)	Overall (n=129)
12 months	53 (74.6%)	45 (77.6%)	98 (76.0%)

PFIQ-7 (MCID Scores >36[†]

Visit	Stage II (n=70)	Stage III (n=56)	Overall (n=126)
12 months	36 (51.4%)	22 (39.3%)	58 (46.0%)

[*]6, 5 and 11, respectively for Stage II, III and overall could not reach PFDI-20 MCID threshold since their baseline score started lower than the possible MCID score

[†]23, 29 and 52, respectively for Stage II, III and overall could not reach PFIQ-7 MCID threshold since their baseline score started lower than the possible MCID score CR Approved 4-1-09

References

1. Barber, MD et al. AJOG 2005;193:103
2. Cohen, J. Statistical power analysis for the behavioral sciences; 1988
3. Barber, MD et al. AJOG 2006;194:1492-8

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**