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Kinjo M[1], Okegawa T[1], Nutahara K[1]
1. *Kyorin Univerity Scool of Medicine*

DOES MIRABEGRON TREATMENT AFFECT THE MENTAL STATUS OF TREATMENT-NAÏVE FEMALE PATIENTS WITH OVERACTIVE BLADDER?

Hypothesis / aims of study
Patients with overactive bladder (OAB) have storage-type lower urinary tract symptoms, such as urgency with or without urge incontinence, usually accompanied by daytime frequency and nocturia.
OAB has a negative impact on many aspects of patients' quality of life, including their daily activities, sleep, personal relationships, and mental health. Some studies have detected a relationship between depression/anxiety and OAB. Indeed the use of OAB medication, such as antimuscarinic agents, botulinum toxin injection therapy, and neuromodulation, has been shown to improve depression. Although antimuscarinic drugs are the most commonly used pharmacological treatment for OAB, they exhibit side effects and poor efficacy in some patients, and the β3-adrenoreceptor agonist mirabegron has been used as an alternative treatment for OAB. While many studies have reported that mirabegron is safe and effective against OAB symptoms, little is known about the influence of this medicine on patients' mental status.
The aim of this study was to evaluate the efficacy of mirabegron against OAB symptoms and its effects on the mental status of treatment-naïve female patients with OAB.

Study design, materials and methods
A total of 112 female treatment-naïve OAB patients who presented to female urology department were enrolled in this study. The study had a prospective, flexible dose, one-arm (with an 8-week active treatment period) design. All patients received oral mirabegron tablets (25~50 mg) once daily and were subjected to a diagnostic work-up including medical history taking, a physical examination, and post voided residual (PVR) measurements before they were started on the medication.
In order to examine the efficacy of the drug and the patients' mental status, the following tools were used to evaluate the patients before treatment and after 4 weeks' and 8 weeks' treatment: the overactive bladder symptom score (OABSS, which assesses daytime urinary frequency, nighttime urinary frequency, urgency, and urge urinary incontinence and has been validated in Japan), the International Consultation of Incontinence Questionnaire-Short Form (ICIQ-SF), and the Hospital Anxiety and Depression Scale (HADS, a validated tool for detecting anxiety and depression in a non-psychiatric outpatient population). Also, the PVR was measured before treatment and after 8 weeks' treatment.
All subjects provided oral informed consent before entering the study.
The Wilcoxon signed-rank test was used for the statistical analyses, and p-values of <0.05 were considered statistically significant.

Results
The patients' median age, median body mass index, and median parity values were 66 (range: 48-91) years, 22 (range: 14.8-34.7) kg/m^2, and 2 (range: 0-3), respectively, and 96 patients (85.7%) were postmenopausal.
At the baseline, 21 patients (18.8%) had been diagnosed with clinical anxiety (HADS-Anxiety score: ≥8), and 25 patients (22.3%) had been diagnosed with clinical depression (HADS-Depression score: ≥8).
After 4 weeks of medication, the subjects' median OABSS total score, median ICIQ-SF total score, median HADS-Anxiety score, and median HADS-Anxiety score were significantly improved compared with their baseline values (OABSS: 8.5 →5.5, ICIQ-SF: 10.0→7.0, HADS-Anxiety: 4.0→3.0, HADS-Depression: 4.0→3.5) ($p<0.05$).
After 8 weeks of treatment, significant changes continued to be seen in the median OABSS total score, median ICIQ-SF total score, median HADS-Anxiety score and median HADS-Depression score (OABSS: 8.5→5.0, ICIQ-SF: 10.0→6.0, HADS-Anxiety: 4.0→3.0, HADS-Depression: 4.0→3.5) ($p<0.05$). There was no significant change in the median PVR (12.0→13.5 ml) (n.s.).

Interpretation of results
This study demonstrated that mirabegron treatment significantly improved not only OAB symptoms but also anxiety and depression symptoms, as assessed by validated questionnaires, in treatment-naïve female OAB patients. It is assumed that the improvement of the patients' OAB symptoms helped to relieve their anxiety and depressive conditions.

Concluding message
To the best of our knowledge, this is the first report to evaluate the effects of mirabegron on both the OAB symptoms and mental status of female OAB patients. Administrating mirabegron to improve the OAB symptoms simultaneously released anxiety and depression symptoms.

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