# Behavioral Therapy With or Without Biofeedback and Pelvic Floor Electrical Stimulation for Persistent Postprostatectomy Incontinence

## A Randomized Controlled Trial

Patricia S. Goode, MSN, MD
Kathryn L. Burgio, PhD
Theodore M. Johnson II, MD, MPH
Olivio J. Clay, PhD
David L. Roth, PhD
Alayne D. Markland, DO, MSc
Jeffrey H. Burkhardt, PhD
Muta M. Issa, MD, MBA
L. Keith Lloyd, MD

**Context** Although behavioral therapy has been shown to improve postoperative recovery of continence, there have been no controlled trials of behavioral therapy for postprostatectomy incontinence persisting more than 1 year.

**Objective** To evaluate the effectiveness of behavioral therapy for reducing persistent postprostatectomy incontinence and to determine whether the technologies of biofeedback and pelvic floor electrical stimulation enhance the effectiveness of behavioral therapy.

**Design, Setting, and Participants** A prospective randomized controlled trial involving 208 community-dwelling men aged 51 through 84 years with incontinence persisting 1 to 17 years after radical prostatectomy was conducted at a university and 2 Veterans Affairs continence clinics (2003-2008) and included a 1-year follow-up after active treatment. Twenty-four percent of the men were African American; 75%, white.

**Interventions** After stratification by type and frequency of incontinence, participants were randomized to 1 of 3 groups: 8 weeks of behavioral therapy (pelvic floor muscle training and bladder control strategies); behavioral therapy plus in-office, dual-channel electromyograph biofeedback and daily home pelvic floor electrical stimulation at 20 Hz, current up to 100 mA (behavior plus); or delayed treatment, which served as the control group.

**Main Outcome Measure** Percentage reduction in mean number of incontinence episodes after 8 weeks of treatment as documented in 7-day bladder diaries.

**Results** Mean incontinence episodes decreased from 28 to 13 per week (55% reduction; 95% confidence interval [CI], 44%-66%) after behavioral therapy and from 26 to 12 (51% reduction; 95% CI, 37%-65%) after behavior plus therapy. Both reductions were significantly greater than the reduction from 25 to 21 (24% reduction; 95% CI, 10%-39%) observed among controls ($P=.001$ for both treatment groups). However, there was no significant difference in incontinence reduction between the treatment groups ($P=.69$). Improvements were durable to 12 months in the active treatment groups: 50% reduction (95% CI, 39.8%-61.1%; 13.5 episodes per week) in the behavioral group and 59% reduction (95% CI, 45.0%-73.1%; 9.1 episodes per week) in the behavior plus group ($P=.32$).

**Conclusions** Among patients with postprostatectomy incontinence for at least 1 year, 8 weeks of behavioral therapy, compared with a delayed-treatment control, resulted in fewer incontinence episodes. The addition of biofeedback and pelvic floor electrical stimulation did not result in greater effectiveness.

**Trial Registration** clinicaltrials.gov Identifier: NCT00212264

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Men in the United States have a 1 in 6 lifetime prevalence of prostate cancer.[1] Although survival is excellent, urinary incontinence is a significant morbidity following radical prostatectomy,[1-4] often the treatment of choice for localized prostate cancer. Patient surveys indicate that as many as 65% of men continue to experience incontinence up to 5 years after surgery.[2] Loss of bladder control can be a physical, emotional, psychosocial, and economic burden for men who experience it.[2,4]

Postprostatectomy incontinence has been attributed to intrinsic sphincter deficiency and/or detrusor dysfunction, leading to stress and/or urgency incontinence, respectively.[3] Surgical interventions for incontinence are quite effective[5-7] but are usually reserved for moderate to severe incontinence, and many prostate cancer survivors are reluctant to undergo another surgery.

**For editorial comment see p 197.**

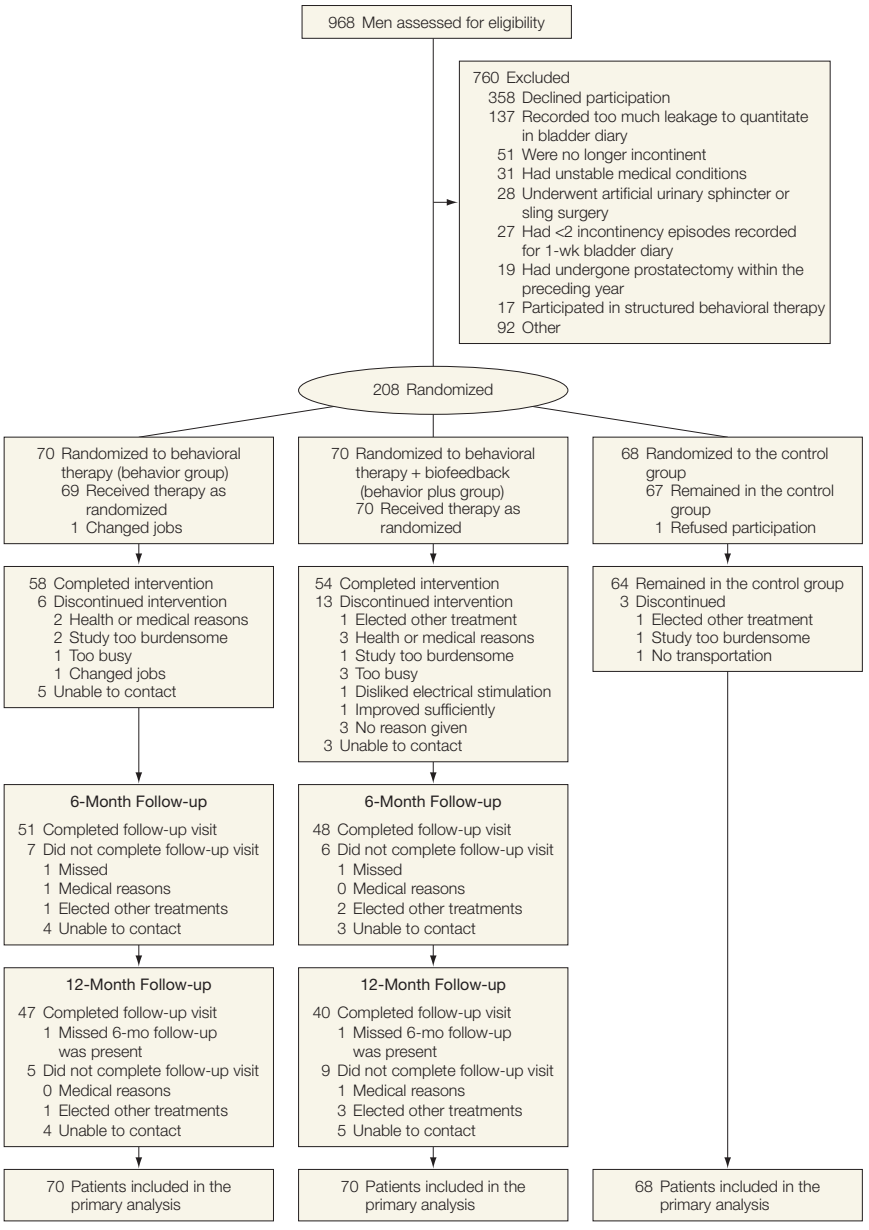
Several randomized trials have examined the effectiveness of perioperative pelvic floor muscle training and shown

**Author Affiliations** are listed at the end of this article.
**Corresponding Author:** Patricia S. Goode, MD, University of Alabama Birmingham Center for Aging, 933 19th St S, Birmingham, AL 35294-2041 (pgoode@uab.edu).

a significant reduction in duration and severity of incontinence in the early postoperative period.[8-12] However, no previous trials have tested the effectiveness of behavioral therapy for incontinence persisting more than a year after prostatectomy. Biofeedback, which assists patients to properly contract pelvic floor muscles,[8] and pelvic floor electrical stimulation of the pudendal nerves, which produces a maximal pelvic floor contraction and improves urethral closure pressure as well as reducing detrusor overactivity,[12,13] are often used together in practice and are thought to enhance the effectiveness of behavioral therapy, but empirical evidence of a benefit is lacking.[10,12]

The objectives of this trial were to evaluate the effectiveness of behavioral therapy for reducing persistent postprostatectomy incontinence and impact on quality of life and to determine whether the technologies of biofeedback and electrical stimulation enhance its effectiveness.

**Figure 1.** Study Participants




## METHODS

This study was a multisite, randomized controlled trial comparing behavioral therapy (pelvic floor muscle exercises, bladder control techniques, and fluid management) with or without biofeedback and pelvic floor electrical stimulation with a delayed-treatment control condition that was conducted between January 2003 and June 2009. The institutional review boards at the participating sites approved the study.

### Participants

Community-dwelling men with incontinence persisting at least 1 year after radical prostatectomy were recruited through advertisements, prostate cancer support groups, and the investigators' clinical practices. Written informed consent was provided by each participant. After telephone screening, an evaluation was conducted consisting of a history and physical examination, Mini-Mental State Examination,[14] 7-day bladder diary, urinalysis, hemoglobin $A_{1c}$ for participants with diabetes, simple uroflow, and postvoid residual volume by ultrasound. Race was self-reported using categories provided by the investigators and was assessed because racial differences in incontinence have been reported.[15]

Men who were incontinent before their prostatectomy or men who resolved postprostatectomy incontinence and then developed incontinence at a later time were excluded. Other exclusion criteria included fewer than 2 incontinence episodes per week, prostatectomy within a year of study entry, current active prostate cancer treatment other than hormonal therapy, postvoid residual urine volume greater than 200 mL, prior treatment in a structured behavioral therapy program, artificial urinary sphincter or suburethral sling, cardiac pacemaker, Mini-Mental State Examination score lower than 24, inability to quantitate individual leakage episodes on bladder diary, and unstable medical conditions. Participants taking

**Table 1.** Baseline Demographic Characteristics

| Characteristics | No. of Participants With Data | Treatment Groups | | | *P* Value[a] |
|---|---|---|---|---|---|
| | | Behavior (n = 70) | Behavior Plus (n = 70) | Control (n = 68) | |
| Age, mean (SD), y | 208 | 66.3 (7.5) | 66.8 (7.0) | 66.9 (7.7) | .90 |
| Race/ethnicity | 208 | | | | |
| African American | | 19 (27.1) | 15 (21.4) | 16 (23.5) | .72 |
| White | | 51 (72.9) | 54 (77.1) | 50 (73.5) | |
| Other | | 0 (0.0) | 1 (1.4) | 2 (3.0) | |
| BMI, mean (SD) | 197 | 30.0 (5.2) | 27.9 (4.1) | 29.0 (5.4) | .06 |
| Years since radical prostatectomy, mean (SD) | 205 | 5.1 (4.1) | 3.9 (3.2) | 5.1 (4.4) | .12 |
| Type of incontinence per diary, No. (%) | 208 | | | | |
| Urge | | 1 (1.4) | 2 (2.9) | 1 (1.5) | .95 |
| Stress | | 31 (44.3) | 33 (47.1) | 30 (44.1) | |
| Mixed | | 38 (54.3) | 35 (50.0) | 37 (54.4) | |
| Incontinence severity as recorded in diary, episodes/wk, No. (%) | 208 | 28.1 (22.0) | 25.6 (26.0) | 24.8 (19.9) | .68 |
| Prior treatments, No. (%) | 208 | | | | |
| Pelvic floor muscle exercises | | 25 (35.7) | 39 (55.7) | 32 (47.1) | .06 |
| Antimuscarinic medications | | 11 (15.7) | 14 (20.0) | 19 (27.9) | .20 |
| α-Blocker medications | | 2 (2.9) | 3 (4.3) | 2 (2.9) | .87 |
| Unable to contract pelvic floor muscles during initial physical examination | 208 | 1 (1.4) | 0 (0) | 1 (1.5) | .36 |

Abbreviation: BMI, body mass index, which is calculated as weight in kilograms divided by height in meters squared.
[a] *P* values are from analyses of variance, which determine whether there is an overall group difference for each variable.

an anticholinergic medication for incontinence were eligible after a 2-week washout period. Participants with fecal impaction, urinary tract infection, hematuria, or hemoglobin $A_{1c}$ levels greater than 10% were eligible after appropriate treatment.

### Stratification and Randomization

Participants were stratified by site (1 university and 2 VA medical centers), and by incontinence type (stress, urgency, or mixed) and severity (<5, 5-10, or >10 episodes per week) to ensure equal distribution among treatment groups. For each site, for each of the 9 stratification cells, a random assignment schedule was generated by a computer program written by the biostatistician (D.L.R.). To maintain allocation concealment, group assignments were placed in sealed envelopes and opened sequentially at the time of randomization.

### Outcome Measure

The primary outcome measure was percent reduction in number of incontinence episodes at 8 weeks as measured with a 7-day bladder diary,[16] scored by study staff blinded to group assignment. The American Urological Association–(AUA-7) symptom index[17] was used to measure lower urinary tract symptoms and the International Prostate Symptom Score quality-of-life question to measure effect.[18] Condition-specific quality of life was also measured with the Incontinence Impact Questionnaire[19,20] and the Expanded Prostate Cancer Index Composite (EPIC).[21] General quality of life was measured with the 36-Item Short Form Health Survey.[22] To assess participants' perceptions of treatment effects, we used the Global Perception of Improvement[23] and the Patient Satisfaction Question.[23] All instruments were completed at home, brought to the clinic, and scores tabulated and entered by research staff who were blinded to group assignment.

### Interventions

Behavioral therapy was implemented in 4 visits approximately 2 weeks apart by physician investigators or nurse practitioners. The first visit consisted of an explanation of continence-related anatomy and pelvic floor muscle exercises, followed by teaching using anal palpation. Participants were instructed in pelvic floor muscle contraction without breath holding or contraction of abdominal, thigh, or buttock muscles. Home exercises included 3 daily sessions (1 each lying, sitting, and standing) with 15 repetitions of a 2- to 10-second contraction followed by an equal period of relaxation depending on the participant's demonstrated ability. The contraction and relaxation duration was advanced by 1 second each week to a maximum of 10 to 20 seconds. Participants were instructed to practice interruption or slowing of the urinary stream during voiding once daily for the first 2 weeks. Participants kept daily bladder diaries and exercise logs during the 8 weeks of treatment. Participants received a fluid management handout defining normal intake, which consisted of drinking 6 to 8 eight-fluid-ounce glasses daily, and advising participants to avoid caffeine and distribute fluid consumption throughout the day.

At the second visit, diaries were reviewed and participants were taught bladder control strategies. The strategy for preventing stress incontinence was to contract pelvic floor muscles just before and during activities that caused leakage, such as coughing or lifting. The urge control strategy involved instructions to not rush to the toilet but instead to stay still and contract the pelvic floor muscles repeatedly until urgency abated and then proceed to the bathroom at a normal pace.

In subsequent visits, diaries were reviewed and success or failure with bladder control strategies discussed in detail to improve results and adherence.

If the diary did not document at least a 50% reduction in incontinence episodes at the third visit, pelvic floor muscle training was repeated.

Behavioral therapy plus biofeedback and electrical stimulation (behavior plus) was similarly conducted with the addition of in-office, dual-channel biofeedback and daily home pelvic floor electrical stimulation. At the first visit, pelvic floor muscle exercises were taught using feedback from surface electromyograph electrodes placed over the rectus abdominis muscles and perianally or with an anal probe. The participant was coached to achieve a reliable and sustained contraction without contracting rectus abdominis muscles. Electrical stimulation training was conducted in-office at visit 1, using the home unit, an anal probe, and settings of 20 Hz, pulse width 1 millisecond, duty cycle of 5 seconds on and 15 seconds off, and current up to 100 mA as adjusted by the participant to achieve a palpable pelvic floor contraction. In addition to daily 15-minute sessions of home electrical stimulation, participants were instructed to perform 2 daily sessions of pelvic floor muscle exercises to keep the frequency of exercise sessions similar between treatment groups. Biofeedback was repeated at visit 3 if incontinence frequency had not decreased by 50%.

Participants in the delayed-treatment group kept daily bladder diaries, which were reviewed during their clinic

**Table 2.** Baseline Symptom Scores and Quality of Life Indicators

| Characteristics | No. of Participants With Data | Treatment Groups | | | *P* Value[a] |
|---|---|---|---|---|---|
| | | Behavior (n = 70) | Behavior Plus (n = 70) | Control (n = 68) | |
| EPIC score, mean (SD)[b] | 206 | | | | |
| Urinary domain | | 65.4 (12.9) | 69.0 (11.4) | 64.5 (11.7) | .07 |
| Incontinence subscale | | 40.4 (17.4) | 43.1 (17.2) | 39.1 (16.1) | .37 |
| IIQ score, mean (SD)[c] | 206 | | | | |
| Subscale | | | | | |
| Physical activity | | 26.7 (29.3) | 23.7 (24.9) | 23.4 (22.7) | .72 |
| Travel | | 24.1 (29.9) | 19.8 (22.6) | 21.8 (22.3) | .61 |
| Social relationships | | 25.2 (27.9) | 20.2 (20.7) | 25.3 (21.5) | .35 |
| Emotional | | 27.9 (27.7) | 22.2 (22.2) | 26.9 (21.4) | .33 |
| Total | | 104.0 (108.7) | 86.0 (79.2) | 97.4 (78.7) | .49 |
| SF-36 component summary score, mean (SD)[d] | 200 | | | | |
| Physical | | 48.1 (8.4) | 49.4 (7.9) | 48.7 (7.7) | .61 |
| Mental | | 49.8 (11.4) | 52.4 (8.4) | 51.4 (10.3) | .31 |
| AUA-7 score, mean (SD)[e] | 205 | | | | |
| Subscale | | | | | |
| Voiding | | 4.2 (4.2) | 3.0 (2.7) | 4.0 (3.4) | .10 |
| Storage | | 6.5 (3.5) | 6.0 (3.1) | 7.0 (3.3) | .18 |
| Total | | 10.7 (6.9) | 9.0 (4.7) | 11.0 (5.3) | .08 |
| IPSS QOL question: If you were to spend the rest of your life with your urinary problem the way it is now, how would you feel about that? No. (%) | 205 | | | | |
| Delighted | | 1 (1.4) | 0 (0.0) | 0 (0.0) | .22 |
| Pleased | | 2 (2.9) | 2 (2.9) | 0 (0.0) | |
| Mostly satisfied | | 4 (5.7) | 14 (20.0) | 6 (9.2) | |
| Mixed | | 21 (30.0) | 21 (30.0) | 22 (33.9) | |
| Mostly dissatisfied | | 20 (28.6) | 16 (22.9) | 24 (36.9) | |
| Unhappy | | 14 (20.0) | 13 (18.6) | 9 (13.9) | |
| Terrible | | 8 (11.4) | 4 (5.7) | 4 (6.2) | |
| Activity restriction due to incontinence, No. (%) | 208 | | | | |
| Not at all | | 38 (54.3) | 50 (71.4) | 37 (54.4) | .16 |
| Some of the time | | 22 (31.4) | 16 (22.9) | 27 (39.7) | |
| Most of the time | | 8 (11.4) | 3 (4.3) | 3 (4.4) | |
| All of the time | | 2 (2.9) | 1 (1.4) | 1 (1.5) | |
| How disturbing is leakage of urine? No. (%) | 208 | | | | |
| Not at all | | 1 (1.4) | 5 (7.1) | 2 (2.9) | .28 |
| Somewhat | | 51 (72.9) | 54 (77.1) | 50 (73.5) | |
| Extremely | | 18 (25.7) | 11 (15.7) | 16 (23.5) | |

Abbreviations: AUA-7, American Urological Association Symptom Index; EPIC, Expanded Prostate Cancer Index Composite; IIQ, Incontinence Impact Questionnaire; IPSS QOL, International Prostate Symptom Scale Quality of Life; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey

[a] *P* values are from analyses of variance, which determine whether there is an overall group difference for each variable.

[b] Subscale scores range from 0 to 100 with higher scores representing better health-related quality of life.

[c] Subscale scores range from 0 to 100, total score 0 to 400, with higher scores indicating greater impact.

[d] Scores range from 0 to 100 with higher scores indicating better functional health and well-being.

[e] Total score ranges from 0 to 35; storage subscale (frequency, urgency, and nocturia), 0 to 15; and voiding subscale (reduced stream, hesitancy, and straining) 0 to 20, with higher scores indicating higher symptom frequency.

**Table 3.** Treatment Outcomes at 8 Weeks

| | No. of Participants With Data | Mean (95% Confidence Interval) | | | *P* Value[a] |
|---|---|---|---|---|---|
| | | Behavior | Behavior Plus | Control | |
| Improvement in incontinence episodes on bladder diary, % | 208 | 55 (44 to 66) | 51 (37 to 65) | 24 (10 to 39) | .001 |
| Incontinence episodes per wk on bladder diary | 208 | 13 (12 to 14) | 12 (11 to 13) | 21 (19 to 23) | |
| Change in EPIC score | 172 | | | | |
| Urinary domain | | 11.5 (8.9 to 14.1) | 8.4 (6.0 to 10.9) | 2.6 (0.6 to 4.6) | <.001 |
| Incontinence subscale | | 13.1 (9.1 to 17.1) | 12.3 (8.4 to 16.2) | 2.9 (–0.2 to 5.9) | <.001 |
| Change in IIQ, median (range) | 170 | | | | |
| Physical activity | | –5.6 (–77.8 to 27.8) | –5.6 (–83.3 to 100.0) | 0.0 (–55.6 to 33.3) | .06 |
| Travel | | 0.0 (–81.1 to 27.8) | –5.6 (–72.2 to 100.0) | 0.0 (–77.8 to 94.4) | .03 |
| Social relationships | | –3.3 (–76.7 to 30.0) | –3.3 (–50.0 to 76.7) | 0.0 (–60.0 to 50.0) | .19 |
| Emotional | | –4.2 (–62.5 to 33.3) | –4.2 (–45.8 to 66.7) | 0.0 (–41.7 to 33.3) | .02 |
| Total score | | –13.9 (–269.4 to 88.9) | –15.7 (–185.83 to 289.2) | 1.1 (–210.0 to 159.7) | .03 |
| Change in SF-36 component summary score | 166 | | | | |
| Physical | | 1.4 (0.1 to 2.6) | 2.3 (0.6 to 4.0) | –0.8 (–2.4 to 0.7) | .001 |
| Mental | | 0.9 (–1.0 to 2.9) | 0.9 (–0.6 to 2.4) | –0.2 (–1.9 to 1.5) | .39 |
| Change in AUA-7 symptom index subscale | 168 | | | | |
| Voiding | | –1.0 (–1.8 to –0.2) | –0.5 (–1.1 to 0.2) | –0.3 (–0.8 to 0.2) | .21 |
| Storage | | –1.5 (–2.3 to –0.8) | –1.7 (–2.4 to –1.0) | –0.6 (–1.3 to 0.0) | <.001 |
| Total score | | –2.5 (–3.8 to –1.2) | –2.1 (–3.3 to –1.0) | –0.9 (–1.9 to 0.0) | .003 |

Abbreviations: AUA-7, American Urological Association; EPIC, Expanded Prostate Cancer Index Composite, IIQ, Incontinence Impact Questionnaire; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey.
[a] *P* values are from analyses of variance, which determine whether an overall group difference exists for each variable.

visits every 2 weeks for 8 weeks to control for self-monitoring effects, as well as the attention of the practitioner and clinic staff. After 8 weeks, they were offered off-protocol treatment with their choice of behavioral therapy with or without biofeedback and electrical stimulation.

### Treatment Durability

At 8 weeks, instructions for a maintenance program of daily pelvic floor exercises (fifteen 10-second paired contraction/relaxations), continued use of bladder control strategies and fluid management were provided in the 2 active treatment groups. These participants were seen at 6 and 12 months to assess treatment effect durability.

### Power Calculation

Power was based on the primary outcome variable, mean percent reduction in incontinence episodes on diary, using a within-group standard deviation of 31% based on our previous work and assuming 2-tailed tests. In addition to omnibus main effect tests, sufficient power was desired for conducting 3 possible pairwise comparisons among the 3 groups, so the type I error rate ($\alpha$) was set at .0167 (0.05/3). With these specifications, using an intent-to-treat analysis and predicting a 15% drop-out rate, the planned sample size of 204 enrolled participants would provide power of 0.80 to detect differences between any 2 groups of 17.4% or larger.

### Statistical Analyses

The primary outcome analysis used an intention-to-treat approach. Bladder diaries completed by participants prior to randomization and at 8 weeks were used to calculate percent reduction in the number of incontinence episodes for each participant. For each treatment group, the means of the individual percent reductions were then calculated. In 36 cases (17.3%) for which participants failed to provide posttreatment data, a multiple imputation procedure with 8 imputations was used. Group differences were tested using a 1-way analysis of variance. Pair-wise comparisons between the 3 groups were conducted only if the omnibus *F* statistic from the overall analysis indicated that the null hypothesis should be rejected. Participants in the 2 treatment groups were followed up at 6 and 12 months and additional percent reduction values were calculated for men who completed these visits. *t* Tests were conducted to determine whether the groups statistically differed from each other. For secondary outcome measures, analysis of covariance was used with the baseline observation serving as a covariate. $\chi^2$ Tests were used to compare the groups on categorical outcomes. All analyses were conducted using SAS version 9.1 (SAS Institute Inc, Cary, North Carolina).

## RESULTS

Of 968 men who were screened for eligibility, 208 were randomized, and of these, 176 (85%) completed 8 weeks of treatment. Of the 112 men completing active treatment, 87 (78%) were followed up for 1 year. Reasons for ineligibility and attrition are shown in FIGURE 1. There were no group differences in attrition ($P=.25$) and no differences between completers and noncompleters on the baseline variables. Characteristics of the participants are presented in TABLE 1 and TABLE 2. At baseline, there were no statistically significant differences among the 3 groups.

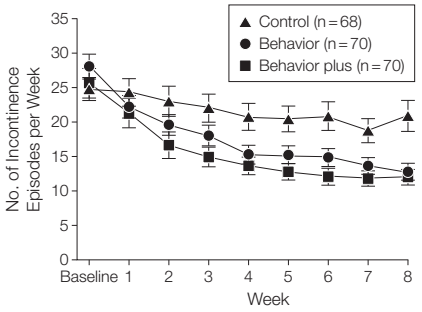
The multiple imputation intent-to-treat analysis demonstrated a significant difference in mean percent reduction of incontinence episodes per week among groups at the end of treatment ($F_{2,205}=7.02$; $P=.001$; TABLE 3,

**Table 4.** Treatment Outcomes and Perceived Quality of Life at 8 Weeks

| | No. of Participants With Data | No. (%) of Participants | | | *P* Value[a] |
|---|---|---|---|---|---|
| | | Behavior | Behavior Plus | Control | |
| IPSS QOL question: If you were to spend the rest of your life with your urinary problem the way it is now, how would you feel about that? | 171 | | | | |
| Delighted | | 2 (3.5) | 3 (5.7) | 0 | .006 |
| Pleased | | 11 (19.0) | 7 (13.2) | 0 | |
| Mostly satisfied | | 14 (24.1) | 13 (24.5) | 9 (15.0) | |
| Mixed | | 15 (25.9) | 19 (35.9) | 19 (31.7) | |
| Mostly dissatisfied | | 9 (15.5) | 3 (5.7) | 14 (23.3) | |
| Unhappy | | 6 (10.3) | 6 (11.3) | 14 (23.3) | |
| Terrible | | 1 (1.7) | 2 (3.8) | 4 (6.7) | |
| Global Perception of Improvement: Overall leakage is "better" or "much better" vs "same," "worse" or "much worse," No./total (%) | 171 | 52/58 (89.7) | 48/53 (90.6) | 6/60 (10.0) | <.001 |
| Able to wear less protection now than before treatment | 171 | | | | |
| Yes | | 32 (55.2) | 22 (41.5) | 3 (5.0) | <.001 |
| No | | 19 (32.8) | 25 (47.2) | 52 (86.7) | |
| Never used protection | | 7 (12.1) | 6 (11.3) | 5 (8.3) | |
| Activity restriction due to incontinence | 170 | | | | |
| Not at all | | 37 (63.8) | 40 (76.9) | 25 (41.7) | .003 |
| Some of the time | | 20 (34.5) | 11 (21.2) | 31 (51.7) | |
| Most of the time | | 1 (1.7) | 1 (1.9) | 4 (6.7) | |
| All of the time | | 0 | 0 | 0 | |
| How disturbing is the leakage of urine? | 171 | | | | |
| Not at all (including not leaking now) | | 16 (27.6) | 22 (41.5) | 6 (10.0) | <.001 |
| Somewhat | | 40 (69.0) | 29 (54.7) | 43 (71.7) | |
| Extremely | | 2 (3.5) | 2 (3.8) | 11 (18.3) | |

Abbreviations: IPSS QOL, International Prostate Symptom Scale Quality of Life question.
[a] *P* values are from analyses of variance, which determine whether overall group difference exists for each variable.

**Figure 2.** Incontinence Episodes per Week on 7-Day Bladder Diary




Analysis was based on multiple imputations of data for all patients as randomized. The change in scores from baseline to 8 weeks was statistically significantly different among groups (*P*=.001).

TABLE 4, and FIGURE 2). At 8 weeks, those in the behavioral therapy group had a mean reduction of 55% (95% confidence interval [CI], 44%-66%; from 28 to 13 episodes per week), which was a significantly greater percent reduction than what was reported by the control group (mean, 24%; 95% CI, 10%-39%; from 25 to 20 episodes per week; b = 30.65; 95% CI, 12.22-49.08; *P*=.001). Those in the behavior-plus group experienced a mean reduction of 51% (95% CI, 37%-65%; from 26 to 12 episodes per week), demonstrating that the addition of biofeedback and electrical stimulation did not improve 8-week results compared with behavioral therapy alone (b, 3.91; 95% CI, –15.07 to 22.88, *P*=.69). Nevertheless, the behavior-plus group achieved significantly better results than the control group (b=26.74; 95% CI, 7.14-46.35; *P*=.01). The improvements achieved by the active treatment groups were sustained for the 12-month follow-up period (TABLE 5 and eTable available at http://www.jama.com).

At the end of the 8-week treatment period, 11 of 70 men (15.7%) in the behavior therapy group, 12 of 70 (17.1%) in the behavior-plus group, and 4 of 68 (5.9%) in the control group achieved complete continence, reporting no incontinence episodes in their 7-day bladder diaries, with a number needed to treat of 10 (95% CI, 5.3-44.6). The urinary domain and the urinary incontinence subscale of the EPIC showed significantly greater improvement among those in the active treatment groups than those in the control group (Table 3). The active treatment groups showed similar statistically significant improvement in their total Incontinence Impact Questionnaire scores and for the travel and emotional subscales, less burden on the International Prostate Symptom Scale quality of life question, and decreases in total symptom score and urine storage subscale on the AUA-7, (Table 3).

Ninety percent of participants in the behavior therapy group and 91% in the and behavior-plus group described their leakage as "better" or "much better" overall compared with 10% of participants in the control group (Table 4). Forty-seven percent of participants in the treatment groups were completely satisfied with their progress. Activity was reported as "not at all restricted" by incontinence in 64% of the behavior group and 77% of the behavior-plus group compared with 42% in the control group. Leakage was extremely disturb-

ing to 4% of those in the active-treatment groups compared with 18% in the control group. Concerning pad use, 55% and 42% of participants in the active-treatment groups reported wearing fewer pads or diapers than before treatment compared with 5% of participants in the control group ($P < .01$ for both active groups).

Adherence to exercises and bladder control strategies in the behavioral and behavior plus therapy groups was 100% and 93% at 8 weeks, 82% and 84% at 6 months, and 91% and 81% at 12 months with no between-group differences. There were 2 study-related adverse events, 2 of 70 men receiving electrical stimulation developed transient hemorrhoidal irritation.

## COMMENT

This randomized controlled trial clearly demonstrated that behavioral therapy with pelvic floor muscle exercises, strategies to prevent stress and urge leakage, fluid management, and self- moni-

**Table 5.** Outcomes at 6 and 12 Months After Treatment

| | No. of Participants With Data | Mean (95% Confidence Interval) | | *P* Value |
|---|---|---|---|---|
| | | Behavior | Behavior Plus | |
| Percent improvement in incontinence episodes on 7-d bladder diary, % | | | | |
| 6 mo | 91 | 55.9 (46.1 to 65.7) | 52.8 (36.4 to 69.1) | .74 |
| 12 mo | 81 | 50.4 (39.8 to 61.1) | 59.0 (45.0 to 73.1) | .32 |
| Episodes per week, No. | | | | |
| 6 mo | | 12.6 (8.7 to 16.6) | 14.6 (7.0 to 22.1) | |
| 12 mo | | 13.5 (9.5 to 17.5) | 9.1 (4.6 to 13.6) | |
| Change in EPIC score | | | | |
| Urinary domain | | | | |
| 6 mo | 98 | 12.2 (9.5 to 14.9) | 7.2 (4.0 to 10.4) | .10 |
| 12 mo | 82 | 12.0 (8.2 to 15.7) | 9.9 (6.2 to 13.7) | .49 |
| Incontinence subscale | | | | |
| 6 mo | 98 | 14.7 (9.7 to 19.6) | 10.1 (6.4 to 13.8) | .19 |
| 12 mo | 82 | 14.4 (8.9 to 19.8) | 13.3 (7.7 to 18.8) | .97 |
| Change in IIQ, median (range) | | | | |
| Physical activity subscale | | | | |
| 6 mo | 97 | –.5.6 (–72.2 to 61.1) | –5.6 (–83.3 to 61.1) | .71 |
| 12 mo | 82 | –5.6 (–77.8 to 50.0) | –5.6 (–83.3 to 77.8) | .06 |
| Travel subscale | | | | |
| 6 mo | 97 | –5.6 (–80.0 to 22.2) | –5.6 (–61.1 to 77.8) | .99 |
| 12 mo | 82 | –2.8 (–72.2 to 22.2) | –7.8 (–72.2 to 22.2) | .03 |
| Social relationships subscale | | | | |
| 6 mo | 97 | –3.3 (–63.3 to 26.7) | –4.2 (–64.8 to 50.0) | .87 |
| 12 mo | 81 | –3.3 (–56.7 to 30.0) | –3.3 (–68.1 to 22.6) | .06 |
| Emotions subscale | | | | |
| 6 mo | 97 | –6.7 (–66.7 to 25.0) | –4.2 (–83.3 to 62.5) | .93 |
| 12 mo | 81 | 0.0 (–66.7 to 33.3) | –4.2 (–66.7 to 54.2) | .10 |
| Total score | | | | |
| 6 mo | 97 | –16.9 (–242.2 to 95.6) | –12.2 (–214.8 to 188.9) | .92 |
| 12 mo | 81 | –14.6 (–256.7 to 99.4) | –19.2 (–238.9 to 176.8) | .04 |
| Change in SF-36 component summary | | | | |
| Physical | | | | |
| 6 mo | 97 | 1.3 (–0.3 to 2.9) | 1.8 (–0.0 to 3.7) | .38 |
| 12 mo | 81 | 0.5 (–1.4 to 2.3) | 1.1 (–0.7 to 3.0) | .51 |
| Mental | | | | |
| 6 mo | 97 | –0.8 (–3.5 to 1.9) | 0.5 (–1.4 to 2.4) | .18 |
| 12 mo | 81 | 0.2 (–2.6 to 3.1) | 0.2 (–1.7 to 2.2) | .64 |
| Change in AUA-7 symptom index scores | | | | |
| Total score | | | | |
| 6 mo | 98 | –3.9 (–5.3 to –2.6) | –2.5 (–3.8 to –1.2) | .53 |
| 12 mo | 84 | –3.4 (–4.9 to –1.9) | –2.1 (–3.2 to –1.1) | .94 |
| Voiding subscale | | | | |
| 6 mo | 98 | –1.6 (–2.3 to –0.9) | –0.6 (–1.2 to 0.1) | .26 |
| 12 mo | 84 | –1.3 (–2.1 to –0.5) | –0.2 (–0.8 to 0.4) | .42 |
| Storage subscale | | | | |
| 6 mo | 98 | –2.3 (–3.1 to –1.5) | –1.9 (–2.8 to –1.0) | .90 |
| 12 mo | 84 | –2.1 (–3.0 to –1.2) | –1.9 (–2.7 to –1.1) | .50 |

Abbreviations: AUA-7, American Urological Association; CI, Confidence Intervals; EPIC, Expanded Prostate Cancer Index Composite; IIQ, Incontinence Impact Questionnaire; PSQ, Patient Satisfaction Question; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey.




Corrected on January 19, 2011

toring with bladder diaries is an effective treatment for postprostatectomy incontinence persisting even years after surgery. Behavioral therapy reduced incontinence frequency and improved urine storage symptoms (frequency, urgency, and nocturia), impact of incontinence on daily activities, and condition-specific quality of life. Based on a PubMed search, the 2008 Fourth International Consultation on Incontinence report,[24] and the 2009 Cochrane Review,[25] this is the first randomized, controlled trial of behavioral therapy involving men with incontinence persisting more than a year after radical prostatectomy.

Although only 16% of men achieved complete continence with behavioral therapy, men with persistent postprostatectomy incontinence were able to reduce their incontinence frequency by more than half. A recent study determined that a 40% reduction in incontinence frequency was the threshold required to achieve a clinically important improvement on the validated, Incontinence Quality of Life questionnaire.[26] The improvement in the Incontinence Impact Questionnaire scores, which reflects the impact of incontinence on daily life, was 22.9 to 29.9, exceeding the "minimally important difference" of 6.5-17, reported by Barber et al.[27] A limitation of these minimally important difference data for reduction in incontinence frequency and Incontinence Impact Questionnaire scores are that they were established in women; more work is needed to assess the validity of these incontinence-related outcome measures in men. Minimally important differences have been established for the AUA symptom index, which measures lower urinary tract symptoms other than incontinence (frequency, urgency, nocturia as well as voiding symptoms). Decreases in AUA symptom index scores of 2.1 in the behavior-plus and 2.5 behavioral groups exceeded the threshold for slight improvement (1.9 for patients with baseline scores between 8 and 19 points) but did not exceed the threshold for moderate improvement (4.0 points) reported by Barry et al.[28] Based on the significant decrease in incontinence frequency and the small number needed to treat (n=10) to achieve complete continence with behavioral therapy, these findings have important implications for urologists, primary care providers, and their patients. Resources for locating centers with expertise in behavioral therapy for incontinence include the National Association for Continence (http://www.nafc.org) and the Wound, Ostomy and Continence Nurses Society (http://www.wocn.org).

The addition of biofeedback and electrical stimulation did not increase the effectiveness of the basic behavioral treatment program. However, a limitation of our study is that it was unblinded. Two relevant randomized trials have previously investigated the addition of electrical stimulation, biofeedback, or both to pelvic floor muscle exercises in the early postoperative period[29,30] and both found no statistical difference between those active treatment groups. Clinical experience of the authors has shown that these techniques are very useful for teaching patients to locate and exercise their pelvic floor muscles; however, it is unusual to encounter men who cannot learn to control their pelvic floor muscles using verbal coaching during physical examination (Table 1). Thus, the use of biofeedback or electrical stimulation does not appear to be essential in initial therapy for postprostatectomy incontinence. This makes it more practical, as well as less costly, to disseminate and administer behavioral treatment.

Many of the participants in our trial reported that they had tried pelvic floor muscle exercises after their surgery but had stopped when they failed to improve sufficiently. Twelve months after starting behavioral treatment in this trial, however, more than 80% of men reported continued adherence to exercises and bladder control strategies. This high adherence rate may have been facilitated by the regular visits and self-monitoring with bladder diaries, as well as the treatment's efficacy. Although our study was not designed to test any of the individual components of behavioral therapy other than the technologies of biofeedback and electrical stimulation, we believe that the bladder control strategies are essential to yield optimal behavioral therapy outcomes.

In conclusion, behavioral therapy, including pelvic floor muscle exercises, bladder control strategies, fluid management, and self-monitoring with bladder diaries is an effective treatment for postprostatectomy incontinence persisting more than 1 year after surgery and adding biofeedback and electrical stimulation did not increase effectiveness. Behavioral therapy should be offered to men with persistent postprostatectomy incontinence because it can yield significant, durable improvement in incontinence and quality of life, even years after radical prostatectomy.

**Author Affiliations:** Department of Veterans Affairs, Birmingham–Atlanta Geriatric Research, Education, and Clinical Center (Drs Goode, Burgio, Johnson, Roth, and Markland); and Departments of Medicine, Division of Gerontology, Geriatrics, and Palliative Care (Drs Goode, Burgio, and Markland), Psychology (Dr Clay), Biostatistics, School of Public Health (Dr Roth), Health Services Administration (Dr Burkhardt), and Surgery, Division of Urology (Dr Lloyd), University of Alabama at Birmingham; and Department of Medicine, Division of Geriatric Medicine and Gerontology, Emory University (Dr Johnson); Department of Veterans Affairs, Atlanta VA Medical Center and Department of Urology, Emory University, Atlanta, Georgia (Dr Issa).
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*Study concept and design:* Goode, Burgio, Burkhardt.
*Acquisition of data:* Goode, Johnson.
*Analysis and interpretation of data:* Goode, Burgio, Clay, Roth, Markland, Issa, Lloyd.
*Drafting of the manuscript:* Goode, Markland.
*Critical revision of the manuscript for important intellectual content:* Goode, Burgio, Johnson, Clay, Roth, Burkhardt, Issa, Lloyd.
*Statistical analysis:* Goode, Clay, Roth.
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