

PROSPECTIVE OBSERVATIONAL STUDY OF PREDICTIVE CLINICAL PARAMETERS IN PATIENTS WITH BENIGN PROSTATIC HYPERTROPHY MEDICATED WITH SILODOSIN FOR THREE YEARS

Hypothesis / aims of study

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

Study design, materials and methods

We prospectively analysed data from 405 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 parameters, residual urine volume, and information about medications were assessed at baseline and at 2-4 weeks, and at 6, 12, 24 and 36 months after the first day of medication. At 36 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 three years (Group 1; n = 142) or stopped taking silodosin with or without a switch to another medication (Group 2; n = 247) 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 three years. This research protocols were approved by the Ethics Committee in our institution. Informed consent was obtained from the all patients.

Results

The percentage of patients who continued taking silodosin at 1, 2 and 3 years was 44.8, 36.5 and 33.2%, respectively. The age was significantly higher in Group 1 than Group 2 (69.2 vs. 67.6). The baseline prostate volume was also significantly larger in Group 1 than in Group 2 (39.0 vs. 35.8 mL). The rate of patients who answered, "no attempt of seminal emission over the past one month" at baseline was significantly higher in Group 1 than in Group 2 (33.7% vs. 19.8%). There was no significant difference in baseline PSA, uroflowmetry parameters, IPSS, OABSS, and IIEF5 scores between Group1 and Group2. On univariate analysis, age, large prostate volume and 'no attempt of seminal emission' were significant predictors for taking silodosin therapy for three years. On multivariate analysis, 'large prostate volume and 'no attempt of seminal emission' remained as a significant predictor.

Interpretation of results

Patients who continued to take silodosin for three years had higher age, larger prostate volume, and lower sexual activity at baseline compared with patients who stopped taking silodosin. In multivariate analysis, larger prostate volume and low sexual activity remained as a significant

Concluding message

Large prostate volume, and decreased sexual activity at baseline have a possibility to be predictive clinical parameters for long-term silodosin therapy.

Disclosures

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