

SAFETY AND EFFECT OF ANTI-CHOLINERGIC COMBINATION TREATMENT DEPENDING ON DOSAGE OF α -BLOCKER IN PATIENTS WITH BPH AND OVERACTIVE BLADDER

Hypothesis / aims of study

The purpose of the study is to evaluate the clinical effect and safety of anti-cholinergic medication depending on dosages of α -blocker in patients with benign prostatic hyperplasia (BPH) and overactive bladder (OAB).

Study design, materials and methods

This was 8-week randomized, open-label, parallel-group study in men aged 40-80 years with BPH and OAB. Inclusion criteria was prostate volume ≥ 20 cc, total international prostate symptom score (IPSS) ≥ 8 , and OAB symptoms score (OABSS) ≥ 3 . Group 1 (N=20) was the patients who were treated by combination with tamsulosin 0.2 mg plus solifenacin 5.0 mg daily for 8 weeks. Group 2 (N=20) was the patients who were treated with tamsulosin 0.4 mg plus solifenacin 5.0 mg combination for 8 weeks. Primary end points included Qmax and post-void residual volume (PVR). Secondary end points included IPSS and OABSS.

Results

In the group 1, 5 patients dropped out due to the loss of follow-up and adverse event (dry mouth and constipation). 3 patients dropped out due to the loss of follow-up and adverse event (dry mouth) in the group 2. Baseline characteristics were not different between the 2 groups.

In the 8 week, there was no significant difference with regard to changes in Qmax and PVR in both groups (group 1: P=0.972, P=0.551, group 2: P=0.434, p=0.163, respectively). However, in both group, there was improvement in IPSS and OABSS (group 1: p=0.002, p=0.004, group 2: p=0.007, p=0.004, respectively).

But, there was no significant difference between the both groups with regard to changes in IPSS total score, OABSS, Qmax and PVR after 8-week treatment (p=0.393, p=0.947, p=0.156, p=0.893, respectively). There was no serious adverse effect such as acute urinary retention.

Interpretation of results

Depending on dosage of α -blocker, there was no significant difference with safety and effects of anti-cholinergic combination treatment in patients with BPH and OAB.

Concluding message

Anti-cholinergic combination therapy with α -blocker in patients with BPH and OAB is safe and effective treatment regardless of dosage of α -blocker.

Disclosures

Funding: This study was undertaken with a research grant from Astellas Pharma Korea Inc. **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** NHIS Ilsan Hospital IRB committee **Helsinki:** Yes **Informed Consent:** Yes