Original article

Stone Expulsion Rates with Medical Expulsion Therapy vs Expectant Management in 5 to 7 mm Distal Ureteric Stones: A Prospective Comparative Study

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Abstract

Introduction: Distal ureteric stones measuring 5–7 mm pose a clinical dilemma as they may pass spontaneously but often cause severe colic and complications. Medical Expulsion Therapy (MET) with alpha-blockers, such as tamsulosin, has been proposed to facilitate passage, but its true benefit over expectant management (EM) remains debated. This study aimed to compare stone expulsion rates, time to passage, and emergency department (ED) visits between MET and EM.

Methods: A prospective observational study was conducted at Shree Birendra Hospital, Kathmandu, Nepal, from June 2024 to June 2025. Adult patients (18–65 years) with a single distal ureteric stone (5–7 mm) confirmed by NCCT-KUB were included. Exclusion criteria were bilateral/multiple stones, anatomical abnormalities, prior ureteric surgery, significant hydronephrosis, pregnancy, single functioning kidney, active UTI and deranged renal function. Patients received either MET with tamsulosin 0.4 mg daily for 4 weeks plus analgesics and hydration (Group A, n=50) or EM with hydration and analgesics alone (Group B, n=50). Outcomes assessed were spontaneous expulsion of stone, time to passage, and ED visits for severe colic.

Results: Spontaneous expulsion was observed in 82% of patients in the MET group versus 74% in the EM group (p=0.334). Median expulsion time did not differ significantly between groups, with most stones passing within two weeks. Notably, ED visits were significantly lower in the MET group (12% vs 30%, p=0.027).

Conclusions: While MET did not significantly improve stone expulsion rates or passage time compared to EM, it significantly reduced ED visits, suggesting a role in symptom control. Larger randomized studies are needed to define the patient subgroup most likely to benefit.

Keywords: Distal ureteric stone; Expectant management; Medical expulsion therapy; Stone passage; Tamsulosin.

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Introduction

Ureteric stones constitute a significant proportion of cases of urolithiasis worldwide.[1] Among these, distal ureteric stones are particularly notorious for causing acute renal colic, substantial patient discomfort, and potential complications such as urinary tract infections and obstruction-induced renal impairment.[2] The management of these stones, particularly those measuring between 5 to 7 mm, remains a subject of clinical debate. Stones measuring 5 to 7 mm in the distal ureter present a clinical challenge i.e. they are small enough to have a chance of spontaneous passage but large enough to cause significant pain and potential complications. While spontaneous passage is possible, intervention is often required to relieve symptoms and prevent complications.[3]

Medical Expulsion Therapy (MET) and Expectant Management (EM) represent two distinct conservative approaches to managing distal ureteric stones.[4] MET involves the administration of pharmacological agents, primarily alpha-blockers such as tamsulosin, to facilitate stone passage by relaxing the ureteral smooth muscle and reducing intra-ureteral pressure.[5] On the other hand, EM adopts a non-interventional approach, relying on sufficient hydration, pain management, and time to allow for spontaneous stone expulsion.

Despite the increasing use of MET, its efficacy in comparison to EM, particularly in the context of 5 to 7 mm distal ureteric stones, remains uncertain.[6] While some studies suggest that MET significantly enhances stone expulsion rates and reduces the time to passage, others have failed to demonstrate a marked benefit over conservative management.[7,8] This inconsistency necessitates a rigorous, prospective investigation to determine the true clinical value of MET relative to EM in this patient cohort.

This study aims to provide evidence by directly comparing MET and EM in terms of stone expulsion rates, time to passage and emergency department visits for severe ureteric colic during the treatment.

Methods

This study is a hospital based prospective observational study conducted in Department of General Surgery, Shree Birendra Hospital, Kathmandu, Nepal from June 15th 2024 to June 14th 2025. Ethical approval for the study was obtained from Institutional Review Committee of Nepalese Army Institute of Health Sciences (Reg No. 1328). Written informed consent was taken from all participants. Sample size was calculated using comparison of two independent proportions based on previously reported expulsion rates of approximately 85% in the MET group and 60% in the control group from earlier randomized study (Al-Ansari et al., 2010).[9] Assuming a two-sided alpha error of 5% and 80% power, the minimum required sample size was calculated to be 46 patients per group. After adjusting for an anticipated 10% attrition rate, a final sample size of 50 patients per group was determined. Adult patients (18-65 years) diagnosed with a single distal ureteric stone of size 5 to 7 mm confirmed via non-contrast computed tomography (NCCT) KUB were included in the study. Distal ureter was defined as distal to the sacroiliac joint on CT and size was defined as the largest diameter in 3 planes. Baseline investigations including urine routine examination and serum creatinine were performed in all patients prior to inclusion. Patients with bilateral ureteric stones, multiple ureteric stones, history of ureteral surgery, anatomical abnormalities of the ureter, single functioning kidney, significant hydronephrosis (defined as moderate to severe pelvicalyceal dilatation on imaging), prior failed MET, active urinary tract infection, deranged renal function tests (serum creatinine above normal reference range), and pregnant women were excluded from the study. This was a non-randomized prospective comparative study. Group allocation was done based on shared decision-making between the treating surgeon and the patient after explaining the potential benefits and risks of both Medical Expulsion Therapy and Expectant Management. No randomization technique was employed. Patients treated with medical expulsion therapy using Tamsulosin 0.4 mg once daily for 4 weeks along with analgesics and sufficient hydration were categorized as Group A and those kept on expectant management with sufficient hydration and analgesics were categorized as Group B. Prophylactic antibiotics were not administered routinely. All patients were kept on regular follow up via phone calls and weekly hospital visit for 4 weeks. Patients were instructed to report spontaneous stone passage, which was subsequently assessed by ultrasonography. NCCT was not routinely repeated to confirm passage in order to minimize radiation exposure and cost. Ultrasonography was used as a follow-up imaging modality despite its lower sensitivity compared to CT. Severe ureteric colic was defined as acute flank pain necessitating an emergency department visit and requiring parenteral analgesia for pain control. Emergency

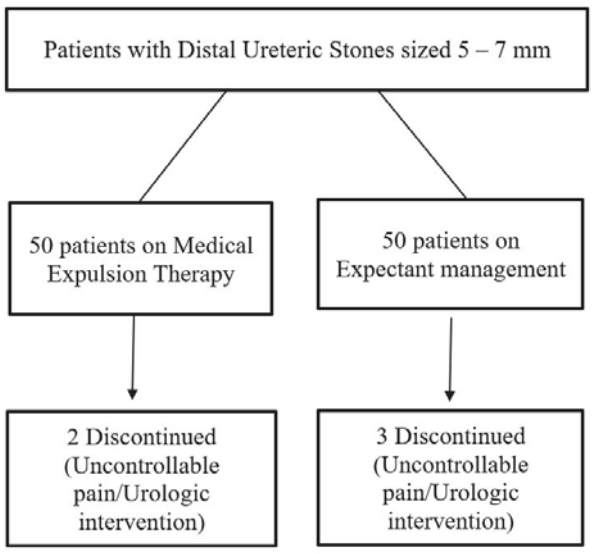

Figure 1. Grouping of patients

department visits meeting this criterion were recorded. Patients who developed uncontrolled pain or complications during follow-up were discontinued from conservative management and underwent urologic intervention (ureteroscopic lithotripsy). Complications monitored during the study included development of urinary tract infection, worsening hydronephrosis, acute kidney injury, persistent uncontrolled pain requiring hospitalization, and failure of stone expulsion within 4 weeks.

The data were analyzed using Statistical Package for Social Sciences (SPSS) version 26.0. Data were shown as median (IQR) and frequency. Chi-square test was used to compare the differences between the group for qualitative variables and independent student's t-test was used for quantitative variables.

Results

In our study including 50 cases each of MET and EM, median age of participants was 38.5 years in MET group and 40 years in EM group. Male predominance was seen in both groups. There was no statistically significant difference in age and gender between the MET and EM groups (p = 0.904 and p = 0.779). There was no significant difference in the size of stones between the groups (**Table 1**).

Table 1. Comparison of demographic and clinical parameters between two groups

	MET Group (N=50)	Expectant Group (N=50)	P-value
Age [Median (Range)]	38.50 (24-58)	40.00 (26-55)	0.896
Sex			
Male	42	43	0.779
Female	8	7	
Side			
Right	28	23	0.317
Left	22	27	
Size			
5.1 – 6.0 mm	23	24	0.841
6.1 – 7.0 mm	27	26	

A total of 85 (85%) patients presented with abdominal pain, making it the most common presenting complaint. Nausea/Vomiting was reported by 20 patients and fever by 6 patients. A few number of patients also reported hematuria. These presenting complaints were not mutually exclusive, and some patients reported more than one symptom at presentation (**Figure 2**).

Spontaneous expulsion of stone was noted in 41 (82%) patients on medical expulsion therapy whereas only 37 (74%) patients reported spontaneous expulsion from expectant management group. Though, the spontaneous

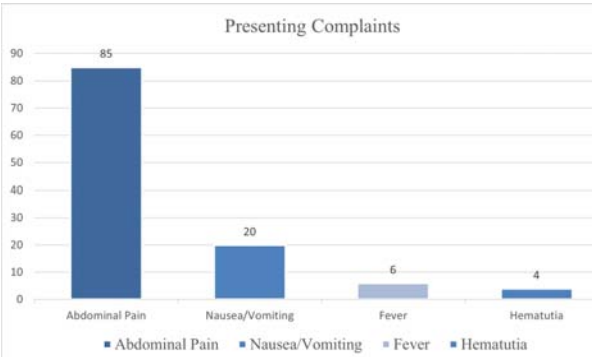

Figure 2. Presenting complaints of patients with distal ureteric stones

expulsion rate was higher in the MET group, difference was not statistically significant (p = 0.334).

39% of patients in the MET group and 37.8% in the expectant group passed stones within 7 days of initiation of treatment, showing nearly identical early expulsion rates. However, between 8–14 days, spontaneous expulsion was slightly higher in the MET group (53.7%) compared to the expectant group (45.9%). For 15–21 days, the expectant group (13.6%) showed a somewhat higher expulsion rate than the MET group (7.3%). Beyond 22 days, only 1 patient (2.7%) in the expectant group expelled stone, while none did in the MET group. The overall distribution of expulsion times between the two groups did not differ significantly (p = 0.558). The majority of spontaneous stone expulsions in both groups occurred within the first two weeks i.e. 92.7% in MET group and 83.7%.

Among the patients with stone sized 5.1 – 6.0 mm, spontaneous expulsion of stone occurred in 86.9% of patients in the MET group and 83.3% in the expectant group. Non-expulsion rates were similar (13.1% vs 16.7%). However, the difference between groups was not statistically significant (p = 0.727). Similarly, among the patients with stone sized 6.1 – 7.0 mm, spontaneous expulsion of stone was observed in 77.8% of the MET group compared to 65.4% in the expectant group. Non-expulsion was slightly

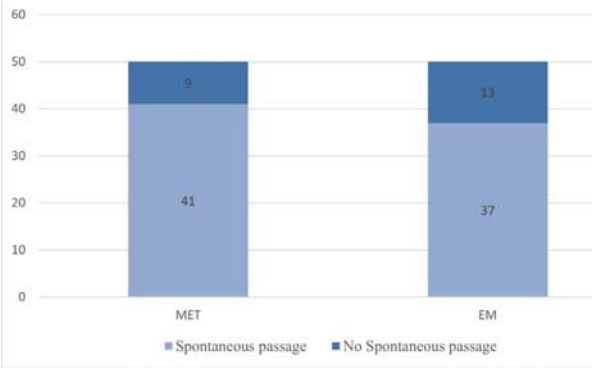

Figure 3. Comparison of spontaneous stone expulsion between two groups

Table 2. Comparison of spontaneous expulsion time between two groups

Spontaneous Expulsion (Time in days)	MET Group: n (%)	Expectant Group: n (%)	P-value
0 – 7	16 (39.0 %)	14 (37.8%)	0.558
8 – 14	22 (53.7%)	17 (45.9%)	
15 – 21	3 (7.3%)	5 (13.6%)	
22 – 28	0 (0%)	1 (2.7%)	
Total	41 (100%)	37 (100%)	

higher in the expectant group (34.6%) compared to MET (22.2%). However, the difference was not statistically significant (p = 0.317). In both stone size categories, the MET group showed numerically higher expulsion rates compared to the expectant group.

Table 3. Comparison of spontaneous expulsion between groups according to size of stone

Size	Spontaneous Expulsion	Group		P-value
		MET: n (%)	Expectant: n (%)	
5.1 - 6.0 mm	Yes	20 (86.9%)	20 (83.3%)	0.727
	No	3 (13.1%)	4 (16.7%)	
	Total	**23 (100%)**	**24 (100%)**	
6.1 - 7.0 mm	Yes	21 (77.8%)	17 (65.4%)	0.317
	No	6 (22.2%)	9 (34.6%)	
	Total	**27 (100%)**	**26 (100%)**	

Table 4 compares emergency department (ED) visits for severe ureteric colic during the treatment period between the MET group and the expectant group. In the MET group, only 12% (6 patients) required ED visits, whereas in the expectant group, 30% (15 patients) required ED visits. The majority of patients in the MET group (88%) did not require ED visits compared to 70% in the expectant group. This difference was statistically significant (p = 0.027).

Discussion

In this prospective observational study, we compared medical expulsion therapy (MET) with expectant management (EM) for distal ureteric stones measuring 5–7 mm. The study demonstrated that the spontaneous stone expulsion rate was higher in the MET group (82%) compared to the EM group (74%), though the difference was not statistically significant. Likewise, in our study, stone passage time and expulsion rates according to stone size were not significantly different between the two groups. However, significantly lower number of patients in the MET group required emergency department (ED) visits during the treatment period, highlighting a potential symptomatic benefit of MET.

Table 4. Comparison of emergency department visits during the treatment period between two groups

Emergency Department Visit	MET Group: n (%)	Expectant Group: n (%)	P-value
Yes	6 (12%)	15 (30%)	0.027
No	44 (88%)	35 (70%)	
Total	50 (100%)	50 (100%)	

The spontaneous passage of distal ureteric stones is influenced by factors such as stone size, shape, and ureteral anatomy. Previous studies have reported that stones <5 mm have a >70–90% chance of spontaneous passage, while those measuring 5–10 mm have a 25–60% chance.[10] The findings of the study by Thomas H et al showed the stone clearance rate in distal ureteric stones with tamsulosin therapy to be 86.7% whereas, 88.9% in placebo group (p=1.0).[11] Our findings are consistent with this study, as overall expulsion rates in both MET and EM groups were relatively high. In contrary, study by Petrit et al revealed statistically significant advantage in MET group in terms of stone expulsion rate (90.4% in MET group vs 71.2% in control group, p=0.023).[12]

The role of MET, particularly with alpha-blockers such as tamsulosin, has been extensively studied. The proposed mechanism involves selective relaxation of ureteral smooth muscle, reduction of peristaltic frequency, and decrease in intraluminal pressure, thereby facilitating stone passage.[13,14] Several randomized controlled trials and meta-analyses have suggested that MET improves expulsion rates, reduces time to passage, and decreases analgesic requirements.[15,16] However, recent large multicenter studies have questioned the benefit of MET, reporting no significant improvement in expulsion rates compared to placebo or EM.[17]

Study by Erhan et al among patients under medical expulsive therapy revealed 28.4% stone clearance within first week, 28.4% in second week, 11.1% in third week and 8.6% in fourth week.[18] In our study, although MET showed numerically higher expulsion rates (82% vs 74%) and shorter stone passage time (39% in first week, 53.7% in second week and 7.3% in third week), these differences did not reach statistical significance when comparing to the stone passage time in expectant group (37.8% in first week, 45.9% in second week, 13.6% in third week and 2.7% in fourth week). This aligns with findings from the recent trials that failed to demonstrate a clear benefit of tamsulosin for stones ≤10 mm.[17] However, the study by Petrit et al showed statistically significant difference in timing of expulsion between MET group and control group (p=0.034).[12] Another study by Hussain et al also revealed shorter expulsion time in MET group vs control group (p=0.015) which is in contrary to our findings.[19]

Subgroup analysis by stone size in our study showed higher expulsion rates with MET for both 5.1–6.0 mm (86.9% vs 83.3%) and 6.1–7.0 mm stones (77.8% vs 65.4%). However, these subgroup analyses involved small sample sizes and were exploratory in nature; therefore, the observed differences should be interpreted with caution. This trend has been noted in prior research, where the benefit of MET was more pronounced in larger distal stones.[9,13] A meta-analysis by Hollingsworth et al also suggested that MET was most effective in distal ureteric stones >5 mm.[15]

A notable finding of this study was the significantly lower rate of ED visits in the MET group compared to the EM group (12% vs 30%, p=0.027). This implies that MET may contribute to better symptom control, particularly reduction in episodes of severe colic requiring emergency care. Similar observations have been reported in previous studies where MET reduced pain episodes and analgesic requirements.[13,14] Thus, even in the absence of a statistically significant improvement in stone passage rates, the reduction in ED visits highlights an important clinical advantage of MET.

The clinical implications of our findings are twofold. First, while the expulsion benefit of MET in 5–7 mm distal stones remains debatable, it may still provide symptomatic relief and reduce healthcare utilization. Second, considering the low side-effect profile of tamsulosin, MET remains a reasonable option in selected patients, particularly those who experience recurrent painful episodes.

This study has several limitations. Being a single-center, non-randomized observational study with a modest sample size, the findings may be subject to selection bias and may have been underpowered to detect small but clinically relevant differences in expulsion rates. Furthermore, follow-up imaging was limited to ultrasonography, which has lower sensitivity than non-contrast CT in detecting small distal ureteric stones. This may have led to under or overestimation of true stone expulsion rates. Patient-reported expulsion may also introduce recall bias. Additionally, subgroup analyses based on stone size further reduced the effective sample size within each category, limiting the statistical power to detect significant differences. Therefore, findings from subgroup comparisons should be considered exploratory rather than confirmatory. Despite these limitations, the study contributes local data to an area of ongoing global debate.

Conclusions

In conclusion, medical expulsion therapy did not significantly improve stone expulsion rates or time to passage compared to expectant management in distal ureteric stones of 5–7 mm. However, MET significantly reduced ED visits, suggesting a role in symptom control and improved patient comfort. Larger multi-center randomized studies are needed to clarify the subgroup of patients who would benefit most from MET.

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