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Original Article

ROLE OF DEFLAZACORT AS AN ADJUVANT TO TAMSULOSIN IN ENHANCING EXPULSION OF MIDDLE AND LOWER URETERIC CALCULI: A PROSPECTIVE COMPARATIVE STUDY

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ABSTRACT

Objective: Ureteric calculi constitute a significant proportion of urolithiasis cases and commonly present with acute colicky pain, urinary symptoms, and recurrent morbidity. Medical expulsive therapy (MET) using α-blockers such as tamsulosin is widely practiced; however, adjunctive corticosteroids may further facilitate stone passage by reducing ureteric edema and inflammation. This study evaluates the effectiveness of combining deflazacort with tamsulosin versus tamsulosin monotherapy in enhancing expulsion of middle and lower ureteric stones.

Methods: This prospective comparative study was conducted at People's Hospital, Bhopal, from November 2022 to March 2024. A total of 170 eligible patients with unilateral middle or lower ureteric calculi (4–8 mm) were randomized into two groups**:** group A received tamsulosin 0.4 mg daily plus deflazacort (6 mg twice daily for 2 w, tapered to 6 mg once daily for 2 more weeks), and group B received tamsulosin monotherapy. Patients were followed for up to 4 w, with serial assessment of stone expulsion, analgesic requirement, and adverse events. Statistical analyses were performed using SPSS v26, with $p<0.05$ considered significant.

Results: Stone expulsion at 3 w was significantly higher in Group A compared to Group B (23.5% vs. 7.1%; $p<0.01$). By 4 w, expulsion rates further increased to 88.2% versus 52.9%, respectively ($p<0.01$). The overall treatment success rate was markedly superior in Group A (90.4%) compared to Group B (56.1%; $p<0.01$). Analgesic requirements were significantly lower with combination therapy (mean 4.59 vs. 6.38 doses; $p<0.01$). Adverse events were mild and comparable between groups.

Conclusion: Deflazacort as an adjunct to tamsulosin significantly enhances stone expulsion rates, accelerates clearance, and reduces analgesic use without increasing adverse effects. Combined MET is a safe and effective strategy for middle and lower ureteric calculi.

Keywords: Tamsulosin, Deflazacort, Medical expulsive therapy, Ureteric calculi, Stone expulsion, Urolithiasis

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INTRODUCTION

Urolithiasis is the formation of stones within the urinary tract, notably in the kidneys, ureters, bladder, or urethra. This condition, characterized by the development of kidney stones, is a painful urological disorder that impacts over 12% of the global population. Recurrence rates are significantly high; for males, they range from 70% to 81%, while for females, they fall between 47% and 60%. An evaluation indicates that at least 10% of individuals in industrialized areas are dealing with urinary stone formation [1, 2].

Stones situated in the mid-ureter typically cause pain that radiates forward, whereas those located in the lower ureter produce discomfort that may extend to the groin due to referred pain stemming from either the genitofemoral or ilioinguinal nerves. Additionally, calculi at the ureter vesical junction can lead to irritative voiding symptoms such as dysuria (painful urination) and increased urinary frequency [3, 4].

Among all types of urinary tract stones, approximately 22% are found in the ureter, with a significant 68% occurring in its distal section. The initial symptom associated with ureteric stones often presents as colicky pain; nearly half of patients experience this discomfort within five years following stone formation. Most patients report symptoms between their thirties and sixties, with peak incidence noted between ages 35 and 45 [5, 6].

Over recent decades, advancements in minimally invasive techniques have revolutionized the management of ureteral stones. Nonetheless, it is crucial to acknowledge that these procedures carry potential risks and can incur high costs.

Numerous studies have explored the impact of corticosteroids on ureteric stones [6, 7]. These agents exhibit anti-inflammatory and anti-edema effects. The presence of stones can induce inflammation in the mucosal lining, leading to swelling. To address or avert these inflammatory responses and facilitate stone passage from the body, corticosteroids may be utilized.

MATERIALS AND METHODS

It was a Prospective Observational Analytical Study conducted at Department of General Surgery of People's Hospital, Bhopal, associated with Peoples College Medical Sciences and Research Centre Bhopal. All patients who have been diagnosed with middle or lower ureteric calculi, who match the inclusion criteria, and who are willing to participate in the study are included in the study between November 2022 to March 2024.

Sample size is calculated using following formulae:

$$n=(Z\alpha/2+Z\beta)xPQ*2/d^2$$

So, by rounding off, we took 8 5 subjectsin each group i. e. a total of 170 subjects.

Eligibility criteria for inclusion were: patients over 18 y of age, both male and female, with unilateral ureteric stones sized 4-8 mm, no active urinary tract infection (UTI), no previous surgeries for ureteric calculi, and normal renal function tests.

Exclusion criteria included morbid obesity (BMI above 40), diabetes, multiple stones, pregnancy, paediatric patients, solitary functioning kidney, deranged renal function tests, previous stone disease surgeries (ESWL/PCNL), and obstructive uropathy.

Methods

Study was commenced after approval from Institutional ethical committee. A total of 170 patients of ureteric calculi presenting at our hospital, meeting the eligibility criteria were taken for study

after informed consent. After detailed history, examination, and investigations as per standard hospital protocol, cases were divided into two treatment arms using computer generated random numbers, the investigator were not be choosing the procedure:

GroupA:-patients were given Tamsulosin 0.4 mg once a day for 2 w and tab deflazacort (6 mg BD for 2 w then the dose was tapered on 6 mg OD for another 2 w)

Group B:-patients were given monotherapy of Tab Tamsulosin 0.4 mg once daily for 2 w.

Statistical analysis

The analysis of statistical data was carried out with SPSS Version 26.0, while graphical representations were constructed using Microsoft Excel 2021. Qualitative data was presented in terms of frequency and percentage. The relationships among qualitative variables were assessed through the Chi-Square test. Quantitative data was reported as mean values accompanied by standard deviations. For comparing quantitative data between the two groups, an unpaired t-test was employed if the data met the 'Normality test' criteria; otherwise, the Mann-Whitney Test was applied. A significance threshold of p-value<0.05 was established, and results were visually represented where deemed appropriate.

RESULTS

A cohort of 170 eligible patients was successfully enrolled and randomised in a 1:1 ratio into the two treatment groups. Baseline characteristics, including demographic and clinical variables, were comparable across both groups, confirming effective randomisation. Table 1 presents the distribution of subjects and the corresponding therapeutic assignments.

Table 1: Distribution of study groups

Group	N	%
Deflazacort+Tamsulosin (GroupA)	85	50.0%
Tamsulosin (Group B)	85	50.0%
Total	170	100.0%

Present study included 170 patients diagnosed as having middle or lower ureteric calculi, meeting the inclusion criteria and willing to participate in study. They were divided into two treatment arms using computer-generated random numbers, the investigator was not be choosing the procedure: Group A patients were given Tamsulosin 0.4 mg once a day and Tab Deflazacort (6 mg BD for 2 w then the dose was tapered on 6 mg OD for another 2 w). Group 2 patients were given monotherapy of Tab Tamsulosin 0.4 mg once a day.

Table 2: Comparison of study groups asper mean dose of analgesics

Variables	Group	N	Mean	SD	p-value
Mean doses of analgesic (1-dose 50 mg Diclo)	A	85	4.59	1.57	<0.01
	B	85	6.38	2.12	

Mean requirement of analgesics was significantly more in group B cases i. e. cases managed by tamsulosin monotherapy as compared to group A i. e. cases managed by combined therapy of tamsulosin with deflazacort (6.38 vs 4.59; p<0.01).

Table 3: Comparison of study groups asper any other intervention

Any other intervention	Group		Total
	A	B	
Yes	7	6	13
	8.2%	7.1%	7.6%
No	78	79	157
	91.8%	92.9%	92.4%
Total	85	85	170
	100.0%	100.0%	100.0%
p-value-1.0			

Supplementary interventions from stone expulsion were required in 8.2% cases of group A as compared to 7.1% cases of group B (p-1.0).

Table 4: Comparison of study groups as per location of calculus

USG-KUB(location of calculus)	2 w		3 w*		4 w*	
	A	B	A	B	A	B
Mid-ureter	37	38	6	18	0	4
	43.5%	44.7%	7.1%	21.2%	0.0%	4.7%
Distal ureter	48	47	59	60	8	33
	56.5%	55.3%	69.4%	70.6%	9.4%	38.8%
No stone visible	0	0	20	6	75	45
	0.0%	0.0%	23.5%	7.1%	88.2%	52.9%
Total	85	85	85	84	83	82
	100.0%	100.0%	100.0%	98.8%	97.6%	96.5%
p-value	1.00		<0.01		<0.01	

*1 case was excluded from study after 2nd week and 4 cases after 3rd week due to ADRs, Stone expulsion after 3 w was observed in 23.5% cases of group A as compared to 7.1% in group B (p<0.01). By end of 4 w, stone expulsion rate was 88.2% in group A as compared to 52.9% in group B (p<0.01).

Table 5: Comparison of study groups as per final outcome

Outcome	Group		Total l
	A	B	
Successful	75	46	121
	90.4%	56.1%	73.3%
Unsuccessful	8	36	44
	9.6%	43.9%	26.7%
Total	83	82	165
	100.0%	100.0%	100.0%
p-value<0.01			

*5 cases were excluded from study due to ADRS, Success as medical expulsive therapy for stone clearance was observed to be significantly higher in cases managed by combined therapy of tamsulosin with deflazacort as compared to tamsulosin monotherapy (90.4% vs 43.9%; p<0.01).

Table 6: Comparison of study groups as per adverse events

Adverse events	Group		Total	p-value
	A	B		
Flushing	3	0	3	
	3.5%	0.0%	1.8%	0.24
Frequent urination	3	4	7	
	3.5%	4.7%	4.1%	1.00
Headache	5	7	12	
	5.9%	8.2%	7.1%	0.76
Light headedness	4	2	6	
	4.7%	2.4%	3.5%	0.47
None	70	70	140	
	82.4%	82.4%	82.4%	1.00

Both the groups were comparable with regards to adverse reactions (p>0.05). Incidence of flushing was 3.5% vs 0%, frequent urination was 3.5% vs 4.7%, headache was 5.9% vs 8.2% and light-headedness was 4.7% vs 2.4%, respectively.

DISCUSSION

The ejection of calculi is influenced by several parameters, including the size, form, and position of the stone, as well as ureteric oedema and ureteric convolutions. The most crucial parameters among them are the placement and magnitude of the calculus.

In the present period, the care of patients with ureteral calculi has undergone significant changes. The primary emphasis is now on a conservative approach, which offers the main advantage of minimising patient morbidity. Typically, conservative non-surgical methods are used to treat distal ureteral stones that are 5-10 mm in size, as they are unlikely to pass on their own [8, 9]

More than 50% of the cases in the current research were in the age range of 31-40 y, with an average age of 39.4 y (p=0.74). The present study showed a higher proportion of men, accounting for 67.1% of the participants, compared to females who accounted for 32.9% (p-0.625). The findings of our study align with previous research, which indicates that the majority of instances involving ureteric calculus occur in individuals in their third decade of life. Additionally, males seem to be more impacted than females [10-12]. Multiple investigations have demonstrated that experiencing severe pain in the side of the body and the lower abdomen on the same side, which spreads to the testicles or the vulvar area, is a distinct symptom of a ureteric calculus. The primary symptom in the majority of patients is lower abdominal discomfort [13-15].

Analgesics were necessary in nearly all cases in both groups (p-1.0). The average need for pain relievers was substantially higher in group B cases, which were treated with only tamsulosin, compared to group A cases, which were treated with a combination of tamsulosin and deflazacort (6.38 vs 4.59; p<0.01). Sinha AR *et al.* [16] reported adverse drug reactions (ADRs) in patients receiving combination treatment (group I) and monotherapy (group II). Retrograde ejaculation was seen in 3 (6%) patients in Group I, whereas nausea was reported by 6 (12%) patients, dizziness by 4 (8%) patients, headache by 7 (14%) patients, vomiting by

5 (10%) patients, constipation by 6 (12%) patients, nasal congestion by 2 (4%) patients, and diarrhoea by 1 (2%) patient. Retrograde ejaculation was seen in 2 (4%) individuals, while nausea was reported by 4 (8%) patients. Dizziness was experienced by 5 (10%) patients, headache by 4 (8%) patients, vomiting by 3 (6%) patients, constipation by 0 (0%) patients, nasal congestion by 3 (6%) patients, and diarrhoea by 1 (2%) patient in Group II. There were no substantial side effects seen in any of the two groups. Kucukpolat S *et al.* [17] likewise found no difference in adverse effects between mono-and combination treatment.

In summary, our study data showed that the use of combination treatment led to a significant increase in the rate of ejection of ureteric stones. Furthermore, it provides expedited elimination of stones, decreased occurrence of painful episodes, and diminished requirement for pain medication. Both drugs are considered to be safe, effective, and well-tolerated, with low side effects.

CONCLUSION

The application of medical expulsive therapy (MET) alongside conservative approaches has gained popularity in recent years for addressing intermediate and distal ureteric stones. In our research, we evaluated the effectiveness of tamsulosin, both alone and in conjunction with deflazacort, as a medical expulsive treatment aimed at facilitating the clearance of stones located in the middle and lower ureters. Our results indicated that the combination therapy significantly increases the rate of ureteric stone expulsion compared to other methods. Furthermore, it promotes quicker stone removal, reduces the frequency of colic episodes, and diminishes the reliance on pain relief medications. Both tamsulosin and deflazacort are considered safe, effective, and generally well tolerated, with only a few sporadic side effects reported.

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AUTHORS CONTRIBUTIONS

All authors have contributed equally

CONFLICT OF INTERESTS

Declared none

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