

## Tamsulosin Versus Alfuzosin as Medical Expulsion Therapy for Distal Ureteric Calculi: An Analytical Study

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### ABSTRACT

#### Introduction

Urolithiasis is one of the most common urological problems. About 20% of urolithiasis accounts for ureteric calculi among which 2/3<sup>rd</sup> patients present with distal ureteric calculi. Alpha blockers are commonly used for effective treatment of ureteric calculi. The aim of this study was to compare effectiveness of Tamsulosin and Alfuzosin as medical expulsion therapy.

#### Methods

This analytical study was carried out at National Medical College Department of Surgery, Urology Unit, Birgunj from October 2020 to March 2021. Ethical clearance (FNMC/439/075/76) was obtained from institutional review committee. Total 100 cases were included in the study who presented with distal ureteric calculi of <10 mm. The patients receiving Tamsulosin were recruited in Group T and those receiving Alfuzosin were recruited into Group A. The choice of treatment was made by the treating surgeons. Tamsulosin 0.4 mg was used for the patients in Group T and 10 mg Alfuzosin was used in Group A. Patients were followed-up weekly for 4 weeks. Stone expulsion rate, time to stone expulsion, colic episodes, emergency visit, use of analgesics and drug-related side-effects were recorded.

#### Results

The rate of expulsion of stone in Tamsulosin group was 64% and that in Alfuzosin group was 66%. The expulsion time in Tamsulosin group was 4.28±3.49 days and that in Alfuzosin group was 5.02±4.09 days which was statistically insignificant (p=0.33). Mean episodes of colic and use of analgesics were similar in both groups. Backache was the most common side effect in both groups.

#### Conclusion

Efficacy of both Alfuzosin 10 mg and Tamsulosin 0.4 mg as medical expulsion therapy is comparable to each other with minimum side effects of both the drugs.

#### Keywords

Alfuzosin, medical expulsion therapy, Tamsulosin, urolithiasis

## INTRODUCTION

Urolithiasis is one of the most common urological problem worldwide with estimated prevalence of 1-5% in Asia.<sup>1</sup> One-fifth of the urinary tract stone is found in ureter of which two-third is seen in distal ureter.<sup>2</sup> When patient presents with flank pain, nausea and hematuria, it is termed as "ureteric colic".

The chance of stone passing spontaneously is based on the number of factors such as stone size and position, degree of impaction and degree of obstruction. Likelihood of spontaneous passage of stone size <2mm is in about 97% of cases whereas >6mm stones has nearly about 1%.<sup>3</sup>

According to 2007 guidelines for management of ureteric calculi of American Urological Association (AUA) and European Association of Urology (EAU), urology guideline recommends wait full watching along with medical treatment with drugs like alpha-adrenergic receptor blocker (a-blocker) which causes relaxation of the smooth muscle for patients with stone of <10mm in diameter.<sup>4,5</sup>

Studies have compared the efficacy of Tamsulosin with other combined therapy where outcome was similar in both groups.<sup>6</sup> In comparing Tamsulosin and Alfuzosin we can say that Alfuzosin alone is also effective in expulsion of distal ureteric calculi as any combined therapy.

Thus aim of the study was to compare efficacy and safety of Alfuzosin and Tamsulosin as medical expulsion therapy in patients with symptomatic uncomplicated ureteric stone that were located in sections of the ureter and also addressed the effect of these drugs in reducing the pain episode in these patients.

## METHODS

An analytical study was done at National Medical College, Department of Surgery, Urology Unit, Birgunj from October 2020 to March 2021. Total 100 cases above 18 years were included in the study who presented with distal ureteric calculi. Written informed consent were obtained from the cases that were included in the study. Ethical clearance (FNMC/439/075/76) was obtained from institutional review committee of NMC Birgunj.

Patients were assessed with ultrasonography (USG) and a plain abdominal X-ray. Intravenous Urography (IVU) or Computed Tomography (CT) was used in few patients depending on specific indications. Symptomatic ureteric stone of size less than 10 mm were included in the study. At the initial visit, history was taken, a physical examination, urine analysis, blood urea nitrogen and serum creatinine levels were measured.

Patients with acute infection, elevated levels

in renal function tests at presentation, severe hydronephrosis, bilateral ureteric stones, pregnancy or lactation, current use of a-blockers, calcium-channel blockers or steroids, age <18 years, and any allergic reaction to the study medication were excluded from the study.

The sample size was calculated using the formula:

$$N = K \frac{p_1(1 - p_1) + p_2(1 - p_2)}{(p_1 - p_2)^2}$$

where,

N = sample size

$p_1$  = successful passage in Tamsulosin = 0.72<sup>7</sup>

$p_2$  = successful passage in Alfuzosin = 0.88<sup>2</sup>

K value at a power of 80% and a level of significance of 95% was 7.9

The required sample size calculated to be 95. We included 100 cases who were eligible and gave written consent to participate in the study. Patient were divided into two groups, Group A (Alfuzosin group) and Group T (Tamsulosin Group). The patients receiving Tamsulosin were recruited in Group T and those receiving Alfuzosin were recruited into Group A. The choice of drug was on the treating surgeons' discretion. The patients were given diclofenac potassium orally 50 mg and/or diclofenac sodium as an intramuscular injection of 75 mg on demand along with oral Pantoprazole 40 mg once daily. Patients in Group A were given 10 mg Alfuzosin per oral once a day and in Group T were given 0.4 mg Tamsulosin per oral once a day.

Patients' demographic study were noted and patients were followed-up weekly for 4 weeks. In every visit a focused history, a physical examination and USG, with pain episodes and any drug-related side-effects were reported. Significant pain episodes were defined as an acute colic episode that necessitated the use of parenteral analgesia and/or hospitalization.

Data collection was done in data collection sheet and later entered in Office Excel version 2016. Data

Table 1. Comparison of different variables (n=100)

Characteristics	Group A n (%)	Group T n (%)	p-value
Stone side			
Right	28 (56%)	27 (54%)	0.84
Left	22 (44%)	23 (46%)	
Expulsion			
Yes	33 (66%)	32 (64%)	0.83
No	17 (33%)	18 (36%)	
Emergency visit			
Yes	23 (46%)	25 (50%)	0.69
No	27 (54%)	25 (50%)	

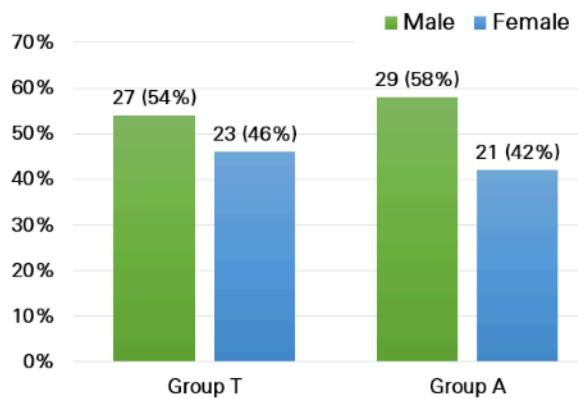


Figure 1. Gender distribution in study groups

analysis was done using Statistical Package for the Social Sciences (SPSS) version 16. Variables were expressed in mean  $\pm$  standard deviation, frequency and percentage where applicable. Comparison between groups was done using independent t-test and Chi-square test.

## RESULTS

A total of 100 patients were included in the study, among which 50 were in Group T and 50 in Group A. The mean age of the study subjects was  $35.34 \pm 11.94$  years. Among 100 patients, 56 (56%) were males and 44 (44%) were females. Figure 1 shows the distribution of gender in two groups.

The presentation of stone was more common in right side (56 patients). The expulsion was seen in 65 patients and 48 patients visited emergency during the treatment time. Table 1 shows the distribution of side, expulsion of stone and emergency visit in 2 groups.

The stone expulsion time, size of stone number of colic and doses of analgesic used were similar in both groups. Table 2 shows the comparison of these variables

Drug related side effects were seen in some of the cases. Backache was frequently complained by 10 (20%) cases of Group A and 8 (16%) cases of Group T. Table 3 shows the frequency of drug related side effects.

## DISCUSSION

There are different methods mentioned to deal with lower ureteric stone like extra corporeal shock wave lithotripsy (ESWL), ureterorenoscopic intra corporeal pneumatic lithotripsy (URS+ICPL), open ureterolithotomy, and medical expulsion therapy (MET) etc. Literature provides variety of results regarding spontaneous passage of stone. Kinder et al reported 94% spontaneous expulsion for stone  $\leq 5$ mm and 45% for stone greater than that.<sup>8</sup> Whereas Ueno et al evaluates more than 500 patients and reports spontaneous expulsion rate of

Table 2. Comparison of different variables (n=100)

Characteristics	Group A (n=50)	Group T (n=50)	p-value
Stone size (mm)	$6.62 \pm 1.49$	$6.47 \pm 1.71$	0.63
Expulsion time (days)	$5.02 \pm 4.09$	$4.28 \pm 3.49$	0.33
Mean no. of colic	$1.52 \pm 0.65$	$1.40 \pm 0.54$	0.31
Mean no. of analgesic (doses)	$2.50 \pm 0.86$	$2.56 \pm 0.86$	0.73

Table 3. Comparison of side effects (n=100)

Side effects	Group A n (%)	Group T n (%)	p-value
Headache	7 (14%)	6 (12%)	0.77
Dizziness	6 (12%)	7 (14%)	0.77
Backache	10 (20%)	8 (16%)	0.60
Postural hypotension	2 (4%)	4 (8%)	0.4
Abnormal ejaculation	2 (4%)	3 (6%)	0.65

57% for 5 mm stone.<sup>9</sup> According to AUA guidelines about 98% of ureteric calculi, size less than 5 mm will pass spontaneously without medical therapy.<sup>10</sup> About 35.2% - 61% ureteric calculi size less than 10mm pass spontaneously.<sup>11-13</sup>

Patients without medical therapy might develop severe complications if waited for longer duration. Thus medical treatment is probably effective for calculi up to 5-10 mm. Medical treatment is found to be cost-effective and justified before embarking upon surgical option.<sup>14</sup> The overall role of surgical intervention is reduced with medical treatment.<sup>15,16</sup>

Wang et al<sup>17</sup> showed that Tamsulosin was associated with an expulsion rate 81%. Another study from China reported that MET using Alfuzosin slow release 10 mg daily was effective in increasing the spontaneous passage of ureteric stone (81.8%) and reducing analgesic use.<sup>18</sup>

The present study showed that Alfuzosin was associated with overall expulsion rate of 66% (33) and with Tamsulosin of 64% (32). The efficacy of Tamsulosin and Alfuzosin has been studied in many previous trials. Agarwal et al<sup>13</sup> compare the efficacy of Tamsulosin, Alfuzosin and placebo and reported expulsion rate of 82.3%, 70.5% and 35.2% for Tamsulosin, Alfuzosin and control group respectively. Ahmed and Al-sayed<sup>2</sup> reported that 25 of 29 patient in Tamsulosin group (86%), 23 of 30 in Alfuzosin group (77%) and 14 of 28 in a control group (50%) expelled the stone. The expulsion rate for stones  $> 6$ mm was 92.9% and that of  $< 6$ mm was 39.4% was seen in a study done by Reddy RKG et al. But the overall expulsion rate of 74% and 72% was seen in Alfuzosin group and Tamsulosin group in the same study. Whereas in placebo group it was only 32%.<sup>7</sup> In present study the overall expulsion

rate was less in comparison to other studies on Medical therapy. But when compared the efficacy of Alfuzosin and Tamsulosin in all studies, it did not show significant difference in the outcome.

Present study showed that in Alfuzosin group the average size of stone was  $6.62(\pm 1.49)$  mm and average time of expulsion was  $5.02(\pm 4.09)$  days. Whereas in Tamsulosin group the average size of stone was  $6.47(\pm 1.71)$  mm with average time of expulsion  $4.28(\pm 3.49)$  days. Miller and Kane<sup>19</sup> reported that the mean time for spontaneous passage of stone of  $\leq 2$ mm, 2-4 mm and for 4-6 mm was 8.2, 12.2 and 22.1 days respectively. Another study done by Reddy RKG et al showed that the time required for expulsion of stone was  $8.57 \pm 4.52$  days and  $7.75 \pm 3.14$  days in Alfuzosin group and Tamsulosin group respectively.<sup>7</sup>

Present study showed that the mean number of colic attack was  $1.52 \pm 0.65$  and  $1.40 \pm 0.54$  in group A and group T respectively. Similarly the required number of analgesic dose was  $2.50 \pm 0.86$  and  $2.56 \pm 0.86$  in group A and group T respectively. The number of colic attack and analgesic use in both group were not significant. Similar result was seen in study done by Reddy RKG et al which showed significance with placebo group but the result was not significant in Alfuzosin and Tamsulosin group.<sup>7</sup>

In present study, there were minor drug-related side effects seen. In group A 27 patient and in group T 28 patients complained of side effects, but they were mild and did not require withdrawal from treatment. The most common side effects complained by both groups was backache which was not complained at the starting of the study. Similar mild side effects were observed in other studies done to see the efficacy of Alfuzosin and Tamsulosin.<sup>2,12,18</sup>

The limitation of this study was that the study was carried out in a single institution so does not represent the whole population. Also the placebo arm was not included in the study.

## CONCLUSION

Use of medical expulsion therapy of both Alfuzosin (10mg) and Tamsulosin (0.4mg) is comparable for expulsion of distal ureteric stone of size  $\leq 10$ mm. Side effects of both drugs are minimal and the drugs are well tolerated by the patients.

## CONFLICT OF INTEREST

None declared.

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