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A Comparative Study on the Safety and Efficacy of Tamsulosin and Alfuzosin in the Management of Symptomatic Benign Prostatic Hyperplasia: a Randomized Controlled Clinical Trial

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This randomized, double-blind, parallel-design trial compared the efficacy and safety of tamsulosin and alfuzosin in 76 men with symptomatic benign prostatic hyperplasia. Patients were randomized to receive 0.2 mg tamsulosin once daily orally (n = 40) or 10 mg alfuzosin once daily orally (n = 36), and changes in the International Prostate Symptom Score (IPSS), maximal urinary flow rate (Q_{max}) and the Danish prostatic symptom sexual function score and morbidity rates were compared after 8 weeks of treatment. There was a mean overall decrease in the IPSS, with no significant difference between the treatment groups. There was an overall increase in the Q_{max}, which again was similar in the two groups. There was no significant change in the sexual function scores in either group. The incidence of adverse events was similar for tamsulosin (25%) and alfuzosin (19.4%) therapy. In conclusion, both treatment regimens similarly improved the IPSS and Q_{max}, did not alter sexual function and were well tolerated.

KEY WORDS: Tamsulosin; Alfuzosin, Lower urinary tract symptoms; Benign prostatic hyperplasia; International Prostate Symptom Score; Urinary flow rate; Danish prostatic symptom sexual function score

Introduction

Benign prostatic hyperplasia (BPH) is one of the most common diseases prompting medical consultation among elderly men. Its prevalence increases with age; by 80 years, almost 90% of men have symptoms attributable to prostatic obstruction.

One of the primary treatment options for symptomatic BPH is the use of α-adrenergic blockers. These agents antagonize the effect of noradrenaline on the α_1-adrenoceptors in the bladder neck, prostatic urethra and the prostate, resulting in the relaxation of prostatic smooth muscle and a reduction in the dynamic component of bladder outlet

obstruction. At least three types of α_1-adrenoceptors have been described; the α_{1a}-receptor appears to be the subtype mainly responsible for mediating prostatic and bladder smooth-muscle tone.

In the Philippines, currently available α-blockers include terazosin, alfuzosin and tamsulosin. Unlike alfuzosin and terazosin, tamsulosin possesses a high α_{1a}-receptor affinity and, because of this 'prostate selectivity', has the theoretical advantage of improving urinary symptoms and flow with fewer adverse effects.[1] A systematic review by Wilt *et al.*[2] assessing the effects of tamsulosin in the treatment of lower urinary tract symptoms suggestive of BPH showed its effectiveness was similar to that of other α-antagonists, with a slight increase in efficacy at higher doses. Long-term non-comparative studies have shown that the improvements in efficacy parameters observed during short-term treatment with tamsulosin were maintained for up to 6 years.[3,4]

In contrast, data from two clinical studies[5,6] have shown that 10 mg alfuzosin once daily was effective at controlling the symptoms associated with BPH over a 3-month period, but that a higher dosage of 15 mg alfuzosin once daily did not provide any additional benefit in terms of efficacy compared with the 10 mg dose. The clinical benefits of 10 mg alfuzosin were maintained for up to 12 months in a 3-month double-blind study followed by a 9-month non-blinded extension phase.[7] This dose of alfuzosin was well tolerated during both short- and long-term treatment.

Only one randomized controlled trial has been published that compared tamsulosin and alfuzosin.[8] This study, using 0.4 mg tamsulosin once daily and 2.5 mg alfuzosin three times daily, showed a similar magnitude of improvement in terms of symptom score and urinary flow rates between the two α-blockers. Tamsulosin had no statistically significant effect on blood pressure, but alfuzosin induced a considerable reduction in both standing and supine blood pressure compared with baseline.

An unpublished randomized trial on tamsulosin and alfuzosin has been reported on the US Food and Drug Administration website.[9] This study was a four-arm trial comparing two doses of alfuzosin (10 mg and 15 mg), 0.4 mg tamsulosin and placebo. Although statistical analysis to compare the results of 10 mg and 15 mg alfuzosin with tamsulosin was not available, the data from this report show similar reductions in symptom score between the three active treatment groups and a modest advantage for tamsulosin in achieving a greater increase in the flow rate after 3 months. A higher adverse event rate of dizziness was reported for alfuzosin, particularly with the 15 mg dose, while a slightly higher rate of impotence was reported for tamsulosin. Alfuzosin 10 mg and tamsulosin had equally low incidences of ejaculation failure. Twice as many patients on 15 mg alfuzosin than on tamsulosin were withdrawn from the study due to adverse events.

Although 0.4 mg tamsulosin is widely used in the USA and European countries, the standard government-approved dosage in the Philippines and other Asian countries is 0.2 mg once daily. The efficacy and tolerability of 0.2 mg tamsulosin in symptomatic BPH were demonstrated in a double-blind, placebo-controlled study in 244 Japanese patients,[10] in a 6-week non-blinded study in 505 Chinese patients[11] and in a 1-year non-blinded long-term study in 211 Korean patients.[12] In studies comparing tamsulosin with 2 mg terazosin[13] or 5 mg finasteride,[13] 0.2 mg tamsulosin had a comparable or better efficacy and tolerability profile.

It should be noted that only the 10 mg dose of alfuzosin is currently available; the 2.5 mg and the 5 mg formulations are being phased out worldwide.

The present study was conducted to contribute to the evidence base on the efficacy and safety of tamsulosin, particularly in comparison with alfuzosin, using formulations available in the Philippines and at doses commonly used in clinical practice.

Patients and methods

PATIENTS

All adult male patients presenting with difficulty in urination and lower urinary tract symptoms at the out-patient clinic of the Division of Urology, University of the Philippines Philippine General Hospital, Manila, Philippines (a tertiary government medical centre), were screened for eligibility to the study.

The inclusion criteria for the study were:

(i) Adult males aged 40 years or over presenting with voiding difficulty;
(ii) A clinical diagnosis of BPH;
(iii) Able to read and comprehend English or Tagalog;
(iv) An International Prostate Symptom Score (IPSS) of at least 13;
(v) A maximal urinary flow rate (Q_{max}) between 4 ml/s and 15 ml/s after two uroflowmetry determinations with voided urine volumes of at least 120 ml using a Bonito urodynamic system (Laborie Medical Technologies, Ontario, Canada).

Exclusion criteria included:

(i) Suspicion of, or proven, prostatic malignancy;
(ii) Urinary retention, defined as a post-void residual volume of at least 100 ml as measured on a bladder scan (BladderScan™, Diagnostic Ultrasound, Bothell, WA, USA);
(iii) An indwelling Foley catheter;
(iv) A history of prostatectomy during the 3 months prior to presentation;
(v) Active, untreated, urinary tract infection;
(vi) Significant, untreated or uncontrolled medical disease such as diabetes, hypertension, renal failure, hepatic dysfunction, cardiac failure or senile dementia;
(vii) Intake of any medication for the treatment of BPH (α-blockers, 5α-reductase inhibitors, plant extracts) in the preceding 2 weeks;
(viii) Intake of α-blockers (e.g. doxazosin, terazosin, prazosin), α/β-blockers (e.g. labetalol), 5α-reductase inhibitors, cholinergic agents, anticholinergics, antispasmodics for any other reason.

The protocol for this trial was reviewed and approved by the Ethics Review Board of the Research Implementation and Dissemination Office (RIDO) of the College of Medicine of the University of the Philippines. The trial was conducted in accordance with the Good Clinical Practice guidelines and was monitored by the RIDO. All the patients who participated in this trial were given full information on the purpose, procedures, advantages and disadvantages, and other matters associated with the conduct of the trial. Written informed consent was obtained from all the study participants.

BASELINE ASSESSMENTS

Baseline assessments included a review of the patient's medical history and intake of medication, a physical examination including a digital rectal examination, the IPSS and Danish prostatic symptom sexual function score (DAN-PSS) questionnaires, uroflowmetry, and post-void residual volume determination by bladder scan. The IPSS questionnaire used was a previously validated Filipino translation of the original. The

DAN-PSS sexual scoring questionnaire used was a non-validated Filipino translation. Both questionnaires were self-administered, although aid and guidance by a research assistant was given when requested.

TREATMENT SCHEDULE

Patients underwent a 1-week run-in period during which they were given a packet of medication each morning and evening, both of which contained vitamin C. The patients were not told what these packets contained.

After the run-in period, patients were randomized to receive either tamsulosin or alfuzosin. Randomization was done using a computer-generated list of random numbers, with odd numbers being allocated to the tamsulosin group and even numbers being allocated to the alfuzosin group. The randomization list was administered by personnel from the Surgical Research Unit (SRU) who were not involved with the trial, and treatment allocation was performed via a telephone request to the SRU from the attending urologist. The patient was not informed of the treatment group to which he was allocated.

During the active treatment period, each patient received a packet of morning medication and a packet of evening medication. In the tamsulosin group, the morning packet contained 16 – 18 capsules of 0.2 mg tamsulosin (one capsule to be taken after breakfast), and the evening packet contained 16 – 18 tablets of vitamin C (one tablet to be taken after dinner). In the alfuzosin group, the morning packet contained 16 – 18 tablets of vitamin C (one tablet to be taken after breakfast), and the evening packet contained 16 – 18 tablets of 10 mg alfuzosin (one tablet to be taken after dinner). The patients were instructed on how to take the medications and were required to return the packets containing the unconsumed medications on the next visit. A research assistant dispensed all the trial drugs.

FOLLOW-UP

All patients were followed up every 2 weeks for a total of 8 weeks of active treatment. During this period, patients were seen by an urologist who assessed the progress of treatment according to standard clinical practice. In addition, the IPSS and DAN-PSS sexual function questionnaires were completed and the occurrence of adverse events was recorded at each visit. Uroflowmetry and post-void residual volume measurements were performed 4 and 8 weeks after the initiation of active treatment. The attending urologist was blinded to the treatment allocation and was not allowed to see the medications taken by the patient, or to ask the patient to describe his study drugs.

Compliance was determined by a research assistant on the basis of the number of tablets returned on each visit; poor compliance was defined as consumption of less than 80% of the expected number of tablets.

OUTCOMES

The primary outcome for the study was the difference in the IPSS between the tamsulosin and alfuzosin groups at the end of 8 weeks' treatment. Other outcomes studied were the mean change in the IPSS, the Q_{max} value, the mean change in Q_{max} value, the DAN-PSS and the incidence of adverse events.

DATA ANALYSIS

On the assumption that the standard deviation of ± 6 is achieved in the IPSS of either group, a study sample size of 70 patients (at least 35 in each arm) was calculated to have 80% power with a 95% confidence interval of detecting a 5-point difference in the IPSS between tamsulosin and alfuzosin at the end of treatment.

Trial data were entered into a database using SPSS software version 11.0 (SPSS Inc., Chicago, IL, USA). The mean IPSS, mean

Q_{max}, mean DAN-PSS sexual score, and the mean percentage change in the IPSS, Q_{max} and DAN-PSS were compared between the two groups at each visit using the Student's *t*-test; a *P*-value < 0.05 was considered to be statistically significant. Analysis was performed on an intention-to-treat basis, and a last-outcome-carried-forward method was used for patients who were lost to follow-up and for those who withdrew from the trial.

Results

A total of 89 patients were screened in the period from June 2003 to April 2004 for possible inclusion into the study. Twelve were ineligible because of clinical suspicion of prostate malignancy (n = 3) or significant urinary retention (n = 9). One patient was already enrolled in another clinical trial on bronchodilators and was therefore prevented from participating in this trial.

The remaining 76 patients were enrolled into the study: 40 in the tamsulosin group and 36 in the alfuzosin group. Three patients (two from the tamsulosin group and one from the alfuzosin group) were unable to complete all the visits: one relocated to another country after the fourth week of active treatment and two were lost to follow-up after the second week of active treatment. Attempts to contact these patients failed. Two patients withdrew from the trial because of adverse events after the first week of treatment. At the end of the study, data for all study visits were available for 71 patients (Fig. 1).

The study population had a mean (± SD) age of 62.7 ± 9.06 years (range 44 – 79 years). The baseline demographic and clinical data of the patients in the two treatment groups were similar (Table 1).

INTERNATIONAL PROSTATE SYMPTOM SCORE AND MAXIMAL URINARY FLOW RATE

During the treatment period, there was progressive improvement in the mean IPSS of both groups at successive visits (Fig. 2). There was no significant difference between the mean IPSS of the two groups at any time

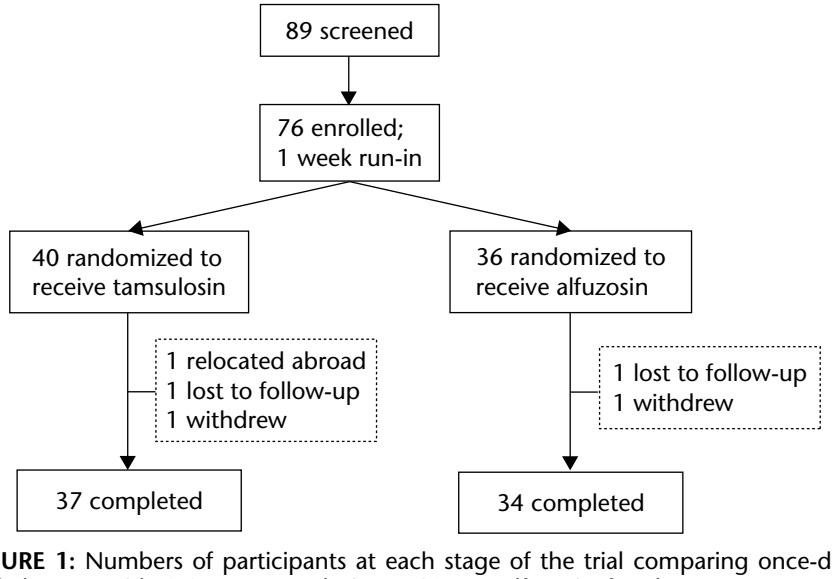

FIGURE 1: Numbers of participants at each stage of the trial comparing once-daily oral therapy with 0.2 mg tamsulosin or 10 mg alfuzosin for the management of symptomatic benign prostatic hyperplasia

TABLE 1:
Demographic and baseline clinical characteristics of 76 patients with symptomatic benign prostatic hyperplasia receiving either 0.2 mg tamsulosin or 10 mg alfuzosin, orally

	Tamsulosin group (n = 40)	Alfuzosin group (n = 36)	P-value
Age (years)	63.15 ± 9.42	62.19 ± 8.76	NS
IPSS total			
Total	21.63 ± 5.27	22.58 ± 5.54	NS
Retention	3.48 ± 1.09	3.61 ± 0.93	NS
Frequency	3.23 ± 1.14	3.28 ± 1.16	NS
Intermittency	3.35 ± 1.35	3.31 ± 1.14	NS
Urgency	2.93 ± 1.33	3.30 ± 1.25	NS
Weak stream	3.03 ± 1.14	3.25 ± 1.18	NS
Straining	2.48 ± 1.30	2.78 ± 1.25	NS
Nocturia	3.20 ± 1.14	2.83 ± 1.06	NS
Q_{max} (ml/s)	9.36 ± 2.72	9.10 ± 2.42	NS
Post-void residual volume (ml)	14.90 ± 21.15	27.78 ± 64.55	NS
DAN-PSS sexual function score			
1a (erection)	1.27 ± 1.06	1.08 ± 1.00	NS
1b (erection, bother)	0.88 ± 1.04	1.31 ± 1.19	NS
2a (amount of ejaculate)	1.50 ± 0.93	1.17 ± 0.94	NS
2b (amount of ejaculate, bother)	0.88 ± 1.07	0.97 ± 1.08	NS
3a (painful/difficult ejaculation)	0.55 ± 0.90	0.58 ± 0.84	NS
3b (painful/difficult ejaculation, bother)	0.70 ± 1.02	0.81 ± 1.06	NS

Values are mean ± SD.
IPSS, International Prostate Symptom Score; Q_{max}, maximal urinary flow rate; DAN-PSS, Danish Prostatic Symptom Sexual Function Score.

point (Table 2). Compared with the baseline IPSS, both groups showed significant improvement at each visit (Table 3). At the end of the 8-week treatment period, there was a mean (± SD) overall decrease in the IPSS of 5.97 ± 5.7 for the whole study population. There was no significant difference in the mean decrease in the IPSS between the treatment groups.

There was progressive improvement in the Q_{max} of patients during the treatment period (Fig. 3), with no difference in the mean Q_{max} of the two treatment groups at 4 and 8 weeks (Table 4). There was an overall increase in the mean (± SD) Q_{max} of 1.36 ± 2.27 ml/s at the end of 8 weeks. At 4 weeks, only the tamsulosin group showed a significant improvement in Q_{max} compared with the baseline ($P < 0.05$), but by 8 weeks both groups showed a significant

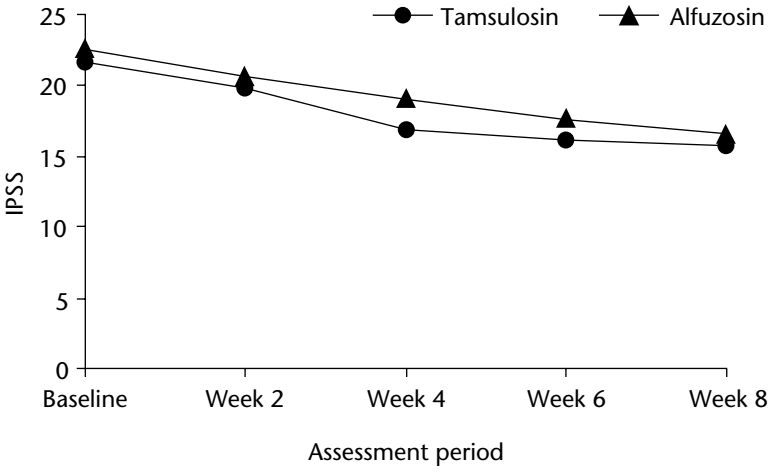

FIGURE 2: Change in the mean International Prostate Symptom Score (IPSS) at each study visit in 76 patients with symptomatic benign prostatic hyperplasia receiving either 0.2 mg tamsulosin or 10 mg alfuzosin, orally

TABLE 2:
International Prostate Symptom Score at each study visit in 76 patients with symptomatic benign prostatic hyperplasia receiving either 0.2 mg tamsulosin or 10 mg alfuzosin, orally

Time of visit	Tamsulosin group (n = 40)	Alfuzosin group (n = 36)	P-value
Baseline	21.63 ± 5.27	22.58 ± 5.54	NS
Week 2	19.78 ± 4.99	20.56 ± 5.27	NS
Week 4	16.83 ± 6.53	19.06 ± 5.77	NS
Week 6	16.15 ± 5.74	17.61 ± 5.59	NS
Week 8	15.73 ± 5.67	16.53 ± 6.16	NS

Values are mean ± SD.

improvement in Q_{max}, which was comparable between the two groups (Table 5).

DANISH PROSTATIC SYMPTOM SEXUAL FUNCTION SCORE

During the treatment period, there was no significant difference in the mean scores for nearly all the questions on the DAN-PSS sexual function questionnaire, or for the corresponding mean bother scores for the two treatment groups at any of the visits (Table 6). The exception was a significantly higher (worse) mean bother score for question 1b in the alfuzosin group (1.19 ± 1.12) compared with the tamsulosin group (0.70 ± 0.0992) ($P < 0.05$). There were no significant changes in the mean scores compared with baseline for all parameters in both groups.

ADVERSE EVENTS

There were a total of 20 adverse events

TABLE 3:
Decrease (visit minus baseline) in International Prostate Symptom Score at each study visit in 76 patients with symptomatic benign prostatic hyperplasia receiving either 0.2 mg tamsulosin or 10 mg alfuzosin, orally

	Tamsulosin group (*n* = 40)			Alfuzosin group (*n* = 36)		
Time of visit	**Mean ± SD**	**95% CI**	***P*-value[a]**	**Mean ± SD**	**95% CI**	***P*-value[a]**
Week 2	4.30 ± 5.75	2.46 – 6.13	0.000	3.61 ± 6.27	1.49 – 5.73	0.001
Week 4	4.80 ± 6.41	2.75 – 6.85	0.000	3.53 ± 5.39	1.70 – 5.35	0.000
Week 6	5.47 ± 6.21	3.49 – 7.46	0.000	4.97 ± 4.9	3.31 – 6.63	0.000
Week 8	5.90 ± 5.45	4.16 – 7.64	0.000	6.06 ± 6.03	4.01 – 8.10	0.000

Values are mean ± SD.
CI, confidence interval.
[a]Compared with baseline.

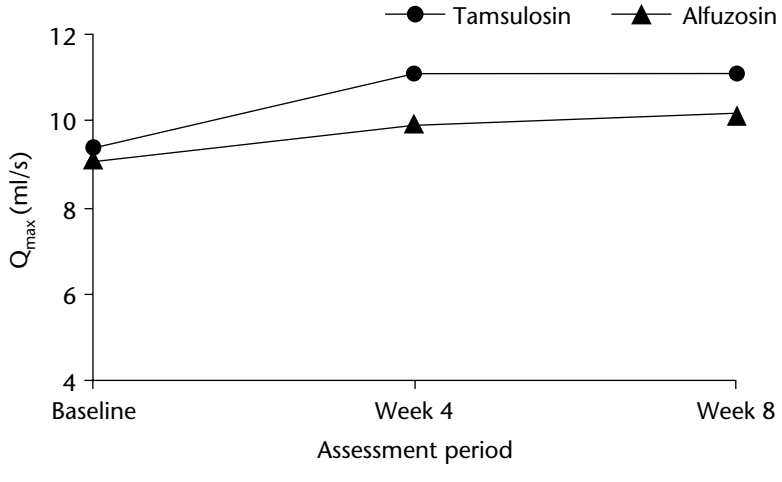

FIGURE 3: Change in mean maximal urinary flow rate (Q_{max}) at each study visit in 76 patients with symptomatic benign prostatic hyperplasia receiving either 0.2 mg tamsulosin or 10 mg alfuzosin, orally

reported by 17 patients (Table 7): 11 in the tamsulosin group (10 patients, with one patient reporting two adverse events) and nine in the alfuzosin group (seven patients, with two patients reporting two adverse events). There was no statistically significant difference in the adverse event rate between the tamsulosin group (10 out of 40; 25%) and the alfuzosin group (seven out of 36; 19.4%). All adverse events were mild and transient except for those in the two patients who withdrew from the study (one in each group), who reported moderate dizziness (tamsulosin) or severe dizziness (alfuzosin). There was no statistically significant difference in the withdrawal rate between the tamsulosin group (one out of 40; 2.5%) and the alfuzosin group (one out of 36; 2.8%).

TABLE 4:
Maximal urinary flow rate (ml/s) at each study visit in 76 patients with symptomatic benign prostatic hyperplasia receiving either 0.2 mg tamsulosin or 10 mg alfuzosin, orally

Time of visit	Tamsulosin group (*n* = 40)	Alfuzosin group (*n* = 36)	*P*-value
Baseline	9.36 ± 2.72	9.10 ± 2.42	NS
Week 4	11.07 ± 3.48	9.90 ± 3.38	NS
Week 8	11.06 ± 2.38	10.09 ± 3.76	NS

Values are mean ± SD.

TABLE 5:
Increase (visit minus baseline) in maximal urinary flow rate (ml/s) at each study visit in 76 patients with symptomatic benign prostatic hyperplasia receiving either 0.2 mg tamsulosin or 10 mg alfuzosin, orally

	Tamsulosin group (*n* = 40)			Alfuzosin group (*n* = 36)		
Time of visit	Mean ± SD	95% CI	*P*-value[a]	Mean ± SD	95% CI	*P*-value[a]
Week 4	1.71 ± 3.11	2.71 – 0.71	0.001	0.81 ± 2.94	–1.81 – 0.18	NS
Week 8	1.71 ± 2.70	2.57 – 0.84	0.000	0.98 ± 2.87	1.96 – 0.01	0.048

Values are mean ± SD.
CI, confidence interval.
[a]Compared with baseline.

Discussion

Variations in the utilization of α-adrenergic antagonists in the treatment of lower urinary tract symptoms in BPH may be due to perceived differences in efficacy and adverse effects as well as differences in cost.[2] The present study comparing the efficacy of 0.2 mg tamsulosin with 10 mg alfuzosin showed comparable improvement in terms of the IPSS and Q_{max} and a similar lack of significant impact on sexual function for both drugs. The only difference between the two drugs was the earlier significant improvement in Q_{max} seen at 4 weeks in the tamsulosin group. Both treatments were well tolerated.

The efficacy results for both α-blockers are consistent with those reported in the literature. Previous clinical studies with 0.2 mg tamsulosin administered for 4 – 24 weeks have reported mean decreases in the IPSS of 4.9 – 9.7;[11 – 14] in the present study, the improvement in the IPSS with tamsulosin was 5.90. The improvement in the IPSS of 6.06 seen in the present study with 10 mg alfuzosin was similar to that observed in previous reports[5,6] and to that reported in data on the US FDA website,[9] in which mean decreases in the IPSS of 3.6 – 6.9 were observed after alfuzosin administration for 12 weeks.

The only published randomized controlled trial directly comparing the efficacy and tolerability of tamsulosin and alfuzosin was reported by Buzelin *et al.*[8] This study utilized 0.4 mg tamsulosin once daily and 2.5 mg alfuzosin three times daily. The results were similar to those in the present

TABLE 6:
Danish Prostatic Symptom Sexual Function Score at each study visit in 76 patients with symptomatic benign prostatic hyperplasia receiving either 0.2 mg tamsulosin or 10 mg alfuzosin, orally

Question	Time of visit	Tamsulosin group (*n* = 40)	Alfuzosin group (*n* = 36)	*P*-value
1a (erection)	Baseline	1.27 ± 1.06	1.08 ± 0.10	NS
	Week 2	1.18 ± 0.96	0.97 ± 0.88	NS
	Week 4	1.18 ± 0.96	0.83 ± 0.88	NS
	Week 6	1.02 ± 0.95	1.06 ± 0.96	NS
	Week 8	1.00 ± 0.96	0.96 ± 0.92	NS
1b (erection, bother)	Baseline	0.88 ± 1.04	1.31 ± 1.19	NS
	Week 2	0.93 ± 1.19	1.39 ± 1.10	NS
	Week 4	1.05 ± 1.04	1.10 ± 1.04	NS
	Week 6	0.90 ± 0.98	0.89 ± 1.04	NS
	Week 8	0.70 ± 0.99	1.19 ± 1.12	0.05
2a (amount of ejaculate)	Baseline	1.27 ± 0.91	1.22 ± 0.83	NS
	Week 2	1.45 ± 0.96	1.36 ± 0.72	NS
	Week 4	1.55 ± 1.01	1.31 ± 0.82	NS
	Week 6	1.25 ± 1.08	1.28 ± 0.78	NS
	Week 8	1.35 ± 1.03	1.19 ± 0.82	NS
2b (amount of ejaculate, bother)	Baseline	0.88 ± 1.07	0.97 ± 1.08	NS
	Week 2	1.02 ± 1.05	0.94 ± 0.96	NS
	Week 4	0.85 ± 1.08	1.03 ± 1.08	NS
	Week 6	0.98 ± 1.03	1.19 ± 1.09	NS
	Week 8	0.85 ± 0.98	1.28 ± 1.09	NS
3a (painful/difficult ejaculation)	Baseline	0.55 ± 0.90	0.58 ± 0.84	NS
	Week 2	0.53 ± 0.75	0.44 ± 0.70	NS
	Week 4	0.48 ± 0.85	0.42 ± 0.65	NS
	Week 6	0.50 ± 0.68	0.39 ± 0.73	NS
	Week 8	0.53 ± 0.78	0.36 ± 0.76	NS
3b (painful/difficult ejaculation, bother)	Baseline	0.70 ± 1.02	0.81 ± 1.06	NS
	Week 2	0.93 ± 1.10	0.83 ± 1.08	NS
	Week 4	0.68 ± 0.97	0.78 ± 0.99	NS
	Week 6	0.80 ± 0.94	0.97 ± 1.06	NS
	Week 8	0.73 ± 1.01	0.97 ± 1.06	NS

Values are mean ± SD.

TABLE 7:
Adverse events reported by 17 of 76 patients with symptomatic benign prostatic hyperplasia receiving either 0.2 mg tamsulosin or 10 mg alfuzosin, orally

Adverse event	Tamsulosin group (*n* = 40)	Alfuzosin group (*n* = 36)
Dizziness	8	4
Weakness	0	3
Fever	0	1
Constipation	1	0
Others	2	1

study. Both treatments produced comparable improvements in Q_{max} and the total Boyarsky symptom score. Differences in the adverse reactions noted for the two treatments were not statistically significant.

The US FDA trial is the only one to compare tamsulosin with the newer 10 mg dose of alfuzosin[9] and showed a reduction in the IPSS of approximately 6 points for both groups, which is very similar to the change seen in the present study. Although no statistically significant difference in Q_{max} was demonstrated in the present study, the higher values seen with the tamsulosin group were also seen in the larger US FDA reported trial,[9] though statistical analysis of the results from the two active groups was not reported.

The impact of treatment for lower urinary tract symptoms in BPH on sexual function has recently been emphasized. Because of its selectivity for the prostate, concerns have been raised regarding the occurrence of retrograde ejaculation in patients receiving tamsulosin. The present study did not show any significant changes in sexual function nor any significant increase in the occurrence of retrograde ejaculation among patients receiving either α-blocker. This is consistent with a previous report by Hofner *et al.*[15] of a randomized controlled trial comparing tamsulosin and alfuzosin and placebo, and their impact on sexual function. They reported improved sexual function in patients receiving the α-blockers compared with placebo, but no significant difference between tamsulosin and alfuzosin.[15] With regard to retrograde ejaculation, while there were more cases reported in the tamsulosin group, the incidence was not statistically different from that in the alfuzosin group. In the US FDA reported trial,[9] there were a higher number of reported cases of impotence among those who received tamsulosin; however, it is doubtful that statistical significance would be reached as the numbers were small.

The present study reinforces the concept of a class effect for all α-antagonists, which have comparable efficacy in improving symptom scores and flow rates and similar tolerability among patients with symptomatic BPH. In addition, the impact of these medications on sexual function seems to follow the same pattern, with no one type showing either significant advantages or disadvantages over another. The present study, however, is limited in terms of showing any statistically significant difference in sexual function scores or adverse event rates, due to its relatively small sample size.

In conclusion, this randomized controlled trial demonstrated that 0.2 mg tamsulosin once daily and 10 mg alfuzosin once daily

both improved the IPSS and Q_{max} to a similar extent among patients with symptomatic BPH. Both treatments did not alter sexual function, and both were well tolerated.

Conflicts of interest

This study was supported by Yamanouchi Pharmaceutical Co., Ltd.

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