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The Use of Selective Alpha Blockers (Silodosin) in Management of Lower Ureteral Stones larger than 6 mm in diameter

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Abstract

Introduction:
-The prevalence of urinary stones has doubled over the past 15 years, mainly due to increasing obesity, poor metabolic syndrome, and diabetes, of all urinary tract stones, ureteral stones constitute 22%, and approximately two-thirds of them are located in the distal ureter.
Management of ureteral stones requires taking into account symptoms and complications.
-This research aims to study the effectiveness of silodosin in the management of lower ureter stones larger than 6 mm in diameter in terms of the affected ureter (right or left), the size of the stone, the degree of hydronephrosis, the rate of stone expulsion(day), whether the stone was completely expelled or not, and the side effects of silodosin.
Methods
A prospective cohort study between Oct 2022 and Oct 2023 enrolled Patients attending the urology Clinic at Al-Assad University Hospital, who meet the criteria for entry into the study during the study period.
A total of 100 participants were diagnosed with a distal unilateral ureteral stone larger than 6 mm in diameter. The sample was divided into two groups, where the first group was the case group, with a population of 50 patients, and the second group was the control group, with a population of 50 patients.
Results
A large percentage of patients who were treated with silodosin (cases) were able to expel the stone completely, at a rate of 76%. On the other hand, 92% of the patients who did not take silodosin (controls) were unable to expel the stone.
We observed a clear decrease in stone excretion rates expulsion (day) in the group of cases who took silodosin, as the rate was 15.2-day in the case group compared to 30.4-day in the controls.
The most common side effect was retrograde ejaculation at 60% of the total sample size, followed by feeling tired at 28%, while the least side effects were diarrhea at 4% and vomiting at 6%.
Conclusion
Silodosin is considered one of the most effective medications in managing and treating lower ureteral stones, as it reduces the time required for stone expulsion.

Keywords: *Silodosin, Lower Ureteral, Ureteral Stones*

Introduction:

The prevalence of urinary stones has doubled over the past 15 years, mainly due to increasing obesity, poor metabolic syndrome, and diabetes [1,2], and of all urinary tract stones, ureteral stones constitute 22%, and approximately two-thirds of them are located in the distal ureter. Ureteral stones are either plain or non-plain, and solid stones can lead to irreversible kidney damage. Patients with non-plain ureteral stones may be asymptomatic and are treated. They are diagnosed by chance, but symptomatic patients may suffer from renal colic pain, hematuria, and urinary tract infection [3].

Management of ureteral stones requires taking into account symptoms and complications, including conservative methods such as Vigilant monitoring for spontaneous stone expulsion, medical expulsive therapy, extracorporeal shock wave lithotripsy, and Invasive procedures such as ureteroscopy, surgical or laparoscopic lithotripsy, except watchful waiting and drug therapy to stimulate stone expulsion, other interventions have higher health care expenses and are relatively invasive [4].

Medical expulsive therapy (MET) has a proven role in promoting stone passage and thus reducing the need for minimally invasive interventions [5]. Although Treatment that stimulates the passage of stones without the need for surgery reduces the morbidity and health care costs associated with this condition, the 2020 European Urological Association guidelines stated that the maximum benefit and effectiveness of drug therapy that stimulates the passage of stones is for patients with distal ureteral stones larger than 5 mm. Alpha-blockers are the mainstay of drug treatment, and various studies have shown that using tamsulosin as a drug that stimulates stone expulsion can increase the rate of stone expulsion, reduce ureteral colic, reduce the time required for stone expulsion, and Reduce the need for analgesics compared to placebo. Silodosin has recently been introduced, as a more selective alpha receptor blocker, and recent studies including a small number of randomized controlled trials have demonstrated the superiority of silodosin over tamsulosin in eliminating ureteral stones [6].

Patients and Methods:

The goal of the research

This research aims to study the effectiveness of silodosin in the management of lower ureter stones larger than 6 mm in diameter in terms of affected ureter (right or left), the size of the stone, the degree of hydronephrosis, the rate of stone expulsion(day), whether the stone was completely expelled or not, and the side effects of silodosin.

Study design, setting, and participants

A prospective cohort study between October 2022 and October 2023 enrolled Patients attending the urology Clinic at Al-Assad University Hospital, who meet the criteria for entry into the study during the study period.

The sample size was 100 participants depending on the Raosoft site [7], with a confidence interval of 95% and a predictive value of 0.05.

Every participant has signed the informed consent.

Inclusion criteria:

- Patients attending the urology Clinic with a distal unilateral ureteral stone larger than 6 mm in diameter.

Exclusion criteria:

- Patients under 18 years of age
- Pregnant women
- Patients with whom we were unable to contact
- Patients treated with silodosin for another reason

- Single kidney patients
- Patients with bilateral ureter stones
- Patients with deteriorating kidney function
- Patients with grades 3rd and 4th of hydronephrosis

Sample collection, clinical Examination, and patient information and history

After applying inclusion and exclusion criteria, we obtained a total sample of 100 patients, we interrogated the sample members and asked them about socio-demographic information, including age and sex. After that, we conducted clinical examinations and reviewed the patient's files to determine the affected ureter (right or left), the size of the stone, the degree of hydronephrosis, the rate of stone expulsion (day), whether the stone was completely expelled or not, and the side effects of silodosin.

Research work plan

We randomly divided the sample into two equal groups, where the first group was the case group, with a population of 50 patients, and the second group was the control group, with a population of 50 patients.

We treated the case group with 8 mg/day of oral silodosin for 21 days. The patients in both groups were advised to take 75 mg/day of diclofenac sodium as an analgesic necessary. Both groups were also advised to remain active, drink at least 2 L of water daily, and pass their urine through filters to catch any passing stones. Patients were invited to the clinic for weekly control visits to be questioned regarding any side effects related to medical therapy, the size of the stone, the degree of hydronephrosis, the rate of stone expulsion/day, and whether the stone was completely expelled or not. All the collected data were recorded. Patients who experienced stone passage were also invited for weekly control visits to record the passage duration and confirm passage of radiopaque stones by X-ray or radiolucent stones by low-dose unenhanced abdominal tomography.

Using the collected data, the groups were compared regarding age, sex, affected ureter (right or left), the size of the stone, the degree of hydronephrosis, the rate of stone expulsion(day), whether the stone was completely expelled or not, and the side effects of silodosin.

Ethics approval and consent to participate

Our study complies with the Declaration of Helsinki, the locally appointed ethics committee has approved the research protocol and written informed consent has been obtained from the subjects.

Statistical Analysis:

We used Excel 2010, and the Statistical Package for the Social Sciences version 23.0 (SPSS Inc., Chicago, IL, United States). P value < 0.05 was considered statistically significant. We relied on frequency, and percentages for categorical variables, meanwhile, for continuous variables, standard deviation, range, and median were used. For the statistical relationships, we used the Chi-square test (X2-test), and the student test to test the basal differences between groups.

Results

1-Socio-demographic data

A total of 100 participants were diagnosed with a distal unilateral ureteral stone larger than 6 mm in diameter. The sample was divided into two groups, where the first group was the case group, with a population of 50 patients, and the second group was the control group, with a population of 50 patients. Of each group, 15 were female and 35 were male.

The largest percentage of participants were in the 31 – 40-year group, at 40% for the case group (median age 37 years), compared to 42% for the control group (median age 36 years). This was followed by participants in the 51 – 60 age group (22 %).

More detailed information about the distribution among case and control groups regarding sex and age is shown in (Table 1)

Table-1: Socio-demographics futures

	Case	Control	P – Value
SEX			-
Male	35 (70%)	35 (70%)	
Female	15 (30%)	15 (30%)	
AGE			0.998
20 – 30	10 (20%)	8 (16%)	
31 – 40	20 (40%)	21 (42%)	
41 – 50	11 (22%)	11 (22%)	
51 – 60	5 (10%)	6 (12%)	
More than 60	4 (8%)	4 (8%)	
Median age	37 years	36 years	

2-Disease data

We studied the distribution of cases according to the affected ureter, right or left, and the degree of hydronephrosis above the affected area (Table 2).

Affected ureter

We found that left ureter stones are more common than right ureter stones in both groups of cases and controls, at a rate of 66% in cases and 62% in controls.

Degree of hydronephrosis

While the grade of hydronephrosis caused by the stone blocking the ureter, we found that the majority were suffering 1st-grade hydronephrosis, at a rate of 44% for cases and 40% for controls, followed by those who did not have hydronephrosis, at 32% for cases and 28% for controls. Finally, patients with 2nd grade constituted 24% of cases and 32% of controls.

Table 2: Disease data

	Case	Control	P – Value
Affected ureter			1
Left	33 (66%)	31 (62%)	
Right	17 (34%)	19 (38%)	
Degree of hydronephrosis			0.7
No hydronephrosis	16 (32%)	14 (28%)	
1st grade	22 (44%)	20 (40%)	
2nd grade	12 (24%)	16 (32%)	

3-Stone information and data

We collected information about the distribution of patients according to the size of the stone and whether the stone was completely expelled or not (Table 3)

Also, we measured a very important value, which is the rate of stone expulsion (day) among patients who took silodosin and patients who didn't

Stone size

Stones with size 6 – 12 mm are more common than other bigger stones.

82% of the cases had a stone size of 6-12 mm, compared to 76% of the controls, while for those who had stones larger than 12 mm, their percentage was 12% in the case group and 18% in the control group.

Stone expulsion

We found that a large percentage of patients who were treated with silodosin (cases) were able to expel the stone completely, at a rate of 76%. On the other hand, 92% of the patients who did not take silodosin (controls) were unable to expel the stone.

Rate of stone expulsion

We observed a clear decrease in stone excretion rates expulsion (day) in the group of cases who took silodosin, as the rate was 15.2-day in the case group compared to 30.4-day in the controls.

Table 3: Stone information and data

	Case	**Control**	**P – Value**
Stone size			0.8
6 – 12 mm	41 (82%)	38 (76%)	
More than 12 mm	24 (12%)	9 (18%)	
Stone expulsion			0.004*
Yes	38 (76%)	4 (8%)	
No	12 (24%)	46 (92%)	
Rate of stone expulsion (day)			-
	15.2	30.4	

* Significant

5- Distribution of side effects resulting from the applied treatment

) Table) showed that the most common side effect was retrograde ejaculation at 60% of the total sample size, followed by feeling tired at 28%, while the least side effects were diarrhea at 4% and vomiting at 6%.

Table 4: Side effects of silodosin

Side effect	**Case**
Retrograde ejaculation	30 (60%)
Hypotension	3 (6%)
Dizziness	9 (18%)
Diarrhea	2 (4%)
Vomiting	3 (6%)
Headache	11 (22%)
Nausea	8 (16%)
feeling tired	14 (28%)

Discussion

A case-control study included 100 individuals who were divided into two groups, the case group and the control group. The aim was to demonstrate the role and effectiveness of silodosin in treating stones of the lower third of the ureter larger than 6 mm in diameter.

The two groups (case and control) were approximately equal in terms of gender and age, and the research showed that males dominated by 70% compared to 30% for females. As for age, the dominant group was 31-40, accounting for 40% of the patients in the cases.

Then we moved on to ask about the affected ureter, and the comparison showed that the left ureter had a greater percentage in the case group than in the control group, at 66%.

Moving on to collect information about stone size, we divided the sample into two categories: 6-12 or

larger than 12. The results showed that the largest percentage of the patient group had stones between 6-12 mm, at a rate of 41%. Moving to the degree of hydronephrosis, the group of cases developed first-degree hydronephrosis with a percentage of 44%, which is the largest percentage of the total categories.
When asked about stone expulsion, the research showed that 76% of the group of cases answered yes, which shows the positive role of the drug, with an elimination rate of 15.2 (day).
Side effects ranged from low blood pressure, dizziness, diarrhea, headache, nausea, and general fatigue.
We compared our research with one of the previously published studies [8], Our study showed a male predominance, which is consistent with the YUKSEL study, but with a greater percentage of 70% compared to 57% for the case group.
As for the comparison in terms of age, Research and statistics showed that the dominant age group was 31-40 years old in both studies, with a mean of 35.23 compared to 37 in our study.
The rate of elimination of ureteral stones was higher when using silodosin, with a statistically significant difference. With silodosin, the average stone expulsion time was 15.2 days.
Finally, the rate of expulsion of ureteral stones with a diameter of (6-12 mm) was higher when using silodosin, reaching 76% compared to 8% when not using tamsulosin, with a significant statistical difference.

Conclusion

Silodosin is considered one of the most effective medications in managing and treating lower ureteral stones, especially those with a size ranging between 6 and 12 mm, as Silodosin reduces the time required for stone expulsion very significantly.

Acknowledgements:

Not applicable

Ethics approval:

All patients were fully informed about the study and its aim, and their consent was taken without any financial compensation.
The research approval (No 475) was given by the Ethics Committee of the Faculty of Medicine, Damascus University, Syria.

Patient consent:

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Conflict of interests:

The authors declare that they have no competing interests.

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Study highlights:

- The prevalence of urinary stones has doubled over the past 15 years
- Management of ureteral stones requires taking into account symptoms and complications
- This research aims to study the effectiveness of silodosin in the management of lower ureter stone
- Silodosin is considered one of the most effective medications in managing and treating lower ureteral stones, especially those with a size ranging between 6 and 12 mm, as Silodosin reduces the time required for stone expulsion very significantly.

Authors' contributions:

Study concept and design: Abdulrazzak Alsulaiman
Acquisition of data: Abdulrazzak Alsulaiman
Analysis and interpretation of data: Abdulrazzak Alsulaiman
Drafting of the manuscript: Alaa Alden Alabdou
Critical revision of the manuscript for important intellectual content: Abdulrazzak Alsulaiman
Statistical analysis: Alaa Alden Alabdou
Administrative, technical, and material support: Abdulrazzak Alsulaiman
Study supervision: Wafik Barakat

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