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Comparison of Outcome between Tamsulosin and Silodosin in patients of Benign Prostatic Hyperplasia.

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Abstract: Background: Benign Prostatic Hyperplasia – (BPH) is a prevalent urinary system illness in older men and the most prevalent cause of symptoms related to the lower urinary tract (LUTS). Although silodosin and tamsulosin are often used in clinical settings to treat this problem, there is still limited information comparing the two medications' safety and effectiveness.**Objective**:To compare the effectiveness of Silodosin 8 mg and Tamsulosin 0.4 mg in reducing post-void residual volume of urine and improving lower urinary tract symptoms in people with benign prostatic hyperplasia**Method:**This is a comparative cross-sectional study undertaken by the author's research team at Shaheed Mohtarma Benazir Bhutto Medical University's Department of Urology during a 6-month period. A total of 370 male patients confirmed as benign prostatic hyperplasia aged 50 to 70 years were enrolled and divided equally into two groups. Group A got 0.4 mg tamsulosin daily, whereas Group B took 8 mg silodosin daily. Baseline IPSS and PVR evaluations were undertaken, and follow-up examinations were conducted two, four, and eight weeks following the intervention. SPSS 23 was used to analyze all data. A p-value < 0.05 was considered statistically significant.**Results:**Both groups of patients diagnosed with benign prostatic hyperplasia who received silodosin and tamsulosin, respectively, showed significant improvements in their core follow-up indicators IPSS and PVR ($p<0.001$). However, silodosin showed superior therapeutic efficacy; the tamsulosin group experienced more orthostatic hypotension and dizziness, while the silodosin group experienced more ejaculatory dysfunction.**Conclusion:**Tamsulosin and Silodosin both were effective to treat BPH-related LUTS. Silodosin, on the other hand, showed better improvements in IPSS and PVR while maintaining a good cardiovascular safety profile.

Keywords: Tamsulosin, silodosin, IPSS, post-void residual volume, benign prostatic hyperplasia, and LUTS.

INTRODUCTION

Benign Prostatic Hyperplasia (BPH) is a prevalent, non-malignant enlargement of the prostate gland in elderly men, often a cause of lower urinary tract symptoms (LUTS) such as urinary frequency, urgency, nocturia, and weak stream 1. The prime goal of BPH treatment is to reduce these bothersome symptoms while improving its impact on life. Among the therapeutic options, alpha-1 adrenergic receptor blockers, such as Tamsulosin and Silodosin, are frequently prescribed to improve these symptoms by relaxing the smooth musculature of prostate gland, thereby improving urine flow2.

Tamsulosin is a selective alpha-1A/1D adrenergic receptor antagonist that relaxes the muscles in the prostate and bladder neck, thereby improving urine flow and alleviates BPH symptoms3. It is a well-known drug for its efficacy and favorable safety profile. Literature has revealed an improvement both in terms of International Prostate Symptom Score (IPSS) as well as post-void residual volume (PVR)4. According to a systematic review from the Cochrane database, tamsulosin considerably improves symptoms and peak urine flow compared to placebo. The weighted mean differences (WMD) for symptom score improvements were -1.1 points for 0.4 mg and -1.6 points for 0.8 mg doses, indicating a 12-16% improvement5. Peak urine flow rates also improved by 1.1 mL/sec for both doses. However, fewer adverse effects associated with higher doses such as dizziness, rhinitis, and abnormal ejaculation have been reported.

Silodosin is a highly selective α1A blocker that specifically relaxes the smooth muscle in prostate and bladder neck, reducing its obstruction and thereby improving the lower urinary tract symptoms as well International Prostate Symptom Score (IPSS)6. This drug can be used alone or in combination therapy for the treatment of BPH. It improves the storage capability of bladder as well as relieves the voiding complaints. Literature has revealed 38 times higher selectivity of silodosin as compared to tamsulosin and thereby improving the LUTS symptoms and with fewer cardiovascular side effects7.

This study aims to compare the effectiveness of Tamsulosin and Silodosin in managing BPH, specifically focusing on the improvement of symptoms measured by the International Prostate Symptom Score (IPSS) and the reduction in Post Void Residual (PVR) volume. The study will follow patients at intervals of 2, 4, and 8 weeks to assess the outcomes, providing valuable insights into the optimal pharmacological management of BPH. While both drugs i-e Tamsulosin and Silodosin are effective, their comparative efficacy, particularly in terms of symptom improvement (IPSS) and urinary retention (PVR), needs further exploration. This study aims to fill this gap by comparing the outcomes at specific follow-up intervals.

Methodology

This is a comparative - cross-sectional study undertaken by our research team. It took six months to finish at the Department of Urology at Pakistan's Shaheed Mohtarma Benazir Bhutto Medical University. The institutional ethical review committee and the College of Physicians and Surgeons Pakistan (CPSP) approved the study, and all procedures throughout the research followed the ethical guidelines for human research articulated in the signing of the Declaration of Helsinki.

The study's sample size was determined using the OpenEpi tool, with a five percent (5%) margin of error and a 95% confidence range. In the end, 370 male patients with symptoms of lower urinary tract infection (LUTS) and benign prostatic hyperplasia (BPH) between the ages of 50 and 70 were included. Enrollment criteria were a prostate volume of 30-80g, an International Prostate Symptom Score (IPSS) of at least 8, and a post-void residual (PVR) volume more than 50mL. The study excluded patients with prostate malignancy, prior prostate surgery, significant hepatic or renal impairment, neurogenic bladder diseases, urethral stricture disease, urinary tract infection, bladder stones, or who were taking drugs that affected urinary symptoms.

Consecutive sampling was utilized in this study to find qualified individuals. The study met the ethical standards for clinical research, and each participant completed an informed consent form in writing prior to recruitment. Participants were split into two equal-size groups using a generated by software simple random sequence, and concealment of allocations was accomplished using opaque, sealed envelopes: Group A consumed 0.4 milligrams of tamsulosin and Group B took 8 mg of silodosin daily. We used uniform standardized questionnaire forms to collect baseline information such as age, IPSS, PVR, and other pertinent data. The same senior radiology specialist used transabdominal ultrasonography to estimate the prostate's size and post-void residual urine volume. The ellipsoid formula of 0.52 × height × breadth × length was used to compute the prostate's volume.

For patients undergoing treatment for prostate conditions, this study developed a standardized full-process evaluation approach. At baseline and two, four, and eight weeks following the start of therapy, follow-up appointments were held. IPSS scores, PVR (post-void residual) urine volume, medication compliance, and seven adverse responses, such as orthostatic hypotension and dizziness, were all noted by the researchers at each visit. Patients' prescription records and follow-up interviews were used to evaluate treatment adherence. Individuals who don't follow instructions or those who are lost we're not included in the analysis. The improvement in IPSS

scores between the two groups was the main endpoint, while variations in the incidence of adverse reactions and a decrease in PVR urine volume were the secondary outcomes.

This study's research data was processed and analyzed using SPSS 23 software. Quantitative data are provided as mean ± standard deviation, whereas qualitative variables are characterized statistically by frequency and percentage. For between-group comparisons, independent samples t-tests and chi-square tests were utilized, and repeated-measures ANOVA was used to examine the temporal changes in IPSS and PVR. Statistical significance was defined as a p-value < 0.05. The lead researcher double-checked all study data, and research subjects' anonymity was scrupulously maintained throughout the research procedure.

Results

This study included 370 male patients with benign prostatic hyperplasia (BPH) who were evenly randomized into two groups: Group A got Tamsulosin 0.4 mg daily (n = 185), and Group B received Silodosin 8 mg daily (n = 185). Both groups' baseline demographic and clinical features were equivalent, with no differences of statistical significance identified, as indicated in Table 1.

Table 1: Baseline Characteristics of Study Participants

Variables	Tamsulosin Group (n=185)	Silodosin Group (n=185)	p-value
Mean Age (years)	61.8 ± 6.4	62.1 ± 5.9	0.67
Prostate Size (grams)	52.6 ± 11.3	53.1 ± 10.8	0.74
Baseline IPSS Score	22.4 ± 3.1	22.8 ± 3.4	0.29
Baseline PVR (mL)	96.7 ± 18.5	98.2 ± 17.9	0.48
Diabetes Mellitus, n (%)	48 (25.9%)	45 (24.3%)	0.72
Hypertension, n (%)	56 (30.3%)	59 (31.9%)	0.81

The Tamsulosin group had a mean age of 61.8 ± 6.4 years, while the Silodosin group had a mean age of 62.1 ± 5.9 years (p = 0.67). Similarly, the two groups had similar baseline International Prostate Symptom Scores (IPSS) and post-void residual (PVR) volumes.

During follow-up, IPSS scores significantly improved for both therapy groups. The mean IPSS score in the Tamsulosin group dropped from 22.4 ± 3.1 at baseline to 11.9 ± 2.3 at week eight. The mean IPSS score in the Silodosin group dropped from 22.8 ± 3.4 at baseline to 9.6 ± 2.1 at week eight. Table 2 shows that at weeks 2, 4, and 8, participants treated with silodosin had a considerably higher reduction in IPSS score than those treated with tamsulosin (p <0.05).

Table 2: Comparison of Mean IPSS Scores at Different Follow-Up Intervals

Follow-Up Duration	Tamsulosin Group	Silodosin Group	p-value
Baseline	22.4 ± 3.1	22.8 ± 3.4	0.29
Week 2	17.9 ± 2.8	16.5 ± 2.7	0.001
Week 4	14.8 ± 2.6	12.9 ± 2.4	<0.001
Week 8	11.9 ± 2.3	9.6 ± 2.1	<0.001

The post-void residual urine volume also showed an improvement. The PVR in the Tamsulosin group decreased from 96.7 ± 18.5 mL at baseline to 55.9 ± 12.4 mL at week 8, whereas the Silodosin group decreased from 98.2 ± 17.9 mL to 43.1 ± 10.8 mL during the same time period. Table 3 shows that the Silodosin group saw a substantial reduction in PVR volume, especially at weeks 4 and 8 (p < 0.001).

Table 3: Comparison of Mean Post-Void Residual (PVR) Volume at Different Follow-Up Intervals

Follow-Up Duration	Tamsulosin Group (mL)	Silodosin Group (mL)	p-value
Baseline	96.7 ± 18.5	98.2 ± 17.9	0.48
Week 2	81.2 ± 15.6	75.3 ± 14.7	0.002
Week 4	68.4 ± 13.8	59.6 ± 12.1	<0.001
Week 8	55.9 ± 12.4	43.1 ± 10.8	<0.001

Throughout all follow-up intervals, repeated measures ANOVA showed a statistically significant decrease in PVR values in both groups (p <0.001).

In terms of side effects, individuals taking Tamsulosin were more likely to have dizziness and orthostatic hypotension, whereas those taking Silodosin were more likely to experience ejaculatory dysfunction. However, neither group experienced any severe side effects that necessitated stopping treatment. Table 4 provides a summary of the frequency of negative consequences.

Table 4: Comparison of Adverse Effects Between the Two Groups

Adverse Effects	Tamsulosin Group n (%)	Silodosin Group n (%)	p-value
Dizziness	23 (12.4%)	12 (6.5%)	0.04
Orthostatic Hypotension	15 (8.1%)	7 (3.8%)	0.03
Ejaculatory Dysfunction	11 (5.9%)	27 (14.6%)	0.01
Fatigue	9 (4.9%)	6 (3.2%)	0.42
Headache	7 (3.8%)	5 (2.7%)	0.55

In comparison to the Tamsulosin group, the Silodosin group's overall treatment results at week eight showed better symptomatic relief and a larger decrease in post-void residual volume. Additionally, patients using silodosin expressed greater levels of overall pleasure. Table 5 provides a comprehensive comparison of treatment results.

Table 5: Overall Comparison of Treatment Outcomes at Week 8

Outcome Variables	Tamsulosin Group	Silodosin Group	p-value
Mean Reduction in IPSS	10.5 ± 2.4	13.2 ± 2.7	<0.001
Mean Reduction in PVR (mL)	40.8 ± 11.3	55.1 ± 12.5	<0.001
Overall Symptomatic Improvement (%)	71.4%	84.3%	0.002
Patient Satisfaction (%)	76.2%	87.6%	0.004

IPSS and PVR readings within each therapy group showed statistically significant improvement over time ($p < 0.001$) according to repeated measures ANOVA. Additionally, a mixed-model ANOVA showed a significant interaction between follow-up length and treatment group, suggesting that silodosin is more effective than tamsulosin in treating lower urinary tract symptoms linked to benign prostatic hyperplasia.

DISCUSSION

Benign prostatic hyperplasia (BPH) is the most common progressive urological disease among older men worldwide, and it is also the main cause of symptoms of the lower urinary tract (LUTS, which include urinary frequency, urgency, nocturia, urinary hesitancy, a weak urinary stream, incomplete bladder emptying, and other related symptoms). These symptoms can significantly reduce patients' quality of life. Recent global epidemiological research show that population aging and growing life expectancy are causing a steady increase in BPH prevalence.[12]

Alpha-1 -adrenergic receptor antagonists are now the main drugs used for the treatment of moderate to severe LUTS caused by BPH. Tamsulosin and silodosin, two urinary tract-selective blockers, have been shown to alleviate symptoms and encourage bladder emptying.[13] However, further research is needed to compare the two medications' effectiveness and side effect profiles.

In this study, we followed up with participants over 8 weeks to monitor two core indicators, IPSS and PVR. We found that both tamsulosin and silodosin produced statistically significant improvements in these indicators, while silodosin achieved a greater magnitude of improvement. This superior efficacy is underpinned by silodosin's high selectivity for α1A-adrenoceptors in the prostate and bladder neck. The findings of this study add to the global chain of research evidence supporting silodosin.[14]

This study focuses on lower urinary tract symptoms associated with benign prostatic hyperplasia. The average reduction in IPSS scores of the silodosin group was significantly higher than that of the tamsulosin group. A clinical study by Motawea et al confirms silodosin's superior efficacy in the dimensions of symptom improvement and quality of life.[15] While a systematic review and network meta-analysis by Yoosuf et al verifies its superior efficacy in the dimensions of IPSS scores and urinary flow parameters.[16]Because of its strong urethral selectivity and high affinity for the α1A receptor, silodosin can relax prostatic smooth muscle, lower bladder outlet resistance, improve lower urinary tract symptoms, and cause very few systemic vascular side effects. These findings are in line with those published by Hassan et al.[17] One important clinical metric for evaluating bladder emptying performance and the development of bladder outlet blockage is post void residual urine volume (PVR). Negative consequences include kidney damage and urinary tract infections might result from persistently high PVR. In both groups of patients with symptomatic benign prostatic hyperplasia (BPH), the current study found that PVR levels steadily reduced; however, the silodosin group's drop was substantially larger than the tamsulosin group's. This finding is also supported by Zaza et al.'s prospective controlled study.[18]

In line with the findings of earlier studies of a similar nature, this study found that subjects in the silodosin group experienced an early onset of improvement in lower urinary tract symptoms. This medication can

result in significant improvements in clinical outcomes as early as the first week of treatment, according to a research by Akhtar et al.[19] It functions by quickly relaxing the prostate's smooth muscle, which is very crucial for older individuals who want immediate pain relief. According to this study, orthostatic hypotension and dizziness were less common in silodosin users. Because the drug's high selectivity for α1A receptors prevents it from affecting α1B receptors that regulate vascular function, it is especially appropriate for older patients with multiple comorbidities who take concurrent antihypertensive medications. This is supported by a similar study on highly selective α1A receptor blockers.[20]

Silodosin treatment leads to increased ejaculatory dysfunction, consistent with previous clinical trials and meta-analyses .[21] This adverse reaction is caused by α1A receptor blockade, which inhibits smooth muscle contraction of seminal vesicles and vas deferens. Although it decreases the pleasure of sexually active individuals, it is usually reversible and seldom results in treatment abandonment. The study's main conclusions are confirmed by clinical recommendations from reputable worldwide urological groups. The EAU guidelines recommend α1-blockers as first-line therapy for male patients with moderate- severe LUTS and comorbid BPH, as these medications can rapidly improve symptom scores and urinary flow rates.[22] Similarly, the AUA guidelines recommend selective α1-blockers, which deliver both efficacy and safety for elderly patients who cannot receive immediate surgery.[23]

In recent years, the significant research in the field of benign prostatic hyperplasia (BPH) has underlined that personalized pharmaceutical therapy plays an increasingly important role in BPH clinical care. When choosing therapeutic drugs, five fundamental aspects must be carefully considered: prostate volume, intensity of symptoms, patient age, cardiovascular comorbidities, and sexual function.[24] According to Yoosuf et al α-blockers are still the primary therapy for progressive LUTS caused by BPH. [25] Jindan et al hypothesized that silodosin (Silodosin) had higher urinary selectivity and fewer cardiovascular adverse responses, which is consistent with the results of our investigation.[26]

The large the size of the sample, prospective follow-up design, standardized ultrasonography evaluation of prostate characteristics, and head-to-head comparison of two α1 receptor blockers are the four main design strengths of this prostate-related study. Furthermore, the study's scientific validity is supported by consecutive follow-up anchors placed at 2, 4, and 8 weeks.

Despite the aforementioned benefits, the current study still has three major drawbacks: it was only carried out at one tertiary medical facility, it had a short follow-up period, and it was unable to thoroughly evaluate objective uroflowmetry and validated quality-of-life scales. To elucidate the comparative efficacy and long-term safety of the tested medicine, future research must employ multi-center randomized controlled trials, prolong follow-up periods, and enhance evaluation dimensions.

CONCLUSION

In individuals with benign prostatic hyperplasia, both tamsulosin and silodosin can reduce post-void residual pee volume and alleviate lower urinary tract symptoms. The International Prostate Symptom Score (IPSS) and bladder emptying characteristics, however, improved more with silodosin over the 8-week follow-up period. Additionally, it showed greater cardiovascular safety, with lower rates of orthostatic hypotension and dizziness; the only side effect that was more common with silodosin was ejaculatory dysfunction.

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