534

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SLEEP DISORDERS AND HRQOL WERE SIGNIFICANTLY IMPROVED BY IMIDAFENACIN, AN ANTICHOLINERGIC AGENT, IN OAB PATIENTS WITH NOCTURIA

Hypothesis / aims of study

Among OAB symptoms, nocturia has the worst negative effect on QOL. There have also been reports that nocturia causes sleep disorders. In this study, the effects of imidafenacin (IM), an anticholinergic, on bladder storage symptoms in OAB patients were examined. Also, the Athens Insomnia Scale, IPSS-QOL, and SF-8 were used to assess whether sleep disorders and QOL improve when nocturia improves.

Study design, materials and methods

A total of 39 patients (24 males: 61.5%, and 15 females: 38.5%), 50 years and older (mean age: 73.2 years) with more than two nocturnal voids per day were enrolled in this study. This was a prospective, single-dose, one-arm study with an 8 week active treatment period. All patients received an IM oral tablet (0.2 mg) twice daily. Nocturia was assessed using the FVC (frequency volume chart) and the OABSS (overactive bladder symptom score), and sleep disorders were assessed using the AIS (Athens Insomnia Scale). Health-related quality of life was assessed using the IPSS-QOL (International Prostate Symptom Score) and SF-8. For statistical analysis, repeated measures ANOVA was used and a p value <0.05 was considered statistically significant.

Results

Among OAB patients with nocturia, 40.7% (11 out of 27 patients) had sleep disorders. This percentage is higher than reports from previous studies done on the general population in other countries using the AIS. Using the FVC, the number of nocturnal voids prior to the administration of IM was 3.0±1.6, and at 4 and 8 weeks it was 2.4±1.5 ($p<0.01$) and 2.6±1.6 ($p<0.01$), respectively. The number of nocturnal voids significantly improved 4 and 8 weeks after the administration of IM. Using the OABSS, the nocturnal voiding score prior to the administration of IM was 2.7±0.5, and at 4 and 8 weeks it was 2.3±0.8 and 2.0±0.9, respectively. There was significant improvement after 4 and 8 weeks of treatment. The AIS score of all of the patients, even patients with sleep disorders (patients with a score higher than the cutoff value) was improved. Before administering IM, the IPSS-QOL score was 4.4±1.1 and after 4 weeks of treatment it was 3.1±1.2 ($p<0.01$), and after 8 weeks it was 2.8±1.4 ($p<0.01$).

On the SF-8, compared to the baseline score, the physical component summary (PCS) was significantly improved after 4 and 8 weeks of treatment. The baseline score, 4 week, and 8 week scores were 42.6±7.3, 45.6±5.3 ($p<0.05$), and 48.4±5.2 ($p<0.01$), respectively. Also, the Mental Component Summary (MCS) on the SF-8 was significantly improved after 8 weeks of treatment ($p<0.05$), and besides body pain, the subscales also significantly improved after 8 weeks of treatment.

Interpretation of results

Treatment with IM improved not only bladder storage symptoms in OAB patients with nocturia, but also the sleep disorders and QOL associated with it.

Concluding message

In cases when elderly patients have sleep disorders, it is important to check whether they have voiding disorders or not. If they have OAB symptoms like nocturia, anticholinergics like IM should be used to improve symptoms.

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