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The Silent Swell - Epidemiology, Clinical Profile, and Treatment patterns of benign prostate hyperplasia in India

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Abstract

Background and Aim: benign prostatic hyperplasia (BPH) is a common age-related condition that significantly impacts the quality of life of older men, leading to lower urinary tract symptoms (LUTS) and potential complications. An understanding of the disease burden and management strategies in this population is crucial for optimizing healthcare delivery. The study aimed to evaluate the demographic and clinical characteristics and treatment patterns in Indian patients diagnosed with BPH.

Methods: The retrospective, multi-centric, cross-sectional design involved the collection of data from various healthcare facilities across India.

Results: The study population comprised 3,182 individuals with a mean age of 65.1 years, Common comorbidities included erectile dysfunction (20.0%) and hypertension (10.8%) and diabetes (8.1). 91.1% patients were managed by medical measures while 8.9% of cases required surgical intervention, most commonly TURP. 65.8% of patients received standard BPH medications (alpha blockers), while 30% patients received dual therapy with an alpha blocker and a 5-ARI. Silodosin (45%), Tamsulosin (40%) were most common alpha blockers while Dutasteride (95%) was most common 5-Alpha Reductase Inhibitor (ARI) used in Indian settings. IPSS scores, mean baseline PSA (8.83 ng/ml), and mean PVR volume (151.38 ml) all decreased post-treatment indicating improved symptoms and bladder emptying. This highlights the effectiveness of the management strategies used in this cohort of Indian patients in alleviating LUTS and improving patient outcomes.

Conclusions: The findings underscore the significant burden of BPH in older Indian men and highlight the importance of effective management strategies to alleviate symptoms and improve quality of life. Given the aging population in India, further research is needed to optimize BPH management in this population, considering factors such as long-term treatment outcomes, cost-effectiveness, and patient adherence.

Keywords: Benign Prostatic Hyperplasia, LUTS, Silodosin, Dutasteride, Treatment Patterns, Elderly Men

1. Introduction

Benign prostatic hyperplasia (BPH) is a histological diagnosis describing the proliferation of smooth muscle and epithelial cells in the prostate's transition zone [1, 2]. The prostate gland undergoes significant growth throughout a man's life, and BPH represents a non-cancerous increase in the number of cells, leading to an enlarged prostate. This process is distinct from hypertrophy, which refers to an increase in cell size. BPH is a prevalent condition in older men, with its incidence increasing with age. It's estimated that approximately 50% of men exhibit histological BPH by the age of 60, and this figure rises to 90% by age 85 [3]. BPH is a major cause of lower urinary tract symptoms (LUTS), which can include urinary frequency, urgency, nocturia, a weak urine stream, incomplete bladder emptying, and hesitancy [4, 5]. These symptoms arise from the physical obstruction of the urethra and changes in bladder function. The impact of these symptoms on a patient's quality of life can be substantial, affecting sleep, daily activities, and overall well-being. LUTS can lead to sleep disturbances due to nocturia, limit daily activities due to the frequent need to urinate, and cause significant distress, affecting overall health and social interactions.

Histological evidence of BPH becomes increasingly common after age 50, with prevalence reaching 50-60% in men in their 60s and up to 80-90% after age 70 [3, 6]. Similarly, LUTS associated with BPH increase with age. While a histological diagnosis, BPH's clinical impact stems from these symptoms. Age is the primary risk factor, but family history and lifestyle

(obesity, inactivity, diet) also contribute to its development [4, 7-9].

The exact etiology of BPH is not fully understood, but it is believed to be a multifactorial process involving hormonal changes associated with aging. The role of dihydrotestosterone, a metabolite of testosterone, is crucial in prostatic growth [5]. An imbalance between cell proliferation and apoptosis in the prostate gland also contributes to BPH [6]. Additionally, inflammation and stromal growth factors may play a role in the development and progression of BPH [7].

The BPH typically manifests as LUTS, broadly classified as obstructive (weak stream, hesitancy, intermittency, incomplete emptying, straining) due to urethral obstruction, and irritative (frequency, urgency, nocturia) arising from altered bladder function [10, 11]. LUTS severity is variable and quantifiable using the International Prostate Symptom Score (IPSS) [8].

A thorough evaluation is essential for diagnosing BPH and ruling out other conditions with similar symptoms, such as prostate cancer, urinary tract infections (UTIs), and neurogenic bladder [12]. Diagnostic procedures may include a detailed inquiry about LUTS, including their onset, duration, and severity, as well as other medical conditions, medications (as some medications can affect urinary function), and lifestyle factors. A digital rectal examination (DRE) is a key component, allowing the physician to assess the prostate size, consistency, and any irregularities [13]. Urinalysis is performed to check for infection, hematuria (blood in the urine), and other abnormalities. While prostate-specific antigen (PSA) testing is used primarily to screen prostate cancer, it can also be elevated in BPH. It is particularly useful in evaluating men with moderate to severe LUTS, an abnormal DRE, or those at higher risk for prostate cancer [14]. Questionnaires such as the IPSS quantify LUTS severity and assess their impact on the patient's quality of life. Uroflowmetry, a non-invasive test that measures the urine flow rate, can help identify obstructive patterns. Post-void residual (PVR) volume measurement determines the amount of urine remaining in the bladder after urination, indicating the degree of bladder emptying. Imaging studies, particularly transrectal ultrasound (TRUS), may be used to assess prostate size more accurately, evaluate the prostate's anatomy, and rule out other abnormalities, such as prostate cancer or bladder stones [15].

The management of BPH aims to alleviate symptoms, improve quality of life, and prevent complications. Treatment options are tailored to the individual patient, considering the severity of symptoms, the patient's preferences, and the presence of any comorbidity. Treatment options include lifestyle modifications, medical therapy, minimally invasive surgical therapies (MISTs), and surgery. For men with mild symptoms, lifestyle changes, including fluid management, dietary changes, and timed voiding, may be sufficient [10, 16]. Medical therapies include alpha-blockers (e.g., silodosin, tamsulosin, alfuzosin), which relax prostate and bladder neck muscles to improve urine flow [11, 17], 5-alpha-reductase inhibitors (e.g., finasteride, dutasteride), which reduce prostate size [12, 18], combination therapy with both [19], and phosphodiesterase-5 inhibitors (e.g., tadalafil) for LUTS relief [13, 20]. MISTs offer alternatives to traditional surgery with fewer side effects and shorter recovery times. Examples include transurethral microwave thermotherapy (TUMT), transurethral needle ablation (TUNA), prostatic urethral lift (UroLift) [21], and water vapor thermal therapy (Rezum) [14, 22]. Surgical intervention, such as transurethral resection of the prostate (TURP), is reserved for severe cases, though it's increasingly replaced by MISTs and laser therapies like holmium laser enucleation of the prostate (HoLEP) and photo-selective vaporization of the prostate (PVP) [23-25]. Open prostatectomy may be necessary for very large prostates. The choice of treatment depends on individual factors, and a shared decision-making approach is recommended.

The present study aims to evaluate the demographic and clinical characteristics, as well as treatment patterns, among patients diagnosed with BPH in India.

2. Methods

2.1 Study Design & Population

It was a retrospective, multi-centric, cross-sectional study, analyzed electronic health records (EHR) or paper-based medical records from healthcare facilities that served older adult populations (aged ≥30 years) who had been diagnosed with BPH at the physician's discretion. Patients were included in the study if their medical records for the specified period were complete. Conversely, individuals with incomplete or missing records were excluded from the study. Data were collected from multiple centers across India, including hospitals, clinics, and healthcare institutes. The primary care physicians, general practitioners, or urologists involved in the BPH study utilized an electronic case report form (eCRF) to collect the retrospective data. The selection of patients was solely based on the treating physician's discretion, and no additional evaluations or investigations were conducted specifically to capture data for this study.

2.2 Data Collection

The retrospective study collected the following data in the eCRF: age, weight, BPH signs/symptoms (frequency, urgency, nocturia, incomplete emptying), IPSS, family history, and comorbidities (hypertension, ischemic heart disease, heart failure, diabetes, obesity, other). Investigations (PSA, urine analysis, USG/TRUS, uroflowmetry, PVR) were recorded if performed. Diagnosis (new or previous diagnosis), pharmacological treatment (monotherapy, combination therapy, or other recommendations), surgical interventions.

2.3 Ethical Considerations

The ethical considerations for this study adhered to the ICMR "Ethical Guidelines for Biomedical research on Human participants," and the protocol was determined to present less than minimal risk. Appropriate Ethics Committee (EC) approval was obtained. Given the retrospective nature of the study, where participants were de-identified and could not be contacted, permission for a waiver of consent was secured from the EC.

2.4 Statistical Analysis

The statistical analysis was conducted using [Specify Software, e.g., SPSS version X, R version Y]. Descriptive statistics were used to summarize demographic characteristics, including age (mean, SD), weight (mean, SD), height (mean, SD), family history of BPH (n, %), previous BPH diagnosis (n, %), and other urological conditions (n, %). Categorical variables were presented as

frequencies and percentages.

Changes in IPSS score, PSA levels, and PVR volume from baseline to post-baseline were evaluated. Outliers, defined as values of 200 and above for IPSS scores and 500mL and above for PVR, were excluded. [Further details on the outlier exclusion method could be added here]. The appropriate statistical test (paired t-test or Wilcoxon signed-rank test) was used to compare baseline and post-baseline values, depending on data distribution. A p-value of <0.05 was considered statistically significant for all analyses.

3. Results

The total study population consists of 3,182 individuals across 550 healthcare centres. The mean age of the participants is 65.1 years, The average weight is 71.6 kg, and the mean height is 166.9 cm, reflecting a relatively uniform body composition across the population. 21.2% of participants reported a family history, while 11.3% had a previous diagnosis of BPH. Additionally, 9.1% reported other urological conditions mainly bladder and renal stones (Table 1).

Table 1: Summary of Demographic Characteristics

	Overall Total (N=3182) n (%)
Age (Years) Mean ± SD	65.1 ± 8.4
Weight (kg) Mean ± SD	71.6 ± 8.7
Height (cm) Mean ± SD	166.9 ± 8.7
Patient with Family History, n (%)	
No	2507 (78.8)
Yes	675 (21.2)
Previous Diagnosis of BPH, n (%)	
No	2822 (88.7)
Yes	360 (11.3)
Other Urological Conditions, n (%)	
No	2893 (90.9)
Yes	289 (9.1)
n: Number of subjects, SD: Standard Deviation, Min: Minimum, Max: Maximum Q1: First quartile, Q3: Third quartile	

Table 2: Summary of key Comorbidities in BPH patients

Comorbidities	**Overall Total (N=3182) n (%)**
Erectile Dysfunction	695 (21.8)
Hypertension	346 (10.8)
Diabetes	264 (8.1)
Percentages are computed using N provided in the Column header	

In this study, a total population of 3182 patients, erectile dysfunction was the most prevalent symptom, reported in 21.84% (n=695). Hypertension (10.87%, n=346) and diabetes (8.29%, n=264) were also common comorbidities (Table 2).

Medical management is the most common approach to treat Indian BPH patients. Among the patients who underwent surgical intervention, TURP was the most common procedure (4.5%), followed by laser surgery (2.5%) and prostatectomy (1.9%). (Table 3)

Table 3: Summary of BPH management

BPH management	**Overall Total (N=3182) n (%)**
Medical	2899 (91.1)
Transurethral Resection of the Prostate (TURP)	143 (4.5)
Laser Surgery	79 (2.5)
Prostatectomy	61 (1.9)
Percentages are computed using N provided in the Column header	

Significant proportion of patients—65.8%—received standard pharmacological treatment for Benign Prostatic Hyperplasia (BPH), primarily in the form of alpha blockers**.** Alpha blockers are widely recognized as first-line agents for relieving lower urinary tract symptoms (LUTS) associated with BPH due to their rapid onset of action and symptom improvement. Furthermore, 30% of patients were prescribed combination therapy consisting of an alpha blocker and a 5-alpha-reductase inhibitor (5-ARI), reflecting adherence to evidence-based practices for patients with larger prostate volumes or a higher risk of disease progression. Among the alpha blockers prescribed**,** Silodosin was the most commonly used (45**%)**, followed closely by Tamsulosin (40%)**.** Silodosin, a highly selective alpha-1A adrenergic receptor antagonist, is often favored for its lower incidence of systemic side effects such as hypotension, making it particularly suitable for elderly patients or those with cardiovascular comorbidities. Tamsulosin remains a popular choice due to its established efficacy, tolerability, and physician familiarity. In combination regimens, the most frequently used 5-ARI was Dutasteride**,** which accounted for 95% of the 5-ARI prescriptions. Dutasteride's dual inhibition of both type I and type II 5-alpha-reductase isoenzymes offers more potent suppression of dihydrotestosterone (DHT) levels compared to finasteride, potentially leading to more pronounced prostate volume reduction and symptom control over time.

There is a notable reduction in IPSS score from Baseline to Post treatment, indicating an improvement in symptoms over time or following treatment (Fig 1).

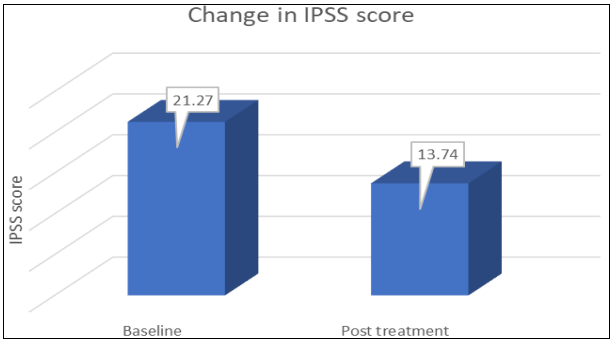

Fig 1: Change in IPSS Score post treatment

The data presented in the bar graph reveal a change in the mean PSA level from baseline to a subsequent measurement. The baseline mean PSA level was 8.83 ng/ml. Following a period or intervention (Post treatment) the mean PSA level decreased to 6.60 ng/ml, indicating an overall reduction (Fig 2).

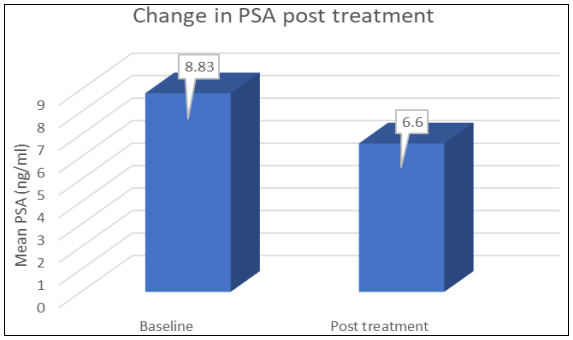

Fig 2: Change in Prostate Specific Antigen level post treatment

At Baseline, the mean Post Voidal Residue (PVR) volume was recorded as 151.38 ml. Following an intervention or a period (indicated as Post treatment), the mean PVR volume decreased to 95.84 ml. This indicates that there was a reduction in the amount of urine remaining in the bladder after voiding from the baseline measurement to the post-baseline measurement. The legend further clarifies that the light blue bar represents the baseline PVR, and the dark blue bar represents the post-baseline PVR (Fig 3).

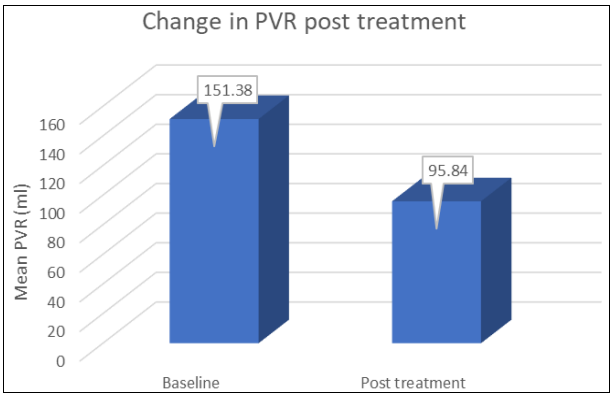

Fig 3: Change in PVR from baseline

4. Discussion

This study presents a comprehensive analysis of 3,182 individuals diagnosed with BPH, predominantly older adults with a mean age of 65.1 years. The age of people in this study matches global patterns, showing that BPH is more common as people get older, highlighting that age is a key factor in this condition [26]. The prevalence of a family history of BPH (21.2%) underscores the potential genetic predisposition to the condition, a factor that has been increasingly recognized in BPH development [4].

The observed comorbidities in our study population, with erectile dysfunction (20.0%) and hypertension (10.8%) being the most common, are consistent with previous research. Erectile dysfunction and BPH often coexist, likely due to shared pathophysiological mechanisms such as decreased nitric oxide bioavailability and increased sympathetic nervous system activity [13, 20]. Similarly, the association between hypertension and BPH has been reported in several studies, although the exact nature of this relationship remains unclear [9]. These findings are consistent with existing literature that highlights the association between BPH and metabolic disorders. A meta-analysis by Kupelian *et al.* demonstrated a significant correlation between LUTS and metabolic syndrome components, including hypertension and diabetes [26].

Surgical intervention was required in 8.9% of cases, with TURP being the most common procedure (4.5%). This is in line with national trends observed between 2013 and 2019, where TURP remained the predominant surgical modality for BPH, despite the emergence of minimally invasive techniques. The continued preference for TURP underscores its efficacy and established role in BPH management [27].

Pharmacological management revealed a preference for Silodosin as monotherapy, followed by Silodosin and Dutasteride combination therapy, reflect the current pharmacological landscape for BPH management. Silodosin's high selectivity for α1A-adrenergic receptors may explain its prevalent use, as this selectivity minimizes hypotensive side effects and dizziness, which are common with less selective alpha-blockers [11, 17]. The frequent use of combination therapy with Silodosin and Dutasteride aligns with the understanding that combining alpha-blockers with 5-alpha-reductase inhibitors provides superior symptom relief and reduces the risk of BPH progression compared to monotherapy [19]. A prospective study by Hagiwara *et al.* assessed the efficacy of this combination (Silodosin and Dutasteride) in patients with acute urinary retention due to BPH, reporting a catheter-free rate of 88.8% at 12 weeks, along with significant improvements in IPSS scores and quality of life [28].

The significant reduction in IPSS scores from baseline to post-baseline demonstrates the effectiveness of the management strategies used in this cohort of Indian patients. This improvement in symptom severity is consistent with the findings of clinical trials that have established the efficacy of both medical therapies and surgical interventions in alleviating LUTS associated with BPH [14, 15].

The decrease in mean PSA levels (from a mean of 8.83 ng/ml at baseline to 6.60 ng/ml post-treatment) following treatment is also noteworthy. While PSA is primarily a marker for prostate cancer, it can also be elevated in BPH, and a reduction may indicate a decrease in prostatic volume and disease activity [12]. This observation is supported by the study conducted by Hagiwara *et al.* which reported a significant decrease in PSA levels following combination therapy [28]. The observed decrease in PVR volume further supports the effectiveness of the interventions in improving bladder emptying [26]. This finding is consistent with the aforementioned study, which demonstrated significant reduction in PVR volumes among patients receiving combination therapy [28].

Several limitations of this study warrant mention. Firstly, its retrospective nature and reliance on existing medical records may have introduced biases in data collection and analysis. Secondly, the heterogeneity in naming conventions posed a challenge in accurately categorizing treatment patterns. Thirdly, the study population, while diverse, may not fully represent the broader Indian population with BPH. Finally, the study does not include long-term follow-up data, limiting our understanding of the durability of treatment effects and the long-term outcomes of BPH in this population.

Despite these limitations, this study provides valuable real-world data on the demographic and clinical characteristics and treatment patterns of Indian patients with BPH. The findings highlight the significant burden of BPH in older Indian men and underscore the importance of effective management strategies to alleviate symptoms and improve quality of life. Further research, particularly prospective studies with longer follow-up periods, is needed to validate these findings and explore the optimal management of BPH in the Indian population.

5. Conclusion

In conclusion, this study offers valuable real-world data on the demographic and clinical characteristics and treatment patterns of Indian patients with BPH. The findings underscore the significant burden of BPH in older Indian men, & also emphasizes the importance of effective management strategies with alpha blocker and 5-ARI to alleviate these symptoms and improve patients' quality of life. While the data provide a useful snapshot of BPH in India, further research, particularly prospective studies with

longer follow-up periods, is needed to validate these findings, explore the long-term outcomes of BPH, and identify the optimal management strategies for this population. Such research also aimed to address the heterogeneity in treatment approaches and considered the specific needs and preferences of Indian patients, which were potentially influenced by cultural factors, healthcare access, and socioeconomic considerations.

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