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WHAT PERCENT OF MEN WITH LOWER URINARY TRACT SYMPTOMS BY PROSTATIC ENLARGEMENT CAN CONTINUE α 1-BLOCKER TREATMENT FOR A LONG TIME?

Hypothesis / aims of study

Although α 1-blockers are the mainstay of treatment for lower urinary tract symptoms (LUTS) by prostatic enlargement, all men do not necessarily continue the same medication for a long time. In this study, we prospectively evaluated what percent of patients dropped out during follow-up after administration of tamsulosin and the reasons why they terminated medication.

Study design, materials and methods

Between February 2002 and November 2003, 115 patients aged 50 years or older who had an international prostate symptom score (IPSS) of 8 or more were enrolled in this prospective multicenter study. Tamsulosin, 0.2 mg/day, which is the approved dosage in our country, was given to the patients. They were followed for at least 4 years with annual evaluation using the IPSS, QOL score, maximum flow rate (Qmax), postvoid residual volume (PVR) and prostate volume (PV) measurement. If tamsulosin had to be terminated during follow-up, the reason was determined. If a patient did not come to the hospital to receive a prescription, a questionnaire asking the reason was mailed to him.

Results

At baseline, the mean age, IPSS, QOL score, Qmax, PVR and PV were 68.8 years old, 17.3, 4.2, 12.3 ml/sec, 64 ml and 30.8 cc, respectively. Of the 115 patients, 78 (67.8%) discontinued tamsulosin during the 4-year follow-up period. Forty-five patients quit coming to the hospital to receive a prescription. The results of the mailed questionnaire demonstrated that the reasons for self-discontinuation were improvement of LUTS (20), no change or progression of LUTS (16), moving (4) and business (3). The reason was not determined for 2 patients because they did not reply to the questionnaire. In the remaining 33 patients, the reasons for termination were conversion to surgical treatment (13), conversion to another α 1-blocker due to disease progression (3), adverse events (3) and deteriorated general condition due to other medical complications or death (14). The discontinuation rates at 6 months, 1, 2, 3 and 4 years determined by the Kaplan-Meier method were 36.5%, 43.5%, 53.0%, 59.2% and 63.7%, respectively. The IPSS, QOL score and PVR were significantly improved in the 37 patients who continued taking the drug at 4 years (IPSS, 16.6 to 11.9, $p < 0.0001$; QOL score, 4.2 to 2.6, $p < 0.0001$; PVR, 66 to 35 ml, $p=0.012$). On the other hand, Qmax showed no significant improvement (12.2 to 12.2 ml/sec, $p=0.812$). The PV significantly increased from 31.9 to 32.5 cc ($p=0.008$).

Interpretation of results

This is the first study that prospectively evaluated the clinical courses of patients who received α 1-blocker treatment for LUTS by prostatic enlargement, including those who dropped out during follow-up. Two-third of men to whom tamsulosin was given terminated the medication by 4 years due to several reasons. The major reason for termination was self-discontinuation.

Concluding message

Only a small portion of patients with LUTS induced by prostatic enlargement continued the α 1-blocker treatment for a long time in real-life clinical practice.

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<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	The Institutional Review Board of Clinical Study of Sapporo Medical University
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes