

## EFFICACY AND SAFETY OF TOLTERODINE EXTENDED RELEASE FOR THE TREATMENT OF LOWER URINARY TRACT SYMPTOMS IN MEN WITH BENIGN PROSTATIC HYPERPLASIA

### Hypothesis / aims of study

To evaluate the efficacy and safety of combined therapy with tolterodine extended release (ER), alpha-blockers and/or 5-alpha-reductase inhibitors (5ARI) for lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia (BPH).

### Study design, materials and methods

Out-patients with LUTS diagnosed BPH were subdivided randomly into two groups: Convention group were treated with doxazosin extended release 4 mg/day for 12 weeks; Combination group were treated with doxazosin extended release 4 mg/day and tolterodine ER 4 mg/day for 12 weeks. All patients with a total prostate volume (TPV) of more than 30ml were received finasteride 5 mg/day too. Primary efficacy end points were International Prostate Symptom Score (IPSS), quality of life index (QOL), maximum flow rate (Qmax), TPV, post-void residual (PVR) volume, 24 hours micturitions, and the incidence of acute urinary retention.

### Results

156 of 200 out-patients with a mean age of 72.5 years completed the study. Patients in the combination group have significant improvements on the total IPSS (-10.5 vs. convention group, -7.1,  $P<0.01$ ), IPSS storage scores (-4.7 vs. -2.5,  $P<0.01$ ), and QOL (-2.7 vs. -1.5,  $P<0.01$ ). The Qmax was improved (2.2 vs. 2.7), and the PVR was reduced (-14.0 vs. -12.3) similarly in both groups by 12 weeks follow-up. The TVP had no significantly reduction compared with the baseline. Patients in combination group compared with in the convention group experienced significant reductions in 24 hours micturitions (-3.0 vs. -1.5,  $P<0.01$ ). The incidence of acute urinary retention requiring catheterization was low and similar in both groups, 2 in convention group and 3 in combination group.

### Interpretation of results

About half of men with BPH also have overactive bladder symptoms, doxazosin can reduce the voiding symptoms, and tolterodine ER can reduce storage symptoms, especially OAB symptoms.

### Concluding message

Alpha-blockers and 5-alpha-reductase inhibitors are the conventional therapy for moderate-to-severe LUTS/BPH, tolterodine ER is effective and safe for patients with significant storage symptoms, and should be a reasonable therapeutic option as initial therapy.

### Disclosures

**Funding:** none **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Ethics Committee of the 2nd Hospital of Shanxi medical University **Helsinki:** Yes **Informed Consent:** Yes