

Comparison of Tamsulosin Versus Silodosin for Treatment of Patients with Benign Prostatic Hyperplasia

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ABSTRACT

Objective: To evaluate the efficacy of drug in improving lower urinary tract symptoms for improved health care and better management of patients.

Study Design: Randomized controlled trial

Place and Duration of Study: Department of Urology, Department of General Medicine and Department of General Surgery, Pakistan Ordinance Factories Hospital, Wah Cantt from 1st January 2021 to 31st July 2022.

Methodology: One hundred patients, age more than 45 years, moderate to severe prostatic hyperplasia and prostrate size >50 gm were included. Detailed demographics were recorded after taking informed written consent. Patients were divided into two groups randomly through lottery method. In group A; patients were given tablet Tamsulosin 0.4 mg once daily and in group B; patients were given tablet Silodosin 4 mg once daily for 12 weeks. Effectiveness between both groups were compared.

Results: In group A, mean age of 59.70±7.45 years. In group B; mean age of 59.74±7.69 years. In group A; pre-treatment mean IPSS score 16.74±1.78 while in group B; mean score was 16.12±2.46. Pre-treatment PVR in group A was 57.62±8.9 while in group B mean PVR was 57.96±8.71. The post-treatment IPSS score showed that group A mean IPSS score of 9.26±1.61 while group B had mean IPSS score was 6.58±1.26 and P<0001. The post-treatment PVR volume results showed that group A mean PVR volume of 29.5±3.03 while group B had mean PVR was 25.12±1.94 and P<0001.

Conclusion: The silodosin is an effective therapy for LUTS in men with benign prostatic hyperplasia.

Keywords: Treatment, Benign prostatic hyperplasia, Lower urinary tract symptoms

INTRODUCTION

Aging people suffer from Lower urinary tract symptoms (LUTS) which include urinary frequency, urgency, nocturia, straining, urinary dribbling, incomplete emptying and poor urine stream. Benign prostatic hyperplasia (BPH) results in lower urinary tract symptoms in elderly males (age > 70 years).¹ Histologically, benign prostatic hyperplasia (BPH) is benign condition resulting from increased prostrate size secondary to glandular as well as stromal tissue hyperplasia.² Pharmacologically LUTS occurs due to increased smooth muscle contraction secondary to alpha 1-adrenoceptors activity.³

Lower urinary tract symptoms can be i.e., obstructive, irritative, and postmicturition.⁴ BPH is treated by different means depending on severity of symptoms. For mild conditions watchful waiting is enough. For moderate to severe disease pharmacological as well as surgical methods are available. Pharmacologic treatment includes alpha1-adrenergic receptor antagonists and/or 5a-reductase inhibitors.⁵

Alpha 1-adrenoceptor blockers (AB) are considered primary treatment of BPH patients. Benefits of Alpha 1-adrenoceptor blockers include increased efficacy, less cost and minimal side effects making it drug of choice for treatment of BPH.⁶ Alpha 1-adrenoceptor blockers mainly act by prostatic and urethral smooth muscle relaxation resulting in improved voiding and alleviating most of lower urinary tract symptoms.⁷

EAU guidelines (2011) recommend alpha-blockers as 1st line treatment for treatment of moderate or severe LUTS/BPH. Alpha-blockers for BPH include alfuzosin, prazosin, doxazosin, tamsulosin, terazosin and silodosin, considered as selective alpha1-adrenergic blockers.^{8,9} Different studies have been conducted comparing different alpha 1 blocker efficacy and showed that silodosin may be better in treating BPH patients as compared to other available drugs and has fewer side effects reported as compared to other drugs.^{10,11}

The purpose of this study is to compare the tamsulosin with silodosin which is most widely used drug for LUTS secondary to BPH, a novel newer drug.

MATERIALS AND METHODS

This randomized controlled trial was done in Urology, General Medicine and General Surgery Department, Pakistan Ordinance

Factories Hospital, Wah Cantt from 1st January 2021 to 31st July 2022. A total of 100 patients were included in study. Patients were divided into two groups randomly through lottery method. In group A; patients were given tablet Tamsulosin 0.4 mg once daily and in group B; patients were given tablet Silodosin 4 mg once daily for 12 weeks. Patients with age more 45 years, with moderate to severe BPH, prostrate size >50 gm were included in the study. Patients wanting surgery, acute urinary retention, chronic urinary tract infection and chronic renal failure were excluded from study. After taking permission from ethical committee of hospital, patients fulfilling inclusion criteria presenting OPD with LUTS; after complete evaluation with history, physical examination, investigations (Blood CP, urine R/E, urine C/S, BSR, RFT) ultrasound for prostrate size was done by consultant radiologist. Baseline IPSS score before starting the treatment was recorded. In group A; patients were given tab. Tamsulosin 0.4 mg once daily and in group B; patients were given tab. Silodosin 4 mg once daily for 12 weeks. Post treatment IPSS score was recorded. All data was entered and analyzed using SPSS-22. Independent sample T-Test was applied to compare mean difference in post treatment IPSS score and post treatment PVR.

RESULTS

There were 4 patients who were below 50 years of age, 27 patients were between age of 50-59 years of age and remaining 13 belonged to age group of 60-69 years in group A with mean age was 59.70±7.56 years while in n group B, there were 5 patients who were below 50 years age, 25 patients were between the age of 50-59 years and remaining 14 belonged to the age group of 60-69 years with mean age was 59.74±7.69 years. The minimum size of prostate gland was 65 gm and maximum size was 112 mg, mean size of gland was 86.18±10.04 mg in group A while in group B; minimum size of prostate gland was 68 gm and maximum size was 112 mg mean size of gland was 90.22±10.12 mg. The minimum PSA level was 3.1 mg/dl and maximum level was 4.6 mg/dl mean PSA level was 3.90±0.47 mg/dl and in group B; minimum PSA level was also 3.1 mg/dl and maximum level was also 4.6 mg/dl with mean PSA level was 3.94±0.44 mg/dl. The minimum IPSS score was 13, maximum score as 21, mean score was 16.74±1.78 in group A while in group B, minimum IPSS score was 12, maximum score as 21 with mean score was 16.12±2.46.

In group A, minimum PVR volume was 43, maximum volume as 76 and mean score was 57.62±8.9 while in group B, minimum PVR score was 42, maximum score as 74 with mean score was 57.96±8.71 (Table 1).

In group A, mean IPSS score of 9.26±1.613 while group B had mean IPSS score was 6.58±1.263 and P value was 0001 (Table 2). The post treatment PVR volume showed that group A, mean of PVR volume was 29.5±3.03 while in group B mean PVR volume was 25.12±1.94 and P-value was 0001 (Table 3).

Table 1: Descriptive statistic of the patients in both groups

Variable	Group A	Group B
Age (years)	59.70±7.45	59.74±7.69
Prostate gland size	86.18±10.04	90.22±10.12
PSA level	3.90±0.47	3.94±0.44
IPSS score	16.74±1.78	16.12±2.46
PVR	57.62±8.90	57.96±8.71

Table 2: Comparison of post-treatment IPSS score in both groups

Group	Mean±SD	P value
A	9.26±1.61	0.001
B	6.58±1.26	

Table 3: Comparison of post-treatment PVR score in both groups

Group	Mean±SD	P value
A	29.50±3.03	0.001
B	25.12±1.94	

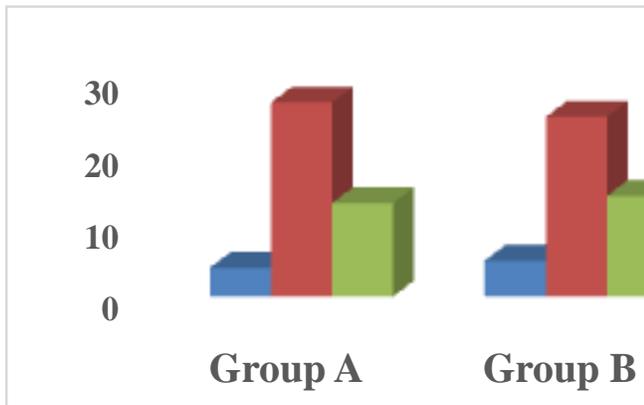


Fig. 1: Frequency of age among both groups

DISCUSSION

In a multicentric RCT comparing silodosin, tamsulosin and placebo showed that both silodosin and tamsulosin were effective in reducing baseline IPSS score when compared to placebo. 66.8% responded to silodosin treatment with improvement in IPSS score. Similar improvement was observed in patients taking tamsulosin (65.4%). However only 50.8% patients taking placebo showed improvements.¹²

Miyamae et al¹³ also conducted RCT in 2009 and they given tamsulosin and half were administered silodosin showed that IPSS score in tamsulosin group 84% patients improved when compared to silodosin which improvement in only 68.5% patients. Similarly; tamsulosin was more effective as compared to silodosin on basis of overactive bladder symptom score OABSS (82.0% vs 57.4%) and P value was <0.001.

Manohar et al¹⁴ conducted the study from 2012 to 2015 including 269 patients who underwent treatment for BPH. Patients were divided into three groups. Group T patients were administered 0.4 mg tamsulosin, group A patients were given 10 mg alfuzosin and group S patients were administered 8 mg silodosin. Baseline IPSS was compared with post treatment IPSS score at first week and 3 months time interval. Group S patients

who were given silodosin showed improvement of IPSS at first week (11.7±4.18, p=0.027) and at 3 months (7.97±3.84, p=0.020).

Pande et al¹⁵ compared tamsulosin with silodosin and results showed comparable efficacy for both drugs. Takeshita et al¹⁶ also compared 4 mg of silodosin with 0.4 mg of tamsulosin. They observed the efficacy on basis of mean IPSS change and showed that both drugs had comparable results but silodosin was much better in improving nocturia when compared to tamsulosin. Another study including 209 patients with BPH undergoing medical treatment with IPSS score of ≥13 were included and divided into two groups. Group A received silodosin 4 mg, BD and group B was administered tamsulosin 0.2 mg OD for 12-week duration., 25% improvement in IPSS score was observed in 86.2% patients in silodosin group vs 81.9% in tamsulosin group (P=0.53).¹⁷

First RCT for comparing tamsulosin and silodosin was done in 2006. Group A patients were administered silodosin 4 mg BD and group B patients were given tamsulosin 0.2 mg OD and group C patients were given placebo for 12-week. Mean change in IPSS was observed. For patients receiving silodosin there was 8.3 decrease in baseline IPSS score, for tamsulosin group mean change was 6.8 and for patients receiving placebo 5.3 decrease in mean IPSS was observed respectively.¹⁸

Ding et al¹⁹ in 2013 conducted RCT in India on BPH patients presenting with lower urinary tract symptoms comparing silodosin 4 mg dosage and tamsulosin 0.2 mg dosage. They showed that both drugs were equally effective for improving LUTS. Similarly other studies with higher doses of silodosin 4mg BD and tamsulosin 0.4 mg have been conducted showing similar results.

CONCLUSION

The current study suggests that silodosin is an effective therapy for LUTS in men with BPH. In the future, higher-quality and long-term RCTs are needed to verify the findings of this study, and studies that compare 8 mg silodosin with 0.4 mg tamsulosin are also needed.

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