



Comparison of the Efficacy of Silodosin vs Tamsulosin, as a Medical Expulsive Therapy, in the Management of Distal Ureteric Calculus in Terms of Stone Clearance Rate

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Abstract

Objective: To compare the efficacy of Silodosin and Tamsulosin as a medical expulsive therapy given for the conservative management of distal ureteric calculus in terms of Stone Clearance Rate.

Patient and Methods: A Prospective Observational Analytical Study was conducted on 120 cases between 18 years and 75 years with Unilateral distal ureteral single calculus (Distal to Iliac vessel crossing) and size less than or equal to 1 cm. The cases of this study were divided into two groups: Group A receiving Silodosin 8 mg tablet once daily and Group B receiving Tamsulosin 0.4mg capsule once daily. These patients were investigated with Serum Creatinine, X-ray KUB and USG KUB during the initial diagnosis. Each group received treatment for a period maximally 1 month. During this period the patient were evaluated for passage of calculus 2 weekly by Clinical history and by USG & NCCT (only incase USG was inconclusive).

Results: There was a significantly higher stone clearance rate of 81.67% in Group A vs 63.33% in Group B. Group A also showed a significant advantage for stone expulsion time.

Conclusions: Our data showed that silodosin is more effective than tamsulosin in the management of lower ureteric calculus for stone clearance rates and stone expulsion times.

Keywords: Silodosin; tamsulosin; distal ureteric stones, stone clearance.

Introduction

Urolithiasis is one of the most common disorders of urinary tract. Urolithiasis affects 5-12% of the population globally. Ureteric stones represent ~ 20% of urolithiasis cases, from which ~70% are situated in the lower third of the ureter and termed 'distal ureteric calculi'.^[1]

The increasing prevalence of ureteric stone is a matter of concern, and it may be linked to dietary habits and other environmental factors. The incidence varies being higher in hilly and arid

areas, for instance in Middle East, Rajasthan & Kutch in western India, Balkan Nations, Scandinavia, Mediterranean and Saharan Africa which probably reflects water content as well as hot weather conditions and dehydration that exist in these areas.^[2]

Over the last two decades, the management of ureteric stones had changed greatly, especially after the introduction of shockwave lithotripsy (SWL) and ureteroscopy.

However, these minimal-invasive treatments are

not pocket-friendly and have complications in 10-20% of the patients in various studies.^[3] Alpha-blockers used as medical expulsive therapy (MET) are the first line of management for small distal ureteric stones.^[4]

A watchful waiting approach has been reported to be associated with spontaneous stone expulsion in up to 50% of cases but a few complications have been observed such as urinary tract infection, hydronephrosis and colic events.^[5]

Alpha1 are the most abundant AR subtypes at the level of ureteric smooth muscle cells.^[6] Three types of alpha1 AR are expressed in the human ureter (alpha1A, alpha1B and alpha1D).^[7]

The α_{1A} -adrenoceptor subtype has been shown to play the major role in mediating phenylephrine-induced contraction of the human isolated ureter.^[8] Antagonists of these receptors have been proved to decrease ureteric basal tone, peristaltic activity, prevent ureteric smooth muscle contraction and contractions thus decreasing intra-ureteric pressure and increasing urine transport.^[9] In turn, the ureteric muscles can relax which can lead to easy passage of stone and relief in ureteric colicky as well. Alpha-blockade has been proved to improve the likelihood of spontaneous stone passage, and to decrease both the time to stone passage and analgesic requirements.^[10]

Both AUA and EAU recommend α -blockers for the treatment of ureteric stones.

Various studies compared alpha1A (AR) antagonist, silodosin with alpha1D (AR) antagonist revealing that silodosin was clinically superior for stone expulsion.^[11]

Material and Methods

Source of Data

This study included 120 patients who presented with symptomatic unilateral lower ureteric stone less than or equal to 1cm during the period from November 2021 to October 2022 to the Department of Urology at Father Muller medical college.

2.1 Technical Design

Prospective Observational Analytical Study.

2.2 Sample Size

120 patients, 60 patients in Silodosin group A and 60 patients in Tamsulosin group B. Sample size was calculated using Epi Info 7 version 7.2.4.0 software with a confidence of 95% and power of 80%.

2.3 Subjects Included in the Study

The cases of this study were divided into two groups: Group A: (60 patients) who received silodosin 8 mg controlled-release capsule once daily at constant time. Group B: (60 patients) who received Tamsulosin 0.4mg capsule once daily at constant time.

In our department, these patients are investigated with Serum Creatinine, X-ray KUB and USG KUB during the initial diagnosis which are necessary for the proper further treatment of patient. So, these investigations were observed and recorded at the time of diagnosis. Each group received treatment for a period maximally 1month. All patients were advised to increase water intake and to filter their urine to see if stone is passed. During this period the patient evaluated every 2 weeks by history and radiologically by USG KUB & NCCT for stone passage (only in case prior investigations are not conclusive). Clinical history for evaluation included relevant questions like attacks of renal colic, analgesic requirements, time of stone passage etc.

2.3.1 Inclusion Criteria

- Patients more than 18 and less than 75 years.
- Unilateral distal ureteral single stone (Distal to Iliac vessel crossing)
- Size of calculus less than or equal to 1 cm.

2.3.2 Exclusion Criteria

- Patients less than 18 and more than 75years.
- Asymptomatic Patients
- Multiple stones

- Bilateral ureteric stones
- History of Fever
- Pyonephrosis
- Serum creatinine >2 mg / dl
- High grade hydronephrosis
- Patient with single kidney
- Pregnancy and lactating women.
- Associated ureteral pathology or aberrant anatomy e.g. ureteral stricture, Retrocaval ureter.
- Cardiac patients.
- Hypersensitivity to the drugs/ NSAID Intolerance.

2.4 Statistical Analysis

Data collected through history, clinical examination, laboratory investigations and outcome measures were entered and analysed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis. According to the type of data, the following tests were used to test differences for significance: Differences between frequencies (qualitative variables) and percentages in groups were compared by Chi-square test. Differences between means (quantitative variables) IN two parametric groups by t test. P value was set at <0.05 for significant results &<0.001 for high significant result.

As per the international standards, Participant consent and Institutional Ethics Committee

clearance was obtained prior to the start of the study.

Results

There were no significant differences among the two groups for patient’s age, gender, stone laterality, and stone size (Table 1)

From the Table 2, stone expulsion was observed in 49 patients (81.67%) from group (A) (Silodosin) with average time of stone expulsion 11.35 days (±1.71) and in 38 patients (63.33%) from group (B) within average time of stone expulsion 14.55 days (±2.13).

There is no statistical significant difference was observed between both groups according to number of attacks of renal colic experienced by patient (Table 3)

As regarding complications of the drugs noticed during follow up, there were 13 patients (21.67%) of group A (silodosin) were suffered from anejaculation and only 3 patients (i.e. 5%) in Tamsulosin group. However, there were 11 patients (18.3%) who were complaining hypotension, headache, dizziness and nasal congestion after being treated with Tamsulosin but Silodosin group showed better profile for these side effects (4 patients) (6.67%).

Discussion

In this study, the statistical difference between 2 groups for demographic data and stone data (size and laterality) was insignificant.

Table 1 The patients’ demographic and stone data

	Group A	Group B
Age in years (Mean, SD)	37.3 (12.17)	34.05 (11.00)
Men (n, %)	32 (53.33 %)	34 (56.67 %)
Women (n, %)	28 (46.67 %)	26 (43.33 %)
Stone size, mm (Mean, SD)	6.7mm (1.9)	6.3mm (1.7)
Laterality (right/ left)	36/24	33/27

The stone clearance rate was significantly greater in the silodosin group compared with the tamsulosin group at (81.67% and 63.33% respectively). The mean stone expulsion time was

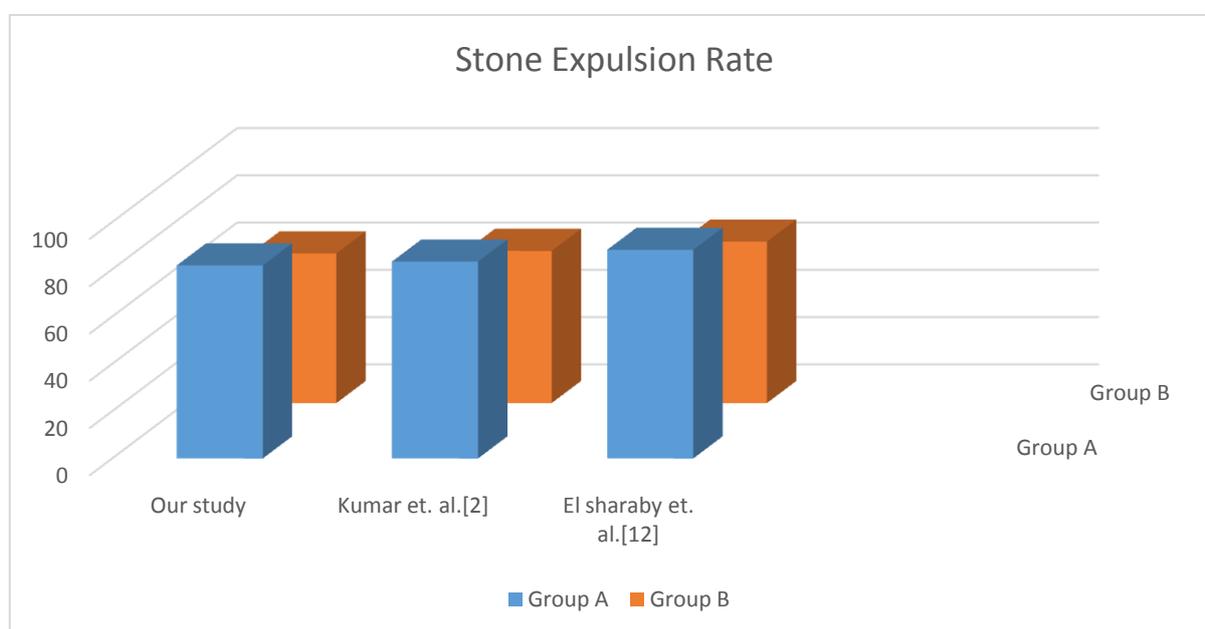
significantly shorter in the silodosin group (11.35 days) compared with the tamsulosin group (14.55 days) as depicted below.

Table 2 Rate and Time of stone expulsion in both groups

		Group A	Group B
Success rate		49 (81.67%)	38 (63.33 %)
Failure rate		11 (18.33%)	22 (36.67%)
Total		60	60
Stone Expulsion Time	Mean (+/- S.D.)	11.35 (+/- 1.71)	14.55 (+/- 2.13)

Kumar et al. ^[2], also confirmed the pervious results as they found that silodosin is better than tamsulosin in expulsion rate and time. Stone expulsion rate was 83.3% in the silodosin group and 64.4% in the tamsulosin group. El Sharaby et al. ^[12] also showed that silodosin was more effective than tamsulosin in the expulsion rate

(88.3% vs 68.3 %) and time (9.5 vs 12.7 days). Dell’Atti^[16] reported the expulsion rate of 80.3% in silodosin group whereas the tamsulosin group showed an expulsion rate of 61.2%, resulting in a significant advantage in favour of silodosin group.^[13]



The reason for this can be explained by the fact that silodosin is highly selective for alpha1A AR, with a 162-fold greater affinity than alpha1B AR and about a 50-fold greater affinity than for alpha1D AR.^[14]

The results of the current study showed a lower mean number of pain episodes in the silodosin compared with tamsulosin group, with not much

statistical difference between both groups.

Kumar et al. reported that the mean of pain episodes of (0.8%) and (1.7%) in silodosin and tamsulosin groups respectively which was none statically different.^[2]

These results were previously supported by Elgalaly et al.^[15] and El Sharaby et al.^[12]

Table 3 Number of attacks of renal colic / patient

	Group A	Group B
No. of attacks of renal colic/patient (Mean ± SD)	1.35 (+/- 1.1)	1.65 (+/- 0.91)

In our study we found that both drugs are well tolerated and safe. The most abundant

complication is An ejaculation which was reported in 13 patients (21.67%) for silodosin group and 3

patients (5%) in other group.

The Retrograde ejaculation, presented as “Anejaculation” by patient, is due to smooth muscle relaxation of bladder neck muscles.

Kumar et al. study showed that retrograde ejaculation was higher (15.6%) for silodosin

group and 11.2% for tamsulosin group.^[2]

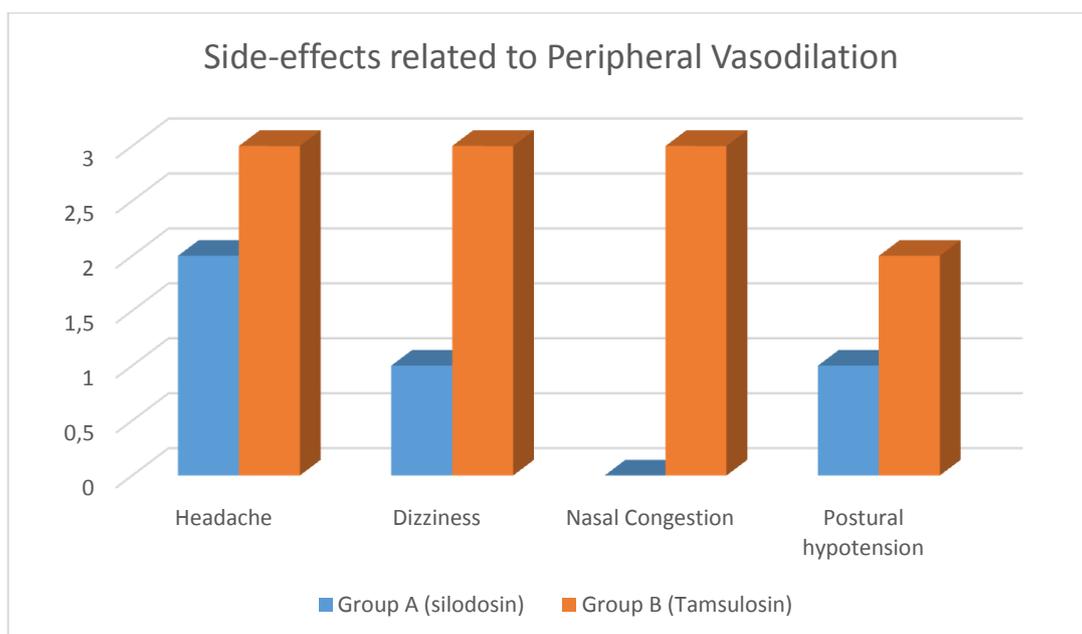
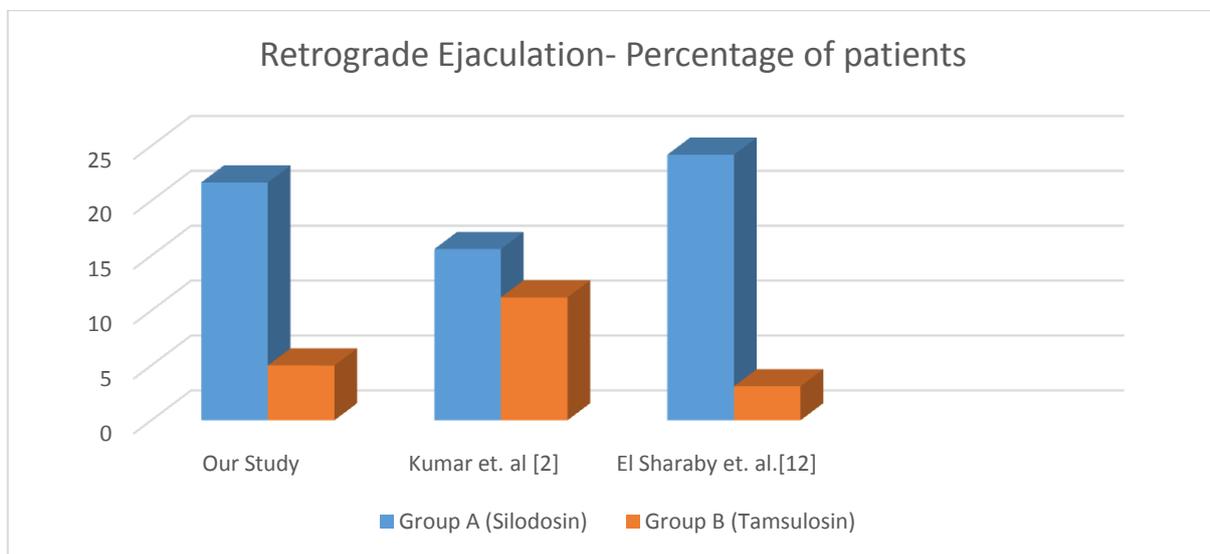
But the complications related to Peripheral Vasodilation in this study as dizziness, nasal congestion, headache and orthostatic hypotension is more common in tamsulosin group (18.3%) than silodosin group (6.67%).

Table 4 Complication among the patients of both groups during follow up

	Group A	Group B
An ejaculation	13 (21.67%)	3 (5%)
Side-effects related to Peripheral Vasodilation (Dizziness, Orthostatic hypotension etc.)	4 (6.67%)	11 (18.3%)

The lower incidence of these kind of side effects related to peripheral vasodilation associated with

silodosin use make it more suitable for older cardiac patients without renal failure.



Clinical benefit of α -blockers for treating Distal ureteric stones had been shown in two meta-analysis, in which spontaneous stone passage in patients given α -blockers were 52% and 44% greater than those not given such medications.^[16,17]

Patients who are elected for MET should have no clinical evidence of sepsis, and should have good renal functional reserve.

Conclusion

In conclusion, according to our study, silodosin is more effective than tamsulosin in the management of DUS for the stone clearance rate and stone expulsion time; and lower incidence of side effects related to peripheral vasodilation, however the higher incidence of Retrograde ejaculation is the major drawback felt in young individuals. A multi-centre study on larger scale is needed to confirm the efficacy and safety of silodosin.

Conflict of Interest: None declared.

Source of Funding: None

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