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## LOWER URETERIC STONES EXPULSION; COMPARISON OF TAMSULOSIN VERSUS EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL)

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ABSTRACT... Objectives: To compare Tamsulosin versus ESWL for lower ureteric stones expulsion. Study Design: Randomized controlled trial. Setting: Outpatient Department of Urology at Services Hospital, Lahore. Period: January 2015 to December 2015. Material & Methods: Total 50 patients were enrolled in study. Patients were divided into 2 groups. In group A, 25 patients received daily oral treatment of 0.4mg Tamsulosin for 28 days, and in group B, 25 patients were treated with ESWL. A stone-free condition, was defined as the complete absence of any stone based on plain abdominal X-rays observed and during followup visits at the time of treatment of stone was noted. Results: The mean age of the patients were recorded as 33.20±9.23 years. There were 40(80%) males and 10(20%) females with male to female ratio of 4:1. Out of 50 patients, 16(32%) presented with hematuria, 3(6%) had fever while 31(62%) appeared with no complication status. Out of 50 patients, 21(42%) presented with expulsion time 08-14 days in which 14(28%) were from tamsulosin group and 07(14%) were from ESWL group, similarly 19(38%) patients appeared with expulsion time of 15-28 days in which 10(20%) were from tamsulosin group and 09(18%) were from ESWL group. Statistically there is insignificant difference between the groups i.e. p-value=0.28 Ns. Conclusion: This study suggests that the tamsulosin helps in the earlier clearance of stone fragments and reduces the complications as compared to ESWL.

 Key words:
 Renal Stone, Expulsion Time, Stone Clearance, Tamsulosin, Extracorporeal Shock Wave Lithotripsy.

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Pakistan is in the 'stone belt' of the world and a large number of patients with renal colic is seen in the hospital casualty departments and by the general practitioners. A ureteral stone travels from kidney to ureter downwards. About 2 million patients of ureteric stone visit each year. Male ratio is more than female. Usually urine is excreted as waste products that form hard masses or stones, built as crystals in the kidneys form a renal stone. Colic presentation include flank pain<sup>1</sup> associated fever.<sup>2</sup> Complications of kidney stones are infection, upper tract dilatation and pyonephrosis.<sup>3</sup>

The stone size and location is very important for suitable treatment.<sup>4</sup> Failed management can lead to complication .new techniques like shock wave lithotripsy and URS have diverted the way from open surgery to these methods and watchful method. Now a days these modalities have changed minds of urologists .but these methods are not available in all countries.<sup>5</sup> It was observed that small size stone pass without causing symptoms.<sup>6</sup> It may be at the cost of some discomfort to the patient, though ureteric stone less than 5 mm pass easily but stones more than 6 mm don't pass spontaneously. Symptoms usually resolve after 6 weeks of treatment.<sup>7</sup> Stones at lower end of right ureter pass more easily than left.<sup>8</sup> Pregnant ladies should be treated with care.<sup>9</sup>

Intramural portion of the ureter and detrusor is having receptors  $\alpha 1D$  in abundance.  $\alpha 1A$  and  $\alpha 1D$ adrenergic receptors are found in lower one third of ureter than other receptors. Uretero-bladder junction of the A1 antagonist play vital role in painless removal of small calculi.<sup>10</sup> Cervenakov ET al, a1 blockers having excellent results in LUTS, but it showed excellent results in expulsion of lower ureteric stones. They also A1 blockers when used reduces the need of analgesics.<sup>11</sup> Tamsolosin when combined with ESWL has very good results even for bigger stones. (Kupeli B, 2004) Alpha blocker has good expulsive effect on lower ureteric stone.<sup>11</sup>

ESWL is established modality of treatment for lower ureteral studies. Several versions of lithotripter are available to fragment the stones. There are different lithotripters available with limitations like Chinese Turkish which don't break stones of lower ureter. In our set up of Urology Department (SIMS) lithotripter of having capacity to focus and fragment in whole of urinary tract is available. Lithotripsy is a method used to manage kidney calculi. Many calculi are passed out by the body through a natural phenomenon during urination. (healthline, 2012). Objective of this study was to compare Tamsulosin versus ESWL for lower ureteric stones expulsion.

### **MATERIALS AND METHODS**

This randomized controlled trial was done from January 2015 to December 2015. After approval from local ethical committee of this randomized controlled trial, 50 cases of radio-opaque distal ureteric stones (<1 cm in size) of age 20-50 years of both genders presented to the outpatient Department of Urology at Services Hospital, Lahore, were selected. Patients with urinary tract infections, hypertension, pregnancy, multiple stones, renal failure and solitary kidney were excluded. Informed, written consent was taken. At study entry baseline demographics were recorded. Randomization was performed by block design. Randomization was 1:1 for Tamsulosin group or Group A and ESWL group or Group B. In group A patients received daily oral treatment of 0.4mg Tamsulosin for 28 days, and group B was treated with ESWL and through physical examination was done at the time of visit in out-patient department. A stone-free condition, as a main outcome from the treatment was defined as the complete absence of any stone based on plain abdominal X-rays.

The collected information was entered in Statistical Package for Social Sciences (SPSS) version 20 and analyzed. Mean and standard deviation was calculated for quantitative data. Frequency and percentage was calculated for qualitative data. Student t-test was applied to determine the mean difference in stone clearance in both groups. Student t-test was applied for qualitative data. Chi square test was applied for qualitative data. P value of <0.05 was considered as statistically significant.

### RESULTS

The mean age of patients in tamsulosin group was noted as 32.12±9.66 years with minimum and maximum ages of 18 and 50 years, whereas the mean age of ESWL patients were noted as 34.28±8.85 years with minimum and maximum ages of 21 & 50 years respectively. Out of 50 patients 40(80%) were males and only 10(20%) were females. The male to female ratio of the patients was noted as 4:1. All the patients appeared with renal pain, Pyuria and tenderness at renal angle. 49(98%) presented with Hematuria, 5(10%) presented with fever and only 7(14%) presented with vomiting (Table-I). The mean size of stones of patients in tamsulosin group was noted as 0.76±0.09 cms, whereas in ESWL group as 0.73±0.10cms (p-value=0.279).

Out of 50 patients, 21(42%) appeared with expulsion time 08-14 days in which 14(28%) were from tamsulosin group and 07(14%) were from ESWL group, similarly 19(38%) patients appeared with expulsion time of 15-28 days in which 10(20%) were from tamsulosin group and 09(18%) were from ESWL group (p-value=0.28) as shown in Table-II.

Out of 50 patients, 16(32%) presented with hematuria in which 05(10%) were from tamsulosin group and 11(22%) were from ESWL group, similarly 31(62%) patients appeared with no complications in which 20(40%) were from tamsulosin group and 11(22%) were from ESWL group and 03(6%) patients appeared with fever and all the 03(6%) patients were from ESWL group (p-value=0.02\*) (Table-III).

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		Group			
		Tamsulosin (n=25)	ESWL (n=25)	p-value	
Hematuria occurred	Yes	24(48%)	25(50%)	0.50	
Fever	Yes	5(10%)	0(0%)	0.02	
Vomiting	Yes	2(4%)	5(10%)	0.20	
	Normal	17(34%)	18(36%)	0.50	
Ultrasound of Kidney	Mild Dilation	8(16%)	7(14%)	0.50	
liltraggund of Lirotor	Low Hydro Ureter	0(0%)	10(20%)	0.00	
Ultrasound of Ureter	Mild Hydro Ureter	25(50%)	15(30%)		

lable-l.	Distribution a	bout signs and	symptoms of the	e patients in accordance	with study groups

Study	Groups	Tamsulosin	ESWL	Total	p-value	
	0-07 Days	0	0	0	0.28	
Expulsion time	08-14 Days	14(28%)	7(14%)	21(42%)		
	15-28 Days	10(20%)	9(18%)	19(38%)		
Total		24(48%)	16(32%)	40(80%)		
Table-II. Description about Expulsion time of the patients in the study groups						
Study	Group	Tamsulosin	FSWI	Total	p-value	

Stu	dy Group	Tamsulosin	ESWL	Total	p-value
Complication	Hematuria	5(10%)	11(22%)	16(32%)	0.02
	No Complaint	20(40%)	11(22%)	31(62%)	
	Fever	0(0%)	3(65)	3(6%)	
Total 25(50		25(50%)	25(50%)	50(100%)	
Table-III. Distribution about Complications of the patients in the study groups					

#### DISCUSSION

Here we will compare the effectiveness of alpha blocker versus ESWL for lower ureteric stone. Different factors should be kept in mind to study about removal of stone from body. There are different studies available done on stone expulsion, calcium channel blockers can help in stone expulsion by increasing peristaltic movements of ureter.<sup>12</sup>

Alpha blocker when given post lithotripsy has excellent results. Expulsion of stone after lithotripsy was much improved almost to 85 percents when combined with alpha blocker that was alone about 60 percents. It was observed great difference in statistical analysis between two groups.<sup>13</sup> Another study was conducted comparing ESWL alone and in combination with tamsulosin which also showed great difference with tamsolosin.<sup>13,14</sup>

In our study, all (100%) patients were observed to have Renal pain, Pyuriaand tenderness at renal angle. Almost all patients [49(98%)] presented with Hematuria, 5(10%) presented with fever and only 7(14%) presented with vomiting. Santosh Kumar Singh et al study shows that ESWL and ureterorenoscopy are ideal methods of treating stones in proximal ureter. Alpha blocker is mostly used in LUTS. It also acts on lower end of ureter because there is abundance of receptors there tamsulosin acts by inhibiting those receptors and helps in stone expulsion.<sup>15</sup>

In a study there were excellent results in expulsion of stone when combined with tamsolosin.<sup>16</sup> In another study results showed excellent success for renal and ureteric stones.<sup>17</sup> Another researcher Gravas showed in study no difference of results patients taking Tamsulosin or not post ESWL.<sup>18</sup> He also studied that tamsulosin is beneficial in terms that it reduces the needs of pain killers in ESWL.<sup>18</sup> This study showed that tamsulosin alone as medical expulsive therapy significantly reduced need of pain killers.<sup>19</sup> Tamsolosin showed excellent results for reduction in need of analgesia in combination with lithotripsy or alone.<sup>20</sup>

Yong Hyun Park and his colleagues reported in their study that there were not significant

difference for need of analgesia between two groups they studied.<sup>21</sup> Recent study showed there was very low rates of stones free in patients after ESWL and URS, in many cases patients has to be disturbed for second surgery.<sup>22</sup> Various studies and practical's done for checking the efficacy of tamsulosin it was observed that mean expulsion time of tamsulosin was about 15 days.<sup>23</sup>

Choi et al., conducted a study that alpha blocker post lithotripsy showed excellent results than calcium channel blocker post ithotripsy.24 Kim et al<sup>25</sup> documented results between alpha blocker and control groups. Upon this it was concluded that alpha blocker has more efficacy than ESWL (RR, 1.38; 95% CI, 1.14 to 1.68).<sup>26</sup> Our study results described that tamsulosin had better effect in removal of renal stone as compared to the ESWL as recommended by above all discussed international studies. Our study results shows that less complications occurred in tamsulosin group as compared to ESWL group patients, (p-value=0.02). Renal stone size had similar effect in both groups (p-value=0.27). Similarly expulsion time had also same effect in both groups (p-value=0.28) while signs and symptoms are statistically different in our study i.e. p-value<0.05.

#### **CONCLUSION**

It was concluded from results of this study that stone can be expelled earlier (within one or two weeks) with tamsulosin in patients (28%)as compared to ESWL (14%) and even complications are less with tamsulosin as compared to ESWL. Although the difference between both groups is insignificant buttamsulosin appears to be more beneficial as compared to ESWL as it does not required expertise or complete set-up and environment to carry out.

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