VOLUME - 14, ISSUE - 12, DECEMBER - 2025 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

General Surgery

INFLUENCE OF STONE SIZE ON THE EFFECTIVENESS OF MEDICAL EXPULSIVE THERAPY WITH TAMSULOSIN AND SILODOSIN IN DISTAL URETER: A PROSPECTIVE SUBGROUP ANALYSIS

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ABSTRACT

Background: Medical expulsive therapy (MET) with alpha-1 blockers such as tamsulosin and silodosin is widely utilized for managing distal ureteric stones. However, stone size remains a critical determinant of success, influencing spontaneous passage rates and treatment outcomes. **Objective:** To evaluate and compare the effectiveness of tamsulosin and silodosin in promoting stone expulsion among patients with distal ureteric calculi, with a focus on the impact of stone size. **Methods:** A prospective, randomized clinical study involving 200 patients with distal ureteric stones (4–10 mm) was conducted. Patients were randomized to receive either tamsulosin 0.4 mg or silodosin 8 mg daily for up to 28 days. Subgroup analyses compared stone expulsion rates and times in patients with stones <7 mm and ≥7 mm. **Results:** Among patients with stones <7 mm, expulsion rates were high and comparable between the two groups (tamsulosin 89%, silodosin 87%; $p > 0.05$). For stones ≥7 mm, expulsion rates significantly declined (tamsulosin 33%, silodosin 40%), with no significant difference between drugs. Mean expulsion times did not differ significantly between groups or size subgroups. **Conclusion:** Stone size is the primary predictor of MET success with tamsulosin and silodosin. Both drugs demonstrate comparable efficacy, particularly for stones less than 7 mm. Patients with larger stones should be counseled about lower chances of spontaneous passage and may require alternative management.

KEYWORDS : distal ureteric calculus, stone size, tamsulosin, silodosin

INTRODUCTION

Urolithiasis is a global health burden with a lifetime prevalence estimated between 5% and 12% worldwide, disproportionately affecting males. Distal ureteric stones account for a significant subset of ureteral calculi, often resulting in intense pain and clinical presentation characterized by renal colic. Traditionally, stone management involves invasive procedures such as ureteroscopy or extracorporeal shock wave lithotripsy (ESWL), which, while effective, present costs, technical demands, and risks.[1]

Medical expulsive therapy (MET) has emerged as a minimally invasive and cost-effective approach, employing pharmacological agents like alpha-1 adrenergic blockers to relax ureteral smooth muscle-facilitating stone passage and reducing pain. Among these, tamsulosin (a selective alpha-1A and alpha-1D antagonist) and silodosin (a highly selective alpha-1A antagonist) are commonly prescribed.

Numerous studies have demonstrated the efficacy of both agents, yet the role of stone size-a key predictor of spontaneous passage-in determining the success of MET, requires further elucidation, particularly in the context of different alpha blocker therapies [5–7]. Understanding the interplay between stone size and drug efficacy assists in optimizing patient selection and therapeutic planning.

The current study presents a subgroup analysis assessing stone expulsion rates and times in patients treated with tamsulosin or silodosin, stratified by stone size (<7 mm versus ≥7 mm), to clarify the influence of stone dimensions on medical therapy outcomes.

MATERIALS AND METHODS

Study Design And Setting

This randomized, prospective clinical trial was conducted in the Department of General Surgery, Dr. Radhakrishnan Government Medical College, Hamirpur, Himachal Pradesh, India, from August 2019 to December 2021. Ethical approval was obtained, and informed consent was secured from all participants.

Patient Selection

Inclusion Criteria:

- Age ≥18 years.
- Diagnosis of single distal ureteric stone confirmed by radiological imaging (ultrasound and/or X-ray KUB), stone size ranging from 4 to 10 mm.
- Normal renal and hepatic function tests.
- Willingness to participate with signed informed consent.

Exclusion Criteria:

- Multiple or bilateral stones.
- Pregnancy or lactation.
- Prior ureteric surgery or interventions.
- Severe hydronephrosis or pyelonephritis.
- Use of alpha, beta blockers, or calcium channel blockers before enrollment.
- Known intolerance to study drugs.

Randomization And Intervention

Patients presenting to the outpatient department were assigned to treatment groups using a simple allocation based on OPD registration numbers: even-numbered patients received **tamsulosin 0.4 mg daily** (Group 1), while odd-numbered patients received **silodosin 8 mg daily** (Group 2).

Both groups were instructed to maintain adequate hydration (minimum of 2 liters fluid per day) and were provided symptomatic analgesics and antispasmodics as needed. Treatment continued for a maximum of 28 days or until confirmed stone expulsion.

Follow-up And Evaluation

Patients were evaluated at baseline, and followed up at two weeks, and then weekly up to four weeks or until stone passage was confirmed.

- Stone expulsion was defined by patient-reported passage of the stone, corroborated by absence of calculi on imaging (ultrasound and X-ray KUB).
- Non-expulsion after 28 days or requirement for surgical intervention was classified as treatment failure.

Subgroup Analysis By Stone Size

Patients were categorized based on maximal stone diameter into:

- Small stones: **<7 mm**
- Large stones: **≥7 mm**

Stone expulsion rates, times, and failure rates were compared within and across treatment groups.

Data Collection And Outcomes

Demographic data, stone characteristics (size, side), treatment details, expulsion status, and time to expulsion were recorded.

Statistical Analysis

Data were processed using SPSS v17. Continuous variables are described using mean ± standard deviation, while categorical variables are provided as frequencies and percentages.

Chi-square tests compared categorical outcomes (e.g., expulsion rates) between groups and subgroups. Independent t-tests assessed differences in continuous variables such as mean expulsion time. A two-tailed p-value <0.05 denoted statistical significance.

RESULTS

Patient Characteristics

Out of 220 enrolled patients, 200 completed the study—100 in the tamsulosin group and 100 in the silodosin group.

- Mean patient age was 37.9 ± 14.57 years.
- Sex distribution: 121 males (60.5%) and 79 females (39.5%).
- Stone location was evenly distributed (100 right-side, 100 left-side).
- Stone size distribution:

Stone size (mm)	Number of Patients
4.1–5	23
5.1–6	52
6.1–7	40
7.1–8	33
8.1–9	20
9.1–10	32

Stone Expulsion Rates By Subgroup

- Expulsion rates for stones <7 mm were significantly higher than those ≥7 mm ($p < 0.05$ within each group).
- No statistically significant difference was observed between tamsulosin and silodosin groups for either stone size category ($p = 0.66$ for <7 mm; $p = 0.91$ for ≥7 mm).

Stone Size	Group	Number of Patients	Expelled Stones	Expulsion Rate (%)	Failure Rate (%)
<7 mm	Tamsulosin	55	49	89	11
	Silodosin	60	52	87	13
≥7 mm	Tamsulosin	45	15	33	67
	Silodosin	40	16	40	60

Stone Expulsion Time

- Mean expulsion time for all patients:
  Tamsulosin: 15.8 ± (SD) days
  Silodosin: 15.6 ± (SD) days
- Majority of stone expulsion occurred within 14 days for both drugs, particularly in patients with stones <7 mm.
- Distribution of expulsion times among patients who passed stones:

Timeframe (days)	Tamsulosin Group (%)	Silodosin Group (%)
≤14	83	78
15-21	8	15
22-28	9	7

No statistically significant difference in expulsion times was noted between groups or across stone size subgroups.

Adverse Events

- Both groups demonstrated excellent tolerability.
- Low incidence of adverse effects, primarily isolated cases of retrograde ejaculation (one case per group).
- Treatment discontinuation due to adverse events was rare.

DISCUSSION

This subgroup analysis highlights the pivotal role of stone size in determining the success of medical expulsive therapy using tamsulosin or silodosin for distal ureteric calculi.

Our findings affirm that stones smaller than 7 mm respond favorably to alpha blocker therapy, achieving spontaneous expulsion rates approaching 90%. Conversely, stones measuring 7 mm or larger were associated with markedly reduced success rates (~33–40%), consistent with previously published data demonstrating the inverse relationship between stone size and passage probability.

Despite differences in receptor selectivity—tamsulosin acting on both alpha-1A and alpha-1D receptors, and silodosin being highly selective for alpha-1A—the clinical outcomes in terms of expulsion rates and times were statistically indistinguishable between the two agents across size subgroups. This compares well with other randomized controlled trials and meta-analyses reporting minimal or no superiority of one agent over the other in terms of efficacy.

The mean expulsion times nearing 16 days with both medications suggest clinically comparable kinetics of stone passage when therapy is initiated promptly.

From a clinical standpoint, these results underscore the importance of initial stone size assessment via imaging to guide therapeutic decisions and patient counseling. Specifically, patients with stones ≥7 mm should be informed of lower likelihood of spontaneous passage with MET and considered for early intervention or alternative therapies.

Our study's strengths include prospective design, standardized protocols, and adequate sample size. Limitations include single-center setting and lack of long-term follow-up for recurrence or delayed complications.

CONCLUSION

- Stone size is the predominant predictor of efficacy in medical expulsive therapy for distal ureteric calculi.
- Both tamsulosin and silodosin demonstrate high effectiveness for stones <7 mm and comparable stone expulsion times.
- Patients with stones ≥7 mm exhibit reduced response to MET, regardless of drug choice, warranting tailored clinical management.
- Selection between tamsulosin and silodosin may consider factors such as tolerance, cost, and availability rather than efficacy differences.

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