Factors associated with the incidence of adverse drug reactions (ADRs) in patients with overactive bladder (OAB) treated with mirabegron: a Japanese post-marketing study

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INTRODUCTION

• Mirabegron is the first ß3-adrenoceptor agonist and was initially approved in Japan for the treatment of OAB symptoms
• Mirabegron is a well-tolerated
• Few musculoskeletal complaints rather off-labels the non-musculoceptors due to interference mechanism of action
• An alternative therapeutic option for patients with resistance to antimuscarinic agents is not contraindicated
• Mirabegron is administered as a wide range of patients is real-world clinical use including elderly patients and patients with concomitant diseases

OBJECTIVES

• To provide real-world data from a Japanese medical database using patients with OAB receiving mirabegron for treatment of OAB symptoms
• To assess the association between treatment characteristics, concomitant disease, mirabegron administration proportion, OAB duration, prior OAB medications, medical history, and concomitant drug use, treatment efficacy and incidence of adverse drug reactions (ADRs)

METHODS

Study design

• A 2-drug trials survey (EDOE5; ClinicalTrials.gov Identifier: NCT01914947) to ensure compliance with Japanese Good Post-Marketing Study Practices regulations
• A database was collected from patients before initiating mirabegron treatment including prior and concurrent drug use
• The observation period was 12 weeks

Patients

• Adult men and women currently receiving mirabegron for treatment of OAB symptoms
• Patients who had previously received mirabegron were excluded

Efficacy assessments

• At entry and at 12 months (D12) or discontinuation

Safety assessments

• Incidence of ADRs was measured, summarized and using symptoms on SOAP (SOG) and patient's report (PR) from the Japanese version of MedDRA (version 15.1)

Statistical analysis

• The influence of patient characteristics on the proportion of patients who achieved the minimal clinically important change (MCIC) in OABSS and the incidence of ADRs was assessed by descriptive analysis

RESULTS

Patient disposition

• Survey data from 10,988 patients were collected from 1111 medical institutions (Figures 1)

Demographic and Baseline characteristics of patients

• Of the 10,988 patients, 4385 (40.2%) were male and 6603 (60.1%) were female

Concomitant disease and prior/current treatment status at baseline

• At entry, 833 patients were considered to be “effective” in the treatment group
• Among patients with concomitant drug use and special patient characteristics (concomitant disease) were used as explanatory variables in the multivariate logistic analysis

Prostate hyperplasia was excluded from this analysis due to its strong association with Age, CYP3A4, and ADRs=adverse drug reactions

Patient characteristics

• Increased with concurrent disease excluded from OAB

Age

• Increased significantly with age (<75 vs ≥75 years), with concomitant disease (i.e., hypertension), with co-existing arrhythmia or diabetes mellitus

Technical characteristics

• Increased with concurrent disease excluded from OAB

Efficacy characteristics

• Increased with concurrent disease excluded from OAB

CONCLUSION

• In a real-world clinical setting where a wide variety of patients with OAB were treated with mirabegron, the incidence of concomitant disease, medical history, and concomitant drug use, treatment efficacy and incidence of adverse drug reactions (ADRs) was determined

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DISCLOSURES

REFERENCES

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