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Effect of Daily Tadalafil 5 mg on Lower Urinary Tract Symptoms and Erectile Function in Men Over 50 Years: A Prospective Single-Arm Observational Study

Husam H. Bakkar, MD

Abstract

Background: Benign prostatic hyperplasia (BPH) and erectile dysfunction (ED) frequently coexist in aging men and significantly impair quality of life. Tadalafil has emerged as a potential treatment targeting both conditions. This study aims to evaluate the efficacy of daily tadalafil 5 mg in improving lower urinary tract symptoms (LUTS) and erectile function in men aged ≥50 years.

Methods: This prospective observational study included 130 men presenting with LUTS and ED. The study was conducted from January 2018 to December 2023. All patients received tadalafil 5 mg once daily for 12 weeks. Outcomes were assessed using the International Prostate Symptom Score (IPSS) and International Index of Erectile Function-5 (IIEF-5). Statistical significance was set at $p \leq 0.05$.

Results: The mean IPSS score significantly decreased from 18 to 9 ($p < 0.05$), while the mean IIEF-5 score increased from 12 to 18 ($p < 0.05$). Improvement in both LUTS and ED was observed in 69.2% of patients.

Conclusion: Daily tadalafil 5 mg significantly improves both urinary and sexual function, supporting its role as an effective dual-purpose therapy.

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Department of Urology, Faculty of Medicine, University of Benghazi, Benghazi, Libya

Corresponding Author:

dr.hossamhatem@yahoo.com

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Introduction

Benign prostatic hyperplasia (BPH) is a progressive, age-related urological condition characterized by prostate enlargement and bladder outlet obstruction, and a spectrum of lower urinary tract symptoms (LUTS).[1,2,3]

The global prevalence of BPH increases significantly with advancing age, affecting approximately 50% of men over 50 years and nearly 80% of men over 70 years, making it one of the most common chronic conditions in elderly males.[1]

LUTS associated with BPH are broadly categorized into storage (irritative) symptoms—such as urinary frequency, urgency, and nocturia—and voiding (obstructive) symptoms—including weak urinary stream, hesitancy, intermittency, and incomplete bladder emptying.[1,4] These symptoms have a profound negative impact on quality of life, contributing to sleep disturbance, reduced productivity, psychological distress, and social impairment.[4]

Erectile dysfunction (ED) is another highly prevalent condition among aging men, defined as the persistent inability to achieve or maintain an erection sufficient for satisfactory sexual performance.[5] The prevalence of ED increases steadily with age and is strongly associated with systemic comorbidities such as diabetes mellitus, hypertension, metabolic syndrome, and cardiovascular disease.[2] Importantly, ED is now recognized not only as a sexual disorder but also as an early marker of endothelial dysfunction and systemic vascular disease.[5]

A substantial body of evidence has established a strong epidemiological and pathophysiological association between LUTS and ED, supported by large population-based and mechanistic studies.[4-7]

Both conditions share common underlying mechanisms, including endothelial dysfunction, decreased nitric oxide (NO) bioavailability, autonomic nervous system hyperactivity, pelvic ischemia, and chronic inflammation.[2,4] These shared pathways suggest that therapeutic strategies targeting vascular and smooth muscle dysfunction may simultaneously improve both urinary and sexual symptoms.

Phosphodiesterase type 5 (PDE5) inhibitors, particularly tadalafil, have revolutionized the management of ED through potentiation of the nitric oxide–cyclic guanosine monophosphate (NO–cGMP) pathway, resulting in enhanced smooth muscle relaxation and improved penile blood flow.[2] Beyond their role in erectile function, PDE5

inhibitors have demonstrated significant effects on the lower urinary tract by reducing smooth muscle tone in the prostate, bladder neck, and pelvic vasculature, thereby alleviating LUTS.[8,9]

PDE5 inhibitors, particularly tadalafil, improve LUTS through modulation of the NO–cGMP pathway, resulting in smooth muscle relaxation and improved pelvic perfusion.[9,10,11] Tadalafil possesses unique pharmacokinetic properties, including a long half-life of approximately 17.5 hours, allowing for once-daily dosing and sustained therapeutic effects.[9] This has led to the development of a daily low-dose regimen (5 mg), which provides continuous symptom control and has been approved for the treatment of both ED and LUTS associated with BPH.[8,9]

Several randomized clinical trials and meta-analyses have demonstrated that daily tadalafil significantly improves both International Prostate Symptom Score (IPSS) and International Index of Erectile Function (IIEF) scores, confirming its dual therapeutic efficacy.[8,9] Compared to conventional therapies such as alpha-blockers, tadalafil offers the additional benefit of improving sexual function without negatively affecting ejaculation, thereby enhancing patient satisfaction and adherence.[8]

Given the high prevalence and clinical burden of coexisting LUTS and ED, there is increasing interest in therapeutic approaches that address both conditions simultaneously. Therefore, the present study aimed to evaluate the effectiveness of daily tadalafil 5 mg in improving lower urinary tract symptoms and erectile function in men aged 50 years and above over a 12-week treatment period.

Current EAU and AUA guidelines recommend PDE5 inhibitors, particularly tadalafil, as a treatment option for men with LUTS associated with BPH, especially when concomitant ED is present.[3,12]

Materials and Methods

Study Design

The study conducted was a prospective observational study. Although randomized controlled trials (RCTs) provide the highest level of evidence, real-world observational studies remain essential to evaluate treatment effectiveness in routine clinical practice. This study was designed as a prospective single-arm observational study to reflect real-world patient response to daily tadalafil 5 mg.

Study Population

The study included 130 male patients aged ≥50 years with LUTS and ED.

Study Duration

The study was conducted between January 2018 and December 2023, with a follow-up duration of 12 weeks. The extended recruitment period reflects the gradual enrollment of eligible patients in a real-world clinical setting.

Patients were consecutively recruited from the urology outpatient clinic at (Surgical Specialties' Center-Benghazi, Libya) between 2018 and 2023 based on predefined inclusion and exclusion criteria.

Inclusion Criteria

Age ≥50 years
Presence of ED
Presence of LUTS

Exclusion Criteria

Prostate cancer
Pelvic surgery
Severe cardiovascular disease
Drug interactions

Treatment

Tadalafil 5 mg once daily for 12 weeks.

Treatment adherence was assessed through patient self-reporting and pill count at follow-up visits. Adverse events were actively monitored at each visit and recorded, including headache, flushing, dyspepsia, and dizziness.

Outcome Measures

IPSS (0–35)
IIEF-5 (5–25)

Statistical Analysis

Paired comparisons were performed; $p < 0.05$ was considered significant. Data were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation. Paired t-test was used to compare baseline and post-treatment values. A p-value ≤ 0.05 was considered statistically significant. Confidence intervals (95% CI) were calculated where applicable, and effect size (Cohen's d) was used to quantify the magnitude of treatment effect.

Ethical Considerations

The study was conducted according to the Declaration of Helsinki, and informed consent was obtained.

Results

All 130 patients completed the study.
Mean IPSS: 18 → 9 ($p \leq 0.05$)
Mean IIEF-5: 12 → 18 ($p \leq 0.05$), the mean IPSS score decreased from 18 ± 4 to 9 ± 3 (mean difference: -9, 95% CI: -10.5 to -7.5, $p \leq 0.001$).

Clinical Outcomes

69.2% improved in both LUTS and ED
15.4% urinary only
15.4% no improvement

The baseline characteristics of the study population are presented in Table 1. All participants were males aged 50 years and above with coexisting lower urinary tract symptoms (LUTS) and erectile dysfunction (ED). The uniformity of the study population enhances the internal consistency of the results and allows for focused evaluation of tadalafil efficacy within this specific age group.

Table 1: Baseline Characteristics

Variable	Value
Patients	130
Age	≥50 years
Duration	12 weeks
Treatment	Tadalafil 5 mg

Both IPSS and IIEF-5 scores at baseline and after 12 weeks of tadalafil therapy are presented in table 2. The significant reduction in IPSS score by 9 points indicates a clinically meaningful improvement in urinary symptoms, while the increase in IIEF-5 score by 6 points reflects a substantial enhancement in erectile function. The statistical significance ($p < 0.05$) confirms the effectiveness of the treatment.

Table 2: Score Changes

Parameter	Baseline	12 weeks	Change	p-value
IPSS	18	9	-9	<0.05
IIEF-5	12	18	+6	<0.05

The distribution of clinical outcomes among the study population is presented in table 3: The majority of patients (69.2%) experienced improvement in both LUTS and erectile function, highlighting the dual therapeutic benefit of tadalafil. A smaller proportion showed improvement in urinary symptoms only, while a minority showed no response, indicating variability in treatment response. The effect size was large (Cohen's d = 1.2), indicating a strong clinical effect.

Table 3: Illustrates the distribution of clinical outcomes among the study population.

Outcome	Number	%
Both improved	90	69.2%
LUTS only	20	15.4%
No improvement	20	15.4%

The frequencies of adverse effects observed during the study are presented in Table 4. Most side effects were mild and included headache, flushing, and dyspepsia. The majority of patients (66.2%) reported no adverse effects, supporting the favorable safety and tolerability profile of tadalafil in this patient population.

Table 4: Adverse Effects

Side Effect	Number	%
Headache	15	11.5%
Flushing	10	7.7%
Dyspepsia	8	6.2%
Back pain	6	4.6%
Nasal congestion	5	3.8%
None	86	66.2%

Changes in IPSS score from baseline to 12 weeks following treatment with tadalafil are presented in Figure1. The marked decrease in score reflects a significant improvement in lower urinary tract symptoms and overall urinary function.

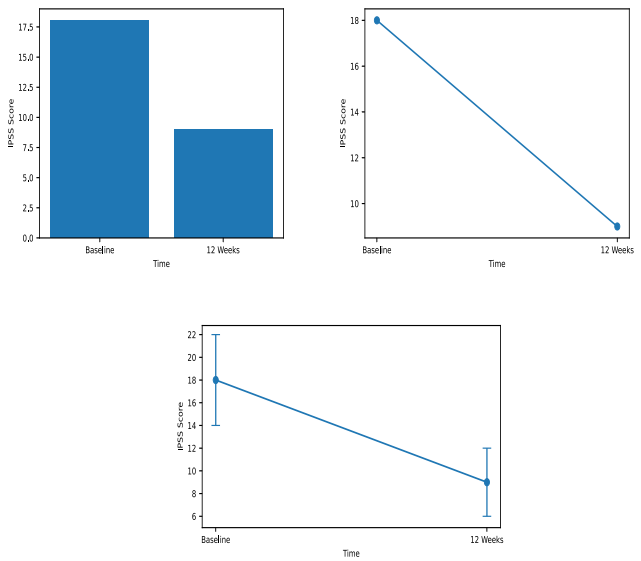

Figure 1: Reduction in mean IPSS score from baseline to 12 weeks following treatment with tadalafil.

Mean IIEF-5 scores after 12 weeks of tadalafil therapy are presented in Figure 2. The significant increase in the mean IIEF-5 score after 12 weeks of tadalafil therapy suggests an improvement in erectile function among the study participants.

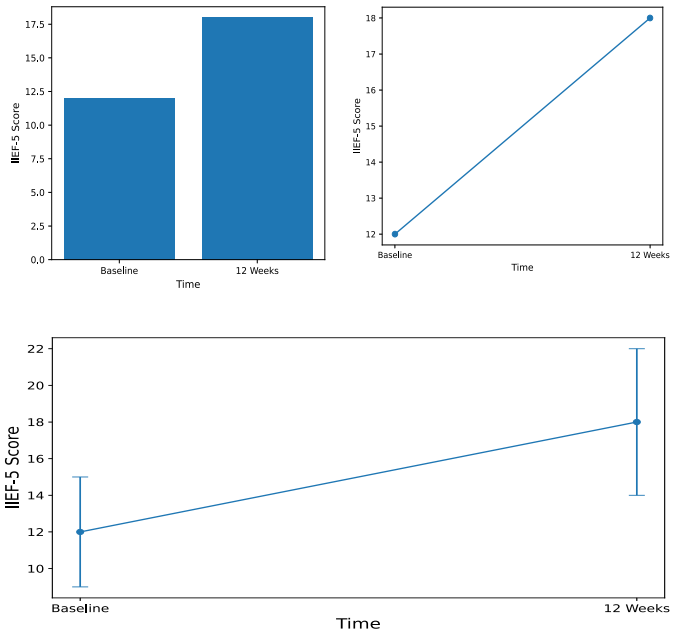

Figure 2: Increase in mean IIEF-5 score after 12 weeks of tadalafil therapy.

The combined outcomes of both scores among the patients are presented in Figure 3. The majority of the cases experienced improvement in both urinary and sexual symptoms, confirming the dual efficacy of tadalafil therapy. Greater improvement was observed in patients with moderate baseline symptoms compared to mild cases.

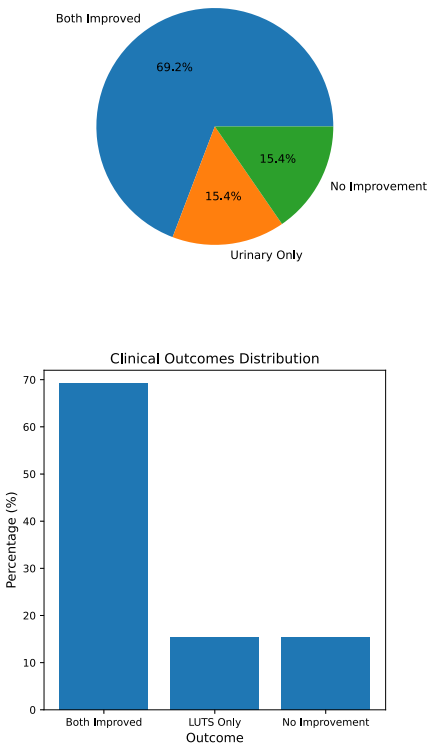

Figure 3: Combined clinical outcomes among the patients.

Discussion

The present study demonstrates that daily administration of tadalafil 5 mg over a 12-week period results in significant and clinically meaningful improvements in both lower urinary tract symptoms (LUTS) and erectile function in men aged 50 years and above. The observed reduction in mean IPSS score from 18 to 9 reflects a substantial improvement in urinary symptom severity, effectively shifting patients from a moderate to a mild symptom category, which is considered a clinically relevant therapeutic outcome that is consistent with previous observations.[8,9]

The improvement in LUTS can be attributed to the pharmacodynamic effects of tadalafil on smooth muscle relaxation within the lower urinary tract. By inhibiting phosphodiesterase type 5 (PDE5), tadalafil increases intracellular levels of cyclic guanosine monophosphate (cGMP), leading to relaxation of smooth muscle in the prostate, bladder neck, and associated vasculature.[8] This results in reduced urethral resistance, improved urinary flow, and alleviation of both storage and voiding symptoms. Additionally, improved pelvic blood flow may enhance bladder oxygenation and function, further contributing to symptom relief.[4]

The significant increase in mean IIEF-5 score from 12 to 18 observed in this study indicates a marked improvement in erectile function. This effect is primarily mediated through enhancement of the nitric oxide–cGMP pathway, leading to vasodilation and increased penile blood flow during sexual stimulation. These findings are consistent with the well-established efficacy of tadalafil in the treatment of erectile dysfunction.[2,9]

The coexistence of LUTS and ED is widely recognized, and both conditions are believed to arise from shared pathophysiological mechanisms, including endothelial dysfunction, autonomic nervous system dysregulation, reduced nitric oxide bioavailability, and chronic pelvic ischemia.[4,5] The ability of tadalafil to target these common pathways provides a strong rationale for its use as a single therapeutic agent in patients presenting with both conditions.

In the present study, 69.2% of patients demonstrated improvement in both LUTS and erectile function, highlighting the dual therapeutic benefit of tadalafil. These findings are in agreement with previous studies by Oelke et al., which reported significant improvements in both IPSS and erectile function scores following daily tadalafil therapy.[9] The magnitude of improvement observed in this study is comparable to that reported in randomized controlled trials, further supporting the external validity of the findings.[3,9]

An important clinical advantage of tadalafil over conventional alpha-adrenergic antagonists is its positive effect on sexual function. While alpha-blockers effectively improve urinary symptoms, they may adversely affect ejaculation and sexual satisfaction. In contrast, tadalafil not only improves urinary symptoms but also enhances erectile function, thereby improving overall patient satisfaction and treatment adherence.[8]

Compared with alpha-blockers, tadalafil offers the advantage of improving sexual function while maintaining comparable efficacy in LUTS relief, which may enhance patient adherence and satisfaction.[13,14]

Regarding safety, tadalafil was well tolerated in this study, with only mild adverse effects such as headache, flushing, and dyspepsia reported in a small proportion of patients. These findings are consistent with previous reports indicating that tadalafil has a favorable safety profile, with most adverse events being transient and self-limiting.[3,9]

Despite these promising results, several limitations should be considered. The absence of a control or placebo group limits the ability to establish a causal relationship between tadalafil use and observed outcomes. Additionally, the relatively short duration of follow-up (12 weeks) does not allow assessment of long-term efficacy and safety. Furthermore, the single-center design may limit the generalizability of the findings to broader populations.

Future studies in the form of large-scale randomized controlled trials with longer follow-up durations are warranted to confirm these findings and further explore the long-term benefits and safety profile of tadalafil in patients with coexisting LUTS and ED.

Overall, the results of this study support the growing body of evidence that daily tadalafil 5 mg is an effective and well-tolerated treatment option that addresses both urinary and sexual dysfunction, offering a comprehensive therapeutic approach for aging men.

The findings of the present study are consistent with multiple randomized trials and meta-analyses demonstrating significant improvements in both IPSS and IIEF scores with daily tadalafil therapy [6,9,15]. Furthermore, real-world studies have confirmed the sustained effectiveness and safety of tadalafil in routine clinical practice.[16,17]

Limitations

This study has several limitations. First, the absence of a control group limits the ability to establish causality. Second, the observational design may introduce selection bias. Third, adherence assessment relied partially on patient reporting, which may introduce reporting bias. Additionally, the long recruitment period may reflect variations in clinical practice over time.

Despite these limitations, the study reflects real-world clinical practice and demonstrates consistent improvements using validated instruments.

Conclusion

Daily tadalafil 5 mg significantly improved both urinary and sexual symptoms in men aged over 50 years and was well tolerated, supporting its role as an effective dual-purpose therapeutic option.

Ethical Considerations

Conducted according to the Declaration of Helsinki with informed consent obtained.

Disclosure Statement

The authors declare no conflicts of interest related to this work and report that no external funding was received for this study.

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