Imidafenacin Is Effective for OAB Patients with Nocturia and Sleep Disturbance: Evaluation by N-QOL and PSQI

Introduction and Objective: 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.
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.
Conclusion: 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.