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INCREASE IN PELVIC FLOOR MUSCLE ACTIVITY AFTER 12 WEEKS' TRAINING: A RANDOMIZED PROSPECTIVE PILOT STUDY

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ABSTRACT

Objectives. To compare electromyography-assisted biofeedback training to pelvic floor muscle training (PFMT) alone in patients with female stress urinary incontinence.

Methods. A prospective randomized pilot study was conducted between March 1998 and February 2000 at the university hospital for outpatient care. Participants were women with urodynamically tested stress incontinence aged 31 to 69 years without previous incontinence operations, 30 volunteers altogether. The biofeedback group received an electromyography-guided biofeedback device for home training and the PFMT-alone group trained without any device at home. All patients were advised to practice for 20 minutes per day five times a week for 12 weeks.

Results. According to the data analysis, muscle forces increased significantly in both supine ($P < 0.001$) and standing ($P < 0.001$) positions. In the supine position, the increase was significantly higher in the biofeedback group ($P = 0.024$). The results showed close to a significant decrease in the leakage index in the biofeedback group ($P = 0.068$), but in the PFMT-alone group, no change occurred. With respect to the pad test, the decrease was significant, but it was the same for both groups ($P = 0.907$).

Conclusions. The findings of this study show that pelvic floor muscle activity is increased and the amount of leaked urine is decreased after 3 months of PFMT. These preliminary results show a significant improvement compared with the PFMT-alone group in PFMT outcome measures in patients using electromyography-assisted biofeedback training. UROLOGY **60:** 1020–1024, 2002. © 2002, Elsevier Science Inc.

The main functional component of the pelvic floor is the levator ani muscle. When this muscle contracts, it compresses the urethra, thus helping to maintain continence.[1] The aim of pelvic floor re-education is to increase the strength and functional activity of these muscles, which, for some patients, may reduce the problem of stress incontinence.[2] Pelvic floor muscle (PFM) exercises are therefore a widely used and well-established form of stress incontinence treatment, with success rates varying from 21% to 84%, although with a better subjective than objective outcome.[3–6]

In an elderly population, a trend toward increased effectiveness of PFM exercises with office-based biofeedback compared with PFM exercises alone was shown in a randomized trial by Burns *et al.*,[4] although the differences in treatment effect between the pelvic muscle exercise and biofeedback groups were not statistically significant. A statistically significant difference between treatment groups was found in the study by Burgio *et al.*[3] Those patients receiving biofeedback showed a better reduction in incontinence and improvement in the contraction force of the pelvic floor compared with controls. However, on the basis of the current evidence available, the effectiveness of biofeedback-assisted pelvic floor muscle training (PFMT) cannot be considered as unequivocal.[7]

The aim of the study was to compare electromyography (EMG)-assisted biofeedback exercise with

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Submitted: January 29, 2002, accepted (with revisions): July 5, 2002

0090-4295/02/$22.00
PII S0090-4295(02)02125-8

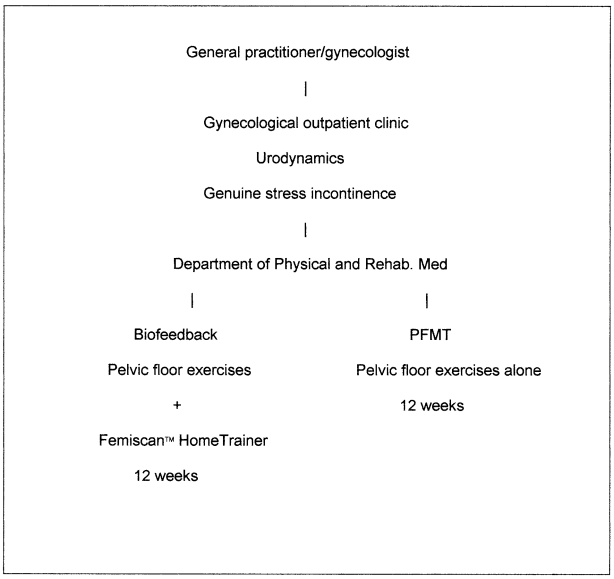

FIGURE 1. *Study protocol.*

PFMT alone in patients with female stress urinary incontinence on an intent-to-treat basis.

MATERIAL AND METHODS

The subjects were recruited consecutively from the gynecologic outpatient clinic during 1998 to 1999. Thirty women with urodynamically tested stress incontinence without previous incontinence operations participated in a PFMT program after a gynecologic interview and examination. Volunteers aged 21 to 70 years with genuine stress incontinence and an abdominal leak point pressure greater than 90 were included. The exclusion criteria were genital protrusion beyond the vaginal hymen, an inability to understand instructions for home training, pregnancy, and any severe disease such as malignancy in the abdominal region, multiple sclerosis, and insulin-dependent diabetes. Patients were informed of the possibility of undergoing an incontinence operation if the PFM exercises did not cure their incontinence.

The local ethical committee approved this study. All women signed written consent forms before participation.

The patients were randomized to either the biofeedback group or the PFMT-alone group. Randomization was done by a random numbers table, in blocks of four (Fig. 1).

PFMT with Visual Biofeedback

All the patients visited the same physiotherapist (P.I.) five times (0, 1, 4, 8, 12 weeks), and PFM activities were measured at each visit in the supine and standing positions. At the first visit, the patients were familiarized with the location of the levator ani muscle and the pelvic anatomy. After that information session, they started biofeedback training. Muscle activity signals were visible on the computer screen. At each session, three 5-second contractions with 10-second intervals in the supine and standing positions were collected for later analysis. The measurements were taken in the same order with every patient. Each patient visited the physiotherapist at the same time of day every time. At each session, the home-training devices were downloaded and the registered data were checked.

Home Program

All patients were given verbal and written instructions for home practice and were advised to practice for 20 minutes per day five times a week. The patients were advised to practice both at rest and during daily exercises. The exercise session was designed to include short and long duration exercises, as both type I and type II muscle fibers need to be exercised. Patients in the biofeedback group were advised to note down when they exercised with or without the device.

EMG-Guided Biofeedback Device

Each participant in the biofeedback group received an individual EMG-assisted biofeedback device (FemiScan, Mega-Electronics, Kuopio, Finland) at the first clinic visit and was requested to return the device at the last visit. The device consists of a vaginal probe and connected headphones. While listening to the home-training program, the patient is free to move around without restrictions. The device emits a voice signal if the contraction is too weak. The device is based on surface EMG for clinical and home use. The EMG parameters and the software system are described in more detail in the study of Airaksinen and Airaksinen.[8]

Main Outcome Measures

The PFM activities expressed in mean values by the software and measured in the supine and standing positions were used for analysis. The increase in muscle activity was expressed as the increase in amplitude (in microvolts). The mean value of three consecutive contractions was used. Twenty-four-hour home pad weights were measured before trial entry and after the last clinical visit. Women chose a typical day that mirrored their average level of activity. The subjective outcomes were the leakage index as described by Bo[9] and were recorded before treatment and at 12 weeks. The leakage index contains 13 types of physical exertions that trigger urinary leakage in women with stress incontinence. A urogynecology nurse conducted the pad test and the leakage test. All patients were asked to keep a training diary.

We analyzed the data on an intent-to-treat basis, so the women were analyzed in the group to which they were originally assigned.

Recordings

In the biofeedback group, the EMG-guided biofeedback measurement device recorded a mean of 68 home-training sessions (range 9 to 130). In addition to those recordings, the patients had written down an average of 47.5 days (range 6 to 93) when they had exercised without the device. In the control group, 2 of 15 subjects did not return the training diary. The mean number of training days was 56.2 (range 21 to 87) in the PFMT-alone group.

Statistical Analysis

The data analysis was based on the analysis of covariance and the analysis of variance for repeated measures. At the first phase, we used analysis of covariance and tested the change between the baseline and follow-up values using the baseline as the covariate. This was done to study the adequacy of the randomization. The analysis of covariance was needed for the pad test and the leakage index. If the covariate was not significant, analysis of variance for repeated measures was carried out. The imputation of missing data was needed at the 12-week pad test for one control patient; the missing observation was imputed by the baseline value. The results were identical with and without the imputation. The level of significance was set equal to 0.05, but we also show exact *P* values. The com-

TABLE I. *Patient characteristics*

Characteristic	Biofeedback Group (n = 15)	PFMT-Alone Group (n = 15)
Age (yr)	51.8 (35.0–61.0)	50.8 (31.0–69.0)
BMI (kg/m^2)	25.9 (21.0–36.0)	25.8 (21.0–36.0)
Vaginal deliveries (n)	2.2 (0–5)	3.1 (0–7)
Postmenopausal women (n)	9	9
Duration of symptoms (yr)	9.0* (1.0–30.0)	7.3* (3.0–16.0)

KEY: BMI = body mass index.
Data presented as the mean, with the range in parentheses, unless otherwise noted.
** n = 14.*

TABLE II. *Summary of collected data*

	Baseline	After 12 wk
Pelvic floor muscle activity (μV)		
Supine		
Biofeedback	15.3 (4.4)	25.8 (10.0)
PFMT	17.8 (6.8)	20.1 (8.6)
Standing		
Biofeedback	13.5 (4.7)	21.4 (10.3)
PFMT	14.7 (7.2)	20.9 (8.6)
Leakage index		
Biofeedback	45.5 (10.1)	34.9 (10.4)
PFMT	38.5 (11.0)	38.1 (10.5)
24-hr pad test (g)		
Biofeedback	28.1 (29.4)	19.0 (19.7)
PFMT	47.1 (34.6)	22.5 (19.6)

Data presented as the mean, with the standard deviation in parentheses.

putation was made using Statistica/Win (Edition '98, StatSoft, Tulsa, Okla) software.

RESULTS

The characteristics of the participants are given in Table I. Initially, each group had 15 patients, but 2 patients interrupted training with the device and continued PFMT alone. The analysis was, however, carried out on an intent-to-treat basis. All 30 patients participated in the 12-week training session. A summary of the collected data is presented in Table II.

When analyzing the supine PFM activity values, a significant change was found over time ($P < 0.001$), and the interaction between the groups and the period was significant ($P = 0.024$). Figure 2 demonstrates that in the PFMT-alone group, no actual change occurred, but in the biofeedback group, the increase from baseline was very clear.

With respect to the standing PFM activity values, a significant increase occurred during the 12-week

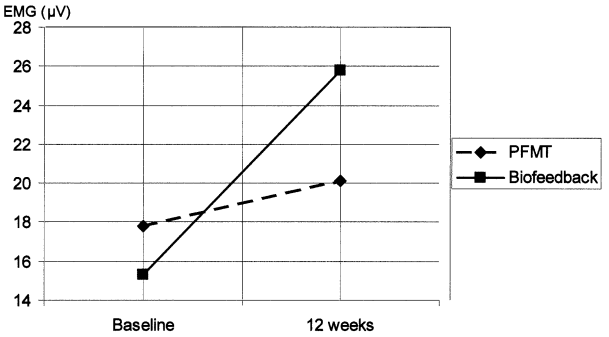

FIGURE 2. *Change in mean PFM activity measured in the supine position.*

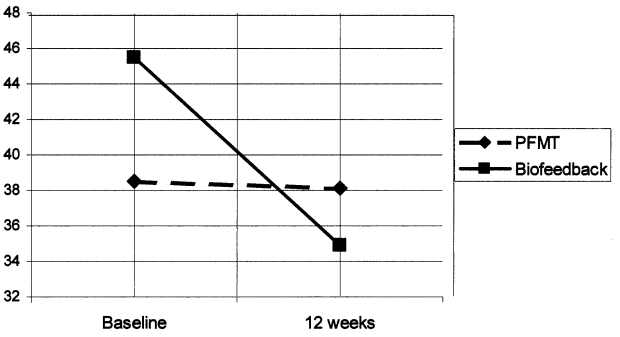

FIGURE 3. *Leakage index values before and after treatment.*

period ($P < 0.001$), but it was identical in both groups (interaction $P = 0.565$).

The groups differed with respect to the baseline values in the pad test; the covariate was significant ($P < 0.001$). Accordingly, we analyzed the change over time and used the baseline values to adjust for change. The crude change mean was 26.4 g for the PFMT-alone group and 9.1 g for the biofeedback group. After adjustment, they were 18.1 g and 17.3 g. The difference was not significant ($P = 0.907$).

With respect to the leakage index, analysis of covariance was also needed. The baseline as the covariate was significant ($P = 0.003$). The crude change in means was 0.33 for the PFMT-alone group and 10.6 for the biofeedback group. After adjustment, the corresponding means were 2.1 and 8.8. The difference was close to statistically significant ($P = 0.068$). Figure 3 supports the result; no actual change occurred in the PFMT-alone group, but for the biofeedback group, the baseline mean was clearly higher, and after 12 weeks, they experienced a clear decrease.

Two patients interrupted the use of the home-training device and continued training without it. They were both postmenopausal and they found the vaginal probe to be uncomfortable. In addition, five others mentioned they had pain while training—three in the PFMT-alone group and two from

the biofeedback group. Three of these women were premenopausal.

COMMENT

The results of this study demonstrate the efficacy of PFM exercises alone and in combination with a biofeedback device in increasing muscle activity. Our results corroborate the randomized studies of Burgio *et al.*[3] and Burns *et al.*,[4] who found a significant increase in pelvic muscle activity after office-based biofeedback training. In the study of Hirsch *et al.*,[10] home-based biofeedback was efficient in 85% of patients with stress and mixed incontinence.

The leakage test contains 13 types of physical exertion that trigger urinary leakage in women with stress urinary incontinence. The decrease in the leakage index and the increase in PFM activity were better in the biofeedback group, a clear indication that adjunctive biofeedback is more effective than PFMT alone.

A reduction in the leakage index and in the pad test can be achieved with PFMT. Although complete cessation is not always achieved, many women consider themselves cured.[5] In our study, both groups achieved a decrease in the amount of leaked urine. It is clear that longer follow-up is needed to reveal whether patients are satisfied with this result or seek a more invasive cure for incontinence.

All women could contract the PFMs at their first visit with physiotherapist, which raises the issue of patient selection. According to Bump *et al.*,[11] 60% of women are able to generate an effective increase in the force of urethral closure after brief verbal instruction. The benefit of the EMG feedback is that this device facilitates the acquisition of physiologic responses that are otherwise undetected,[3] and a small amplitude contraction with low force can be measured.

CONCLUSIONS

These results show a significant improvement in PFMT outcome measures (PFM activity, leakage index) in the biofeedback group compared with the PFMT-alone group. PFM activity clearly increases after 12 weeks' training and can be objectively monitored with an EMG-based biofeedback device.

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EDITORIAL COMMENT

This study compared two methods of EMG biofeedback-assisted pelvic floor muscle exercises (PFMEs) in women with urodynamically tested stress urinary incontinence. All subjects were taught PFMEs by the same physical therapist, using EMG biofeedback treatment in five office visits during a 12-week period. The second group, which the authors call the "biofeedback" group, received an EMG-assisted biofeedback home device that was to be used for home PFME training. Results indicated that the second group or the biofeedback group had an increase in PFM activity in the supine position compared with the control group as measured in microvolts. The biofeedback group also had a statistically significant decrease in urine leakage compared with the control group.

There is a large body of published reports concerning the use of biofeedback-assisted PFMEs. The pioneering work of the obstetrician, Arnold Kegel, involved the use of a pressure-sensitive biofeedback device called a perineometer to assist women with stress urinary incontinence to identify and exercise their pelvic floor muscles. After Kegel's discovery that a biofeedback device could facilitate PFMEs, many clinicians have found this method useful for teaching, motivating, and improving compliance in persons with stress and other types of urinary incontinence. Teaching women to strengthen the pelvic floor muscle as part of a comprehensive behavioral program has been demonstrated to be effective in 50% to 60% of women with stress urinary incontinence. However, as the authors note, most women have difficulty identifying and isolating the pelvic floor muscle. Even after they have learned to do that, there is the additional problem that many find too burdensome the daily exercises necessary to increase muscle strength and control. As a result, the noncompliance rate for this therapy can be high, varying from 10% to 40%. This can be frustrating to clinicians who provide these treatments, as poor outcomes may be secondary to noncompliance and out of their control.

Most researchers in this field have relied on the use of verbal and written instructions for patients to use for home practice