

THE SAFETY, TOLERABILITY AND EFFICACY OF MIRABEGRON FOR THE TREATMENT IN PATIENTS WITH OVERACTIVE BLADDER SYMPTOMS WHO WITHDREW PREVIOUS ANTICHOLINERGIC AGENTS DUE TO ADVERSE EVENTS

Hypothesis / aims of study

Anticholinergic agents, which are the first-line drugs for treating OAB symptoms, are known to have systemic adverse events (AEs), and continued adherence to anticholinergic therapy is low. Mirabegron is a selective β_3 -adrenoreceptor agonist being developed 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.

Study design, materials and methods

Patients who met the diagnostic criteria for OAB provided in the clinical guidelines in Japan for OAB (have urinary urgency at least once weekly and also have one or more other OAB symptom: daytime frequency, night-time frequency, or urgency incontinence) and who withdrew from previous anticholinergic agents because of AEs were enrolled in the present study. 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) more than four weeks. Efficacy was assessed according to their residual urinary volume (RUV) and their IPSS, OABSS, ICIQ-SF, and IPSS-QOL scores as well as the AEs they reported and the patient perceptions of treatment benefit (PPTB).

Results

Twenty-seven patients who met our criteria were enrolled. Their mean age was 77.6 years, 67% were female, and 78% had urgency incontinence. Adherence to the mirabegron regimen was good that only two patients dropped out, one because of persistent constipation and the other because self-judged insufficient efficacy. The patient who dropped out due to the persistent constipation suffered from constipation even after withdrawal of mirabegron. No serious AEs (urinary retention, dry mouth, or constipation) were found during our study. The IPSS storage symptom subscore improved significantly (from 10.1 to 6.1; $P < 0.01$) but the voiding symptom subscore did not (the change, from 3.5 to 3.4, as insignificant). RUV did not change. After 4 weeks of treatment, 25 of the patients had improved significantly: IPSS had changed from 13.6 to 9.4; $P < 0.01$, QOL index had changed from 5.3 to 3.7; $P < 0.01$, and OABSS had changed from 10.5 to 7.1; $P < 0.01$. Their IPSS-QOL score had also improved significantly ($P < 0.05$).

Interpretation of results

Antimuscarinic therapy often produces unacceptable adverse effects and limited or modest symptom relief, leading to poor adherence to prescribed medications. So, both efficacy and tolerability are key influencers of persistence. An improved efficacy and tolerability would provide better persistence with long-term OAB therapy and would result in greater patient satisfaction.

Concluding message

Our results demonstrated that mirabegron was well tolerated and was associated with few AEs. Mirabegron could be a safe and effective treatment alternative for even OAB patients who have quit taking anticholinergic agents because of AEs. There is need, however, for further study with regard to patient satisfaction, sexual function and total OAB-related total costs.

Disclosures

Funding: None **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics not Req'd:** this study is small and a pilot one. **Helsinki:** Yes **Informed Consent:** Yes