Behavioral vs Drug Treatment for Urge Urinary Incontinence in Older Women

A Randomized Controlled Trial

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Context.—Urinary incontinence is a common condition caused by many factors with several treatment options.

Objective.—To compare the effectiveness of biofeedback-assisted behavioral treatment with drug treatment and a placebo control condition for the treatment of urge and mixed urinary incontinence in older community-dwelling women.

Design.—Randomized placebo-controlled trial conducted from 1989 to 1995.

Setting.—University-based outpatient geriatric medicine clinic.

Patients.—A volunteer sample of 197 women aged 55 to 92 years with urge urinary incontinence or mixed incontinence with urge as the predominant pattern. Subjects had to have urodynamic evidence of bladder dysfunction, be ambulatory, and not have dementia.

Intervention.—Subjects were randomized to 4 sessions (8 weeks) of biofeedback-assisted behavioral treatment, drug treatment (with oxybutynin chloride, possible range of doses, 2.5 mg daily to 5.0 mg 3 times daily), or a placebo control condition.

Main Outcome Measures.—Reduction in the frequency of incontinent episodes as determined by bladder diaries, and patients’ perceptions of improvement and their comfort and satisfaction with treatment.

Results.—For all 3 treatment groups, reduction of incontinence was most pronounced early in treatment and progressed more gradually thereafter. Behavioral treatment, which yielded a mean 80.7% reduction of incontinence episodes, was significantly more effective than drug treatment (mean 68.5% reduction; P = .04) and both were more effective than the placebo control condition (mean 39.4% reduction; P < .001 and P = .009, respectively). Patient-perceived improvement was greatest for behavioral treatment (74.1% “much better” vs 50.9% and 26.9% for drug treatment and placebo, respectively). Only 14.0% of patients receiving behavioral treatment wanted to change to another treatment vs 75.5% in each of the other groups.

Conclusion.—Behavioral treatment is a safe and effective conservative intervention that should be made more readily available to patients as a first-line treatment for urge and mixed incontinence.

URINARY INCONTINENCE is a prevalent and costly condition that affects approximately 38% of older community-dwelling women (age ≥60 years). Incontinence predisposes patients to other health problems, contributes to depression and social isolation, is a significant source of dependency among the elderly, and is widely cited as a factor in nursing home admissions. The costs of incontinence are enormous, accounting for an estimated $16 billion each year. Urge incontinence, the involuntary urine loss associated with a strong sensation to void, is especially common among older women and is usually associated with detrusor instability or reduced bladder capacity. It is often characterized by sudden large-volume urinary accidents that can lead to embarrassment and significant restriction of activities.

See also p 2034 and Patient Page.

Urge incontinence is commonly treated with drugs that inhibit detrusor contraction. In addition to pharmacological approaches, behavioral treatments have been shown to improve bladder control by teaching patients new skills or habits. Biofeedback-assisted behavioral training is a form of behavioral treatment that reduces incontinence by teaching patients how to control the physiologic responses of the bladder and pelvic muscles that mediate continence.

Combined bladder-sphincter biofeedback has been used to teach patients to inhibit detrusor contractions and increase intraurethral pressure in the treatment of urge incontinence.

The present study is the first randomized clinical trial comparing the effectiveness of biofeedback-assisted behavioral treatment with both a standard drug treatment (oxybutynin chloride) and a control condition for the treatment of urge incontinence. In addition to testing the effectiveness of behavioral treatment, it is important to compare behavioral and drug treatment because the 2 interventions are both viable options with distinct advantages and disadvantages that need to be considered in clinical decision making.
were offered treatment and reconsideration, severe atrophic vaginitis, or a need to screen for dementia.

State Examination (MMSE) was used to classify incontinence as “urge instability” during filling or provocation. Also, there had to be urodynamic evidence of bladder dysfunction (detrusor instability during filling or provocation or maximal cystometric capacity of ≤350 mL).

Subjects were excluded if they had continual leakage, postvoid residual urine volume more than 200 mL, uterine prolapse past the introitus, narrow-angled glaucoma, unstable angina, decompensated congestive heart failure, history of malignant arrhythmias, or impaired mental status (MMSE score <20).

Subjects were stratified by type and severity of incontinence. Baseline bladder diary and urodynamic test results were used to classify incontinence as “urge only” or “mixed stress and urge.” To ensure between-group comparability on pretreatment severity of incontinence, the baseline bladder diary was used to stratify subjects as having mild (<5 episodes per week), moderate (5-10 episodes per week), or severe (>10 episodes per week) incontinence.

Within each stratum, randomization was performed with computer-generated random numbers using a block size of 6 to avoid inequity in group size. Subjects were randomly assigned to behavioral treatment, drug treatment, or a placebo control condition.

Treatment

For all subjects, treatment consisted of 4 clinic visits at 2-week intervals during an 8-week period. Subjects completed a daily bladder diary throughout treatment. At each visit, bladder diaries were reviewed by clinic staff to ensure that entries were clear and interpretable. Vital signs were recorded and a urine specimen was collected. Anal sphincter pressure was measured using manometry. An adverse effects checklist was completed, which consisted of 5 known adverse effects of oxybutynin (inability to void, confusion, dry mouth, blurred vision, constipation) intermeshed with “dummy” symptoms. Interventions were implemented by nurse practitioners. The control group was intended to control not only for the placebo effect but also for the effects of clinic visits, self-monitoring (bladder diary), and therapist contact.

Behavioral Training.—During clinic visits, patients in the behavior group were taught skills and strategies for preventing incontinence and provided with instructions for daily home practice. In visit 1, anorectal biofeedback was used to help patients identify pelvic muscles and teach them how to contract and relax these muscles selectively while keeping abdominal muscles relaxed. Visit 2 was devoted to teaching patients how to respond adaptively to the sensation of urgency (“urge strategies”). Instead of rushing to the toilet, which increases intra-abdominal pressure and exposure to visual cues that can trigger incontinence, subjects were encouraged to pause, sit down if possible, relax the entire body, and contract pelvic muscles repeatedly to diminish urgency, inhibit detrusor contraction, and prevent urine loss. When urgency subsided, they were to proceed to the toilet at a normal pace. In visit 3, pelvic muscle biofeedback was repeated for subjects who had not achieved at least a 50% reduction in frequency of accidents as documented on bladder diary. Combined bladder-sphincter biofeedback was used to teach patients to contract pelvic muscles against increasing volumes of fluid, in the presence of increasing urgency, and during detrusor contraction (Figure 1). Visit 4 was used to review progress, “fine-tune” home practice, and encourage persistence.


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Home practice included 45 pelvic muscle exercises every day (15 exercises, 3 times per day). Duration of individual contraction and relaxation was based on the ability demonstrated by each patient in the biofeedback session and gradually increased across sessions to a maximum of 10 seconds each. Patients were advised to practice in various positions, including lying, sitting, and standing. They were encouraged to contract pelvic muscles during activities that commonly resulted in incontinence. Finally, patients were instructed to practice interrupting or slowing the urinary stream during voiding once per day.

Drug Treatment and Control Condition.—Assignment to drug treatment or the placebo control condition was double-blinded, so all patients in these groups were managed as if they were taking oxybutynin. The protocol was initiated at 2.5 mg of oxybutynin chloride 3 times daily, half the usual recommended adult dosage. Oxybutynin and placebo were dispensed in identical capsules containing 500 mg of riboflavin phosphate as a marker. Clinic visits were also used to review bladder diaries, monitor progress, manage adverse effects, and make dosage adjustments using a minimum dosage of 2.5 mg/d and a maximum of 5.0 mg 3 times daily. The goal during the 8 weeks was to stabilize the patient taking the most effective dose she could tolerate long-term while controlling adverse effects and avoiding dropout. The protocol was flexible to be comparable with actual clinical practice.

Posttreatment Assessment

Following treatment, subjects completed 2 weeks of posttreatment bladder diaries and returned to the clinic to complete a final urine specimen, adverse effects checklist, cystometrogram, and patient satisfaction questionnaire administered by the nurse practitioner. Subjects were asked to describe their progress (much better, better, about the same, or worse), satisfaction with progress (completely, somewhat, or not at all satisfied), and perceived improvement (estimated percent improvement, 0% [none] to 100% [dry]). Patients also reported whether they were comfortable enough with biofeedback to continue indefinitely (yes or no) and whether they wished to receive treatment to continue indefinitely (yes or no).

Table 1.—Reasons for Ineligibility for Incontinence Trial

<table>
<thead>
<tr>
<th>Reasons for Ineligibility</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urge incontinence was not the predominante type</td>
<td>82</td>
</tr>
<tr>
<td>Elevated postvoid residual (&gt;200 mL)</td>
<td>8</td>
</tr>
<tr>
<td>Too few accidents (&lt;2/wk)</td>
<td>30</td>
</tr>
<tr>
<td>Normal urodynamic findings</td>
<td>9</td>
</tr>
<tr>
<td>Could not be instrumented for urodynamic testing</td>
<td>3</td>
</tr>
<tr>
<td>Could not complete bladder diary</td>
<td>17</td>
</tr>
<tr>
<td>Impaired mental type</td>
<td>8</td>
</tr>
<tr>
<td>Narrow-angle glaucoma</td>
<td>2</td>
</tr>
<tr>
<td>Unstable medical problem</td>
<td>31</td>
</tr>
<tr>
<td>Declined participation</td>
<td>41</td>
</tr>
<tr>
<td>Failed to return</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>271</td>
</tr>
</tbody>
</table>

In drug treatment, dosage was individualized and titrated. The final dosages ranged from 2.5 to 15.0 mg/d as follows: 2.5 mg (7.5%), 5.0 mg (19.4%), 7.5 mg (24.4%), 10.0 mg (17.9%), and 15.0 mg (26.9%). During treatment, 2 adverse effects, dry mouth and inability to void, distinguished the intervention groups (Table 3). The drug therapy group reported a significantly higher incidence of dry mouth (P < 0.001) and inability to void (P = 0.002) than did the control group. In addition, the behavioral group had even less dry mouth than the control group (P = 0.03).

The attrition rate was 6.2% in the behavioral group, 17.9% in drug treatment, and 18.5% in the control condition. Seven patients (Figure 2) dropped out before a follow-up bladder diary could be completed so 190 patients were included in the analysis.

Figure 2.—Patient flow diagram. Reasons for dropouts were illness or health problems (4, 4, and 6 in behavioral, drug, and control groups, respectively); depression (1, drug group); adverse effects (7, drug group and 4 in control group); and 1 each for personal reasons and dissatisfaction with progress (both in the control group). ITT indicates intention-to-treat analysis.

Effects of Intervention

Before treatment, frequency of incontinence was similar across the 3 groups (Table 4). After treatment, the groups were significantly different with the highest frequency of incontinence reported in the control group and the lowest in the behavioral group (P = 0.05). Behavioral training, which resulted in a mean 80.7% improvement, was significa-
cantly more effective than drug treatment (mean, 68.5%; improvement; \(P = .04\)) and the control condition (mean, 39.4% improvement; \(P < .001\)). In addition, the drug treatment was more effective than the control condition (\(P = .009\)).

Similarly, a larger proportion of sub-
jects in the behavioral group achieved at least 50% and 75% reductions of incontinence (\(P = .002, P < .001\); Figure 3). Although the values for full recovery of continence (100%) followed a similar pattern, the differences were not statistically significant (\(P = .07\)). In addition, it is noteworthy that some patients had more accidents after treatment than before (1 [1.6%] of 63 in behavior treatment, 3 [4.6%] of 65 in drug treatment, and 10 [16.1%] of 62 in the control condition).

Figure 4 displays the mean frequency of incontinence across time. In all groups, reduction of incontinence was most pronounced early in treatment and progressed more gradually thereafter.

### Patient Satisfaction and Comfort

Several secondary outcome measures were used to assess the patient’s perceptions (Table 5). On every parameter, the behavioral group re-

![Figure 3](https://example.com/fig3.png)  
**Figure 3.** Proportions of subjects by group who reduced frequency of incontinence by 100%, 75%, and 50%.

![Figure 4](https://example.com/fig4.png)  
**Figure 4.** Mean number of accidents per week across baseline, intervention, and posttreatment periods.

reported the highest perceived improve-
ment and satisfaction with treatment progress (\(P < .001\)). Of particular interest are the findings that 96.5% of the behavior group reported being com-
fortable enough with the treatment to continue indefinitely, while only 14.0% wished to receive another form of treatment. Despite the beneficial effects of drug treatment, only 54.7% said they could continue indefinitely and 75.5% said they wished to receive another form of treatment. Subjects who were not completely dry in the 2-week posttreatment period were invited to enter combined treatment. In the behavioral group, 46.5% wished to add drug treatment to their regimen, while 53.3% of those in the drug group wished to receive behavioral treatment.

### Bladder Capacity

Fifty-three percent of subjects (105/ 197) completed posttreatment cys-
Behavioral intervention has the advantage that incontinence can be reduced without the adverse effects that are common with pharmacological intervention. A total of 96.5% of patients reported being comfortable enough with behavioral intervention to continue it indefinitely. Most subjects were completely satisfied with their progress, and few wished to receive an alternate form of treatment. Little is known, however, of the long-term durability of the treatment and how well patients can sustain treatment adherence. A limitation of the behavioral treatment is that it depends on the active participation of a motivated patient, indicating that its value may be limited in individuals with cognitive impairment or those with less motivation.

An advantage of drug treatment is that it demands little effort from the patient; thus, it is attractive to many patients. The cystometric data on bladder capacity suggest that increased bladder capacity could be a mechanism for successful treatment with oxybutynin. Another advantage is that it requires less clinician time. However, it should be noted that the 68.5% mean improvement in this trial reflects multiple visits and more clinician time than might ordinarily be spent to prescribe medication. This study optimized effectiveness with follow-up visits, careful management of adverse effects, and individualized dosage titration during a period of 8 weeks. In addition to optimizing drug therapy, it was also important, for the sake of design validity, to keep the number of visits and amount of therapist contact as constant as possible across the 3 intervention groups. The results are based on an intention-to-treat analysis, but the data are derived from the last diaries available and therefore reflect a period during which dropouts were still taking their medication. Despite improvement with medication, 10.4% of subjects were unwilling or unable to continue oxybutynin treatment due to adverse effects.

The significant improvement achieved by the control group (mean, 39.4% reduction) is worth noting. The control condition should not be interpreted as a no-treatment condition, since like the other groups, they were active participants in treatment. Control patients consumed capsules that they knew could have contained the medication, completed detailed bladder diaries throughout the 8-week intervention phase, attended 4 clinic visits, completed an adverse effects checklist at each visit, and received therapeutic attention from a nurse practitioner who reviewed the diaries with them and inquired about their progress and concomitant events.

Thus, in addition to the placebo effect, attention, interaction, care, expectations of improvement, and mobilization of patient effort could have contributed to the therapeutic outcome. In addition, close self-monitoring by bladder diary can enhance awareness of bladder habits and leakage patterns and may reduce incontinence by giving the patient insights into behavioral alterations that can decrease urge accidents. No doubt any or all of these components could have contributed to improvement in all 3 groups and could account for the significant improvement of the control group. Because these effects were thought to be significant in previous studies, the control group in this study was intended to control for these possible nonspecific effects so that the unique effects of behavioral intervention and drug therapy could be determined. Similar control group effects have been reported in previous clinical trials of medication for urge incontinence.27,28

Table 5.—Patient Perceptions of Progress in Treatment

<table>
<thead>
<tr>
<th>Patient Perceptions</th>
<th>Behavioral Treatment</th>
<th>Drug Treatment</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Much better</td>
<td>74.1 (43/58)</td>
<td>50.9 (28/55)</td>
<td>26.9 (14/52)</td>
</tr>
<tr>
<td>Better</td>
<td>25.9 (15/58)</td>
<td>30.9 (17/55)</td>
<td>38.5 (20/52)</td>
</tr>
<tr>
<td>About the same</td>
<td>0.0 (0/58)</td>
<td>16.4 (9/55)</td>
<td>28.8 (15/52)</td>
</tr>
<tr>
<td>Worse</td>
<td>0.0 (0/58)</td>
<td>1.8 (1/55)</td>
<td>5.8 (3/52)</td>
</tr>
<tr>
<td>Estimate of percent improvement, mean (SD)</td>
<td>61.6 (18.6)</td>
<td>66.4 (35.4)</td>
<td>45.1 (36.6)</td>
</tr>
<tr>
<td>Having fewer accidents, % (No.)</td>
<td>100.0 (58/59)</td>
<td>87.3 (48/55)</td>
<td>67.3 (35/52)</td>
</tr>
<tr>
<td>Accidents are smaller, % (No.)</td>
<td>67.3 (48/55)</td>
<td>78.8 (41/52)</td>
<td>54.0 (27/50)</td>
</tr>
<tr>
<td>Able to weal less protection, % (No.)</td>
<td>76.0 (38/50)</td>
<td>56.0 (28/50)</td>
<td>34.1 (14/41)</td>
</tr>
<tr>
<td>Comfortable enough to continue indefinitely, % (No.)</td>
<td>96.5 (55/57)</td>
<td>54.7 (29/53)</td>
<td>43.1 (22/51)</td>
</tr>
<tr>
<td>Patient satisfaction with progress, % (No.)</td>
<td>77.6 (45/58)</td>
<td>49.1 (27/55)</td>
<td>28.0 (14/50)</td>
</tr>
<tr>
<td>Completely satisfied</td>
<td>22.4 (13/58)</td>
<td>40.0 (22/55)</td>
<td>34.0 (17/50)</td>
</tr>
<tr>
<td>Not at all satisfied</td>
<td>0.0 (0/58)</td>
<td>10.9 (6/55)</td>
<td>38.0 (19/50)</td>
</tr>
<tr>
<td>Wish to receive another form of treatment, % (No.)</td>
<td>14.0 (8/57)</td>
<td>75.5 (40/53)</td>
<td>75.5 (37/49)</td>
</tr>
</tbody>
</table>

*For all comparisons, P < .001.
One limitation inherent in this trial is that it was not possible to blind the patients or the nurses regarding assignment to behavioral vs drug treatment. However, the research assistant who scored the outcome measures was kept blinded. Another possible limitation is the reliance on the bladder diary as the primary outcome measure. Accuracy of self-report data is always a matter of concern; however, the bladder diary has been found to be a reliable method of evaluating frequency of urine loss. Compared with urodynamic testing, the diary is perhaps less objective, yet we would assert that it is a more clinically relevant measure in that it documents incontinence in vivo during a considerably longer period.

The role of behavioral treatment was addressed at the National Institutes of Health-sponsored Consensus Conference on Urinary Incontinence in Adults. The consensus panel recommended that the least invasive or dangerous procedures should be tried first, and that for many forms of incontinence, this criterion is met by behavioral treatments. Behavioral treatment has also been recommended as a first-line treatment in the Clinical Practice Guideline for Urinary Incontinence developed under the auspices of the Agency for Health Care Policy and Research. Previous studies by our group and others have demonstrated that the behavioral procedures described in this article are practical and can be implemented effectively by non-physician providers in outpatient office settings.11,14 A behavioral intervention with these characteristics has the potential for widespread application. Currently, drug treatment is readily available and widely used. The results of this study indicate that behavioral treatment should also be made more available and offered routinely as an option for first-line treatment for urge incontinence.

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References