

IMMEDIATE EFFECT ON OVERACTIVE BLADDER SYMPTOMS FOLLOWING ADMINISTRATION OF IMIDAFENACIN

Hypothesis / aims of study

Overactive bladder (OAB) is characterized by urgency, with or without urgency incontinence, and usually with frequency and nocturia. Despite not being life-threatening, OAB symptoms have a marked adverse effect on the patient's quality of life. Patients require long-term therapy with agents that have good efficacy and tolerability. Although one of the factors influencing patient compliance is thought to be the time to reach clinical effectiveness after commencing drug therapy, there have been few reports regarding the time to efficacy for various drugs.

Imidafenacin, as a novel antimuscarinic agent to treat OAB, selectively acts on the bladder over salivary gland tissue, and favorable safety, tolerability, and efficacy profiles of administration were clinically shown over 52 weeks. Imidafenacin is rapidly absorbed with maximum plasma concentrations occurring 1–3 h after oral administration. This rapid absolute bioavailability of imidafenacin suggest immediate clinical efficacy after administration. We investigated the immediate effect of imidafenacin on the symptoms of OAB by recording daily changes in the subjective efficacy for 2 weeks after treatment.

Study design, materials and methods

Patients aged at least 20 years with OAB diagnosed according to the ICS definition were enrolled into this study. Exclusion criteria included clinically significant bladder outlet obstruction and/or postvoid residual volume >100 mL, obvious urinary tract infection, glaucoma or serious complications, and use of anticholinergic drugs within 1 month prior to the study. All patients provided informed consent prior to enrollment in the study.

Imidafenacin (0.1 mg) was administered to the patients orally twice daily; this dosage is clinically recommended for treating OAB. The medication period in all cases was 4 weeks. OAB symptom scores (OABSS) of the patients were evaluated before administration, and at 2 and 4 weeks postadministration. Uroflowmetry with postvoid residual volume was performed at the same time. Following enrollment, patients were asked, "To what extent did you feel the effects of this medicine?" daily over a period of 2 weeks. Patients gave their answers on a five-points scale: 0 (not at all), 1 (a little), 2 (moderately), 3 (a great deal), and 4 (my symptoms are gone). Adverse events were examined through history-taking, as conducted by the attending physician. Statistical assessments were performed using the paired *t* test, and *P* < 0.05 was considered statistically significant.

Results

Twenty-four patients who consulted our department between September 2008 and May 2009 were enrolled in this study. All cases were evaluated for safety and 20 were evaluated for efficacy with OABSS and uroflowmetry with postvoid residual volume at 2 and 4 weeks postadministration. Nineteen patients completely recorded daily changes of the subjective efficacy over the 2-week study period. The patients ranged in age from 57 to 87 years, with a mean age of 74 years. Five patients were male and the remaining 19 were female. Seventeen patients had urge incontinence, and the remaining 7 were without urge incontinence.

The mean total OABSS scores were 9.4 preadministration, 7.4 at 2 weeks postadministration, and 4.4 at 4 weeks postadministration. The mean total OABSS score decreased gradually, and there were significant differences between those at preadministration and at 2 weeks after administration, and between 2 and 4 weeks. The mean scores for nighttime micturition, urgency, and urge incontinence decreased significantly at 2 and at 4 weeks after administration compared to those preadministration.

As the changes in patients' subjective efficacy for imidafenacin during the 2 weeks after administration, patients reported the drug's efficacy beginning three days after commencement of administration. The patients' subjective efficacy for imidafenacin seemed to increase favorably during the 2-week study period.

The mean rates of maximum and average urinary flow at preadministration were 17.1 mL/s and 9.4 mL/s, respectively. Those at 2 weeks postadministration were 18.4 mL/s and 9.7 mL/s, respectively, and those at 4 weeks were 13.1 mL/s and 6.8 mL/s, respectively. There were no significant differences between each group. The mean preadministration postvoid residual volume was 21.1 mL, while those at 2 and 4 weeks postadministration were 20.3 mL and 8.0 mL, respectively. There were no significant differences between each volume.

There were no severe side effects over the 4 weeks of this study.

Interpretation of results

The subjective efficacy of imidafenacin was observed from 3 days after commencement of administration. Symptom scores decreased gradually at 2 and 4 weeks postadministration. Urinary flow rates and postvoid residual volumes did not change with administration of imidafenacin.

Concluding message

Imidafenacin may have immediate efficacy in patients with overactive bladder symptoms. This agent can be expected to be well tolerated and show satisfactory effects in patients.

Specify source of funding or grant	none
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	No

<i>This study did not require ethics committee approval because</i>	<i>using a commercial drug and routine examinations clinically</i>
<i>Was the Declaration of Helsinki followed?</i>	<i>Yes</i>
<i>Was informed consent obtained from the patients?</i>	<i>Yes</i>