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Bø K[1], Hilde G[1], Tennfjord M K[2], Jensen J S[3], Siafarikas F[3], Engh M E[3]

***1.*** *Norwegian School of Sport Sciences, Dept of Sports Medicine,* ***2.*** *Norwegian School of Sport Sciences. Dept of Sports Medicine and Akershus university hospital,Dept of Obstet Gynecol,* ***3.*** *Akershus university hospital, Dept of Obstet Gynecol*

# RANDOMIZED CONTROLLED TRIAL OF PELVIC FLOOR MUSCLE TRAINING TO PREVENT AND TREAT PELVIC ORGAN PROLAPSE IN POSTPARTUM PRIMIPAROUS WOMEN

Hypothesis / aims of study

It has been estimated that about 50% of all parous women have lost some of the supportive mechanism of the pelvic floor (1). Several randomized controlled trials have shown that pelvic floor muscle training (PFMT) is effective in treating pelvic organ prolapse (POP) in middle aged women (2), and that PFMT reduces the levator hiatus area, lifts the bladder neck and rectal ampulla, increases pelvic floor muscle strength and thickness and reduces muscle length (3). However, search on PubMed did not reveal any studies on the effect of PFMT in prevention and treatment of POP in the postpartum period. The aim of the present study was to assess the effect of a four month postpartum PFMT program on symptoms of POP and POP-Q stage in primiparous women.

Study design, materials and methods

This was an assessor blinded randomized controlled trial (RCT) evaluating the effect of PFMT on POP-Q variables, bladder neck position and symptoms of POP. At six weeks postpartum 175 primiparous women were stratified on major defect of the levator ani muscle (LAM) or not (assessed with 3/4D transperineal ultrasound) and , thereafter, randomized to either PFMT or control with usual care. Inclusion criteria were giving birth to a singleton healthy baby, no serious diseases to the mother or child and ability to understand the native speaking language. Exclusion criteria were delivery by caesarean section and 3$^{rd}$ and 4$^{th}$ degree perineal tears. This was the secondary analyses of a RCT with the primary aim of evaluating postpartum PFMT for prevention and treatment of urinary incontinence. Power calculation was done on primary outcomes. With a power of 0.90 and significance level of 5% 31 participants were required in each group. Assuming approximately the same prevalence of women with loss of supportive mechanism and UI, but including a stratum of women with major defects of LAM, statistical advice was to include 80 women in the PFMT and 80 women in the control group.

Both groups were thoroughly taught how to perform a correct PFM contraction, and feedback of ability to contract was given by trained physiotherapists based on observation and vaginal palpation. POP was assessed by gynaecologists using POP-Q. Symptoms of POP in terms of feeling a bulge inside/outside the vagina were assessed by an electronic questionnaire using ICIQ-VS. Transperineal ultrasound was used to assess bladder neck (BN) position in the mid-sagittal planer. PFM strength and endurance were assessed by a high precision vaginal pressure transducer connected to a vaginal balloon. The PFMT group attended weekly PFMT classes led by trained physiotherapists for 4 months starting at 6 weeks postpartum. In addition, they were asked to perform 3 daily sets of 8-12 close to maximum PFM contractions at home Adherence was reported by the group training instructors and home training reported in a diary. The control group had the same thorough instruction in how to perform a correct contraction, but had no supervision or follow up. The gynecologists and physiotherapists assessing POP-Q, BN position and PFM variables were blinded to group allocation and symptoms, Data are analysed as intention to treat (ITT). Differences between groups are analysed with Chi-Square or T-tests. P-value is set to ≤ .05

Results

Mean age of the participants was 29.8 (SD 4.1) and mean BMI at 6 weeks postpartum was 25.7 kg/m$^2$ (SD 4.0). There were significantly more women in the control group with higher education (p=.010) and more women reporting bulging inside the vagina at baseline (p<.01). No significant differences were found for any other variables at baseline. Twenty-seven and 28 women were diagnosed with major LAM in the PFMT and control group, respectively. Having a major defect did not influence the number of women with bulging. Loss to follow up was 12 and 3 in the PFMT and control group, respectively. Ninety-six% of the participants adhered to ≥ more than 80% of both group and home training sessions. There was a significant change in PFM strength (p<0.01) and endurance (p<0.01) in favour of the PFMT group. Table 1 shows number of women reporting bulging inside and outside the vagina, POP-Q assessment and BN position at rest before and after the intervention period. No statistically significant changes within or between groups were found in any of the variables.

Table 1. Symptoms of pelvic organ prolapse (bulging), POP-Q variables and transperineal ultrasound assessment of bladder neck (BN) position at rest before and after the intervention in the PFMT and control group (C). Numbers with % or mean cm with SD

| | 6 weeks postpartum | 6 months postpartum |
|---|---|---|
| Bulging inside the vagina (n) | PFMT: 7 (8%)<br>C: 21 (23.9%) | PFMT: 8 (9.2%)<br>C: 22 (25%) |
| Bulging outside the vagina (n) | PFMT: 5 (5.7%)<br>C: 6 (6.8%) | PFMT: 6 (6.9%)<br>C: 5 (5.7%) |
| POP-Q Ap | PFMT: -2.78 (0.4)<br>C: -2.78 (0.5) | PFMT: -2.71 (0.7)<br>C: -2.74 (0.4) |
| POP-Q Bp | PFMT: -2.78 (0.4)<br>C: -2.76 (0.6) | PFMT: -2.79 (0.4)<br>C: -2.75 (0.4) |

| | | |
|---|---|---|
| POP-Q Aa | PFMT: -2.21 (0.7)<br>C: -2.12 (0.8) | PFMT: -2.23 (1.1)<br>C: -2.37 (0.9) |
| POP-Q Ba | PFMT: -2.28 (0.6)<br>C: -2.23 (0.8) | PFMT: -2.36 (0.7)<br>C: -2.40 (0.7) |
| POP-Q C | PFMT: -6.52 (1.3)<br>C: -6.14 (1.2) | PFMT: -6.53 (1.3)<br>C: -6.59 (1.2) |
| POP-Q gh | PFMT: 3.73 (0.8)<br>C: 3.81 (0.8) | PFMT: 3.33 (0.6)<br>C: 3.40 (0.7) |
| POP-Q pb | PFMT: 4.07 (0.7)<br>C: 4.02 (0.7) | PFMT: 3.70 (0.7)<br>C: 3.71 (0.7) |
| BN position rest | PFMT: 2.63 (0.3)<br>C: 2.64 (0.3) | PFMT: 2.81 (0.3)<br>C: 2.74 (0.4) |

Interpretation of results

As far as we have ascertained this is the first RCT evaluating the effect of PFMT in prevention and treatment of POP in the postpartum period. No differences within or between groups were found. The strength of the present study is the RCT design, blinding of assessors, use of supervised training following recommendations for strength training, high adherence and use of reliable and valid outcome measures. Limitations are the high proportion of women with major LAM which may have reduced the effect of PFMT, loss to follow up and the risk of type II error as fewer women than expected had POP symptoms (bulging) at 6 weeks postpartum.

Concluding message

This assessor blinded RCT did not find any effect of postpartum PFMT on symptoms of bulging, POP-Q variables or position of the BN. The number of postpartum women with perception of bulging inside and outside the vagina stayed the same in both groups, hence the lack of treatment effect cannot be explained by natural remission. There is a need for further RCTs evaluating the effect of PFMT in the postpartum period. Based on the results of the present study we recommend to plan a future RCT in postpartum women with symptoms of POP and with individual supervised PFMT.

References

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