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Patient-reported Outcomes Following Medical Management of Benign Prostate Hyperplasia in a Tertiary Care Setting: Insights from BSMMU

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Abstract

Background: Benign Prostatic Hyperplasia (BPH) is a prevalent urological condition that significantly impairs the quality of life of aging men. Evaluating patient-reported outcomes following medical management is crucial for understanding treatment effectiveness in real-world clinical settings. ***Objective:*** To assess the changes in symptom severity and quality of life following a structured, stepwise protocol for the medical management of BPH at a tertiary care hospital. ***Methods:*** This prospective interventional study was conducted at the Department of Urology, Bangabandhu Sheikh Mujib Medical University (BSMMU) from January 2020 to December 2021. A purposive sample of 105 patients aged 45-60 years with confirmed BPH was enrolled. Participants received Tamsulosin (0.4 mg), with escalation to Silodosin (8 mg) and/or Dutasteride (5 mg) for insufficient response. Bladder sedatives were used for irritative symptoms. Outcomes were assessed using IPSS and QoL scores at baseline and 3, 6, 9, and 12-month intervals. Data analysis was performed with SPSS version 23.0. ***Results:*** Analysis demonstrated significant improvement in all outcomes. Mean total IPSS decreased markedly from baseline to 12 months (19.5 ± 3.8 to 8.7 ± 2.5, $p<0.001$). Quality of life and uroflowmetry parameters (Qmax) also improved significantly ($p<0.001$). Over 80% of patients reported satisfaction with treatment. While 64.8% responded to initial monotherapy, escalation to combination therapy in non-responders was highly effective. The adverse event profile was favorable. ***Conclusion:*** A stepwise medical management protocol for BPH significantly improves patient-reported symptoms, quality of life, and objective flow parameters. This approach is highly effective and well-tolerated in a tertiary care setting, with high patient satisfaction.

Keywords: Benign Prostatic Hyperplasia, BPH, IPSS, Irritative symptoms, Patient-reported outcomes, Quality of life.

INTRODUCTION

Benign Prostatic Hyperplasia (BPH) is a non-malignant, progressive enlargement of the prostate gland and represents one of the most common conditions affecting the aging male population globally [1]. Its clinical significance lies not in the histologic proliferation itself, but in its tendency to lead to Lower Urinary Tract Symptoms (LUTS), which can severely impair quality of life, sleep, and daily activities [2]. The prevalence of BPH rises dramatically with age, affecting approximately 50% of men by the age of 60 and nearly 90% by the ninth decade of life, making it a major public health concern with substantial socioeconomic implications [3, 4]. The pathophysiology of BPH is multifactorial, involving hormonal changes associated with aging, particularly the role of dihydrotestosterone (DHT), as well as cellular proliferation and stromal-epithelial interactions [5]. Clinically, this manifests as LUTS, which are categorized into obstructive (or voiding) symptoms, such as weak stream, hesitancy, and straining, and irritative (or storage) symptoms, including frequency, urgency, and nocturia [6]. The diagnosis and assessment of BPH and its related LUTS rely on a combination of patient-reported outcome measures, physical examination, and objective investigations. The International Prostate Symptom Score (IPSS) questionnaire, which includes a quality of life (QoL) index, is the internationally standardized tool for quantifying symptom severity and its impact on the patient's life [7]. This is complemented by digital rectal examination (DRE), measurement of prostate-specific antigen (PSA) to rule out malignancy and uroflowmetry to quantify urinary flow impairment [8] objectively. For the majority of patients with moderate to severe symptoms, medical management is the first-line treatment modality [9]. The current pharmacological arsenal primarily includes Alpha-1 Adrenergic Blockers (e.g., Tamsulosin, Silodosin), which relax the smooth muscle of the prostate and bladder neck to improve urine flow rapidly, and 5-Alpha Reductase Inhibitors (e.g., finasteride, Dutasteride), which reduce prostate volume by suppressing the conversion of testosterone to DHT, providing long-term control of disease progression [10]. In cases where storage symptoms predominate, anticholinergic medications or beta-3 agonists may be added to manage bladder overactivity [11]. While the efficacy of these medications is well-established in rigorous clinical trials, there is a growing recognition of the importance of evaluating their effectiveness in "real-world" clinical settings [12]. Patient-Reported Outcomes (PROs) have emerged as critical endpoints, as they capture the patient's direct experience of their health status and the treatment's impact on their daily life, beyond what purely objective parameters can measure [13]. Prospective studies monitoring PROs in routine tertiary care practice are vital for validating treatment guidelines and optimizing patient-centric care pathways. In Bangladesh, the burden of BPH is significant, yet there is a relative paucity of local prospective data on PROs following standardized medical therapy. Therefore, this study was designed to evaluate the changes in symptom severity and quality of life, using the IPSS and QoL index, in patients with BPH undergoing a structured, stepwise medical management protocol at a tertiary care hospital in Dhaka.

METHODOLOGY

Study population: This prospective interventional study was conducted at the Department of Urology, Bangabandhu Sheikh Mujib Medical University (BSMMU), from January 2020 to December 2021. A total of 105 male patients with symptomatic BPH were recruited for the study using a purposive sampling technique.

Inclusion criteria: Patients aged between 45 and 60 years, with a prostate size of 25-60 grams confirmed by trans-rectal ultrasound, a normal PSA level, and objective evidence of bladder outlet obstruction (maximum flow rate, Qmax <15 mL/sec and mean flow rate, Qmean <10 mL/sec on uroflowmetry) were included.

Exclusion criteria: Patients with a history of prostate surgery, prostate cancer, neurogenic bladder, significant renal impairment, or urethral stricture were excluded from the study. Those with a known hypersensitivity to the study medications were also not enrolled.

Study procedure: All enrolled patients were initiated on Tamsulosin 0.4 mg once daily. Treatment was escalated after 3 months to Silodosin 8 mg if symptoms did not improve, with Dutasteride 0.5 mg added for prostate volumes >35 grams. Bladder sedatives were prescribed for predominant irritative symptoms. Patient-reported outcomes were assessed using the International Prostate Symptom Score (IPSS) and Quality of Life (QoL) index at baseline and 3, 6, 9, and 12-month follow-ups.

Data analysis: The collected data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 23.0. Descriptive statistics were presented as means and standard deviations for continuous variables. Changes in IPSS and QoL scores over the follow-up periods were analyzed using appropriate statistical tests, with a p-value of <0.05 considered statistically significant.

RESULT

A total of 105 patients with a mean age of 52.4 ± 4.7 years were enrolled and completed the 12-month follow-up. The baseline characteristics revealed a mean prostate volume of 42.8 ± 9.5 grams and a mean Qmax of 10.2 ± 2.1 mL/sec, confirming moderate obstruction. The baseline mean total IPSS was 19.5 ± 3.8, indicating severe symptoms, with a corresponding mean QoL score of 3.5 ± 0.7. Following the intervention, a significant improvement in urinary symptoms was observed. The mean total IPSS showed a progressive and statistically significant decline from baseline to the 12-month follow-up. The voiding sub score improved more rapidly, while the storage sub score also demonstrated a significant reduction over time. The quality of life of the patients mirrored this improvement, with the mean QoL score decreasing significantly across all follow-up intervals. Objective uroflowmetry parameters corroborated the subjective patient reports. The maximum flow rate (Qmax) increased significantly from a baseline mean to the 12-month value. The post-void residual urine volume also showed a significant reduction throughout the study period. The treatment pathway analysis revealed that 68 patients (64.8%) responded adequately to Tamsulosin monotherapy. The remaining 37 patients (35.2%) required treatment escalation at the 3-month mark, with 25 of these patients receiving Silodosin + Dutasteride due to a prostate volume >35 grams. Both the monotherapy and combination therapy groups showed significant within-group improvements in total IPSS from baseline to 12 months, though the magnitude of improvement was greater in the combination group. Patient satisfaction at the endpoint of the study was high, with 82.9% of participants reporting being either satisfied or very satisfied with their treatment outcome. Only 4.8% reported being dissatisfied. The therapeutic regimen was well-tolerated, with a low incidence of adverse effects. The most commonly reported were retrograde ejaculation (14.3%) and dizziness (6.7%), with no serious adverse events leading to treatment discontinuation.

Table 1: Baseline characteristics of the study participants (N=105)

Characteristic	Mean ±SD / n (%)
Age (Years)	52.4 ± 4.7
Prostate volume (gm)	42.8 ± 9.5
Serum PSA (ng/mL)	1.8 ± 0.6
Qmax (mL/sec)	10.2 ± 2.1
Total IPSS	19.5 ± 3.8
IPSS voiding sub score	14.2 ± 2.9
IPSS storage sub score	7.3 ± 1.8
Quality of life (QoL) index	3.5 ± 0.7

Table 2: Change in IPSS and quality of life (QoL) scores over the study period

Assessment Point	Total IPSS	IPSS voiding	IPSS storage	QoL index
	(Mean ± SD)			
Baseline	19.5 ± 3.8	14.2 ± 2.9	7.3 ± 1.8	3.5 ± 0.7
3 Months	15.1 ± 3.2	9.5 ± 2.3	5.6 ± 1.4	3.2 ± 0.8
6 Months	11.4 ± 2.8	6.8 ± 1.9	4.6 ± 1.2	2.4 ± 0.7
12 Months	8.7 ± 2.5	4.9 ± 1.6	3.8 ± 1.1	1.8 ± 0.6
p-value	<0.001	<0.001	<0.001	<0.001

Table 3: Change in objective uroflowmetry parameters

Parameter	Baseline	6 Months	12 Months	p-value
	(Mean ± SD)			
Qmax (mL/sec)	10.2 ± 2.1	13.8 ± 2.5	16.5 ± 2.9	<0.001
Qmean (mL/sec)	5.8 ± 1.4	8.1 ± 1.7	9.9 ± 1.9	<0.001
PVR (mL)	85.5 ± 25.3	45.2 ± 18.7	25.8 ± 12.4	<0.001

Data analyzed by Repeated Measures ANOVA. PVR = Post-Void Residual Urine Volume

Table 4: Treatment pathways and response at 3 months

Treatment pathway	n (%)	Mean IPSS at 3 months (Mean ± SD)
Continued on tamsulosin monotherapy	68 (64.8%)	13.1 ± 2.5
Escalated to silodosin	12 (11.4%)	16.8 ± 1.9
Escalated to silodosin + dutasteride	25 (23.8%)	18.2 ± 2.1
Total	105 (100%)	15.1 ± 3.2

Table 5: Comparison of final efficacy between treatment groups

Treatment group	n	Baseline IPSS	12-Month IPSS	Mean change (Δ)	p-value
		(Mean ± SD)			(Within 6roup)
Tamsulosin monotherapy	68	20.1 ± 3.2	7.2 ± 1.8	-12.9	<0.001
Combination therapy	37	24.0 ± 3.5	9.5 ± 2.2	-14.5	<0.001

Combination Therapy includes patients on Silodosin or Silodosin +Dutasteride. Within-group p-values from Paired T-test

Table 6: Patient satisfaction and adverse effects at 12 months

Parameter	n	%
Treatment satisfaction		
Very satisfied	52	49.5
Satisfied	35	33.3
Neutral	13	12.4
Dissatisfied	5	4.8
Reported adverse effects		
Retrograde ejaculation	15	14.3
Dizziness	7	6.7
Dry mouth	4	3.8
No adverse effects	79	75.2

DISCUSSION

This prospective study demonstrates that a structured, stepwise medical management protocol for BPH results in significant and sustained improvements in both patient-reported symptoms and

objective uroflowmetry parameters over 12 months. The findings are consistent with the established efficacy of alpha-blockers and 5-alpha reductase inhibitors, but they uniquely highlight the outcomes within a real-world tertiary care setting in Bangladesh, providing valuable insights for clinical practice in similar healthcare contexts. The baseline characteristics of our cohort, with a mean total IPSS of 21.5, are indicative of a population suffering from severe LUTS [7]. The significant reduction in total IPSS to 8.7 at 12 months underscores the profound effectiveness of the medical regimen. This improvement is not only statistically significant but also clinically relevant, as it represents a shift from "severe" to "mild" symptom categories [14]. The parallel and marked improvement in the QoL index further reinforces the treatment's success, as the ultimate goal of BPH management is to enhance the patient's daily life and well-being [13]. Our findings align with large-scale trials, such as those of the MTOPS study, which confirmed the long-term benefits of medical therapy in preventing disease progression and improving symptoms [15]. The objective data from uroflowmetry provide robust corroboration for the subjective patient reports. The significant increase in Qmax from 10.2 mL/sec to 16.5 mL/sec objectively confirms the relief of bladder outlet obstruction achieved through treatment. This aligns with the known mechanism of action of alpha-blockers, which reduce dynamic obstruction by relaxing prostatic and bladder neck smooth muscle [10]. The reduction in post-void residual urine volume further indicates improved bladder emptying, reducing the risk of complications such as urinary tract infections [16]. A key finding of this study is the validation of the stepwise treatment approach. The fact that 64.8% of patients were successfully managed on Tamsulosin monotherapy highlights its efficacy as a first-line agent. For the 35.2% of patients who required therapy escalation, the addition of Silodosin or Dutasteride provided significant additional benefit, as evidenced by the substantial within-group improvement in their IPSS. This approach is both clinically pragmatic and cost-effective, allowing for tailored therapy based on individual patient response and prostate characteristics, a strategy supported by current guidelines [9,17]. The greater mean change in IPSS in the combination therapy group, despite their higher baseline severity, suggests that this escalation strategy is particularly effective for more advanced cases. The high patient satisfaction rate (82.9% satisfied or very satisfied) is a critical outcome measure. This high level of acceptance is likely multifactorial, stemming from effective symptom control, a clear management pathway, and the manageable nature of the observed adverse effects. The adverse effect profile was consistent with the known pharmacodynamics of the drugs used, with retrograde ejaculation being the most common. Yet, it did not lead to treatment discontinuation in any participant [18]. This study has some limitations. Its single-center design and purposive sampling may limit the generalizability of the findings. The absence of a control group and the relatively short 12-month follow-up period for a chronic condition like BPH are also acknowledged. Future studies with longer follow-up and randomized controlled designs are recommended to solidify these findings further. This study provides strong evidence that a stepwise medical management protocol for BPH, initiated with Tamsulosin and escalated based on clinical response, leads to significant improvements in symptom scores, objective flow parameters, and quality of life. The high patient satisfaction and favorable safety profile observed support the adoption of this patient-centric approach in tertiary care settings in Bangladesh and similar populations.

Limitations:

The main limitations of this study are its single-center design, relatively small sample size, and the use of purposive sampling, which may affect the generalizability of the findings to the broader population with BPH.

CONCLUSION

This study demonstrates that a structured, stepwise protocol for the medical management of BPH, initiated with Tamsulosin and escalated to silodosin or tamsulosin + dutasteride/finasteride or tadalafil + dutasteride/finasteride based on clinical response, is highly effective in a real-world tertiary care setting. The strategy resulted in statistically significant and clinically meaningful improvements in

patient-reported symptoms, quality of life, and objective uroflowmetry parameters over 12 months, with a high satisfaction rate and a favorable safety profile.

Recommendation:

This effective stepwise protocol should be integrated into standard clinical practice for BPH management in similar tertiary care settings. Future research should focus on long-term outcomes and explore the possibility of avoiding surgery in the management of BPH.

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