International Journal of Scientific Reports
Warudkar S et al. Int J Sci Rep. 2022 Nov;8(11):323-329
http://www.sci-rep.com
pISSN 2454-2156 | eISSN 2454-2164
DOI: https://dx.doi.org/10.18203/issn.2454-2156.IntJSciRep20222649

Original Research Article

Evaluating the demographic profile and mapping the prevalence of overactive bladder in benign prostrate hypertrophy patients: a retrospective, observational study

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Received: 30 September 2022
Revised: 10 October 2022
Accepted: 14 October 2022

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ABSTRACT

Background: The objectives of the study was to evaluate the demographic profile of benign prostatic hyperplasia (BPH) patients and prevalence of overactive bladder (OAB) among these patients.
Methods: A real-world, retrospective, observational study (DEMO-2) on BPH patients was conducted across India from April-2021 to March-2022. Demographics, BPH characteristics, status of OAB, and their management were evaluated.
Results: A total of 5881 BPH patients were included with a mean age of 65.3 years and mean BPH duration of 3.2 years. Majority (80.98%) of the patients had associated comorbidity; hypertension (50.2%), diabetes (26.9%) and dyslipidemia (13%) were the most common. Majority (63%) of the patients complained of incomplete bladder emptying. In BPH patients, 29.9% had OAB. These patients had a higher mean prostate volume (44.96 vs. 42.17 cc) and prostate specific antigen (PSA) levels (4.11 vs. 3.79 ng/ml) versus BPH patients without OAB. For BPH, tamsulosin was the most prescribed drug (85.90%) followed by dutasteride (66.90%); tamsulosin + dutasteride was most common combination therapy (32.6%). In BPH patients with OAB, 82% received OAB medications and solifenacin (63.9%) was the most common medication.
Conclusions: Majority of the BPH patients were between the ages of 50-75 years. Tamsulosin was the most commonly prescribed medication in BPH patients. Combination of tamsulosin and dutasteride was the mainstay of treatment. OAB was seen in 29.9% of the BPH patients, and solifenacin was the most commonly utilized (63.1%) medication in BPH patients with OAB. About 18% of these patients did not receive any specific medication for OAB. Adequate treatment strategies need to be adopted for BPH patients with OAB.

Keywords: Benign prostrate hypertrophy, BPH, Overactive bladder, OAB, Treatment

INTRODUCTION

Benign prostatic hyperplasia (BPH), characterized by non-cancerous growth of the prostate gland, is a common disorder in men.[1] BPH has an age-related increase in the prevalence with an estimated prevalence of 20% for men within 40 years of age, up to 60% for men in their 60s, and up to 90% for men in their 70s and 80s.[2] The lower urinary tract symptoms (LUTS) are generally present in these patients, and an age related increase in the prevalence of both BPH and LUTS has been reported.[3] LUTS may arise out of issues related to urinary storage, voiding, or those occurring post micturition. Although the prevalence of LUTS related to voiding is more, the symptoms related to urinary storage are more bothering and embarrassing.[4]

In patients with LUTS, the disorder related to storage is generally regarded as overactive bladder syndrome (OAB). In OAB there is an 'urgency, with/ without urge incontinence, and is generally associated with frequency and nocturia.[5] OAB is known to impact the daily activities and have a negative influence on the social functioning like work, exercise, sexual function, sleep, and traveling.[6] The symptoms of BPH and OAB overlap and the coexistence of these diseases may further negatively impact the quality-of-life (QOL) of the patients.[7] Overall, the treatment goals in these patients include relief from LUTS and slowing down the clinical progression of BPH along with improving the patient's QOL.[8]

With the above context, the present observational study was conducted to understand the demographic profile of the patients suffering from BPH and determine the prevalence of OAB among Indian men with BPH.

METHODS

Study design

This real world, cross sectional, retrospective, observational DEMO-2 (evaluating the DEmographic profile and Mapping the prevalence of Overactive bladder in benign prostrate hypertrophy-2) study was conducted at various centers including hospitals, clinics, and health care institutes. The study inclusion criteria were patients with BPH who received treatment at the study centers. Patients with a diagnosis other than BPH were excluded. The data was retrospectively collected by physicians and urologists across India from April 2021 to March 2022.

Study variables

Patients were selected based on treating clinician's discretion, and no additional evaluation or investigations were performed during data capture in this real-world, observational study. The demographic parameters like age, height, weight, body mass index (BMI), status of alcohol and tobacco consumption including smoking habits were recorded. Associated comorbidities, history of sleep disturbance and other coexisting psychological issues were also noted. Diagnosis of the disease, its duration, associated clinical symptoms, status of OAB, size of the prostate gland and levels of prostate specific antigen (PSA) were analysed. Disease management approach and treatment medications were also determined.

Sample size and statistical analysis

Patients' data was collected retrospectively without any predetermined sample size. The study did not test any hypothesis and only the observations from patient's records were analyzed. Data of BPH patients was collected from various centres across India and statistical analysis was performed at Lambda Therapeutic Research Ltd., Ahmedabad, India. Demographic and baseline characteristics were summarized using descriptive statistics. Categorical variables were summarized with frequency and percentage. Continuous variables were summarized with count, mean, standard deviation, etc. Graphical presentation of data was done using bar chart as appropriate. Statistical analyses were performed using SAS® Version 9.4 (SAS Institute Inc., USA). Independent *t*-test was performed to analyze inter group differences.

Ethics statement

This retrospective study protocol carried less than minimal risk according to the Indian council of medical research 'Ethical guidelines for biomedical research on human participants'.[9] The study was conducted after due approval from Om Institutional Ethics Committee, Ahmedabad, India. This was a retrospective study without patient identifiers; hence, the informed consent of patients was not taken. There was no confidentiality breach of the data during its analysis and interpretation.

RESULTS

The data of 5881 patients with BPH from 1638 centers across India from April 2021 to March 2022 were evaluated. Table 1 provides the demographic details of patients in this study. The patients had a mean (SD) age of 65.3 (7.8) years. The mean (SD) duration of BPH was 3.2 (1.8) years. Majority (87.8%) of the patients were between the age of 50 and 75 years. The mean BMI was 26.3 kg/m^2; 36.36% patients were overweight. About 40.9% of the patients were current smokers and 31.4% had positive alcohol consumption status. Almost half of the patients (48.4%) had complaints of sleep disturbance.

Coexisting psychological issues were present in 19.9% patients; anxiety was present in 10.9% patients, depression in 7.7% patients and depression along with anxiety in 1.3% patients.

Table 1: Patient characteristics (n=5881).

Parameters	All patients
Age, years, mean (SD)	63.5 (7.8)
Age group (years), N (%)	
<50	122 (2.2)
50-75	4900 (87.8)
>75	559 (10)

Continued.

Parameters	All patients
Weight status, N (%)	
Underweight	14 (4.5)
Normal BMI	2413 (42.37)
Overweight	2683 (36.36)
Obese	471 (16.76)
Mean BMI, kg/m^2	26.3
Duration of BPH, years, mean (SD)	3.2 (1.8)
Smoking status, N (%)	
Yes	2281 (40.9)
No	3300 (59.1)
Alcohol consumption, N (%)	
Yes	1751 (31.4)
No	3830 (68.6)
Sleep disturbance, N (%)	
Absent	2878 (51.6)
Present	2703 (48.4)
Co-existing psychological conditions, N (%)	
No	4470 (80.1)
Yes	1111 (19.9)
Anxiety	608 (10.9)
Depression	428 (7.7)
Anxiety and depression	75 (1.3)
Co-existing overactive bladder, N (%)	
Yes	1670 (29.9)
No	3911 (70.1)
Prostate volume, CC, mean (SD)	42.96 (13.29)
PSA level, ng/ml, mean (SD)	3.79 (3.3)

BMI-body mass index; BPH-benign prostatic hypertrophy; PSA-prostate specific antigen; SD-standard deviation.

Comorbid conditions

At least one co-existing comorbid condition was present in 80.98% patients. Half of the patients had hypertension (50.2%) followed by diabetes (26.9%) and dyslipidemia (13%). About 28.7% of the patients had ≥ 2 co-morbid conditions (Figure 1).

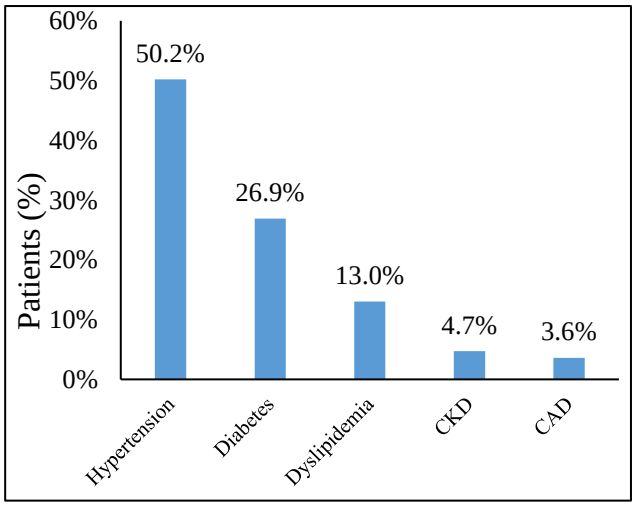

Figure 1: Prevalence of comorbid conditions in BPH patients.

BPH, benign prostatic hyperplasia; CAD, coronary artery disease; CKD, chronic kidney disease.

Clinical presentation

Majority of the patients had voiding symptoms like incomplete emptying (63%) and weakness of urinary stream (61%) whereas storage symptoms like frequency, urgency and nocturia were present in 51%, 44% and 43% of patients, respectively (Figure 2).

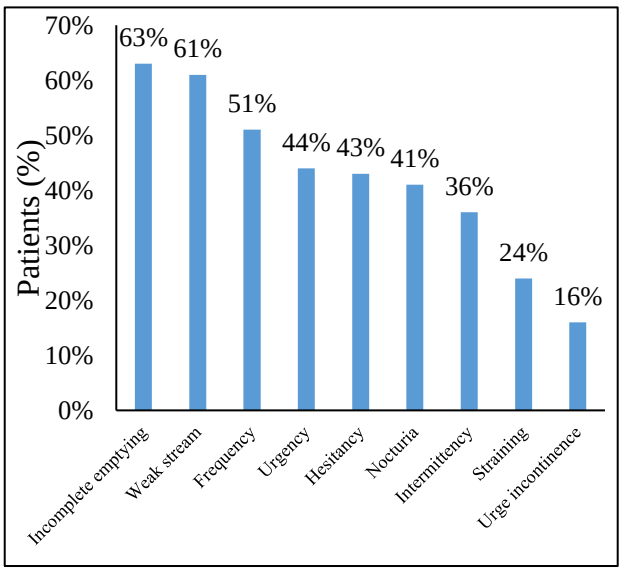

Figure 2: Clinical symptoms of patients.

Comparison of prostate volume and PSA level between men with OAB and without OAB

In BPH patients with coexisting OAB, the mean (SD) prostate volume [44.96 (16.44) cc] was significantly higher than BPH patients without OAB [42.17 (11.72) cc]. Similarly significantly higher PSA levels were found in patients with coexisting OAB [4.11 (3.21) ng/ml] than BPH patients without OAB [3.63 (3.27) ng/ml] (Table 2).

Table 2: Prostate volume and PSA levels in BPH patients with or without OAB.

Parameters	BPH without OAB (n=3911)	BPH with OAB (n=1670)	P value
Prostate volume (cc), mean (SD)	42.17 (11.72)	44.96 (16.44)	<0.0001
PSA level (ng/ml), mean (SD)	3.63 (3.27)	4.11 (3.21)	0.0034

OAB, overactive bladder; PSA, prostate specific antigen.

Choice of management approach

Lifestyle management was recommended in <1% of patients whereas pharmacological management was the cornerstone of treatment. Monotherapy (α adrenergic antagonist) was prescribed in (16%) of patients whereas combination therapy (α adrenergic antagonist plus 5-α reductase inhibitors [ARIs]) was prescribed in majority (67%) of the patients. Combination of tamsulosin (α adrenergic antagonist) and dutasteride (5α-reductase types I and II inhibitor) was the mainstay of treatment, which was prescribed to 32.6% of the patients. Tamsulosin was the most prescribed drug (85.90%), followed by dutasteride (66.90%) and solifenacin (21.90%) (Figure 4). Surgical management approach was used in 16% patients.

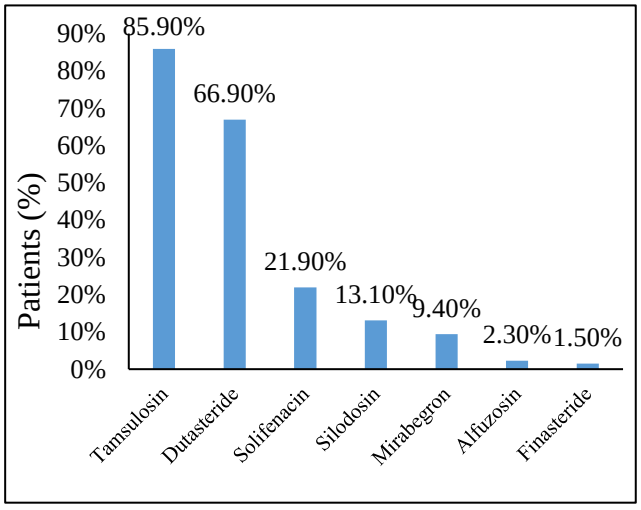

Figure 4: Medications prescribed to BPH patients.

OAB medications prescribed to BPH patients having OAB

About 82% of BPH patients having OAB as associated condition were prescribed specific medications for OAB management. Solifenacin was the most prescribed drug (63.9%), followed by mirabegron (25.2%). Combination of mirabegron and solifenacin was prescribed in 10.9% of these patients.

Medications prescribed in BPH patients for co-morbidities other than OAB

About 28.14% of patients were prescribed drugs for morbidities other than BPH and OAB. The commonly prescribed drugs included amlodipine (25%), telmisartan (14.6%), atorvastatin (8.7%) and atenolol (8.6%).

DISCUSSION

This real-world observational study provides the demographics, disease characteristics and management approaches in 5881 BPH patients with or without OAB from India. Majority (87.8%) of the patients in this study were between the age of 50-75 years with a mean disease duration of 3.2 years. Majority of the patients had an associated comorbidity. About 29.9% patients had OAB as an accompanying condition. Tamsulosin was the most prescribed drug (85.90%), followed by dutasteride (66.90%) and solifenacin (21.90%). About 18% of the patients with BPH having OAB did not receive any medication for OAB, reflecting scope of improvement in management of BPH patients with OAB. Solifenacin was the most common drug prescribed drug (63.1%) for OAB in this study.

BPH, the hyperplasia of the prostate gland, is an age-related phenomenon in nearly all men, starting at approximately 40 years of age. Most men, living long enough, develop some histologic features consistent with BPH.[10] The mean age in the study population was 65.3 years, with the majority being between ages 50 and 75 years. At population level, BPH is associated with risk factors including modifiable (sex hormones, the metabolic syndrome, obesity, diabetes, physical activity, diet, and inflammation) and non-modifiable (age, region, genetics). As per recent evidence, presence of metabolic syndrome increases risk of BPH and LUTS.[11] Meigs et al reported that men diagnosed with at least three components of the metabolic syndrome had an 80% increased prevalence of LUTS compared with those with no components.[12] Studies have reported that men with heart disease are at significantly increased risk of both BPH and LUTS.[13,14] This has also been reported that increased adiposity is positively associated with prostate volume.[15] With an increase in BMI by 1 kg/m^2, the prostate volume is increased by a 0.41 cc.[16] Obese participants have 3.5-fold increased risk of prostate enlargement compared with non-obese participants.[16] Evidence also demonstrated that obesity increases the

risks of BPH surgery, initiation of BPH medical therapy and LUTS[17] and decreases the efficacy of dutasteride.[18] Studies have positively linked the presence of diabetes with greater risk of prostate enlargement, clinical BPH, BPH surgery and LUTS.[19,20] A recent study demonstrated that diabetic men on medical therapy have decreased odds of moderate/severe LUTS compared with those men not on medications.[21] With respect to alcohol, meta-analysis of 19 studies observed that alcohol intake is associated with decreased and increased risks, respectively, of BPH and LUTS.[22] Other modifiable risk factors for which clear patterns of risk have not yet emerged include hypertension, serum lipids and lipoproteins and smoking.[23] Majority of study patients had either modifiable risk factors like hypertension (50.2%), smoking (59.1%), alcohol consumption (68.6%), obesity (36.6%), diabetes (26.9%) or non-modifiable risk factor, mainly old age.

Different definitions are used for BPH, including radiologic benign prostate enlargement, histological analysis of prostate tissue, altered urodynamics, decreased urinary flow rates, and physician-diagnosed BPH.[24] In the present study, majority (63%) of the patients had complaints of incomplete emptying. Urine stream weakness was present in 61% along with other symptoms like increased frequency (51%), urgency (44%), hesitancy (43%), and nocturia (41%).

Another important contributing factor for BPH is aging.[25] There is an increase in the prostate volume with increasing age with a prostate growth rate of 2.0% to 2.5% per year in older men.[26,27] This increases the chance of BPH clinical progression, urinary retention and need for prostate surgery.[28] Baseline serum PSA and/or prostate volume are useful tools to aid physicians in predicting the risk of BPH-related outcomes and choosing therapy for BPH.[29] In this study, the BPH patients had high mean prostate volume (42.96 cc) and PSA (3.79 ng/ml) levels. In the present study, 29.9% patients had OAB as an accompanying condition. Previously published evidence reports a similar incidence of co-existing OAB (39.6%).[30] In this study, BPH patients with coexistent OAB were observed to have higher prostate volume and PSA levels as compared to BPH patients without OAB. These finding are consistent with findings from Yi et al who reported higher prostate volume and PSA levels in patients with co-existing OAB versus those without OAB.[30]About 18% of the BPH patients with OAB did not receive any treatment in this study. Similar data was reported by Burnett et al, who showed that a significant proportion of BPH patients with OAB were deprived of medications this proportion was more than BPH patients without OAB.[31]

The therapeutic target for BPH include improving or relieving LUTS that results from OAB and/or due to neurophysiological changes of bladder neck and urinary bladder. Tamsulosin being selective α-adrenergic antagonist provides rapid symptomatic and urinary flow improvement.2 Compared to other α-adrenergic antagonists, tamsulosin is generally well-tolerated even in patients with cardiovascular diseases including hypertension.[32] Majority of the patients in this study had some or other comorbidity. Studies have reported that tamsulosin has a favorable drug-drug interaction profile and is well-tolerated without significant interactions with the medications prescribed for comorbidities such as hypertension, diabetes and dylipidemia.[33] 5α- reductase inhibitors (finasteride and dutasteride) decrease serum concentrations of dihydrotestosterone[34] and prevent clinical progression of BPH and LUTS.[35] Dutasteride inhibits both 5α-reductase types I and II.[36] Majority (67%) of patients in present study were prescribed combination therapy whereas 16% of the patients received a monotherapy. Tamsulosin was prescribed in majority (85.9%) of the patients, while 66.9% received dutasteride. In long-term studies, both drugs have been associated with a greater than 50% reduction in the risk of acute urinary retention and the risk for surgical intervention; additionally, this benefit in terms of risk reduction increases with increasing prostate size and increasing serum PSA values.[29,37] In the present study, 63.9% BPH patients with OAB were prescribed solifenacin, followed by mirabegron (25.2%). Combination of mirabegron and solifenacin was also prescribed in 10.9% of the patients. Solifenacin has demonstrated efficacy and safety in patients with OAB with BPH in several studies, and can be considered a preferred anticholinergic agent in this condition owing to better efficacy and tolerability profile over other agents.[38] Surgical intervention is appropriate for individuals with moderate-to-severe LUTS, acute urinary retention, or those with other complications due to BPH.[39] In the present study 16% of the patients underwent surgery for their BPH. The study strength encompasses the inclusion of patients across the country covered throughout the year overruling seasonal trends influencing BPH. The limitations include the retrospective nature of the study, and the treatment outcomes were not captured.

CONCLUSION

The prevalence of BPH was more pronounced between 50 and 75 years of age. About one-third of the BPH patients had coexisting OAB, who were reported to have higher prostate volume and PSA levels as compared to those without OAB. Among pharmacological management, tamsulosin was the most commonly prescribed α-blocker as monotherapy whereas tamsulosin (α adrenergic antagonist) and dutasteride (5α-reductase inhibitor) was the most commonly utilized combination therapy. Solifenacin was the most commonly prescribed OAB medication in BPH patients with OAB. About 18% of BPH patients with OAB were not treated with any OAB medication. Considering complexity of LUTS and overlapping symptoms of BPH and OAB, management strategies around patient and physician level need to be adopted so that all BPH patients with OAB receive adequate treatment.

ACKNOWLEDGEMENTS

The authors would like to thank the DEMO-2 study investigators for their contribution. The authors also thank Mr. Shreekant Sharma (CMPP™ ISMPP) and Dr. Parloop Bhatt for medical writing assistance. The authors acknowledge Biostatistics and Programming department of Lambda Therapeutic Research Ltd., India for conducting statistical data analysis for this study.

Funding: Intas Pharmaceuticals Limited
Conflict of interest: Dr. Sandesh Warudkar, Dr. Amit B. Jain, and Dr. Nilanj Dave are employees of Intas Pharmaceuticals Limited, Ahmedabad, Gujarat, India. Ms. Ankita Shah is an employee of Lambda Therapeutic Research Ltd., Ahmedabad, Gujarat, India
Ethical approval: The study was approved by the Om Institutional Ethics Committee, Ahmedabad, India

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Cite this article as: Warudkar S, Jain AB, Dave N, Shah A. Evaluating the demographic profile and mapping the prevalence of overactive bladder in benign prostrate hypertrophy patients: a retrospective, observational study. Int J Sci Rep 2022;8(11):323-9.