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THE EFFECTS OF VAGINAL TAMPON TRAINING ADDED TO PELVIC FLOOR MUSCLE TRAINING IN WOMEN WITH STRESS URINARY INCONTINENCE: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

Pelvic floor muscle training (PFMT) is recommended as a first-line treatment for stress urinary incontinence (SUI) (Grade A evidence) (1). It has been reported that PFMT can be performed with special vaginal/rectal devices in the form of resistance training (2, 3). Bø suggested a different way of resistance training with a vaginal cone, by which the cone is placed into the vagina and the patient was asked to contract around the cone while a physiotherapist or the patient simultaneously try to pull it out (3). This new training results in the elimination of the weight of the cone during the process of pulling it out of the vagina. So, we preferred to use inexpensive, hygienic, and single-use vaginal tampons in this training method. To the best of our knowledge, there is no randomized controlled trial (RCT) investigating the additional effect of resistance training with vaginal tampons in SUI. Therefore, the aim of this RCT was to assess vaginal tampon training (VTT) combined with PFMT results in better outcomes than PFMT alone for the treatment of SUI.

Study design, materials and methods

The present study was designed as a randomized, controlled, and single-center study comprising of two parallel arms (PFMT+VTT and PFMT). Inclusion criteria were being 35-60 years of age, having symptoms of SUI according to MESA urinary incontinence questionnaire, being able to contract the pelvic floor muscles, and had sufficient literacy. Women excluded from the present study who: had undergone surgery for incontinence; were taking medications for UI; had neurological disorders; had recent/recurrent urinary tract infections; had Pelvic Organ Prolapse (POP) score ≥ Stage 3 according to POP Quantification System; were pregnant or in a postnatal period of under 6 months. After a comprehensive clinical evaluation and a screening for the inclusion criteria, a computer-based block randomization procedure was used to assign blocks of four participants to each study arm (PFMT+VTT or PFMT).

A standardized 12 weeks of training protocol was performed for both study groups. In PFMT protocol, fast and sustained contractions were taught to all participants. In VTT, the tampon was inserted into the vagina by a physiotherapist (in clinic) or by the patient (at home) and while the patient was instructed to contract her pelvic floor muscles around the tampon, the physiotherapist or patient tried to pull it out of the vagina (a total of five days per week; two days by physiotherapist, three days by themselves). In PFMT alone group, biweekly visits were performed to check the progression of training and to increase the adherence of the treatment.

The primary outcome measure was a self-reported improvement by 4-item Likert-type scale (worse, same, better, cured). Secondary outcome measures included the severity of urinary incontinence by Incontinence Severity Index (ISI), symptom distress and quality of life score by King's Health Questionnaire (KHQ), number of UI episodes and micturition frequency by urinary diaries, pelvic floor muscle strength (PFMS) and pelvic floor muscle endurance (PFME) by vaginal perineometer. Treatment adherence was also evaluated with 100 mm Visual Analog Scale (VAS). All outcome measures except the self-reported improvement were assessed at baseline, 4th week, 8th week and 12th week. Values were analyzed with Friedmann test (non-normally distributed data) and Chi-Square tests (for categorical variables). Mann-Whitney U and Wilcoxon tests were used to compare values (non-normally data) between and within groups, respectively. Alpha was set at 0.05.

Results

A total of 34 women who had symptom of SUI (mean age: 48.26 SD: 6.49 year, BMI: 27.98 SD:3.26 kg/m^2) had completed this study [PFMT+ VTT (n=16), PFMT(n=18)]. There were no statistically significant differences between two groups in terms of the physical/demographic characteristics and baseline outcome measures ($p>0.05$). Adherences to PFMT were also similar between groups at 4th, 8th and 12th weeks ($p>0.05$).

No statistically significant difference was found in self-reported improvement between groups at 4th week, 8th week and 12th week ($p>0.05$). However, both groups had high subjective total cure and improvement rates (total cure+improvement rate: % 75 and % 72.2 at 4th week, % 87.5 and % 88.9 at 8th week, % 93.8 and % 94.4 at 12th week for PFMT+VTT and PFMT groups, respectively). Within-group analysis showed that both treatment groups experienced statistically significant improvements in terms of the ISI score, symptom distress score, PFMS, PFME, UI episodes, micturation frequency, and all domains of KHQ except personal relationships over the time ($p<0.05$). However, between-group analysis showed that there were no statistically significant differences in terms of the incontinence severity, symptom distress score, PFMS, PFME, UI episodes, micturation frequency and in all domains of KHQ scores except social limitations at all time points ($p>0.05$). According to pairwise analysis, the PFMT+VTT group experienced a statistically significant improvement in PFMS and PMFE starting from the 8th week until the end of the treatment. On the other hand, there was a significant improvement in PFMS and PFME only at 12th week in the PFMT group. In addition, the increase in PFMS and PFME between baseline and 12th week in the PFMT+VTT group was significantly greater than the PFMT group ($p=0.37$, $p=0.32$).

Table 1. Comparisons of outcome measures within and between groups.

	Groups	Baseline	4th week	8th week	12th week	p^1
ISI score	PFMT+VTT	8(4-9)	3.5(2-5)	2(1.25-3.5)	2(0.25-4)	<0.001*
	PFMT	6(3.75-12)	4(2-6.75)	2(0.75-6)	2(0-4,5)	<0.001*
	p^2	0.72	0.20	0.61	0.75	
UI episod	PFMT+VTT	0.83(0.33-2.57)	0.83(0.33-2.57)	0.33(0-1.0)	0(0-0.33)	<0.001*
	PFMT	1.0(0-3.25)	0.49(0-3.16)	0(0-1.66)	0(0-1.41)	<0.001*
	p^2	0.99	0.54	0.92	0.30	
PFMS	PFMT+VTT	4.6(3.15-7.72)	5.48(3.14-8.32)	6.15(3.47-8.34)	6.85(4.35-9.22)	<0.001*
	PFMT	5.80(2.86-6.48)	5.53(2.73-7.03)	5.73(3.39-7.16)	6.06(3.43-8.27)	<0.001*
	p^2	0.74	0.52	0.53	0.14	
PFME	PFMT+VTT	66.0(49.6-76.6)	73.6(57.0-84.6)	81.8(70.7-88.3)	83.4(72.7-90.0)	<0.001*
	PFMT	74.5(54.4-85.2)	76.4(68.9-83.1)	75.7(67.8-85.2)	78.6(70.6-91.6)	0.01*
	p^2	0.24	0.97	0.38	0.70	

p^1: within group differences value, p^2: between group differences value. * p<0.05.

Interpretation of results

This is the first RCT investigating the additional effect of the different type of resistance training with vaginal tampons to PFMT in the treatment of SUI. The findings from the present study showed that pelvic floor exercises with and without vaginal tampon exercises had similar effectiveness on the symptoms and severity of SUI, quality of life, and subjective cure+improvement rates. Although between group analysis showed no statistically difference in PFMS and PFME at all time points, it appears that the combination therapy may also lead to an earlier and greater increase in PFMS and PFME. While the significant improvements in PFMS and PFME were shown in PFMT+VTT group at the end of the 8th week, in PFMT group the improvement was only seen at the end of the 12th week.

Concluding message

Although there was an earlier and greater improvement in PFMS and PFME in the PFMT+VTT group, combination therapy did not promote greater gains in the subjective cure/improvement rates, severity of urinary incontinence, incontinent episodes, quality of life compared with PFMT alone. We think that resistance training with vaginal tampons may be added to an early phase of training due to the additional effect on PFMS and PFME. Further long-term follow-up RCTs with VTT as an only home-based programme or comparing PFMT with VTT alone are needed.

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