

Role of Tamsulosin in aiding spontaneous expulsion of lower ureteric calculi in patients on conservative therapy

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Abstract

This is a prospective, single centered based observational study carried out at our rural medical college in Bihar in the period from 01 Jan 2014 to 30 Jun 2015. The present study was done to evaluate the role of Tamsulosin in aiding the spontaneous expulsion of distal ureteric calculi. Patients who were diagnosed to have distal ureteric calculi less than 10mm in size on initial imaging with X-Ray Kidney Ureter Bladder (KUB) or Ultrasonography (USG) KUB were included in the study. Proper Informed Consent was taken from every patient those who were included in this study. A sample size of 50 was taken for the study. The patients included in the study was divided into Group A and Group B corresponding to the Test and Control groups. Based on the calculus size, patients were further subdivided for the purpose of analysis of data. They were followed up on fortnightly basis or earlier, depending on the calculus expulsion with imaging (X-Ray KUB or USGKUB). The result thus obtained was analyzed statistically using the Chi Square test and unpaired t-Test at the end of the study. Two groups was made after randomly drawing out coupons from a closed box containing folded papers of equal size bearing the numbers 1 to 50. Patients were unaware of this group allocation. Group A composed of patients who was administered Cap Tamsulosin 0.4 mg HS along with Tab Diclofenac 50mg for pain relief while Group B composed of patients who received only Tab Diclofenac 50mg for symptomatic relief. Patients were asked to return for follow up fortnightly, or on spontaneous passage of calculus in the urine, whichever was earlier. The end point of the study was 1) Spontaneous stone passage by 4 weeks or earlier 2) Treatment discontinuation. At the end of the study, 24 patients (48%) passed calculus spontaneously in the total study group. Out of them, 17 patients (68%) were from Group A and 7 patients (28%) were from Group B.

Keywords: Tamsulosin, lower ureteric calculi.

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INTRODUCTION

Urinary stones constitute one of the commonest diseases in the world. The disease is as widespread as it is old,

particularly in countries with dry, hot climate. These *Stone Belt regions* of the world are located in countries of Middle East, North Africa, the Mediterranean Regions, North Western state of India and Southern State of USA and areas around the great lakes. In India, the *Stone Belt* occupies parts of Maharashtra, Gujarat, Punjab, Haryana, Delhi and Rajasthan. In these regions, the disease is so prevalent that most of the members of a family will suffer from kidney stones sometime in their lives^{1,2} On presentation, 66-75% of all stones are located in the ureter, and 80% of these are in the lower ureter, of which 75-80% passes spontaneously. The various factors affecting the management of lower ureteric calculi are detailed in Table below³.

Stone Factors	Clinical factors	Technical factors
Location	Symptom severity	Equipment availability
Size	Infection	Cost
Degree of obstruction	Solitary kidney	
Composition	Patient expectations	
	Abnormal ureteral anatomy	

Advances in endourological techniques and instrumentation have largely diverted the management of ureteral stones by open surgeries to either minimal invasive methods like ESWL and ureterorenoscopic removal of stones or to watchful waiting. The minimal invasive therapies for ureteral stone are now the accepted gold standards. Nevertheless, these techniques are not risk-free, are quite expensive and are not widely available in the developing countries⁴. Watchful waiting is appropriate for small stones that are not causing acute symptoms and that are likely to pass spontaneously, although it may occur at the expense of some discomfort to the patient. In recent years, there has been a quantum leap in the understanding of the ureteral physiology and the pathophysiology of ureteral obstruction due to calculus. The main factors associated with calculus retention include, thus: ureteral muscle spasm, submucosal edema, inflammation and infection within the ureter. Because ureteral edema and ureteral spasm have been postulated to affect stone passage, these effects have been targeted for pharmacologic intervention⁵. Alpha receptors are found in abundance in the detrusor and the intramural part of the ureter. More specifically, Alpha 1A and Alpha 1D adrenergic receptors are present more densely in the distal 1/3 of ureter (including intramural part) than other adrenergic receptors. When stimulated, these receptors inhibit the basal tone, peristaltic wave frequency and the ureteral contractions even in the intramural part of lower ureter, thereby leading to retention of urine. Antagonism of these receptors has the opposite effects⁴. The minimally invasive modalities of treatment of distal ureteral calculi, while effective, are fraught with their own risks and complications. It is recognized that patients with small distal ureteric calculi, in the absence of any complications, should be given a trial of conservative management with “Wait and Watch” approach. As an adjunct to this, MET with Alpha adrenergic antagonists is in practice in recent times. Tamsulosin has been the most commonly studied alpha-blocker in the treatment of ureteral stones. Tamsulosin has equal affinity for Alpha 1A and 1D receptors⁶. The present study was done to evaluate the role of Tamsulosin in aiding the spontaneous expulsion of distal ureteric calculi.

AIMS AND OBJECTIVES

This clinical study is intended

1. To identify the role of Tamsulosin, an alpha adrenergic blocker, in aiding the spontaneous expulsion of distal ureteric calculus of less than 10 mm in size.
2. To compare the rates of calculus expulsion for small (5mm or less) and large calculi (6 – 10mm) with and without Tamsulosin
3. To compare the effect on Time to expulsion of calculus in patients on and without Tamsulosin therapy

MATERIALS AND METHODS

This study is a single hospital based prospective observational study conducted in the “Department of Surgery, M.G.M Medical College and L.S.K. Hospital”. The study is approved by the Institutional Ethics Committee of the Hospital. The study population comprised of villagers residing through the district of Kishanganj and nearby seeking medical attention at the M.G.M. MEDICAL COLLEGE and L.S.K. HOSPITAL, KISHANGANJ. OPD patients who were diagnosed to have distal ureteric calculi less than 10mm in size on initial imaging with X-Ray Kidney Ureter Bladder (KUB) or Ultrasonography (USG) KUB were included in the study. Proper Informed Consent was taken from every patient those who will be included in this study

Exclusion Criteria

1. Impacted Calculus, confirmed on Intravenous Urography (IVU) series
2. Multiple calculi on the same side
3. Solitary functioning kidney with distal ureteric calculus,
4. Patients taking Alpha blockers or Calcium Channel blockers for other illness
5. Previous ureteral surgery
6. Ureteral Stricture
7. Impaired renal function
8. Pregnancy

A sample size of 50 was taken for the study. The patients included in the study was divided into Group A and Group B corresponding to the Test and Control groups. Based on the calculus size, patients were further subdivided for the purpose of analysis of data. They were followed up on fortnightly basis or earlier, depending on the calculus expulsion with imaging (X-Ray KUB or USG KUB). The results thus obtained was analyzed statistically using the Chi Square test and Unpaired t-Test at the end of the study. It comprised of detailed clinical history and examination of the patients. Presence and location of calculus was confirmed on imaging. Baseline hematological and biochemical investigations was done

to rule out any complications which would affect the study. Urinalysis and Urine culture was done to rule out infection. IVU series study was done to assess renal function and for anatomy of the pelvicalyceal system. Patients were followed up subsequently every fortnightly, or on spontaneous expulsion of calculus, whichever was earlier. Two groups was made after randomly drawing out coupons from a closed box containing folded papers of equal size bearing the numbers 1 to 50. Patients were unaware of this group allocation. Group A composed of patients who was administered Cap Tamsulosin 0.4 mg HS along with Tab Diclofenac 50mg for pain relief while Group B composed of patients who received only Tab Diclofenac 50mg for symptomatic relief. All the patients were advised to drink adequate fluids (about 2.5 to 3 litres) per day. Patients were asked to return for follow up fortnightly, or on spontaneous passage of calculus in the urine, whichever was earlier.

The end point of the study was

1. Spontaneous stone passage by 4 weeks or earlier
2. Treatment discontinuation

The criteria for treatment discontinuation were as follows

1. Passage of stone
2. Failure to pass stone after 4 weeks
3. Uncontrolled pain requiring early surgical/endoscopic intervention
4. Onset of fever, related to UTI

RESULTS

Out of the total of 50 patients, 15 (30%) were Female patients and 35 (70%) were Males. Group A comprised of 16 (64%) Male patients and 9 (36%) Females while in Group B, there were 19 (76%) Males and 6 (24%) Female patients. The age of the patients varied between 20 and 54 yrs. The average age of the entire study group was 37.3 yrs. In Group A, the age of patients ranged from 21 to 54 years with a mean age of 38.2 years, while in Group B, the age ranged from 20 to 49 years with a mean of 36.4 years. Both the Groups were, thus, comparable with respect to the age and sex distribution of the patients. Of the total study group, there were 15 patients (30%) with calculus of 5mm or less in size and 35 patients (70%) with more than 5mm calculus. In Group A, there were 7 patients (28%) with calculus measuring 5mm or less while 18 patients (72%) had large calculi measuring more than 5mm. In Group B, 8 patients (32%) had small calculus and 17 patients (68%) had calculi measuring more than 5mm in size. The average calculus size was 6.2mm for Group A and 6.3mm for Group B. For the total study group, the calculus size was 6.25mm. All the patients in the study group had distal ureteric calculi. Thirteen patients had calculi on the Right side in Group A while 14 patients had calculi in the Right ureter in Group

B. In the entire study population, 27 patients had calculi in the Right Ureter and 23 had Left sided calculi. At the end of the study, 24 patients (48%) passed calculus spontaneously in the total study group. Out of them, 17 patients (68%) were from Group A and 7 patients (28%) were from Group B. Of the patients who passed Small calculi (5mm or less), 6 out of 7 (85.7%) were from Group A and 3 out of 8 (37.5%) from Group B. The overall expulsion rate of Small calculi was, thus, 52.9%. In the case of patients with Large calculi (more than 5mm) who passed them spontaneously, 11 out of 18 patients (61.1%) were from Group A and 4 out of 17(23.5%) from Group B. The expulsion rate for large calculi was 42.8% for the total study population.

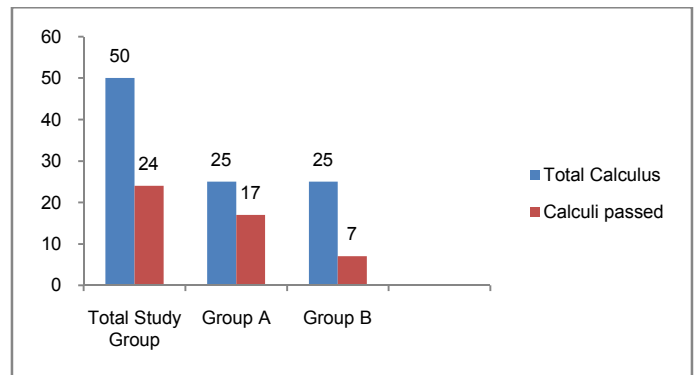


Figure 1: Overall Calculus Expulsion

Time to Expulsion of Calculus

The average time to expulsion of the calculus was 7.5 days for the entire study group. In Group A, the average time was 7.2 days and for Group B, it was 8.4 days. Longest time taken for spontaneous passage was 15 days for a 7.5mm calculus (Pt no A17) in Group A, while in Group B, 12 days was the longest duration for calculus expulsion in a 6.5mm calculus (Pt B15). For patients with small calculus, the average time for expulsion was 5.6 days for the entire study group, 5.0 for Group A and 6.7 days for Group B. In Group A, 4 days was the shortest time to expulsion of Small calculi (Patients A21 and A24), while in Group B it was 6 days (Pt B1 and B6). The average expulsion time for large calculi was 8.4 days for Group A and 9.8 days for Group B, 8.7 being the average expulsion time for large calculi for the entire study group. On statistical analysis using the unpaired t-Test, however, Group A patients had a significant advantage over Group B patients only in cases of small calculi, with significant reduction in the time to calculus expulsion.

Table 1: Summary of Results

	Group A	Group B	p Value
Average Calculus Size	6.2mm	6.3mm	-
Total Calculus Passed	17	7	
Total Pass Percentage	68%	28%	<0.05
% of Calculus 5mm or less passed	85.7% (6 out of 7)	37.5% (3 out of 8)	Not significant
% of Calculus >5mm passed	61.1% (11 out of 18)	23.5% (4 out of 17)	<0.05
Time for Expulsion of all calculi	7.2 days	8.4 days	Not significant
Time for Expulsion of Calculi 5mm or less	5.0 days	6.7 days	<0.05
Time for Expulsion of Calculi >5mm	8.4 days	9.8 days	Not significant

CONCLUSION

1. Tamsulosin has a significant role in aiding the spontaneous expulsion of distal ureteric calculi less than 10 mm in size.
2. The increase in rates of expulsion is more significant for calculus measuring more than 5mm in size.
3. Tamsulosin increases the rates of expulsion in case of calculus less than 5mm compared to the control group but the difference is not statistically significant.
4. Tamsulosin significantly reduces the time to expulsion of calculi measuring 5mm or less in size.

5. Use of Tamsulosin is recommended as a first line therapy for management of all distal ureteric calculi less than 10mm in size, and in the absence of any complicating factors.

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