

EFFICACY AND SAFETY OF LOW DOSE PROPIVERINE (10MG) IN LUTS/BPH -PROSPECTIVE, RANDOMIZED, SINGLE-BLINDED AND MULTI-CENTER CLINICAL TRIAL-

Hypothesis / aims of study

Urologists are scare about side effects of anticholinergics including acute urinary retention in treating frequency and other storage symptoms in men with LUTS/BPH. The aim of this study is to evaluate that a low-dose anticholinergics with alpha 1 antagonist might be to continue the effect of alpha blocker, decrease the side effect of anticholinergics and improve the symptoms of lower urinary symptoms in LUTS/BPH management.

Study design, materials and methods

Two hundred five men with LUTS/BPH (IPSS > 12; storage symptoms >4) were randomized in a prospective, multi-centered and single-blind fashion to receive either Group 1(control group; alfuzosin (10mg, once daily) of 77 patients, or Group 2(combine group); alfuzosin (10mg, once daily) and propiverine (10mg, once daily) of 132 patients for 2 months. International Prostate Symptom Score (IPSS), Uroflowmetry (Qmac) and postvoided volume (PVR) were used to grade symptoms, and the side effects and the quality of life (QoL) impact at the start, 1 month and 2 months of the study

Results

There was no significant difference in patients backgrounds in Group 1 vs Group 2, including age (64.7+10.0 vs 62.3+10.3), prostatic size (26.9+8.9 vs 26.1+7.8), maximum flow rate (15.1+8.4 vs 14.7+7.8mL/s) and PVR (44+37.7vs 41.7+31.8mL). In Group 2, I-PSS total score (from 23.2+6.8 to 14.9+4.7) and I-PSS storage symptom score (from 10.0+2.8 to 6.0+2.2), were significantly improved than in Group 1 (I-PSS total score from 19.0+6.3 to 11.2+5.6, I-PSS storage symptom score; from 8.1+3.4 to 4.7+2.3). I-PSS voiding symptom score, QoL, Qmax and PVR did not different significantly. There was no significant side effect in either group.

Interpretation of results

Management with Alfuzosin with low dose propiverine improved I-PSS total score and I-PSS storage score. However I-PSS voiding symptom score, QoL, Qmax and PVR did not different significantly with Alfuzosin with low dose propiverine.

Concluding message

Alfuzosin with low dose propiverine is more effective than alfuzosin alone in the respect to storage symptoms of LUTS/BPH.

Specify source of funding or grant	No
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	Yes
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Dankook University College of Medicine IRB
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes