ORIGINAL RESEARCH

An open-label, prospective interventional study of the tolerability and efficacy of 0.4 mg oral tamsulosin oral controlled absorption system in men with lower urinary tract symptoms associated with benign prostatic hyperplasia who are unsatisfied with treatment with 0.2 mg tamsulosin

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Purpose: The aim of this study was to investigate the efficacy and tolerability of switching from 0.2 mg tamsulosin to 0.4 mg tamsulosin oral controlled absorption system (OCAS) over a 12-week period in Taiwanese men with lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).

Patients and methods: Taiwanese male patients who were dissatisfied with treatment with 0.2 mg tamsulosin were enrolled in this clinical study and switched to 0.4 mg tamsulosin OCAS. Efficacy was assessed over a 12-week period by an International Prostate Symptom Score (IPSS) questionnaire and analysis of urinary flow by uroflowmetry.

Results: A statistically significant improvement was observed in total IPSS scores from baseline (14.94±7.41, moderate) to 12 weeks (7.36±5.77, mild) in 81 patients who were switched from 0.2 to 0.4 mg tamsulosin OCAS ($P<0.001$). The IPSS subscores for storage, voiding, nocturia, and quality of life (QOL) were also significantly improved over the 12-week period. Uroflowmetry analysis demonstrated significantly increased maximum flow rate, average flow rate, and mean voided volume from baseline to the end of the 12-week period. The 0.4 mg tamsulosin OCAS dose was well tolerated, with only mild dizziness (five patients) and headache (two patients) as the most frequent adverse events. No clinically significant reduction was observed in blood pressure or vital signs.

Conclusion: Treatment with 0.4 mg tamsulosin OCAS in Taiwanese men with LUTS associated with BPH who were dissatisfied with 0.2 mg tamsulosin significantly improved IPSS scores, urinary flow, and QOL and was well tolerated, suggesting that this should be the recommended dose offered to Taiwanese male patients.

Keywords: prostate, neoplasms, α1-adrenergic receptor, LUTS, outcomes

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Introduction

Benign prostatic hyperplasia (BPH) is an age-related condition resulting from smooth muscle and epithelial cell proliferation in the prostate gland.[1] Older adult males typically experience BPH,[2] and this may cause lower urinary tract symptoms (LUTS) through direct bladder outlet obstruction and increased smooth muscle tone in the transition zone of the prostate.[3] The main LUTS associated with BPH are voiding, storage, and

postmicturition symptoms, which may be caused by a pro-truded prostate or detrusor underactivity.[4,5]

A population-based study of LUTS associated with BPH in the USA showed that 13% of men between 40 and 49 years had moderate-to-severe LUTS, whereas 28% of men >70 years had moderate-to-severe LUTS.[6] The aim of treatment for LUTS associated with BPH is to reduce symptoms of prostatic enlargement and complications associated with BPH/LUTS and thus improve the quality of life (QOL).

The American Urological Association (AUA) guidelines recommend that α1-adrenoceptor antagonists should be used as a treatment option for patients with LUTS associated with BPH and that 5α-reductase inhibitor or combination therapy is used for men with prostatic enlargement.[7] The relaxation of smooth muscle in the bladder neck and prostate by α1-adrenergic blockade results in an improvement in urinary flow rate and a reduction in symptoms of BPH. Due to the wide distribution of α-receptors in the peripheral vasculature, several nonselective α-adrenoreceptors antagonists have been associated with cardiovascular adverse effects.[8]

Tamsulosin is a super selective α1-adrenergic receptor antagonist that decreases smooth muscle tone in the prostate, urethra, and bladder neck, thereby reducing urinary flow resistance. Tamsulosin has comparable efficacy and better tolerability than other α1-adrenergic receptor antagonists in the treatment of LUTS associated with BPH.[9] The oral controlled absorption system (OCAS) of tamsulosin contributes to tolerability by controlling release >24 hours from a nonionic gel matrix, thus maintaining a steady serum concentration over a longer period.

In the USA and European countries, patients with LUTS associated with BPH are most often dosed with 0.4 mg tamsulosin.[7] In contrast, 0.2 mg tamsulosin is routinely prescribed by physicians in Taiwan who consider this to be the optimal tolerable dose. However, patients receiving 0.2 mg tamsulosin may become dissatisfied with the effectiveness of this dose. In the present study, we present the first data from a clinical study investigating the tolerability and efficacy of 0.4 mg tamsulosin OCAS in Taiwanese male patients who were dissatisfied with the efficacy of the 0.2 mg tamsulosin dose that they were receiving previously.

Patients and methods
Study design
This was a Phase IV, prospective, single-center, open-label single-arm study (study number: HAURO-1201-TW, study identifier: NCT02180789 at ClinicalTrials.gov) initiated

(date of first enrollment) on February 6, 2014 and completed (date of last evaluation) on January 23, 2015. It was conducted >3 months and included screening (Week 1, Visit 1), baseline (Week 0, Visit 2), and assessments at 4, 8, and 12 weeks (Visits 3–5) of the treatment period. The alpha blockers have an onset of action within 3–5 days;[10] therefore, the patients were evaluated by these intervals. This study was conducted in accordance with the clinical study protocol, Good Clinical Practice, International Conference on Harmonisation guidelines, applicable regulations and guidelines governing clinical study conduct, and the ethical principles of the Declaration of Helsinki. The protocol was approved by an Independent Ethics Committee – Institutional Review Board of Chang Gung Medical Foundation, and all subjects provided written informed consent.

Study participants
The patients enrolled were male, aged ≥45 years, diagnosed with LUTS-associated BPH, taking oral 0.2 mg tamsulosin for at least 4 weeks, dissatisfied with their current treatment (defined by patient's answer to investigator question "Are you satisfied with your current treatment?" prior to study enrollment), and had an International Prostate Symptom Score – Quality of Life score of ≥3. Key exclusion criteria included prostatectomy up to 1 year prior to this study, complications such as neurogenic bladder dysfunction, bladder neck sclerosis, urethral stricture, prostatic cancer, cystolithiasis, severe vesical diverticulum, urinary tract infection, and others, which might have caused voiding dysfunction, clinically significant conditions such as severe hepatic dysfunction, renal dysfunction, cardiovascular disorders, orthostatic hypotension, senile dementia, or others that made the patients unsuitable for the trial, and participation in any other investigational drug study presently or within 3 months prior to this study. Tamsulosin 0.4 mg OCAS was given to patients on an empty stomach. Other concomitant medications that may affect voiding function were discontinued. Transrectal ultrasound was done in 97% of the men, but the prostate volume was not included in this study.

Study assessment
Primary endpoint
Efficacy was determined by assessing the primary endpoint, which was changed from baseline of total IPSS. This consists of seven questions related to urinary symptoms that provided a subjective measure of urinary status; it was scored from 0 (asymptomatic) to 5 (highly symptomatic), resulting in a

maximum score of 35. Total IPSS values were categorized as mildly (Scores 0–7), moderately (Scores 8–19), and severely (Scores 20–35) symptomatic.[11] Questionnaires were completed by patients at each visit, and the QOL scores added to the total score.

Secondary endpoints

Uroflowmetry parameters were measured at each visit using a DANTEC Urodyn 1000 Urine Analysis and Flow Meter (MedPro, Elmont, NY, USA). Postvoid residual volume (milliliter) was assessed by ultrasound bladder scan. A visual analog scale (VAS) was used to evaluate patients' feelings of satisfaction by marking a 100 mm line on a cartoon-style facial expression chart that assessed satisfaction, ranging from 0 as "unsatisfactory" to 100 as "satisfied". This is a particularly useful tool in busy clinics with elderly patients. IPSS storage scores, voiding scores, and nocturia criteria were also included as secondary endpoints.

Safety was assessed by summarizing the incidence of adverse events (AEs), clinical laboratory tests, vital signs, and treatment-emergent adverse events (TEAEs) summarized by MedDRA system organ class and preferred terms.

Statistical analysis

Patients in the full analysis set (FAS) and safety analysis set (SAS) were given at least one dose of study drug during treatment period. Primary and secondary efficacy endpoints were statistically analyzed on the FAS using paired t-test to assess the absolute mean change and the percent mean change of IPSS scores. Differences were considered statistically significant at $P < 0.05$. Safety analyses were based on the SAS.

Results
Demographics and baseline characteristics

A total of 100 male patients were enrolled in this study from February 2014 to January 2015, with an average age of 64.81 years, a mean weight of 68.16±9.55 kg, and an average prostate-specific antigen value of 2.95 ng/mL (Table 1). A total of 81 patients completed the study and were included in the study analysis. Of the 19 patients who did not complete the study, 11 patients refused to continue treatment, three patients had serious adverse nontreatment-related events (leukemia, hepatocellular carcinoma, and abdominal hernia), three patients had other AE (cataract, malaise, and urinary tract infection), one patient was lost to follow up, and one

Table 1 Demographics and baseline benign prostatic hyperplasia status in patients dosed with 0.4 mg tamsulosin OCAS

Variables	Statistics/status	Full analysis set (N=100)
Age (years)	n	100
	Mean ± SD	64.81±9.20
	Median (min, max)	64.50 (45.00, 99.00)
Height (cm)	n	100
	Mean ± SD	165.20±5.63
	Median (min, max)	165.00 (154.70, 179.50)
Weight (kg)	n	100
	Mean ± SD	68.16±9.55
	Median (min, max)	68.80 (45.90, 90.40)
Gender	Male	100 (100.0%)
Tobacco use	Nontobacco user	89 (89.00%)
	Extobacco user	3 (3.00%)
	Tobacco user	8 (8.00%)
Alcohol use	Nondrinker	96 (96.00%)
	Exdrinker	3 (3.00%)
	Drinker	1 (1.00%)
Duration of disease (years)	n	100
	Mean ± SD	1.95±1.89
	Median (min, max)	1.67 (0.00, 6.58)
PSA (ng/mL)	n	100
	Mean ± SD	2.95±3.11
	Median (min, max)	1.55 (0.10, 16.40)
Assessment method	Digital rectal examination	3 (3.00%)
	Transrectal ultrasonography	97 (97.00%)

Abbreviations: Max, maximum; min, minimum; n, number; OCAS, oral controlled absorption system; PSA, prostate-specific antigen.

patient was noncompliant. Demographics and baseline characteristics are detailed in Table 1.

Primary efficacy – total IPSS scores

Total IPSS questionnaire scores determined the severity of symptoms through subjective patient self-assessment. A statistically significant improvement in total IPSS scores was observed from baseline (14.94±7.41, moderate) to the last patient visit (7.36±5.77, mild) in patients who were switched from 0.2 to 0.4 mg tamsulosin OCAS ($P < 0.001$; Figure 1). The percentage of mean change in IPSS scores from baseline to 12 weeks was −42% ($P < 0.0001$).

Secondary efficacy – IPSS storage scores, voiding, nocturia, QOL, and uroflowmetry

The IPSS storage score showed a statistically significant reduction from baseline (5.57±3.51) to the last visit at Week 12 (3.42±2.65) ($P < 0.0001$; Figure 2A), indicating an improvement in storage after increasing the dosage from
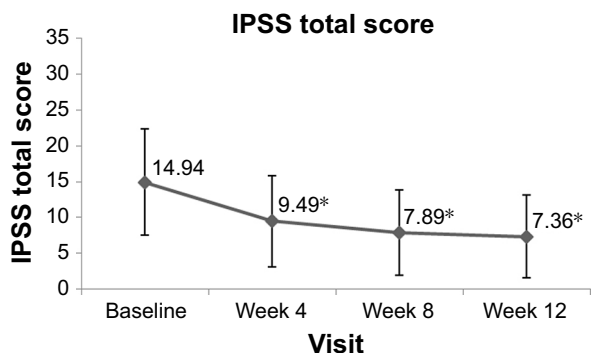
IPSS total score

Figure 1 Analysis of IPSS total scores in patients with LUTS associated with BPH who were switched from 0.2 to 0.4 mg tamsulosin OCAS.
Notes: Analysis of primary efficacy was determined by assessing change from baseline in total IPSS (scores from seven questions based on urinary symptoms) to 12 weeks after initiating treatment with 0.4 mg tamsulosin OCAS. Significant reductions in mean IPSS total scores from baseline were observed at Week 4, Week 8, and Week 12 after 0.4 mg tamsulosin OCAS treatment ($P<0.001$). *Statistically significant ($P<0.001$) change from baseline values determined by paired t-test.
Abbreviations: BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; OCAS, oral controlled absorption system.

0.2 to 0.4 mg tamsulosin OCAS. The IPSS subscore for voiding also showed a significant reduction from baseline (9.37±5.29) to Week 12 (3.94±3.91; $P<0.0001$; Figure 2B). Similarly, significant improvements were shown in nocturia

IPSS subscores, with a reduction from baseline (2.05±1.13) to last patient visit at Week 12 (1.47±1.00; Figure 2C). Patients receiving 0.4 mg tamsulosin OCAS also had significant improvements in QOL, from 3.95±0.80 at baseline to 1.99±0.87 at Week 12 (Figure 2D).

In patients who switched to 0.4 mg tamsulosin OCAS, measurement of uroflowmetry parameters showed that maximum flow rate (Qmax) increased significantly from baseline (11.73±6.04 mL/second) to Week 12 (13.06±6.18 mL/second; P=0.0037). Similarly, the average flow rate (Qave) values also improved significantly from baseline (5.3±2.87 mL/second) to Week 12 (6.21±3.19 mL/second; P=0.0003). The mean voided volume also increased significantly from 241.26±149.8 mL at baseline to 269.43±162.21 mL at the end of the study (P=0.037). Ultrasonography of the bladder showed that the mean postvoid residual volume at baseline (39.23 mL) was not significantly different from the mean postvoid residual volumes measured at Week 12 (43.4 mL; P=0.5486).

The VAS score analysis showed that the satisfaction level of patients on 0.4 mg tamsulosin OCAS had improved significantly from a mean baseline value of 39.75±10.24 to 75.93±12.22 at Week 12 ($P<0.0001$; Figure 3).
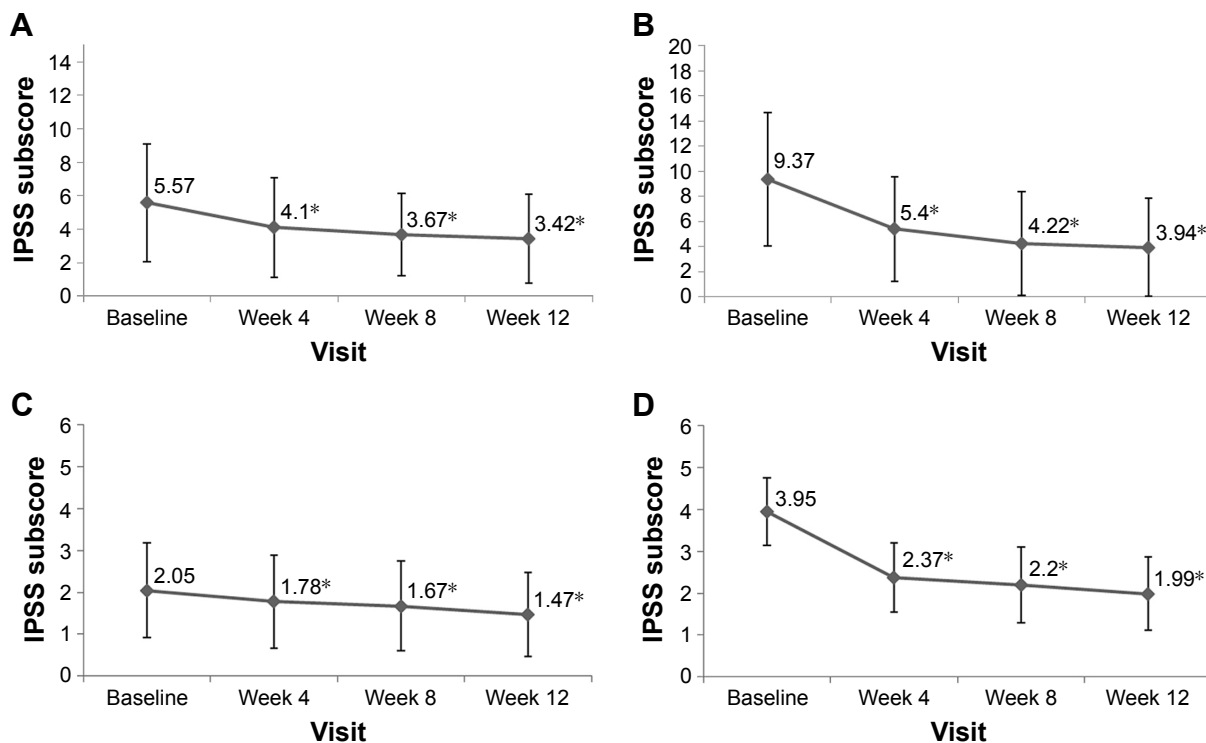

Figure 2 Analysis of urine efficacy assessments in patients with LUTS associated with BPH who were switched from 0.2 to 0.4 mg tamsulosin OCAS.
Notes: Analysis of urine efficacy was determined by assessing change from baseline in total IPSS (scores from seven questions based on urinary symptoms), up to 12 weeks after initiating treatment with 0.4 mg tamsulosin OCAS. Significant reductions in mean IPSS from baseline were observed at Week 4, Week 8, and Week 12 after 0.4 mg tamsulosin OCAS treatment for (**A**) IPSS storage, (**B**) IPSS voiding, (**C**) IPSS nocturia, and (**D**) IPSSQOL. *Statistically significant ($P<0.05$) change from baseline values determined by paired t-test.
Abbreviations: BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; IPSSQOL, IPSS – quality of life; LUTS, lower urinary tract symptoms; OCAS, oral controlled absorption system.
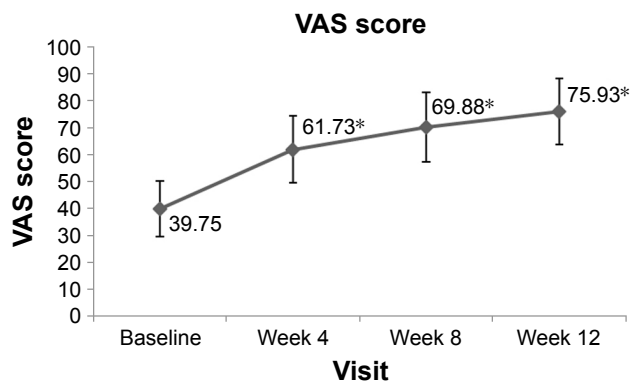
VAS score

Figure 3 Analysis of satisfaction (VAS) in patients with LUTS associated with BPH who were switched from 0.2 to 0.4 mg tamsulosin OCAS.
Notes: Analysis of patients' feeling of satisfaction was determined by using the VAS at baseline and up to 12 weeks after initiating treatment with 0.4 mg tamsulosin OCAS. Significant increases in VAS scores were observed up to Week 12 after 0.4 mg tamsulosin OCAS treatment. *Statistically significant ($P<0.05$) change from baseline values determined by paired t-test.
Abbreviations: BPH, benign prostatic hyperplasia; LUTS, lower urinary tract symptoms; OCAS, oral controlled absorption system; VAS, visual analog scale.

Safety

A total of 15 TEAEs occurring in 11 (11%) of the 100 patients were reported (Table 2). The most common TEAEs reported were mild dizziness (five patients) and mild headache (two patients),

which the investigator considered to be related to the medication. All other TEAEs were reported by ≤1 patient. Most (93.33%) of the TEAEs were mild to moderate in severity. A total of three serious adverse nontreatment-related events occurred, including one each of leukemia, hepatocellular carcinoma, and abdominal hernia, none of which were treatment related according to the investigators.

The mean systolic blood pressure (SBP) was 136.94 ± 20.40 mmHg at baseline and was reduced significantly to 133.80 ± 17.66 mmHg at last visit ($P=0.0421$). The mean diastolic blood pressure (DBP) was also reduced significantly from 81.24 ± 11.98 mmHg at baseline to 77.46 ± 10.56 mmHg at last visit ($P=0.0007$).[12,13]

The mean pulse rate at baseline was 75.72 ± 11.47 beats/minute and increased significantly to 78.89 ± 11.96 beats/minute at last visit ($P=0.0161$). Although statistically significant changes were noted in these vital sign parameters, these changes may not be clinically meaningful.

Discussion

Tamsulosin is the most commonly prescribed $\alpha1$-adrenoreceptor antagonist because it has been shown to have

Table 2 Summary of incidence of treatment-emergent adverse events and treatment-related AEs stratified by system organ class, preferred term, and grade in BPH/LUTS patients receiving 0.4 tamsulosin OCAS for 12 weeks

System organ class Preferred term	SAS (N=100)								
	Mild			Moderate			Severe		
	Event	Subject		Event	Subject		Event	Subject	
	E	n	%	E	n	%	E	n	%
Incidence of all AEs									
Eye disorders									
Cataract	0	0	0.00	1	1	1.00	0	0	0.00
Gastrointestinal disorders									
Abdominal hernia	0	0	0.00	1	1	1.00	0	0	0.00
General disorders and administration site conditions									
Malaise	0	0	0.00	1	1	1.00	0	0	0.00
Infections and infestations									
Urinary tract infection	1	1	1.00	0	0	0.00	0	0	0.00
Injury, poisoning, and procedural complications									
Fall	1	1	1.00	0	0	0.00	0	0	0.00
Neoplasms benign, malignant, and unspecified (including cysts and polyps)									
Hepatocellular carcinoma	0	0	0.00	1	1	1.00	0	0	0.00
Leukemia	0	0	0.00	0	0	0.00	1	1	1.00
Nervous system disorders									
Dizziness	5	5	5.00	0	0	0.00	0	0	0.00
Headache	2	2	2.00	0	0	0.00	0	0	0.00
Psychiatric disorders									
Anxiety	1	1	1.00	0	0	0.00	0	0	0.00
Incidence of treatment-related AEs									
General disorders and administration site conditions									
Malaise	0	0	0.00	1	1	1.00	0	0	0.00
Nervous system disorders									
Dizziness	5	5	5.00	0	0	0.00	0	0	0.00
Headache	2	2	2.00	0	0	0.00	0	0	0.00

Note: AE percentage=100%×the number of patients occurred event in the category (n)/the number of patients occurred event (N).
Abbreviations: AE, adverse event; BPH, benign prostatic hyperplasia; E, event; LUTS, lower urinary tract symptoms; n, number; OCAS, oral controlled absorption system; SAS, statistical analysis set.

beneficial effects for treating men with LUTS associated with BPH, with minimal cardiovascular adverse effects.[9,12] In the Asian population, the typical dose of tamsulosin prescribed is 0.2 mg, since Asian men have a lower body mass index compared to men from Western countries who routinely receive a starting dose of 0.4 mg. Although 0.4 mg tamsulosin OCAS was approved in Taiwan in 2011 for LUTS/BPH patients, no clinical study of this dosage has ever been conducted in the Taiwanese population. The present clinical study of 81 Taiwanese male patients with LUTS associated with BPH provides unique results demonstrating that switching from 0.2 to 0.4 mg tamsulosin OCAS for 12 weeks resulted in significantly improved IPSS total scores, QOL, storage, voiding, and nocturia. In addition, uroflowmetry parameters (urinary flow rate and volume) improved significantly after 12 weeks of treatment, with no clinically significant increases in the incidence of AEs. These results suggest a beneficial effect of treatment with 0.4 mg tamsulosin OCAS in Taiwanese men with LUTS associated with BPH.

Several studies have investigated the efficacy and tolerability of dosing with 0.4 mg tamsulosin in Asian men with LUTS associated with BPH. A Japanese study evaluated patients with BPH for whom the tamsulosin dose was increased from 0.2 to 0.4 mg for 4 weeks and demonstrated significant improvements in Qmax and residual volume but no improvements in QOL or total IPSS scores.[13] In another study, Korean men with LUTS associated with BPH switched from 0.2 to 0.4 mg tamsulosin showed significant improvements in IPSS, QOL, and Qmax from baseline to week 16.[14] In a study of 51 Thai men with LUTS associated with BPH, 0.4 mg tamsulosin OCAS was given for 8 weeks, with significant improvements in total IPSS scores, voiding and storage, QOL, and nocturia, as well as sleep and uroflowmetry parameters, although some mild dizziness was reported.[15] Although 0.2 mg tamsulosin has been routinely used, results of these studies may allay the concerns of medical practitioners in Taiwan and encourage them to switch to a higher 0.4 mg dose for improved efficacy and the support of an acceptable safety and tolerability profile.

The OCAS formulation has a better cardiovascular safety profile than the modified release (MR) formulation due to its slower release and more stable serum concentration.[16] Nonetheless, the two most frequently reported AEs of tamsulosin OCAS are dizziness and abnormal ejaculation.[17,18] Dizziness is an important consideration since men with LUTS associated with BPH tend to be older adults who might be on antihypertensive medication due to underlying cardiovascular disorders, which may contribute to this

effect. Several studies have shown an increased incidence of dizziness with tamsulosin OCAS treatment. For instance, after 8 weeks of treatment with 0.4 mg OCAS, 3.3% of 61 patients reported dizziness as the most common AE.[19] However, several studies show that the incidence of dizziness increases in a dose-dependent fashion with a lower incidence at lower (0.4 mg) rather than higher tamsulosin OCAS doses (0.8 mg or 1.2 mg). A 12-week study examining 0.4, 0.8, and 1.2 mg tamsulosin OCAS in 839 men with LUTS associated with BPH showed that dizziness was the most common AE and incidence increased from the 0.4 mg dose (0.5%) to the higher doses (0.8 mg [5.8%] and 1.2 mg [4.3%]). A larger Phase IIIa study in 2,152 men with LUTS associated with BPH dose for 12 weeks also showed dizziness to be the most common AE, with a slightly higher incidence in the 0.8 mg OCAS tamsulosin dose group (2.4%), compared with the 0.4 mg OCAS (1.4%) and 0.4 mg MR (1.7%) tamsulosin groups.[19] In the present study, five of the 100 (5%) patients reported dizziness and these were considered mild treatment-associated AEs. Taken together, these results agree with the finding that 0.4 mg tamsulosin OCAS is a feasible dose for treating men with LUTS associated with BPH.

Elderly men with LUTS associated with BPH may be more susceptible to falling at night during frequent nocturia, and any increase in dizziness or orthostatic hypotension may contribute adversely to this circumstance. Results in the present study showed an overall mean reduction in blood pressure after 12 weeks, and although these reductions achieved statistical significance (P=0.0007), mean blood pressure values were still within the acceptable normal range and unlikely to be of any clinical significance, since the incidence of symptoms caused by orthostatic hypotension (dizziness and/or weakness) was minimally identified. The reduction of 3 mmHg in SBP did not reduce the cardiovascular risk or defines as orthostatic hypotension. In a meta-analysis that included 464,000 people, the authors showed that for a BP reduction of 10 mmHg systolic or 5 mmHg diastolic, there were a 22% reduction in coronary heart disease events and a 41% reduction in stroke.[20] Orthostatic hypotension is defined as a reduction of a SBP of ≥20 mmHg or a DBP of ≥10 mmHg within 3 minutes of standing or head-up tilt to an angle of at least 60°.[21] This is consistent with previous findings that orthostatic hypotension did not appear to be a clinically significant AE in other studies investigating 0.4 mg tamsulosin OCAS in men with LUTS associated with BPH.[22] Interestingly, higher incidences of orthostatic hypotension were reported in the package label of 0.4 mg tamsulosin

capsule, where at least one positive orthostatic test result was observed in 81 (16%) of 502 treatment-naive patients receiving 0.4 mg tamsulosin during two 13-week studies in the USA.[23,24] In a US study of 383,567 men aged between 40 and 85 years with BPH, severe hypotension requiring hospital admission was experienced by 2,562 patients during the first 8 weeks of treatment with tamsulosin.[22] These results suggest that physicians should focus on counseling strategies and carefully monitor blood pressure within the initial treatment period with tamsulosin. It is conceivable that the favorable safety profile of OCAS formulation and a gradual titration from 0.2 to 0.4 mg tamsulosin may help reduce orthostatic hypotension.

According to AUA guidelines, the AE profile of tamsulosin suggests that the probability of ejaculatory dysfunction is likely with increased dosage for this drug. However, in the present study, none of the 100 patients reported abnormal ejaculatory function after dosing with 0.4 mg tamsulosin OCAS. This may be due in part to the mean age (64.81±9.20 years) of the patient population and that ejaculation function was not routinely checked. The relatively lower 0.4 mg dose (compared with 0.8 mg prescribed in the EU and USA) might also help explain why abnormal ejaculatory function was not observed in our study.[25]

The limitations in this study are being a single-arm study and lack of IPSS subcategories analysis. This single-arm study was unable to show the comparison effect of treatment. An analysis to the subcategories of IPSS may give more thorough information on how the increased dosage improves patients' satisfaction.

The IPSS questionnaire is one of the most widely used tools for assessing storage and voiding symptoms. In the present study, a wide variation in baseline IPSS scores was noted, presumably because these were subjective scores obtained from patients who were dissatisfied with their previous treatment with 0.2 mg tamsulosin. Nonetheless, results of this study demonstrate statistically significant improvements in total IPSS scores and IPSS subscores for storage and voiding, as well as QOL, indicating that switching to 0.4 mg tamsulosin OCAS provides better patient outcomes. Patients on 0.4 mg tamsulosin OCAS also showed significant improvements in urinary flow after 12 weeks of treatment.

Conclusion

About 0.4 mg tamsulosin OCAS is efficacious and tolerable for Taiwanese male patients dissatisfied with their previous 0.2 mg tamsulosin treatment, providing significant improvements in LUTS associated with BPH with no additional safety concerns. Our data demonstrated significant improvements in urinary flow rates, IPSS subscores (storage, voiding, and nocturia), and patients' overall QOL and levels of satisfaction. Moreover, the safety profile of 0.4 mg tamsulosin OCAS is favorable, with only mild-to-moderate AEs. These results suggest that physicians in the Taiwanese clinical setting should consider switching patients who are dissatisfied with a 0.2 mg tamsulosin dose to the 0.4 mg tamsulosin OCAS formulation before considering other therapeutic agents.

Author contributions

The article was prepared by P-SY with the assistance/contribution of C-LC, C-PH, Y-HL, and K-HT. P-SY contributed to the analysis and interpretation of data, drafting of the article, critical revision of the article, and literature research. C-LC, C-PH, and Y-HL contributed to the acquisition of data, critical revision of the article, and clinical studies. K-HT contributed to the conception and design, acquisition of data, critical revision of the article, and clinical studies. All authors contributed toward data analysis, drafting and revising the paper and agree to be accountable for all aspects of the work.

Disclosure

C-LC, C-PH, Y-HL, and K-HT received investigator fees from Astellas Taiwan Pharma, Inc., for conducting the study. The authors report no other conflicts of interest in this work.

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