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FEMALE PELVIC FLOOR SYMPTOMS BEFORE AND AFTER BARIATRIC SURGERY

Hypothesis / aims of study

Obesity is a known risk factor for urinary and fecal incontinence, as well as pelvic organ prolapse (1).The hypothesis of this study was that morbidly obese women that undergo bariatric surgery will report a significant improvement in pelvic floor symptoms at 6 and 12 months after surgery. The primary objective was to determine whether there was a difference in the subjective reporting of such symptoms after a significant weight loss has occurred using validated questionnaires, the Pelvic Floor Distress Inventory – 20 (PFDI-20) and the Pelvic Floor Impact Questionnaire – 7 (PFIQ-7).

Study design, materials and methods

This was a prospective cohort study of female patients that underwent bariatric surgery between June 2008 and February 2009. To be included in the study, patients had to fulfill the National Institute of Health criteria for bariatric surgery (body mass index (BMI) of ≥ 40kg/m^2, or a BMI ≥ 35kg/m^2 with at least two co-morbidities, and has attempted to lose weight in the past). Patients interested in the procedure were either self-referred or physician-referred for consultation. Only patients that underwent laparoscopic gastric bypass or laparoscopic sleeve gastrectomy were included in the study. Patients completed a demographic questionnaire as well as the PFDI-20 and PFIQ-7 2 weeks prior to surgery. The patients then repeated the PFDI-20 and PFIQ-7 at 6 and 12 months following surgery. Questionnaires were completed in the clinic unless the patient did not return for follow-up whereby the questionnaires were mailed in or completed over the telephone.

The PFDI-20 score was used to calculate the necessary sample size. The minimum clinically important difference for this questionnaire has been shown to be 45 points (15%) or more in the overall summary score of the PFDI-20 (2). It was expected that the mean pre-operative score would be approximately 200 (on a scale of 0-300). Assuming a mean decrease of 45 points at 6 months post-surgery would be considered significant and assuming the standard deviation of the changes would be 100, 55 subjects would provide 90% power to detect the this difference using a two-sided paired test with a significance level $\alpha = 0.05$. Allowing for a possible 20% dropout rate, a minimum of 70 subjects were necessary to see such a difference.

BMI was described as means and were compared between baseline and 6 and 12 months using Student's t-tests ($P<0.05$ considered statistically significant). Questionnaire scores were described using medians with minimum and maximum ranges, and were compared between baseline and 6 months, as well as between 6 months and 12 months using the Wilcoxon matched pairs test for non-parametric data. Since two tests were performed in this comparison, the significance level was adjusted using a Bonferonni correction, whereby P-values <0.025 were considered significant. A Spearman's rank correlation coefficient was calculated between BMI and PFDI-20 scores at each time point to determine the strength of association between the two variables.

Results

Initially 83 patients were consented for the procedure, 19 of which did not go through with the surgery as planned, leaving 64 patients eligible for follow-up. At the end of 12 months, 63 patients had completed the study. Within this cohort, the age range was 23 to 69 years (mean of 48 years), 83% were Caucasian, 47% were post-menopausal, 66% had one or more vaginal deliveries, 36% had a prior hysterectomy, 3% had prior prolapse surgery, and 2% had prior incontinence surgery. Within this cohort, 61% had hypertension, 30% had type II diabetes, 33% had osteoarthritis, and 36% had obstructive sleep apnea.

The mean BMI prior to surgery was 43.7kg/m^2. At 6 months following surgery the mean BMI was 31.7kg/m^2 ($P<0.001$ when compared to baseline BMI) and at 12 months following surgery the mean BMI was 29kg/m^2 ($P<0.001$ when compared to 6 month BMI). Questionnaire data and comparisons are shown in Table 1. Correlation coefficients between BMI and PFDI-20 scores were the following: 0.2 at baseline ($P=0.07$), 0.15 at 6 months ($P=0.3$), and 0.2 at 12 months ($P=0.07$).

Interpretation of results

Patients showed a significant reduction in BMI at both 6 and 12 months after bariatric surgery. Baseline PFDI-20 and, in particular, PFIQ-7 scores were relatively low (median score <100) indicating that prior to this surgical intervention these patients already had minimal pelvic floor symptoms with little effect on quality of life. Despite the small baseline scores, there was a significant reduction in PFDI-20 and PFIQ-7 scores at 6 months after surgery and this reduced score was maintained at 12 months after surgery. Urinary symptoms appeared to be the most prevalent as indicated by the UDI-6 and UIQ subscale scores. The magnitude of the correlation coefficients between BMI and PFDI-20 scores at each time point were small (<0.4) indicating that the PFDI-20 scores were not necessarily dependent on or influenced by patient BMI.

Concluding message

At 6 and 12 months following bariatric surgery, female patients showed a small but significant improvement in pelvic floor symptoms as demonstrated by validated questionnaires. Although there was a significant reduction in patient weight following surgery, questionnaire scores were not found to directly correlate with BMI.

Table 1: Questionnaire scores before and after bariatric surgery.

	Baseline Score[a]	6 Month Score[a]	P-Value[b]	12 Month Score[a]	P-Value[c]
PFDI-20[d,e]	62 (0, 177)	27 (0, 111)	<0.001*	22 (0, 129)	0.09
Subscales[f]:					
UDI-6 [d]	35 (0, 79)	8 (0, 63)		4 (0, 38)	
CRADI-8[d]	13 (0, 91)	16 (0, 53.1)		9 (0, 63)	
POPDI-6[d]	8 (0, 58)	0 (0, 29)		0 (0, 42)	
PFIQ-7[d,e]	5 (0, 133)	0 (0, 276)	<0.001*	0 (0, 214)	0.8
Subscales[f]:					
UIQ[d]	5 (0, 86)	0 (0, 95)		0 (0, 71)	
CRAIQ[d]	0 (0, 48)	0 (0, 86)		0 (0, 86)	
POPIQ[d]	0 (0, 33)	0 (0, 95)		0 (0, 71)	

[a]Scores described as median (minimum, maximum).
[b]Scores compared between baseline and 6 months.
[c]Scores compared between 6 and 12 months.
[d]Abbreviations: PFDI-20 – Pelvic Floor Distress Inventory 20; POPDI-6 – Pelvic Organ Prolapse Distress Inventory 6; CRADI-8 – Colorectal-Anal Distress Inventory 8; UDI-6 – Urinary Distress Inventory 6 ; PFIQ-7 – Pelvic Floor Impact Questionnaire 7; UIQ – Urinary Impact Questionnaire; CRAIQ – Colorectal-Anal Impact Questionnaire; POPIQ – Pelvic Organ Prolapse Impact Questionnaire.
[e]PFDI-20/PFIQ-7 score ranges: 0 to 300.
[f]Subscale score ranges: 0 to 100.
* Statistically significant P <0.025.

References
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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**
Specify Name of Ethics Committee	**IUPUI and Clarian/Methodist Research Instituitional Review Board, IRB #08-006**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**