

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, 53 patients have been enrolled into 4 groups; the patients freshly received silodosin (16 patients) or naftopidil (15 patients), or changed from tamsulosin to silodosin (11 patients) or naftopidil (11 patients). IPSS, QoL, Qmax, and residual urine are used as efficacy criteria. Statistical significance was determined by Student's *t* test, with $p < 0.05$ considered to be statistically significant.

Results

In the alpha-blocker naïve patients at eight weeks, both of silodosin and naftopidil significantly improved the total IPSS and QoL, but only silodosin significantly improved the Qmax. In the patients changed from tamsulosin at eight weeks, silodosin significantly improve the total IPSS, whereas naftopidil did not show any significant improvement of the efficacy criteria. In addition, in the alpha-blocker naïve patients at four weeks, silodosin significantly showed the better improvement of total IPSS compared with naftopidil.

Interpretation of results

Both of silodosin and naftopidil improved the some clinical criteria in the alpha-blocker naïve patients; however silodosin showed the better clinical effects compared with naftopidil at four weeks. In the patients changed from tamsulosin, only silodosin showed the significant improvement of IPSS.

Concluding message

This ongoing study showed the clinical usefulness of silodosin in the treatment of LUTS associated with BPH. Additional patients will be enrolled to this study until the presentation.

Specify source of funding or grant	None
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Ethics Committee of Kobe University Hospital
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes