

Efficacy of Silodosin and Tamsulosin inpatient of Ureteric Calculi: A Comparative Study

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Abstract

Background: The urinary stone disease is one of the most common afflictions of the modern society and it has been described since antiquity with the westernization of global culture. It has led to a lot of distress physically, mentally and financially to the affected individuals. Aim of this study is to compare the efficacy of Silodosin and Tamsulosin as a medical expulsive therapy, in the management of ureteric stone in the term of stone clearance and stone expulsion time.

Method: This prospective randomized study was conducted on 60 patient aged >15 year who had unilateral or bilateral ureteric stone < 6 mm or 6mm. patient were divided in two group. Group A received Tamsulosin (0.4mg) and group B received Silodosin (8 mg) daily for 28 days the patient were followed up by ultrasonography, plain radiograph of kidney, ureter and bladder and IVU.

Results: There is significantly higher stone clearance rate of 73% in Group A VS in group B of 90%(p value<0.05). Group B also showed a significant advantage for stone expulsion time. No severe complication were recorded during the treatment period. In Group A, out of 30 patient, 8 patient required ureteroscopic removal of stone or open ureterolithotomy but in group B, only 3 patient required the same.

Conclusion: Our data show that silodosin is more effective than tamsulosin in the management of ureteric stone < 6mm or 6mm for stone clearance rate and stone expulsion rate.

Keywords: Efficacy, Expulsion Time, Expulsion Rate.

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Introduction

The urinary stone disease is one of the most common affection of modern society and has been described since antiquity with the westernization of global culture, affecting 13% of men and 7% of women.[1] The life time risk of urinary stone disease is estimated to be between 5% and 12%, in Europe and US, among all urinary stone, 20% present as uretric stone, of which 70% found in lower third of ureter.[2] To date, minimally invasive therapy, such as extracorporeal shock wave lithotripsy and ureterolithotripsy, represent efficacious treatment modalities in almost all case. Nevertheless, these procedure imply high cost and not risk free.[3] A watchful waiting approach has been reported to be associated with spontaneous stone expulsion in up to 50% of the case, but some complication may occur such as urinary tract infection.[4]

There has been a paradigm shift in the management of ureteric calculi in the past decades, with the introduction of lesser invasive method and newer drugs. The alpha -1 blocker which were first developed as an anti-hypertensive drug, now being effectively use in the treatment of benign prostatic hyperplasia, due to their relaxing property on urinary tract. Recent studies have reported excellent results with medical expulsion therapy for distal ureteric calculi, with alpha 1 blocker. Both American urological association (AUA) and European association of urology (EAU) also recommended alpha 1 blocker for the treatment of ureteric stone. Their use in the treatment of distel ureteric stone arose from the consent that they could induce a selective relaxation of ureteral smooth muscles, which could inhibit the urethral spasm and results in dialation of ureteral lumen.

In 1970, Malin et al demonstrated the presence of alpha and beta adrenergic receptor (AR) in the human ureter.[5] Alpha 1 are the most abundant subtype at the level of ureteric smooth muscles.[6] Itoh et al alpha 1a, alpha 1B, alpha 1D). Antagonist of these receptor have been prove to decrease ureteric basal tone, peristalsis activity and contraction thus decreasing intraureteric pressure and increasing urine transport. These meta-analysis have confirmed a positive effect of alpha blocker therapy on stone expulsion rate.[7] Alpha blocker has been proved to improve the likelihood of spontaneous stone passage and to decrease both the time to stone passage and analgesic requirement.[8]

According to European Association of urology Guideline, alpha blocker are recommended for Medical expulsion therapy.[9] Patient who elect for MET should have well controlled pain, no clinical evidence of sepsis and adequate renal function reserve.[10]

The alpha 1A/D selective alpha blocker TAMSULOSIN has been demonstrated to be safe and effective drug that enhance spontaneous passage of distal ureteric stone seized 10 mm or smaller.[11] recent studies have demonstrated that the Alpha 1A subtype plays the major role in mediating phenylephrine induced contraction in the human isolated ureter. Kobayashi et al found that the selective alpha 1A adrenergic receptor antagonist, SILODOSIN was more effective than the selective alpha 1D adrenergic receptor antagonist, BMY-7378, for noradrenaline induced contraction in the human ureter.[12] According to Tsuzaka et al, silodosin was clinically superior for stone expulsion when compare to tamsulosin.[13]

Hence, a study was planned to see the efficacy of SILODOSIN (8mg/day) – a new alpha 1a antagonist with TAMSULOSIN (0.4mg/day) -alpha 1A/ 1D antagonist.

Material and Methods

All cases with lower abdomen discomfort or flank pain accompanied by urine symptoms were admitted to either the emergency department or the outpatient department at SKMCH, Muzaffarpur, Bihar. Following a thorough evaluation, 60 patients with ureteric calculi who did not have any congenital abnormalities, hydronephrotic alterations, or signs of infection were chosen for the study.

This prospective study was conducted during the period of July 2025 to December 2025 in Department of General Surgery, Sri Krishna Medical College & hospital, Muzaffarpur, Bihar.

Each patient was examined thoroughly after taking detailed history. The diagnosis and examination was made with history, clinical features and CBC, B/Urea, S/ Creatinine, Routine urine, digital X-

RAY KUB, IVU, USG of whole abdomen to support the diagnosis.

- The patients evaluated with ureteric stones were managed conservatively. Every patient provided consent after receiving information about nature of study, time of study end, adverse effect, and the possibility of intervention if needed.

The patients confirmed with stone in ureter were divided in two groups by random selection. The patients were divided into two groups as follows :

- Group A: Patients with ureteral calculi received single dose of Tamsulosin (0.4mg/day)
- Group B: patient with ureteric calculi received single dose of Silodosin (8 mg/day).

Both the group were strictly instructed to drink minimum of 2 litre of water daily and to use symptomatic treatment with tab diclofenac on demand. All the patients were advised to filter/strain their urine stream to detect stone passage or collect the urine in transparent container and to stop medication when the stone was expelled and report for confirmation.

The duration of trial was until expulsion of the stone, but no longer than 4weeks.

The patients was then observed weekly and asked for any history of passage of calculi and digital X-RAY KUB &ultrasound scan was repeated after 15 days to look for any passage of calculi.

The findings were recorded and the patients were monitored and followed up for a period of one month. The passage of stones, was confirmed with ultrasonography & digital X-RAY KUB.

After 1 month if treatment failed, conservative management was discontinued and patient was advised for surgical intervention in higher centre where facilities for URS and ESWL is available.

Inclusion criteria

- Patients with age > 15 years
- Calculus in the ureter with stone size 6mm or less
- Stones at multiple sites were also included.

Exclusion criteria:

- Stone larger than 6mm
- Patient who undergone same treatment before
- Clinical and laboratory signs of urinary tract infections (UTIs)
- Severe hydronephrosis on ultrasound examination (gross pelvicalyceal dilatation with parenchymal thinning).
- Co-morbid conditions such as diabetes, alteration in renal parameters (serum creatinine>1.5mg/dl).

- Previous history or ureteral manipulation and/or surgery.
- Pregnancy.
- Urethral stricture
- Patient on alpha / beta blocker or CCB or steroid.
- Patient who are hypersensitive to tamsulosin or silodosin.

In each case studied, an elaborate history and physical examination and relevant investigations were carried out as depicted in proforma.

The treatment of the cases consisted of Alpha blocker drug tamsulosin(0.4 mg/daily) and silodosin 8mg/day given orally for 30 patients in each group along with NSAIDs, prednisolone in tapering dose and plenty of oral fluids. Patients who failed to expel the calculus with the above

treatment were sent to Department of Urology for ureteroscopic removal of stone.

The patients were followed up for one month.

Result

Patient demographics, socioeconomic status, stone status, stone size and location, stone ejection rate, and side effect incidence were all gathered and compared.

Group A's stone removal rate was 73%, whereas group B's was 90% (p=0.05), indicating a significant difference between the two groups. With a mean of 19.1 days as opposed to Group A's mean of 22.9 days, Group B's stone expulsion time was likewise noticeably shorter.

Table 1 : Treatment outcome parameters in these Group

	Tamsulosin (A)	Silodosin (B)	P-value
Expulsion rate	73% (23)	90% (27)	<0.05
Stone expulsion time(mean)	22.9	19.1	<0.05
Failure rate	27%	10%	<0.05

Table 2 : Demographic characteristics of these group

Characteristic	Group A (Tamsulosin)	Group B (Silodosin)
Mean Age (in year)	32.6	29.6
Sex (male/female)	17/13	18/12
Laterality (right/left)	19/11	13/17
Location (upper/middle/lower)	3/10/17	6/6/18
Mean Stone size (in mm)	5.7(1.2)	5.3(1.6)

In our study, In the group A, 3% of patients passed the ureteric calculus within 7 days, 6.7 % of the patients passed the calculus within 14 days, 30% of the patients passed the calculus within 21 days and 33.3% of the patients passed the calculus within 28 days of follow up with mean expulsion time is 22.9 days. 26.6% patients did not pass the calculus. P value is less than 0.05, hence

statistically significant.

In group B, 13% of patient passed stone within 1st week, 23% passed stone with in 2nd week, 26.6% of patient passed stone in 3rd week and same 26.6% of patient passed stone within 4th week with mean expulsion time is 19.1 days. 10% patient did not pass the calculus. P value is less than 0.05, hence statistically significant.

Table 3 : Time of expulsion of stone in both the Group

Time of expulsion in week	Group A (Tamsulosin)	Group B (Silodosin)
1 st week	1	4
2 nd week	2	7
3 rd week	9	8
4 th week	10	8
Failure(in number)	8	3
Failure%	26.6	10
Mean expulsion time	22.9 days (5.6)	19.1 days (7.2)

In Group A, 6.7% (2 patient) of the patient had orthostatic hypotension which was the most common side effect of this group only one patient had dizziness, retrograde ejaculation, dizziness, nasal congestion and headache.

But in group B, 10% (3 patients) of the patient had retrograde ejaculation which was the most common side effect of this group. Two patient developed mild nasal congestion and only one patient had mild headache. None of the patient of group B developed orthostatic hypotension and dizziness.

Table 4: Side effects in both the Group

Side effects	Group A	Group B
Orthostatic hypotension	2	0
Retrograde ejaculation	1	3
Dizziness	1	0
Nasal congestion	1	2
Headache	1	1

Discussion

The best treatments for ureteric stones are still ureteroscopy and SWL, although they are costly and not risk-free. Up to 50% of cases may result in spontaneous stone expulsion. However, complications such hydronephrosis, UTI, and ureteric colic might happen. The use of several adjuvant medications as MET for ureteric stones has recently been shown to improve the rate of stone removal and lessen pain and complications.[12, 13]

The alpha 1A and alpha 1D adrenoreceptor are the most abundant subtype in distal ureter, stimulation of these $\alpha 1$ adrenoreceptor leads to increase in both the frequency of ureteric peristalsis and force of contraction. However, blockade of these receptor decrease basal ureteric tone, decrease peristalsis frequency and amplitude leading to decrease in intraluminal pressure while the rate of urine transport increase and thus increasing chance of stone passage.[14]

Highly selective $\alpha 1a$ adrenoreceptor blockers have been developed to minimize the cardiovascular adverse effect while maintaining the efficacy on urinary tract.[15] Tamsulosin is selective $\alpha 1$ blocker with 10 fold greater affinity for $\alpha 1A$ and $\alpha 1D$ adrenoreceptor subtype than the $\alpha 1B$ subtype, while the affinity of Silodosin for $\alpha 1A$ subtype is about 162 and 50 fold greater than its affinity for the $\alpha 1B$ and $\alpha 1D$ adreno receptor subtype respectively, which explain weak cardiovascular adverse effect of Silodosin.

In our present study, the stone clearance rate was significantly higher in silodosin group (90%) compared with the tamsulosin group (73%) with $p < 0.05$. Mean stone expulsion time in silodosin group is significantly low (19.1 days) as compare to tamsulosin (22.9 days). Study done by Gupta et al [16] who reported stone clearance rate of 82% and 64% for silodosin and tamsulosin respectively with stone expulsion time in the silodosin and tamsulosin, at 12.5(3.5) vs 19.5 (7.5) days respectively. However, Imperatore et al [17] reported a nonsignificant difference of stone clearance rate between silodosin (88%) and tamsulosin (84%).

For safety issue and adverse effect, both drug are safe and well tolerated and the most frequently

encountered side effect in Silodosin group was retrograde ejaculation which is reported in 10% and 3% in tamsulosin group (A). Postural hypotension is most common in tamsulosin group (6.7)% which was managed conservatively. No patient discontinued treatment because of retrograde ejaculation and postural hypotension as both were reversible.

Conclusion

The safe and efficient medications tamsulosin and silodosin improve the spontaneous passage of stones that are 6 mm or smaller. In terms of stone expulsion rates (90% and 73%, respectively; p value < 0.05) and expulsion times (19.1 ± 5.6 days and 22.9 ± 7.2 days, respectively; p value < 0.05), silodosin is more successful than tamsulosin. Additionally, compared to tamsulosin (3.3%), our study shows that silodosin has a little higher incidence of anomalous ejaculation (10%) but a lower incidence of orthostatic hypotension (0%).

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