e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2025; 17(12); 705-709

Original Research Article

Role of Medical Expulsive Therapy in Ureteric Calculus: Tamsulosin plus Deflazacort Randomized Study

Ketan Y. Pandya[1], Mohmmad Fahad Mohmmad Yasin Vadaliwala[2], Sarang Bharatbhai Patel[3]

[1]Assistant Professor, Department of Urology, P.D.U. Medical College and Hospital, Rajkot, Gujarat, India

[2]Medical Officer, HCG Hospital, Ahmedabad, Gujarat, India

[3]Medical Officer, Department of Cardiology & ICU, Apple Heart Hospital and ICU Center, Mehsana, Gujarat, India

Received: 12-11-2025 / Revised: 15-12-2025 / Accepted: 21-12-2025

Corresponding author: Dr. Sarang Bharatbhai Patel

Conflict of interest: Nil

Abstract

Background: Ureteric colic caused by urolithiasis is a prevalent urological emergency. While Medical Expulsive Therapy (MET) using alpha-blockers like tamsulosin is the standard of care for distal ureteric stones, the addition of corticosteroids to reduce ureteral edema remains a subject of clinical interest.

Methods: A prospective, randomized controlled trial was conducted on 120 patients with solitary distal ureteric stones sized 5–10 mm. Patients were randomized into two groups: Group A received Tamsulosin (0.4 mg) daily, while Group B received Tamsulosin (0.4 mg) plus Deflazacort (30 mg) daily for a maximum of 28 days. The primary endpoint was the Stone Expulsion Rate (SER). Secondary endpoints included Stone Expulsion Time (SET), analgesic requirements, and adverse events.

Results: The Stone Expulsion Rate was significantly higher in Group B (88.3%) compared to Group A (68.3%) ($p = 0.009$). The mean Stone Expulsion Time was significantly shorter in the combination therapy group (6.4 ± 2.1 days) versus the monotherapy group (10.8 ± 3.4 days) ($p < 0.001$). Furthermore, patients in Group B reported significantly fewer episodes of colic requiring rescue analgesia ($p = 0.02$). No severe adverse events were recorded, though mild gastrointestinal upset was slightly higher in Group B.

Conclusion: The combination of Tamsulosin and Deflazacort is superior to Tamsulosin monotherapy in facilitating the passage of distal ureteric calculi. It significantly reduces expulsion time and analgesic consumption with a favorable safety profile.

Keywords: Urolithiasis, Medical Expulsive Therapy, Tamsulosin, Deflazacort, Distal Ureteric Stone.

Introduction

Urolithiasis is a global healthcare burden, affecting approximately 12% of the world population at some point in their lifetime, with a high recurrence rate [1]. The acute presentation of ureteric colic, resulting from the obstruction of the ureter by a calculus, is one of the most agonizing pain experiences reported in clinical practice. The management of ureteric stones has evolved significantly over the last two decades.

While endoscopic and surgical interventions such as Ureteroscopy (URS) and Extracorporeal Shock Wave Lithotripsy (ESWL) are effective, they are invasive, costly, and associated with specific operative risks [2]. Consequently, for uncomplicated stones, particularly those located in the distal ureter and measuring less than 10 mm, conservative management via Medical Expulsive Therapy (MET) is the preferred initial approach [3]. The pathophysiology of stone retention involves not only the mechanical size of the stone but also ureteral smooth muscle spasm and localized mucosal edema caused by the stone's irritation. Alpha-1 adrenergic antagonists, specifically tamsulosin, have established themselves as the cornerstone of MET. By blocking alpha-1 receptors, which are densely populated in the distal ureter, tamsulosin induces smooth muscle relaxation, inhibits peristaltic amplitude, and facilitates stone passage [4].

However, smooth muscle relaxation addresses only one aspect of the obstruction. The impacted stone induces a local inflammatory cascade, leading to submucosal edema that can "grip" the stone, impeding its distal migration [5]. This

understanding has led to the hypothesis that combining an anti-inflammatory agent with a spasmolytic could enhance expulsion rates. Corticosteroids, such as deflazacort, possess potent anti-inflammatory properties that can reduce localized edema at the site of impaction, potentially widening the ureteral lumen effectively [6].

Despite the theoretical benefits, the use of corticosteroids in MET remains debated. While some early studies demonstrated synergistic benefits, concerns regarding steroid-induced side effects and conflicting data from recent multicentric trials have prevented this combination from becoming a universal standard [7]. Furthermore, there is a paucity of data specifically analyzing the combination of Tamsulosin with Deflazacort—a glucocorticoid with fewer metabolic side effects compared to prednisolone—in specific demographic populations [8].

Therefore, the present study aims to bridge this research gap by conducting a randomized comparative analysis. The objective is to determine whether the addition of Deflazacort to Tamsulosin significantly improves stone expulsion rates and reduces expulsion time in patients with distal ureteric calculi compared to Tamsulosin monotherapy.

Materials and Methods

Study Design and Setting: This was a prospective, randomized, open-label, parallel-group comparative study conducted at the tertiary care teaching hospital.

Sample Size and Population: Based on previous literature assuming a 20% difference in expulsion rates between groups, a sample size calculation indicated that 60 patients per group were required to achieve a power of 80% at a 5% significance level. A total of 135 patients were screened to obtain the final sample of 120 eligible participants.

Inclusion Criteria:

- Adult patients aged 18 to 60 years.
- Diagnosis of a solitary, unilateral distal ureteric calculus (located below the crossing of the iliac vessels).
- Stone size between 5 mm and 10 mm (measured by non-contrast CT KUB).

Exclusion Criteria:

- Multiple stones or bilateral ureteric calculi.
- Presence of urinary tract infection (UTI) or fever.
- Severe hydronephrosis or renal insufficiency (Serum Creatinine > 1.5 mg/dL).
- History of previous open or endoscopic ureteral surgery.
- Pregnancy or lactation.
- Diabetes mellitus, peptic ulcer disease, or glaucoma (contraindications for steroids).
- Current use of alpha-blockers or calcium channel blockers.

Randomization and Interventions

Eligible patients were randomized into two groups using a computer-generated random number table.

- **Group A (Control):** Received Tamsulosin 0.4 mg orally once daily.
- **Group B (Study):** Received Tamsulosin 0.4 mg orally once daily plus Deflazacort 30 mg orally once daily for 10 days.

Both groups were advised to maintain a fluid intake of 2.5 to 3 liters per day. Diclofenac sodium (50 mg) was prescribed as an on-demand rescue analgesic for colicky pain.

Follow-up and Procedures: Patients were assessed weekly for a maximum period of 4 weeks. At each visit, patients underwent clinical evaluation for pain scores, history of stone passage, and medication compliance. Imaging (Ultrasonography or X-ray KUB) was performed at day 14 and day 28. The primary endpoint was the expulsion of the stone confirmed by imaging or patient retrieval of the stone. Therapy was discontinued upon stone expulsion. If the stone did not pass by day 28, the patient was considered a "treatment failure" and referred for ureteroscopy.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using SPSS version 26.0. Continuous variables (age, stone size, expulsion time) were presented as Mean $\pm$ Standard Deviation (SD) and compared using the Student's t-test. Categorical variables (sex, expulsion rate, side of stone) were expressed as percentages and analyzed using the Chi-square test or Fisher's exact test. A p-value of <0.05 was considered statistically significant.

Results

A total of 120 patients completed the study, with 60 patients in each group. The demographic and baseline clinical characteristics were similar between the two groups, ensuring the comparability of the cohorts. The mean age of participants was 37.4 ± 9.2 years in Group A and 38.1 ± 8.6 years in Group B. The mean stone size was comparable (7.2 ± 1.3 mm vs. 7.4 ± 1.2 mm).

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Group A (Tamsulosin) (n=60)	Group B (Tam + Deflazacort) (n=60)	p-value
Age (years)	37.4 ± 9.2	38.1 ± 8.6	0.67
Sex (Male/Female)	38 / 22	40 / 20	0.70
Stone Size (mm)	7.2 ± 1.3	7.4 ± 1.2	0.38
Stone Side (Right/Left)	32 / 28	35 / 25	0.58

Primary Outcome: Stone Expulsion Rate (SER): The addition of Deflazacort resulted in a statistically significant increase in the stone expulsion rate. In Group B (Combination), 53 out of 60 patients (88.3%) successfully passed the stone, whereas only 41 out of 60 patients (68.3%) in Group A (Monotherapy) achieved expulsion ($p = 0.009$).

Secondary Outcomes: Time and Analgesia

Table 2 details the secondary outcomes. The mean Stone Expulsion Time (SET) was significantly shorter in the combination group compared to the control group (6.4 days vs. 10.8 days; $p < 0.001$). Furthermore, patients in Group B required significantly fewer doses of rescue analgesics, indicating better pain control.

Table 2: Comparison of Efficacy Outcomes

Outcome Measure	Group A (Tamsulosin)	Group B (Tam + Deflazacort)	p-value
Stone Expulsion Rate [n (%)]	41 (68.3%)	53 (88.3%)	0.009*
Mean Expulsion Time (days)	10.8 ± 3.4	6.4 ± 2.1	<0.001*
Analgesic use (mg of Diclofenac)	450 ± 150	250 ± 100	<0.001*
Hospitalization for pain [n (%)]	5 (8.3%)	1 (1.7%)	0.09

Statistically significant

Adverse Events: The safety profile of both regimens was acceptable (Table 3). While adverse events were slightly more frequent in the combination group, they were generally mild (Grade I). Retrograde ejaculation was reported in both groups due to Tamsulosin. Group B showed a slightly higher incidence of dyspepsia/gastritis (11.7% vs 5.0%), likely attributable to the corticosteroid, but this did not necessitate withdrawal from the study.

No cases of glucose intolerance or hypertension were noted due to the short duration of steroid use.

Table 3: Incidence of Adverse Events

Adverse Event	Group A [n (%)]	Group B [n (%)]	p-value
Retrograde Ejaculation	4 (6.7%)	5 (8.3%)	0.73
Dizziness/Orthostatic Hypotension	3 (5.0%)	4 (6.7%)	0.69
Dyspepsia/Gastritis	3 (5.0%)	7 (11.7%)	0.18
Headache	2 (3.3%)	2 (3.3%)	1.00
Total Adverse Events	12 (20.0%)	18 (30.0%)	0.21

Discussion

The management of distal ureteric calculi has seen a paradigm shift toward conservative MET, aiming to minimize surgical intervention. The results of this randomized controlled trial strongly support the hypothesis that adding a corticosteroid (Deflazacort) to an alpha-blocker (Tamsulosin) enhances the efficacy of MET.

Efficacy of Combination Therapy: Our study demonstrated a Stone Expulsion Rate (SER) of 88.3% in the combination group versus 68.3% in the monotherapy group. These findings are consistent with the physiological rationale that addressing both muscle spasm and mucosal edema is superior to addressing muscle spasm alone. Tamsulosin acts by blocking the alpha-1A and alpha-1D adrenergic receptors, which inhibits the basal tone and peristaltic frequency of the distal ureter while preserving tonic propulsive contractions [9]. However, the mechanical irritation of the stone causes a local inflammatory response, characterized by the release of histamine, serotonin, and prostaglandins, leading to submucosal edema. This edema narrows the functional lumen of the ureter. Deflazacort, a synthetic glucocorticoid, suppresses this inflammatory cascade, thereby reducing edema and facilitating stone progression [10].

Our results align with the findings of Dellabella et al., who first proposed the utility of adding corticosteroids to alpha-blockers. In their study, the expulsion rate was significantly higher in the combination group, and the expulsion time was reduced [11]. Similarly, a study by Porpiglia et al. utilizing tamsulosin and prednisone showed comparable benefits [12]. However, our study utilized Deflazacort, an oxazoline derivative of prednisolone, which has a potentially better safety profile regarding glucose metabolism and calcium

retention, making it a suitable choice for short-term therapy [13].

Reduction in Expulsion Time and Pain: A critical finding in our study was the significant reduction in Stone Expulsion Time (SET) in Group B (6.4 days) compared to Group A (10.8 days). Rapid expulsion is clinically significant as it reduces the duration of obstruction, thereby preserving renal function and reducing patient anxiety. Furthermore, the combination group required significantly less rescue analgesia. This analgesic-sparing effect is likely twofold: firstly, the faster expulsion reduces the window of time for colic episodes; secondly, corticosteroids inhibit the synthesis of prostaglandins, which are key mediators of pain and ureteral spasm in renal colic [14]. By mitigating the inflammatory component of pain, Deflazacort provides an adjunct analgesic benefit.

Safety Considerations: Safety is a primary concern when prescribing corticosteroids. In our study, the incidence of side effects was slightly higher in the combination group, primarily manifesting as mild dyspepsia, but the difference was not statistically significant. We excluded patients with diabetes and peptic ulcer disease to mitigate risks. The use of Deflazacort for a short duration (10 days) appears to be well-tolerated. This contrasts with some meta-analyses suggesting that the risks of steroids might outweigh the benefits for very small stones (<5mm) which have a high spontaneous passage rate [15]. However, for stones sized 5-10mm, as included in this study, the risk-benefit ratio seemingly favors combination therapy.

Clinical Implications and Limitations: The findings suggest that for healthy patients with distal ureteric stones between 5 and 10 mm, combination therapy should be considered a first-line option. This could significantly reduce the burden on surgical units and lower healthcare costs associated with ureteroscopy [16]. Limitations of this study include its open-label design, which may introduce observer bias regarding subjective outcomes like pain. Additionally, the exclusion of high-risk patients (diabetics) limits the generalizability of the findings to the broader population with comorbidities. Finally, we did not perform a cost-effectiveness analysis, though the reduction in analgesic use and potential avoidance of surgery suggests economic viability.

Conclusion

The present study concludes that Medical Expulsive Therapy utilizing a combination of Tamsulosin and Deflazacort is significantly more effective than Tamsulosin monotherapy for the management of distal ureteric calculi sized 5 to 10 mm. The combination regimen yielded a higher stone expulsion rate, a faster time to expulsion, and reduced analgesic requirements. The safety profile of the combination was comparable to monotherapy, with no severe adverse events observed during the short treatment course. Consequently, the addition of Deflazacort to Tamsulosin represents a valuable therapeutic strategy to enhance stone passage and minimize the need for surgical intervention in eligible patients.

References

1. Sorokin I, Mamoulakis C, Miyazawa K, Rodgers A, Talhamy J, Paik J. Epidemiology of stone disease across the world. World J Urol. 2017;35(9):1301-20.
2. Turk C, Petrik A, Sarica K, Seitz C, Skolarikos A, Straub M, et al. EAU Guidelines on Interventional Treatment for Urolithiasis. Eur Urol. 2016;69(3):475-82.
3. Hollingsworth JM, Rogers MA, Kaufman SR, Bradford TJ, Saint S, Wei JT, et al. Medical therapy to facilitate urinary stone passage: a meta-analysis. Lancet. 2006;368(9542):1171-9.
4. Griwan MS, Singh SK, Paul H, Pawar DS, Verma M. The role of tamsulosin in lower ureteric stones. Urol Ann. 2010;2(3):116-9.
5. Srirangam SJ, Hickerton B, Van Cleynenbreugel B. Management of urinary calculi in primary care. BMJ. 2008; 336(7659): 1469-72.
6. Seitz C, Liatsikos E, Porpiglia F, Tiselius HG, Zierle-Ghosh A. Medical therapy to facilitate the passage of stones: what is the evidence? Eur Urol. 2009;56(3):455-71.
7. Pickard R, Starr K, MacLennan G, Lam T, Thomas R, Burr J, et al. Medical expulsive therapy in adults with ureteric colic: a multicentre, randomised, placebo-controlled trial. Lancet. 2015;386(9991):341-9.
8. Pardo M, Silva V. Deflazacort vs. prednisone in children with nephrotic syndrome. Pediatr Nephrol. 2010;25:2183.
9. Yilmaz E, Batislam E, Basar MM, Tuglu D, Ferhat M, Basar H. The comparison and efficacy of 3 different alpha1-adrenergic blockers for distal ureteral stones. J Urol. 2005;173(6):2010-2.
10. Sener NC, Bas O, Sener E, Zengin K, Ozturk U, Altunoluk B, et al. Desloratadine and prednisolone in the treatment of distal ureteral stones. Int Braz J Urol. 2016;42(6):1164-9.
11. Dellabella M, Milanese G, Muzzonigro G. Efficacy of tamsulosin in the medical management of juxtavesical ureteral stones. J Urol. 2003;170(6):2202-5.
12. Porpiglia F, Vaccino D, Billia M, Renard J, Cracco C, Ghignone G, et al. Corticosteroids and tamsulosin in the medical expulsive

therapy for symptomatic distal ureter stones: single drug or association? Eur Urol. 2006; 50(2): 339-44.
13. Nayak B, Kumar A. Deflazacort: A better alternative to Prednisolone? J. Assoc Physicians India. 2008;56:397.
14. Holdgate A, Pollock T. Nonsteroidal anti-inflammatory drugs (NSAIDs) versus opioids for acute renal colic. Cochrane Database Syst Rev. 2004;(1):CD004137.
15. Campschroer T., Zhu Y., Duijvesz D., Grobbee D.E., Lock M.T. Alpha-blockers as medical expulsive therapy for ureteral stones. Cochrane Database Syst Rev. 2014; (4): CD008509.
16. Bensalah K., Pearle M., Lotan Y. Cost-effectiveness of medical expulsive therapy using alpha-blockers for the treatment of distal ureteral stones. Eur Urol. 2008;53(2):411-9.