491

Chung B[1], Hong S J[1]
1. Department of Urology,Yonsei University, college of Medicine

DOXAZOSIN GITS IS EFFECTIVE LONG-TERM TREATMENT FOR IMPROVING SYMPTOMS AND FLOW RATE IN PATIENTS WITH BPH

Hypothesis / aims of study

The long-term efficacy and safety of extended-release doxazosin gastrointestinal therapeutic system (GITS) were assessed under routine clinical care conditions over 12 months in Korean men with and without coexisting hypertension. We sought to evaluate whether or not improvements observed in symptoms, quality of life (QoL), and urine flow rate observed with doxazosin GITS were maintained with long-term therapy in patients with and without concomitant hypertension.

Study design, materials and methods

This prospective, multicenter, open-label, noncontrolled, flexible-dose study was designed to evaluate the effects of doxazosin GITS in men aged at least 40 years with clinical evidence of BPH who were outpatients of the urology departments of 40 centers during the period from April 2002 to December 2003. Patients were evaluated at baseline and at 1, 2, 6, and 12 months. The primary efficacy variable was Clinician's Global Assessment of Change (CGAC; improved, no change, or worse). Secondary efficacy variables were International Prostate Symptom Score (IPSS), QoL, maximum flow rate (Q_{max}), and postvoid residual (PVR) urine volume. Adverse events (AEs) and blood pressure (BP) were also recorded.

Results

A total of 475 men were enrolled; 186 patients completed the study. Based on the CGAC, most patients (n=155; 83.8%) improved and 31 patients (16.2%) had no change in symptoms at 12 months. The mean change (±SD [standard deviation]) in IPSS was significant from baseline (**Figure 1**; –9.0±6.8; $P<0.05$). QoL was significantly improved from baseline to the end of long-term treatment (–1.6±1.4; $P<0.05$). Significant increases were observed in Q_{max} from 10.5±4.3 at baseline to 13.6±4.9 at Week 8 (**Figure 2**; $P<0.05$). These improvements were maintained through the end of the trial (13.7±6.3; $P<0.05$). PVR urine volume decreased significantly from 39.1±37.0 at baseline to 20.1±21.3 at Week 8 ($P<0.05$) and was maintained at 12 months (23.2±33.7; $P<0.05$). Decrease in systolic BP (SBP) and diastolic BP (DBP) from baseline was significantly greater in hypertensive patients (n=52) compared with normotensive patients (n=134; SBP/DBP –9.5±18.4/–13.4±10.9 vs –3.3±12.5/–1.4±9.5, $P<0.05$) at 12 months. No difference was observed between the normotensive and hypertensive patients for BPH symptom improvement (IPSS) or the QoL index. The reduction in IPSS was significantly greater in the normotensive group then in the hypertensive group only at Week 4 ($P<0.05$); changes in IPSS in hypertensive and normotensive groups was not different at other times measured. A total of 47 AEs were reported in 41/475 patients (8.6%). Most frequently reported AEs were dizziness (2.7%), impotence (1.1%), dry mouth (1.1%), prostatic disorder (0.6%), and postural hypotension (0.4%).

Figure 1. Improvements in IPSS in all patients. $^{*}P<0.05$ vs baseline.

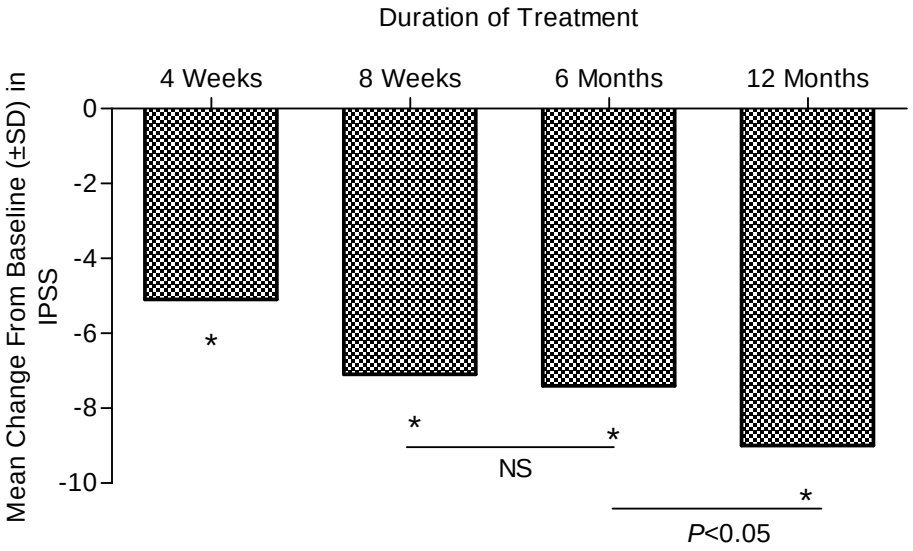
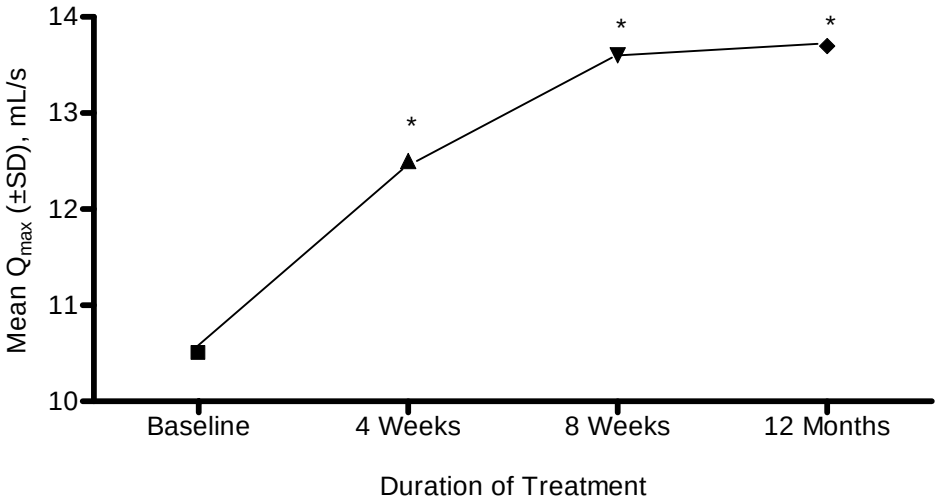


Figure 2. Improvements in Q_{max} in all patients. $^{*}P<0.05$ vs baseline.



Interpretation of results

After 12 months, treatment with doxazosin GITS resulted in symptom improvement in more than 83% of patients based on CGAC. Significant improvement was also observed in all symptoms and flow rate measures: IPSS, QoL, Q_{max}, and PVR. The incidence of AEs was low.

Concluding message

This study, which was conducted under routine clinical conditions, demonstrated that long-term therapy with doxazosin GITS was effective and well tolerated in Korean patients with and without concomitant hypertension.