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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. 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 (LUTS) associated with benign prostatic hyperplasia (BPH).

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 8weeks. At this point, 30 patients have been enrolled into 4 groups; the patients freshly received silodosin (9 patients) or naftopidil (7 patients), or changed from tamsulosin to silodosin (7 patients) or naftopidil (7 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, both of silodosin and naftopidil tended to decrease the total IPSS ($p < 0.1$) and significantly improved the QoL and residual urine volume at 8 weeks. In the patients changed from tamsulosin, silodosin tended to improve the total IPSS and QoL ($p < 0.1$) and significantly reduced the residual urine volume, whereas naftopidil did not show any tendency of improvement of the efficacy criteria.

Interpretation of results

Both of silodosin and naftopidil improved the some of clinical criteria in the alpha-blocker naïve patients, however silodosin showed the better clinical effects compared with naftopidil in the patients changed from tamsulosin.

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.

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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	Kobe University Institutional Ethics Committee
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes