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Original Article

Efficacy and safety of silodosin in the treatment of lower urinary tract symptoms in elderly men taking antihypertensive medications

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ABSTRACT

Background: Both hypertension and lower urinary tract symptoms (LUTS) are common conditions in the elderly population. This study investigated the efficacy and safety of silodosin in the treatment of LUTS in elderly men who were taking antihypertensive medications.

Methods: This is an observational study which collected the medical records of patients who started silodosin medication for their LUTS between April 2015 and December 2015. Inclusion criteria were age $\geq$ 65 years, currently taking antihypertensive medication, and International Prostate Symptom Score (IPSS) $\geq$ 8. Pretreatment evaluation included IPSS, Male Sexual Health Questionnaire, systemic symptoms, blood pressure, and uroflowmetry. Post-treatment evaluation was performed 3 months after the initial administration of silodosin medication.

Results: Mean age of the total 48 patients was 70.7 ± 5.2 years. Thirty-two (66.7%) patients who continued silodosin single treatment showed a significant decrease in IPSS Quality of life scores (4.2 ± 1.1 vs. 3.0 ± 1.6, $P = 0.001$) and an increase in the maximum flow rate (10.7 ± 6.0 mL/s vs. 14.0 ± 4.5 mL/s, $P = 0.001$). Blood pressures did not change, and none of the patients needed to adjust their antihypertensive medication. New development of orthostatic hypotension was observed in one (2.5%) patient. Among the six patients who had orthostatic hypotension before silodosin treatment, none of the patients showed symptom aggravation. Ejaculatory dysfunction that required discontinuation of silodosin medication developed in only one (2.5%) patient.

Conclusion: Silodosin is an effective and safe agent in elderly men who are taking antihypertensive medications. Silodosin has an advantage in the treatment of LUTS in this population, even if the patients have orthostatic hypotension before treatment.

1. Introduction

As men get older, the risk of various comorbidities increases. Both hypertension (HTN) and lower urinary tract symptoms related to benign prostatic hyperplasia (LUTS/BPH) are common disorders in elderly men. In the Korea National Health and Nutrition Examination Survey, the age-standardized prevalence of HTN was approximately 30% among adults over 30 years of age.[1] Between 2007 and 2011, the prevalence of HTN in men aged 65 years or older increased from 49.3% to 58.4%.[1] Among men with HTN, the

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percentage of those receiving medical treatment for HTN was 51.7% in the 2008 to 2011 period.[1]

LUTS/BPH is a highly prevalent condition in the elderly population. The previous study demonstrated that 64.3% of participants sampled from the general population reported at least one LUTS.[2] In men aged 60 years or older, the prevalence of LUTS was increased to 80.7%.[2] The epidemiology of LUTS study also reported that 72.3% of men and 76.3% of women had at least one LUTS at least sometime in their life.[3] The Krimpen study also reported that the prevalence of clinical BPH in men aged 50–75 years ranged from 9% to 20% depending on the definition used.[4]

In this context, a considerable proportion of aged men who visit the urologic clinic because of LUTS/BPH are likely to have HTN. Therefore, assessing whether they are taking antihypertensive medications is important for determining which of various alpha adrenoceptor antagonists, the first-line medical treatment for LUTS/BPH, is a safe and effective prescription in men with both LUTS/BPH and HTN.[5] This is important considering that an alpha adrenoceptor antagonist was originally developed as an antihypertensive drug, and it can induce orthostatic hypotension and dizziness.[6] Among the recently used alpha adrenoceptor blockers, silodosin is regarded to have a minimal effect on the cardiovascular system because of high selectivity for the alpha 1A adrenergic receptor.[7,8] Therefore, silodosin appears to have the advantage of cardiovascular safety during the treatment of patients with LUTS/BPH who are taking antihypertensive medications. However, there is scarcity of data on the safety and efficacy of silodosin in men with both LUTS/BPH and HTN who are taking antihypertensive medications.

In this study, we aimed to determine the efficacy and safety of silodosin in the treatment of LUTS/BPH in men who were taking antihypertensive medications, in real clinical practice.

2. Materials and methods

This was a multicenter, observational study approved by the Institutional Review Boards of all the hospitals included (Konkuk University Hospital, Korea University Ansan Hospital, Dongguk University Ilsan Medical Center, and Seoul Metropolitan Government – Seoul National University Boramae Medical Center). This study collected the clinical data of elderly patients who took antihypertensive medication for more than 6 months, and started administration of silodosin for LUTS/BPH between April 2015 and December 2015.

2.1. Patients

Patients with LUTS/BPH who newly visited the outpatient departments of the participating centers from April 2015 to December 2015 were candidates for this study. The severity of LUTS/BPH was evaluated by the International Prostate Symptom Score (IPSS) questionnaire. Inclusion criteria were men age $\geq$ 65 years, current administration of antihypertensive medications for more than 6 months, IPSS $\geq$ 8 points, and initiation of silodosin medication during the study period. Patients who met any of the following criteria were excluded: any history of administration of alpha adrenergic antagonists before silodosin treatment; initial administration of combination therapy involving any medication for LUTS (antimuscarinic agents, 5 alpha reductase inhibitors, beta 3 adrenoceptor agonists, and desmopressin) and silodosin; unusual dosage of silodosin except 8 mg once or 4 mg twice daily; symptomatic urinary tract infection; history of urethral or prostatic surgery; history of prostate cancer or bladder cancer; renal insufficiency defined by serum creatinine level $\geq$ 2.0 mg/dL; or serum prostate specific antigen level > 10 ng/mL.

2.2. Pretreatment evaluation

Before prescribing silodosin, demographic characteristics and previous medical history were collected. Demographic data included age, height, and body weight. Medical history included underlying diseases, information on medications which the participants were taking, previous surgical history, and systemic symptoms. The underlying diseases were categorized according to the Klabunde modification of the Charlson comorbidity index.[9] The IPSS questionnaire and the overactive bladder symptom score (OABSS) questionnaire were used to evaluate the severity of LUTS/BPH. The ejaculatory function domain of the Male Sexual Health Questionnaire (MSHQ) was used to evaluate ejaculatory status. Microscopic urinalysis, serum creatinine, and serum prostate specific antigen test were performed for checking fulfillment of the inclusion and exclusion criteria. Maximal flow rates and postvoid residual urine volumes were measured, and prostate volume was evaluated using transrectal ultrasonography. Systolic and diastolic blood pressures were checked in the sitting position after resting for more than 5 minutes.

2.3. Post-treatment evaluation

Post-treatment evaluation was performed at 3 months after administration of silodosin. When a participant did not visit the clinic at 2–4 months from the initiation of treatment, he was considered lost to follow up. The medication of silodosin and other newly added medications related to LUTS/BPH were also recorded during the study period. When a participant underwent BPH surgery or experienced acute urinary retention, it was regarded as clinical progression. To evaluate the efficacy of treatment, IPSS and OABSS questionnaires were administered, and maximum flow rate and postvoid residual urine volume were measured. To evaluate the safety, the presence of systemic symptoms was collected and compared to that during the pretreatment status. When a new symptom developed or a patient stated that a symptom was more severe than before, it was regarded as aggravation. Improvement was defined by disappearance of symptoms. Evaluation of the ejaculatory function domain of the MSHQ was repeated to identify ejaculatory dysfunction at each visit. Blood pressure was measured again using a method identical to pretreatment evaluation. In addition, a newly developed questionnaire composed of six items was administered to assess subjective satisfaction with silodosin treatment and bothersomeness of ejaculatory dysfunction (Appendix I).

2.4. Statistical analysis

All statistical analyses were performed using SPSS version 19.0 (SPSS, Inc., Chicago, IL, USA). Data are presented as mean ± standard deviation. Variables were evaluated with respect to statistically significant differences between baseline and 3 months after silodosin treatment using the paired *t* test for parametric values and the Wilcoxon signed-rank test for nonparametric values. A P value < 0.05 was considered statistically significant.

3. Results

Baseline characteristics of a total of 48 patients are presented in Table 1. The mean age of 48 patients was 70.7 ± 5.2 years, and mean prostate volume was 40.5 ± 16.4 mL. The most common comorbidity excluding HTN was diabetes (27.1%), followed by stroke (10.4%). Half of the patients were taking two or more antihypertensive drugs. The most common antihypertensive drug was a calcium channel blocker (58.3%), followed by angiotensin II

Table 1
Baseline characteristics of the study population.

Characteristics	Value
No. of patients	48
Age (y)	70.7 ± 5.2
Height (cm)	166.6 ± 5.5
Weight (kg)	67.3 ± 7.7
Body mass index (kg/m^2)	24.2 ± 2.3
Blood pressure (mmHg)	
Systolic blood pressure	125.7 ± 10.5
Diastolic blood pressure	76.3 ± 9.3
Total prostate volume (mL)	40.5 ± 16.4
Transitional zone volume (mL)	18.5 ± 11.8
Prostate specific antigen (ng/mL)	2.5 ± 1.7
Creatinine (mg/dL)	1.0 ± 0.3
Co-morbidity (*n*, %)	
Hypertension	48 (100.0)
Diabetes	13 (27.1)
Myocardial infarction	4 (8.3)
Congestive heart failure	3 (6.3)
Peripheral vascular disease	0 (0.0)
Stroke	5 (10.4)
Chronic obstructive pulmonary disease	2 (4.2)
Dementia	0 (0.0)
Chronic kidney disease	1 (2.1)
Liver disease	0 (0.0)
Peptic ulcer disease	2 (4.2)
Rheumatologic disease	0 (0.0)
Paralysis	0 (0.0)
Others[a)]	2 (4.2)
Antihypertensive medication	
Number of drugs	
1	24 (50.0)
2	19 (39.6)
3	3 (6.3)
4	2 (4.2)
Category of drugs	
Diuretics	13 (27.1)
Alpha blocker	2 (4.2)
Beta blocker	14 (29.2)
Calcium channel blocker	28 (58.3)
Angiotensin converting enzyme inhibitor	0 (0.0)
Angiotensin II receptor blocker	22 (45.8)

Data are presented as the mean ± standard deviation or *N* (%).
[a)] Others, one case of herniated intervertebral disc and one case of thyroid disease.

receptor blocker (45.8%). Two patients were taking an alpha blocker (terazosin 2 mg once daily) as an antihypertensive drug.

A dose of 4 mg of silodosin twice daily was prescribed in eight (16.7%) patients and a dose of 8 mg of silodosin once a day was prescribed in 40 (83.3%) patients. At 3 months from the initiation of administration of silodosin, eight (16.7%) patients were lost to follow up, and four (8.3%) patients discontinued silodosin medication because of insufficient efficacy (n = 2, 4.2%) or an adverse event (n = 2, 4.2%). One patient who discontinued silodosin medication complained of ejaculatory dysfunction as an adverse event, and the other patient complained of orthostatic hypotension. Addition of other drugs for LUTS during the 3-month follow up visit was observed in four (8.3%) patients. Antimuscarinic agents were prescribed in two patients; a 5 alpha reductase inhibitor was prescribed in one patient, and desmopressin was prescribed in one patient. Thirty-two (66.7%) patients continued silodosin medication without any additional drug.

In patients who continued silodosin single treatment, total IPSS, voiding score sum, storage score sum, and quality of life score were decreased significantly after treatment (Table 2). To exclude the effect of other combined medications, efficacy profile was compared only in patients who continued silodosin alone treatment (n = 32). Night-time frequency and urgency scores on the OABSS questionnaire were also improved, although daytime frequency or urge incontinence scores did not improve. An objective increase in the maximal flow rate and a decrease in postvoid residual urine volume were also observed. None of the patients experienced clinical progression. Subjective improvement in urinary function was observed in 25 out of these 32 (78.1%) patients and overall satisfaction was high for silodosin treatment (Table 3)

Table 2
Efficacy of silodosin treatment in patients who continued silodosin alone treatment (N = 32).

	Baseline	Follow-up	*P*
IPSS			
Voiding symptom score	10.6 ± 4.7	6.8 ± 4.5	< 0.001
Storage symptom score	7.8 ± 3.1	5.7 ± 2.7	< 0.001
Quality of life score	4.2 ± 1.1	3.0 ± 1.6	0.001
Total Score	18.4 ± 7.0	12.5 ± 6.4	< 0.001
OABSS			
Day-time frequency (score 0–2)	0.7 ± 0.6	0.6 ± 0.6	1.000
Night-time frequency (score 0–3)	2.0 ± 0.8	1.6 ± 0.8	0.007
Urgency (score 0–5)	2.0 ± 1.7	1.4 ± 1.5	0.042
Urge incontinence (score 0–5)	1.5 ± 1.8	1.0 ± 1.3	0.065
Uroflowmetry			
Maximal flow rate (mL/s)	10.7 ± 6.0	14.0 ± 4.5	0.001
Postvoid residual urine volume (mL)	47.5 ± 51.6	25.0 ± 26.3	< 0.001

IPSS, international prostate symptom index; OABSS, overactive bladder symptom index.

The safety profile was assessed in all patients (n = 40), except for men who were lost to follow up. Change in systemic symptoms is presented in Table 4. Aggravation of dizziness was not observed in any of the patients. Six (15.0%) patients already had the symptom of orthostatic hypotension before treatment. After silodosin treatment, two (5.0%) patients replied that the symptom had disappeared, and one (2.5%) patient replied that there was a newly developed symptom of orthostatic hypotension. Interestingly, a proportion of patients replied that symptoms of visual disturbance (n = 8, 20.0%), fatigue (n = 7, 17.5%), and dyspepsia (n = 7, 17.5%) had improved. Objective systolic and diastolic blood pressures did not change significantly (systolic blood pressure, 125.3 ± 11.6 mmHg vs. 124.6 ± 8.8 mmHg, P = 0.533; diastolic blood pressure, 75.8 ± 10.5 mmHg vs. 77.7 ± 8.2 mmHg, P = 0.070). Change or dose modification of the antihypertensive medication was not observed in any of the patients. Only 12 (30.0%) patients were sexually active. The MSHQ ejaculatory function domain score was decreased significantly in this patient group, although ejaculation bother score did not change (Table 5). The newly developed questionnaire showed that four (33.3%) patients experienced a decrease in ejaculatory volume or anejaculation (Table 6), while only one (8.3%) patient replied that the ejaculatory change caused discomfort.

Table 3
Satisfaction with silodosin treatment according to the newly developed questionnaire in patients who continued silodosin alone treatment (N = 32).

Questions	*N* (%)
Question 1. Improvement in urinary function	
Much aggravated	0 (0.0)
Aggravated	0 (0.0)
No change	7 (21.9)
Improved	24 (75.0)
Much improved	1 (3.1)
Question 6. Overall satisfaction with silodosin treatment	
Much dissatisfied	0 (0.0)
Dissatisfied	0 (0.0)
No difference	10 (31.3)
Satisfied	21 (65.6)
Much satisfied	1 (3.1)

Table 4
Change in systemic symptoms after silodosin treatment ($N = 40$).

Symptoms	Baseline	Follow-up	Improvement	Aggravation
Headache	2 (5.0)	2 (5.0)	0 (0.0)	0 (0.0)
Dizziness	3 (7.5)	3 (7.5)	0 (0.0)	0 (0.0)
Orthostatic Hypotension	6 (15.0)	5 (12.5)	2 (5.0)	1 (2.5)
Visual disturbance	12 (30.0)	4 (10.0)	8 (20.0)	0 (0.0)
Fatigue	14 (35.0)	7 (17.5)	7 (17.5)	0 (0.0)
Rhinorrhea	5 (12.5)	1 (2.5)	4 (10.0)	0 (0.0)
Cough	0 (0.0)	1 (2.5)	0 (0.0)	1 (2.5)
Nasal obstruction	3 (7.5)	3 (7.5)	1 (2.5)	1 (2.5)
Chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chest discomfort	2 (5.0)	3 (7.5)	0 (0.0)	1 (2.5)
Palpitation	7 (17.5)	4 (10.0)	3 (7.5)	0 (0.0)
Dry mouth	7 (17.5)	6 (15.0)	1 (2.5)	0 (0.0)
Nausea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vomiting	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspepsia	12 (30.0)	7 (17.5)	7 (17.5)	2 (5.0)
Anorexia	1 (2.5)	1 (2.5)	0 (0.0)	0 (0.0)
Abdominal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal Discomfort	5 (12.5)	3 (7.5)	2 (5.0)	0 (0.0)
Loose stool	6 (15.0)	2 (5.0)	4 (10.0)	0 (0.0)
Diarrhea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Itching	4 (10.0)	3 (7.5)	1 (2.5)	0 (0.0)
Edema	2 (5.0)	3 (7.5)	0 (0.0)	1 (2.5)
Tingling sensation	6 (15.0)	3 (7.5)	3 (7.5)	0 (0.0)
Decreased libido	8 (20.0)	6 (15.0)	4 (10.0)	2 (5.0)

Data are presented as *N* (%).

Table 5
Change in the MSHQ ejaculatory domain in sexually active patients ($N = 12$).

MSHQ items	Baseline	Follow-up	*P*
MSHQ 7, Anejaculation	4.1 ± 1.6	3.3 ± 1.8	0.075
MSHQ 9, Decrease in ejaculation volume	3.1 ± 1.7	2.1 ± 1.3	0.032
MSHQ 10, Decrease in ejaculatory satisfaction	2.4 ± 0.9	2.6 ± 0.9	0.399
MSHQ 5 − 11, Total Ejaculation Score	24.2 ± 7.2	20.0 ± 7.2	0.020
MSHQ 12, Ejaculation Bother Score	4.1 ± 1.0	3.8 ± 1.0	0.166

MSHQ, Male Sexual Health Questionnaire.

4. Discussion

Silodosin is a highly selective α1A adrenergic receptor antagonist, and the receptor subtype selectivity contributes to the favorable cardiovascular safety profile of silodosin. Silodosin showed a 56-fold selectivity for the α1A versus α1D subtype and a 583-fold selectivity for the α1A vs. α1B subtype.[10] The relatively low selectivity for the α1B adrenergic receptor, which is mainly involved in the regulation of blood pressure, allows silodosin to have minimal effects on the cardiovascular system.[10–12] In a randomized controlled study to evaluate the noninferiority of silodosin to tamsulosin, silodosin caused no significant change in systolic BP, diastolic BP, and heart rate from baseline; in contrast, tamsulosin produced a statistically significant decrease in systolic BP.[13] Based on this safety profile, we could assume that silodosin has advantages in LUTS patients with HTN. This observational study showed that administration of silodosin in patients who were taking antihypertensive medications was effective and safe in real practice. The incidence rate of cardiovascular adverse events (orthostatic hypotension) that required discontinuation of silodosin medication in this patient group was only 2.5%.

Alpha adrenoceptor antagonists have potentially blood pressure lowering effects because they were developed initially as antihypertensive drugs. Moreover, an alpha adrenoceptor antagonist medication with other antihypertensive medications may increase the risk of declining blood pressure. However, the development of an α1A selective alpha adrenoceptor antagonist, such as tamsulosin, diminished the concern of the blood pressure lowering effect. In the past, one randomized controlled study showed that coadministration of tamsulosin and nifedipine, enalapril, or atenolol produced no clinically significant differences in pulse rate and blood pressure, and it did not alter electrocardiographic or Holter monitoring results.[14] In addition, there was no increase in adverse events, and there was no need to adjust the dose of antihypertensives. Therefore, the authors concluded that tamsulosin had an advantage over other alpha-blocking agents used to treat patients with BPH.

Table 6
Change in ejaculatory volume and subjective feeling about ejaculatory dysfunction according to the newly developed questionnaire in sexually active men ($N = 12$).

Questions	*N* (%)
Question 3. Ejaculatory volume	
Anejaculation	1 (8.3)
Much decrease	1 (8.3)
Decrease	2 (16.7)
No change	8 (66.7)
Increase	0 (0.0)
Question 4. Physical pleasure from ejaculation	
Much decrease	1 (8.3)
Decrease	2 (16.7)
No change	9 (75.0)
Increase	0 (0.0)
Much increase	0 (0.0)
Question 5. Subjective feeling about ejaculatory change	
No change	5 (41.7)
More comfortable	0 (0.0)
Does not matter	5 (41.7)
Tolerable	1 (8.3)
Discomfort	1 (8.3)

After the safety profile of tamsulosin was well documented, there were few studies on alpha adrenoceptor antagonists and blood pressure, but one recent study thoroughly evaluated the effect of alpha-blocker add on treatment on blood pressure in symptomatic BPH with or without concomitant HTN.[15] In that study, patients were assigned to four groups based on HTN and antihypertensive medication, and four alpha adrenoceptor antagonists including tamsulosin, alfuzosin, doxazosin, and terazosin were administered. As a result, normotensive groups, irrespective of antihypertensive medication, showed no significant BP changes from baseline after an alpha adrenoceptor antagonist medication, but hypertensive groups showed significant reductions in systolic and diastolic BP after doxazosin medication. In that study, dizziness or postural hypotension that required discontinuation or change of the current alpha adrenoceptor antagonist medication was observed in 4.1%, 5.9%, 10.7%, and 9.0% of patients after treatment with tamsulosin 0.2 mg, alfuzosin 10 mg, doxazosin 4 mg, and terazosin 2 mg, respectively.[15]

Orthostatic hypotension is one of the major adverse events after the use of alpha adrenoceptor antagonists. The prevalence of orthostatic hypotension increased exponentially with age, and it was consistently higher in males.[16] In community-based studies, the prevalence of orthostatic hypotension is approximately 5% in middle-aged adults.[17–19] In community dwellers older than 65 years, the prevalence of orthostatic hypotension is as high as 16.2%, and it increases exponentially with age, affecting most commonly men.[16,20,21] The burden of orthostatic hypotension also increases dramatically among the elderly in nursing homes and geriatric wards, affecting up to 54% and 68% of patients, respectively.[22,23] Orthostatic hypotension is caused by multiple factors. Being one of the common causes of acute orthostatic hypotension, prescribed medications including tricyclic antidepressants, α1 adrenoceptor antagonists, antiparkinsonian drugs, and antihypertensives such as diuretics, sympatholytics, and vasodilators can induce or exacerbate orthostatic hypotension.[24–26]

In our study, 15.0% of patients already had orthostatic hypotension before silodosin treatment. After silodosin medication, 12.5% of patients had orthostatic hypotension, but most of them had orthostatic hypotension before treatment. The incidence of newly developed orthostatic hypotension that required discontinuation of silodosin was only 2.5%. One of the remarkable findings of this study was that silodosin add on treatment in all patients who already had orthostatic hypotension did not aggravate the symptom, but rather it improved the symptom in two patients. It is difficult to explain this improvement; however, improvement in the general condition after silodosin treatment could be one of the reasons. In addition, the trend of improvement in symptoms including visual disturbance, fatigue, and dyspepsia could be interpreted as improvement in the general condition after silodosin treatment.

Despite cardiovascular safety, ejaculatory dysfunction is the major adverse event associated with silodosin treatment. In contrast to low incidence of reduced ejaculatory volume after treatment with tamsulosin (2.6%) and naftopidil (2.4%), anejaculation developed in 24.4% of patients after silodosin treatment.[27] However, the clinical significance of ejaculatory dysfunction is decreased in elderly patients because erectile dysfunction increases and ejaculation frequency decreases with age. In a European phase IV clinical study of silodosin, ejaculatory failure was the most common treatment-emergent adverse event; however, the incidence decreased to 7.3% in patients aged $\geq$ 75 years, compared to an incidence of 19.6% in men aged < 75 years.[28]

Another interesting finding of this study was that ejaculatory dysfunction that required discontinuation or change of medication occurred only in one (2.5%) patient. Decrease or absence of ejaculatory volume was not infrequent (33.3%) in sexually active men, which was similar to other studies.[27] However, the proportion of sexually active men among elderly patients taking antihypertensive medications was as low as 30%. Moreover, most of the patients did not consider ejaculatory change as a bothersome symptom. It was previously reported that further improvement of LUTS in patients who developed ejaculatory disorder might contribute to the low rate of bothersomeness of ejaculatory change.[29]

This study had several limitations. Most importantly, the study design using observation without randomization or a control and the small number of participants were the major limitations of this study. In addition, more objective measurement of orthostatic hypotension such as blood pressure in three positions was not obtained. Subjective reply to questions was used for evaluating systemic symptoms. Decrease or absence of ejaculatory volume was also evaluated based on the patient's answers. However, we think this study is meaningful because it is the first study to report the real practice data on silodosin treatment in patients taking antihypertensive medications.

In conclusion, silodosin was an effective and safe drug for treatment of LUTS in patients who were taking antihypertensive medications. Among the study participants, 15.0% of men had orthostatic hypotension, and silodosin treatment did not aggravate the symptom. Only 2.5% of the patients discontinued medication because of orthostatic hypotension. Although ejaculatory dysfunction was not a rare adverse event, only 2.5% of the patients discontinued medication due to ejaculatory change because of low sexual activity and low rate of bothersomeness of the symptoms in this study population. Silodosin could be considered as the treatment of choice for management of LUTS in elderly men who are taking antihypertensive drugs.

Conflicts of interest

The authors declare no conflicts of interest.

Appendix I. Questionnaire for assessing satisfaction with medication for benign prostatic hyperplasia

1. How much do you think the urinary symptoms have improved after medication for benign prostatic hyperplasia?

① Much aggravated ② Aggravated ③ No change ④ Improved ⑤ Much improved

2. In the last 3 months, did you perform any sexual activity, including masturbation, intercourse, oral sex, or any other type of sex?

① Yes ② No (go to question 6)

3. Is there any change in the amount of ejaculatory fluid after taking benign prostatic hyperplasia medication?

① Absence of ejaculatory fluid ② Much decreased ③ Decreased ④ No change ⑤ Increased

4. Is there any change in physical pleasure during ejaculation after taking benign prostatic hyperplasia medication?

① Much decreased ② Decreased ③ No change ④ Increased ⑤ Much increased

5. If you have experienced a decrease in the ejaculatory fluid, what do you think about it?

① Ejaculatory fluid has not reduced.

② I feel more comfortable because of decrease of absence of ejaculatory fluid.

③ I think it does not matter that the ejaculatory fluid has decreased.

④ Although the decrease in the ejaculatory fluid is not satisfactory, it does not matter because the urinary symptom has improved.

⑤ I want to discontinue or change benign prostatic hyperplasia medication because the decrease in the ejaculatory fluid causes discomfort.

6. Are you satisfied with your medication for benign prostatic hyperplasia?

① Much dissatisfied ② Dissatisfied ③ A little satisfied ④ Satisfied ⑤ Much satisfied

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