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ORIGINAL ARTICLE

Effects of vaginal tampon training added to pelvic floor muscle training in women with stress urinary incontinence: randomized controlled trial

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Abstract

Introduction and hypothesis We evaluated whether vaginal tampon training (VTT) combined with pelvic floor muscle training (PFMT) results in better outcomes than PFMT alone for treating stress urinary incontinence (SUI).

Methods This was a randomized, controlled study. Patients were allocated to either the combined program, consisting of PFMT and VTT over 12 weeks [PFMT and VTT group ($n = 24$)] or to PFMT alone [PFMT group ($n = 24$)]. The primary outcome measure was self-reported improvement, while secondary outcome measures were severity of incontinence, quality of life (QoL), urinary parameters, and pelvic floor muscle strength (PFMS) and endurance (PFME). Values were analyzed with Friedman, Mann–Whitney *U*, Wilcoxon, and chi-square tests.

Results Between-group analysis showed no statistically significant differences in self-reported improvement, severity of incontinence, symptom distress score, PFMS, PFME, urinary parameters, and all domains of QoL scores, except social limitations, at weeks 4, 8, and 12 ($p > 0.05$). However, the increase in PFMS and PFME between baseline and week 12 and earlier improvement was significantly greater in the PFMT and VTT than in the PFMT group (both $p < 0.05$)

Conclusion Short-term results demonstrated that PFMT with and without VT exercises had similar effectiveness on the symptoms of SUI and QoL.

Keywords Stress urinary incontinence · Pelvic floor · Exercise · Randomized controlled trial

Abbreviations

BMI	Body mass index
ICS	International Continence Society
KHQ	King's Health Questionnaire
MESA	Medical, Epidemiologic, and Social Aspects of Aging
PFME	Pelvic floor muscle endurance
PFMS	Pelvic floor muscle strength
PFMT	Pelvic floor muscle training
RCT	Randomized controlled trial
SUI	Stress urinary incontinence
UI	Urinary incontinence
V_{10s}	Value at the end of 10 s
V_{max}	Maximum value
V_{rest}	Rest value
VAS	Visual analog scale
VTT	Vaginal tampon training

Previous meeting Our research (The Effects of Vaginal Tampon Training Added to Pelvic Floor Muscle Training in Women with Stress Urinary Incontinence: A Randomized Controlled Trial) was presented at 47th Annual Meeting of the International Continence Society (ICS) 2017 (12–15 September 2017, Florence, Italy), and the abstract of this study was published in *Neurourology and Urodynamics* (Volume 36, Issue S3)

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Introduction

Urinary incontinence (UI) has been defined by International Continence Society (ICS) and International Urogynecological Association (IUA) as involuntary urinary leakage [1]. The most common type is stress urinary incontinence (SUI), which is defined occurring during activities that increase intra-abdominal pressure, such as laughing, coughing, sneezing,

or physical effort [1]. UI is a socially embarrassing condition and is associated with a decreased quality of life (QoL) [2]. Pelvic floor muscle training (PFMT) is recommended as a first-line treatment for SUI (Grade A evidence) [3]. The aim of PFMT is to improve the strength, endurance, and coordination of the PFMs and increase support of the proximal urethra and bladder neck to prevent urinary leakage [4]. PFMT can be performed with exercises alone or in combination with biofeedback techniques, electrical stimulation, and/or special vaginal devices in the form of strength training [5–7]. A pilot study demonstrated that a pelvic toner device is a feasible, safe, and well-tolerated adjunct in PFMT [5]. Kashanian et al. [6] found that the effect of exercises performed with and without the assisting device had similar effects on UI in women.

Unlike vaginal devices, vaginal cones developed by Plevnik are small weights that are placed in the vagina above the levator plate [8]. The theory behind the use of vaginal weights in strength training is that the reflex or voluntarily contraction of PFMs prevents the cone from slipping out of the vagina [9]. Trying to keep the cones in place with PFM contraction for 15–20 min may reduce blood circulation and oxygen consumption, leading to muscle fatigue and pain [10]. Also, as the vagina is not a vertical cylinder, the natural pelvic tilt can help in carrying these weights [11]. Radiography confirmed that cones lie in a transverse position in the vagina [11] and can therefore train PFMs, but the generated force depends on the vaginal angle of each individual [9]. Therefore, Bø suggested a different training method using a vaginal cone in which the cone is placed into the vagina and the patient is asked to contract around the cone while a physiotherapist or the patient simultaneously attempts to pull it out [12]. For this particular strength training, the patient or physiotherapist generates an inverse pulling force with the cone during PFM contraction. This technique eliminated the weight of the cone during the pulling process. In our study, we used inexpensive, hygienic, and single-use vaginal tampons for strength training. To our knowledge, no previous randomized controlled trial (RCT) has investigated the effects using this method. Therefore, our aim was to investigate the additional effects of vaginal tampon training (VTT) to PFMT on self-reported improvement, SUI symptoms, QoL, and PFM strength and endurance. The hypothesis of our study was that VTT added to PFMT would be much more effective in improving SUI symptoms, QoL, and strength and endurance of PFMs compared with PFMT alone in women with SUI.

Materials and methods

Study design and participants

This was a randomized, controlled, single-center study consisting of two parallel arms—PFMT and VTT and PFMT alone—involving 48 women diagnosed with pure SUI or stress-predominant UI. Participants were regular patients at the university outpatient gynecology clinic recruited and monitored by gynecologists and physiotherapists. The protocol was approved by the ethics committee (no: GO16/506–18) and registered at ClinicalTrials.gov (ID: NCT02924740). Prior to inclusion, all participants provided written informed consent according to the principles stated in the Declaration of Helsinki.

Inclusion criteria were 35–60 years of age, having symptoms of pure SUI and stress-predominant UI according to the Medical, Epidemiologic, and Social Aspects of Aging (MESA) questionnaire [13] with the ability to contract PFMs and having sufficient literacy to complete assessment forms and training protocols. According to previous research, we chose this age group since conservative treatment was most frequently demanded such women [7, 14]. Exclusion criteria were previous surgery for incontinence, currently taking medications for UI, neurological disorders, pelvic organ prolapse (POP) stage ≥3 according to the POP Quantification (POP-Q) system, pregnancy or in a postnatal period <6 months, recent or recurrent urinary tract infections UTI, and prior physiotherapy. Women using psychological or diuretic medications, with complaints of chronic constipation, chronic cough, or voiding dysfunction were also assessed. After comprehensive clinical evaluation (medical history; general, physical, and neurologic examination; disease-specific questionnaires, pad test, and bladder diary), participants were evaluated for inclusion or exclusion.

Randomization

After comprehensive clinical evaluation and completion of baseline outcome measures, a computer-based block randomization procedure, prepared by an independent researcher uninvolved in the study, was used to assign four participants to each arm (PFMT and VTT or PFMT). Results were placed into opaque envelopes, which were sealed until interventions were assigned.

Treatment

Both groups received a standardized 12 weeks of treatment. Before beginning the exercise therapy, physiotherapists specialized in pelvic floor rehabilitation made participants aware of the location and function of PFMs, lower urinary tract, and continence mechanisms via anatomical models. The effects of pelvic floor exercises on UI symptoms were explained on an individual basis, and vaginal palpation was performed to assess the participant's ability to perform PFM contraction correctly. Participants were instructed how to prevent straining and contraction of different muscles, such as abdominals, hip adductors, and gluteal muscles, or pelvic tilt during contraction and taught how to perform both fast and sustained contractions.

In the PFMT group, biweekly visits were carried out to check training progression and to increase treatment adherence. In the PFMT and VTT group, vaginal tampon training was also conducted. All participants were provided with an information sheet about VTT and/or PFMT, and exercise diaries were used to increase adherence and encourage the correct performance of the exercises [15].

Vaginal tampon training

Participants in the PFMT and VTT group were encouraged to perform two sets of 15 repetitions of vaginal tampon exercises for 5 days a week (by physiotherapist on 2 days, by themselves on 3 days) for 12 weeks; 24 outpatient sessions, each lasting ~10–15 min, were conducted. In the VTT group, the tampon was inserted by a physiotherapist (in the clinic) or by the participant (at home), and while the participant was instructed to contract her PFMs around the tampon, the physiotherapist or participant attempted to pull it out of the vagina.

Pelvic floor muscle training

All participants were instructed to complete a standardized PFMT program consisting of fast and sustained voluntary contractions over a 12-week period. One set of exercises comprised ten fast and ten sustained voluntary contractions. In consideration of the progressive overload principle, participants were instructed to increase the number of repetitions after each supervised session. During weeks 1 and 2, they performed two sets of exercises (20 fast and 20 sustained) per day, which was progressively increased by two sets: four sets (40 fast and 40 sustained) per day at weeks 3 and 4; six sets (60 fast and 60 sustained) per day at weeks 5 and 6; eight sets (80 fast and 80 sustained) per day at weeks 7 and 8; ten sets (100 fast and 100 sustained) per day from week 9 to week 12. Exercises in different positions, such as supine, sitting, standing, and semisquatting. Our protocol was developed according to previous research [16].

Outcomes

Sociodemographic (age, education level, marital status, occupation, smoking habit) and clinical variables [height (cm), weight (kg), body mass index (BMI, kg/m^2), gynecological and obstetric anamnesis, and menstrual status] were obtained at the initial visit. An outcome assessor blinded to group allocation evaluated outcome measures. All participants completed diaries and questionnaires under the supervision of the outcome assessor. Instruction sheets were given to patients for completing 24-h frequency volume charts and a 24-h pad test. With the exception of self-reported improvement, all outcome measures were assessed at baseline and weeks 4, 8, and 12.

Primary outcome measure

Self-reported improvement

Perception of UI improvement compared with baseline was assessed using the four-item Likert-type scale (worse, same, better, cured). This is a reliable method for evaluating subjective perception of improvement of patients with UI [17].

Secondary outcome measures

UI severity

UI severity and objective cure in SUI was assessed using a 24-h pad test. Participants were instructed to bring one unused pad of the same type when they came back to the clinic. Pad weight was measured using a clinically sensitive balance (Sartorius BP 310 S). Unused pad weight was multiplied by the number of pads used, and amount of urine leakage was calculated by subtracting this weight from the total weight of used pads. In the 24-h pad test, values >4 g were considered significant and classified as mild (4–20 g/24 h), moderate (21–74 g/24 h), and severe (>75 g/24 h) UI [18].

Severity was also assessed using the Incontinence Severity Index (ISI), which consists of two questions: (1) How often do you experience urinary leakage? (0 = never, 1 = less than once a month, 2 = a few times a month; 3 = a few times a week; 4 = every day and/or night); (2) How much urine do you lose each time? (0 = none, I do not leak urine; 1 = drops; 2 = small splashes; 3 = more) [19]. Total score (0–12) was obtained by multiplying the score of answers to two questions.

Urinary diary parameters

To evaluate urinary diary parameters, participants were asked to complete a 24-h frequency-volume chart on three separate days (e.g., 2 working days and 1 weekend day). Frequency of micturition and number of UI episodes obtained from three diaries were recorded as outcomes [20].

Quality of life and symptom severity

QoL and symptom distress scores were evaluated using the Turkish version of the King's Health Questionnaire (KHQ), which Kaya et al. [21] reported as being a valid and reliable condition-specific QoL questionnaire for UI, is frequently used to assess QoL of patients with UI, and includes 32 items and two parts [22].

Pelvic floor muscle strength and endurance

PFMS and PFME were measured using a noninvasive vaginal perineometer (Cardio Design Pty Ltd., Australia). PFMS was

calculated by subtracting the rest value (V_{rest}) from the maximum value (V_{max}) observed on the perineometer during contraction. The holding time at maximum contraction was recorded for $PFME_s$. PFME was also defined as a percentage of maximum contraction that could be maintained at the end of 10 s and ability to maintain that maximum for 10 s. The value observed at the end of 10 s (V_{10s}) was recorded, and $PFME_{\%}$ was calculated using the formula developed by Kaya et al. [15]:

$$PFME_{\%} = \frac{V10sec - Vrest}{Vmaks - Vrest} x100$$

Treatment adherence

Compliance with exercises was assessed using the 100-mm visual analog scale (VAS). Participants were asked to mark the place that best expressed their exercise adherence on a 100-mm line (0 = I never performed the exercises; 10 = I performed all exercises) [15].

Statistical analysis

Based on results of previous studies [23, 24], we planned to recruit 40 women (20 per group), giving a statistical power of 80% ($\alpha = 5\%$). As a result, we estimated a dropout rate of 20% and thus aimed for a sample size of 24 in each group. Statistical analyses were performed using Statistical Package for the Social Sciences software, version 21 (SPSS Statistics; IBM Corporation, Armonk, NY, USA). The normality of data distribution was checked using visual (histogram and probability plots) and analytical (Kolmogorov–Smirnov) methods. Descriptive statistics for each parameter were presented as mean ± standard deviation (SD) for normally distributed quantitative data, median (25–75%) for nonnormally distributed

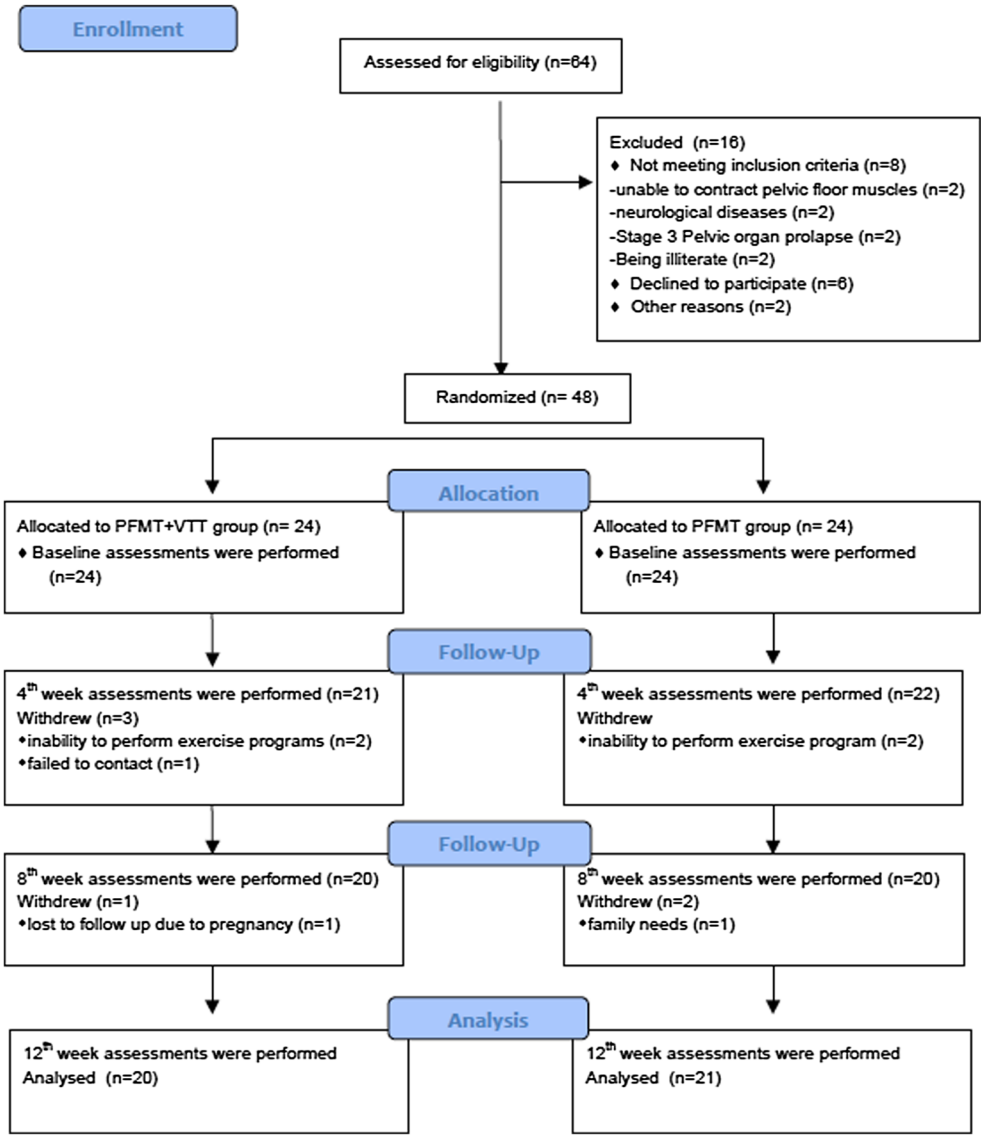

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT)

quantitative and ordinal data, and number (%) for categorical variables. The Mann–Whitney *U* test was conducted to compare the differences in terms of nonnormally distributed quantitative data between groups at baseline and weeks 4, 8, and 12. The Friedman test was used to assess statistical significance of change in nonnormally distributed quantitative data within groups over time (baseline, weeks 4, 8, 12). The Wilcoxon test was used to assess the significance of pairwise differences (baseline–week 4, baseline–week 8, baseline–week 12) using the Bonferroni correction to adjust for multiple comparisons. The corrected *p* value was <0.008. Differences between groups were analyzed using the chi-square test for categorical data at all time points. Statistical significance was assumed at $p < 0.05$.

Results

A total of 64 women were screened between August 2016 and May 2017; 48 met inclusion criteria and were randomized to the study groups. Four PFMT and VTT group participants discontinued due to inability to perform the exercise program ($n = 2$), failure to contact ($n = 1$), and pregnancy ($n = 1$). Three patients withdrew from the PFMT group due to inability to perform the exercise program ($n = 2$) and family needs ($n = 1$). Thus, 41 women (mean age 48.31 ± 6.76 years, BMI 28.28 ± 3.44 kg/m^2, mean UI duration 5.14 ± 4.11 years) completed this study (PFMT and VTT 20, PFMT 21). Figure 1 shows a flow diagram of the participants.

Participant demographics and characteristics were homogenous (Table 1). There were also no significant differences in PFMT adherence between groups at all time points ($p > 0.05$) (Table 1). Mean frequency of attendance at the outpatient sessions was 21.1 ± 2.10 in the PFMT and VTT group. Compliance with vaginal tampon exercises was also high at all time points: $\text{mean}_{\text{week 4}}$ 81.05, $\text{mean}_{\text{week 8}}$ 74.90, and $\text{mean}_{\text{week 12}}$ 79.35.

Table 1 Characteristics of patients and treatment adherence values of the Pelvic Floor Muscle Training and Vaginal Tampon Training (PFMT and VTT) and Pelvic Floor Muscle Training (PFMT) groups[a]

	PFMT and VTT ($n = 20$)	PFMT ($n = 21$)	*P* value
Age (years)	47.75 ± 7.19	48.85 ± 6.45	0.33[b]
BMI (kg/m^2)	27.60 ± 3.17	28.94 ± 3.63	0.16[b]
Education (years)	15 (11–15)	11 (8–15)	0.28[b]
Duration of SUI (years)	4.0 (2.0–5.0)	4.0 (2.5–7)	0.72[b]
Pregnancies (*n*)	3.0 (2.0–5)	4.0 (2.5–5.0)	0.45[b]
Parity (*n*)	2.0 (2.0–3.0)	2.0 (2.0–3.5)	0.40[b]
Mode of delivery			0.70[c]
No delivery	1 (5)	- (0)	
Vaginal	14 (70)	17 (81)	
Cesarean	4 (20)	3 (14.3)	
Vaginal and cesarean	1 (5)	1 (4.8)	
Working status, yes	12 (60)	10 (47.6)	0.53[c]
Smoking status, yes	2 (10)	2 (9.5)	0.99[c]
Chronic constipation, yes	3 (15)	5 (23.8)	0.69[c]
Chronic cough, yes	3 (15)	5 (23.8)	0.69[c]
Use of diuretics, yes	1 (5)	2 (9.5)	0.99[c]
Use of antidepressants, yes	1 (5)	3 (14.3)	0.60[c]
Treatment adherence (PFMT)			
week 4	82.70	89.80	0.13
week 8	79.40	85.20	0.12
week 12	84.00	83.80	0.93

PFMT pelvic floor muscle training, *VTT* vaginal tampon training, *BMI* body mass index, *SUI* stress urinary incontinence

[a] Mean ± standard deviation, median (25–75%), or frequency (%)

[b] Mann–Whitney *U* test for continuous variables

[c] Chi-square or Fisher's exact test for categorical variables

Primary outcome

No statistically significant difference was found between groups in self-reported improvement at weeks 4, 8, and 12 ($p > 0.05$; chi-square test (Table 2).

Secondary outcomes

UI severity

There were no statistically significant differences between groups on the pad test at weeks 4, 8, and 12 ($p > 0.05$) (Table 2). However, statistically significant differences were found in both groups from the third (week 8) to the following (week 12) visit compared with baseline. There were no statistically significant differences in ISI score at weeks 4, 8, and 12 according to between-group analysis ($p > 0.05$). Pairwise analysis revealed that incontinence severity significantly improved in both groups at weeks 4, 8, and 12 compared with baseline values (Table 3).

Urinary diary parameters

According to between-group analysis, there were no statistically significant differences in frequency of micturition and UI episodes at all time points ($p > 0.05$). Pairwise analysis showed that the frequency of micturition and UI episodes significantly improved at weeks 8 and 12 in the PFMT and VTT group. However, there was a statistically significant improvement in UI episodes weeks 8 and 12 only in the PFMT group (Table 3).

QoL and symptom severity scores

There were no statistically significant differences in Symptom Severity scores between groups at weeks 4, 8, and 12

Table 2 Self-reported improvement and 24-h pad test[a]

	Time point	Condition	PFMT and VTT	PFMT	*P* value[b]
Self-reported improvement	Week 4	Worse	- (0)	- (0)	0.99
		Same	7 (35)	8 (38.1)	
		Better	13 (65)	13 (61.9)	
		Cured	- (0)	- (0)	
	Week 8	Worse	- (0)	- (0)	0.99
		Same	5 (25)	6 (28.6)	
		Better	15 (75)	15 (71.4)	
		Cured	- (0)	- (0)	
	Week 12	Worse	- (0)	-(0)	0.62
		Same	2 (10)	2 (9.5)	
		Better	14 (70)	17 (81)	
		Cured	4 (20)	2 (9.5)	
24-h pad test	Baseline	No UI	- (0)	- (0)	0.96
		Mild	13 (65.0)	13 (61.9)	
		Moderate	5 (25.0)	6 (28.6)	
		Severe	2 (10.0)	2 (9.5)	
	Week 4	No UI	1 (5.0)	3 (14.3)	0.79
		Mild	13 (65.0)	12 (57.1)	
		Moderate	4 (20.0)	4 (19.0)	
		Severe	2 (10.0)	2 (9.5)	
	Week 8	No UI	6 (30.0)	7 (33.3)	0.99
		Mild	10 (50.0)	10 (47.6)	
		Moderate	3 (15.0)	3 (14.3)	
		Severe	1 (5.0)	1 (4.8)	
	Week 12	No UI	10 (50)	10 (47.6)	0.74
		Mild	8 (40)	4 (33.3)	
		Moderate	2 (10)	3 (14.3)	
		Severe	- (0)	1 (4.8)	

PFMT pelvic floor muscle training, *VTT* vaginal tampon training, *UI* urinary incontinence

[a] Frequency (%)

[b] Chi-square test

($p > 0.05$). Pairwise analysis revealed that Symptom Severity score significantly improved at weeks 4, 8, and 12 (Table 3).

Figure 2 shows the distribution of Incontinence Impact, Role Limitations, Physical Limitations, Emotional Problems, Sleep and Energy Disturbances, and Severity Measures domains of the KHQ at baseline and weeks 4, 8, and 12. Between-group analysis revealed no statistically significant differences in any KHQ domains at all time points, except for Social Limitations ($p > 0.05$). Within-group analysis showed statistically significant improvements in all domains in both groups over time ($p < 0.05$).

PFMS and PFME

According to the between-group analysis, there were no statistically significant differences in PFMS, $PFME_{\%}$, and $PFME_s$ scores at weeks 4, 8, and 12 ($p > 0.05$) (Table 4).

Pairwise analysis showed that the PFMT and VTT group experienced a statistically significant improvement in PFMS, $PFME_{\%}$. and $PFME_s$ scores from week 8 until the end of the treatment (Table 4). In the PFMT group, significant improvements in PFMS, $PFME_{\%}$, and $PFME_s$, were observed only at week 12. The increase in PFMS and $PFME_{\%}$ between baseline and week 12 was significantly greater in the PFMT and VTT : $mean_{PFMT\ and\ VTT}$ 1.58; $mean_{PFMT}$ 0.83, $p = 0.01$ for PFMS; $mean_{PFMT\ and\ VTT}$ 18.15; $mean_{PFMT}$ 8.43, $p = 0.009$,for $PFME_{\%}$.

Discussion

Short-term results of this RCT demonstrated that PFMT with and without VT exercises had similar effectiveness on subjective cure and improvement rates, UI severity, urinary parameters of micturition frequency and UI episodes, and QoL.

Table 3 Comparisons of ISI scores at baseline and weeks 4, 8, and 12 for micturition frequency, urinary incontinence episodes, and symptom severity scores within and between groups[a]

	Time point	PFMT and VTT	PFMT	*P* value*
ISI score	Baseline	8 (4–9)	6 (3.5–12)	0.77
	Week 4	4 (2–6)[b]	4 (2–8.5)[b]	0.26
	Week 8	2 (2–4)[c]	2 (1–7)[c]	0.49
	Week 12	2 (1–4)[d]	2 (0.5–7)[d]	0.62
	P value**	<0.001***	<0.001***	
Frequency	Baseline	6.33 (6.0–9.32)	7.0 (5.16–9.83)	0.90
	Week 4	6.33 (5.16–8.08)	6.0 (5.0–9.49)	0.93
	Week 8	5.83 (5.0–8.24)[c]	6.33 (5.16–9.0)	0.57
	Week 12	5.83 (4.74–7.83)[d]	6.33 (5.0–9.0)	0.49
	P value**	<0.001***	0.01***	
UI episodes	Baseline	1.16 (0.33–2.57)	1.0 (0–3.0)	0.89
	Week 4	1.0 (0.33–2.57)	0.66 (0–3.0)	0.55
	Week 8	0.49 (0–1.24)[c]	0 (0–1.33)[c]	0.58
	Week 12	0 (0–1.83)[d]	0 (0–1.16)[d]	0.80
	P value**	<0.001***	<0.001***	
Symptom severity score (KHQ)	Baseline	7 (4–11.75)	9 (5.5–13)	0.30
	Week 4	3.5 (2–6.5)[b]	7 (2–9)[b]	0.25
	Week 8	3 (1–4)[c]	4 (1.5–8.5)[c]	0.17
	Week 12	1.5 (0.25–2.75)[d]	3 (0–6)[d]	0.25
	P value**	<0.001***	<0.001***	

PFMT pelvic floor muscle training, *VTT* vaginal tampon training, *ISI* Incontinence Severity Index, *UI* urinary incontinence, *KHQ* King's Health Questionnaire

*Between-groups differences; **within-group differences; ***$p < 0.05$

[a] Median (25–75%)

[b] Pairwise comparisons between baseline and week 4

[c] Pairwise comparisons between baseline and week 8

[d] Pairwise comparisons between baseline and week 12, $P < 0.008$ according to Wilcoxon test

When changes in PFMS and PFME from baseline to the end of week 12 were compared, there were significantly greater improvements in the combined-therapy group.

To our knowledge, the present study is the first RCT to investigate the additional effects of different type of strength training with vaginal tampons in treating SUI. In the literature, it was suggested that this type of exercise might be performed with vaginal cones considering the exercise physiology [12]. As there is no study applying this type of exercises with vaginal cones, it is hard to compare the results of the present study with the previous studies investigating the effects of vaginal cones [24–26].

In the present study, we choose the single-use vaginal tampons instead of vaginal cones as a tool of PFMT in the new training method. In order to carry out this particular strength training, the patient or physiotherapist has to generate an inverse pulling force during the PFM contraction. However, when the vaginal cone is used for this purpose and pulled down by the patient or physiotherapist during the PFM contraction, the weight of the vaginal cone is eliminated. Despite the elimination of the weight of vaginal cones, using them only to generate the traction would increase the cost of this study. Another advantage of the vaginal tampons are being disposable, inexpensive and hygienic. We also used the tampons with an applicator that makes the insertion of the tampon into the right place easier. Moreover, we believe that they are well tolerated by women, as different sizes of vaginal tampons are available.

In the literature, many PFMT protocols have been composed and suggested, however there is no consensus on the standard program. When the systematic reviews have been examined, it was found that the duration of the treatments ranged from 6 weeks to 6 months and the number of daily voluntary PFM contractions ranged from 36 to 200 [4, 27]. Intensive training program including of fast and sustained contractions were performed in our research. The number of contractions was gradually increased. Patients started with 40 contractions per day and progressed to 10 sets maximum of 200 contractions per day. The holding time was also increased, and patients were instructed to perform exercises in different positions. According to the American College of Sport Medicine (ACSM) guideline, increasing the number of contractions is more related to the endurance training [28]. In the literature, previous studies applied the combination of strength

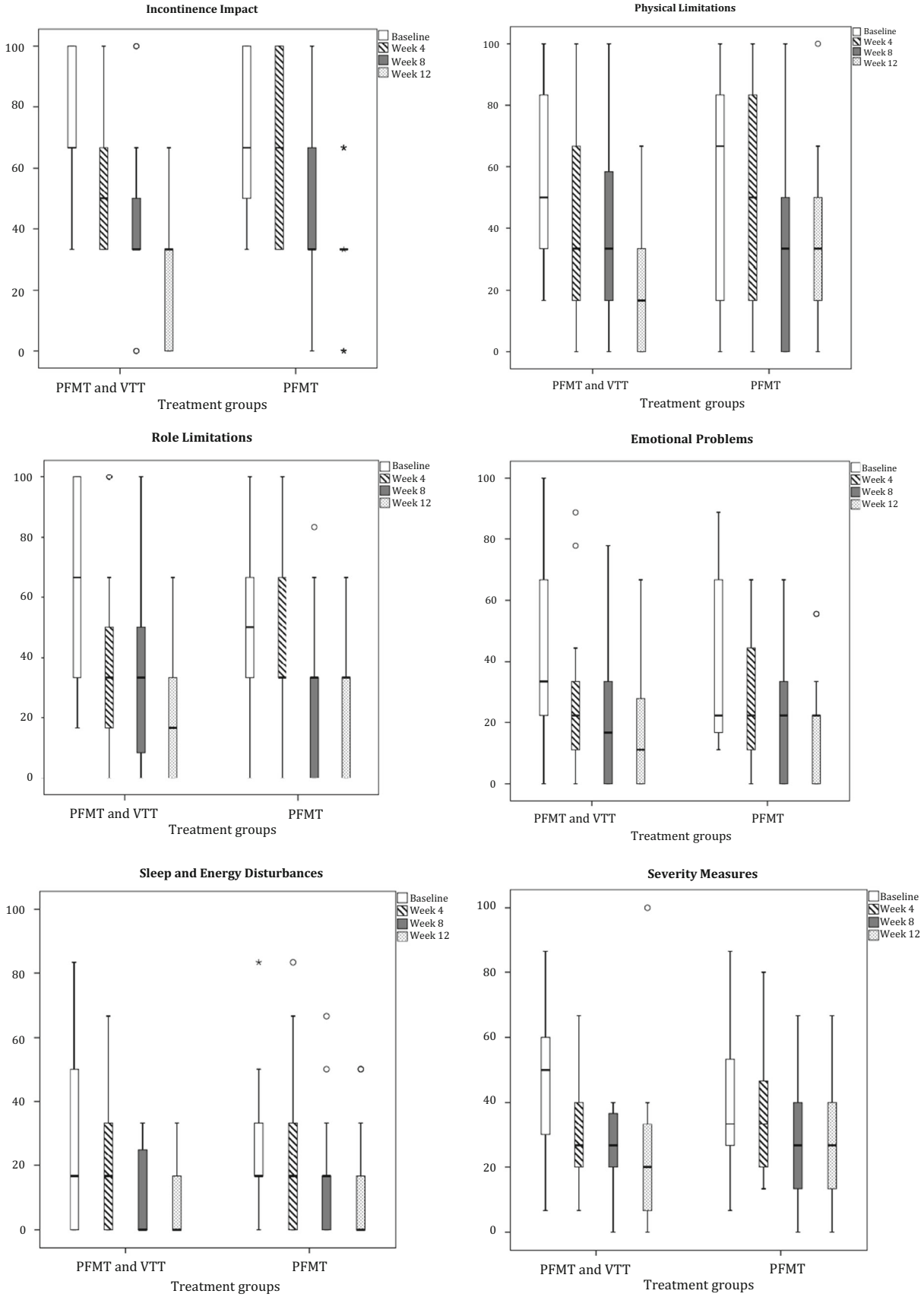

Fig. 2 Distribution of Incontinence Impact, Role Limitations, Physical Limitations, Emotional Problems, Sleep and Energy Disturbances, and Severity Measures domains of the King's Health Questionnaire (KHQ) at baseline and weeks 4, 8, and 12

Table 4 Comparisons of pelvic floor function data[a]

	Time points	PFMT and VTT	PFMT	*P* value*
PFMS	Baseline	4.65 (3.15–7.12)	5.60 (3.04–6.63)	0.88
	Week 4	5.48 (3.14–7.75)	5.60 (2.79–6.83)	0.61
	Week 8	6.15 (3.47–8.10)[b]	5.66 (3.54–7.18)	0.53
	Week 12	6.85 (4.35–9.10)[c]	5.73 (3.54–8.15)[c]	0.19
	*P***	<0.001***	<0.001***	
PFME (%)	Baseline	64.08 (39.44–76.66)	74.83 (52.64–85.44)	0.10
	Week 4	67.09 (56.97–84.38)	75.96 (67.18–83.75)	0.62
	Week 8	79.61 (62.42–88.35)[b]	75.36 (67.49–85.43)	0.58
	Week 12	79.61 (62.84–90.90)[c]	80.62 (69.82–91.70)[c]	0.95
	*P***	<0.001***	0.009***	
PFME (s)	Baseline	1.0 (1.0–1.66)	1.33 (1.0–2.0)	0.28
	Week 4	1.66 (1.0–3.57)	2.0 (1.0–2.66)	0.78
	Week 8	2.0 (1.0–3.357)[b]	2.0 (1.0–2.83)	0.79
	Week 12	2.0 (1.08–3.33)[c]	2.0 (1.0–3.33)[c]	0.86
	*P***	<0.001***	<0.001***	

PFMT Pelvic floor muscle training, *VTT* vaginal tampon training

*Between-group differences; **With group differences; ***$P < 0.05$

[a] Median (25–75%)

[b] Pairwise comparisons between baseline and week 8

[c] Pairwise comparisons between baseline and week 12, $p < 0.008$ according to Wilcoxon test.

and endurance training similar to the present study [15, 29–32]. Fast contractions of 1–3 s and long sustained contractions of 6–10 s were included in the PFMT [15, 29–32]. According to the results of these researches, UI severity [15, 31] and UI episodes [15, 29, 32] were reduced and QoL [15, 30, 32], PFMS [30–32] and PFME [15] were improved in patients with UI.

Our study did not include a control group receiving no treatment or inactive control treatments such as standard care, simple lifestyle alterations, and advice on incontinence pads or motivational phone calls. This situation prevents us from knowing the amount of improvement in the PFMT and VTT and PFMT groups when compared with the standard care. On the other hand, ethical considerations may lead to the lack of a control group in the study design. In the literature, similarly to our study, there have been previous studies investigating the effects of vaginal device with or without PFMT [5, 6] or additional effects of combined therapy (PFMT + vaginal cones) compared to PFMT alone [33, 34], which are also lack control or inactive therapy groups.

Subjective total cure and improvement rates were high in the present study. However, it appears that the improvement rates were similar at the end of the week 12 in both groups. High improvement rates may be related to the individual training sessions for pelvic floor exercises, frequent follow-ups, and more intensive treatment programs [12]. It has been known that individual training was performed by experienced pelvic floor physiotherapists per week or biweekly sessions in high cure RCTs [35, 36]. Furthermore, it has been reported that adherences to exercises were high and the drop out rates were low in these studies [35, 36].

The assessment of QoL is suggested by ICS to support the clinical measures of UI [37]. It has also been emphasized that the improvements in the QoL were important to understand the clinical relevance of the changes in the pad test and urinary diary parameters in the literature [37]. In the present study, both treatment groups showed improvement in QoL scores. Improvements in the QoL have also been reported in other studies in which the effects of standard PFMT with the vaginal devices on urinary incontinence we compared [5, 6].

In this study, PFMS and PFME significantly increased over time in both treatment groups and improved earlier in the combined-therapy group. In addition, when the changes in PFMS and PFME from baseline to the end of week 12 were compared, there were significantly greater increases in the combined-therapy group. PFMS and PFME improved by 38% and 41%, respectively in the PFMT and VTT group; there were increases of 20% and 17%, respectively in the PFMT group. However, we were unable to draw absolute conclusions due to study duration (12 weeks), since maximal muscle strength is not achieved until 4–6 months of strength training according to recommendations of the ACSM [28]. Studies with long-term follow-up are needed to reveal these effects better. On the other hand, we assessed PFMS using the vaginal pressure device connected to a pressure manometer. We had no device to measure the pulling force of PFMs.

Further studies may reveal more comprehensive results by assessing this pulling force with a specially designed device.

Vaginal devices activate the sensory-motor biofeedback mechanism [38], and such activation leads to higher levels of neural gains with greater activation and synchronization of motor units [39]. Also, improvement in proprioception of PFMs may trigger involuntary muscle contractions and increase the ability to perform voluntary and specific contractions of the PFMs [9, 40]. With regard to our study, we believe that vaginal tampon exercises may stimulate biofeedback mechanisms through increased sensory input and contraction strength and activation of a greater number of motor units during contraction. This may result in improvements in pelvic floor function in the short term. According to these short-term results, VTT may be added to the early phase of treatment by stimulating sensory-motor biofeedback and improving proprioception to encourage and motivate patients to perform maximum and intensive PFM contractions.

Strengths of our study are the randomized controlled design; using objective, validated, and reliable measures; and frequent follow-up to improve adherence to treatment. Furthermore, we believe that vaginal tampons are safe and well tolerated. Some potential limitations are that therapists who carried out treatments were not blinded to treatment group with regard to PFMT and/or VTT. However, objective, reproducible, valid, and reliable outcome measures were used to prevent the effect of this situation on treatment outcomes. Second, participant self-reports were used to determine compliance. Although valid and reliable questionnaires have been used to evaluate treatment compliance in previous studies, nonpharmacological use of these questionnaires has not been confirmed [14]. Another limitation was that the study focused only on the immediate effects of treatments and not on their long-term effects. However, this is the first study to demonstrate the additional effects of VT exercises on SUI.

In conclusion, the short-term results of this study showed that combination therapy did not promote greater gains in subjective cure/improvement rates, incontinence severity, urinary parameters such as micturition frequency and UI episodes, and QoL compared with PFMT alone, although there was an earlier and greater improvement in PFMS and PFME in the PFMT and VTT group. Further long-term follow-up RCTs in which VTT is used as a home-based program only, or that compare PFMT with VTT alone, are required.

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Compliance with ethical standards

Conflicts of interest None.

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