The Safety, Tolerability and Efficacy of Mirabegron for Treatment in Patients with Overactive Bladder Symptoms Who withdrew Previous Anticholinergic Agents Due to Adverse Events

Introduction and Objective: Anticholinergic agents, which are the first-line drugs to treat OAB symptoms, are known to develop some systemic adverse events (AEs) and continued adherence to anticholinergic therapy is low. Mirabegron is a selective beta 3-adrenoreceptor agonist in development for the treatment of OAB. The purpose of this study is to examine the safety, tolerability and efficacy of Mirabegron in the treatment of OAB over a 4-week period.
Materials and Methods: Patients who met the diagnostic criteria for OAB provided in the clinical guidelines in Japan for OAB (patients who have urinary urgency at least once weekly as an essential symptom and at least one of the other OAB symptoms including daytime frequency, nighttime frequency, and urgency incontinence) and who withdrew previous anticholinergic agents due to AEs were enrolled. Patients with neurologic disease, UTIs, a history of urinary retention, lower urinary tract surgery, or radiotherapy for the pelvic organs were excluded. All patients were treated with Mirabegron 25-50 mg over 4 weeks. Efficacy was assessed according to IPSS, OABSS, ICIQ-SF, residual urinary volume (RUV) and Patient Perceptions of Treatment Benefit (PPTB) and IPSS-QOL included AEs reporting.
Results: Twenty-seven patients who met our criteria were enrolled. Mean age was 77.6 years, 67% were female and 78% had urgency incontinence. Adherence to Mirabegron was good, only two patients dropped out because of persistent constipation in one and insufficient efficacy by self-judgment in one. No serious AEs including urinary retention, dry mouth and constipation were found during our study. The storage symptom of IPSS subscore improved significantly (from 10.1 to 6.1; $P<0.01$), whereas the voiding symptom did not improve (from 3.5 to 3.4; *NS*). RUV did not change. After 4 weeks of treatment, IPSS (from 13.6 to 9.4; $P<0.01$), QOL index (from 5.3 to 3.7; $P<0.01$) and OABSS (from 10.5 to 7.1; $P<0.01$) of 25 patients improved significantly. Regarding QOL, IPSS-QOL improved significantly ($P<0.05$).
Conclusions: Our results demonstrated that mirabegron was well tolerated with low levels of AEs. Mirabegron could be a safe and effective treatment alternative for OAB patients who withdrew previous anticholinergic agents due to AEs.