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Shirakawa T[1], Haraguchi T[2], Matsumoto Y[2], Takeda M[2], Morishita S[3], Minayoshi K[4], Miyazaki J[5], Yamada Y[6], Tanaka K[2], Takenaka A[2], Fujisawa M[2]

1. *CID, Kobe University Graduate School of Medicine,* ***2.*** *Division of Urology, Kobe University Graduate School of Medicine,* ***3.*** *Department of Urology, Kobe Century Memorial Hospital,* ***4.*** *Shakaihoken Kobe Central Hospital,* ***5.*** *Kobe Ekisaikai Hospital,* ***6.*** *Hyogo Prefectural Amagasaki Hospital*

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 <15ml/s, a prostate volume of <20ml are eligible for this study. The patients have never received alpha-blocker before the enrollment, or are receiving tamuslosin 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, 93 patients have been enrolled into 4 groups; the patients freshly received silodosin (28 patients) or naftopidil (24 patients), or changed from tamuslosin to silodosin (21 patients) or naftopidil (20 patients). IPSS, QoL, Qmax, and residual urine (RU) 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 four and eight weeks, both of silodosin and naftopidil significantly improved the total IPSS and QoL. In the patients changed from tamsulosin, both of silodosin and naftopidil significantly improve the total IPSS at four and eight week, the siginificant improvement of QoL was observed at four and eight week by silodosin and at eight week by naftopidil. In addition, only in the alpha-blocker naïve patients at four and eight week, silodosin significantly showed the better improvement of total IPSS compared with naftopidil. Furthermore, in the patients with prostate volume more than 50ml, silodosin improved total IPSS score of seven out of nine patients, whereas naftopidil improved none in seven patients. The Qmax and RU were not significantly changed in all treatment groups.

Interpretation of results

Both of silodosin and naftopidil improved the some clinical criteria 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 patients having prostate more than 50ml volume.

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**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics commitee of Kobe University Hospital**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**