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ORIGINAL ARTICLE

The effect of pelvic floor exercises performed with EMG biofeedback or a vaginal cone on incontinence severity, pelvic floor muscle strength, and quality of life in women with stress urinary incontinence: a randomized, 6-month follow-up study

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Abstract

Introduction and hypothesis The objective was to assess the effectiveness of pelvic floor exercises performed with electromyographic (EMG) biofeedback or a vaginal cone on incontinence severity, muscle strength, social activity level, quality of life, treatment success, and treatment satisfaction in women with stress urinary incontinence (SUI).

Methods This prospective, randomized study included 40 female patients diagnosed with SUI. Patients were randomly divided into two groups as the group receiving pelvic floor muscle exercise (PFME) with a vaginal cone at home ($n = 20$) and the group receiving PFME with EMG biofeedback in the hospital ($n = 20$). The measurement of urinary incontinence severity with a 1-h pad test, assessment of social activity with the social activity index (SAI), assessment of incontinence-specific quality of life, manual measurement of pelvic floor muscle strength, and the assessment of treatment satisfaction were performed in the pre-treatment period and post-treatment at 3 and 6 months.

Results In intragroup analyses, an improvement was observed in both groups in the pad test, muscle strength, SAI, quality of life, and treatment satisfaction measurement compared with the pre-treatment period ($p < 0.05$). No significant difference was found between the groups in terms of assessment parameters in intergroup analyses during follow-up ($p > 0.05$).

Conclusion It was concluded that both EMG biofeedback assisted PFME and PFME with a vaginal cone had curative effects on incontinence in patients with SUI. We believe that both protocols can be used as acceptable and effective conservative therapy methods in the treatment of women with SUI considering their preference.

Keywords Urinary incontinence · Pelvic floor muscle training · Biofeedback · Vaginal cone

Introduction

Urinary incontinence is a serious health problem that can lead to significant deterioration of the quality of life and division of social relationships, as well as psychological problems associated with shame and social withdrawal in individuals [1, 2]. One of the most common forms of incontinence in women is stress urinary incontinence (SUI), which can develop owing to physical activities causing an increase in intra-abdominal pressure [3].

There are conservative therapy options such as behavioral therapies, bladder training, pelvic floor muscle exercises (PFMEs), electrical stimulation, biofeedback, and pharmacological therapy in the treatment of SUI [4]. PFME is one of the main conservative therapy methods, the efficiency of which has been proven with various randomized controlled studies and meta-analyses in SUI [5]. These exercises are aimed at improving the function of pelvic floor muscles through several mechanisms [6]. Vaginal cones, electrical stimulation, and biofeedback are among the assistive methods used with PFMEs in clinical practice [7]. Cones, because of their ease of use, may be an alternative for women who cannot adequately contract their pelvic floors to perform PFMEs, but their results are less well documented [4]. Electromyographic (EMG) biofeedback is a low-risk and non-invasive method used with

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surface electrodes. In the literature, the rates of improvement with exercise methods combined with biofeedback have been reported to be between 78% and 90% [4]. There are studies reporting that the improvement continues for at least 6 months after the pelvic floor rehabilitation program with biofeedback [8].

Although the positive effects of conservative methods in the treatment of SUI have been reported in the literature, the number of comparative studies on this subject is very low and there are still many questions about which is the most effective method. To the best of our knowledge, there is no study comparing the effectiveness of PFME with a vaginal cone or EMG biofeedback. This study was aimed at investigating the effects of pelvic floor exercises performed with EMG biofeedback or a vaginal cone on incontinence severity, pelvic floor muscle strength, social activity level, quality of life, treatment success, and treatment satisfaction in women with SUI.

Materials and methods

Patients

A total of 40 female patients who were referred with stress urinary incontinence to our outpatient clinic and diagnosed with SUI were included in this prospective and randomized study. Figure 1 summarizes the patient recruitment, participation, and attrition during the study period. The inclusion criteria were as follows: female patients older than 20 years, having SUI after urodynamic testing, having no genital anatomical abnormality, and being able to understand and follow verbal stimulants. The exclusion criteria were as follows: pregnancy, having an active vaginal or urinary system infection or malignancy, loss of integrity of pelvic floor muscles or dysfunctional pelvic floor muscles, having a neurological disorder that will prevent the woman from feeling the contraction of the pelvic floor muscles, having a

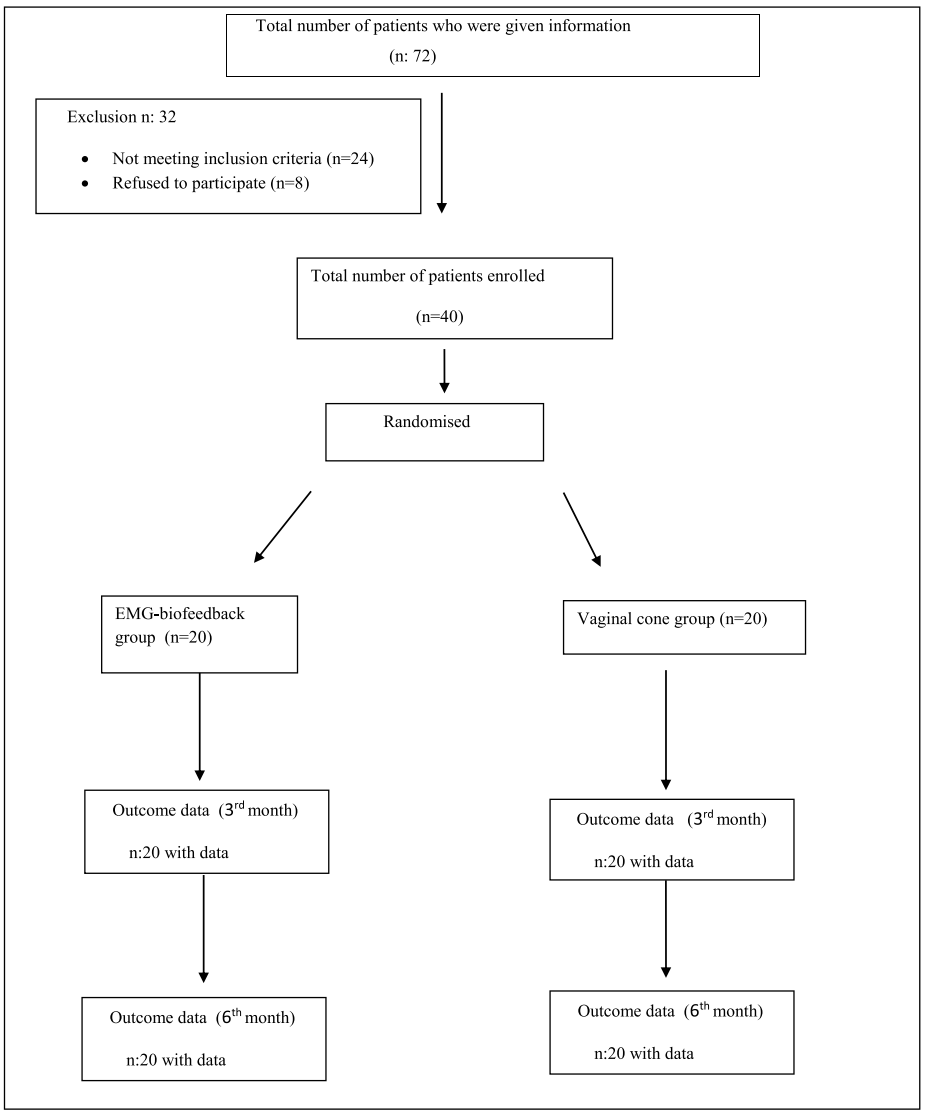

Fig. 1 Flow diagram of the study

history of surgery for SUI, having undergone a urogynecology surgery within the last 2 months, having pelvic organ prolapse above stage 2, and having a condom allergy or an allergy to the lubricating gel used in the perineometer.

Data collection

Patients' data (age, occupation, comorbidities, medication, incontinence duration, cigarette use, daily consumption of tea and coffee, alcohol consumption, parity, type of delivery, episiotomy, state of menopause, and use of hormone treatment) were obtained from the patient files and through face-to-face interviews.

All the patients included in the study underwent incontinence severity measurement with a 1-h pad test, manual pelvic floor muscle measurement, social activity assessment with the Social Activity Index, quality of life assessment with the Incontinence Impact Questionnaire-7 (IIQ-7), and treatment satisfaction assessment with a Likert scale in the pre-treatment period and post-treatment at 3 and 6 months. In the 1-h pad test; the patients were asked to wear a clean pad and walk for 30 min after drinking 500 ml of water and in the 45th min, they were asked to stand up from sitting 10 times, cough 10 times, pick up objects from the floor, and wash their hands for 3 min. In the 60th min, the pad was weighed in grams on a microbalance and the difference, calculated by subtracting the dry weight from the wet weight, was assessed [9].

Assessment of pelvic floor muscle strength with digital palpation is a method that subjectively and manually assesses the pelvic floor muscle strength. The patients are placed in lithotomy position and the person who performs the test puts his or her two fingers into the vagina and the patients are asked to contract their pelvic floor muscles as if they are preventing urine and gas output. The Modified Oxford Scale scored between 0 and 5 is mostly used to measure the muscle strength in scoring the test [10].

The Social Activity Index is an assessment method performed using a visual analog scale (VAS) scored between 0 and 10 for women experiencing problems in participating in social activities. In scoring, 0 means "it is impossible to participate in social activities" and 10 means "there is no problem participating in social activities" [11].

The IIQ-7 is a quality-of-life scale developed to assess the thoughts of patients about their incontinence problem and the level of its effect on their quality of life. Complaints of the patients are scored as none (0), low (1), moderate (2), and high (3). The total score ranges from 0 to 21. A lower score means a lower influence on the quality of life [12].

In the Likert Scale, patients were asked to assess their satisfaction with the treatment they received with a score from 1 to 3 (1, not satisfied; 2, no change; and 3, satisfied) [13].

Interventions

Patients were divided into two groups using the block randomization method as group 1 ($n = 20$) receiving pelvic floor muscle exercises (PFMEs) with a vaginal cone at home and group 2 ($n = 20$) receiving PFME with EMG biofeedback.

Both groups received the pelvic floor muscle training programs as an hour in each day for 3 weeks. The first group received pelvic floor muscle training with EMG biofeedback in our clinic and the patients were placed in lithotomy position. The vaginal probe covered with a condom was intravaginally positioned. During the study, mode EMG Biofeedback (Chattanooga Intelect Advanced Color Stim + EMG -2 Channel combined electrotherapy and EMG biofeedback) of the device was used. The biofeedback device was used that had a sensitivity value of 100 mV and a threshold value of 1 mV in application. Each session was applied for 20 min, for a total of 40 cycles, with a working time of 10 s and a resting time of 40 s [11]. The second group received pelvic floor muscle training with a vaginal cone at home and the patients did the exercises for 20 min followed by contraction for 10 s and relaxation for 20 s.

No side effects developed during the therapies and exercises used.

All patients participated after giving written informed consent, and the study was approved by the Ethics Committee of the University (decision number: 2019/143).

Statistics

Statistical analyses were performed using IBM SPSS Statistics 11.0 (International Business Machines Corporation, USA) software. Descriptive data were expressed in mean ± standard deviation. The Kruskal–Wallis test was used to analyze baseline demographic and clinical variables for the numerical data. The intergroup differences with respect to categorical variables were assessed using Chi-squared tests. Mann–Whitney *U* test was used in a comparison of two independent groups. Friedman test was used in the analysis of repeated measures (more than two times) and in case there was a significant difference, paired comparisons were performed with Bonferroni corrected Wilcoxon test. The significance level was accepted as $p < 0.05$ for all statistical analyses.

Results

No difference was found between the groups in terms of baseline demographic data of the patients included in the study (Table 1).

According to intragroup comparisons, a significant difference was found between pre-treatment and post-treatment

Table 1 Baseline demographic and clinical characteristics of the patients

Variables	EMG biofeedback group, $n = 20$	Vaginal cone group, $n = 20$	p
Age	61.5 ± 11.2	60 ± 10.6	0.99
Occupation			0.598
Housewife	19 (95%)	18 (90%)	
Retired	1 (5%)	1 (5%)	
Others	–	1 (5%)	
Incontinence duration (months)	88.2 ± 67.6	51.4 ± 37.7	0.082
Additional diseases			
Thyroid disease (yes)	3	2	1
Diabetes mellitus (yes)	12	6	0.112
Hypertension (yes)	10	7	0.522
Cardiovascular diseases (yes)	–	3	0.145
Others	6	9	0.514
Cigarette (yes)	3 (15)	5 (25)	0.347
Alcohol (yes)	–	1 (5)	1
Number of births			0.091
1–3	14 (70)	19 (95)	
>4	6 (30)	1 (5)	
Type of births			0.605
Vaginal delivery	19 (95)	17 (85)	
Cesarean	1 (5)	3 (15)	
Episiotomy (yes)	14 (70)	13 (65)	1
Menopausal status			1
Premenopausal	2 (10)	1 (5)	
Postmenopausal	18 (90)	19 (95)	

EMG electromyographic

at the 3- and 6-month assessments in incontinence severity (pad test) and quality of life in both therapy groups ($p = 0.000$; Tables 2, 3). There was also a statistically significant difference between the 3- and 6-month assessments ($p = 0.000$; Tables 2, 3). A significant difference was observed between the pre-treatment and post-treatment 3- and 6-month assessments in manual muscle strength and Likert scale (treatment satisfaction) in both groups (Tables 2, 3); however, there was a significant difference only in manual muscle strength between post-treatment 3- and 6-month assessments ($p = 0.046$) in the EMG group (Table 2).

In the assessment of social activity level, a significant difference was found between pre-treatment and post-treatment at 3- and 6-month assessments in the EMG biofeedback group ($p = 0.000$; Tables 2, 3). There was also a statistically significant difference between the 3- and 6-month assessments ($p = 0.000$; Tables 2, 3). A significant difference was observed between pre-treatment and post-treatment 3- and 6-month assessments in the vaginal cone group ($p = 0.000$); however, there was no statistically significant difference between the post-treatment 3- and 6-month assessments (Tables 2, 3).

According to intergroup comparisons, no statistically significant difference was found between the groups in the post-treatment 3- and 6-month assessments in terms of assessment parameters ($p > 0.05$; Table 4).

The power of the study calculated using the "G. Power-3.1.9.2" program. As a result of the analysis applied to 40 people, including the first group of 20 and the second group of 20, the effect size was found to be 1.2587 and the strength of the study calculated post hoc was 0.97. The minimum power value for post hoc analysis is 0.67. In this case, the power is acceptable.

Discussion

In this prospective randomized study in which the effectiveness of EMG biofeedback-assisted pelvic floor exercises or pelvic floor exercises with use of a vaginal cone on incontinence severity, pelvic floor muscle strength, social activity

Table 2 Comparison of evaluation parameters of electromyographic biofeedback group before and after treatment

Variables	Pre-treatment	Post-treatment 3 months	Post-treatment 6 months	Pre- to post-treatment at 3 months, p**	Pre- to post-treatment 6 months, p**	Post-treatment 3month to post-treatment 6 months, p**
Incontinence severity (g; mean ± SD)	16.7 ± 11.6	11.9 ± 7.9	8 ± 5.6	0.000	0.000	0.000
Pelvic floor muscle strength (mean ± SD)	2.2 ± 1.0	3.3 ± 1.08	3.5 ± 0.9	0.000	0.000	0.046
Social Activity Index (mean ± SD)	2.9 ± 1.6	4.8 ± 1.6	6 ± 1.5	0.000	0.000	0.000
IIQ-7 (mean ± SD)	14.1 ± 4.7	11.1 ± 4.1	9.6 ± 3.8	0.000	0.000	0.001
Satisfaction with the treatment	1 ± 0.0	2.4 ± 0.8	2.2 ± 0.6	0.000	0.000	0.197

IIQ-7 Incontinence Impact Questionnaire-7

Table 3 Comparison of evaluation parameters of the vaginal cone group before and after treatment

Variables	Pre-treatment	Post-treatment3 months	Post-treatment 6 months	Pre- to Post-treatment 3 months, p^{**}	Pre- to post-treatment 6 months, p^{**}	Post-treatment 3 months to post-treatment 6 months, p^{**}
Incontinence severity (g) (mean ± SD)	9.7 ± 6.6	7.5 ± 5.8	6.1 ± 4.9	0.000	0.000	0.001
Pelvic floor muscle strength (mean ± SD)	3.4 ± 0.9	3.8 ± 0.9	3.8 ± 0.6	0.005	0.003	0.655
Social Activity Index (mean ± SD)	4.2 ± 1.3	5.5 ± 1.2	5.9 ± 1.5	0.000	0.001	0.032
IIQ-7 (mean ± SD)	11.2 ± 3.286	9.25 ± 3.242	8.05 ± 2.981	0.000	0.000	0.000
Satisfaction with the treatment	1.1 ± 0.447	2.35 ± 0.587	2.05 ± 0.759	0.000	0.001	0.034

IIQ-7 Incontinence Impact Questionnaire-7

level, quality of life, and treatment satisfaction in women diagnosed with SUI was investigated, both groups had a significant improvement in all assessment parameters compared with the baseline values in their post-treatment 3- and 6-month assessments and no difference was found between the groups.

The agency for clinical practice guideline, "The Agency for Healthcare Policy and Research," recommended trying the conservative therapy before surgical therapy for urinary incontinence except for special conditions [14]. The Cochrane Incontinence Group stated that pelvic floor exercises had better results than the placebo group and the group receiving no therapy and could be recommended as the primary conservative therapy for women with incontinence [15]. However, it is hard to learn how to contract the pelvic floor muscles correctly in order to make this method effective. In clinical practice, assistive methods such as vaginal cones and biofeedback can be used in combination with the exercises for that purpose and various studies have revealed the effectiveness of these methods in the treatment of incontinence [4].

High-quality evidence showed that biofeedback improved urinary incontinence compared with no active treatment [16]. In a three-arm study on women with SUI ($n = 53$), the addition of perineal electromyographic biofeedback or intravaginal pressure biofeedback was found to be superior to PFMT performed alone at home in terms of urinary incontinence severity, results for treatment or recovery and pelvic floor muscle strength [7]. In another study, the effectiveness of EMG biofeedback with PFMEs and vaginal electrical stimulation (ES) + PFME therapies was investigated in 85 women with SUI. All the patients received therapy as two sessions (30 min for each session) per week for 10 weeks and their UI questionnaires (UI-5 and Incontinence Questionnaire-Short Form) and urinary incontinence-specific quality-of-life test (King's Health Questionnaire) were assessed. As a result of the study, 84% of the patients in group 1 and 80% of the patients in group 2 were cured, with the treatment and quality of life increasing in both groups. Therefore, both conservative methods were reported to be effective and feasible in SUI [17].

In a randomized controlled study on women with SUI by Huebner et al. [18], the patients were divided into three groups (group 1: PFME + EMG biofeedback + traditional ES; group 2: PFME + EMG biofeedback + dynamic ES; group 3: PFME + EMG biofeedback), and a visual analog scale and quality of life were used as primary criteria. The number of pads used, Modified Oxford Scale with

Table 4 Comparison of evaluation parameters between groups

Variables	Pre-treatment, p	Post-treatment 3 months, p	Post-treatment, 6 months, p
Incontinence severity	0.024	0.085	0.323
Pelvic floor muscle strength	0.001	0.216	0.284
Social Activity Index	0.012	0.098	0.718
IIQ-7	0.024	0.121	0.171
Satisfaction with the treatment	0.317	0.621	0.685

IIQ-7 Incontinence Impact Questionnaire-7

pad weight test and pelvic floor muscle contractility with intravaginal EMG were used as secondary criteria in the outcomes of therapies. After 12 weeks, the quality of life among women significantly increased, the number of pads used decreased, and the pad weight test and pelvic floor muscle contractility significantly improved. No significant difference was found among these three groups in terms of these outcomes.

Vaginal cones, owing to their ease of use, may be an alternative for women who cannot adequately contract their pelvic floors to perform PFMEs, but their results are less well documented [19]. In a meta-analysis in which the results of conservative therapy methods for SUI were assessed, pooled estimates from studies were sufficiently precise to demonstrate that the use of vaginal cones resulted in better quality of life scores than in the control group [4]. When the efficacies of PFMEs and vaginal cones were compared, the studies were not precise enough to differentiate whether they had a superior, a lesser, or an indifferent effect in terms of assessment parameters such as the pad test and satisfaction and it was stated that further studies were needed [4]. In another study investigating the effectiveness of functional electrostimulation and vaginal cones on 45 women with SUI, there was no difference between the outcomes of ES of the pelvic floor and the vaginal cones for the treatment of SUI, and there was a significant improvement in the Incontinence Quality of Life index of the patients in both therapy groups. It was also found that there was a significant decrease in pad weight and that there was a significant decrease in the number of urinary leakage episodes evaluated by the micturition diary [20].

We cannot directly make a comparison as there is no study in which EMG biofeedback-assisted pelvic floor exercises or pelvic floor exercises with a vaginal cone have been compared head-to-head in the literature. As a result of our study, no drop out was observed in either therapy group. Both therapies were tolerated well and no side effects were observed. Our primary outcomes were incontinence severity and pelvic floor muscle measurements and we obtained a significant improvement in both therapy groups during the follow-ups in terms of these parameters. SUI is a problem that also adversely affects the quality of life. When we compared the quality of life of the patients, although neither of the therapy groups revealed any advantage in the comparisons, the general improvement was statistically significant.

The most important limitation of the study was that in pre-treatment, there were statistically significant differences between the groups in incontinence severity, pelvic floor muscle strength, Social Activity Index, and IIQ-7, and this made it difficult to interpret our results. Second, the number of patients included in the study was relatively low. However, the strength of the study post hoc was calculated as 0.97, and we believe the results of our study will be guiding for future studies, as there are no studies comparing EMG biofeedback-assisted pelvic floor muscle training and pelvic floor muscle training with a vaginal cone in SUI in the literature. Also, we were unable to mask group allocation from the participants; therefore, there was a potential risk of detection bias. There is no complete standardization available for biofeedback therapy. The duration and application type of biofeedback protocols are very variable. Therefore, different results can be obtained with therapies using different protocols. Our study did not include a control group in which the women did not receive any therapy, which is also one of the limitations of our study.

Conclusion

Pelvic floor muscle exercises combined with adjuvant therapies were effective in the treatment of SUI. These techniques allow identification, awareness of correct muscle contraction, and inhibition of synergistic muscles, enhancing the results. In this study, both the EMG biofeedback-assisted pelvic floor muscle training and pelvic floor muscle training with a vaginal cone had curative effects on incontinence in patients with SUI. We believe that both protocols can be used as feasible and effective conservative therapy methods in the treatment of women with SUI, considering their preference.

Contributions N. Sahin: project development, data collection, manuscript writing; H. Yesil: data collection, analyzing, manuscript writing; B. Gorcan: project development, data collection, manuscript writing.

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