The Impact of Tamsulosin Oral Controlled Absorption System (OCAS) on Nocturia and the Quality of Sleep: Preliminary Results of a Pilot Study

Bob Djavan\textsuperscript{a,}, Shirin Milani\textsuperscript{a}, Jonathan Davies\textsuperscript{b}, John Bolodeoku\textsuperscript{b}

\textsuperscript{a}Department of Urology, University of Vienna, Währinger Gürtel 18–20, 1090 Vienna, Austria
\textsuperscript{b}Yamanouchi Europe, Egham, UK

Abstract

Objectives: This randomised, double-blind, placebo-controlled, 8-week exploratory study was designed to assess the effect of the new formulation of tamsulosin (oral controlled absorption system: OCAS) on nocturia, the hours of undisturbed sleep and quality of life in patients with LUTS/BPH.

Methods: After a two-week single-blind, placebo run-in period, older men (≥45 years) with lower urinary tract symptoms (LUTS: total International Prostate Symptom Score (I-PSS) ≥13) suggestive of benign prostatic hyperplasia (BPH: maximum flow rate 4–12 ml/s) and ≥2 nocturnal voids per night were randomised to 8 weeks of treatment with placebo or tamsulosin OCAS 0.4 mg once daily in a 1:1 ratio. The primary efficacy variable was the mean change from baseline to endpoint in mean hours of undisturbed sleep, defined as the time from falling asleep to the first awakening to void. Nocturnal voids, I-PSS nocturia sub-score and quality of life were also assessed. The relationship between improvement of nocturia and hours of undisturbed sleep, nocturia and quality of life, and hours of undisturbed sleep and quality of life were investigated. Tolerability was mainly assessed by documenting adverse events (AEs) reported by the patient.

Results: A total of 117 patients were randomised to placebo (\(N = 56\)) and tamsulosin OCAS 0.4 mg (\(N = 61\)). The mean increase in Hours of Undisturbed Sleep (HUS) from baseline was 60 minutes for placebo and 82 minutes for tamsulosin OCAS (\(p = 0.198\)). The mean decrease in number of nocturnal voids from baseline was 0.7 for placebo and 1.1 for tamsulosin OCAS (\(p = 0.099\)). The mean reduction in total I-PSS score was statistically significant different with 8.0 points for tamsulosin OCAS and 5.6 points for placebo (\(p = 0.0099\)). The decrease in I-PSS nocturia score for tamsulosin OCAS was 1.0 points and for placebo 0.7 points, this difference was stastically significant (\(p = 0.028\)). The improvement of QoL was statistically significant different between tamsulosin OCAS and placebo with a reduction in score of 2.0 and 1.3 respectively (\(p = 0.0087\)). A reduction in the number of nocturnal voids correlated with an increase in hours of undisturbed sleep (Spearman coefficient −0.63) and a reduction of I-PSS nocturia correlated with an improvement in the I-PSS QoL (Spearman coefficient 0.64). The two most frequently reported AEs were dizziness (3.3% in the tamsulosin OCAS group and 0% in placebo group) and nasopharyngitis (0% in the tamsulosin OCAS group and 3.6% in placebo group). No cases of orthostatic hypotension were reported. A total of 18 treatment-emergent adverse events were reported, 8 in the tamsulosin OCAS group and 10 in the placebo group. No patients were withdrawn due to AEs.

Conclusions: Tamsulosin OCAS 0.4 mg is efficacious in the treatment of nocturia in LUTS/BPH. An improvement in nocturia, increase of the hours of undisturbed sleep and improvement in the I-PSS QoL were observed. This exploratory study confirms the relationship between the treatment of one of the most bothersome symptoms of LUTS/BPH with tamsulosin OCAS 0.4 mg and an improvement in the hours of undisturbed sleep and QoL.

© 2004 Elsevier B.V. All rights reserved.

Keywords: Nocturia; Quality of sleep; Lower urinary tract symptoms; Benign prostatic hyperplasia; \(\alpha_1\)-adrenoceptor antagonists; Tamsulosin oral controlled absorption system
1. Introduction

Nocturia, defined by the International Continence Society (ICS) as “the complaint that the individual has to wake at night one or more times to void” [1] is a common condition among men, with the prevalence increasing with increasing age [2]. Lower urinary tract symptoms suggestive of benign prostatic obstruction (LUTS/BPH) is one of the major causes of nocturia in older men [3]. LUTS/BPH is associated with a decreased bladder capacity due to detrusor overactivity or high post-void residuals (PVR) which results in reduced voided volumes and increased micturition frequency [2,4]. Nocturia is associated with sleep disturbance and poor sleep quality [5]. An epidemiologic cross-section study among Dutch older men (≥50 years) showed that nocturia was reported as the most frequent cause for disturbed sleep maintenance (Fig. 1) [6]. The number of men reporting nocturia as a cause for disrupted sleep increased with increasing age. Several studies have also shown that the more severe the nocturia, the greater the impact on the quality of sleep as demonstrated in poorer sleep, increased disturbance of sleep maintenance and increased difficulty in falling asleep again after voiding [5]. Nocturia is considered to be a very bothersome condition. Indeed, LUTS/BPH patients report that nocturia is one of the most bothersome symptoms associated with their disease [7,8]. In an Austrian epidemiological cross-sectional study of nocturia, almost two-thirds of the men with 2 voids per night reported that their nocturia had a negative impact on their quality of life (QoL) [9]. Increased severity of nocturia was positively correlated with increased bothersomeness [9]. The sleep disruption and lack of sleep caused by nocturia is not only highly bothersome but may also seriously impair health. Poor sleep is associated with daytime fatigue, cognitive impairment, loss of energy and concentration, mood alterations and increased susceptibility to disease [5]. Nocturnal voiding is also associated with depression and an increased mortality rate [10,11]. Nocturia and its effects on sleep quality impose not only a significant burden on the patient but also on their partners and caregivers [12,13]. In the older patient, nocturia increases the risk for falls and fractures during trips to the toilet [14]. Nocturia is also a predisposing factor for premature nursing home admission [5]. In patients who have an active professional and social life, impaired sleep leads to a decline in work performance, decreased levels of activity and increased rates of sick leave [15,16]. The fatigue due to sleep deprivation further augments the risk for accidents on the road and at the workplace. Hence, the costs of nocturia and associated sleep problems are considerable both for patients and society.

As LUTS/BPH plays an important role in the aetiology of nocturia, treatment for LUTS/BPH should also effectively improve nocturia and contribute to a better QoL for the patient and his partner. Recently a new formulation of the α1-adrenoceptor (AR) antagonist tamsulosin has been developed and introduced to the market: tamsulosin oral controlled absorption system (OCAS). This was developed to improve the pharmacokinetic profile of the existing tamsulosin modified release (MR) formulation. This OCAS system provides more consistent release of tamsulosin over 24 hours, thereby providing a better efficacy/safety ratio. The OCAS technology is a controlled release system of a gel matrix type that rapidly hydrates and is maintained in this hydrated state in the colon. The gel matrix then has sufficient strength to achieve drug release in the colon where water is poorly available [17]. It is this feature of the OCAS formulation that results in more consistent delivery of tamsulosin over 24 hours [18]. In single dose studies a favourable peak trough ratio of tamsulosin plasma concentration was clearly shown. In steady state studies with tamsulosin OCAS the therapeutic plasma levels of tamsulosin were maintained over 24 hours. No direct comparative steady state studies with both the MR and OCAS formulation have been performed to date. Comparative data from steady state studies does however clearly show this favourable PK profile of tamsulosin OCAS over tamsulosin modified release (Fig. 2). A double-blind, randomised, placebo-controlled direct-comparative study indeed confirmed that tamsulosin OCAS had an improved efficacy/tolerability ratio in the treatment of LUTS/BPH compared to the tamsulosin MR formulation [19].

2. Material and methods

This study was conducted in accordance with the Declaration of Helsinki and the protocol was approved by institutional review boards and/or independent ethics committees.
2.1. Study design

The rationale for this pilot study is that nocturia, nocturnal urgency and the associated disturbances of night rest are considered the most bothersome symptoms of LUTS/BPH. This was an exploratory study to assess the effect of tamsulosin OCAS 0.4 mg once daily compared to placebo on improvement in quality of sleep, defined as the duration of the first period of undisturbed sleep, as well as the relationship between improvement of nocturia, hours of sleep and quality of life. This was a double-blind, multinational (3 countries), multi-centre (15 European centres) randomised, placebo-controlled, exploratory study with two parallel groups (tamsulosin OCAS 0.4 mg and placebo). The study comprised a 2-week single-blind placebo run-in, followed by an 8-week randomised double-blind treatment period, in patients with LUTS associated with BPH. Eligible patients were randomised to one of the two groups in a 1:1 ratio (tamsulosin OCAS 0.4 mg tablets or placebo once daily). During the 8-week treatment period, patients visited the clinic at 0, 2, 4 and 8 weeks.

It was expected that relief of the disturbance in the patient’s night rest, either by decreasing the number of nocturnal voids, or by decreasing the number of awakenings due to the feelings of urgency should have beneficial effect on the I-PSS score and the patient’s overall quality of life.

2.2. Study population (inclusion and exclusion criteria)

Men aged 45 years or older with voiding (“obstructive”) and storage (“irritative/filling”) symptoms diagnosed as LUTS/BPH with a total International Prostate Symptom Score (I-PSS) ≥13 (at the enrolment and randomisation visit), ≥2 nocturnal voids per night, and a maximum flow rate ($Q_{\text{max}}$) ≥4 ml/s and ≤12 ml/s (for a voided volume ≥120 ml) during free flow studies were suitable for enrolment into the study if they had given written informed consent. The exclusion criteria were those usually applied in LUTS/BPH clinical trials with a1-AR antagonists. These included any other urological procedures or conditions, which may cause LUTS (e.g. previous surgery to the LUT or pelvic region, neurological bladder disorders, bladder neck stenosis, stone in the bladder or urethra, recurrent urinary tract infections, bladder or prostate cancer, urethral stricture or other conditions which may affect micturition such as large bladder diverticulae). Patients with hepatic or renal insufficiency, clinically significant cardiovascular or cerebrovascular diseases within six months prior to enrolment (e.g. uncontrolled angina, myocardial infarction, heart failure (NYHA class III–IV), stroke, orthostatic hypotension or significant ventricular arrhythmias), central nervous system conditions (e.g. senile dementia, multiple sclerosis, Parkinson’s disease and psychiatric disorders) or life-threatening diseases were excluded. Patients with alcohol consumption of more than 15 units per week were excluded. Patients with a post-voiding residual volume of >250 ml by ultrasound or catheterisation in at least two assessments over the last 3 months were excluded. Patients who were taking or had taken other drugs for LUTS/BPH (i.e. 5α-reductase inhibitors within three months, and/or a1-AR antagonists and/or plant extracts within one month prior to enrolment), were hypersensitive to a1-AR antagonists or their excipients, were taking drugs which could interfere with the pharmacodynamics of tamsulosin OCAS (e.g. other a1-AR antagonists, a1-AR agonists, a/b-AR antagonists, cholinergics or anti-cholinergics) or were taking or had taken other investigational drugs within the previous three months were excluded from enrolment.

2.3. Assessment of efficacy

Efficacy of tamsulosin OCAS on quality of sleep was primarily assessed by evaluating the change from baseline to endpoint in mean hours of undisturbed sleep as defined as the time from falling asleep to the first awakening to void. To assess the mean hours of undisturbed sleep, a sleep diary, which was to be completed on three consecutive weekdays was provided to the patients at every visit for self-administration. The diary consisted of 2 sections, one to be completed before going to bed and the other to be completed after waking-up (Table 1). The mean hours of undisturbed sleep were calculated as the mean of the 3 consecutive days. Secondary efficacy variables were the change from baseline to endpoint in mean hours of sleep per night and mean number of nocturnal voids. These were also assessed by means of the sleep diary. In addition, the diary contained 2 questions: “rate how you felt today” and “how would you characterise last night’s sleep”. As secondary efficacy variables total I-PSS score and the I-PSS QoL score were also assessed [20]. In the I-PSS questionnaire the patient had to rate the frequency of seven urinary symptoms (incomplete emptying of the bladder, intermittency, weak stream, hesitancy, frequency, urgency and nocturia) on a scale from 0 to 5 with a total score range from 0 to 35. In addition, they had to indicate how they would feel if they were to spend the rest of their life with their urinary condition as it was at the time of completing the questionnaire, using the I-PSS disease-specific QoL single question to be rated from 0 to 6 (also referred to as the bother score).

Fig. 2. Tamsulosin pk profiles of tamsulosin OCAS steady state (study 617c1302) and tamsulosin modified release steady state (study YM12617).
The endpoint visit was defined as the last post-baseline assessment during double-blind treatment for which efficacy evaluations were available.

2.4. Assessment of safety/tolerability

Tolerability was assessed by asking the patient at every visit whether he had experienced any untoward medical occurrence, whether or not considered to be related to the study medication. If these occurred for the first time or worsened in intensity after the start of double-blind treatment or a relationship to study medication had arisen, they were defined as treatment-emergent adverse events (TEAEs). The intensity (mild, moderate, severe) and relationship to study medication (possibly, probably or unlikely related) were also documented. In addition, vital signs (supine and standing blood pressure and pulse rate) were measured at each visit. Physical examinations were performed at the enrolment and final visit.

2.5. Statistical methods and sample size

Changes in mean hours of undisturbed sleep per night, the mean number of nocturnal voids, the total I-PSS and I-PSS sub-scores for filling, voiding and nocturia were subjected to statistical analysis. Correlations between nocturnal voids and hours of undisturbed sleep, and I-PSS nocturia and I-PSS QoL were also performed. The study was exploratory in nature. The statistical characteristics of hours of undisturbed sleep of patients treated with tamsulosin OCAS or placebo are not yet known. Fifty randomised patients per treatment arm were considered a sufficient number of patients to explore the hours of undisturbed sleep, and numerically compare tamsulosin OCAS and placebo. Changes from baseline to endpoint in mean hours of undisturbed sleep were subjected to Analysis of Covariance (ANCOVA) including treatment as fixed factor, centre as random factor and baseline as continuous covariate. The ANCOVA was followed by calculation of point estimates and 95% confidence limits of the contrast tamsulosin OCAS 0.4 versus placebo. The point estimate was tested against 0 by means of the corresponding t-statistic at a two-sided significance level of 0.05. To check the sensitivity of the primary analysis results (the FAS population), the analysis was also performed for the Per Protocol Set (changes from baseline to visit 5).

3. Results

3.1. Demographics and other baseline characteristics

A total of 117 patients were randomised to placebo (N = 56) and tamsulosin OCAS 0.4 mg (N = 61). The demographics and other baseline characteristics are presented in Table 2. The mean age was approximately 67 years. The mean total I-PSS was around 18.5 points, the mean number of nocturnal voids calculated over three consecutive days was 2.9, the mean Qmax almost 10 ml/s and the mean prostate volume 57 ml. There were no relevant differences between the treatment groups for any of the baseline characteristics.

All but one of the randomised patients completed the study. This one patient discontinued due to non-compliance and was from the tamsulosin OCAS arm.

3.2. Efficacy results

All results are presented for the intent-to-treat (ITT) of full analysis set (FAS) population, i.e. all patients who took at least one dose of double-blind medication and provided primary efficacy data at baseline and at least 1 post-baseline visit. This means that all 117 randomised patients were analysed.

3.3. Hours of undisturbed sleep (HUS)

The mean change in total HUS (defined as time between falling asleep and first awakening to void) is shown in Fig. 3. The mean increase at endpoint with tamsulosin OCAS 0.4 mg (81 minutes, or 60%) was not statistically significantly different from that with placebo (60 minutes or 40%; difference 21 minutes; p = 0.198). The change from baseline to endpoint of total amount of sleep did not differ between the

| Table 2
<table>
<thead>
<tr>
<th>Demographics and other enrolment characteristics (safety population)</th>
<th>Mean (S.D.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>Tamsulosin OCAS 0.4 mg</td>
</tr>
<tr>
<td>SAF</td>
<td>N = 56</td>
</tr>
<tr>
<td>Age (years)</td>
<td>67.6 (7.6)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>81.2 (11.9)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>174.3 (6.3)</td>
</tr>
<tr>
<td>Total I-PSS</td>
<td>18.1 (3.5)</td>
</tr>
<tr>
<td>Qmax (ml/s)</td>
<td>9.5 (1.7)</td>
</tr>
<tr>
<td>Prostate volume (ml)</td>
<td>59.0 (38.5)</td>
</tr>
<tr>
<td>PSA (ng/ml)</td>
<td>2.51 (1.77)</td>
</tr>
</tbody>
</table>
tamsulosin OCAS and placebo groups (1, –3 minutes respectively, \( p = 0.587 \)).

3.4. Nocturnal voids

The mean decrease in nocturnal voids as measured by means of voiding diary (defined as time between falling asleep and first awakening to void) is shown in Fig. 4. The mean decrease at endpoint with tamsulosin OCAS 0.4 mg was not statistically significantly different from that with placebo (1.0 and 0.7 respectively, odds ratio 0.56; \( p = 0.099 \)).

3.5. I-PSS questionnaire

The mean change in total I-PSS from baseline to endpoint is shown in Fig. 5. The mean reduction at endpoint with tamsulosin OCAS 0.4 mg (8.0 points) was statistically significantly larger from that with placebo (5.6 points; difference 2.4; \( p = 0.0099 \)). The changes observed for the voiding and filling I-PSS sub-scores were very similar to those for the total I-PSS (Table 3). The reduction from baseline for the voiding I-PSS were 4.6 and 3.4 for tamsulosin OCAS and placebo respectively (\( p = 0.0383 \)). The reduction from baseline for the filling I-PSS were 3.2 and 2.2 for tamsulosin OCAS and placebo respectively (\( p = 0.0244 \)).

The mean change in the I-PSS nocturia domain (question 7 of the I-PSS questionnaire) from baseline to endpoint is shown in Fig. 6. The mean reduction at endpoint with tamsulosin OCAS 0.4 mg (1.1 points) was statistically significantly larger than that with placebo (0.7 points; difference 0.4; \( p = 0.028 \)).

<table>
<thead>
<tr>
<th>Table 3</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effect of treatment on the total I-PSS score, and voiding and storage I-PSS sub-scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (S.D.)</td>
</tr>
<tr>
<td>Placebo</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Total I-PSS</td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Change at endpoint</td>
</tr>
<tr>
<td>Difference vs. placebo</td>
</tr>
<tr>
<td>Voiding I-PSS</td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Change at endpoint</td>
</tr>
<tr>
<td>Difference vs. placebo</td>
</tr>
<tr>
<td>Storage I-PSS: mean (SD)</td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Change at endpoint</td>
</tr>
<tr>
<td>Difference vs. placebo</td>
</tr>
</tbody>
</table>

\( ^* p < 0.01 \).

\( ^{**} p < 0.05 \).
3.6. Improvement of the patient’s condition

The reduction in urinary symptoms was associated with an improvement in the patient’s QoL with significantly greater mean improvements in IPSS QoL with tamsulosin OCAS 0.4 mg than with placebo (Fig. 7). The mean reduction at endpoint with tamsulosin OCAS 0.4 mg was statistically significantly larger than that with placebo (2.0 and 1.3 respectively; odds ratio 2.4; \( p = 0.0087 \)).

A separate questionnaire was used to assess the level of tiredness or alertness during the day. The questionnaire used was not a validated tool and the study was used to assess the validity of this questionnaire. The mean increase at endpoint with tamsulosin OCAS 0.4 mg was not statistically significantly different from that with placebo (0.49 and 0.32 respectively; odds ratio 0.672; \( p = 0.27 \)).

3.7. Proof of concept

The treatment of LUTS/BPH with tamsulosin OCAS decreases nocturia and therefore increases the hours of undisturbed sleep, which should have a beneficial effect on the patient’s overall quality of life. To assess the validity of this concept, correlation calculations were performed between these parameters.

The correlation between the number of nocturnal void and the HUS for both placebo and tamsulosin OCAS has a Spearman coefficient for all patients of \(-0.63\). A correlation was also found between the I-PSS nocturia and I-PSS QoL domains (Spearman coefficient 0.64).

3.8. Safety results

All safety results are presented for the safety population (SAF), i.e. all patients who took at least one dose of double-blind medication and provided post-baseline safety information. All treatments were well tolerated. The percentage of patients with at least one TEAE was 12.5% in the placebo group and 8.2% in the tamsulosin OCAS group (Table 4). No patients were withdrawn from the study due to a TEAE.

4. Discussion

This report contains the preliminary results of a pilot study designed to investigate the relationship between the treatment of LUTS/BPH with tamsulosin OCAS and the increase of HUS and the effect on QoL. Previous reports have suggested that there is a clear link between decreasing the number of nocturnal voids and subsequent increase of hours of undisturbed sleep and increase in daytime energy [21]. Although such a link may be considered intuitive, studies to investigate this link between the treatment of LUTS/BPH and HUS have not been performed to date. This novel pilot study is the first of its kind to measure these effects and to test methods to establish this link.

Table 4

<table>
<thead>
<tr>
<th>Treatment-emergent AEs (i.e. MedDRA coded terms) (SAF)</th>
<th>( N ) (%) of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo Tamsulosin OCAS 0.4 mg</td>
<td></td>
</tr>
<tr>
<td>SAF ( N = 56 )</td>
<td>( N = 61 )</td>
</tr>
<tr>
<td>Total number of TEAEs</td>
<td>8</td>
</tr>
<tr>
<td>At least one TEAE(^a)</td>
<td>7 (12.5%)</td>
</tr>
<tr>
<td>Most common TEAEs</td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>2 (3.4%)</td>
</tr>
</tbody>
</table>

\(^a\) Some AEs may occur simultaneously in one patient.
The decrease in I-PSS nocturia sub-score and the statistically significant difference versus placebo for this measurement clearly show the efficacy of tamsulosin OCAS in decreasing nocturia. Equally, the I-PSS QoL shows a statistically significant improvement of QoL in patients treated with tamsulosin OCAS over placebo. Together with the total I-PSS, voiding and filling I-PSS sub-scores this reinforces the findings of previous studies that have shown that tamsulosin OCAS is efficacious in the treatment of LUTS/BPH, even when a small number of patients is used.

A clear increase was found in the HUS in the tamsulosin OCAS group. Although no statistically significant difference was found versus the placebo group, a clear correlation was found between the number of nocturnal voids, either measured by diary data or I-PSS and the HUS.

The new questionnaire introduced to assess how tired or alert the patient felt during the day did not perform as expected. The outcomes of this diary measurement certainly did not conform with the I-PSS QoL question results. This perhaps points to the fact that a more sensitive measurement tool should be used to assess the alertness of patient during the day. The N-QOL seems to be an appropriate candidate for this [22].

The effects on nocturia I-PSS score obtained by tamsulosin OCAS compare well with the results obtained in other studies [23–25]. The I-PSS however does not measure how an improvement in nocturia relates to the quality of sleep or QoL [26]. A reduction of 1 nocturnal void may be sufficient for an improvement in quality of sleep if the time the patient awakes to void is delayed by 1 or 2 hours and the patient can therefore sleep 1 or 2 hours more. In particular, an increase in the number of hours slept in the first third to first half of the night when deep sleep predominates is expected to have a positive impact on the body’s restorative function and daytime alertness and energy [27].

The impact of nocturia on HUS and QoL in this study was analysed by looking at the correlation between these parameters. These analyses clearly show the relationship between the improvement of nocturia and HUS and the improvement of nocturia. This shows that the concept investigated in this pilot study is promising and as such warrant further investigation with a sufficient number of patients.

5. Conclusions

Although the data presented here represent a preliminary analysis of this pilot study data, the outcomes confirm the efficacy of tamsulosin OCAS in the treatment of LUTS/BPH, and the treatment of nocturia in particular. Since nocturia is perceived as one of the most bothersome symptoms of LUTS/BPH this finding is indeed encouraging. Also, this pilot study clearly confirms the concept of the relationship between the reduction of nocturia in LUTS/BPH patients and the increase of hours of undisturbed sleep and QoL.

The increase in HUS shows a favourable trend for tamsulosin OCAS over placebo and should be further investigated. More appropriate measuring tools to assess the actual sleep patterns of the patients may yield better results, since self-administered diaries on night-time behaviour may contain inaccuracies. Also, the recently developed N-QOL questionnaire may provide a better insight into the patients’ sleep quality and daytime energy levels.

Clearly, further analysis of this data is needed to establish the limitations of the design of this study and to confirm or redefine the methods and tools used in this study. After such a full analysis an appropriately powered and designed study should be undertaken to confirm the findings of this study.

References

[18] Omnic OCAS SmPC.