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Treatment of Stress Incontinence with Pelvic Floor Exercises and Biofeedback

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Recent surveys—including the Medical, Epidemiological, and Social Aspects of Aging (MESA) Survey, the National Health and Nutrition Examination Survey (NHANES), and the Established Populations for Epidemiologic Studies of the Elderly (EPESE)—estimate the prevalence rate of incontinence to be at least 30%.[1–3] In the MESA study, 37.6% of the women ($n = 1145$) had symptoms of urinary incontinence. Thirty-five percent reported a combination of urge and stress symptoms (mixed incontinence), whereas 26.7% had only stress incontinence and 9.1% reported urge incontinence. These prevalence rates rise to over 50% in institutionalized populations.[4,5]

Numerous medical, surgical, and behavioral treatment modalities have been reported in the literature.[6] Yet many questions have been raised regarding the efficacy of behavioral regimens for the treatment of elderly incontinence. A consensus of the workshop on "Related Therapies for Urinary Incontinence in the Elderly," sponsored by the National Institute on Aging, proposed that the collaboration of experts in urodynamics, behavioral sciences, geriatrics, and nursing could facilitate substantial progress on this significant health problem. They recommended that multidisciplinary randomized controlled clinical trials (RCTs) be conducted to investigate various behavioral treatments for incontinence in the elderly.[7]

Research focusing on biofeedback as a behavioral incontinence treatment began with Kegel's early work with pelvic floor exercises and utilization of a perineometer. In this study, participants ($n = 455$) demonstrated a 90% reduction in urine loss. Despite these promising results, further studies were not conducted until the late 1970s.[8] Cardozo used biofeedback to treat detrusor instability in 27 patients, which resulted in an 81% reduction in symptoms.[9] Shepherd also used biofeedback as a technique in treating 11 community-dwelling women with visual feedback, as compared to 11 subjects without biofeedback. Ninety-one percent ($n = 10$) showed improvement or were cured in the biofeedback group, whereas only 55% ($n = 6$) had similar results without visual reinforcement.[10] More recently, a study of 19 stress-incontinent women conducted by Burgio et al succeeded in reducing the frequency of incontinent episodes an average of 82% after receiving bladder–sphincter biofeedback.[11] In a later study, they examined the effectiveness of teaching pelvic floor exercises with visual bladder–sphincter biofeedback as compared to verbal feedback solely during contraction of the vaginal muscles. The biofeedback group averaged a 75.9% reduction in incontinence, which was significantly greater than the 51% reduction seen in the verbal feedback group.[12]

This article describes the preliminary results from a randomized clinical trial that compared the effectiveness of biofeedback therapy with a program of pelvic floor exercises for the treatment of stress or mixed incontinence. This study improves on earlier research by using a randomized design to compare pelvic floor exercises with/without biofeedback to a similar number of control subjects.

METHODS

Study subjects, all women, were recruited from a northeastern city through advertisements, referrals from physicians, and a poster campaign.[13] Three screening techniques were used to determine eligibility for the single-blinded trial. The first screening procedure consisted of a telephone interview by the nurse coordinator. At this time, the study was explained and the nature of severity of the urine-loss problem was assessed. Candidates who were having a minimum of three losses per week proceeded to the second screening

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procedure. At this time, subjects completed an informed consent, Mini-Mental State Exam[14] and CES-D Depression Scale,[15] and were assessed for the etiology of their incontinence with a physical examination. Those who demonstrated urine loss upon increased intraabdominal pressure and had a Mini-Mental score of 23 or more proceeded to the third screening. This final screening consisted of urodynamic evaluation and urinalysis. Those individuals who received a diagnosis of stress or mixed incontinence and were free of microscopic evidence of a urinary tract infection were randomized into the study.

Urodynamic Evaluation The urodynamic assessments were performed on all subjects before beginning treatment and again at completion of eight weeks of therapy. Methods, definitions, and units conform to the standards recommended by the International Continence Society.[16] The procedure began with uroflowmetry and measurements of residual urine. Subjects with obstructive uropathy, defined as urine flow rates less than 15 mL/sec ($n = 5$) or a residual urine greater than 50 mL ($n = 5$) were eliminated from the study. The urodynamic procedure was performed using a 7-French Gaeltec microtip transducer catheter with a sensor at the distal tip and a second sensor 6 cm proximally. These sensors were positioned laterally. Maximal urethral pressure was measured during a Kegel maneuver in the lithotomy position. Static urethral closure pressure profilometry (UCPP) was performed with the bladder empty and full in the lithotomy position, and again when full in the standing position.[17] Stress profilometry (stress UCPP) was performed in the latter two positions. The static UCPPs were performed with the catheter puller and the chart recorder moving continuously at 1 mm/sec. These were repeated twice in each position, and all measurements were averaged. During stress UCPP, the procedure was carried out using the same technique with the subject coughing every two to three seconds on command. Maximal urethral closure pressure was defined as the maximal urethral pressure seen on static UCPP minus the bladder pressure. Cystometry was performed in the lithotomy position infusing room temperature water at 50 mL/min via a peristaltic pump. If detrusor instability was not identified, an additional standing position with heel bouncing and running water provocation was employed. Uroflowmetry was then repeated. The diagnosis of stress incontinence was made if the subjects: (1) lost urine with coughing and/or straining upon physical examination, in either the supine or erect position, and (2) demonstrated detrusor stability on cystometrogram with or without a loss of urethral closure pressure on stress UCPP. Mixed urinary incontinence was diagnosed when subjects: (1) lost urine while performing stress maneuvers on physical examination; (2) evidenced detrusor instability on cystometrogram; and (3) lost urethral closure pressure on stress UCPP.

Randomization Of the 1,042 women recruited, 135 met study criteria and were randomized into three groups: a Kegel exercise group (Group 1), a biofeedback with Kegel exercise group (Group 2), and a control group (Group 3). A single-blinded two experimental, one control group design was employed. The principal investigator was the only person who knew the group assignments; the remaining clinical trial personnel performed the procedures and collected outcome measures (ie, tallies of urine losses, urethral pressures, and electromyograph [EMG] readings). This design was utilized to avoid reporting biased outcome data. Randomized blocking was employed to balance the number of subjects in each group, as well as to assess the possible impact of seasonal changes and time of entry into the clinical trial on the study outcomes. This clinical trial had ten blocks of 12 subjects; the eleventh block contained 15 subjects. The two treatment groups were compared to the control group to assess the effectiveness of these interventions. The Kegel exercise group performed the following pelvic floor exercises on a progressive basis four times a day: *quick*—tighten and relax the pubococcygeus (PC) muscle as rapidly as you can; *slow*—tighten the PC muscles and hold for a slow count of three, then relax. The Kegel exercise subjects kept a daily urine-loss diary and returned to evaluate their progress once a week for eight weeks. Subjects in the biofeedback group received therapy on a weekly basis. This therapy involved a 20-minute coaching session, at which time these subjects were taught to contract and relax the pubococcygeus muscle using a vaginal probe and while observing a computer screen display of their contractions.[18,19] Study outcomes were measured by the following dependent variables: (1) episodes of urine loss; (2) pelvic muscle activity recorded on an electromyograph machine in microvolts; and (3) maximal urethral closure pressures as determined during urethral profilometry.

Sociodemographics The sample subjects were predominantly white, middle-class, married, and with a mean age of 62 years (Table 1). On average, subjects had a 12.38-year history of urine loss and reported 18 losses per week. Seventy-four percent of the sample had cystoceles, 41.5% had rectoceles, and 31.1% had both forms of pelvic relaxation. Over 40% of the sample had hysterectomies with 25.9% reporting bladder-suspension surgeries. All subjects were mentally competent (Mini-Mental Status = 29.1, SD = 1.1), and nondepressed (CES-D = 7.55, SD = 5.74). Evaluation of cystometrograms provided a diagnosis of stress incontinence for 123 individuals and mixed incontinence for the remaining 12 subjects. The overrepresentation of stress incontinent individuals in this study was a direct result of the clinical trial's aim to limit subjects to mainly

TABLE 1. SOCIODEMOGRAPHIC CHARACTERISTICS OF STUDY SUBJECTS ($n = 135$)

Sociodemographics	Response	
	n	%
Age		
55–60	61	45.2
61–70	60	44.4
≥71	14	10.4
Ethnic		
White	132	97.8
Black	3	2.2
Marital Status		
Married	95	70.4
Not married	40	29.6
Education		
Post high school	84	62.2
High school completed or less formal education	51	37.8
Income		
0–$9,999	27	20.0
$10,000–$19,999	47	34.8
$20,000–$39,999	41	30.4
$40,000 or more	20	14.8

stress urine loss, allowing a minimal selection of mixed incontinent individuals.

RESULTS

To assess whether the groups were equivalent on the dependent measures before treatment interventions, analyses of variance were performed using groups and blocks as the independent variables. The results of these analyses showed no significant groups, blocks, or groups by blocks effects for symptoms, EMG during quick contractions, or urethral closure pressures (all F values < 1). Thus, at the onset of treatment, all three groups were equivalent on these measures and neither seasons nor time of entry into the study had any impact on the sample.

Next, in order to gain an overall assessment of pre- to posttreatment improvement, a percent of improvement was calculated with the following formula:

$$\frac{(\text{Pretreatment losses} - \text{posttreatment losses})}{\text{Pretreatment losses}} \times 100$$

Analysis of variance was performed using the above measure as the dependent variable and groups as the independent factor. The use of blocks was dropped due to the lack of significant findings in the pretreatment analysis. Results indicated a significant group effect ($F[2,118] = 15.60$, $P < .001$). The Kegel exercise ($n = 43$) and biofeedback ($n = 40$) treatment groups showed similar *reductions* in losses (54% and 61% for the Kegel exercise and biofeedback groups, respectively), whereas the control ($n = 38$) group evidenced a 9% *increase* in symptoms. When group contrasts were performed, the Kegel exercise and biofeedback groups did not significantly differ from each other ($t < 1$), whereas both the Kegel exercise ($t[67] = 4.02$, $P < .001$) and biofeedback groups ($t[53] = 4.87$, $P < .001$) showed significantly greater improvement than the control group. The biofeedback group had nine complete cures (absence of urine loss), the Kegel exercise group had seven, and the control group had only one.

For subsequent analyses on the remaining dependent measures (EMG during quick contractions and urethral closure pressures) analysis of covariance was used. The pretreatment measure of the dependent variable under consideration was used as the covariate with treatment groups as the independent factor. Results for the quick contractions yielded a significant effect for groups ($F[2,115] = 6.22$, $P < .005$) and for the covariate ($F[1,115] = 57.69$, $P < .001$). As might have been expected, the covariate effect indicated that those individuals with higher contractions initially also had higher contractions at the end of treatment. The means for posttreatment quick contractions in Table 2 suggest that the biofeedback group showed improvement, whereas the other two groups did not. Group comparisons confirmed this, showing that the biofeedback group improved significantly more than did both the Kegel exercise group ($F[1,75] = 8.75$, $P < .005$) and the control group ($F[1,78] = 7.73$, $P < .007$), whereas the Kegel exercise and control groups did not differ from one another ($F < 1$). Of importance for this finding is the significant negative relationship found in all study subjects between pretreatment symptoms and pretreatment EMG quick contractions ($r = -.15$), indicating that weak contractions were associated with a greater number of urine losses.

For urethral closure pressures, the covariate was again significant ($F[1,83] = 28.85$, $P < .001$), indicating higher pretreatment closure pressures were associated with higher posttreatment pressures (Table 3). The groups' effect was not significant ($F < 1$), suggesting that neither the biofeedback nor Kegel exercise treatment programs had any influence on increasing resting urethral closure pressure.

TABLE 2. ELECTROMYOGRAPH CONTRACTIONS AS A FUNCTION OF STUDY GROUP*

Group	Pretreatment		Posttreatment	
	$\bar{X}$	SD	$\bar{X}$	SD
Kegel exercise ($n = 38$)	2.85	3.23	3.00	3.37
Biofeedback ($n = 40$)	3.50	3.00	5.96	5.06
Control ($n = 40$)	3.43	3.92	3.49	4.44

**Quick contractions measured in microvolts (MCV). See text for statistical analyses.*

TABLE 3. MEAN URETHRAL CLOSURE PRESSURES* AS A FUNCTION OF STUDY GROUP

Group	Pretreatment $\bar{X}$	Pretreatment SD	Posttreatment $\bar{X}$	Posttreatment SD
Kegel exercise ($n = 30$)	30.87	14.45	30.20	14.04
Biofeedback ($n = 30$)	28.43	3.00	28.73	12.19
Control ($n = 27$)	31.06	16.51	28.06	11.02

Standing position with full bladder measured in cm H_2O. See text for statistical analyses.

DISCUSSION

Several interesting findings emerge from these preliminary analyses. A significant decrease in symptoms occurred in both Kegel exercise and biofeedback treatment groups, suggesting that both behavior-based treatments have a role in the therapeutic management of stress/mixed incontinence. The reduction in symptoms found in this study are comparable to those obtained in prior research, but further comparison of methodologies and outcomes appears to be warranted.[9–12] Also, these findings have limited generalizability because of the homogeneous sample of female subjects whose symptoms were due almost exclusively to stress incontinence alone.

Although these two treatments showed similar impact on self-reports of urine loss, a significant differential effect was seen on the EMG readings. The biofeedback group significantly increased the EMG scores on quick contractions over either the Kegel exercise or control group ($P < .007$). Biofeedback provided a mechanism for clients to identify the appropriate muscle as well as a sense of accomplishment as they increased their contraction scores. Of added importance is the fact that these EMG scores were negatively correlated with urine losses; therefore, any subject who achieved a higher EMG reading would have a greater decrease in symptoms.

Future analysis of biofeedback as a behavioral treatment should focus on ascertaining whether a significant differential effect occurs according to symptom severity. In addition, because of the marginal effect of biofeedback as an adjunctive therapy to pelvic floor exercises, it appears appropriate to target women who are most likely to demonstrate significant improvement. Further data analysis should be directed at an investigation of long-term treatment compliance and its effects.

REFERENCES

1. Diokno AC, Brock BM, Brown MB, Herzog AR: Prevalence of urinary incontinence and other urological symptoms in the noninstitutionalized elderly. J Urol 135:1022, 1986
2. Harris T, Guralnik J, Madans J: The National Health and Nutrition Survey I Follow-up: prevalence and correlates of urinary incontinence in community dwelling elders. Presented at the 39th Annual Scientific Meeting of the Gerontological Society of America, Chicago, 1986
3. White LR, Kohout F, Evans DA, et al: Related health problems, *in* Cornoni-Huntley J, Brock DB, et al (eds): Established populations for epidemiologic studies of the elderly: resource data book. Washington, DC, National Institute on Aging, U.S. Department of Health and Human Services, 1986
4. Ouslander JG, Kane RL, Itamar B, et al: Urinary incontinence in elderly nursing home patients. JAMA 248(10):1194, 1982
5. Resnick NM: Urinary incontinence: a major health care issue for older women. Public Health Rep 102:67, 1987
6. Bissada N, Finkbeiner A: Nondiversionary Surgical and Mechanical Methods of Treatment: Lower Urinary Tract Function and Dysfunction Diagnosis and Management. New York, Appleton-Century-Crofts, 1978, p 93
7. Hadley E, Abbey J, Awad S, et al: "Bladder training" and related therapies for urinary incontinence: prospects and problems for clinical trials in the elderly. Workshop proceedings sponsored by the National Institute on Aging, Bethesda, MD, April 26, 1983
8. Kegel A: Stress incontinence of women: physiological treatment. J Int Coll Surg 25:484, 1956
9. Cardozo LD, Abrams PD, Stanton SL, et al: Idiopathic bladder instability treated by biofeedback. Br J Urol 50:521, 1978
10. Shepherd AM, Montgomery E: Treatment of genuine stress incontinence with a new perineometer. Physiotherapy 69(4):113, 1983
11. Burgio KL, Whitehead WE, Engel BT: Urinary incontinence in the elderly. Ann Intern Med 104:507, 1985
12. Burgio KL, Robinson JC, Engel BT: The role of biofeedback in Kegel exercise training for stress urinary incontinence. Am J Obstet Gynecol 154:58, 1986
13. Burns P, Calucci-Pakosz R, Reis J, et al: Recruitment and treatment maintenance strategies for elderly stress incontinent females. Proceedings of the Third Joint Meeting of the International Continence Society and the Urodynamics Society, Boston, 1986, p 364
14. Folstein MF, Folstein S, McHugh PR: Mini-Mental State: a practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res 12:189, 1975
15. Radloff LS: The CES-D Scale: a self-report depression scale for research in the general population. Appl Psychol Measurement 1:385, 1977
16. Abrams P, Blaivas JG, Stanton SL, et al: Standardisation of terminology of lower urinary tract function. Neurourol Urodynam 7:403, 1988
17. Asmussen M, Ulmsten U: A new technique for measurements of the urethra pressure profile. Acta Obstet Gynecol Scand 55:167, 1976
18. Burns P, Marecki M, Dittmar S: Kegel's exercises with biofeedback therapy for treatment of stress incontinence. Nurs Pract J 10(29):34, 1985
19. Neeson J, Stockdale C: The Practitioners Handbook of Ambulatory OB/GYN. New York, John Wiley & Sons, 1981, p 320