

BEHAVIORAL THERAPY WITH OR WITHOUT BIOFEEDBACK AND PELVIC FLOOR ELECTRICAL STIMULATION FOR PERSISTENT POST-PROSTATECTOMY INCONTINENCE – A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

Although severe incontinence is temporary for most men after radical prostatectomy, persistent incontinence is not uncommon and has significant impact on quality of life. While perioperative pelvic floor muscle training has been shown in several high-quality studies to improve post-operative recovery of continence, there are no randomized trials of conservative therapy for post-prostatectomy incontinence persisting for more than 1 year after surgery. The aim of this study was to evaluate the effectiveness of conservative therapies for persistent post-prostatectomy incontinence by comparing a behavioral therapy program with and without biofeedback and pelvic floor electrical stimulation to a no-treatment control condition.

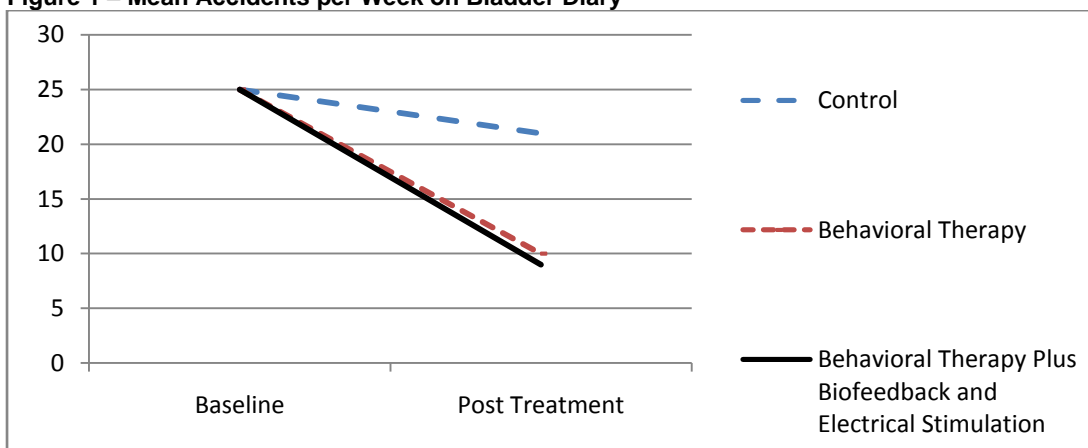
Study design, materials and methods

This study was a randomized controlled trial of behavioral therapy (pelvic floor muscle exercises and bladder control strategies) with and without biofeedback and pelvic floor electrical stimulation for incontinence persisting 1 year or more after prostatectomy. Between January 2003 and March 2008, 207 volunteers from a university medical center and 2 Veterans Affairs medical centers were stratified by type and frequency of incontinence and randomized to 8 weeks of 1) behavioral therapy, 2) behavioral therapy with in-office, computer-assisted, dual-channel biofeedback and daily home pelvic floor electrical stimulation at 20 Hz, pulse width 1 msec, current up to 100 mA, or 3) no treatment control. Outcomes were measured by 1-week bladder diary [1] and validated questionnaires, including the Expanded Prostate Index Composite (EPIC) [2], the patient's Global Perception of Improvement [3], and the Patient Satisfaction Question [3].

Results

Patients were 51-84 years of age; 24% African American, 74% white, 2% other; 44% had stress incontinence, 1% urge incontinence, and 55% mixed stress and urge incontinence; and they were 12 to 201 months post-prostatectomy (mean = 53 months). Analysis of the 172 (83%) participants who completed 8 weeks of treatment showed that incontinence decreased from a mean of 25 to 10 accidents/week (60% reduction) after behavioral therapy, 25 to 9 accidents/week (64% reduction) after behavioral therapy plus biofeedback and electrical stimulation, and 25 to 21 accidents/week (16% reduction) in the control group ($P < .0001$) [Figure 1]. Quality of life as measured by the EPIC Urinary Incontinence Subscale improved from a score of 42 to 55 with behavioral therapy, 44 to 56 with behavioral therapy plus biofeedback and electrical stimulation, and 39 to 42 in the control group ($P < .0001$). Patient's Global Perceptions of Improvement were significantly better in the treatment groups compared with control, with 50% of patients "much better" after behavioral therapy, 30% "much better" after behavioral therapy plus biofeedback and electrical stimulation, and 0% "much better" in the control group (paired comparisons each $P < .05$). Percent of patients who were "completely satisfied" with their treatment progress was 48% in the behavioral therapy group and 47% in behavioral therapy plus biofeedback and electrical stimulation ($P = .92$).

Figure 1 – Mean Accidents per Week on Bladder Diary



Interpretation of results

Behavioral therapy (pelvic floor muscle exercises and bladder control strategies) is effective for post-prostatectomy incontinence persisting more than 1 year after surgery, yielding better results than no treatment on bladder diary, the EPIC Urinary Incontinence Subscale, and Patient's Global Perception of Improvement. In-office, computer-assisted, dual-channel biofeedback and home pelvic floor electrical stimulation did not increase the effectiveness of the behavioral therapy.

Concluding message

Behavioral therapy should be offered as a first line treatment to men with urinary incontinence persisting after radical prostatectomy, since it can yield significant improvement in incontinence and quality of life, even years after the prostatectomy.

References

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3. Burgio KL, Goode PS, Richter HE, Locher JL, Roth DL. Global Ratings of Patient Satisfaction and Perceptions of Improvement with Treatment for Urinary Incontinence: Validation of Three Global Patient Ratings. *Neurourology and Urodynamics* 2006; 25, 411-417

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<i>Is this study registered in a public clinical trials registry?</i>	Yes
<i>Specify Name of Public Registry, Registration Number</i>	Clinical Trials.gov NCT00212264
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	University of Alabama at Birmingham Institutional Review Board
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes