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IMPROVEMENT IN URGENCY PERCEPTION AFTER TOLTERODINE TREATMENT IS ASSOCIATED WITH PATIENT SATISFACTION WITH TREATMENT

Hypothesis / aims of study

Overactive bladder (OAB) is a highly prevalent, debilitating condition characterized by symptoms of urinary urgency and frequency, with or without urge incontinence. To fully evaluate the beneficial effects of treatment for OAB, it is important to assess not only objective improvements in bladder function but also subjective improvements in patients' perception of their bladder condition and treatment benefit. We evaluated the efficacy of tolterodine tartrate (TOL) versus placebo (PBO) with regard to patients' perception of urinary urgency, bladder condition, and treatment benefit in men and women with OAB.

Study design, materials and methods

This was a retrospective subanalysis of data collected from a clinical trial of TOL for patients with symptoms of OAB. Patients (aged ≥18 years) with ≥8 micturitions/24 h and incontinence (≥5 episodes/wk) were randomized to receive TOL extended release (ER; 4 mg once daily) or PBO for 12 weeks. Bladder function (ie, incontinence episodes, pad use, voided volume, voiding frequency) was assessed using 7-day micturition diaries. Patient perceptions of urgency and bladder condition were assessed at baseline and week 12 using 3- and 6-point ordered categorical scales, respectively. Patient perception of treatment benefit was evaluated at week 12 using a 2-step assessment and ordered categorical scale. Perception of urgency was assessed with the question, "Regarding your experiences of desire to void, which of the following alternatives would apply to your situation? " and 3 answers, (1) I was usually not able to hold urine, (2) I was usually able to hold urine until I reached a toilet (without leaking) if I went there immediately, or (3) I was usually able to finish what I was doing before going to toilet (without leaking).

Results

The TOL ER (n=506) and PBO (n=508) groups who reported perception of urgency were comparable with respect to demographics, baseline micturition variables, and previous pharmacologic treatment for OAB. A high percentage of patients who received TOL ER (89%) and PBO (87%) completed the study. After 12 weeks of treatment, patients who received TOL ER showed significant improvements in objective and subjective endpoints compared with patients who received PBO. A significantly larger percentage of TOL ER patients (39%) reported an improved perception of urgency than did PBO patients (26%; $P<0.0001$). The percentage of patients not able to hold urine decreased by more than 50% in the TOL ER group compared with a 27% decrease with PBO. There was a 5-fold increase from baseline to week 12 in the patients' ability to complete a task before needing to void with TOL ER (6% to 30%); there was a 2-fold increase with PBO (7% to 16%; $P<0.001$). Almost twice as many PBO as TOL ER patients reported deterioration in urgency after 12 weeks of treatment (11% vs 5%, respectively). In addition, patients' perception of urgency correlated with other subjective and objective measures of bladder function (Table).

Interpretation of results

Compared with PBO, patients who received TOL treatment showed significant improvements in OAB symptoms, including perception of urinary urgency. Improvements in urinary urgency perception were associated with improved perceptions of treatment benefit and bladder condition and with other objective measures of bladder function.

Concluding message

In patients with OAB, treatment with TOL ER resulted in significant improvements in their perceptions of urinary urgency. Improvements in urgency symptoms were correlated with other subjective and objective efficacy measures. Improvements in these efficacy endpoints contributed to the patients' overall satisfaction with treatment.

Table. Proportion of Patients Reporting Improved Perception of Urgency and the Correlations With Other Subjective and Objective Efficacy Endpoints

	PBO		TOL ER		
Improved Urgency *and*:	**%**	***r***	**%**	***r***	***P* value***
"Much" treatment benefit	13.7	0.41	25.1	0.33	<0.0001
Improved bladder condition	18.3	–0.34	30.4	–0.35	<0.0001
≥1 decrease in micturitions/d	18.5	–0.24	28.3	–0.29	0.0003
≥70% decrease in incontinence episodes/d	13.5	–0.28	26.2	–0.24	<0.0001
≥30% decrease in pad use/d	17.5	–0.20	31.5	–0.21	0.0001
≥45 mL increase in volume/micturition	6.3	0.06	17.2	0.13	<0.0001

PBO=placebo; TOL ER=tolterodine extended release.
*Chi-square test for percentages in the TOL ER versus PBO treatment groups.

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