Research Article

# Tamsulosin alone versus tamsulosin plus tadalafil for lower urinary tract symptoms associated with benign prostatic hyperplasia: a prospective randomised study

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**Abstract**

Introduction: Lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) frequently coexist with erectile dysfunction (ED). This study compared tamsulosin alone with tamsulosin plus tadalafil. Methods: In this prospective, randomised, open-label study conducted from October 2015 to February 2017, 100 men aged over 45 years were allocated to tamsulosin 0.4 mg daily (n=50) or tamsulosin 0.4 mg plus tadalafil 5 mg daily (n=50). IPSS, IPSS quality-of-life score, IIEF-5, Qmax, and Qmean were assessed over 12 weeks. Four participants discontinued treatment because of adverse events; reported efficacy analyses included 48 participants per group. Results: At 12 weeks, mean IPSS decreased from 14.92 to 9.00 in Group A and from 15.44 to 7.30 in Group B. Mean quality-of-life score decreased from 4.00 to 2.52 and from 4.02 to 1.60, respectively. Mean IIEF-5 increased from 12.71 to 14.21 and from 12.71 to 18.50. The report describes greater improvement with combination therapy for IPSS, quality of life, and IIEF-5, but no significant between-group difference for Qmax or Qmean. Adverse effects were reported in two and four participants, respectively; two participants in each group discontinued. Conclusions: Combination therapy was associated with greater reported improvement in urinary symptoms, quality of life, and erectile-function scores, but not urinary flow rates. The findings require cautious interpretation because of the open-label design, short follow-up, and incomplete statistical reporting.

**Keywords:** benign prostatic hyperplasia; lower urinary tract symptoms; tamsulosin; tadalafil; erectile dysfunction; randomised trial

## 1. Introduction

Lower urinary tract symptoms are common in ageing men and may substantially impair quality of life. LUTS attributed to BPH frequently coexist with erectile dysfunction, and epidemiological studies have reported an association between symptom severity and sexual dysfunction. Shared vascular, autonomic, and nitric-oxide-related mechanisms have been proposed, although the relationship is multifactorial and not fully explained. 1,2

Alpha-1 adrenoceptor antagonists such as tamsulosin are established pharmacological treatments for bothersome LUTS associated with BPH. Phosphodiesterase type 5 inhibitors (PDE5Is), including tadalafil, improve erectile function and can also reduce LUTS.

Randomised trials have evaluated tadalafil alone and in combination with alpha blockers. 3-6 In an Indian randomised trial published in 2014, tamsulosin, tadalafil, and their combination were compared in three treatment arms. 7 Another Indian study subsequently evaluated tamsulosin plus tadalafil in men with LUTS/BPH without erectile dysfunction. 8 Consequently, the present study should not be described as the first Indian evaluation of this drug combination.

The present prospective study compared tamsulosin 0.4 mg once daily with tamsulosin 0.4 mg plus tadalafil 5 mg once daily over 12 weeks in men presenting to a urology service with LUTS attributed to BPH. The intended contribution is a further assessment of the 5 mg tadalafil combination regimen in this clinical setting, including urinary symptom scores, quality of life, erectile-function scores, urinary flow measurements, and reported adverse events. The study is interpreted as confirmatory rather than as establishing a previously unreported treatment strategy.

# 2. Materials and Methods

### 2.1. Study design and setting

This was a prospective, randomised, open-label, parallel-group study conducted between October 2015 and February 2017 in the Department of Urology at a tertiary care center in Bijapur city.

Follow-up continued for 12 weeks after treatment initiation.Approval by the hospital scientific advisory committee and ethics board was taken and documented.Informed consent was obtained from participants.

### 2.2. Participants

Men aged over 45 years were eligible if they had LUTS attributed to BPH for at least six months, an IPSS greater than 9, a maximum urinary flow rate (Qmax) greater than 5 mL/s and less than 15 mL/s, a minimum voided volume greater than 150 mL at ultrasound screening, and willingness to provide written informed consent and comply with study procedures. Exclusion criteria included contraindications or known allergy to study drugs; use of another alpha-adrenergic agent; history of syncope or orthostatic hypotension; bladder outlet obstruction due to malignancy, calculi, or urethral stricture; previous transurethral resection of the prostate; neurological disorders affecting storage or voiding; prostatitis or prostate cancer; acute urinary retention within four weeks before study initiation; and documented urinary tract infection.

### 2.3. Randomisation and interventions

The eligible participants were allocated according to a computer-generated random table. Group A received tamsulosin 0.4 mg once daily. Group B received tamsulosin 0.4 mg plus tadalafil 5 mg once daily. Participants were instructed to take medication at approximately the same time each day. The manuscript states that there were no restrictions on food intake or timing of sexual activity. Participants were advised not to use other BPH medications during the study period.

### 2.4. Outcomes and follow-up

IPSS and IPSS QoL, Qmax, and post-void residual urine (PVR) were primary efficacy measures at three months, with erectile function assessed using the IIEF-5 as a secondary measure. Assessments were undertaken at baseline and at approximately four and 12 weeks. Compliance and drug-related side effects were assessed at follow-up visits.

### 2.5. Safety assessment

Adverse effects and treatment compliance were assessed at follow-up visits. The adverse effects recorded in the manuscript include headache, backache, nasal congestion, and myalgia. Four participants discontinued treatment because of adverse events, two in each treatment group.

### 2.6. Statistical analysis

Analyses were performed using SPSS version 16.0 and that data were summarised as means with standard errors. A paired t-test was reported for statistical significance, with $P<0.05$ considered statistically significant. The original sample-size description states 80% power, a one-sided alpha of 0.05, assumed standard deviation of 5.0, and target differences of 3 points for IPSS and IIEF and 2 mL/s for Qmax; it reports a required sample size of 86 participants, although it is not clear whether this was the total sample or the number per group.

### 2.7. Ethics, registration, and data availability

The ethics committee of the hospital agreed upon to conduct this study under strict supervision of trained residents and surgeons.The ethics committee clearance was obtained and documented as per the norms of Geneva convention.

# 3. Results

### 3.1. Participants and baseline characteristics

A total of 100 men were randomised: 50 to Group A and 50 to Group B. Two participants in each group discontinued the intervention because of adverse events.Around 48 participants in each group (96 overall) were allocated. No participant was reported as excluded before randomisation. The reconstructed participant-flow diagram is supplied separately as Figure 1.

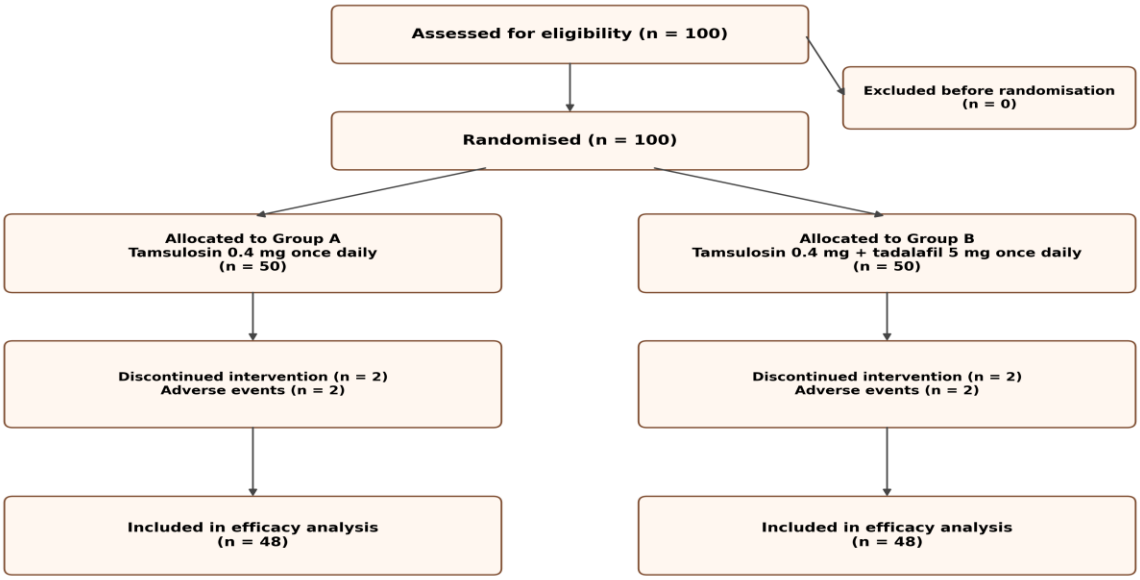


**Figure 1. Flow of participants through eligibility assessment, randomisation, allocation, discontinuation, and efficacy analysis.**

The mean age was 63.9 years and states that baseline characteristics were similar between groups.Mean prostate size of approximately 35 g and an overall mean IPSS of approximately 15.2. It also reports that 65% of participants had erectile dysfunction.

**3.2. Four-week assessment**

At four weeks, mean IPSS decreased from 14.92 to 10.21 in Group A and from 15.44 to 9.40 in Group B.It was reported that the numbers were statistically significant within-group reductions in both groups. It describes the between-group difference in IPSS change as not statistically significant (P=0.087 in the text; the table reports P<0.08). Mean QoL score decreased from 4.00 to 2.79 in Group A and from 4.02 to 2.06 in Group B; A rather statistically significant improvement in both groups and a between-group difference favouring combination therapy.

**3.3. Twelve-week assessment**

At 12 weeks, mean IPSS decreased from 14.92 to 9.00 in Group A and from 15.44 to 7.30 in Group B. Mean QoL score decreased from 4.00 to 2.52 in Group A and from 4.02 to 1.60 in Group B. It was also reported that greater improvement was seen in IPSS and QoL with combination therapy than with tamsulosin alone.

Mean IIEF-5 increased from 12.71 to 14.21 in Group A and from 12.71 to 18.50 in Group B.The within-group change was not statistically significant in Group A (P=0.356) and was statistically significant in Group B (P<0.05), with a between-group difference favouring combination therapy.

Mean Qmax increased from 11.50 to 13.56 mL/s in Group A and from 11.25 to 13.88 mL/s in Group B. Mean Qmean increased from 6.11 to 7.41 mL/s in Group A and from 5.69 to 7.25 mL/s in Group B.There was no statistically significant between-group difference for Qmax or Qmean. The exact between-group P values require verification because the manuscript reports them as “P<0.647” and “P<0.341”, respectively, despite describing the comparisons as non-significant.

**3.4. Adverse events and discontinuations**

Adverse effects in two participants in Group A and four participants in Group B. In Group A, reported symptoms were headache and backache. In Group B, reported symptoms included headache, backache, nasal congestion, and myalgia. Two participants in each group discontinued treatment because of adverse events.

## 4. Discussion

In this 12-week open-label comparison, Data showed improvement from baseline in urinary symptom scores, quality-of-life scores, erectile-function scores, and urinary flow measurements in both treatment groups. This manuscript reports greater improvement with tamsulosin plus tadalafil for IPSS, QoL, and IIEF-5, but does not demonstrate a statistically significant additional benefit for Qmax or Qmean. The clinical message should therefore be restricted to the outcomes that were measured and statistically compared; the study does not show that combination therapy improves all aspects of bladder outlet physiology or should be given to every male with BPH.

The findings are consistent with the broader evidence that PDE5 inhibitors can improve LUTS and erectile function in selected men, and that adding a PDE5 inhibitor to an alpha blocker may provide additional symptom benefit. However, the size of the incremental effect and its clinical importance vary across trials. A 2023 meta-analysis of six randomised trials (441 participants) found combination therapy favoured total IPSS, QoL, Qmax, and IIEF, while also finding more pain-related and overall adverse events; discontinuation due to adverse events was not significantly different. 9 A 2025 meta-analysis of 11 trials (940 participants) reported pooled improvements in IPSS, IIEF, QoL, Qmax, and PVR, but also higher odds of pain and overall adverse events; substantial heterogeneity was present for several outcomes. 10 These pooled estimates are not estimates from the present study and should not be substituted for its own treatment effects.

A prior Indian randomised trial by Singh and colleagues compared tamsulosin, tadalafil, and their combination in three arms. 7 A further Indian study examined the combination in men with LUTS/BPH without ED. 8 These publications mean that the current study cannot claim to be the first Indian study or the first randomised evaluation of this treatment strategy. Its defensible contribution is narrower: an additional clinical dataset evaluating the 5 mg tadalafil plus 0.4 mg tamsulosin regimen over 12 weeks. Even that contribution is confirmatory and should be presented without an unsupported claim of novelty.

A 2026 Indian multicentre phase IV study evaluated a fixed-dose combination of tamsulosin 0.4 mg prolonged-release and tadalafil 5 mg in a single-arm cohort of 172 men with BPH and ED. Over 12 weeks, the investigators reported 12 treatment-emergent adverse events in 10 participants (5.81%) and improvements from baseline in symptom, quality-of-life, erectile-function, urinary-flow, and post-void residual measures. Because the study had no comparator group, it cannot estimate the incremental effect of adding tadalafil to tamsulosin; its population and design also differ from the present two-arm study. 11

The current European Association of Urology guideline recommends considering an alpha-1 blocker plus a PDE5 inhibitor in men with bothersome LUTS, particularly when improvement in erectile function is also desired; the recommendation is weak and patients should be informed that the magnitude of benefit is modest. 12 This is not a recommendation to use combination therapy routinely in all men with BPH. Selection should be individualised according to symptom burden, erectile-function priorities, contraindications, concomitant medication, haemodynamic risk, tolerability, and patient preference. These contemporary recommendations provide clinical context but do not convert this small, short-duration study into evidence for universal treatment.

Several limitations affect interpretation. The study was open-label, so patient-reported outcomes such as IPSS, QoL, and IIEF-5 may have been influenced by expectations; the supplied documents do not establish whether outcome assessors were blinded. The study followed patients for only 12 weeks and included no tadalafil-only arm.

The sample was modest, and the supplied manuscript does not clearly document allocation concealment, the analysis population, missing-data handling, the exact between-group tests, or confidence intervals. PVR is mentioned as an outcome but no PVR results are presented. There are inconsistencies in baseline denominators, percentage changes, and reported P values that must be resolved from the original dataset and statistical output. The number of reported adverse events was numerically higher in the combination group, but no reliable between-group safety estimate is available in the manuscript as supplied.

The study was conducted before current CONSORT 2025 reporting recommendations. A revised report should nevertheless provide the relevant information that can be recovered, including the trial-registration status, protocol and statistical-analysis-plan availability, intervention delivery, harms ascertainment, participant flow, analysis populations, and missing-data handling. 13 If the trial was not prospectively registered, that fact must be disclosed rather than corrected retrospectively.

## 5. Conclusions

Tamsulosin plus tadalafil was associated with greater reported improvement in IPSS, quality of life, and IIEF-5 than tamsulosin alone, but no additional between-group benefit in Qmax or Qmean was demonstrated. These short-term open-label findings may support selective use when erectile-function improvement is also a goal, but do not justify routine combination treatment for all men with BPH.

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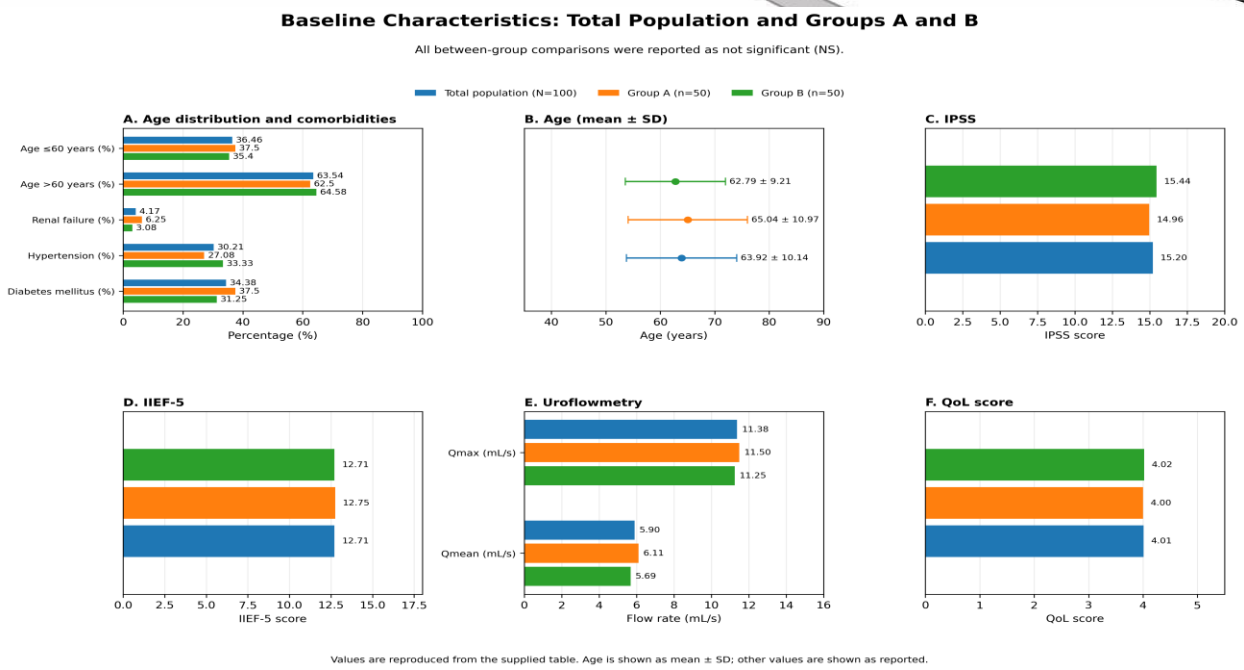


**Figure.2. The figure illustrates the comparison of baseline demographic and clinical characteristics between the total study population, Group A, and Group B. Age distribution, comorbidities, IPSS, IIEF-5, uroflowmetry parameters, and QoL scores were comparable across the groups, with no statistically significant differences (all p-**

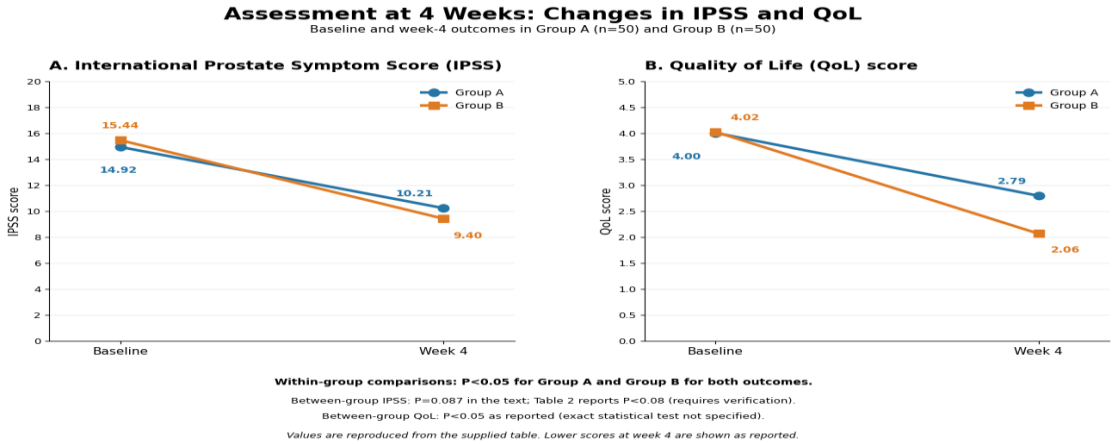


**Figure.3. Comparison of IPSS and QoL scores at baseline and 4 weeks between Group A and Group B.This Panel consists of:**

- **A: International Prostate Symptom Score (IPSS)**
- **B: Quality of Life (QoL) score**
- **X-axis: Assessment time point (Baseline and Week 4)**
- **Y-axis: Respective clinical scorevalues NS).**

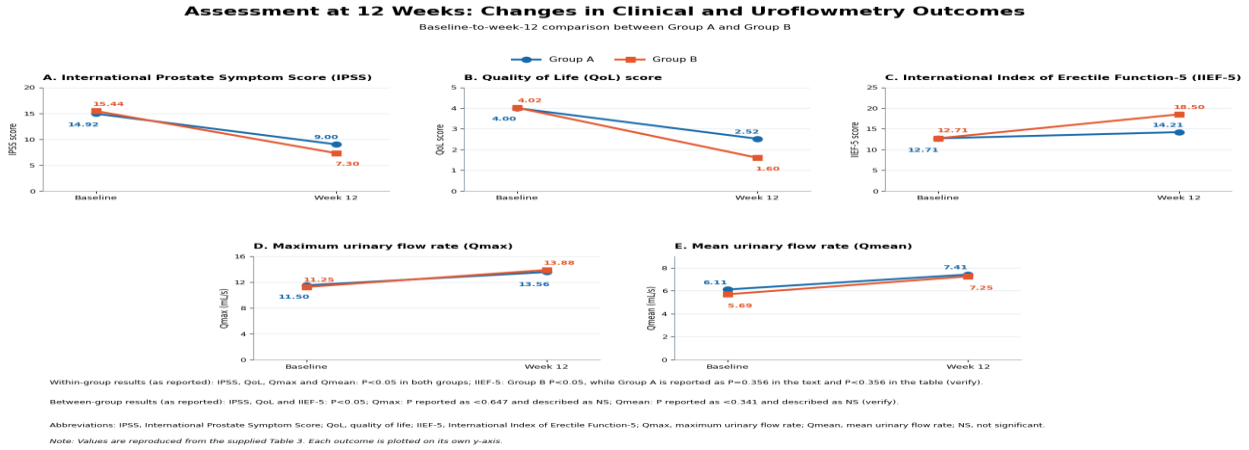


**Figure.4. The figure illustrates changes in IPSS, QoL, IIEF-5, Qmax and Qmean scores from baseline to 12 weeks in both groups. Both groups demonstrated improvements across the measured parameters, with the between-group statistical results reported as shown in Table 3.**

## Tables

**Table 1. Baseline characteristics**

| Parameter | Total population (N=100) | Group A (n=50) | Group B (n=50) | P value |
|---|---|---|---|---|
| Age, years | 63.92 ± 10.14 | 65.04 ± 10.97 | 62.79 ± 9.21 | NS |
| Age ≤60 years, % | 36.46 | 37.5 | 35.4 | NS |
| Age >60 years, % | 63.54 | 62.5 | 64.58 | NS |
| Renal failure, % | 4.17 | 6.25 | 3.08 | NS |
| Hypertension, % | 30.21 | 27.08 | 33.33 | NS |
| Diabetes mellitus, % | 34.38 | 37.5 | 31.25 | NS |
| IPSS | 15.20 | 14.96 | 15.44 | NS |
| IIEF-5 | 12.71 | 12.75 | 12.71 | NS |
| Qmax, mL/s | 11.38 | 11.50 | 11.25 | NS |
| Qmean, mL/s | 5.90 | 6.11 | 5.69 | NS |
| QoL score | 4.01 | 4.00 | 4.02 | NS |

*Abbreviations: IPSS, International Prostate Symptom Score; IIEF-5, International Index of Erectile Function-5; Qmax, maximum urinary flow rate; Qmean, mean urinary flow rate; QoL, quality of life; NS, not significan*

**Table 2. Assessment at 4 weeks**

| Outcome | Group | Baseline mean | Week 4 mean | Within-group P | Between-group result as reported |
|---|---|---|---|---|---|
| IPSS | Group A | 14.92 | 10.21 | P<0.05 | Between groups: P=0.087 in text; table says P<0.08 [verify] |
| IPSS | Group B | 15.44 | 9.40 | P<0.05 | |
| QoL | Group A | 4.00 | 2.79 | P<0.05 | Between groups: P<0.05 [verify exact test] |
| QoL | Group B | 4.02 | 2.06 | P<0.05 | |

*Abbreviations: IPSS, International Prostate Symptom Score; QoL, quality of life. P values are reproduced as reported*

**Table 3. Assessment at 12 weeks**

| Outcome | Group | Baseline mean | Week 12 mean | Within-group P | Between-group result as reported |
|---|---|---|---|---|---|
| IPSS | Group A | 14.92 | 9.00 | P<0.05 | P<0.05 |
| IPSS | Group B | 15.44 | 7.30 | P<0.05 | |
| QoL | Group A | 4.00 | 2.52 | P<0.05 | P<0.05 |
| QoL | Group B | 4.02 | 1.60 | P<0.05 | |
| IIEF-5 | Group A | 12.71 | 14.21 | P=0.356 in text; table says P<0.356 [verify] | P<0.05 |
| IIEF-5 | Group B | 12.71 | 18.50 | P<0.05 | |
| Qmax, mL/s | Group A | 11.50 | 13.56 | P<0.05 | P reported as <0.647; described as NS [verify] |
| Qmax, mL/s | Group B | 11.25 | 13.88 | P<0.05 | |
| Qmean, mL/s | Group A | 6.11 | 7.41 | P<0.05 | P reported as <0.341; described as NS [verify] |
| Qmean, mL/s | Group B | 5.69 | 7.25 | P<0.05 | |

*Abbreviations: IIEF-5, International Index of Erectile Function-5; IPSS, International Prostate Symptom Score; Qmax, maximum urinary flow rate; Qmean, mean urinary flow rate; QoL, quality of life; NS, not significant. P values are reproduced as reported and require independent verification.*