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Prospective Study on Outcome of Medical Expulsive Therapy in Ureteric Calculi

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Abstract: ***Urolithiasis represents a highly prevalent and clinically challenging urological disorder causing severe morbidity and operational strains on healthcare systems globally. Medical Expulsive Therapy (MET) serves as an effective, non-invasive intermediate strategy to facilitate spontaneous stone clearance and minimize immediate endourological surgery loads. This prospective observational clinical investigation evaluated 237 adult subjects presenting with a single unilateral, uncomplicated ureteric stone measuring 10 mm or less within a high-volume tertiary hospital in Maharashtra, India. All participants received a standardized conservative regimen consisting of oral tamsulosin 0.4 mg once daily combined with supportive analgesia (diclofenac) for a maximum duration of 4 weeks. Weekly follow-up evaluations tracked symptom relief, medication adherence, side-effect profiles, and radiological clearance using targeted ultrasonography (USG), plain X-ray, or non-contrast computed tomography (NCCT) imaging. The overall successful stone expulsion rate was 78.48% (186 out of 237 patients), with a mean duration to expulsion of 10.90 ± 5.03 days. Active endourological surgical conversion (predominantly ureteroscopy with holmium laser lithotripsy) was required in 18.14% of cases due to persistent severe colic or tracking complications. Distal/lower third stone location was identified as the single strongest categorical predictor of clearance, yielding an 83.66% success rate (p = 0.002). Furthermore, successful passage correlated significantly with a smaller baseline mean stone diameter (6.17 ± 1.56 mm vs. 6.66 ± 1.44 mm, p = 0.037). Tamsulosin-based MET is highly efficacious, safe, and easily tolerated, modernizing conservative stone management and optimizing operating theater caseload dynamics in public healthcare systems.***

Keywords: Tamsulosin, Ureteric Colic, Predictors of Spontaneous Passage, Outpatient Conservative Management

1. Introduction

Urolithiasis is one of the most common and historically recurrent disorders of the human urinary tract, imposing immense socio-economic and clinical strains on general surgical and urological practices worldwide [1]. Over the past few decades, its global prevalence and incidence have risen considerably due to complex interactions between rising ambient temperatures, occupational heat exposure, obesity, changing dietary patterns, metabolic syndromes, and structural shifts in human nutritional habits [2]. In tropical geographic zones and developing countries like India, environmental heat exposure combined with low baseline fluid consumption significantly accelerates urinary crystallization cascades, leading to hyper-saturation, crystal nucleation, aggregation, and physical retention within the renal parenchyma before stones migrate distally [3].

Crucially, stone disease exhibits a peak incidence within the active working-age bracket of the third to fifth decades of life. Because this directly targets the economically productive workforce, the sudden onset of disease frequently causes profound loss of working days, sudden financial strain on families, and increased healthcare utilization costs. Once these calculi enter the ureter, they tend to become physically impacted at specific physiological narrowings—most frequently at the pelvi-ureteric junction (PUJ), the crossing of the common iliac vessels, and the vesico-ureteric junction (VUJ). This mechanical occlusion creates a sudden, marked increase in proximal intraluminal pressure, secondary hyper-peristalsis, and smooth muscle spasms, clinically presenting as acute, excruciating flank pain radiating toward the groin (the classic ureteric colic).

Persistent or neglected obstruction can quickly compromise long-term renal function, causing chronic hydronephrosis, bacterial tracking, localized pyonephrosis, or systemic sepsis, which require immediate endourological decompression. Therefore, managing clinicians must balance the probability of spontaneous stone clearance against the long-term risks of obstructive uropathy. While advanced treatments like Ureteroscopy (URS) and Extracorporeal Shock Wave Lithotripsy (ESWL) provide definitive stone clearance, they demand substantial hospital infrastructure, specialized equipment, and anesthesia [4]. They also carry inherent risks of strictures, mucosal injuries, or infections. Medical Expulsive Therapy (MET) addresses this challenge by utilizing targeted pharmacological agents to lower intra-ureteric pressure, reduce severe colic episodes, and actively facilitate stone clearance [5].

The physiological framework of MET leverages alpha-1 adrenergic receptor antagonists, especially tamsulosin, to target the high density of alpha-1A and alpha-1D receptors located in the human ureter [4]. This blockade relaxes smooth muscle tone, reduces the frequency of localized spasms, and widens the lumen without completely abolishing normal fluid peristalsis. While international clinical trials support MET, its real-world effectiveness can vary due to patient compliance, differences and local resource limitations [6]. This prospective research was designed to evaluate short-term outcomes and identify clinical and radiological predictors of successful stone passage within an Indian tertiary public hospital environment.

2. Materials and Methods

2.1 Study Setting and Institutional Ethics

This institutional prospective observational study was conducted within the Department of General Surgery at a high-volume tertiary care teaching hospital in Maharashtra, India, over an 18-month period. Prior to initiation, the institutional protocol received full ethical clearance from the Institutional Ethics Committee. The study was conducted in strict compliance with the ethical tenets of the Declaration of Helsinki, and all data were collected without modifying standard clinical care lines.

2.2 Patient Selection Protocol

Eligible candidates were screened from individuals presenting to the surgical outpatient clinics, casualty units, or emergency wards with acute symptoms matching ureteric colic. Every participant provided voluntary, written informed consent in their native language prior to enrollment.

Inclusion criteria required: patients aged more than 18 years, of either sex, presenting with a radiologically confirmed single, uncomplicated unilateral ureteric stone with a maximum diameter of 10 mm or less, who were hemodynamically stable and suitable for conservative outpatient tracking. Exclusion criteria ruled out pediatric or pregnant patients, bilateral ureteric stones, an obstructed solitary kidney, pre-existing acute kidney injury (AKI), active urinary tract infections (UTI), pyonephrosis, systemic sepsis, or intractable pain requiring continuous intravenous narcotic infusions.

2.3 Intervention and Monitoring Matrix

Enrolled patients were initiated on standard institutional MET: oral tablet tamsulosin 0.4 mg once daily following a post-meal schedule for up to 4 weeks. Supportive treatment included oral tablet diclofenac for prostaglandin-mediated pain control. Short courses of oral antibiotics or antiemetics were used selectively based on clinical indicators. Patients were counseled to maintain baseline hydration but were explicitly instructed to avoid forced excessive water intake during acute colic, preventing increases in proximal renal pelvic pressure. Every subject was instructed to filter or strain urine to facilitate physical stone verification.

Prospective monitoring occurred at scheduled 1, 2 and 4-week follow-up intervals, or immediately if severe warning indicators developed. Visual Analogue Scale (VAS) pain values and any drug-related adverse side effects were documented at each visit. Successful clearance required direct stone capture history or follow-up imaging (USG, X-ray or low-dose non-contrast CT KUB and RFT) confirming complete stone clearance and resolution of obstruction. Stable patients who failed to pass stones within 4 weeks, developed secondary infections, or experienced recurrent intractable colic were converted to active interventional lines.

2.4 Statistical Plan

Data analysis was completed via Microsoft Excel and SPSS software. Continuous parameters were expressed as mean ± SD and compared using Student T-test. Categorical variables were expressed as frequencies and percentages and compared using the Chi-square test or Fisher's exact test. P value of < 0.05 was considered statistically significant.

3. Observations and Results

The study evaluated a final sample of 237 stable patients. The mean age of the cohort was 42.16 ± 12.48 years (range 18–78 years), with peak clustering inside the active working brackets: 41–50 years (29.96%, 71 cases) and 31–40 years (25.74%, 61 cases). Males represented 68.78% (163 cases) and females constituted 31.22% (74 cases). Geographic tracking showed 37.97% lived in rural settings, 37.55% in semi-urban sectors, and 24.47% in urban zones. Comorbidity tracking indicated that 70.04% had no chronic conditions, while hypertension (12.66%) and diabetes mellitus (10.13%) were the most common chronic conditions noted.

The mean duration of tracking symptoms prior to hospital presentation was 3.73 ± 2.47 days. Acute, classic ureteric colic was the most common primary complaint, reported by 43.46% of patients, followed by flank pain with vomiting in 22.78%, and flank pain with dysuria in 15.19%. Associated baseline signs included vomiting in 40.51%, dysuria in 18.57%, and a past medical history of stone disease in 19.41%. The initial pain severity was high, with a mean baseline VAS score of 6.89 ± 1.17.

Table 1: Baseline Demographics & Clinical Metrics

Clinical Variable Parameter	Mean ± SD	Min	Max
Patient Age (Years)	42.16 ± 12.48	18	78
Symptom Duration (Days)	3.73 ± 2.47	1	13
Calculus Size (mm)	6.28 ± 1.55	3	10
Baseline VAS Pain Value	6.89 ± 1.17	4	10

The overall mean stone diameter was 6.28 ± 1.55 mm. In terms of size groups, 22.36% were ≤5 mm, 46.84% were between 5.1–7 mm, and 30.80% were between 7.1–10 mm. Lower third (distal) ureteric stones formed the largest anatomical subgroup with 153 patients (64.56%), while middle third stones constituted 19.83% (47 cases) and upper third stones constituted 15.61% (37 cases). Left-sided stones occurred in 121 cases (51.05%), and right-sided stones occurred in 116 cases (48.95%). Concurrently, proximal hydroureter was visible in 93.25% of cases. Mild hydronephrosis was present in 51.48%, moderate hydronephrosis in 31.65%, and severe hydronephrosis was limited to 13 cases (5.49%).

The overall successful stone expulsion rate using tamsulosin-based MET was 78.48% (186 out of 237 patients). For these successful cases, the mean time to complete expulsion was 10.90 ± 5.03 days (ranging from 2 to 26 days). Spontaneous stone clearance rates increased progressively over the study duration: 20.25% (48 patients) passed the calculus within 1 week, 61.18% (145 patients) by week 2, and reaching the final success rate of 78.48% (186 patients) at the 4-week mark. Stone clearance was confirmed via follow-up ultrasound

(43.46%), direct physical stone capture (28.27%), follow-up KUB radiographs (16.46%), and follow-up NCCT KUB scans (11.81%).

A total of 43 patients (18.14%) experienced treatment failure and required conversion to active surgical intervention. Ureteroscopy Retrieval was the most common surgical procedure (13.08%, 31 cases), followed by ESWL sessions (2.95%, 7 cases), and urgent double-J stenting (2.11%, 5 cases). The primary clinical reasons for surgical conversion included persistent, unmanageable colic (6.33%), secondary urinary tract infections (3.38%), and worsening proximal hydronephrosis (0.84%). The conservative alpha-blocker therapy was well tolerated; 201 patients (84.81%) remained entirely free of complications or side effects. Among the mild side effects reported, temporary dizziness was the most common (6.75%), followed by orthostatic hypotension (4.22%), mild headaches (2.95%), and retrograde ejaculation (1.27% of male participants).

Bivariate analysis identified stone location as a key predictor of successful MET clearance, with lower third calculi yielding an 83.66% success rate compared to 56.76% in upper third locations ($p = 0.002$). Continuous parameter evaluation showed that the successful treatment group had a significantly smaller mean stone diameter than the treatment failure group (6.17 ± 1.56 mm vs. 6.66 ± 1.44 mm, $p = 0.037$).

Table 2: Bivariate Predictors of Stone Expulsion Success

Predictor Category	Expelled (n)	Success (%)	Failed (n)	p-value
Lower Ureter	128	83.66%	25	**0.002**
Middle Ureter	37	78.72%	10	
Upper Ureter	21	56.76%	16	
Stone Size ≤5 mm	47	88.68%	6	0.122
Stone Size 5.1–7 mm	84	75.68%	27	
Stone Size 7.1–10 mm	55	75.34%	18	

4. Discussion

Managing acute stone disease in high-volume public hospitals requires balancing procedural efficacy against available resources. In this study, the overall tamsulosin-based clearance rate of 78.48% demonstrates that conservative management can successfully resolve four out of five cases of uncomplicated ureteric calculi up to 10 mm. This strategy helps avoid the costs, anesthetic requirements, and potential complications associated with immediate surgical intervention. Our clearance metrics align with current clinical guidelines from the European Association of Urology (EAU) and the American Urological Association (AUA), which heavily endorse alpha-blockers as a primary option for small, uncomplicated distal stones.

Our findings were compared with key international clinical trials and observational cohorts to contextualize outcomes. Jayawardene et al. reported a final success rate of 92.3% in a South Asian cohort; however, their protocol allowed an extended MET trial lasting up to 12 weeks [6]. Our 4-week trial achieved a 78.48% clearance rate, showing that most stones clear early in treatment. This suggests that a shorter, 4-week trial can minimize the risk of silent obstruction while capturing the majority of successful passages, matching the duration profiles studied by Erdoğan et al. [7]. Pandey et al. achieved a 66.4% spontaneous stone passage rate verified by low-dose CT imaging [8]. The higher clearance rate in our study is likely due to selection criteria that favored a higher proportion of distal/lower third calculi (64.56%).

The multi-center SUSPEND trial (Pickard et al.) found no significant difference in intervention rates between MET and placebo groups when analyzing all stone sizes and locations together. This highlights the importance of careful patient selection [5]. Rather than using MET indiscriminately, it should be focused on specific subgroups, such as patients with stones larger than 5 mm or those located in the distal ureter, where the treatment effect is most pronounced. The strong correlation with distal stone location (83.66% success vs. 56.76% in proximal locations) is supported by the anatomy of the ureter. The distal third has a significantly higher concentration of alpha-adrenergic receptors. Consequently, tamsulosin therapy is particularly effective at reducing tone and opening the lumen in this region, facilitating final passage into the bladder [9].

The low rate of side effects (15.19%) confirms that tamsulosin 0.4 mg once daily is safe for outpatient use in diverse populations. Most side effects, such as mild dizziness and minor headaches, were temporary and did not require stopping the medication. Transient retrograde ejaculation occurred in 1.27% of male patients. This is an important point for patient counseling, but it did not affect overall compliance or treatment success in our study cohort [10].

5. Conclusion

This prospective study demonstrates that tamsulosin-based MET is an effective, safe, and reliable initial treatment option for patients with uncomplicated ureteric stones measuring 10 mm or less. Over a 4-week treatment period, the regimen achieved a 78.48% stone expulsion rate, with a mean passage time of approximately 11 days. Stones located in the distal ureter and those with smaller diameters had the highest probability of successful clearance. From a healthcare management perspective, using structured MET protocols can significantly reduce the immediate need for surgical procedures, shorten hospital stays, and optimize resource allocation in busy public medical centers.

5.1 Study Limitations

The study was conducted at a single tertiary center, which may limit how well these findings apply to different geographical regions or diverse clinical settings. Follow-up imaging was not completely standardized across all patients. Passed calculi did not undergo chemical or mineral composition analysis, preventing us from evaluating how different stone types might respond to MET. Monitoring medication adherence and fluid intake relied primarily on patient self-reports, which introduces potential recall bias.

5.2 Future Research Scope

Future research should focus on large-scale, multi-center randomized controlled trials that compare standard MET directly against structured observation. Incorporating regular non-contrast CT metrics—such as Hounsfield Unit (HU)

density and detailed Ureteric Wall Thickness (UWT) measurements- could help refine patient selection. Additionally, combining metabolic evaluations with long-term follow-up would allow researchers to track recurrence rates and evaluate the long-term cost-effectiveness of these interventions.

References

[1] E. M. Worcester, F. L. Coe, "Nephrolithiasis," Primary Care, vol. 35, no. 2, pp. 369-391, 2008.
[2] A. Trinchieri, "Epidemiology of urolithiasis: an update," Clinical Cases in Mineral and Bone Metabolism, vol. 5, no. 2, pp. 101-106, 2008.
[3] Y. Liu, Y. Chen, B. Liao, et al., "Epidemiology of urolithiasis in Asia," Asian Journal of Urology, vol. 5, no. 4, pp. 205-214, 2018.
[4] T. Campschroer, X. Zhu, R. W. M. Vernooij, M. T. W. T. Lock, "Alpha-blockers as medical expulsive therapy for ureteral stones," Cochrane Database of Systematic Reviews, vol. 2018, no. 4, p. CD008509, 2018.
[5] R. Pickard, K. Starr, G. MacLennan, et al., "Medical expulsive therapy in adults with ureteric colic: a multicentre randomised placebo-controlled trial," The Lancet, vol. 386, no. 9991, pp. 341-349, 2015.
[6] M. D. Jayawardene, B. Balagobi, A. L. A. M. C. Ambegoda, et al., "Outcome of uncomplicated ureteric calculi managed with medical expulsive therapy in the outpatient clinic of a urology unit in Sri Lanka," BMC Research Notes, vol. 10, p. 636, 2017.
[7] E. Erdoğan, M. F. Akbulut, A. Yıldırım, et al., "Optimal duration of medical expulsive therapy for lower ureteral stones: a critical evaluation," Urolithiasis, vol. 52, no. 1, p. 31, 2024
[8] A. Pandey, S. Mandal, S. Kuramaswamy, et al., "Medical expulsive therapy in adults with ureteral calculi: a prospective evaluation of patient-reported outcomes," Urology Research and Practice, vol. 49, no. 5, pp. 273-279, 2023.
[9] M. R. Viswas, et al., "Predictors of spontaneous passage of ureteral calculi in patients receiving medical expulsive therapy," Indian Journal of Urology, vol. 30, no. 1, pp. 60-64, 2014.
[10] C. Türk, A. Neisius, A. Petřík, et al., "EAU guidelines on urolithiasis," European Association of Urology Guidelines, vol. 2024, pp. 1-85, 2024.

Author Profile

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