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A COMPARATIVE STUDY ON THE CLINICAL EFFECTS OF SILODOSIN AND NAFTOPIDIL IN PATIENTS WITH LOWER URINARY TRACT SYMPTOMS ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA

Hypothesis / aims of study

Silodosin is a novel alpha-adrenoceptor (AR) antagonist highly selective to subtype alpha1A, and has been used in clinical in Japan from 2006 and approved by the U.S. Food and Drug Administration (FDA) in October, 2008, for the treatment of the signs and symptoms of BPH (Benign Prostatic Hyperplasia). In the present ongoing study, we attempt to evaluate a clinical effects of silodosin compared with naftopidil in patients who are alpha-blocker naïve or receiving tamsulosin with lower urinary tract symptoms associated with benign prostatic hyperplasia.

Study design, materials and methods

A randomized, open-label controlled study is being conducted at multi-centres in Japan. Men aged ≥ 50 years with an International Prostate Symptom Score (IPSS) of ≥ 8 , a quality-of-life (QoL) score of ≥ 3 , a maximum urinary flow rate (Qmax) of < 15 ml/s, a prostate volume of < 20 ml are eligible for this study. The patients have never received alpha-blocker before the enrollment, or are receiving tamsulosin 0.2mg once daily at the enrollment. After the enrollment, patients were randomized to receive silodosin 4mg twice daily or naftopidil 50mg once daily for 8 weeks. At this point, 121 patients have been enrolled into 4 groups; the patients freshly received silodosin (35 patients) or naftopidil (33 patients), or changed from tamsulosin to silodosin (26 patients) or naftopidil (27 patients). IPSS, QoL, Qmax, and residual urine (RU) are used as efficacy criteria. Statistical significance was determined by The Wilcoxon signed-ranks test and the Mann-Whitney's U-test, with $p < 0.05$ considered to be statistically significant.

Results

In the alpha-blocker naïve patients and the patients changed from tamsulosin at four and eight week, both of silodosin and naftopidil significantly improved the total IPSS and QoL (the Wilcoxon signed-ranks test). On the comparison of clinical effects between silodosin and naftopidil, silodosin significantly showed the better improvement of total IPSS score only in the alpha-blocker naïve patients at four and eight week (the Mann-Whitney's U-test). The Qmax and RU were not significantly changed in all treatment groups.

Interpretation of results

Both of silodosin and naftopidil improved the IPSS and QoL in the alpha-blocker naïve patients and the patients changed from tamsulosin; however silodosin showed the better clinical effect on IPSS compared with naftopidil in the alpha-blocker naïve patients at four and eight week.

Concluding message

This study showed the clinical usefulness of silodosin in the treatment of LUTS associated with BPH.

Disclosures

Funding: None **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Ethics Committee of Kobe University Hospital **Helsinki:** Yes **Informed Consent:** Yes