Original Article ISSN (O):2395-2822; ISSN (P):2395-2814

Treatment of Lower Urinary Tract Symptoms in Benign Prostatic Hyperplasia Tamsulosin vs Tadalafil: A Comparative Study

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Received: January 2020
Accepted: January 2020

ABSTRACT

Background: In the Management of lower urinary tract symptoms secondary to benign prostatic hyperplasia, Tadalfil and Tamsulosin have both been approved by U.S Food and Drug Administration We conducted a Randomized control prospective study aiming to assess the efficacy and safety of Tadalafil compared with Tamsulosin. **Methods:** A total of 50 patient presenting with lower urinary tract symptoms (LUTS) due to BPH were selected and randomized using a computer generated random numbersto receive either 5mg tadalafil daily or 0.4 mg tamsulosin daily. Base line Q max , PVR(post void residual), IPSS(International prostate symptom score), International Prostate Symptom Score Quality of life (IPSS QoL) and Sex Health Inventory for Men(SHIM) Scoring , were noted at start of study and at end of 12 weeks. Patient with history of drug treatment, history of prostate surgery and raised PSA were excluded from study. **Results:** In tadalafil group, 6 (24%) patients were having mild LUTS and 19 (76%) were having moderate LUTS. In tamsulosin group, 5 (10%) patients were having mild LUTS and 21 (84%) patients were having moderate LUTS. 8 (32%) patients in tadalafil group had associated ED (erectile dysfunction) and 7(28%) patients had associated ED in tamsulosin group. **Conclusion:** In comparison between the drug Tadalafil and Tamsulosin, in this study tamsulosin showed better efficacy than tadalfil in treatment of LUTS Secondary to BPH.

Keywords: Tadalafil, Tamsulosin, Benign Prostatic Hyperplasia. Erectile dysfunction, Lower Urinary Tract Symptoms.

INTRODUCTION

Lower Urinary track Symptoms suggestive of Benign Prostatic Hyperplasia (LUTS/BPH) may include urgency, increased urinary frequency, nocturia, weak urinary stream, intermittent stream, straining, and incomplete emptying.[1,2] Benign prostatic hyperplasia (BPH) is highly prevalent in elderly men and often results in lower urinary tract symptoms (LUTS). LUTS secondary to BPH increases with age and negatively impacts patients' quality of life. The current standard of care in men with moderate to severe LUTS secondary to BPH is treatment with alpha-blockers or in men with enlarged prostates with5-alpha-reductase inhibitors either alone or in combination and transurethral surgery in those who have failed medical therapy.[3-5] The phosphodiesterase type 5 (PDE5) inhibitor tadalafil has recently received approval in the USA and European Union for the treatment of LUTS/BPH, with or without erectile dysfunction (ED). Tadalafil has demonstrated significant improvements vs placebo in the IPSS across registrational studies, with treatment difference vs placebo in pooled analysis of −2.3 (P <0.001).[6]

Several studies have been conducted in men presenting with LUTS consistent with benign prostatic hyperplasia (BPH/LUTS) with and without concomitant ED to determine whether phosphodiesterase type 5 inhibitors (PDEIs) are effective for the treatment of symptomatic BPH.[5] The prevalence of LUTS/BPH increases with age, and LUTS/BPH can significantly impact Health related quality of Life.[7] As LUTS/BPH are usually chronic and progressive,[8–9] treatment is typically long-term, thus making treatment satisfaction an essential component of successful therapy.[10,11] The current scientific evidence is insufficient to predict the differential response of either of the drugs and response of one of the agents when there is no response to the other for the treatment of LUTS. Hence, the best way to compare the efficacy would be a cross over study design.

The present study purpose was to compare the efficacy of tamsulosin and tadalafil with regard to LUTS and Erectile Dysfunction in cases of BPH in a

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crossover design. The objective was to compare the magnitude of effect of Tamsulosin and Tadalafil in relieving BPH/LUTS using International Prostate Symptom Score (IPSS).

MATERIALS AND METHODS

Study Design:

Randomized controlled prospective single blinding study, conducted in Department of Urology CAIMS, Karimnagar, including 50 Patients with LUTS to BPH, after approval of ethical institutional Committee

Sample Size:

Total 50 patients were included in this study. Group-Tad (Tadalafil Group): 25 patients,
Group- Tam (Tamsulosin Group): 25 patients

Inclusion Criteria:

- All patients who presented with LUTS secondary to BPH.

Exclusion Criteria:

Patients presenting with acute urinary retention, neurogenic bladder dysfunction, bladder neck contracture, urethral stricture, bladder calculi, active urinary tract infection (UTI), prostate cancer, history of pelvic radiotherapy, prostatectomy, any disease affecting urinary function, clinically significant cardiac disease, chronic renal failure, severe hepatic illnesses, discontinuation of treatment. And those who unwilling to participate were excluded form study.

After approval by Institutional Ethical Committee, CAIMS, Karimnagar and obtaining informed consent from the patients.

The patients were randomized into one of the two sequences in a single blind manner by using a computer generated random numbers for 50 patients with 1:1 ratio making 50 patients in each group. The two drug treatment interventions (A) Tadalafil (B) Tamsulosin were administered for a period of 12 weeks and with an intervening 4-week period

Procedure

A standard investigation protocol which included general clinical examination with abdominal examination, examination of external genitalia and digital rectal examination, focused neurological examination was done to exclude any neurological deficit, uroflowmetry, abdominal ultrasound, blood tests including RFT (renal function tests), serum PSA (prostate specific antigen), urinalysis, urine culture was done.

All patients were explained about the IPSS (International Prostate Symptom Score) and the IPSS scoring sheet was provided to quantify the severity of LUTS and Sexual Health Inventory for Men (SHIM) scoring in patients with erectile dysfunction. All the patients participating in the study were properly informed about the trial.

Informed written consent was obtained from patients (properly explaining the aims, methods, anticipated benefits and potential drawbacks relevant for the decision to participate in the trial). The drug was taken 30 min after dinner. Patients were assessed at baseline, 1 week, 4 weeks and 12 weeks with efficacy measures being Qmax, PVR (post void residual urine), IPSS, IPSS QoL (International Prostate Symptom Score Quality of Life). Sexual Health Inventory for Men (SHIM) scoring was evaluated at baseline, 4 weeks and 12 weeks.[12] Evaluation included clinical determination of IPSS, Qmax, PVR, QoL, and prostate size were recorded

Statistical Analysis

Recorded observation were entered in the spread sheet using Microsoft excel 2016 for further statistical analysis. All the observation were quantitative so that descriptive statistics (Mean, standard Deviation, Range) were calculated and by using Descriptive statistics inferential statistics were done by using t-test and ANOVA in statistical software SPSS Version 25.

P-value less than 0.05 consider as statistical significant at 5% and less than 0.01 considered as highly significant at 5%.

RESULTS

In baseline findings the mean age was 59.09 ±7.52 years in the tadalafil group and 64.78 ±9.24 years in the tamsulosin group. In this study, in the tadalafil group, 12 (48%) patients had a prostate gland size less than 30 g and 13 (52%) patients had a prostate gland size more than 30g. In the tadalfil group, 13 (52%) patients had a prostate gland size less than 30 g and 12(42%) patients had a prostate gland size more than 30 g.

A total of 10 (42%) patients were hypertensive in the tadalafil group and 8 (32%) patients in the tamsulosin group. Where 8 (32%) in the tadalafil group and 9 (36%) in the tamsulsoin group were with Diabetes mellitus. In the tadalafil group, 6 (24%) patients had mild LUTS and 19 (76%) had moderate LUTS. In the tamsulosin group, 5 (10%) patients had mild LUTS and 21 (84%) patients had moderate LUTS. 8 (32%) patients had associated ED in the tadalafil group and 7 (28%) patients had associated ED in the tamsulosin group.

In this study, 3 patients received washout therapy in the tadalafil group and 3 patients in the tamsulosin group. Baseline (BS) characteristics of both the groups recorded at day 0 of the trial were compared and are presented in Table 1. Parameters such as age, and PVR found statistically significant and others variables such as prostate volume (g), total IPSS score, quality of life score, maximal urinary flow

rate were not significantly different between both groups [Table 1].

In this study, both the groups showed a response to the treatment after 1 week of initiation. The group receiving tadalafil showed a response in all the parameters with no statistical value. The group receiving tamsulsoin showed a significant change in Qmax and PVR but not in IPSS and IPSS-QoL after 1 week of treatment. After 4 weeks of initiation, both the groups showed response in all the efficacy measures. Patients receiving tamsulsoin had statistically significant improvement in Qmax, reduction in PVR and IPSS, also in IPSS-QoL but this was not statistically significant. Patients who received tadalafil showed a response in all parameters but with no statistical significance.

After 12 weeks of treatment, both groups showed a response in all the efficacy variables and these were maintained. Patients who received tadalafil showed a statistically significant change from baseline with improvement in Qmax, reduction in IPSS and IPSS QoL Scores. PVR was reduced in the tadalafil group but showed no statistical significance. Patients who received tamsulosin showed further significant efficacy in all the measures, rise in Qmax, reduction in IPSS, IPSS QoL scores and PVR.

Maximal urinary flow rate was significantly improved from baseline with both tadalafil and tamsulosin during the treatment period. Tamsulosin treatment resulted in a more significant change from baseline in Qmax of +5.59 compared to +1.27 in the tadalafil group with statistical significance, p = 0.007. The mean decrease in the residual urine volume in the tadalafil group was 11.55 ml and in the tamsulosin group was 62.84 ml. Tamsulosin treatment showed significant reduction in PVR compared to the tadalafil with a p value of 0.02 [Table 2].

IPSS score was improved from the baseline to 12 weeks after treatment in both groups; reduction in IPSS was greated in the tamsulsoin group when compared to the tadalafil group, but this was of no statistical significance. The overall mean reduction of IPSS score in the tadalafil group is 1.1 compared to 1.27 IPSS reduction in the tamsulosin group [Table 2]. The mean change in quality of life was noted in both groups, but this was not statistically significant, with a mean change from baseline of 0.11 in the tadalafil group and 0.76 in the tamsulosin group.

Table 1: Baseline Characteristic in Tadalafil and Tamsulosin

	Tadalafil			Tamsulosin			p-value
	Mean	SD	Range	Mean	SD	Range	
Age	59.09	7.528	41-75	64.78	9.247	46-79	0.021*
Prostate Size	32.7225	9.34724	14-48	33.0049	11.0369	18-60	0.923
Qmax	12.7544	4.06804	4-20	11.4751	3.8091	1-21	0.257
PVR	55.9785	32.44324	4-110	90.9322	63.75189	6-220	0.018*
IPSS	12.98	4.691	4-20	13.17	5.015	6-22	0.888
IPSS QoL	2.66	1.145	0-5	2.94	0.862	1-4	0.321

Table 2: Comparison of mean change from baseline in all the efficacy variables between Tadalafil and Tamsulosin

	Tadalafil			Tamsulosin			p-value
	Baseline	12 weeks	Difference	Baseline	12 weeks	Difference	
Qmax	12.7544	14.03	1.27	11.4751	17.07	5.59	0.007*
PVR	55.98	44.42	-11.55	90.93	28.09	-62.84	0.02*
IPSS	12.98	11.88	-1.1	13.17	11.9	-1.27	0.987
IPSS QoL	2.66	2.55	-0.11	2.94	2.18	-0.76	0.053

Table 3: Change from baseline to 12 weeks in SHIM score in men with associated erectile dysfunction in Tadalafil and Tamsulosin

	No.	Range	Baseline (Mean)	4 weeks (Mean)	12 Weeks (Mean)	Difference (Baseline - 12 Weeks)	p-value
Tadalfil	9	5-20	13.09	11.09	16.10	3.01	0.04*
Tamsulosin	7	2-20	11.88	14.15	9.77	2.11	0.3

Table 4: Mean change in efficacy variables in patients with associated erectile dysfunction between Tadalafil and Tamsulosin

	Tadalfil (n=9)			Tamsulosin (n=7)		
	Baseline	12 weeks	Difference	Baseline	12 weeks	Difference
Qmax	13.2	14.38	1.18	13.43	16.89	3.46
PVR	51.23	38.65	-12.58	60.46	25.30	-35.16
IPSS	13.65	12.42	-1.23	13.42	11.03	-2.39
IPSS QoL	2.96	2.37	-0.59	2.98	2.32	-0.66
SHIMS	11.86	14.63	2.77	12.36	15.23	2.87

In Present study, 9 patients in the tadalafil group had associated erectile dysfunction and 7 patients had associated erectile dysfunction in the tamsulosin group. The change in the SHIM score in the tadalafil

group was 16.10 compared to a baseline of 13.09 and with tamsulosin treatment it was 9.77 compared to a baseline of 11.88. The mean change form baseline SHIM to 12 weeks after initiating treatment was noted in both groups, with tadalafil it was 3.01 (p = 0.04) which is statistically significant and with tamsulosin it was 2.11 (p = 0.3) with no statistical significance [Table 3].

Above table showed that there was no difference in the mean change from baseline to 12 weeks Observed with tadalafil in all the efficacy variables in men associated with ED to that of overall population. The mean change observed with tamsulosin in all the efficacy variables from baseline to 12 weeks in men associated with ED was similar to that of the overall population. In present study, significant change in Qmax and PVR was noted in tamsulosin when compared with tadalafil in men associated with ED which is similar to that of overall population. There was no difference in mean change in IPSS and IPSS QoL in men associated with ED to that of overall population. Significant response was seen in SHIM score with tadalafil when compared to tamsulosin.

DISCUSSION

LUTS and Erectile dysfunction are highly related diseases as both had increased incidence and prevalence with increasing age.[13,14] For a long time both were considered as two different diseases and were treated separately. Many times erectile dysfunction part is neglected both by patient and physician as it is considered normal part of ageing and untreatable. Treatment used for LUTS also has negative impact on sexual function of male patient and worsen the disease. LUTS and ED, both impact the quality of life of an individual patient. Alfa blockers, which are the standard of care for BPH related urinary symptoms, have not shown consistent improvement in the erectile function, though there are some studies that report improvement.[15,17]

The 2016 Guidelines on the Management of Male LUTS (including benign prostatic obstruction) published by the European Association of Urology (EAU) and guidelines compiled by the American Urological Association (AUA) recommend the use of several different pharmacotherapies for the treatment of LUTS, depending on the clinical situation. Alpha-blockers and 5-ARIs are considered the first-line medical treatment in men with moderate to severe LUTS. The newest drug class, PDE5-Is, are mentioned in the 2013 EAU guidelines.[18,19] The aim of present study was to make a direct comparison of two medical treatment options for patients with LUTS secondary to BPH in daily clinical practice.

In a dose-finding study, tadalafil 5 mg was approved to provide a positive risk benefit profile compared with other doses for 12 weeks.[20] The insignificant increase in Qmax for all doses suggested that tadalafil can exert its clinical activity differently compared to the traditional BPH treatment with alpha- blockers. Tamsulosin, a uroselective alpha-blocker, relaxes smooth muscle in the prostate and bladder neck, thereby enhancing bladder emptying.

In randomized, controlled clinical trials using standardized instruments, tamsulosin improves lower urinary tract symptoms by at least 25% in 65–80% of patients with symptomatic benign prostatic hyperplasia.[21] Oelke et al. reported a significant outcome in Qmax (+2.4 ml/s, p <0.05) in men with a lower baseline obstruction (Qmax at baseline: 9.9 ml/s) with tadalafil, which is nearly similar to our study (+1.27 ml/s, p = 0.007).[2] Chapple et al. reported the results of a meta-analysis of two multicenter randomized controlled trials, where tamsulosin treated patients had a greater increase in peak urinary flow rate and a more significant decrease in PVR when compared with patients in the placebo group.[22]

In present study, comparison between tadalafil and Tamsolusin showed more efficacy in raising Qmax. These results were similar to study conducted by Abrams et al. and Lepor et al. who stated that patients treated with tamsulosin experienced a greater increase in peak urinary flow.[23–26] In our analysis, IPSS score was improved from the baseline to 12 weeks after treatment in both groups, with a greater reduction in IPSS in the tamsulosin group when compared to the tadalafil group, but this was of no statistical significance.

According to AUA guidelines, a 3-point change from baseline IPSS is considered significant, which is nearer to the results seen with tamsulosin in our study. Consistent with the clinically meaningful improvement in total IPSS seen in this study for tamsulosin (-1.27), as well there is improvement in IPSS with tadalafil (-1.1) which was not statistically significant and similar to findings in the study by Dunn et al.[27] The IPSS findings from the present study were consistent with those from other studies of tadalafil 5 mg and tamsulosin 0.4 mg in Asian and non-Asian men with LUTS secondary to BPH.[28–33]

The mean change in IPSS QoL from baseline to 12 weeks with tadalafil (0.11) is comparable to tamsulosin (0.76) in our study, but not statistically significant, agreeing with other randomized, double-blind, placebo controlled study by Oelke M et al. and another study by McVary et al.[2,34] Though our study was not specially designed to demonstrate efficacy in treating ED, tadalafil showed significant mean change in SHIM when compared to tamsulosin (p = 0.04 and p = 0.3, respectively), which is consistent with study by Oelke et al.[2] Broderick et al.[35] compared the efficacy of tadalafil in BPH patients with and without ED and reported that the relief in LUTS caused by tadalafil was not influenced by ED according to Alexander Govorov et al.[18] which is similar to our study. Both drugs

were very well tolerated in our study. They have an almost negligible rate of adverse events, comparable to Oelke M et al.[2]

CONCLUSION

Tamsulosin 0.4 mg once daily for 12 weeks resulted in clinically meaningful improvements in Qmax, PVR, IPSS and IPSS-QoL in patients with LUTS secondary to BPH, which were statistically significant. Tadalafil also showed significant improvement in ED which was not seen with tamsulosin. When both groups were compared, tamsulosin showed better efficacy than tadalafil in treating LUTS secondary to BPH with significant difference in Qmax and PVR between both groups. Present study provides evidence supporting the above-mentioned conclusion and suggests that once Tadalafil 5 mg daily monotherapy is able to improve ED and overall LUTS (IPSS and Qmax) after 12 weeks. However, the addition of tamsulosin 0.4 mg to tadalafil 5 mg can further enhance the improvement of voiding symptoms and Qmax. Combination therapy is well tolerated.

Limitation of Study

There are a few limitations of our study. The sample size is small and these findings need to be confirmed in a large database for further recommendations. The men enrolled in the trial may represent a highly motivated sample, seeking medical advice for their LUTS and ED, which may not represent the true association of these two conditions overall. Further studies, with longer follow-ups, are still required to assess long term efficacy and safety of tadalafil and tamsulosin administration.

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How to cite this article: Murthy SK, Rathi A, Rao P, Kamble A, Teja R. Treatment of Lower Urinary Tract Symptoms in Benign Prostatic Hyperplasia Tamsulosin vs Tadalafil: A Comparative Study. Ann. Int. Med. Den. Res. 2020; 6(2):SG30-SG35.

Source of Support: Nil, **Conflict of Interest:** None declared