

ACHIEVING CONTINENCE WITH ANTIMUSCARINIC THERAPY FOR OVERACTIVE BLADDER: DO BASELINE INCONTINENCE AND MICTURITION DIARY LENGTH AFFECT OUTCOME?

Hypothesis / aims of study

Patients with overactive bladder (OAB) symptoms including urgency urinary incontinence (UUI) report a higher degree of symptom bother than patients with urinary urgency and frequency alone[1]. Thus, in many clinical trials of pharmacotherapies for OAB, reduction in UUI episodes is a primary outcome measure. However, the proportion of patients that achieves total dryness (UUI episodes = 0 in diary period) in a given study may be influenced by a number of factors. We performed a post hoc analysis of data from a 12-week placebo-controlled trial of tolterodine extended release (ER) to examine the effect of micturition diary length and number of baseline UUI episodes on total dryness rates.

Study design, materials and methods

This was a 12-week, multicenter trial of patients (≥ 18 y of age) with symptoms of urinary frequency (≥ 8 micturitions/24 h) and UUI (≥ 5 episodes/wk) for ≥ 6 months. Patients were randomized to once-daily treatment with placebo or tolterodine ER (4 mg). Micturition diaries were completed for 7 days before the baseline visit and again before the week 12 visit. All micturitions and UUI episodes were recorded at the times they occurred. This post hoc analysis included only patients with < 21 weekly UUI episodes at baseline who received treatment with tolterodine ER. We evaluated the proportion of patients reporting total dryness during the 3-, 5-, and 7-day periods immediately preceding the week 12 visit and assessed the relationship between total dryness rates and baseline number of UUI episodes.

Results

621 and 473 patients were included from the intent-to-treat (ITT) and per protocol (PP) populations, respectively. For each category of baseline number of UUI episodes, the percentages of patients becoming dry increased with decreasing diary length. Baseline frequency of UUI was negatively associated with total dryness rate by week 12, regardless of diary length (**Table 1**). As expected, higher percentages of patients in the PP population than the ITT population achieved total dryness (**Table 2**).

Table 1. Total Dryness Rates* For ITT Population After 12 Weeks of Treatment

Baseline Weekly UUI Episodes	Diary Length (Days)					
	7		5		3	
	Placebo	Tolterodine ER	Placebo	Tolterodine ER	Placebo	Tolterodine ER
<21	22%	32%	26%	36%	33%	45%
<14	25%	37%	29%	41%	34%	48%
<7	25%	54%	29%	50%	32%	59%

*Patients reporting UUI=0 at end of treatment.

ITT=intent-to-treat; UUI=urgency urinary incontinence.

Table 2. Total Dryness Rates* For PP Population After 12 Weeks of Treatment

Baseline Weekly UUI Episodes	Diary Length (Days)					
	7		5		3	
	Placebo	Tolterodine ER	Placebo	Tolterodine ER	Placebo	Tolterodine ER
<21	26%	34%	30%	41%	38%	52%
<14	31%	40%	36%	47%	41%	57%
<7	36%	58%	41%	59%	43%	69%

*Patients reporting UUI=0 at end of treatment.

PP=per protocol; UUI=urgency urinary incontinence.

Interpretation of results

A single UUI episode is less likely to be captured in a 3-day micturition diary than in a 7-day diary. Thus, data from 3-day diaries produced higher total dryness rates than did data from 7-day diaries. Furthermore, despite meaningful reductions in UUI episodes with tolterodine ER, patients with greater frequency of UUI episodes at baseline were less likely to achieve total dryness than were patients with less frequent UUI.

Concluding message

Total dryness rates with pharmacotherapy can be influenced by a number of factors, including the severity of UUI at baseline, the length of micturition diaries, and the study population analyzed. Higher dryness rates are typically associated with less severe UUI at baseline, shorter micturition diaries, and analysis of the PP rather than ITT patient population.

Reference

1. The impact of urinary urgency and frequency on health-related quality of life in overactive bladder: Results from a national community survey. *Value in Health*. 2004;7(4):451–459.

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