Combined Effects of Behavioral Intervention and Tolterodine in Patients Dissatisfied With Overactive Bladder Medication

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Purpose: We assessed the effect of tolterodine extended release plus behavioral intervention on treatment satisfaction and bladder diary variables in patients with overactive bladder who had been previously treated and were dissatisfied with tolterodine or other antimuscarinics.

Materials and Methods: This 16-week, multicenter, open label study included eligible patients 18 years old or older who reported overactive bladder symptoms 3 months or greater in duration, 8 or greater micturitions and 2 or greater urgency related micturitions per 24 hours, and 1 or greater urgency urinary incontinence episodes in a 5-day bladder diary at baseline as well as dissatisfaction with prior antimuscarinic medication. Patients received tolterodine extended release plus self-administered behavioral intervention, consisting of an educational pamphlet with verbal reinforcement, for 8 weeks. Satisfied patients continued with this therapy and dissatisfied patients received tolterodine extended release plus individualized behavioral intervention, consisting of in-depth interaction with a clinician to refine behavioral techniques, for 8 weeks thereafter. Patients rated treatment satisfaction at weeks 8 and 16, and completed a 5-day bladder diary at weeks 4, 8, 12 and 16, respectively.

Results: At weeks 8 and 16, 346 and 357 patients or 91% of the total cohort reported being at least a little satisfied with tolterodine extended release plus behavioral intervention, including 201 (53%) and 252 (64%), respectively, who were very satisfied. Of the 33 patients who were dissatisfied at week 8, 25 (76%) reported treatment satisfaction at week 16 after individualized behavioral intervention. Compared with baseline all bladder diary variables were significantly improved by week 4 (p < 0.0001). Patients who were dissatisfied with prior tolterodine or other antimuscarinic treatment reported similar results.

Conclusions: Tolterodine extended release plus behavioral intervention resulted in high treatment satisfaction and improved bladder diary variables in patients who had previously been treated and were dissatisfied with tolterodine or other antimuscarinics.

Key Words: urinary bladder, overactive; health behavior; tolterodine; urinary incontinence, urge; combination therapy

OVERACTIVE bladder is defined by the International Continence Society as urgency, with or without urgency incontinence, usually with increased daytime frequency and nocturia.1 In a large epidemiological study in which current International Continence Society definitions of OAB and OAB symptoms were used, approximately 11% of men and 13% of

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§ Financial interest and/or other relationship with Pfizer.

Abbreviations and Acronyms
ER = extended release
OAB = overactive bladder
UUI = urgency urinary incontinence
women in Europe and North America reported OAB symptoms.2 OAB symptoms are bothersome and they can negatively affect emotional well-being, social interactions, work productivity, sexual quality of life and relationships.3

Antimuscarinics, the first line pharmacological treatment for OAB, are associated with improvement in OAB symptoms and health-related quality of life.4 However, patients often fail to ingest antimuscarinics as prescribed, which can result in poor treatment outcomes.5 This challenge to optimal treatment outcomes is not specific to OAB, but rather a widespread concern for health care providers who treat patients with chronic conditions.

Behavioral interventions aimed at teaching continence skills and changing patient behavior are also available for OAB and UUI,6–8 of which the efficacy has been established for the frequency of UUI episodes and patient reported outcomes.6,9 Behavioral training with pelvic floor muscle exercise and urgency control strategies is a multicomponent technique used with or without biofeedback7,10 that has demonstrated efficacy in older women with UUI.9,10

Combining behavioral intervention with pharmacotherapy is a promising strategy for OAB and UUI.7 For example, combining a simple educational intervention and treatment with the antimuscarinic tolterodine significantly decreased voiding frequency and increased voided volume per micturition compared with those of tolterodine alone.11 Another study showed that significantly more patients receiving tolterodine plus educational intervention started or continued with drug treatment and reported improvement in bladder symptoms compared with that in patients receiving tolterodine alone.12 It was also reported that adding oxybutynin to behavioral therapy and vice versa yielded an additional treatment benefit in older women with UUI who were not satisfied with the results of each therapy alone.13

We addressed whether a combination of tolterodine ER with standardized self-administered or individualized behavioral intervention might improve OAB symptoms and treatment satisfaction in patients with OAB who had reported being dissatisfied with the most recent antimuscarinic therapy.

MATERIALS AND METHODS

Study Design

This was a 16-week, multicenter, multiphase, single arm, open label study of patients recruited at 66 centers in the United States. The study protocol was approved by the institutional review board at each participating investigational center. Patients were compensated for travel expenses at study center discretion. Patients reporting dissatisfaction with tolterodine or another antimuscarinic agent at screening received a morning or nighttime dose of 4 mg tolterodine ER combined with self-administered behavioral intervention for the first 8 weeks of the study. Study physicians and/or nurses (nurse practitioners, physician assistants or registered nurses) instructed patients on the dosing regimen. Patients who reported treatment satisfaction at 8 weeks continued this treatment, while patients who reported dissatisfaction at 8 weeks received tolterodine ER and an individualized behavioral intervention for 8 weeks thereafter. Compliance, defined as ingesting 80% or greater of the study medication, was assessed by monitoring unused medication at each visit.

Patients

Eligible patients were male and female outpatients 18 years old or older who reported OAB symptoms 3 months or greater in duration with 8 or greater micturitions per 24 hours, 2 or greater urgency-related micturitions per 24 hours, 1 or greater UUI episode in a 5-day bladder diary at baseline, dissatisfaction with prior antimuscarinic treatment and at least some moderate problems on the Patient Perception of Bladder Condition questionnaire.14 Urgency-related micturitions were defined as micturitions rated 3 or greater on the 5-point urinary sensation scale, including 1—no urgency, 2—mild urgency, 3—moderate urgency, 4—severe urgency and 5—UUI.15 Enrolled patients reported being a little dissatisfied or very dissatisfied with previous treatment with 1 to 2 antimuscarinic OAB medications, including tolterodine, tolterodine ER or any other OAB medication, on the Perception of Treatment Satisfaction question at screening. Patients were excluded from analysis when they had received behavioral intervention training 1 year or less, or antimuscarinic treatment 2 weeks or less before screening. All patients underwent vaginal or rectal pelvic floor examination at baseline to assess the ability to localize the pelvic floor muscles.

Behavioral Interventions

The self-administered behavioral intervention consisted of a focused, patient friendly 2-page educational pamphlet providing general information about OAB, scheduled voiding, pelvic floor muscle training, urgency control strategies and lifestyle interventions, ie fluid modifications, avoiding bladder irritants, bowel regularity, smoking cessation and weight loss (figs. 1 and 2). Study physicians and/or nurses reviewed the pamphlet with patients for up to 10 minutes at each visit and encouraged them to use it at home. Patients reporting dry mouth or constipation during the study were provided with additional handouts on management strategies.

In the individualized behavioral intervention study physicians and/or nurses assessed the behavioral interventions attempted or currently used by the patient, and provided education, encouragement and assistance to refine the strategies in the educational pamphlet to fit patient preferences and needs. This intervention required approximately 30 minutes and was performed at weeks 8 and 12. Patients also underwent pelvic floor examination performed by the study physicians and/or nurses to ensure proper pelvic floor muscle exercise technique but no biofeedback equipment was used.
Efficacy Assessments
The primary end point of this study was the proportion of patients who reported being at least a little satisfied with current OAB treatment at week 16 using the validated Perception of Treatment Satisfaction question, which was administered by the investigator.16 Response options in-
Pelvic floor muscles surround the bladder opening. When they are contracted (or tightened), they help hold in urine. As with many other muscles, exercise can strengthen this group. Success takes doing the exercises the right way and on a regular basis. As with all muscles, you must keep exercising to keep seeing a benefit.

You probably know these muscles. They are the same ones you squeeze to try to hold gas in your rectum. To help find them, try to slow down or stop your flow of urine. (Try this when you’re almost done going.) If you can, you have found the right muscles. Make sure you’re not using your stomach or buttock muscles at the same time.

When you isolate the pelvic floor muscles, you will not see or feel any movement on the outside of your body.

**Pelvic floor muscle exercise regimen:**
Your muscles may not be strong at first. So you may not be able to repeat the action or hold it for very long. But KEEP TRYING. It will get better as weeks go by. You should see full results after 15 to 30 weeks. Keep exercising to keep seeing results.

Do it 10 times at first. Hold the contraction for 3 seconds. If this is very easy, try holding for 5 seconds. Rest between contractions for the same amount of time. (That way, you won’t get tired as fast.)

Over time, work up to holding a contraction for 6 to 10 seconds. Then rest for 10 seconds. Do at least 30 to 50 per day. Exercise in sets of 10 at first. As you get stronger, you can do more sets fewer times a day. It is best to exercise each day if you can. If you can’t, 3 to 4 times per week will still help.

Do the exercises lying down, sitting, or standing. This will help you to have more control.

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**Other things you can do to help yourself**

- **Watch how much you drink:** Some people try to drink less to reduce OAB symptoms. But this can concentrate urine, which can irritate the bladder and make you constipated.

  How much fluid you need each day depends on how much you sweat (from heat or being active). Most people should drink 4 to 6 cups of fluid a day. At least half of your fluids should be water.

- **Avoid food and drinks that may bother your bladder:**

  Try to avoid these foods and drinks for 3-5 days. If your symptoms improve, avoid them as much as you can.

  - Coffee and drinks with caffeine
  - Carbonated drinks (like soda)
  - Fruits, especially citrus
  - Citrus drinks (like orange or grapefruit juice)
  - Artificial sweeteners
  - Spicy foods (like salsa)

- **Try to stay regular:** Normal bowel activity is an “easy” nonpainful movement at least every other day. Avoid straining to empty your bowels.

  Eat fiber, drink enough and exercise to help stay regular.

- **Watch your weight:** If you’re overweight, weight loss can improve OAB symptoms.

- **Stop smoking:** Chemicals from smoking can irritate the bladder.

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**Figure 2**

Include being very satisfied, a little satisfied, a little dissatisfied or very dissatisfied.

Secondary end points were the proportion of patients who reported treatment satisfaction at week 8, changes in total micturitions per 24 hours, urgency related micturitions per 24 hours, nocturnal micturitions and UUI episodes per 24 hours from baseline to weeks 4, 8, 12 and 16, as assessed from 5-day bladder diaries in which patients
recorded the time of every micturition and rated the sensation associated with each micturition episode using the urinary sensation scale.15

Statistical Analysis
The safety analysis set included all patients who ingested 1 or greater doses of study drug, while the full analysis set included all patients who ingested 1 or greater doses of study drug and underwent 1 or greater efficacy assessments at or after baseline. Patients were stratified at screening into groups that had received tolterodine or another antimuscarinic agent. Descriptive statistics were used to assess treatment satisfaction. The significances of mean changes in bladder diary variables from baseline were tested using the paired t test with significance considered at p < 0.05. Correlations between changes in bladder diary variables and treatment satisfaction ratings were assessed post hoc using Pearson correlation coefficients.

RESULTS
Of the 417 enrolled patients 416 received tolterodine ER treatment combined with self-administered behavioral intervention. A total of 48 (12%) patients discontinued the study. Of the withdrawals 11 (3%) were study drug related, including 10 (2%) due to an adverse event and 1 (0.2%) due to a lack of efficacy, while 37 (9%) were unrelated to study drug, of which 23 (6%) were due to default on study protocol and 5 (1%) were due to an adverse event unrelated to the study drug.

The 191 patients who had previously received tolterodine and the 225 who had previously received other antimuscarinics did not differ in demographic or clinical characteristics (table 1). Mean patient age was approximately 60 years, 87% of them were women and 79% were white. Of the patients 391 (99%) reported at least some moderate problems on the Patient Perception of Bladder Condition. The remaining 4 patients who reported some minor problems were in default of study enrollment criteria. In the full analysis set the mean percent of compliance with study medication was 98% (176 patients) and 99% of the 198 who had previously been dissatisfied with tolterodine and other antimuscarinics, respectively. Of the patients 405 (98%) were assessed as being able to isolate the pelvic floor muscles at baseline.

A total of 357 patients (91%) reported being at least a little satisfied at week 16, including 167 (92%) who had previously been dissatisfied with tolterodine and 190 (90%) who had previously been dissatisfied with another antimuscarinic (fig. 3, B). These data include patients who elected to continue self-administered behavioral intervention and those who elected individualized behavioral intervention at week 8. Notably 252 patients (64%) reported being very satisfied, including 128 (70%) and 124 (59%) who had previously been dissatisfied with tolterodine or another antimuscarinic, respectively.

A total of 346 patients (91%) who expressed dissatisfaction at baseline reported being at least a little satisfied at week 8 with the combination of tolterodine ER and self-administered behavioral intervention, including 160 (89%) who had been dis-

<table>
<thead>
<tr>
<th>Table 1. Baseline demographic data on safety population and clinical characteristics in full analysis population</th>
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<tbody>
<tr>
<td>Previous Antimuscarinic</td>
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<tr>
<td></td>
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<tr>
<td>Tolerodine</td>
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<tr>
<td>No. pts</td>
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<tr>
<td>No. women (%)</td>
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<tr>
<td>Mean ± SD age (range)</td>
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<tr>
<td>Mean ± SD kg wt (range)</td>
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<tr>
<td>Mean ± SD cm ht (range)</td>
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<tr>
<td>No. race (%):\</td>
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<tr>
<td>White</td>
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<tr>
<td>Black</td>
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<tr>
<td>Asian</td>
</tr>
<tr>
<td>Other</td>
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<tr>
<td>Mean yrs since first hypertonic bladder diagnosis (range)</td>
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<tr>
<td>Mean ± SD No. bladder diary variables:</td>
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<tr>
<td>Total micturitions/24 hrs</td>
</tr>
<tr>
<td>UUI episodes/24 hrs</td>
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<tr>
<td>Urgency related micturitions/24 hrs</td>
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<tr>
<td>Nocturnal micturitions</td>
</tr>
<tr>
<td>No. pt bladder condition perception (%)*:</td>
</tr>
<tr>
<td>Some minor problems</td>
</tr>
<tr>
<td>Some moderate problems</td>
</tr>
<tr>
<td>Severe problems</td>
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<tr>
<td>Many severe problems</td>
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</tbody>
</table>

* No patients perceived no problems at all or some very minor problems.
satisfied with previous tolterodine treatment and 186 (94%) who had previously been dissatisfied with another antimuscarinic (fig. 3, A). Furthermore, 201 patients (53%) reported being very satisfied at week 8 with tolterodine ER plus self-administered behavioral intervention, including 94 (52%) who had previously been dissatisfied with tolterodine and 107 (54%) who had previously been dissatisfied with another antimuscarinic. Congruently 328 patients (87%) elected to continue self-administered behavioral intervention at week 8 and 50 (13%) elected to receive individualized behavioral intervention.

Of the 50 patients (13%) who elected individualized behavioral intervention at week 8, 33 (9%) reported being dissatisfied with tolterodine ER and self-administered behavioral intervention. Of these patients 25 (76%) became satisfied with treatment at week 16, including 16 (80%) who had previously been dissatisfied with tolterodine and 9 (69%) who had previously been dissatisfied with another antimuscarinic (fig. 4). The remaining 17 patients (4%) had reported satisfaction with tolterodine ER and self-administered behavioral intervention at week 8 but, nevertheless, elected individualized behavioral intervention.

In patients who had previously been dissatisfied with tolterodine ER or with another antimuscarinic, tolterodine ER plus behavioral intervention resulted in significant decreases from baseline in the total number of micturitions, urgency related micturitions, UUI episodes per 24 hours and nocturnal micturitions at weeks 4, 8, 12 and 16 (each p <0.0001, fig. 5). Changes in all bladder diary variables were larger in the very satisfied and a little satisfied treatment satisfaction categories vs the dissatisfied and a little dissatisfied treatment satisfaction categories (table 2). Correlations between bladder diary variables and treatment satisfaction ratings were statistically significant but of moderate to weak strength (each p <0.01, table 2). The most common treatment related adverse events were dry mouth in 25 patients (6%) and constipation in 20 (5%).

**DISCUSSION**

In this study 91% of patients who had previously been dissatisfied with antimuscarinic treatment became at least a little satisfied after 8 weeks on tolterodine ER plus self-administered behavioral intervention, consisting of patient educational handouts with verbal reinforcement. Of the patients 53% reported being very satisfied. Notably the proportion of patients who reported being very satisfied increased to 64% at week 16. Most patients who were dissatisfied at week 8 became satisfied with tolterodine ER plus individualized behavioral intervention at week 16. The rates of dry mouth and constipation were similar to those in another study of tolterodine combined with behavioral intervention.11
Patients also reported significant improvements in all bladder diary variables, including nocturnal frequency, consistent with findings in other open label studies of tolterodine. These improvements likely contributed to treatment satisfaction since individuals report being bothered by different OAB symptoms. This notion is supported by significant correlations between treatment satisfaction ratings and symptom improvement.

**Table 2. Changes in bladder diary variables from baseline to weeks 8 and 16 by treatment satisfaction rating**

<table>
<thead>
<tr>
<th>24-Hr Bladder Diary Variables</th>
<th>Very Satisfied</th>
<th>Little Satisfied</th>
<th>Little Dissatisfied</th>
<th>Very Dissatisfied</th>
<th>Pearson Correlation Coefficient</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. micturitions:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wk 8</td>
<td>−3.6 ± 3.3</td>
<td>−2.5 ± 2.4</td>
<td>−1.7 ± 1.9</td>
<td>0.0 ± 3.5</td>
<td>0.26</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Wk 16</td>
<td>−4.0 ± 3.5</td>
<td>−2.9 ± 2.6</td>
<td>−1.8 ± 2.2</td>
<td>−0.6 ± 2.8</td>
<td>0.26</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No. UUI episodes</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Wk 8</td>
<td>−1.3 ± 1.5</td>
<td>−0.9 ± 1.6</td>
<td>−0.5 ± 1.4</td>
<td>−0.2 ± 1.7</td>
<td>0.16</td>
<td>0.0014</td>
</tr>
<tr>
<td>Wk 16</td>
<td>−1.4 ± 1.8</td>
<td>−1.0 ± 1.0</td>
<td>−0.6 ± 1.4</td>
<td>−0.4 ± 1.4</td>
<td>0.17</td>
<td>0.0010</td>
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<tr>
<td>No. urgency related micturitions:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Wk 8</td>
<td>−5.7 ± 3.9</td>
<td>−3.3 ± 4.0</td>
<td>−1.9 ± 2.7</td>
<td>0.1 ± 6.3</td>
<td>0.35</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Wk 16</td>
<td>−6.3 ± 4.6</td>
<td>−3.8 ± 3.5</td>
<td>−1.4 ± 4.2</td>
<td>−0.7 ± 4.1</td>
<td>0.35</td>
<td>&lt;0.0001</td>
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<tr>
<td>No. nocturnal micturitions:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Wk 8</td>
<td>−0.9 ± 1.1</td>
<td>−0.7 ± 1.1</td>
<td>−0.2 ± 1.0</td>
<td>−0.2 ± 1.6</td>
<td>0.16</td>
<td>0.0015</td>
</tr>
<tr>
<td>Wk 16</td>
<td>−1.0 ± 1.4</td>
<td>−0.8 ± 1.1</td>
<td>−0.2 ± 1.1</td>
<td>−0.2 ± 1.0</td>
<td>0.20</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

* Satisfaction with self-administered behavioral intervention plus tolterodine ER at week 8 and with self-administered or individualized behavioral intervention plus tolterodine ER at week 16.
and improvements in bladder diary variables, including 24-hour micturitions, urgency episodes, UUI episodes and nocturnal micturitions, similar to a previous study.16

In an earlier series women with UUI who were dissatisfied with behavioral training with biofeedback or oxybutynin treatment after 8 weeks were offered combination therapy for an additional 8 weeks.13 In patients dissatisfied with drug therapy the mean decrease in incontinence episodes improved from 73% after drug therapy alone to 84% after the addition of behavioral training. In patients dissatisfied with behavioral therapy alone the mean decrease in incontinence episodes improved from 58% with single therapy to 89% after adding oxybutynin. These findings are consistent with the current results in suggesting that combination therapy can improve the outcome in patients who do not respond satisfactorily to drug treatment or behavioral intervention alone. Further supporting the current results, another study showed that a simplified bladder training regimen combined with tolterodine was more effective for decreasing voiding frequency in patients with OAB than tolterodine alone.11 However, combined therapy did not enhance improvements in the number of incontinence episodes over tolterodine alone in that study.

In contrast to the current results, a randomized, parallel group study demonstrated that the improvements in bladder diary variables and health related quality of life elicited by darifenacin treatment were not enhanced by adding a self-administered behavioral modification program.18 However, these investigators did not specify dissatisfaction with prior antimuscarinic treatment as a study inclusion criterion. Moreover, the behavioral program used multiple pamphlets and multimedia materials, contrasting with the focused self-administered behavioral intervention in our series.

The question of whether a simple educational intervention might result in higher patient compliance with OAB pharmacotherapy was addressed in a 16-week, open label, randomized trial of tolterodine.12 Although patient compliance with combined treatment was higher than with tolterodine treatment alone, this difference was not significant. However, significantly more patients in the intervention group started and/or continued with behavioral therapy.

Although to our knowledge the mechanisms by which behavioral therapies improve incontinence symptoms remain to be established, they likely differ from those underlying drug therapy, suggesting that additive or synergistic treatment effects might result from combining these therapies.7 A recent study showed that adding behavioral training to drug therapy decreased the incontinence frequency.19 However, the number of patients who could discontinue drug therapy while maintaining improved urinary incontinence did not increase. Thus, behavioral intervention appears to provide a simple conservative method to help dissatisfied patients achieve an improved outcome with pharmacological treatment. Providing additional handouts on management strategies for dry mouth or constipation may also have contributed to treatment satisfaction. The results also suggest that changing from 1 drug to another when a patient is dissatisfied with treatment may not be necessary. It may be possible to achieve patient satisfaction by introducing focused behavioral intervention instead. This may be particularly relevant in patients who have been referred to an incontinence specialist after being started on drug treatment without behavioral intervention.

A limitation of this study is that it was not possible to determine the effects of behavioral intervention alone in this study because all patients received combined therapy. Another limitation is that the treatment satisfaction question may have been asked by the same individual who delivered the behavioral intervention, possibly influencing patient ratings. Finally, the reasons for patient dissatisfaction with previous antimuscarinic treatment were not collected at the beginning of this study. However, interviews with a small sample of patients after the study showed that the most common reasons for dissatisfaction with prior medication were lack of efficacy, adverse events and medication cost.20

CONCLUSIONS

Results show that combining tolterodine ER therapy with behavioral intervention enhances treatment satisfaction and improves OAB symptoms in patients who had previously been dissatisfied with antimuscarinic treatment. Many patients with OAB may benefit from a simple, self-administered behavioral intervention using patient education materials and verbal reinforcement, in addition to antimuscarinic medication. This approach introduces little cost or burden on the clinician aside from the time needed to introduce the behavioral intervention and it is easily implemented and well suited to primary and specialty care settings. Patients who do not respond to self-administered behavioral therapy may benefit from individualized intervention involving pelvic floor muscle training and in-depth interaction with a health care provider, in addition to antimuscarinic medication.

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