

INITIAL COMBINATION TREATMENT USING TAMSULOSIN AND SOLIFENASIN FOR BPH/OAB PATIENTS; A PROSPECTIVE, MULTI-CENTER STUDY

Hypothesis / aims of study

We hypothesized that initial combination treatment of Tamsulosin and solifenasin for OAB/BPH patients would perceive treatment benefit than would men who received Tamsulosin without risk of acute urinary retention and voiding difficulty. We prospectively evaluated the efficacy and safety of combination treatment using Tamsulosin and solifenasin at initial treatment for BPH/OAB patients.

Study design, materials and methods

This study was conducted at 4 urology clinics in Korea involving men 50 years or older who had a total International Prostate Symptom Score (IPSS) of 12 or higher (storage sub-score of 6 or higher) and a bladder diary documenting frequency (≥ 8 micturitions per 24 hours) and urgency (≥ 1 episode of urgency rating ≥ 3 per 24 hours). Patients were recruited between June 2008 and July 2009, and a total of 139 BPH/OAB patients were randomly assigned to receive Tamsulosin (Group I, n=69) or Tamsulosin plus Solifenasin (Group II, n=70) for 4 weeks. After that, all patients were treated with Tamsulosin and Solifenasin combination for 8 weeks.

IPSS, Overactive bladder symptom score (OAB-SS), bladder diary (5-point urgency rating scale), maximal flow rate (Qmax), residual volume, and transrectal ultrasonography (TRUS) were assessed. IPSS voiding & storage sub-score were also analyzed.

Results

In both groups, there was improvement in IPSS including storage symptom, OAB-SS, and urgency of voiding diary after 4 and 12 weeks treatment ($P < 0.001$). In the 4th week, the IPSS storage symptom sub-score was significantly lower in group II compared with group I (6.426 ± 2.591 versus 5.450 ± 2.235) ($P=0.029$). OAB-SS (5.459 ± 1.988 versus 5.067 ± 1.745) was not significantly improved in group II compared with group I. In the 12th week, the IPSS storage symptom score, OAB-SS, and the time of urgency above level 3 was 5.143 ± 2.504 versus 4.595 ± 2.803 , 4.429 ± 2.014 versus 4.476 ± 2.039 , 2.075 ± 2.315 versus 2.617 ± 2.944 , respectively, showing no significant difference between the 2 groups.

Interpretation of results

On the aspect of storage symptom, in the 4th week, Tamsulosin and Solifenasin combination was more efficacious than Tamsulosin monotherapy.

Concluding message

Initial combined treatment with Tamsulosin and Solifenasin was more efficacious than Tamsulosin alone after 4 weeks and did not increase the risk of voiding difficulty and acute urinary retention in BPH/OAB patients..

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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	Seoul St. Mary's Hospital, The Catholic University of Korea, Clinical Research Coordinating Center / Institution Review Board
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes