

Individualized Pelvic Floor Muscle Training with Single Session Versus Long Term Biofeedback for Treating Stress Urinary Incontinence: A Prospective Randomized Trial

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ABSTRACT

Objective: This study was planned to compare the effects of individualized pelvic floor muscle training (PFMT) in the treatment of stress urinary incontinence (SUI) applied with a single session versus long-term biofeedback (BF).

Methods: Thirty-three female patients with SUI were randomized into two groups. Sixteen patients in the first group were given an individualized PFMT program with BF, 2 days a week for 8 weeks, and a home exercise program on the other days. Seventeen patients in the second group were given a home exercise program after individualized PFMT with BF in a single session. After 8 weeks, both groups continued the exercises as a home program for another 4 weeks. Primary outcome parameters included a 3-day bladder diary, 1-hour pad test, maximum contraction pressure, duration of sustained contractions, King's Health Questionnaire, incontinence impact questionnaire, incontinence quality of life scale and Beck depression inventory. Patients were questioned in terms of fecal incontinence, sexual dysfunction and treatment satisfaction as a secondary outcome parameters.

Results: Thirty patients were able to complete the treatment. In the evaluations made at the 8th and 12th weeks, all of the primary outcome parameters improved in both groups ($p < .001$), and no statistically significant difference was found between the groups ($p > .05$). There was also improvement in secondary outcome parameters in both groups.

Conclusion: In the treatment of SUI, it was determined that individualized exercise program might be continued as a home program after BF was used as a single session to teach the exercises correctly in PFMT.

Keywords: Biofeedback, pelvic floor muscle training, stress urinary incontinence

1. INTRODUCTION

Urinary incontinence (UI), the involuntary loss of urine, is a common condition affecting women worldwide, impacting their quality of life (QoL) (1). Stress urinary incontinence (SUI), characterized by involuntary loss of urine during *physical exertion or effort* affects upto 37.5-53% in adult women with UI (2,3).

Initial management for all women with stress, urge and mixed UI is conservative management. The findings of the Cochrane review suggest that pelvic floor muscle training (PFMT) can be included in first-line conservative management for women with UI. Based on the data available, PFMT can cure or improve symptoms of SUI (4).

Many studies have shown that; even after individual training, more than 30% of women fail to contract PFMs correctly in their initial assessment (5,6). The most common

mistake is contracting the hip adductors, abdominal and gluteal muscles (7). It has been determined that 25% of women use pushing force instead of lifting movement (6). Findings highlight the importance of instructing precise PFM contraction for successful treatment. Biofeedback (BF), can be used for the treatment of SUI to show PFMs activity at rest and during contraction. BF is particularly helpful for patients who have difficulty recognizing and isolating the correct muscles. The main contribution of the use of BF in PFMT is facilitating learning, improving contractions and encouraging the patients by providing exercise motivation. BF allows the patient to contract the PFMs voluntarily and accurately, provides the opportunity to correct and change the contractions to achieve better contraction; and also increases the patient's self-confidence and commitment to training in exercise performance (8).

Considering that the most important benefit of BF is to teach the correct contraction of the PFM, we aimed to investigate whether performing PFMT with an individually designed home program after teaching the correct contraction of the PFM with a single session of BF in women with SUI could provide the same effectiveness as a long-term application of BF. As far as we know, this is the first study in the literature to compare the effectiveness of single session BF and long-term BF in PFMT in women with SUI. In case of similar efficacy, it may be recommended that women with SUI do PFMT at home, with an individually prepared home program after a one-time BF training, instead of going to the hospital for a long time.

2. METHODS

This prospective randomized study included 33 patients diagnosed with SUI admitted to the Ege University Medical Faculty, Obstetrics and Gynecology outpatient clinic between May 2019 and June 2020. The local ethics committee of Ege University Medical Faculty approved the study (date: 05.06.2018, no: 18-6/33). Patients were informed about the purpose and contents of the study and all women gave written consent to participate.

Female patients aged >18 years with mild to moderate symptoms of SUI and an increase in pad test measurement greater than 2 g were included in the study. Symptom severity was assessed by the 1-hour pad test, with a 1-10 g increase in pad weight indicating mild incontinence, an 11–50 g increase in moderate and a >50 g increase in severe incontinence (9). Patients with a previous history of genitourinary or SUI surgery, receiving pharmacological incontinence treatment, conservative treatment in the last 6 months, vaginal or urinary tract infection, genitourinary malignancy, overactive bladder, PFM strength <3/5 according to Modified Oxford Scale, stage 2 or more prolapse according to POP-Q, psychiatric or neurological disease that prevents feeling of PFM contractions, patients with poor perception that prevent to understand the verbal or visual instructions and patients who had known allergic response or sensitivity to the condom used with probe were not included in the study.

Thirty-three patients included in the study were divided into two groups according to the simple randomization scheme. All the participants were informed about the anatomical structure of PFM and their importance in incontinence mechanism and treatment. Sixteen patients in the first group were given an individualized PFMT program with pressure – BF, lasting 20 minutes, 2 days a week for 8 weeks, and a home exercise program on other days. Seventeen patients in the second group were given a home exercise program after individualized PFMT with pressure-BF in a single session. BF was applied with Sonoplus 692, (Enraf-Nonius, Rotterdam, The Netherlands) device. An intravaginal pressure probe was used during the procedure. A disposable condom was placed on the pressure probe before each application. The probe was advanced 3-5 cm into the vagina while the

patients were lying on their back with hip and knee flexion. They were trained how to contract the PFM correctly without contracting abdominal, gluteal and hip adductor muscles. Individualized exercise program was arranged according to the baseline values determined by BF. The rapid maximal contraction exercises were continued as 1 second contraction and 2 seconds relaxation, and it was aimed to start with the number of fast contractions that the patient could do and reach a period of 10 repetitive fast contractions. Endurance exercises were started as long as the patient was able to maintain the contraction, and an endurance exercise program consisting of 10 repetitions was prepared with cycles followed by a resting period of twice the duration of the contraction. It was aimed to reach the target of 10 seconds of sustained maximal contractions and 20 seconds of relaxation in weekly increments. An individualized exercise program was planned in the form of 3 sets of 10 repetitions for each contraction type, in which rapid maximal contractions, sustained maximal contractions and then rapid maximal contractions were applied sequentially. A training session included 90 contractions in total, with 1-2 minutes of resting period between sets. Patients were asked to do the daily PFMT program twice a day for 8 weeks, to continue this until the 12th week, and to complete a regular exercise schedule.

Patients in the first group receiving regular BF training were instructed to repeat the exercises once more on the same day as their BF session, and to perform the exercises twice daily on the remaining days as part of their home program. Once the patients in the second group received accurate instruction in performing PFM exercises with BF during a single session, they were instructed to adhere to the home program, consisting of exercise sets similar in the first group, twice daily, every day.

Weekly exercise follow-up of the patients in the home exercise program was provided by phone calls. From the 4th week, the patients were told to do the exercise sets twice a day, one set in lying position, one set in sitting, and one set in standing position. From the end of the 8th week to the 12th week, all patients in both groups were told to continue the home exercise program consisting of 3 sets of exercises twice a day. At the end of the 8th week, all of the patients were taught the Knack maneuver and were asked to contract the PFM just before and during activities that increase abdominal pressure such as coughing, sneezing, and laughing.

2.1. Evaluation Parameters

2.1.1. Bladder diary: The UI frequency and the number of pads used determined by the 3-day bladder diary.

2.1.2. One-hour pad test: A 1-hour pad test was performed to assess incontinence severity (9).

2.1.3. Maximum PFM Contraction Pressure (cmH₂O): Maximum contraction pressure of the PFM was evaluated with intravaginal pressure probe of the BF. When the correct

contraction was achieved, the values of three consecutive contractions were recorded and the average value was used.

2.1.4. Sustained PFM contraction duration (sec.): The duration of the PFMs to sustain maximum or near-maximum contraction was measured with intravaginal pressure probe of the BF. The time to the point where the maximum contraction pressure is reduced to half was recorded. The average duration of three repeated contractions was used.

2.1.5. King's Health Questionnaire (KHQ): The KHQ is designed to measure the effects of UI symptoms on quality of life (QoL) and is used to evaluate improvement after treatment (10,11). The KHQ is composed of three sections. The first two sections of the KHQ, which consists of 21 items in nine areas, were used in this study. In these two sections, the results are scored between 0-100, lower scores indicate good health.

2.1.6. Incontinence Impact Questionnaire (IIQ-7): IIQ-7 is a 7-item quick questioning scale that shows the effects of incontinence on QoL (12,13). Lower scores indicate good health.

2.1.7. Incontinence Quality of Life Scale (I-QOL): I-QOL consists of 22 items that evaluate the effects of incontinence on QoL (14,15). Higher scores indicate better QoL.

2.1.8. Beck Depression Inventory (BDI) : BDI is a 21-item self-report questionnaire on which presence and severity of depressive symptoms are assessed (16,17).

Turkish validity and reliability studies of all the questionnaires used in this study were conducted (11,13,15,17).

2.1.9. Presence of sexual dysfunction and fecal incontinence: The presence of any of the symptoms of reluctance to have sexual intercourse, pain during intercourse, dissatisfaction, UI and lack of pleasure were stated as SD. Fecal incontinence was recorded as present or absent .

2.1.10. Visual Analog Scale (VAS): Treatment satisfaction is evaluated with a VAS. In the VAS evaluation, the far left of the 10 cm line was determined as "no improvement with treatment" and the far right as "much improvement with treatment".

All of them were recorded at the beginning of the treatment, at the end of the treatment (8th week), and at the end of the 12th week. As a secondary outcome of this study, patients were questioned in terms of flatus/fecal incontinence and sexual dysfunction (SD) at the beginning of the treatment and at the end of the 12th week. Treatment satisfaction was also evaluated as a secondary outcome by visual analog scale (VAS) at the end of treatment (8th week) and at the end of the 12th week.

2.2. Statistical Analysis

In this study, numerical data were summarized with mean, standard deviation, median, minimum and maximum values,

and categorical data were summarized using frequency and percentage values with the help of IBM SPSS Statistics 25.0 (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) package program. The significance level was determined as 0.05 in all analyzes (except for interaction, $p < .1$). The conformity of quantitative variables to normal distribution was evaluated with the Shapiro Wilk test. While demographic quantitative data were compared between groups with the Mann Whitney U test, the relationship between qualitative data and groups was evaluated with the Pearson – Chi-square test or Fisher's exact probability test. Time-dependent changes of measurements and questionnaire data in groups were analyzed with non-parametric Brunner-Langer model (F1-LD-F1 design), using R 3.5.2 software (R software, version 3.5.2, package: nparLD, R Foundation for Statistical Computing, Vienna, Austria; <http://r-project.org>). When significant differences were found between the times, pairwise comparisons were made under the same design and p-values were given with Bonferroni correction.

3. RESULTS

During the treatment period, one participant from the long-term BF group and two participants from the single-session BF group were excluded from the study. Two participants were excluded due to non-compliance with study requirements and follow-ups, while one participant was diagnosed with malignancy during treatment. At the end of the 12-week period, the outcomes of 30 participants were assessed (Figure 1). No adverse effects or incidents necessitating treatment discontinuation were noted during either the BF sessions or the home exercise programs.

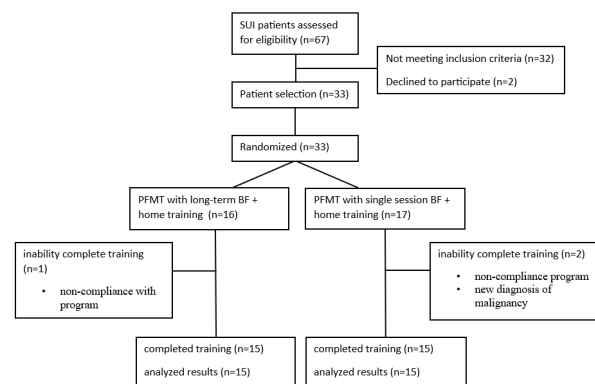


Figure 1. Flow diagram. SUUI, stress urinary incontinence; PFMT, pelvic floor muscle training; BF, biofeedback.

Age, education level, symptom duration, body mass index (BMI), smoking habits, tea and coffee consumption, number of births, mode of delivery, history of episiotomy, menopausal status, and hormone replacement therapy history did not exhibit any statistically significant differences between the groups (Table 1).

Table 1. Baseline comparison of demographic data

	Group 1 (n= 15)	Group 2 (n= 15)	p
Age (years) mean ± SD (median; min-max)	51.6 ± 8.92 (50; 41-73)	53.5 ± 10.07 (51; 42-73)	.617 *
BMI (kg/height m ²) mean ± SD (median; min-max)	28.3 ± 4.28 (28.9; 19.4-35.4)	25.9 ± 8.18 (26.8; 20.1-37.9)	.481 *
Symptom time (years) mean ± SD (median; min-max)	5.1 ± 4.55 (3.0; 0.5-15.0)	5.7 ± 4.97 (4.0; 1.0-20.0)	.722 *
Education level, n, %			.482 **
literate	2 (13.3)	1 (6.7)	
primary school	5 (33.3)	9 (60.0)	
high school	4 (26.7)	2 (13.3)	
university	3 (20.0)	1 (6.7)	
Smoking, n, %			.651 ***
yes	2 (13.3)	4 (26.7)	
no	13 (86.7)	11 (73.3)	
Daily tea consumption, n, %			.156 **
0	3 (20.0)	0 (0)	
1-2 cup	2 (13.3)	4 (26.7)	
>3 cup	10 (66.7)	11 (73.3)	
Daily coffee consumption, n, %			.188 **
0	5 (33.3)	1 (6.7)	
1-2 cup	8 (53.3)	11 (73.3)	
>3 cup	2 (13.3)	3 (20.0)	
Childbirth, n, %			.260 **
0	2 (13.3)	0 (0)	
1-3	11 (73.3)	14 (93.3)	
>4	2 (13.3)	1 (6.7)	
Delivery, n, %	(n=13)	(n=15)	.746 **
vaginal	10 (76.9)	13 (86.7)	
cesarean section	1 (7.7)	1 (6.7)	
vaginal+ C/s	2 (15.4)	1 (6.7)	
Episiotomy, n, %	(n=13)	(n=14)	.568 **
yes	7 (53.8)	6 (42.9)	
no	6 (46.2)	8 (57.1)	
Menopause, n, %			1.000 **
yes	6 (40)	6 (40)	
no	9 (60)	9 (60)	
Hormone medication, n, %			.543 **
yes	1 (6.7)	2 (13.3)	
no	14 (93.3)	13 (86.7)	
Sexual dysfunction, n, %			.456 **
yes	10 (66.7)	8 (53.3)	
no	5 (33.3)	7 (46.7)	
Flatus/feces incontinence, n, %			.456 **
yes	5 (33.3)	7 (46.7)	
no	10 (66.7)	8 (53.3)	

Group1: Long-term BF+PFMT, Group 2: Single session BF+PFMT, PFMT: pelvic floor muscle training, BF: biofeedback, SD: Standart deviation, min: minimum, max: maximum, BMI: Body mass index (kg/m²)

* Mann Whitney U test was used for comparison between groups. ** Relationship between nominal data and groups was analyzed with Pearson – Chi-square test and *** Fisher's full probability test.

In the evaluations conducted at the 8th and 12th weeks, both patient groups receiving PFMT, either via long-term BF or single-session BF, displayed significant improvements across primary outcome parameters. These improvements encompassed reductions in the number of daily UI episodes, daily pad usage, and urine volume measured during the 1-hour pad test. Additionally, measures of voluntary rapid maximum contraction pressure and duration of sustained contractions, as measured by BF, exhibited increases. Statistical analysis revealed notable enhancements in KHQ, IIQ-7, I-QOL, and BDI data, indicating significant improvement ($p < .001$). Temporal variations in the data were deemed statistically significant in both groups ($p < .001$). However, there was no statistical significance observed regarding group-time interaction concerning the changes over time. Consequently, the lack of difference in interaction suggests that the temporal change between groups was not statistically significant ($p > .05$). Furthermore, no statistically significant differences were observed between groups at any time point across all evaluation parameters ($p > .05$). These findings indicate that both the group-time effect and the intergroup effect were not statistically significant, and baseline values were comparable in both groups across all quantitative measures and questionnaire data ($p > .05$) (Table 2 and 3). Moreover, upon examining the evaluation criteria through pairwise comparisons at different time points, statistically significant improvements were evident in both groups at the 8th and 12th weeks compared to the commencement of treatment, across all quantitative data and questionnaire inquiries ($p < .001$). It was noted that this significant improvement persisted between the 8th and 12th weeks in all questionnaire data, except for the BDI, and in numerical data such as maximum contraction pressure, contraction duration, and daily pad use ($p < .05$).

The change in VAS scores assessing treatment satisfaction between the 8th and 12th weeks proved statistically significant in both groups ($p < .05$). However, there wasn't a statistically significant difference at any time point in the groups concerning group-time interaction ($p > .05$) (Table 2). In the initial assessment of patients queried for SD, symptoms of SD were identified in 10 (66.7%) and 8 (53.3%) individuals in group 1 and group 2, respectively. Upon reevaluation at the 12th week, it was noted that the number of patients reporting SD decreased to 5 in both groups. These results indicated a statistically significant temporal variation of SD within both groups ($p < .05$). However, no statistical significance was observed in the time-dependent variation between the groups ($p > .05$) (Table 4). Similarly, among patients queried for the presence of fecal incontinence, 5 (33.3%) in group 1 and 7 (46.7%) in group 2 initially reported complaints. Upon reevaluation at the 12th week, 2 patients in group 1 and 3 patients in group 2 reported fecal incontinence. The temporal change of fecal incontinence within both groups was statistically significant ($p < .05$). However, no statistical significance was found in the time-dependent variation of symptoms between the groups ($p > .05$) (Table 4).

Table 2. Intergroup and time-dependent comparison of measurement results

Variables	Group 1 (n= 15) mean ± SD (median; min-max)			Group 2 (n= 15) mean ± SD (median; min-max)			p*	
	Before treatment	8th week	12th week	Before treatment	8th week	12th week	group	interaction
Contraciton pressure (cmH2O)	14.4 ± 8.21 (14; 4-30)	21.7 ± 12.24 (20; 7.5-50) **	24.6 ± 12.41 (18; 8-40) **	16.8 ± 7.53 (15; 5-30)	22.8 ± 12.98 (20; 5-60) **	24.6 ± 13.55 (21; 12-65) **	.713	0.339
Contraction duration (s)	3.8 ± 1.01 (3.0; 3.0-5.0)	7.1 ± 2.30 (6.5; 5.0-10.0) **	8.6 ± 1.91 (10; 5-10) **	3.9 ± 1.03 (3.0; 3.0-5.0)	6.8 ± 2.26 (7; 3-10) **	7.3 ± 2.79 (7; 3-10) **	.446	0.110
Incontinence frequency	4.9 ± 4.52 (3.3; 0.6-10.0)	1.3 ± 1.61 (0.6; 0-5) **	0.7 ± 0.92 (0.3; 0-3) **	4.0 ± 2.11 (4.0; 1.0-8.0)	1.6 ± 1.50 (1; 0-4) **	1.0 ± 1.22 (1; 0-4) **	.802	0.774
Daily pad	2.8 ± 2.48 (2; 1-5)	0.9 ± 0.88 (1; 0-3) **	0.6 ± 0.91 (0; 0-3) **	2.0 ± 1.25 (2; 1-4)	1.1 ± 0.99 (1; 0-3) **	0.8 ± 0.86 (1; 0-2) **	.771	0.262
1 h pad test (g)	9.2 ± 10.85 (6; 2-39)	3.6 ± 5.00 (3; 0-20) **	2.7 ± 2.46 (2; 0-7) **	12.8 ± 15.38 (7; 2-50)	6.6 ± 10.59 (3; 0-40) **	6.1 ± 9.60 (2; 0-30) **	.496	0.650
Treatment satisfaction (VAS)	-	7.5 ± 1.72 (8; 3-10)	7.6 ± 2.02 (8; 3-10) ***	-	6.4 ± 2.03 (7; 2-10)	7.0 ± 1.98 (8; 3-10) ***	.208	0.345

Group1: Long-term BF+PFMT, Group 2: Single session BF+PFMT, PFMT: pelvic floor muscle training, BF: biofeedback, VAS: Visual Analogue Scale, h:hour, s:second, g:gram, SD: standart deviation, min:minimum, max: maximum

* The time-dependent change in the groups was similar (interaction $p>.1$) and time was found significant ($p<.001$) in all variables, among the group, time and group-time interaction effects were analyzed with the Brunner-Langer method, but only the group and interaction p values are given in the table.

** In the binary time comparison results with Bonferroni-corrected Brunner-Langer, the p value at 8 and 12 weeks compared to pretreatment: $<.001$

*** Time effect p value calculated by Brunner-Langer method: $<.05$

Table 3. Intergroup and time-dependent comparison of patient-based questionnaire

	Group 1 (n= 15) mean ± SD (median; min-max)			Group 2 (n= 15) mean ± SD (median; min-max)			p**	
	Before treatment	8th week	12th week	Before treatment	8th week	12th week	group	interaction
Incontinence Quality of Life Questionnaire (I-QOL)	42.5 ± 25.84 (39.7; 4.5-86.3)	69.3 ± 17.99 (67.0; 45.4-98.8) *	78.9 ± 15.21 (79.5; 47.7-98.8) *	41.5 ± 26.28 (45.4; 3.4-81.8)	64.5 ± 27.38 (65.9; 10.2-97.7) *	68.8 ± 26.90 (75; 10.2-98.8)*	.513	0.509
Incontinence Impact Questionnaire (IIQ-7)	69.2 ± 31.68 (85.7; 0-100)	37.1 ± 2.88 (38.0; 0-85.7) *	19.6 ± 16.87 (23.8; 0-52.3) *	62.8 ± 28.29 (66.6; 9.5-100)	39.0 ± 33.24 (33.3; 0-100) *	34.6 ± 30.93 (19.0; 0-95.2) *	.728	0.127
King Health Questionnaire (KHQ)								
General health	53.3 ± 24.76 (50; 25-100)	31.6 ± 11.44 (25; 25-50) *	25.0 ± 18.89 (25; 0-50) *	55.0 ± 19.36 (50; 25-75)	38.3 ± 15.99 (25; 25-75) *	33.3 ± 15.43 (25; 25-75) *	.267	0.757
Incontinence impact	84.4 ± 24.77 (100; 33.3-100)	53.3 ± 21.08 (66.6; 33.3-100) *	37.7 ± 17.21 (33.3; 0-66.6) *	77.2 ± 25.29 (66.6; 25-100)	46.6 ± 24.55 (33.3; 0-100) *	39.9 ± 31.37 (33.3; 0-100)*	.607	0.463
Role limitations	63.3 ± 34.61 (66.6; 0-100)	32.2 ± 18.32 (33.3; 0-66.6) *	18.8 ± 18.75 (16.6; 0-66.6) *	65.5 ± 31.15 (66.6; 0-100)	34.4 ± 32.40 (33.3; 0-100) *	22.2 ± 31.28 (16.6; 0-100) *	.986	0.901
Physical limitations	79.9 ± 28.31 (83.3; 0-100)	41.1 ± 21.69 (33.3; 0-66.6) *	22.1 ± 21.41 (16.6; 0-66.6) *	71.1 ± 28.49 (83.3; 0-100)	43.3 ± 32.61 (33.3; 0-100) *	31.1 ± 33.84 (16.6; 0-100) *	.932	0.206
Social limitations	57.0 ± 39.09 (66.6; 0-100)	24.4 ± 18.87 (22.2; 0-66.6) *	14.0 ± 16.48 (11.1; 0-44.4) *	57.3 ± 31.38 (66.0; 11.1-100)	33.3 ± 33.06 (33.3; 0-100) *	25.1 ± 33.91 (16.6; 0-100) *	.542	0.795
Personal relationship	46.4 ± 35.31 (33.3; 0-100)	14.2 ± 15.81 (8.3; 0-33.3) *	7.1 ± 14.19 (0; 0-33.3) *	47.4 ± 29.53 (66.6; 0-83.3)	26.3 ± 33.67 (16.6; 0-100) *	19.4 ± 32.43 (0; 0-100) *	.467	0.546
Emotions	58.3 ± 35.84 (55.5; 3-100)	30.7 ± 22.89 (33.3; 0-77.7) *	11.4 ± 12.67 (11.1; 0-33.3) *	66.2 ± 33.10 (66.6; 11.1-100)	34.07 ± 31.27 (33.3; 0-100) *	22.9 ± 32.65 (0 (0-100) *	.479	0.583
Sleep/energy	47.7 ± 34.42 (33.3; 0-100)	27.4 ± 18.12 (33.3; 0-50) *	11.1 ± 13.60 (0; 0-33.3) *	47.4 ± 30.56 (33.3; 11.1-100)	22.2 ± 24.93 (16.6; 0-83.3) *	19.9 ± 29.68 (16.6; 0-100) *	.946	0.126
Incontinence severity measures	71.9 ± 24.19 (80; 20-100)	37.7 ± 19.70 (33.3; 6-80) *	19.5 ± 18.93 (13.3; 0-73.3) *	68.8 ± 21.77 (66.6; 26.6-100)	43.5 ± 28.82 (33.3; 6.6-100) *	29.3 ± 29.99 (13.3; 0-100) *	.638	0.295
Symptom severity	15.4 ± 5.97 (15; 7-30)	9.0 ± 2.75 (10; 4-14) *	5.6 ± 4.14 (5; 0-15) *	15.1 ± 4.8 (15; 7-23)	9.2 ± 4.63 (9; 3-18) *	6.7 ± 6.01 (5; 0-24) *	.917	0.896
Beck Depression Inventory (BDI)	19.4 ± 15.15 (19; 0-46)	11.0 ± 11.41 (6; 0-35) *	5.8 ± 8.37 (2; 0-29) *	15.8 ± 10.17 (12; 2-35)	9.5 ± 10.53 (6; 0-35) *	9.0 ± 9.61 (6; 0-32) *	.691	0.216

Group 1: Long-term BF+PFMT, Group 2: Single session BF+PFMT, PFMT: pelvic floor muscle training, BF: biofeedback, SD: standart deviation, min:minimum, max: maximum

* From the binary time comparison results with Bonferroni-corrected Brunner-Langer, the p value at weeks 8 and 12 compared to pretreatment: $<.001$

** The time-dependent change in the groups was similar (interaction $p>.1$) and time was found significant ($p<.001$) in all variables, among the group, time and group-time interaction effects tested with the Brunner-Langer method, but only the group and interaction p values are given in the table.

Table 4. Comparison of sexual dysfunction and flatus/feces incontinence between groups

	Group 1 (n= 15) n (%)		Group 2 (n= 15) n (%)		p*		
	Before treatment	12th week	Before treatment	12th week	group	time	interaction
Sexual dysfunction	10 (66.7)	5 (33.3)	8 (53.3)	5 (33.3)	0.646	0.013	0.535
Flatulence/ fecal incontinence	5 (33.3)	2 (13.3)	7 (46.7)	3 (20.0)	0.455	0.012	0.721

Group 1: Long-term BF+PFMT, Group 2: Single session BF+PFMT, PFMT: pelvic floor muscle training, BF: biofeedback

* Time-dependent change in groups was similar (interaction $p>.1$) and time was significant ($p<.001$) in all variables from group, time and group-time interaction effects tested with the Brunner-Langer method

4. DISCUSSION

The PFMT program is considered the first-line treatment for stress, mixed, and urge UI (18). A Cochrane systematic review noted that the addition of BF to PFMT did not yield additional benefits in QoL scales, pad tests, PFM strength, or incontinence frequency compared to those exclusively following the PFMT program. However, patients reported a significant increase in recovery rates at the end of treatment. This subjective perception of recovery observed in patients may be attributed to variations in treatment program intensity, enhanced control during BF treatment, and increased face-to-face contact opportunities with the physiotherapist (8).

In a systematic review exploring the role of PFMT with BF in treating SUI, it was noted that the studies demonstrated low methodological quality and utilized varied treatment protocols (19). The review concluded that PFMT with BF did not yield additional benefits in terms of QoL scales and PFM strength compared to the PFMT alone. However, prior to commencing the PFMT program, it has been suggested that BF could serve as an initial training regimen to help women learn to contract their PFMs correctly. It has been emphasized that the primary clinical benefit of PFMT with BF in patients with SUI may be linked to the enhancement of PFM contraction perception rather than solely focusing on strengthening the PFMs. A recent systematic review found moderate evidence that PFME combined with BF were significantly more effective than PFME alone in managing UI (20).

In our study, significant improvements were found in both groups receiving regular BF and single-session BF treatment in terms of contraction strength, contraction duration, frequency of incontinence, pad test, QoL scales, and treatment satisfaction. However, no difference was observed between the groups. These findings suggest that when PFM exercises are taught accurately through single-session BF training and practiced consistently, similar results can be achieved compared to long-term BF training.

In our present study, patients were taught how to perform PFM exercises correctly through a single session of BF.

Those who received a home program were monitored through weekly phone. When patient follow-up is conducted at regular intervals, it has been demonstrated that individuals who received PFMT with a single session of BF achieved comparable improvements in QoL scales, pad test measurements, PFM strength, and endurance results compared to those who underwent regular BF training by the end of the treatment period.

Ozlu et al. (21) conducted a randomized controlled study comparing the efficacy of three intervention groups: home exercise alone, home exercises combined with intravaginal pressure-BF, and home exercises combined with perineal electromyography-BF in patients with SUI. It was stated that the groups that continued the exercises with BF showed statistically significantly more improvement in PFM strength, treatment satisfaction, incontinence severity and pad test results compared to the home exercise group. The results of this study show that, BF is more effective than home exercise program in improving muscle function and incontinence symptoms. One of the issue that may have an effect on obtaining different results from our study in favor of BF may be that women in the BF group were given a more intense exercise program compared to our study. Women in both BF groups were received PFMT with BF, 3 times a week for 8 weeks in addition to the basic PFMT program given to the home exercise group. Another issue that may affect the results against the home exercise group is, women in the home exercise group were given PFMT with digital palpation only once, and no supervision or follow-up was made for 8 weeks.

In a meta-analysis performed by Cheng et al. (22), depression and anxiety levels of patients with UI are found to be high. Additionally, Yazdany et al. (23) reported that the prevalence of depression and anxiety tends to rise among patients who do not undergo treatment for UI. Moreover, in the presence of depression and anxiety, continuing PFMT is insufficient (24). A study by Weber-Rajek et al. (25) demonstrated a significant enhancement in BDI and KHQ scores following a PFMT program among SUI patients, compared to an untreated cohort. In our study, we observed significant improvements in BDI and KHQ scores in both groups. Screening and addressing depression in women with UI may not only ameliorate depressive symptoms but also potentially enhance adherence to exercise regimens and improve continence outcomes.

Women with SUI often experience SD as part of pelvic floor dysfunction (26). Liebergall et al. (27) found that improvement in SD post-PFMT correlated with better QoL scales and pad test values. Our study similarly noted a significant reduction in SD post-treatment across both groups. Additionally, PFMT is advocated by the ICS as the primary treatment for fecal incontinence, with significant symptom alleviation observed in our study (28).

To the best of our knowledge, our current study is the first study in the literature to compare the effectiveness of individually designed PFMT with long term BF and a single session BF in addition to home exercise in women with

SUI. In the treatment of SUI, it is essential to teach PFM exercises correctly, and if PFM exercises are taught correctly to the patient with a single session BF, similar results can be obtained with long-term BF.

There are some limitations in our study including the lack of a control group in which PFMT was given, for example, only with verbal training, the low number of participants and the lack of long-term follow-up after the treatment was completed. Although the recommended duration of treatment is at least 12 weeks, due to the difficulty of patients coming to treatment for a long time, the treatment was performed for 8 weeks and the patients were evaluated for control at the 12th week. In the future, it would be appropriate to plan studies with larger numbers of patients and control groups and long-term follow-up after treatment.

5. CONCLUSION

PFMT with BF is used to increase the patient's awareness of PFMs, to create effective contraction and to increase the patient's compliance with the exercise program. When correct PFM contraction is taught with single session BF, a similar level of improvement is achieved in SUI symptoms, muscle strength and quality of life with long term BF. In clinical practice, in patients who cannot participate in BF treatment regularly, it may be recommended that patients continue PFMT as a home program with close follow-up after training with a single session BF.

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