Original Research Article

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Role of tamsulosin in the management of lower ureteric stone at tertiary care hospital in Western Rajasthan, India

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ABSTRACT

Background: Many minimally invasive interventional techniques as well as expectant treatments exist for the management of lower ureteric calculi.

Methods: 100 patients [group A (50 patients) patients given capsule tamsulosin 0.4mg, 1 daily up to 4 weeks while group B (50 patients) patients given regularly practiced treatment without Tamsulosin] with distal ureteric stone included in the study. Study duration was 6 months and study performed at S.P. Medical College. Bikaner, Rajasthan, India

Results: Group A showed a statistically significant advantage in terms of the stone expulsion rate. 41 patients (82%) in group A and 30 patients (60%) in group B expelled stones. Overall patients in group A had mean expulsion time of 7.86 days, whereas in group B mean expulsion time was 18.64 days. In group A stone expulsion rate was higher as compared to group B. In group A only 12 (24%) patients experienced pain relapses whereas in group B 32 (64%) patients reported pain relapses. The diclofenac dosage required in group A was observed to be 1.62 tablets whereas in group B it was 2.6 tablets.

Conclusions: It is concluded that tamsulosin should be considered for uncomplicated distal ureteral calculi before ureteroscopy or extracorporeal lithotripsy. Tamsulosin has been found to increase and hasten stone expulsion rates, decrease acute attacks by acting as a spasmolytic, reduces mean days to stone expulsion and decreases analgesic dose usage.

Keywords: Lower ureteral calculi, Tamsulosin

INTRODUCTION

Symptomatic ureteric calculi represent the most common condition encountered by a urologist in an emergency setting. Among all ureteral stones, 70% are found in the lower third of the ureter. The goal of the surgical treatment of patients suffering from ureteral calculi is to achieve complete stone clearance with minimal morbidity. Many minimally invasive interventional (e.g. ESWL, ureterorenoscopy, the holmium: YAG laser and basket devices) as well as expectant (watchful waiting) treatments exist for the management of lower ureteric

calculi. But the choice of the ideal method to be taken up largely depend on the type of equipment available, location, type and size of stone, needs of the patient and skills of the surgeon.⁴ The stone burden remains the primary factor in deciding the appropriate treatment for a patient with ureteral calculi.⁵ Ureteral calculi discovered in distal ureter at the time of presentation have a 50% chance of spontaneous passage, in contrast to a 25% and 10% chance in the mid and proximal ureter respectively.⁶ Consequently, observation has been advocated for small ureteral stones with a high probability to pass. Recently, medical expulsion therapy (MET) has been investigated

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as a supplement to observation in an effort to improve spontaneous stone passage rates, which can be unpredictable. Because ureteral edema and ureteral spasm have been postulated to affect stone passage, these effects have been targeted for pharmacologic intervention. Therefore, the primary agents that have been evaluated for MET are calcium channel blockers, steroids, nonsteroidal anti-inflammatory drugs (NSAIDs), and α_1 adrenergic receptor antagonists. Alpha-1-adrenergic receptor antagonists have some degree of selectivity for the detrusor and the distal ureter and have therefore been the next agents investigated for their potential to promote stone expulsion and decrease pain.^{7,8} The likely mechanism that α -blockers use in stone passage has been to reduce ureteral spasm, increase pressure proximal to the stone, and relax the ureter in the region of and distal to the stone.¹² The rationale in using α_1 antagonists in MET has been that they are capable of decreasing the force of ureteral contraction, decreasing the frequency of peristaltic contractions, and increasing the fluid bolus volume transported down the ureter. 9-11 Tamsulosin has been the most commonly studied α_1 -blocker in the treatment of human prostate and ureteral stones; however, the data have been extrapolated and clinically tested on other α -blockers as well. At least three discrete alpha1adrenoceptor subtypes have been identified: alpha1a, alpha1b and alpha1d; their distribution differs between human organs and tissue. Tamsulosin has equal affinity for α_{1a} and α_{1d} receptors. 13 The α_{1d} receptor is the most common receptor in the ureter and is most concentrated in the distal ureter.14

METHODS

The present study titled "Role of tamsulosin in the lower ureteric stone management in a tertiary care hospital of Western Rajasthan" was performed in Department of Surgery, Sardar Patel Medical College and Associated Group of Hospitals, Bikaner, Rajasthan, India in 2016 on 100 patients with distal ureteric calculus. These patients were divided into 2 groups randomly. First group was treated with tamsulosin whereas second group was prescribed regular treatment.

Aims of present study were to see impact of tamsulosin in expulsion of distal ureteral stone, reducing colicky painful episodes and analgesic requirement in patients of distal ureteric calculus.

It was a comparative prospective hospital based study. All patients with age >18 years and <60 years and 4-10mm sized stone in distal 1/3 of ureter were included in the study. Patients with distal ureteric stricture, solitary kidney, aberrant ureteral anatomy, radiolucent stone and pregnant females were excluded from study.

100 patients were included in study. These patients were divided into two groups A and B. Group A (50 patients) Patients were given capsule tamsulosin 0.4mg, 1 daily up to 4 weeks or till spontaneous passage of stone

(whichever is earlier). Analgesic tab diclofenac 50mg was given as on demand during the study. Group B (50 patients) patients were given regularly practiced treatment like high fluid intake, analgesic diclofenac tab 50mg as on demand during study.

Procedure of data collection

Basic investigations like blood CBC, RFT, urine R/E done. X-ray KUB and USG KUB done at the beginning of treatment. IVP or CT done on required basis. After starting of treatment USG KUB done weekly or earlier while X-RAY KUB done fortnightly.

Successful results were defined as complete stone passage of stone as evidenced by patient was confirmed by usg kub within 4 week or earlier. Failure was considered if the patient failed to pass the stone at the end of 28 days or uncontrolled pain and /or uroseptic fever to patient. For data analysis Microsoft excel and statistical software SPSS was used and data was analyzed with the help of frequencies, figures, proportions, measures of central tendency, appropriate statistical test wherever required. P-value<0.05 was considered significant.

RESULTS

This study titled role of tamsulosin in lower ureteric stone performed in 100 patients. Group A patients were given cap tamsulosin while group B patients were given regularly practiced treatment. The observation of present study are as follows.

Table 1: Demographic and clinical characteristics of both groups.

	Cases (group A) n=50	Controls (group B) n=50
Mean patient age (years)	34.04	35.04
Sex (male:female)	35:15	39:11
Stone size		
4-6mm	32	33
7-10mm	18	17
Mean size (mm)	5.62	5.14

Table 1 shows that there was no statistical significant difference in age, gender and stone size distribution between the two groups. In group A 32 (64%) patients had stone size 4-6mm whereas 18 (36%) had stone size 7-10mm. In group B 33 (66%) patients had stone size 4-6 mm and 17 (34%) had stone size 7-10mm. Mean ureteric calculus size in group A and B were 5.62mm and 5.14mm respectively.

Table 2 explains distribution of patients according to number of pain relapses they had in follow up/admission. In group A only 12 (24%) patients experienced pain relapses whereas in group B 32 (64%) patients reported

pain relapses. In group A 38 (76%) patients experienced no episode of pain relapse whereas only 18 (36%) patients were pain free in group B.

Table 2: Distribution of patients in both groups according to episodes of pain relapses during admission/ follow up.

No. of relapses	Cases (group A) n=50		Controls (group B) n=50	
	No.	%	No.	%
0	38	76	18	36
1-3	8	16	22	44
4-7	4	8	6	12
>7	0	0	4	8

Table 3 states distribution of patients in both groups according to stone expulsion time. Overall patients in group A had mean expulsion time of 7.86 days, whereas in group B mean expulsion time was 18.64 days. In group A stone expulsion rate was higher as compared to group

B. The difference between duration of stone expulsion in both groups was found to be statistically significant (p=0.012).

Table 3: Distribution of cases and controls according to stone expulsion time.

Stone size	Duration of stone expulsion (number of days)		
(mm)	Cases (group A) n=50	Controls (group B) n=50	
	Mean	Mean	
4-6	3.2	7.6	
7-10	10.42	20.06	
Overall	7.86	18.64	

Table 4 states distribution of patients in both groups according to expulsion rate; Overall 41 patients (82%) in group A and 30 patients (60%) in group B expelled calculus.

Table 4: Distribution of patients in both groups according to expulsion of stone.

Stone size (mm)	CASES (group A) n=50		Controls (group B) n=50			
	No. of patients	No. of patients expelled stone	•	No. of patients	No. of patients expelled stone	% of patients expelled stone
4-6	32	27	84.38%	33	20	60.61%
7-10	18	14	77.78%	17	10	58.82%
Total	50	41	82%	50	30	60%

In group A and B maximum number of patients 27 (84.38%) and 20 (60%) respectively, who expelled calculus were in 4-6mm size. In patients with 7-10mm calculus size expulsion rate of group A was higher as compared to group B as 14 (77.78%) and 10 (58.82%) respectively.

The number of patients in both groups when analyzed for size of stone expelled were observed to be statistically highly significant (p=0.028).

Distribution of patients in both groups according to analgesic requirement.

Stone size (mm)	Cases (group A) n=50 Mean doses of diclofenac tab	Controls (group B) n=50 Mean doses of diclofenac tab
4-6	1	1.58
7-10	4.875	6.18
Total	1.62	2.6

Table 5 states distribution of patients in both groups according to doses of tablet Diclofenac sodium required

by them during pain relapses; Overall the diclofenac dosage required in group A was observed to be 1.62 tablets whereas in group B it was 2.6 tablets. The variation between doses required by patients in both groups was found to statistically significant (p=0.02).

DISCUSSION

In present study in group A 32 (64%) patients had stone size 4-6mm and 18 (36%) had stone size 7-10mm whereas in group B 33 (66%) patients had stone size 4-6mm and 17 (34%) had stone size 7-10mm. In group A mean stone size is 5.62mm and in group B it is 5.14mm and the difference was observed to be statistically significant. Dellabella M et al observed in their study that mean stone size in two groups was 5.8 and 6.7 mm (p=0.001). Ahmed H et al reported mean stone size to be 5.78mm (range 4-8mm) in greatest dimension. Sebastein V et al studied that out of total 129 patients, at inclusion, mean (SD) stone diameters were 3.2 (1.2) and 2.9 (1.0) mm in the placebo and tamsulosin groups. 17

In present study in group A only 12 (24%) patients experienced pain relapses whereas in group B 32 (64%) patients reported pain relapses. In group A 38 (76%)

patients experienced no episode of relapse of pain whereas only 18 (36%) patients were pain free in group B. Maximum number of patients 8 (16%) and 22 (44%) were having 1-3 episodes of pain relapses in group A and B respectively.

Resim S et al observed that as group 1 patients were passing their stones, they had more ureteral colic episodes than group 2 patients.²² This difference was statistically significant and correlated well with the administration of tamsulosin (P=0.038). Group 1 patients reported higher scores according to a visual analog scale than group 2 patients. Also, this difference was statistically significant (P=0.000). Mohammed AB et al found in their study that the number of pain episodes was significantly lower in group B (tamsulosin group) and mean use of analgesics was lower for group B (0.14±0.5 vials) than group A (2.78±2.7 vials).²¹ M S Griwan et al observed that group II (tamsulosin group) showed a statistically significant advantage in terms of mean number of pain episodes.¹⁶

In present study mean time of stone expulsion for group A and B were 7.86 and 18.64 days respectively with difference of 11 days in both groups. Among stone sized based categories also stone expulsion time of group A was lesser as compared to group B. The difference between duration of stone expulsion between both groups was found to be statistically significant (p=0.012). Abdullah AA et al observed in their double blind randomized controlled trial that Median time to stone passage was 7 days in the tamsulosin arm and 10 days in the placebo arm (log-rank test, p=0.36). Ahmed H et al observed in a randomized control trial that group A patients, who were given capsule tamsulosin 0.4mg had stone expulsion rate of 85.71% (42 patients) and 54.20% (26 patients) in group B patients (placebo group).

Group A revealed statistically significant advantage in term of stone expulsion rate (p=0.032). Considering expulsion time in days group A showed statistically significant advantage (p=0.015). Ferre MR et al found in their study that successful spontaneous stone expulsion at 14 days was similar between the groups, with 27 (77.1%) subjects in the tamsulosin group and 24 (64.9%) subjects in the standard therapy group, a difference of 12% (95% CI- 8.4% to 32.8). Dellabella M et al observed in their study that Mean expulsion time was 111.1 hours for control group and 65.7 hours for tamsulosin group (p=0.020). Mohammed AB et al found in their study that the average time to expulsion was 12.53±2.12 days for group A (control group) and 7.32±0.78 days for group B (tamsulosin group) (p=0.04). Explain the state of the stat

In present study in group A 27 out of 32 patients (84.38%) successfully expelled stone who had stone size of 4-6 mm whereas in group B this proportion was 20 out of 33 (60.61%). In stone size range of 7-10mm, 77.78% patients (14 out of 18) successfully expelled stone in group A whereas in group B this proportion was also

lower i.e. 58.82% (10 out of 17). Overall expulsion rate in group A was 82% whereas in group B it was only 60%. Mohammed AB et al found in their study that the stone expulsion rate was 51.1% for group A (regular), compared to 88.9% for group B (Tamsulosin) (p=0.001).²¹ The proportion of cases and controls when analysed for size of stone expelled were observed to be statistically highly significant ($\chi^2=11.67$, df=1, p=0.001). Abdullah AA et al observed in their double blind randomized controlled trial that no statistically significant differences in patient characteristics and stone size (median: 4.1 mm [tamsulosin arm] vs 3.8 mm [placebo arm], p = 0.3) were found between the two treatment arms.¹⁹ The stone expulsion rate was not significantly different between the tamsulosin arm (86.7%) and the placebo arm (88.9%; p=1.0). Gupta G et al observed stone free rate were higher in tamsulosin group and less number of times use of diclofenac as well as less time to expulsion of fragments were prominent findings of study.15

In present study tablet diclofenac sodium requirement in patients of group A was observed to be 1.62 tablets whereas in patients of group B it was 2.6 tablets. The variation between doses required in patients of both groups was found to statistically significant (p=0.02).

Dellabella M et al observed in their study that the mean number of diclofenac injections was 2.83 for group 1 and 0.13 for group 2 (p<0.0001). Griwan MS et al observed a statistically significant advantage in terms of mean dose of diclofenac sodium used by both groups 63.33 ± 55.60 mg per patient in group I and 30.00 ± 33.73 mg in group II. Griwan MS et al observed a statistically significant advantage in terms of mean dose of diclofenac sodium used by both groups 63.33 ± 55.60 mg per patient in group I and 30.00 ± 33.73 mg in group II.

CONCLUSION

It is concluded that tamsulosin should be considered for uncomplicated distal ureteral calculi before ureteroscopy or extracorporeal lithotripsy. Tamsulosin has been found to increase and hasten stone expulsion rates, decrease acute attacks by acting as a spasmolytic, reduces mean days to stone expulsion and decreases analgesic dose usage.

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