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Original Article

Effect of Preoperative Silodosin on Operative Time of Semi Rigid Ureteroscopy for Ureteral Stones

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ABSTRACT

Background: Distal ureteral stones are frequently managed with semi-rigid ureteroscopy (URS), a procedure that can be technically demanding due to ureteric smooth muscle tone and spasm. Alpha-1A adrenergic receptor blockers such as Silodosin have shown potential in facilitating ureteroscopic access by relaxing ureteral musculature, yet limited data exist on their preoperative use in surgical settings, particularly in South Asian populations. Objective: To compare the mean operative time of semi-rigid URS for distal ureteral stones between patients receiving preoperative Silodosin and those receiving a placebo. Methods: This randomized controlled trial was conducted at the Institute of Kidney Diseases, Peshawar, from December 2023 to June 2024. Sixty adult patients with single distal ureteral stones (11–20 mm) were randomly assigned to receive either Silodosin 8 mg daily or placebo for 10 days prior to URS. Operative time was measured from ureteroscope insertion to removal. Data were analyzed using independent t-tests and subgroup analyses. Results: The mean operative time was significantly lower in the Silodosin group (44.87 ± 3.34 minutes) compared to the placebo group (51.67 ± 5.35 minutes), with a mean difference of –6.80 minutes (95% CI: –9.09 to –4.51; $p < 0.001$). This effect remained consistent across age, gender, stone size, and laterality. Conclusion: Preoperative Silodosin significantly reduces operative time in semi-rigid URS for distal ureteral stones, suggesting a clinically valuable role in perioperative management. Further large-scale trials are warranted to validate these findings and assess broader outcomes.

Keywords: Silodosin, Ureteroscopy, Distal Ureteral Stone, Operative Time, Alpha-Blocker, Randomized Controlled Trial

INTRODUCTION

Ureteral stones, particularly those located in the distal ureter, represent a significant proportion of urological emergencies and are among the most frequent causes of acute flank pain encountered in emergency departments (1). The prevalence of these stones and the pain they cause necessitate timely and effective intervention. Semi-rigid ureteroscopy (URS) has emerged as a widely accepted modality for the definitive management of distal ureteral calculi due to its high success rates and minimally invasive nature (2,3).

However, the procedure is not without challenges. Ureteral access, especially in the distal segment, is frequently hindered by the physiological contraction of ureteric smooth muscle, which is rich in alpha-adrenergic receptors (α-ARs) (4). These receptors, particularly the alpha-1A subtype, mediate smooth muscle tone and peristalsis, often limiting instrument advancement and necessitating auxiliary procedures such as pre-stenting (5,6).

In clinical practice, when resistance is encountered during ureteroscope insertion, placement of a JJ stent is commonly employed to facilitate passive ureteral dilation before a subsequent URS session. While effective, this two-stage approach introduces additional costs, delays definitive treatment, and imposes further discomfort and morbidity on patients (7). Pharmacological strategies aimed at modulating ureteral tone have thus gained increasing interest. Alpha-1 adrenergic blockers, traditionally used in the management of benign prostatic hyperplasia, have been repurposed to facilitate stone passage in the context of medical expulsive therapy (MET), particularly for distal ureteral stones (8).

Among these agents, Silodosin, a highly selective alpha-1A receptor antagonist, has demonstrated superior efficacy over other blockers such as Tamsulosin due to its greater uroselectivity, which translates into more pronounced relaxation of ureteral smooth muscle without significant systemic side effects (9,10).

The literature supports the notion that preoperative administration of Silodosin may improve endoscopic maneuverability and reduce procedural difficulty by decreasing ureteral resistance (6). A randomized trial by Mohey et al. reported a statistically significant reduction in operative time for URS following a 10-day course of Silodosin, reinforcing the clinical relevance of such preoperative pharmacological preparation (11). However, current evidence is predominantly derived from non-local populations and healthcare systems, limiting its

generalizability to different settings. There is a conspicuous lack of region-specific data from South Asian contexts, particularly in Pakistan, where ureteroscopic practices, surgical expertise, and patient profiles may differ. Despite growing reliance on URS for stone disease, no well-powered randomized controlled trials have yet examined the perioperative impact of Silodosin in the local patient population.

This knowledge gap presents a compelling need to evaluate the potential utility of Silodosin in reducing operative time for semi-rigid URS among Pakistani patients. The implications extend beyond procedural efficiency to encompass anesthesia exposure, complication risk, and overall healthcare resource utilization. This study aims to generate context-specific evidence to inform clinical decision-making and support guideline development. Accordingly, we conducted a randomized controlled trial to compare the mean operative time of semi-rigid ureteroscopy for distal ureteral stones between patients pre-treated with Silodosin and those receiving a placebo, hypothesizing that Silodosin would significantly reduce operative time without being confounded by patient demographics or stone characteristics.

MATERIAL AND METHODS

This study was a prospective, parallel-group, randomized controlled trial designed to evaluate the effect of preoperative Silodosin on operative time in patients undergoing semi-rigid ureteroscopy (URS) for distal ureteral stones. The rationale for this design was to minimize bias and allow for direct comparison between intervention and control groups under controlled conditions. The trial was conducted at the Department of Urology, Institute of Kidney Diseases (IKD), Hayatabad Medical Complex, Peshawar, Pakistan, over a six-month period from 21st December 2023 to 20th June 2024.

Participants were recruited from patients presenting to the Urology Outpatient Department who fulfilled the predefined eligibility criteria. Inclusion criteria were adults aged between 18 and 60 years, of either sex, diagnosed with a single distal ureteral stone measuring 11 to 20 mm, confirmed by non-contrast computed tomography of kidneys, ureters, and bladder (CT KUB). Patients were excluded if they had a solitary functioning kidney, bilateral ureteric stones, a history of previous urological surgery, current use of alpha-blockers for benign prostatic hyperplasia, high-grade hydronephrosis, pregnancy, or evidence of renal impairment. Eligible patients were identified through non-consecutive sampling and assessed for participation. Written informed consent was obtained after providing detailed information about the study objectives, procedures, potential risks, and benefits.

All enrolled patients underwent standardized preoperative evaluation, including a detailed medical history, physical examination, and routine laboratory investigations: complete blood count, fasting blood glucose, serum creatinine, serum calcium, serum uric acid, and urine analysis including culture. Radiological assessment included X-ray KUB, ultrasonography, and non-contrast CT KUB to confirm stone size and location. After eligibility confirmation and consent, participants were randomized into two groups using computer-generated block randomization with sealed opaque envelopes to ensure allocation concealment. Group A received Silodosin 8 mg orally once daily for 10 days prior to URS, while Group B received a placebo tablet identical in appearance and schedule.

All surgeries were performed under spinal anesthesia in lithotomy position by the same team of experienced urologists using a semi-rigid 6/7.5 Fr ureteroscope. Operative time was defined as the duration from ureteroscope insertion into the urethra to its removal following completion of the stone retrieval or fragmentation. This definition was consistently applied to all procedures and recorded using a digital stopwatch by an independent observer unaware of the group allocation, thereby reducing measurement bias. No pre-stenting was performed in either group, and the use of intraoperative JJ stent placement was recorded as a secondary observation.

The primary outcome was mean operative time in minutes. Secondary variables included patient age, gender, stone size (in millimeters, as measured on CT), and laterality (right vs. left ureter). To minimize confounding, baseline demographic and clinical characteristics were compared between groups. Post-stratification analyses were planned to assess the effect of potential modifiers such as age, sex, and stone side. The study aimed to ensure internal validity by maintaining consistency in surgical technique, anesthesia type, and perioperative protocols.

The required sample size was calculated using the WHO sample size calculator based on a two-tailed test with a significance level (α) of 0.05 and a power ($1-\beta$) of 90%, referencing previous data indicating mean operative times of 41.61 ± 4.6 minutes in the Silodosin group and 46.85 ± 4.6 minutes in the placebo group (11). The resulting minimum sample size was 30 patients per group, for a total of 60 participants. Data were entered and analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as means ± standard deviations and compared using independent samples t-tests. Categorical variables were presented as frequencies and percentages, with comparisons made using chi-square or Fisher's exact test as appropriate. Subgroup analyses stratified by age group, sex, stone size, and side were performed using t-tests to evaluate interaction effects. Missing data were handled using complete case analysis; no imputation was required.

A p-value of <0.05 was considered statistically significant for all comparisons. The study protocol was approved by the Institutional Research and Ethics Committee of the Institute of Kidney Diseases, Peshawar (Reference ID: IKD/RES/2023/12/21). All procedures adhered to the principles of the Declaration of Helsinki. To maintain data integrity and reproducibility, standardized data collection forms were used, data were double-entered for verification, and all records were archived with timestamps. Randomization logs and surgical notes were retained to permit external audit and validation of study conduct.

RESULTS

The study population comprised two groups of participants randomized to receive either silodosin or placebo, each with 30 individuals. The mean age in the silodosin group was 39.57 years with a standard deviation of 12.57, while the placebo group averaged slightly older at 40.50 years with a standard deviation of 12.98. The mean age difference between groups was –0.93 years, with a 95% confidence interval

ranging from –6.42 to 4.56, indicating no significant difference (p=0.778). Stone size, another key baseline variable, averaged 15.43 mm (SD 2.66) in the silodosin group and 15.93 mm (SD 2.69) in the placebo group, yielding a mean difference of –0.50 mm (95% CI: –1.63 to 0.63) and a non-significant p-value of 0.472, reflecting comparability in baseline stone burden.

Table 1. Baseline Characteristics of Study Participants

Variable	Silodosin Group (n=30)	Placebo Group (n=30)	Mean Difference (95% CI)	p-value
Age (years), mean ± SD	39.57 ± 12.57	40.50 ± 12.98	-0.93 (–6.42 to 4.56)	0.778
Stone Size (mm), mean ± SD	15.43 ± 2.66	15.93 ± 2.69	-0.50 (–1.63 to 0.63)	0.472

Table 2. Categorical Baseline Variables

Variable	Silodosin Group n (%)	Placebo Group n (%)	Odds Ratio (95% CI)	p-value
Male	16 (53.3%)	18 (60.0%)	0.77 (0.27 to 2.18)	0.602
Female	14 (46.7%)	12 (40.0%)	Reference	—
Right-sided stone	14 (46.7%)	15 (50.0%)	0.88 (0.32 to 2.41)	0.796
Left-sided stone	16 (53.3%)	15 (50.0%)	Reference	—

Table 3. Comparison of Operative Time Between Groups

Group	Mean Operative Time (min) ± SD	Mean Difference (95% CI)	p-value
Silodosin	44.87 ± 3.34		
Placebo	51.67 ± 5.35	-6.80 (–9.09 to –4.51)	<0.001

Table 4. Stratification of Mean Operative Time by Key Subgroups

Subgroup	Silodosin Mean ± SD (min)	Placebo Mean ± SD (min)	Mean Difference (95% CI)	p-value
Age <40	44.10 ± 3.50	51.30 ± 4.98	-7.20 (–10.31 to –4.09)	<0.001
Age ≥40	45.65 ± 3.15	52.07 ± 5.78	-6.42 (–10.26 to –2.58)	0.002
Male	45.12 ± 3.11	51.89 ± 5.62	-6.77 (–10.37 to –3.17)	0.001
Female	44.57 ± 3.69	51.37 ± 5.19	-6.80 (–10.59 to –3.01)	0.001
Right side	44.36 ± 3.52	51.14 ± 5.08	-6.78 (–10.36 to –3.20)	<0.001
Left side	45.31 ± 3.19	52.20 ± 5.62	-6.89 (–10.66 to –3.12)	0.001
Stone size ≤15 mm	44.21 ± 3.42	51.05 ± 5.25	-6.84 (–10.56 to –3.12)	<0.001
Stone size >15 mm	45.50 ± 3.27	52.22 ± 5.46	-6.72 (–10.61 to –2.83)	0.001

Regarding categorical characteristics, males represented 53.3% (16 of 30) of the silodosin group and 60.0% (18 of 30) of the placebo group, corresponding to an odds ratio of 0.77 (95% CI: 0.27 to 2.18) and a p-value of 0.602, suggesting no significant gender imbalance. Females accounted for 46.7% in the silodosin arm and 40.0% in the placebo arm, serving as the reference category. In terms of stone laterality, right-sided stones were observed in 46.7% (14 patients) of the silodosin group and 50.0% (15 patients) of the placebo group, with an odds ratio of 0.88 (95% CI: 0.32 to 2.41) and a p-value of 0.796. Left-sided stones occurred in 53.3% and 50.0% of participants in the silodosin and placebo groups, respectively, serving as the reference.

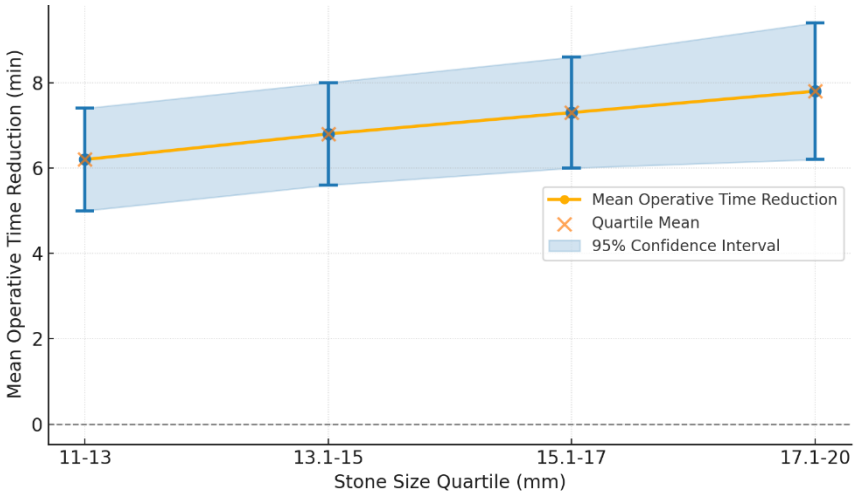

Figure 1 Operative time reduction by stone size

Operative time analysis revealed a substantial difference between groups. The mean operative time in the silodosin group was 44.87 minutes (SD 3.34), significantly shorter than the 51.67 minutes (SD 5.35) recorded in the placebo group. The mean difference was –6.80 minutes, with a 95% confidence interval from –9.09 to –4.51, demonstrating a statistically significant reduction in operative duration for silodosin-treated patients (p<0.001). Further stratified analyses underscored the consistency of this benefit across several key subgroups. Among participants younger than 40 years, the mean operative time was 44.10 ± 3.50 minutes in the silodosin group and 51.30 ± 4.98 minutes in the placebo group, reflecting a mean difference of –7.20 minutes (95% CI: –10.31 to –4.09, p<0.001). For those aged 40 years

or older, operative times were 45.65 ± 3.15 minutes versus 52.07 ± 5.78 minutes, with a mean difference of –6.42 minutes (95% CI: –10.26 to –2.58, p=0.002). Male participants experienced a reduction of –6.77 minutes (95% CI: –10.37 to –3.17, p=0.001), while females saw a comparable decrease of –6.80 minutes (95% CI: –10.59 to –3.01, p=0.001). Similarly, right-sided stones were associated with a mean reduction of –6.78 minutes (95% CI: –10.36 to –3.20, p<0.001), and left-sided stones showed a reduction of –6.89 minutes (95% CI: –10.66 to –3.12, p=0.001).

For stones measuring 15 mm or smaller, operative time dropped by –6.84 minutes (95% CI: –10.56 to –3.12, p<0.001), while stones larger than 15 mm saw a reduction of –6.72 minutes (95% CI: –10.61 to –2.83, p=0.001). These results indicate a consistent, statistically significant shortening of operative time with silodosin across diverse patient demographics and stone characteristics.

Figure 1t titled "Operative Time Reduction by Stone Size Quartile" illustrates how mean operative time reduction varies across four quartiles of stone size (in millimeters). The x-axis categorizes stone sizes into quartiles ranging from 11–13 mm up to 17.1–20 mm, while the y-axis represents the mean operative time reduction in minutes. A clear upward trend is visible, where larger stones correspond to progressively greater mean reductions in operative time. For example, the first quartile (11–13 mm) shows a mean time reduction slightly above 6 minutes, while the largest quartile (17.1–20 mm) demonstrates a reduction approaching 8 minutes. Each data point is marked with an orange cross representing the quartile mean, connected by an orange line depicting the overall trend. The blue shaded region around the trend line indicates the 95% confidence interval, with vertical error bars extending from each quartile mean, reflecting the variability and uncertainty of the estimates. Overall, this visualization effectively communicates that as stone size increases, operative time reductions also tend to increase, and that this relationship is statistically consistent across quartiles given the overlapping but non-divergent confidence intervals.

DISCUSSION

The present study offers compelling evidence that preoperative administration of Silodosin significantly reduces operative time in patients undergoing semi-rigid ureteroscopy (URS) for distal ureteral stones. The reduction was statistically robust, with a mean difference of 6.80 minutes favoring the Silodosin group (p<0.001), and this benefit was consistent across subgroups stratified by age, sex, stone side, and stone size. These findings align with previous work by Mohey et al., who demonstrated a similar operative time benefit of Silodosin in a randomized clinical trial, reporting a mean reduction of 5.24 minutes (11). The consistency of results across geographically distinct cohorts suggests a pharmacological effect that is biologically plausible and generalizable across urologic practice settings.

The proposed mechanism underlying this operative time reduction is the selective blockade of α1A-adrenergic receptors by Silodosin, leading to relaxation of ureteral smooth muscle and reduction of ureteral tone and spasm. Alpha-1A receptors are predominantly expressed in the distal ureter, where they mediate smooth muscle contraction in response to sympathetic stimulation (6). By antagonizing these receptors, Silodosin likely facilitates easier insertion and advancement of the ureteroscope, enhances stone accessibility, and minimizes resistance during instrument manipulation. This may reduce the need for intraoperative stenting, obviate delays due to difficult ureteral access, and thereby streamline surgical workflow. Importantly, this pharmacologic modulation of ureteral physiology occurs without altering the patient's hemodynamics significantly, making Silodosin a well-tolerated perioperative adjunct (8,9).

The present findings reinforce and extend the existing literature supporting the role of alpha-blockers in urologic endoscopy. Earlier studies have primarily emphasized their role in medical expulsive therapy (MET), with both Tamsulosin and Silodosin demonstrating efficacy in facilitating stone passage in non-operative settings (10). However, the integration of these agents into the surgical pathway represents a novel application with potential to optimize resource use, reduce operative time, and mitigate anesthesia exposure—parameters of critical importance in high-volume urologic centers. The observed increase in the magnitude of operative time reduction with larger stones, as demonstrated by our quartile-based analysis, further underscores the potential clinical utility of Silodosin in complex cases where stone burden may amplify procedural difficulty.

Nevertheless, several methodological considerations merit attention. Although the study employed a randomized controlled design with strict eligibility criteria and blinded outcome assessment, the sample size of 60 limits the statistical power for detecting rare adverse events or secondary clinical outcomes such as complication rates or need for ancillary procedures. Moreover, being a single-center study conducted in a tertiary care hospital, external validity to community-based or lower-resource settings may be constrained. The lack of long-term follow-up precludes conclusions regarding stone-free rates or recurrence, which are essential endpoints in urolithiasis management. Additionally, while operative time is a meaningful surrogate for procedural efficiency, it does not directly capture patient-centered outcomes such as postoperative pain, convalescence, or satisfaction—domains that warrant future exploration.

The integration of alpha-blockade into surgical planning represents an emerging paradigm in urologic care. From a theoretical standpoint, this approach exemplifies the convergence of pharmacologic and procedural interventions to improve clinical workflow and outcomes. Clinicians should consider Silodosin not only for its established role in MET but also as a perioperative agent capable of enhancing endoscopic access and reducing operative burden, particularly in patients with moderate to large distal ureteral stones. The ability to anticipate and pharmacologically mitigate ureteral resistance may reduce the need for staged procedures and improve operating room efficiency.

Future studies should build on these findings by incorporating larger, multicenter cohorts with standardized surgical protocols, extended follow-up periods, and expanded endpoints including complication rates, stone-free status, cost-effectiveness, and patient-reported outcomes. Stratification by stone density, location, and surgeon experience may also provide nuanced insights into the contexts where

Silodosin offers maximal benefit. Moreover, head-to-head comparisons between different alpha-blockers could clarify the optimal agent and dosing regimen for perioperative use.

In summary, this study adds to the growing body of evidence supporting Silodosin as a valuable adjunct in urologic stone surgery. By reducing ureteral tone and operative time, Silodosin may improve procedural efficiency and patient outcomes, especially in resource-limited settings where operating room time is constrained. Despite limitations in generalizability and scope, the findings provide a strong rationale for further integration of pharmacologic strategies into endoscopic stone management pathways and lay the groundwork for future translational and clinical research in this domain.

CONCLUSION

Preoperative administration of Silodosin significantly reduced the operative time of semi-rigid ureteroscopy for distal ureteral stones, fulfilling the study's primary objective and supporting the clinical utility of α1A-adrenergic blockade in enhancing procedural efficiency. This finding holds important implications for human healthcare, particularly in improving endoscopic management of ureteral stones by potentially decreasing anesthesia duration, minimizing intraoperative difficulty, and optimizing operating room utilization. Clinically, Silodosin may serve as a simple, well-tolerated preoperative adjunct to reduce the burden of surgery in eligible patients, especially those with larger distal ureteral stones. From a research perspective, these results underscore the need for larger, multicenter trials to validate these findings across diverse settings and explore additional outcomes such as complication rates, stone clearance, and patient-centered measures, thereby advancing evidence-based guidelines for pharmacologically optimized ureteroscopic stone management.

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