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Evaluation of Tamsulosin–Tadalafil combination therapy versus tamsulosin monotherapy in men with benign prostatic hyperplasia: A prospective comparative study

Chandan Gumra[1*], Gurpreet Singh Bhangu[2], Rachhpal Singh[2], Prabhjot Kaur Gill[3]
[1] Junior Resident, Department of Surgery, SGRDIMSR, Sri Guru Ram Das University of Health Sciences, Punjab, India
[2] Professor, Department of Surgery, SGRDIMSR, Sri Guru Ram Das University of Health Sciences, Punjab, India
[3] Professor, Centre for Advanced Research and Development, Department of Genetics, SGRDIMSR, Sri Guru Ram Das University of Health Sciences, Punjab, India
Corresponding Author: Chandan Gumra
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Abstract
Aim: To compare the efficacy and safety of Tamsulosin–Tadalafil combination therapy with Tamsulosin monotherapy in patients with symptomatic BPH.
Study design: A comparative prospective study
Place and duration of study: This hospital-based comparative prospective study was conducted in the Department of Surgery at SGRDIMSR tertiary care teaching hospital, Amritsar from July 2024 to December 2025.
Methodology: In this prospective comparative study, 150 men with BPH were assigned to either Tamsulosin–Tadalafil combination therapy or Tamsulosin monotherapy (75 patients per group). Treatment efficacy was evaluated using IPSS, Qmax, and PVRU over a 30-day follow-up period, along with safety and quality-of-life assessments.
Results: Baseline demographic and clinical characteristics were comparable between the groups. By Day 30, the combination therapy group demonstrated significantly greater improvement in all outcome measures. Mean IPSS decreased from 22.77±3.53 to 12.26±2.40 compared with 22.86±3.62 to 16.74±2.80 in the monotherapy group ($p<0.001$). Qmax increased from 9.75±1.62 to 13.96±1.58 mL/s versus 9.48±1.77 to 11.78±1.81 mL/s ($p<0.001$). PVRU decreased from 94.10±27.34 to 50.68±19.33 mL compared with 97.09±30.50 to 70.25±26.37 mL ($p<0.001$). Percentage improvement was significantly greater with combination therapy for IPSS (46.16% vs. 26.77%), Qmax (43.18% vs. 24.26%), and PVRU (46.14% vs. 27.64%) (all $p<0.001$). Adverse events were mild and comparable between groups. QoL scores were significantly better in the combination therapy group (1.8 vs. 2.6; $p=0.001$).
Conclusion: Tamsulosin–Tadalafil combination therapy provides significantly greater symptomatic and functional improvement than Tamsulosin monotherapy in men with BPH, without a meaningful increase in adverse effects. The combination regimen represents an effective and well-tolerated treatment option for patients with moderate-to-severe LUTS secondary to BPH.

Keywords: Benign prostatic hyperplasia, lower urinary tract symptoms, Tamsulosin, Tadalafil, uroflowmetry, postvoid residual urine

Introduction

Benign prostatic hyperplasia (BPH) is one of the most common urological disorders affecting aging men and represents a major cause of lower urinary tract symptoms (LUTS). It is characterized by non-malignant enlargement of the prostate gland, predominantly involving the transitional and periurethral zones of the prostate [1, 2]. The prevalence of BPH increases progressively with age, affecting approximately 50% of men in their fifth decade and up to 80% of men older than 80 years. Recent global estimates have suggested that more than 94 million men were affected by BPH in 2021, highlighting its substantial public health burden worldwide [3].

The pathophysiology of BPH-related LUTS is multifactorial and involves both static and dynamic components of bladder outlet obstruction. The static component results from prostatic enlargement, whereas the dynamic component is mediated by increased smooth muscle tone within the prostate and bladder neck through α1-adrenergic receptor stimulation [1]. Hormonal factors, particularly the conversion of testosterone to dihydrotestosterone (DHT), play a critical role in prostatic stromal and epithelial proliferation [4]. Persistent bladder outlet obstruction may subsequently lead to detrusor hypertrophy, impaired bladder compliance, recurrent urinary tract infections, acute urinary retention, and deterioration of renal function [2, 5, 6].

Current medical management primarily aims to alleviate LUTS, improve urinary flow, and prevent disease progression. Alpha-1 adrenergic receptor antagonists such as tamsulosin are widely used because they provide rapid symptomatic relief through relaxation of smooth muscle in the prostate and bladder neck. However, many patients continue to experience residual symptoms despite treatment. Furthermore, erectile dysfunction frequently coexists with LUTS in men with BPH, creating an additional therapeutic challenge that may not be adequately addressed by conventional monotherapy [7].

Phosphodiesterase type-5 (PDE5) inhibitors have emerged as a valuable therapeutic option in the management of LUTS associated with BPH. Tadalafil, the only PDE5 inhibitor approved for this indication, enhances nitric oxide-mediated cyclic guanosine monophosphate (cGMP) signalling, resulting in smooth muscle relaxation, improved pelvic perfusion, and modulation of lower urinary tract

function. The combination of tamsulosin and tadalafil offers a complementary mechanism of action whereby tamsulosin reduces adrenergic-mediated outlet resistance while tadalafil improves smooth muscle relaxation through the NO-cGMP pathway [8]. Clinical studies have demonstrated that combination therapy can produce greater improvements in International Prostate Symptom Score (IPSS), maximum urinary flow rate (Qmax), and quality-of-life measures compared with monotherapy [9, 10].

Kim *et al*. [11] reported that fixed-dose combination therapy with tamsulosin and tadalafil significantly improved LUTS and urinary flow parameters while maintaining an acceptable safety profile. Similarly, Zhou *et al*. [12] in a systematic review and meta-analysis, concluded that the combination of tadalafil and tamsulosin was superior to tamsulosin alone in improving symptom scores and objective urinary outcomes among men with BPH-related LUTS.

Despite encouraging evidence from international studies, data regarding the effectiveness of this therapeutic strategy in routine clinical practice within the Indian population remain limited. Variations in demographic characteristics, healthcare accessibility, lifestyle factors, and disease presentation may influence treatment outcomes. Therefore, the present study was undertaken to compare the efficacy of tamsulosin monotherapy with tamsulosin–tadalafil combination therapy in patients with benign prostatic hyperplasia using both subjective and objective outcome measures, including the International Prostate Symptom Score (IPSS), maximum urinary flow rate (Qmax), and post-void residual urine volume (PVRU).

Materials and Methods

Study Design and Setting

This prospective comparative observational study was conducted in the Department of General Surgery, Sri Guru Ram Das Institute of Medical Sciences and Research (SGRDIMSR), Amritsar, Punjab, India, over a period of 18 months from July 2024 to December 2025. The study was designed to compare the efficacy of combination therapy with Tamsulosin and Tadalafil versus Tamsulosin monotherapy in patients diagnosed with benign prostatic hyperplasia (BPH).

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee of Sri Guru Ram Das Institute of Medical Sciences and Research (Approval No. SGRD/IEC/2024-311). Written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

Study Population and Participant Selection

Male patients presenting to the outpatient and inpatient surgical services with clinical features suggestive of benign prostatic hyperplasia were screened for eligibility. Consecutive eligible patients meeting the inclusion criteria during the study period were recruited until the desired sample size was achieved.

A total of 150 patients were enrolled and allocated into two treatment groups:

Group 1 (Combination Therapy Group, n=75): Patients received Tamsulosin 0.4 mg once daily in combination with Tadalafil 5 mg once daily.

Group 2 (Monotherapy Group, n=75): Patients received Tamsulosin 0.4 mg once daily.

Inclusion Criteria: Male patients aged ≥50 years, clinically diagnosed benign prostatic hyperplasia, Prostate volume less than 45 g as determined by ultrasonography, Presence of lower urinary tract symptoms attributable to BPH, Willingness to participate and provide written informed consent.

Exclusion Criteria: Prostate volume greater than 45 g, History or clinical evidence of prostatitis, Suspected or confirmed carcinoma of the prostate, Previous prostate surgery, Neurogenic bladder dysfunction, Urethral stricture disease, Active urinary tract infection, Patients receiving medications that could significantly influence urinary symptoms.

Clinical Assessment and Follow-Up

At baseline, demographic and clinical information including age, symptom duration, prostate volume, and relevant medical history were recorded. All participants underwent a detailed physical examination and standard urological evaluation.

Symptom severity was assessed using the International Prostate Symptom Score (IPSS). Objective evaluation included measurement of maximum urinary flow rate (Qmax) using uroflowmetry and post-void residual urine volume (PVRU) using ultrasonography.

Participants were followed up at 15 days and 30 days after initiation of therapy. The following outcome measures were recorded at each visit:

1. International Prostate Symptom Score (IPSS)
2. Maximum urinary flow rate (Qmax, mL/s)
3. Post-void residual urine volume (PVRU, mL)
4. Adverse drug reactions and treatment tolerability
5. Quality-of-life assessment

Outcome Measures

The primary outcome was the change in International Prostate Symptom Score (IPSS) from baseline to Day 30.

Secondary outcomes included:

1. Change in maximum urinary flow rate (Qmax)
2. Change in post-void residual urine volume (PVRU)
3. Incidence of adverse events
4. Patient-reported quality-of-life improvement

Bias Control

To minimize selection bias, all eligible consecutive patients presenting during the study period were considered for enrolment. Baseline demographic and clinical characteristics were compared between groups to ensure comparability. Standardized assessment tools and measurement techniques were used throughout the study.

Sample Size

A convenience sampling technique was employed for participant recruitment. All consecutive eligible patients who fulfilled the inclusion criteria and provided written informed consent were recruited during the study period. A

total of 150 eligible patients were enrolled and allocated into two treatment groups comprising 75 participants each. The sample size was determined by the number of patients presenting to the study center during the study period who met the predefined inclusion and exclusion criteria and required medical management for benign prostatic hyperplasia.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages.

Normality of data distribution was assessed using the Shapiro–Wilk test. Within-group comparisons between baseline and follow-up measurements were performed using the paired t-test. Between-group comparisons were conducted using the independent sample t-test for continuous variables and the Chi-square test or Fisher's exact test for categorical variables, as appropriate.

All statistical tests were two-tailed. A p-value <0.05 was considered statistically significant, while p<0.001 was considered highly significant.

Results

Table 1: Baseline Demographic and Clinical Parameters (Group 1 vs. Group 2)

Parameter	Group 1 (Combo) (n=75)	Group 2 (Mono) (n=75)
Age (Years)	65.45±6.70	67.40±9.31
Prostate Size (gm)	38.93±4.20	38.81± 4.52
Baseline IPSS	22.77±3.53	22.86±3.62
Baseline Q_{max} (mL/s)	9.75±1.62	9.48±1.77
Baseline PVRU (ml)	94.10±27.34	97.09±30.50

Table 1 demonstrates that the two treatment groups were comparable at baseline. The mean age of participants was similar in the combination therapy group (65.45±6.70 years) and monotherapy group (67.40±9.31 years). Mean prostate volume, baseline IPSS, Qmax, and PVRU values were also comparable between the groups. These findings indicate a balanced distribution of demographic and clinical characteristics, ensuring that subsequent differences in treatment outcomes can be attributed primarily to the therapeutic interventions rather than baseline disparities.

Table 2: Comparative Trends in IPSS, Q_{max}, and PVRU over 30 Days

Parameter	Period	Group 1 (Co3mbo)	Group 2 (Mono)	Inter-group p-value
IPSS Score	Day 0	22.77±3.53	22.86±3.62	0.873
	Day 15	16.46±2.78	19.28±3.20	<0.001
	Day 30	12.26±2.40	16.74±2.80	<0.001
Q_{max} (mL/s)	Day 0	9.75±1.62	9.48±1.77	0.809
	Day 15	12.25±1.53	10.58±1.78	<0.001
	Day 30	13.96±1.58	11.78±1.81	<0.001
PVRU (mL)	Day 0	94.10±27.34	97.09±30.50	0.883
	Day 15	66.38±22.18	82.62±28.14	<0.001
	Day 30	50.68±19.33	70.25±26.37	<0.001

Table 2 demonstrates a significantly greater improvement in urinary symptoms and functional outcomes with combination therapy. While baseline IPSS, Qmax, and PVRU values were comparable between groups, patients receiving Tamsulosin plus Tadalafil showed markedly lower IPSS scores, higher urinary flow rates, and greater reduction in residual urine volume at both Day 15 and Day 30 (p<0.001), indicating superior therapeutic efficacy compared to Tamsulosin monotherapy.

Table 3: Summary of Mean Percentage Improvement (Baseline to Day 30)

Clinical Metric	Group 1 (% Improvement)	Group 2 (% Improvement)	p-value
IPSS Reduction	46.16%	26.77%	<0.001
Q_{max} Increase	43.18%	24.26%	<0.001
PVRU Reduction	46.14%	27.64%	<0.001

Table 3 highlights the superior efficacy of combination therapy over monotherapy. Patients receiving Tamsulosin plus Tadalafil demonstrated significantly greater improvements in all evaluated parameters, with nearly double the reduction in IPSS (46.16% vs. 26.77%) and PVRU (46.14% vs. 27.64%), along with a greater increase in Qmax (43.18% vs. 24.26%). These differences were highly significant (p<0.001), indicating enhanced symptomatic relief and urinary function with combination therapy.

Table 4: Adverse Effects and Patient Satisfaction (QoL)

Adverse Events	Group 1 (n=75)	Group 2 (n=75)	p-value
Dizziness	2 (2.7%)	3 (4.0%)	0.649
Retrograde Ejaculation	2 (2.7%)	3 (4.0%)	0.649
Dyspepsia/ Myalgia	4 (5.4%)	0 (0%)	0.121
Headache	2 (2.7%)	0 (0%)	0.155
Total Adverse Events	12 (16.0%)	10 (13.3%)	0.642
Mean QoL (Day 30)	1.8 (Satisfied)	2.6 (Mixed)	0.001

P-values for categorical variables were calculated using Fisher's Exact Test. Statistically significant difference between the groups (p<0.05).

Table 4 summarizes the safety profile and patient-reported outcomes of both treatment regimens. The incidence of adverse events was low and comparable between the groups, with dizziness and retrograde ejaculation being the most frequently reported events. Dyspepsia, myalgia, and headache were observed only in the combination therapy group but were mild and self-limiting. Despite similar tolerability, patients receiving Tamsulosin plus Tadalafil reported greater satisfaction and better quality-of-life scores at Day 30 compared to those receiving Tamsulosin alone.

Discussion

The present prospective comparative study evaluated the efficacy and safety of Tamsulosin–Tadalafil combination therapy compared with Tamsulosin monotherapy in patients with benign prostatic hyperplasia (BPH) and lower urinary tract symptoms (LUTS). The findings demonstrated that combination therapy resulted in significantly greater improvements in both subjective and objective outcome measures, including International Prostate Symptom Score (IPSS), maximum urinary flow rate (Qmax), and post-void residual urine volume (PVRU), while maintaining a favorable safety profile.

At baseline, both treatment groups were comparable with respect to age, prostate volume, symptom severity, urinary

flow parameters, and residual urine volume, thereby minimizing the possibility of selection bias and strengthening the validity of intergroup comparisons. Following 30 days of treatment, patients receiving Tamsulosin plus Tadalafil experienced a significantly greater reduction in IPSS compared with those receiving Tamsulosin alone (46.16% vs. 26.77%; $p<0.001$). Similarly, improvements in Qmax and reductions in PVRU were substantially greater in the combination therapy group. These findings indicate that combination pathway therapy offers superior relief of bladder outlet obstruction and LUTS compared with α1-blocker monotherapy.

The results of the present study are consistent with those reported by Pattanaik et al. (10) who demonstrated that the combination of Tamsulosin and Tadalafil produced significantly greater improvement in LUTS and quality-of-life scores than either agent alone. Similarly, Kim *et al*. [11] observed that fixed-dose combination therapy significantly improved IPSS, urinary flow parameters, and patient satisfaction while maintaining an acceptable safety profile. The superior efficacy of combination therapy observed in our study is further supported by the systematic review and meta-analysis conducted by Zhou *et al*. [12] which concluded that Tadalafil plus Tamsulosin was associated with significantly greater improvements in symptom scores, urinary flow rate, and quality-of-life measures compared with Tamsulosin monotherapy. These observations collectively suggest that combination therapy may provide a more comprehensive approach for managing LUTS secondary to BPH.

The enhanced therapeutic efficacy observed in the present study can be explained by the complementary mechanisms of action of the two drugs. Tamsulosin selectively antagonizes α1A-adrenergic receptors located in the prostate, bladder neck, and prostatic urethra, thereby reducing smooth muscle tone and relieving dynamic bladder outlet obstruction. In contrast, Tadalafil inhibits phosphodiesterase type-5, resulting in increased intracellular cyclic guanosine monophosphate (cGMP) levels, smooth muscle relaxation, improved pelvic blood flow, and modulation of afferent neural signaling pathways. The simultaneous targeting of adrenergic and nitric oxide-cGMP pathways likely contributes to the superior improvements in urinary flow dynamics and bladder emptying observed with combination therapy. Furthermore, improved tissue perfusion and oxygenation within the lower urinary tract may enhance detrusor function and reduce irritative urinary symptoms.

An important finding of the present study was the significant improvement in maximum urinary flow rate among patients receiving combination therapy. By Day 30, the mean Qmax increased by 43.18% in the combination group compared with 24.26% in the monotherapy group. Similar findings have been reported by Guo et al. [9] in their meta-analysis, which demonstrated that combination therapy was associated with significantly greater improvement in uroflowmetric parameters than either agent alone. Improved urinary flow is clinically relevant because it reflects reduced outlet resistance and improved bladder emptying, both of which contribute substantially to symptom relief and quality of life.

Likewise, the reduction in post-void residual urine volume was significantly greater in the combination therapy group. Persistent residual urine is a recognized risk factor for recurrent urinary tract infections, bladder dysfunction, and acute urinary retention. Therefore, the greater reduction in PVRU observed with Tamsulosin–Tadalafil therapy may have important long-term clinical implications by reducing the risk of disease progression and BPH-related complications.

Safety and tolerability remain critical considerations when introducing combination pharmacotherapy. In the present study, adverse events were infrequent and generally mild in severity. Although dyspepsia, myalgia, and headache were observed exclusively in the combination therapy group, no participant required treatment discontinuation. The overall incidence of adverse events was comparable between the two treatment groups. These findings are consistent with those reported by Kim *et al*. [11] and Tawfik *et al*. [13] who demonstrated that the addition of Tadalafil modestly increased the occurrence of minor adverse effects without significantly affecting treatment adherence or overall safety. The favorable tolerability profile observed in the current study supports the clinical feasibility of combination therapy in routine practice.

Patient-reported outcomes further reinforced the superiority of combination therapy. Participants receiving Tamsulosin plus Tadalafil reported greater satisfaction and better quality-of-life scores at the end of the study period compared with those receiving Tamsulosin alone. Because LUTS substantially affects sleep quality, daily activities, social functioning, and psychological well-being, improvements in patient-perceived quality of life are particularly important when evaluating treatment effectiveness. The higher satisfaction scores observed in the present study suggest that the benefits of combination therapy extend beyond objective clinical parameters and translate into meaningful improvements in daily functioning.

The findings of this study have important clinical implications. Given the rapid onset of symptom relief, significant improvements in urinary flow parameters, and acceptable safety profile, Tamsulosin–Tadalafil combination therapy may be considered a valuable therapeutic option for patients with moderate-to-severe LUTS associated with BPH, particularly in those who continue to experience bothersome symptoms despite α1-blocker therapy alone. Additionally, the use of Tadalafil may offer added advantages in patients with concomitant erectile dysfunction, a common comorbidity in the aging male population.

The present findings are particularly relevant in the Indian healthcare setting, where BPH contributes substantially to outpatient urological consultations among elderly men. The observed clinical benefits suggest that combination therapy may offer an effective non-surgical treatment option in appropriately selected patients.

Limitations

The present study has certain limitations. Being a single-center study, the findings may not be fully generalizable to other populations. The follow-up period was limited to 30 days, restricting the assessment of long-term efficacy and safety. Erectile function was not evaluated despite the established role of tadalafil in men with concomitant erectile dysfunction. Additionally, treatment adherence and long-term disease progression were not assessed.

Conclusion

The present study demonstrates that the combination of Tamsulosin and Tadalafil provides significantly greater improvement in lower urinary tract symptoms, urinary flow rate, and bladder emptying compared with Tamsulosin monotherapy in patients with benign prostatic hyperplasia. The combination regimen was well tolerated and associated with higher patient satisfaction without a meaningful increase in adverse effects. These findings suggest that Tamsulosin–Tadalafil combination therapy is an effective treatment option for men with symptomatic BPH and may offer superior clinical benefits over monotherapy.

Future Directions

Further multicenter studies with larger sample sizes and longer follow-up are required to validate these findings and determine the long-term benefits of combination therapy. Future research should also evaluate sexual function, treatment adherence, cost-effectiveness, and long-term patient-reported outcomes to better define the role of Tamsulosin and Tadalafil in the management of benign prostatic hyperplasia.

Ethics Committee Approval: This prospective hospital-based study was conducted after approval from the Institutional Ethics Committee of SGRDIMSR (Approval No. SGRD/IEC/2024-303).

Informed Consent: Written informed consent obtained from all the participants

Competing interests Disclaimer

The authors declare that they have no known competing financial interests, non-financial interests, personal relationships, or affiliations that could have appeared to influence the work reported in this manuscript.

Artificial Intelligence (Ai) Disclosure

The AI tools were not used for data collection, data analysis, interpretation of results, generation of scientific conclusions, or decision-making. All scientific content, study design, data accuracy, interpretations, and final manuscript revisions were reviewed, verified, and approved by the authors, who take full responsibility for the integrity and accuracy of the work.

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