

PELVIC FLOOR MUSCLE TRAINING FOR TREATMENT OF PELVIC ORGAN PROLAPSE: RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

The purpose of the present study was to evaluate the effectiveness of a pelvic floor muscle training (PFMT) intervention for women with pelvic organ prolapse.

Study design, materials and methods

Women attending by medical section of urogynecology, with previously untreated prolapse of stage II (confirmed by one gynecologist using the POP-Q), were asked to participate in the trial. Consenting women were randomized by a computer-generated random number generator to receive individualised home PFMT and lifestyle advice or a lifestyle advice leaflet. The main investigator was blinded to the intervention group allocation. The outcomes of primary interest were prolapse severity (POP-Q) measured by gynecologist blind to the women's study group allocation, and the secondary outcome was pelvic floor muscle changes.

At the first appointment, a standardized history was taken, and pelvic floor muscle assessment was carried out. The PFM evaluation included: (a) evaluation of pelvic floor muscle (PFM) function, considered strength and endurance. To evaluation of muscle strength, a score from 0-5 was given according to the previously validated Oxford Scale. Endurance was registered via PERFECT assessment scheme. Endurance was expressed as the length of time, up to 10 s, that a maximal voluntary contraction (MVC) could be sustained. Thus, the contraction was timed until the muscle started to fatigue; (b) surface electromyography (sEMG) evaluation of pelvic floor performed by vaginal probe. Three maximum, voluntary and successive contractions were required from the pelvic floor. Each contraction was recorded in microvolts (μV). The evaluation parameter used was the arithmetic mean of the three contractions. Each evaluation was carried out with a 2-min interval.

A standardized lifestyle advice sheet was given to both groups (containing instructions on seeking advice where appropriate about weight loss, constipation, avoidance of heavy lifting and coughing). The protocol intervention given to women in the PFMT group consisted of six appointments with a specialist women's health physiotherapist over a 14-week period (appointments at weeks 0,1,2,6, 10 and 14). In 1-2 weeks, patients participated of three sessions to achieve sensory awareness of the pelvic floor muscles. Then, 12-weeks home exercise programme was prescribed, and women were encouraged to perform three sets of exercises daily (one set consisted of eight maximum voluntary contractions held for 6 s, with 12 s rest between each contraction, followed by three fast contractions in a row), with the use of an exercise diary to record compliance. Fortnightly, the same physiotherapist maintained contact with the patient by telephone to answer questions and monitor the performance of exercises. The control group received instructions to perform PFM contractions without defined protocol immediately after evaluation. This group did not see a physiotherapist and had no planned contact with the doctor until the 12-week follow-up appointment.

The physiotherapist responsible for the study only collected data. Randomization was performed by another physiotherapist, research assistant. Data analysis was performed by another professional who was blinded to the group allocation and had no knowledge of interpretation of results.

Results

Thirty seven women, mean age 55 (SD 8) years, were randomized in the 17-month recruitment period from september 2008 to february 2010, distributed in the intervention group ($n = 21$) and control group ($n = 16$). Recruitment was completed and this study is open to three months follow up. The response rate to intervention and control groups was 100% and 76.2%, respectively.

Of all studied women, 21 (56.7%) had anterior wall vaginal prolapse, four (10.8%) had posterior wall vaginal prolapse and 12 (32.4%) had association of these types.

There were no significant differences with respect to age ($p = 0.322$), parity ($p = 0.132$), body mass index ($p = 0.509$) and hormonal status ($p = 0.860$) between the intervention and control groups at baseline.

Fifteen (71.4%) women of intervention group reported to perform the entire protocol registered by exercise diary. Comparing intervention group vs control group, there was significant improvement in muscle strength ($p < 0.001$), endurance ($p < 0.001$) and MVC ($p = 0.008$) measured by electromyography in intervention group.

All women complete POP-Q at baseline and after 14-weeks treatment. A test of the difference in POP-Q stage showed significantly greater improvement in the intervention group to anterior wall vaginal prolapse (Wilcoxon signed rank test, $p < 0.001$) and posterior wall vaginal prolapse ($p = 0.025$). Distribution in 14-weeks severity stage can be observed in Table 1.

Table 1. Changes observed in POP-Q stage at 14-weeks divided into anterior and posterior compartment.

POP-Q Stage	<i>n</i> [Freq. (%)]			
	Control		Intervention	
	Anterior	Posterior	Anterior	Posterior
+2 stages	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
+1 stage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
No change in stage	11 (78.6)	4 (80)	6 (31.6)	5 (41.7)
-1 stage	3 (21.4)	1 (20)	13 (68.4)	4 (33.3)

-2 stages 0 (0.0) 0 (0.0) 0 (0.0) 2 (16.7)

A negative value indicates an improvement at 14 weeks.

Interpretation of results

The PFMT should be recommended as a first-line conservative management program for stress urinary incontinence (SUI)(1). Bo et al (2) describes that the same hypotheses of mechanisms on how PFMT may be effective in the prevention and treatment of SUI may apply for a possible effect of PFMT on POP. Women are taught to perform regular strength training over time in order to build up 'stiffness' and structural support of the pelvic floor. A greater improvement on POP-Q stage to wall vaginal prolapse anterior and posterior, strength, endurance and MVC registered by sEMG and was detected in the intervention group. There is a lack of trials in this area, but one similar RCT study was used for comparison. Hagen et al (3) evaluated PFMT for stages I and II POP (measured by POP-Q) and also reported positive findings for severity of POP and strength. Only intervention women showed an improvement in their POP-Q stage (five out of 11 intervention women improved versus zero out of nine controls, p=0.038). Control women's stage remained either unchanged or worsened. Therefore, of 15 women of PFMT group evaluated at baseline and 16-weeks, there was an improvement in muscle strength (p=0.008).

To date, no studies were found that include eletromyographic evaluation on POP treatment. Bo et al (2) describes that PFMT would facilitate a more effective automatic motor unit firing (neural adaptation), preventing descent during increase in abdominal pressure.

The results indicate that strength training may build up the structural support of the pelvis by elevating the levator plate to a permanent higher location inside the pelvis. The training may also lift the pelvic floor and thereby the protruding organs in a cranial direction.

Concluding message

PFMT is effective to improve POP stage and pelvic floor function evaluated by digital palpation and electromyography. It may contribute to treatment of pelvic organ prolapse. However, more studies are necessary to confirm these evidences.

References

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3. Hagen S, Stark D, Glazener C, Sinclair L, Ramsay I. A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Jan;20(1):45-51. Epub 2008 Sep 20.

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<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<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>	Ethics research committe of Federal University of São Paulo
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes