440

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CLINICAL OUTCOMES OF IMIDAFENACIN IN ADDITION TO TAMSULOSIN FOR PATIENTS WITH OVERACTIVE BLADDER AND BENIGN PROSTATIC HYPERPLASIA (ADDITION STUDY)

Hypothesis / aims of study

Overactive bladder with benign prostatic hyperplasia (OAB/BPH) causes bothersome symptoms and deterioration of quality of life (QOL). We are evaluating the one-year efficacy, safety and tolerability of antimuscarinic drug, using imidafenacin (IM) 0.2mg/day, combined with tamsulosin (TAM) 0.2mg/day in OAB/BPH patients who did not respond to alpha1-blocker monotherapy (Addition study). As first report, we assessed the efficacy and safety of IM plus TAM vs TAM alone for up to 12 weeks.

Study design, materials and methods

In this randomised, open-labeled, parallel-group, multicenter study, OAB/BPH patients aged 50 years old or older were randomly assigned to IM+TAM group or TAM alone group. The study population had 1 or more urgency episode per one week and 3 or higher of Overactive bladder symptom score (OABSS) after taking TAM for 8 or more weeks. Efficacies were assessed using OABSS, a frequency volume chart (FVC) and International prostate symptom score (IPSS) before and after the therapy. For the IPSS, the change in score was evaluated by calculating the overall score, voiding symptoms and storage symptom. QOL was assessed using the IPSS-QOL and BPH impact index (BII). For statistical analysis, Wilcoxon two-sample test, ANOVA, and Fisher's exact test were used, and p value <0.05 was considered statistically significant.

Results

A total of 308 men were enrolled. After 12 weeks treatment, total OABSS significantly improved in IM+TAM group compared to TAM alone group (-4.4 vs -2.1, p<0.05). At week 12, subjects in IM+TAM group had significantly greater improvements, compared to TAM alone group in 24-h micturitions (-1.9 vs -0.5; p<0.05), daytime micturitions (-1.4 vs -0.3; p<0.05), nighttime micturitions (-0.5 vs -0.2; p<0.05) and 24-h urgency episodes (-1.8 vs -0.7, p<0.05); IPSS storage subscale (-3.8 vs -1.8; p<0.05); IPSS-QOL score (-1.7 vs -0.8; p<0.05) and BII total score (-3.2 vs -1.4; p<0.05), bothersome score (-1.0 vs -0.4; p<0.05). There were no serious adverse events in each group and no clinically significant changes in postvoid residual volume.

Interpretation of results

Recently, 3 point change of total OABSS has been reported as the minimal clinically important change (MCIC) [1)]. The change of total OABSS in IM+TAM group (-4.4) reached the MCIC, whereas, that of TAM alone group (-2.1) did not. Furthermore, the related QOL and bother significantly more improved in IM+TAM group, compared to TAM alone group. These results suggest that the add-on therapy of IM is beneficial for men with persistent OAB symptoms despite continued alpha-blocker therapy.

Concluding message

IM+TAM therapy for 12 weeks in men with OAB/BPH was useful and well tolerated. One year follow-up of the currently on-going study will reveal the efficacies and durability of the IM+TAM therapy.

1) Gotoh M, et al. Responsiveness and minimal clinically important change in overactive bladder symptom score. Urology 2011; 78: 768-73

References

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