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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

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†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

Funding: Astellas Pharma Inc Clinical Trial: Yes Registration Number: NCT01919047 RCT: No Subjects: HUMAN Ethics not Req'd: The study was performed in accordance with the standards for Good Post-Marketing Study Practice (GPSP of the Japanese Ministry of Health, Labour and Welfare). Helsinki not Req'd: The study was performed in accordance with the standards for Good Post-Marketing Study Practice (GPSP of the Japanese Ministry of Health, Labour and Welfare). Informed Consent: Yes