

A RANDOMIZED CONTROLLED STUDY TO EVALUATE THE EFFICACY OF ALPHA 1-ADRENOCEPTOR ANTAGONIST IN MONOTHERAPY AND COMBINATION THERAPY WITH EVIPROSTAT ON MALE LOWER URINARY TRACT SYMPTOMS WITH OVERACTIVE BLADDER

Hypothesis / aims of study

Eviprostat, a plant extract, has often been used clinically for lower urinary tract symptoms (LUTS). Several animal experiments provided evidence of inhibitory effects of Eviprostat on the micturition reflex and the possible anti-inflammatory effects of the bladder in a chemical cystitis model. Therefore, Eviprostat has a possibility to make an effect in not only the voiding symptom but also the storage symptom, such as overactive bladder (OAB) symptom. However, there have been no prospective-randomized studies on its efficacy for OAB. In the present study, we verified the efficacy of Eviprostat and alpha 1-adrenoceptor antagonist combination therapy compared with alpha 1-adrenoceptor antagonist monotherapy in male LUTS patients with OAB.

Study design, materials and methods

We conducted a prospective, open-label, randomised study at multicenter in Oita, Japan. 111 male LUTS patients with OAB were randomly assigned to tamsulosin hydrochloride (0.2mg daily) for 12 weeks or Eviprostat DB (3 tablets daily) and tamsulosin (0.2mg daily) for 12 weeks. The primary outcome was to evaluate by using Questionnaires for urinary symptoms (International prostate symptom score; IPSS and overactive bladder symptom score; OABSS) at 4, 8 and 12 weeks. This study is registered with UMIN-CTR, UMIN 000002782.

Results

99 patients (49 in the tamsulosin monotherapy group and 50 in the Eviprostat-tamsulosin combined therapy group) were included in the favorable analyses. Significant improvement in IPSS was noted in the Eviprostat-tamsulosin combined therapy group compared to tamsulosin monotherapy group at 4 (-7.5 vs -4.6), 8 (-9.1 vs -5.4) and 12 weeks (-9.9 vs -6.6), respectively. Especially, voiding symptom subscores showed greater decreases from baseline in Eviprostat-tamsulosin combined therapy group (-4.2 vs -2.1 at 12 weeks). Meanwhile, Eviprostat-tamsulosin combined therapy did not reveal superiority in OABSS and the storage symptom subscore of IPSS compared to tamsulosin monotherapy. Drug-related adverse events in the both groups were infrequent and generally were not treatment limiting.

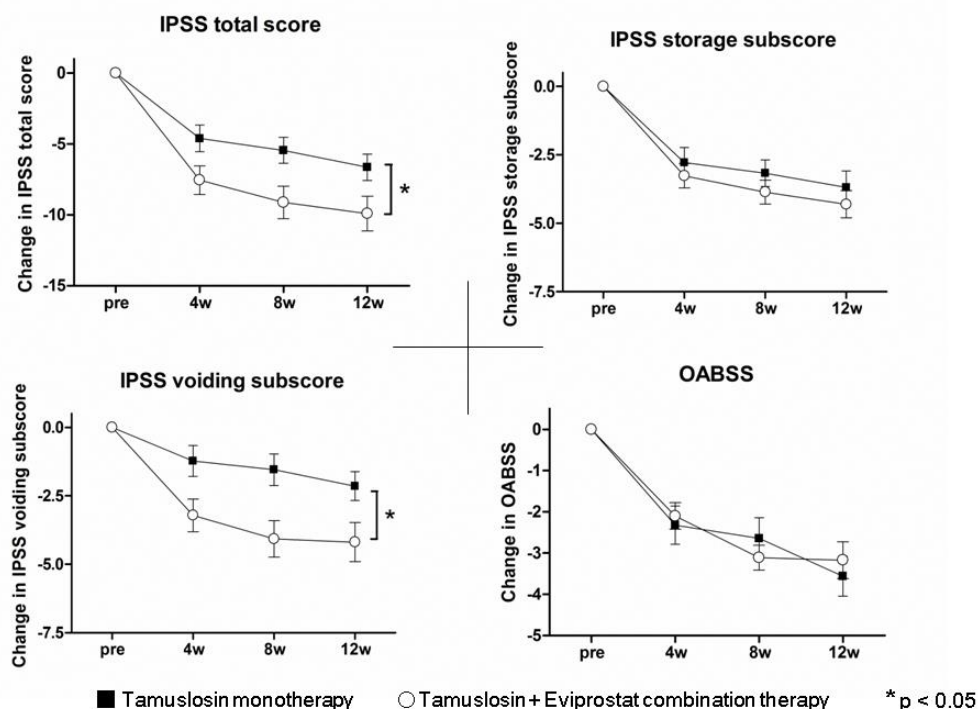


Figure: Changes in individual IPSS, including storage and voiding subscore, and OABSS

Interpretation of results

Eviprostat and alpha 1- adrenoceptor antagonist combination therapy improved male LUTS in patients with OAB, which was especially effective for the patients with voiding symptom. However, the present results did not reveal significant usefulness for OAB symptoms

Concluding message

The present randomized controlled study did not reveal significant usefulness of Eviprostat for OAB symptoms in male LUTS patients. Further long-term prospective studies might be necessary.

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Oita University Institutional Review Board **Helsinki:** Yes **Informed Consent:** Yes