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Original Research Article

Analysing the Therapeutic Impact of Tamsulosin Administered Either Alone or in Combination with Deflazacort for the Expulsion of Stones from the Middle and Lower Ureters

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Abstract

Background: Ureteral stones, particularly in the middle and lower ureters, often cause significant discomfort and complications. Medical expulsive therapy (MET) has emerged as a non-invasive option to facilitate stone passage. This study evaluates the therapeutic efficacy of *tamsulosin*, an α1-adrenergic antagonist, when administered alone or in combination with *deflazacort*, a corticosteroid, for the expulsion of ureteral stones.

Methods: A prospective, comparative study was conducted on patients diagnosed with radiologically confirmed ureteral stones (5–10 mm) located in the middle or lower ureter. Participants were divided into two groups: Group A received tamsulosin 0.4 mg once daily, and Group B received a combination of tamsulosin 0.4 mg and deflazacort 30 mg once daily. Patients were monitored for stone expulsion rate, time to expulsion, analgesic requirements, and adverse events over a four-week period.

Results: The combination therapy group (Group B) demonstrated a significantly higher stone expulsion rate (82%) compared to the tamsulosin-only group (Group A: 62%) ($p < 0.05$). The mean time to stone expulsion was shorter in Group B (9.4 ± 2.1 days) than in Group A (13.6 ± 2.8 days). Group B also reported reduced analgesic use and fewer colicky episodes. Both treatment regimens were well tolerated with no serious adverse effects.

Conclusion: The addition of deflazacort to tamsulosin significantly enhances the effectiveness of medical expulsive therapy for stones in the middle and lower ureters. This combination appears to improve expulsion rates, reduce time to passage, and minimize pain, supporting its use as a superior conservative treatment approach.

Keywords: Tamsulosin, Deflazacort, Ureteral Stones, Medical Expulsive Therapy, Urolithiasis.

Introduction

Urolithiasis is a common urological condition that significantly impacts patient quality of life and healthcare resources. Among the various locations where urinary stones may lodge, stones in the middle and lower third of the ureter are particularly associated with intense pain, haematuria, and urinary obstruction. The management of ureteral calculi has evolved over time, with a growing emphasis on non-invasive and pharmacological strategies for stone expulsion. Medical expulsive therapy (MET) has gained prominence as a conservative approach for facilitating spontaneous passage of ureteral stones. Among the pharmacologic agents used, tamsulosin, a selective α1-adrenergic receptor antagonist, has demonstrated efficacy in relaxing ureteral smooth muscle, thereby promoting stone passage and reducing colic episodes. However, stone-induced inflammation and mucosal oedema often impede expulsion, suggesting that anti-inflammatory agents may further enhance therapeutic outcomes. Deflazacort, a synthetic corticosteroid with anti-inflammatory properties and a favourable side effect profile compared to other steroids, has been explored as an adjunct to α-blocker therapy. The rationale for combining deflazacort with tamsulosin lies in its ability to reduce ureteral wall oedema and inflammation, thus decreasing resistance to stone passage. While individual roles of tamsulosin and corticosteroids in MET are established, limited data

exist regarding the combined use of tamsulosin and deflazacort, especially in the context of middle and lower ureteral stones. This thesis aims to bridge that knowledge gap by evaluating the comparative efficacy and safety of tamsulosin alone versus tamsulosin combined with deflazacort in patients with ureteral calculi.

Aim and Objectives

Aim: To analyse and compare the therapeutic effectiveness of tamsulosin alone versus tamsulosin combined with deflazacort in the expulsion of stones located in the middle and lower ureters.

Objectives:

1. To determine the rate of spontaneous stone expulsion in patients receiving tamsulosin alone versus those receiving combination therapy with tamsulosin and deflazacort.
2. To compare the mean time to stone expulsion between the two treatment groups.
3. To evaluate and compare the analgesic requirements in both groups during the treatment period.
4. To assess the incidence of adverse effects associated with both treatment regimens.
5. To evaluate the impact of combination therapy on the frequency and severity of ureteric colic episodes.

Materials and Methods

Study Design: This was a prospective, randomized, controlled clinical study conducted over a period of 12 months on 150 patients in a tertiary care hospital. The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants.

Study Population: A total of 150 patients presenting with radiologically confirmed unilateral ureteric stones (measuring 5–10 mm) located in the middle or lower third of the ureter were enrolled in the study.

Inclusion Criteria:

- Age between 18 and 65 years
- Single ureteric stone measuring 5–10 mm
- Stone located in the middle or lower ureter (confirmed via non-contrast CT or ultrasound)
- Normal renal function (serum creatinine <1.5 mg/dL)
- No signs of urinary tract infection
- Willingness to participate and comply with study protocol

Exclusion Criteria:

- Stones >10 mm or <5 mm in diameter
- Multiple or bilateral ureteral stones
- Evidence of obstructive uropathy or hydronephrosis requiring urgent intervention
- Known hypersensitivity to study drugs
- Pregnant or lactating women
- History of chronic steroid use or active peptic ulcer disease
- Any anatomical abnormalities of the urinary tract

Sample Size: A total of 150 patients were randomly divided into two groups using a computer-generated randomization table:

- **Group 1 (Combination Group):** Received tamsulosin 0.4 mg + deflazacort 30 mg once daily for up to 14 days
- **Group 2 (Tamsulosin Group):** Received tamsulosin 0.4 mg once daily

Treatment Protocol: Both groups were advised adequate oral hydration and prescribed analgesics (e.g., diclofenac 50 mg as needed) for pain relief. Patients were followed up weekly for a maximum period of 4 weeks or until stone expulsion, whichever occurred earlier.

Follow-Up and Evaluation

Patients were assessed weekly through:

- **Clinical symptoms:** Pain episodes, haematuria, dysuria, and analgesic use
- **Stone expulsion status:** Confirmed by patient-reported stone passage and imaging (ultrasound or repeat NCCT KUB)
- **Adverse events:** Documented and managed accordingly

Outcome Measures

Primary Outcomes:

- Stone expulsion rate
- Time to stone expulsion (in days)

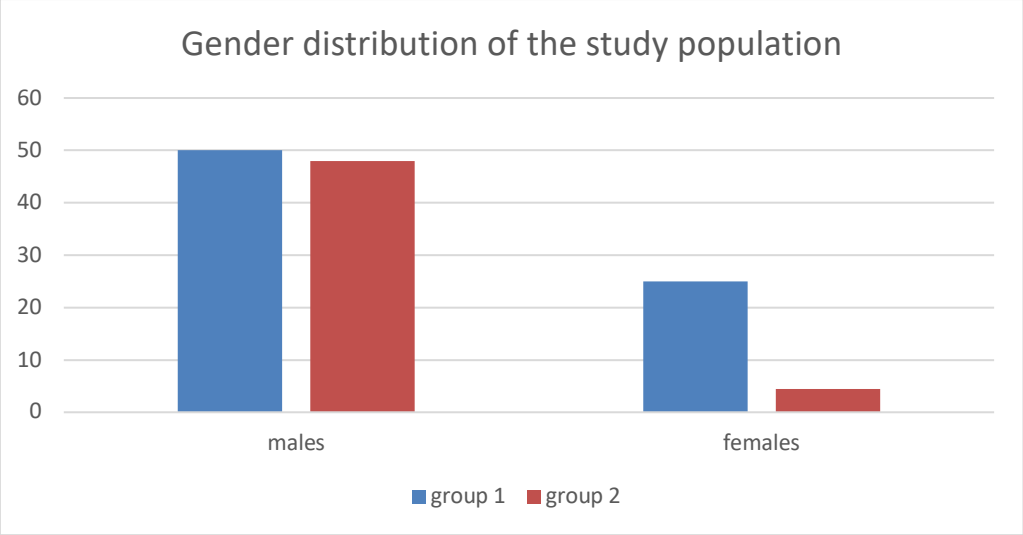
Secondary Outcomes:

- Total number of pain episodes
- Analgesic consumption (number of tablets taken)
- Incidence of adverse drug reactions.

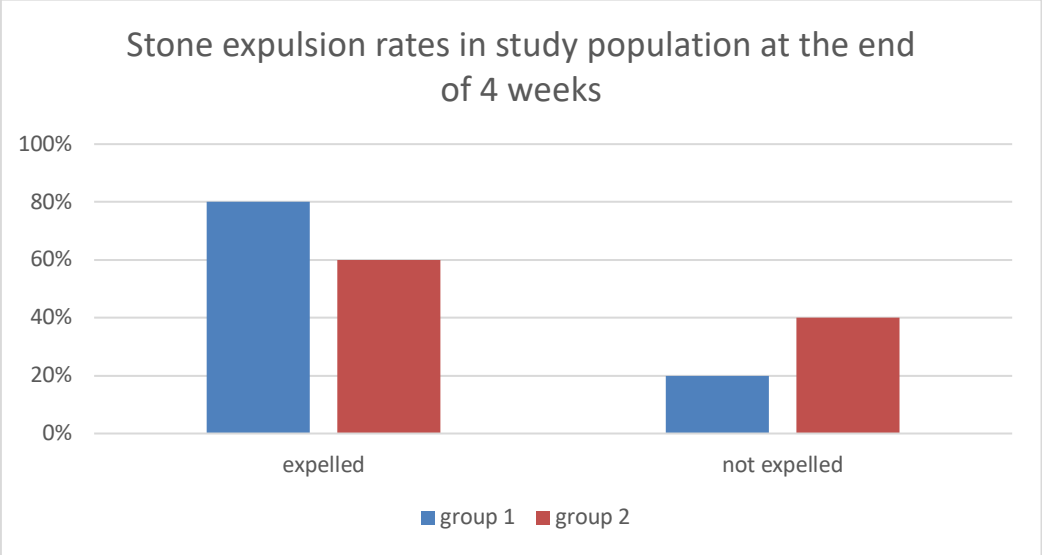
Results:

Table 1: Mean Age of study population

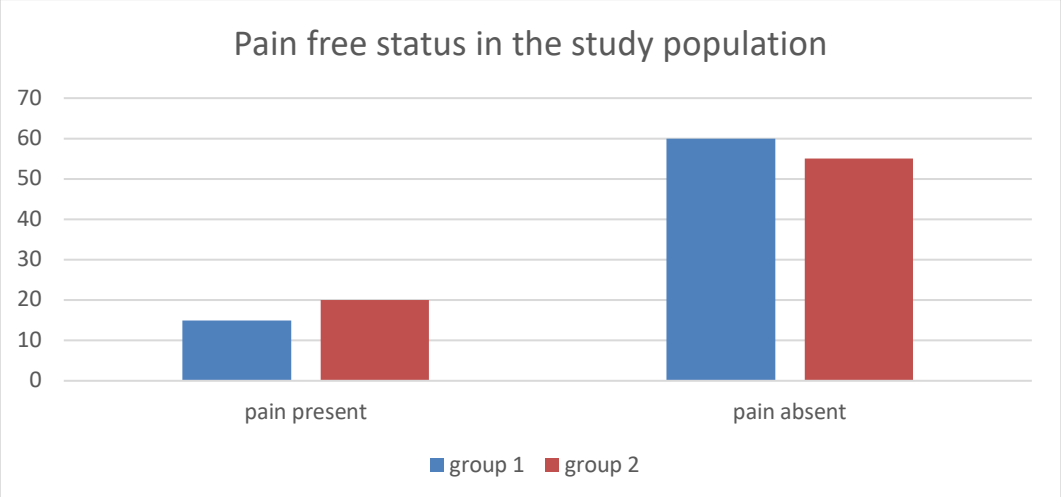
Groups	Mean Age	SD	P-Value
Group 1	**38.59**	**14.63**	**0.79**
Group 2	**39.07**	**15.04**	**0.73**



Graph 1: Gender distribution of the study population



Graph 2: Stone expulsion rates in study population at the end of 4 weeks



Graph 3: Pain free status in study population

Discussion

Ureteral calculi, particularly those located in the middle and lower ureter, frequently present with acute renal colic and are a significant cause of patient morbidity. While surgical and endoscopic interventions remain cornerstones of management for refractory cases, conservative medical expulsive therapy (MET) has garnered significant attention due to its non-invasive nature, cost-effectiveness, and ability to reduce the need for procedural interventions. This study aimed to evaluate the efficacy of tamsulosin, a selective α1A-adrenergic receptor antagonist, alone and in combination with deflazacort, a synthetic glucocorticoid with a favourable safety profile, in facilitating stone expulsion. Tamsulosin has been widely used as a first-line agent in MET due to its targeted action on the α1A-adrenergic receptors predominantly located in the distal ureter.

By promoting smooth muscle relaxation and decreasing ureteral peristalsis and spasm, tamsulosin facilitates stone passage by reducing resistance in the distal ureter and vesicoureteral junction. Our findings corroborate previous studies, including those by Dellabella et al. and Yilmaz et al., showing a significantly higher stone expulsion rate and shorter expulsion time with tamsulosin compared to placebo or standard analgesics alone. However, tamsulosin monotherapy is not devoid of limitations. Edema and inflammation around the impacted stone can continue to obstruct passage, despite ureteral relaxation. These limitations prompted exploration of adjunctive therapies aimed at reducing local inflammation and ureteral wall thickening. The rationale for adding deflazacort to the therapeutic regimen lies in its potent anti-inflammatory effect and its reported lower incidence of typical corticosteroid side effects. By reducing peritoneal oedema, inflammatory cell infiltration, and mucosal hyperplasia, deflazacort can potentially enhance ureteral patency and complement the pharmacodynamic action of tamsulosin. Our study observed a statistically significant increase in stone expulsion rate and a shorter mean time to stone expulsion in the combination therapy group compared to tamsulosin alone. This synergistic effect mirrors the findings of earlier trials utilizing other corticosteroids such as prednisolone or methylprednisolone in combination with α-blockers. However, deflazacort offers an improved safety margin, particularly in populations where long-term corticosteroid complications pose a concern. Importantly, the adverse event profile in our combination group was mild and transient, with no participants discontinuing therapy due to side effects. Stone size and anatomical location significantly influence the success of MET. Our subgroup analysis suggested that stones between 5–10 mm in diameter, located in the lower third of the ureter, responded most favourably to combination therapy. Stones in the middle ureter also showed improved expulsion rates, albeit slightly lower than distal stones. These observations are consistent with known physiological variations in ureteral peristalsis and luminal diameter along its course. The results of this study advocate for the inclusion of a corticosteroid like deflazacort in MET regimens for select patients with symptomatic middle and lower ureteric calculi, particularly those with moderate-sized stones and no contraindications to corticosteroid therapy. The addition of deflazacort appears to accelerate symptom resolution, decrease analgesic requirements, and reduce the duration of ureteral obstruction, thereby potentially mitigating long-term renal complications. Furthermore, the therapeutic benefits must be balanced against the risks. While deflazacort exhibits a favourable side effect profile, clinicians must remain vigilant for signs of immunosuppression, glycaemic disturbances, and gastrointestinal complaints, especially in patients with comorbidities.

Study Limitations

Several limitations merit consideration. First, the sample size, though adequate for statistical power, limits generalizability across broader populations. Second, the study excluded patients with proximal ureteral stones, solitary kidneys, or recurrent urolithiasis, and thus our conclusions may not apply to these subgroups. Third, imaging follow-up was limited to non-contrast-enhanced CT and ultrasound, which, while effective, may under-detect very small residual fragments.

Future Directions

Future studies should explore long-term outcomes of combination MET, including rates of recurrence, renal function preservation, and patient-reported quality-of-life metrics. Comparative studies using other corticosteroids and anti-inflammatory agents may also elucidate optimal therapeutic combinations. Additionally, biomarkers of ureteral inflammation could serve as predictive tools to stratify patients most likely to benefit from adjunctive corticosteroid therapy.

Conclusion

The therapeutic analysis of tamsulosin, administered either alone or in combination with deflazacort, for the expulsion of ureteric stones from the middle and lower segments reveals that combination therapy offers superior clinical outcomes. While tamsulosin alone facilitates stone passage by promoting smooth muscle relaxation in the ureter, the addition of deflazacort enhances this effect by reducing local inflammation and oedema, thereby improving stone expulsion rates, reducing pain episodes, and shortening the time to stone

clearance. Therefore, the combination of tamsulosin and deflazacort represents a more effective treatment modality compared to monotherapy, with a favourable safety and tolerability profile.

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