Safety and Efficacy of a Prolonged-Release Formulation of Alfuzosin 10 mg Once Daily in Patients with Lower Urinary Tract Symptoms Suggestive of Benign Prostatic Hyperplasia

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Objective: *Assess safety and efficacy of 10-mg prolonged-release alfuzosin (Xatral® XL) in benign prostatic hyperplasia (BPH) patients with lower urinary tract symptoms (LUTS).*
Material and Method: *A multicenter observational study looking at safety by adverse events (AEs) incidence, efficacy by changes in International Prostate Symptom Score (I-PSS), quality of life index (QOL), sexual function using Danish Prostate Symptom Score (DAN-PSS sex), and flow rates. Patients were allocated to receive alfuzosin (Xatral XL) 10 mg once daily tablet along with a meal for 6 months. Patients were assessed at 3 months and 6 months.*
Results: *In 118 males, 22% had AEs (most common was dizziness). Ten patients discontinued the treatment. Of those patients, five had serious AEs, which only one was related to the study. At month 6, there were improvements from baseline in mean I-PSS (-9.3, $p < 0.001$), in QOL index (-2.96, $p < 0.001$), in symptom (-0.72, $p < 0.05$) and bothersome (-1.13, $p < 0.01$) subscores on DAN-PSS sex, and in mean flow rate (0.92, $p < 0.01$). Approximately 74% patients improved within two weeks. There was one case of Acute urinary retention (AUR), which none required surgery.*
Conclusion: *A 10-mg prolonged-release alfuzosin safely and rapidly relieves LUTS and maintains improvement. It also improves BPH-associated sexual dysfunction.*

Keywords: *Adrenergic alpha-antagonists, Prostatic hyperplasia, Safety, Urinary retention, Urologic diseases*

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Benign prostatic hyperplasia (BPH) is a common condition among older men globally. It is estimated that nearly half of BPH patients will develop moderate to severe lower urinary tract symptoms (LUTS)[1]. These urinary symptoms strongly interfere with the normal activities of patients and reduce their quality of life (QOL)[2].

BPH is a progressive disease, which may lead to unfavorable outcomes such as acute urinary retention (AUR). Overall, it is estimated that a 60-year-old man who survives a further 20 years has a 23% probability of experiencing an episode of AUR[1].

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Hence, it is necessary to address the symptoms of BPH before they worsen or lead to complications.

There are a number of treatment options for BPH. These include watchful waiting, medical therapy, and various surgical procedures. Recently, an important change in the management of BPH has been observed. While surgery remains an imperative indication in the case of BPH complications (recurrent AUR, renal failure, bladder stones, and recurrent urinary tract infections [UTIs]), the number of prostatectomies is declining worldwide[3,4]. Medical treatment has become a much more common option in patients with bothersome urinary symptoms.

The most commonly used monotherapy for LUTS is alpha-1 adrenoreceptor antagonist as it acts rapidly and provides greater symptomatic relief than 5-a-reductase inhibitors[5]. AUR results from a high degree of sympathetic stimulation, such as the use of a- adrenoreceptor agonist drugs, over-distension of the bladder due to excessive fluid intake, deferred voiding, or alcohol intake, etc[6]. In these cases, medical management with α-1 adrenoceptor antagonist drugs such as alfuzosin relieves bladder outflow obstruction by relaxing smooth muscle fibers located in the prostate and its capsule, the proximal urethra, and the bladder base, and provides symptomatic relief from AUR[7-9].

Many double-blind, placebo-controlled studies have shown that alfuzosin immediate-release (2.5 mg TID) and sustained-release (5 mg BID) formulations are effective in improving urinary symptoms and maximum flow rates with minimal cardiovascular and sexual adverse effects[10-20].

A prolonged-release formulation for once daily administration (alfuzosin hydrochloride 10 mg OD-Xatral® XL) is found to be bioequivalent to both immediate- and sustained-release formulations and was intended to improve patient compliance even more by offering once a day dosage. This new formulation of alfuzosin has been shown to be effective in alleviating LUTS, and is associated with a low incidence of AUR and BPH surgery. Overall safety was satisfactory, even in elderly patients and those receiving antihypertensive treatments[21]. However, most studies on alfuzosin treatment compared the drug with either a placebo or another drug of the same class and were conducted in a controlled population[21-25]. These studies do not reflect the real-life scenario when alfuzosin is used under daily practice conditions in an uncontrolled population of patients with BPH. In addition, despite being approved for use in Thailand since April 2001, there is a lack of data about its use in the Thai population.

This 6-month study was undertaken to assess, under daily practice conditions, the safety and efficacy of alfuzosin 10 mg OD (Xatral XL) and to evaluate its effect on the occurrence of AUR and the need for prostatic surgery in an unselected population having LUTS suggestive of BPH.

Material and Method

Study design

A 6-month open labeled, multi-center, observational study was conducted at eight urology centers in Thailand. The present study protocol was approved by the central institutional review board or ethics committee of each participating site. The present study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki. Written informed consent was obtained from all patients enrolled in the present study.

Ambulatory males suffering from LUTS suggestive of BPH with varying degrees of storage symptoms (day-time frequency, nocturia, and urgency) and voiding symptoms (difficulty in initiating micturition, impaired quality of the stream, feeling of incomplete voiding, and interruption of the urine stream) were enrolled in the present study. Patients were excluded from the present study if they had mandatory need for BPH surgery due to BPH complications (acute/chronic renal obstruction, bladder stone, or recurrent UTI, etc), previously not improved by alpha-1 blocker treatment at an adequate dose, symptoms satisfactorily controlled by other BPH medication, history of postural hypotension or syncope, hepatic insufficiency, unstable angina pectoris, neuropathic bladder, history of previous surgery for BPH, hypersensitivity to alfuzosin, combination with other alpha-1 blockers, or severe concomitant conditions threatening life.

Screening examination was done at day 0 (D0) and patients who met inclusion and exclusion criteria were enrolled into the present study. At D0, PSA (Prostate Specific antigen) was measured. In cases of patients having higher PSA than normal range, prostate size was measured by transrectal ultrasonography. PSA values were again measured at the end of the present study. Patients were allocated to receive alfuzosin (Xatral XL) 10 mg once daily tablet along with a meal for 6 months and were instructed to swallow the tablets whole (without chewing or crushing). Patients were assessed at 3 months (M3) and 6 months (M6).

Study parameters

Safety parameters:

Safety was assessed by capturing the incidence of adverse events (AEs) through spontaneous reports or observed by the investigator during follow-up visits. AEs were classified according to the WHO adverse reaction terminology 1998 version[26]. Routine blood examination and biochemistry evaluations were done at D0 before enrollment into the present study and at the end of the treatment period. Cardiovascular safety was assessed by vital signs (blood pressure and heart rate) measured at each visit.

Primary efficacy parameters:

An assessment of LUTS severity was done at D0, M3, and M6 by using the International Prostate Symptom Score (I-PSS). I-PSS is a validated eight-item scale that assesses the severity of incomplete emptying, urinary frequency, intermittency, urgency, weak stream, and nocturia. The first seven items have an ordered categorical response that can be scored 0-5, with an overall score of 0-35. The severity of symptoms was classified as none (I-PSS 0) or symptomatic: mild (I-PSS < 7), moderate (8-19) or severe (> 20)[22]. The eighth question assessed QOL, with responses scored from 0 (delighted) to 6 (terrible). BPH progression events (AUR and need for BPH-related surgery) were recorded (Fig. 1).

Secondary efficacy parameters:

Sexual function was assessed by the Danish Prostate Symptom Score sexual function questionnaire (DAN-PSS sex). This questionnaire, which corresponded to the last three questions of the DAN-PSS questionnaire validated in 1995 by B.J. Hansen, assessed erectile capacity, ejaculation, and discomfort during ejaculation (Fig. 2). Each question was divided into two parts, part A assessed the severity of symptoms (rated 0 to 3), and part B assessed the bothersomeness of symptoms (rated 0 to 3). For each question, a weighted score was obtained by multiplying the symptom score with the bothersome score.

In addition to subjective parameters (I-PSS and DAN-PSS sex), the various uroflowmetry parameters (maximum flow rate [mL/sec]), and mean flow rate [mL/sec]) were assessed at D0, M3, and M6. All uroflowmetry readings were carried out using a correctly calibrated Urodyn 1000® uroflowmeter (Dantec Electronics Limited, Bristol, UK).

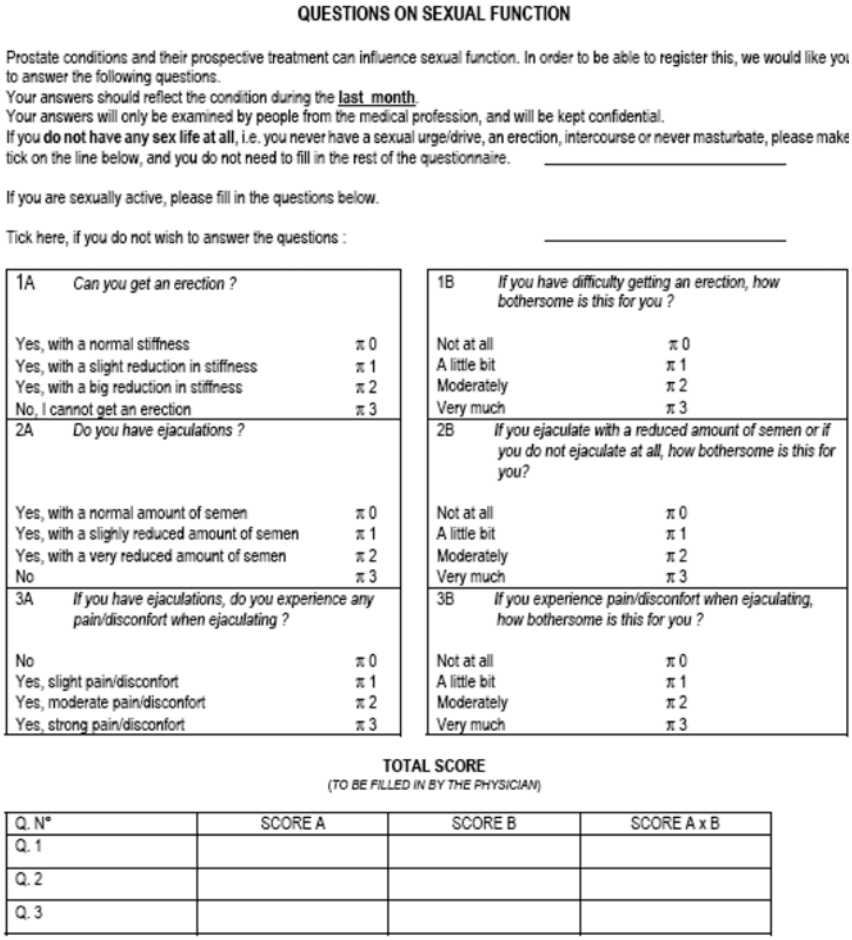
INTERNATIONAL PROSTATE SYMPTOM SCORE (I-PSS)

	Never	About 1 time in 5	About 1 time in 3	About 1 time in 2	About 2 times in 3	Almost always	
1. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating ?	0	1	2	3	4	5	
2. Over the past month, how often have you had to urinate again less than two hours after you finished urinating ?	0	1	2	3	4	5	
3. Over the past month, how often have you found you stopped and started again several times when you urinated ?	0	1	2	3	4	5	
4. Over the past month, how often have you found it difficult to hold back urinating after you have felt the need ?	0	1	2	3	4	5	
5. Over the past month, how often have you noticed a reduction in the strength and force of your urinary stream ?	0	1	2	3	4	5	
6. Over the past month, how often have you had to push or strain to begin urination ?	0	1	2	3	4	5	
	None	1 time	2 times	3 times	4 times	5 or more times	
7. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning ?	0	1	2	3	4	5	
					Total I-PSS Score S =		

QUALITY OF LIFE DUE TO URINARY SYMPTOMS

1. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that ?	Delighted	Pleased	Mostly satisfied	Mixed about equally satisfied and dissatisfied	Mostly dissatisfied	Unhappy	Terrible
	0	1	2	3	4	5	6
					Quality of Life assessment index L =		

Fig. 1 I–PSS scale



QUESTIONS ON SEXUAL FUNCTION

Prostate conditions and their prospective treatment can influence sexual function. In order to be able to register this, we would like you to answer the following questions.
Your answers should reflect the condition during the **last month**.
Your answers will only be examined by people from the medical profession, and will be kept confidential.
If you **do not have any sex life at all**, i.e. you never have a sexual urge/drive, an erection, intercourse or never masturbate, please make tick on the line below, and you do not need to fill in the rest of the questionnaire. _____

If you are sexually active, please fill in the questions below.

Tick here, if you do not wish to answer the questions : _____

1A	*Can you get an erection ?*	1B	*If you have difficulty getting an erection, how bothersome is this for you ?*
Yes, with a normal stiffness	π 0	Not at all	π 0
Yes, with a slight reduction in stiffness	π 1	A little bit	π 1
Yes, with a big reduction in stiffness	π 2	Moderately	π 2
No, I cannot get an erection	π 3	Very much	π 3
2A	*Do you have ejaculations ?*	2B	*If you ejaculate with a reduced amount of semen or if you do not ejaculate at all, how bothersome is this for you?*
Yes, with a normal amount of semen	π 0	Not at all	π 0
Yes, with a slighly reduced amount of semen	π 1	A little bit	π 1
Yes, with a very reduced amount of semen	π 2	Moderately	π 2
No	π 3	Very much	π 3
3A	*If you have ejaculations, do you experience any pain/disconfort when ejaculating ?*	3B	*If you experience pain/disconfort when ejaculating, how bothersome is this for you ?*
No	π 0	Not at all	π 0
Yes, slight pain/disconfort	π 1	A little bit	π 1
Yes, moderate pain/disconfort	π 2	Moderately	π 2
Yes, strong pain/disconfort	π 3	Very much	π 3

TOTAL SCORE
(TO BE FILLED IN BY THE PHYSICIAN)

Q. N°	SCORE A	SCORE B	SCORE A x B
Q. 1			
Q. 2			
Q. 3			

Fig. 2 DAN-PSS sexual function questionnaire

Statistical analysis

The data was analyzed for safety, primary efficacy, and secondary efficacy parameters for the intent-to-treat population (ITT) comprising all included patients who took at least one study drug and in whom at least one evaluation of the primary criteria was done at D0 and at a subsequent follow-up visit. Due to the rather high drop-out rate in the present study (30.5%), results were reported only at the end-point in the ITT population.

The paired Student's t-test (with level of significance alpha = 1%) was used to analyze the change in I-PSS scores from D0 to M3 and M6. The Wilcoxon signed-rank test was used to analyze the changes from D0 to M3 and M6 in the secondary efficacy parameters, *i.e.*, change in QOL, DAN-PSS sex scores, and flow rates. AEs were expressed as numbers and percentages of the total enrolled population. AUR episodes and AUR-related surgery were presented as the number of events during the treatment period.

Results

Demographic data

One hundred eighteen patients enrolled into the present study and 82 patients (69.5%) completed the present study. The patient status at the end of the present study and the reasons for study discontinuation are indicated in Table 1. The demography and clinical characteristics of the enrolled patients are shown in Table 2. The duration of BPH-related symptoms was 17.21 ± 20.70 months. The mean level of prostate-specific antigen was 4.61 ± 7.15 mg/mL. Only a few patients had a previous history of AUR (1.7%), UTI (0.9%), and hypertension (26.3%).

Table 1. Disposition of patients and reasons for discontinuation of study

Patient disposition (n = 118)	n (%)
Trial Completed	82 (69.5)
Drop-outs	36 (30.5)
Lost to Follow-up	6
Lack of Efficacy	2
Adverse Events	10
Poor Compliance	1
Patient Recovered	3
Protocol Violation	6*
Other	8

* 2 patients dropped out due to inclusion criteria violation (liver function test > 1.5 times upper limit of normal)

Table 2. Demography and clinical characteristics

Variables (n = 118)	
Baseline data (mean ± SD [range])	
Age (years)	66.24 ± 9.80 [37.67-88.50]
Weight (Kg)	67.15 ± 10.61 [42-104]
Duration of symptoms (months)	17.21 ± 20.70 [0.0-132.0]
PSA (ng/mL) (n = 92)	4.61 ± 7.15 [0.01-44.73]
History of cardiovascular pathology [n (%)]	
Treated hypertension	31 (26.3)
Ischemic heart disease	7 (5.9)
Heart failure	1 (0.9)
BPH History [n (%)]	
Urinary tract infection	1 (0.9)
Macroscopic hematuria	1 (0.9)
Prior acute urinary retention	2 (1.7)

Safety data

During the 6-month treatment, 26 patients (22%) reported one or more AEs, five patients (4.2%) experienced serious AEs (SAEs) that required hospitalization, and ten patients (8.5%) discontinued treatment due to AEs (Table 3). The main AEs were dizziness (n = 9, 7.6%), skin manifestations such as urticaria, eczema or rash (n = 3, 2.5%), muscular pain (n = 3, 2.5%), dry mouth (n = 2, 1.7%), and upper respiratory tract infection (n = 2, 1.7%). Of the five SAEs; four were UTI, liver cirrhosis, cerebral infarction, and total knee replacement. They were not related to the study drug. One SAE of dizziness was related to the study drug. Of the ten patients who discontinued treatment, five patients experienced an AE (dizziness or dry mouth or constipation or lesion of oral mucosa) that was related to the study drug. The other five patients experienced one or more AEs (UTI or cerebral infarction or nasal congestion, insomnia and rash or dizziness, and/or dry mouth), which might indeed be related to the mechanism of action of di-adrenoceptor blocker. There were no clinically significant changes in sitting systolic (3.01 ± 17.7 mm Hg), diastolic blood pressures (2.31 ± 13.53 mm Hg), or heart rate (1.75 ± 10.39 beats/min) between the baseline and 6 months.

Efficacy data

Approximately 74% of patients showed the onset of improvement within two weeks of alfuzosin treatment. The number of patients with mild, moderate, and severe LUTS and QOL scores at D0, M3, and M6 is given in Fig. 3a and 3b. The percentage of patients with mild LUTS on I-PSS increased from 5.1% at D0 to 32.6% at M3 and 46.3% at M6 and patients with severe LUTS decreased from 43.6% at D0 to 7.6% at M3 and 3.8% at M6 (Fig. 3a). Similar trend of results was observed in the change in QOL (Fig. 3b) from D0 to M3 and M6. A significant decrease in I-PSS score (from 18.25 to 8.95, -9.3, $p < 0.001$) and in QOL (from 4.5 to 1.5, -2.96, $p < 0.001$) were observed at the end of 6 months of alfuzosin treatment (Table 4).

There was a decrease in the percentage of patients with sexual symptoms and bothersome symptoms (as measured by DAN-PSS sex scores) from the baseline to M3 and end of treatment (Fig. 4a, 4b). There was statistically significant improvement in sexual function evaluated by DAN-PSS sex questionnaire for both symptomatic (mean change of -0.72 from baseline, $p < 0.05$) and bothersome (mean change of -1.13 from baseline, $p < 0.01$) subscores at M6 (Table 4). In this population, which was not obstructed (mean maximum flow rate at baseline of 14.3 mL/s), there was only a slight improvement in maximum flow rate, which was not statistically significant. However, the mean flow rate increased significantly from 6.69 mL/sec at D0 to 7.61 mL/sec at M6 ($p < 0.01$, Table 4).

There were two spontaneous episodes of AUR before D0, but no recurrences of AUR during the study period. An episode of AUR occurred in only one patient at M6, just prior to the M6 uroflowmetry. There was no AUR-related surgery during the 6-month treatment period.

Table 3. Incidence and relatedness of adverse events

Event	Incidence of adverse events (%)	
	All	Drug-related
Type of adverse event	31 (26.27)	14 (11.86)
Dizziness	9 (7.63)	7 (5.93)
Dry mouth	2 (1.69)	1 (0.85)
Constipation	1 (0.85)	1 (0.85)
Urticaria / Eczema / Rash	3 (2.54)	1 (0.85)
Upper respiratory tract infection	2 (1.69)	-
Urinary tract infection	1 (0.85)	-
Pain: muscle, low back, left scapular	3 (2.54)	1 (0.85)
Liver cirrhosis	1 (0.85)	-
Cerebral infarction	1 (0.85)	-
Lesion of oral mucosa	1 (0.85)	1 (0.85)
Urinary retention	1 (0.85)	-
Left total knee replacement	1 (0.85)	-
Nasal congestion	1 (0.85)	-
Insomnia	1 (0.85)	-
Common cold	1 (0.85)	1 (0.85)
Hypotension	1 (0.85)	-
Chest pain	1 (0.85)	1 (0.85)
Serious adverse events	5 (4.24)	1 (0.85)
Discontinued treatment	10 (8.5)	5 (4.24)

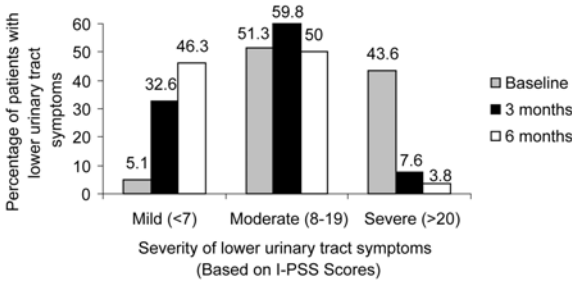


Fig. 3a Change in severity of lower urinary tract symptoms (LUTS) from baseline to 3 months and 6 months

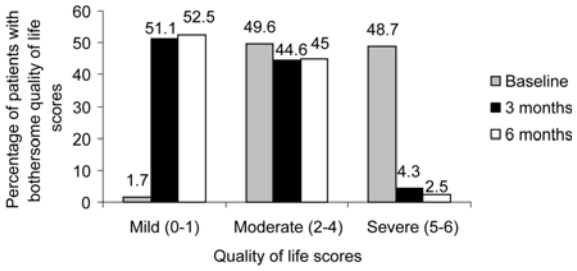


Fig. 3b Change in quality of life (QOL) from baseline to 3 months and 6 months

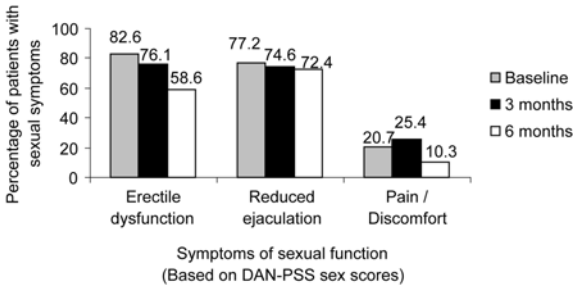


Fig. 4a Change in symptoms of sexual function from baseline to 3 months and 6 months

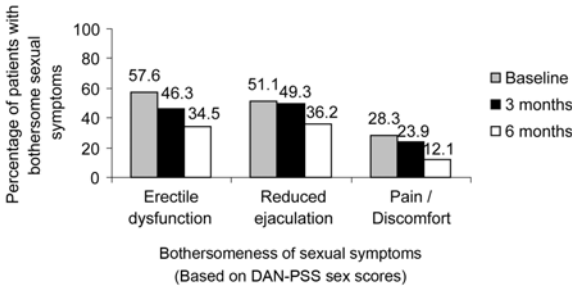


Fig. 4b Change in bothersomeness of sexual symptoms from baseline to 3 months and 6 months

Table 4. QOL assessment: change in variables between baseline and 3 months / 6 months

Variable	Mean ± SD	n	p-value
I-PSS score (D0 v/s M3)□			
D0	18.46 ± 7.09	92	0.000**
M3	10.23 ± 5.88		
I-PSS score (D0 v/s M6)□			
D0	18.25 ± 7.13	80	0.000**
M6	8.95 ± 6.14		
QOL score (D0 v/s M3)□			
D0	4.54 ± 1.21	72	0.000**
M3	1.71 ± 1.35		
QOL score (D0 v/s M6)□			
D0	4.50 ± 1.30	46	0.000**
M6	1.54 ± 1.28		
Symptom subscore of DAN-PSS sex (D0 v/s M3)□			
D0	3.02 ± 1.95	57	0.446
M3	2.84 ± 1.94		
Symptom subscore of DAN-PSS sex (D0 v/s M6)□			
D0	3.18 ± 1.92	39	0.025*
M6	2.46 ± 1.78		
Bothersome subscore of DAN-PSS sex (D0 v/s M3)□			
D0	2.05 ± 2.08	56	0.155
M3	1.66 ± 1.96		
Bothersome subscore of DAN-PSS sex (D0 v/s M6)□			
D0	2.23 ± 2.12	39	0.004**
M6	1.10 ± 1.41		
Maximum flow rate on uroflowmetry (in mL/sec) (D0 v/s M3)□			
D0	15.85 ± 14.85	69	0.220
M3	14.41 ± 7.71		
Maximum flow rate on uroflowmetry (in mL/sec) (D0 v/s M6)□			
D0	14.30 ± 5.77	46	0.076
M6	15.75 ± 6.72		
Mean flow rate on uroflowmetry (in mL/sec) (D0 v/s M3)□			
D0	7.96 ± 12.09	71	0.042
M3	6.96 ± 3.85		
Mean flow rate on uroflowmetry (in mL/sec) (D0 v/s M6)□			
D0	6.69 ± 3.02	46	0.009**
M6	7.61 ± 3.75		

□ by Paired Student's t-test, □ by Wilcoxon signed ranks test
* Significant at $p < 0.05$, ** Significant at $p < 0.001$

Discussion

An open label, single arm 'Alfuzosin XL-lower urinary tract symptoms efficacy and sexuality (ALEX-XL) study' was conducted at eight urology centers in Thailand with a primary objective to assess the safety profile of alfuzosin 10 mg once a day (Xatral XL) administered for 6 months under daily practice conditions. Patients with LUTS suggestive of BPH were selected for the present study in an uncontrolled real-life environment. The incidences of AEs, AUR episodes and the need for AUR-related surgery were recorded. The efficacy of alfuzosin was assessed by the symptomatic improvement in urinary function (I-PSS), quality of life (QOL), sexual function (DAN-PSS sex score), and by uroflowmetry.

The safety results of ALEX-XL study (AEs reported in 22% patients) are better than results from other short-term studies of alfuzosin with 40% AEs[22]. Only one patient experienced an episode of AUR at the end of 6 months, which is similar to that previously observed in an open label study[27]. No AUR-related surgery was reported. This is corroborated by a large

prospective placebo-controlled clinical trial that showed that alfuzosin 10 mg significantly reduced the need for surgery[23]. Similar to the results of other studies, the present study also reported Vasodilatory-related adverse events (10.2%) such as dizziness, dry mouth, and hypotension that might be caused by the vasodilatory mechanism of diadrenoceptor blocker[21,22]. Ten patients (8.5%) withdrew from the present study due to AEs, which is higher than the 4% observed in a similar observational study but lower than the 9.5% found in a pooled analysis[27,28]. There were five (4.2%) SAEs, although only one of them was related to the study drug. While studies such as ALFORT1 also did not have any SAE[21], a Canadian study using a similar design with 353 patients reported seven (2%) SAE[27].

The efficacy of alfuzosin treatment has been demonstrated in large double-blind, placebo-controlled and randomized clinical trials in patients with LUTS and symptomatic BPH[21-25,29,30]. Alfuzosin treatment showed an improvement in the urinary function and in the QOL of patients with LUTS. In this study, there were statistically significant improvements in I-PSS ($p < 0.001$) and QOL ($p < 0.001$) scores, and the reduction in I-PSS score (-9.3) and QOL score (-2.5) at M6 was greater compared to results from other published clinical studies[21,23-25,29]. There was also an increase in the maximum flow rate and in the mean flow rate on uroflowmetry and an improvement in voiding symptoms. This trial differed from phase III randomized studies by the fact that there was no inclusion criterion based on maximum flow rate[21,25]. Therefore, most patients were not obstructed at enrollment (mean maximum flow rate of 14.3 mL/s). This is the reason why the change in maximum flow rate was slightly lower in the present trial. Men with lower UTI are usually prone to have abnormality in sexual function, and alfuzosin has shown a positive effect on sexual function. In the present study, there was significant symptomatic improvement in erectile dysfunction, reduced ejaculation, pain, and discomfort. The DAN-PSS sex score was significantly increased in both symptoms ($p < 0.05$) and the bothersome subscore ($p < 0.01$). No AEs were reported related to sexual function. These results are also supported by observations from the ALF-ONE study of 4,857 men in a 'real life practice'[31].

Conclusion

Under daily practice conditions, the prolonged-release 10 mg once daily formulation of alfuzosin (Xatral XL) can be used safely relieve lower urinary tract symptoms and maintain improvement. Results also suggest that it may improve quality of life and sexual function in patients with benign prostatic hyperplasia.

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ความปลอดภัยและประสิทธิภาพของยาอัลฟูโซซินขนาด 10 มิลลิกรัม ชนิดการออกฤทธิ์เนิ่นนานในผู้ป่วยที่มีอาการทางเดินปัสสาวะส่วนล่างผิดปกติจากต่อมลูกหมากโต

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การศึกษาชนิดสังเกตติดตามในหลายสถาบัน เพื่อประเมินความปลอดภัยและประสิทธิภาพของยาอัลฟูโซซิน (Xatral® XL)ขนาด 10 มิลลิกรัม ชนิดออกฤทธิ์เนิ่นนานในผู้ป่วยต่อมลูกหมากโตที่มีอาการผิดปกติของทางเดินปัสสาวะส่วนล่าง ประเมินความปลอดภัยของยาโดยดูจากอุบัติการณ์อาการไม่พึงประสงค์ ประเมินประสิทธิภาพจากการเปลี่ยนแปลงของ International Prostate Symptom Score (I-PSS) ดัชนีคุณภาพชีวิต สมรรถภาพทางเพศโดยใช้ Danish Prostate Symptom Score (DAN-PSS sex) และอัตราไหลของปัสสาวะ การศึกษาทำในชายไทย 118 ราย 22% เกิดอาการไม่พึงประสงค์ อาการมึนงงเป็นอาการที่พบบ่อยสุด, 1 ใน 5 อาการไม่พึงประสงค์ชนิดร้ายแรงเกี่ยวข้องกับยาที่ศึกษา, ผู้ป่วย 10 รายหยุดรับยาเนื่องจากอาการไม่พึงประสงค์ พบอาการทางเดินปัสสาวะอุดกั้นเฉียบพลัน 1 รายซึ่งไม่ต้องใช้การรักษาทางศัลยกรรม

การติดตามที่ 6 เดือน พบค่าเฉลี่ยคะแนน I-PSS (-9.3, $p < 0.001$), ดัชนีคุณภาพชีวิต (-2.96, $p < 0.001$), คะแนนสมรรถภาพทางเพศ DAN-PSS ทางด้านอาการ (-0.72, $p < 0.05$), ด้านการรบกวน (-1.13, $p < 0.01$) ตลอดจนอัตราไหลของปัสสาวะ (0.92, $p < 0.01$) เปลี่ยนแปลงในทางดีขึ้น ประมาณ 74% อาการดีขึ้นภายใน 2 สัปดาห์

การศึกษานี้แสดงให้เห็นว่า ยาอัลฟูโซซิน (Xatral® XL) ขนาด 10 มิลลิกรัม ชนิดออกฤทธิ์เนิ่นนานปลอดภัยและช่วยบรรเทาอาการผิดปกติของทางเดินปัสสาวะส่วนล่างได้เร็วและดีขึ้นต่อเนื่อง นอกจากนี้ยังช่วยให้สมรรถภาพทางเพศที่เกี่ยวเนื่องกับภาวะต่อมลูกหมากโตดีขึ้นด้วย