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Original Research Article

ROLE OF TAMSULOSIN IN SPONTANEOUS EXPULSION OF LOWER URETERIC CALCULI WITH DECREASE IN ANALGESIC DOSAGE

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ABSTRACT

Background: Urolithiasis is a prevalent illness affecting males and females alike. With modern day armamentarium of instrumentation, the technique of stone removal has become minimally invasive however the character of alpha-1 adrenergic blockers like tamsulosin still have a role to play in spontaneous expulsion of small (<5mm) lower ureteric stones thereby decreasing treatment cost and morbidity of patients.

Materials and Methods: In this research, we prospectively examined 100 consecutive patients presenting with the distal ureteric stones. The participants were categorized into 2 distinct groups namely control and tamsulosin group, by randomization. A thorough clinical history was obtained, and a detailed clinical evaluation was carried out as per the standard proforma. Expulsion rate, expulsion time and analgesic dose were noted and compared for both the groups.

Results: Among 50 patients in the control group, 21 successfully passed the lower 1/3rd ureteric and uretero-vesical junction calculus within four weeks of diagnosis, conversely 29 patients did not experience expulsion, resulting to expulsion rate of 42%. In comparison, an 82% expulsion rate was achieved in the tamsulosin group, where 41 out of 50 patients spontaneously expelled the calculus. In the tamsulosin class, the mean duration of expulsion of stones was 4.48 days, in contrast to 7.38 days in the control group. In another group, the average analgesic dosage was 813 mg, while for the patient consuming tamsulosin, the mean analgesic dose was 282 mg.

Conclusion: Tamsulosin has demonstrated an ability to elevate and expedite expulsion rates of stones, mitigate the acute attacks by acting as an spasmolytic, reduce the overall duration of expulsion of stone, and also reduce utilization of analgesic doses.

Keywords: Urolithiasis, Distal Ureteric Stones, Uretero Vesical Junction, Tamsulosin, Alpha 1 Adrenergic Blockers.

INTRODUCTION

Urinary stone disease is a not so uncommon condition and its prevalence is increasing. Globally, incidence of the urinary tract stones has been assessed to range from 5% to 20% approximately and affects approximately 13% of males and 7% of females. The relapse rate is around 50%, and it constitutes around half of the total urinary stone burden, about 20% are ureteric stones, which mostly present in the lower segments of the ureters and primarily this tends to manifest the symptoms; hence to reduce discomfort they warrant immediate management.[1-6]

Those patients with larger (> 5 mm) stones require active treatment whereas 98% of small distal ureteric stones may be ejected naturally. When the diameter of the stone is 5 mm, The anticipated occurrence of the stones passing spontaneously is estimated to be 68%, The likelihood decreases approximately 47%

for the stones larger than 5 mm and is infrequent for those smaller than 10 mm.[5,7-9]

The recent studies have proven without doubt the the effectiveness of the less invasive treatments like extracorporeal shock wave lithotripsy (ESWL) and ureteroscopy (URS) in addressing distal ureter stones.10 These less invasive therapeutic approaches have some limitations as they are not without risks; at times, they can pose additional challenges, and they are typically associated with the higher costs.[11]

There are many factors for success of the minimally invasive modalities. The important factors for success of such therapies include sizes of stones and location of procedure, the equipment utilized, and the expertise of the clinicians involved.; Moreover, repeat interventions and occasional secondary procedures may influence overall efficacy of the treatments. In the last two decades Adoption of the novel, less invasive procedures such as percutaneous nephrolithotomy (PCNL), flexible ureteroscopy, ESWL, and laser techniques for treating ureteral stones has significantly transformed the traditional therapeutic approaches for this condition. However, this advancement has been accompanied by a noteworthy rise in treatment costs.

Additionally, addressing the potential factors leading to stone detainment, such as edema, infection, and ureteral spasm, is an option. This involves attempting to facilitate stone expulsion through the use of medications like calcium antagonists, steroids and glyceryl trinitrate.

There are several studies which have shown that alpha 1-adrenergic blockers may represent preferred treatment for the lower urinary tract symptoms. Recent research has shown promising outcomes regarding medical expulsive therapy (MET) in context of distal ureteral calculi. Therapy, employing medications such as prednisolone and nifedipine, has demonstrated the efficacy in promoting stone expulsion and managing ureteral colic pain by modifying the function of the obstructed ureter caused by the stones. In this context, recently recommended alpha1A receptor blocker is tamsulosin. This compound is alpha 1-adrenoceptor antagonist, originally designated for exclusive treatment of benign prostatic hyperplasia. It has high selectivity for alpha-1a adrenoceptors in urinary tract, distinguishes its use in this context.[12]

It boasts high bioavailability and also exhibits a prolonged half-life ranging from 9 to 15 hours. Extensive metabolism occurs in liver. Tamsulosin is characterized by negligible cardiovascular effects, the absence of a first-dose effect, and infrequent occurrences of dizziness. Clinical trials have reported adverse effects such as weakness, headache, dizziness, and nasal congestion. Notably, abnormal ejaculation was most prevalent adverse effect, occurring in almost 8% of patients at doses of 0.4 mg/day and in 18% at doses of 0.8 mg/day.[13,14]

So much work has been conducted in western world Especially in the prosperous regions, there is a discernible variability in outcomes. Range of diseases in the developing country contrasts with the patterns observed in more advanced nations. This discrepancy could primarily stem from the delays in diagnosis, investigative procedures, and lack of awareness, all of which have the potential to impact the outcomes in conditions such as ureteric stones or, indeed, any disease. Sophisticated interventional resources are not always readily accessible in the subcontinent, so it was thought pertinent conducting a study to contrast tamsulosin cohort compared to control cohort in our setting, aiming to assess the efficacy of tamsulosin in promoting the expulsion of lower ureteral calculi within a short timeframe, thus eliminating necessity for the hospitalization, endoscopic intervention, or shock wave lithotripsy.[15-17]

Our objective is to assess effectiveness of tamsulosin in facilitating the expulsion rate and duration of stones situated in the lower third of the ureter and at the uretero-vesical junction. Additionally, we aim to examine impact of administering the tamsulosin on the frequency of analgesic utilization for alleviating ureteral colic associated with these calculi.

MATERIALS AND METHODS

This hospital based prospective study included consecutive one hundred patients in Kasturba Hospital, exhibiting the symptoms indicative of ureteral stones between March 2016 to April 2017. All participants were assessed as outpatients, undergoing a standard transabdominal ultrasonography examination with special attention to the kidney, ureters and urinary bladder regions.

Only those patients were considered for study where the stones were located in distal 1/3rd of the ureter or at uretero-vesical region. The study protocol was comprehensively communicated to each of the participant, and they were given autonomy to discontinue participation in the study at any juncture as per their preference. Patients meeting all the inclusion criteria were enrolled in the study. 100 patients were divided into 2 groups- Control and tamsulosin group by randomization. A thorough clinical history was obtained, and a detailed clinical evaluation was carried out as per the standard proforma. Expulsion rate, expulsion time and analgesic dose were noted and compared for both the groups.

Inclusion criteria:

Patients appraised within a hospital setting, presenting with ureteral colic caused by radiologically verified distal ureteral stones measuring 10mm or less, and undergoing conservative management with informed written consent participated in the study.

Exclusion criteria:

The various criteria for exclusion encompassed: 1) Stones exceeding 10 mm in size, 2) Patients exhibiting clinical and laboratory indications of urinary tract infections (UTIs), 3) Pronounced

hydronephrosis identified through ultrasound examination (marked pelvicalyceal dilatation with parenchymal thinning), 4) Presence of the co-morbid conditions such as diabetes, abnormalities in renal parameters (serum creatinine and blood urea), 5) Individuals with an history of ureteral manipulation or surgery, 6) Those with multiple ureteral stones, 7) Known sensitivity to alpha blockers, and, Pregnant women were not included in study.

Statistical Analysis: The gathered data was inputted into an MS Excel spreadsheet and subsequently subjected to analysis through Student t-test and Chi-square test employing SPSS software.

RESULTS

In the control arm [C], mean age was 38.72 years, whereas in the tamsulosin arm [T], it was 35.48 years, accompanied by standard deviations of 13.735 and 9.840, respectively. The resulting p-value of 0.178 suggests the lack of noteworthy distinction in age between the two cohorts.

In the control arm [C] 78% of patients are male while 22% are females. In the tamsulosin arm [T] 80% of patients are males while 20% are females. In total 79% of patients in present study are male and 21% are female. Applying chi square test p value is 0.806 and hence significant.

The average size of calculi in the control arm [C] was 7.14 mm, while in the tamsulosin arm [T], it measured 6.96 mm, with corresponding standard deviations of 1.414 and 1.384, respectively. The calculated p-value of 0.5204 indicates a lack of statistical significance.

Within the control arm [C], the left side was the location for 44% of the identified stones, and On the right side, 56% of the stones were situated. Conversely, in the tamsulosin arm [T], 54% of the stones were situated on the left side, and 46% on the right side. Overall, 49% of stones were found to be on left side, and 51% on the right side. The calculated p-value was 0.3172, indicating a lack of statistical significance.

In the control group of our study, 21 out of 50 patients successfully expelled the lower 1/3rd of the stones. Stones expelled within a span of four weeks from the point of diagnosis, whereas 29 patients did not, with expulsion rate of 42%. In sharp contradistinction, 41 out of 50 patients in tamsulosin group experienced spontaneous expulsion of the calculus, resulting in an expulsion rate of 82%. The p-value for this parameter was 0.000 (less than 0.001), indicating a highly significant outcome.

The average duration for stone expulsion (among those who successfully expelled the stone) the control arm was 7.38 days, whereas the mean time was 4.48 days in the tamsulosin arm. The p value was 0.000 (<0.001) which is highly significant.

Analgesic dose

The patient in the control arm consumed mean analgesic dose of 813 mg, while for the patient consuming tamsulosin, the mean analgesic dose was 282 mg. The obtained p-value was 0.000 (less than 0.001), signifying a notably high level of significance.

Adverse Drug Reaction [ADR]

In study group of tamsulosin out of 50 patients only 4 patients complained of transient hypotension, dizziness and hypotension. only one patient experienced retrograde ejaculation. So total 5 patients (10%) had adverse drug reactions who received tamsulosin.

Table 1: Age Distribution

Group	Age						
	<20	20-29	30-39	40-49	50-59	>60	Total
C	3	12	9	13	9	4	50
T	1	12	23	8	5	1	50
Total	4	24	32	21	14	5	100

Table 2: Sex Distribution

Gender	Group		Total
	C	T	
Male	39 (78%)	40 (80%)	79 (79%)
Female	11 (22%)	10 (20%)	21 (21%)
Total	50	50	100

X2 = 0.0603, P= 0.80605 (Significance level 0.05)

Table 3: Calculus size distribution

Group	Calculus Size						
	<5	6	7	8	9	10	Total
C	6	12	14	8	7	3	50
T	9	11	12	10	7	1	50
Total	15	23	26	18	14	4	100

Table 4: Calculus side distribution

		Group		Total
		C	T	
Side	Left	22 (44.0%)	27 (54.0%)	49 (49.0%)
	Right	28 (56.0%)	23 (46.0%)	51 (51.0%)
Total		50 (100.0%)	50 (100.0%)	100 (100.0%)

x2 = 1.0004, p=0.3172, NS

Table 5: Expulsion Rate

		Group		Total
		C	T	
Expulsion	No	29 (58.0%)	09 (18.0%)	38 (38.0%)
	Yes	21 (42.0%)	41 (82.0%)	62 (62.0%)
Total		50 (100.0%)	50 (100.0%)	100 (100.0%)

X^2= 16.977, p=0.000038, HS

Table 6: Time to expulsion

EXPL Group	N	Mean	Std. Deviation	
C	21	7.38	2.31	t = 4.977, p=0.000, HS
T	41	4.48	2.09	

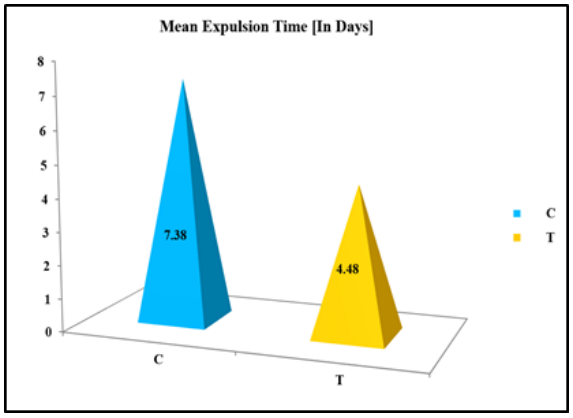

Figure 1: Expulsion Time

DISCUSSION

Approximately 12% of the population is facing Urinary stone disease. Moreover, its occurrence is on rise. Ureteral stones hold a significant position in routine urological practice, prompting clinicians to frequently contemplate the suitable treatment approaches. The effectiveness of the minimally invasive treatments, including extracorporeal shock wave lithotripsy and ureteroscopy, has been substantiated by numerous studies, unequivocally establishing them as the definitive interventions for ureteric calculi. However, these procedures come with an inherent risk, pose increased challenges, and entail significantly higher costs. Conversely, numerous studies have indicated that adopting a vigilant observation strategy is applicable in a substantial number of cases, yielding spontaneous passage rates as high as 98% for small distal ureteral stones.

The objectives of conservative medical therapy are aimed at averting the modifiable factors, enhancing rate of stone expulsion, reducing the duration until expulsion, and managing the painful symptoms until the stone is expelled. In our investigation, we utilized selective alpha-1a blocker, tamsulosin, to examine the efficacy of medical expulsive therapy specifically for calculi located in lower 1/3rd of the ureter and at the uretero-vesical junction, with a size equal to or less than 10 mm.

The present study observed an 82% spontaneous expulsion rate in the tamsulosin group, consistent with findings reported in studies conducted by other researchers.[18,20-22]

In the present study, the average duration until expulsion in tamsulosin cohort in the current investigation was 4.48 days and in control group was 7.38 which was in comparable with Dellabella study (4.4 days) and Autorino study (4.8 days).[21,22]

We observed that the mean dosage of the analgesic utilized significantly decreased in tamsulosin group during the current study (282 vs 813 mg) which was in concurrence with studies by other authors.[17,21,22] Nonetheless, there was significant fluctuation in absolute analgesic dosage, potentially stemming from the diverse factors like the individual patient's pain tolerance. and difference in the standard dose available.

No noteworthy side effects were observed in either group, affirming clinical safety profile of the tamsulosin and diclofenac. In this present study, none of the patients required hospitalization for any complications. Only 4 Patients in study cohort encountered adverse effects. and only one elderly male reported complaint of retrograde ejaculation. Meanwhile, additional individuals in the control group encountered adverse effects transient hematuria and mild nausea.

In prior clinical studies, adverse effects of Tamsulosin included weakness, dizziness, nasal congestion, headache and were noted. Unusual ejaculation was the most prevalent adverse effect, observed in 8% of the patients taking dose of 0.4 m g /day of tamsulosin versus 18% at the dose of 0.8 mg /day.[18,19]

Table 7: Comparison of Outcome Parameters

Study	Expulsion Rate	Expulsion Time	Analgesic Dose
Cervenakov,[20]	80.1%	-	-
Dellabella,[21]	90%	4.4 days	P=0.003
Autorino,[22]	88%	4.8 days	P=0.003
M S Girwan,[17]	90%	<7days (50%)	P=0.001(30±33.37mg)

Hence, we propose that the impact of tamsulosin on obstructed ureter is to stimulate the rise in the intraureteral pressure gradient above the stones, This is likely attributable to augmentation in the urine bolus above the stones. This results in elevation of intraureteral pressure above the stone, coupled with

diminished peristalsis below the ureter, consequently leading to the reduction in intraureteral pressure below the stones. These changes are observed in conjunction with the decline in basal and urinary pressures at bladder neck.[16]

These factors contribute to intensified urge for stone expulsion. Moreover, the reduction in the frequency of the phasic peristaltic contractions in obstructed ureteral tract, induced by tamsulosin, results in a diminished or absent algogenic stimulus, aligning with our study findings.

CONCLUSION

It can be inferred that considering the MET for straightforward distal ureteral calculi prior to opting for ureteroscopy or extracorporeal lithotripsy is warranted. Tamsulosin, through its spasmolytic action, has demonstrated ability to enhance and expedite the stone expulsion rates, diminish acute episodes, shorten the average duration to stone removal, thereby diminishing the necessity for analgesic medications. When used judiciously, this approach may yield significant economic advantages by lowering the need for invasive procedures and mitigating risk of acute episodes.

The study results underscore the clear and vital contribution of tamsulosin to conservative expulsive therapy in handling the distal 1/3rd ureteral and uretero-vesical stones. This implies an extension of pharmaceutical alternatives as opposed to relying primarily on endoscopic interventions for treating this condition

Ureteroscopic removal of lower 1/3rd ureteric calculi and vesical calculi is undoubtedly the definitive treatment for ureteric calculi, but pharmacological modality is worth trying as it is found to be effective in present study i.e. 82% expulsion rate (p=0.000). It was also found in present study that combination of tamsulosin with analgesic (diclofenac) was better compared to analgesic alone as the frequency and duration of analgesic requirement was much less when used with Tamsulosin (present study mean analgesic dose was 282 mg. p=0.000). The added advantage of MET (tamsulosin) is that it can be tried at lower centers where superspeciality services are not available.

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