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DEFINING RESPONSE TO ANTIMUSCARINIC THERAPY IN PATIENTS WITH OVERACTIVE BLADDER

Aims of Study

Previous studies of antimuscarinic agents for overactive bladder have focused on objective improvements in symptoms. However, patients' own subjective assessment of their bladder condition has seldom been considered and it is not clear what degree of improvements in micturition diary variables are meaningful to patients. The objective of this study was to define a meaningful response to treatment using subjective measures and to investigate whether this correlated with changes in micturition variables.

Methods

Patients (≥18 years old) with symptoms of urinary frequency (≥8 micturitions/24 h) and urgency with or without urge incontinence, were enrolled into a multicenter, prospective, open-label study in which they received extended-release (ER) tolterodine 4 mg once daily for 12 weeks. Patients were categorized based on their previous exposure to pharmacotherapy for overactive bladder: naïve patients were those who had not previously received treatment for overactive bladder, while experienced patients were those currently receiving treatment other than tolterodine for overactive bladder. Experienced patients were required to enter a wash-out period of 7 days prior to the 7-day run in period. The primary efficacy variable was patient perception of bladder condition (PPBC), which was assessed using a validated 6-point categorical scale: my bladder condition; [1] does not cause me any problems at all; [2] causes me some very minor problems; [3] causes me some minor problems; [4] causes me (some) moderate problems; [5] causes me severe problems; [6] causes me many severe problems. Physicians were asked to assess whether treatment had been beneficial using a 3-point scale: [1] no; [2] yes, a little benefit; [3] yes, very much benefit. Micturition diary variables were also evaluated (micturitions/24 h, incontinence episodes/24 h and urgency episodes/24 h). Patients were defined as either responders or non-responders to treatment based upon patient and physician perception variables. Patients with an improvement of at least 1 point on the PPBC scale and a positive physician assessment after 12 weeks were defined as true responders. Partial responders were patients who achieved an improvement in either PPBC or physician assessment but not both. Non-responders were those patients without any improvement in either PPBC or physician assessment. Efficacy analyses were performed on all patients who received 12 weeks of therapy and adhered to protocol criteria (per-protocol population).

Results

A total of 1147 patients were enrolled, of whom 911 (79%) completed 12 weeks of treatment. Forty-six patients who completed therapy were excluded due to protocol violations: thus, 865 patients were eligible for per-protocol analysis (naïve, n=560; experienced, n=305). A high level of response to treatment with tolterodine ER was reported after 12 weeks, with 70% of patients (n=602) classed as true responders and 24% as partial responders (n=208). Only 6% of patients were non-responders (n=55). The proportion of patients who were true responders was higher among naïve than experienced patients (75% vs 60%), whereas the proportions of partial responders and non-responders were higher in the experienced group (31% vs 20% and 9% vs 5%, respectively). Among true responders, the improvement in PPBC was rapid, with 64% of naïve patients and 60% of experienced patients reporting an improved bladder condition after 1 week. A rapid response was also apparent from physicians' assessment of treatment, with benefit being reported for over 90% of true responders after 1 week (naïve 92%, experienced 93%).Tolterodine ER also produced rapid and significant improvements in micturition diary variables. These improvements tended to be greater in naïve compared with experienced patients and correlated with improvements in subjective assessments, with true responders generally having greater median reductions in micturitions/24 h (naïve 35%, experienced 27%), incontinence episodes/24 h (naïve 100%, experienced 86%) and urgency episodes/24 h (naïve 91%, experienced 83%) than partial or non-responders.

Conclusions

A high level of response to treatment with tolterodine ER was reported based on PPBC and physician assessment. Response to treatment as defined by these subjective assessments correlates well with improvements in micturition diary variables. Defining response with these subjective measures appears to be a valid and useful means of evaluating antimuscarinic therapy.