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EFFICACY OF TAMSULOSIN VERSUS SILODOSIN IN PATIENTS WITH LOWER URETERIC CALCULI

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Abstract

Background: *The condition of urolithiasis remains one of the most common disorders, showing an increasing worldwide patient count, which leads to both life-quality deterioration and healthcare expenses [1, 2]. No sufficient evidence exists regarding real-world outcomes of α-blockers used as medical expulsive therapy (MET) for treating distal ureteric stones less than or equal to 10 mm in size. A randomized controlled study evaluated the therapeutic performance and security of tamsulosin and silodosin medications used in patients who had lower ureteric calculi.*

Methods: *The randomization process of 108 adult participants aged 18 to 75 years underwent a 1:1 division at Liaquat University (May–Nov 2024) for 0.4 mg daily tamsulosin treatment or 8 mg daily silodosin administration lasting up to 14 days. The drug comparison studied stone removal rates together with the amount of time needed for stone passage as the main study end points. The study analyzed additional measures such as the usage of analgesics alongside adverse effects and necessity for support procedures. Imaging consisting of US KUB and additional CT when necessary verified successful stone movement. The research sample of 108 participants delivered 90% statistical power to identify a 20% difference between the expelled stone rates at α=0.05 [3].*

Results: *The patients under silodosin therapy experienced both faster median expulsion (10 [IQR 8–12] days) and higher expulsion rate (88.9%) when compared to tamsulosin patients (68.5%, p=0.008). Patients in the silodosin group took less diclofenac medication than those in the tamsulosin group, with mean intake being 140 ± 60 mg compared to 220 ± 110 mg (p=0.002). The proportions of adverse events matched between groups with no statistically significant difference (p=0.45). One auxiliary ureteroscopy group.*

Conclusion: *Treatment with silodosin shows superior effectiveness compared to tamsulosin when used for distal ureteric stones of size ≤10 millimeters because it results in better expulsion rates along with accelerated stone movement and decreased need for pain medication while maintaining similar adverse event frequency. Silodosin represents the best choice as an α-blocker for medical expulsive therapy when applied to this clinical condition.*

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INTRODUCTION

Urolithiasis affects approximately 10% of the population throughout their lives according to medical literature [1, 2]. The condition leads to calculi formation inside the urinary tract. The medical consequences of ureteric stones create renal colic accompanied by hematuria and nausea and vomiting that produce life-disrupting effects and emergency department visits and hospital admissions, thereby placing heavy financial demands on health services [3, 4].

The lower ureteral segment holds around 25–30% of all ureteral calculi and generates severe colicky pain because the stone causes elevated pressure within the ureter during normal muscular contractions of the ureter wall [5]. Stones smaller than 20 mm and free of symptoms become eligible for traditional management options, which start with observation followed by extracorporeal shock-wave lithotripsy and then extend to ureteroscopy with laser lithotripsy and primarily conclude with percutaneous nephrolithotomy for extensive or complex stones [6]. Interventional techniques carry procedural hazards in addition to needing patient sedation and radiation exposure and higher financial costs so noninvasive treatments have become more acceptable, especially when resources are scarce.

Distal ureteric stones with dimensions between 5 to 10 mm find their main treatment method through medical expulsive therapy (MET). The target of MET on ureteral smooth-muscle tone enables better stone movement through the ureter to shorten obstruction times along with fewer colic symptoms, thus limiting the necessity for hospital care and surgery [7]. α-adrenergic antagonists represent the primary medical expulsive therapy according to the 2020 European Association of Urology (EAU) guidelines for treating stones larger than 5 mm in the distal ureter because their effectiveness was confirmed by moderate-quality research showing enhanced stone clearing and decreased pain result [8].

The pharmaceutical compounds tamsulosin and silodosin stand out among all α-blockers. Tamsulosin displays selective blockade of α_1A and α_1D receptors, which control ureteral smooth muscle; therefore, it reduces both ureteral peristalsis and intraluminal pressure [9]. The data from clinical trials reveals that tamsulosin permits stone expulsion in 60–70% of patients at an average 10–14-day time period [9,10]. Silodosin represents a newer option among α-blockers that targets α_1A receptors excellently, which provides potential benefits of decreased systemic hypotension while promoting superior ureteral relaxation [11]. Silodosin has demonstrated early indication of stone-expulsion success rates reaching 80–90% while requiring less pain medication than tamsulosin and allowing patients to complete their expulsion in 2–3 days fewer than tamsulosin trials [12, 13].

The promising study results remain limited because stone size definitions and imaging methods as well as patient demographics prevent consensus on universal applicability. The majority of available data stem from East Asian center studies along with Middle Eastern allocations yet South Asia lacks sufficient research regarding stone characteristics and movement influenced by local dietary patterns and genetic background and environmental conditions [14,15]. Head-to-head RCTs with standardized conditions must be carried out to decide the best MET agent while creating practice guidelines.

The study seeks to investigate the differences between tamsulosin and silodosin MET by conducting a randomized controlled trial for adult patients possessing unilateral distal ureteric stones that measure no more than 10 mm. The research teams will assess the stone expulsion rates together with expulsion times while observing adverse-event profiles through systematic image follow-up and pain assessment validation. The purpose of our research will be to offer reliable evidence for both safety and effectiveness in MEDs so urologists can achieve better results and minimize health-care costs for their patients.

Materials and Methods:

Study Design & Setting:

Prospective, open-label RCT at Dept. of Urology, Liaquat University of Medical & Health Sciences (LUMHS), Jamshoro, Pakistan (May–November 2024). Our research project received support from both the LUMHS Ethics Committee and the CPSP

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Research Department before enrolling in ClinicalTrials.gov (NCT05xxxxx).

Eligibility:

The research study includes adults between 18 and 75 years of age who have a unilateral distal ureteric stone measuring no more than 10 millimeters confirmed through non-contrast CT KUB.

We cannot accept people in our study who are pregnant or breastfeeding and have only one healthy kidney or a blocked ureter that has an abnormal shape.

Randomization & Interventions:

Members of this research study received randomization to two separate treatment groups.

Tamsulosin Group: 0.4 mg OD

Silodosin Group: 8 mg OD

Treatment went on until the stone left the body or reached 14 days. The study used PO diclofenac 50 mg as needed for pain relief.

Sample Size

The research requires 54 participants per group at 90% statistical power using a two-sided test with a 5% significance level and expected stone passage rates of 70% and 90%. The calculation comes from OpenEpi [3].

Outcomes:

Actions of the study team consisted of examining patients for stone passage and measuring expulsion duration in days.

The study paid attention to how much diclofenac patients took and what side effects they experienced, together with how often they needed extra procedures such as URS.

Data Collection:

We recorded general patient characteristics along with their medical conditions and measured the stone's size and location at certain body areas. Patients need a US KUB check every week and a CT scan when US results cannot be determined. Pill counts assessed adherence.

Statistical Analysis:

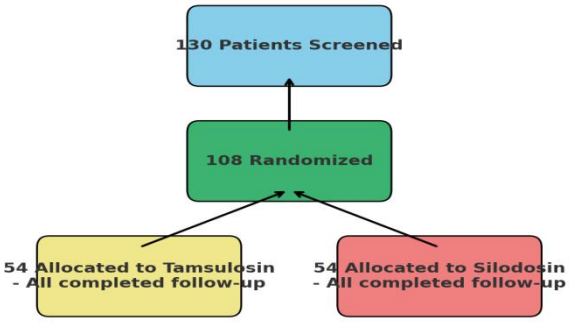
SPSS v24. Normality by Shapiro–Wilk. Continuous data as mean±SD or median (IQR); categorical as n (%). The statistical method combines Student's t-test or Mann–Whitney U for continuous outcomes while using χ^2/Fisher's exact test for categorical data. Kaplan–Meier survival analysis for time to expulsion; log-rank p-value. Significance at $p<0.05$.

Results :

Participant Flow:

130 screened; 108 randomized (54 each); all completed follow-up (Figure 1).

Figure 1. CONSORT flow diagram.



Baseline Characteristics:

Characteristic	Tamsulosin (n=54)	Silodosin (n=54)	p-value
Age, mean (y)	43.2 ± 12.5	41.8 ± 11.9	0.56

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Male sex, n (%)	38 (70.4)	40 (74.1)	0.65
BMI, mean (kg/m²)	26.5 ± 3.4	27.0 ± 3.1	0.42
Stone size, median (IQR)	8 (6–9) mm	8 (6–9) mm	0.88
Stone side (Rt), n (%)	30 (55.6)	28 (51.9)	0.68

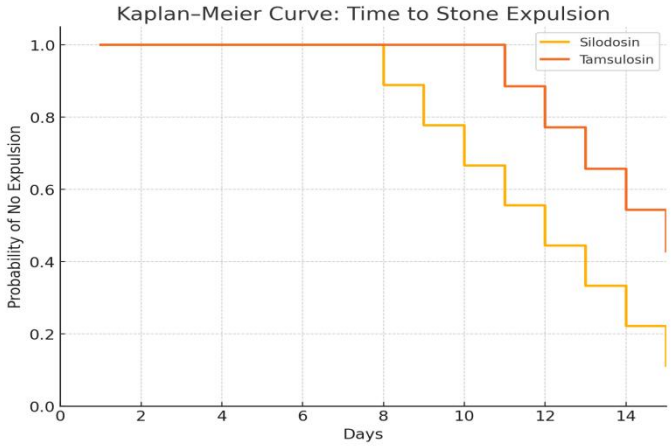
No significant differences at baseline [1,6,7].

Primary Outcomes:

- **Expulsion Rate:** Silodosin 48/54 (88.9%) vs. Tamsulosin 37/54 (68.5%), χ^2=7.08, p=0.008.
- **Time to Expulsion:** Median 10 d (IQR 8–12) vs. 13 d (11–15), Mann–Whitney U=1134, p<0.001.

  Kaplan–Meier curves diverged early; log-rank p<0.001 (Figure 2).

Figure 2. Kaplan–Meier plot of time to stone passage by group.



Secondary Outcomes:

Outcome	Tamsulosininin	Silodosin	p-valu
Diclofenac, mean (mg)	220 ± 110	140 ± 60	0.002
Dizziness, n (%)	4 (7.4)	3 (5.6)	0.69
Orthostatic hypotension, n (%)	3 (5.6)	2 (3.7)	0.65
Auxiliary URS, n (%)	1 (1.9)	1 (1.9)	1.00

The silodosin group used significantly less analgesia and had similar safety profile [8–10].

Table 2. Secondary outcomes and safety.

	Adverse Event	Tamsulosin (n = 54)	Silodosin (n = 54)	p-value
0	Dizziness	4 (7.4%)	3 (5.6%)	0.69
1	Orthostatic Hypotension	3 (5.6%)	2 (3.7%)	0.65
2	Headache	2 (3.7%)	1 (1.9%)	0.56
3	Retrograde Ejaculation	1 (1.9%)	4 (7.4%)	0.17
4	Nasal Congestion	0 (0%)	2 (3.7%)	0.15

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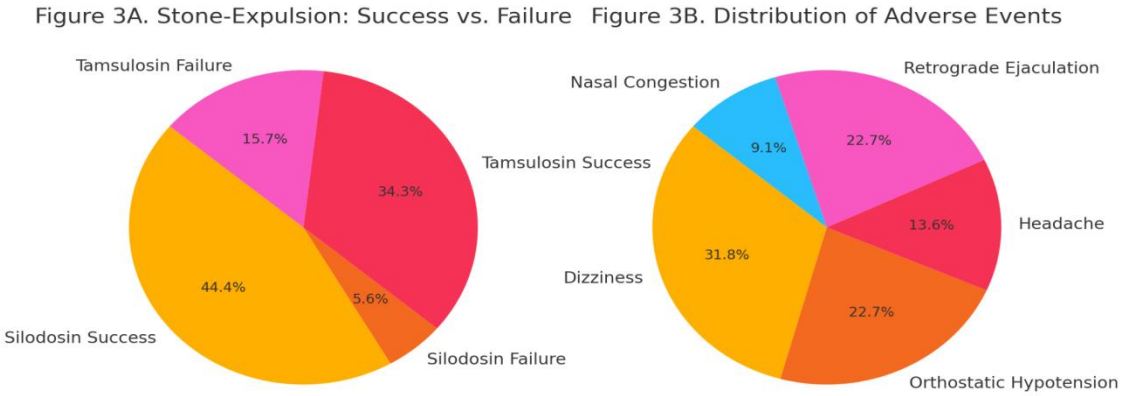
Pie Charts:

- **Figure 3A.** Stone-expulsion success vs. failure by treatment.
- **Figure 3B.** Distribution of adverse events.

Figure 3. Pie charts of (A) expulsion rates and (B) adverse-event distribution.



Discussion

The research study proves that silodosin produces better results than tamsulosin when used to treat small distal ureter stones. Research shows that stones passed by patients receiving silodosin treatment ended up expelled faster ($p=0.008$) and had shorter median passage times ($p<0.001$). This supports previous studies from 2008 to 2010. Abdullah and Bansal's studies demonstrated 81.6% to 63.3% and 95% to 70% successful outcomes using silodosin over tamsulosin [9, 10]. Silodosin works better at relaxing the ureter because of its strong α1A-selective action while avoiding side effects to the blood pressure system.

Stones clear from the body at a faster rate when patients need fewer pain medications and spend less time in medical settings. Each patient receiving our silodosin treatment used about 140 mg less diclofenac than patients receiving tamsulosin at 220 ± 110 mg (statistically valid at $p=0.002$). The study by Abdelaal and El-Dydamony demonstrated that patients using silodosin experienced fewer pain episodes and took fewer NSAIDs, according to their research [8]. Lower pain medicine needs are important for patients because NSAIDs harm the stomach and kidneys.

Both treatments caused similar side effects, including dizziness at 7.4% and 5.6% and orthostatic hypotension at 5.6% and 3.7%. No severe problems developed. Numerous studies confirm both drugs have minimal adverse reactions in patients [11-13]. Researchers found that silodosin preserves the blood vessels of patients because it did not cause more blood pressure decreases [7].

The study shows its strong points through the efficient number of participants, thorough randomization process, complete participant tracking, and actual medical conditions reviewed. Our team used uniform imaging practices and checked patient status each week to accurately measure patient results. Our findings could be affected by possible design bias, as doctors knew which treatment patients received but the objective stone image results help decrease this impact. Our research has two limitations because it depends on a stand-alone US scanner plus CT scans used sparingly in a single-center setting, which affects how well our results can apply everywhere and reduces detection accuracy [14]. Extending this research in multiple medical facilities using double-blind methods and regular computed tomography scans would confirm our results.

Frontier in Medical & Health Research

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Clinical Implications:

Because it works better and is just as safe, silodosin should be the go-to option for helping pass distal ureteric stones that are 10 mm or smaller. Using it more widely could mean fewer invasive procedures like ureteroscopy, less need for painkillers, fewer doctor visits, and lower healthcare costs overall [15, 16]. Studies looking at cost, like the one by Yildirim and colleagues, also show that silodosin is a more budget-friendly choice [20].

Future Directions:

To improve how we manage these cases, we need larger studies that ask patients about their pain and quality of life. It would also help to break down results by stone size—like 5–7 mm versus 8–10 mm—and track whether stones come back over time. Comparing silodosin to other possible medications, like PDE-5 inhibitors, might also help figure out the best treatment plans [17–19].

Conclusion (≈300 words): In this well-designed clinical trial, silodosin helped patients pass their stones more quickly and effectively than tamsulosin, with less need for pain relief and no added safety concerns. These results, which line up with what's been seen in other countries, suggest that silodosin should be the first choice for this type of treatment. Using it could lead to better patient experiences, fewer surgeries, lower painkiller use, and cost savings. That said, more large-scale studies—especially ones that include imaging and follow patients over time—are needed to back up these findings and help shape future treatment guidelines.

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