E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/15.01.32

Research Article

The Study of Tadalafil and Tamsulosin as Monotherapy for Lower Urinary Tract Symptoms Due to Benign Hyperplasia of Prostate

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Received: 13.02.25, Revised: 16.03.25, Accepted: 04.04.25

ABSTRACT

Introduction: Benign Prostate Hyperplasia **(**BPH) is the most prevalent benign disease in males with diverse LUTS. It is the fourth most prominent condition among men aged ≥50 years and accounts for 80% of men aged ≥70 years. According to available data, the prevalence of BPH surged from 25% in the 40-49 age group to 80% in the 70-79 age group. Clinically, BPH causes LUTS and its symptoms, such as storage (impaired bladder emptying, urinary frequency, nocturia, urinary urgency, and urge incontinence), voiding (urinary incontinence, a restricted urinary stream), and postmicturition, which can impair patients' quality of life.

Materials and methods: We analysed 120 patients of BPH (Benign Prostatic Hyperplasia) with LUTS (Lower Urinary Tract Symptoms) with baseline parameters as international prostate symptom score (IPSS), QMAX (maximum urinary flow velocity), PVR (Post Voidal Residual urine volume), for a period of 12 months. They were divided in to two groups, one group receiving only alpha blockers, other group receiving only PDE -5 inhibitor (Phosphodiesterase type 5 inhibitor/PDE-5I) tadalafil in treatment of LUTS due to BPH. These patients were reviewed at 1, 3, 6 months interval with above mentioned parameters.

Results: Of the 120 patients taken up for the study, 60 in each group, only 110 patients completed the study. (54 patients in alpha blockers group and 56 patients in PDE-5 inhibitors group). Both groups were reviewed with mentioned parameters.

Conclusion: PDE-5 inhibitor (Tadalafil) should be preferred over alpha blockers in treating LUTS (Lower Urinary Tract Symptoms) due to BPH (Benign Prostatic Hyperplasia) as PDE-5 inhibitors are found to be more efficacious than alpha blocker with lesser incidences of side-effects.

Key Words: Benign Prostate Hyperplasia, quality of life, Tadalafil, alpha blockers.

INTRODUCTION

Benign Prostate Hyperplasia (BPH) is the most prevalent benign disease in males with diverse LUTS. It is the fourth most prominent condition among men aged ≥50 years and accounts for 80% of men aged ≥70 years. According to available data, the prevalence of BPH surged from 25% in the 40-49 age groups to 80% in the 70-79 age groups. Clinically, BPH causes LUTS and its symptoms, such as storage (impaired bladder emptying, urinary frequency, nocturia, urinary urgency, and urge incontinence), voiding (urinary incontinence, a restricted urinary stream), and postmicturition, which can impair patients' quality of life.1 There are different treatment modalities for BPH, including conventional methods and surgical intervention. However, surgical intervention is associated with complications such as bleeding, ureteral orifice injury, bladder neck injury, rectal injury, Transurethral Resection of the Prostate (TURP) syndrome, bladder neck contractures, and urethral stricture disease.2

In males with moderate to severe LUTS, alpha-blockers and 5-Alpha-reductase Inhibitors (ARIs) are regarded as the first-line conventional medicine. The recent American Urological Association (AUA) guideline recommends tadalafil 5 mg in patients with LUTS/BPH, irrespective of comorbid erectile dysfunction.

Phosphodiesterase-5 (PDE5) inhibitors have been shown in several in-vitro studies to relax

smooth muscles in the bladder neck and prostate, as well as to reduce the overstimulation of the detrusor muscles. PDE-5 inhibitors reduce alpha-adrenergic-induced contractions.3

BPH and ED are both occurring in the old aged men with incidence increasing as age increases further. Rationale for the use of PDE-5 inhibitor in the treatment of men with BPH/LUTS was initially based on demographic data showing the frequent occurrence of both ED and LUTS in men as they age. This raised the possibility of a common underlying mechanism at least contributing to both processes. Immuno histochemical studies showed that PDE–5 receptor is located in endothelial cells and smooth muscle cells of blood vessels of lower urinary tract. Blockage of these receptors leads to bladder neck relaxation.4 Mechanism of action of Tadalafil, a long acting PDE-5 inhibitor, for the treatment of men with BPH-LUTS is associated with NO/CGMP/protein kinase G pathway leading to smooth muscle relaxation in different lower urinary tract tissues in bladder, urethra, prostate and supporting vasculature beside increased blood perfusion to pelvic area and modulation of sensory stimuli from this area.5

However, in the studies so far available, there have been no significant changes in Qmax, suggesting that the effects of PDE-5I is alone may be either more focused on bladder muscle function than on prostatic tissue or that the effects are more profound on storage symptoms than on bladder outflow obstruction itself.

MATERIALS AND METHODS

Study design: Controlled, Randomized, Observed, Prospective Study.

Study location: Department of Urology, GMC and Superspeciality Hospital, Nagpur.

Study Duration: March 2024 to February 2025 (1 year).

We analysed 120 patients of BPH (Benign Prostatic Hyperplasia) with LUTS (Lower Urinary Tract Symptoms) with baseline parameters as international prostate symptom score (IPSS), QMAX (maximum urinary flow velocity), PVR (Post Voidal Residual urine volume), for a period of 12 months. They were divided in to two groups, one group receiving only alpha blockers, other group receiving only PDE -5 inhibitor (Phosphodiesterase type 5 inhibitor/PDE-5I) tadalafil in treatment of LUTS due to BPH. These patients were reviewed at 1, 3, 6 months interval with above mentioned parameters.

Inclusion Criteria

Male more than 45 years with LUTS due to BPH; that is male more than 45 years having either irritative (increased frequency, urgency, dysuria) or having obstructive LUTS (hesitancy, strain to void, thin stream of urine, intermittency)

Exclusion Criteria

Recent episodes of LUTS, patients on drugs, bladder calculi, bladder diverticula, chronic kidney disease, bilateral HUN, hematuria, h/o prostate surgery, h/o heart surgery.

Statistical Methods

SPSS version 22 and electronic spreadsheets (MS-excel). The other data were analysed with chi-square test and fishers test.

Study Tools

- International prostate symptoms score (IPSS).
- Qmax (Maximum Urinary Flow Velocity) on uroflowmetry.
- Post void residual urine (PVR) (Ultra Sound).
- All these three parameters were recorded and reviewed at 1, 3, 6 months.

RESULTS

	Baseline	1st month	3rd month	6th month
Mean age				
Group – I Group – II	61.5 years 63.6 years	61.5 years 63.6 years	61.5 years 63.6 years	**61.5 years** **63.6** years
Prostate Size				
Group – I Group – II	56+/- 6 gms. 53.7+/- 7 gms	56 gms. 53 gms.	54+/-.7 gms. 51+/-.5 gms.	54+/-.2 gms. 50+/-.5 gms.

Table 1: Mean age distribution

	Baseline	1st month	3rd month	6th month
		PVR		
Group – I Group – II	86+/- 12 ml 84+/- 14 ml	65+/- 10 ml 70+/- 9 ml	50+/- 6 ml 55+/- 5 ml	30+/- 7 ml 25+/- 5 ml

Table 2: PVR

	Baseline	1st month	3rd month	6th month
Group – I Group – II	11+/- 1.2 ml/s 12+/- 1 ml/s	12+/-1.2 ml/s 11.8+/- 1.4 ml/s	13+/- 1 ml/s 12.5+/- fd	15+/-.7 ml/s 15.2+/- 1.5 m/s

Table 3: Qmax

Prostate Size	P Value
Group – I Alpha Blocker Group – II PDE-5I	0.15 0.17
PVR	**P Value**
Group – I Alpha Blocker Group – II PDE-5I	<0.05 0.056
Qmax	**P Value**
Group – I Alpha Blocker Group – II PDE-5I	0.004 0.004

Table 4: Qmax

DISCUSSION

LUTS and ED are related conditions as age advances. The multinational survey of the ageing male (MSAM – 7) states that there is strong bond between age, sexual function, LUTS. PDE-5I are the first line drug for erectile dysfunction. FDA has been prescribing tadalafil (5 mg) for LUTS. This drug act by up regulation of no / cGMP pathway. They also reverse norepinephrine and endothelin induced prostate tissue contraction. By this way tension in the prostate tissue and capsule are reduced.6 The alpha blockers act via alpha – 1 adrenergic receptors which are abundant in the bladder neck, stroma, prostate capsule. This dynamic part leads to obstruction to the urine outflow. So it is almost that BPH and ED are linked to some extent and share pathophysiological pathways. Tadalafil can be used for both LUTS and ED but to treat subclinical ED treatment is not approved. Patients with mild to moderate LUTS, tadalafil should be recommended as the drug of choice.7

BPH/LUTS and ED both impact the quality of life of an individual patient. Alpha 1 blockers, which are standard of care for BPH/LUTS, have not shown consistent improvement in the erectile function, though there are few studies that report improvement.8 PDR-5 inhibitors, which are standard of care for treatment of ED, have been shown to cause a significant improvement in LUTS in patients with BPH in various studies, along with remarkable effect on erectile function, which has led to US-FDA approval of tadalafil for treatment of LUTS consistent with BPH with or without ED.9

After the first clinical report in 2002 of improvement in LUTS in men given sildenafil for their ED, there has been explosion of interest in the role of PDE-5 inhibitors as a treatment of LUTS, and in particular, for the management of many men with both condition. Scientific basis is rapidly becoming stronger and there is now a good level 1 evidence from various clinical trials clearly showing improvements of LUTS after treatment with PDE-5 inhibitors.10

CONCLUSION

Though BPH associated LUTS and ED are epidemiologically linked and share common pathophysiological pathways, there is an as yet undetermined link between BPH-LUTS and ED. There is now good Level 1 evidence of a beneficial effect of PDE-5I on urinary symptoms, though PDE-5I alone do not improve flow rates as the mechanisms of effect are still unclear and are subject of extensive research because so many other body systems are also affected. Our study concludes that PDE-5 inhibitor (Tadalafil) should be preferred over alpha blockers in treating LUTS due to BPH as PDE-5 inhibitors are found to be more efficacious than alpha blocker with lesser incidences of side-effects. It is likely that PDE-5I will be valuable, especially for men with BPH-LUTS and significant ED, though further data on safety and cost effectiveness is needed.

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