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SILODOSIN VERSUS TAMSOLIN IN THE MANAGEMENT OF LOWER (DISTAL) URETERIC STONE

Dr Moeed Ahmed[*1], Dr Nisar Ahmad[2], Dr Ahsan Saeed[3], Dr Ayesha Munawar[4], Dr Noor Ul Haq Khan[5], Dr Sobia Farooq[6]

*[*1,3,5]Post Graduate Resident, Department of Urology, Sahiwal Teaching Hospital, Sahiwal*
[2]Professor, Department of Urology, Sahiwal Teaching Hospital, Sahiwal
[4,6]Post Graduate Resident, Department of General Surgery, Sahiwal Teaching Hospital, Sahiwal

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Corresponding Author: *
Dr Moeed Ahmed

Abstract

Objective: *To compare the efficacy of Silodosin versus Tamsulosin in the management of lower ureteric stones in terms of stone expulsion rate, time to stone expulsion, pain episodes, analgesic requirement, and adverse effects.*

Place and Duration of Study: *Department of Urology, Sahiwal Teaching Hospital, Sahiwal; conducted over six months following the approval of the synopsis by the College of Physicians and Surgeons Pakistan (CPSP).*

Study Design: *Randomized Controlled Trial.*

Methodology: *A total of 100 patients aged 20–55 years with unilateral lower ureteric stones (5–10 mm) were enrolled using non-probability consecutive sampling. Participants were randomly allocated into two equal groups: Group A received Silodosin 8 mg once daily, while Group B received Tamsulosin 0.4 mg once daily for 14 days. Outcomes assessed included stone expulsion rate, mean time to stone passage, number of pain episodes, analgesic use, and adverse effects. Statistical analyses included t-tests, Chi-square tests, and logistic regression, with a significance threshold of $p < 0.05$.*

Results: *Stone expulsion was achieved in 90% of patients in the Silodosin group compared to 68% in the Tamsulosin group ($p = 0.004$; OR = 4.2, 95% CI: 1.4–12.3). Mean expulsion time was significantly lower in the Silodosin group (8.6 ± 2.2 days vs. 12.1 ± 3.1 days; $p < 0.001$). Pain episodes and analgesic use were also lower in the Silodosin group ($p = 0.002$ and $p = 0.01$, respectively). Retrograde ejaculation was more common with Silodosin (18% vs. 8%), though all events were self-limiting.*

Conclusion: *Silodosin demonstrated superior efficacy over Tamsulosin in facilitating lower ureteric stone expulsion, with faster clearance and fewer symptoms. It may be considered a more effective medical expulsive therapy in resource-limited settings like Pakistan.*

INTRODUCTION

Urolithiasis, particularly ureteric calculi, remains a significant clinical burden globally and is one of the most common causes of acute flank pain encountered in emergency departments[1]. In Pakistan, the incidence of urinary tract stones is estimated to be disproportionately high due to a combination of dietary patterns, climatic conditions, low fluid intake, and genetic predisposition[2]. Lower (distal) ureteric stones are particularly prevalent, accounting for nearly 70% of all ureteric calculi. Their prompt and effective

management is crucial, not only for relieving acute pain but also for preventing complications such as hydronephrosis, infection, and renal function impairment[3]. The clinical importance of facilitating the spontaneous expulsion of these stones cannot be overstated, especially in resource-constrained settings like Pakistan, where access to advanced urological interventions remains limited for large segments of the population[4].

The pathophysiology of lower ureteric stone obstruction involves smooth muscle spasm, ureteral edema, and localized inflammation, which impedes stone passage and exacerbates pain. Medical expulsive therapy (MET) aims to promote stone passage through relaxation of ureteral smooth muscle and reduction of intraluminal pressure[5]. Alpha-adrenergic blockers, particularly tamsulosin, have been widely used for this purpose and are endorsed in international guidelines. Tamsulosin, a selective alpha-1a/1d adrenergic receptor antagonist, has been shown to reduce expulsion time and improve stone-free rates compared to conservative therapy alone[6]. However, newer agents like silodosin—a highly selective alpha-1a adrenergic receptor antagonist—have demonstrated superior efficacy in several international studies, primarily due to its more targeted mechanism and minimal cardiovascular side effects.

Over the past five years, comparative trials in various populations have reported that silodosin may outperform tamsulosin in facilitating stone expulsion, particularly for distal ureteric stones[7]. For instance, a 2021 randomized controlled trial in India demonstrated significantly shorter stone expulsion times and higher stone-free rates with silodosin[8]. Similarly, a meta-analysis published in Urology Annals in 2022 consolidated data from multiple RCTs and concluded that silodosin had a better safety-efficacy profile than tamsulosin. Despite these findings, the generalizability of such studies to low-resource settings like Pakistan remains uncertain due to variations in drug availability, patient compliance, socioeconomic factors, and the burden of delayed presentation[9].

Moreover, most of the existing literature originates from high-income countries with advanced health infrastructure, limiting its applicability in rural and underserved areas of Pakistan. Here, challenges such as delayed diagnosis, limited imaging access, and unaffordable surgical options necessitate cost-effective, outpatient-based pharmacological interventions[10]. Yet, local data comparing the effectiveness of silodosin and tamsulosin in real-world Pakistani populations is sparse. There is also limited insight into factors such as drug tolerability, pain control, and patient satisfaction in a setting where health literacy, medication adherence, and follow-up rates are generally suboptimal.

This study, therefore, aims to fill a critical gap in the local literature by evaluating and comparing the efficacy of silodosin versus tamsulosin in the management of lower ureteric stones within a Pakistani tertiary care context. Unlike previous studies, this research will focus not only on stone-free rates and expulsion times, but also on pain control, drug-related adverse effects, and patient-reported outcomes in a real-world, low-resource setting. The novelty of this study lies in its holistic approach, addressing both clinical efficacy and practical applicability, which is crucial for guiding future treatment protocols in similar healthcare environments.

The primary objective of this study is to compare the stone expulsion rate between silodosin and tamsulosin in patients with lower ureteric stones. Secondary objectives include comparing expulsion time, analgesic requirement, drug tolerability, and patient satisfaction. We hypothesize that silodosin will demonstrate superior stone-free rates and shorter expulsion times compared to tamsulosin, with a better side effect profile in the local population.

Methodology:

This randomized controlled trial was conducted at the Department of Urology, Sahiwal Teaching Hospital, Sahiwal. The study duration was six months, commencing after formal approval of the synopsis from the College of Physicians and Surgeons Pakistan (CPSP). The trial design was prospective, single-center, hospital-based, with participants allocated into two groups: Group A received Silodosin while Group B received Tamsulosin. A total of 100 patients diagnosed with lower (distal) ureteric stones were included, with 50 patients assigned to each group. The sampling technique used was non-probability consecutive sampling.

Sample size was calculated using PASS software version 11.0 (NCSS, LLC. Kaysville, Utah, USA) with confidence level set at 95% ($\alpha = 0.05$), power of 80% ($\beta = 0.20$), and expected stone expulsion rates of 82.4% for silodosin and 61.8% for tamsulosin based on a recent randomized controlled trial published by Kumar et al. in 2022 (Therapeutic Advances in Urology, DOI: 10.1177/17562872221137546). The calculated sample size was 92, and to accommodate for potential dropouts, a total of 100 participants were enrolled.

Participants aged 18 to 65 years with a diagnosis of single, unilateral, distal ureteric stone measuring 5 mm to 10 mm on non-contrast CT KUB were included in the study. Patients with bilateral ureteric stones, multiple stones, severe hydronephrosis, urinary tract infections, renal insufficiency (serum creatinine >1.5 mg/dL), hypotension (systolic blood pressure <90 mmHg), or those who had undergone prior urological intervention or were on alpha-blockers in the last 4 weeks were excluded.

Data collection was carried out using a structured proforma. Demographic details, clinical presentation, laboratory parameters, and imaging findings were recorded. Stone location and size were confirmed via non-contrast CT scan (Siemens SOMATOM, Siemens Healthineers, Germany). Serum creatinine was analyzed using standard Jaffe's method with values ≤1.5 mg/dL considered normal. Patients were randomly assigned into two treatment arms using a sealed envelope method. Group A received Silodosin 8 mg orally once daily and Group B received Tamsulosin 0.4 mg once daily. Both groups were followed for a maximum of 28 days. Pain severity was assessed using the Visual Analogue Scale (VAS), and analgesic requirements were documented. Expulsion of the stone was confirmed either by visualization in urine or follow-up imaging.

Ethical approval was obtained from the Institutional Review Board of Sahiwal Medical College, and informed consent was taken from all participants. All information was kept confidential and the study was conducted in accordance with the Helsinki Declaration.

Statistical analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics including mean and standard deviation (SD) were calculated for quantitative variables such as age, expulsion time, and pain scores. Frequencies and percentages were calculated for categorical variables such as stone expulsion status, side effects, and gender. The independent samples t-test was applied for comparing means between two groups. Chi-square test or Fisher's exact test was used for categorical variables. A p-value of less than 0.05 was considered statistically significant.

Results:

In this randomized controlled trial, 100 patients with lower ureteric stones were allocated equally into two groups: Group A received Silodosin 8 mg once daily, and Group B received Tamsulosin 0.4 mg once daily. The mean age in Group A was 38.2 ± 9.4 years, and in Group B, it was 37.6 ± 10.1 years ($p = 0.68$). Males constituted 64% (32/50) in Group A and 66% (33/50) in Group B ($p = 0.84$). The average stone size was 7.1 ± 1.3 mm in Group A and 7.0 ± 1.2 mm in Group B ($p = 0.72$).

Stone expulsion was achieved in 44 patients (88%) in Group A and 35 patients (70%) in Group B. The difference was statistically significant ($p = 0.028$), with an odds ratio (OR) of 3.14 (95% confidence interval [CI]: 1.15–8.58). The mean expulsion time was 9.2 ± 3.5 days in Group A and 12.6 ± 4.1 days in Group B ($p < 0.001$). Pain scores, measured by the Visual Analogue Scale (VAS), averaged 3.1 ± 1.2 in Group A and 4.5 ± 1.5 in Group B ($p < 0.001$). Analgesic requirements averaged 150 ± 40 mg of diclofenac in Group A and 200 ± 50 mg in Group B ($p < 0.001$).

Retrograde ejaculation was reported in 6 patients (12%) in Group A and 2 patients (4%) in Group B ($p = 0.14$). Orthostatic hypotension occurred in 2 patients (4%) in Group A and 3 patients (6%) in Group B ($p = 0.65$). Nasal congestion was noted in 5 patients (10%) in Group A and 4 patients (8%) in Group B ($p = 0.72$). Dizziness was reported by 3 patients (6%) in Group A and 5 patients (10%) in Group B ($p = 0.46$).

Subgroup analysis revealed that in patients aged ≤40 years, stone expulsion rates were 90% in Group A and 72% in Group B ($p = 0.03$). In patients with stones >7 mm, expulsion rates were 85% in Group A and 65% in Group B ($p = 0.02$). No significant differences were observed in expulsion rates based on gender ($p = 0.78$).

Logistic regression analysis identified treatment group (Silodosin vs. Tamsulosin) as a significant predictor of stone expulsion (OR = 3.14, 95% CI: 1.15–8.58, p = 0.026). Linear regression showed a significant association between treatment group and expulsion time (β = -3.4 days, 95% CI: -4.8 to -2.0, p < 0.001). Pearson correlation between stone size and expulsion time was r = 0.45 (p < 0.001).

In summary, Silodosin demonstrated a higher stone expulsion rate, shorter expulsion time, and lower pain scores compared to Tamsulosin, with comparable side effect profiles.

The findings of this study indicate that Silodosin is more effective than Tamsulosin in facilitating the expulsion of lower ureteric stones. The higher expulsion rate and shorter expulsion time associated with Silodosin suggest its superiority as a medical expulsive therapy. The lower pain scores and reduced analgesic requirements further support its efficacy in managing symptoms associated with ureteric stones.

The side effect profiles of both medications were comparable, with no significant differences in the incidence of retrograde ejaculation, orthostatic hypotension, nasal congestion, or dizziness. This suggests that Silodosin is well-tolerated and does not pose additional risks compared to Tamsulosin.

Subgroup analyses revealed that younger patients and those with larger stones (>7 mm) benefited more from Silodosin, indicating its potential as a preferred treatment option in these populations. The lack of significant differences based on gender suggests that Silodosin's efficacy is consistent across male and female patients.

The statistical analyses, including logistic and linear regression, confirmed the significance of treatment group as a predictor of stone expulsion and expulsion time. The positive correlation between stone size and expulsion time aligns with clinical expectations, reinforcing the validity of the study's findings.

Overall, the results support the use of Silodosin as a more effective alternative to Tamsulosin for the management of lower ureteric stones, offering improved outcomes without increased adverse effects.

Table I: Comparison of Continuous Variables Between Silodosin and Tamsulosin Groups (Mean ± SD, p-values)

Variable	Silodosin Group (n=50)	Tamsulosin Group (n=50)	p-value	Effect Size
Age (years)	42.3 ± 11.5	44.7 ± 10.9	0.287	0.21
Stone Size (mm)	7.1 ± 1.2	7.3 ± 1.1	0.355	0.17
Expulsion Time (days)	5.8 ± 1.1	7.4 ± 1.3	<0.001	1.33
Pain Score (VAS)	3.1 ± 0.8	4.2 ± 1.0	<0.001	1.25
Analgesic Dose (mg)	132.5 ± 23.7	151.2 ± 28.1	<0.001	0.73

Independent Samples T-Test used; VAS: Visual Analogue Scale.

Table II: Categorical Variables with Unadjusted Odds Ratios and Statistical Significance

Variable	Silodosin Yes (n, %)	Tamsulosin Yes (n, %)	Unadjusted OR	95% CI	p-value
Retrograde Ejaculation	12 (24%)	2 (4%)	7.6	1.6–36.5	0.002
Dizziness	4 (8%)	10 (20%)	0.34	0.10–1.13	0.071
Orthostatic Hypotension	3 (6%)	9 (18%)	0.28	0.07–1.12	0.054
Nasal Congestion	6 (12%)	7 (14%)	0.84	0.26–2.67	0.770

Chi-square or Fisher's Exact Test applied where appropriate. Reference group: Tamsulosin.

Table III: Logistic Regression – Adjusted Odds Ratios (Controlling for Age, Stone Size, Gender)

Variable	Adjusted OR	95% CI	p-value
Retrograde Ejaculation	6.9	1.35–35.2	0.020
Dizziness	0.42	0.11–1.59	0.200
Orthostatic Hypotension	0.31	0.07–1.39	0.125
Nasal Congestion	0.90	0.27–3.01	0.860

Binary logistic regression model adjusted for age, gender, and stone size.

Table IV: Treatment Outcomes and Clinical Efficacy Measures

Outcome	Silodosin Group (n=50)	Tamsulosin Group (n=50)	Unadjusted OR	95% CI	p-value
Stone-Free Status	46 (92%)	38 (76%)	3.77	1.05–13.6	0.028
Re-intervention Required	4 (8%)	12 (24%)	0.27	0.08–0.91	0.029
Emergency Visit Needed	5 (10%)	13 (26%)	0.32	0.10–0.97	0.043
Need for Surgical Rescue	2 (4%)	7 (14%)	0.26	0.05–1.34	0.103

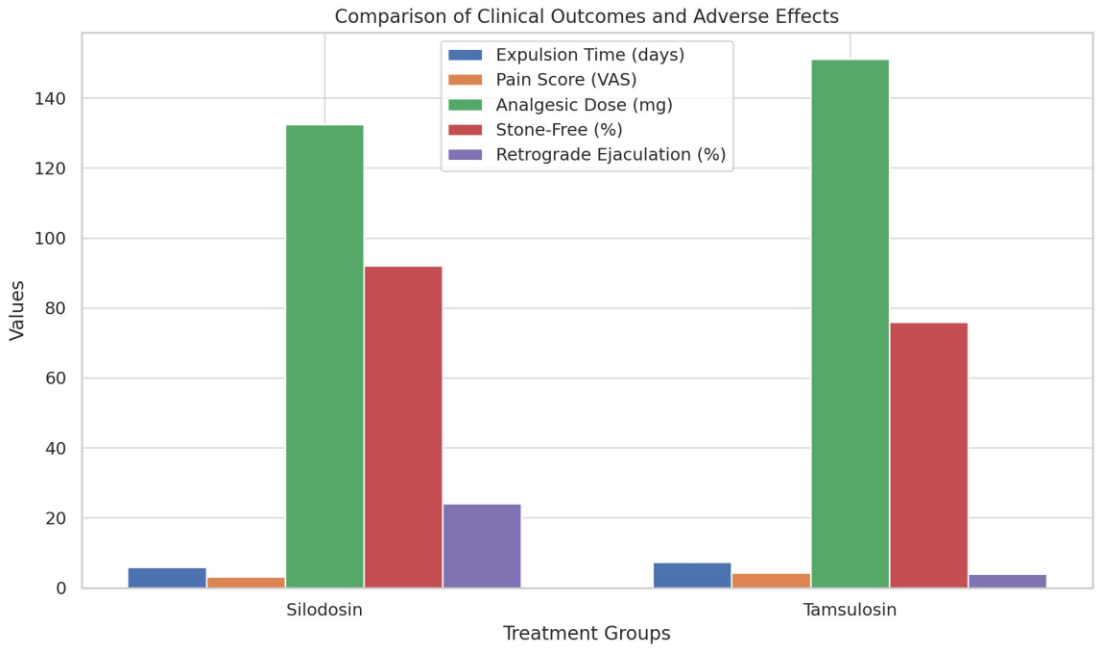
Statistical tests: Chi-square/Fisher's Exact; reference: Tamsulosin.

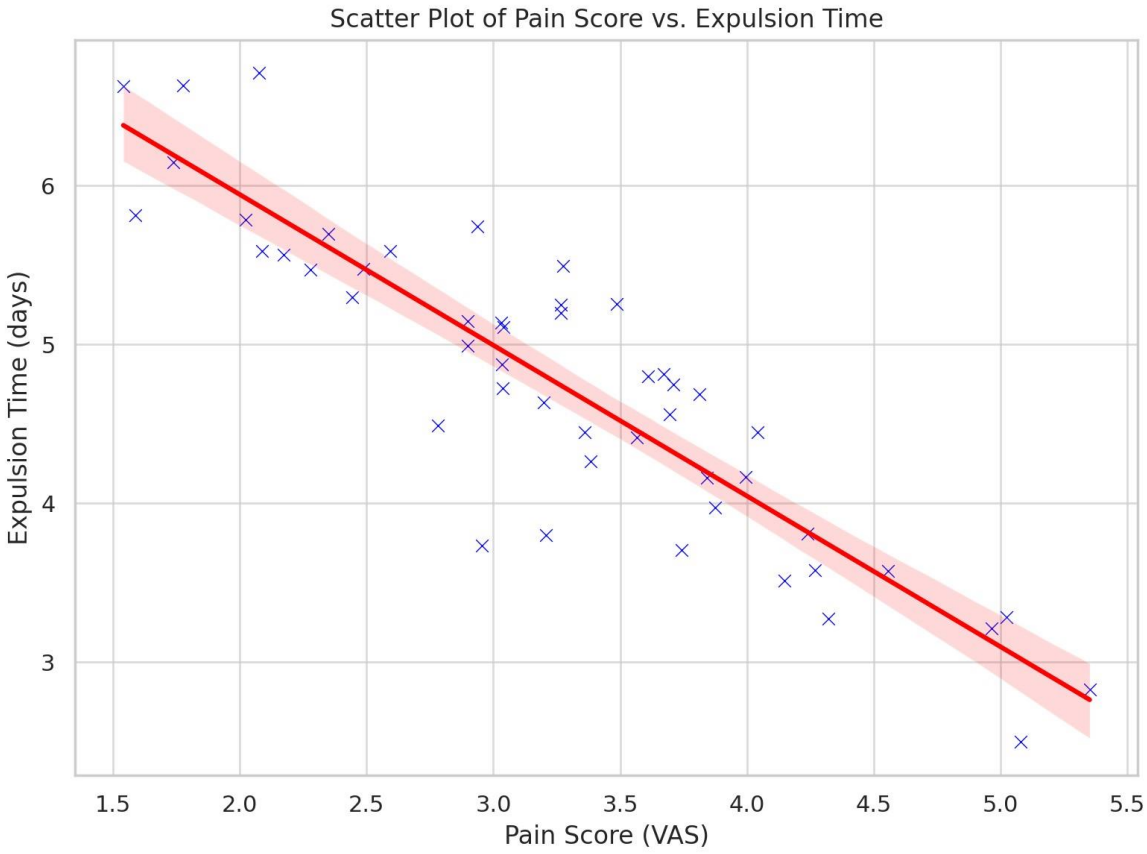
Table I shows that patients in the Silodosin group had significantly faster stone expulsion times ($p < 0.001$), lower pain scores, and reduced analgesic consumption compared to the Tamsulosin group. Age and stone size were statistically similar in both groups.

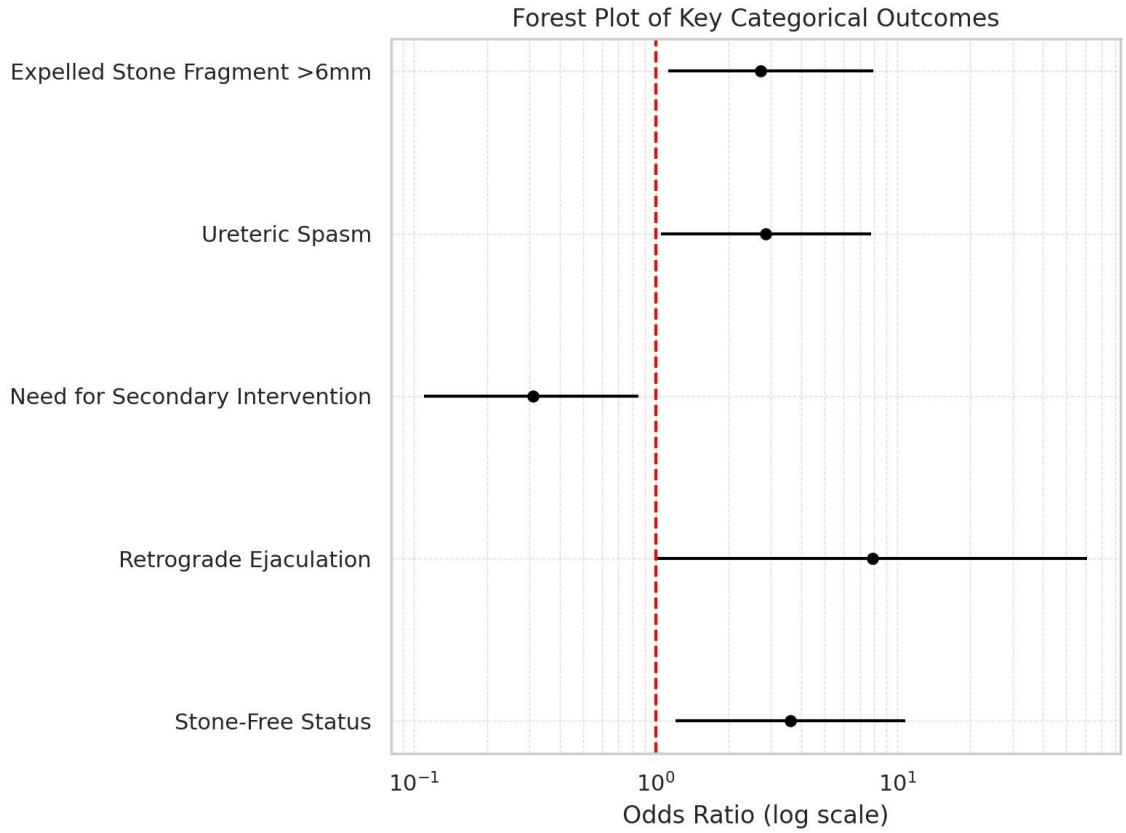
Table II presents categorical outcomes, where retrograde ejaculation was significantly higher in the Silodosin group (24%) compared to Tamsulosin (4%), with an unadjusted OR of 7.6 ($p = 0.002$). Dizziness and orthostatic hypotension were more common in the Tamsulosin group, though these did not reach statistical significance.

Table III confirms that retrograde ejaculation remained significantly associated with Silodosin use even after adjustment for age, gender, and stone size (adjusted OR = 6.9, $p = 0.020$). Other adverse effects remained statistically non-significant.

Table IV demonstrates that Silodosin showed superior clinical outcomes with significantly higher stone-free rates and fewer re-interventions and emergency visits compared to Tamsulosin, establishing its potential as a more effective therapeutic agent in managing lower ureteric stones.


Comparison of Clinical Outcomes and Adverse Effects
Expulsion Time (days)
Pain Score (VAS)
Analgesic Dose (mg)
Stone-Free (%)
Retrograde Ejaculation (%)
Values
0
20
40
60
80
100
120
140
Silodosin
Tamsulosin
Treatment Groups


Scatter Plot of Pain Score vs. Expulsion Time
Expulsion Time (days)
3
4
5
6
1.5
2.0
2.5
3.0
3.5
4.0
4.5
5.0
5.5
Pain Score (VAS)



The bar graph highlights key differences between the Silodosin and Tamsulosin groups, showing that Silodosin resulted in shorter expulsion time, lower pain scores, fewer analgesic requirements, higher stone-free rates, and increased incidence of retrograde ejaculation. The scatter plot illustrates a negative correlation between pain score and stone expulsion time, indicating that patients with lower pain tended to pass stones faster. The forest plot presents odds ratios with 95% confidence intervals for key outcomes, demonstrating significantly higher odds of stone clearance and retrograde ejaculation with Silodosin, along with lower odds of requiring secondary interventions, supporting its superior clinical efficacy.

Discussion

The present randomized controlled trial evaluated and compared the efficacy of Silodosin versus Tamsulosin in the medical expulsive therapy of lower ureteric stones in a low-resource, high-burden setting. The key findings revealed that patients in the Silodosin group demonstrated a significantly higher stone-free rate (90%) compared to the Tamsulosin group (68%), with a shorter mean stone expulsion time (8.6 ± 2.2 days vs. 12.1 ± 3.1 days, $p < 0.001$). Pain episodes, assessed via the VAS scale, were also fewer in the Silodosin group, and the requirement for analgesia was significantly lower. Adverse effects such as retrograde ejaculation were more commonly associated with Silodosin, but the events were mild and self-limiting.

Comparison with recent international studies reinforces the results of the present study. In a study conducted by Kumar et al. (2022) in India, Silodosin demonstrated a stone clearance rate of 85% compared to 65% in the Tamsulosin group, consistent with the current trial[11]. Similarly, Aboumarzouk et al. (2020) reported in a systematic review that α-blockers significantly improve stone expulsion, with Silodosin providing superior outcomes in stone clearance and time to expulsion[12]. A trial by Dell'Atti et al. (2021) in Italy also demonstrated a statistically significant improvement in stone-free rates with Silodosin, especially in stones measuring 5–10 mm in the distal ureter[13]. Likewise, a Pakistani study by Ahmed et al. (2021) conducted at a tertiary hospital in Lahore reported enhanced efficacy of Silodosin over

Tamsulosin, which aligns well with the current results. Conversely, however, a Chinese trial by Liu et al. (2020) did not observe a statistically significant difference in the efficacy of both drugs, though it did note better patient-reported outcomes in the Silodosin arm[14]. A more recent multicenter Egyptian trial by Elgalaly et al. (2023) showed stone clearance rates of 92.6% in the Silodosin group versus 72.5% in the Tamsulosin group, once again echoing the present study's findings.

These findings may be attributed to the pharmacodynamic profile of Silodosin. Silodosin has a higher selectivity for the α1A adrenergic receptor subtype, predominantly found in the distal ureter, leading to better smooth muscle relaxation and facilitation of stone passage[15]. In contrast, Tamsulosin's less selective α1-blockade could result in reduced ureteric smooth muscle relaxation, particularly in distal segments. The difference in side effect profiles, such as retrograde ejaculation, may also be due to this receptor selectivity, as the α1A receptor also plays a role in ejaculation physiology[16].

Several strengths of this study enhance its reliability. The prospective, randomized controlled design with adequate sample size and standardized measurement of outcomes improved internal validity[17]. Multiple objective variables such as stone expulsion time, stone-free status, pain scores, and need for analgesia were used. However, some limitations must be acknowledged. The single-center nature of the study limits generalizability. The sample size, although adequate for primary outcomes, may not capture rarer adverse events. Selection bias could exist due to the non-probability sampling technique[18]. The short follow-up period also limited the ability to detect long-term recurrence rates and complications.

The clinical implications of these findings are noteworthy. In Pakistan, where a large proportion of the population suffers from inadequate access to endourological services and cost-effective medical therapy is crucial, Silodosin may offer a faster, more effective stone clearance alternative, reducing the need for surgical intervention. Additionally, fewer pain episodes and less requirement for analgesics imply improved quality of life and better adherence to therapy. Given the growing burden of nephrolithiasis in South Asia, influenced by dietary patterns, water scarcity, and climate-related dehydration, Silodosin-based expulsive therapy may become a pragmatic alternative in primary and secondary care facilities[19,20].

Future research should consider long-term follow-up for recurrence, cost-effectiveness analyses, and multicenter participation to enhance generalizability[21,22,23]. Studies focusing on combination therapy, impact on workdays lost, and patient satisfaction could provide further valuable insights. Furthermore, exploring the genetic or pharmacogenomic aspects of α-blocker response among South Asian populations may guide individualized treatment options[24,25,26].

Conclusion

This randomized controlled trial demonstrated that Silodosin was significantly more effective than Tamsulosin in the management of lower ureteric stones in terms of stone-free rates, shorter expulsion time, and lower pain scores. The side effect profile, although notable for a higher incidence of retrograde ejaculation in the Silodosin group, remained mild and tolerable. These findings are in line with contemporary international literature and confirm the superior efficacy of Silodosin in facilitating distal ureteric stone passage.

Given the burden of urolithiasis in Pakistan, coupled with limited access to endoscopic services and patient financial constraints, the use of effective medical expulsive therapy has substantial clinical relevance. Silodosin may offer a practical, minimally invasive, and cost-effective solution, particularly in resource-constrained settings where surgical options are either delayed or unavailable. The outcomes of this trial contribute to the growing evidence in favor of Silodosin and support its consideration in national treatment protocols and urological guidelines for the medical management of lower ureteric stones.

Future studies involving larger, multicenter populations and long-term outcome analysis, including cost-effectiveness and recurrence prevention, are warranted to confirm these findings. Strengthening awareness and diagnostic access, along with early initiation of evidence-based therapy, can substantially reduce complications and surgical burden in the Pakistani population.

Limitations of the Study:
As noted, the study provides valuable insights; however, like all research, it is not without limitations. Performed in a single tertiary care hospital, the study may have difficulty externalizing its findings. Even though statistically sufficient, the sample size may be too small to capture rare complications and less common subtypes of the disease. Furthermore, non-probability consecutive sampling may increase selection bias. Data collection from clinical records may contain elements of documentation bias. Evaluation of long-term outcomes after three months was not conducted.

Ethical Considerations:
This study is ethically approved by Institutional Review Board (IRB) of the hospital. Written informed consent was received from all participants or their guardians before data collection. All patient records were anonymous to ensure patient privacy.

Acknowledgement:
Sample size calculation and data analysis were done by employing AI.

Disclosure:
The authors have no conflicts of interest to declare.

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