

IMPROVEMENT OF MENTAL CONDITION IN TREATMENT-NAÏVE FEMALE OVERACTIVE BLADDER PATIENTS BY B₃-ADRENORECEPTOR AGONIST (MIRABEGRON)

Hypothesis / aims of study

Overactive bladder (OAB) is a common health problem and negatively impacts patients' quality of life (QOL) and increased rates of depression in women. We reported that severity of OAB symptom correlates with depression status and also improvement of the OAB symptoms with anticholinergics seems to provide a relief of depressive condition.

Although antimuscarinics have been the main treatment of OAB, the use of these drugs can be limited by their side effects such as dry mouth, constipation, which compromise patient adherence. 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. There are many reports which showed the efficacy and safety of Mirabegron on OAB symptoms, however the influence of this medicine on mental status is scant. Therefore, we evaluated the effectiveness of Mirabegron not only on OAB symptoms but also on mental status in treatment-naïve Japanese female patients with OAB.

Study design, materials and methods

A total 87 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 of the drug and mental status the following parameters were evaluated before and 4 weeks, 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), Hospital Anxiety and Depression Scale (HADS, validated to detect anxiety and depression in a nonpsychiatric outpatient population), and the incidence and grade of the side effect. Also before and 8 weeks after, PVR were analyzed. 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

Mean age, mean Body Mass Index (BMI), mean number of parity were 65.7 ± 11.0 years, 22.6 ± 3.2 kg/m², 1.4 ± 1.0 respectively, and all patients were postmenopausal.

After 4 weeks of medication, OABSS total score, ICIQ-SF total score, both of HADS-Anxiety and HADS-Depression scores were significantly improved compared to before treatment, respectively (OABSS; $8.2 \pm 2.8 \rightarrow 5.7 \pm 2.9$, ICIQ-SF; $8.8 \pm 5.2 \rightarrow 7.5 \pm 4.8$, HADS-Anxiety; $5.8 \pm 3.5 \rightarrow 4.8 \pm 4.3$, HADS-Depression; $5.3 \pm 3.2 \rightarrow 4.7 \pm 3.7$) (p<0.05). Even after 8 weeks of the treatment, those scores were maintained unchanged (OABSS; $8.2 \pm 2.8 \rightarrow 5.3 \pm 3.4$, ICIQ-SF; $8.8 \pm 5.2 \rightarrow 6.8 \pm 4.8$, HADS-Anxiety; $5.8 \pm 3.5 \rightarrow 4.2 \pm 3.0$, HADS-Depression; $5.3 \pm 3.2 \rightarrow 4.8 \pm 3.3$) (p<0.05). There was no significant change in PVR (15.1 ± 20.7 vs 25.0 ± 12.1) (NS).

Constipation was reported in 2 cases (2.3%), dry mouth was reported in 2 cases (2.3%), gastrointestinal adverse event in 1 case (1.1%) but they can continue the medication. Rush was reported in 1 case (1.1%), dizziness was reported in 1 case (1.1%) and these patients discontinued the medication for side effects.

Interpretation of results

This study clearly demonstrated that Mirabegron treatment significantly improved the OAB symptoms and was well tolerated in treatment-naïve female OAB patients. Compared to antimuscarinics, the side effect was moderate and 97.7% of patients could continue the medication for 8 weeks. Furthermore, it is assumed that improvement of OAB symptoms provided the relief of anxiety and depressive condition.

Concluding message

At the best of our knowledge, this is the first report that shows the efficacy of Mirabegron not only on OAB symptom but also on mental status in Japanese female OAB patients.

Disclosures

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