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Original Article

Comparison of Tamsulosin and Silodosin in the Management of Acute Urinary Retention Secondary to Benign Prostatic Enlargement

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ABSTRACT

Objective: To compare the efficacy of tamsulosin and silodosin in patients suffering from acute urinary retention.
Study Design: Quasi experimental study.
Place and Duration of study: Armed Forces Institute of Urology Rawalpindi, Pakistan from Jul 2023 to Aug 2024.
Methodology: One hundred and thirty-five patients aged between 45 to 60 years having acute urinary retention due to benign prostatic enlargement were recruited. were randomly sub-divided in two groups. Patients who received tamsulosin 0.8mg/day were named Group-A (n=70), and those prescribed silodosin 8mg/day were labelled Group-B (n=65). The trial involved no catheter use. Based on every 4 weeks follow up, results were analyzed on international prostate symptoms score (IPSS).
Results: Group-B indicated better catheter free success rate (67%) as compared to Group-A (59%). Successful voiding mean time was recorded as 38 hours in Group-B whereas it was 44 hours in Group-A. Post void mean residual volume was less in silodosin (53 mL) as compared to tamsulosin patients (68 mL). Recurrence of 5.7% was seen in G as compared to roup-B10.7% in Group-A.
Conclusion: Silodosin demonstrated higher success rate in catheter free voiding as compared to Tamsulosin.

Key words: Acute Urinary Retention, Benign Prostatic Enlargement, Trial Without Catheter.

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INTRODUCTION

Prostate enlargement is a common condition in aging males. Though it is a natural outcome of aging but may frequently result into lower urinary tract symptoms (LUTS). Alpha-1 adrenergic antagonists, such as tamsulosin and silodosin, play a pivotal role in alleviating lower urinary tract symptoms (LUTS) in the management of benign prostatic enlargement.[1,2] Both medications function by selectively targeting alpha-1 receptors in the smooth muscle of the prostate and bladder neck, leading to improved urine flow and reduced symptoms. Current work is aimed at comparative assessment of both tamsulosin and silodosin in management of acute urinary retention in patients with BPE.

Tamsulosin offers a favorable side effect profile, particularly with regard to cardiovascular effects. In contrast, silodosin is also selective for alpha-1A receptors but is noted for a potentially stronger impact on improving urine flow and reducing residual urine volume. This might translate to quicker relief for some patients, although it is also associated with a higher incidence of retrograde ejaculation.[3,4] While both drugs are effective, silodosin's profile might offer advantages for concerned with symptom relief speed and urine flow improvement.[5,6]

In one study, the authors concluded that both drugs have the efficacy to improve symptoms in patients but silodosin has slightly better success rates in TWOC cases.[7,8] Similar research found that significantly higher proportion of patients in silodosin Group-Achieved catheter-free success compared tamsulosin Group-After 72 hours of treatment. Silodosin has demonstrated a more rapid recovery in cases of acute urinary retention (AUR) compared to tamsulosin. Studies have revealed that median time to successful voiding was significantly shorter with silodosin than with tamsulosin.[9] Silodosin has also been reported by researchers to have effective reduction in post-void residual volume than tamsulosin after similar lengths of treatment periods.[10]

We conducted this study to compare the efficacy of tamsulosin and silodosin in patients suffering from acute urinary retention.

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METHODOLOGY

This quasi-experimental study was carried out from July 2023-Aug 2024 at Armed Forces Institute of Urology (AFIU) Rawalpindi, Pakistan. Approval of Institutional review board (Uro-Trg-1/IRB/2023/018 Dated 07Jul 23) was obtained to use patient's data.

Inclusion Criteria: Adult males with age ranging from 45 to 60 years presenting in emergency department with first episode of AUR, which was defined as and having an inability to void without catheter despite having full bladder, and inability to urinate without catheter were included.

Exclusion Criteria: Patients with urinary tract infection, recurring nature of urinary retention, urinary retention beyond 1000 mL and the ones who could not void without catheter despite medication were excluded.

The sample size was calculated by using the WHO sample size calculator. The estimated population proportion using tamsulosin having successful trial without catherization was 20%, whereas it was 70% in population using silodosin.[11] The minimum sample size size came out to be 32 patients in each group. We used non probability consecutive sampling technique for our study.

We included 135 patients in our study. Group-A constituted patients administered with 0.8 mg/day of tamsulosin (n=70) whereas, Group-B included patients administered with 8mg/day silodosin (n=65), as seen in Figure-1. Written informed consent was taken from all patients selected for this study.

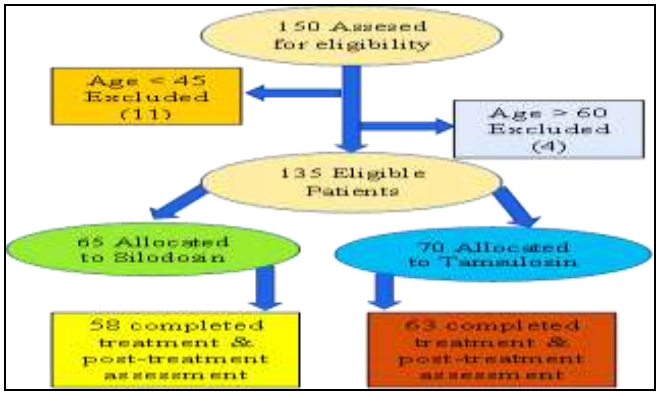

Figure-1: CONSORT Patient Flow Diagram

Patient's drug response was considered as successful if there was less than 100 mL residual urine volume post void. Recurrence of symptoms up to 6 months of initial administration of drug was taken as a benchmark. Uroflowmetry (UFR) was used to assess urine flow and volume. Clinical details, patient history and Digital rectal examination (DRE) were also used as useful data inputs during the course of this study.

Data analysis was carried out using the Statistical Package for Social Sciences (SPSS) version 25. Mean±SD were determined for quantitative variables like age, duration of symptoms, serum creatinine, serum PSA levels and prostate volume. Frequency and percentages were determined for qualitative variables like successful urination and complications. Normalcy of continuous variables was ascertained using Shapro-wilk test. All variables were normally distributed. Independent sample t test was applied to compare the quantitative variables while Chi square test was applied to compare the qualitative variables taking *p*-value of less than 0.05 as significant.

RESULTS

A total of 135 patients were included in study all of whom were all were males (100%). Mean age of study group was 57.17±4.83 years, mean duration of symptoms was 3.60±1.35 years, pre-void volume 716.23±116.47 ml, serum creatinine 0.07±0.04 mg/dl, prostate volume 43.16±8.14 ml and PSA levels 4.09±1.01 ng/dl. Successful symptom relieve occurred in 84 patients (62%) out of all e patients(n=135). Table-I summarizes patient's vitals at presentation.

Table-I: Summary of Patient's Vitals and age Groups (n=135)

Parameters	Group-A n=70 Mean±SD	Group-B n= 65 Mean±SD	*p*-value
Age (years)	57.14±5.31	57.21±4.29	0.931
Duration since lower urinary tract symptoms (years)	3.64±1.43	3.68±1.29	0.885
Pre-void volume (mililiters)	718.5±104.9	713.5±128.5	0.813
Sr. Creatinine (miligram/deciliter)	0.08±0.04	0.07±0.03	0.147
PSA (nanogram/deciliter)	3.78±1.01	4.42±0.89	<0.001
Prostate volume (miligram)	42.31±8.03	44.07±8.21	0.210

The median time to catheter free urination without pain (success) was recorded at 67% for Group-B, while Group-A achieved 59% success rate in 72 hours post-medication. Furthermore, mean time to successful voiding was significantly shorter (38 hours) for patients receiving Silodosin compared to those receiving Tamsulosin (44 hours). This difference, with

a p-value of less than 0.05, indicates that Silodosin may provide a more rapid therapeutic effect in alleviating acute urinary retention. The post void volume in all patients 57.97±18.43 ml. Comparison between the two groups is shown in Table-II below.

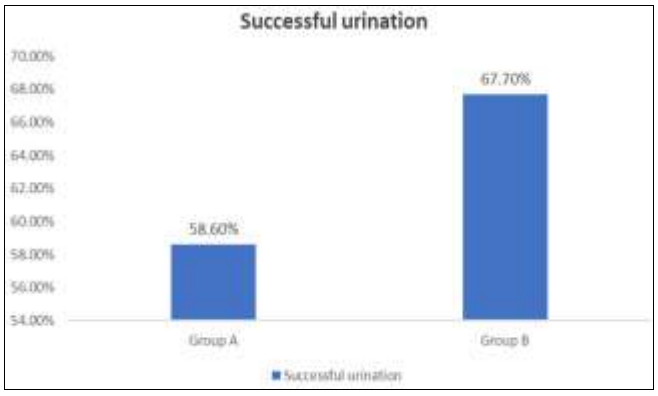

Figure-2: Showing Successful Urination in Both Groups

Table II: Comparison of Both Groups in Terms of post-void Volume (n=135)

Parameters	Group-A n=70 Mean±SD	Group-B n=65 Mean±SD	*p*-value
Post-void volume (mililiters)	52.91±16.25	63.38±19.21	0.001

During the follow-up period, the recurrence rate of AUR was lower in Group-B (5.7%) compared to Group-A (10.8%), though the difference was not significant (p=0.353), suggesting that silodosin might offer more sustained relief from AUR. Both treatment groups experienced similar adverse effects of minor emergency. Dizziness was reported in 13.8% of tamsulosin patients and 31.4% of silodosin patients. Retrograde ejaculation was observed in 4.6% of tamsulosin patients and 8.6% of silodosin patients. The occurrence of these adverse effects did not differ significantly between the two groups (p=0.529), indicating comparable safety profiles. The results also indicate that silodosin is associated with a quicker resolution of acute urinary retention and a lower rate of recurrence compared to tamsulosin, while both medications present similar adverse effects. Figure-3 indicates comparatively lower adverse effects in patients from Tamsulosin group.

DISCUSSION

Benign prostatic enlargement is a progressive medical condition with mild symptoms at the beginning and turning into serious complication such as urinary retention requiring surgical intervention.[11-13]. Among immediate treatment options, the most widely used one is bladder decompression with urethral catheter. Most cases subsequently require surgical intervention after turning into complicated cases of AUR. It is due to the risks associated with prolonged catheterization and prostatic surgery that such interventions are generally avoided or used cautiously in the management of acute urinary retention.[14-16] Trial without Catheter is therefore gaining popularity in researches wherein urethral catheter is removed between 24 to 48 hours of initial presentation and allows the patients to be observed for void with medication doses.

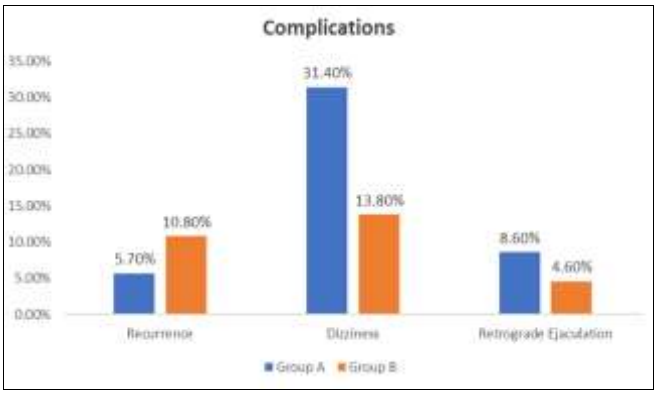

Figure-3: Adverse effects of Tamsulosin and Silodosin in Terms of Recurrence of AUR, Dizziness and Retrograde Ejaculation

Results reveal that the tamsulosin group (Group-A) achieved comparatively lower success rate after 72 hours post-medication. Successful voiding was achieved in mean time of 44 hours. In contrast, the silodosin group (Group-B) resulted into shorter mean time to successful voiding (38 hours).

The reduced time to catheter-free urination is particularly significant as prolonged catheterization is associated with an increased risk of urinary tract infections, patient discomfort, and other complications. Hence, the quicker relief offered by silodosin may contribute to a more favorable patient experience and fewer complications related to catheter use.[17-20] Findings are consistent with previous studies that have shown silodosin to have a rapid onset of action due to its higher selectivity for alpha-1A adrenergic receptors in the prostate, leading to more efficient bladder neck relaxation and reduced urethral resistance. Tamsulosin, while also an alpha-1 blocker, has less selectivity for the alpha-1A subtype, which

may explain the comparatively slower time to successful voiding observed in this study.[21]

In our study, silodosin showed a 67% success rate in achieving catheter-free urination within 72 hours compared to 59% for tamsulosin, align with existing literature that highlights the efficacy of both medications in treating AUR. Several studies have reported success rates ranging from 55% to 70% for tamsulosin in facilitating catheter-free voiding in patients with AUR due to benign prostatic enlargement (BPE). For instance, a trial by Prieto et al. observed a catheter-free urination success rate of approximately 61% in patients treated with tamsulosin over a similar timeframe, which is comparable to the 59% observed in our study.

The efficacy of silodosin has been demonstrated to be consistently higher in several comparative studies. A trial conducted by Andersson *et al*. reported a 65% success rate for silodosin, which is similar to the 67% rate found in the current research. Other studies, such as the one by Utsunomiya *et al*. also found silodosin to outperform tamsulosin in terms of quicker symptom relief and higher catheter-free voiding rates and success rates as high as 68%. Slight variations in success rates across studies may be attributed to differences in study populations, dosage regimens, or the criteria used to define successful voiding. The success rate is slightly lower than the one reported for both drugs by Kumar *et al*. with 76% success rate for silodosin. Other authors such as Ginka *et al*. reported 72% and 66% success rates for silodosin and tamsulosin respectively. Numerous other researchers in recent years have also reported higher efficacy of silodosin over tamsulosin in TWOC trials. The results in our study therefore, are well aligned with past work in AUR clinical research.

The shorter mean time to successful voiding observed in this study for silodosin (38 hours) compared to tamsulosin (44 hours) also corroborates findings from prior research. For example, Yamaguchi *et al*. reported a mean time to successful voiding of around 35-40 hours for Silodosin, further emphasizing its rapid onset of action compared to tamsulosin. This supports the notion that silodosin's greater selectivity for alpha-1A adrenergic receptors in the prostate leads to quicker bladder neck relaxation, resulting in faster symptom relief. Relatively small difference in success rates (67% vs. 59%) suggests that while silodosin may offer a slight edge in efficacy, tamsulosin remains an effective alternative, particularly in patients for whom silodosin may not be suitable due to side effect profiles or contraindications.

LIMITATIONS OF STUDY

A small sample size, as well as being conducted at a single centre may limit the generalizability of our study. Also, lack of follow-up for long-term success may only give short term success of drugs used in our study.

CONLUSION

Our findings suggest that silodosin may offer a more rapid and effective treatment option for patients with acute urinary retention (AUR) secondary to benign prostatic enlargement (BPE) than tamsulosin.

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Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

GA & BM: Conception, study design, drafting the manuscript, approval of the final version to be published.

UA & AYK: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

MTA & MFS: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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