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**Research Article**

### THE AGE DISTRIBUTION AND EFFECTIVENESS OF LOW DOSE TAMSULOSIN IN LOWER URETERIC STONES

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**Abstract:**

**Objective:** To determine the effectiveness of low dose tamsulosin as a medical expulsive therapy in patients with lower ureteric stones.

**Patients and Methods:** The six months randomized control trial was conducted on all patients with either gender, age range 30-60 years and stone size 4-10 mm in the lower 1/3<sup>rd</sup> of the ureter determined on ultrasound at tertiary care hospital. Group A patients was offered low dose tamsulosin (0.2 mg) one tablet daily in the morning for a maximum of 4 weeks and group B served as control. The final outcome was measured at the end of 4th week of treatment. Patients were instructed to note the time and the date of expulsion of stone. Absence of echoic shadows on lower 1/3<sup>rd</sup> of ureteric line on ultrasound was taken as effectiveness (expulsion of stone).

**Results:** In control group mean age was 45.52 ±6.70 years whereas in low dose Tamsulin mean age was 46.72 ±6.73 years. Frequency of male was higher in both control and low dose Tamsulin group, i.e. 39 (78%) and 21 (42%) respectively. In control group effectiveness was found 3 (6%) patients whereas in low dose Tamsulin group effectiveness was found in 47 (94%).

**Conclusion:** In our study the effectiveness of low dose tamsulosin as a medical expulsive therapy in patients with lower ureteric stones was higher as compared to control.

**Keywords:** Low dose tamsulosin, Lower ureteric stones, Medical expulsive therapy

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**INTRODUCTION:**

Urolithiasis is an ancient disease with global distribution and has perplexed human beings and physicians for many centuries. Pakistan is situated in the middle of Afro-Asian stone belt, a high region of stone incidence. [1] Treatments for ureteric stones traditionally include watchful waiting, extracorporeal shock wave lithotripsy, ureteroscopy and open ureterolithotomy. Minimally invasive techniques, such as shock wave lithotripsy and endourology, are now being used more frequently. Even minimally invasive surgery, however, is not free of complications and the cost is high.[2] Stone size and location are the main factors that can influence their passage; a stone smaller than 4 mm is usually passed after conservative treatment. [2] The human ureter contains a high number of alpha adrenergic receptors, especially  $\alpha_1$ -receptors at the lower part of the ureter. [3,4] Tamsulosin is a combined alpha selective adrenergic antagonist that is an alternative to other medications, such as calcium channel blockers, corticosteroids, and analgesic and anti-inflammatory drugs, for the treatment of distal ureteric stones. [5-7] The standard dose of tamsulosin for the treatment of distal ureteric stones is 0.4 mg/day; many reports from Asian countries have confirmed that low-dose tamsulosin (0.2 mg/day) is effective in the treatment of benign prostatic hyperplasia (BPH). [5-7] There are few published clinical studies dealing with low-dose tamsulosin for medical expulsive therapy for ureteral stones. [8,9] In a randomized controlled trial (RCT) the ureteral stones expulsion rate was 4%, 40% and 68% in control, low dose (0.2mg) and standard dose (0.4 mg) tamsulosin groups respectively. [10] In another RCT The stone expulsion rate was significantly higher in low dose tamsulosin group than in control group (77% vs 50%, P=0.002). No significant differences were noted in the stone expulsion time and analgesic use between the groups. [11] There was a validity issue in the above mentioned studies as the sample sizes were and hence the results cannot be generalized [10-11]. Furthermore no local data is available on this topic locally and there is dearth of literature internationally as well. Therefore the present study was designed with proper calculation of sample size to assess the effectiveness of low dose tamsulosin in relation to age, so that if found to be effective then the same could be used in future with confidence in patients with lower ureteric stones.

**PATIENTS AND METHODS:**

The six months randomized controlled trial was conducted for the determination of the demographical

profile and effectiveness of low dose tamsulosin as a medical expulsive therapy in patients with lower ureteric stones at tertiary care hospital. The lower ureteric stones were considered as presence of echoic shadows on lower 1/3<sup>rd</sup> of ureteric line on ultrasound was taken as lower ureteric stones while the effectiveness was labeled when no stone in the lower 1/3<sup>rd</sup> of the ureter at the end of 4<sup>th</sup> week of treatment, confirmed on ultrasound was taken as effectiveness positive. The inclusion criteria were the patients with stone size 4-10 mm determined on ultrasound, presence of stone in the lower 1/3<sup>rd</sup> of the ureter either gender and age range 30-60 years while the exclusion criteria were urinary tract infection, multiple stones, pregnancy, severe hydronephrosis, hypotension, ureteral stricture and current use of calcium antagonists or alpha adrenergic blockers. To make two groups random allocation was done by a third person not involved in the study by asking patients to pick one sealed, opaque envelop bearing a card in it of group A and B. Group A patients was offered low dose tamsulosin (0.2 mg) one tablet daily in the morning for a maximum of 4 weeks and group B served as control. All patients were prescribed 50 mg diclofenac suppository on demand for pain relief. Patients were further advised to take minimum 2 liters of water daily. The patients were followed up on weekly basis along with X-ray KUB and ultrasonography. The final outcome was measured at the end of 4<sup>th</sup> week of treatment. Patients were instructed to note the time and the date of expulsion of stone. Absence of echoic shadows on lower 1/3<sup>rd</sup> of ureteric line on ultrasound was taken as effectiveness (expulsion of stone). The status of stone expulsion in terms of effectiveness and the demographics like age, gender, size of stone and time taken for stone expulsion was noted and entered in the questionnaire attached as annexure. Statistical Package for Social Sciences (SPSS) version 17 was used for data entry and analysis. Frequency and percentages was calculated for gender and effectiveness (stone expulsion).

**RESULTS:**

Mean age of the patients in control group was 45.52  $\pm$  6.70 years whereas mean age of the patients in low dose Tamsulosin was 46.72  $\pm$  6.73 years. (Table 1) There were more male in both control and low dose Tamsulosin group, i.e. 39 (78%) and 21 (42%) respectively.(Figure 1) Mean stone size of the patients in control group was 6.16  $\pm$  1.20mm whereas mean stone size of the patient in low dose Tamsulin was 6.52  $\pm$  1.19mm. The results are presented in Table 1-4 and figure 1.

**TABLE 1: AGE OF THE PATIENTS n=100**

AGE OF THE PATIENTS (in years)	Control	Tamsulosin	Mean Difference	P-value	95% C.I
	Mean ±SD	Mean ±SD			
	45.52 ±6.70	46.72 ±6.73	-1.2	0.374	-3.8 to 1.46

SD= Standard Deviation

**TABLE 2: COMPARISON OF EFFECTIVENESS IN BOTH GROUPS n=100**

Effectiveness	Group		Total	p-value
	Control	Tamsulosin		
Yes	3 (6)	19 (38)	22 (22)	0.001
No	47 (94)	31 (62)	78 (78)	
Total	50 (100)	50 (100)	100 (100)	

n (%)

**TABLE 3: ≤45 YEARS AGE GROUPCOMPARISON OF EFFECTIVENESS IN BOTH GROUPS n=100**

Effectiveness	Group		Total	p-value
	Control	Tamsulosin		
Yes	3 (7.5)	14 (37.8)	17 (22.1)	0.001
No	37 (92.5)	23 (62.2)	60 (77.9)	
Total	40 (100)	37 (100)	77 (100)	

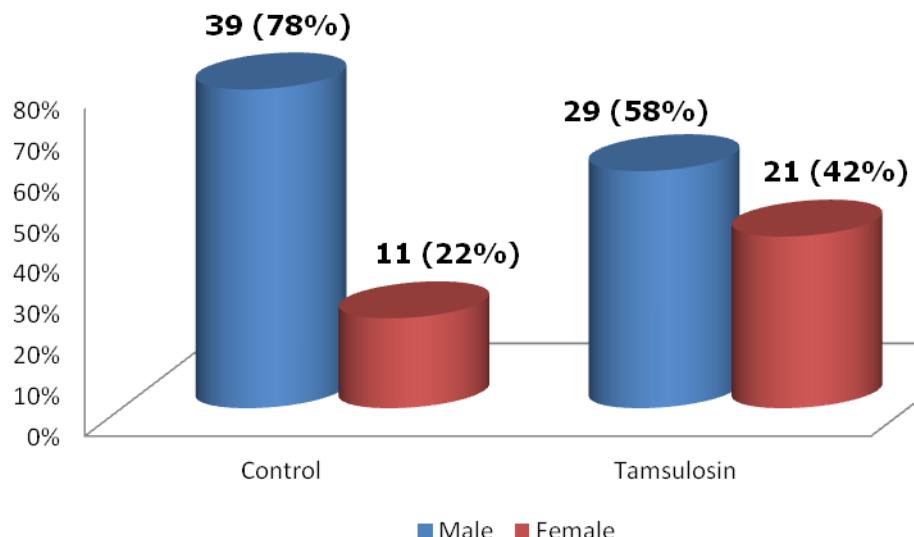
n (%)

**TABLE 4: >45 YEARS AGE GROUPCOMPARISON OF EFFECTIVENESS IN BOTH GROUPS n=100**

Effectiveness	Group		Total	p-value
	Control	Tamsulosin		
Yes	0 (0)	5 (38.5)	5 (21.7)	.027
No	10 (100)	8 (61.5)	18 (78)	
Total	10 (100)	13 (100)	23 (100)	

n (%)

## Figure 1: Gender Distribution



**FIG.1: GENDER DISTRIBUTION**

### DISCUSSION:

There are few published clinical studies dealing with low-dose tamsulosin for medical expulsive therapy for ureteral stones [8,9]. In a randomized controlled trial (RCT) the ureteral stones expulsion rate was 4%, 40% and 68% in control, low dose (0.2mg) and standard dose (0.4 mg) tamsulosin groups respectively [10]. In another RCT the stone expulsion rate was significantly higher in low dose tamsulosin group than in control group (77% vs 50%, P=0.002). No significant differences were noted in the stone expulsion time and analgesic use between the groups [11]. Improved detection of stones, increasing lifespan, and dietary changes may be related to the increased prevalence of stone disease [12]. A meta-analysis by the American Urological Association (AUA) Guidelines Panel determined that ureteral stones with a diameter of less than 5 mm will pass in up to 98% of cases. [14] For stones with diameters greater than 7 mm, the overall chance of spontaneous passage is low. [15, 16] Overall passage rate is 25% for proximal, 45% for middle and 75% for distal ureteric stones. [14] In this study, Overall effectiveness was found in 22 (22%) of the patients. In control group effectiveness was found 3 (6%) patients whereas in low dose Tamsulin group effectiveness was found in 47 (94%). Chi-square test was applied and statistically sufficient evidence of significant relationship was observed as p-value was found to be less than level of significance (p-value <0.01).

### CONCLUSION:

The effectiveness of low dose tamsulosin as a medical expulsive therapy in patients with lower ureteric stones was higher as compared to control.

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