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IMIDAFENACIN IS EFFECTIVE FOR OAB PATIENTS WITH NOCTURIA AND SLEEP DISTURBANCE: EVALUATION BY N-QOL AND PSQI

Hypothesis / aims of study

Among OAB symptoms, nocturia has the worst effect on QOL. We evaluated the impact of nocturnal polyuria on sleep disorders and QOL in OAB patients with nocturia using the N-QOL questionnaire. We also assessed the efficacy of Imidafenacin (IM), an antimuscarinic, on nocturia and nocturnal QOL in patients with or without nocturnal polyuria.

Study design, materials and methods

A total of 165 (males 73, females 92; mean age 68.8 years old) Japanese OAB patients who had more than two nocturnal voids per day were enrolled in this study. The design was prospective, single-dose, one arm with 8 weeks active treatment period. All of the patients received an IM oral tablet (0.1mg) twice daily for 8 weeks. Nocturia was assessed using a frequency volume chart (FVC) and the Overactive Bladder Symptom Score (OABSS). Nocturnal polyuria was defined as having a nocturnal polyuria index (NPI) of more than 33% of a 24 hour urine volume. Sleep disorders were assessed using the Pittsburgh Sleep Quality Index (PSQI) and QOL was assessed using the Nocturia Quality of Life questionnaire (N-QOL). For the N-QOL, the change in score was evaluated by calculating the overall score, subscale, the various items, and overall well-being. For statistical analysis, Wilcoxon signed-rank test, ANOVA, and Fisher's exact test were used, and p value <0.05 was considered statistically significant.

Results

During the observation period, nocturia was 3.7±1.4 times according to FVC, and was 2.6±0.5 points (full: 3 points) using OABSS. PSQI was above 5.5 (cutoff value) in 88 subjects (59.9%). The percentage of sleep disorders is higher than the average population (38.0%). After 8 weeks of IM administration, nocturia in FVC decreased significantly from 3.7±1.4 to 2.8±1.2 times (p<0.001). Nocturia in OABSS decreased significantly from 2.6±0.5 to 1.8±0.9 points (p<0.001). Decreases were seen in PSQI values for sleep disorders (p<0.001). Regarding the N-QOL, the overall and subscale (sleep/energy and bother/concern) scores were significantly improved at 4 weeks of administration. There was a correlation between the amount of change in number of nocturnal voids and N-QOL, and the amount of change in PSQI and N-QOL (r=-0.407, -0.551, respectively, in both p<0.001).

The prevalence of nocturnal polyuria was 60 % (90 patients). During the observation period, the number of nocturnal voids in the group with nocturnal polyuria was 4.0±1.3 times, and it was 3.2±1.3 times in the group without nocturnal polyuria. The PSQI values in the groups with and without nocturnal polyuria were 6.6 and 6.7, respectively. The overall N-QOL scores were 65.0 and 65.2, with and without nocturnal polyuria. Nocturnal polyuria did not have any effect on the degree of sleep disturbance, or sleep-related QOL disturbance, or QOL.

Interpretation of results

By using the PSQI and N-QOL, we demonstrated that anticholinergic drug therapy for OAB patients with nocturia is strongly correlated with the improvement of sleep disorders and QOL.

Concluding message

Nocturnal polyuria does not have any effect on QOL or sleep disturbance in OAB patients. The effect of IM, anti-muscarinic, is effective in OAB patients complaining nocturia with or without nocturnal polyuria.

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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	University of Yamanashi, School of Medicine
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes