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A comparative study of Silodosin vs. Tamsulosin in the management of Benign Prostatic Hyperplasia: Outcomes in a tertiary care setting in Karachi.

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Abstract

Background: Lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) are prevalent among aging males, with acute urinary retention (AUR) being a common urological emergency. Alpha-blockers, such as tamsulosin and silodosin, are widely used in managing BPH-related LUTS and improving outcomes in Trial Without Catheter (TWOC). However, the comparative efficacy of these two medications remains a topic of clinical interest. This study aims to compare the efficacy of tamsulosin versus silodosin in achieving successful TWOC and improving the International Prostate Symptom Score (IPSS) in patients with BPH at a tertiary care hospital in Karachi.

Methodology: A randomized controlled trial was conducted involving 100 male patients with BPH, aged 45-85 years, who were randomly assigned to two groups: Group A (silodosin, 50 patients) and Group B (tamsulosin, 50 patients). The primary outcomes included successful TWOC (defined as a post-void residual volume of <100 ml) and improvement in IPSS after one month. Statistical analyses were performed using the chi-square and Mann-Whitney U tests, with a significance level set at $P \leq 0.05$.

Results: In Group A, 70% of patients achieved a successful TWOC, compared to only 20% in Group B ($P = 0.001$). The mean IPSS score in Group A was significantly lower than in Group B ($P = 0.001$), indicating better symptom control with silodosin.

Conclusion: Silodosin demonstrated superior efficacy in facilitating TWOC success and reducing LUTS compared to tamsulosin. These findings suggest that silodosin should be considered the preferred alpha-blocker for managing BPH, especially in patients with AUR, offering improved outcomes for both catheter removal and symptom relief.

Keywords

Benign Prostatic Hyperplasia, Alpha-Blockers, Tamsulosin, Silodosin, Trial Without Catheter.

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Introduction

Lower urinary tract symptoms (LUTS) are a prevalent concern in aging males, with benign prostatic hyperplasia (BPH) being the leading cause of these symptoms, particularly in men over the age of 70. BPH often begins in men during their 50s, and by the age of 60, approximately 50% of men show histological evidence of the condition. Moreover, around 28% of men in their 70s experience moderate to severe LUTS related to BPH[1]. One of the most significant complications of BPH is acute urinary retention (AUR), a urological emergency that necessitates urgent catheterization and, historically, was followed by prostatic surgery[2].

Any intervention aimed at increasing the success rate of Trial Without Catheter (TWOC) following an episode of acute urinary retention is potentially beneficial for these patients. TWOC refers to the process in which a catheter, initially inserted for urinary drainage, is removed to assess whether the patient can pass urine spontaneously without the need for further catheterization[3,4]. This procedure has become a standard practice worldwide for male patients with BPH and AUR. In most cases, an alpha-blocker is prescribed before starting TWOC, which has been shown to significantly improve the success rate, especially when AUR is linked to increased sympathetic activity in the prostatic smooth muscles[5,6].

Alpha-blockers are effective in reducing symptoms and improving urodynamic parameters associated with BPH-induced obstruction. However, the optimal duration of alpha-blocker therapy and its cost-effectiveness following a successful TWOC remain unclear[7,8]. While surgery is the definitive management for symptomatic BPH to alleviate obstruction caused by the enlarged prostate, it carries risks such as potential permanent urinary incontinence, making it a less desirable option for some patients[9,10].

Previous studies, such as that by Ginka et al., have indicated a slightly higher success rate for TWOC with Silodosin compared to Tamsulosin (72.33% vs 66.7%, respectively)[11]. Silodosin also demonstrated a more significant reduction in the International Prostate Symptom Score (IPSS) at two weeks, with a change in the quality-of-life score of -1.7 for Silodosin compared to -1.4 for Tamsulosin. However, there was minimal change in prostate size in both groups as measured by ultrasonography[12]. Similarly, a study by Patil et al. compared Silodosin and Tamsulosin in patients with BPH, showing successful TWOC outcomes of 67.5% for Silodosin versus 60% for Tamsulosin, and IPSS scores of 12.1 ± 2.8 and 11.9 ± 2.1, respectively[13].

Alpha-blockers are now considered first-line medications for managing BPH. Silodosin, a selective α1A-adrenoceptor blocker, has recently been introduced to the Pakistani market and is noted for its high selectivity for this receptor subtype. Given the potential complications associated with surgical intervention and the clinical uncertainty regarding the efficacy of alpha-blockers in managing BPH, there is a compelling rationale to conduct further research in this area. Moreover, there is a pressing need for more data on the pharmacological management of symptomatic BPH. The findings from this study could contribute valuable insights into the development of more effective treatment protocols for BPH.

Therefore, the aim of this study is to compare the outcomes of treatment with Silodosin versus Tamsulosin in patients with benign prostatic hyperplasia at a tertiary care hospital in Karachi.

Methodology

Trial Design

This study was a randomized controlled trial conducted at the Department of Urology, Liaquat National Hospital, Karachi, over a six-month period following the approval of the study synopsis. The objective of this trial was to evaluate the efficacy of two medications, silodosin and tamsulosin, in patients with BPH. The outcomes of interest were the success of the TWOC and improvement in symptoms, as measured by the IPSS, after a 12-week intervention period.

Participants

This study included 100 patients, aged 45-85 years, diagnosed with BPH. The selection of participants was based on specific inclusion and exclusion criteria, ensuring that the sample was appropriate for assessing the outcomes of the intervention.

Inclusion Criteria

- They were aged between 45 and 85 years.
- They had a diagnosis of BPH, which was confirmed through ultrasound findings showing:
  1. A prostate volume greater than 30 mL, calculated as width × height × length × 0.52.
  2. An enlarged central gland with hypoechoic or mixed echogenicity.
  3. The presence of calcifications within the enlarged gland or pseudocapsule.
  4. An elevated post-micturition residual (PVR) volume, often accompanied by bladder wall hypertrophy and trabeculation.
- They presented significant LUTS, including weak stream, incomplete bladder emptying, and increased urinary frequency, which are commonly associated with BPH.

Exclusion Criteria

- Patients with erectile dysfunction, as this could impact urinary function and treatment response.
- Those with hypertension or cardiovascular conditions such as arrhythmias, as these could affect overall health and interfere with the study's outcomes.
- Patients with renal or ureteric stones, as these could present complications unrelated to BPH.
- Those with a history of stroke, chronic liver disease, chronic renal failure, chronic obstructive pulmonary disease (COPD), congestive heart failure, or myocardial infarction, as these conditions might complicate the interpretation of the results.

Interventions

Participants were randomly assigned into two groups. Group A received silodosin 8 mg (Silorap) once daily for 12 weeks, while Group B received tamsulosin 0.4 mg (Flomax) controlled-release capsule once daily after dinner for the same duration. The medications were repackaged in air-tight, screw-cap containers, ensuring that both the patients and the researchers assessing the outcomes were blinded to the specific treatment each patient received. The capsules were removed from their commercial blister packaging and coded as trial medications by staff not involved in the study, which helped to maintain blinding. This ensured allocation concealment, thus reducing the risk of bias in treatment assignment.

Outcomes

The primary outcomes of the study were the success of the Trial Without Catheter (TWOC) and changes in the International Prostate Symptom Score (IPSS). The success of the TWOC was measured by the ability of patients to pass urine spontaneously without the need for further catheterization, defined by a post-void residual (PVR) volume of less than 100 mL after voiding at least 100 mL of urine, measured one month post-treatment. The IPSS was used to assess the severity of BPH symptoms, with scores recorded at baseline and again after one month of treatment to evaluate changes in symptom severity.

Sample Size

The sample size for this study was initially calculated to be 808 patients (404 in each group), using OpenEpi software with an alpha level of 5% and a power of 90%. However, due to the lack of previous studies on the subject in the local context, the sample size was reduced to 100 patients, with 50 patients assigned to each treatment group. This smaller sample size was considered sufficient to provide an initial estimate of the effect of the interventions.

Randomization

Participants were randomly assigned to one of the two treatment groups using a computer-generated randomization scheme. Randomization was carried out in a 1:1 ratio to ensure equal distribution between the two groups. Allocation concealment was achieved by using serially numbered, opaque, sealed envelopes, which were prepared by an independent researcher. The envelopes were

opened only after a patient was enrolled in the study, ensuring that neither the patients nor the researchers could influence the treatment assignment. The randomization list and code-breaking authority were kept by a senior pharmacologist who was not directly involved in patient care or outcome assessment.

Blinding

The study was designed as a double-blind trial, meaning that both the participants and the healthcare providers assessing the outcomes were unaware of the treatment each participant received. The medications were repackaged in identical containers with coded labels to conceal their identity, ensuring that the trial could be conducted without any bias in treatment administration or outcome assessment. This blinding process helped ensure the validity of the findings by minimizing the potential for subjective bias in evaluating the primary outcomes.

Statistical Methods

Data analysis was performed using SPSS Version 20. Descriptive statistics were employed to summarize patient demographics and clinical characteristics. For continuous variables such as age and duration of BPH, the mean and standard deviation were reported if the data were normally distributed, as assessed by the Kolmogorov–Smirnov test. For non-normally distributed variables, the median and interquartile range (IQR) were used. Categorical variables, such as residence status, family income, and the success of the TWOC (Yes/No), were summarized using frequencies and percentages.

To compare the outcomes between the two groups, the Chi-square test was used for categorical variables, such as the success or failure of TWOC, while the Mann-Whitney U test was applied to compare the IPSS scores between the groups. Potential confounders, such as age, residence status, family income, occupational status, educational level, and duration of BPH, were controlled for by stratifying these variables. Post-stratification analyses were conducted using the Chi-square test and Mann-Whitney U test to evaluate the effects of these confounders on the outcome measures. A p-value of ≤ 0.05 was considered statistically significant for all comparisons.

Ethical Considerations

The study was conducted in accordance with the ethical guidelines set by the College of Physicians and Surgeons Pakistan and approved by the institutional ethical review committee. Prior to enrollment, all patients provided written informed consent, and they were fully informed about the nature of the study, the potential risks of treatment, and their right to withdraw at any time without consequence. The study was conducted with the utmost consideration for patient safety and confidentiality, ensuring that all ethical standards were upheld throughout the course of the trial.

Results

Recruitment

A total of 100 patients diagnosed with benign prostatic hyperplasia (BPH) were enrolled in this randomized controlled trial at the Department of Urology, Liaquat National Hospital, Karachi. These patients were randomly assigned to one of two groups: Group A (Silodosin) or Group B (Tamsulosin), with 50 patients in each group. The recruitment process involved screening for BPH using ultrasound and verifying the presence of significant lower urinary tract symptoms (LUTS), which met the study's inclusion criteria. Consent was obtained from each patient, and the study followed ethical guidelines throughout the recruitment process.

Baseline Data

The baseline characteristics of the patients in both study groups (Silodosin and Tamsulosin) were comparable. Patients in both groups were aged between 45 and 85 years, with a similar distribution of demographic factors such as age, residence status, family monthly income, and educational background. The baseline International Prostate Symptom Score (IPSS) and prostate volume measurements were also similar between the two groups, ensuring that any observed differences in

outcomes could be attributed to the interventions rather than initial disparities between the groups.

Numbers Analyzed

Out of the 100 patients initially enrolled, all 100 completed the study, with no dropouts or lost follow-ups. Both groups were fully analyzed for the primary outcomes: success rates of Trial Without Catheter (TWOC) and the change in International Prostate Symptom Score (IPSS) after 12 weeks of treatment. Thus, 50 patients were included in the analysis for each intervention group.

Outcomes and Estimation

The primary outcome was the success rate of TWOC, as shown in Table 1. In Group A (Silodosin), 35 out of 50 patients (70%) experienced a successful TWOC, meaning they were able to pass urine without further catheterization.

In contrast, Group B (Tamsulosin) had only 10 out of 50 patients (20%) who succeeded in the TWOC procedure. This resulted in a significant difference between the two groups, with a P-value of 0.001, indicating a statistically significant higher success rate for Group A (Silodosin) compared to Group B (Tamsulosin).

Table 1: Comparison of success proportion of TWOC between two study groups.

Study Groups	Total	Successful TWOC	Failed TWOC	Percentage of Success	P-value
Silodosin (Group A)	50	35	15	70%	0.001*
Tamsulosin (Group B)	50	10	40	20%	

*p<0.05 is considered statistically significant

The second primary outcome, the change in IPSS scores, was analyzed and compared between the two groups. As shown in Table 2, Group A (Silodosin) had a mean rank of 33.47, with a sum of ranks of 1673.5. Group B (Tamsulosin) had a significantly higher mean rank of 67.53, with a sum of ranks of 3376.5. The U-value for this comparison was 398.5, and the P-value was 0.001, indicating that Silodosin led to a more significant improvement in IPSS scores compared to Tamsulosin. These results confirm the superiority of Silodosin in alleviating symptoms of BPH as measured by the IPSS.

Table 2: Comparison of IPSS scores between study groups.

Study Groups	Total	Mean Rank	Sum of Ranks	U-value	P-value
Silodosin (Group A)	50	33.47	1673.5	398.5	0.001*
Tamsulosin (Group B)	50	67.53	3376.5		

*p<0.05 is considered statistically significant.

Harms

There were no serious adverse events reported during the study period. However, both groups were informed of the potential risks of postural hypotension and erectile dysfunction, which are common side effects of both Silodosin and Tamsulosin. No patients in either group experienced these side effects to a degree that required discontinuation of treatment or intervention beyond routine management. These findings suggest that the interventions were well tolerated by the participants.

Discussion

This study demonstrates a significant difference in the outcomes of TWOC and IPSS between two treatment groups, Silodosin (Group A) and Tamsulosin (Group B). The success rate of TWOC was notably higher in Group A, with 70% of patients successfully completing the procedure, compared to only 20% in Group B. This substantial difference suggests that Silodosin may be more effective than Tamsulosin in facilitating the successful removal of the catheter, a crucial step for patients with acute urinary retention (AUR) caused by BPH.

This finding is consistent with prior studies indicating that Silodosin, as a selective alpha-1 receptor blocker, leads to enhanced relaxation of the smooth muscle in the prostate and bladder neck, thereby improving voiding function. A 2006 randomized controlled trial comparing Silodosin and Tamsulosin reported a greater improvement in IPSS with Silodosin, showing a decrease of 8.3 points, compared to 6.8 points for Tamsulosin[14]. This suggests that Silodosin offers more significant symptom relief for patients with BPH-related LUTS. Similar findings were observed in a study by Pande et al.,[15] which found comparable effectiveness between the two medications but noted that Silodosin demonstrated a greater reduction in another study involving 209 patients with BPH found that 86.2% of those treated with Silodosin experienced a 25% improvement in their IPSS score, compared to 81.9% of patients receiving Tamsulosin[16].

In this study, Group A (Silodosin) demonstrated a significant improvement in both TWOC success and IPSS compared to Group B (Tamsulosin), further supporting Silodosin's superior efficacy. These results are in line with those of Dilawer et al., who found that Silodosin treatment led to a greater reduction in IPSS compared to Tamsulosin, indicating its higher effectiveness in treating LUTS associated with BPH[17]. A narrative review by Jinda et al., supports the use of Silodosin, either as monotherapy or in combination, for effectively managing both storage and voiding symptoms in BPH patients, with a notable increase in TWOC success[18].

The clinical implications of these results are significant for the management of patients with BPH and LUTS. Given the superior outcomes observed with Silodosin in terms of TWOC success and symptom management, it may be considered as a first-line treatment for patients attempting TWOC. This could reduce the need for prolonged catheterization, improve patient comfort, and minimize the risk of complications associated with long-term catheter use. Moreover, the improvement in IPSS scores with Silodosin suggests that it not only aids in the removal of the catheter but also provides long-term relief from LUTS.

While this study provides robust evidence supporting the efficacy of Silodosin over Tamsulosin, future research is necessary to explore the underlying mechanisms responsible for these differences. Additionally, long-term studies could determine whether these short-term benefits translate into sustained improvements in patient outcomes. It would also be valuable to investigate whether certain patient subgroups, such as those with specific comorbidities or severity of symptoms, respond better to one treatment over the other.

Conclusion

The findings of this study suggest that Silodosin outperforms Tamsulosin in both TWOC success rates and symptom management as assessed by IPSS. These results have important clinical implications, particularly in the management of patients undergoing TWOC for BPH-related LUTS, and may guide treatment decisions, emphasizing the role of Silodosin as a preferred option for improving patient outcomes in this context.

Conflicts of Interest

The author(s) have no conflicts of interest.

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References

1. Emberton M, Fitzpatrick JM. The Reten-World survey of the management of acute urinary retention: preliminary results. BJU Int. 2008;101(Suppl 3):27–32.
2. Altarac S. Alpha-adrenergic blockers as a support in the treatment of acute urinary retention. Lijec Vjesn. 2006;128:233–237.
3. McNeill SA. The role of alpha-blockers in the management of acute urinary retention caused by benign prostatic obstruction. Eur Urol. 2004;45:325–332.
4. Emberton M. Definition of at-risk patients: dynamic variables. BJU Int. 2006;97(Suppl 2):12–15.
5. Pande S, Hazra A, Kundu AK. Evaluation of silodosin in comparison to tamsulosin in benign prostatic hyperplasia: a randomized controlled trial. Indian J Pharmacol. 2014;46(6):601-607.
6. Reznicek SB. Common urologic problems in the elderly. Prostate cancer, outlet obstruction, and incontinence require special management. Postgrad Med. 2000;107:163–164.
7. Kumar S, Tiwari DP, Ganesamoni R, Singh SK. Prospective randomized placebo-controlled study to assess the safety and efficacy of silodosin in the management of acute urinary retention. Urology. 2013;82:171–175.
8. Hua LX, Wu HF, Sui YG, Chen SG, Xu ZQ, Zhang W, Qian LX. Tamsulosinin the treatment of benign prostatic hyperplasia patients with acuteurinary retention. Zhonghua Nan KeXue. 2003;9:510–511.
9. Pogula VR, Kadiyala LS, Gouru VR, Challa SR, Byram R, Bodduluri S. Tadalafil vs. tamsulosin in the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: a prospective, randomized study. Cent European J Urol. 2019;72(1):44.
10. Yu HJ, Lin AT, Yang SS, Tsui KH, Wu HC, Cheng CL, Cheng HL, Wu TT, Chiang PH. Non-inferiority of silodosin to tamsulosin in treating patients with lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) BJU Int. 2011;108:1843–1848.
11. Patil SB, Ranka K, Kundargi VS, Guru N. Comparison of tamsulosin and silodosin in the management of acute urinary retention secondary to benign prostatic hyperplasia in patients planned for trial without catheter. A prospective randomized study. Cent European J Urol. 2017;70(3):259-63.
12. Natarajan B, Kalra Y. Silodosin versus tamsulosin in symptomatic benign prostatic hyperplasia-Our experience. IOSR J Pharm. 2015;5(6):8-10.
13. Ginka B. A prospective study of silodosin in comparision with tamsulosin in the management of patients in acute urinary retention due to benign hyperplasia of prostate. J Urol. 2015;(193 Suppl):e330–31
14. Kawabe K, Yoshida M, Homma Y. Silodosin Clinical Study Group. Silodosin, a new alpha1A-adrenoceptor-selective antagonist for treating benign prostatic hyperplasia: results of a phase III randomized, placebo-controlled, double-blind study in Japanese men.BJU Int. 2006;98:1019-1024.
15. Pande S, Hazra A, Kundu AK. Evaluation of silodosin in comparison to tamsulosin in benign prostatic hyperplasia: a randomized controlled trial. Indian J Pharmacol. 2014; 46: 601-607.
16. Takeshita H, Moriyama S, Arai Y, Washino S, Saito K, Chiba K, Horiuchi S, Noro A. Randomized crossover comparison of the short-term efficacy and safety of single half-dose silodosin and tamsulosin hydrochoride in men with lower urinary tract symptoms secondary to benign prostatic hyperplasia. Low Urin Tract Symptoms 2016; 8: 38-43
17. Abdullah OD, Yasmin R, Kazmi TH, Mohammad Ali S. Comparison of Tamsulosin Versus Silodosin for Treatment of Patients with Benign Prostatic Hyperplasia. Pakistan Journal of Medical and Health Sciences, (2022).;16(12):287-289.
18. Luo J, Wang X, X, Liping. Evolving role of silodosin for the treatment of urological disorders – A narrative review. Drug Des Devel Ther. 2022;16:2861-2884.