162

Kim S[1], Cho K J[1], Lee D H[1], Kim H G[2], Kim J C[1]
1. *Department of Urology, College of Medicine, The Catholic University of Korea,* ***2.*** *Department of Urology, Konkuk University of Medical center*

THE EFFECTS OF FLEXIBLE-DOSE TAMSULOSIN ON LOWER URINARY TRACT SYMPTOMS AND TREATMENT SATISFACTION IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA: 12-WEEK, OPEN-LABEL, OBSERVATIONAL STUDY

Hypothesis / aims of study
Effects of alpha-blockers for lower urinary tract symptoms (LUTS) are the proportionate relationship to the dosage of alpha-blockers. We investigated the effects of flexible-dose tamsulosin on LUTS and treatment satisfaction in patients with benign prostatic hyperplasia (BPH).

Study design, materials and methods
Patients aged ≥ 50 years who had International Prostate Symptom Score (IPSS) of ≥ 8 and maximum uroflow rate of ≤ 15 mL/s were enrolled prospectively. Those with neurogenic bladder, histories of acute urinary retention or prostate surgery, anatomical lower urinary tract abnormalities beyond BPH and symptomatic urinary tract infections were excluded. Enrolled patients received tamsulosin 0.2mg/d for the first 4 weeks and divided into two groups by IPSS or treatment satisfaction questions (TSQ). Tamsulosin 0.2mg group was maintained starting dose and tamsulosin 0.4mg group was increased 0.4mg for the remaining 8 weeks. Patients with a reduction of IPSS ≤ 3 or dissatisfaction in TSQ after tamsulosin 0.2mg treatment for 4 weeks were decided to receive tamsulosin 0.4mg. The primary endpoint of this study was to assess the change in total IPSS and treatment satisfaction by flexible-dose tamsulosin at week 12. Secondary endpoints included the proportion of patients with escalation of tamsulosin dose from 0.2mg to 0.4mg, changes of IPSS quality of life (QoL) score, storage subscore and voiding subscore by flexible-dose tamsulosin, change of total IPSS in tamsulosin 0.4mg group, comparison of total IPSS at week 12 between tamsulosin 0.2mg group and 0.4mg group, and baseline factors affecting 0.4mg dose escalation. Safety assessments included adverse events.

Results
121 patients were enrolled and received tamsulosin 0.2mg. 95 patients completed the study, 52 (54.7%) in tamsulosin 0.2mg group and 43 (45.3%) in tamsulosin 0.4mg group. Total IPSS was significantly improved by flexible-dose tamsulosin in this study ($P < 0.001$). Satisfaction rate on 12 weeks flexible-dose tamsulosin treatment was 59% and dissatisfaction rate was 27.3%. IPSS QoL score, voiding subscore and storage subscore were significantly improved by flexible-dose tamsulosin too. Total IPSS after 0.4mg dose escalation was significantly improved compared to IPSS before dose escalation in tamsulosin 0.4mg group. However, total IPSS changes from baseline to week 12 in tamsulosin 0.4mg group were lower than in 0.2mg group. Maximum uroflow rate was an independent factor affecting tamsuloin 0.4mg dose escalation. Most adverse events were mild, and none were severe.

Interpretation of results
Flexible-dose tamsulosin treatment, 0.2mg maintenance or 0.4mg dose escalation by treatment satisfaction and LUTS after tamsulosin 0.2mg treatment for 4 weeks in patients with BPH showed significant improvement of LUTS, high satisfaction rate and well tolerated. Maximum uroflow rate was an independent factor affecting tamsuloin 0.4mg dose escalation.

Concluding message
Flexible-dose tamsulosin treatment in patients with BPH successfully improved LUTS, satisfaction rates and well tolerated.

Disclosures
Funding: None **Clinical Trial:** Yes **Registration Number:** Institutional Review Board **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Institutional Review Board **Helsinki:** Yes **Informed Consent:** Yes