Original Article

Comparing the Efficacy and Safety of Silodosin versus Extracorporeal Shockwave Lithotripsy for the Management of Lower Ureteric Stone

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ABSTRACT

Objective: To compare efficacy and safety of Silodosin versus extracorporeal shockwave lithotripsy for the management of lower ureteric stone.

Study Design: Randomized controlled trial

Place and Duration of Study: This study was conducted at the Out Patient Department of Urology, Nishtar Hospital, Multan in 1 year duration from March 2021 to February 2022.

Materials and Methods: A total of 145 patients were enrolled and divided into two groups A and B by lottery method. In group A, patients were given 8 mg oral capsule of silodosin for 28 days and were advised to collect their urine and discontinue Silodosin in case of stone passage. In group B, patients were undergone extracorporeal shockwave lithotripsy (one session weekly for 3 weeks) by a single team with assistance of researcher. SPSS version 23 was used for data analysis.

Results: In silodosin group retrograde ejaculation was noted in 2.9% patients and in ESWL it was noted in 11.4% patients (p-value=0.049). In silodosin group postural hypotension was noted in 4.3% patients and in ESWL it was noted in 15.7% patients (p-value=0.024). In silodosin group dizziness was noted in 1.4% patients and in ESWL bleeding was noted in 5.3% patients (p-value=0.172).

Conclusion: Results of this study reveal that Silodosin is significantly more efficacious and safe drug in terms of outcome as compared to extracorporeal shockwave lithotripsy for the management of lower ureteric stone size of 5-10 mm.

Key Words: Extracorporeal Shockwave Lithotripsy, Silodosin, Lower Ureteric Stone**,** Stone clearance, Efficacy, Safety

Citation of article: Abdul Razaq, Hyder I, Bilal A, Ata ur Rehman R. Comparing the Efficacy and Safety of Silodosin versus Extracorporeal Shockwave Lithotripsy for the Management of Lower Ureteric Stone. Med Forum 2022;33(11):6-9.

INTRODUCTION

A common health problem is urolithiasis having incidence rate of 13% in men and up to 7% in women of older age[1]. In Asian countries urolithiasis is most prevalent disease, according to a survey conducted in 2012 among Pakistani population and prevalence rate was noted up to 16%[2]. In different areas of world prevalence of urolithiasis reported as 7-13%, 5-9%, in North America and Europe respectively. But in last few years its prevalence have increased, contributing causes are involve dietary habits and living style [3].

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Received: June, 2022
Accepted: August, 2022
Printed: November, 2022

Recent advances and technologies used in its management enabled the medical professionals to manage urolithiasis in a better way with minimum complications[4]. Number of minimally invasive techniques is available for management of ureteric stones but associated with different side effects[5]. Conservative management have complication of prolong pain and open surgical technique may lead to trauma and post-operative complications. Lithotripsy and ureteroscopy are two successful methods having minimal complications[6].

In recent advances a non invasive treatment technique for management of ureteric stone is extracorporeal shock wave lithotripsy which is widely used in clinical management. Because of its simplicity, cost effectiveness and less pain it can be used as outpatient's department procedure[7,8]. Expulsive therapy is a usual treatment that can be helpful in removal lower ureteric calculi which include some alpha blockers that acts on smooth muscles[9,10].

The studies comparing Silodosin versus ESWL to treat lower ureteric stones are scarce. So, we have planned to conduct this study to get local evidence and in future

our study may help us to determine more appropriate method for treatment of lower ureteric stones in local setting.

MATERIALS AND METHODS

After obtaining approval from hospital ethical committee and review board, 140 patients who meet inclusion criteria, were enrolled in this study from Out Patient Department of Urology, Nishtar Hospital, Multan in 1 year duration from March 2021 to February 2022. Patients were explained about research and informed consent was taken. Patients of age 16-75 years, both genders, presenting with lower ureteric stone size 5-10 mm (as per operational definition) were included. Patients already taken trial of medical expulsive therapy, single kidney (on medical record), bilateral ureteric stones, history of previous ureteric surgery, history of stone passage, ureteric strictures, pregnancy, prior long-term α-AR blocker use for benign prostatic hyperplasia, radiolucent Stones were excluded.

Demographics like name, age, gender, BMI, duration of symptoms, history of diabetes (BSR>200 mg/dl) and history of hypertension (BP≥140/90 mmHg) was obtained. All base line investigations including computed tomography KUB plain was done. The size of stone was measured on computed tomography KUB. Two groups were made by non-random consecutive sampling technique. In group A, patients were given 8 mg oral capsule of silodosin for 28 days and were advised to collect their urine and discontinue Silodosin in case of stone passage. The date of stone passage was noted. In group B, patients were undergone extracorporeal shockwave lithotripsy (one session weekly for 3 weeks) by a single team with assistance of researcher. First 500 shocks were delivered at energy level of 2 and next 2000 shocks at energy level of 3 and 4. And patient was followed up weekly with X-Ray KUB plain. Post procedure treatment of the patient was comprised Tab. Diclofenac sodium 50mg twice a day during 1st week and was repeated later in the case of pain.

After 28 days of treatment, patients were undergone computed tomography scan to detect any residual stone or stone fragment in the ureter. If there was no stone and stone fragment, stone free status was labeled (as per operational definition). Patients were also evaluated for bleeding, pain and dizziness. Patients with complications were managed as per standard protocol. All the data was recorded in proforma.

Data was analyzed on SPSS version 22.0. Mean and standard deviation was calculated for quantitative variables like age, BMI, duration of symptoms and size of stone. Frequency and percentage was calculated for categorical variables like gender, smoking, diabetes, hypertension, lateral side and outcome (stone free status, bleeding and pain). Both groups were compared for outcome by using chi-square test and *P*-value ≤ 0.05 was considered as significant.

RESULTS

In this study total 140 patients were enrolled. The mean age of the patients was 50.74years with minimum and maximum ages of 17 & 75 years respectively. In silodosin group the mean age of the patients was 50.23±13.82 years and in ESWL group the mean age of the patients was 51.25±14.27 years. In this study 91 (65%) patients were male and 49 (35%) patients were females. In silodosin group 45 (64.3%) patients were male and in ESWL group 46 (65.7%) patients were male. The mean BMI of the patients was 26.43±3.71 kg/m2 with minimum and maximum BMI of 20 & 32 kg/m2 respectively. In silodosin group the mean BMI of the patients was 26.27±3.76 kg/m^2 and in ESWL group the mean BMI of the patients was 26.60±3.68 kg/m^2. The mean duration of symptoms of the patients was 5.45±3.29 weeks and the mean stone size of the patients was 5.52±2.15 mm. In silodosin group the mean duration of the patients was 5.17±3.42 weeks and in ESWL group the mean duration of the patients was 5.74±3.16 weeks (p-value=0.307). In silodosin group the mean stone size of the patients was 5.48±1.96 mm and in ESWL group the mean duration of the patients was 5.57±2.34 mm. According to this study 49 (35%) patient were diabetic. In silodosin group 22 (31.4%) patients were diabetic and in ESWL group 27 (38.6%) patients were diabetic. In this study 67 (47.86%) patients were hypertensive. In silodosin group 31 (44.3%) patients were hypertensive and in ESWL group 36 (51.4%) patients were hypertensive (Table-1).

In silodosin group stone clearance was noted in 57 (81.4) patients and in ESWL stone clearance was noted in 44 (62.9%) patients (p-value=0.014). In silodosin group pain was noted in 30 (42.9%) patients and in ESWL pain was noted in 45(64.3%) patients (p-value=0.011). In silodosin group bleeding was noted in 24 (34.3%) patients and in ESWL bleeding was noted in 40 (57.1%) patients (p-value=0.007) (Table-2)

Table No.1: Demographics and clinical characteristics

Characteristics	Silodosin	ESWL
Age	50.23 ± 13.8	51.25 ±14.2
Male	45 (64.3%)	46 (65.7%)
Female	25 (35.7%)	24 (34.3%)
BMI kg/m^2	26.27 ± 3.6	26.60 ± 3.68
Duration of symptoms (weeks)	5.17 ± 3.42	5.74 ± 3.16
Stone size (mm)	5.48 ± 1.96	5.57 ± 2.34
Diabetes Mellitus		
Yes	22 (31.4%)	27 (38.6%)
No	48 (68.6%)	43 (61.4%)
Hypertension		
Yes	31 (44.3%)	36 (51.4%)
No	39 (55.7%)	34 (48.6%)

In silodosin group retrograde ejaculation was noted in 2 (2.9%) patients and in ESWL it was noted in 8 (11.4%) patients (p-value=0.049). In silodosin group postural hypotension was noted in 3 (4.3%) patients and in ESWL it was noted in 11 (15.7%) patients (p-value=0.024). In silodosin group dizziness was noted in 1(1.4%) patients and in ESWL bleeding was noted in 4 (5.3%) patients (p-value=0.172) (Table-2a).

Table No.2: Comparison of complications between study groups

Characteristics		Study Groups		Total	p-value
		Silodosin	ESWL		
Stone Clearance	Yes	57	44	101	0.014
		81.4%	62.9%	72.1%	
	No	13	26	39	
		18.6%	37.1%	27.9%	
Pain	Yes	30	45	75	0.011
		42.9%	64.3%	53.6%	
	No	40	25	65	
		57.1%	35.7%	46.4%	
Bleeding	Yes	24	40	64	0.007
		34.3%	57.1%	45.7%	
	No	46	30	76	
		65.7%	42.9%	54.3%	

Table No.3: Comparison of complications between study groups

Characteristics		Study Groups		Total	p-value
		Silodosin	ESWL		
Retrograde Ejaculation	Yes	2	8	10	0.049
		2.9%	11.4%	7.1%	
	No	68	62	130	
		97.1%	88.6%	92.9%	
Postural Hypotension	Yes	3	11	14	0.024
		4.3%	15.7%	10.0%	
	No	67	59	126	
		95.7%	84.3%	90.0%	
Dizziness	Yes	1	4	5	0.172
		1.4%	5.7%	3.6%	
	No	69	66	135	
		98.6%	94.3%	96.4%	

DISCUSSION

Urolithiasis is third most common disease after pathologic conditions and urinary tract infection with an estimated prevalence of 2 to 3 % and a life time recurrence rate of approximately 50%. Urolithiasis is one of the most prevalent urologic diseases in Asia. In Pakistan the reported prevalence is 16.0% as reported in 2012[1]. In another study Sorokin et al[11] reported 7-13% prevalence rate in North American population.

Yang et al[12] conducted a meta analysis on comparison of silodosin and ureteral stones in terms of safety and efficacy and concluded that silodosin is safe as minimum side effects are associated with it and it is effective in terms of stone expulsion time and post operative analgesic requirements. In another study by Sadasivam et al[13] on Indian population concluded that Silodosin is effective management method as it is associated with shorter stone expulsion time, less pain and other complications as compare to extracorporeal shock wave lithotripsy.

Ichiyanagi et al[14] and Akin et al[15] reported in their studies that extracorporeal shockwave lithotripsy is an established modality of treatment for ureteric stones. ESWL is a non-invasive technique for the treatment of urinary stone disease. It is widely used for the management of lower ureteric stones and this method of treating stones has advantages such as a Non-invasive technique, less painful and cost effective. The stone-free rates after extracorporeal shockwave lithotripsy of renal/ureteric calculi are widely discussed in the literature.

It has also been reported that extracorporeal shockwave lithotripsy was effective in 80.7% cases for complete removal of lower ureteric stones upto 1cm of size[16]. While another trial reported that extracorporeal shockwave lithotripsy was effective in 66.25% cases for complete removal of ureteric stones ≤ 1cm of diameter[17]. Lopes Neto study conducted in 2012 reported much less success rate of extracorporeal shockwave lithotripsy in treatment of lower ureteric stones. Ureterorenoscopy is accepted globally for safe and effective ureteric stones removal and is being widely used now a day with low rate of intra- and post-operative complications. However, ureteroscopy requires considerable surgical skills and anesthesia and is associated with complications such as retropulsion of stone, postoperative bleeding, infection, and ureteral stricture[18].

The researchers concluded that efficacy of a selective α-1a antagonist (silodosin) as medical expulsive therapy in patients with ureteral calculi did not demonstrate a benefit to the entire length of ureter. It had been reported that the silodosin was successful in complete removal of stones in 91.94% cases within 24-48 hours, while 94.64% in 28 days of treatment[19].

A study was conducted by Catalin Pricop et al[20] reported that after ESWL use of alpha-blocker along with silodosin (8 mg) have stone free rate similar to tamsulin (0.4 mg). Silodosin at lower doses of 4 mg is not having good results and it is statistically significant that stone size does not mean it.

CONCLUSION

Results of this study reveal that Silodosin is significantly more efficacious and safe drug in terms of outcome as compared to extracorporeal shockwave lithotripsy for the management of lower ureteric stone size of 5-10mm.

Author's Contribution:

Concept & Design of Study: Abdul Razaq

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Conflict of Interest: The study has no conflict of interest to declare by any author.

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