Section: General Surgery

Original Research Article

ADVERSE EFFECT OF THE SPONTANEOUS PASSAGE OF LOWER URETERIC CALCULI 5-10MM SIZE UPON USAGE OF TAMSULOSIN AND DEFLAZACORT IN COMPARISON TO USAGE OF TAMSULOSIN ALONE

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Received *: 08/02/2026*
Received in revised form *: 24/03/2026*
Accepted *: 13/04/2026*

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DOI: 10.70034/ijmedph.2026.2.191

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2026; 16 (2); 1130-1134

ABSTRACT

Background: Urolithiasis remains a significant urological disorder worldwide, with lifetime prevalence estimates ranging between approximately 4 % and 15 % in various populations and a recurrence rate reaching up to 50 % in some series. The aim is to evaluate and compare the adverse effects associated with the spontaneous passage of 5–10 mm lower ureteric calculi in patients receiving combination therapy of tamsulosin and deflazacort versus tamsulosin alone.
Materials and Methods: This is a prospective comparative observational study conducted over 18 months at the Department of Urology, a tertiary care centre, including 60 patients with lower ureteric calculi measuring 5–10 mm.
Results: In the present study involving 119 patients, adverse effects were generally mild and comparable between the two groups. Headache was reported in 25 patients (41.67%) in Group A and 21 patients (35.59%) in Group B, with no significant difference (p = 0.496). Dizziness occurred in 21 patients (35%) from Group A and 18 patients (30.51%) from Group B (p = 0.602).
Conclusion: We concluded that , the spontaneous passage rates of 5–10 mm lower ureteric calculi were comparable between patients receiving tamsulosin with deflazacort (Group A) and those receiving tamsulosin alone (Group B), demonstrating similar overall efficacy. Group A showed a significantly higher passage rate for stones located in the lower ureter compared to VUJ stones, suggesting a potential benefit of combination therapy in specific stone locations.
Keywords: Urolithiasis, Tamsulosin, Deflazacort, Spontaneous stone passage and Ureteric colic.

INTRODUCTION

Urolithiasis remains a significant urological disorder worldwide, with lifetime prevalence estimates ranging between approximately 4 % and 15 % in various populations and a recurrence rate reaching up to 50 % in some series.[1] Among ureteric stones, those located in the lower ureter carry greater symptomatic burden owing to increased incidence of renal colic, hematuria, lower urinary tract symptoms, and renal drainage impairment. The likelihood of spontaneous passage of ureteric calculi is influenced importantly by stone size and location. Stones measuring less than 5 mm often pass spontaneously in a high proportion of patients, but those in the 5–10 mm size range — particularly in the lower ureter — demonstrate substantially lower spontaneous passage rates, reported in some series as low as 25–53 %.[2] Given the morbidity associated with ureteric stones and the costs and risks of invasive interventions, conservative approaches aiming to facilitate stone expulsion have become increasingly important.Medical expulsive therapy (MET) has emerged as a pragmatic, non-invasive strategy for selected patients with distal ureteric stones. Among the pharmacological agents used in MET, the α_1-adrenergic receptor antagonist Tamsulosin has been extensively studied. Tamsulosin acts by relaxing ureteric smooth muscle tone and reducing ureteral spasm, thereby facilitating stone passage and decreasing time to expulsion in several meta-analyses and randomized trials.[3] In addition to the effect of smooth muscle relaxation, adjunctive therapies targeting the inflammatory changes and oedema of

the ureteric wall caused by calculi have been explored. In this regard, corticosteroids — such as Deflazacort — have been used in combination with tamsulosin to reduce local ureteric oedema and inflammation, hypothesised to augment stone passage rates and reduce expulsion time.[4] Several studies have compared tamsulosin alone versus tamsulosin combined with deflazacort or other corticosteroids. For instance, a randomized trial by Francesco Porpiglia et al. demonstrated that the combination therapy significantly improved passage rates of distal ureteric stones ≤10 mm compared to tamsulosin alone.[5] Likewise, more recent observational studies in Indian populations have similarly reported enhanced expulsion outcomes with the addition of low-dose deflazacort to tamsulosin—even when focusing on medium-sized stones in the 5-10 mm range.[6] To evaluate and compare the adverse effects associated with the spontaneous passage of 5–10 mm lower ureteric calculi in patients receiving combination therapy of tamsulosin and deflazacort versus tamsulosin alone.

MATERIALS AND METHODS

Type of Study: Prospective comparative observational study.

Place of Study: Patients attending the out-patient department and In-Patients at Department of Urology, at a tertiary care centre.

Study Duration: The study was completed within a period of 18 months.

Sample Size: 60 lower ureteric calculi measuring 5–10 mm patients

Inclusion Criteria

- Patients aged 18–65 years.
- Diagnosed with lower ureteric calculus measuring 5–10 mm confirmed by imaging (USG, KUB X-ray, or NCCT).
- Patients planned for medical expulsive therapy (MET) with tamsulosin, with or without deflazacort.
- Patients who provide informed consent for participation in the study.

Exclusion Criteria

- Patients with allergy or contraindication to tamsulosin or deflazacort.
- Presence of urinary tract infection or sepsis at presentation.
- Renal insufficiency or chronic kidney disease.
- Pregnant or lactating women.
- Patients with bilateral ureteric stones or multiple stones.
- Patients with ureteric strictures, congenital anomalies, or prior ureteric surgery.

Study Variables

- Tamsulosin alone
- Tamsulosin + Deflazacort
- Gastrointestinal
- Insomnia or mood changes

Statistical Analysis: Data were entered into Excel and subsequently analyzed using SPSS and GraphPad Prism. Continuous variables were summarized as means with standard deviations, while categorical variables were presented as counts and percentages. Comparisons between independent groups were performed using two-sample t-tests, and paired t-tests were applied for correlated (paired) data. Categorical data were compared using chi-square tests, with Fisher's exact test applied when expected cell counts were small. A p-value of ≤ 0.05 was considered statistically significant.

RESULTS

Table 1: Comparing age, Size of Calculus, Expulsion time (days), No of colic episodes between two groups.

	GROUP A			GROUP B			p -value
	Mean	Median	Std. Deviation	Mean	Median	Std. Deviation	
Age	33.38	31	10.15	31.72	30.5	9.08	0.4
Size of Calculus	7.48	7.25	1.53	7.1	7	1.45	0.199
Expulsion Time (Days)	10.93	10	5.26	11.26	10	4.78	0.686
No of Colic episodes	2.65	2	2.84	2.64	2	2.45	0.726

Table 2: Distribution of Age, Side, Location, and Spontaneous Passage of Calculus

Parameter	Category	Group A n (%)	Group B n (%)	Total n (%)	P-value
Age Distribution	18–20	1 (1.67)	0 (0)	1 (0.83)	0.309
	21–30	28 (46.67)	30 (50)	58 (48.33)	
	31–40	17 (28.33)	23 (38.33)	40 (33.33)	
	41–50	9 (15)	3 (5)	12 (10)	
	51–60	4 (6.67)	4 (6.67)	8 (6.67)	
	61–70	1 (1.67)	0 (0)	1 (0.83)	
	Total	60 (100)	60 (100)	120 (100)	
Side Distribution	Left	17 (28.33)	19 (31.67)	36 (30)	0.69
	Right	43 (71.67)	41 (68.33)	84 (70)	
	Total	60 (100)	60 (100)	120 (100)	
Location of Calculus	Lower ureteric calculi	42 (70)	35 (58.33)	77 (64.17)	0.183
	Vesico-ureteric junction	18 (30)	25 (41.67)	43 (35.83)	
	Total	60 (100)	60 (100)	120 (100)	
Spontaneous Passage	No	5 (8.33)	6 (10)	11 (9.17)	0.752
	Yes	55 (91.67)	54 (90)	109 (90.83)	
	Total	60 (100)	60 (100)	120 (100)	

Table 3: Spontaneous passage for Right and Left side calculus

Group			Side		Total	P -value
			Left	Right		
Group A	Spontaneous Passage	No	2(11.76)	3(6.98)	5(8.33)	0.616
		Yes	15(88.24)	40(93.02)	55(91.67)	
	Total		17(100)	43(100)	60(100)	
Group B	Spontaneous Passage	No	2(10.53)	4(9.76)	6(10)	0.926
		Yes	17(89.47)	37(90.24)	54(90)	
	Total		19(100)	41(100)	60(100)	

Table 4: Comparing the spontaneous passage for the location of calculus in the individual groups

Group			Location		Total	P- value
			Lower Ureteric Calculi (except VUJ)	Vesico Ureteric Junction		
Group A	Spontaneous Passage	No	1(2.38)	4(22.22)	5(8.33)	0.025
		Yes	41(97.62)	14(77.78)	55(91.67)	
	Total		42(100)	18(100)	60(100)	
Group B	Spontaneous Passage	No	4(11.43)	2(8)	6(10)	0.663
		Yes	31(88.57)	23(92)	54(90)	
	Total		35(100)	25(100)	60(100)	

Table 5: Analgesics usage in group A and group B

		Group A	Group B	Total	P-value
Analgesic Usage	No	29(48.33)	18(30.51)	47(39.5)	0.047
	Yes	31(51.67)	41(69.49)	72(60.5)	
Total		60(100)	59(100)	119(100)	

Table 6: Comparison of Adverse Effects (Headache, Dizziness, Orthostatic Hypotension, and Gastritis) between Group A and Group B

Parameter	Category	Group A n (%)	Group B n (%)	Total n (%)	p-value
Headache	No	35 (58.33)	38 (64.41)	73 (61.34)	0.496
	Yes	25 (41.67)	21 (35.59)	46 (38.66)	
	Total	60 (100)	59 (100)	119 (100)	
Dizziness	No	39 (65)	41 (69.49)	80 (67.23)	0.602
	Yes	21 (35)	18 (30.51)	39 (32.77)	
	Total	60 (100)	59 (100)	119 (100)	
Orthostatic Hypotension	No	48 (80)	48 (81.36)	96 (80.67)	0.851
	Yes	12 (20)	11 (18.64)	23 (19.33)	
	Total	60 (100)	59 (100)	119 (100)	
Gastritis	No	39 (65)	43 (72.88)	82 (68.91)	0.353
	Yes	21 (35)	16 (27.12)	37 (31.09)	
	Total	60 (100)	59 (100)	119 (100)	

In our study the mean age of patients in Group A was 33.38 ± 10.15 years (median = 31), while in Group B it was 31.72 ± 9.08 years (median = 30.5), showing no significant difference (p = 0.4). The mean size of calculus was slightly higher in Group A (7.48 ± 1.53 mm; median = 7.25) compared to Group B (7.10 ± 1.45 mm; median = 7), but the difference was not statistically significant (p = 0.199). The mean expulsion time was 10.93 ± 5.26 days in Group A and 11.26 ± 4.78 days in Group B (p = 0.686). The average number of colic episodes was comparable between the two groups—2.65 ± 2.84 in Group A and 2.64 ± 2.45 in Group B—with no significant difference (p = 0.726). In the present study of 120 patients (60 in each group), most were aged 21–40 years, with 28 (46.67%) and 30 (50%) patients aged 21–30 years, and 17 (28.33%) and 23 (38.33%) aged 31–40 years in Groups A and B, respectively (p = 0.309). Right-sided calculi predominated in both groups—43 (71.67%) in Group A and 41 (68.33%) in Group B (p = 0.69). Lower ureteric calculi were more common, found in 42 (70%) and 35 (58.33%) patients in Groups A and B, respectively, while vesico-ureteric junction calculi occurred in 18 (30%) and 25 (41.67%) patients (p = 0.183). Spontaneous passage was observed in 55 (91.67%) patients of Group A and 54 (90%) of Group B, with no significant difference (p = 0.752). In Group A, spontaneous passage of calculi occurred in 55 patients (91.67%), while 5 patients (8.33%) did not pass the stones spontaneously. Among these, 15 (88.24%) of 17 left-sided and 40 (93.02%) of 43 right-sided calculi passed spontaneously, showing no statistically significant association between side and spontaneous passage (p = 0.616). Similarly, in Group B, spontaneous passage was observed in 54 patients (90%), while 6 patients (10%) did not. Among them, 17 (89.47%) of 19 left-sided and 37 (90.24%) of 41 right-sided stones passed spontaneously, with no significant side-wise difference (p = 0.926). In Group A, spontaneous passage of calculi occurred in 55 patients (91.67%), while 5 patients (8.33%) failed to pass the stones. Among lower ureteric calculi (excluding VUJ), 41 out of 42 patients (97.62%) achieved spontaneous passage, compared to 14 out of 18 patients (77.78%) with vesico-ureteric junction

calculi. This difference was statistically significant (p = 0.025), indicating a higher passage rate for lower ureteric stones than for VUJ stones. In contrast, Group B showed spontaneous passage in 54 patients (90%) and failure in 6 patients (10%). Among these, 31 out of 35 patients (88.57%) with lower ureteric calculi and 23 out of 25 patients (92%) with VUJ calculi achieved passage, with no significant difference between locations (p = 0.663). Analgesic use was reported in 31 patients (51.67%) in Group A and 41 patients (69.49%) in Group B, while 29 (48.33%) and 18 (30.51%) patients in Groups A and B, respectively, did not require analgesics. Overall, 72 out of 119 patients (60.5%) required analgesic medication. The difference between the two groups was statistically significant (p = 0.047). In the present study involving 119 patients, adverse effects were generally mild and comparable between the two groups. Headache was reported in 25 patients (41.67%) in Group A and 21 patients (35.59%) in Group B, with no significant difference (p = 0.496). Dizziness occurred in 21 patients (35%) from Group A and 18 patients (30.51%) from Group B (p = 0.602). Orthostatic hypotension was observed in 12 (20%) and 11 (18.64%) patients of Groups A and B, respectively, showing no significant variation (p = 0.851). Gastritis was reported in 21 (35%) patients of Group A and 16 (27.12%) of Group B, again with no statistically significant difference (p = 0.353).

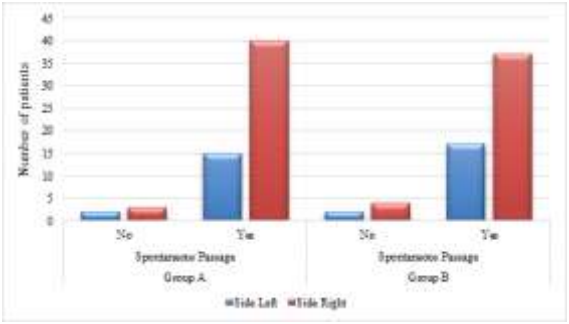

Figure 1: Spontaneous passage for Right and Left side calculus

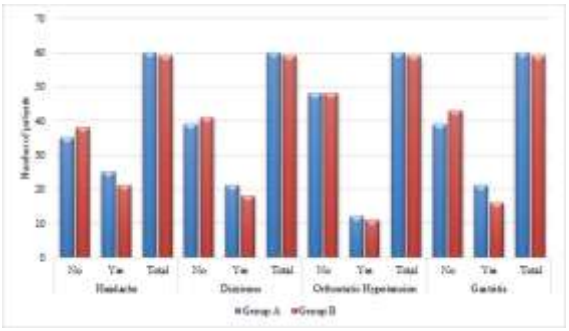

Figure 2: Comparison of Adverse Effects between Group A and Group B

DISCUSSION

We found that both groups were comparable in their baseline characteristics, including age, stone size, expulsion time, and number of colic episodes, with no statistically significant differences between them. The mean age was 33.38 ± 10.15 years in Group A and 31.72 ± 9.08 years in Group B (p = 0.4), and the mean stone size was 7.48 ± 1.53 mm and 7.10 ± 1.45 mm, respectively (p = 0.199). The mean expulsion time and number of colic episodes were also similar between the groups (p = 0.686 and p = 0.726, respectively). Most patients in both groups were within the 21–40-year age range, and right-sided lower ureteric calculi were predominant, showing no significant group-wise difference (p = 0.69). Spontaneous stone passage occurred in 91.67% of patients in Group A and 90% in Group B, indicating comparable efficacy (p = 0.752). When analyzed according to side, no significant difference in passage rates was observed in either group. However, when analyzed by stone location, a significant difference was noted in Group A, where lower ureteric stones had a higher spontaneous passage rate (97.62%) compared to vesico-ureteric junction (VUJ) stones (77.78%) (p = 0.025), while Group B showed no such difference (p = 0.663).Analgesic requirement differed significantly between the groups, with 51.67% of patients in Group A and 69.49% in Group B requiring analgesics (p = 0.047). This finding suggests that patients in Group A experienced less pain or discomfort, reflecting better overall tolerance and comfort during treatment. In similar study by Ye et al. (2018),[7] who reported a pooled expulsion rate of 86% in patients receiving medical expulsive therapy (MET) with tamsulosin for distal ureteral stones ≤10 mm. Similarly, Shalaby et al. (2022),[8] found an 88% expulsion rate among patients treated with α-blockers, demonstrating comparable efficacy to our findings. Pickard et al. (2015),[9] in the large randomized SUSPEND trial, reported no significant difference between tamsulosin and placebo in stone expulsion, particularly for smaller stones, highlighting the variability of MET outcomes across trials. When analyzed by stone location, our study found that Group A had a significantly higher spontaneous passage rate for lower ureteric stones (97.62%) compared with vesico-ureteric junction (VUJ) stones (77.78%) (p = 0.025). This finding agrees with the observations of Vincendeau et al. (2010),[10] who reported that distal stones, particularly those just above the VUJ, have variable passage rates influenced by local ureteric peristalsis and anatomic narrowing. Wood et al. (2014),[11] also emphasized that the success of MET depends on stone location, size, and ureteric smooth muscle tone. The significant difference in analgesic requirement between groups—51.67% in Group A and 69.49% in Group B (p = 0.047)—suggests that patients in Group A experienced less pain and required fewer analgesics during treatment. Similar results were noted by Meltzer et al. (2018),[12] who reported a lower frequency of colic episodes and analgesic use among patients receiving α-blockers compared with placebo. Rahman et al. (2018),[13] also found that silodosin, an α1A-selective blocker, significantly reduced pain episodes and analgesic requirement

compared to tamsulosin and combination regimens. Our findings are further supported by Wang et al. (2016),[14] whose meta-analysis concluded that α-blockers not only facilitate distal ureteral stone expulsion but also reduce analgesic consumption and time to stone passage.

We observed that the incidence of adverse effects was comparable between Group A and Group B, indicating that both treatment regimens were generally well tolerated. Headache was slightly more frequent in Group A (41.67%) compared to Group B (35.59%), but the difference was not statistically significant (p = 0.496). Similarly, dizziness occurred in 35% of patients in Group A and 30.51% in Group B (p = 0.602), showing no meaningful variation. Orthostatic hypotension was reported in 20% of Group A and 18.64% of Group B (p = 0.851), while gastritis was noted in 35% and 27.12% of patients, respectively (p = 0.353). These findings suggest that both groups experienced similar rates of mild adverse effects, with no severe or treatment-limiting complications. In other study by Orthostatic hypotension was observed in 20% of patients in Group A and 18.64% in Group B in our study, which corresponds closely to the findings of Rahman et al. (2018),[15] who reported transient hypotension in 15–20% of patients treated with α-blockers.

CONCLUSION

We concluded that , the spontaneous passage rates of 5–10 mm lower ureteric calculi were comparable between patients receiving tamsulosin with deflazacort (Group A) and those receiving tamsulosin alone (Group B), demonstrating similar overall efficacy. Group A showed a significantly higher passage rate for stones located in the lower ureter compared to VUJ stones, suggesting a potential benefit of combination therapy in specific stone locations. Analgesic requirement was significantly lower in Group A, indicating better pain control and patient comfort. Both regimens were generally well tolerated, with mild adverse effects such as headache, dizziness, orthostatic hypotension, and gastritis occurring at similar rates, and no severe or treatment-limiting complications were observed. These findings support the safety and tolerability of both treatment approaches.

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