



CODEN [USA]: IAJPB

ISSN: 2349-7750

**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**

<http://doi.org/10.5281/zenodo.3840191>

Available online at: <http://www.iajps.com>

Research Article

“A COMPARATIVE STUDY OF EFFICACY OF TAMSULOSIN VERSUS ALFUZOSIN FOR THE EXPULSION OF URETERIC STONES”

Dr. Mubeena Javed¹, Dr. Hammad Yousaf Khan Niazi², Dr. Aisha Saif²

¹Allama Iqbal Medical College (AIMC)/Jinnah Hospital Lahore, ²Jinnah Hospital Lahore.

Article Received: May 2020

Accepted: May 2020

Published: May 2020

Abstract:

Introduction: The aim of the study is to compare the efficacy of Tamsulosin and Alfazocin for the removal of ureteric stone.

Methodology:

Study Design: Comparative

Study Setting:

The study will be conducted at Jinnah Hospital, Lahore.

Sample Size:

Sample size of 206 cases; 119 cases in Tamsulosin group and 87 cases in alfzocin was calculated by 95% confidence level with 80% power of test and taking magnitude of efficacy as 86.2% with tamsulosin (Ahmed and Al-sayed, 2010) and 68% with alfuzosin.

Results: once daily for 28 days or till spontaneous stone passage (which ever was first).

Results: The average age of Tamsulosin patients was 35.8±10.4 years with the minimum and maximum ages 19-59 years respectively (Table 1). The average age of Alfazocin patients was 41.4±11.4 years with the minimum and maximum ages 24-77 years respectively (Table 5). The average stone size in group I was 6.63±1.45 mm and in group II it was 6.93±1.39 mm. The range of stone size in group I was 4.5 -9mm and in group II it was 5 -10mm. In group I the stone was discharged in 65 out of 119 patients and in group II stone was discharged in 45 out of 87 patients only. The average expulsion time in group II was significantly less than group I [P = 0.001]

Conclusion: Alpha 1 antagonist (Tamsulosin) increases spontaneous expulsion of small distal ureteral stones.

Keywords: Efficacy, Lower ureteric stone, shock wave lithotripsy, ureteroscopy

Corresponding author:

Dr. Mubeena Javed,

Allama Iqbal Medical College (AIMC)/Jinnah Hospital Lahore

QR code



Please cite this article in press Mubeena Javed *et al.*, A Comparative study of efficacy of Tamsulosin versus Alfuzosin on the expulsion of ureteric stones, *Indo Am. J. P. Sci.*, 2020; 05[07].

INTRODUCTION:

Urolithiasis is a medical issue of overall significance. Ureteral stones represent 20% of urolithiasis, and 70% of ureteral stones are situated in the lower third of the ureter. Ureteric stones have incredible bearing on the wellbeing just as personal satisfaction of the patient. The malady range in a creating nation like our own is not quite the same as that in created nations, for the most part in light of deferral in analysis, examinations and absence of mindfulness which tend to change the result in instances of ureteral stone or so far as that is concerned any ailment. All the more along these lines, progressed interventional offices in this piece of the world are not effectively accessible. For the purpose of determining the site of impacted stone, ureter is divided into different sections. Section-1 extends from UPJ (uretero-pelvic junction) to the lower border of kidney; section-2 extends 2.5 cm below, section-3 extends upto the upper border of sacroiliac joint; section-4 is parallel to the sacroiliac joint, section-5 is upto the ischial spine and section-6 is upto the vesico-ureteric junction (Talati et al., 1994). Section 1, 2 and 3 constitute proximal ureter, section-4 constitute middle and section 5 and 6 lower ureter. It is estimated that 68% stone of about 5 mm size and 47% stone of over 5 mm to under 10 mm size may pass spontaneously and stones of over 10 mm size need intervention (Talati et al., 1994). Few decades back ureteral stones were managed by open ureter lithotomy. Then with time there was refinement of semi-rigid ureteroscopes, extracorporeal shock wave lithotripsy (ESWL) machines, laparoscopic procedures and flexible ureterorenoscopic (URS) resulting in enormous change in the management of ureteral stones. Each of these modalities have high efficacy when used for the appropriate indication both in adults and children (Iqbal et al., 2016). Preferences of patients and surgeons play a pivotal role in the decision of choosing one or the other procedure (Iqbal et al., 2016). For treating proximal ureteral stones, ESWL is a minimally invasive procedure and can be performed as an outdoor patient procedure, however it has disadvantages as well, such as a high retreatment rate, long treatment time, and poor patient compliance in some cases (Nasseh et al., 2013). Nowadays, medical expulsive therapy (MET) has been used and is an excellent treatment modality for distal USs in spite of conservative treatment (Sameer et al., 2014). There are certain factors which influence the passage of USs such as stone size, configuration, location, smooth muscle spasm, submucosal edema, and anatomy (Wang et al., 2016, Mustafa et al., 2016). Alpha blockers, calcium channel blockers are the most commonly used drugs for MET. Tamsulosin has been the most commonly studied α -1 blocker; however,

alfuzosin is a combined α -1 A and α 1 D selective adrenergic antagonist resulting in relaxation of distal ureteric smooth muscles to facilitate passage of stone and relieving pain. It is easily available and has less cardiac and ejaculatory side effects (Mustafa et al., 2016).

METHODOLOGY:**Study Design:**

Comparative

Study Setting:

The study will be conducted at Jinnah Hospital, Lahore.

Sample Size:

Sample size of 206 cases; 119 cases in Tamsulosin group and 87 cases in alfuzosin was calculated by 95% confidence level with 80% power of test and taking magnitude of efficacy as 86.2% with tamsulosin (Ahmed and Al-sayed, 2010) and 68% with alfuzosin (Singal et al., 2017) by using following formula:

$$Z_{1-\alpha/2} = 95\% = 1.96$$

$$Z_{1-\beta} = 80\% = 0.80$$

$$\text{Population Proportion (P1)} = 86.2\% = 0.862$$

$$\text{Population Proportion (P2)} = 68\% = 0.68$$

$$P = P1 - P2$$

$$n = 166$$

Sampling Technique:

Non-Probability Purposive Sampling

SAMPLE SELECTION**Inclusion criteria**

- Patients of age 18-75 years
- Patients of both gender
- Patients with ureteric stone with normal renal function (serum creatinine 0.7 – 1.5 mg/dl)

Exclusion criteria

- Patients with renal failure
- Pregnant women
- Sepsis and Co-morbid cardiac (Hypertension, Diabetes Mellitus)
- Respiratory diseases (Asthma, COPD)
- Coagulation disorder (INR 1 – 1.4)
- Severe hydronephrosis (renal pelvis > 6 mm diameter and cortex < 1 cm on ultrasound KUB)
- Multiple ureteric stones (more than 2)

DATA COLLECTION PROCEDURE

After approval from hospital ethical committee, patients fulfilling the inclusion criteria will be enrolled in this study. Informed consent will be obtained and patient demographic information (name, age, gender) will be recorded. Patients will be randomly divided in two equal groups by computer generated method. Seventy-two each will be placed in group-A treated with tamsulosin, in group-B treated with alfuzosin.

Every case will be assessed on ultrasonography (USG) and X-ray kidney, ureter, and bladder (KUB) will be done. All patients would receive the first treatment of diclofenac 75 mg by intramuscular injection, with a second dose after 30 min if necessary. If diclofenac will give inadequate pain relief, then injection drotin will be preferred by intramuscular or intravenous route. If the pain will be resolved, the patient will be dismissed and automatically enrolled in the study.

Group-I would receive oral tamsulosin 0.4 mg/day and Group-II would receive alfuzosin 10 mg orally/day for 21 days. Patients will be asked to take the study medication once at the same time each day. The treatment will be discontinued after the spontaneous stone expulsion, intervention, or at the end of the therapy (i.e., after day 21). They will be advised to take plenty of fluids during the study and continue with their daily routine. The patients will be followed-up weekly for 3 weeks, with urinalysis and serum creatinine measurement. Abdominal USG and X-ray KUB will be done to assess the stone status. For patients with a stone-free ureter on final USG but unnoticed stone expulsion, the date of last positive stone status will be recorded. The absence of stone expulsion after day 21 will be considered failed therapy.

DATA ANALYSIS PROCEDURE

Data will be entered and analyzed in statistical software Statistical Package for Social Sciences (SPSS) v25.0. Frequency and percentage will be computed for categorical variables like gender, socio-economic status and complaints. Mean and standard deviation will be computed for quantitative measurement like age and stone size. Chisquare test will be applied to compare proportion of efficacy between groups. A p-value ≤ 0.05 will be considered as a level of significance.

RESULTS:

The average age of Tamsulosin patients was 35.8 ± 10.4 years with the minimum and maximum ages 19-59 years respectively (Table 1). The average age of Alfazocin patients was 41.4 ± 11.4 years with the minimum and maximum ages 24-77 years respectively (Table 5). The average weight of Tamsulosin group patients was 74.4 kg and average weight of Tamsulosin group patients was 173 cm (Table 1). The average weight of the Alfazocin patients was 74.7 kg and the average height of the Alfazocin group patients was 173.5 cm (Table 5). The average stone size in group I was 6.63 ± 1.45 mm and in group II it was 6.93 ± 1.39 mm. The range of stone size in group I was 4.5 -9mm and in group II it was 5 -10mm. In group I the stone was discharged in 65 out of 119 patients and in group II stone was discharged in 45 out of 87 patients only. The average expulsion time in group II was significantly less than group I [P = 0.001]

Table 1: shows of the demographic data of Group 1 subjects subjected to Tamsulosin.

Descriptive Statistics					
	N	Minimum	Maximum	Mean	Std. Deviation
age	119	19.000	59.000	35.80672	10.471331
weight	119	52.000	94.000	74.54622	8.846859
height	119	159.0000	186.0000	173.445378	5.5260515
Valid N (listwise)	119				

Table 2 shows the relationship of ureteric stone with fever.

Size of Stone * Fever Crosstabulation					
			Fever		Total
			no fever	fever	
Size of Stone	stone size less than 0.5	Count	38	12	50
		% of Total	31.9%	10.1%	42.0%
	stone size between 0.5 & 0.8	Count	26	16	42
		% of Total	21.8%	13.4%	35.3%
	stone size greater than 0.8	Count	19	8	27
		% of Total	16.0%	6.7%	22.7%
Total	Count	83	36	119	
	% of Total	69.7%	30.3%	100.0%	

Table 3 shows the relationship of ureteric stone with vomiting.

Size of Stone * Vomiting Crosstabulation					
			Vomiting		Total
			no vomitimg	vomiting	
Size of Stone	stone size less than 0.5	Count	37	13	50
		% of Total	31.1%	10.9%	42.0%
	stone size between 0.5 & 0.8	Count	29	13	42
		% of Total	24.4%	10.9%	35.3%
	stone size greater than 0.8	Count	17	10	27
		% of Total	14.3%	8.4%	22.7%
Total	Count	83	36	119	
	% of Total	69.7%	30.3%	100.0%	

Table 4 shows relationship of ureteric stone with hematuria

Size of Stone * Hematuria Crosstabulation

			Hematuria			Total
			absence of RBC on urine complete examination	presence of RBC on urine complete examination	3.00	
Size of Stone	stone size less than 0.5	Count	50	0	0	50
		% of Total	42.0%	0.0%	0.0%	42.0%
	stone size between 0.5 & 0.8	Count	0	42	0	42
		% of Total	0.0%	35.3%	0.0%	35.3%
	stone size greater than 0.8	Count	0	26	1	27
		% of Total	0.0%	21.8%	0.8%	22.7%
Total	Count	50	68	1	119	
	% of Total	42.0%	57.1%	0.8%	100.0%	

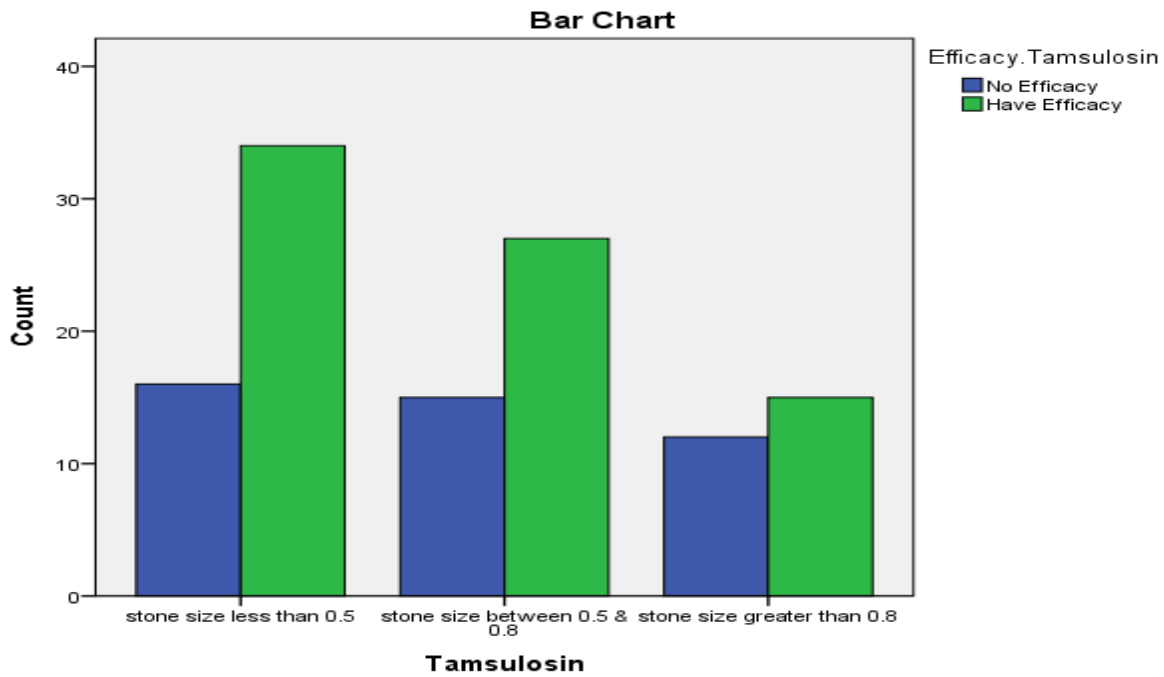


Figure 1 shows the efficacy of Tamsulosin with the size of ureteric stone.

Table 5 shows the demographic data of Group 2 Alfazocin patients.

Descriptive Statistics					
	N	Minimum	Maximum	Mean	Std. Deviation
age	87	24.00	77.00	41.4138	11.45218
weight	87	52.00	92.00	74.7011	7.90954
height	87	160.00	186.00	173.5057	5.05291
Valid N (listwise)	87				

Table 6 shows the relationship of ureteric stone with fever.

Size of Stone * Fever Crosstabulation					
			Fever		Total
			no fever	fever	
Size of Stone	stone size less than 0.5	Count	27	9	36
		% of Total	31.0%	10.3%	41.4%
	stone size between 0.5 & 0.8	Count	19	13	32
		% of Total	21.8%	14.9%	36.8%
	stone size greater than 0.8	Count	14	5	19
		% of Total	16.1%	5.7%	21.8%
Total	Count	60	27	87	
	% of Total	69.0%	31.0%	100.0%	

Table 7 shows the relationship of ureteric stone with vomiting.

Size of Stone * Vomiting Crosstabulation					
			Vomiting		Total
			no vomitimg	vomiting	
Size of Stone	stone size less than 0.5	Count	26	10	36
		% of Total	29.9%	11.5%	41.4%
	stone size between 0.5 & 0.8	Count	23	9	32
		% of Total	26.4%	10.3%	36.8%
	stone size greater than 0.8	Count	12	7	19
		% of Total	13.8%	8.0%	21.8%
Total	Count	61	26	87	
	% of Total	70.1%	29.9%	100.0%	

Table 8 shows the relationship of ureteric stone with hematuria.

Size of Stone * Hematuria Crosstabulation

		Hematuria			Total	
		absence of RBC on urine complete examination	presence of RBC on urine complete examination	3.00		
Size of Stone	stone size less than 0.5	Count	36	0	0	36
		% of Total	41.4%	0.0%	0.0%	41.4%
	stone size between 0.5 & 0.8	Count	0	32	0	32
		% of Total	0.0%	36.8%	0.0%	36.8%
	stone size greater than 0.8	Count	0	18	1	19
		% of Total	0.0%	20.7%	1.1%	21.8%
Total		Count	36	50	1	87
		% of Total	41.4%	57.5%	1.1%	100.0%

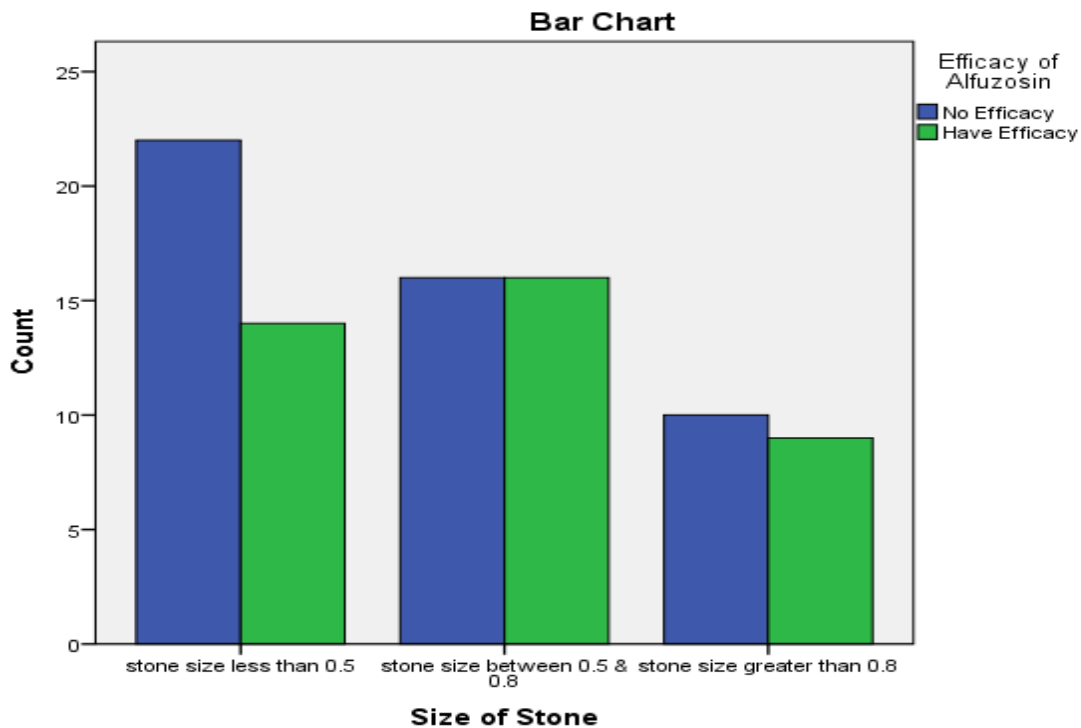


Figure 2 show the efficacy of Alfuzocin group patients on size of the ureteric stone.

CONCLUSION:

A conservative approach should be considered as an option in the management of small uncomplicated distal ureteral stones. We have observed the treatment with tamsulosin (alpha 1 blocker) improved the rate of spontaneous stone expulsion as well as time of distal ureteral stone expulsion from start of therapy as compared to control group. It also decreased the pain episodes, so the use of alpha 1 blocker is recommended in treatment of small distal ureteral stones because of its high efficacy, excellent patient satisfaction and cost effectiveness.

REFERENCES:

1. AHMED, A.-F. A.-M. & AL-SAYED, A.-Y. S. 2010. Tamsulosin versus alfuzosin in the treatment of patients with distal ureteral stones: prospective, randomized, comparative study. *Korean journal of urology*, 51, 193-197.
2. HUSSAIN, M., RIZVI, S. A. H., ASKARI, H., SULTAN, G., LAL, M., ALI, B. & NAQVI, S. A. A. 2009. Management of stone disease: 17 years experience of a stone clinic in a developing country. *Hypertension*, 6819, 17.6.
3. IQBAL, N., HUSSAIN, I., WAQAR, S., SADAF, R., TASHFEEN, R. & NISA NABIL, N. 2016. Ureteroscopy for management of ureteric stones in children—a single centre experience. *J Coll Physicians Surg Pak: JCPSP*, 26, 984-8.
4. ISSLER, N., DUFEK, S., KLETA, R., BOCKENHAUER, D., SMEULDERS, N. & VAN'T HOFF, W. 2017. Epidemiology of paediatric renal stone disease: a 22year single centre experience in the UK. *BMC nephrology*, 18, 136.
5. LIU, N., ZHANG, Y., SHAN, K., YANG, R. & ZHANG, X. 2019. Sonographic twinkling artifact for diagnosis of acute ureteral calculus. *World journal of urology*, 1-7.
6. MAHMOOD, S. N. & BAJALAN, D. H. 2016. Ureteroscopic Management of Ureteral Calculi: Pneumatic versus Holmium: YAG Laser Lithotripsy. *Open Journal of Urology*, 6, 36.
7. MUSTAFA, A. S. M. F., ISLAM, M. S., AL MAMUN, A. & KHALID, M. S. 2016. Efficacy of tamsulosin in the medical management of juxtavesical ureteral stones: a randomized control trial. *Bangladesh Medical Research Council Bulletin*, 42, 78-83.
8. NASSEH, H., POURREZA, F., KAZEMNEJAD LEYLI, E., ZOHARI NOBIJARI, T. & BAGHANI AVAL, H. 2013. Laparoscopic transperitoneal ureterolithotomy: a single center experience. *Journal of Laparoendoscopic & Advanced Surgical Techniques*, 23, 495-499.
9. SAMEER, S. L., CHARAK, K., CHAKRAVARTI, S., KOHLI, S. & AHMAD, S. 2014. Efficacy of nifedipine and alfuzosin in the management of distal ureteric stones: A randomized, controlled study. *Indian journal of urology: IJU: journal of the Urological Society of India*, 30, 387.
10. SINGAL, R., BHATIA, G., MITTAL, A., SINGAL, S. & ZAMAN, M. 2017. To compare the efficacy of tamsulosin and alfuzosin as medical expulsive therapy for ureteric stones. *Avicenna journal of medicine*, 7, 115.
11. TALATI, J., KHAN, L., NOORDZIJ, J., MOHAMMAD, N., MEMON, A. & HOTIANA, M. 1994. The scope and place of ultrasound-monitored extracorporeal shock wave lithotripsy in a multimodality setting and the effects of experiential, audit-evoked changes on the management of ureteric calculi. *British journal of urology* 73, 480-486.
12. WANG, C. J., TSAI, P. C. & CHANG, C. H. 2016. Efficacy of silodosin in expulsive therapy for distal ureteral stones: a randomized double-blinded controlled trial. *Urology journal*, 13, 2666-2671.