

Original Research**Role of Tamsulosin In Ureteric Stones - A Prospective Study****Anish G verghese¹, Kim Mammen², Uttam George³**¹*Assistant Professor, Department of Surgery, CMC&H, Ludhiana*²*Professor & HOD, Department of Urology, AIIMS, Rishikesh*³*Professor & HOD, Department of Radiology, CMC&H, Ludhiana*

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ABSTRACT

We have done a study using tamsulosin for ureteric stones less than or equal to 8mm. All the patients were randomized into study and control group. In study group patients who had ureteric colic due to ureteric calculi that measures less than or equal to 8mm were given tamsulosin along with symptomatic treatment for pain and hydration therapy. In control group the patient who had ureteric colic due to ureteric calculi that measure less than or equal to 8mm were given pain relief and hydration therapy.

We concluded- the average episodes of colic per week was less in the study group (1.06 in the study and 1.29 in the control group). The average dose of the most commonly used injectable analgesic(morphine) in the present study was 1mg while it was 1.66mg in the control group. The average no. of injectable boluses required by a patient in the study group was less compared to the control group, 1 and 1.66in the study and control group respectively. The fact that our control group had all the patients with calculus less than 5mm in size influenced the results with the fact that spontaneous expulsion without any treatment would be more in the control group.

INTRODUCTION

Ureteric colic has been an age-old problem encountered in medical practice. Ureteric stones are a known cause of this problem. Many conservative medical therapies have been researched and studied. Tamsulosin, an Alpha 1A specific inhibitor which was initially used in the treatment of benign prostatic hyperplasia has recently been shown to increase the rate of spontaneous passage of distal ureteral stones.¹ Alpha 1 adrenergic blocker Tamsulosin reduces muscles spasm in the ureteric wall, decreases peristalsis below and raises pressure above the stone thus facilitating stone passage. Use of Tamsulosin 0.4mg daily in patients with distal ureteric stones is clinically safe and cost effective.²

A study was done to compare the effectiveness of two different medical therapies. Tamsulosin and Nifedipine were compared. Tamsulosin was found to be better in respect of average stone size expelled and average expulsion time.³ Effect of Tamsulosin on the number and intensity of ureteric colic in patients with lower ureteral calculus was studied. Higher rate of spontaneous expulsion was noted when Tamsulosin

was used along with hydration and pain relief. It was found to be more effective in terms of decreasing the number of ureteric colic episodes and the intensity of pain during spontaneous passage of the lower ureteral calculi.⁴

In another study, efficacy of Alfuzosin was compared to Tamsulosin in the management of lower ureteric stones. Though Tamsulosin appeared to be better than Alfuzosin, there was no statistical significance between the two and Alfuzosin was associated with fewer side effects than Tamsulosin.⁵

Alpha 1 blocker have also been used following Extracorporeal Shock Wave Lithotripsy (ESWL) for lower ureteric stones. But no benefit was noted in regard to increasing stone expulsion rate or decreasing expulsion time.⁶

Tamsulosin treatment is recommended for patients with stone diameter smaller than 8mm because of its feasibility, effectiveness and safety. ESWL is more appropriate management for patients whose stones are larger than 8mm.⁷ Nearly all stones are expelled spontaneously when their diameter is smaller than 4mm. However, the spontaneous expulsion rate of distal ureteric stones is about 25% If their size is

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between 4-6 mm and 5% if greater than 6mm.⁸ Calculi over 8mm are very rarely eliminated spontaneously.⁹ Thereafter active treatment is recommended for individuals with calculus larger than 5mm.¹⁰

In general, it is believed that conservative medical management should be applied first and if unsuccessful ESWL or Ureteroscopic treatment should be performed.¹¹ We have done a study using tamsulosin for ureteric stones less than or equal to 8mm.

Aims and Objectives

1. To evaluate the efficacy of Tamsulosin in expulsion of ureteric calculi.
2. To evaluate the clinical outcome of patients with ureteric calculi treated with Tamsulosin.
3. To analyze the side effects of Tamsulosin when used for patients with ureteric calculi.

Materials and Methods

This prospective study was conducted in the department of urology CMC Ludhiana on patients with colic due to ureteric stones. Patients diagnosed with ureteric stones from OPD/Casualty and wards were included in the study. All the patients were randomized into study and control arms.

Study group- the patients who had ureteric colic due to ureteric calculi that measures less than or equal to 8mm and were given Tamsulosin along with symptomatic treatment for pain and hydration therapy.

Control group- The patients who had ureteric colic due to ureteric calculi that measures less than or equal 8mm and were given pain relief and hydration therapy.

Inclusion Criteria

1. All patient who presented with ureteric colic due to stones that were less than or equal to 8mm.
2. Age 12 years or above.

Exclusion Criteria

1. All patients who presented with indications of surgical intervention.
 - a. Severe back pressure changes.
 - b. Compromised renal function.
 - c. Urosepsis and infected hydroureteronephrosis
2. Patients who did not show compliance with the treatment on terms of duration and defaulting.

3. Those patients who did not fulfill the following criteria.

Randomization

The two groups were randomized using block randomization with one ratio one in blocks of 2 and 4. Patients presenting with ureteric colic were managed as per the protocol listed below.

1. Treatment of acute pain
 - Injection morphine 5mg stat IV (Titrated dose)
 - Injection morphine infusion pump for intractable pain
2. Treatment for nausea/ retching
 - Injection /Tablet Domperidone 10 mg IV/Oral/PRN
 - Injection Ondansetron 4mg IV slowly PRN
 - Treatment of dehydration if present
 - IV Fluids- as required

Routine Investigations

1. Full blood count
2. Renal function test
3. Electrolytes
4. Urine routine examination
5. Urine culture sensitivity
6. Non-Contrast CT KUB
7. USG KUB when indicated

The patients who were randomized into the study groups were prescribed Tab Tamsulosin 0.4mg once daily till the expulsion of stone. The patients in the control group were given only symptomatic relief and hydration therapy (at least 2 liters a day).

The data collected included additional symptoms, duration of symptoms, pain score and frequency of ureteric colic, size of stone, analgesic dose that provides pain relief, size of calculus, degree of hydroureteronephrosis, colic's per week, dosage of analgesics, number of days to get pain control or expulsion of stone, findings on repeat imaging, duration of treatment. Side effects of the drug like retrograde ejaculation, erectile dysfunction, gastritis, positional hypotension and floppy iris syndrome were observed. These patients were followed up for a period of minimum of 6 months or till the time they passed the stone. The data collected was statistically analyzed and was subjected to appropriate statistical tests. Descriptive analysis, frequency distribution T-test, co-relational analysis and ANOVA tests were used as required.

The patients were evaluated on admission or initial presentation in the OPD, casualty or in the ward and a detailed physical examination was done. Imaging by NCCT KUB, USG KUB, X-ray KUB and IVU was done for evaluation. Medical treatment with Tab

Tamsulosin 0.4mg OD daily was initiated in the patients randomized into the study arm and these patients were followed up with telephonic interviews and outpatient consultation to determine the extent of ante grade expulsion of stones by history of passage of stones, assessment of relief of symptoms and serial imaging according to the protocol attached. The expulsion of stone after initiation of therapy was monitored, the side effect profiles of the study medication was evaluated and the clinical outcome of study patient was assessed. **End Point:** when the patient had expelled the stone (observed by the patient on the strainer while passing urine) or had relief of symptoms. The passage of calculus was confirmed with an imaging modality which was usually ultrasound KUB (showing absence of calculus or resolution of hydroureteronephrosis) or an X-ray KUB. In case of multiple stones, the end point was taken as when all the stones on the symptomatic side had passed out.

Ethical Approval

The permission was taken from institutional ethics committee prior to starting the project. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Results and Analysis

This study was conducted on 27 randomly selected in-patients who presented in our hospital urology department with ureteric colic.

According to the study protocol this was a one-year prospective study of 60 patients (30 in the study arm and 30 in the control arm). Out of 49 patients screened for the study over a period of one year only 27 patients were recruited into the study fulfilling all eligibility criteria. Out of the 27 patients recruited 15 patients were in the study group and 12 in the control group. Many patients could not be included in the study due to various reasons such as:

1. There were 8 patients who went out of the study as they were not followed up on the designated dates.
2. There were 3 patients who underwent ureteroscopy and stone removal.
3. There were 10 patients who did not have a follow up ultrasound or x-ray KUB done as they were relieved of pain.
4. There was one patient who passed the ureteric stone while he was awaiting the non-contrast CT KUB.

Age distribution of patients in study and control groups

Majority of the individuals were in the age group 12 to 30 years (17 out of 27 – i.e. 62.7 %). The mean ages among the study and control groups were 35.4 years (SD 15.3) and 27 years (SD 7.17) respectively. The maximum age of patients recruited in the study arm was 60 years and, in the control, arm was 44 years. The minimum age among the study arm patients was 16 years whereas it was 19 years in the control arm. The mean difference of age was 8.23 and this was not found to be statistically significant using the t test ($t = 1.85$, $p = 0.079$).

Distribution of patients according to gender

There was male preponderance with 22 males and 5 females and the male: female ratio was 4:1. The number of males in the study group was 12 (54.5%) while in the control arm it was 10 (45.4%). Female patients were relatively less, both in the study and control groups with 3 patients in the study and 2 in the control arms respectively. Though the numbers of males were much more than females there was no significant statistical difference between the number of males and females in the group ($p=0.814$)

The size was determined by the larger of the 2 diameters other than the cranio-caudal diameter. The number of patients with calculus more than 5 mm were less when compared to the number of patients with 5 mm or less than 5 mm. The largest calculus in the study group, measured 8 mm while the same was 4 mm in the control group. The minimum size of the calculus in the study and control group was 3 mm and 2 mm respectively. The mean diameter of calculus in the study and control groups was 4.67 mm (SD-1.718) and 3.17 mm (SD-0.718) respectively. The mean difference was 1.5 and this was found to be statistically significantly using t test ($t = 3.063$, $p = 0.006$).

The total number of patients with calculus on the right side exceeded the number on the left side (17 and 10 respectively). This was true in the study and control arms individually as well. In the study group there were 8 patients with calculus on the right side and 7 on the left side while the control arm had 9 on the right side and 3 on the left. There was no

statistically significant difference in the number of patients according to the location of calculus in the two groups ($p = 0.249$).

Majority of the patients included in the study had ureteric calculus located in the lower ureter. This was the same for patients in the study and control arms. There were 12 (80%) patients in the study group who had a lower ureteric calculus while the control group had 9 (75%) patients. There were only 2 patients with upper ureteric calculus in each of the arms while there was only 1 patient with mid ureteric calculus in both the groups ($p = 0.083$).

Pain Score at presentation

Majority of the patients had a subjective sensation of pain with a pain score of over 5 out of 10 at presentation (25 out of 27). The minimum pain score at presentation was 4 in the study group whereas it was 7 in the control group. The mean score in the study and control arms were 8.13 and 8.25 respectively. The mean difference was -0.12 . There was no statistical significance between the two groups according to t test ($t = -0.232$, $p = 0.815$).

***Visual Analogue Pain Score¹³**

Majority of the patients (81 %) presented with mild hydroureteronephrosis in both the groups, suggesting that the patients presented when they just began to get early back pressure changes. Back pressure changes usually set in by 4 weeks. There were 12 patients in the study group with mild hydroureteronephrosis while patients in the control arm with mild hydroureteronephrosis were 10. There was one patient in the study arm who presented with moderate hydroureteronephrosis while there were none with similar back pressure changes in the control arm at presentation. There was no statistically significant difference in the degree of hydroureteronephrosis noted in the two groups ($p = 0.835$).

Majority of the patients in both groups presented to us when they had only 1 to 2 episodes of colics suggesting the excruciating nature of the pain. One patient presented with pain in the lumbar region with episodes of exacerbations. The minimum number of colics per week was 1 while the maximum was 7 with an average of 1.85 colics per week. The mean number of colics per week was 1.93 (SD=1.534) in group A while that in group B was 1.75 (SD=1.138). The

mean difference was 0.18 and the statistical difference was insignificant according to the t tests ($t = 0.345$, $p \text{ value} = 0.733$).

The maximum number of patients in the both groups who passed out calculus did so in the first 7 days. There was 1 patient in each group who did not pass the stone even at the end of the 6 months follow up period. The minimum number of days for expulsion of calculi in the study and control arm was 1 day. The maximum number of days for stone expulsion in the study group was 21 while in the control group it was 20 days. The mean time taken for expulsion of calculi in the study of control and arm was 6.53 and 7.16 days respectively. The mean difference was 0.9 days therefore the number of days taken for stone expulsion by the study group in comparison to the control group was statistically significant ($p = 0.640$).

In the first 7 days of the study 66.66% of the study arm patients passed out the calculus where as it was 83.33 % in the control arm. Majority of the individuals included in the study passed the stone in the first 28 days i.e. 4 weeks. Many studies compare the test and control groups at 4 weeks because hydroureteronephrosis usually develops by this time period. At the end of four weeks the percentages of patients who passed the stone in the test and control groups were 93 and 91.6 percent respectively.

Time to Attain pain control

Majority of the patients in both study and control groups had pain control between 1 to 5 days (66.6% and 50% each). The maximum number of days taken for a patient to become pain free was 20 and 30 days in study and control groups respectively. The minimum number of days to get pain free was 1 day in both the groups with an average of 12.5 days in each group respectively. There was no significant difference in the days taken to pain control in the two groups ($p = 0.538$).

Protocol for pain management

Patients were started on analgesics immediately on arrival at the Emergency Room. The choice of analgesics depended on the severity of colic. Patients with moderate to severe Pain were started on injectable analgesics Morphine. The size of the stone was assessed by Non contrast CT scan (KUB). Patients were switched over to oral medication with Tab Drotaverine twice or thrice daily (although

Table 1: Size of Calculus (in mm) in the study and control groups

Diameter of Calculus(mm)	Study		Control	
	n=15	Percentage	n=12	Percentage
<5	9	60	12	100
5 and >5	6	40	0	0

Table 2: Location of Calculus

Location of Calculus	Study (n)	Control (n)	Total
Right	8	9	17
Left	7	3	10
Total	15	12	27

Table 3: Site of calculus in the Ureter

Site of Calculus	Study	Control
Upper	2	2
Middle	1	1
Lower	12	9
Total	15	12

Table 4: Severity of Hydronephrosis

Hydronephrosis	Group A	Group B
Nil	1	1
Mild	12	10
Mild to Moderate	1	1
Moderate	1	0

Table 5: Frequency of colicky pain - group wise distribution

Colics/Week	Study Group (A)		Study Group (B)	
	n=15	Percentage	n=12	Percentage
1	7	46.6	6	50
2	6	40	5	41.6
3	1	6.6	0	0
>3	1	6.6	1	8.3

Table 06: Duration for stone expulsion

Stone Passage (in days)	Study group (A)		Control group (B)		Total	
	n=15	Percentage	n=12	Percentage	n=27	Percentage
1 to 7	10	66.66	10	75	20	74.07
8 to 14	1	6.66	0	0	1	3.7
15 to 21	3	20	1	16.6	4	18.5
22 to 28	0	0	0	0	0	0
>28	0	0	0	0	0	0
Did not pass	1	6.6	1	8.3	2	7.4

Table 7: Duration till passage of calculus

Stone Passage (in days)	Percentage of individuals (%)	
	Study	Control
1 to 7	66.66	83.33
1 to 14	73.26	83.33
1 to 21	93.3	91.6
1 to 28	93.3	91.6

Table 8: Number of colics and analgesic boluses following treatment

	Study (n=15)	Control (n=12)
Colics / week	1.06	1.29
Injectable boluses / patient	1	1.66

Table 9: Size of stone Vs. Duration for expulsion

Size of Calculus (in mm)	Average time for stone expulsion (in days)
2 to 4	6.41
5 to 6	7.18
7 to 8	11.5

Paracetamol and Diclofenac Sodium were also used depending on the severity of colic) after attaining pain control with injectable analgesics.

Patients who presented to OPD with mild symptoms were sent home on tablet drotaverine 40 mg twice or thrice daily for pain control.

Depending on the score of pain on follow up and diameter of calculus pain medication was either stopped or stepped up. In case of progressive increase in pain score patients were hospitalized for pain

relief. Patients having intractable pain or large diameter of calculus (10 mm and above) were excluded from the study and were planned for ureterorenoscopy and stone removal. Hydration therapy was continued along with this therapy.

The average colics experienced by patients following commencement of treatment in the study group was 1.06 whereas it was 1.29 in the control group. Most of the individuals following treatment experienced relief within 4 weeks while only three patients continued to have pain even after 4 weeks There were 2 patients

who did not pass the stone and had pain throughout the follow up period of 6 months. The average bolus of was 1.66 in the control group.

Adverse effects of Tamsulosin

The side effects of tamsulosin observed in other studies were dizziness, headache, rhinitis, fatigue, gastritis, retrograde ejaculation and floppy iris syndrome. Dizziness was the only side effect noted during the study period. This was a subjective symptom due to postural hypotension. There was no need to stop the drug to reverse symptoms in our study.

The average time taken for stone expulsion was found to progressively increase with the increase in the size of stone. The smallest calculus measured 2 mm while the largest measured 8 mm in diameter. The size of calculus was determined by the larger of the 2 diameters i.e. anteroposterior or transverse. The craniocaudal diameter was not used in the estimation of stone size. In the patients with calculus diameter between 2 mm to 4 mm the mean time taken for stone expulsion was 6.41 days while the same in individuals with calculus size 7 mm to 8 mm was 11.5 days.

Discussion

This study was conducted on 27 randomly selected patients who presented to the urology department in our hospital.

In our study only 49 candidates were screened and after the exclusion criteria 27 patients met all the criteria for statistical analysis. The mean age of patients included in our study was 31.74 years.

Ansari et al⁸ conducted a similar study, where 100 patients were enrolled. The mean age in the study was 37.18 years.

In our study a total of 12 males and 3 females were recruited for the study group while in the control group the same was 10 and 2 respectively. The study had a total number of 22 males and 5 females with a male to female ratio of 4:1. **Ansari et al⁸** had 2:1 female ratio in their study.

Size of Calculus

In our study the number of patients with calculus less than 5mm was 9 in the study group and 12 in the control group. The number of patients who presented with calculus of 5mm and above were 6 in the study group and while there were none in the control group. The average size of calculus was 4 ± 1.718 mm and 3.84 ± 0.718 mm in the study and control groups respectively. The range of size of calculus was 3mm to 8mm in the study group while it was 2mm to 4 mm

in the control group. **Ansari et al** in their study found the average size of stone was 5.88 ± 2.39 mm and 6.04 ± 2.5 mm in the study and placebo arms respectively.

Location of Calculus

In our study 8 patients with calculus on the right side and 7 patients with calculus on the left side in study arm while it was 9 and 3 in the control arm respectively. **Ansari et al⁸** found 13 patients with calculus on the right side while there were 16 patients with calculus on the left side in the Tamsulosin group while in the placebo arm there were 15 patients with calculus on the right and 13 patients on the left.

The present study had preponderance for right side stones (17 on the right and 10 on the left side) but other studies mentioned did not show any trend on the location of stone.

Site of calculus

The calculus on non-contrast CT was noticed at various levels in the ureter in upper, middle and lower ureter. In our study majority of the calculus were found to be in the lower ureter. There were 12 patients in the study group with lower ureteric calculus (75%) while there were 9 patients in the control group with lower ureteric calculus (80%). **Pedro et al¹²** in their study noted 32 out of 35 patients (91.42%) in the study arm with lower ureteric stones while the study arm had all the 35 patients with lower ureteric stone.

Duration of expulsion

In our study we followed up the patients till they passed the calculus or a minimum of 6 months. It was found that 14 out of 15 (93%) patients in the study and 11 out of 12 (91.6%) patients in control group expelled the stone. The mean expulsion time of calculus was 6.53 days in the study group while it was 7.16 days in the control group. **Ansari et al⁸** found 41 out of 50(82%) patients in the study group had passed the stone while in the control group only 28 out of 46 (60.86%) had passed the calculus. The average time for stone expulsion was 6.4 ± 2.77 days in the study group whereas it was 9.87 ± 5.4 days in the control group.

Our study followed the patients till they passed the stone or minimum of 6 months and excluded all the patients who had an intervention following persisting symptoms. Some of the patients who were advised ureteroscopy and stone removal passed the stone while they were awaiting intervention for stone removal.

The studies mentioned above show a significant decrease in the number of days taken to expel the stone (an average of 5 days) by the Tamsulosin group in comparison to the control arm. The present study showed a similar trend but did not produce significant

results. All stones in the control group arm after randomization were less than 5mm in size while in the study group 6 patients with stone size greater than 5mm suggesting that the rate of spontaneous expulsion in the control group would be much faster in the study group. The percentage of stone expelled in both the groups in present study was also similar (93%) and (91%) in the study and control groups respectively.

Pain Episode and Analgesia

To compare the relief of pain, average episodes of colicky pain per week following commencement of treatment was compared. In our study following treatment the average pain episodes per week was found to be 1.06 in the study group while it was 1.29 in the control group. The average number of injectable analgesics needed per patient in the study group was 1 whereas it was 1.66 in the control group. The most common injectable analgesic used in our study was morphine. The average dose of injectable morphine used in the study group was 6.66mg per patient whereas it was 7.77mg per patient in the control group. Ansari et al⁸ found that the average episodes of pain per week with treatment in the study and control groups were 1.6 +/- 1.3 and 2.3 +/- 1.4 respectively. The mean number of injectable boluses of diclofenac given was 0.9 +/- 0.93 in the study group where as it was 1.8 +/- 1.3 in the control group. The average dose of diclofenac administered to the patients in the study group was 67.5 +/- 69.8mg where as in the control group it was 127.2 +/- 89.3mg.

Most common injectable analgesic used in other studies was diclofenac sodium whereas morphine was the common injectable analgesic in our study. The studies that used diclofenac sodium as the injectable form of analgesia used the same drug in the oral form to be taken at home after initial pain relief. There were only 2 patients in the study group and 1 in the control group who were given diclofenac sodium for pain relief in our study. Tamulosin is a medical expulsive therapy for ureteral stones. Yu Cui et al in their studies reported that Tamulosin was associated with the higher stone expulsion rate, a shorter expulsion time, a lesser incidence of ureter colic and fewer incidence of requiring subsequent intervention.¹⁴

Significant Findings in The Present Study

- a) The average episode of colic per week was less in the study group (1.06 in the study group and 1.29 in the control group).
- b) The average dose of the most commonly used injectable analgesic (morphine) in the

present study was 1mg while it was 1.66mg in the control group.

- c) The average number of injectable boluses required by a patient in the study group was less compared to the control group, 1 and 1.66 in the study and control group respectively.

The fact that our control group had all the patients with calculus less than 5mm in size influenced the results with the fact that spontaneous expulsion without any treatment would be more in the control group.

Adverse Effects

In our study only a few instances of adverse effects of the drug in tamsulosin group where they had giddiness due to postural hypotension. No other side effects were noted.

Most of the patients in the study tolerated the drug well. The comparatively a smaller number of patients in both the study and control groups was one of the reasons. There was no need to discontinue the drug to reverse the symptoms in our study.

In our study incidence of lower ureteric calculus was found to be far more common than upper and middle and ureteric calculus. Right sided ureteric stones were found to be more common than left sided stones in the present study. Tamsulosin an adrenergic blocker was found to decrease the required dosage of the analgesic used, decrease the frequency of colic, decrease the number of injectable doses of analgesic needed, increase the rate of expulsion, and decrease the time of expulsion of ureteric calculus with minimal side effects in the present study. It was tolerated well by most patients. Tamulosin was found to be useful in the expulsion of ureteric calculi, though statistical significance was not achieved in our study because of small sample size.

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