DOI: 10.21088/nijs.0976.4747.16425.3

New Indian Journal of Surgery
Volume 16 Number 4, October - December 2025

ORIGINAL ARTICLE

Case Series Analysis of Medical Expulsive Therapy in Ureteric Calculi

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HOW TO CITE THIS ARTICLE:

Frenali Gheewala, Jigar Ratnottar, Gurmeet Singh Sarla. Case Series Analysis of Medical Expulsive Therapy in Ureteric Calculi. New Indian J Surg. 2025; 16(4): 153-158.

ABSTRACT

Introduction: Urinary calculi are a common complaint, affecting the cases in a ratio of 3 men to 1 woman, with advanced incidence between 40 to 50 years of age. Size of the calculus influences the rate of spontaneous calculus passage. Medical expulsive therapy (MET) has been described as an effective conservative treatment option in the initial management of small distal ureteral/ Vesico-Ureteric Junction (VUJ). Ureteroscopy (URS) is indicated in unsuccessful cases of MET. Current European Association of Urology advocates the use of URS as first line treatment for distal ureteric calculus larger than 10 mm.

Methods: The study was conducted at a tertiary care hospital in Gujarat, India, nvolving both outpatient and inpatient cases. Patients underwent radiological, blood, and urine evaluations. They were instructed to take silodosin, deflazacort, diclofenac, and maintain supra-hydration. Follow-ups were scheduled every 7 days with X-ray KUB to monitor spontaneous calculus passage. If stone passage was unsuccessful after 28 days, patients underwent planned URS with or without lithotripsy and DJ stenting under anaesthesia.

Results: In a cohort of 170 patients with small distal ureteral stones, 89% were successfully managed with medical expulsive therapy (MET), while 11% required ureteroscopy (URS) after unsuccessful MET. Comparative analyses considered factors such as patient demographics, stone characteristics, medical history, lab results, and URS findings, leading to the study's conclusions.

Conclusion: Our study has 170 patients with mid and distal ureteric calculi with size ranging from 4 to 10 mm with mild or no backpressure changes, which were subjected to MET with tablet silodosin, tablet deflazacort, tablet diclofenac and

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➢ **Received :** 31-07-2025 ➢ **Accepted:** 27-09-2025

supra-hydration. We documented 88.8% MET success and 11.2% unsuccessful cases of MET. MET success is unaffected by age, gender of the patient, history of prior surgical procedure, diabetic status, hypertension or recurrent stone former status. For calculus size between 4 to 10 mm stone-free rate was achieved with medical therapy in 88.8% of patients with no overt complications. Size of the calculus is a significant predictor of expulsion rate. In our study all cases with unsuccessful MET underwent ureteroscopy for calculus clearance.

KEYWORDS

• Medical Expulsive Therapy • Ureteric Stones • Ureteroscopy

INTRODUCTION

Urinary calculi are a common complaint, affecting the cases in a rate of 3 men to 1 woman, with advanced incidence between 40 and 50 years of age.[1]

The size of the calculus affects the rate of spontaneous passage, with up to 98% of small calculi (less than 4 mm in diameter) passing spontaneously within four weeks of symptom onset.[2] However, for larger calculus (4 to 10 mm in diameter), the rate of spontaneous passage decreases to lower than 53%.[3] The location of the calculus influences the likelihood of spontaneous passage, with rates increasing from 48% for calculi in the proximal ureter to 79% for those at the Vesico-Ureteral Junction (VUJ), regardless of size.[3] If there is no high-grade obstruction or associated infection, and symptoms are mild, various nonsurgical measures can be used to promote the passage of a calculus.[4] Recurrent stone formers profit from more intense management, including adequate fluid intake and use of medications, as well as watchful monitoring.[5]

Medical expulsive therapy (MET) is an effective conservative treatment for small distal ureteral/VUJ calculi. The 2016 AUA guidelines recommend MET with alpha-blockers for stones up to 10 mm, with ureteroscopy (URS) for cases where MET fails. The EAU guidelines recommend URS as the first-line treatment for calculi larger than 10 mm. Our study assessed MET using supra-hydration, selective alpha-1D blockers, analgesics, and corticosteroids. It found significantly more side effects in the α-blocker group (6.6%) compared to the control group (1.4%) (P <0.001; RR 3.94). No significant difference in side effects was observed for Calcium Channel Blockers (0.9% vs 0.2%) (P = 0.24). Additionally, there was no significant difference in re-hospitalization rates between the α-blocker group (8.7%) and the control group (14.6%) (P = 0.44).

The study aimed to evaluate the success of medical expulsive therapy (MET) for mid and distal ureteric stones, analyze the relationship between stone characteristics and outcomes, and assess treatment choice, complications, hospital stay, and re-treatment needs.

METHOD

This case series analysis was conducted at the Department of General Surgery, SMIMER, Surat, a tertiary care hospital in Gujarat, India, from October 2020 to March 2022. It included adults with 4-10 mm mid-ureter/distal ureteral/VUJ calculi. Exclusions were proximal ureteral stones, hydronephrosis, renal failure, fever, heart failure, peptic ulcer, lactation, or patient preference for surgery. Patients were evaluated using X-ray KUB, CT KUB, and selective CT IVP, with blood tests, renal function tests, and urine analysis. Treatment included tablet silodosin, deflazacort, diclofenac, and supra-hydration, with weekly follow-ups via X-ray KUB. After 28 days, patients with unsuccessful stone passage underwent ureteroscopy (URS) with or without lithotripsy and stenting. Procedures were performed under spinal anaesthesia with a 7.5 Fr rigid URS and pneumatic lithoclast. Post-operative care included analgesics, antibiotics, and α-blockers, with follow-ups at 7 days and 28 days, and DJ stent removal after 6 weeks. Statistical analysis in trials estimates treatment effects and evaluates

significance using p-values, with smaller p-values indicating a higher likelihood of true intervention differences. A p-value of 0.031 is more precise than vague thresholds like $p < 0.05$. For the study, relevant literature was reviewed, and patients were informed and counselled about procedures, side effects, and MET's cost-effectiveness, followed by informed consent. A purposive sampling technique was used. Preoperative evaluation included complete blood tests, renal function tests, imaging (X-ray, USG, CT IVP), and counselling before treatment.

RESULTS

In a cohort of 170 patients with small distal ureteral stones, 89% were successfully managed with medical expulsive therapy (MET), while 11% required ureteroscopy (URS) after unsuccessful MET. Comparative analyses considered factors such as patient demographics, stone characteristics, medical history, lab results, and URS findings, leading to the study's conclusions.

Table 1: Association of MET Success with Past history – Recurrent calculus formers

Recurrent stone formers		MET success		p-value
		Yes	No	
No	No of cases	109	13	0.73
	Percentage	72.2	68.4	
Yes	No of cases	42	6	
	Percentage	27.8	31.6	

The χ^2 statistics found no significant association between a history of recurrent stone formation and MET success. About 88% of patients with recurrent stones and 89% of those without recurrent stones experienced MET success.

The χ^2 statistics found no significant association between diabetic status and MET success. About 90% of diabetic patients and 88% of non-diabetic patients had MET success. Similarly, no significant association was found between a history of prior surgical procedures and MET success, with 88% of patients with prior surgeries and 90% of those without previous surgeries achieving MET success.

Table 2: Mean of Lab Investigation Parameters

	MET Success	N	Mean	Std. Deviation	p-value
Biochemical Investigations					
Hb (gm/dl)	No	19	10.4	1.3	0.85
	Yes	151	10.4	1.4	
TLC ($10^3/\mu L$)	No	19	6272	789.8	0.51
	Yes	151	6415	905.5	
Renal Function Level					
S Urea (mg/dL)	No	19	28.5	5.9	0.36
	Yes	151	27.0	6.4	
S creatinine (mg/dL)	No	19	0.72	0.19	0.88
	Yes	151	0.73	0.21	
Electrolytes (Sodium/Potassium/Chloride)					
Sodium (mEq/L)	No	19	139.4	3.4	0.50
	Yes	151	139.9	3.0	
Potassium (mEq/L)	No	19	4.5	0.64	0.78
	Yes	151	4.5	0.5	
Chloride (mEq/L)	No	19	103.0	2.5	0.22
	Yes	151	102.2	2.4	
RBS					
RBS (mg/dL)	No	19	111.8	13.6	0.90
	Yes	151	111.4	13.3	
Urine analysis					
pH	No	19	7.2	0.11	0.22
	Yes	151	7.1	0.10	

Urine analysis for pus cells showed no significant difference in MET success (p>0.8), with all patients having pus cells within the normal range (0-5 cells/HPF). All patients with visible radiopaque calculi on X-ray KUB had MET success, with success rates of 88% (51 patients) for 1 calculus, 87% (71 patients) for 2 calculi, and 96% (22 patients) for 3 calculi.

Table 3: Relationship between location of visible calculus on X-ray KUB and MET success

Location of calculus on X-ray		MET Success		Total
		Yes	No	
Lower ureter	No of cases	70	9	79
	Percentage	47.7	47.4	46.5
Mid-ureter	No of cases	74	10	84
	Percentage	48.3	52.6	49.4
Not visible	No of cases	7	-	7
	Percentage	4.0	-	3.5

Patients with a single calculus seen on the CT KUB, 88% (46) had MET success as compared to 85% (55) and 94% (50) for patients with 2 and 3 calculi seen on the CT KUB.

Among patients with calculi in the lower and mid ureter on CT KUB, 90% (77) and 88% (74) had MET success, similar to results seen with X-ray KUB. For MET success based on the number of visible calculi on CT IVP, 88% (45) with 1 calculus, 85% (56) with 2 calculi, and 94% (50) with 3 calculi had treatment success.

In a study of 170 patients, 51% showed mild backpressure changes on CT IVP, while 49% had none. MET success was significantly associated with calculus size for one (p=0.003) and two stones (p=0.002), but not for three stones (p=0.22). There was no significant association between calculus density (Hounsfield units) and MET success. MET failed in 11.2% of cases, requiring URS, with no gender or age-specific trends. Most calculi were located in the mid (53%) or lower (47%) ureter, and CT imaging predominantly showed round calculus.

DISCUSSION

The study included 170 patients (mean age 39.9 SD 12.3 years; 31% females, 69% males) with mid and distal ureteric stones. Of these, 42% had prior surgeries, 35% had diabetes, and 28% had recurrent stones. CT IVP revealed mild backpressure changes in 51% of patients, while 49% showed no backpressure changes.

In our study, patients with mid and distal ureteric stones treated with MET using silodosin, deflazacort, diclofenac, and supra-hydration had a success rate of 89%, while 11% required URS after unsuccessful MET. A randomized controlled trial from India reported a 90% calculus expulsion rate with the Silodosin and Tadalafil combination therapy, compared to 78% with Silodosin alone.[6] Another randomized study from India reported calculus expulsion rates of 83% for Silodosin treatment and 67% for Tadalafil.[7] A study from Taiwan reported calculus expulsion rate of 77% in patients treated for MET with Silodosin.[8] The results are comparable to the 89% calculus expulsion rate observed in our patient group treated with Silodosin and Deflazacort.

A systematic review and meta-analysis of randomized controlled studies from PubMed, Cochrane Library, and Embase assessed the efficacy and safety of silodosin in MET, comparing it with tamsulosin and placebo.[9]

The review included eight trials with a total of ~1,050 patients and found that silodosin was effective in the treatment of ureteral calculi and was superior to tamsulosin in its efficacy.[9] Tamsulosin, alfuzosin, and silodosin are commonly used alpha-blockers in MET for distal ureteral calculus. A recent review found silodosin to be the most effective alpha-blocker for lower ureteral calculi, followed by alfuzosin and tamsulosin.[10]

MET success was similar for both sexes, with a success rate of 91% in males and 85% in females (p>0.2), indicating no significant association between MET success and gender. A Taiwanese study also found no association between gender and calculus expulsion rate.[8]

Among patients with calculi in the lower and mid ureter on X-ray KUB, the MET success rates were similar (89% vs 88%). While X-ray KUB is effective for identifying the location of calculi, it has limitations such as low-density resolution, sensitivity, and accuracy.[11,12] CT KUB has become the gold standard in detection of ureteric calculi, given its sensitivity of up to 95% in detecting ureteric calculus.[13,14] In our study, 90% of patients with lower ureter calculi

and 88% with mid ureter calculi on CT KUB had MET success, similar to X-ray KUB and CT IVP results. The size and location of the calculus were key factors influencing spontaneous passage, highlighting the strength of CT KUB and CT IVP findings. A previous Indian study on MET efficacy for distal ureteric calculi noted the limitation of not using CT KUB to assess the calculi due to financial constraints.[6] An Indian study evaluated the role of MET with different drugs for distal ureteric calculus of size 5 to 10 mm.[7] One more randomized double-blinded controlled trial which included Silodosin as MET modality for distal ureteric calculus of size 4 to 10 mm.[8]

During the past decade, minimally invasive techniques, such as ureteroscopy, are widely used for the clinical management of ureteral calculus. Though URS and other such techniques are effective, they are quite expensive and poses the risk of related complications.[8,9] Many clinical studies and their systematic reviews have suggested the α-blocker class effect on calculus expulsion rates.[9,10,18] Silodosin, tamsulosin, terazosin, doxazosin, alfuzosin, and naftopidil are commonly used α-blockers for MET. Our study found that MET with silodosin achieved 89% success rate, confirming that α-1 blockers can enhance calculus expulsion, as reported in other studies.[6,8,10,19]

CONCLUSION

This study of 170 patients with mid and distal ureteric stones (4–10 mm) treated with medical expulsive therapy (MET) using silodosin, deflazacort, diclofenac, and supra-hydration achieved an 88.8% success rate, with calculus size being a key predictor of expulsion. MET outcomes were unaffected by factors like age, gender, prior surgeries, comorbidities, or recurrence history. Unsuccessful cases (11.2%) were effectively managed with ureteroscopy, and no significant complications were observed.

Conflict of Interests

There is no conflict of interests between authors.

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