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INITIAL COMBINATION TREATMENT USING ANTI-CHOLINERGICS PLUS A-BLOCKER FOR THE TREATMENT OF MEN WITH OVERACTIVE BLADDER AND BENIGN PROSTATIC HYPERTROPHY PATIENTS; A PROSPECTIVE, RANDOMIZED, MULTI-CENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

Hypothesis / aims of study

To evaluate the efficacy and safety of combination treatment using anti-cholinergics plus α-blocker at initial treatment for both overactive bladder and other lower urinary tract symptoms (LUTS) associated with BPH. We hypothesized that initial combination treatment of anti-cholinergics plus α-blocker for OAB/BPH patients would perceive greater treatment benefit than would men who received placebo plus doxazosin without risk of acute urinary retention and voiding difficulty.

Study design, materials and methods

Randomized, double-blind, placebo-controlled trial conducted at 4 urology clinics in Korea involving men 50 years or older who had a total International Prostate Symptom Score (IPSS) of 14 or higher (voiding sub-score of 8 or higher and storage sub-score of 6 or higher) and, an IPSS quality-of-life (QOL) item score of 3 or higher, a bladder diary documenting micturition frequency (≥8 micturitions per 24 hours) and urgency (≥1 episode of urgency rating ≥3 per 24 hours). Patients were recruited between January 2006 and August 2008 and a total of 95 were randomly assigned to receive 4mg of doxazosin plus placebo or 4mg of doxazosin plus 4mg of tolterodine SR once a day for 12 weeks. IPSS, bladder diary variables, 5-point urgency rating scale, Patient Perception of Bladder Condition (PPBC), maximal urinary flow rate (Qmax), residual volume, and transrectal ultrasonograpy (TRUS) were assessed. Total IPSS and IPSS sub-score (voiding & storage) were also analyzed.

Results

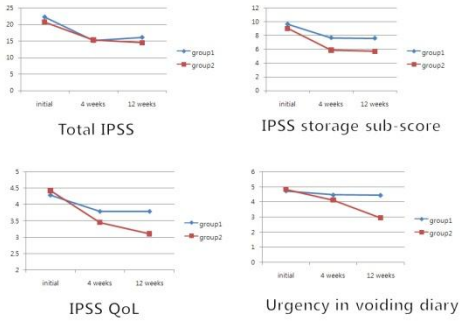
Eight patients discontinued the study prematurely owing to adverse events or lack of efficacy and the remaining 87 were eligible for efficacy analysis. Compared with placebo group, patients receiving anti-cholinergics plus α-blocker experienced significant reductions in IPSS storage subscore and QOL item, urgency episodes as well as micturition frequency at week 4 and 12. However, it failed to improve PPBC at week 4 as well as at week 12. Earlier intervention with anti-cholinergics plus α-blocker was well tolerated including urinary retention (n=1) and dry mouth (n=2). One patient taking placebo demonstrated dry mouth.

Interpretation of results

An initial combination treatment of anti-cholinergics plus α-blocker in OAB/BPH patients improved all parameters except residual urine compared with placebo group. PPBC is not a good tool for evaluation of OAB/BPH patients.

Concluding message

Initial combination treatment of anti-cholinergics plus α-blocker provides benefit for men with OAB/BPH symptoms and did not increase the risk of voiding difficulty and acute urinary retention. Considering the burden of keeping a bladder diary and limitation of PPBC as efficacy parameter, IPSS categorized by voiding and storage sub-score might be used as efficient tool for the diagnosis and treatment follow-up in men with OAB/BPH.



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Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**