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DOES A RING PESSARY IN SITU INFLUENCE THE PELVIC FLOOR MUSCLE FUNCTION OF WOMEN WITH PELVIC ORGAN PROLAPSE WHEN TESTED IN SUPINE?

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ABSTRACT

Introduction and Hypothesis. It has been suggested that repositioning pelvic organ prolapse (POP) by pessary support may improve pelvic floor muscle (PFM) function. The aim of the present study was to compare vaginal resting pressure and maximal voluntary contraction (MVC) of the PFM measured with and without a ring pessary in situ.

Methods. This was a short term experimental study with women acting as their own controls. Twenty-two women with POP quantified II-IV were included. Vaginal resting pressure and MVC was measured with a manometer (Camtech AS) in supine position. Difference between measurements with and without the ring pessary was analysed by Paired Sample T-test and Wilcoxon Signed Rank test. Significance level: <0.05

Results. There was a statistically significant difference in measurement of vaginal resting pressure ($p<0.01$), but not of MVC ($p=<0.68$) with the ring pessary in situ.

Conclusions. Measurement of PFM strength can be done without repositioning the prolapse.

Key words: measurement, pelvic floor muscles, pessary, strength, vaginal resting pressure

Brief summary: A ring pessary in situ significantly changes measurement of vaginal resting pressure, but not maximal voluntary contraction in supine position.

INTRODUCTION

The prevalence of symptomatic pelvic organ prolapse (POP) is reported to be 3-28% [1-5]. Mechanical symptoms such as vaginal bulging and pelvic heaviness are the most specific symptoms of POP [5,6], and these symptoms may greatly impair quality of life and restrict participation in physical activities and other areas of life.

It is estimated that approximately 50 % of all women lose some of the supportive mechanisms of the pelvic floor due to childbirth, leading to variable degrees of pelvic organ prolapse (POP) [1,7]. Prolapse may be asymptomatic until the descending organ is through the introitus, and therefore POP may not be recognized until an advanced condition is present [6,7]. In some women the prolapse advances rapidly, while others remain stable for many years. A recent prospective population based study has also found a spontaneous regression in POP symptoms without any intervention [8].

POP has been associated with avulsion of the levator ani from the pubic arch, size of the levator hiatus and weak pelvic floor muscles (PFM) [9,10]. DeLancey et al [9] found that women with POP could contract the PFM with only 43% of the force generated by women with no POP. A relevant clinical question is whether the PFM contraction and the strength measurements are affected by the prolapse. Handa & Jones [11] postulated that pessary support may allow recovery from passive stretch, resulting in improved levator function and muscular support of the pelvic organs. Hence repositioning the prolapse either manually or with the use of a pessary ring may make it easier for the patients to contract the PFM. 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 compare vaginal resting pressure and PFM strength in supine position measured with and without a pessary ring in situ in women with grade II – IV prolapse.

MATERIALS AND METHODS

Design

This was a short term experimental study comparing vaginal resting pressure, PFM strength and endurance in POP women, with and without a vaginal ring pessary in situ. All women acted as their own controls.

Participants

Women attending the outpatient clinic at the Department of Obstetrics and Gynecology at Akershus University Hospital, Lørenskog, Norway diagnosed with POP grade II-IV according to the Pelvic organ prolapse quantified (POP-Q) [12], were invited to participate in the study. The study was approved by The Regional Ethics Committee South-East (REK Sør-øst) and the Data Inspectorate (Personvernombudet, Akershus University Hospital) of Norway.

Included were women of all ages able to understand information and instruction in Norwegian language and able to contract the PFM correctly. A correct contraction was defined as a visible and palpable inward lift and squeeze around the pelvic openings [13,14]. Exclusion criteria were inability to understand information and instructions given in Norwegian language, inability to perform a correct PFM contraction, intolerance to insertion of the ring pessary, neurological or musculoskeletal diseases that may interfere with ability to contract, pregnancy, breastfeeding and a prolapse too advanced to allow for introduction of the measurement catheter into the vagina.

Power calculation:

Sample size was calculated according to the following assumptions: SD from previous reproducibility study had CI= 9-20 in test 1 giving SD=9.5, whereas the CI of test 2 was 7-21, giving SD= 12.1 [14]. Assuming that t-method was used to calculate CI, where t (13 degrees of freedom)=2.16 and a correlation between test1 and test 2 values equal to 0.5, gives estimated SD for the difference: SD(diff)= 9.5*9.5+12.1*12.1-9.5*12.1=11.0. A clinical relevant difference between two tests was set to 5 cm H_2O. N= [(1.96+0.84)**2]* (11.0/5.0)**2 = 38 participants.

Assessment of ability to contract the PFM

Following standard procedure for assessment of PFM function and strength [13,14], the physical therapist (KB) taught the patients how to perform a correct PFM contraction. Correct contraction was verified by observation of inward perineal movement (classified as yes /no) and vaginal palpation. Classification of the contraction by palpation was: correct, no contraction, contraction only with co-contractions of outer pelvic muscles (except the deep abdominals), and straining [13].

Assessment of PFM strength

Vaginal resting pressure and PFM strength (maximal voluntary contraction (MVC) was measured using a fiberoptic microtip transducer connected to a balloon catheter (Camtech AS, Sandvika Norway). The method has been tested for intra-observer reliability, and has shown to be reliable [14]. Muscle endurance was measured as ability to hold the contraction for ≥ 10 seconds and registered as yes or no. The balloon was placed according to usual procedure with the middle of the balloon 3.5 cm from the introitus [15]. To avoid invalid measurements only contractions with simultaneous visible inward movement of the catheter /perineum were considered correct. [13]. Three MVC followed by a short resting period and one holding period were performed without repositioning the prolapse, and the same procedure was followed with a vaginal ring pessary in situ. All measurements were done in supine position

Procedure

The women were recruited and underwent a gynecological examination including evaluation of degree of prolapse on maximal Valsalva maneuver at least one day before the recording of vaginal pressure measurements. After emptying their bladder, the women answered a short structured interview about age, menopausal stage, parity, height and weight (BMI), concomitant diseases, physical activity level and educational background. The women were taught how to perform a correct PFM contraction using drawings and models. The physical therapist (KB) assessed ability to perform a correct contraction using visual inspection and vaginal palpation. If correct contraction was confirmed, PFM strength was measured first without repositioning the prolapse and then after insertion of a fitted vaginal ring pessary. The pessary was inserted by two experienced gynaecologists (MM or MEE). The size of the pessary was chosen to be loose-fitting, but large enough to retain the prolapse.

Statistical methods

Background variables are presented as means with standard deviation (SD) or numbers /percentages. The results are presented as means with SD, and differences between the two measurements as means with 95% confidence intervals (CI). Differences between the two measurements with and without the ring pessary in situ were analysed by Paired Sample T-test and Wilcoxon Signed Rank Test. Significance level was set to 5%.

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.

Table 1 shows background variables of the participants. 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). Six of the patients had previous pelvic surgery. Four women had never heard about PFM training, 8 were exercising the PFM at present while 12 never had trained the PFM.

Table 2 shows the results of the measurements with and without the ring pessary in situ. There was a statistically significant difference between measurements 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 $\geq$ 10 sec without and with the ring, respectively.

DISCUSSION

This study did not find any difference in measurement of PFM strength or ability to hold the contraction with and without a ring pessary in situ. There was, however, a significant difference in vaginal resting pressure with a significantly higher pressure measured with the ring pessary in place.

An assumed effect size of 5 cm H_2O was used in the original power calculation, whereas the observed value was less than 0.5 cm H_2O with an upper 95% CI of 2.7. This means that 950 women would have had to be included, Clinical judgment of little difference during the study made us do an interim analysis of 22 patients. Since a statistically significant difference was found in vaginal resting pressure with the same number of women and comparable standard deviation, we trust that the results are correct and therefore stopped further inclusion to the study.

This study only assessed the immediate effect of repositioning 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 morphology and function. In the study of Handa & Jones [11] 56 women were assessed after one year of pessary use. Twenty-one percent (95% CI: -0.2-43.7%) had an improvement in stage of prolapse limited to the women with anterior vaginal prolapse. They hypothesized that the improvement might have been due to improved PFM function because the pessary may allow recovery from passive stretch. However, they did not find any change in width of the genital hiatus, length of the perineal body or the total vaginal length at rest measured with POP-Q. The observed improvement might therefore also to some extent be explained by spontaneous regression of the POP [5].

Morphological changes of the pelvic floor have now been shown in a randomized controlled trial (RCT) of PFM training in women with POP. Brækken et al [16] randomized 109 women with POP to 6 months of PFM training + lifestyle advice and teaching of precontraction of the PFM during cough (“the Knack”) or lifestyle advice and teaching of precontraction using 2 and 3D ultrasound to assess morphological changes. We found that the training group significantly improved muscle strength, increased PFM thickness, reduced muscle length and levator hiatus and lifted the bladder neck and rectal ampulla compared to the control group that had no change. In the study by Brækken et al [16] the training was done without repositioning the prolapse. The results of the present study suggest that there is no difference in subject’s ability to perform a MVC with and without reposition. Recent RCTs have shown that PFM training can reduce prolapse stage and symptoms [17-20]. Based on the results of the present study, measurement of PFM strength can be done without repositioning the prolapse. However, there is a need for an RCT comparing use of pessary alone with PFM training alone or pessary + PFMT on PFM function, symptoms and stage of prolapse.

Theoretically one could assume that the immediate response to repositioning the prolapse would be a reduction of vaginal resting pressure as the prolapse would have increased the pressure against the balloon. The opposite was found. One hypothesis is that the pessary may only reinstate anatomy to a certain degree, pushing the vaginal walls and uterus up above the pelvic floor, but the distended walls may still fill up the vaginal space where the catheter is placed. The pessary, even if fitted as accurately as possible can be oriented differently depending on the anatomy of the individual woman and might influence both resting pressure and ability to contract and hold the contraction. Another theory is that insertion of the pessary may reduce the distention of the puborectal muscle forming the walls of the levator hiatus, thereby increasing resting pressure.

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. In a case –control study comparing women with and without prolapse stage 1-3, we found that women with POP had lower vaginal resting pressure than women without prolapse [10]. The association was lost in multivariate analysis, but there was a significant interaction between PFM strength and vaginal resting pressure. The combination between weak PFM and low vaginal resting pressure gave much higher Odds Ratio for POP than strong PFM and high resting pressure, strong PFM and low vaginal resting pressure or weak PFM and high vaginal resting pressure. Another of our studies evaluating 109 women with POP-Q stage I-III, found a strong association between vaginal resting pressure and levator hiatus area and resting position of the bladder neck measured with 3D transperineal ultrasonograpy [21]. MRI or ultrasonography would probably be the recommended measurement methods to study anatomy with and without repositioning the prolapse, and further studies are warranted on vaginal resting pressure in general.

The strengths of the present study were that we performed an a-priori power calculation based on measurements with the same methodology, the method used has been found to be reproducible and valid [13,14], and all women had thorough instruction and confirmation of ability to perform a correct PFM contraction before entering the study. Limitations of the study are that the order of the two procedures was not randomized, and therefore a learning effect could be present. Looking at our data, such a learning effect, which would have given a systematic higher MVC with the prolapse ring in situ, was not observed. We chose not to randomize the order of the two maneuvers as we assumed that the prolapse ring could systematically influence pelvic floor anatomy, and to resemble clinical practice as much as possible. Possible limitations are that the measurements were done in supine position only, and that only one type of pessary, ring pessary, was used. Generalization to other positions and other pessaries eg a Gellhorn can therefore not be made based on our study. Supine position is the preferred position to gain reliable results of PFM testing [22,23]. Jones et al [24] reported that changes in genital hiatal dimensions were found after only 2 weeks with a Gellhorn pessary. The Gellhorn, however, is more seldom used in clinical practice [24] and does not reflect clinical practice in our patient group. In addition, the numbers with different stages of prolapse were small in our study and subgroup analysis was therefore not undertaken,

Conclusion

A statistically significantly higher vaginal resting pressure was found with a ring pessary in situ. There was no difference in measurement of PFM strength or number of women able to hold the contraction for 10 seconds with and without repositioning the prolapse in the supine position. Based on the results of the present study, measurement of PFM strength can be done without repositioning of the prolapse. Further studies are needed to evaluate a possible long term effect of pessary use on PFM function.

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Table 1. Background variables of the participants (N= 22). Mean with standard deviations (SD) and number and %.

Age (years)	60.6 (SD 13.0)
BMI (vekt/h2)	24.5 (SD 3.6)
Parity	2.1 (SD 1.4)
Postmenopausal (N)	18 (81.8%)
Estrogen replacement therapy (N)	8 (36.4%)

Table 2: 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