

# The Management of Lower Ureteric Stones: A Comparison of Silodosin and Extracorporeal Shock Wave Lithotripsy with Regard to Efficacy and Safety

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## ABSTRACT

**Objectives:** To compare the efficacy and safety of silodosin versus extracorporeal shock wave lithotripsy for the management of lower ureteric stone.

**Study design:** Randomized controlled trial

**Place & Duration of Study:** Conducted at Liaquat University of Medical and Health Sciences Jamshoro during from the period September 2022 to August 2023.

**Methods:** Total 110 patients of either gender with ureteric stone were included. All the cases were equally divided in to two groups i.e. Group I in which patients received extracorporeal shock wave lithotripsy and group II patients were given 8mg silodosin orally for 3 weeks and advised to discontinue if stone passage.

**Results:** Majority of patients were male in Group I and II 36 (65.45%) and 37 (67.27%). Mean age in group I was 37.42±7.24 years while in group II, the mean age was 36.55±6.87 years. The success rate in term of clearance of stones, Group I had 72.73% while Group II had 90.91%. The difference was statistically significant p-value 0.012. Complications were more in ESWL group as compared to silodosin group p-value <0.05.

**Conclusions:** The silodosin is more efficacious and safe than extracorporeal shock wave lithotripsy for elimination of ureteric stones.

**Keywords:** Ureteric Stone, Silodosin, Extracorporeal shock wave lithotripsy

## INTRODUCTION

The incidence rate of urolithiasis is 13% in men and up to 7% in women of older age<sup>1</sup>. Urolithiasis is a prevalent health disease that affects a lot of people. According to a survey that was carried out in 2012 among the population of Pakistan, the prevalence rate of urolithiasis was found to be as high as sixteen percent<sup>2</sup>. Urolithiasis is the illness that is most widespread in Asian nations. In various regions of the world, the prevalence of urolithiasis has been observed to range from 7-13% in North America and Europe, respectively, and from 5-9% in Europe. However, during the past several years, its prevalence has grown, and the factors that have contributed to this growth include dietary habits and lifestyle choices<sup>3</sup>.

There have been several instances in which minimally invasive therapies, such as extracorporeal shock wave lithotripsy, ureterolithotripsy, and percutaneous nephrolithotomy, have been demonstrated to be successful treatments. On the other hand, these operations are not only financially burdensome but also fraught with danger<sup>4</sup>. It is possible to take a conservative strategy that involves close monitoring in the majority of patients. This method is gaining popularity as a consequence of advancements in pharmaceutical therapy, which can lessen symptoms and make it easier for stones to be expelled<sup>5,6</sup>. Medical expulsive treatment (MET), which involves the utilization of  $\alpha$ -adrenoceptor antagonists, has emerged as a viable alternative approach for the initial management of small distal ureteral stones<sup>7</sup>.

The number of research that compare Silodosin to ESWL for the treatment of lower ureteric stones is quite limited. Consequently, we have decided to carry out this study in order to gather evidence from the local community. In the future, our study may assist us in determining a strategy that is better suitable for the treatment of lower ureteric stones in the local environment.

## MATERIAL AND METHODS

This randomized controlled trial was conducted at Liaquat

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University of Medical and Health Sciences Jamshoro during from the period September 2022 to August 2023. Patients details demographics were recorded after taking written consent. Patients with severe medical illness and those did not provide written consent were excluded from this study.

One hundred and ten patients were split into two groups, with Group I (ESWL) and Group II (Silodosin) each receiving an equal amount of treatment. On intravenous urography (IVU), a single renal and upper ureteric stone was included. Additionally, stones measuring up to 2 centimeters in size on ultrasonography of the kidneys, ureters, and bladder (KUB) and radio-opaque stones were also included. In addition to being pregnant, individuals who had bleeding problems (INR more than 1.5) and urinary tract infections (urine culture and sensitivity) were not included in the study. Over the course of three weeks, patients in group II were given 8 milligrams of silodosin orally for three weeks and were told to stop taking the medication if they experienced a stone passing. The total number of shockwaves that were delivered during each session in the ESWL group was 3200. A follow-up examination of the kidneys, ureters, and bladder (KUB) was performed on patients following the conclusion of their therapy in order to evaluate the level of success achieved. A SPSS-24 analysis was performed on the data.

## RESULTS

There were 36 (65.45%) male patients and 19 (34.55%) female patients in group I. In group II, there were 37 (67.27%) male patients and 18 (32.73%) were females. Mean age in group I was 37.42±7.24 years while in group II, the mean age was 36.55±6.87 years. (table 1)

In group I, stone clearance was seen among 40 (72.73%) while 15 (27.27%) patients had no stone clearance on KUB. In group II 50 (90.91%) patients had stone clearance while 5 (9.09%) had no stone clearance. There was statistically significant difference between the two groups (p-value 0.012) (Table 2 and figure 1).

In group II retrograde ejaculation was noted in 5 (9.09%) patients and in ESWL (group I) it was noted in 0 (0%) patients (p-value=0.038). In group II (Silodosin) postural hypotension was

noted in 2 (3.64%) patients and in ESWL (Group I) it was noted in 9 (16.36%) patients (p-value=0.029). In group I dizziness was noted in 5 (9.09%) patients and in group II noted in 1 (1.82%) patients (p-value=0.041)

Table 1: Baseline details of both groups

Characteristics	Group I	Group II
Mean Age (Years)	37.42±7.24	36.55±6.87
Gender		
Male	36 (65.45%)	37 (67.27%)
Female	19 (34.55%)	18 (32.73%)
Stone Size (mm)	5.24±1.6	5.33±2.24
Comorbidities		
DM	8 (14.55%)	7 (12.73%)
Hypertension	10 (18.18%)	8 (14.55%)

Table 2: Comparison between both groups by stone clearance

Stone clearance	Group I (ESWL)		Group II (Silodosin)		P value
	No.	%	No.	%	
Yes	40	72.73	50	90.91	0.012
No	15	27.27	5	9.09	



Figure 1: Comparison of success rate between Group I and II

Table 3: Comparison of complications between both groups

Characteristics	Group I	Group II	P-value
Retrograde Ejaculation			0.038
Yes	0 (0%)	5 (9.09%)	
No	55 (100%)	54 (98.18%)	
Postural Hypotension			0.029
Yes	9 (16.36%)	2 (3.64%)	
No	44 (83.64%)	53 (96.36%)	
Dizziness			0.048
Yes	5 (9.09%)	1 (1.82%)	
No	50 (90.91%)	54 (98.18%)	

**DISCUSSION**

Since 1980, shock wave lithotripsy has been the major therapy modality that is utilized for the treatment of urinary stones. When it comes to treating symptomatic upper urinary stones, SWL is effective in treating as much as 70 percent of cases. However, around fifty percent of patients who undergo SWL treatment do not have their stone burdens eliminated by this procedure.<sup>8-10</sup>

Within the scope of this study, we investigated the efficacy of two different oral treatment methods, namely ESWL and Silodosin 8mg. The findings provided evidence in favor of the Silodosin. Compared to Silodosin, which had a 90.91% effectiveness rate (p-value <0.05), the ESWL group had a 72.73% effectiveness rate. There have been very few clinical research that have compared the efficacy of various techniques in the published literature.

Silodosin is safe since it is linked with a minimal number of adverse effects, and it is successful in terms of stone expulsion time and post-operative analgesic needs, according to Yang et al.<sup>11</sup>, who did a meta-analysis on the comparison of silodosin and

ureteral stones in terms of safety and efficacy. They came to the conclusion that silodosin is safe. As compared to extracorporeal shock wave lithotripsy, Silodosin is related with a shorter stone ejection time, reduced discomfort, and other consequences. An additional study conducted by Sadasivam et al.<sup>12</sup> on the Indian population came to the conclusion that Silodosin is an effective treatment strategy by virtue of these characteristics.

According to the findings of the research conducted by Ichiyanagi et al.<sup>13</sup> and Akin et al.<sup>14</sup>, extracorporeal shockwave lithotripsy is a well-established method of therapy for ureteric stones. In the treatment of urinary stone disease, ESWL is a method that does not involve any invasive procedures. There are several benefits associated with this approach of treating stones, including the fact that it is a non-invasive treatment, that it is less uncomfortable, and that it is cost effective. It is frequently used for the management of lower ureteric stones. In the literature, there is a significant amount of discussion on the stone-free rates that occur following extracorporeal shockwave lithotripsy of renal and ureteric calculi. It has also been reported that extracorporeal shockwave lithotripsy was successful in 80.7% of instances for the total removal of lower ureteric stones that were up to 1 centimeter in size<sup>15</sup>. It was observed in another experiment that extracorporeal shockwave lithotripsy was successful in 66.25 percent of cases for the total removal of ureteric stones with a diameter of less than or equal to one centimeter<sup>16</sup>.

According to the findings of a study that was carried out by Lopes Neto in 2012, the success rate of extracorporeal shockwave lithotripsy in the treatment of lower ureteric stones was much lower. Ureterorenoscopy is commonly utilized nowadays with a low risk of intra- and post-operative problems, and it is widely regarded across the world as a safe and effective method for the removal of ureteric stones without causing any issues. Nevertheless, ureteroscopy necessitates a significant amount of surgical expertise and the administration of anesthesia. Additionally, it is linked to a number of problems, including the retropulsion of stones, postoperative hemorrhage, infection, and ureteral stricture<sup>17</sup>. Based on their findings, the researchers came to the conclusion that the use of a selective α-1a antagonist, namely silodosin, as a medical expulsive treatment in patients who had ureteral calculi did not exhibit any positive effects on the full length of the ureter. It had been found that the silodosin was successful in completely removing stones in 91.94% of instances within 24 to 48 hours, and in 94.64% of cases after 28 days of therapy<sup>18</sup>.

According to the findings of a research that was carried out by Catalin Pricop and colleagues [19], the use of an alpha-blocker in conjunction with silodosin (8 mg) has a stone-free rate that is comparable to that of tamsulin (0.4 mg) following ESWL. At smaller dosages of 4 mg, silodosin is not producing satisfactory results, and it is statistically significant that the size of the stone does not indicate that it is effective.

**CONCLUSIONS**

When it comes to the removal of ureteric stones, silodosin is preferred over extracorporeal shock wave lithotripsy since it is both more effective and safer. For a more accurate estimation of the results, however, multi-center studies conducted over a longer period of time are necessary.

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