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Research Article

Safety and Efficacy of Tamsulosin and Combination of Tamsulosin with Deflazacort in Patients Diagnosed with Ureteric Calculi

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ABSTRACT

Introduction: Urinary tract stones lodged within the ureter, clinically referred to as ureteric calculi, represent a significant and growing burden in urological practice, with global estimates suggesting that roughly 5–10% of individuals are affected at some point in their lives. Approximately one in five urinary stones ultimately becomes lodged in the ureter, and a substantial proportion of these settle in the lower ureteric segment. Although technological advances have expanded minimally invasive surgical options, Medical Expulsive Therapy (MET) continues to be a cornerstone of non-surgical management for distal ureteric stones. Whether a stone passes spontaneously or not depends on a range of interacting variables, including its dimensions, exact location within the ureter, the degree of smooth muscle spasm, surrounding mucosal swelling, ongoing inflammatory changes, and the inherent anatomical characteristics of the individual's ureter.

Objectives: To compare the safety and efficacy of Tamsulosin alone and Tamsulosin combined with Deflazacort in patients diagnosed with ureteric calculi. The comparison was carried out based on stone expulsion rate and the time required for stone expulsion.

Methods: A prospective observational study was conducted among patients diagnosed with ureteric calculi according to predefined inclusion and exclusion criteria. Safety and efficacy parameters were assessed throughout the treatment period.

Results: Both treatment groups showed improvement in stone expulsion rate and reduction in stone expulsion time. However, the combination therapy group receiving Tamsulosin with Deflazacort demonstrated better outcomes compared to Tamsulosin alone. The combination therapy resulted in faster stone passage and greater improvement in expulsion rate.

Conclusion: Tamsulosin is effective in promoting the expulsion of ureteric stones. However, the combination of Tamsulosin with Deflazacort appears to be more effective in increasing stone expulsion rate and reducing expulsion time, thereby reducing the need for invasive procedures.

Keywords: Ureteric Calculi, Tamsulosin, Deflazacort, Medical Expulsive Therapy.

INTRODUCTION

Stones lodged within the ureter rank among the most clinically significant urological conditions encountered in everyday medical practice, frequently presenting as debilitating flank pain accompanied by varying degrees of urinary obstruction. These stones typically form within the renal collecting system and subsequently descend into the ureter, where they may impede urine flow partially or completely. Three distinct anatomical regions along the ureteric course are especially prone to stone trapping: the ureteropelvic junction at the upper end, the point where the ureter crosses the pelvic brim, and the ureterovesical junction near the bladder — all locations where the ureteric lumen naturally narrows or changes direction [(1,2)].Rising rates of

urolithiasis across populations have been linked to shifts in dietary patterns, increasing rates of obesity, insufficient fluid intake, metabolic disturbances such as hyperuricemia and hypercalciuria, and broader environmental changes. When classified by composition, calcium oxalate accounts for the majority of stones encountered clinically, with uric acid stones, struvite, cystine, and calcium phosphate varieties following in decreasing frequency [3,4].When a ureteric stone causes obstruction, the clinical presentation is characteristically dramatic. The hallmark complaint is intense, wave-like pain originating in the flank and radiating toward the groin or inner thigh, often accompanied by blood in the urine, nausea, vomiting, a burning sensation on urination, and an increased urge to void. The nature and severity of these symptoms are closely tied to where exactly the stone has lodged and how large it is [5,6]. Establishing a diagnosis relies on a combination of laboratory workup and cross-sectional imaging. Among the available imaging tools, Non-Contrast Computed Tomography of the Kidney, Ureter and Bladder (NCCT-KUB) has earned its status as the preferred first-line investigation owing to its ability to reliably detect stones of virtually all compositions with excellent diagnostic accuracy. Ultrasound and plain X-ray KUB remain useful adjuncts, particularly when radiation dose is a concern or resources are limited [7,8]. Management of ureteric calculi depends on stone size, location, severity of symptoms, and associated complications. Medical Expulsive Therapy (MET) is commonly used for stones smaller than 10 mm to facilitate spontaneous stone passage and reduce the need for surgical intervention [9,10]. Tamsulosin, a highly selective antagonist of α1-adrenergic receptors, works by relaxing the smooth musculature of the ureter, which in turn diminishes ureteric spasm, promotes propulsive peristalsis, and encourages the stone to move toward the bladder. Patients treated with tamsulosin also tend to experience fewer and less severe episodes of renal colic [11,12]. Deflazacort, a synthetic corticosteroid with pronounced anti-inflammatory activity, may augment the stone-passage process by dampening the inflammatory oedema that accumulates around the lodged stone, effectively widening the space through which the stone must travel. Published data comparing combination therapy — tamsulosin alongside deflazacort — with tamsulosin monotherapy have generally reported higher expulsion rates and shorter time-to-expulsion in favour of the combined approach [13,14]. Hence, evaluating the safety and efficacy of tamsulosin alone and in combination with deflazacort is important to optimize treatment outcomes and reduce unnecessary surgical interventions in patients with ureteric calculi.

Objectives

To assess the safety parameters [Headache, Dizziness, Orthostatic Hypotension, Rhinitis, Arthralgia, Insomnia, Diarrhea] in Ureteric Calculi patients, treated with Tamsulosin and combination of Tamsulosin with Deflazacort. To assess Efficacy parameters using Non-Contrast Compound Tomography-Kidney, Ureter and Bladder [NCCT-KUB] and Douleur Neuropathique 4 pain questionaries [DNQ 4].

METHODS

The study was carried out at Kiran Kidney Care, Hanamkonda, Telangana, India over a period of six months as a prospective and observational study. A total of 500 patients diagnosed with Ureteric Calculi screened in this study. Patients aged above 18 years with Ureteric stones measuring 3–10 mm were included in the study. Patients with multiple stones, urinary tract infections, renal insufficiency, and pregnancy were excluded. Safety parameters such as headache, dizziness, orthostatic hypotension, rhinitis, insomnia, arthralgia, and diarrhea were monitored during the treatment period. Efficacy was evaluated using NCCT-KUB, X-ray KUB, Renal Function Tests, and DN4 questionnaire scores before and after treatment. Collected data were analyzed using GraphPad Prism and MS Excel by applying Paired and Unpaired t-tests.

RESULTS

Gender Distribution

Table 1: Gender Distribution of Study Subjects

GENDER	SUBJECT	PERCENTAGE
MALE	306	61%
FEMALE	194	39%

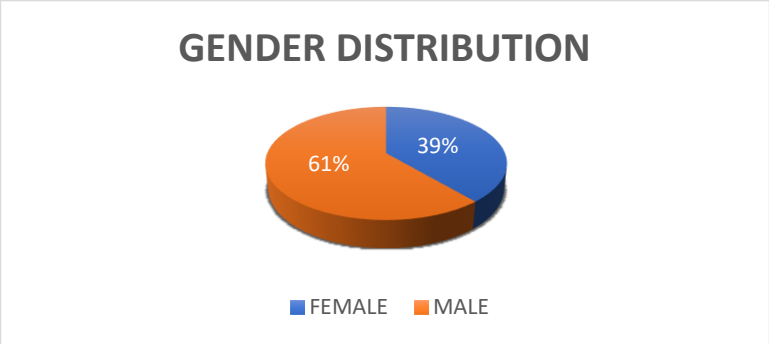

Figure 1: Graphical Representation of Age Distribution

The graphical representation shows that ureteric calculi were more common among male participants than female participants in the study population (N=500). Out of the total subjects, 61% (n=306) were males, while 39% (n=194) were females, indicating a clear male predominance in the occurrence of ureteric calculi. This difference may be related to factors such as dietary habits, occupational conditions, lower fluid intake, metabolic variations, and lifestyle practices, which are known to contribute to a higher risk of stone formation among males.

Table 2: Gender Distribution in the T Group (Tamsulosin)

GENDER	SUBJECT	PERCENTAGE
MALE	131	57%
FEMALE	99	43%

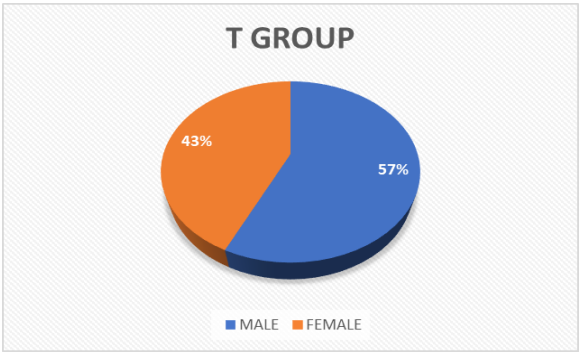

Figure 2: Graphical Representation of Gender Distribution in T Group

The graph shows the gender-wise distribution of patients in the Tamsulosin (T) treatment group. Among the 230 participants included in this group, males accounted for 57% (n=131), while females made up 43% (n=99). The findings suggest that ureteric calculi were more commonly observed among male patients receiving tamsulosin therapy. Although both genders were well represented in the study, a male predominance was still evident, which is consistent with the overall epidemiological trend of ureteric calculi seen in the general study population.

Table 3: Gender Distribution in T+D Group (Tamsulosin + Deflazacort)

GENDER	SUBJECT	PERCENTAGE
MALE	175	65%
FEMALE	95	35%

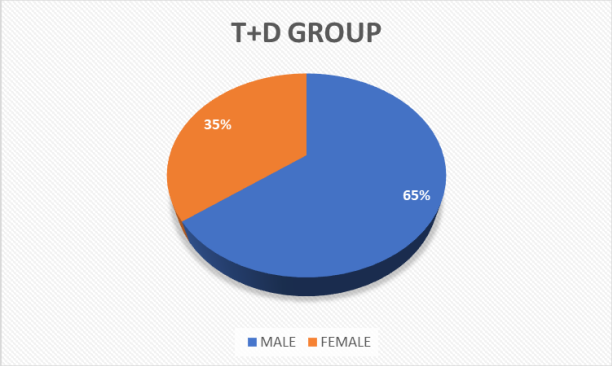

Figure 3: Graphical Representation of Gender Distribution in T+D Group

The graphical representation of the Tamsulosin + Deflazacort (T+D) group showed that male patients formed the majority of the study participants. Out of the 270 subjects included in the combination therapy group, 65% (n=175) were males, while 35% (n=95) were females. These findings indicate that ureteric calculi were more frequently observed among male patients receiving combination therapy. The higher proportion of males in both treatment groups further supports the well-known observation that urolithiasis is more common in men than in women.

Age Distribution

Table 4: Age Distribution in T Group (Tamsulosin)

AGE CRITERIA	SUBJECTS T GROUP	PERCENTAGE
18-27	20	8.7%
28-37	89	38.7%
38-47	51	22.2%
48-57	30	13.0%
58-67	27	11.7%
68-77	12	5.2%
78-87	1	0.4%

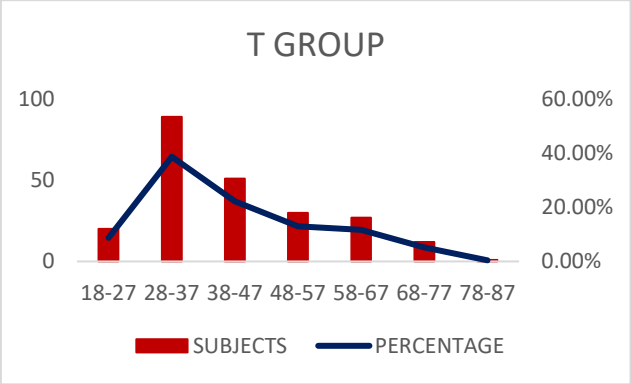

Figure 4: Graphical Representation of Age Distribution in T Group

The graphical representation of age distribution in the Tamsulosin (T) group shows that most patients belonged to the younger and middle-aged population. Among the total participants (N=230), the highest number of patients was seen in the 28–37 years age group, accounting for 38.7% (n=89). This was followed by the 38–47 years age group, which comprised 22.2% (n=51) of the study population. Moderate numbers of patients were observed in the 48–57 years and 58–67 years age groups, contributing 13.0% (n=30) and 11.7% (n=27), respectively. The 18–27 years age group accounted for 8.7% (n=20) of cases, while the lowest number of patients was found among older individuals aged 68–77 years and 78–87 years, representing 5.2% (n=12) and 0.4% (n=1), respectively. Overall,

the findings suggest that ureteric calculi were more commonly observed in individuals between 28–47 years of age in the Tamsulosin treatment group, indicating a higher prevalence of stone disease during the active and productive years of adulthood.

Table 5: Age Distribution in T+D Group

AGE CRITERIA	SUBJECTS T+D GROUP	PERCENTAGE
18-27	35	12.96%
28-37	71	26.30%
38-47	50	18.52%
48-57	50	18.52%
58-67	46	17.04%
68-77	14	5.19%
78-87	4	1.48%

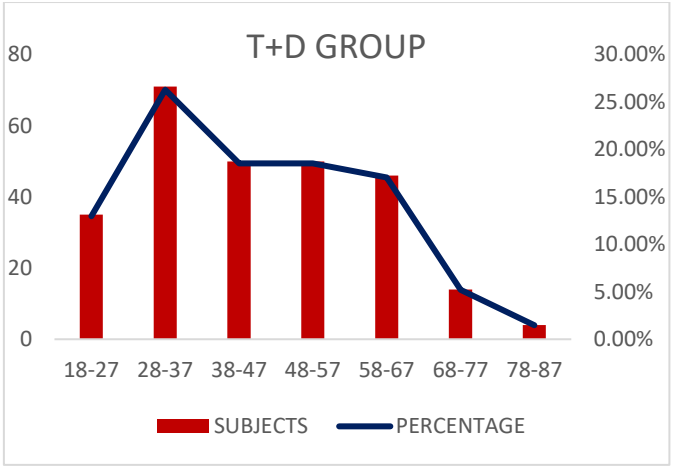

Figure 5: Graphical Representation of Age Distribution in T+D Group

The graph indicates that the majority of subjects in the T + D group belonged to the younger and middle-aged population. The highest proportion of patients was observed in the 28–37 years age group, accounting for 26.30% of the study population. This was followed by the 38–47 years and 48–57 years age groups, each contributing 18.52% of the participants. Moderate representation was seen among patients aged 58–67 years (17.04%) and 18–27 years (12.96%). In contrast, only a small number of cases were reported in the elderly age groups, particularly among individuals aged 68–77 years (5.19%) and 78–87 years (1.48%). Overall, the findings suggest that ureteric calculi were more commonly observed in younger and middle-aged adults within the T + D treatment group.

Table 6: Age Distribution in T and T+D Groups

AGE CRITERIA	SUBJECTS T+(T=D) GROUPS (n=230 + 270)	PERCENTAGE
18-27	55	11%
28-37	160	32%
38-47	101	20.2%
48-57	76	15.2%
58-67	73	14.6%
68-77	26	5.2%
78-87	9	1.8%

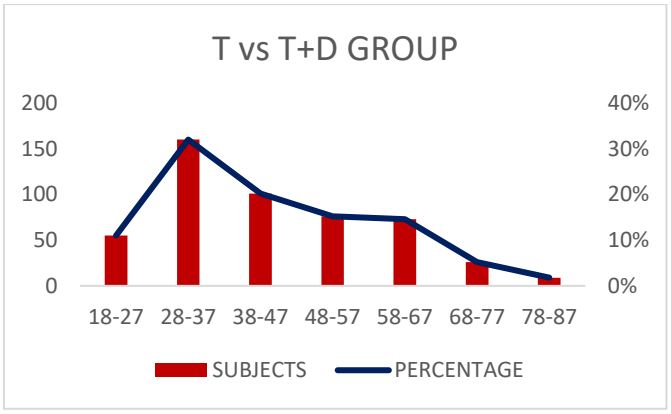

Figure 6: Graphical Representation of Age Distribution in T and T+D Groups

The graph shows that the highest proportion of subjects in the combined T and T + D groups belonged to the 28–37 years age group, accounting for 32% of the study population. This was followed by the 38–47 years age group, which contributed 20.2% of the participants. Moderate representation was observed among individuals aged 48–57 years (15.2%) and 58–67 years (14.6%). Lower proportions were seen in the 18–27 years age group (11%), while the least number of cases were reported among older adults aged 68–77 years (5.2%) and 78–87 years (1.8%). Overall, the findings indicate that the majority of subjects in the combined study groups were from the younger and middle-aged population, suggesting that ureteric calculi are more commonly seen during the active years of adulthood.

Parameters Assessed
Safety Parameters:

Table 7: Safety Parameters in T Group

SAFETY PARAMETERS	T GROUP	PERCENTAGE
HEADACHE	223	32.79%
DIZZINESS	224	32.94%
ORTHOSTATIC HYPOTENSION	4	0.59%
RHINITIS	0	0%
INSOMNIA	0	0%
DIARRHOEA	229	33.68%

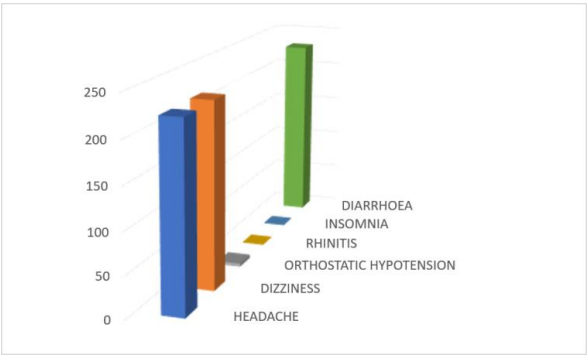

Figure 7: Graphical Representation of Safety Parameters in T Group

The graph indicates that diarrhoea (33.68%) was the most commonly reported adverse event in the T group, followed closely by dizziness (32.94%) and headache (32.79%). A much lower incidence was observed with orthostatic hypotension (0.59%), while no cases of rhinitis or insomnia were reported during the study period. Overall, these findings suggest that the T group exhibited a relatively mild and manageable safety profile among the study population.

Table 8: Safety Parameters In T+D Group

SAFETY PARAMETERS	T+D GROUP	PERCENTAGE
HEADACHE	257	32.53%
DIZZINESS	258	32.66%
ORTHOSTATIC HYPOTENSION	25	3.16%
RHINITIS	0	0%
INSOMNIA	0	0%
DIARRHOEA	250	31.65%

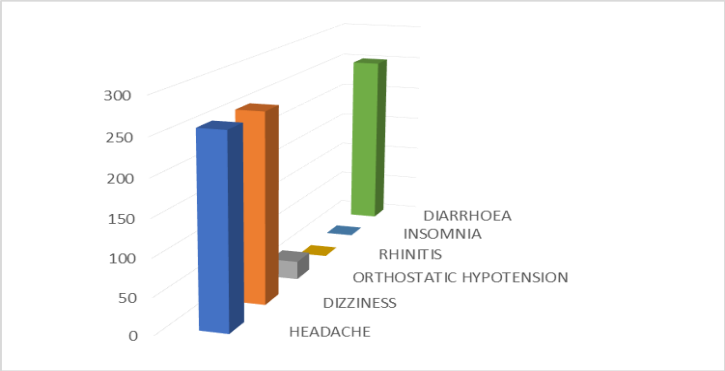

Figure 8: Graphical Representation of Safety Parameters in T+D Group

The graph shows that dizziness (32.66%) and headache (32.53%) were the most commonly reported adverse events in the T + D group, followed closely by diarrhoea (31.65%). A lower incidence of orthostatic hypotension (3.16%) was observed, while no cases of rhinitis or insomnia were reported during the study period. Overall, the findings suggest that the combination therapy was associated with comparatively higher adverse effects when compared to the T group alone, although the reported events were generally manageable.

Table 9: Safety Parameters in T Group Vs T+D Group

SAFETY PARAMETERS	T GROUP	T+D GROUP
HEADACHE	223	257
DIZZINESS	224	258
ORTHOSTATIC HYPOTENSION	4	25
RHINITIS	0	0
INSOMNIA	0	0
DIARRHOEA	229	250

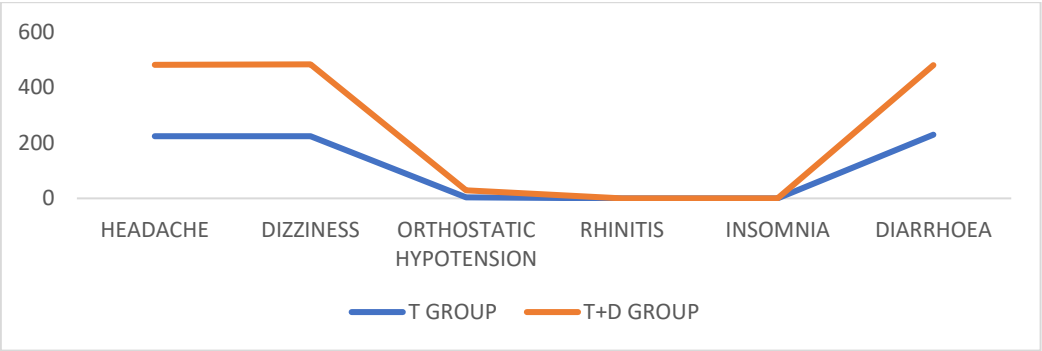

Figure 9: Graphical Representation of Safety Parameters in T Vs T+D Group

The graph indicates that adverse events were comparatively more common in the T + D group than in the T group. Dizziness, headache, and diarrhoea were the most frequently reported adverse events in both treatment groups, while orthostatic hypotension was observed more often among patients receiving the combination therapy. No cases of rhinitis or insomnia were reported in either group. Overall, the findings suggest that

the addition of Deflazacort to Tamsulosin therapy was associated with a relatively higher incidence of side effects compared with Tamsulosin alone.

Efficacy Parameters

Table 10: Efficacy Parameters in T Group

EFFICACY PARAMETERS IN T GROUP	
BEFORE TREATMENT	5.85 ± 1.56
AFTER TREATMENT	3.21 ± 3.52
P VALUE	<0.0001****

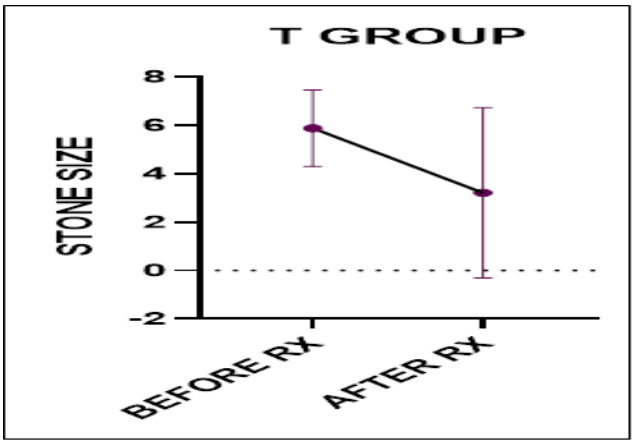

Figure 10: Graphical Representation of Efficacy Parameters in T Group

The graph shows a statistically significant reduction in ureteric calculi stone size in the T group following treatment with Tamsulosin. The mean stone size decreased from 5.85 ± 1.56 before treatment to 3.21 ± 3.52 after treatment ($p < 0.0001$****). These findings demonstrate that Tamsulosin was effective in reducing stone size among patients in the study group.

Table 11: Efficacy Parameters in T+D Group

EFFICACY PARAMETERS IN T+D GROUP	
BEFORE TREATMENT	5.98 ± 1.82
AFTER TREATMENT	1.82 ± 3.48
P VALUE	<0.0001****

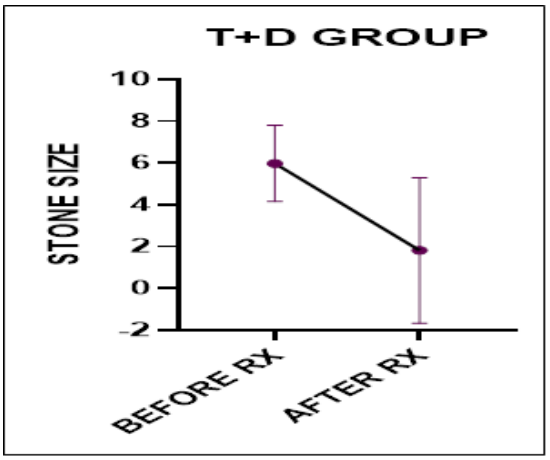

Figure 11: Graphical Representation of Efficacy Parameters in T+D Group

The graph shows a statistically significant reduction in ureteric calculi stone size in the T + D group following treatment with Tamsulosin and Deflazacort. The mean stone size decreased from 5.98 ± 1.82 before treatment to 1.82 ± 3.48 after treatment ($p <$

0.0001****). These findings suggest that the combination therapy was highly effective in reducing stone size and produced greater improvement compared to baseline values.

Table 12: Efficacy of Drugs before Treatment

EFFICACY OF DRUGS BEFORE TREATMENT		
BEFORE TREATMENT	TAMSULOSIN	5.87 ± 1.56
	TAMSULOSIN + DEFLAZACORT	5.98 ± 1.82
P VALUE	>0.05	

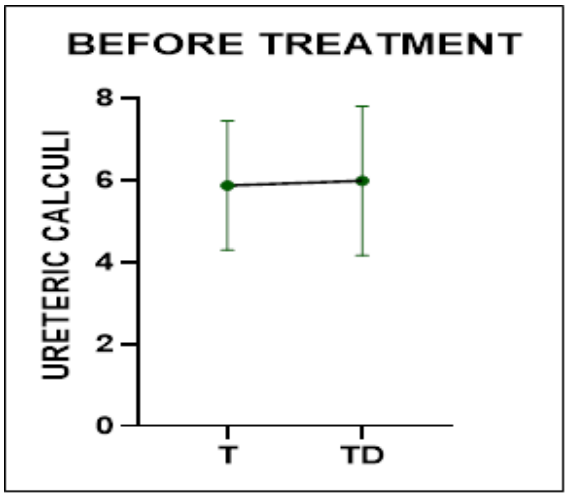

Figure 12: Comparision of Drugs before Treatment

The graph compares the baseline ureteric calculi stone size between the T group and the T + D group before the initiation of treatment. The mean stone size was 5.87 ± 1.56 in the T group and 5.98 ± 1.82 in the T + D group. No statistically significant difference was observed between the two groups (p > 0.05), indicating that both groups had comparable stone sizes at baseline before treatment was started.

Table 13: Efficacy of Drugs after Treatment

EFFICACY OF DRUGS AFTER TREATMENT		
AFTER TREATMENT	TAMSULOSIN	3.21 ± 3.52
	TAMSULOSIN + DEFLAZACORT	1.82 ± 3.48
P VALUE	<0.0001****	

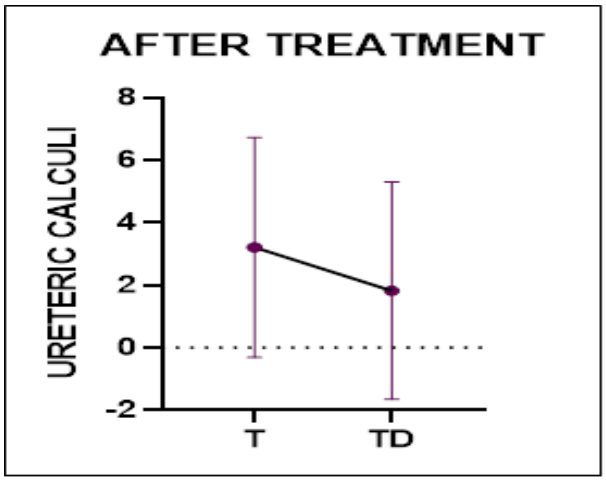

Figure 13: Comparision of Drugs after Treatment

The graph shows a statistically significant reduction in ureteric calculi stone size after treatment in both study groups, with a greater reduction observed in the T + D group.

Following treatment, the mean stone size was reduced to 3.21 ± 3.52 in the T group and 1.82 ± 3.48 in the T + D group ($p < 0.0001$****). These findings indicate that the combination therapy of Tamsulosin and Deflazacort was more effective in reducing stone size compared with Tamsulosin alone.

DISCUSSION

In this prospective observational investigation, we set out to examine how tamsulosin performs as a standalone treatment compared with its use alongside deflazacort in patients carrying a diagnosis of ureteric calculi. Ureteric stone disease is a routine yet challenging clinical scenario that clinicians frequently encounter, and its hallmarks — sudden-onset flank pain and obstructed urinary flow — continue to drive a substantial proportion of urology referrals. The demographic profile that emerged from our data aligned closely with what published epidemiological literature has documented, namely that stone disease disproportionately affects working-age adults and is associated with modifiable risk factors such as dietary excesses, inadequate hydration, weight gain, and underlying metabolic conditions, as described by Trinchieri, 1996[3]; Belhachem *et al.,* 2024[4].

On clinical presentation, the majority of our patients came to attention with the expected constellation of symptoms: episodes of cramping, severe flank pain that swept toward the groin area, visible or microscopic blood in the urine, nausea, painful urination, and a persistent urge to void. These observations from our study cohort are consistent with what has been documented by Dave 2025[5] and Glazer *et al.,* 2024[6], who noted that how prominently symptoms manifest is largely a function of stone size and its position along the ureter. Stones situated in the distal segment tend to provoke more troublesome irritative voiding complaints, a pattern that likely reflects the close anatomical relationship between the lower ureter and the trigone of the bladder.

Radiological investigations formed the backbone of both initial diagnosis and therapeutic monitoring throughout our study. NCCT-KUB proved invaluable in precisely characterising stone dimensions and localisation, reinforcing published evidence that positions this modality as the first-choice investigation for suspected urinary calculi given its outstanding ability to detect stones regardless of composition, as reported by Kazmierczak *et al., 2025*[7]; Wein *et al., 2021*[8]. X-ray KUB and renal function tests also contributed to monitoring treatment response and disease progression during therapy.

Both treatment groups demonstrated improvement during the study period; however, the combination therapy group receiving tamsulosin with deflazacort showed better clinical outcomes when compared with tamsulosin alone. The stone expulsion rate was comparatively higher and the expulsion time was shorter in patients treated with combination therapy. These findings are consistent with the observations of Nayak *et al.,* 2008[13] and Modi *et al.,* 2024[14], who reported enhanced stone clearance with the addition of corticosteroids to alpha-blocker therapy.

The superior performance of combination therapy can be understood by examining what each drug contributes mechanistically. Tamsulosin belongs to the class of selective α1-adrenergic receptor antagonists; when it occupies these receptors on ureteral smooth muscle, it diminishes baseline muscular tone, blunts spasmodic contractions, and lowers the pressure within the ureteric lumen — collectively creating conditions that favour stone descent and expulsion, as described by Hollingsworth *et al., 2019*[11] and Franco-Salinas *et al.,2010*[12] who further demonstrated that by attenuating ureteric contractions, alpha-blockers not only raise the rate of stone expulsion but also bring meaningful relief from pain episodes during MET.

Deflazacort contributes through a different but complementary pathway. As a glucocorticoid, it suppresses the local inflammatory response triggered by stone impaction, thereby reducing the mucosal swelling that often forms a collar of oedematous tissue around the trapped stone. When this oedema resolves, the effective diameter of the ureteric lumen increases, potentially giving the stone enough clearance to descend. Prior work by Nayak *et al.,2008*[13] similarly found that adding a corticosteroid to an alpha-blocker regimen produced additive benefits in terms of stone clearance, an effect that was most pronounced in stones situated in the distal ureteric segment.

Evaluation of pain-related outcomes through the DN4 questionnaire and other symptom measures revealed a more pronounced reduction in pain burden among patients who

received the combination regimen. Those on combined treatment reported fewer pain episodes and lower overall pain intensity, an improvement that likely reflects the dual action of faster stone passage and diminished ureteral wall irritation. From a patient perspective, this reduction in pain has real significance — it translates to better daily functioning, improved treatment adherence, and a higher overall quality of life during the treatment period.

From a tolerability standpoint, both regimens were handled without significant difficulty by the study participants. Side effects recorded during follow-up — including headache, dizziness, postural drops in blood pressure, nasal congestion, joint pain, sleep disturbance, and loose stools — were transient and of low severity in the vast majority of cases, and none necessitated stopping treatment altogether. This tolerability data is broadly consistent with what earlier investigators have reported regarding the safety profiles of both tamsulosin and deflazacort when applied in the context of MET, as documented by Franco-Salinas *et al.,* 2010[12]; Calcort, 2008[15].

The outcomes from our study sit comfortably within the broader framework established by major international urological guidelines, which endorse the use of alpha-adrenergic blockers as a front-line pharmacological strategy for ureteric stones not exceeding 10 mm. Authoritative guidance from the European Association of Urology, alongside a body of randomised and observational evidence, has consistently highlighted that MET carries the potential to spare patients from invasive procedures while meaningfully enhancing the rate of spontaneous stone clearance Turk *etal.,* 2016([10]; Lee *et al.,* 2021[9].

Taken together, the data from this study make a persuasive case that combining tamsulosin with deflazacort delivers more reliable and clinically meaningful gains than tamsulosin alone. The advantage of the two-drug approach was evident not only in higher stone expulsion rates and shorter time-to-passage but also in the improved symptom control patients experienced — all while the safety profile remained acceptable and comparable to monotherapy.

Several limitations deserve acknowledgment when contextualising these findings. The investigation was carried out at a single institution, which inherently restricts the diversity of the patient population and may limit how broadly the results can be generalised. The sample size, while reasonable for a prospective observational design, was not large enough to draw definitive conclusions about all subgroups. Additionally, the follow-up window was relatively brief, precluding any meaningful assessment of stone recurrence or late complications. These shortcomings call for future research using multi-centre designs, larger cohorts, and longer observation periods to build a more robust evidence base.

In conclusion, this study adds to a growing body of evidence that positions the tamsulosin–deflazacort combination as an effective and well-tolerated treatment strategy for patients presenting with ureteric calculi. Its particular value lies in improving the likelihood of spontaneous stone passage in the distal ureter, thereby reducing the burden on both patients and healthcare systems by limiting the need for procedural intervention.

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