

ARE SYMPTOMS OF PELVIC ORGAN PROLAPSE MORE COMMON AMONGST WOMEN WHO HAVE UNDERGONE TRAM FLAP PROCEDURES COMPARED TO A CONTROL POPULATION? A CASE CONTROL STUDY

Hypothesis / aims of study

Chronic conditions that cause raised intra-abdominal pressure, such as obesity, chronic cough and constipation are risk factors in the development of pelvic organ prolapse. Abdominoplasty and transverse rectus abdominis musculocutaneous flap (TRAM flap) for reconstruction following mastectomy for breast cancer, reduce the volume of abdominal cavity, resulting in a raised intra-abdominal pressure, and consequently a chronic increase in pressure on the pelvic floor in patients post-operatively. The aim of this study is to assess if there is increased risk of pelvic organ prolapse associated with TRAM flap reconstruction compared to controls.

Study design, materials and methods

39 patients who had TRAM flaps for breast reconstruction following mastectomy for breast cancer between years 1997 to 2004 were recruited as cases. Validated questionnaires (Pelvic floor distress inventory PFDI-20) were sent to them to complete. Demographic data were also collected. These cases were matched by age with 36 controls, who have had breast cancer but did not have TRAM flap reconstruction as part of their treatment, and were asked to complete the same questionnaires. Chi square tests were used to assess the differences in the frequency of categorical variables between case and control patients. The Mann Whitney U test was used for continuous variables. Mixed effect analysis of variance was used to assess if there is any statistical difference in the mean PFDI-20 scores between cases and controls, adjusted by age, parity, BMI and history of gynaecological surgery, such as hysterectomy and urogynaecological procedures.

Results

	Case	Control	p value*
Age	59(7)	61(7)	0.10
BMI	26(5)	24(4)	0.03
Smoking	1(2.6%)	3(8.3%)	0.27
Parity	2(2,3)	2(2,3)	0.90
0	4(10.3%)	7(19.4%)	
1-2	24(61.5%)	17(47.2%)	
3-5	11(28.3%)	12(33.4%)	
Number of normal vaginal delivery	2(0, 2)	2(1,2)	0.28
0	12(30.8%)	8(22.2%)	
1-2	22(56.4%)	22(61.1%)	
3-4	5(12.9%)	6(16.6%)	
Number of instrumental delivery	0(0,1)	0(0,1)	>0.90
0	29(74.3%)	26(72.2%)	
1-2	9(23.1%)	10(27.8%)	
3	1(2.6%)	0(0%)	

Number of Caesarean delivery			
0	31(79.5%)	34(94.4%)	
1-2	7(17.9%)	2(5.6%)	
3-4	1(2.6%)	1(2.6%)	0.15
Significant Gynaecological Surgery	17(43.6%)	18(50%)	0.58
PFDI-20 Score	13(3, 29)	5.5(1.0, 11.0)	0.02

Interpretation of results

The case group has significantly higher mean PFDI-20 score than the control group, 13 (3-29) vs 5.5(1-11), MH odds ratio 1.8 (1.1-2.8), p-value 0.02. When adjusted for age, parity, BMI and history of gynaecological surgery, the p-value was 0.07.

Concluding message

Women who have undergone TRAM flap reconstruction appeared to have more pelvic prolapse symptoms, compared to women who did not have the procedure as part of their treatment for breast cancer. Further studies with larger sample sizes are required to confirm the correlation.

<i>Specify source of funding or grant</i>	None
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Northern X Regional Ethics Committee, New Zealand
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes