

EVALUATING THE MAGNITUDE OF IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES IN OVERACTIVE BLADDER PATIENTS: A POOLED ANALYSIS OF TWO MIRABEGRON CLINICAL TRIALS

Hypothesis / aims of study

The efficacy of medications used to treat overactive bladder (OAB) is generally quantified by objective outcomes, eg, improvements in micturitions and episodes of urinary incontinence. Patient-reported outcomes (PROs) give clinicians valuable insight into how a patient perceives a treatment on drug efficacy and improvement in symptomatology in OAB [1]. Several validated and reliable instruments exist to measure PROs for OAB patients [2]. This study sought to evaluate magnitude of PRO improvement stratified by age in patients enrolled in 2 mirabegron Phase 3 clinical trials that included PRO data.

Study design, materials and methods

Pooled North American patients from studies 178-CL-047 and 178-CL-074 randomized to 50 mg of mirabegron were compared to patients randomized to placebo on 1) Patient Perception of Bladder Condition (PPBC) score, 2) Treatment Satisfaction—Visual Analog Scale (TS-VAS), and 3) Overactive Bladder Questionnaire (OABq) total health-related quality of life score. All measures were stratified by age subgroups to evaluate marginal differences across cohorts: 1) <65 years, 2) ≥65 years, 3) <75 years, and 4) ≥75 years. Changes in PPBC, TS-VAS, and OABq total and subscores from baseline to 12 weeks were calculated for patients receiving active (mirabegron 50 mg) and placebo treatment. Change in scores were assessed using an analysis of covariance (ANCOVA) model with treatment group, gender, study, subgroup, and subgroup by treatment group interaction as fixed factors and baseline as a covariate, with an a priori $\alpha = 0.05$. Power calculations were not completed as data from two previously completed clinical trials were pooled.

Results

Pooled populations included 745 patients aged <65, 445 patients aged ≥65, 1,036 patients aged <75, and 156 patients aged ≥75. Results of the ANCOVA model are contained in Table 1.

Table 1. Change in PROs for Mirabegron 50 mg vs Placebo

	<65 years		≥65 years		<75 years		≥75 years	
	Δ	p-value	Δ	p-value	Δ	p-value	Δ	p-value
TS-VAS	0.75	0.001	1.34	0.001	0.97	0.001	0.97	0.048
PPBC	0.03	0.690	-0.32	0.001	-0.08	0.220	-0.26	0.120
OABq	1.77	0.150	5.70	0.001	2.81	0.007	6.06	0.028

Interpretation of results

Compared to the <65 cohort, patients ≥65 reported higher numerical improvement vs placebo ($p < 0.0001$) across all measures, including the OABq; only one measure in the <65 group was significant. Magnitude of difference for the ≥65 cohort increased in 2 of 3 measures when further stratified to ≥75 ($p < 0.05$).

Concluding message

Patients from all age groups generally perceived mirabegron 50 mg to be more efficacious than placebo in treating symptoms of OAB, with the most pronounced effect in patients aged ≥65 years. Further analyses are needed to determine the physiological or psychological basis for these results.

References

1. Coyne KS, Tubaro A, Brubaker L, Bavendam T. Development and validation of patient-reported outcomes measures for overactive bladder: A review of concepts. *Urology*. 2006; 8(2):S9-S16.
2. Brubaker L, Chapple C, Coyne KS, Kopp, Z. Patient-reported outcomes in overactive bladder: Importance for determining clinical effectiveness of treatment. *Urology*. 2006;68(2):S3-S8.

Disclosures

Funding: Study was funded by Astellas Scientific and Medical Affairs, Inc. **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** The present study is a pooled analysis of patient-reported outcomes collected in two pivotal clinical trials at a previous point in time. There was no intervention performed on patients specifically for the purposes of this study. **Helsinki:** Yes **Informed Consent:** No