

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.

incontinence are enormous, accounting for an estimated \$16 billion each year.³ 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.⁴⁻¹⁴ 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.^{4,5,15-18} Combined bladder-sphincter biofeedback has been used to teach patients to inhibit detrusor contractions and increase intraurethral pressure in the treatment of urge incontinence.^{8-10,12,14,19}

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.

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URINARY INCONTINENCE is a prevalent and costly condition that affects approximately 38% of older community-dwelling women (age ≥ 60 years).¹ 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.² The costs of

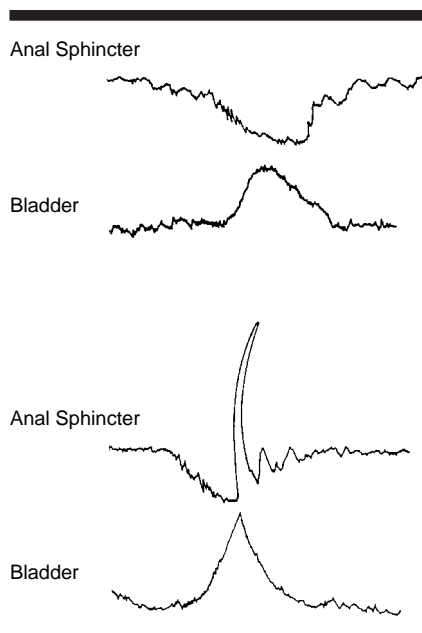


Figure 1.—Sample tracings of anal sphincter and bladder pressure. Top, Detrusor contraction accompanied by sphincter relaxation (normal physiologic response). Bottom, Voluntary external anal sphincter contraction accompanied by detrusor inhibition (learned response).

METHODS

Subjects

Subjects were older, community-dwelling women with urge incontinence. They were recruited through local advertisements and professional referrals and screened by telephone for eligibility. Subjects had to be at least 55 years of age, be ambulatory, and describe urge incontinence occurring at least twice per week and persisting for at least 3 months. Informed consent procedures approved by the university institutional review board were followed. The study was conducted between July 1, 1989, and August 30, 1995.

Clinical Evaluation

Potential subjects who met initial criteria were scheduled for a clinical evaluation to identify those who were not appropriate for treatment with oxybutynin or behavioral methods. The evaluation consisted of a patient's continence and medical history and a physical examination; postvoid catheterization for residual urine; urodynamic evaluation; determination of electrolyte levels, serum urea nitrogen, and creatinine; and urinalysis. In addition, the Mini-Mental State Examination (MMSE)²⁰ was used to screen for dementia.

In cases of urinary tract infection (urine colony count, $\geq 10\,000$), fecal impaction, severe atrophic vaginitis, or a correctable metabolic problem, subjects were offered treatment and reconsid-

ered at a later date. When hematuria was present on urinalysis, the decision to enroll the subject was based on urologic consultation.

Urodynamic testing consisted of 2-channel supine water cystometry using a No. 12 Foley catheter, a rectal balloon, and a filling rate of 50 mL/min. Threshold volumes were recorded for first desire to void, strong desire to void, detrusor contraction, cystometric capacity, and urine loss. With the urinary catheter removed, maneuvers were performed to provoke urge or stress incontinence: positional changes (lying to sitting, sitting to standing), coughing (4 times while lying and standing), listening to running water while standing (20 seconds), washing hands in running water (20 seconds), heel bouncing (4 times), and walking to the toilet. The purpose of the testing was to document bladder dysfunction (inclusion criterion) and to classify the type of incontinence for stratification.

Baseline Bladder Diary

Subjects were provided with 2 weeks of bladder diary booklets to document the time of every void and incontinent episode, the volume of urine loss (large or small), and the circumstances of each episode. The main purpose of the diary was to document pretreatment frequency of incontinence.

Inclusion and Exclusion Criteria

To be included, subjects had to have at least 2 urge accidents per week on the 2-week baseline bladder diary, and urge incontinence had to be the predominant pattern (the number of urge accidents had to exceed the number of stress accidents). 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-angle glaucoma, unstable angina, decompensated congestive heart failure, history of malignant arrhythmias, or impaired mental status (MMSE score < 20).

Design

The study was a randomized placebo-controlled trial. Following enrollment, 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 epi-

sodes 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").²¹ 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.

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 treatment to continue indefinitely (yes or no) and whether they wished to receive another form of treatment (yes or no).

Data Management and Analysis

The 3 treatment groups were first compared using χ^2 tests and analysis of variance (ANOVA) to determine whether differences existed between the groups on key variables prior to treatment. The primary outcome measure was reduction in the frequency of incontinent episodes

Table 1.—Reasons for Ineligibility for Incontinence Trial

Reasons for Ineligibility	No.
Urge incontinence was not the predominate type	82
Elevated postvoid residual (>200 mL)	8
Too few accidents (<2/wk)	30
Normal urodynamic findings	9
Could not be instrumented for urodynamic testing	3
Could not complete bladder diary	17
Impaired mental status	8
Narrow-angle glaucoma	2
Unstable medical problem	31
Declined participation	41
Failed to return	40
Total	271

as derived from bladder diaries. A research assistant, blinded to treatment group, scored bladder diaries and managed the data. The pretreatment and posttreatment frequencies of incontinence were used to calculate a percentage reduction for each subject (0%, no improvement; 100%, totally dry). Mean reductions were analyzed using a rank-based ANOVA procedure²² (to accommodate the nonnormality of the data) and post-hoc comparisons (Duncan multiple range tests using an overall α level of .05).^{22,23} χ^2 Analysis was used to compare the groups on the categorical outcome measures. These analyses were computed using SPSS (SPSS Inc, Chicago, Ill) and SAS (SAS Institute Inc, Cary, NC) software, and when cell sizes did not permit a valid use of the χ^2 statistic, the STATXACT software package.²⁴ The analysis was based on intention-to-treat and thus included all subjects. When subjects did not complete treatment, calculation of improvement was based on the most recent bladder diaries.

RESULTS

Subjects

Of 468 women who were evaluated clinically, 271 were ineligible or did not participate (Table 1), and 197 (ages 55–92 years) were randomized (Figure 2). Characteristics of the subjects are presented in Table 2. Before treatment, the groups were comparable on all key parameters except that subjects in behavioral treatment had more children, were less likely to have a high school education, and more likely to have a rectocele.

Features of Intervention

In the behavioral treatment group, 73.8% (n = 48) of subjects received a single session of anorectal biofeedback. Another 9.2% (n = 6) underwent a second training session of anorectal biofeedback because of uncertainty about correct muscle contraction. The remaining 16.9% (n = 11) had a second session in which combined bladder-sphincter bio-

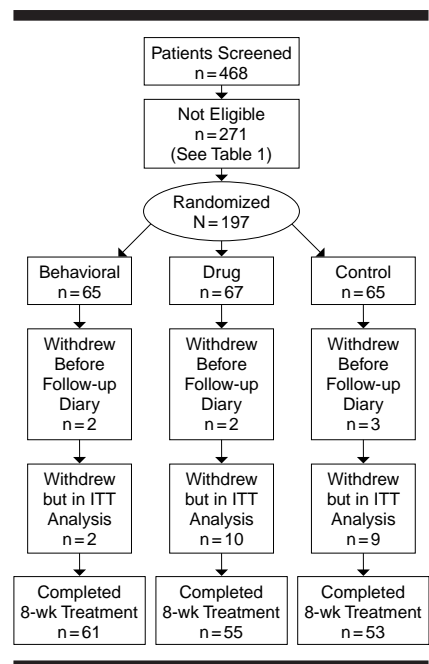


Figure 2.—Patient flow diagram. Reasons for dropouts were illness or health problems (4, 4, and 6 in behavioral, drug, and control groups, respectively); depression (1, drug group); adverse effects (7, drug group and 4, control group); and 1 each for personal reasons and dissatisfaction with progress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

feedback was used. No patients received more than 2 sessions of biofeedback.

In drug treatment, dosage was individually 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 ($P < .001$) and inability to void ($P = .002$) than did the control group. In addition, the behavioral group had even less dry mouth than the control group ($P = .03$).

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.

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 ($P = .005$). Behavioral training, which resulted in a mean 80.7% improvement, was signifi-

Table 2.—Baseline Characteristics of the Study Sample*

Characteristics	Behavioral Treatment (n = 65)	Drug Treatment (n = 67)	Control Group (n = 65)	Total Sample (N = 197)
Demographics				
Age, mean (SD), y	67.3 (7.6)	68.2 (7.5)	67.6 (7.6)	67.7 (7.5)
High school graduate, %†	84.4	97.0	93.8	91.8
History				
Parity, mean (SD), No.†	2.8 (2.0)	2.1 (1.4)	2.7 (1.8)	2.5 (1.7)
Duration of symptoms, mean (SD), y	9.4 (10.8)	9.8 (11.9)	12.7 (15.9)	10.6 (1.5)
Using diuretics, %	20.0	14.9	12.3	15.7
Using estrogen, %	32.3	38.8	35.4	35.5
Previous treatment with medication, %	27.7	35.8	30.8	31.5
Previous treatment with surgery, %	20.0	26.9	29.2	25.4
Activity restricted by UI, %	30.8	32.8	38.5	34.0
Pelvic examination				
Urethrocele, %	34.4	25.8	35.9	31.9
Cystocele, %	71.4	68.7	73.0	71.0
Rectocele, %†	55.6	32.8	54.0	47.2
Atrophic mucosa, %	46.0	37.3	41.5	41.5
Uterine prolapse, %	3.2	3.0	1.6	2.6
Bladder capacity, mean (SD), mL	284.5 (97.1)	302.4 (96.7)	311.2 (97.7)	299.4 (97.3)
Type of UI (on diary and urodynamics)				
Urge UI only, %	49.2	49.3	47.7	48.7
Mixed stress and urge UI, %	50.8	50.7	52.3	51.3
Severity classification, %				
Mild (<5 accidents per week)	18.5	17.9	18.5	18.3
Moderate (5-10 accidents per week)	29.2	29.9	27.7	28.9
Severe (>10 accidents per week)	52.3	52.2	53.8	52.8

*UI indicates urinary incontinence.
†*P* < .05.

Table 3.—Adverse Effects Reported During Treatment

Adverse Effects	Behavioral Treatment, No. (n = 63)	Drug Treatment, No. (n = 65)	Control Group, No. (n = 62)	<i>P</i> Value
Dry mouth	34.9	96.9	54.8	<.001
Inability to void	6.3	21.5	3.2	.002
Constipation	22.2	38.5	37.1	.10
Blurred vision	9.5	15.4	9.7	.50
Confusion	6.3	7.7	11.3	.59

Table 4.—Results of Intervention on Frequency of Incontinent Episodes

Results	Behavioral Treatment (n = 63)	Drug Treatment (n = 65)	Control Group (n = 62)	<i>P</i> Value
Accidents per week, No.				
Pretreatment, mean (SD)	15.8 (14.5)	15.9 (14.1)	15.4 (13.4)	.98
Posttreatment, mean (SD)	2.8 (4.7)	5.7 (9.8)	8.2 (11.6)	.005
Percent reduction				
Mean (SD)	80.7 (24.8)	68.5 (37.2)	39.4 (80.0)	<.001
Range	-9.0 to 100	-85.7 to 100	-400.0 to 100	

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 subjects 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 behavioral 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 of treatment (Table 5). On every parameter, the behavioral group re-

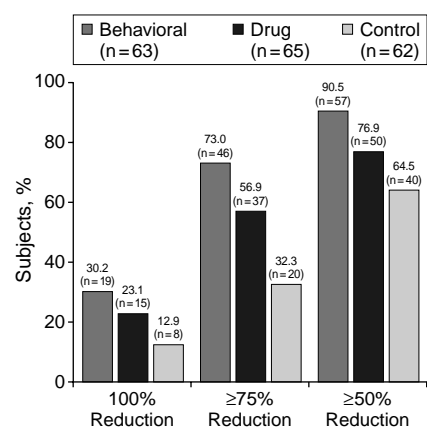


Figure 3.—Proportions of subjects by group who reduced frequency of incontinence by 100%, 75%, and 50%.

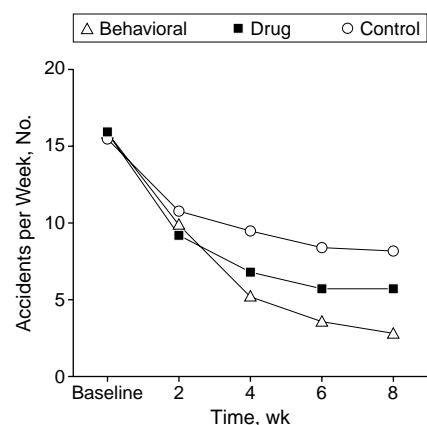


Figure 4.—Mean number of accidents per week across baseline, intervention, and posttreatment periods.

ported the highest perceived improvement and satisfaction with treatment progress (*P* < .001). Of particular interest are the findings that 96.5% of the behavioral group reported being comfortable 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, 14.5% 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 cysto-

metrogram. This subsample of subjects with complete pretreatment and post-treatment urodynamic data were compared with the remaining subjects on outcome (number of accidents) and all 17 baseline characteristics reported in Table 2. The groups did not differ significantly for any variable except that subjects in the subsample were less likely to have atrophic mucosa (35% vs 48.9%; $P = .05$). Bladder capacity increased by a mean of 17.3 mL in the behavioral group ($P = .30$) and 70.9 mL in the drug group ($P < .001$), and decreased by a mean of 5.9 mL in the placebo group ($P = .61$).

COMMENT

This study is the first randomized clinical trial of biofeedback-assisted behavioral treatment for urge incontinence and the first to compare this therapy with a standard pharmacological treatment. The results of this clinical trial show clearly that biofeedback-assisted behavioral training is an effective and acceptable conservative treatment for urge incontinence. It was more effective than oxybutynin, the pharmacological agent of choice for urge incontinence, and it is safe, yields high levels of patient satisfaction, and is practical for older individuals. The mean 80.7% reduction of incontinence achieved is similar to that of previous studies of bladder-sphincter biofeedback and was obtained with a less intensive approach than has been described in earlier reports.^{8-10,12,19} In previous studies, most subjects were catheterized to provide bladder pressure biofeedback and in most cases they were re-instrumented. The present study tested a staged approach in which anorectal biofeedback was used alone in 1 session and only repeated or combined with bladder pressure biofeedback in subjects whose initial response was unsatisfactory. Most subjects in this study (73.8%) required a single biofeedback session. This suggests that the pelvic muscles were usually identified properly in a single visit, requiring less repetition of biofeedback than was previously thought to be necessary.

In the previous literature on urge incontinence, a form of bladder training is described in which bladder habits are altered through specified voiding schedules and techniques for postponing urination.^{6,7,13} Pelvic muscle training and exercise are generally reserved for the treatment of stress incontinence.^{15,16,25,26} In the present study, pelvic muscle training and exercise were the primary components in the treatment of urge incontinence. The results support the concept that learned pelvic muscle contractions can prevent urine loss by inhibiting and aborting detrusor contraction (Figure 1).

Table 5.—Patient Perceptions of Progress in Treatment*

Patient Perceptions	Behavioral Treatment	Drug Treatment	Control Group
Patient description of progress, % (No.)			
Much better	74.1 (43/58)	50.9 (28/55)	26.9 (14/52)
Better	25.9 (15/58)	30.9 (17/55)	38.5 (20/52)
About the same	0.0 (0/58)	16.4 (9/55)	28.8 (15/52)
Worse	0.0 (0/58)	1.8 (1/55)	5.8 (3/52)
Estimate of percent improvement, mean (SD)	81.6 (18.6)	66.4 (35.4)	45.1 (36.6)
Having fewer accidents, % (No.)	100.0 (58/58)	87.3 (48/55)	67.3 (35/52)
Accidents are smaller, % (No.)	87.3 (48/55)	78.8 (41/52)	54.0 (27/50)
Able to wear less protection, % (No.)	76.0 (38/50)	56.0 (28/50)	34.1 (14/41)
Comfortable enough with treatment to continue indefinitely, % (No.)	96.5 (55/57)	54.7 (29/53)	43.1 (22/51)
Patient satisfaction with progress, % (No.)			
Completely satisfied	77.6 (45/58)	49.1 (27/55)	28.0 (14/50)
Somewhat satisfied	22.4 (13/58)	40.0 (22/55)	34.0 (17/50)
Not at all satisfied	0.0 (0/58)	10.9 (6/55)	38.0 (19/50)
Wish to receive another form of treatment, % (No.)	14.0 (8/57)	75.5 (40/53)	75.5 (37/49)

*For all comparisons, $P < .001$.

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 the 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 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}

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.²⁹ 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.³⁰ 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.³ 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 nonphysician providers in outpatient office settings.^{10,11,14} A behavioral intervention with these characteristics has the poten-

tial 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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