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ORIGINAL ARTICLE

Efficacy of biofeedback-assisted pelvic floor muscle training in females with pelvic floor dysfunction

Ibrahim Khalil Ibrahim [a], Mowafaa Moustafa Abdel Hameed [a], Engy Mohamed Taher [b], Enas Mohamed Shaheen [a], Mervat Sheta Ali Gawdat Elsawy [a,*]

[a] *Rheumatology and Rehabilitation Department, Main University Hospital, Faculty of Medicine, Alexandria, Egypt*
[b] *Obstetrics and Gynecology Department, El Shatby Hospital, Faculty of Medicine, Alexandria, Egypt*

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Abstract *Background:* Stress urinary incontinence (SUI), fecal incontinence (FI) and/or pelvic floor dyssynergia, with pelvic organ prolapse (POP) are described as pelvic floor dysfunction (PFD). Pelvic floor muscle training (PFMT) is the first-line therapy in the treatment of PFD either alone or combined with biofeedback assisted pelvic floor muscle training (BF-assisted PFMT). Clinical practice regarding BF-assisted PFMT is controversial.

Aims: To evaluate the efficacy of BF-assisted PFMT in females with mild to moderate PFD after a maximum duration of up to twelve weeks.

Materials and subjects: 52 females with PFD were classified into 2 groups: Group 1(26 females with (SUI)) and Group 2 (26 females with (FI)) with or without stages I and II (POP). Females older than 20 years old and pelvic floor muscles grade 3–4 were included. Each group was divided in two equal groups (13 patients each): intervention group: performed BF-assisted PFMT and home exercise program (HEP) and control group: performed (HEP). All females were evaluated before and after the end of PFMT program by assessment questionnaires, PFM strength measurements using PFMs grading according to modified oxford score (MOS) and PFM contraction manometric measurements.

Results: Participation rate was 90%. A Significant improvement was detected in 19 females (79.2%) in the intervention group compared to 7 females (31.8%) in the control group. Initial clinical and electrophysiological assessments were predictive for female improvement.

Conclusion: Biofeedback-assisted PFMT is an effective therapy compared to PFMT alone for well-motivated females with mild to moderate PFD.

* Corresponding author. Tel.: +20 35911552.
E-mail address: shetasawy@yahoo.com (M.S.A.G. Elsawy).

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1. Introduction

Pelvic floor dysfunction (PFD) is a general term that describes an interrelated group of conditions such as voiding, anorectal, pelvic organ support and sexual dysfunctions which often coexist together sharing common risk factors adversely influencing the efficacy of pelvic floor functions which fail to work properly in a coordinated manner.[1] In PFD, there is a wide range of clinical presentations which rarely occur in isolation including stress urinary incontinence (SUI), fecal incontinence (FI) and/or pelvic floor dyssynergia, with pelvic organ prolapse (POP).[2] It is a frequent problem affecting more than 50% of women.[3] Recent data considered the pathophysiology of PFD to be multifactorial. These factors were classified into extrinsic factors such as childbirth, history of previous hysterectomy, co-morbidities, occupation, socioeconomic and obesity and other intrinsic factors like anatomical, genetics, aging, postmenopausal status, racial and pregnancy.[4] Although mortality is rare due to PFD, it has been shown that it presents as a particularly embarrassing and distressing condition with a significant medical, social and economic implications.[5]

Several methods exist in the investigations for PFD such as clinical, urodynamic, manometric, imaging and neurophysiologic assessments.[6] Neurophysiological studies including pudendal nerve terminal motor latency (PNMTL) and pelvic floor electromyography (EMG) are essential to localize and assess the severity and mechanism of injury.[7] Pelvic floor muscle training (PFMT) is considered as first-line therapy in the treatment of PFD either PFMT alone or combined with adjunctive biofeedback assisted pelvic floor muscle training (BF-assisted PFMT).[8] Performance of a correct maximum pelvic floor muscle (PFM) contraction is important to achieve the best training effect. Studies have shown that there is a co-contraction of the abdominal muscles during attempts of a correct, maximal contraction.[9] Biofeedback can enhance the awareness, of correct PFMs contraction and motivation to practice repetitively this correct response through visual, auditory, and tactile means to enable the female to learn to control and improve their PFM function.[10]

Up till now, there is no consensus on recommendation for clinical practice regarding BF-assisted PFMT of PFD. A few good quality randomized controlled studies (RCT) compared the effectiveness of BF-assisted PFMT to PFMT alone in women with PFD, with the treatment duration ranging from 4 weeks to 6 months.[11–13] On the other hand, another study found no significant differences in the outcomes measured including objective or subjective cure rates, quality of life or social activity.[14]

The uncertainty about which of these strategies are most effective in training women presenting with PFD to strengthen their PFMs to cure or improve symptoms has been identified by a wide panel of females and experts to be one of the key clinical questions which needs to be prioritized because BF-assisted PFMT is more costly than PFMT alone. Pelvic floor training cannot be studied without the consideration of resistance training and adherence factors. Therefore, further randomized controlled trail (RCT) studies are needed to assess BF-assisted PFMT efficacy and factors affecting both for treatment for and to encourage compliance and adherence to PFMT.

2. Materials and subjects

This study was carried out on fifty-two females presenting with PFD attending the outpatient clinic at the Physical Medicine, Rheumatology and Rehabilitation Department, Main University Hospital, Faculty of Medicine in the period from 2011 to 2013. Females were classified into 26 with (SUI) and 26 with (FI) with or without stage I and II (POP) according to pelvic organ prolapse quantification (POPQ). Females older than 20 years old and Pelvic floor muscles grade 3–4 according modified oxford score (MOS) were only included.

2.1. Exclusion criteria

Females with neurological conditions that affect sphincteric function or colorectal, pelvic, gynecological or genitourinary surgery or malignancy where the exciting pathology interferes with the prescribed PFMT program were excluded. Conditions where BF-assisted PFMT were not suitable were also excluded for example pregnancy, vulvar and vaginal inflammation or infection, or psychosexual disorders.

Females who were instructed to perform prescribed home exercise program (HEP) only were referred as the control group. While those who performed BF-assisted PFMT in the form of two time weekly sessions of a minimal 45 min plus the prescribed HEP in between sessions were referred as the intervention group.

2.2. Assessment questionnaires

Before and after end of the PFMT program, they were used to assess the severity of the problem and its impact on females' quality of life including pelvic floor questionnaire (PFQ) for identification of PFD different symptoms by a summary index scores which were formed by summing the four PFD symptom responses.[15] Pelvic floor impact questionnaire-7 (PFIQ-7) was also used as a companion questionnaire to the PFQ for measurement of females' symptom effect on their quality of life including house hold chores, physical entertainment, social activities, feeling and emotional health.[16] Questionnaires regarding the associated complaint during PFMT program such as pain or fatigue or its interference with daily activities were also filled in by the therapist.

2.3. Clinical and electrophysiological assessment

Grading of PFMs strength using MOS is performed by introducing the index and middle fingers two to three centimeters inside the vagina.[17] Manometric measurements were performed in the outpatient clinic using the manometric BF device (Myomed 632® equipment, Enraf Nonius, Delft, and the Netherlands). Before measurement the female was positioned in the lithotomy position then the vaginal perfusion catheter was connected to vaginal pressure sensor. The tip of the pressure sensor was lubricated with a sterile gel. The vaginal pressure sensor was easily inserted about three to four cm from the introitus with 1 cm remaining outside where its sensitive area crosses muscle sheet of PFMs. Vaginal pressure sensor was extended by gradual air injecting with a syringe in the vaginal

catheter to be felt internally by the female then pressure was set to zero to start measurements. For measurement of maximal pressure pelvic floor muscle contraction (MPPFMC), the female was asked to squeeze forcibly to perform three maximum PFMs contractions holding each for ten seconds if possible with one minute rest intervals then the average of the three peak values taken from the three tests to make up the baseline and follow up scores for each female.[18] Electrophysiological examination done only at baseline assessment (including bilateral measurement of Pudendal Nerve Motor Latency, with a cut-off value of 2.28 ms) was measured bilaterally using (St. Mark's pudendal electrode, Medtronic AIS, Skovlunde, Denmark) to distinguish between pure neurogenic, myogenic or a mixed injuries. In addition, concentric needle EMG of puborectalis muscle (PRM) was done for all females sharing in the study.[19]

2.4. Pelvic floor muscle training program

All females were treated on an outpatient basis. Educational course was implemented at the first visit prior to PFMT program application including a presentation about pelvic floor anatomy, function and pathogenesis of PFD received individually to each female. Each female received a standardized life advice leaflet sheet with instructions.[20,21] Standardized proper PFMT instruction leaflet was also given to each female to teach females how to contract PFMs effortlessly and correctly with an emphasis on maintaining accessory muscles relaxed.

Individualized HEP was prescribed for each female to practice them five sets daily. Each set consisted of strengthening, flicks and endurance training exercises. At strengthening exercises, females were asked to increase duration time pelvic floor muscle contraction (DTPFMC) for up to ten seconds according to her ability. The number of repetitions of the MPPFMC was encouraged more than that determined at baseline assessment. A rest period of up to 4 s is permitted between contractions. Rapid waves of flick-like successive contractions-relaxations of PFM (up to 10 waves) are encouraged after a rest period of not shorter than 1 min. At endurance training exercises, females were instructed to hold submaximal PFM contractions for increasingly longer periods of time.[22] The skill of correct and isolated PFM contraction was checked every two weeks in the control group and every BF session in the intervention group. As skill contraction developed, the females were instructed to practice PFMT during usual daily activities (e.g., work, travel, socializing) and while standing.

Both improvement record and exercises training diaries were filled daily by females. According to the daily improvement record diary, the female was made to record times, circumstances of their daily incontinence episodes to detect onset of improvement from her subjective observation. Exercise training diary was also used to report the intensity, frequency and duration of exercises practiced daily to increase female's motivation for the PFMT program and to detect their compliance and adherence.

2.5. Biofeedback therapy[18]

Manometric BF-assisted PFMT was performed two times weekly to females in the intervention group only using Myomed 632® equipment, Enraf Nonius, Delft, and the Netherlands). Menstruating females were temporarily withdrawn from BF sessions till end of the menses. In females presenting with SUI, vaginal pressure sensor was used for BF training while in those with FI, rectal pressure sensor was used. Self-application of sensors was practiced by females with the same above mentioned procedure in the baseline assessment of vaginal manometric pressure measurements. In BF training, visual and auditory feedbacks were provided to stimulate their correct performance in addition to positive verbal reinforcement which was provided by the investigator to encourage learning of the abdomino-pelvic muscular coordination. Getting the right technique of PFM contraction was only the beginning of BF-assisted PFMT program which included individually designed and supervised sessions which were based on the DTPFMC evaluated at the beginning of each BF session to be used as the working period where the female was highly motivated to increase DTPFMC, depending on the female's ability and to rest four seconds in between contractions. These work/rest cycles were repeated several times during the session where females were also encouraged to practice endurance training and flicks exercises several times for up to forty-five minutes which is considered as the total time committed to BF session. The time spent on BF session was dependent on the female's response, for example when PFM contractions began to show fatigue, or the female began to compensate with abdominal muscles, it was time to end the session.

The study duration was up to 12 weeks maximally. The prescribed pelvic floor muscle training programs were electively terminated in patients reporting complete symptom resolution. Upon program termination, re-evaluation was performed through assessment questionnaires (PFQ and PFIQ-7), grading of pelvic floor muscle according to MOS and manometric pressure measurement of MPPFMC and DTPFMC. Partial improvement was defined as: improvement of at least PFQ score (being a subjective component) and MPPFMC score (being an objective component with a higher accuracy than clinical assessment of MOS) compared with base line assessment score. Complete improvement was defined as improvement of scores of all re-evaluation tools.

3. Statistical analysis

Statistical analysis was performed using SPSS® Statistics Version 20. Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), (mean and median) and dispersion (mean ± standard deviation). Comparison between different groups regarding categorical variables was tested using Chi-square test. When more than 20% of the cells have expected count less than 5, correction for Chi-square was conducted using Fisher's exact test or Monte Carlo correction. The distributions of quantitative variables were tested for normality using Kolmogorov–Smirnov test, Shapiro–Wilk test and D'Agostino test, also Histogram and QQ plot were used for vision test. If it reveals normal data distribution, parametric tests was applied. If the data were abnormally distributed, non-parametric tests were used. For normally distributed data, comparison between two independent populations was done using independent *t*-test, also paired *t*-test is used to analyze two paired data. For abnormally distributed data or ordinal

data, comparison between two independent populations was done using Mann Whitney test. To compare between the different periods Wilcoxon signed ranks test was applied. $P < 0.05$ was considered statistically significant. Correlations between two quantitative variables were assessed using Spearman coefficient. Significance test results are quoted as two-tailed probabilities. Significance of the obtained results was judged at the 5% level.

4. Results

The study included 52 female patients (26 in each group). Demographic data of our cohort are shown in Table 1. Those in the control group were asked to perform prescribed HEP only. While those in the intervention group received BF-assisted PFMT in the form of two times weekly sessions plus the prescribed HEP in between sessions. Assessment questionnaires, PFM strength grading according to (MOS) and manometric measurements including (MPPFMC) and (DTPFMC) were performed in both groups before and after PFMT program for a maximum duration up to three months. Follow-up was achieved for 24 females in the intervention group. One patient was dropped from follow-up and one patient died due to a non-related cause. In the control group, follow-up was achieved in only 23 females. Two patients were missed from follow-up and one patient withdrew upon her own request.

There were no significant differences between two groups in duration of complaint and baseline electrophysiological assessment. Mean duration of complaint was 98.27 ± 84.66 weeks and 92.0 ± 85.74 in the intervention and control groups respectively. At the end of PFMT, a significant difference was found in incidence and onset of improvement between both groups. In the intervention group, 19 patients showed improvement (79.2%) compared to only 7 females (31.8%) in the control group. Similarly, in the intervention group, mean onset of improvement was after 9.71 ± 2.4 weeks compared to 11.8 ± 0.45 in the control group.

Regarding the ability to correctly isolate PFM contraction, patients in the intervention group showed a significantly higher ability to isolate PFMs (15 females, 5.7%) compared to only 3 females (11.5%) in the control group. This isolation was encountered after a significantly shorter duration in the intervention group (8.3 ± 3.2 weeks) versus a significantly longer duration in the control group (11.35 ± 1.7 weeks).

Regarding evaluation of females' response to treatment program using PFQ and PFIQ-7, patients in the intervention group showed significantly higher percentages of score improvement than patients in the control group. In the intervention group, PFQ showed a 38.2% of improvement versus only 11.3% in the control group. Similarly, PFIQ-7 showed a 34% improvement in the intervention group versus only 11.5% in the control group. Clinical assessment at the end of the study using MOS score revealed a 10.7% of improvement in the intervention group versus 0% in the control group. MPPFMC at the end of the study revealed similarly a significantly higher % of improvement in the intervention versus the control group (22.3% versus 6.1%, respectively). Age and duration of complaint were not predictive factors of outcome between both groups. Table 2 shows that the base line assessment of females in the intervention group (using MOS, MPPMC, PFQ and PFIQ-7) is a predictor of the efficacy of biofeedback-assisted PFMT. Females showing higher base line clinical assessment scores showed a statistically significantly higher percentage of improvement of their symptoms versus those who had lower base line scores. Patients with unilateral pudendal neuropathic lesion showed a significantly higher % of improvement than those bilateral pudendal neuropathic lesion. These results are illustrated in Table 3.

Table 1 Demographic data of the intervention and control groups.

	Intervention (n = 26)		Control (n = 26)	
	No.	%	No.	%
Occupation				
House wife	13	50.0	21	80.8
Work	13	50.0	5	19.2
$^{\chi^2}p$	0.020*			
Age				
Min.–Max.	30.0–64.0		33.0–68.0	
Mean ± SD	49.88 ± 10.39		50.19 ± 10.34	
Median	51.0		49.0	
^{t}p	0.915			
Body mass index (BMI)				
Normal	14	53.8	11	42.3
Over weight	1	3.8	4	15.4
Obese grade I	5	19.2	8	30.8
Obese grade II	5	19.2	2	7.7
Obese Grade III	1	3.8	1	3.8
^{MW}p	0.115			

p: p value for comparing between the two studied groups, χ^2: Chi-square test, t: Student t-test, MW: Mann Whitney test.
* Statistically significant at $p \leqslant 0.05$.

5. Discussion

Pelvic floor muscle training is the most commonly recommended physical therapy treatment for women with PFD due to its effectiveness and its nature as a non-invasive treatment modality with fewer side effects.[23] Biofeedback is used as an additional strategy to increase patient compliance to PFMT and consequently optimize its benefit.[24]

Females who received BF-assisted PFMT with HEP in the intervention group were significantly more likely to report improvement compared to those who received the prescribed HEP alone in the control group. This goes in accordance with similar reports in the literature. Recent large sized randomized trials in women with SUI based on symptoms, signs and urodynamic study proved that women who received BF-assisted PFMT were significantly more likely to report improvement or complete cure of SUI compared to those who received PFMT alone.[12]

Significant earlier and correct PFM isolation were also observed in 15 patients (57.7%) in the intervention group. Lee and his colleagues found that BF-assisted PFMT has been introduced to demonstrate proper exercise techniques by targeting PFMs specifically and in order to optimize the effectiveness of restoring their strength.[25] Similar reports supported these results.[26–29]

Table 2 Relation between degree of improvement and baseline assessment in intervention group (24 patients).

	Improvement		*p* Value
	No improvement	Improvement	
MOS baseline			
3	5 (20%)	7 (30%)	$P = 0.023$*
4	0	12 (50%)	
MPPMC			
Less than 60 mmHg	5 (20%)	7 (30%)	$P = 0.002$*
More than 60 mmHg	0	12 (50%)	
*PFQ***			
Less than 56 points	4 (16.6%)	6 (25%)	$P = 0.029$*
More than 56 points	2 (8.3%)	12 (50%)	
*PFIQ****			
Less than 150 points	3 (12.5%)	6 (25%)	$P = 0.005$*
More than 150 points	3 (12.5%)	12 (50%)	

MOS: modified Oxford grading system, MPPMC: maximal pressure of pelvic muscle contraction, PFQ: pelvic floor questionnaire, PFIQ: pelvic floor impact questionnaire.
* Statistically significant difference at $P = 0.005$.
** Maximum score is 112.
*** Maximum score is 300.

Table 3 Relation between degree of improvement and type of pudendal neuropathy lesion in intervention group.

	Degree of improvement						*P*
	No ($n = 5$)		Partial ($n = 10$)		Complete ($n = 9$)		
	No.	%	No.	%	No.	%	
Type of pudendal neuropathy							
Unilateral pudendal neuropathy	0	0	1	80	5	66.6	0.005*
Bilateral pudendal neuropathy	5	100	9	20	4	33.3	

* Statistically significant difference at $P = 0.005$.

Testing PFM function is a challenging task. But several subjective and objective tools were designed to achieve this aim. Assessment questionnaires have been proved to play a significant role as a reliable subjective tool. Culligan et al. used PFQs to compare PFM training to Pilates exercise program in patients with PFD.[30] Similarly, Barber et al. designed different quality of life questionnaires to assess the outcome of PFM treatment programs.[31] We assessed the subjective element of PFMs function using two forms of assessment questionnaires (PFQ and PFIQ-7). Objective assessment should also be an integral part of the PFM assessment for proper evaluation of different treatment modalities. Hirakawa et al. compared PFM training alone to that combined with BF programs using vaginal squeeze pressure in his patients.[32] We adopted the MPPFMC as a reasonable comparing tool in our study.

Unexpectedly, female age and duration of complaint were not predictive factors of outcome of our treatment program. Emery et al. agreed to this opinion during analysis of etiological and therapeutic factors in patients with PFD.[33] However, clinical and electrophysiological baseline assessment correlated to the outcome. In a previous study, it was found that women with more mild symptoms of SUI showed a higher percentage of cure approximating 88% after the same treatment program than women with severe symptoms, who showed a complete failure of treatment program (0% cure rate).[34]

In our study, the high success rate in the intervention group can explain the role of BF in helping females to isolate correctly their PFMs maximizing the benefit of PFMT program. We believe that the patient's willingness to cure her PFD is an important factor in therapeutic success. In conclusion, the study showed that BF-assisted PFMT is an effective therapy compared to PFMT alone for well-motivated females with mild to moderate PFD.

Conflict of interest

All authors declare that they have no conflict of interest.

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