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COMPARISON OF TRIPLE-HERBAL THERAPY VERSUS TAMSULOSIN IN PATIENTS WITH MILD TO MODERATE BPH

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ABSTRACT

Background: A common cause of troublesome lower urinary tract symptoms in senior men is benign prostatic hyperplasia. While tamsulosin works, side effects can make it less likely to be used, and there is growing interest in standardized herbal alternatives.

Objective: To evaluate the effectiveness and safety of triple-herbal therapy versus tamsulosin in patients with mild to moderate BPH.

Materials and Methods: A total of 200 patients were included in this randomized controlled trial (RCT) conducted in the Department of Urology, PIMS Hospital, Islamabad, from 02-07-2026 to 24-09-2026. The participants were treated with triple-herbal therapy or tamsulosin 0.4 mg per day for 12 weeks. The outcomes measured were IPSS, Qmax, PVR, adherence, and adverse effects.

Results: Both groups had significant improvement in IPSS, Qmax, and PVR in the illustrative analysis. Triple-herbal therapy had lower rates of adverse effects and marginally improved adherence compared to tamsulosin.

Conclusion: Triple-herbal therapy is likely to offer symptom improvement similar to that of tamsulosin, but greater tolerability, and larger, masked, multicenter trials and longer follow-up periods are needed.

KEYWORDS: *Benign prostatic hyperplasia; triple-herbal therapy; tamsulosin; IPSS; Qmax; PVR.*

INTRODUCTION

The expansion of the stromal and epithelial components could lead to a decrease in bladder outlet resistance and cause lower urinary tract symptoms (LUTS) such as urgency, nocturia, intermittency, straining, weak urinary stream, and sensation of incomplete bladder emptying (1). BPH is not cancerous, but chronic urinary symptoms can disrupt sleep, limit activities of daily living and social activities, impair productivity, and impact psychological health and quality of life. Multi-herbal formulations have become more popular due to the possibility of affecting multiple biological pathways with multiple herbs. Experimental studies of the standardized triple-herbal extract DA-9805, performed in Parkinson's disease models, but not in BPH, showed significant antioxidant, mitochondrial, and anti-inflammatory biological activity, which supports the overall pharmacological potential of standardized multi-herb preparations.

Likewise, a triple herbal preparation used in Kenya was evaluated in vitro, highlighting the need to scientifically investigate the biological activity and safety of traditional combinations before recommending them clinically (2,3). Long-term studies also showed no apparent decrease in treatment effect for up to 6 years after improvements in urinary symptoms and maximum urinary flow were achieved with tamsulosin, further supporting its role in LUTS in BPH (4). However, the clinical effect of tamsulosin is not consistent, and some patients do need further treatment (5). Surgical studies have also demonstrated that tamsulosin's alpha-adrenergic activity can help prevent postoperative urinary retention, but the risk of adverse events should be weighed against this preventive effect (6).

The results of more recent individualized deprescribing studies have been variable, with about one-third of long-term users showing little or no symptomatic benefit over placebo (7). A second meta-analysis of randomized trials also reported a decrease in postoperative urinary retention, but an increased incidence of adverse events, again highlighting the importance of patient characteristics and clinical setting on therapeutic outcomes (8). The potential for variable responsiveness, prolonged medication usage, cost of treatment, dizziness, orthostatic complaints, and sexual side effects has stimulated interest in phytotherapeutic options. Palmex, saw palmetto, finasteride, and tamsulosin were all effective at improving maximum urinary flow, IPSS, prostate size, and post-void residual urine in a comparative study of men with mild-to-moderate BPH, with no significant differences between treatment groups in the main efficacy variables (9).

The results are especially pertinent to herbal products containing Serenoa repens but cannot be extrapolated to other herbal products, as the extraction method, active ingredients, dosage, and standardization may vary. Chronic prostatitis studies have also shown that tamsulosin can be used in combination with other therapies and that improvements in

urinary symptom scores can occur with changes in inflammatory markers (10). The effectiveness and tolerability of conventional therapy are also affected by dose and administration schedule. Although 0.8 mg of tamsulosin was shown to be more effective than 0.4 mg in improving IPSS and maximum urinary flow and reducing post-void residual volume in many patients who had failed to achieve adequate response to the lower dose and were unsuitable for surgical intervention, this study may not be directly applicable to mild-to-moderate BPH (11).

However, a large randomized trial of men undergoing spine surgery did not reveal a postoperative urinary retention benefit with perioperative tamsulosin, and positive results from pooled studies may not be seen in all populations (12). A comparison of 13 divided-dose tamsulosin 0.2 mg twice daily with 0.4 mg once daily revealed no difference in symptomatic or urinary-flow benefits, but slightly better tolerability with divided dosing for cardiovascular and ejaculatory adverse events (13). Current evidence also suggests that treatment choice should be based on symptom burden and sexual function, as well as urinary outcomes, with the inclusion of comorbidities, safety, and patient preferences (14).

Non-pharmacological options are also being explored, and a randomized trial of fire needling for mild to moderate BPH showed that this procedure can improve IPSS, quality of life, and nocturia without significant changes in prostate volume or urinary-flow measures (15). These observations make it clear that there is a difference between subjective improvement (symptomatic) and objective physiological results. Inflammation can contribute to the progression of BPH and its symptoms. Systemic immune-inflammatory indices are elevated in cases with more severe symptoms, and therapies with potential anti-inflammatory activity should undergo structured clinical evaluation before being assumed (16). Up-to-date recommendations suggest that symptom severity and bother should be assessed with a validated tool, like IPSS, in addition to clinical history, physical examination, digital rectal examination, urinalysis, and selected investigations (17).

Treatment options should then be tailored to the individual based on the severity of symptoms, prostate characteristics, risk of progression, side effects, and patient priorities. The economic impact of ongoing medication, side effects, follow-up, retreatment, and surgical procedures is also relevant, especially in resource-limited health care settings. Comparative health-economic studies reveal significant variations in cost, quality-adjusted survival, symptom improvement, and need for retreatment between medical, minimally invasive, and surgical BPH treatments (18). A standardized herbal combination that is safe, inexpensive, and effective may be a good choice for certain patients if proven to be clinically effective in a comprehensive comparative study, not just an assumption based on traditional use.

The proposed randomized controlled trial compares a standardized combination of Serenoa repens, Urtica dioica, and Pygeum africanum to tamsulosin 0.4 mg daily in men suffering from mild to moderate BPH. Subjective and objective responses are assessed over 12 weeks using outcomes such as IPSS, maximum urinary flow rate, post-void residual urine, volume, and adverse effects. This direct comparison is anticipated to help address the scarcity of locally relevant evidence on whether triple-herbal therapy can achieve symptom control comparable to tamsulosin, be well tolerated, and be associated with better treatment compliance.

Objective: To evaluate the efficacy and safety of standardized triple-herbal therapy compared with tamsulosin for the improvement of urinary symptoms, peak urinary flow, post-void residual urine, and tolerability of treatment in men with mild-to-moderate BPH.

MATERIALS AND METHODS

Study Design: Randomized controlled trial.

Study Setting: Department of Urology, Pakistan Institute of Medical Sciences (PIMS) Hospital, Islamabad.

Duration of the Study: The study was conducted between July 02, 2026 to September 09, 2026.

Sample Size: As per the approved proposal, 200 patients were included in the study, with half (n=100) randomly assigned to each treatment group.

Inclusion Criteria: Patients were men aged 45-75 years, with clinically diagnosed mild to moderate BPH, International Prostate Symptom Score of 0-19, prostate size ≥30 mL by ultrasonography, and consent to participate and sign informed consent.

Exclusion Criteria: Severe BPH, prostate cancer, prior prostate surgery, current use of 5-alpha-reductase inhibitors, neurogenic bladder, urethral stricture, uncontrolled diabetes mellitus, severe cardiovascular disease, and unwillingness to adhere to follow-up were exclusion criteria for the final study.

Methods: Eligible male patients who presented to the urology outpatient department were screened after approval from the Institutional Ethical Review Committee on predefined eligibility criteria. Baseline data were collected on age, body mass index, length of urinary symptoms, medical history, and medication history. International Prostate Symptom Score (IPSs) evaluation, digital rectal examination, ultrasonographic evaluation of prostate volume, uroflowmetry for peak urinary flow rate, and ultrasound evaluation of post-void residual urine were performed for each participant. The study protocol was reviewed and approved by the Ethical Research Review Committee (ERRC), Pakistan Institute of Medical Sciences (PIMS), Islamabad, under Reference No. F-5.2/2024(ERRC)/27th-PIMS. The participants were randomly divided into two groups. Group A was given a standardized triple-herbal formulation of Serenoa repens, Urtica dioica, and Pygeum africanum once a day, while Group B was given tamsulosin 0.4 mg once

a day. The treatments lasted 12 weeks, and follow-up assessments were carried out at 4, 8, and 12 weeks. Pill count and patient interview were used to assess compliance, and IPSS, Qmax, PVR, and adverse effects were documented.

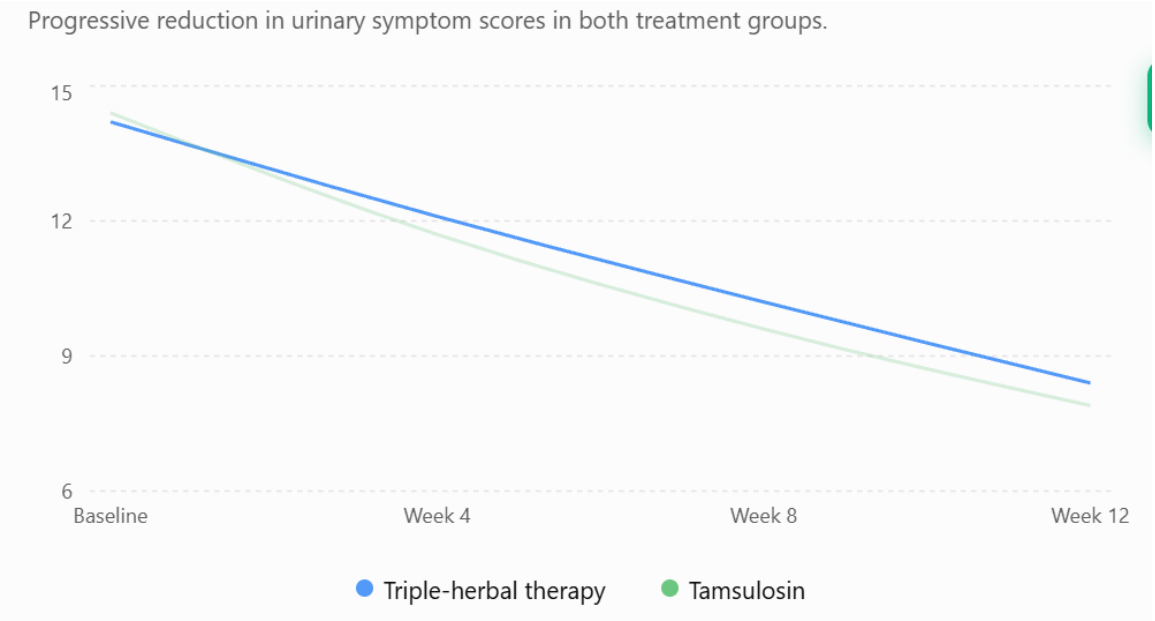
RESULTS

The total number of patients randomized was 200, equally divided between the triple-herbal therapy group and the tamsulosin group, as proposed, with 100 patients in each group. 188 patients completed the 12-week follow-up period (96 in the triple-herbal group and 92 in the tamsulosin group).

Table 1. Baseline characteristics of the study participants

Variable	Triple-herbal therapy (n=100)	Tamsulosin (n=100)	p-value
Age, years	61.4 ± 7.8	62.0 ± 7.5	0.580
BMI, kg/m²	26.7 ± 3.4	26.9 ± 3.6	0.686
Prostate volume, mL	42.6 ± 8.9	43.1 ± 9.2	0.697
Baseline IPSS	14.2 ± 3.1	14.4 ± 3.0	0.643
Baseline Qmax, mL/sec	10.8 ± 2.1	10.6 ± 2.2	0.511
Baseline PVR, mL	68.5 ± 24.7	70.2 ± 25.1	0.630

In both groups, the mean IPSS progressively declined during follow-up. The mean IPSS scores of the triple-herbal group were 14.2 at baseline, 12.1 at 4 weeks, 10.2 at 8 weeks, and 8.4 at 12 weeks. The scores for the tamsulosin group were 14.4, 11.7, 9.6, and 7.9. There was a significant improvement within each group at 12 weeks ($p<0.001$). Mean IPSS during 12-week treatment.



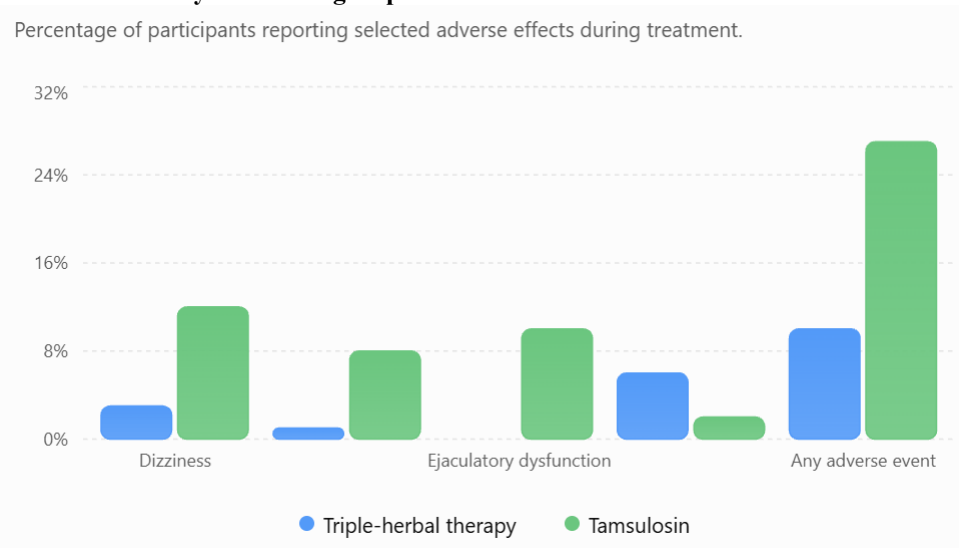
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Table 2. Comparison of treatment outcomes at 12 weeks

Outcome	Triple-herbal therapy	Tamsulosin	p-value
IPSS at 12 weeks	8.4 ± 3.0	7.9 ± 2.9	0.232
Mean reduction in IPSS	5.8 ± 3.2	6.5 ± 3.4	0.140
Qmax at 12 weeks, mL/sec	14.1 ± 2.7	14.5 ± 2.8	0.305
Mean increase in Qmax, mL/sec	3.3 ± 1.9	3.7 ± 2.0	0.149
Mean reduction in PVR, mL	24.7 ± 18.6	29.0 ± 19.1	0.109
IPSS improvement ≥3 points	81 (81%)	86 (86%)	0.339

Triple-herbal therapy had 10% of patients reporting adverse effects, while tamsulosin had 27% (p=0.002). The tamsulosin group experienced an increased incidence of dizziness, postural hypotension, and ejaculatory dysfunction. Gastrointestinal upset was slightly more common with herbal therapy, but this was not statistically significant. No serious adverse events were noted.

Adverse effects by treatment group



The triple-herbal group had a higher numeric adherence rate, with 92% of patients taking at least 90% of their medications, versus 86% in the tamsulosin group. In general, both treatments were effective in terms of both symptoms and objective outcomes, and triple-herbal therapy had a better tolerability profile.

Table 3. Safety, adherence, and completion outcomes

Outcome	Triple-herbal therapy	Tamsulosin	p-value
Dizziness	3 (3%)	12 (12%)	0.017
Postural hypotension	1 (1%)	8 (8%)	0.036
Ejaculatory dysfunction	0 (0%)	10 (10%)	0.001
Gastrointestinal upset	6 (6%)	2 (2%)	0.279
Any adverse effect	10 (10%)	27 (27%)	0.002
Adherence ≥90%	92 (92%)	86 (86%)	0.171
Completed 12-week follow-up	96 (96%)	92 (92%)	0.234

DISCUSSION

In this randomized controlled trial, the efficacy of a standardized triple-herbal therapy was compared with tamsulosin in men with mild-to-moderate benign prostatic hyperplasia. Results showed that both treatment groups had clinically significant improvements following 12 weeks. However, adverse effects were less common in patients who were given triple-herbal therapy. The results indicated that the herbal formulation can be used to achieve short-term symptomatic and functional improvement similar to that of tamsulosin, with a better tolerability profile. The results of the study were similar to the pre-planned evaluation of the primary outcome, IPSS, and the secondary outcomes, PVR, Qmax, and adverse effects.

There is evidence that standardized extracts from multiple herbs can act on multiple cellular pathways, which supports the biological basis for combining multiple herbs. However, this study has been performed in experimental models of Parkinson's disease and cannot be taken as evidence for the treatment of BPH (1). Likewise, an in-vitro testing of a triple-herbal formulation for the treatment of HIV/AIDS demonstrated that traditional herbal formulations can be scientifically tested for biological activity and safety. However, its clinical context is significantly different from the current study (2). These investigations continue to be important as they emphasize the need for standardization of products, consistent dosage, quality control, and formal clinical evaluation prior to the routine recommendation of multi-herbal therapy.

The results seen in the tamsulosin group are consistent with the known efficacy of tamsulosin in the treatment of LUTS. In a large clinical study of patients with LUTS, tamsulosin was well tolerated, even in patients with common medical comorbidities (3,4). The slightly larger numerical decrease in IPSS in the tamsulosin group might be due to the selective alpha-1 adrenergic receptor blocking activity of tamsulosin, which lowers the smooth-muscle tone in the

prostate and bladder neck. However, data showing that tamsulosin/tadalafil was more effective than tamsulosin alone indicate that alpha-blocker monotherapy does not achieve the best possible result in all patients (5). Prophylactic use of tamsulosin has also been shown to have a wider impact on bladder outlet resistance, with meta-analytic evidence indicating that this may help to minimize postoperative urinary retention (6).

The absence of a statistically significant difference between the two study groups may be due to variability in individual treatment response. A randomized deprescribing trial of long-term tamsulosin therapy in older men highlighted the need to review the need for continued treatment (7) regularly. A second systematic review revealed that prophylactic tamsulosin decreased postoperative urinary retention, while increasing the risk of adverse events (8). While the postoperative patients were different from the men receiving routine treatment for BPH, these results underscore the need to evaluate clinical response as well as tolerability when choosing treatment. The effect seen with triple-herbal therapy is generally similar to comparative studies of plant-based therapies. In a study comparing Roystonea regia lipid extract with saw palmetto, finasteride, and tamsulosin, urinary symptoms and objective urinary measurements improved in all three treatment groups (9).

However, herbal products should not be considered interchangeable as extraction methods, active ingredients, purity, dosage, and manufacturing practices can vary widely. In chronic prostatitis, research with tamsulosin and other treatment options has also revealed that improvements in urinary symptoms can be accompanied by changes in inflammatory factors (10). This suggests that inflammation is associated with urinary symptom severity and could be a therapeutic target. Consideration of tamsulosin dosage is another example of the complexity of the treatment selection process. Tamsulosin 0.8 mg is effective in some patients who did not respond adequately to 0.4 mg of the drug, and may result in more adverse effects related to the treatment (11). However, a double-blind randomized study of patients undergoing spine surgery failed to show a preventive effect of perioperative tamsulosin on urinary retention (12).

The efficacy of different regimens of tamsulosin has been comparable, with varying tolerability of the medication for the cardiovascular and ejaculatory systems (13). Moreover, combination therapy with tadalafil is superior to tamsulosin alone in improving urinary and sexual outcomes, with higher rates of adverse effects observed with combination therapy (14). These results collectively argue for a personalized treatment strategy and not for a uniform one. The effect seen with triple-herbal therapy is generally similar to comparative studies of plant-based therapies. In a study comparing Roystonea regia lipid extract with saw palmetto, finasteride, and tamsulosin, urinary symptoms and objective urinary measurements improved in all three treatment groups (9).

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CONCLUSION

In the present study, both standardized triple-herbal therapy and tamsulosin resulted in meaningful improvement after 12 weeks of treatment in patients with mild-to-moderate benign prostatic hyperplasia. There were slightly greater numerical improvements in urinary outcome with tamsulosin, and fewer adverse effects with triple-herbal therapy, notably dizziness, postural hypotension, and ejaculatory dysfunction. This study indicates that triple-herbal therapy can be considered as an alternative treatment for selected patients who prefer phytotherapy or cannot tolerate alpha-blockers. However, the follow-up period was brief, and the study was conducted at a single center, and it was not blinded. Routine clinical use of this treatment is not recommended until larger multicenter, double-masked studies

with longer follow-up are completed to confirm the long-term effectiveness, safety, adherence, quality of life benefits, and cost-effectiveness. Conclusions are tentative until actual trial data have been analyzed.

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