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PELVIC FLOOR MUSCLE TRAINING IN TREATMENT OF PELVIC ORGAN PROLAPSE - A SINGLE BLIND RANDOMISED CONTROLLED TRIAL.

Hypothesis / aims of study

Prevalence rates of pelvic organ prolapse (POP) vary between 2% to 50%. To date there is scant knowledge about the effect of pelvic floor muscle training (PFMT) for women with POP (1). The aim of the study was to investigate the effectiveness of PFMT to reverse POP and reduce symptoms in women with pelvic organ prolapse quantified (POP-Q) stage I, II and III (2).

Study design, materials and methods

In this single blinded randomised control trial 109 women were stratified on degree of POP according to POP-Q and randomly allocated by computer generated random numbers to intensive PFMT or a control group. Eligibility criteria were more than one year since last delivery. Exclusion criteria were grade 0 or 4 on POP-Q, inability to contract the PFM, breastfeeding, previous POP surgery, radiating back pain, pelvic cancer, neurological or psychiatric disorders, untreated urinary tract infections or planning to become pregnant or to be away for more than 4 weeks of the intervention period. As preliminary data on effect size of PFMT to treat POP was not found, an effect size 0.6 on PFMT on stress urinary incontinence was used to calculate sample size. With a two-sided alpha of 0.05 and power of 80%, a sample size of 45 per group was required. Due to possible drop-outs we chose to include at least 50 women in each group. The gynaecologist performing the POP-Q was blinded to group allocation. Participants filled out a validated symptom-bother questionnaire concerning frequency of mechanical, bladder, bowel and sexual problems, and a 4-point bother score (3) prior to a semi structured interview and clinical evaluation by a physical therapist.

Women in the PFMT group were asked to participate in 18 individual exercise sessions with a skilled physical therapist and to do 3 sets of 8-12 contractions per day during the six months intervention period. Both groups received written information about POP and were advised to not strain when defecation and to contract their pelvic floor muscles (PFM) prior and during increases in abdominal pressure (coughing, sneezing, heavy lifting). Primary outcome measures were stages of POP (POP-Q), symptoms and bother (3). Secondary outcomes were women's report of symptom change (semi-structured interview) and PFM function (strength, endurance and resting pressure) measured with a reliable and valid vaginal squeeze pressure device.

Statistical analysis was performed using SPSS version 15. Results are given as frequencies and percentage for categorical data and means with 95% confidence intervals (CI) for continuous data. Differences between groups were analysed with Mann Whitney U tests for continuous data and for ordinal categorical data. The size of the treatment effect was calculated as differences in proportions for categorical data and differences in means for continuous data. Additionally, effect size for continuous data was calculated as differences in mean per standard deviation (SD) unit. P-values <0.05 were considered significant. The results are analysed as intention to treat.

Results

Fifty women were randomly allocated to the control group and 59 to the PFMT group. The mean age of the participants was 48.9 years (range 27-88), parity 2.4 (range 1-5) and mean body mass index (BMI) 25.9 kg/m^2 (SD ± 4.5). Out of 109 participants, 19 were classified as POP stage I, 65 as stage II and 24 as stage III. Seven (6%) women had POP in one vaginal compartment, 30 (28%) women had POP in two compartments and 71 (65%) women had POP in all three compartments, when POP was defined as POP-Q stage I or more. Sixty-nine 69 (63%) participants had mechanical symptoms, 87 (80%) had bladder symptoms and 65 (60%) had bowel symptoms. There were no significant differences between the groups at baseline regarding degree of POP, age, parity, postmenopausal status, BMI, bladder or bowel symptoms. Two women dropped out. For women in the PFMT group the mean number of days performing PFMT was 161.2 (SD ± 26.8) out of 180 possible and mean number of visits to the physical therapist was 15.5 (SD ± 3.2) out of 18 possible. Forty-seven (79%) women in the PFMT group reached an adherence level of 80% (≥14 physiotherapy visits and ≥144 days with home exercise). No adverse effects were reported.

Eleven (19%) women in the PFMT group and four (8%) women in the control group improved one POP stage (p=0.04). Based on the standardised questionnaire significant more women in the PFMT group than in the control group reduced their frequency of symptoms; feeling of vaginal bulge (22 (37%) versus 4 (8%), p=0.004), perception of pelvic pressure (23 (39%) versus 7 (14%), p=0.003), stress urinary incontinence (29 (49%) versus 8 (16%), p<0.001), urge urinary incontinence (16 (27%) versus 4 (8%), p=0.005) and flatus (18 (31%) versus 8 (16%), p=0.01). Significantly more women in the PFMT group compared to the control group did reduce bother of vaginal bulge (23 (39%) versus 7 (14%), p=0.003), pelvic pressure (20 (34%) versus 7 (14%), p=0.04), stress urinary incontinence (27 (46%) versus 8 (16%), p<0.001), urge urinary incontinence (15 (25%) versus 3 (6%), p=0.002), flatus (16 (27%) versus 5 (10%), p=0.003) and fecal incontinence (11 (19%) versus 0, p=0.02). The PFMT group had significantly greater improvement than the control group in PFM strength (13.1 cmH^2O 95%CI: 10.6-15.5 versus 1.1 cmH^2O 95%CI: 0.4 - 2.7, p<0.01) and PFM endurance (107 cmH^2Osec 95%CI: 77.0 - 136.4 versus 8 cmH^2Osec 95%CI: -7.4 - 24.1, p<0.01). The net difference in change was 12.0 cmH^2O (95%CI: 8.9 – 14.9) for PFM strength and 98.8 cmH^2Osec (95%CI: 64.2-133.4) for PFM endurance. The effect size for muscle strength and endurance was 1.21 and 0.96, respectively. Based on the interview the net improvement rate in favour of the PFMT group was 76% (95% CI: 62-89) for mechanical symptoms, 71% (95%CI: 57-84) for bladder symptoms and 28% (95%CI: 14-42) for bowel symptoms.

Interpretation of results

The present study demonstrated that PFMT can improve stage of POP. Although statistical significant differences were found between groups, the number of women improving POP-Q stage may be considered relatively low. However, during a valsalva manoeuvre the PFM are stretched and pushed in a caudal direction, opposite to the PFM function. Hence, an improvement in POP-Q may not be expected. In the present study the results regarding symptoms and bother were analysed conservatively, including

both symptomatic and asymptomatic women. Nevertheless, statistical significant differences and large effect sizes in reducing symptoms were found in favour of PFMT.

Concluding message

Supervised and intensive PFMT over six months can reverse POP and reduce mechanical, bladder and bowel symptoms.

References

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**The study is registered in the clinical register trial registry at ww.ClinicalTrials.gov (NCT00271297).**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The study was approved by the Regional Medical Ethics Committee (S-05146)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**