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DOES A RING PESSARY IN SITU IMPROVE PELVIC FLOOR MUSCLE FUNCTION IN WOMEN WITH PELVIC ORGAN PROLAPSE?

Hypothesis / aims of study

Pelvic organ prolapse (POP) is a prevalent condition in women, and mechanical symptoms such as heaviness and bulging may greatly impair quality of life and restrict participation in physical activities. POP has been associated with weak pelvic floor muscles (PFM) (1) and PFM training has demonstrated to be effective in strengthening the muscles, reduce muscle length, increase muscle thickness and reduce hiatal dimensions in a randomized controlled trial (RCT) (2). It has been suggested that pessary support may result in improved PFM function, but so far there is no data to support this hypothesis (3). To date there is no consensus to whether or not the prolapse should be repositioned during measurement and PFM training. The aim of the present study was to evaluate whether there is a difference in vaginal resting pressure, PFM strength and endurance measured with and without a ring pessary in situ in women with grade II – IV POP.

Study design, materials and methods

This was a short term experimental study comparing vaginal resting pressure, PFM strength and endurance in POP women, with and without a ring pessary in situ. All women were assessed with and without the ring, and acted as their own controls. Inclusion criteria were women with POP grade 2-4, being able to perform a correct PFM contraction. Exclusion criteria were inability to perform a correct PFM contraction, intolerance to insertion of the prolapse ring, pregnancy and diseases that could interfere with PFM function. Stage of POP was assessed by Pelvic organ prolapse quantified (POP-Q) by two experienced gynecologists. The size of the pessary was chosen to be loose-fitting, but large enough to retain the prolapse. Ability to contract the PFM was assessed by visual observation of inward movement of the perineum and vaginal palpation. PFM strength was measured with a fiberoptic microtip transducer connected to a vaginal balloon (Camtech AS) and measured as the maximum voluntary contraction (MVC). Mean of three contractions were used for analysis. Muscle endurance was measured as ability to hold the PFM contraction for ≥10 sec. All PFM measurements were done with the women in supine position and by an experienced physical therapist. Power calculation was based on a previous reliability study and assumption of a clinical relevant difference of 5 cmH_2O, and a correlation between the two tests of 0.5. SPSS, version 18 was used for data analysis. The results are presented as means with standard deviation (SD) and difference between the two measurements as means with 95% CI. Differences between the two measurements with and without the ring pessary in place were analysed by Paired Sample T-test and Wilcoxon Signed Rank Test. Significance level was set at $p < .05$.

Results

Twenty-seven women were enrolled in the study. Five were excluded; two because they were straining instead of performing a correct PFM contraction, and three because of pain and intolerance to insertion of the ring pessary. Mean age of the 22 participants was 60.6 years (SD 13.0), mean BMI 24.5 (SD 3.6) and mean parity 2.1 (SD 1.4). Eighteen were postmenopausal and 8 used some form of estrogen replacement therapy. Nine women had POP-Q stage 2, 12 stage 3 and one stage 4. Mean duration of POP symptoms (bulging and heaviness) was 2.5 years (SD 3.4). Four women had never heard about PFM training, 8 were exercising the PFM at present while 12 had never trained the PFM. Table 1 shows the results of the measurements with and without the ring pessary in situ. There was a statistically significant difference between measurement with and without the ring pessary in vaginal resting pressure, difference: -5.3 cm H_2O (95% CI:-7.7- -2.9), but not in MVC: difference: 0.45 cm H_2O (95% CI: -1.8-2.7). Six and 8 women were able to hold the PFM contraction for ≥ 10 sec without and with the ring, respectively.

Table 1: Pelvic floor muscle strength measured as mean maximum voluntary contraction (MVC) and vaginal resting pressure in 22 women without and with a ring pessary in situ.

	Without ring pessary (n=22)	With ring pessary (n=22)	p-value
Mean MVC (cm H_2O)	11.4 (SD 5.4)	10.9 (SD 5.4)	0.686
Mean vaginal resting pressure (cm H_2O)	18.8 (SD 4.7)	24.1 (SD 7.6)	0.000

Interpretation of results

This study did not find any difference in measurement of PFM strength with and without a ring pessary in situ. An assumed effect size of 5 cm H_2O was used in the original power calculation, whereas the observed value was 0.5 cm H_2O with an upper 95% CI of 2.7. There was a statistically significant difference in vaginal resting pressure with the same number of women and comparable SD. Hence, we trust that the results are correct and therefore stopped further inclusion to the study as no significant differences could be expected. This study only assessed the immediate effect of reposition of the prolapse on PFM function, and further studies are needed to evaluate whether there is a long term effect of a more permanent use of a ring pessary on different aspects of PFM function. Recent RCTs have shown that PFM training can improve muscle strength and reduce prolapse stage and symptoms. Based on the results of the present study measurement of PFM strength and PFM training can be done without reposition of the prolapse. Theoretically one could assume that reposition of the prolapse would reduce vaginal resting pressure while the opposite was found. There are few studies on vaginal resting pressure in the PFM literature, and interpretation of the statistically significant increase in vaginal resting pressure with the ring pessary in situ needs further investigation.

Concluding message

A statistically significant higher vaginal resting pressure was found with a ring pessary in situ. There was no difference in measurement of PFM strength with and without reposition of the prolapse. Further studies are needed to evaluate a possible long term effect of pessary use on PFM function.

References

1. Braekken IH, Majida M, Ellstrøm ME, Bø K. Pelvic floor function is independently associated with pelvic organ prolapse. BJOG, 116, 13:1706-1714, 2009
2. Brækken IHB, Maijida M, Engh ME, Bø K:Morphological changes after pelvic floor muscle training.
3. Handa VL, Jones M. Do pessaries prevent the progression of pelvic organ prolapse? Int Urogynecol J, 13: 349-352, 2002

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