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Research Article

ASSESSMENT OF LOWER URINARY TRACT SYMPTOMS IN BENIGN PROSTATIC HYPERPLASIA TREATED BY CONSERVATIVE MANAGEMENT

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ABSTRACT

Objective: The objective of the study is to evaluate the effectiveness of prescribed drug therapy for patients with benign prostatic hyperplasia (BPH) and to analyze the quality of life (QOL) of these patients.

Methods: A prospective observational study was conducted over 1 year, from October 2019 to September 2020, aiming to assess the effectiveness of medications used in BPH treatment. Urine flow was measured at each follow-up visit using an uroflow meter to evaluate treatment effectiveness. The American Urological Association's QOL and the International Prostate Symptom Score (IPSS) were utilized to assess patients' QOL.

Results: Out of 250 patients screened, 138 were eligible for the study, with 82 (59.43%) in the 60–80 age group. A total of 1212 medications were prescribed, with alpha-adrenergic blockers and 5-alpha reductase inhibitors (5-ARIs) making up 34.08% of all prescriptions. Urine flow increased from 13.42 mL/s at the first visit to 14.46 mL/s at the second visit, reaching 15.62 mL/s by the third visit. The IPSS score decreased from 15.44 at the first visit to 13.51 at the second and further to 12.28 at the third.

Conclusion: Alpha-adrenergic blockers such as tamsulosin (30.12%) and silodosin (3.96%), along with the 5-ARI dutasteride (0.50%), were prescribed for BPH treatment. A statistically significant improvement ($p<0.05$) in lower urinary tract symptoms and QOL was observed at each follow-up visit.

Keywords: Effectiveness, Benign prostatic hyperplasia, International prostate symptom score, Quality of life.

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INTRODUCTION

Benign prostatic hyperplasia (BPH) is a non-cancerous enlargement of smooth muscle and stromal cells in the transitional zone of the prostate, leading to various lower urinary tract symptoms (LUTS) [1]. BPH can result in complications such as urinary incontinence, renal insufficiency, urinary tract infections, and acute urinary retention (AUR). The quality of life (QOL) of patients with BPH can be significantly impacted, leading to anxiety, sleep disturbances, and sexual dysfunction [2].

Most patients with BPH experience satisfactory outcomes following treatment. The primary objectives of BPH management are to alleviate LUTS, enhance QOL, slow disease progression, and minimize complications. A variety of medications is currently available for BPH treatment, including alpha-1 blockers, 5-alpha reductase inhibitors (5-ARIs), muscarinic receptor antagonists, phosphodiesterase 5 inhibitors, and beta-3 adrenoceptor agonists.

In the present study, we employed two components for evaluation: (a) subjective assessment based on patient feedback using the international prostate symptom score (IPSS) and (b) objective assessment through urine flowmetry and prostate-specific antigen (PSA) measurements. Changes in QOL were documented at each visit to assess treatment response [3].

METHODS

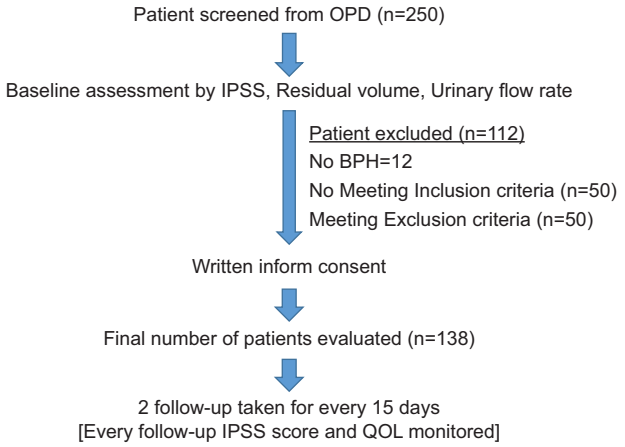
An observational study was carried out in the Urology department of a tertiary care center from October 2019 to September 2020. The study received approval from the Institutional Ethics Committee (IEC) (PDU/MCR/IEC/19983/2019 dated October 25, 2019). Patients diagnosed with BPH who attended the urology outpatient department (OPD) were screened according to specific inclusion and exclusion criteria on Tuesdays, Wednesdays, and Fridays. Both previously diagnosed and newly diagnosed patients who had been on pharmacotherapy for at least 15 days were included in the study. Informed written consent was obtained from all participants. Patients were followed up 15 days after their initial visit (second visit) and again 15 days after the second visit (third visit) to assess treatment effectiveness by measuring urine flow using an uroflowmeter.

The sociodemographic profile of participants, including age, weight, height, and education level, was documented alongside clinical details such as diagnosis, disease duration, prior treatments, and laboratory investigations. Specific assessments for BPH included digital rectal examinations (DRE), urine flow measurements, and post-void residual volume (PRV). Effectiveness data were gathered using the IPSS [4] and QOL assessments [5]. Treatment information was also collected from the treatment sheets.

Statistical analysis

Data entry was conducted using Microsoft Excel 2016, while statistical analysis was performed with Epi Info Version 7.1.5. Results were presented in the form of percentages and graphs as needed.

Flow chart for inclusion and exclusion and final evaluation of patients:



RESULTS

Out of 250 patients screened, 138 were eligible for the study. The inclusion criteria for participant selection included a DRE result greater than Grade 1 (1–2 cm), a urine flow rate of <10 mL/s, and a PSA level >4.0 ng/mL. The majority of patients with BPH were in the 60–69 age group, followed by those aged 70–79. The mean age of BPH patients was 63.70 years, with a standard deviation of 9.21 years. Most patients (60, or 43.47%) weighed between 60 and 69 kg, while more than half (54, or 39.13%) had weights in the range of 50–59 kg. The average weight of BPH patients was 60.17 kg, with a standard deviation of 8.18 kg. Regarding height, the majority (66, or 47.82%) were between 163 and 165 cm tall, followed by those measuring 158–160 cm (42, or 30.43%). The mean height of BPH patients was 163 cm, with a standard deviation of 0.38 cm. More than half of the patients (65.21%) were illiterate, while 34.79% were considered literate, defined as individuals who can read, write, and understand the vernacular language.

Among the 138 patients, 65 (47.10%) had comorbidities. The comorbid conditions included hypertension (15 patients, or 10%), diabetes (10 patients, or 7%), diabetes with hypertension (6 patients, or 4%), cystitis (12 patients, or 9%), inguinal hernia (6 patients, or 4%), both right and left irreducible inguinal hernias (8 patients, or 6%), AUR (2 patients, or 2%), constipation (2 patients, or 2%), diarrhea (2 patients, or 2%), back trauma (1 patient, or 1%), and thyroid issues (1 patient, or 1%). Hypertension was the most prevalent comorbidity, affecting 10% of the patients.

The duration of the disease ranged from 1 to 47 weeks for more than half of the patients (62, or 44.92%), while 22 patients (15.94%) had a duration of 48–94 weeks. This included both newly diagnosed and previously diagnosed individuals. The majority (70%) of patients had received prior treatment for BPH, while 30% had not undergone any treatment.

The baseline data for the investigational parameters showed the following mean values: DRE was 1.5±0.50 cm, urine flow was 13.37±1.51 mL/s, PRV was 140±90 cc, and PSA was 1.7±1.1 ng/mL.

After starting the treatment for 15 days, the urine flow increased to 15.62 mL on 3rd visit (15 days after the 2nd visit) which was 13.42 mL on 1st visit (at the time of diagnosis) and 14.46 mL on 2nd visit (15 days after the 1st visit). By applying analysis of variance test, improvement in urine flow with subsequent visits was found to be statistically significant (Table 2). Majority of the cases belonged to moderate IPSS severity score in every follow-up visits (1st visit–106, 2nd visit–114, 3rd visit–101) (Table 3). IPSS score decreased to 12.28 in 3rd visit as compared to 1st visit (15.44) and 2nd visit (13.51). Decrease in IPSS score was statistically significant by applying Friedman's test (Table 4). A total of 138 patients were assessed in each subsequent visit for AUA QOL scale. In 1st visit, 84 patients were dissatisfied while in 2nd (98) and 3rd visit (96), patients felt mixed type of reaction (Table 4). QOL score was 3.88 on 1st visit which was decreased on 2nd visit (3.07) and 3rd visit (2.83). This decreased QOL score was found to be statistically significant (Table 5).

Table 1: Drugs used in the treatment of BPH (n=138)

Group	No. of prescriptions (%)
Alpha-adrenergic blocker	413 (34.08)
5-α reductase inhibitors	6 (0.5)
Antibiotics	127 (10.48)
Antacids	248 (20.47)
NSAIDS	213 (17.57)
Anti-hypertensive	30 (1.48)
Anti-spasmodic	99 (8.17)
Anti-diabetic	21 (1.73)
Others	55 (4.54)

n=414 prescriptions/encounters (includes all visits by 138 patients), Total number of drugs prescribed 1212 in 414 prescriptions issued. Drugs prescribed per prescription are 2.92. BPH: Benign prostatic hyperplasia, NSAIDS: Non-steroidal anti-inflammatory drugs

Table 2: Comparison between effectiveness of drugs and urine flow output at subsequent visits (n=138)

Urine flow (mL)	1st visit	2nd visit	3rd visit
Mean	13.42	14.46	15.62
Variance	2.4	2.33	4.09

Analysis of variance test – df=2, p≤0.001

Table 3: Assessment of IPSS severity score in each follow-up visit (n=138)

Severity (score)	1st	2nd	3rd
Mild (1–7)	8	10	30
Moderate (8–19)	106	114	101
Severe (20–35)	24	14	7

IPSS: International prostate symptom score

Table 4: Comparison between effectiveness of drugs and IPSS score at subsequent visits (n=138)

IPSS score	1st	2nd	3rd
Mean	15.44	13.51	12.28
Std. deviation	4.31	4.14	4.45

Friedman's test=241.8, df=2, p≤0.001. IPSS: International prostate symptom score

DISCUSSION

BPH is a prevalent condition affecting older males [6]. A decade ago, surgical intervention and watchful waiting were the primary management options for BPH. However, there has been a notable shift toward medication as the most commonly employed treatment, significantly altering clinical practice in urology. Patients with BPH often experience considerable deterioration in their QOL due to symptom severity [7], as this condition is recognized as a quality-of-life disorder that impacts a man's ability to initiate or control urine flow. These symptoms can disrupt normal activities and diminish overall well-being [8].

In our study, the majority of patients were aged 60–69, with a mean age of 63.70±9.21 years. This aligns with previous findings that report the same age group as most common, with a mean age of 66.60±7.10 years [9]. The mean weight of patients in our study was 60.17±8.18 kg, which contrasts with a study by Schulman *et al*., [10] which reported a mean weight of 77.6±10.3 kg.

Table 5: Assessment of quality of life in each follow-up visit (n=138)

QOL	1st	2nd	3rd
0 and 1	0	0	0
2	4	17	33
3	32	98	96
4	84	20	9
5	13	3	0
6	5	0	0

QOL: Quality of life

Table 6: Comparison between effectiveness of drugs and quality of life at subsequent visits (n=138)

QOL	1st	2nd	3rd
Mean	3.88	3.07	2.83
Std. deviation	0.75	0.59	0.52

Friedman's test value=212.8, df=2, p≤0.001. QOL: Quality of life

The results indicate a significant improvement in urine flow after treatment, corroborated by similar findings from Zhou *et al*., [9] where uroflowmetry analysis revealed a notable increase in maximum flow rates (Q max) relative to baseline in the treatment group at each time point ($p<0.001$).

IPSS severity scores were assessed at each visit, showing a mean score of 15.44 at the first visit, which decreased to 13.51 at the second and 12.28 at the third visit. These changes were statistically significant, as confirmed by Friedman's test ($p<0.001$). In a study by Hutchison *et al*., [11] baseline IPSS scores were also found to significantly decrease over time, from 26.73 at baseline to 14.56 at 1 month and further to 7.87 by the 3rd month. Similarly, Tomar *et al*. [12] reported significant improvements in IPSS scores following tamsulosin treatment, particularly in voiding symptoms.

While patients may focus on their individual health changes, caregivers often consider the broader impact on family life. However, quality-of-life studies specific to medical management of BPH are limited. Suzuki *et al*. [8] described the effectiveness of α1-blocker treatments on both disease-specific and generic QOL, highlighting improvements in QOL scores alongside IPSS outcomes.

In our study, the comparison of drug effectiveness and QOL at subsequent visits, analyzed using Friedman's test, indicated significant improvements in QOL scores (mean values: 3.88, 3.07, and 2.83, respectively; $p<0.001$). This aligns with findings from Pramana *et al*., [13] which reported improved QOL scores across visits.

The primary medications used for BPH included tamsulosin and 5-ARIs, with antibiotics prescribed for comorbid conditions. Our findings showed that tamsulosin was the most frequently prescribed medication, accounting for 34.08% of prescriptions, which is consistent with Hutchison *et al*.'s results, [11] where over 90% of clinicians preferred alpha-blockers as the first-line treatment.

In our study, silodosin was prescribed in 3% of cases, and the 5-ARI dutasteride was used in only 0.5%. Hutchison *et al*. [11] also reported a preference for alpha-blockers, with only 5.1% of clinicians opting for 5-ARIs. This trend reflects a focus on rapid symptom relief, enhancing patient satisfaction with tamsulosin as part of BPH management. Notably, 50% of our study population received monotherapy with alpha-blockers, while the other half was treated with a combination of an alpha-blocker and a 5-ARIs.

Overall, our study underscores the shift toward effective medical management of BPH, highlighting the importance of tailored treatment strategies that prioritize patient outcomes and QOL.

CONCLUSION

Alpha-adrenergic blockers – tamsulosin (30.12%), silodosin (3.96%), and 5-α reductase inhibiter – dutasteride (0.50%) were drugs prescribed for BPH in our study. There was significant ($p<0.05$) improvement observed in LUTS and QOL at each visit.

CONFLICTS OF INTERESTS

None.

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