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EFFICACY AND SAFETY OF B3-ADRENORECEPTOR AGONIST (MIRABEGRON) IN TREATMENT-NAÏVE JAPANESE FEMALE PATIENTS WITH OVERACTIVE BLADDER

Hypothesis / aims of study

Overactive bladder (OAB) is a common health problem and negatively impacts patients' quality of life (QOL). Although lifestyle interventions and antimuscarinics have been the main treatment, the use of antimuscarinics can be limited by their side effects such as dry mouth, constipation, which compromise patient adherence. Such adverse events as well as poor efficacy in some patients had promoted the search for new drugs with improved safety and efficacy.

Mirabegron has been developed as a new treatment drug for OAB. It is an orally active β_3-adrenoreceptor agonist that produces detrusor relaxation only in the storage phase and improve OAB symptom. Some of the premarketing clinical trials showed that mirabeguron was well tolerated and with significant efficacy in reducing the number of incontinence episodes and voiding frequency.

In the present study, we evaluated the efficacy and safety of mirabegron in the treatment of female OAB.

Study design, materials and methods

A total 49 female treatment-naïve OAB patients who presented to female clinic were enrolled in the study. The design was prospective, single-dose, one arm with 8-week active treatment period. All patients received mirabegron oral tablet (50mg) once daily. All patients were subjected to a diagnostic work-up of medical history, physical examination, 3 days voiding chart, and post voided residual (PVR) before starting medication. In order to examine efficacy, tolerability and safety of the drug, the following parameters were evaluated before and 4weeks, 8 weeks after the medication; the overactive bladder symptom score (OABSS, scoring the daytime urinary frequency, nighttime urinary frequency, urgency and urge urinary incontinence, validated in Japan), International Consultation of Incontinence Questionnaire of Sort Form (ICIQ-SF), number of pads use a day, and the incidence and grade of the side effect. Also before and 8 weeks after, PVR were analysed.

All participants provided oral informed consent before entering the study.

For statistical analysis, paired t-test was used and p value <0.05 was considered statistically significant.

Results

38 out of 49 (77.6%) patients were complete the study. Mean age, mean Body Mass Index (BMI), mean number of parity were 65.6±11.0 years, 22.8±2.3 kg/m^2, 1.4±1.0 and all patients ware postmenopausal.

After 4 weeks of treatment, OABSS total score, ICIQ-SF total score and number of pads were significantly improved compared to those of control, respectively (OABSS; 8.1±2.9 → 6.2±3.2, ICIQ-SF; 8.6±5.2 → 3.5±2.4, number of pads;2.3±2.7→1.5±1.0) ($p<0.05$). Even after 8 weeks of the treatment, those scores were maintained unchanged (OABSS; 6.2±3.2→6.4±3.6, ICIQ-SF; 3.5±2.4→3.2±2.7, number of pads; 1.5±1.0→1.1±1.0). There was no significant change in PVR (15.1±20.7 vs 25.0±12.1) (NS).

Constipation was reported in 2 cases (5.3%), dry mouth was reported in 1 case (2.6%), and gastrointestinal adverse event in 1 case (2.6%) but continue the medication because of those side effect. Rush was reported in 1 case (2.6%) and this patient discontinued the medication.

Interpretation of results

This study clearly demonstrated that mirabegron significantly improved the OAB symptoms and well tolerated to managing OAB symptom in treatment-naïve female OAB patients. Compared to antimuscarinics, the side effect was moderate and 94.1% could continue the medication for 8 weeks.

Concluding message

At the best of our knowledge, this is the first clinical study showing the efficacy and safety of β_3-adrenoreceptor agonist, mirabegron.

References

1. Expert Opin.Drug Saf.2011;10(2):287-294

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