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A RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY TO EVALUATE THE EFFICACY AND SAFETY OF NEW, HIGHLY SELECTIVE A1A-ADRENOCEPTOR ANTAGONIST SILODOSIN IN KOREAN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA

Hypothesis / aims of study

To evaluate the efficacy and safety of the new α_{1A}-adrenoceptor-selective antagonist silodosin compared with placebo in Korean patients with lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia(BPH).

Study design, materials and methods

This randomized, double-blind, placebo-controlled study was conducted at 8 centers in Korea. Men aged from 50 to 75 years with an International Prostate Symptom Score(IPSS) of ≥8, quality of life(QoL) score of ≥3, a maximum urinary flow rate(Qmax) of <15mL/s, prostate volume of ≥20mL and a post void residual urine volume of <100mL were eligible for enrolment. Patients were randomized to receive silodosin 4mg twice daily or placebo for 12 weeks. The primary endpoint was the change in IPSS from baseline. Safety was assessed by adverse events, physical examination, vital signs and laboratory tests.

Results

Totally, 208 patients were randomized (silodosin 105, placebo 103). In the all randomized patients, maximum efficacy evaluation population were 172 patients(silodosin 86, placebo 86). The change in the total IPSS from baseline in the silodosin, placebo was -7.7, -5.6, respectively.

The incidence rates of adverse events and drug-related adverse events were 66.0%, 40.2% and 52.4%, 18.6% in the silodosin and placebo group, respectively. There were no significant cardiovascular effects, including syncope, in the silodosin group, thus supporting the hypothesis that high α_{1A}-adrenoceptor selectivity is not associated with blood pressure effects that are commonly reported with nonselective α_1-blockers. There was extremely low incidence of orthostatic hypotension that is typically seen with different α_{1A}-adrenoceptor agents.

Interpretation of results

There was a significant difference between silodosin and placebo group from 4 week to 12 week in the change of IPSS. The proportion of patients with ≥25% improvement in IPSS was 72.1%, 54.7% in the silodosin, placebo group, respectively, and there was a significant difference.

High α_{1A}-adrenoceptor selectivity is not associated with blood pressure effects.

Concluding message

Silodosin was generally effective and tolerable. The result of this study showed that silodosin is clinically useful for managing LUTS associated with BPH.

References

1. Early efficacy of silodosin in patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia

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	**Ewha Institutional Review Board for human research**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**