

Effect of Behavioral Training With or Without Pelvic Floor Electrical Stimulation on Stress Incontinence in Women

A Randomized Controlled Trial

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PELVIC FLOOR ELECTRICAL STIMULATION (PFES) has been used for the treatment of urinary incontinence since 1952.¹ In the original study, PFES was added to pelvic floor muscle exercises and cured 7 of 17 women who had failed previous attempts to treat their stress urinary incontinence with exercise alone. The treatment of PFES using a vaginal probe was not reported in the literature until 1967 when interest in this therapy resurfaced.² Since then, PFES has become widely used and is now approved for reimbursement by Medicare and many other insurance plans.

Pelvic floor electrical stimulation activates pudendal nerve afferents, which in turn results in activation of pudendal and hypogastric nerve efferents, causing contraction of smooth and striated periurethral muscles and striated pelvic floor muscles.³ This provides a form of passive exercise with the goal of improving the urethral closure mechanism. In addition, PFES can be

See also p 395 and Patient Page.

Context Pelvic floor electrical stimulation (PFES) has been shown to be effective for stress incontinence. However, its role in a multicomponent behavioral training program has not been defined.

Objective To determine if PFES increases efficacy of behavioral training for community-dwelling women with stress incontinence.

Design and Setting Prospective randomized controlled trial conducted from October 1, 1995, through May 1, 2001, at a university-based outpatient continence clinic in the United States.

Patients Volunteer sample of 200 ambulatory, nondemented, community-dwelling women aged 40 to 78 years with stress or mixed incontinence with stress as the predominant pattern; stratified by race, type of incontinence (stress only vs mixed), and severity (frequency of episodes).

Interventions Patients were randomly assigned to 8 weeks (4 visits) of behavioral training, 8 weeks (4 visits) of the behavioral training plus home PFES, or 8 weeks of self-administered behavioral treatment using a self-help booklet (control condition).

Main Outcome Measures Primary outcome was percentage reduction in the number of incontinent episodes as documented in bladder diaries. Secondary outcomes were patient satisfaction and changes in quality of life.

Results Intention-to-treat analysis showed that incontinence was reduced a mean of 68.6% with behavioral training, 71.9% with behavioral training plus PFES, and 52.5% with the self-help booklet ($P=.005$). In comparison with the self-help booklet, behavioral training ($P=.02$) and behavioral training plus PFES ($P=.002$) were significantly more effective, but they were not significantly different from each other ($P=.60$). The PFES group had significantly better patient self-perception of outcome ($P<.001$) and satisfaction with progress ($P=.02$). Significant improvements were seen across all 3 groups on the Incontinence Impact Questionnaire but with no between-group differences.

Conclusions Treatment with PFES did not increase effectiveness of a comprehensive behavioral program for women with stress incontinence. A self-help booklet reduced incontinence and improved quality of life but not as much as the clinic-based programs.

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useful in teaching pelvic floor muscle contraction to women who cannot identify or contract these muscles voluntarily because of extreme weakness.

Previous research has demonstrated the efficacy of PFES compared with sham PFES.^{4,5} There is also some evidence that PFES yields results similar to

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those of pelvic floor muscle training,⁶ although some investigators have found pelvic floor muscle exercise training to be superior.⁷ Several studies have combined PFES with various methods of pelvic floor muscle training and exercise and reported successful outcomes.⁸⁻¹¹

Only 2 studies have examined the issue of whether electrical stimulation improves the outcomes of pelvic floor muscle training. A single, small study (N=14) compared pelvic floor muscle exercise and exercise augmented with PFES and found that the addition of PFES improved outcome as measured with bladder diaries and muscle strength.¹² In the other study, pelvic floor muscle exercises augmented with both PFES and biofeedback produced greater improvements in symptoms and muscle strength compared with pelvic floor muscle exercises alone.¹³ However, because PFES and biofeedback were used together, it is not possible to isolate the effect of adding PFES. Thus, while PFES shows promise in the treatment of stress incontinence, the role of electrical stimulation in behavioral treatment with pelvic floor muscle training and exercise has not been clearly defined.

The present study was designed to determine whether PFES enhances the outcome of behavioral training in the treatment of stress incontinence. A multicomponent behavioral treatment protocol with and without home PFES was compared with a control condition consisting of self-administered behavioral treatment.

METHODS

Participants

Community-dwelling older women with stress incontinence were recruited through local advertisements, community outreach, and professional referrals, and then screened by telephone to determine eligibility. To be scheduled for an evaluation, women had to be 40 years or older, ambulatory, and describe a pattern of predominantly stress incontinence occurring at least twice per week and persisting for at least 3 months. Informed consent procedures were approved by the university's institutional

review board for human use, and all patients provided informed consent. The study was conducted from October 1, 1995, through May 1, 2001.

Clinical Evaluation

The evaluation consisted of a continence and medical history, physical examination, postvoid catheterization for residual urine, urodynamic evaluation, level of hemoglobin A_{1c} measured for patients with diabetes, and urinalysis (urine dipstick on clean-catch specimen with microscopic evaluation if indicated). A Q-tip test was performed to identify patients with bladder neck hypermobility, defined as greater than or equal to 30° of rotation.¹⁴ In addition, the Mini-Mental State Examination was used to screen for dementia.¹⁵ If patients had a urinary tract infection (urine colony count >10000), fecal impaction, severe atrophic vaginitis, or uncontrolled diabetes, they were offered or referred for treatment and reconsidered for study participation when the symptoms of these underlying conditions were resolved.

Urodynamic testing was performed according to International Continence Society guidelines¹⁶ in the Continence Research Clinic by specially trained nurse practitioners to document stress leakage (for inclusion) and to classify the type of incontinence for stratification (stress only vs mixed stress and urge). Two-channel supine water cystometry was performed using a No. 12 Fr double lumen urodynamic catheter, a rectal balloon, and room temperature sterile water at a continuous filling rate of 50 mL/min up to a maximum of 500 mL. Presence of detrusor instability was noted as well as the bladder capacity. The catheter was removed and several maneuvers were performed to provoke stress incontinence: changes in position (lying to sitting, sitting to standing), coughing (4 times while lying, 4 times while standing), and heel bouncing (4 times).

Bladder Diary and Quality-of-Life Measures

To measure pretreatment frequency of incontinence, patients were given 2 weeks of bladder diary booklets.¹⁷ Pa-

tients documented the time of every void and incontinent episode, the volume of each episode of urine loss, and the circumstances of each episode. Volume of an incontinence episode was estimated as small if the urine would wet only their underwear and as large if the volume was sufficient to dampen their outer clothing if a pad were not in place. The Hopkins Symptom Checklist 90-R (psychological distress),¹⁸ Incontinence Impact Questionnaire,¹⁹ and Short Form 36 Health Survey²⁰ were completed by patients at home and returned with baseline diaries at the second evaluation visit.

Inclusion and Exclusion Criteria

To be included, patients had to average at least 2 incontinence episodes per week on the 2-week baseline bladder diary, and stress incontinence had to be the predominant pattern (ie, the number of stress episodes had to exceed the number of urge and other episodes). Also, stress incontinence had to be objectively demonstrated during urodynamic testing. Patients were excluded if they had continual leakage, postvoid residual urine volume greater than 150 mL, severe uterine prolapse (past the vaginal introitus), decompensated congestive heart failure, hemoglobin A_{1c} ≥9, or impaired mental status (Mini-Mental State Examination score <24).

Design

The study was a randomized controlled trial. Patients were randomized to behavioral training (biofeedback-assisted pelvic floor muscle training, home exercises, bladder control strategies, and self-monitoring with bladder diaries), or the same program with the addition of home PFES treatments, or a control condition consisting of self-administered behavioral training administered with a self-help booklet. Stratification procedures were used at randomization to ensure that groups had similar types and severity of incontinence and race distribution (black or white). Race was self-identified by the patient. Baseline bladder diaries and urodynamic test results were used to classify incontinence as stress only or mixed

stress and urge. The baseline bladder diaries were also used to stratify patients as having mild (<5 episodes/wk), moderate (5-10 episodes/wk), or severe incontinence (>10 episodes/wk). Within each stratum, patients were randomized using a block size of 6 to ensure equity in group size. The randomization schedule was computer-generated by the biostatistician and implemented by the nurse practitioners. A sample size of 200 was selected to allow detection of 15% differences in reduction of episodes on bladder diary between treatment groups with 85% power and a significance level of .05, assuming a 2-sided hypothesis test and a pooled within-group SD of 20%.

Intervention

For all patients, treatment was implemented over an 8-week period. Patients completed a daily bladder diary throughout treatment.

Behavioral Training. Treatment consisted of 4 clinic visits at 2-week intervals. Interventions were implemented by female nurse practitioners who were specially trained by the behavioral psychologist (K.L.B.) and physician principal investigator (P.S.G.) in behavioral treatment of incontinence. At each visit, clinic staff reviewed bladder diaries to ensure that entries were clear and interpretable.

During visit 1, anorectal biofeedback was used to help patients identify pelvic floor muscles and teach them how to contract and relax these muscles selectively while keeping abdominal muscles relaxed.^{21,22} A 3-balloon probe provided manometric feedback of anal sphincter pressure (representing pelvic floor muscles) and rectal pressure (reflecting intra-abdominal pressure).²³ Using biofeedback, the nurse practitioner taught the patient to isolate the pelvic floor muscles. The patient practiced pelvic floor muscle contraction and relaxation until she and the nurse practitioner felt the patient was ready to do the exercises at home without biofeedback. The biofeedback session typically lasted 20 minutes.

Patients were given verbal and written instructions for 3 sessions of pel-

vic floor muscle exercises daily. Each session consisted of 15 repetitions of 2- to 4-second contractions with equal periods of relaxation. The initial duration of each individual contraction was determined based on the ability demonstrated by the patient in the training session. Patients were advised to do 1 session lying, sitting, and standing, and whenever possible to integrate the exercises into other daily activities. Once daily they were to practice interruption or slowing of the urinary stream during voiding.

During visit 2, the bladder diary was reviewed. Patients were then taught to use "stress strategies" to prevent urine leakage.^{21,22,24} Specifically, they were instructed to contract their pelvic floor muscles during any activity that usually resulted in leakage (eg, coughing, sneezing, lifting, standing up from a chair). If they forgot to use the stress strategy and experienced urine leakage during an activity, they were to tighten their pelvic floor muscles immediately, with the expectation that this would strengthen the habit of using their muscles in the future. They were also taught to manage the sensation of urgency using the "urge strategy."^{21,22,24} Instead of rushing to the toilet, which increases pressure on the bladder and exposes patients to visual cues that can trigger incontinence, patients were encouraged to stand or sit still, relax the entire body, and contract pelvic floor muscles repeatedly to diminish urgency, inhibit detrusor contractions, and prevent urine loss. When urgency subsided, they were instructed to proceed to the toilet without rushing.

During visits 2, 3, and 4, the home exercise regimen was adjusted by gradually increasing the duration of each contraction to a maximum of 10 seconds, with an equal period of relaxation between contractions. Progress was reviewed and persistence with exercises and bladder control strategies reinforced. Also during visit 3, patients who had not achieved at least 50% improvement were offered a repeat biofeedback session.

Pelvic Floor Electrical Stimulation.

This treatment included all of the components of behavioral training with the addition of home PFES. During treatment visit 1, a home unit (Hollister InCare, Libertyville, Ill) was programmed to deliver stimulation via vaginal probe with the following parameters: biphasic pulses (frequency of 20 Hz), pulse width of 1 millisecond, and pulse train to rest period of 1:1 (to keep the exercise and relaxation phases the same among treatment groups). Frequency settings between 20 and 50 Hz have been reported as optimal for sphincter closure and pelvic floor muscle contraction, and 5 to 20 Hz for reflex detrusor inhibition.²⁵⁻²⁹ Therefore, 20 Hz was selected since many of the patients were expected to have mixed stress and urge incontinence. The current intensity was adjusted by the patient to the maximum level she could tolerate comfortably, up to 100 mA. Simultaneous with each muscle contraction induced by PFES, patients performed a voluntary pelvic floor muscle contraction.

All patients felt comfortable enough with the PFES unit to take it home after session 1. Patients were instructed to use the PFES unit for 15 minutes every other day. On alternate days, to keep the exercise time consistent between groups, patients were instructed to perform 3 sessions of pelvic floor muscle exercises (as in the behavioral training group).

Self-administered Behavioral Training: Control Condition. The self-help booklet provided written instructions for an 8-week self-help behavioral program that was based on the behavioral training program described above but was completely self-administered, without benefit of professional expertise or equipment. The booklet included the entire program in simple lay language: isolating the pelvic floor muscles, progressive home exercise, self-monitoring, and bladder control strategies. The text was adapted from the self-help book *Staying Dry: A Practical Guide to Bladder Control*.²⁴ Patients were given the booklet and an appointment for a return visit in 8 weeks. They were also given a supply of bladder diaries

and stamped envelopes for returning completed diaries each week.

Assessment After Treatment

Following treatment visit 4, patients completed 2 weeks of posttreatment bladder diaries and a patient satisfaction questionnaire, and repeated the Hopkins Symptom Checklist 90-R, the Incontinence Impact Questionnaire, and the Short Form 36 Health Survey. These materials were collected when they returned for their posttreatment visit. During this visit patients were encouraged to repeat urodynamic testing.

Data Management and Analysis

To determine any baseline differences on key variables, the treatment groups were compared using χ^2 analysis and analysis of variance (ANOVA). The primary outcome measure was reduction in the frequency of incontinent episodes as recorded in the bladder diaries. The pretreatment and posttreatment fre-

quency of incontinence were used to calculate a percentage reduction for each patient ($[\text{pretreatment frequency} - \text{posttreatment frequency}] \div [\text{pretreatment frequency}] \times 100\%$)^{21,22,30} Thus, 100% represented total continence, 0% signified no improvement, and a negative percentage indicated an increase in incontinent episodes. One-way ANOVA was used to test for differences between the 3 groups on treatment outcome. This study was based on intention-to-treat analysis, using the last value carried forward, along with careful attrition analysis. Thus, when patients did not complete treatment, the most recent bladder diaries were used to calculate outcome. Post-hoc analyses were conducted to make pairwise comparisons of the treatment groups.

Differences between the groups on patient satisfaction and subjective assessment of treatment outcome were tested using the χ^2 statistic for categorical variables or the Kruskal-Wallis test

for ordinal variables. Other outcome measures, including the Incontinence Impact Questionnaire, the Hopkins Symptom Checklist 90-R, the Short Form 36 Health Survey, and urodynamic measures were examined using 3 (for number of treatment groups) by 2 (for pretreatment vs posttreatment) repeated measures ANOVA, using a more conservative value of $P < .01$ as significant to provide additional protection against committing type 1 errors due to multiple comparisons.

RESULTS

Of 508 women who were evaluated clinically, 308 were ineligible or did not participate, and 200 were randomized (FIGURE 1). The attrition rate was 18.2% in the behavioral group, 11.9% in the PFES group, and 37.3% in the self-help booklet group ($P = .001$). Figure 1 details reasons for attrition. No one withdrew because of adverse effects. The PFES group reported 4 (6%) occurrences of vaginal irritation, 3 due to slippage of the PFES probe resulting in a pinching sensation, and 1 due to the conduction gel, which resolved after changing brands.

Characteristics of the participants are presented in TABLE 1. Before treatment, there were no significant differences among the 3 treatment groups on any of the key parameters ($P > .10$ for all comparisons).

Reductions in Incontinence: Bladder Diary

Before treatment, the weekly frequency of incontinence was similar across the 3 groups ($P = .94$) (TABLE 2). Behavioral training resulted in a mean 68.6% reduction in frequency of episodes; behavioral training plus PFES, a mean 71.9% reduction; and treatment with the self-help booklet, a mean 52.5% reduction ($P = .005$). In comparison with the self-help booklet, post-hoc tests revealed behavioral training with PFES ($P = .002$) and without PFES ($P = .02$) were significantly more effective. However, the addition of PFES did not seem to improve the results of behavioral training ($P = .60$). Similarly, a larger proportion of pa-

Figure 1. Patient Flow Diagram

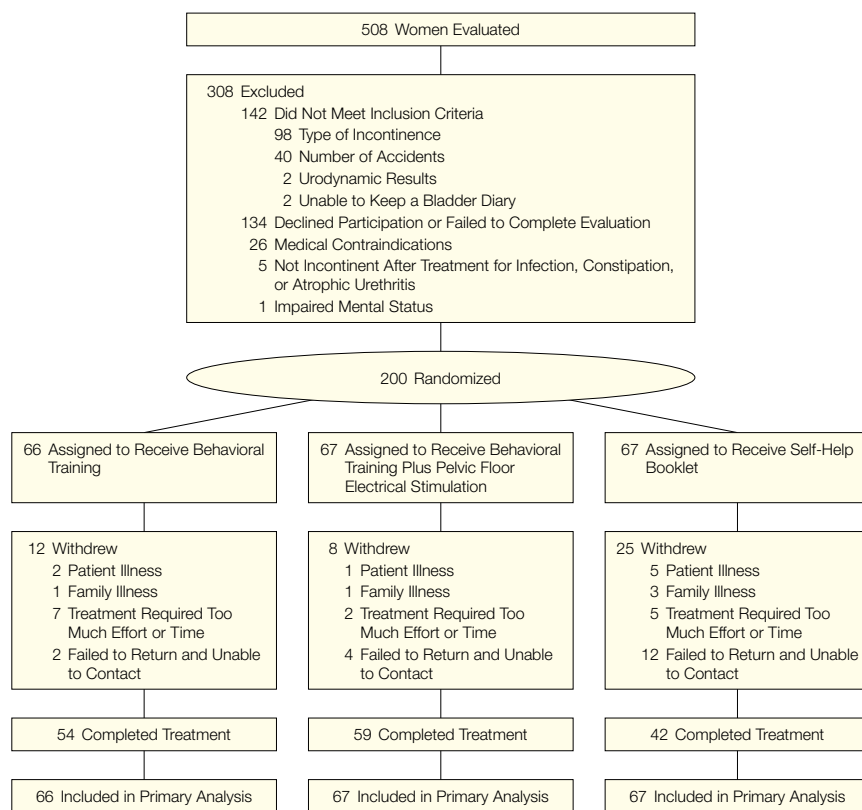


Table 1. Baseline Characteristics*

Characteristic	Type of Treatment			Total Sample (N = 200)
	Behavioral Training (n = 66)	Behavioral Training Plus PFES (n = 67)	Self-help Booklet (n = 67)	
Demographics				
Age, mean (SD), y	57.7 (10.0)	54.9 (9.4)	55.9 (10.1)	56.2 (9.8)
High school graduate	60 (90.9)	63 (94.0)	66 (98.5)	189 (94.5)
Black	11 (16.7)	11 (16.4)	14 (20.9)	36 (18.0)
History				
Parity, mean (SD)	2.2 (1.3)	2.6 (1.5)	2.4 (1.6)	2.4 (1.5)
Duration of symptoms, mean (SD), y	6.9 (8.3)	9.3 (9.7)	10.3 (11.7)	8.9 (10.1)
Diuretic use	4 (6.1)	9 (13.4)	12 (17.9)	25 (12.5)
Estrogen use	41 (62.1)	36 (53.7)	38 (56.7)	115 (57.5)
Hysterectomy	32 (48.4)	33 (49.2)	41 (61.2)	106 (53.0)
Surgery for incontinence	11 (16.7)	5 (7.5)	12 (17.9)	28 (14.0)
Activity restricted by incontinence	37 (56.1)	37 (55.2)	38 (56.7)	112 (56.0)
Disturbed by incontinence	60 (90.9)	64 (95.5)	62 (92.5)	186 (93.0)
Pelvic examination				
Cystocele 2° or 3°	23 (34.8)	27 (40.3)	27 (40.3)	77 (38.5)
Rectocele 2° or 3°	11 (16.7)	10 (14.9)	11 (16.4)	32 (16.0)
Uterine prolapse	5 (7.6)	2 (3.0)	4 (6.0)	11 (5.5)
Bladder neck hypermobility	32 (48.5)	28 (41.8)	26 (38.8)	86 (43.0)
Bladder capacity, mean (SD), mL	338 (125)	305 (133)	327 (141)	323 (134)
Type of incontinence (on diary and urodynamics)				
Stress only	19 (28.8)	23 (34.3)	25 (37.3)	67 (33.5)
Mixed stress and urge	47 (71.2)	44 (65.7)	42 (62.7)	133 (66.5)
Severity classification, episodes/wk				
Mild (<5)	13 (19.7)	15 (22.4)	17 (25.4)	45 (22.5)
Moderate (5-10)	20 (30.3)	17 (25.4)	18 (26.9)	55 (27.5)
Severe (>10)	33 (50.0)	35 (52.2)	32 (47.8)	100 (50.0)

Abbreviation: PFES, pelvic floor electrical stimulation.

*Values expressed as number (percentage) unless otherwise indicated.

tients in the behavioral training and the PFES groups achieved at least 50% improvement of incontinence ($P < .001$) although there was no difference in the number of cures (100% improvement) in each group ($P = .95$) (FIGURE 2).

We investigated whether baseline characteristics were associated with treatment outcome. Percentage reduction of episodes was not related to severity of incontinence as measured by number of episodes on bladder diary ($P = .99$) or to type of incontinence ($P = .23$). Subgroup analysis revealed that only the PFES group exhibited a difference in outcome by type of incontinence with patients with stress incontinence having a mean 85.1% reduction of episodes and patients with mixed incontinence having a mean 65.0% reduction in episodes ($P = .02$). Whether treatment outcome differed for the subgroup of patients with detru-

Table 2. Results of Behavioral Treatment on Frequency of Incontinent Episodes*

	Type of Treatment			P Value
	Behavioral Training (n = 66)	Behavioral Training Plus PFES (n = 67)	Self-help Booklet (n = 67)	
No. of episodes/wk, mean (SD)				
Before treatment	15.1 (13.7)	15.6 (13.1)	14.8 (13.9)	.94
After treatment	4.5 (6.1)	5.6 (13.3)	7.5 (12.1)	.09
Reduction, %				
Mean (SD)	68.6 (32.4)	71.9 (32.8)	52.5 (42.7)	.005
Median (range)	77.5 (-18.2 to 100)	83.7 (-43.8 to 100)	63.2 (-42.9 to 100)	

Abbreviation: PFES, pelvic floor electrical stimulation.

*The percentage reduction in frequency of incontinent episodes was the preplanned outcome analysis. The post-treatment mean comparison was performed post hoc.

sor overactivity on urodynamic testing could not be determined because of small sample size in this subgroup.

Efficacy Analysis

Posttreatment reduction of incontinence was examined in the subgroup of patients who completed treatment.

The mean percentage reduction for the 54 participants in the behavioral training subgroup was 80.2%; for the 59 in the behavioral training plus PFES subgroup, 78.3%; and for the 42 in the self-help booklet subgroup ($n = 42$) 75.3%. Outcomes did not differ by treatment group ($P = .64$).

Urodynamic Testing

Thirty (45.5%) of 66 participants in the behavioral training group, 36 of 67 (53.7%) in the PFES group, and 16 (23.9%) of 67 in the self-help booklet group agreed to complete posttreatment urodynamic testing. These individuals were compared on all baseline characteristics in Table 1 and they did not differ significantly. On posttreatment stress testing, 27.6% of the behavioral training group, 47.2% of the PFES group, and 37.5% of the self-

help booklet group no longer had leakage ($P = .27$). On cystometry, mean (SD) bladder capacity decreased from 329.2 (130.0) mL to 326.4 (146.2) mL in the behavioral training group ($P = .88$); increased from 327.9 (128.4) mL to 370.4 (143.4) mL in the PFES group ($P = .03$); and increased from 326.2 (138.4) mL to 355.4 (115.3) mL in the self-help booklet group ($P = .31$). The main effect for treatment group was not significant ($P = .24$).

Patient Satisfaction and Perceptions of Progress

The patient perceptions of progress and satisfaction with treatment are presented in TABLE 3. Post-hoc pairwise testing revealed that significantly more women in the PFES group thought that they were much better than in the behavioral training ($P = .048$) or self-help booklet groups ($P < .001$), and that more women in the behavioral training group thought they were much better than in the booklet group ($P = .01$). Furthermore, PFES resulted in more patients who were completely satisfied than did the self-help booklet ($P = .002$), but other pairwise comparisons were not signifi-

cant. Thus, from the viewpoint of the patients, all 3 treatments yielded positive results, with behavioral training plus PFES yielding better overall outcomes and satisfaction with progress.

Impact of Incontinence, Psychological Distress, and Quality of Life

Repeated measures ANOVA revealed significant improvement on total incontinence-related quality-of-life scores as well as all 4 subscales of the Incontinence Impact Questionnaire ($P < .001$ for all). Total Incontinence Impact Questionnaire score improved from a mean score of 93.1 to 57.6 following treatment. Changes in mean subscale scores were 24.2 to 15.5 for physical activity; 22.1 to 13.7 for travel; 19.1 to 11.2 for social; and 28.5 to 18.4 for emotion. However, there were no significant group effects or group by time interactions on the total score or the subscales ($P = .23$ to $P = .90$). Thus, Incontinence Impact Questionnaire scores improved substantially across all 3 treatment groups, but no differences among treatment groups were found.

Repeated measures ANOVA revealed no statistically significant changes in psychological distress as measured by the Global Severity Index of the Hopkins Symptom Checklist 90-R or any of its 9 subscales. Likewise, the Short Form 36 Health Survey did not demonstrate any statistically significant changes in quality of life.

COMMENT

The results of this study show that PFES did not enhance the outcomes of biofeedback-assisted behavioral training for stress incontinence in women. This finding differs from the results of a previous study, which has reported that adding PFES improved outcomes of pelvic floor muscle training.¹² However, that study was small ($N = 14$) and the women did not receive biofeedback. It is possible that PFES enhances outcomes by helping women to identify their pelvic floor muscles. When women are already receiving biofeedback training to help them identify pel-

Figure 2. Proportion of Patients With Reduction in Frequency of Incontinence, by Study Group

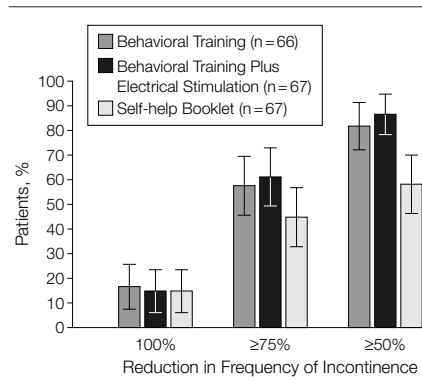


Table 3. Patient Perceptions of Outcomes

Patient Perceptions	Type of Treatment, No. (%)*			P Value†
	Behavioral Training	Behavioral Training Plus PFES	Self-help Booklet	
Description of treatment outcome				<.001
Much better	27 (57.4)	36 (76.6)	12 (30.0)	
Better	18 (38.3)	9 (19.1)	20 (50.0)	
About the same	1 (2.1)	2 (4.3)	8 (20.0)	
Worse	1 (2.1)	0 (0)	0 (0)	
Having fewer episodes	45 (95.7)	45 (95.7)	36 (92.3)	.72
Episodes are smaller	34 (73.9)	40 (85.1)	27 (69.2)	.14
Able to wear less protection	31 (66.0)	38 (80.9)	27 (67.5)	.31
Incontinence no longer restricts activities	33 (70.2)	37 (78.7)	26 (66.7)	.43
Comfortable enough with treatment to continue indefinitely	45 (95.7)	43 (93.5)	31 (83.8)	.12
Satisfaction with progress				.02
Completely	31 (66.0)	38 (80.9)	20 (50.0)	
Somewhat	15 (31.9)	8 (17.0)	15 (37.5)	
Not at all	1 (2.1)	1 (2.1)	5 (12.5)	

Abbreviation: PFES, pelvic floor electrical stimulation.

*Numbers and percentages do not total the number (percentage) of patients included in the main intention-to-treat analysis because patient perception of outcomes data could not always be obtained on dropouts. For bladder diary data, the last value was carried forward because bladder diaries were kept continuously. But for data that were collected at baseline and at the end of this study, this procedure was not possible.

†Analysis of variance comparing the 3 groups.

vic floor muscles, then adding PFES may not make a significant difference. This would be consistent with another previous study, which showed that adding both biofeedback and PFES together to pelvic floor muscle exercise produced better outcomes.¹³ Thus, the current evidence suggests that the 2 technologies may overlap in function. Either may improve the results of pelvic floor muscle exercise training, but both technologies apparently are not needed in the same protocol for most women with stress incontinence.

It is possible that neither technology is needed as part of initial therapy for urinary incontinence but should be reserved for patients who do not improve with a less invasive behavioral program. We recently reported a clinical trial of women with urge incontinence who did equally well if taught pelvic muscle exercises by a nurse practitioner using biofeedback or using manual palpation as a part of a comprehensive behavioral program.³⁰ A stepped approach in which biofeedback or PFES technologies can be added if a less invasive program fails is consistent with current reimbursement policies of the Centers for Medicare and Medicaid Services, which allow reimbursement for PFES or biofeedback only after a patient has failed a course of pelvic floor muscle training without these technologies.^{31,32}

Although PFES did not improve results on the primary outcome measure (reduction of incontinent episodes), patient self-reports indicated that women in the PFES group perceived significantly better outcomes. Thus, apparently some subjective treatment outcomes were affected by the addition of electrical stimulation but were not reflected in the measure of incontinent episodes. Alternatively, patients' knowledge that they were receiving the electrical stimulation may have led to some degree of placebo effect reflected in their subjective assessment of improvement.

The other component of behavioral therapy that was examined in this study

was the contact with clinical staff to manage the training. The self-help group received the complete behavioral program, but it was administered via a self-help booklet and without clinic visits. Although the intention-to-treat analysis showed that both the behavioral training with biofeedback and the training enhanced with PFES were superior to the self-administered behavioral training, it is important to note that the dropout rate in the self-help group (37.3%) was higher than that of the other 2 groups (18.2% in behavioral training and 11.9% in PFES). In the efficacy analysis, including only treatment completers, there were no significant differences among the groups on reduction of incontinent episodes. Thus, the self-help condition was less effective mainly because of its higher rate of attrition.

In a trial of a similar self-help booklet for urge incontinence,³⁰ the dropout rate in the booklet group was no greater than that for women enrolled in a comprehensive behavioral program with clinic visits every 2 weeks. Therefore, unlike the present study of stress incontinence, the self-administered behavioral therapy was equally effective in reducing episodes as was the behavioral therapy administered in the clinic. It is quite possible that patients with stress incontinence discontinued the self-help treatment due to lack of efficacy. Perhaps pelvic muscle strength is more important to prevent stress episodes than to prevent urge episodes. Women with urge incontinence may experience early success in suppressing urgency, but women with stress incontinence may become discouraged before developing sufficient strength to contract their pelvic muscles sufficiently to prevent stress episodes without the reinforcement of the nurse practitioner. The results suggest that behavioral training for stress incontinence is optimally implemented in the clinic in which clinicians can ensure that patients are exercising the correct muscles and can encourage patients to persist with their efforts long enough for the training to yield results.

In both the intention-to-treat analysis and the analysis of completers, the self-administered behavioral treatment program was effective for both stress and urge incontinence. These findings are promising for the dissemination of behavioral training because a booklet can be given to women with incontinence in a number of clinical settings including primary care. However, the results of the self-help intervention in these clinical trials could differ from the results of implementing this intervention in a clinical practice for several reasons. The booklet in these clinical trials was administered to patients in a specialty continence clinic after a complete evaluation of their incontinence. In addition, because one of the specific aims of these clinical trials sponsored by the National Institutes of Health was to investigate the mechanisms by which behavioral treatment improves incontinence, we assessed pelvic floor muscle strength. Although it was imbedded in the urodynamic procedures and used the same instrumentation, measurement of the strength of muscle contraction necessitated assisting the patient to identify and contract the muscles. Thus, we may have inadvertently given patients extra pelvic floor muscle instruction that they would otherwise have not received by simply receiving a booklet.

The self-help intervention may be sensitive to patient motivation, and the highly motivated participants in clinical trials may not be representative of the general clinic population. Furthermore, the self-help program included keeping continuous bladder diaries that were mailed in weekly. All of these factors may have produced results better than what would be achieved in a clinic population by simply handing out a booklet. The logical next step is a trial of this self-help program in a clinic population of women with stress and urge incontinence. Also, studies with longer follow-up are needed to ascertain the durability of behavioral treatments.

In conclusion, a biofeedback-assisted multicomponent behavioral

training program in healthy, nonde- mented, community-dwelling women was as effective in improving stress in- continence as the program with the ad- dition of PFES. A self-help booklet re- duced incontinence but not as much as the clinic-based program.

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