WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 14, Issue 19, 1202-1216. Research Article ISSN 2277–7105

COMPARATIVE EFFICACY AND SAFETY STUDY OF FINASTERIDE VERSUS DUTASTERIDE, IN ADDITION TO TADALAFIL, IN THE TREATMENT OF LOWER URINARY TRACT SYMPTOMS DUE TO BENIGN PROSTATIC HYPERPLASIA

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Article Received on
20 August 2025,

Revised on 10 Sept. 2025,
Accepted on 01 Oct. 2025

https://doi.org/10.5281/zenodo.17278212

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ABSTRACT

Background: Tadalafil is approved globally for the treatment of erectile dysfunction, the signs and symptoms of benign prostate hyperplasia with lower urinary tract symptoms (BPH-LUTS). Coadministration of tadalafil 5 mg with a 5α-reductase inhibitor, i.e., finasteride/dutasteride, leads to statistically significant improvements in total International Prostate Symptom Scores as early as 1 to 2 weeks after beginning therapy. **Aim:** To compare the efficacy and safety of finasteride versus dutasteride when in combination with tadalafil in the treatment of LUTS because of BPH. **Methods:** This was a randomised controlled trial conducted over one year in which the eligible patients were randomised in a 1:1 ratio to either of the 2 study arms: Tadalafil 5 mg plus finasteride or Tadalafil 5 mg plus dutasteride, for 8 weeks. The primary endpoint was a decrease in total International Prostate Symptom Score (IPSS-T) at 4 and 8 weeks from baseline. Secondary endpoints included (i) change in IPSS Quality of Life Index score ; (ii) change in IPSS storage sub score; (iii) change in IPSS voiding sub score; (iv) decrease in prostate volume; and (v) decrease in post-void residual volume**. Results:** Of the 55 patients screened, 25 were enrolled in each group, and 20 patients in each group were available for final analysis. At baseline, both groups were comparable. The tadalafil/finasteride group exhibited a statistically significantly greater reduction in IPSS-T (10.55±1.98 vs 12.3±1.38; $p < 0.05$), IPSS-V (6.05±1.35 vs 7.15±1.59; $p<0.05$), and post-void residual volume (111±10.77 vs 118.75±13.17; $p<0.05$) at 8 weeks compared to the tadalafil/dutasteride group. There was

also a greater improvement in QoL with the tadalafil/finasteride group (overall change in IPSS-QoL: 2.8±0.52 in tadalafil/finasteride vs 3.2±0.41 in tadalafil/dutasteride group; $p<0.05$). No major adverse events were reported in the two groups. **Conclusion:** The study shows tadalafil plus finasteride or tadalafil plus dutasteride therapy was both safe and effective in patients with LUTS because of BPH. A statistically significantly better response was observed with tadalafil plus finasteride. Therefore, tadalafil plus finasteride is the better choice in comparison to tadalafil plus dutasteride in the treatment of LUTS because of BPH.

KEYWORDS: Tadalafil, finasteride, dutasteride, BPH, PDE-5 inhibitor, International Prostate Symptom Score, prostate volume, post-void residual volume.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a clinical entity defined by urinary symptoms caused by increased stromal and epithelial cells in the transitional zone surrounding the urethra, resulting in urethral pathway narrowing and bladder outlet obstruction (BOO), as well as secondary bladder changes that promote over- or under detrusor muscle activity, resulting in lower urinary tract symptoms (LUTS).[1] Mild LUTS were present in 60% of men with symptomatic BPH at the time of diagnosis. BPH and LUTS are expected to become more prevalent as individuals live longer and use screening and diagnostic technology more frequently.[3] The symptoms of LUTS linked to BPH, such as urgency, nocturia, diminished and intermittent force of stream, and the feeling that the bladder is not emptying, are nonspecific. However, BOO is the most frequent cause of LUTS and can happen in two ways. First, an excess of prostate tissue blocks the urinary flow. Second, the number and tone of prostatic smooth muscle cells increase, making the urethra more resistant to urine flow.[2]

In addition to having a detrimental impact on quality of life metrics, LUTS can result in storage symptoms, e.g., increased frequency, urgency, or incontinence, and voiding symptoms, e.g., slow, inconsistent urine flow or straining.[3] LUTS is measured using the International Prostate Symptom Score (IPSS), where mild symptoms are scored 0–7, moderate symptoms are scored 8–19, and severe symptoms are scored 20–35.[3] A rise in LUTS over time is indicative of BPH progression, and in certain men, and acute urine retention (AUR) may develop, necessitating surgical intervention such as transurethral resection of the prostate (TURP).[2]

Pharmacotherapy of BPH includes antimuscarinic drugs, 5α-reductase inhibitors (5-ARIs), α1-adrenoreceptor antagonists, phosphodiesterase-5 inhibitors (PDE5-Is), and vasopressin analogues.[4]

Alpha-adrenergic antagonists treat LUTS by lowering smooth muscle tone in the neck of the bladder and prostate. Alpha-adrenergic blockers have been shown to improve urine flow rates, quality of life, and scores for obstructive and irritative symptoms. Still, they do not lower the risk of AUR or the requirement for surgery associated with BPH. Common adverse effects include nasal congestion, orthostatic hypotension, dizziness, exhaustion, and retrograde ejaculation.[4]

In men with LUTS and enlarged prostates >30 ml, 5-ARI use has been demonstrated to significantly improve symptoms, increase urinary flow rate, reduce the risk of AUR, and reduce the need for BPH-surgery.[5]

According to the LUTS treatment guidelines, it is common and advised to combine therapy with fast-acting drugs that have been approved for the treatment of LUTS, such as alpha-blockers (e.g., terazosin, tamsulosin), to achieve quicker symptom relief.[3]

The goals of BPH treatment are to eliminate symptoms, improve quality of life, lower BOO, lower post-void residual volume, treat renal insufficiency and urine retention when they occur, and prevent the disease from getting worse.[2]

The number of persons LUTS because of BPH is rising at an alarming rate all over the world, especially in low- and middle-income countries. Medical therapy for the treatment of LUTS in men with significant prostatic enlargement frequently begins with either an α-blocker or finasteride/dutasteride; however, improvements in LUTS with these monotherapies are gradual, and significant improvement in LUTS is typically not observed until 6 to 12 months of therapy, and sexual adverse effects are common. With finasteride/dutasteride and tamsulosin (α-blocker) coadministration, adverse effects related to sexual or ejaculatory dysfunction appear to increase. Due to these side effects, newer approaches for treating BPH are being studied.

Tadalafil is the only PDE5-I approved globally for daily use to treat men with ED, LUTS because of BPH, and men with both disorders. Coadministration of tadalafil 5 mg with a 5α-reductase inhibitor, i.e., finasteride/dutasteride, leads to statistically significant improvements

in IPSS total scores as early as 1 to 2 weeks after beginning therapy. Thus, it has a rapid onset of action, and it also lacks adverse sexual side effects.[3]

The literature search revealed that no studies directly compared the IPSS-T, IPSS-V, IPSS-S, post-void residual volume, and prostate volumes in groups treated with tadalafil + finasteride versus tadalafil + dutasteride for the treatment of LUTS due to BPH.

MATERIALS AND METHODS

The study was conducted in the Department of Pharmacology in collaboration with the Department of Urology, Pt. B. D. Sharma PGIMS, Rohtak, on 40 patients. All patients who participated in the study received complete information about the survey and provided their consent after being fully informed of the details. This study was conducted in accordance with the principles of Good Clinical Practice (GCP) and the Declaration of Helsinki. Ethical clearance was obtained from the Institutional Ethics Committee (IEC) vide office order no. CTRI/2023/08/056028 before starting the study.

STUDY POPULATION

Patients presenting in the outpatient clinic of the Department of Urology were recruited according to the following inclusion and exclusion criteria and randomly divided into two groups, i.e., group A and group B, using computer-generated random numbers. A sufficient number of patients were recruited for the study. Patients were assessed according to the protocol and 20 patients in each group completed the study.

SELECTION CRITERIA

Inclusion criteria: Patients above 65 years of age, history of lower urinary tract symptoms/benign prostatic hyperplasia for the last 6 months, International Prostate Symptom Score $\geq$ 13, prostate volume $\geq$ 30 ml.

Exclusion criteria: Patients having hypertension, coronary artery disease, cardiac arrhythmias, or patients diagnosed as a case of carcinoma prostate, or patients with hepatic function impairment.

STUDY METHODOLOGY

Enrolled patients were informed about the study through a patient information sheet, and written informed consent was obtained from all the patients. The details of all the participants were recorded in the Case Record Form (CRF). On day 1 of the study, all subjects underwent

a general physical examination, including pulse rate, blood pressure, ECG, LFT, and an ultrasound examination of the prostate gland. Patients underwent follow-up at 4 and 8 weeks of the study.

TREATMENT INTERVENTION

The participant patient groups got medication once daily in the morning for eight weeks.

Group A- Tablet finasteride 5mg plus tablet tadalafil 5 mg;

Group B- Tablet dutasteride 0.5 mg plus tablet tadalafil 5 mg.

ASSESSMENT

Assessment of Effect

International Prostate Symptom Score-total (IPSS-T) and voiding (IPSS-V) and storage sub-score (IPSS-S): At 0 week, 4 weeks, and 8 weeks

IPSS is based on the responses to seven questions about urinary symptoms and one question about the quality of life. The patient may select one of 6 options (0–5) for each question about LUTS, with each option denoting a higher severity of the associated symptom. Thus, the total IPSS score can range from 0 to 35. (from asymptomatic to very symptomatic).

The IPSS can be broken down into the IPSS voiding sub-score (IPSS-V) and the IPSS storage sub-score (IPSS-S). The IPSS-V is the total of the answers to questions 1 (incomplete emptying), 3, 5 (weak stream), and 6 (straining to void). By contrast, the IPSS-S is the sum of the answers to questions 2 (frequency), 4 (urgency), and 7 (nocturia). The IPSS sub-scores can be used to measure the severity of symptoms or the effectiveness of treatment.

Prostate Volume: At 0 week, 4 weeks, and 8 weeks

Prostate volume is a crucial parameter in the diagnosis of BPH, which was evaluated using ultrasound. Patients with prostate volumes greater than 30 mL were enrolled in the study, and the decrease in prostatic volume was assessed at weeks 4 and 8.

Post-void residual volume (PVR): At 0 weeks, 4 weeks, and 8 weeks

In older individuals, a PVR volume of 50 mL to 100 mL is considered normal. PVR more than 200 mL is abnormal due to incomplete bladder emptying or bladder outlet obstruction. PVR volume was measured at weeks 0, 4, and 8 using ultrasound.

International Prostate Symptom Score-Quality of life (IPSS-QoL): At 0 week, 4 weeks and 8 weeks

To evaluate QoL, the International Scientific Committee (ISC), supported by the WHO and the International Union Against Cancer (UICC), suggests using just one question from the 0 to 6 QoL score of the IPSS (ranging from "delighted" to "terrible").

Safety assessment

A safety assessment was conducted in groups A and B throughout the study by recording any adverse effects of the treatment intervention. The patients were instructed to report any serious side effects immediately.

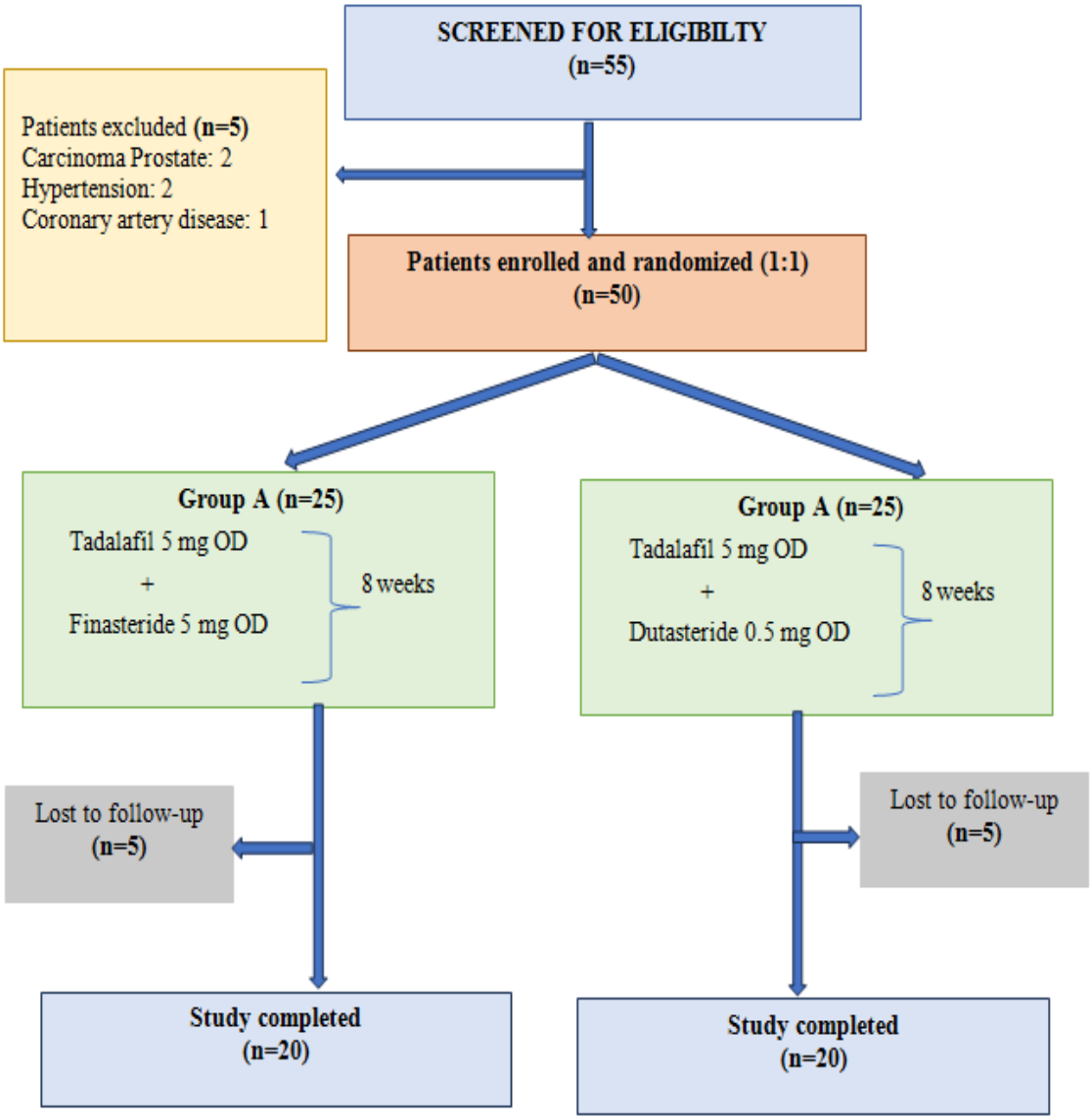
The adverse effects of all treatments were recorded in the adverse drug monitoring proforma, based on the known adverse effects of the study medications, along with provision for recording any new adverse effects that may arise. The Pharmacovigilance Programme of India (PvPI) form was used and filled as and when an ADR was reported, and subsequently uploaded to the WHO-UMC database using the Vigi Flow software. Any dropout from the study because of adverse drug effects was noted.

STATISTICAL ANALYSIS

Data was tabulated in a Microsoft Excel Sheet and was expressed as mean ± SEM. Both intergroup and intragroup analyses were done. The intergroup analysis was done using ANOVA, and the intragroup analysis was done using a paired t-test. All the statistical analyses were performed using SPSS version 20.0 software. A p-value of < 0.05 was considered statistically significant.

FLOW CHART OF THE STUDY

ENROLLMENT OF THE STUDY POPULATION



OBSERVATIONS

The mean age of the patients (in years) in Group A was 67.15 ± 1.77, and in Group B was **66.3 ± 1.86**, and were comparable. In Group A, the mean pulse rate was 77.5 ± 4.43, and in Group B, it was **79.5± 3.3**. The mean systolic BP (mm Hg) was **126.5 ± 4.97** and **126.8 ± 4.69** in Groups A and B, respectively. Likewise, the diastolic BP (mm Hg) was **78.8 ± 3.07** and **79.2 ± 1.76** in both groups, respectively. All the above-mentioned parameters were comparable.

Table 1: Baseline characteristics of study population.

Variables	**Group A** Finasteride 5 mg + Tadalafil 5 mg **(n=20)**	**Group B** Dutasteride 0.5 mg + Tadalafil 5 mg **(n=20)**
	Mean ±SD	**Mean ±SD**
International Prostate Symptom Score total - **IPSS- T**	19.35 ± 2.94	18.65 ± 2.13
International Prostate Symptom Score Quality of life - **IPSS QoL**	4.6 ±0.75	4.25 ± 0.63
International Prostate Symptom Score storage sub-score - **IPSS-S**	8.25 ± 1.4	8.3 ± 1.45
International Prostate Symptom Score voiding sub-score - **IPSS- V**	11.1 ± 2.02	10.35 ± 1.26
Prostate volume - **PV (ml)**	37.85 ± 3.15	36.15 ± 3.51
Post-void residual volume -**PVR (ml)**	152.55 ± 17.78	147.35 ± 15.52

There was no statistically significant difference **(p>0.05)** in any of the baseline parameters in the two groups.

Table no. 2: Comparison of mean Total International Prostate Symptom Score (IPSS-T) between the two groups.

Total International Prostate Symptom Score (IPSS-T)	**Mean ± SD**		**p-value**
	Group A (n=20)	**Group B (n=20)**	
Baseline	19.35 ± 2.94	18.65 ± 2.13	0.395
4 weeks	15.05 ± 2.16	15.8 ± 1.64	0.224
8 weeks	10.55 ± 1.98	12.3 ± 1.38	0.003
p-value (Intra-group)	<0.001	<0.001	

Mean ± SD of IPSS-T at baseline, week 4, and week 8 in group A were **19.35 ± 2.94, 15.05 ± 2.16,** and **10.55 ± 1.98,** and in group B were **18.65 ± 2.13, 15.8 ± 1.64**, and **12.3 ± 1.38,** respectively, with a significant difference at week 8 between them (Table 2).

As shown in Table 2, no significant difference was seen in IPSS-T at week 4 of the study period (p-value = 0.224) between groups A and B. However, at week 8 of the study, the difference in scores was statistically significant between the two groups (p-value = 0.003).

Both groups showed significant improvement in their IPSS-T scores over time ($p < 0.001$ for both groups).

Table 3: Comparison of mean IPSS-QoL between the two groups.

	Mean ± SD		p-value
	Group A (n=20)	Group B (n=20)	
Baseline	4.6 ±0.75	4.25 ± 0.63	0.121
4 weeks	3.7 ± 0.57	3.8 ± 0.52	0.567
8 weeks	2.8 ± 0.52	3.2 ± 0.41	0.011
p-value (Intra-group)	<0.001	<0.001	

Mean ± SD of IPSS QoL at baseline, week 4, and week 8 in group A were **4.6 ±0.75, 3.7 ± 0.57,** and **2.8 ± 0.52,** and in group B were **4.25 ± 0.63, 3.8 ± 0.52**, and **3.2 ± 0.41,** respectively, with a significant difference at week 8 between them (Table 3). Both groups showed significant improvement in their IPSS QoL scores over time ($p < 0.001$ for both groups).

No significant difference was observed in the IPSS QoL at week 4 of the study period (p-value = 0.567) between groups A and B, as shown in Table 3. Whereas at week 8 of the study, the difference in scores was statistically significant between the groups (p-value = 0.011).

Table 4: Comparison of mean IPSS-S between the two groups.

IPSS-S	Mean ± SD		p-value
	Group A (n=20)	Group B (n=20)	
Baseline	8.25 ± 1.4	8.3 ± 1.45	0.913
4 weeks	6.5 ± 1.14	6.8 ± 1.28	0.440
8 weeks	4.5 ± 1.14	5.2 ± 1.1	0.057
p-value (Intra-group)	<0.001	<0.001	

Mean ± SD of IPSS storage sub score at baseline, week 4, and week 8 in group A were **8.25 ± 1.4, 6.5 ± 1.14**, and **4.5 ± 1.14,** and in group B were **8.3 ± 1.45, 6.8 ± 1.28**, and **5.2 ± 1.1,** with no significant difference between the two groups (Table 4). Both groups showed significant improvement in their IPSS-S scores over time ($p < 0.001$ for both groups).

No significant difference was seen in the IPSS storage sub-score at week 4 (p-value = 0.440) and week 8 (p-value = 0.057) of the study period between groups A and B (Table 4).

Table 5: Comparison of mean IPSS-V between the two groups.

IPSS-V	Mean ± SD		p-value
	Group A (n=20)	Group B (n=20)	
Baseline	11.1 ± 2.02	10.35 ± 1.26	0.168
4 weeks	8.55 ± 1.39	9 ± 1.25	0.290
8 weeks	6.05 ± 1.35	7.15 ± 1.59	0.024
p-value (Intra-group)	<0.001	<0.001	

Mean ± SD of IPSS voiding sub score (IPSS-V) at baseline, week 4, and week 8 in group A were **11.1 ± 2.02, 8.55 ± 1.39**, and **6.05 ± 1.35,** and in group B were **10.35 ± 1.26, 9 ± 1.25** and **7.15 ± 1.59,** respectively, with a significant difference at week 8 between them (Table 5). Both groups showed significant improvement in their IPSS-V scores over time ($p < 0.001$ for both groups).

As shown in Table 5, no significant difference was observed in the IPSS voiding sub-score at week 4 of the study period (p-value = 0.290) between groups A and B. In contrast, by week 8 of the study, the difference in scores between the groups was statistically significant (p-value = 0.024).

Table 6: Comparison of mean prostate volume between the two groups.

Prostate volume (mL)	Mean ± SD		p-value
	Group A (n=20)	Group B (n=20)	
Baseline	37.85 ± 3.15	36.15 ± 3.51	0.115
4 weeks	34.25 ± 3.14	33.55 ± 3.39	0.503
8 weeks	30.15± 3.31	30.4 ± 3.25	0.811
p-value (Intra-group)	<0.001	<0.001	

Mean ± SD of prostate volume at baseline, week 4, and week 8 in group A were **37.85 ± 3.15, 34.25 ± 3.14,** and **30.15± 3.31**, and in group B were 36.15 ± 3.51, 33.55 ± 3.39, and 30.4 ± 3.25, respectively, with no significant difference between the groups (Table 6). Both groups showed significant reductions in prostate volume over time ($p < 0.001$ for both groups).

No significant difference was seen in prostate volume at week 4 (p-value = 0.503) and week 8 (p-value = 0.811) of the study period between groups A and B (Table 6).

Table 7: Comparison of mean post-void residual volume (PVR) between the two groups.

PVR (mL)	Mean ± SD		p-value
	Group A (n=20)	Group B (n=20)	
Baseline	152.55 ± 17.78	147.35 ± 15.52	0.331
4 weeks	131.8 ± 14	132.95 ± 13.47	0.793
8 weeks	111 ± 10.77	118.75 ± 13.17	0.049
p-value (Intra-group)	<0.001	<0.001	

Mean ± SD of PVR baseline, week 4, and week 8 in group A were **152.55 ± 17.78, 131.8 ± 14,** and **111 ± 10.77,** and in group B were **147.35 ± 15.52, 132.95 ± 13.47,** and **118.75 ± 13.17,** respectively, with a significant difference at week 8 between them (Table 7). Both

groups, however, showed substantial reductions in post-void residual volume over time ($p < 0.001$ for both groups).

No significant difference was seen in PVR volume at week 4 of the study period (p-value = 0.793) between groups A and B (Table 7). Whereas at week 8 of the study, the difference in scores was statistically significant between the groups (p-value = 0.049).

Five (25%) patients in the tadalafil plus finasteride group and six (30%) patients in the tadalafil plus dutasteride group reported some ADRs, respectively. The ADRs reported were headache, backache, and nasal congestion in both groups. All the ADRs were only of a mild grade. The causality assessment of all the reported ADRs was possible. In this study, no patient in either of the study groups had severe ADRs, i.e., initial/prolonged disability or life-threatening ADRs.

DISCUSSION

The present study was conducted in patients above 65 years of age with BPH for the last 6 months, with an IPSS score of> 13, and was divided into two groups. Group A received tadalafil and finasteride, while Group B received tadalafil and dutasteride. Following the baseline assessment, patients were monitored for the following parameters at 4 and 8 weeks: the primary endpoint, which included a decrease in the IPSS-T, and the secondary endpoints, which included a reduction in the IPSS-QoL, IPSS-S, IPSS-V, prostate volume, and post-void residual volume. Safety assessments were conducted in both groups throughout the study.

In this study, no significant difference was seen in total IPSS at week 4 of the study period (p-value = 0.224) between groups A and B. However, at week 8 of the study, the difference in scores was statistically significant between the groups (p-value = 0.003).

In a study by Porst et al. (2011) involving a population of 325, once-daily tadalafil significantly improved BPH-LUTS compared to placebo, as measured by total IPSS and the IPSS storage and voiding subscores, and it improved the IPSS-QoL index. Tadalafil significantly improved the International Index of Erectile Function-Erectile score in sexually active males with erectile dysfunction.[12]

Tadalafil + finasteride (TAD/FIN) improved LUTS in men with prostatic enlargement secondary to BPH as measured by improvements (compared with placebo + finasteride) in IPSS total scores, IPSS voiding and storage sub-scores, and IPSS-QoL in a randomised,

double-masked, placebo-controlled study on 695 men for 6 months by Casabé et al. (2014).[8] In the current study, no significant difference was observed in the IPSS QoL at week 4 of the study period (p-value = 0.567) between groups A and B. However, at week 8 of the study, the difference in scores was statistically significant between the groups (p-value = 0.011). Gotoh D et al. (2022) conducted a study to evaluate the efficacy and safety of add-on therapy with tadalafil in Japanese men with LUTS due to BPH treated with dutasteride, in which a total of 24 patients were enrolled. At 12 weeks, there was a significant improvement in the OABSS and sexual health inventory for men (SHIM), which persisted for 24 weeks.[9]

According to a recent study by Roehrborn et al. (2015) on 742 men to evaluate the efficacy and safety of a fixed-dose combination (FDC) of dutasteride and tamsulosin treatment compared with watchful waiting, with initiation of tamsulosin therapy if symptoms do not improve, FDC had a substantially larger change in IPSS at 24 months compared to watchful waiting.[2]

In a study by Basiri A. et al (2024), 165 men were randomised into five groups (each N = 33): receiving tamsulosin 0.4mg plus either of A: finasteride 3mg, B: placebo, C: dutasteride 0.25mg, D: finasteride 5mg or E: dutasteride 0.5mg for 6 months. Differences in IPSS change were observed between treatments at the first, third, and sixth months. Bonferroni corrections revealed that groups C, D, and E had significantly higher IPSS reductions than the control group B at months 1,3, and 6.[10]

In the present study, no significant difference was observed in the IPSS voiding sub-score at week 4 of the study period (p-value = 0.290) between groups A and B. However, at week 8 of the study, the difference in scores was statistically significant between the groups (p-value = 0.024). A 6-month, randomised, double-masked study comparing finasteride plus tadalafil with finasteride plus placebo by Roehrborn et al. (2015) on 695 subjects was conducted to assess treatment satisfaction and clinically meaningful symptom improvement in men with lower urinary tract symptoms and prostatic enlargement secondary to benign prostatic hyperplasia. In the study, at week 26, treatment satisfaction with tadalafil/finasteride was significantly higher than with placebo/finasteride, as indicated by the total treatment satisfaction scale score (p value = 0.031) and the satisfaction with efficacy subscore.[3]

The current study showed no significant difference in prostate volume at week 4 (p-value = 0.503) and week 8 (p-value = 0.811) of the study period between groups A and B. Nickel JC

et al. (2011) conducted the Enlarged Prostate International Comparator Study (EPICS) on 1630 men to assess the efficacy and safety of dutasteride compared with finasteride for treating benign prostatic hyperplasia:). Both dutasteride and finasteride were effective in reducing prostate volume, with no significant difference between the two treatments.[7]

In this study, no significant difference was seen in total IPSS at week 4 of the study period (p-value = 0.793) between groups A and B. However, at week 8 of the study, the difference in scores was statistically significant between the groups (p-value = 0.049). Tak et al. (2019) evaluated the effectiveness of tadalafil 5 mg with dutasteride 0.5 mg and tadalafil 5 mg with placebo for LUTS secondary to BPH over 6 months in a prospective, double-masked, randomised, placebo-controlled study involving 30 men. IPSS and Uroflow at 24 weeks showed statistically significant improvement for the dutasteride plus tadalafil arm compared to the tadalafil plus placebo arm ($p<0.05$).[11] The findings in the present study were consistent with the studies mentioned above.

In both groups, mild-grade headache, backache, and nasal congestion were the ADRs that were reported, requiring no treatment discontinuation.

CONCLUSIONS

In this study, tadalafil plus finasteride therapy and tadalafil plus dutasteride therapy were both safe and effective in patients with LUTS because of benign prostatic hyperplasia. Both combination therapies improved various efficacy parameters and the quality of life of patients. However, a better treatment response was observed with tadalafil plus finasteride, as patients depicted better response in the IPSS, prostate volume, post-void residual volume, and quality of life index. Therefore, according to the present study, tadalafil plus finasteride is a better choice than tadalafil plus dutasteride in the treatment of LUTS associated with BPH.

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