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LONG-TERM EFFICACY OF SILODOSIN FOR THE TREATMENT OF LOWER URINARY TRACT SYMPTOMS SUGGESTIVE OF BENIGN PROSTATIC HYPERPLASIA

Hypothesis / aims of study

Silodosin, an alpha1A-adrenoceptor selective antagonist, has been reported to be effective for storage and voiding symptoms in BPH patients [1,2]. It has been used for the treatment of lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH) for more than four years in Japan. The short-term efficacies of silodosin have been verified in randomized controlled trials [1,2]. The aim of the present study is to evaluate the long-term efficacy of silodosin for the treatment of LUTS/BPH up to four years in Japan.

Study design, materials and methods

A total of 75 male patients with LUTS/BPH, aged 71.9± 8.5 (50-93) years old, were treated with silodosin (8mg daily). Prostate volume and serum PSA level were 42.1±4.0 (range 20.2-111.7) ml and 3.2±3.6 (range 0.4-20.3) ng/ml, respectively. Three patients whose serum PSA level was over 4.0 ng/ml and who were suspected of having prostate cancer underwent a needle biopsy of the prostate and were determined to be cancer-free. The international prostate symptom score (IPSS), QOL score, average and maximum flow rate (Qave and Qmax, respectively), and postvoid residual urine volume (PVR) were determined at baseline and after the treatments.

Results

At present, 39 patients (52 %) are still on silodosin (for 44.1±13.2 months). 36 (48%) patients withdrew after 14 months on average. The reasons for withdrawal are: lost to follow-up for unknown reasons in 17 patients (44%), detection of prostate cancer or rectal cancer in 2 (6%), insufficient therapeutic response in 11 (28%) (1 patient stopped medication, 1 patient added dutasteride, and 9 underwent surgery), side effects in 4 (10%), satisfied with the current condition in 1 patient (3%), moved to other institution in 1 (3%).

The baseline total I-PSS, the total storage and voiding symptom subscores, Post micturition symptom score (feeling of incomplete emptying), QOL score, Qmax, PVR and are summarized in the table.

The mean total I-PSS, the total storage symptom subscores, the total voiding symptom subscores, the post-micturition score and the QOL score decreased significantly (all $p<0.0001$) at 1 month after the treatment and remained stable up to 48 months. Qmax increased significantly ($p=<0.0001$) and PVR decreased significantly ($p=0.0003$) at 1 month after the therapy, and these changes were sustained for up to 4 years.

	OM	1M	3M	6M	12M	24M	36M	48M
IPSS	18.9 (7.0)	13.2 (7.6)	11.6 (7.2)	12.0 (8.0)	13.0 (7.9)	11.7 (7.3)	12.0 (7.5)	12.0 (7.1)
Storage Symtoms	7.4 (3.7)	5.5 (3.5)	5.0 (3.0)	5.1 (3.3)	5.5 (3.4)	5.3 (3.0)	4.8 (3.3)	4.8 (3.4)
Voiding symptoms	8.6 (3.9)	6.2 (4.2)	5.2 (4.1)	5.5 (44)	5.9 (4.1)	5.0 (4.0)	6.0 (4.0)	6.0 (3.8)
Post-micturition Score	2.9 (1.7)	1.5 (1.5)	1.4 (1.6)	1.4 (1.6)	1.6 (1.7)	1.3 (1.6)	1.2 (1.4)	1.1 (1.2)
QOL score	4.6 (1.1)	3.4 (1.5)	3.1 (1.5)	3.0 (1.4)	2.9 (1.5)	2.9 (1.5)	2.8 (1.5)	2.6 (1.7)
Number	75	70	65	59	58	45	36	16
Qmax	7.5 (2.9)	10.4 (5.0)	11.0 (6.6)	11.7 (4.8)	10.9 (4.6)	10.8 (4.3)	12.5 (9.9)	10.5 (3.5)
PVR (ml)	94.0 (92.7)	63.9 (58.7)	53.8 (51.0)	56.1 (65.9)	57.1 (54.7)	49.3 (62.4)	79.9 (83.2)	56.9 (61.7)
Number 77	70	69	67	61	47	36	16	

Interpretation of results

The withdrawal rate was 52% in patients with LUTS/BPH who were treated with silodosin. Discontinuation due to side effects was noted in 14 patients (19%). Efficacies of tamsulosin for the treatment of LUTS/BPH were noted at 1 month and were stable for 12-48 months.

Concluding message
Silodosin appears to be effective and safe for long-term in patients with LUTS/BPH.

Table
Results of total IPSS, QOL score, Qave, Qmax and PVR before (0M) and after the treatment.
Mean (SD)

References
1. BJU Int. 2006; 98:1019-24.
2. J Urol 2009; 181: 2634–2640
3. Open Access J Urol 1: 1–7, 2009.

Disclosures
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