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EFFICACY OF LOW-DOSE TAMSULOSIN ON LOWER URINARY TRACT SYMPTOMS SUGGESTIVE OF BENIGN PROSTATIC HYPERPLASIA A NONBLIND MULTICENTER KOREAN STUDY

Hypothesis / aims of study
To evaluate the efficacy and tolerability of tamsulosin 0.2mg once-daily in Korean patients with lower urinary tract symptoms (LUTS) suggestive of a benign prostatic hyperplasia (BPH), who were treated for up to 1 year.

Study design, materials and methods
Of the 211 patients from seven urology outpatient centers who participated in this investigation 146 patients were evaluable. Tamsulosin 0.2 mg/day was orally administered in a nonblind design for a 1 year period. The primary efficacy parameters were improvement in the total, obstructive and irritative International Prostate Symptom Score (IPSS), measured at baseline and at weeks 12, 24, 36 and 52, and in the maximal urinary flow rate (Qmax) measured at baseline and at weeks 24 and 52. The secondary efficacy parameters were a decrease of $\geq$30% in IPSS, and an increase in Qmax of $\geq$30% from baseline. Changes in parameters between baseline and 52 weeks were assessed using Student's paired t-test.

Results
Statistically significant, gradual improvements in all efficacy parameters were observed over the 1-year period. Tamsulosin 0.2 mg/day resulted in a mean reduction of 41.1% in total IPSS [$p<0.001$] and a mean increase of 4.56 ml/s in Qmax at 52 weeks [$p < 0.001$].

Interpretation of results
Tamsulosin was well tolerated; adverse events occurred in 6.2% of patients and there were no withdrawals as a result of adverse events. There were no significant changes in blood pressure or pulse rate during the study.

Concluding message
One-year treatment with tamsulosin 0.2 mg/day in Korean patients with suspected BPH, was well tolerated and effective in improving LUTS and urinary flow. The effect on symptoms was apparent after 12 weeks of treatment, and symptom improvement was observed for up to 1 year.