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ORIGINAL ARTICLE

The effect of home biofeedback training on stress incontinence

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Background. To compare the effectiveness of pelvic floor training (PFT) with the aid of a home biofeedback device to PFT alone for urodynamic stress urinary incontinence (SUI) in women after a 1-year follow-up.
Methods. A randomized study comparing two conservative interventions was conducted in an outpatient clinic of a university hospital. Thirty-five consecutive women were randomized to either the PFT with home biofeedback group or the PFT alone group. The intensive training period lasted 12 weeks. After 1 year, 33 women could be evaluated according to the protocol. At the 1-year visit pelvic floor muscle activity was measured and the need for surgical intervention was evaluated. Logistic multivariate analysis was used to predict response to the PFT.
Results. In the home biofeedback training group 11/16 (68.8%) avoided surgery vs. 10/19 (52.6%) in the PFT alone group. The difference was not statistically significant. In the nonoperated home biofeedback group the increase in pelvic floor muscle activity ($p = 0.005$ in supine, $p = 0.005$ in standing) and the decrease in leakage index ($p = 0.05$) was significant after 12 weeks and pelvic floor activity remained constant. By contrast, in the nonoperated PFT group the increase in pelvic floor muscle activity after 12 weeks predicted a good result for conservative treatment.
Conclusions. This randomized controlled trial suggests that the home biofeedback method in PFT has a good success rate of 68.8%. The change achieved in leakage index after 12 weeks of training predicted an effective outcome for conservative treatment.

Key words: pelvic floor training; biofeedback; stress urinary incontinence; female

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The role of adjunctive biofeedback in pelvic floor training (PFT) in stress urinary incontinence (SUI) is controversial (1,2), and few studies have examined the impact of home biofeedback devices on PFT. One study reported an improvement or cure rate of 85% after electromyography (EMG)-based home biofeedback training in stress and mixed incontinence (3). In a randomized controlled trial by Mørkved et al., the objective cure rate after 6 months of home biofeedback training was 67% with a biofeedback device in urodynamic SUI (4). In addition to hometraining, their patients made 16 visits to a physiotherapist.

Modern technology has allowed the development of a variety of vaginal and rectal probes sensitive to pressure or EMG activity (5). The devices can measure and collect the data of muscle exercises for later analysis, thus allowing less frequent clinic visits. Individual training programs with audio instructions are also available in more sophisticated versions (4,6). The aim of

Abbreviations:
PFT: pelvic floor training; SD: standard deviation; TVT: tension-free vaginal tape; EMG: electromyography; SUI: stress urinary incontinence.

this randomized controlled trial was to evaluate the effectiveness of PFT with or without a home biofeedback device with a 1-year follow-up. The primary outcomes were pelvic floor muscle activity, the need for surgical intervention after conservative treatment and the patients' subjective evaluation of PFT at the 1-year follow-up visit. We also used multivariate analysis to predict the response to PFT.

Materials and methods

The subjects were recruited consecutively from the gynecologic outpatient clinic of a teaching hospital during the years 1998–99. Thirty-five urodynamically tested stress incontinent women without previous incontinence operations participated in a PFT program after a gynecologic interview and examination. The women were aged 21 to 70 years. The diagnosis of SUI was based on a positive history and a positive stress sign. Other urodynamic criteria were maximal urethral closure pressure over 20 cmH_2O and cough leak point pressure over 90 cmH_2O.

Exclusion criteria were genital protrusion beyond the vaginal hymen, inability to understand instructions for home training, pregnancy, severe diseases such as malignancies in the abdominal region, multiple sclerosis and diabetes mellitus requiring insulin. All patients were informed of the possibility of undergoing an incontinence operation if the pelvic floor muscle exercises did not cure their incontinence.

The local ethical committee approved this study. All women gave their written informed consent before participation. Patients were randomized either to the home biofeedback group or to the PFT group. Randomization was performed by a random numbers table, in blocks of four.

Pelvic floor training

All the patients visited the same physiotherapist five times (0, 1, 4, 8, 12 weeks) during the intensive training period of 12 weeks. After the 12 weeks of intensive training the patients were advised to continue training on their own initiative. After 1 year the women visited the physiotherapist again. They were asked about previous surgery or any other treatment for SUI and their desire for further treatment. Women's opinion about the PFT regimen was registered on a five-point scale (from harmful to very effective).

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 a computer screen. At each session, three 5-s contractions with 10-s intervals in the supine and standing position were collected for later analysis. 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, hometraining devices were downloaded and the registered data were checked.

Each participant in the home biofeedback group received a personal EMG-assisted biofeedback device (FemiScan^{TM}, MegaElectronics, Kuopio, Finland) (Fig. 1) at the first clinic visit and they were requested to return the device after 12 weeks of intensive training. The ability of this type of surface EMG to measure pelvic floor muscle activity has been reported in a previous article (7). The home biofeedback monitor has an internal microprocessor that contains a training program, a sound processor for verbal instructions and enough memory to collect training performed at home. The initial results of this pilot study were promising and showed an increase of pelvic floor muscle activity in both groups after 12 weeks of training, but in the supine position the increase was significantly higher in the biofeedback group. These results have been published previously (6).

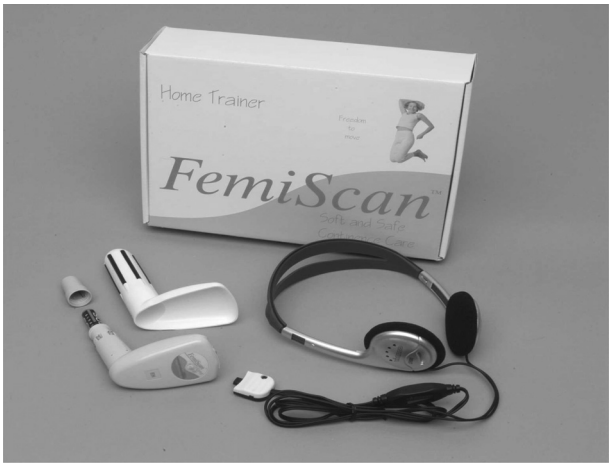

Fig. 1. A personal EMG-assisted biofeedback device (FemiScan^{TM}, MegaElectronics, Kuopio, Finland) that contains an internal microprocessor capable of collecting training performed at home. Patient hears instructions for pelvic floor training by headphones.

Home program

All patients were given verbal and written instructions for home practice and they were advised to practice for 20 minutes a 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. The PFT group kept a training diary.

The subjective outcomes were leakage index as described by Bø (8), and they were recorded before the treatment and at 12 weeks. The leakage index contains 13 types of physical exertions that trigger urinary leakage in women with stress incontinence.

Statistical analysis

The description of the data was made using cross-tabulations and percentages for dichotomous variables, and means (SD) and medians for continuous variables. Differences between groups for dichotomous variables were assessed with the χ^2-test. Differences for the changes within subgroups over time were assessed with the Wilcoxon rank test. The multivariate data analysis was based on logistic regression with surgery for stress incontinence as the dependent variable and possible risk factors as the explanatory variables. The possible risk factors were device, and the changes in the EMG measurements and leakage index over time. The continuous variables were analyzed in logarithm-transformed form. A forward stepwise model was used, and the limits to enter and to remove variables were set equal to 0.10 and 0.15, respectively. The results of the multivariate analysis must be regarded only as a trend; because of the small sample size the confidence intervals of significant risk factors are wide. The imputation was carried out by replacing the missing observations by the respective subgroup means. The computation was carried out using

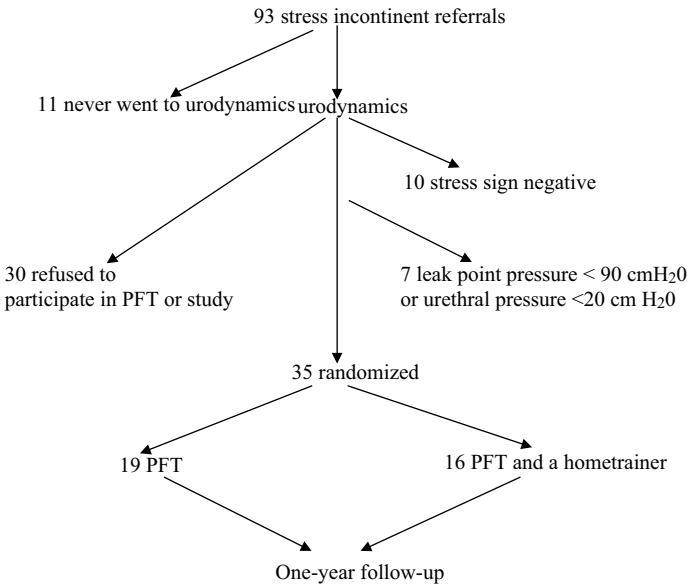

Fig. 2. Flow chart showing stages in the study protocol and the number of participants.

SPSS for Windows (version 11.0) and Statistica for Windows (version 6) software.

Results

The flow chart of the study is shown in Fig. 2. Initially, there were 16 patients in the home biofeedback group and 19 in the PFT group but two patients stopped training with the device and continued PFT alone. However, the analysis was carried out based on the intention to treat. The patients' characteristics are shown in Table I. All 35 patients participated in the 12-week training session. In the biofeedback group, a mean of 68 (min 10, max 131) home training sessions were recorded by the EMG-guided biofeedback measurement device. In addition to those recordings, the patients had written down an average of 46 (min 6, max 76) days when they had exercised without the device. In the control group, one out of 19 subjects did not return the training diary. The mean number of training days was 61 (min 21, max 87) in the PFT group.

After 1 year two women could not be reached, and two were interviewed by phone. Altogether, 31 women out of 35 attended the 1-year follow-up visit. The hospital records of all patients were reviewed for gynecologic surgeries. Fourteen women underwent surgery or were waiting for an incontinence operation. There were 5/16 (31.3%) operations in the home biofeedback training group and 9/19 (47.4%) in the PFT group. The difference was not statistically significant.

Logistic regression analysis showed that the change in leakage index was associated with the operation. Decrease in the leakage index decreased the risk for an operation (OR 0.033; 95% confidence interval 0.001–1.085, $p = 0.056$). It is clearly seen in the biofeedback group that change in pelvic floor activity occurred during the intensive treatment period (Table II). By contrast, in the PFT nonoperated group the change was significant after intensive training. Only the nonoperated home training group achieved a significant reduction in the leakage index during the training period ($p = 0.005$).

Table I. The characteristics of the patients. Values are means (SD, min–max) unless stated otherwise

	PFT + hometrainer $n = 16$	PFT $n = 19$	*T*-test
Age (years)	51.4 (6.1, 35–61)	49.4 (9.5, 31–69)	Not significant
Body mass index	26.4 (4.1, 21–36)	25.8 (4.2, 21–36)	Not significant
No. of vaginal deliveries	2.1 (1.3, 0–5)	3.0 (1.7, 0–7)	Not significant
No. of cesarean sections	0	0.1 (0.3, 0–1)	Not significant
Duration of symptoms (years)	8.5 (8.6, 1–30)	6.6 (3.9, 1–16)	Not significant
Leakage index at beginning	44.3 (10.8, 27–70)	37.8 (12.1, 10–58)	Not significant
No. of postmenopausal women	9	12	Not significant
Urgency score	6.1 (2.7, 2–11)	7.6 (3.3, 2–14)	Not significant
Urinary incontinence severity score (%)	46.9 (19.2,15–95)	50.8 (18.2, 10–58)	Not significant

Table II. Electromyographic (EMG) results for the women randomized into pelvic floor muscle training with biofeedback and pelvic floor muscle training alone

	Pelvic floor muscle activity while supine (μV)			*p*-value*	
	Before treatment	After 12 weeks	After 1 year	Before treatment–12 weeks	After 12 weeks–1 year
Hometrainer group					
Not operated	14.50 (3.20) 15.00	23.90 (7.89) 22.50	23.80 (8.55) 22.00	0.005	0.799
Operated	17.00 (6.20) 13.00	25.00 (12.18) 19.00	21.40 (3.13) 22.00	0.345	0.893
PFT group					
Not operated	17.25 (7.81) 15.50	15.12 (7.68) 13.00	24.65 (9.08) 25.62	0.151	0.021
Operated	18.43 (5.94) 17.00	25.86 (5.73) 26.00	26.71 (6.10) 25.00	0.046	0.866

Values are presented as the mean (SD), with the median value on the second line.
*Wilcoxon rank test

Of the women interviewed, 67% considered PFT to be effective or very effective and none considered home biofeedback PFT to be harmful.

Discussion

The success rate, that is cured or improved and thus avoiding surgery, in the PFT with home biofeedback was good, at 68.8%. The success rate was higher than the 52.6% found in the group engaging in PFT alone. Although the study was underpowered to show a statistical difference, the difference between the groups may nonetheless be clinically relevant. These results are also comparable to the previous clinic-based biofeedback trials for treatment of SUI in women (9,10) and to home biofeedback training with clinic visits (4).

Supervised home training provides better adherence to rehabilitation (11). In this study the hometrainer recorded an average of 5.7 home training sessions per week per women and the patients visited a physiotherapist five times. Considerably more contacts with a physiotherapist have been reported in other studies (4,10,12), which require more time from both physiotherapists and patients. However, the adherence and following improvement are dependent on supervision and motivation at the outset (11). Another study (12) found that biofeedback as a support to SUI therapy was most important in the first 2 weeks, during the first six treatments. Thus intensive PFT with assisted biofeedback may prevent frustration resulting from long-term training.

It is often claimed that sooner or later after PFT, women seek an incontinence operation. Nevertheless, there are studies of the long-term effect of PFT indicating that this is not the case. Mouritsen et al. (13) reported that for patients who were cured immediately after exercises the effect was permanent in 85% of cases. In a 5-year follow-up Bø and Talseth (14) reported that 3/23 had been treated surgically, and 70% of their patients were satisfied and did not want further treatment. Their patients participated in a 6-month training program. Consistent with the findings from the logistic regression analysis in our study, they showed that in some cases more than 3 months of training would be beneficial.

The advantage of an EMG-based home biofeedback device is that it offers the possibility of demonstrating the contraction strength to the patients and thereby may improve their motivation. Previous authors have speculated whether the improvement is a result of better isolated muscle training (10). In this study the pelvic floor muscle activity increased during the intensive training period and remained at the same level for 1 year in the nonoperated home training group, but in the nonoperated PFT group the increase was greater after intensive therapy. Two women in the nonoperated PFT group trained with a hometrainer after the study period on their own initiative. Altogether, this may indicate that with the aid of home biofeedback the effect of PFT or the need of a future incontinence operation can be assessed earlier than with PFT alone.

Previous studies have shown that age, parity, pelvic muscle strength in palpation or maximal urethral closure pressure do not have any significant influence on PFT treatment outcome (3,13,15,16). A weak correlation between a reduction in incontinence episodes per week and an increase in maximum sustained vaginal pressure in SUI women $\geq$ 45 years was found in a randomized study of behavioral therapy (16). The pressure was measured with a water-filled balloon.

Burns et al. (9) found that pelvic muscle activity was significantly correlated with decreases in incontinent episodes, and only the biofeedback subjects showed significant improvement in EMG. From the methodological point of view EMG and squeeze pressure are two different methods to measure pelvic floor muscle function and give feedback. The present study encourages the use of recordable EMG-based home biofeedback regardless of whether EMG records only levator muscles or other related structures.

Our study was underpowered for showing a statistical difference in the magnitude likely to be expected from previous studies. However, the tension-free vaginal tape (TVT) operation was introduced to our clinic at the beginning of 1998. This procedure has gained increasing attention because of its simplicity compared to older incontinence operations. That might have influenced patients and clinicians toward surgery as a primary treatment for SUI. The long-term cure rate of the TVT procedure is 84.7% (17). In 2000, SUI physiotherapy treatment for one patient cost 508 € and a TVT operation 1508 €. Even only with a 60% cure rate it is less expensive to first try conservative treatment, and then if it fails, perform an incontinence operation. We share the opinion of previous researchers that intensive PFT should precede surgery, as exercises have a permanent effect in as many as 70% of patients (13). Although patients in this trial underwent urodynamic testing before PFT, urodynamic testing before initiation of PFT in women with an uncomplicated history of stress incontinence symptoms may be unnecessary, given the low cost of PFT (18).

This randomized, controlled pilot study found a good success rate for home biofeedback in PFT. The benefits of the biofeedback device used in this study include the possibility to follow compliance in training, privacy, and a greater increase in muscle activity and improved continence than with PFT alone. With regard to pelvic floor muscle activity the primary results after 12 weeks of training were promising. At the 1-year follow-up the overall cure or improvement rate was comparable with other PFT studies. A larger randomized trial is needed to conform a real difference between PFT with home biofeedback and PFT alone.

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