Effect of dutasteride on the symptoms of benign prostatic hyperplasia, and patient quality of life and discomfort, in clinical practice

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OBJECTIVE

To assess the improvements in symptoms, quality of life (QoL), discomfort and satisfaction in patients with symptomatic benign prostatic hyperplasia (BPH) treated with dutasteride in clinical practice.

PATIENTS AND METHODS

In a prospective, multicentre open-label study, we evaluated the efficacy and safety in clinical practice of dutasteride, 0.5 mg/day for 24 weeks, in patients with symptomatic BPH. The primary endpoint was the proportion of patients achieving at least a 3-point decrease from baseline in the International Prostate Symptom Score (IPSS) after 24 weeks of treatment. The secondary endpoints included changes from baseline in measures of QoL (IPSS item 8 and BPH Impact Index score, BII), and patient discomfort and satisfaction (visual analogue scales, VAS) at 12 and 24 weeks.

RESULTS

Of the 366 patients assessed, 72.5% achieved at least a 3-point reduction in IPSS at 24 weeks; the IPSS decreased from 15.3 at baseline to 10.2 at 12 weeks, and to 9.1 at 24 weeks. There were significant ($P < 0.001$) decreases in all the individual IPSS items at 12 and 24 weeks, with more marked improvements in voiding symptoms than storage symptoms. There were also significant ($P < 0.001$) improvements in the BII and VAS scores for patient discomfort and satisfaction at both times.

CONCLUSIONS

Dutasteride treatment for 24 weeks significantly improved BPH symptoms, QoL and patient discomfort and satisfaction, and was well tolerated in clinical practice.

KEYWORDS

BPH, IPSS, discomfort, quality of life, BII, visual analogue scale, 5α-reductase inhibitor, dutasteride

INTRODUCTION

BPH is a common condition in ageing men, affecting over half of men in their seventh decade and 90% of men in their eight and ninth decade [1]. The condition is characterized histologically by stromal and epithelial hyperplasia [2,3], and clinically by LUTS, which are typically divided into irritative (storage) symptoms (i.e. increased frequency, nocturia and urgency) and obstructive (voiding) symptoms (i.e. incomplete emptying, weak stream, intermittency and hesitancy). Disease progression can lead to worsening of LUTS and a greater risk of acute urinary retention (AUR) and BPH-related surgery [4]. Thus, the aims of therapy for BPH are to provide symptom relief and improve the quality of life (QoL) of patients, while also reducing the risk of severe, long-term BPH-related complications.

5α-reductase inhibitors (5ARIs) specifically inhibit the conversion of testosterone into dihydrotestosterone, the primary androgen responsible for prostate growth, and reduce significantly the risk of long-term BPH-related complications [4,5]. The enzyme 5α-reductase exists in two isoforms, type 1 and type 2. Finasteride is a type 2-specific 5ARI, while dutasteride is a dual-acting 5ARI. Inhibition of both the type 1 and type 2 isoenzymes with dutasteride results in near-maximal suppression of dihydrotestosterone (>90%), which is evident within a few weeks and sustained for up to 48 months [6,7]. Large, prospective, randomized, placebo-controlled trials showed that in men with symptomatic BPH, dutasteride provides significant improvements in symptoms and peak urinary flow rate and significant reductions in prostate volume and the risk of AUR and BPH-related surgery over 4 years of treatment [8,9]. In these studies, dutasteride also had a favourable safety profile. While these clinical trials provide robust statistical evidence of the efficacy and safety of dutasteride in this setting, confirmation of the impact of dutasteride in real-life clinical practice is warranted [10]. The extent to which results from clinical trials can be generalized to clinical practice can be limited by several factors, e.g. the restrictive inclusion and exclusion criteria, close monitoring, restrictions on concomitant therapy and lack of variation in dosing commonly implemented in clinical trials. In addition, efficacy endpoints in clinical trials might not reflect measures of treatment success, as judged by patients. Treatment satisfaction has important implications for patient compliance and therefore the overall treatment success rate in clinical practice. BPH is known to cause a deterioration in QoL and increase patient discomfort [11,12], and, in recognition of the importance of patient discomfort and satisfaction, BPH guidelines now recommend that patients are involved in discussions on the choice of therapeutic approach [13–15].

In the current study we evaluated the effect of dutasteride, 0.5 mg once daily for

24 weeks, on symptoms, QoL and patient discomfort and satisfaction among men with symptomatic BPH in real-life clinical practice.

PATIENTS AND METHODS

This was a French prospective, multicentre, noncomparative study of patients receiving dutasteride, 0.5 mg once daily for 24 weeks, in French clinical practice. The efficacy and safety endpoints were assessed at screening, baseline, 12 and 24 weeks of treatment; safety data were also collected at an intermediary visit at 4 weeks. The final follow-up was at 16 weeks after the final dose. The study protocol was approved by the Ethics Committee of the Saint Louis Hospital (Paris, France) and all patients provided written, informed consent.

Patients aged ≥50 years with symptomatic BPH and a minimum prostate volume of 30 mL, estimated by a DRE, were included in the study. Patients with a history of prostate cancer, prostate surgery or AUR within 6 months before study entry, those previously treated with 5ARIs, and those who had received α-blockers, phytotherapy, drugs with anti-androgenic properties, or anabolic steroids within the 2 weeks before study entry were excluded.

The primary endpoint was the proportion of patients reporting a decrease of ≥3 points in the IPSS [16] after 24 weeks of treatment. Secondary endpoints included changes from baseline at 12 and 24 weeks in the following variables: mean IPSS (0–7, 8–19 and 20–35, representing mild, moderate and severe symptoms, respectively); mean voiding symptom (IPSS Q1, 3, 5 and 6) and storage symptom (IPSS Q2, 4 and 7) subscores; mean BPH Impact Index score (BII, graduated from 0 to 13) [17]; a visual analogue scale (VAS) on patient discomfort (graduated from 0 to 100 by patients, with higher scores indicating greater discomfort); a VAS on treatment satisfaction (graduated from 0 to 100 by patients, with higher scores indicating greater satisfaction); and any correlation between IPSS and the other variables. The cumulative distribution of patients as a function of the mean change in IPSS at 24 weeks was also evaluated. Baseline sexual function data were collected from answers to the following simple questions: 1. Are you sexually active?; 2. Now or during the last 3 months have you experienced: impotence, a decrease in libido or any ejaculation disorders? The safety profile of dutasteride was analysed during the 24-week treatment and 16-week follow-up.

Variable	Value
Mean (SD):	
Age, years	66 (8.1)
Total IPSS	15.3 (6.4)
BII score	5.1 (2.9)
VAS discomfort self-assessed by patients	48.9 (20.0)
BPH symptom duration, months	43.1 (39.4)
N (%):	
Symptom severity:	
mild (IPSS, 0–7)	48 (13)
moderate (IPSS, 8–19)	216 (59)
severe (IPSS, 20–35)	102 (28)
Previous treatments	218 (60)
α-blockers	113 (52)
phytotherapy	62 (28)
α-blockers phytotherapy	35 (16)
other	8 (4)
Sexually active within the last 3 months:	273 (75)
ED	107 (29)
Decrease in libido	110 (30)
Ejaculation disorders	60 (17)

TABLE 1 Baseline characteristics (366 patients)

The efficacy analysis included all enrolled patients who received at least one study treatment dose and for whom data on at least one of the efficacy endpoints was available. The safety analysis included all patients who received at least one study treatment dose. Estimation of the sample size, using a logistic regression method [18], was based on previous results [19,20] and the following assumptions: the probability of a patient with the mean baseline discomfort failing to achieve at least a 3-point IPSS decrease is 35%; and the odds ratio for a patient with baseline discomfort one SD above the mean failing to achieve a 3-point IPSS decrease is 1.4. This calculation showed that to achieve a significance level of 5% and power of 90%, a total of 382 patients was required.

Baseline predictive factors for at least a 3-point decrease of IPSS found to be significant in univariate regression analyses were introduced into multivariate logistic regression analyses. Two regressions were used, one with baseline IPSS as a continuous variable and one with baseline IPSS as a discrete variable. Voiding and storage symptom subscores were only included in the model with IPSS as a discrete variable.

RESULTS

In all, 400 patients were recruited at 72 centres in France between April 2003 and September 2004; of these, 399 were included in the safety analysis and 366 in the efficacy analysis. Of the 399 patients, 72 (18%) withdrew from the study; the reasons for withdrawal included adverse events (11%), consent form withdrawal (3%), lost to follow-up (<1%), protocol deviations (<1%) and other reasons (3%).

The mean patient age was 66 years and the mean baseline IPSS was 15.3, indicating moderate symptom severity (Table 1). The mean VAS for discomfort of 48.9 also confirmed the enrolment of patients who were moderately bothered by their symptoms. At baseline, 158 (43%) patients reported at least one sexual disorder (erectile dysfunction, ED; reduced libido; or ejaculation disorder), and of these patients, 13% presented with two disorders and 10% with three. At screening, more than half the patients were already receiving treatment for BPH.

After 24 weeks of treatment with dutasteride, 72.5% (95% CI, 67.3–77.2%) of patients reported at least a 3-point decrease in IPSS (Fig. 1). Results from the multivariate models indicated that the only statistically significant predictive factors for achieving at least a

FIG. 1.
The cumulative distribution of patients as a function of the mean change from baseline in IPSS after 24 weeks of dutasteride treatment.

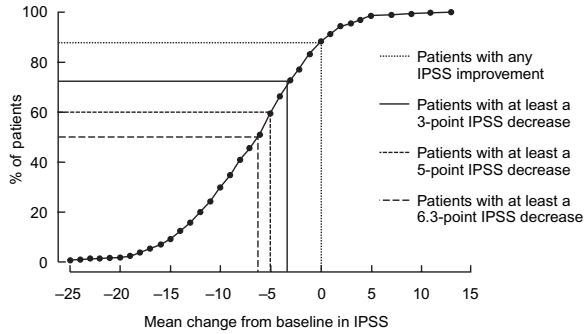
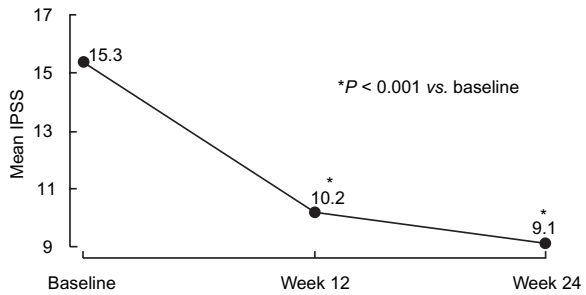


FIG. 2.
Change in the mean IPSS during treatment with dutasteride over 24 weeks.



Variable	Odds ratio (95% CI)	P
IPSS	1.27 (1.18–1.36)	<0.001
IPSS subscores		
voiding symptoms	1.40 (1.23–1.60)	<0.001
storage symptoms	1.25 (1.05–1.49]	0.011
IPSS by category:		
severe vs mild	1.16 (0.36–3.74)	0.808
moderate vs mild	0.22 (0.02–2.01)	0.179
IPSS Q8 (QoL)	1.02 (0.73–1.44)	0.766
BII score (QoL)	1.01 (0.87–1.17)	0.998
VAS discomfort score (patient assessed)	1.00 (0.98–1.03)	0.760

IPSS, IPSS Q8, BII and VAS were calculated from the model with baseline IPSS as a continuous variable, while IPSS subscores and IPSS by category were calculated from the model including IPSS as a discrete variable.

TABLE 2
The effect of baseline variables on the probability of achieving a 3-point decrease in IPSS at 24 weeks: results from multivariate analyses

3-point improvement in IPSS were baseline total IPSS and IPSS subscores for both voiding and storage symptoms (Table 2). Patients with more severe symptoms had a higher probability of having an improvement in the IPSS. The predictive value of the BII and patient-assessed VAS for discomfort was not statistically significant.

There was a significant ($P < 0.001$) decrease in the mean (SD) IPSS from 15.3 (6.4) at baseline to 10.2 (5.5) at 12 weeks and to 9.1 (5.6) at 24 weeks (Fig. 2). The mean percentage change from baseline in IPSS was −28.4% at 12 and −35.4% at 24 weeks.

At baseline, 13%, 59% and 28% of patients had mild (IPSS, 0–7), moderate (IPSS, 8–19) and severe (IPSS, ≥20) symptoms, respectively. After 24 weeks of dutasteride treatment, the severity of symptoms was reduced, with 46%, 48% and 6% reporting mild, moderate and severe symptoms, respectively. In all, 43% of patients had an

TABLE 3 The mean (SD) change from baseline in IPSS and individual IPSS items at 12 and 24 weeks

IPSS item	12 weeks	24 weeks
Q1	−0.8 (1.4)	−0.9 (1.6)
Q2	−0.8 (1.4)	−0.9 (1.4)
Q3	−0.6 (1.5)	−0.7 (1.5)
Q4	−0.7 (1.4)	−0.8 (1.5)
Q5	−1.0 (1.6)	−1.3 (1.6)
Q6	−0.7 (1.6)	−0.9 (1.6)
Q7	−0.5 (1.0)	−0.6 (0.9)
Q8	−1.4 (1.5)	−1.7 (1.6)
IPSS	−5.2 (5.7)	−6.2 (6.2)

Q1, incomplete emptying; Q2, increased frequency; Q3, intermittency; Q4, urgency; Q5, weak stream; Q6, straining; Q7, nocturia; Q8, QoL.

improvement by one category in symptom severity (from severe to moderate or from moderate to mild), 7% an improvement by two (from severe to mild) and 2% a worsening by one category (from mild to moderate or from moderate to severe). No patients had a worsening of symptom severity by two categories. The changes (Table 3) and percentage changes (Fig. 3) from baseline at 12 and 24 weeks in individual items of the IPSS questionnaire (Q1–7, voiding and storage symptoms) were all statistically significant ($P < 0.001$). Between 12 and 24 weeks there were further significant improvements in items 5 ($P < 0.001$) and 6 ($P < 0.05$). There were greater decreases from baseline in voiding symptom subscores than in storage symptom subscores at 12 (– 3.2 vs −2.0) and 24 weeks (– 3.9 vs −2.3; Fig. 4).

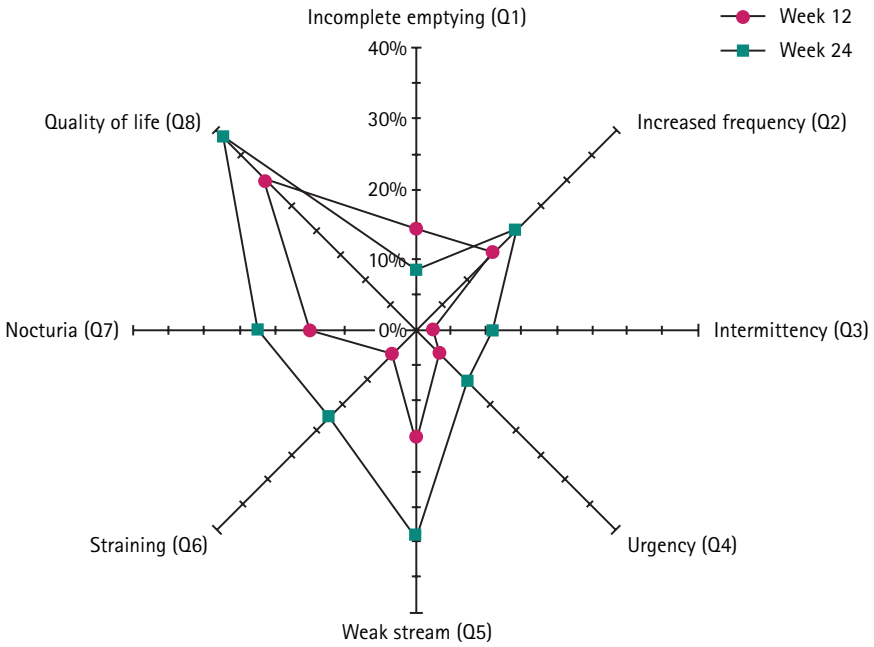
The changes (Table 3) and percentage changes (Fig. 3) from baseline at 12 and 24 weeks in the supplementary Q8 (defining patient QoL, not included in the IPSS) were all statistically significant ($P < 0.001$). The proportion of patients with a Q8 score of ≤3 points increased from 11% at baseline to 50% at 12 and to 62% at 24 weeks (Fig. 5). Between 12 and 24 weeks there were further significant improvements in item 8 ($P < 0.001$).

There were significant ($P < 0.001$) reductions from baseline in the BII score at 12 weeks, at 5.1 (2.9) vs 3.1 (2.9), and 24 weeks, at 5.1 (2.9) vs 2.8 (2.6) (Table 4). The correlation between the IPSS and BII score was statistically significant ($P < 0.001$).

The mean VAS score for discomfort decreased from 48.9 (20.0) at baseline to 31.6 (20.5) at 12 weeks and 28.6 (20.1) at 24 weeks (both $P < 0.001$; Table 4). There were also significant ($P < 0.001$) increases in VAS scores for patient satisfaction, from the baseline value of 0, at 12 and 24 weeks. The correlations between the IPSS and both VAS scores for discomfort and patient satisfaction were statistically significant ($P < 0.001$).

Overall, 157 patients (39%) had at least one adverse event during the treatment period. There were adverse events related to the study drug in 77 (19%) patients; of these, 11% were sexual disorders (7% ED, 4% decrease in libido and <1% ejaculatory disorders), 4% gastrointestinal disorders (mainly abdominal pain and diarrhoea) and 2% gynaecomastia (including mammary tension). Of the 44 patients who had sexual dysfunction during the 24-week treatment period, 10 (23%) had already reported these complaints at study entry.

FIG. 3. The mean percentage change from baseline in individual items of IPSS (Q1–8) at 12 and 24 weeks. The reductions from baseline in all IPSS items were significant (P < 0.001) at both times. There were further significant reductions from week 12 to week 24 in Q5 (P < 0.001), Q6 (P < 0.05) and Q8 (P < 0.001).



DISCUSSION

Clinical trials show that 5ARIs improve urinary symptoms and, by modifying disease progression, reduce the risk of long-term, severe BPH-related complications, e.g. AUR and surgery [4,8,9,21]. In the present study, the impact of dutasteride in real-life clinical practice was investigated. The IPSS is currently the recommended tool for assessing the severity of LUTS, and it is the BPH symptom scale most commonly implemented in international clinical trials [4,5,13,19]. In addition to the monitoring of urinary symptoms, guidelines highlight the importance of assessing the impact of BPH on the QoL and discomfort experienced by patients [4]. Indeed, it was recently reported that due to the variability in the relationship between symptom severity and the amount of bother reported by patients, symptom scores alone might not capture the real impact of symptoms in men with BPH [22]. Patient perceptions are increasingly important in clinical decision-making, and patient satisfaction has important implications for patient compliance and therefore overall treatment success rate in clinical practice. The present study showed that after 24 weeks of treatment with the dual 5ARI, dutasteride, 72.5% of patients in clinical practice had an improvement of at ≥3 points in the IPSS. In addition, there were significant improvements in QoL, patient discomfort and satisfaction, and dutasteride was well tolerated.

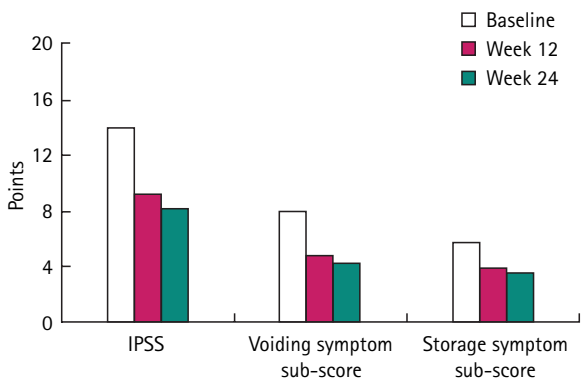


FIG. 4. The IPSS, voiding and storage symptom subscores at baseline and after 12 and 24 weeks of treatment with dutasteride.

A cumulative frequency distribution of threshold improvements is an established method for illustrating the overall change in IPSS [23]. In the present study, this analysis showed that 90% of patients treated with dutasteride for 24 weeks reported an improvement in IPSS, 60% at least a 5-point IPSS decrease and 50% at least a 6.3-point IPSS decrease.

A review of publications for the latest AUA Guidelines, which involved mainly randomized clinical trials, showed that the improvement in IPSS after 3–9 months of treatment was 4.4–6.2 points for α-blocker therapy, 3.4 points for finasteride therapy and 2.4 points for placebo [5]. In the present study in clinical practice, dutasteride therapy resulted in a 5.1-point decrease in IPSS from the third month of treatment and a 6.2-point decrease after 6 months. These improvements in IPSS are also greater than those reported in large dutasteride clinical trials (decrease of 2.6 and 3.2 points at 3 and 6 months, respectively) [8]. However, the significant decrease in each of the seven individual IPSS items and the more marked improvement in voiding symptoms than storage symptoms

FIG. 5. The distribution of patients according to the score for Q8 IPSS at baseline and after 12 and 24 weeks of treatment with dutasteride.

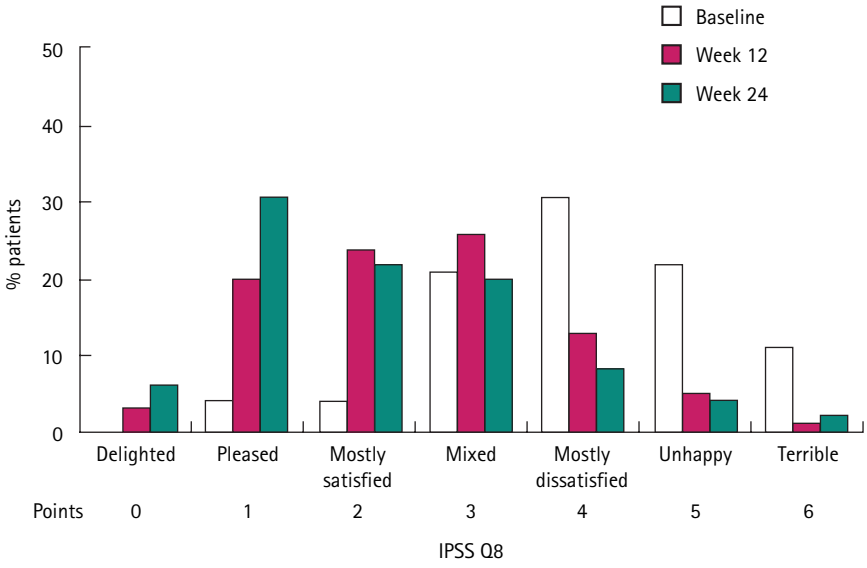


TABLE 4
Change from baseline in measures of QoL and patient discomfort at 12 and 24 weeks

Variable	Mean (95% CI) change from baseline at 12 weeks	24 weeks
IPSS Q8		
points	−1.4 (−1.6 to −1.3)	−1.7 (−1.9 to −1.6)
% change	−29.6 (−34.4 to −24.8)	−38.7 (−44.1 to −33.3)
BII score		
points	−2.0 (−2.3 to −1.7)	−2.3 (−2.6 to −2.0)
% change	−27.4 (−36.6 to −18.1)	−34.9 (−41.7 to −28.1)
VAS score for patient discomfort		
points	−17.8 (−20.2 to −15.4)	−20.6 (−23.4 to −17.9)
% change	−27.1 (−34.0 to −20.3)	−15.1 (−44.0 to 13.9)

are in agreement with the findings from dutasteride clinical trials [9]. The finding that baseline IPSS was the most powerful predictor of a decrease in symptom score is also consistent with previous reports [24].

In addition to improving symptoms, dutasteride significantly improved QoL, patient discomfort and satisfaction in clinical practice, as assessed by IPSS Q8, the BII and VAS. The decreases in BII in the present study of 2.0 and 2.3 points at 12 and 24 weeks, respectively, are greater than those for the BII reported in dutasteride clinical trials (0.4 and 0.6 after 3 and 6 months, respectively) [25]. Several patient surveys showed that sexual activity is an important measure of QoL for men with BPH [26,27], and the finding that 75% of the present men were sexually active is consistent with this. Improvements in BPH symptoms are associated with improvements in sexual function, and therefore QoL, as perceived by the patient [28]. Confirming significant improvements in patient discomfort and satisfaction during dutasteride treatment in clinical practice is of particular interest following recent reports of the significant impact of patient perceptions and patient satisfaction on treatment success [22].

The present study has limitations inherent in observational studies in clinical practice and, as discussed, comparisons between these results and results from prospective, randomized, placebo-controlled clinical trials must be made with caution, due to the significant differences in study design. However, it is interesting and encouraging that the improvements in symptoms and QoL with dutasteride, confirmed in controlled clinical trials, are achievable and might actually be even greater in real-life clinical practice. Indeed, randomized clinical trials also have limitations, e.g. restricted patient groups, and the value of proof-of-efficacy in clinical practice studies is widely recognized [10].

Evaluating the safety profile of drug therapy in clinical practice is also considered to be of value due to the limitations of clinical trials [10]. In this study, dutasteride was well tolerated, with an adverse event profile similar to that reported in the clinical trials [8]. Sexual disorders were the most common adverse event during treatment, but almost a quarter of patients affected presented with these disorders at study entry.

In conclusion, these results show that in real-life clinical practice, dutasteride is well tolerated and significantly improves urinary symptoms, QoL, patient discomfort and satisfaction after 12 and 24 weeks of treatment. Thus, this study adds to the growing body of evidence establishing dutasteride as an effective treatment option for men with BPH.

CONFLICT OF INTEREST

A. Comenducci is an employee of sponsor; all other authors are study investigators funded by sponsor. Source of funding: GSK.

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Abbreviations: **AUR**, acute urinary retention; **BII**, BPH impact index; **ED**, erectile dysfunction; **VAS**, visual analogue scale; **QoL**, quality of life; **5-ARI**, 5α-reductase inhibitor.