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A Comparison of Effectiveness of Biofeedback and Pelvic Muscle Exercise Treatment of Stress Incontinence in Older Community-Dwelling Women

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Background. Research using biofeedback as a treatment for sphincteric incontinence began with Kegel's early studies using a perineometer and pelvic muscle exercises demonstrating a 90% improvement in urine loss symptoms. More recent studies using varying combinations of biofeedback and pelvic muscle exercises found symptom reduction rates of 78% to 90%, but these studies lacked the rigor of a "phase three," or randomized controlled clinical trial.

Methods. A randomized controlled trial assessed the efficacy of biofeedback for older women for treatment of sphincteric incompetence. One hundred thirty-five community-dwelling women were randomized in a single-blind trial to three groups: biofeedback, pelvic muscle exercise, or control. Incontinent episodes were monitored over 8 weeks of treatment and at 3 and 6 months thereafter.

Results. The number of incontinent episodes decreased significantly in the biofeedback and pelvic muscle exercise subjects but not in the control subjects for all severity of incontinence frequency subgroups. Improvement was maintained within the moderate and severe symptom subgroups for both treatments for at least 6 months but declined in subjects with mild incontinence frequency. Pelvic muscle activity (EMG) was significantly correlated with decreases in incontinent episodes, and only the biofeedback subjects showed significant improvement in EMGs.

Conclusions. Biofeedback and pelvic muscle exercises are efficacious for sphincteric incompetence in older women. Benefits are maintained and improvement continues for at least 6 months postintervention. These therapies may be useful before considering invasive treatment.

URETHRAL sphincteric incompetence (SI) results in incontinence when sudden increases in intraabdominal pressure produce involuntary urine loss (1). Commonly called stress urinary incontinence, it is generally associated with a hypermobile urethra lacking posterior support. Additionally, it may be seen in instances where a well-supported urethra no longer functions as a sphincter (Type III urinary incontinence) (2). A community-based epidemiologic study of persons age 60 or over in Washtenaw County, Michigan found that 26.7% of incontinent women suffered from symptoms of stress incontinence and 55.5% had mixed (urge and stress) incontinence (MI) (3).

SI has been treated with a variety of surgical, pharmacological, and behavioral interventions. The most common surgical procedure used in treating SI is bladder-neck suspension, which carries the hazards of anesthesia and operative intervention (4). Alpha sympathomimetic agents such as pseudoephedrine and phenylpropanolamine, that increase tone of the urethral smooth musculature, are also useful in the treatment of incompetence of the sphincteric mechanism (5). However, drug side effects may exacerbate hypertension and cardiovascular disease and produce other untoward effects. Behavioral treatments such as pelvic muscle exercises, intravaginal stimulation, and biofeedback are noninvasive, without side effects, and have been reported to have some success in managing incontinent symptoms produced from SI (6–9).

Research using biofeedback as a treatment for SI began with Kegel's early studies using a perineometer and pelvic muscle exercises demonstrating a 90% improvement in urine loss symptoms (10). More recent studies using varying combinations of biofeedback and pelvic muscle exercises found symptom reduction rates of 78% to 90%, but these studies lacked the rigor of a "phase three" or randomized controlled clinical trial (11–16).

In contrast to earlier studies that lacked an untreated control group, this study employed a randomized, controlled, single-blind experimental design to determine the effectiveness of pelvic muscle exercises alone and augmented with biofeedback in treating older women with SI and in maintaining long-term treatment effects. A preliminary report of some outcomes found in this clinical trial has been previously presented (17). Because severity of incontinence secondary to SI varies greatly among individuals, treatment efficacy was evaluated relative to frequency of baseline urine loss. To understand the physiologic bases of response to treatment, we further investigated the effects of pelvic muscle exercises and biofeedback on urodynamic measures and pelvic muscle performance. In addition, long-term treatment effects are presented as percentages of improvement and complete "cures" at 3 and 6 months following program completion.

METHODS

Experimental design and sample selection. — Implementation of this clinical trial required 3½ years (March 1985 through October 1988). Subjects were female volunteers aged 55 and older (NIA/NCNR cooperative agreement age criteria) recruited through newspaper advertisements and a poster campaign (18). Individual informed consent was obtained prior to procurement of study data. The following selection criteria were established to obtain a homogeneous sample of cognitively intact subjects with predominantly *stress incontinent* symptoms: minimum of three urine losses per week, able to demonstrate urine loss with stress maneuvers during physical examination, a diagnosis of SI or MI during urodynamic evaluation, a score of 23 or greater on the Mini-Mental State Exam (19), absence of glycosuria or pyuria (>5 WBCs/HPF), a residual urine <50 cc, and a peak urine flow >15 cc/second. As described in a previous publication (17), 123 female subjects with SI and 12 with MI met study criteria and were randomized in blocks of 12 into either a biofeedback group, pelvic muscle exercise group, or control group. A single-blind, two-experimental, one-control-group design was employed to test the effectiveness of biofeedback and pelvic muscle exercises for reduction of urine loss symptoms.

Evaluation. — Complete histories were obtained to determine the nature of the urine loss problem and any previous surgical treatments. Physical examinations were performed on all subjects to determine: (a) the presence and degree of pelvic relaxation (cystoceles and rectoceles); (b) atrophic vaginitis; and (c) presence of urine loss with stress maneuvers. The following criteria were used to grade cystoceles: (a) *first degree* — the appearance of a slight protrusion; (b) *second degree* — protrusion at the introitus; and (c) *third degree* — protrusion beyond the introitus (20). A similar grading scale was used for rectoceles. Atrophic vaginitis was diagnosed by a pale vaginal mucosa with decreased rugae and/or localized areas of vaginitis in the posterior fornix and around the urethral orifice (20). The presence of stress incontinence due to SI was evaluated by requiring subjects to drink 400 cc of water approximately 45 minutes before coughing or bearing down in a supine and/or standing position. SI was considered to be present if a spurt of urine loss was noted immediately upon coughing or bearing down.

Urodynamic evaluations were performed as the final step in the study selection process and again upon completion of treatment as described previously (17). All investigations were conducted using a Dantec 2100 urodynamic system that included a six-channel recorder and a uroflometer that operates on the rotating disk principle (Dantec Medical, Santa Clara, CA) (21). Methods, definitions, and units conformed to the standards recommended by the International Continence Society except where specifically noted (1). The subjects were placed in the lithotomy position and a rectal balloon catheter was passed to monitor intraabdominal pressure. The urethra was catheterized with a size 7-French Gaeltec Microtip transducer (Medical Measurements, Inc., Hackensack, NJ) with a sensor at the distal tip and 6 cm proximally. Static urethral closure pressure profilometries were performed using an automatic puller at 1 mm per minute with the sensors oriented in the 3 o'clock position. Cystometry was next performed in the supine position with room temperature sterile water delivered via a peristaltic pump at 50 cc per minute. Cystometry was completed when the patient felt an intense urge to void. Maximal cystometric capacity was defined as the volume at which the subject felt this urge.

Dynamic urethral closure pressure profilometries were then obtained in a supine position with a full bladder and the sensors oriented as described above. Subjects were instructed to cough strongly enough every few seconds to develop at least 100 cm H_2O intravesical pressure. Static and dynamic urethral closure pressure profilometries were again performed in the standing position. Subjects without uninhibited contractions while supine underwent cystometry in the standing position with additional detrusor provocation produced by heel bouncing and running water. A diagnosis of stress incontinence due to SI was made if subjects lost spurts of urine with coughing and/or straining upon physical examination in either the supine or erect position and demonstrated detrusor stability on cystometrogram. MI was diagnosed when subjects lost urine while performing stress maneuvers on physical examination, evidenced detrusor instability (DI), defined as the presence of uninhibited contractions during cystometry while attempting to inhibit voiding, and lost urethral closure pressure on dynamic urethral closure pressure profilometries. Loss of urethral closure pressure was defined on dynamic urethral closure pressure profilometries by evidence of at least one deflection between bladder neck and the point of maximal urethral pressure showing complete loss of urethral closure pressure with the remaining deflections in this area demonstrating greater than a 50% loss of their baseline urethral closure pressure.

Behavioral treatment. — Biofeedback treatment for urinary incontinence was accomplished through the use of a vaginal probe (EMS-10, EMS-20, Farrall Instruments, Grand Island, NE) attached to an electromyograph (J&J Model M-53) and digital integrator (J&J Model D-200) (J&J Enterprises, Biomedical Instruments, Inc., Warren, MI) as described previously (22). A computer program designed specifically for this clinical trial (Technical Computer Services, Buffalo, NY) sampled EMG activity at one-second intervals and displayed the data as a line graph on a microcomputer (IBM-XT). This display corresponded to the subject's muscle contraction around the vaginal probe and provided visual feedback of the subject's performance. A nurse, trained in biofeedback techniques, coached all study subjects to relax and contract the pelvic muscles for 3 seconds (quick flicks), then relax again until the precontraction reading was obtained. The second type of exercise required the subject to contract, attempt to sustain the contraction for 10 seconds, and again relax to a precontraction resting state. This protocol was performed 10 times at each of eight weekly biofeedback sessions. The pelvic muscle exercise protocol was described to both groups in a 12-minute videotape. All subjects performed pelvic muscle exercises beginning with 4 sets of 20 (10 quick and 10 sustained) and increased by 10 per set over 4 weeks until a daily maximum of 200 exercises was attained (10,20). Each subject received a pamphlet that further explained the pelvic anatomy, pelvic exercises, and completion of the urine-loss-and-exercise diary. In addition, a personalized exercise schedule was mutually established by the subject and nurse therapist. Approximately 25–35 minutes per visit were spent in eight weekly intervention visits for both treatment groups. Treatment consisted of reviewing diaries and urine loss progress (both groups) and further exercise instruction (Group 1) or biofeedback therapy (Group 2). To enhance treatment compliance, the following cuing procedures were used with both treatment groups: weekly and 3- and 6-month telephone reminder calls for appointments and exercise reminder cards between follow-up visits. In addition, subjects were counseled that they would need to continue the exercises on a daily basis and return for reevaluation of their incontinence symptoms 3 and 6 months postintervention.

Subjects randomized to the control group were assigned to 8 weeks without treatment, diary completion, or contact with study personnel. During the eighth week, these subjects were contacted and told to begin keeping a urinary diary for the next 2 weeks and given an appointment for a follow-up urodynamic evaluation. Upon completion of their second urodynamic evaluation, all control subjects received their choice of either treatment.

Outcome measures. — The major subjective outcome measure was self-reported urine losses. All subjects kept a 24-hour diary of the following urinary activities: time of normal voids; time of urine loss episodes; and type of activity associated with urine loss (i.e., coughing, sneezing, laughing, etc.). For the treatment groups, these diaries were kept 2 weeks prior to randomized treatment assignment, during the 8 weeks of treatment, 2 weeks following treatment completion, at the 3-month follow-up (20–21 weeks), and at the 6-month follow-up (32–33 weeks). For the control group, these diaries were kept 2 weeks prior to randomization and 2 weeks following the 8-week nontreatment period. Severity of the urine loss problem was considered as a potential influence on subsequent outcome measures. Severity was defined as the frequency of losses indicated on the preintervention urinary diaries. Subjects were categorized into three subgroups: mild (7 or fewer losses per week); moderate (8 to 21 losses per week); and severe (22 or more losses per week).

Treatment outcomes were also analyzed using the electromyograph measures obtained during performance of a series of sustained pelvic muscle contractions. Pelvic muscle activity was recorded using a perineometer and a J&J electromyograph. Electromyograph activity (in microvolts) for the quick contractions was obtained at one-second intervals over 3 seconds. The strongest voltage recorded was termed the "peak contraction." Subjects then relaxed for 10 seconds or until they resumed a baseline reading. This procedure was repeated five times with an average of the five peak quick contractions comprising the dependent electromyograph measure. Pearson correlations of the peak measures had a mean of .90 with a range of .83 to .93. Electromyograph activity (in microvolts) for the sustained contractions was obtained at one-second intervals over 10 seconds. The strongest voltage recorded was again termed the "peak contraction." The sustained contraction score was derived by averaging the peak microvoltage with four subsequent one-second readings. An average of five of these scores comprised the dependent sustained electromyograph measure. Pearson correlations of the five sustained measures again showed statistical consistency with a mean of .89 and a range of .78–.95.

Urodynamic outcome measures used for evaluating treatment effectiveness were changes in maximal urethral closure pressure and functional urethral length as measured during urethral pressure profilometry with a full bladder in the standing position. These measures were chosen in an attempt to demonstrate the effects of our interventions on the urethral sphincteric mechanism. Maximal urethral closure pressure was defined as the maximum difference between the urethral pressure and the intravesical pressure. The procedure was performed twice on a majority of subjects with high correlation between the two measures ($r = .86$, $p < .001$). Functional urethral length was defined as the length of the urethra along which the urethral pressure exceeds intravesical pressure (1). As with the urethral closure pressures, the procedure was performed twice. The correlation between these two measures was also highly significant ($r = .94$, $p < .001$), indicating a reliable measurement procedure. For both maximal urethral closure pressure and functional urethral length, an average of the first and second measurements was used as the dependent variable. For the occasional subject that could not perform both repetitions of the measures, we used the first or sole measurement for statistical analyses. However, obtaining these measures in the standing position proved too rigorous for our more frail subjects, resulting in only 94 subjects with valid MUCP and FUL measurements.

Statistical analyses. — A variety of data analysis methods were used to evaluate the impact of treatment on the primary dependent measure of urine loss. Initially, analysis of variance was employed using postintervention urine loss as the dependent variable, and treatment groups (pelvic muscle exercise, biofeedback, and control) and incontinence frequency level (mild, moderate, and severe) as the independent factors. Because the trial's main interest was to determine the relative effect of the treatments, specific a priori treatment group contrasts were performed (biofeedback vs control, biofeedback vs pelvic muscle exercise, and pelvic muscle exercise vs control). In addition, because impact could have varied as a function of frequency (23), between-treatment group contrasts were also made within levels of this factor.

The impact of treatment on urine losses was also evaluated using percentage of improvement categories. Percentage of improvement was calculated with the following formula:

$$\frac{\text{(Preintervention losses - postintervention losses)}}{\text{Preintervention losses}} \times 100$$

Categories were formed for 100% improvement (cured subjects), 50–99% improvement, and less than 50% improvement. Chi-square tests were then performed within each category to assess whether differences existed between treatment groups.

Repeated measures analysis of variance was used to assess the stability of improvement across time. Percentage of improvement was calculated relative to preintervention losses for postintervention, 12-week, and 24-week follow-up time periods. Stevens (24) indicates that repeated measures is the appropriate analysis to employ when assessing performance trends over time. The Statistical Package for the Social Sciences (SPSS) (25) was utilized, with repeated measures contrasts specified for the within–subjects repeated measure. In this analysis, the repeated measures consisted of postintervention percent of improvement, 3-month follow-up percent of improvement, and 6-month follow-up percent of improvement. The between–subjects factors in this analysis were treatment groups (biofeedback and pelvic muscle exercise) and incontinence frequency (mild, moderate, and severe). Univariate statistics with Greenhouse-Geisser (26) adjustment for degrees of freedom were reported in this study. However, results from multivariate tests were also significant.

A repeated measures analysis of variance was performed to assess whether the pattern of change over time differed for the two treatment groups, to discern when the treatment had a significant impact on the urine loss problem, and to ascertain whether the time course of response to treatment differed for the two treatment groups. The contrasts specified for use in the analysis consisted of differences between adjacent weeks. Significance tests were obtained for the contrasts to assess when the treatment had an initial significant impact. Simple effects tests within specific treatment groups were also performed to ascertain whether the significant point of impact differed for the two treatment groups.

For the other dependent measures — EMG sustained contractions, functional urethral length, and maximal urethral closure pressure — separate analyses of covariance were used. The preintervention measures were used as the covariate, postintervention measures as the dependent variable, and treatment groups as the independent factor. Between-treatment group contrasts were also employed, to more specifically assess the relative effects of the treatments.

RESULTS

Participant characteristics. — Throughout the clinical trial period (3 1/2 years), 135 women met study criteria and were randomized. Ten women withdrew during treatment (7% attrition rate), and two subjects lacked complete urinary diaries. Data are reported on a final sample of 123 subjects. Table 1 presents the sociodemographic characteristics of this sample (n = 123) according to treatment groups. The average subject's age was 62 years with only 4% in the oldest age range (75 or older). They were mainly White (98%) and middle class (57%) with a majority (61%) having received at least some high school education.

Table 1 shows that the distributions for pelvic relaxation, atrophic vaginitis, bladder capacity, maximal urethral closure pressure, and functional urethral length were equivalent for the three clinical trial groups. Fifty-six percent had first degree cystoceles, 19% had second degree cystoceles, 36% had first degree rectoceles, 7% had second degree rectoceles, and approximately 50% were experiencing atrophic vaginitis. Eighty-nine percent had experienced urethral dilatations and 28% urethral suspensions as previous treatment for incontinence. Estrogen therapy was being used by 25% of the total sample. This percentage was evenly distributed among the three groups. Urodynamic parameters showed that 73% of the subjects had bladder capacities between 200–399 cc with an average capacity of 328 ± 87 cc for the entire sample. Functional urethral length measured in the standing position with a full bladder averaged 20 ± 6 mm. The overall average urethral closure pressure was 30 ± 16 cm H_2O. Of the 123 subjects, 112 were diagnosed with SI and 11 with MI. The distribution of subjects with MI was relatively equivalent between groups, with four each in the biofeedback and control groups, and three in the pelvic floor exercise group.

Table 1. Sociodemographic, Gynecologic Findings, and Urodynamic Measures of Study Subjects

	Biofeedback n (%)	Pelvic Exercises n (%)	Control n (%)	Total n (%)
Age				
50–64	25 (63)	30 (70)	26 (65)	81 (66)
65–75	14 (35)	10 (23)	13 (33)	37 (30)
75 +	1 (2)	3 (7)	1 (2)	5 (4)
Mean ± *SD*	63 ± 6	63 ± 6	63 ± 5	63 ± 6
Education				
<High school	15 (38)	16 (37)	17 (43)	48 (39)
High school	25 (62)	27 (63)	23 (57)	75 (61)
Gynecologic findings				
Cystocele	31 (78)	28 (65)	33 (83)	92 (75)
First degree	21 (53)	21 (49)	27 (68)	69 (56)
Second degree	10 (25)	7 (16)	6 (15)	23 (19)
Rectocele	16 (40)	22 (51)	15 (38)	53 (43)
First degree	14 (35)	18 (42)	12 (30)	44 (36)
Second degree	2 (5)	4 (9)	3 (8)	9 (7)
Atrophic vaginitis	18 (45)	20 (47)	23 (58)	61 (50)
Estrogen therapy	12 (30)	10 (23)	9 (23)	31 (25)
Previous urethral procedures				
Dilatations	34 (85)	38 (88)	37 (93)	109 (89)
Suspensions	7 (18)	10 (23)	17 (43)	34 (28)
Bladder capacity				
≤199 ml	0 (0)	3 (7)	3 (8)	6 (5)
200–399 ml	35 (88)	28 (65)	28 (70)	91 (73)
≥400 ml	5 (12)	12 (28)	9 (22)	26 (22)
Mean ± *SD*	321 ± 76	340 ± 101	322 ± 83	328 ± 87
Maximal urethral closure pressure*				
Mean ± *SD*	30 ± 13	31 ± 19	29 ± 18	30 ± 16
Functional urethral length*				
Mean ± *SD*	21 ± 6	21 ± 8	18 ± 5	20 ± 6

*Due to lack of complete pre/post measures there were 10 pelvic floor exercise, 8 biofeedback, and 11 control subjects.

Assessment of equivalence of experimental and control groups. — To determine if the experimental groups were equivalent at the onset of treatment, baseline measures for the dependent variables (frequency of urine loss, maximal urethral closure pressure, functional urethral length, and electromyograph measures) were subjected to ANOVAs. No significant treatment group or block effects (time of entry into the study) were found, suggesting that the randomization process was successful and that time of entry into the study was not an influential factor on outcome measures. Treatment block was eliminated from postintervention evaluation because of a lack of any significant effects on these preliminary analyses.

To assess the independence of urine loss frequency from treatment groups, a chi-square analysis was performed. The analysis yielded a nonsignificant chi square, χ^2 (df = 4, n = 123) = 3.2, indicating that frequency levels were relatively equivalent across group assignment.

Effects of treatments on symptoms. — Effects of treatments on symptoms are summarized in Table 2. ANOVA revealed a significant effect on number of urine losses for treatment groups ($p < .001$). Group contrasts revealed that relative to the control group, both the biofeedback ($p < .001$ [61% fewer losses]) and pelvic muscle exercise group ($p < .001$ [54% fewer losses]) at completion of treatment showed significantly decreased losses. However, no significant difference was found between the biofeedback and pelvic muscle exercise group ($F = 1$).

The main effects for severity of incontinence frequency ($p < .001$) and the severity of incontinence frequency by treatment group interaction ($p < .005$) were also significant. The interaction was probed with separate ANOVAs within each urine loss frequency level in order to determine if treatment had a differential impact based on frequency of baseline urine loss. Relative to the control group, for all three urine loss frequency levels, both the biofeedback and pelvic muscle exercise groups showed significantly fewer episodes (all p's $< .01$). The pattern of means in Table 2 shows that the two treatments had similar impacts on mild, moderate, and severe urine loss groups (all F's < 2).

The above analyses were also performed using previous urethral suspensions as a factor. No significant effects were found that could be attributed to previous surgery (all F's $<$ 1), suggesting that the treatments had a similar impact on subjects with or without urethral suspensions, obviating the need to consider this as a factor in the analyses.

Time course of response to treatment. — Repeated measures ANOVAs on self-reported urine losses over the 8 weeks of intervention using groups (biofeedback and pelvic muscle exercise) and severity of incontinence frequency as the independent factors found no significant overall differences in the time course of response to treatment between the two intervention strategies (Figure 1). Similarly, no significant differences between interventions were found in adjacent week changes (all F's <2). Analyses within each treatment group showed that both biofeedback ($p < .008$) and pelvic muscle exercises ($p < .01$) led to significant decreases in losses by the third intervention week.

The overall initial analysis also showed a significant time by severity of incontinence frequency interaction ($p < .001$). The impact of treatment across the intervention period was assessed for the mild, moderate, and severe symptom subgroups (Figure 2). Repeated measures ANOVAs showed no significant pattern of decline in urine loss frequency in the mild symptom group over the 8-week intervention period ($F < 1$). There were no significant changes from week to week and no significant linear or curvilinear trends. The moderate and severe symptom groups each showed significant patterns of decline over the 8-week intervention period, significant linear trends ($p < .001$), and significant weekly declines for weeks 3 and 8 (moderate) and weeks 2, 4, and 7 (severe).

Table 2. Urine Loss Improvement as a Function of Treatment Groups and Frequency of Incontinence

	Losses/Week	Overall (Mean ± *SD*)			% of Subjects by % of Improvement*		
Group Assignment	*N*	Pre/Rx	Post/Rx	% of Improvement	≤0–49	50–99	100
Biofeedback	40	13 ± 12	5 ± 6	61†	32†	45‡	23§
Mild	13	4 ± 2	2 ± 2	63§	39	23	39
Moderate	19	12 ± 4	5 ± 5	57§	37	47	16
Severe	8	32 ± 12	11 ± 8	68§	12	75	13
Pelvic exercises	43	18 ± 15	8 ± 10	54†	40†	44‡	16§
Mild	10	4 ± 2	1 ± 2	76§	10	30	60
Moderate	19	13 ± 4	6 ± 6	44§	48	47	5
Severe	14	34 ± 14	16 ± 11	52§	50	50	0
Control	39	18 ± 18	17 ± 19	6	82	15	3
Mild	14	4 ± 1	4 ± 2	0	86	14	0
Moderate	14	12 ± 3	13 ± 7	−10	86	7	7
Severe	12	40 ± 18	36 ± 23	12	75	25	0

*Because of rounding, percentages do not total 100.
†$p < .001$ compared to controls.
‡$p < .005$ compared to controls.
§$p < .05$ compared to controls.

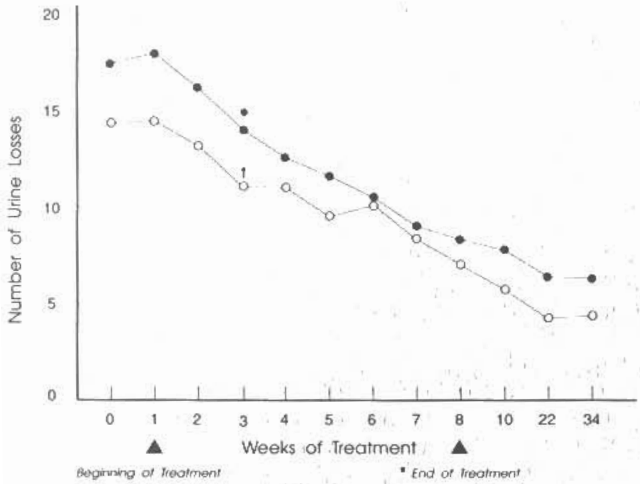

Figure 1. Weekly number of urine losses during treatment and follow-up periods as a function of treatment group. —●— represents those subjects in the pelvic floor exercise group. —○— represents those subjects in the biofeedback group. *$p < .05$; †$p < .001$.

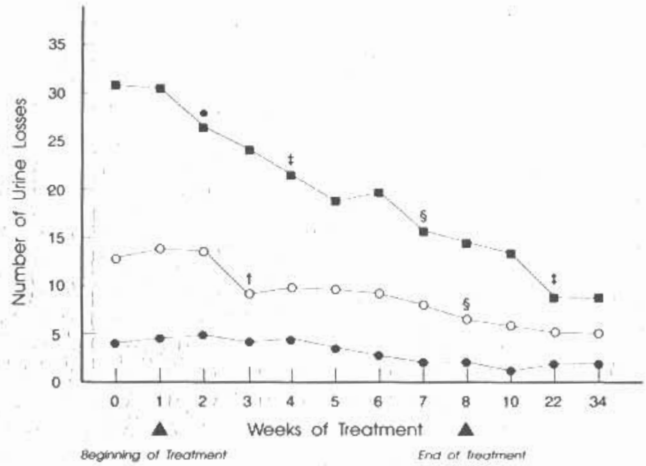

Figure 2. Weekly number of urine losses by severity of incontinence during treatment and follow-up. —●— represents those subjects with mild symptoms. —○— represents those subjects with moderate symptoms. —■— represents those subjects with severe symptoms. *$p < .005$; †$p < .001$; ‡$p < .01$; §$p < .05$.

Percentage and stability of symptom improvement. — Twenty-three percent of biofeedback subjects and 16% of pelvic muscle exercise subjects had complete remission of symptoms compared to only 3% of control subjects (Table 2). As compared to controls, significantly more subjects in the biofeedback ($p < .05$) and pelvic muscle exercise groups ($p < .01$) demonstrated a 50–99% reduction in urine losses. In contrast, significantly more subjects in the control group than in the intervention groups (biofeedback [$p < .01$] and pelvic muscle exercise [$p < .05$]) did not attain what was considered a minimal level of reduction in urine losses (50%).

The repeated measures ANOVA on the percent of improvement across the postintervention, 12-week, and 24-week follow-up periods revealed only a significant severity of incontinence frequency by time interaction ($p < .05$), suggesting that maintenance was dependent upon frequency of initial urine loss. Simple effects tests indicated that the mild group ($p < .007$) had a significant worsening of their symptoms across the follow-up period. This was reflected by a reduction from nine to five subjects, and from five to three subjects, with complete remissions at intervention completion, and at 3-month and 6-month follow-ups, respectively. In contrast, Figure 2 shows the severe group had a significant improvement from postintervention to the 3-month follow-up period ($p < .01$) and maintained a stable degree of improvement through the 6-month follow-up period ($F < 1$). Considering 100% cure rates for the severe symptom group, the one subject who showed 100% improvement at postintervention continued as a complete cure through the 3-month follow-up, and an additional four subjects experienced a 100% improvement from preintervention. Four of the five subjects who were completely cured at 3 months continued to have complete remission at 6 months, with the lone exception showing a reduction to 93% improvement. The moderate symptom group maintained stable rates of improvement through 6 months of follow-up ($F < 1$). In this group, of the four complete remissions, only three had follow-up data available. At 3 months postintervention, one subject maintained a 100% improvement rate, while the other two subjects reduced to 73% and 87%, respectively. In addition, two more subjects showed complete reduction of symptoms. The three cured subjects continued to be symptom-free at the 6-month follow-up, and an additional seven subjects had a complete remission of symptoms.

Table 3. Treatment Changes in Maximal Urethral Pressure (MUCP), Functional Urethral Length (FUL), and Electromyograph (EMG) Measures

Group Assignment	MUCP ($cm H_2O$)* (Mean ± *SD*)	FUL ($cm H_2O$)* (Mean ± *SD*)	EMG (Microvolts) (Quick)	EMG (Microvolts) (Sustained)
Biofeedback	(n = 32)		(n = 40)	(n = 35)
Pre	28 ± 13	20 ± 6	3.5 ± 3.0	2.0 ± 1.5
Post	28 ± 12	21 ± 6	6.0 ± 5.1	4.0 ± 3.1
Pelvic exercises	(n = 33)		(n = 38)	(n = 33)
Pre	32 ± 18	21 ± 8	2.9 ± 3.2	1.7 ± 1.6
Post	31 ± 18	20 ± 4	3.0 ± 3.4	1.8 ± 2.0
Control	(n = 29)		(n = 40)	(n = 34)
Pre	27 ± 12	18 ± 5	3.4 ± 3.9	1.8 ± 1.5
Post	30 ± 19	18 ± 6	3.5 ± 4.4	2.0 ± 1.8

*Measures obtained in standing position with full bladder.

Pelvic muscle performance and urodynamic parameters. — Table 3 shows urodynamic parameters and pelvic muscle EMG contraction scores, before and after intervention. In a previous publication (17) we noted the biofeedback group's postintervention quick contraction EMG scores increased significantly more than those of the pelvic muscle exercise or control groups (neither of which showed significant increases). Similar results were found for sustained pelvic muscle contractions, with the biofeedback group showing significantly more improvement than the pelvic muscle exercise group ($p < .001$) and the control group ($p < .005$). Noteworthy were the significant correlations between percentage of improvement in incontinent episodes and increases in electromyograph performance on both quick ($r = .26$, $p < .005$) and sustained ($r = .22$, $p < .03$) pelvic muscle contractions.

Significant preintervention relationships were also found between urine losses and functional urethral length ($r = -.29$, $p < .005$) and maximal urethral closure pressure ($r = -.19$, $p < .05$). As shown by the negative direction of these correlations with urine losses, the lower the urethral closure pressure and the shorter the functional length, the greater the urine loss frequency reported by the subjects. In contrast, the relationship between postintervention measures was no longer significant, and analysis of covariance (ANCOVA) revealed that neither intervention significantly changed maximal urethral closure pressures or functional urethral lengths. Considering that subjects did decrease their urine losses, these findings suggest that other factors were catalysts for the improvement.

Discussion

This controlled trial demonstrated the efficacy of pelvic muscle exercises and biofeedback in reducing incontinence due to SI in older women. These findings confirm results from earlier studies lacking untreated controls (9–16). Both behavioral treatments had significant effects on rates of complete remission and on symptom frequency (27–30). The trial also demonstrated that older women will accept and maintain these regimens with a low attrition rate, and that beneficial effects are maintained at least 6 months after completion of the initial intervention.

Although differences in treatment effects between the pelvic muscle exercise and biofeedback groups were not significant, our findings raise the possibility that biofeedback might be more effective than pelvic muscle exercises for some individuals. The somewhat higher success rate in the biofeedback group is consistent with earlier studies (11,12). Our data suggest that for moderate and severe incontinence frequency, biofeedback may be more effective than pelvic muscle exercise alone and vice versa for mild urine loss symptoms. Evidence for this can be found in percent of improvement categories in Table 2. As shown, 90% of pelvic muscle exercise subjects with mild frequency showed at least 50% improvement in comparison to 62% in the biofeedback group. In contrast, for those subjects with moderate urine loss frequency, 63% of the biofeedback and only 52% of the pelvic muscle exercise group had at least a 50% reduction rate; for those subjects with severe frequency, 88% of the biofeedback group and only 50% of the pelvic muscle exercise group had a similar 50% reduction. While the treatment group comparisons (pelvic exercises vs biofeedback) did not show significance, the effect size for these comparisons was only .10 yielding a power of .17. Given this small effect size (31), at least 300 subjects per treatment would be necessary to have adequate power to detect significance at the .05 level.

The significant correlation we observed between changes in electromyograph scores and improvement in self-reported urine losses suggests that the ability to increase pelvic muscle activity may be a factor in decreasing urine loss symptoms. However, this should be considered a preliminary finding given that the relationship accounted for only 5% and 7% of the variance in improvement of urine loss. Significant relationships among maximal urethral closure pressure, functional urethral length, and urine loss were found prior to intervention; however, this finding was not sustained postintervention. The fact that incontinent episodes significantly decreased without a corresponding increase in urethral closure pressure or functional urethral length suggests that the reduction of incontinence by biofeedback/pelvic exercises may be due to an influence on other parameters affecting the continent mechanism. One such possibility is that behavioral treatments may sharpen the pelvic muscle response to sudden increases in intraabdominal pressure.

Maintenance of symptom improvement was not only stable but also showed an increased cure rate over the 6-month follow-up in subjects with moderate and severe symptoms. However, incontinence increased at the 3- and 6-month follow-ups for those with mild symptoms. Figure 2 indicates that at the 6-month follow-up, the severe symptom subjects were now almost similar to the mild frequency subjects (averaging slightly more than one loss per day), and the moderate frequency subjects were actually experiencing mild symptoms (<1 loss/day). The declining linear trend in incontinence frequency for subjects with severe and moderate symptoms may motivate these subjects to sustain their efforts to maintain improvement after the intervention ends. Those women with mild symptoms may not perceive their incontinence as a problem warranting sustained effort, while women with many daily losses recognize it as a problem and put forth persistent effort as positive response occurs. Design and analysis of subsequent clinical trials of behavioral therapies for incontinence should take into account the possible effects of such factors on long-term compliance and outcomes.

The magnitude of symptom reduction with pelvic muscle exercises or biofeedback and the proportion of patients with total remission of symptoms, though lower than reported for surgical procedures, indicate that these techniques may be valuable initial therapeutic steps for older women with stress incontinence, especially considering their safety and low cost (32–34). A recent report also indicates that pelvic muscle exercises have comparable efficacy to pharmacologic treatment for stress incontinence (9). Several studies have reported efficacy with fewer pelvic muscle contractions than the 200 per day required in this study's protocol. It would be useful to determine if a less intense version of this regimen is equally efficacious.

Recently, similar rates of improvement (but slightly lower cure rates) were reported in a slightly older population of community-dwelling women with stress and mixed incontinence using an alternative behavioral technique (i.e., bladder training) (23). The possible benefits of combining bladder training with pelvic muscle exercise and/or biofeedback remain to be explored.

The generalizability of this study's findings are limited to cognitively intact, middle-class, community-dwelling women age 55 or older with SI. Further studies should be conducted with a more heterogeneous sample of varying socioeconomic levels and ages. Future research should also analyze the effectiveness of pelvic muscle exercises and adjunctive biofeedback on other types of incontinence, especially MI. Clinical trials to evaluate treatment efficacy of urinary incontinence should consider the relationships (noted in this study) between urine loss frequency and short- and long-term treatment efficacy.

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