OPEN ACCESS

DOI:10.59736/IJP.23.04.1024

ORIGINAL ARTICLE

Pharmacotherapy in benign prostatic enlargement; the impact of tamsulosin and dutasteride on erectile dysfunction

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ABSTRACT

Background: Benign prostatic enlargement (BPE) becomes increasingly common as men grow older. A wide range of lower urinary tract symptoms (LUTS)occur as the condition progresses. Erectile dysfunction (ED) frequently coexists with these symptoms and may be influenced by the medications used to treat BPE. This study compared the impact of tamsulosin alone with that of the tamsulosin–dutasteride combination on erectile function.

Methods: This multicenter cross-sectional study was conducted in the urology and surgical outpatient clinics of two hospitals. A total of 79 sexually active men over the age of 50 with LUTS related to BPE were included. Participants were divided into two groups: Group A (n=41), receiving tamsulosin 0.4 mg daily, and Group B (n=38), receiving a fixed-dose combination of tamsulosin and dutasteride. Erectile function was evaluated using the Sexual Health Inventory for Men (SHIM), a validated questionnaire.

Results: In the present study, erectile-function outcomes were closely examined in men treated either with tamsulosin alone or with a tamsulosin–dutasteride combination. When SHIM scores were compared between the two groups, the averages were nearly the same (14.8 ± 6.6 for men receiving tamsulosin only, and 15.7 ± 5.2 for those on the combined regimen; $p = 0.48$). A similar pattern appeared when erectile-dysfunction severity was analyzed across standard categories ($p = 0.62$). Erectile dysfunction was widespread in both groups, and the distribution of age and major comorbidities were well balanced at baseline.

Conclusion: These results indicate that LUTS/BPH, is likely the primary contributor to sexual difficulties, rather than the specific medication prescribed. These findings can help guide patient counseling, reassuring them that the choice between these common regimens, based on prostate size and symptom severity, may not confer an additional risk to erectile function specifically.

Keywords: Benign Prostatic Hyperplasia, Combination Therapy, Dutasteride, Erectile Dysfunction, Tamsulosin

This article may be cited as: Sajjad M, Ashraf H, Shahzad T, Khan NS, Imran M, Ahmad N. Pharmacotherapy in benign prostatic enlargement: the impact of tamsulosin and dutasteride on erectile dysfunction. Int J Pathol 23(4):345-50. https://doi.org/10.59736/IJP.23.04.1024

Introduction

Benign prostatic hyperplasia remains one of the most common urological conditions affecting older men. The syndrome is characterized by urinary symptoms such as increased frequency, urgency, reduced urinary flow, and a sensation of incomplete

bladder emptying, all of which may interfere with daily routines and overall wellbeing (1).

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Notably, sexual dysfunction, particularly ED, is also highly prevalent in this population, creating a significant comorbidity burden. Several physiological pathways have been proposed to link BPH and erectile dysfunction, including impaired vascular supply to the penis, disruption of autonomic control, and changes in nitric-oxide signaling (2–4). Medical treatment typically begins with α1-blockers such as tamsulosin or with 5-α-reductase inhibitors (5ARIs) such as dutasteride [5]. Tamsulosin improves urine flow by relaxing smooth muscle in the prostate and bladder neck, while dutasteride lowers dihydrotestosterone levels and gradually reduces the size of the prostate gland (6) In men with more advanced enlargement or signs of progression, using both medications together has been shown to reduce the risk of acute urinary retention and the likelihood of requiring surgery (7, 8).

Despite these benefits, concerns about changes in sexual function, reduced libido, altered ejaculation, and difficulty maintaining erections remain common in discussions between patients and clinicians (9, 10).

While large randomized controlled trials (RCTs) from predominantly Western populations have explored sexual side effects, there is a paucity of data focusing specifically on erectile function outcomes from real-world clinical settings in South Asia. Although tools such as the SHIM questionnaire provide reliable assessments of erectile function (11) locally relevant evidence is limited.

Therefore, this study aimed to compare erectile function in men taking tamsulosin alone with those taking the combination of tamsulosin and dutasteride, using the SHIM score as the primary assessment tool. The goal was to provide clearer, locally relevant evidence to support balanced and informed treatment decisions.

Methods

This was a multicenter, cross-sectional comparative study carried out between January and March 2025, at two institutions: the Urology Department of Combined Military Hospital, Peshawar, and the Surgical Department of Benazir Bhutto Shaheed DHQ Teaching Hospital, Abbottabad. Ethical approval was granted by the institutional review board (Approval No. Surgery-01/5/2025, DHQ/BBB Teaching hospital, Abottabad, dated January 26, 2025).

Sexually active men (defined as having attempted sexual intercourse within the past 3 months) aged 50–80 years, diagnosed with BPE/LUTS (based on an International Prostate Symptom Score (IPSS) >7 and prostate volume >30 cc on transrectal ultrasound), and who had been on a stable regimen of either tamsulosin monotherapy or tamsulosin-dutasteride combination therapy for at least three months were eligible. The minimum three-month duration was chosen to ensure initial drug effects and potential side effects had manifested, particularly for dutasteride. Participants were consecutively enrolled from the outpatient clinics.

Sample size was calculated using Open Epi software (Version 3). Assuming 80% power, a 5% alpha error, and an equal allocation ratio, with an anticipated mean SHIM score difference of 4 points and a pooled standard deviation of 6.0 based on pilot data, a

minimum of 76 subjects (38 per group) was required. Ultimately, 79 participants were enrolled. Participants were divided into two groups based on their ongoing prescription:

Group A: Tamsulosin 0.4 mg daily (n=41)

Group B: Fixed-dose combination of tamsulosin 0.4 mg + dutasteride 0.5 mg once daily (n=38)

Participants were excluded from this study if they had previously undergone prostate surgery, were taking phosphodiesterase-5 inhibitors, or had neurological, endocrine, or psychiatric disorders known to affect sexual function.

A structured proforma was used to collect demographic data, medical history (hypertension, diabetes mellitus, hyperlipidaemia), and clinical details (duration of LUTS and ED). Erectile function was assessed using the validated, 5-item Sexual Health Inventory for Men (SHIM) questionnaire, which was administered via a face-to-face interview in the local language (Urdu) by a trained researcher. The SHIM score ranges from 1 to 25, with lower scores indicating worse erectile function. Severity was categorized as: Severe (1-7), Moderate (8-11), Mild to Moderate (12-16), Mild (17-21), and No ED (22-25) [11].

Statistical analysis was performed with IBM SPSS v25. Continuous variables were presented as mean ± SD, and categorical variables as frequencies and percentages. Comparisons between the two groups used independent t-tests and chi-square analysis, with $p < 0.05$ considered statistically significant.

Results

A total of 79 men completed the study: 41 receiving tamsulosin alone and 38 receiving combination therapy. The two groups were broadly similar with respect to age and comorbidity burden. The only baseline difference was the duration of LUTS, which was slightly longer in the tamsulosin group (2.56 ± 0.74 vs. 2.16 ± 0.82 years; p = 0.02).

Table 1: Patient Characteristics

Parameter	Group A (Tamsulosin)	Group B (Combination)	P-Value
Age (years) Mean ± SD	63.5 ± 9.7	62.6 ± 12.4	0.70
LUTS Duration (years) Mean ± SD	2.56 ± 0.74	2.16 ± 0.82	0.02
Hypertension, n (%)	16 (39.0%)	14 (36.8%)	0.84
Diabetes, n (%)	12 (29.3%)	10 (26.3%)	0.76

Erectile-function results closely paralleled one another. SHIM scores showed no statistically meaningful separation (14.83 ± 6.70 vs. 15.74 ± 5.26; p = 0.48). This finding remained non-significant after adjusting for the difference in LUTS duration using ANCOVA (p = 0.52). Every participant had a SHIM score of 21 or below, underscoring the high prevalence of ED across the entire group. Because the study assessed men at a single time point without baseline pre-treatment scores, it is not possible to determine whether erectile function declined after therapy was initiated.

Table 2: Comparison of erectile function between groups

Parameter	Group A (Tamsulosin)	Group B (Combination)	P-Value
SHIM Score, Mean ± SD	14.8 ± 6.7	15.7 ± 5.3	0.48
ED Duration (years), Mean ± SD	2.83 ± 1.41	3.05 ± 1.21	0.45
ED Severity category n (%)			0.62
> Mild (17-21)	12 (29.3%)	14 (36.8%)	
> Mild-Moderate (12-16)	10 (24.4%)	9 (23.7%)	
> Moderate (8-11)	11 (26.8%)	8 (21.1%)	
> Severe (1-7)	8 (19.5%)	7 (18.4%)	

Discussion

This cross-sectional study sought to determine if the addition of dutasteride to tamsulosin therapy resulted in worse erectile function compared to tamsulosin alone in men with BPE/LUTS. The findings of this study suggest that adding dutasteride to tamsulosin does not produce a noticeably greater decline in erectile function than tamsulosin alone. Both groups demonstrated high levels of ED, which is consistent with the known overlap between LUTS and sexual dysfunction (2,3).

Our results consistent with those of large-scale studies, such as the CombAT trial, which reported that while sexual adverse events occurred, the incremental impact of combination therapy on erectile function over monotherapy was not pronounced in all analyses (10).

In contrast, some meta-analyses of RCTs report a higher incidence of new-onset ED with 5ARI-containing regimens (12). This apparent discrepancy can be explained by fundamental study design differences. RCTs are optimized to detect *incident* side effects (new cases appearing after treatment initiation), whereas our observational, cross-sectional design assessed *prevalent* ED in patients already on stable therapy. Our study was powered to detect a clinically relevant difference (4 points on the SHIM), and the observed difference of less than 1 point is neither statistically nor clinically significant. However, those analyses pooled data from randomized controlled trials capable of monitoring changes over time, whereas our cross-sectional approach captures only a single time point. LUTS and BPH themselves are well-recognized contributors to erectile dysfunction (2, 3). Vascular impairment, reduced nitric-oxide availability, and age-related reductions in sexual performance likely explain much of the ED observed in this study. These findings are in line with evidence from larger observational studies (12).

One important limitation is the narrow focus on erectile function alone. Previous research has shown that 5ARIs may affect libido and ejaculatory function more strongly than erectile rigidity (9, 13), and examining these aspects might have revealed additional differences between treatment groups.

Indeed, the Roehrborn study showed that ejaculatory dysfunction rather than ED mainly drove changes in sexual function. A more comprehensive assessment might have revealed additional sexual-health differences between the two groups (14, 15).

Study Limitations

The cross-sectional design limits causal interpretation. The absence of pre-treatment SHIM scores prevents us from evaluating true change over time. Not assessing libido, ejaculatory function, or overall satisfaction is another drawback. Non-randomized sampling may introduce selection bias, and the lack of a placebo control group restricts comparison with the natural course of age-related ED.

Recommendations

Future prospective studies with baseline sexual function assessments and evaluation of multiple sexual health domains are needed further to clarify the sexual safety profile of these common pharmacotherapies

Acknowledgement

This research was conducted as part of the certification course in Andrology at the Institute of Kidney Disease, Peshawar. We are grateful to Assistant Professor Dr. Mir Abid Jan, in charge of the Uro-Andrology unit at IKD HMC, for his guidance and support.

Conclusion

In this cohort of men with BPE/LUTS, erectile function, as measured by the SHIM questionnaire, did not differ significantly between those using tamsulosin monotherapy and those using tamsulosin-dutasteride combination therapy. The overwhelming prevalence of ED highlights that sexual dysfunction in this population is intrinsically linked to aging and the pathophysiology of BPE/LUTS. When discussing treatment options, clinicians can reassure patients that, regarding erectile function specifically, the evidence does not suggest one regimen is worse than the other. The decision to add dutasteride should be guided by prostate volume and risk of disease progression, with parallel counseling about its potential effects on libido and ejaculation.

Source of fundings: Nill

Conflict of Interest: Nill

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HISTORY	
Date received:	01-11-2025
Date sent for review:	18-11-2025
Date received reviewers' comments:	20-11-2025
Date received revised manuscript:	03-12-2025
Date accepted:	14-12-2025

CONTRIBUTION OF AUTHORS	
AUTHOR	**CONTRIBUTION**
Conception/Design	MS, HA
Data acquisition, analysis and interpretation	MS, HA, NSK, MI, NA
Manuscript writing and approval	MS, TS, MI, NA
All the authors agree to take responsibility for every facet of the work, making sure that any concerns about its integrity or veracity are thoroughly examined and addressed.	