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IS THERE A DIFFERENCE IN THE TOLERABILITY OF OVERACTIVE BLADDER MEDICATIONS?

Hypothesis / aims of study

Medications for overactive bladder (OAB) differ in their reported adverse events. We conducted a 20-week, double-blind, two-period, crossover trial comparing patient tolerability (primary endpoint) and preference for mirabegron (a β3-adrenoceptor agonist) vs tolterodine ER (an antimuscarinic) (Clinicaltrials.gov NCT02138747).

Study design, materials and methods

Treatment-naïve adults with OAB for ≥3 months (≥3 urgency episodes grade 3 or 4 and average of ≥8 micturitions/day) were randomly assigned to mirabegron (M) 25 mg for 4 weeks titrated to 50 mg for 4 weeks or tolterodine ER (T) 4 mg for 8 weeks, followed by a 2-week washout and crossover to the alternative treatment for 8 weeks (Fig). Sixty patients were assigned to repeat their original treatment after washout. Primary endpoint was patient tolerability measured by the Overactive Bladder Satisfaction (OAB-S) Medication Tolerability scale. Mean tolerability scores were calculated by treatment period (scored from 0 to 100 with a higher score representing better tolerability, with assessment for interaction by sequence). Adverse Events (AEs) were captured over the course of the study. Statistical analysis was performed comparing adjusted mean tolerability scores and frequency of AEs of interest.

Results

A total of 358 patients were randomized and completed ≥1 OAB-S Tolerability Scale post-baseline (M+T n=154, T+M n=144, M+M n=30, T+T n=30). The M+T sequence had more patients ≥65 years (24.0%, vs 16.7% in T+M) and more patients with incontinence at baseline (76.0% vs 61.8% in T+M).

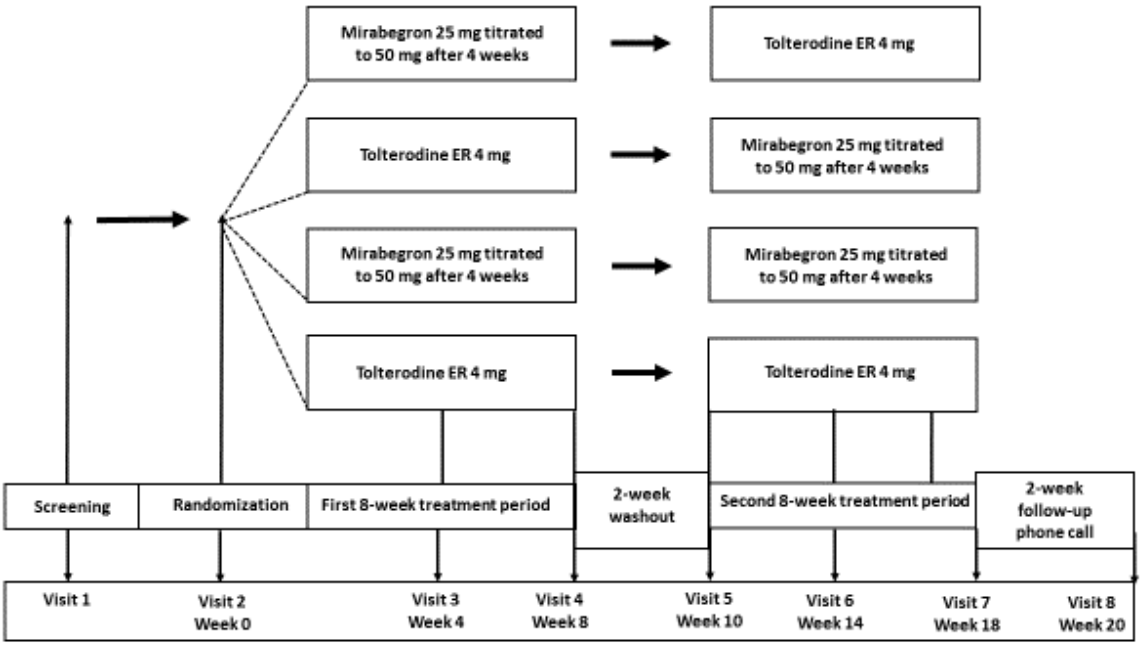
Patients reported a higher OAB-S Tolerability Score on mirabegron than tolterodine (adjusted difference 2.89; p=0.004). Fewer AEs were reported for mirabegron vs tolterodine (20.4% vs 27.4%, M vs T for overall anticholinergic AEs, p=0.042; 14.7% vs 22.5%, M vs T for gastrointestinal disorders, p=0.015. There was no difference in the reporting of cardiac, hypersensitivity, urinary retention, or urinary tract infection AEs between treatments (all p>0.05). There was no significant effect for treatment sequence (p=0.955).

Interpretation of results

Mirabegron demonstrated statistically significantly higher mean OAB-S Tolerability Scores and fewer AEs than tolterodine ER.

Concluding message

This crossover trial of two treatments for OAB demonstrates improved tolerability with mirabegron vs tolterodine ER. The tolerability score findings were substantiated by the AE reporting during the course of the study.



Disclosures

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