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SAFETY AND EFFECTIVENESS OF MIRABEGRON IN PATIENTS ≥75 YRS WITH OVERACTIVE BLADDER: ANALYSIS OF A JAPANESE POST-MARKETING COMMITMENT STUDY

Hypothesis / aims of study

Prevalence of OAB increases with age among both men and women. A 12-wk post-marketing study was conducted to provide real-world data on baseline data of Japanese patients with OAB who initiated treatment with the β3-adrenoceptor agonist mirabegron. This subanalysis focuses on safety and effectiveness of mirabegron in patients aged <75 yrs and ≥75 yrs.

Study design, materials and methods

Before initiating mirabegron treatment, full medical histories were collected. Following 12-wks' treatment with mirabegron, physicians assessed the incidence of adverse drug reactions (ADRs) and treatment effectiveness. Patients completed the Overactive Bladder Symptom Score (OABSS) and International Prostate Symptom Score-Quality of Life (I-PSS QoL) at Baseline (BL) and 12 wks (end of treatment; EoT). A reduction of ≥3 points in total OABSS from BL to EoT was defined as a minimal clinically important change (MCIC).

Table: Safety and effectiveness of treatment with mirabegron

Incidence of ADRs in the Safety Analysis Population					
Overall					
Any adverse reaction, n (%)	595 (6.07)				
Subgroups	<75 yrs (n=5011)	≥75 yrs (n=4784)			
Any adverse reaction, n (%)	260 (5.19)	335 (7.00)			
Common ADRs present at ≥0.3% in patients ≥75 yrs, events (%)					
Constipation	47 (0.94)	48 (1.00)			
Residual urine volume increased	30 (0.60)	40 (0.84)			
Dysuria	18 (0.36)	25 (0.52)			
Thirst	21 (0.42)	25 (0.52)			
Dizziness	5 (0.10)	22 (0.46)			
Urinary retention	9 (0.18)	21 (0.44)			
Cystitis	9 (0.18)	15 (0.31)			
Effectiveness					
	'Effective', n (%)				
Overall (n=9394)	7582 (80.7)				
<75 yrs (n=4815)	3952 (82.1)				
≥75 yrs (n=4579)	3630 (79.3)				
OABSS Score	**BL (mean ± SD)**	**EoT (mean ± SD)**	**BL to EoT changes (mean ± SD)**	**Within-group comparison***	**MCIC Achieved n (%)**
Overall (n=4153)	9.0 ± 2.53	5.3 ± 3.25	−3.7 ± 3.11	P<0.001	2641 (63.6)
<75 yrs (n=2195)	8.6 ± 2.49	4.8± 3.09	−3.8 ± 3.01	P<0.001	1447 (65.9)
≥75 yrs (n=1958)	9.5 ± 2.50	5.9 ± 3.32	−3.6 ± 3.22	P<0.001	1194 (61.0)
Between-group comparison†	P<0.001	N/A	P=0.002	N/A	P<0.001
I-PSS QoL Score	**BL (mean ± SD)**	**EoT (mean ± SD)**	**BL to EoT changes (mean ± SD)**	**Within-group comparison***	N/A
Overall (n=3833)	5.0 ± 0.93	2.8 ± 1.61	− 2.1 ± 1.77	P<0.001	N/A
<75 yrs (n=2028)	5.0 ± 0.90	2.8 ± 1.63	− 2.2 ± 1.76	P<0.001	N/A
≥75 yrs (n=1805)	4.9 ± 0.97	2.9 ± 1.58	−2.0 ± 1.77	P<0.001	N/A
Between-group comparison†	N/A	N/A	P<0.001	N/A	N/A

N/A, not available; SD, standard deviation
*Between BL and EoT
†Between those <75 yrs and those ≥75 yrs

Results

Of the 9795 patients analyzed, patients ≥75 yrs (48.8% of the population) showed significantly longer duration of OAB at BL, higher OABSS, more renal dysfunction, increased residual urine volume and lower body mass index (BMI) vs patients <75 yrs (51.2% of the population), and were more likely to be male (all P<0.001). A larger number of patients ≥75 yrs (77.8%) vs patients <75 yrs (66.0%) had comorbidities, notably hypertension, benign prostatic hyperplasia, prostate cancer, angina, arrhythmia, osteoporosis and constipation. In total, 58.3% of patients ≥75 yrs and 48.7% of patients <75 yrs reported concomitant drug use. Incidence of total ADRs was low in both groups, however, it was statistically higher in those ≥75 yrs (7.0%) vs those <75 yrs (5.19%; P<0.001; Table). Mirabegron treatment was reported as 'effective' by the physician in 79.3% of patients ≥75 yrs and 82.1% of patients <75 yrs. At EoT, mean total OABSS decreased significantly from BL in both groups, and the changes exceeded the MCIC in 61.0% and 65.9% of patients ≥75 yrs and <75 yrs, respectively. Additionally, significant changes were observed for I-PSS QoL in both groups (Table).

Interpretation of results

Patients aged ≥75 yrs had more comorbidities and more concomitant drug use than those <75 yrs. In addition, elderly patients had more severe OAB and longer duration of OAB.

Concluding message

Mirabegron was well tolerated and effective in both elderly patients aged ≥75 and <75 yrs with OAB.

Disclosures

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