

PROSPECTIVE OBSERVATIONAL STUDY OF PREDICTIVE CLINICAL PARAMETERS IN PATIENTS WITH BENIGN PROSTATIC HYPERTROPHY MEDICATED WITH SILODOSIN FOR OVER ONE YEAR

Hypothesis / aims of study

Data from outpatients with benign prostate hypertrophy (BPH) on long-term medication with the alpha1-adrenoceptor antagonist silodosin were prospectively analyzed to elucidate predictive clinical parameters.

Study design, materials and methods

We prospectively analyzed data from 403 patients who were diagnosed with BPH and initially medicated with silodosin (8 mg/day) in our institution and at our affiliated hospitals between October 2008 and March 2014. We determined the natural history of silodosin therapy by confining the first administration to silodosin alone. Thereafter, no restrictions were imposed and additional medications, switching to a different alpha1-adrenoceptor antagonist, or surgical interventions were allowed according to the clinical judgment of their physicians at the outpatient clinic. Clinical parameters such as International Prostate Symptom Scores (IPSS), overactive bladder symptom scores (OABSS), the International Index of Erectile Function (IIEF5), our original questions about seminal emission, prostate volume, PSA, uroflowmetry, residual urine volume, and information about medications were assessed at baseline and at 2-4 weeks, and at 6 and 12 months after the first day of medication. At 12 months after the first administration of silodosin, the patients were assigned to groups based on whether they continued to take silodosin with or without additional medications for one year (Group 1; n = 182) or stopped taking silodosin with or without a switch to another medication (Group 2; n = 220) and then differences in clinical parameters at baseline were compared between them. Univariate and multivariate analysis were performed to identify associated parameters for taking silodosin for one year. This research protocols were approved by the Ethics Committee in our institution. Informed consent was obtained from the all patients.

Results

The baseline prostate volume was significantly larger in Group 1 than in Group 2 (39.7 vs. 34.9 mL). Residual urine volumes at baseline were also significantly larger in Group 1 than in Group2 (71.5 vs. 53.9 mL). Baseline seminal emissions significantly differed between the two groups. The rate of patients who answered, "no attempt of seminal emission over the past month" at baseline was significantly higher in Group 1 than in Group 2 (40 [31.2%] of 128 vs. 36 [20.9%] of 172 patients). There was no significant difference in baseline IPSS, OABSS, and IIEF5 scores between Group1 and Group2. On univariate analysis, large prostate volume, large residual urine volume and 'no attempt of seminal emission' were significant risk factors for taking silodosin therapy for one year. On multivariate analysis, large prostate volume remained as a significant predictor (HR, 0.984; 95% CI 0.972-0.995; p=0.004).

Interpretation of results

Patients who continued to take silodosin for one year had larger prostate volume, larger residual urine volumes and lower sexual activity at baseline compared with patients who stopped taking silodosin. In multivariate analysis, larger prostate volume remained as a significant predictor for taking silodosin therapy for over one year.

Concluding message

Prostate volume, residual urine volume, and decreased sexual activity at baseline have a possibility to be predictive clinical parameters for long-term silodosin therapy. Another three-year prospective observational study is scheduled.

Disclosures

Funding: NONE **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Ethics Committee of Tohoku University Graduate School of Medicine **Helsinki:** Yes **Informed Consent:** Yes