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EARLY EFFICACY OF SILODOSIN IN PATIENTS WITH LOWER URINARY TRACT SYMPTOMS SUGGESTIVE OF BENIGN PROSTATIC HYPERPLASIA

Hypothesis / aims of study

The first line medication for lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH) is alpha1-blocker. Recently, high alpha1A-adrenoceptors selective drug, silodosin, was used for BPH patients in Japan. Silodosin has been evaluated for improvement in subjective symptoms with the International Prostate Symptom Score (I-PSS) in one-year period. The purpose of this study is to evaluate the early efficacy of silodosin for treatment of the LUTS suggestive of BPH patients.

Study design, materials and methods

Patients who complained of LUTS suggestive of BPH according to physician judgement were recruited. Inclusion criteria of this study is their I-PSS >= 8 and Quality of Life (QOL) index of >= 2. A total of 68 patients were orally administered usual dosage of 4mg silodosin twice daily. The patient was handed a treatment diary on the first visit and recorded I-PSS and QOL scores, Day1, 2, 3, 4, 5, 6, 7, 14, and 28, respectively. The values for Day 14 and Day 28 are the average of the observed values for the previous three days including the day of observation. We evaluated the change of I-PSS and QOL index before and after each point of administration of silodosin. Then, we evaluate the subscores of I-PSS, as voiding symptoms (using the sum of the scores for intermittency, weak stream, and hesitancy), storage symptoms (using the sum of the scores for frequency, urgency, and nocturia), and post micturition symptoms (using the score for feeling of incomplete emptying). We assessed changes in I-PSS total score based on severity level of I-PSS or QOL index.

All values are expressed as the mean ± SD. Statistical comparisons before and after the administration were done using Wilcoxon signed rank test. $P<0.05$ was considered statistically significant.

Results

Mean age of 68 patients was 67.5 ± 8.0 years (range 48-92 years).Total I-PSS was 19.38 ± 7.46, subscores of voiding symptoms, storage symptoms, and post voiding symptoms were 8.93 ± 3.95, 7.97 ± 3.88, 2.49 ± 1.70, respectively. QOL index was 4.68 ± 1.07. The number of patients of severe (IPSS >=20) and moderate (IPSS 8-19) symptoms according to total IPSS were 36 and 32. The number of patients of severe (QOL index 5, 6) and moderate (QOL index 2-4) symptoms according to QOL index were 39 and 29.

IPSS total scores and QOL index significantly improved from 19.38 ± 7.46, 4.68 ± 1.07 at baseline to 15.81 ± 7.40, 4.22 ± 1.30 at day 1. Symptom relief was very rapid and maintained throughout the study. The subscores of voiding, storage, and post micturition symptoms were significantly decreased from 8.93 ± 3.95, 7.97 ± 3.88, and 2.49 ± 1.70 at baseline to 7.28 ± 4.09, 6.52 ± 3.47, and 2.02 ± 1.56 at day 1. This was improved throughout the study. Regardless of the severity in IPSS total score and QOL index, IPSS total scores are significantly decreased at day 1 and maintained throughout the study.

Interpretation of results

Our results suggested the selective alpha1A blocker, silodosin, improved the BPH/LUTS symptoms and QOL in very short time. Moreover, not only voiding symptoms, but also storage and post micturition symptoms are improved by this selective alpha1A blocker.

Concluding message

Silodosin may be considered a promising treatment for rapid improvement to LUTS suggestive of BPH patients.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**this study is not placebo-controlled randamized study. Patients received usual dosage of drug in practice. Informed concent was obtained for all patients.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**