46

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THE EFFECT OF A PHYSIOTHERAPY EXERCISE PROGRAM ON BLADDER, PROLAPSE AND BOWEL OUTCOMES IN WOMEN UNDERGOING GYNAECOLOGICAL SURGERY: AN ASSESSOR-BLINDED RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study
Very little is known about the effect of physiotherapy after gynaecological surgery, despite this intervention being a recommended therapy in clinical practice. A previous study in women undergoing pelvic organ prolapse (POP) and/or urinary incontinence (UI) surgery showed a positive effect on bladder function at 3 months post-operatively (1), but the effects on POP and bowel function, and longer term effects were not measured. The aim of this study was to investigate whether physiotherapy, as an adjunct to surgery, would demonstrate significant improvement in bladder, POP and bowel symptoms compared to a control group at 3, 6, and 12 months post-operatively.

Study design, materials and methods
This study was an assessor-blinded randomised controlled trial. Included were women of any age undergoing vaginal or laparoscopic-assisted vaginal surgery for either POP repair (primary or recurrent), and/or hysterectomy, at six metropolitan private hospitals. Exclusion criteria were surgery for cancer or surgery for UI. Participants were randomised to receive either physiotherapy-supervised pre- and post-operative pelvic floor exercises, or 'usual care' provided by the surgeon and hospital. The physiotherapy intervention comprised a pelvic floor muscle (PFM) strength training protocol, supplemented by bladder and bowel advice. This was provided over 8 sessions: one pre-operative and seven post-operative sessions; at day 3 post-operatively, week 6, 7, 8, 10 and 12, and a final appointment at 9 months post-operatively. The main outcomes of bladder and POP symptoms were measured by the Urogenital Distress Inventory (UDI-19, including sub-scales for Irritative, Stress and Obstructive symptoms) and the Incontinence Impact Questionnaire (IIQ-7). Secondary outcomes of bowel symptoms were measured by the Modified Wexner Score, and the Constipation Scoring System (CSS). All outcomes were measured at 4 time points: pre-operatively, and 3, 6 and 12 months post-operatively. A sample size calculation based on the primary outcome measure – presence of UI – indicated that a sample size of 25 participants per group would be required to detect a 20% difference in prevalence of symptoms between the groups, with 80% power and an alpha of 0.05. Baseline statistical analyses consisted of comparisons of demographic variables and outcome measures using Independent-samples *t*-tests, Fisher's Exact test or Mann-Whitney U-tests as appropriate. Analyses of outcome measures over time were done both between- and within-group, using 2 methods: an overall analysis (univariate analysis of change score – Time 1 minus Time 4, with Time 1 as a covariate in the change score); and a repeated-measures analysis (comparing Times 2, 3 and 4, using Time 1 as a covariate – ANCOVA).

Results
A total of 244 women were screened for eligibility to the trial, 58 agreed to participate and 51 received the allocated intervention. Using intention to treat analysis, data from 49 participants were available for 12 month analysis. The groups were similar at baseline on most demographic variables, but there were significant differences on the primary outcome measure. The treatment group demonstrated significantly poorer scores on the UDI total score (p=0.03), UDI Obstructive sub-scale (p=0.002) and the IIQ score (p=0.02). Because of these baseline differences, the Time 1 score was used as a covariate in further analyses. Table 1 shows the results of the between-group comparisons on two analyses. There were no differences between groups on either the overall analyses, or the repeated measures analyses. Baseline scores on the UDI and bowel outcome measures were strongly predictive of subsequent scores for both control and treatment groups.

Table 1 Between-group comparisons, n=49 (Control Group n=26, Treatment Group n=23)

Outcome	**Change from Time 1 to Time 4**	***p* value**	**Repeated measures analysis, interaction between time and group: *p* value**	**Effect of Time 1 as a predictor of subsequent scores: *p* value**
UDI total score				
Control	44.1 (5.1) *			
Treatment	54.0 (5.4) *	0.20	0.46	0.000
UDI Irritative				
Control	12.5 (1.8) *			
Treatment	12.9 (1.9) *	0.88	0.41	0.000
UDI Stress				
Control	9.6 (3.6) *			
Treatment	15.1 (3.8) *	0.31	0.48	0.000
UDI Obstructive				
Control	23.4 (1.2) *			
Treatment	24.0 (1.3) *	0.77	0.72	0.04
IIQ			Time 2: 0.45;	
Control	0.0 (14.0) ~		Time 3: 0.07;	
Treatment	10.0 (19.0) ~	0.09	Time 4: 0.33	-
Wexner scale				
Control	1.5 (0.5) *			
Treatment	1.4 (0.5) *	0.86	0.29	0.000
CSS				
Control	1.8 (0.5) *			
Treatment	1.5 (0.5) *	0.63	0.63	0.000

* =Mean (± SEM); ~=Median (IQR)

The results of the within-group analyses in the Time 1 minus Time 4 change score demonstrated that there were significant changes for both the control and treatment groups in all scores, except the control group in the UDI Stress sub-scale. For the repeated measures analysis, neither group demonstrated significant changes from 3 to 12 months post-operatively on any of the outcomes.

Interpretation of results

Both control and treatment groups demonstrated an improvement in bladder, POP and bowel symptom scores following surgery, however the differences between groups were not significant. While the treatment group showed a trend towards more improvement than the control group, the trends did not reach significance. The improvements following surgery at 3 months were sustained at 12 months. Pre-operative scores strongly predicted post-operative scores. The results from this study demonstrated that the intervention of PFM training did not improve the outcomes of bladder, POP and bowel symptom scores beyond that provided by surgery. The reasons for this finding may include: insufficient sample size – the power calculation based on prevalence data did not predict the variance seen in this population; insufficient training dosage for the treatment group, and participation in PFM training by the control group; and heterogeneity of the cohort with regard to the surgical procedure.

Concluding message

This exploratory study did not show a significant benefit of a pre- and post-operative PFM training program in women undergoing gynaecological surgery. Further studies with a larger sample size and a more intensive training dosage may be required to demonstrate an effect beyond that achieved by surgery alone. Since pre-operative scores were strongly associated with post-operative outcomes, targeting women with poorer scores in the pre-operative phase with a PFM training program may improve post-operative outcomes in a higher-risk group.

References

1. ANZJOG (2004) 45; 300-303

Specify source of funding or grant	**Cabrini Hospital, Malvern, Victoria.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**phdData.org**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**This study was approved by the The University of Melbourne, Cabrini Hospital Malvern, Cliveden Hill Private Hospital East Melbourne, Freemasons Hospital East Melbourne, Cabrini Hospital Brighton, Mercy Private Hospital East Melbourne, Waverley Private Hospital Mt Waverley, Victoria, Australia.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**