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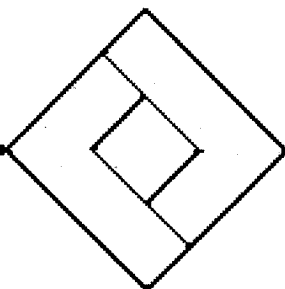
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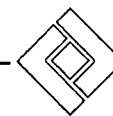
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A Self-directed Home Biofeedback System for Women With Symptoms of Stress, Urge, and Mixed Incontinence

Dorothy B. Smith, RN, MS, CWOCN, FAAN, Michel A. Boileau, MD, and Lisa D. Buan, BS

Purpose: To evaluate a self-directed home biofeedback treatment system in a group of community dwelling, otherwise healthy women with symptoms of stress, urge, and mixed urinary incontinence (UI).

Setting and subjects: Fifty-five women, aged 25 to 81 years, participated in the study.

Methods: Initial evaluation included a self-reported continence assessment, a 24-hour bladder and fluid habits diary, severity indices for stress and urge UI, and assessment of pelvic floor strength using a pneumatic biofeedback device. Subjects completed a 16-week self-directed program. Assessment and severity index data were self-reported using a continence assessment form, a 24-hour bladder habit and fluid form, and stress and urge incontinence severity indices. Strength level of the trainer, number of digital bands lit on the screen during contraction, number of sessions, and program (starter, intermediate, advanced, or maintenance) were recorded on data sheets.

Instruments: The treatment system includes an 8-minute educational and motivational video; a journal for education, instructions, and daily documentation forms; and a home biofeedback trainer with pneumatic vaginal sensors that displays the strength of pelvic muscle contraction.

Results: Forty-four women completed the 16-week program. At the end of treatment, 19 (43%) were dry and 16 (36%) reported 50% or more improvement in number of leaks per day, number of voids per day, or both. Women with stress leakage experienced a significant reduction in the number of incontinent episodes per day and the mean severity index of incontinence ($P < .001$). Participants with urge UI experienced a significant reduction in the mean number of voids per day and mean severity index for UI ($P < .001$). Younger subjects were more likely to improve when compared with older participants, but no significant differences were found when comparing women who take estrogen with those who do not take estrogen or when comparing those with a history of bladder surgery with those who had no previous surgery.

Conclusions: These data suggest that self-selected healthy women with symptoms of urge, stress, and mixed incontinence can improve their symptoms and lower their severity index with a minimal intervention, comprehensive, self-directed home biofeedback continence system. (J WOCN 2000;27:240-6)

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Urinary incontinence (UI) is a major health problem that affects approximately 25 million Americans^{1,2} and costs more than \$26 billion annually.³ Appell⁴ states that UI affects quality of life more than any other medical condition except depression. As the population of older women steadily increases, the national cost burden related to incontinence becomes enormous in terms of decreased quality of life, lost economic productivity, and direct health care costs. However, the problem is not limited to the aged. In a study of 144

female, nulliparous college athletes (mean age 19.9 years) by Nygaard and colleagues,⁵ 28% reported urine loss while participating in their sport. Sherman and Davis⁶ studied 450 female soldiers and found that one third had problematic UI during field training exercises. Treatment options include surgical, pharmacologic, and behavioral methods. Currently, non-surgical behavioral therapy with biofeedback for UI is most often done in a clinic or outpatient setting with a physician, nurse, or therapist present.

The Agency for Healthcare Research and Quality (AHRQ) (formerly the Agency for Health Care Policy and Research) found evidence that treating UI can improve or alleviate urine loss in most patients.⁷ A panel of experts convened by the AHRQ recommended behavioral methods as a first course of treatment for UI. Pelvic muscle exercises (PME) were recommended for women with stress incontinence, men and women with urge incontinence, and men after prostate removal. The guideline also supported PME for older adults.

PME as a recommended treatment for UI is not new. In 1948, Dr Arnold Kegel proposed progressive resistance exercises for restoration of the perineal muscles.⁸ Once thought to be primarily for women with stress incontinence, pelvic muscle exercises are now considered treatment options for men and women with stress, urge, and mixed UI.^{6,9-11} An excellent review of the literature by Palmer¹² points to the role of pelvic muscle rehabilitation as a solo treatment option for UI, a possible adjunct to surgical intervention, and a proposed method of maintaining continence in continent women. The importance of the pelvic floor muscles in producing occlusive forces on the urethra and assisting in continual continence, as well as during events of intraabdominal pressure increases, is well documented.^{13,14} Exercise of the pelvic floor muscles results in an increase in type I and II muscle fiber recruitment and an increase in contractile force of both types.^{15,16} Contraction of the pelvic muscle during or before an acute rise in abdominal pressure is a habit that can be learned during repetitive training.^{17,18} Pelvic muscle contractions also inhibit detrusor activity through the sacral reflex, which can benefit patients with urge UI.¹⁹⁻²³ In a study by Burgio and colleagues²¹ of 197 women with urge incontinence, biofeedback-assisted behavioral treatment was significantly more effective than drug treatment.

Pelvic floor re-education works in 3 ways: (1) it increases muscular strength and endurance of the pelvic floor muscles; (2) it increases the reflex action of these muscles through fast-twitch fiber recruitment; and (3) it increases awareness of these muscles.^{8,24} Two major principles of strength training are specificity (using the correct muscles) and overload (recruitment of more fibers).^{25,26} In a study by Bump and colleagues,²⁷ 50% of women

given verbal instructions about how to perform a pelvic muscle contraction were unable to perform an effective contraction. One fourth adopted a technique that could make their symptoms worse. The goals of pelvic muscle re-education are to learn the ability to produce a voluntary contraction or a trained reflex contraction (for urge symptoms) and to keep a contraction during stress situations to keep the urethrovesical junction within the abdominal cavity for sufficient pressure transmission to the urethra.

Biofeedback is sometimes discredited and called experimental therapy. However, it is widely used and accepted in clinical medicine. Examples of biofeedback devices include the sphygmomanometer, the thermometer measures temperature, the pulsometer, scales for measuring weight, and the incentive spirometer for measuring inspired air volume. Biofeedback is also a useful method for pelvic floor muscle re-education.²⁸⁻³⁰ It can be used to instruct the person about correct contractions, to maximize the contraction effort by demonstrating strength, and to show progress in strength and endurance of the muscle contraction long before symptoms improve supporting motivation. Biofeedback is also effective in treating patients with multiple voiding symptoms.³¹

Patient compliance is an issue for many types of prescribed therapies. Researchers have reviewed compliance factors with diabetic schedules, cardiac rehabilitation, allergen immunotherapy, and daily medications for conditions such as hypertension and AIDS in an effort to strengthen conformity.³²⁻³⁴ Behavioral programs depend on compliance for maximal effectiveness. Compliance is preceded by awareness of the problem, education about the solution, and motivation to succeed. The rising cost of health care and a generation of educated consumers are feeding an increase in the use of self-care, behavioral-type programs.³⁵ Programs about nutrition, exercise, rehabilitation, life-style changes, and substance abuse all have behavioral components, and compliance is essential to their success. Visual and audio aids used with behavioral programs have been shown to be effective in encouraging motivation and compliance.^{17,36-38} The use of diaries and telephone-linked care may also enhance compliance.^{15,39} Perhaps the strongest motivator for compliance is the participant's value of the outcome and ability to perceive progress toward the therapeutic goal.⁴⁰

The purpose of this study was to evaluate the effectiveness of a nonsurgical, self-directed home biofeedback treatment for stress and urge UI. The treatment system included education, awareness, pelvic muscle exercises with biofeedback in the participant's home, and telephone support.

MATERIALS AND METHODS

Procedures

Project participants were recruited at a lecture on UI sponsored by a local medical center, at a national incontinence symposium, and through brochures left at an athletic club. An introductory project letter, an initial assessment form, a 24-hour bladder/fluid habit sheet, stress and urge UI severity indices, an informed consent document, and a commitment form were mailed to the participants. The assessment form, bladder habit sheet, and severity indices were reviewed for acceptance by two nurses. Two patients were excluded from participation in the study because of a history of cerebral vascular accident and Parkinson's disease. Inclusion criteria were females with symptoms of urge, stress, or mixed UI; no history of systemic neurologic problems such as CVA, Parkinson's disease, or multiple sclerosis; intact cognition; and commitment to do the 16-week behavioral program. Remuneration for completion of the project was keeping the Persist Treatment System at no cost to the participant.

Each participant was asked to complete a data sheet of her status (by phone, mail, or e-mail) every 2 weeks. At the end of weeks 8 and 16, the participants were asked to complete their second and third continence assessments, a 24-hour bladder/fluid sheet, and urge and stress severity indices. A final program evaluation was completed at week 16.

Instruments

A treatment system was mailed to all participants. The system is a prescription home biofeedback and behavioral program for urinary incontinence. It consists of an 8-minute educational and motivational video and a journal for education, instructions, and documentation. The system also provides a personal trainer with a pneumatic sensor to measure pelvic muscle contractions and provide immediate feedback, along with software that guides the patient through preset protocols, a

Web site, a toll-free phone support line, and a quarterly educational newsletter. The participants were asked to view the video and review the instructions and practice session in the journal. They were also asked to perform 5-minute sessions of pelvic muscle exercises 3 times a day for 16 weeks. The Persist Trainer provided 3 resistance levels for increased strength development (strengths 1, 2, and 3) and a choice of 5- and 10-second contraction time, with a 10-second relax period between contraction times. The program consisted of a 5-minute session for endurance and strength training of long muscle fibers as well as a "winks" session for quick contractions and training of short muscle fibers. A pneumatic vaginal sensor was used to measure contraction strength. Feedback was provided on a liquid crystal diode screen that also guided the user through the session with instructions. The journal described 4 program levels (starter, intermediate, advanced, and maintenance), provided a calendar of suggested protocols for the 16 weeks, and included documentation forms that allowed daily recording of goals, number of sessions, program level, strength level, voids, number of leaks, pads, and fluid intake. A toll-free phone number was available to all participants Monday through Friday, 7 AM to 5 PM (Pacific Standard Time) for questions.⁴¹

Data Analysis

The Statistical Package for the Social Sciences (SPSS, Inc) Base 8.0 software was used as an aid to compute and correlate data related to severity indices, leaks, strength of contraction, and demographics. An independent consultant performed statistical analyses. Unless otherwise indicated, the *P* values reported result from either a *t* test or analysis of variance (ANOVA). Because of the assumption that a normal distribution was not achieved in many cases, an alternative nonparametric test was performed for each test to confirm results.

A 30-point urge severity index and a 27-point stress severity index were developed as self-rating scales for the participants to rate the severity of their symptoms. Although this measurement is subjective, it has value in the meaning of the symptoms to the participant. The point system was used to provide a numeric measure of symptom severity for weeks 1 and 16. Psychometric evaluation of these indices has not been completed.

RESULTS

Fifty-five healthy women with a mean age of 54 years (range 25 to 81 years) volunteered for the 16-week project. Subject characteristics are summarized in the Table. Eighteen participants were local and 37 lived throughout the continental United States. Although some of the women had visited a urologist, this characteristic was not consistent among the group and was not a prerequisite for admission to the project. Forty-four subjects completed the 16-week program, for a completion rate of 80%. Reasons given for leaving the project were as follows: newly diagnosed with interstitial cystitis, recent move, personal conflict, recurrent yeast infection, illness, alcoholism, and death of a close friend. Three participants gave no reason for not completing the project, and one person was lost to follow-up. The data and demographics in this report reflect the 44 participants who completed the study. Leaks per day, voids per day, time between voids, and strength levels were quantified measurements. Severity indices were done on a self-rating scale for both stress and urge symptoms. The participants were grouped for data review (Table).

Nineteen (43%) of the 44 participants were dry, with the criteria of zero (0) leaks per day by week 16. Another 16 (39%) gained significant improvement with a reported 50% or greater reduction in either leaks per day, voids per day, or both by week 16. The group mean for leaks per day was initially 2.9; this figure decreased to 1.1 by week 16. The mean voids per day for the group decreased from 10.8 at week 1 to 8.1 by week 16. The stress severity index decreased from 12.9 to 4.6. The urge severity index decreased from 12.4 to 5.5 (Figure 1).

Participants with symptoms of stress incontinence (stress and mixed) improved by a mean of 2.26 leaks/day, a significance of $P < .001$. Those with symptoms of urge incontinence decreased voids per day by a mean of 3.17 for a significant P value of $< .001$ (Figure 2). The difference in both the stress and the urge severity indices was significant at a P value of $< .001$. To compare the improvement of leaks per day between the 3 age groups, an ANOVA test was performed, yielding $P = .05$. A least significant difference pairwise comparison revealed a significant difference in improvement between the youngest and

Table. Characteristics of the 44 women in the project

Characteristic	No.
Age (y)*	
<40	7
41-60	25
>60	12
Parous	37
Nonparous	7
Estrogen	20
Nonestrogen	24
Hysterectomy	18
Previous bladder surgery	7
Type of symptoms	
Stress	7
Urge	8
Mixed	29
Onset of symptoms	
>2 y	22
<2 y	22
History of:	
Smoking	5
Frequent UTI	8
Depression	9
Lower back problems	6
Diabetes	1
Sessions per day	
1	14
2	23
3	7

UTI, Urinary tract infection.
*Range, 25 to 81; mean, 53.5.

oldest age groups, $P = .02$. Although each group showed an overall improvement, the differences in improvement between the youngest and middle-age groups and the middle-age and oldest groups were not significant. A statistical difference in the improvement of leaks per day between the youngest age group and the oldest age group was also found, for a P value of .05 (Figure 3). No statistical differences were found in the improvement of leaks per day between the groups that did and did not take estrogen. The estrogen group improved by 2.4 leaks per day, and the nonestrogen group improved by 2.05 leaks per day for a P value of .616. No statistical differences in the improvement of the participants related to prior bladder surgery were found. The group that did not have bladder surgery improved from 2.8 to 0.9 mean leaks per day, and the number of leaks per day of those who had

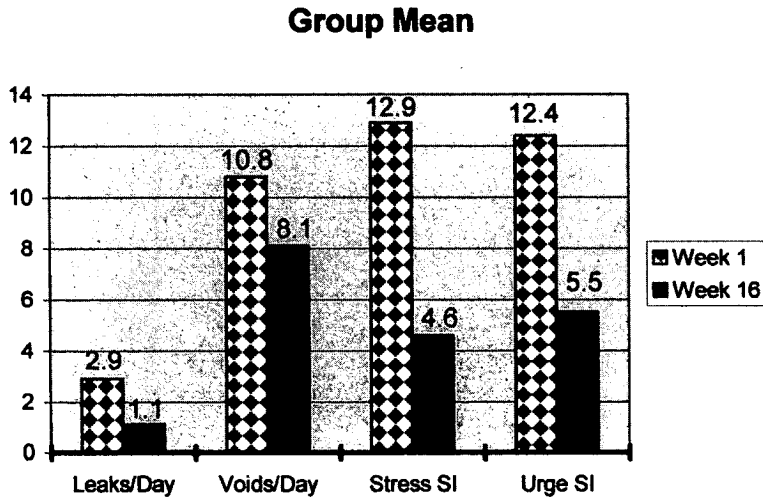


Figure 1. The overall group mean in leaks per day, voids per day, stress severity, and urge severity indices.

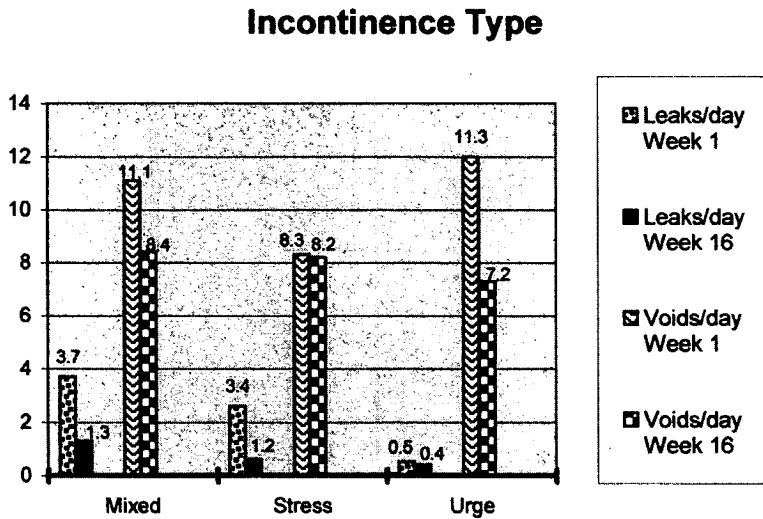


Figure 2. Improvement in leaks per day and voids per day by incontinence type.

undergone prior bladder surgery decreased from 3.4 to 2.0 ($P = .368$).

The number of sessions per day revealed a trend toward greater improvement for persons completing 3 sessions daily compared with those completing 1 or 2 sessions per day; however, this difference did not reach statistical significance ($P = .853$).

DISCUSSION

Compliance is a factor with any behavioral program, and it must be addressed to maximize success.^{10,33} Methods to provide participants with interactive feedback and support in the privacy of their home showed success in this pilot study. The

techniques we used also proved to be successful in older women. Subjects with multiple lower urinary tract symptoms and more severe symptoms achieved the greatest gains. Several factors may have contributed to this outcome. Urinary leakage may be analogized to pain as a motivator for personal involvement and behavior change. For persons with severe UI, the impact is here, now, and often. This phenomenon may explain why compliance with medication and lifestyle change is so poor in patients who have conditions with silent symptoms, such as hypertension or asymptomatic heart disease. The motivation to commit to a behavioral program for a "silent symptom" or consequence in the future may not be as acute or strong.

Although the majority of the participants experienced improvement, the cure rate was less than the improvement rate. However, cure may not be a realistic goal in every case of UI treatment. UI is primarily a quality of life disorder, and outcomes such as improvement, success, and severity are viewed individually. Although this project used leaks per day and voids per day as quantitative measures, sleeping through the night, not having to search for a toilet every hour, or being able to go on a trip may have been viewed as powerful indicators of success to an individual and as reflected by pretreatment and posttreatment differences on the urge and stress severity indices.

The optimum number of pelvic muscle exercises or number of sessions per day has not been determined, and the optimal number of sessions per day remains unknown.^{7,8,13} For example, three 5-minute sessions may be difficult for some patients to complete, but others may find this regimen more realistic compared with a longer, single daily session. In this study, 23 participants completed an average of 2 sessions per day, and 7 participants averaged 3 daily sessions. This variability reflects knowledge that, as with any exercise program, the individual begins with a prescribed protocol, obtains experience, and evaluates her or his response. Based on this feedback, the individual implements strategies appropriate for her or his needs and lifestyle.

The principles of strength development, endurance, and fatigue that have been learned in muscle fitness studies clearly play a role in pelvic muscle fitness, and it has been asserted that this type of treatment

requires specially trained health care providers in a clinical situation.³⁹ However, the results of this study show that, given appropriate education and support, otherwise healthy women can improve with a self-directed home treatment program using a combination of biofeedback and clinician support via telephone. We believe that having a home biofeedback system contributes to success, and 85% of the participants commented that being able to own the biofeedback system provided motivation for them to complete the project.

Limitations

This study was a pilot project with one particular treatment system. It was limited in size, gender, control group, and treatment system. A larger, randomized study to review the role of a comprehensive behavioral program with the same system in women and men with stress, urge, and mixed UI is warranted from these positive results.

CONCLUSION

Pelvic muscle re-education and biofeedback have shown to be effective for a variety of UI symptoms. This pilot project demonstrated that a self-directed treatment system using a home biofeedback device, educational materials, and clinical support via telephone successfully improved urinary symptoms in a group of otherwise healthy community dwelling women with symptoms of stress, urge, and mixed UI.

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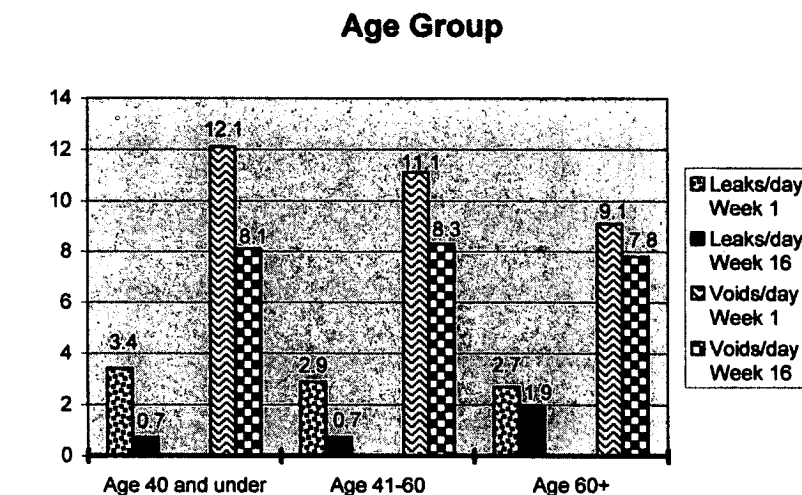


Figure 3. Improvement in leaks per day and voids per day by age groups.

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