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
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