

Effect of electromyographic biofeedback as an add-on to pelvic floor muscle exercises on neuromuscular outcomes and quality of life in postmenopausal women with stress urinary incontinence: A randomized controlled trial

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Aims: To compare the efficacy of pelvic floor muscle exercises (PFME) with and without electromyographic biofeedback (BF) in increasing muscle strength, improving myoelectric activity, and improving pre-contraction and quality of life in postmenopausal women with stress urinary incontinence.

Methods: Randomized controlled trial of 49 postmenopausal women with stress urinary incontinence. Participants were allocated across three groups: control, PFME alone, and PFME + BF. Forty-five women completed the study (14 control, 15 PFME, 16 PFME + BF; mean age 58.26 years). Outcome assessment was carried out using digital palpation (modified Oxford grading scale), electromyography, and the International Consultation Incontinence Questionnaire-Short Form (ICIQ-SF) quality of life instrument. The treatment protocol consisted of eight twice-weekly, 20-min one-on-one sessions. Controls were assessed only at baseline and after 1 month.

Results: The PFME and PFME + BF groups exhibited significant increases in muscle strength (Oxford scale) ($P < 0.0001$), precontraction while coughing ($P < 0.0001$), maximum voluntary contraction, duration of endurance contraction, and ICIQ-SF scores ($P < 0.0001$). PFME + BF was associated with significantly superior improvement of muscle strength, precontraction while coughing, maximum voluntary contraction, and duration of endurance contraction as compared to PFME alone ($P < 0.05$).

Conclusions: This preliminary study suggests that pelvic floor muscle training, with and without biofeedback, is associated with increased muscle strength, myoelectric activity, precontraction of pelvic floor muscles, and improved quality of life in postmenopausal women with stress urinary incontinence.

KEYWORDS

physiotherapy, quality of life

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1 | INTRODUCTION

Menopause is a period of the life cycle characterized by a decline in estrogen production, which leads to a series of

bodily changes, including urogenital manifestations. The main symptoms are caused by a deterioration and atrophy of vaginal and periurethral tissues, which may be associated with involuntary urine loss on exertion and increased urinary urgency and frequency.¹

Urinary incontinence (UI) is defined by the International Continence Society as the complaint of any involuntary loss of urine. Stress urinary incontinence (SUI) is the most prevalent form, and is defined as the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.² Deficient or inadequate pelvic floor muscle (PFM) function is an etiological factor in the development of SUI,³ and has a direct impact on quality of life in postmenopausal women.⁴

Conservative treatment, recommended by the International Continence Society as first-line therapy, consists of assessment of pelvic floor strength and functional use of pelvic floor muscle training (PFMT).⁵ PFMT increases the contraction and holding strength, coordination, velocity, and endurance of the PFM to keep the bladder elevated during rises in intra-abdominal pressure, maintain adequate urethral closure pressure, and support and stabilize the pelvic organs.⁶ Furthermore, clinicians can assess the myoelectric activation of these muscle groups and train them using electromyographic biofeedback (EMG-BF).^{7,8} EMG-BF can be regarded as an adjuvant to PFMT,⁶ designed to assess muscle integrity and allowing both patient and physical therapist to observe correct PFM contraction and relaxation, thus facilitating neuromuscular learning or re-adaptation in the setting of pelvic dysfunction.

Surface electromyography (EMG) techniques are based on the recording of electrical signals generated by depolarization of muscle cell membranes at the time of muscle contraction and can allow physical therapists to teach patients to contract and relax muscles in an appropriate, functional way while monitoring the progress of the intervention.⁹

Analysis of the literature reveals conflicting results with addition of EMG-BF to PFMT, and its actual benefits remain unclear. Within this context, the objective of the present study was to compare the efficacy of PFME with and without electromyographic biofeedback in increasing muscle strength, improving myoelectric activity, improving precontraction and quality of life in postmenopausal women with stress urinary incontinence.

2 | METHODS

This randomized, controlled clinical trial was conducted from January through September 2014 at the outpatient clinics of our institution. The project was approved by the Research Ethics Committee on 10 December 2013, and registered at ClinicalTrials.gov with accession number NCT02275728.

The inclusion criteria were postmenopausal status, age 50-65 years, a complaint of loss of urine on exertion (detected by the International Consultation on Incontinence Questionnaire), and provision of written informed consent. The exclusion criteria were presence of a urinary tract infection, failure to understand pelvic floor muscle contraction, cognitive alterations, collagen- or muscle-related diseases, or neurological abnormalities.

The participants were selected consecutively as they presented to the clinic. Those who met the inclusion criteria were randomized across three groups:

- Group 1, pelvic floor muscle exercise group (PFME);
- Group 2, pelvic floor muscle exercise + biofeedback group (PFME + BF);
- Group 3, control group (CG) (Fig. 1).

This allocation was performed by a blinded, independent researcher not otherwise involved in the study. In brief, randomization was performed using envelopes containing the letters A, B, and C, where each letter corresponded to a specific group to which the participant would be allocated, by order of presentation to the study facility.

The study was conducted by two investigators (1 and 2). Assessment of groups before and after intervention was performed by investigator 1, while training was performed by investigator 2. Both had been previously trained.

The participants completed an interview designed to collect identifying information and data on age, weight, height, body mass index (BMI), severity of urine loss on exertion, number of pregnancies, mode of delivery, and use of hormone therapy (systemic or topical). The ICIQ-SFQoL instrument, in its Portuguese-language version, was administered to participants in all three groups, at the start and end of the study, in the form of an investigator-led interview.⁴

Shortly thereafter, participants were shown a diagram of the pelvic floor muscles and taught how to contract these muscles through intravaginal palpation, with the command “squeeze my fingers and pull toward your belly button.” The therapist's other hand was placed on the participant's infra-abdominal region to monitor for accessory muscle use during the contraction. Once the contraction was verified to occur, the therapist assessed muscle strength by vaginal palpation and graded it on the Modified Oxford scale.¹⁰

Myoelectric activation was assessed by EMGs, using a Miotool 400 system (Miotec). This device features high-precision EMG signals (14-bit resolution), 3000 V subject isolation, highly accurate signal representation across all channels (2000 samples/second per channel), two analog input channels, and a low noise level (<2 least significant bits [LSB]), connected via a USB type B port to a computer running Biotrainer URO software (Miotec). Vaginal palpation and EMG-BF were performed with participants

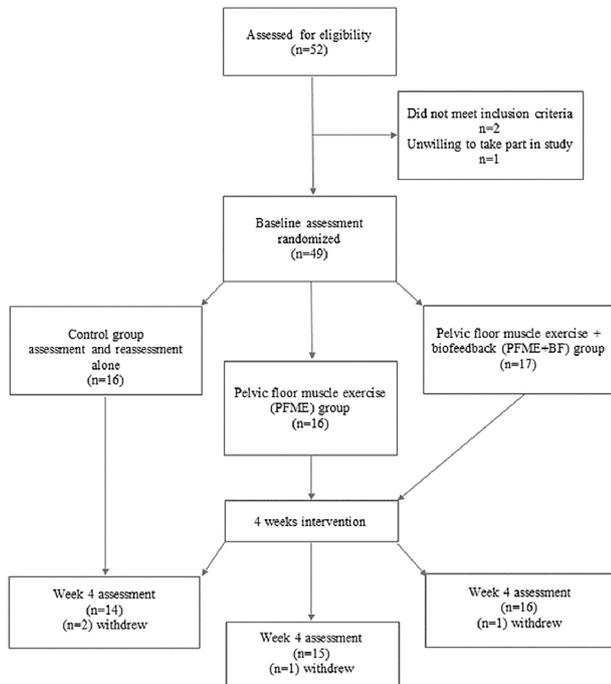


FIGURE 1 Flow diagram of participant recruitment and treatment

in the lithotomy position. For EMG-BF, a disposable intracavitary probe electrode (Miotec) was placed in the vaginal area manually by the investigator. Briefly, the probe was lubricated with hypoallergenic gel (KY, Johnson & Johnson, São Paulo, Brazil) and the metal sensors placed against the lateral walls of the vaginal cavity; the participant was then asked to “squeeze and suck” the electrode into her vagina, and this movement was observed by the investigator. Two surface patch electrodes were also placed on the abdomen, on a diagonal line three finger breadths away from the examiner and three finger breadths below the rib cage on the right, over the external oblique muscle, as well as an external electrode placed over a bony surface to act as ground or reference, decreasing electrical artifacts. The assessment protocol was applied by investigator 1. The participant was asked to look at the screen, where channel 1 corresponded to the pelvic floor and channel 2, to the abdomen. For data collection, the participant was first given an explanation of each evaluation protocol that would be performed. The investigator issued the initial commands for the contraction and let the participant complete the rest of the contraction on her own. The evaluation protocol consisted of assessment at initial and final baseline for 60 s, the mean of three maximum voluntary contractions (MVCs) lasting 3 s each with 5 s for relaxation, followed by a 2-min rest; then, the participant's ability to sustain one contraction for up to 10 s was assessed,¹¹ with monitoring of abdominal accessory muscles, observing for presence of precontraction, during three coughs.¹²

Immediately thereafter, participants in all groups were assessed. Those in the PFME and PFME + BF groups began an 8-session protocol of pelvic floor muscle training and were reassessed 4 weeks later. The control group was assessed on day 1 and reassessed at 6 weeks, and received no treatment in the intervening period.

The proposed PFME protocol consisted of 20-min sessions twice weekly for a total of eight sessions:

1. Sustained contractions lasting 6 to 10 s, with the same resting time, 6-10 repetitions, 1-2 sets.
2. Phasic contractions lasting 2 s, with twice the resting time, 10 repetitions, 1-3 sets.
3. Phasic contractions sustained for 3 to 5 s, with twice the resting time, 8-10 repetitions, 1-2 sets.
4. Guided-imagery training on a white background, asking participants to contract the pelvic floor before performing an abdominal strain, in order to generate or enhance precontraction (involuntary PFM co-contraction secondary to increased abdominal pressure).¹²

The same protocol was applied in the supine, seated, and standing positions, as the patient improved. This proposed protocol was led by investigator 2 (a physical therapist), who, based on the principles of exercise physiology,¹³ monitored the progression of the number of repetitions and duration of sustained contraction that the participant was able to perform on initial assessment, conducted by investigator 1 (also a physical therapist). The protocol was administered through eight twice-weekly, 20-min, one-on-one sessions.

PFME + BF group participants followed the same protocol, but combined with BF (20-min sessions twice weekly for a total of eight sessions), whereby the participant looked at the EMG-BF screen during exercises, while investigator 2 monitored her progress and conducted the protocol. All participants were given written instructions to perform these exercises at home twice a day on non-study training days. At every visit, the investigator reminded participants to perform their exercises at home. After completion of the study, controls group received the same training as the PFME group. During the study period, the control group was simply assessed and reassessed; control participants were told that they would receive group treatment after the end of the study, and did not receive any instructions regarding exercises during the period between evaluations.

2.1 | Statistical Analysis

Data were processed and analyzed in IBM SPSS Statistics 20.0 for Windows (SPSS Inc., Chicago, IL). Descriptive analysis consisted of frequencies, means, and standard deviations. The Shapiro-Wilk test and Levene's test were used to test the assumptions of normality of data distribution

and homogeneity of variances respectively. One-factor ANOVA was used to compare continuous independent variables between groups. Pearson's χ^2 test was used to examine association among categorical variables. Generalized estimating equations (GEE) analysis for correlated data was used to compare effects between treatments. Bonferroni's adjustment for multiple comparisons was used as a post hoc test. The significance level was set at $P < 0.05$.

3 | RESULTS

Initially, 52 postmenopausal participants with SUI were recruited. Two were excluded due to failure to meet the inclusion criteria or refusal to participate. Thus, 49 participants were randomized; of these, four withdrew from the study, for a total of 45 participants at study completion, as shown in the flow diagram (Fig. 1).

The sample was homogeneous in terms of baseline demographic, anthropometric, and gestational data, as well as type of urinary incontinence and topical and systemic hormone therapy use, with no significant differences among the three groups (Table 1).

In this study, we observed improvement in muscle strength (as measured by the modified Oxford scale) in the PFME group at baseline and post-treatment ($P < 0.0001$) and when comparing this group to controls ($P < 0.001$) in the PFME + BF group at baseline and post-treatment ($P < 0.0001$), as well as on comparison of this group to controls ($P < 0.0001$) and to PFME alone ($P < 0.05$) (Table 2).

On EMG examination, in the PFME and PFME + BF groups, a significant ($P < 0.0001$) improvement was observed in precontraction between baseline and post-treatment, whereas in the PFME + BF group, significant differences in this parameter were observed when comparing this group to the PFME group ($P < 0.05$). Only in the PFME group was the initial EMG baseline significantly increased at post-treatment assessment ($P < 0.05$). On analysis of the difference between final and initial EMG baseline, the period of rest was found to be significantly reduced in the PFME group ($P < 0.05$) after intervention. Duration of endurance contraction was significantly longer at reassessment in controls ($P < 0.05$) and in the PFME and PFME + BF groups ($P < 0.0001$), before and post-treatment. MVC was significantly increased at post-treatment ($P < 0.0001$ vs baseline) in both the PFME and PFME + BF groups. On between-group comparison, PFME + BF was superior to PFME alone ($P < 0.05$) (Table 2).

Significant improvements in QoL were observed both after PFME ($P < 0.0001$ vs baseline) and after PFME + BF ($P < 0.0001$ vs baseline); no such difference was observed in the control group. However, there were no differences in QoL between the PFME and PFME + BF groups.

4 | DISCUSSION

Despite its limitations (brief follow-up period, small sample, and unblinded design), the present study demonstrated that PFME was associated with increased PFM strength and improvement in precontraction during abdominal straining,

TABLE 1 Demographic, anthropometric, and gestational parameters at baseline in the study groups

Variable	Control (n = 14)	PFME (n = 15)	PFME + BF (n = 16)	P-value
Age, years	57.1 ± 5.3	59.3 ± 4.9	58.4 ± 6.8	0.591*
BMI (kg/m ²)	26.8 ± 3.6	27.7 ± 3.6	27.5 ± 2.6	0.740*
No. pregnancies	2.6 ± 1	2.3 ± 1.3	2.6 ± 1	0.731*
Mode of delivery				0.635**
Did not deliver	–	1 (6.7)	–	
Vaginal	14 (71.4)	9 (60)	11 (68.8)	
Cesarean	1 (7.1)	3 (20)	1 (6.7)	
Vaginal and cesarean	3 (21.4)	2 (13.3)	4 (25)	
Severity of urinary leakage				0.445**
At minimal exertion	4 (28.6)	6 (40)	8 (50)	
At moderate exertion	9 (64.3)	6 (40)	5 (31.2)	
At heavy exertion	1 (7.1)	3 (20)	3 (18.8)	
Systemic hormone therapy	2 (28.6)	2 (28.6)	3 (42.9)	0.906**
Topical hormone therapy	3 (27.3)	4 (36.4)	4 (36.4)	0.946**

BMI, body mass index; PFME, pelvic floor muscle exercise; PFME + BF, pelvic floor muscle exercise + biofeedback.

Results expressed as means, standard deviations, and proportions.

*One-factor ANOVA; **Pearson's χ^2 test. $P < 0.05$.

TABLE 2 Comparison of surface electromyographic examination findings across the study groups

Variable	Control (n = 14)		PFME (n = 15)		PFME ± BF (n = 16)	
	Baseline	Post	Baseline	Post	Baseline	Post
Precontraction	0.71 ± 0.68	0.21 ± 0.11	0.13 ± 0.9	0.67 ± 0.12*	0.12 ± 0.8	0.81 ± 1***
Initial EMG baseline (µv)	14.1 ± 4.68	13.78 ± 4	14.7 ± 4.4	16.3 ± 2.9**	15.2 ± 4.8	16.6 ± 2
Final EMG baseline (µv)	14.5 ± 4.4	13.85 ± 3.7	15.5 ± 3.3	15.9 ± 2.4	15.4 ± 3.2	16.1 ± 2
Duration of endurance contraction (s)	1.78 ± 2	2.35 ± 2.30**	1.66 ± 2.55	6.8 ± 2.01*	2.75 ± 2.54	8.37 ± 1.67***
Maximum voluntary contraction (µv)	15.1 ± 7.6	15.9 ± 7	10.3 ± 2.11	20 ± 5.21*	13.8 ± 5.7	27.5 ± 8.84***
ICIQ-SF quality of life score	11.1 ± 4.5	10 ± 4.8	11.1 ± 2.9	4.3 ± 3.2*	12.7 ± 3.6	4.5 ± 3.6*

Results expressed as means and standard deviations. Generalized estimating equations analysis. Bonferroni adjustment for multiple comparisons.

*<0.0001 versus baseline; **<0.05 versus baseline; ***<0.05 PFME versus PFME + BF.

myoelectrical activity during MVCs, and duration of contraction. Several studies have shown that PFME programs are effective for the treatment of SUI as compared with placebo or no treatment,¹⁴ with cure rates of 28-84%,¹⁵ especially in postmenopausal women, the group with the highest prevalence of SUI. PFMEs increase maximal strength and endurance contraction and improve function, reducing leakage in patients with SUI. The theoretical foundation for strength training of the dysfunctional pelvic floor is based on improving structural support, prolonging activation time, and enhancing precontraction, which may reduce leakage or prevent it altogether.¹² In terms of muscle strength, these physiological gains can be achieved with at least 5 months of proper training.^{16,17}

In the present study, we also observed improvements in muscle strength and EMG activity in the PFME + BF group, with the most significant gains observed for precontraction, endurance, and MVCs. The addition of BF to treatment of muscle dysfunctions seeks to improve voluntary motor activity by inducing the neuroplasticity or functional neural regeneration mechanisms of the central nervous system through exposure to new demands. This neuroplasticity can help patients control and monitor their future muscle activities and movements, allowing the patient to manipulate these physiological events as the activity is taking place.¹⁸ A literature review conducted by Glazer¹⁹ included 13 prospective, randomized trials comparing PFME alone versus PFME + BF. Seven articles found significant improvement with addition of BF, whereas six found no such improvement. In a 2012 study with 40 women, addition of BF had a positive influence on strength, endurance, and quick contractions ($P < 0.001$), and BF-augmented training was recommended to reduce urinary symptoms and improve QoL, corroborating the results of the present study.²⁰ Conversely, Aukee et al,²¹ in a 1-year follow-up of 35 patients, found no significant effects of adding BF to PFME. A meta-analysis of 37 articles, published in 2016, concluded that PFME was more effective than no treatment in terms of improving quality of life, whereas PFME + BF produced better results on the pad test.²² A 1998 single-blind

randomized trial of 27 women with mild-to-moderate SUI demonstrated improvement in SUI and ability to develop adequate precontraction 1 week after instruction, with significant improvement in urine loss during cough.¹² In 2014, a study of 55 women with incontinence found that a combined pelvic rehabilitation program of precontraction training, coordination training, vaginal palpation, ultrasonography, and perineal biofeedback yielded an improvement of around 67% in women with SUI and 78% in those with overactive bladder.²³ Although we did not observe PFM hyperactivity in any of the participants of this study, adequate assessment of initial and final baseline electrical activity is essential before PFM training can be indicated. In some cases of pelvic floor dysfunction, an increase in pelvic floor electrical activity at rest is observed, which decreases muscle strength during training, leading to neuromuscular inefficiency. In these cases, pretreatment with techniques that normalize tension in the muscles and aponeurotic layer is recommended.²⁴

In the present study, we also observed improvement in QoL scores in the PFME and PFME + BF groups, with no significant between-group difference. The QoL of women with UI is affected in many ways, which lead to functional, behavioral, and social changes. In a clinical trial of 72 women with UI, eight sessions of an intervention consisting of electrostimulation, PFME, and behavioral therapy yielded improvements in urinary frequency and QoL as measured by the short-term ICIQ-SF score, as seen in the present study.²⁵ A 2005 study of PFME + BF observed significant improvement on all domains of the King's Health Questionnaire.²⁶

Many PFM training protocols have been proposed, but no accepted standard exists. The protocol developed for the present study was based on a systematic review conducted by Marques et al,¹³ which recommended that any such protocols be based on the tenets of exercise physiology. The (short-term) improvements in neuromuscular activity and QoL observed in the present study may have been provided both by PFME and by the plastic effect generated by adding BF to the proposed training protocol, thus improving participant adherence to and perceptions of treatment.

5 | CONCLUSIONS

This study suggests that a program consisting of pelvic floor muscle exercises, with or without biofeedback, may be indicated in postmenopausal women with stress urinary incontinence and can improve both the neurofunctional capacity of the pelvic floor and quality of life outcomes in this population.

POTENTIAL CONFLICTS OF INTEREST

The authors have no conflicts of interest to disclose.

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