

Comparison of Silodosin and Tamsulosin in Medical Expulsive Therapy of Distal Ureteric Calculi

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ABSTRACT

Objective: To carry out comparative analysis of Silodosin and Tamsulosin in medical expulsive therapy of distal ureteric calculi, in terms of stone clearance rate and stone expulsion time.

Study Design: Randomized clinical trial (clinicaltrials.gov - NCT05790902).

Place and Duration of Study: Urology OPD, Armed Forces Institute of Urology, Rawalpindi Pakistan, from Sep 2022 to Feb 2023.

Methodology: A total of 142 cases with unilateral Distal Ureteric Calculi (DUC) of <8 mm in size were enrolled and allocated randomly into two groups, each having 71 cases. Patients of Group-A and Group-B used 8 mg of Silodosin and 0.4 mg of Tamsulosin daily respectively. They were followed weekly until stone passage/four weeks, to document Stone Clearance Rate (SCR), no of Ureteric Colic Episodes (UCE), Stone Expulsion Time (SET), Postural Hypotension (PH) and Abnormal Ejaculation (AE).

Results: Group-A had significantly better SCR than Group-B (80.3% vs 54.9%) ($p=0.001$). The Group-A exhibited significant advantages of shorter mean SET (13.0 ± 2.07 vs 15.55 ± 1.74) and fewer no of UCE ($p<0.001$). Two patients (2.8%) of Group-A had PH as compared to three (4.2%) of Group-B ($p=0.649$). AE was observed more in Group-A than Group-B (28.2% vs 25.4%) ($p=0.705$).

Conclusion: Silodosin surpasses Tamsulosin in MET of DUC, in terms of SCR, SET and UCE; however, it has more retrograde ejaculation.

Keywords: Silodosin, Tamsulosin, Ureterolithiasis.

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INTRODUCTION

Urinary tract stone disease is a common urological disorder, having high presentation in emergencies and OPDs. It globally affects approximately 12 % of the population. About 20 % of these stones involve ureter, out of which 70% are found in distal ureter.¹ Global statistics indicate its increasing prevalence, leading to enhanced burden on economy.² Medical Expulsive Therapy (MET), Uteroscopy (URS) and Extracorporeal Shock Wave Lithotripsy are recommended modalities for managing distal ureteric calculi (DUC), having size of less than 10 mm.³ The patients prefer MET because of spontaneous expulsion of ureteral stones, as well as to avoid invasiveness and high costs of ESWL/URS. The α -blockers, calcium channel blockers, Furosemide, and corticosteroids had been utilized in MET as these could promote expulsion of DUC.⁴⁻⁶

Several studies have shown superior results with use of α -blockers. The α -1 adrenergic receptor

antagonists relax the ureteral smooth muscles, thus dilating its lumen and promoting stone expulsion.⁷ The ureter has three subtypes of α -1 receptor (α -1A, α -1B & α -1D). The most significant role of α -1A receptors have been reported in the ureteric contractions and peristalsis in recent research⁸. Tamsulosin selectively blocks α -1A & α -1D receptors equally and various RCTs have demonstrated its effectiveness in enhancing clearance rate and reducing the time of expulsion of DUC with minimal morbidity.³ Silodosin is a recently developed highly selective α -1A adrenergic receptor antagonist and it has 162 times more affinity for α -1A than α -1B receptors.⁹ As a result of this characteristic feature, Silodosin has revealed more efficacy and fewer untoward effects (especially postural hypotension) in MET of DUC than Tamsulosin.¹⁰

A recent trial has comparatively analyzed the efficacy of Silodosin and Tamsulosin in the treatment of DUC in respect of stone clearance rate (SCR), stone expulsion time (SET), postural hypotension (PH) and retrograde ejaculation. It revealed that Silodosin had significantly higher SCR (83% vs 57%), lower mean SET (16.7 ± 5.2 vs 13.3 ± 4.1) and less no of cases having

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PH (2 vs 4)³. No local comparative study has been carried out.

The rationale of this study was to comparatively analyze Silodosin and Tamsulosin in MET of DUC in our local setup, to ascertain the best drug that promptly and swiftly relieves the ailment; hence promoting early return to functionality, with less adverse effects.

METHODOLOGY

This Randomized Clinical trial was performed in the Urology Outpatient Department of Armed Forces institute of Urology, Rawalpindi Pakistan, from September 2022 to February 2023. The approval of hospital ethical committee was attained (vide AFIU Rawalpindi ID no Uro-Trg-1/IRB/2022/009 dated 01 Sep 2022). The clinical trial was registered on clinicaltrials.gov (Registry ID - NCT05790902). Using World Health Organization (WHO) Sample Size Calculator, sample size of 142 patients (71 patients in each group) was calculated; by using 5% level of significance, 90% power of test with expected percentage of Stone Clearance Rate (SCR) of 83% and 57 % in Silodosin and Tamsulosin groups respectively.³

Inclusion Criteria: Patients of either gender, having age of 18-55 years, presenting in OPD with loin pain, and having single and unilateral DUC of less than 8 mm in size on plain Computerized Tomography of Kidney Ureter Bladder.

Exclusion Criteria: All patients having solitary kidney, proximal and mid ureteric calculi, bilateral ureteric calculi, Urinary Tract Infection, moderate and gross hydronephrosis, deranged renal function tests, any history of URS or ureterolithotomy, pregnancy, diabetes mellitus, and those taking steroids or any other immunomodulator drugs were excluded from the study.

A total of 142 patients fulfilling inclusion and exclusion criteria were selected by consecutive sampling. After detailed explanation of the clinical trial, untoward outcomes, and the prospects of URS if needed, an informed consent was obtained from every enrolled patient. The patients were halved in groups of 71 each randomly (Lottery method) as shown in Figure-1. In Group-A, 8 mg of Silodosin was used by the patients once daily whereas in Group-B, 0.4 mg of Tamsulosin was utilized once daily (both at night). Tab Diclofenac sodium (50 mg) was prescribed for ureteric colic. The participants were instructed to intake of sufficient water, ensure filtering of the urine

to notice passage of stone and apprise us once the stone passed. The primary outcome was SCR & SET and secondary was no of UCE. Patients were followed up each week to document stone passage, time of stone passage, no of UCE, and symptoms of PH and abnormal ejaculation (AE). The development of PH was an intolerable effect and hence led to stoppage and failure of treatment. However, patients were counselled about transient effects of AE and advised to continue treatment. The participants were reviewed weekly, until passage of calculus (proved by plain CT KUB) or the end of 4 weeks of drug regular usage; surgical intervention (URS) was done in patients who did not pass stone. All individual records were maintained on a follow up performa.

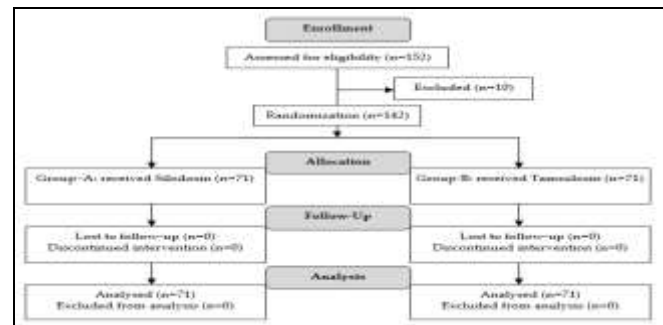


Figure-1: phases of the study

The compiled data was assessed by means of Statistical Package for Social Sciences (SPSS) version 26.0. The quantitative variables like age and SET were presented in the forms of mean and standard deviation. Whereas percentages and frequencies of the qualitative variables like gender, SCR, PH and abnormal ejaculation were calculated. The comparative analysis of quantitative variables was carried out by utilizing independent sample t-test and qualitative variables by Chi-Square test. Statistical significance was considered when p -value was ≤ 0.05 . Comparison of SET of both groups was depicted in Kaplan-Meier function curve.

RESULTS

A total of 142 patients were enrolled and data of 71 cases of each group was evaluated statistically. No participant dropped out or failed to follow up at any stage during the trial. The age distribution of the trial ranged from 18-55 years. Males were 83(58.5%) patients were males and 59(41.5%) were females. There was no significant difference between two groups in terms of mean age, mean stone size, gender and stone side (Table-I).

Table-I: Comparison of Groups for The Demographic and Stone Data (n=142)

Variable(s)			Group-A Silodosin (n=71)	Group-B Tamsulosin (n=71)	p-value
Age in Years		mean±SD	34.34±10.51	32.86±10.34	0.34#
Gender	Male	n(%)	44(62%)	39(54.9%)	0.40*
	Female	"	27(38%)	32(45.1%)	
Stone Side	Right	"	40(56.3%)	39(54.9%)	0.87*
	Left	"	31(43.7%)	32(45.1%)	
Stone Size (mm)		mean±SD	6.56±0.88	6.52±0.84	0.77#

* - Chi Square Test, # - t Test

SCR was achieved in 57 patients (80.3%) and 39 patients (54.9%) in Group A & B respectively with statistically significant difference ($p<0.001$). The Group-A had significantly shorter mean SET than Group-B (13.0 ± 2.07 vs 15.55 ± 1.74) ($p<0.001$) (Figure-2).

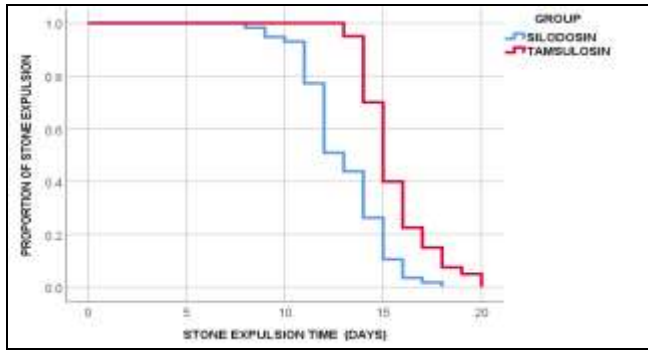


Figure-2: Kaplan-Meier function curve

The Group-A had significantly fewer no of UCE than Group-B ($p<0.001$). Two patients (2.8%) of Group-A and 3(4.2%) of Group-B had PH ($p=0.649$), so lead to stoppage of treatment. AE was observed more in Group-A than Group-B (28.2% vs 25.4%) ($p=0.705$) (Table-II).

Table-II: Comparison of Groups for the study outcomes (n=142)

Variable			Group-A Silodosin (n = 71)	Group-B Tamsulosin (n = 71)	p-value
Stone Clearance Rate		n(%)	57(80.3%)	39(54.9)	0.001*
Stone expulsion time in days		mean±SD	13.0±2.07	15.55±1.74	<0.001#
No of Ureteric Colic episodes	Nil	n(%)	31(44.0%)	13(18.0%)	<0.001*
	1 episode	n(%)	26(36.0%)	13(18.0%)	
	2 episodes	n(%)	14(20.0%)	26(37.0%)	
	3 episodes	n(%)	0(0.0%)	19(27.0%)	
Postural Hypotension		n(%)	2(2.8%)	3(4.2%)	0.649*
Abnormal Ejaculation		n(%)	20(28.2%)	18(25.4%)	0.705*

DISCUSSION

The findings of our study show that Silodosin surpasses Tamsulosin in MET of DUC (<10 mm in size), as it significantly increases distal ureteric stone

expulsion along with fewer uretic colic episodes during the management.

Distal Ureteric calculi are frequent disabling disorder due to severe colicky pain and functional constraints. The ideal management approach of DUC should be easily performed and cost-effective technical modality, which successfully relieves the disorder and has minimum post procedure morbidity.¹¹ MET is a recommended modality for DUC of <10 mm in size, as it increases SCR and reduces pain episodes. α -blockers are commonly used for MET of DUC with encouraging results.¹²

The α -1 adrenoceptors are quite abundant in the distal ureter. The most frequent subtypes of these receptors are α -1A and α -1D. These subtypes have major role in ureteric contractions and peristalsis. The antagonism of these subtype receptors specifically relaxes the ureteral smooth muscles, thus dilating its lumen and promoting stone expulsion.^{13,14} Hence, selective α -1A antagonists demonstrate fewer untoward effects (especially cardiovascular), though exhibiting good effectiveness in terms of SCR and SET.¹⁵ Tamsulosin is a well-known α -1 blocker, having ten folds more affinity in respect of α -1D & α -1A than α -1B receptor subtypes.^{16,17} Whereas, silodosin has about 160 and 50-folds greater affinity for α -1A than that for the α -1B and α -1D- subtypes respectively.⁸ This high selectivity of Silodosin infers comparatively superior results in MET with fewer cardiovascular adverse effects.³⁻⁶

Our study has also shown that Silodosin has better efficacy than Tamsulosin. Silodosin demonstrated significantly higher SCR (80.3% vs 54.9%) and less mean SET (13.0 ± 2.07 vs 15.55 ± 1.74) as compared to Tamsulosin. The results of our study are concordant with Elgalaly *et al.*,³ who reported significantly higher SCR (83% and 57%) and shorter mean SET (13.3 ± 4.1 vs 16.7 ± 5.2 days) in the silodosin group as compared to the tamsulosin group. Gharib *et al.*,¹ reported SCR was 82.4 & 61.5% and SET were 9.4 ± 3.8 & 12.7 ± 5.1 days in Silodosin and tamsulosin groups respectively with significant difference. Gupta *et al.*,¹⁰ found SCR of 82% & 58% and mean SET of 12.5 ± 3.5 & 19.5 ± 7.5 days for Silodosin and Tamsulosin groups respectively. A study by Kumar *et al.*,¹⁸ revealed SCR of 83.3% & 64.4% and mean ST of 14.8 ± 3.3 & 16.5 ± 4.6 days for the Silodosin and Tamsulosin groups respectively. Insignificant differences of SCR of 88 % & 84% and mean SET of 6.7 and 6.5 days between Silodosin and Tamsulosin

groups were deduced by Imperatore *et al.*¹⁹ While Sur *et al.*,²⁰ reported that the silodosin has SCR of 52% of all ureteric calculi.

Our study revealed that the patients using Silodosin had significantly less mean no of UCE than Tamsulosin (1.35 ± 0.48 vs 2.10 ± 0.74). These inferences correspond with the study by Elgalaly *et al.*³, which showed insignificantly low mean number of UCE in the silodosin and tamsulosin groups (1.3 ± 0.4 and 1.4 ± 0.3). Imperatore *et al.*,¹⁹ revealed insignificant difference between mean no of UCE of the Silodosin and Tamsulosin groups (1.6 ± 0.4 and 1.7 ± 0.4 respectively). Similarly, Kumar *et al.*,¹⁸ inferred fewer mean no of UCE in the Silodosin group (0.8 ± 0.9 vs 1.70 ± 1.2).

In order to analyze untoward effects and safety issues, the most common side effects of PH and AE were compared between two groups in our study. Two patients (2.8%) of Silodosin group and 3 (4.2%) of Tamsulosin Group had PH so lead to stoppage and failure of treatment. AE was observed more with Silodosin than Tamsulosin (28.2% vs 25.4%). No patient having AE discontinued treatment, as this transient untoward effect was counselled at the start of the study and it was reversed within weeks after completion of the treatment. These results of both adverse effects were statistically insignificant ($p > 0.05$).

In the study by Elgalaly *et al.*,³ PH was reported in two patients (3.8%) in the silodosin group and four (7.8%) in the tamsulosin group, with statistically insignificance. Gharib *et al.*,¹ reported fewer no of cases with PH in the Silodosin group (1.5% vs 3.1%). Kumar *et al.*,¹⁸ also found similar results in the Silodosin and Tamsulosin groups (3.3% vs 6.6%). Fewer no of cases with PH were insignificantly reported in silodosin group in a trial by Imperatore *et al.*,¹⁹ (2% vs 6%). There were insignificantly more no of cases with AE in silodosin group in a study by Elgalaly *et al.*,¹ (17.3% vs 5.9%). Gharib *et al.*,¹ stated that AE had insignificant results in the Silodosin and Tamsulosin groups (23.3% vs 12.2%). Imperatore *et al.*,¹⁹ found statistical significance between Silodosin (2%) & Tamsulosin (8%) in respect of no of patients having AE.

Hence, the present RCT when evaluated in background of this contemporary research infers that Silodosin is superior to Tamsulosin for MET of DUC, in terms of SCR, SET and UCE; both drugs have comparable safety, with insignificant more AE in Silodosin.

LIMITATION OF STUDY

The effects of additional variables like size of stone, bilateral stones, presence of hydronephroureter, infection and other side effects of drugs etc. warrant for carrying out further large multicentric, randomized clinical trials, yielding comprehensive evidence regarding the efficacy and safety of Silodosin and Tamsulosin.

CONCLUSION

Silodosin surpasses Tamsulosin in MET of DUC (<10 mm in size), as it significantly increases distal ureteric stone expulsion along with fewer uretic colic episodes during the management.

Conflict of Interest: None.

Funding Source: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AJA & MRZ: Data acquisition, data analysis, critical review, approval of the final version to be published.

AA & MSA: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

AA & AA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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