418

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EFFECTIVENESS AND SAFETY OF IMIDAFENACIN IN JAPANESE FEMALE UNTREATED OVERACTIVE BLADDER PATIENTS

Hypothesis / aims of study

Overactive bladder (OAB) is a common health problem and negatively impacts patients' quality of life (QOL). Although lifestyle interventions and antimuscarinics have been the main treatment, the use of antimuscarinics can be limited by their side effects, especially by dry mouth. Imidafencin has been developed for the treatment of OAB as a new antimuscarinics which has higher affinity for muscarinic M3 and M1 receptors compared with other antimuscarinic agents. Basic research demonstrated that imidafenacin has organ selectivity for the bladder more than for the salivary gland without influence on the central nervous system such as a disturbance of spatial learning and memory. In the present study, we evaluated the effectiveness and safety of imidafenacin in the treatment of female OAB.

Study design, materials and methods

A total 51 patients with an average age of 48.8 years were enrolled in the study. The design was prospective, single-dose, one arm with a 4-week active treatment period. All patients received imidafenacin oral tablet (0.2mg) twice daily. In order to examine efficacy, tolerability and safety of the drug, the following four parameters were evaluated before and after the medication; (a) the overactive bladder symptom score (OABSS, scoring the daytime urinary frequency, nighttime urinary frequency, urgency and urge urinary incontinence, validated in Japan), (b) King's Health Questionnaire (KHQ), (c) the incidence and grade of the side effect and (d) the time length required to get subjective symptom improvement. For statistical analysis, paired t-test was used and p value <0.05 was considered statistically significant.

Results

OABSS was significantly improved in nighttime urinary frequency, urgency and urge urinary incontinence domain, respectively ($p<0.05$). The KHQ was significantly improved in 6 domains out of 9 domains (incontinence impact, role limitations, physical limitations, social limitations and emotions, $p<0.05$). Dry mouth was reported in 31.4 %, but there was no case who could not continue the medication. Constipation was reported in 19.6% and 2 cases failed to continue the medication because of this adverse effect. Rush was reported in one case (1.9%) and quit the medication. The mean time length required to get subjective symptom improvement was 4.7 days and the median value was 3 days.

Interpretation of results

Our study showed that imidafenacin significantly improved the OAB symptoms and QOL at the early stage of the medication. Compared to other conventional antimuscarinics, the effect of imidafenacine seems to be swift. Side effect was not severe and 94.1% could continue the medication for 4 weeks.

Concluding message

At the best of our knowledge, this is the first clinical study showing the efficacy and safety of imidafenacin.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Kyorin University Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**