IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS)
e-ISSN:2278-3008, p-ISSN:2319-7676. Volume 18, Issue 4 Ser. 2 (July. – August. 2023), PP 20-30
www.Iosrjournals.Org

Efficacy and Safety of Tamsulosin Vs Silodosin in the Medical Expulsion Therapy of Distal Ureteric Stones in a Secondary Care Hospital, Guntur: An Observational Cohort Study

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ABSTRACT
BACKGROUND: *This observational study aimed to compare the efficacy and safety of tamsulosin (0.4mg) vs. silodosin (8mg) in association with risk factors as a medical expulsion therapy in the management of DUS in terms of stone expulsion rate and expulsion time in a secondary care hospital in Guntur, India.*
PATIENTS & METHODS: *A Prospective observational cohort which was carried out at Lalitha super specialty hospital, Guntur; the study population included 89 patients, aged 19-65 who had unilateral DUS of 5-7mm size are randomly assigned in to two groups. Group 1 received Tamsulosin (0.4mg) and Group 2 received silodosin (8mg). The patients are followed up by X- RAY KUB, USG Ultrasonography and CT SCAN for stone expulsion.*
RESULTS: *The Group B had a considerably higher stone ejection rate of 77.5% compared to the Group A 67.5%, the mean (SD) stone expulsion time was significantly shorter in Group B 8.2(2.828) days compared to Group B 8.84(3.289) days. The current study found that both groups had a low mean number of pain episodes. During the research period, no serious problems were observed. Orthostatic hypotension, Nasal congestion, headache was recorded in both Groups.*
CONCLUSION: *In terms of stone clearance rates and stone expulsion times, our findings demonstrate that silodosin is more successful than tamsulosin in the management of DUS. There is a direct relation between the stone size and the stone passage rate.*
KEY WORDS: *DUS, Tamsulosin, Silodosin, CT scan, X-Ray KUB and Ultrasonography of Abdomen.*

Date of Submission: 29-07-2023 Date of Acceptance: 09-08-2023

I. INTRODUCTION

The terms "ouron" for urine, "oros" for flow, and "lithosis" for stone are three Greek words that gave rise to the phrase"urolithiasis. **(Thakore P, 2022 Jan.)**

Stones growing in the kidneys are known as nephrolithiasis. Urolithiasis is the medical term for the disorder that occurs when these stones depart the renal pelvis and go to the ureter, bladder, and urethra. Ureteric stones typically exhibit symptoms early on in the course of the disease before growing to be huge. The most recent data analysis reveals that people with stone illnesses are using more healthcare resources than before. **(Arda E, 2017 Nov 15).**

Urinary system stone disease is the third most common urological condition, behind benign prostatic hyperplasia (BPH) and urinary tract infections. Urinary calculi are collections of crystals that often include calcium or phosphateas well as minute amounts of proteins and glycoproteins. Kidney stones are classified into several categories based ontheir composition, with calcium oxalate or phosphate stones accounting for 80% of the total, uric acid (9%), struvite (10%), and cystine (1%). based on the incidence. When a stone enters the ureter, it intermittently raises the pressure in the pyelocaliceal system, resulting in an acute bout of colic pain. (**Gandhi HR, 2013 Dec).**

Three factors contribute to the transit of stones from the kidney into the bladder via the ureter: 1) Smooth muscle spasm 2) Submucosal edema; and 3) discomfort. The size, structure, and smooth muscle activity of the ureters all play a role in the spontaneous transit of calculi. The terminal section of the ureter, particularly the intramural "detrusor tunnel," is the most difficult hurdle to the transit of calculi. Many caliculi of 4mm or smaller pass spontaneously however not without discomfort and intramural ‘detrusor tunnel’. Many 4 mm or less calculi pass on their own, but not without discomfort and expense to the patient. Any size urinary calculus is

frequently accompanied by urinary blockage, thus when deciding whether to treat actively or expectantly, we must use the utmost caution to avoid doing irreparable harm to the kidney. **(Ali Q, 2020).**

The prevalence of urolithiasis is rising overall. In 1994, the National Health and Nutrition Examination Survey foundthat 4.1% of women and 6.3% of men had urolithiasis. This ratio had risen to 10.6% of men and 7.1% of women by 2012. **(Leslie SW, 2022).** Urolithiasis affects 12% of the world's population **(Thakore P, 2022 Jan).** Ureteric stonesaccount for 20% of urolithiasis cases, with 70% located in the bottom portion of the ureter and referred to as 'distal ureteric stones' (DUS) **(Ross and Wilson, 2014).**

The annual prevalence is approximately 3-5%, while the lifetime prevalence is approximately 15- 25%. Urolithiasis is a recurring condition in the majority of renal calculi patients. Renal stone recurrence rates range from 10% per year, 50% over five to ten years, and 75% over twenty years. An individual country's geographical regions affect the incidence rate of urolithiasis. Renal calculi reoccur in patients at rates of 14% in the first year, 35% in the fifth year, and 52% in the tenth year following the initial occurrence. An estimated 2 million Indians experience renal stone disease each year. **(Atul Sohgaura and Papiya Bigoniya, 2017).**

Chronic renal disease, hypertension, gout, diabetes mellitus, hyperlipidemia, obesity, endocrine disorders, and malignancies all enhance the risk of kidney stone formation. Obesity, hyperlipidemia, and type 2 diabetes have all been linked to calcium oxalate and uric acid stones. Patients with a history of hyperlipidemia, hypertension, or type 2 diabetes mellitus frequently consume diets heavy in animal-derived proteins, salt, and sugar, which puts them at a higher risk of stone development **(Taylor EN, 2005 Jan).** Insulin resistance causes metabolic changes that raise the risk of stone formation due to increased urine calcium and uric acid excretion in obesity and type 2 diabetes mellitus.A history of kidney stones and insulin resistance discovered higher Urine pH and decrease urinary acid excretion bothof which promote Urolithiasis **(Aune D, 2018 Nov).**

The optimal therapeutic choice is determined by the size, location, composition of the stone, degree of obstruction, symptoms, and anatomy of the urinary system **(Kumar S, 2015) (Wang CJ, 2016).** There are three types of distal ureteric stone treatment: observation and medicinal therapy, shock wave lithotripsy ureteroscopy, and open surgery laparoscopic stone removal. **(Abdelaziz AS, 2017).**

Over the ultimate two decades, the organization of ureteric stones had changed hugely, especially after the introduction of shockwave lithotripsy (SWL) and ureteroscopy, as insignificantly less invasive procedures. In any case, these procedures are exorbitant and are not chance free. By and large complications after ureteroscopy have been evaluated to be 10–20% in various considers, in which major complications, such as ureteric avulsions, gaps, and strictures, happened in 35% of cases **(Segura JW, et al. 1997).** As of late, alpha-blockers utilized as medical expulsive treatment (MET) **(Cervenakov I, 2002)** have supplanted negligibly intrusive strategies as the primary line of administration for minor ureteric stones **(Tzortzis V, 2009).** Some of the drugs used for medical expulsive therapy (MET) include α-blockers, calcium channel antagonists, phosphodiesterase inhibitors, and corticosteroids, which have all been shown to aid ureteric stones flow **(Yu B, 2021).** MET aims to increase fluid intake in order to enhance urine volume, hydrostatic pressure, and ureteric peristaltic activity **(Shabana W, 2016).** In MET, the relaxing of the ureteric smooth muscle, a decrease in ureteral mucosal edema, and an increase in the hydrostatic pressure proximal to the stone aid in stone transit **(Rahman MJ, 2018).**

Both the American Urological Association (AUA) **(American Urological Association, 2007)** and the European Association of the Department of Urology (EAU) recommend α-blockers for the treatment of ureteral stones **(Tiselius HG, et al. 2001)**. Recently, the α1A adrenergic receptor this subtype has been shown to play a major role in intercedingphenylephrine-induced contractions of the human isolated ureter **(Sasaki S, 2011).**

Ureteroscopy and Shock Wave Lithotripsy stay the foremost viable therapy for DUS; in any case, they are costly and not hazard free. Unconstrained stone ejection can happen in up to 50% of cases, in any case, numerous complications such as ureteric colic, UTI, and hydronephrosis, may happen **(Porpiglia F, 2000).** As of late, the utilization of different adjuvant therapy as MET for DUS has made a difference to decrease discomfort and complications, and incrementingthe rate of stone clearance **(Dellabella M, 2005).**

The α1A- and α1D-adrenoceptors are the foremost inexhaustible subtypes within the distal ureter, incitement of these α1-adrenoceptors leads to an increase in both the recurrence of ureteric peristalsis and the constrain of ureteric contractions. Blocking these receptors, on the other hand, lowers baseline ureteric tone, lowers peristaltic frequency and amplitude, and increases the pace of urine transport, which enhances the likelihood of stone passage **(Griwan MS, 2010).** Tamsulosin, alfuzosin, silodosin, and naftopidil are the most commonly recommended α-blockers for medical expulsive therapy **(Sridharan K, 2018).**

Exceedingly specific α1A-adrenoceptor blockers have been created to play down the cardiovascular unfavorable impacts whereas keeping up their viability on the urinary tract. Tamsulosin could be a specific α1-blocker with a 10-fold more prominent partiality for the α1A- and α1D-adrenoceptor subtypes than for the α1B-adrenoceptor subtype, whereas the liking of silodosin for the α1A-adrenoceptor subtype is 162- and 50-fold more noteworthy than its partiality for the α1B- and α1D-adrenoceptor subtypes separately, which clarify the powerless cardiovascular antagonistic impacts of silodosin **(Rossi M, 2010).**

II. MATERIALS AND METHODS

The study was carried out at Lalitha super specialty hospital which is a secondary care 250 bedded hospital, in Guntur, Andhra Pradesh. This prospective observational study was conducted between December 2021 and May 2022, the cohort comprised 89 adult patients (55 men and 34 female) who presented with a symptomatic, unilateralDUS of 5-7mm.

Study design: This project approach employed a prospective observational cohort study design to achieve the studyobjectives.
Study Location: This was a secondary care hospital-based study done in department of Urology, at Lalitha SuperSpecialty hospital, Guntur, Andhra Pradesh.
Study Duration: December 2021 to May 2022.
Sample Size: 89 patients.

Sample Size Calculation: The study population obtained were 89 patients, in which 6 patients from both groups were withdrawal before the study and during follow-up 3 patients were lost. The sample size included in this study were 40patients in Group A and 40 patients in Group B.

Subjects & Selection method: From December 2021 to May 2022, the study population was drawn from distal ureteric stone patients who came to Lalitha super specialty hospital and were prescribed the necessary α-blockers andhad X-ray KUB or CT scan before treatment initiation. The study population was divided into two groups, each with40 patients. The following α-blocker dosages were prescribed for patients with distal ureteric stones: Group A (40 patients) received 0.4mg of tamsulosin daily, while Group B (40 patients) received 8mg of silodosin daily.

Inclusion criteria:
1. Patients of age >18 years of age
2. Patients with stone size measuring from 5-7mmof size
3. Patients who are prescribed with Tamsulosin or Silodosin
4. Patients with mild to moderate Hydronephrosis (HDUN) and
5. Drug naïve patients.

The included patients were assessed with history, physical examination with measurement of vital signs, urine analysis, blood urea, and serum Cr levels, serum electrolytes, X-Ray KUB, Ultrasonography, and non-contrast CTscan.

Exclusion criteria:
1. Patients age < 18 years
2. Patients with multiple or bilateral ureteric stones
3. Patients with urinary tract infections
4. Patients with solitary kidney, abnormal renal function, and
5. Patients with voiding dysfunction.
6. Pregnant women

Procedure and methodology

After receiving information on the nature of the study, the time frame for completion, side effects, and the possibility of intervention, if necessary, each patient provided informed written consent. After receiving informed consent from patients over the age of 18. The patients were randomly assigned 1:1 into two groups. Group A (45 patients) received a single daily dose of Tamsulosin (0.4 mg), while Group B (44 patients) received a daily dose of Silodosin (8mg). Tools used in the study are for pain assessment, we used the pelvic pain urgency/frequency patientsymptom scale, a designed patient proforma for documenting the subject's data.

Follow up:

Follow-up visits were performed every 10 days, during which patients were queried about stone expulsion, episodes of renal colic, the timing of stone passage, and symptoms related to drug side effects. At the end of the study, radiological examinations with X-ray KUB and ultrasound for radiopaque stones and CT scans for radiolucent stones were performed. Primary outcomes were stone expulsion rate and duration; secondaryoutcomes included drug side effects and several pain episodes. Patients were observed until the passage of the stone was confirmed by X-ray KUB or CT scan.

Statistical analysis

SPSS software was used to analyze the data. Data were presented as the mean (SD) for quantitative variables, andthe number and percentage for categorical variables. To determine the significance of the difference between mean values, the students t-test was utilized, and chi-square tests were used to test for categorical variable

III. RESULTS

The patients' ages in both groups ranged between 19 and 65 years. Three patients in group A and three patients in group B withdrew before treatment because of voluntary withdrawal. During follow-up, three patients were lost (twoin group A and one in group B). Thus, the total number of patients analyzed was 40 in Group A and 40 in Group B.

There was no significant difference between the two groups in terms of patient age and gender,with 60% (48/80 patients) males and 40% (32/80 patients) females. Group A consists of 62.5% (25) males and 37.5% (15) females, while Group B males at 57.5% (23), and females at 42.5% (17), is shown in Fig.1.

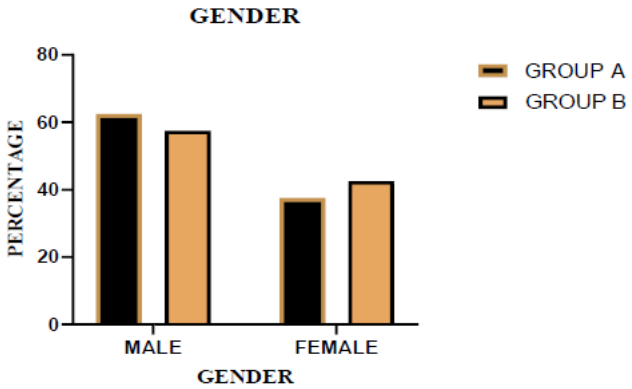

Fig.1: Patients with distal ureteric stones among the Gender

The age distribution of DUS patients in both groups shows that the age range between 59-69 has the highest number of patients at 32.5%, followed by 48-58 (25%), 37-47 (22.5%), 26-36 (12.5%), and 15-25 (7.5%) in Group A. Simultaneously, the age group 59-69 had the highest number of patients (37.5%) in group B, followed by 48-58 (27.5%), 37-47(20%), 26-36 (10%), and 15-25 (5%), as shown in Fig.2.

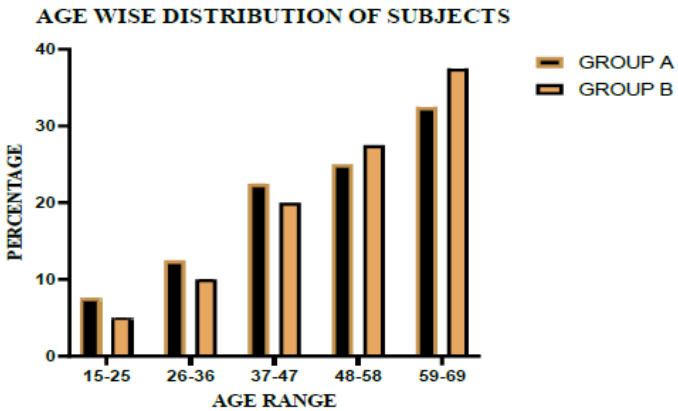

Fig.2: Patients with distal ureteric stones among the Age frequency

The patients with distal ureteric stones range from 5-7mm stone size in both groups shows that 15 patients (37.5%) of Group A had a stone size of 5mm, 14 patients (35%) had a stone size of 6mm, and 11 patients (27.5%) had a stone size of 7mm. Following that, in Group B 16 patients (40%) had a stone size of 5mm, 14 patients (35%) hada stone size of 6mm, and 10 patients (25%) had a stone size of 7mm, respectively. Which is observed in Fig.3.

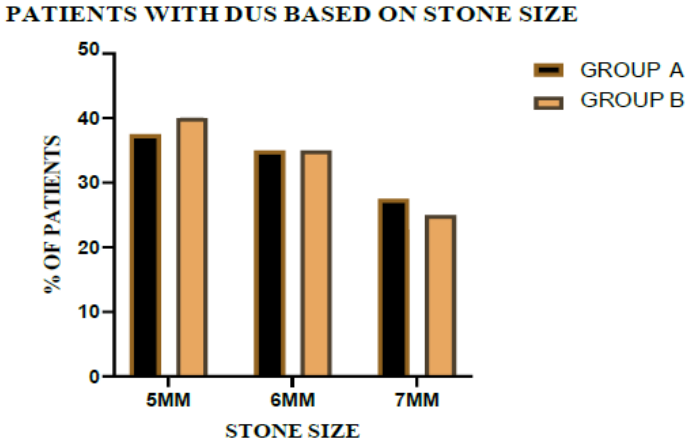

Fig.3: percentage of patients with distal ureteric stones based on the stone size

Among the recognized risk factors for the DUS, Age, diabetes mellitus and hypertension rank highest, at 57.5% (23 patients) followed by 75% (30 patients) and 62.5% (25 patients) in Group A, and 65% (26 patients) followedby 67.5% (27 patients) and 52.5% (21 patients) in Group B, respectively. Other risk factors discovered include recurring stones, urethral strictures and BPH, in decreasing order, as shown in Fig.4.

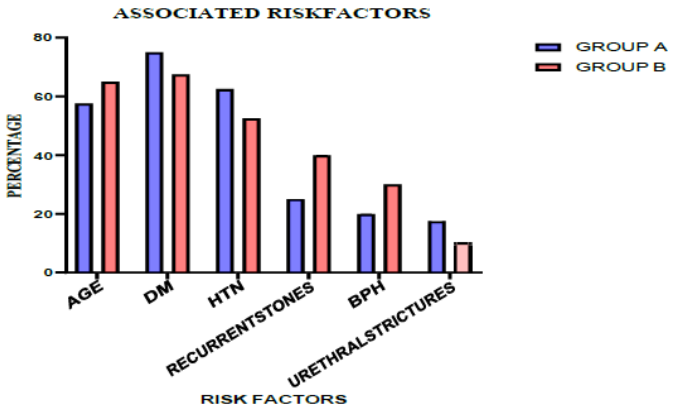

Fig.4: Associated risk factors among the patients

Calcium stones were the most common stone type, occurring at 47.5% (19 patients) in Group A and 52.5% (21 patients) in Group B, respectively, followed by uric acid stones at 32.5% (13 patients) in Group A and 37.5% (15 patients) in Group B, respectively, struvite stones at 17.5% (7 patients) in Group A and 10% (4 patients) in GroupB, respectively, and cystine stones at 2.5% (1 patient) in Group A and 0 patients in Group B. which was observedin Fig.5.

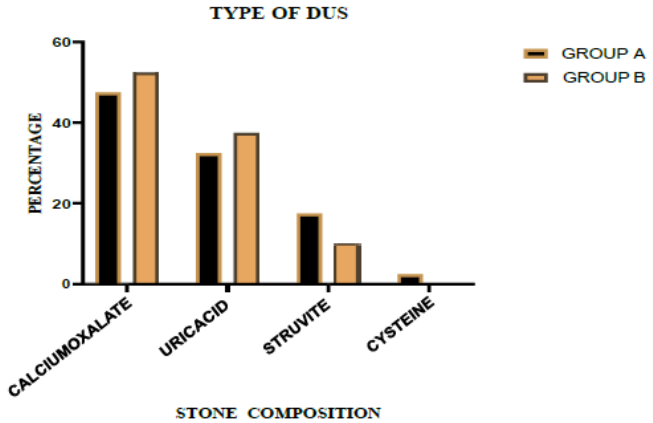

Fig.5: Composition of stones among the patients

The stone expulsion rate or stone passage rate between the groups were identified at 73.33% expulsion rate in patients with 5mm stone size, 71.42% in patients with 6mm stone size and 54.54% in patients with 7mm stone size in Group A. Simultaneously, Stone Expulsion rate in group B at 87.5% in patients with 5mm stonesize, 78.57% in patients with 6 mm stone size and 60.1% in patients with 7mm stone size. The stone expulsion rate in both groups of 5-7mm stone size was shown in Fig.6.

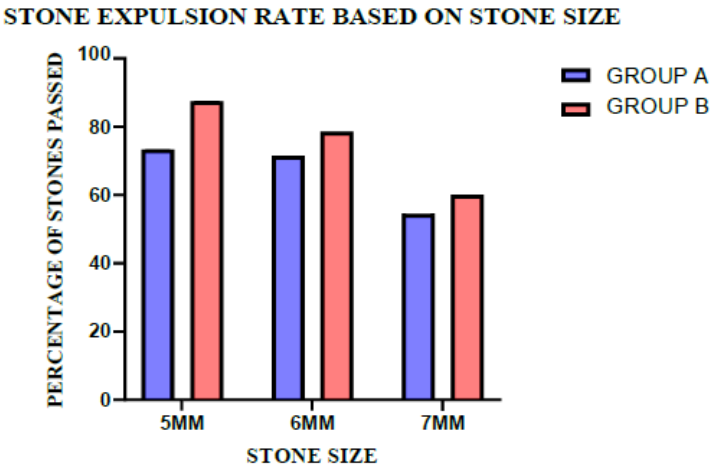

Fig.6: Stone Expulsion rate of patients among the stone size

The mean expulsion time between both groups were identified as 7.81 days in patients with stone size 5mm, 8.9 days in patients with stone size 6mm, and 9.83 days in patients with 7mm stone size in Group A. simultaneously, the mean expulsion time in group B was found to be 7.35 days in patients with stone size 5mm, 8.09 days in patients with stone size 6mm, and 9.16 days in patients with 7mm stone size. The mean expulsion time of stone size ranging from 5-7mm in both groups was shown in Fig.7.

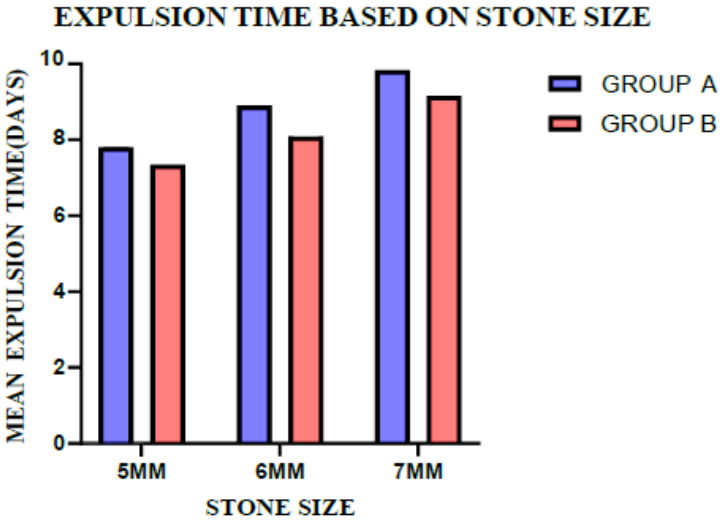

Fig.7: Expulsion time of stone in patients based on the stone size

Pain assessment during the enrollment in to study of the patients with DUS was identified at 32.5% (13/40 patients) in Group A reported a pain score of 6-8 followed by 27.5% (11/40 patients) with a pain score of 0- 2, 22.5% (9/40 patients) reported a score of 2-4 and 17.5% (7/40 patients) reported 4-6. In contrast the highest percent of the population in Group B 37.5% (15/40 patients) reported a pain score of 2-4, followed by 27.5% (11/40 patients) with a pain score of 6-8, 22.5% (9/40 patients) with 0-2 and 12.5% (5/40 patients) with a pain score of 4-6. Shown in Fig.8.

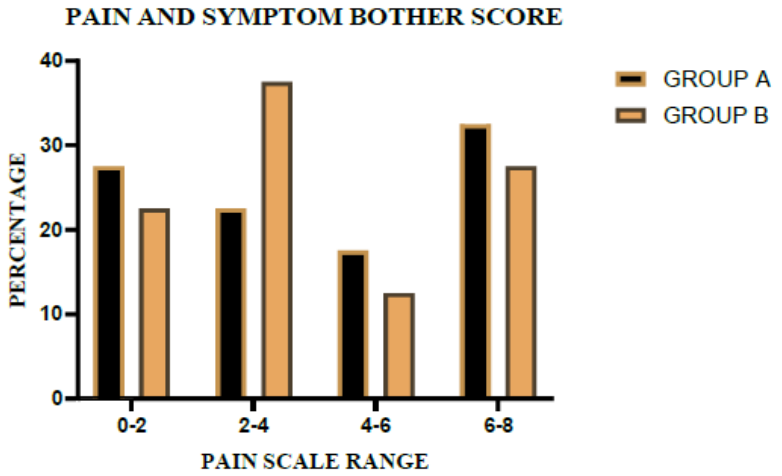

Fig.8: Pain and bother score of patients with stones

The stone expulsion rate of 5-7mm stone size in patients with DUS was significantly different between groups at 77.5% (27/40 patients) in Group B vs 67.5% (31/40 patients) in Group A, respectively ($P < 0.017$) shown in Fig.9. In Group B (silodosin) the stone expulsion time was also shorter when compared to Group A (tamsulosin) at a mean (SD) of 8.2 (2.828) days vs 8.84 (3.289) days, respectively ($p< 0.0375$) shown in Fig.10. Also, there were fewer pain episodes in Group B compared to Group A at the mean (SD) of 1.22 (1.1) and 1.5(1.2), respectively ($p< 0.023$) was shown in Fig.11. The results were represented in the following Table.1.

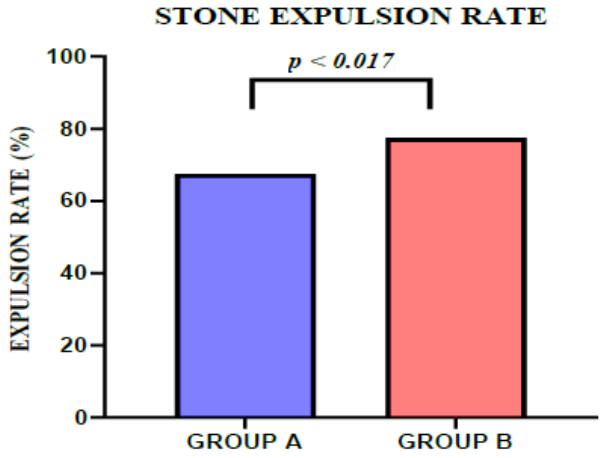

Fig.9: Stone Expulsion Rate

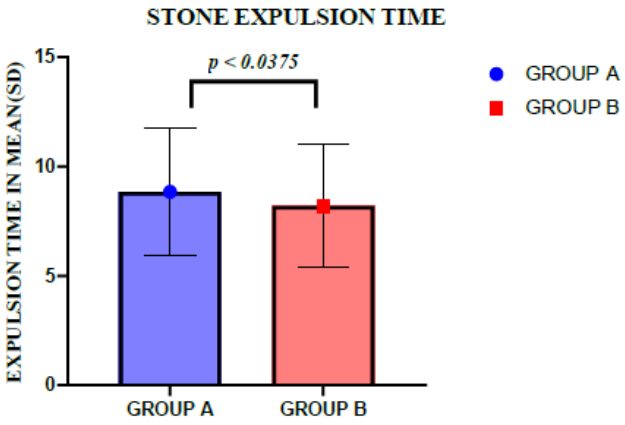

Fig.10: Mean Expulsion Time

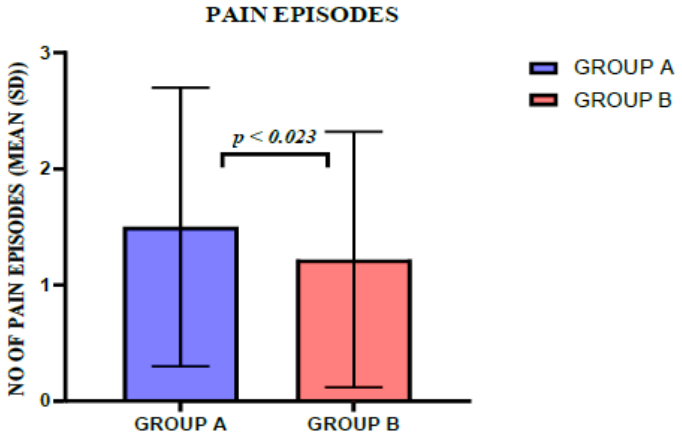

Fig.11: Mean Pain Episodes

SIDE EFFECTS ENCOUNTERD

12.5% of patients reported dizziness followed by nausea 10%, orthostatic hypotension 7.5%, nasal congestion,and headache 7.5%, in group A. whereas 10% population reported dizziness followed by nausea, and nasal congestion in 7.5% of the population followed by 5% each reported orthostatic hypotension and headache in group B. The adverse event profile was observed in Fig.12

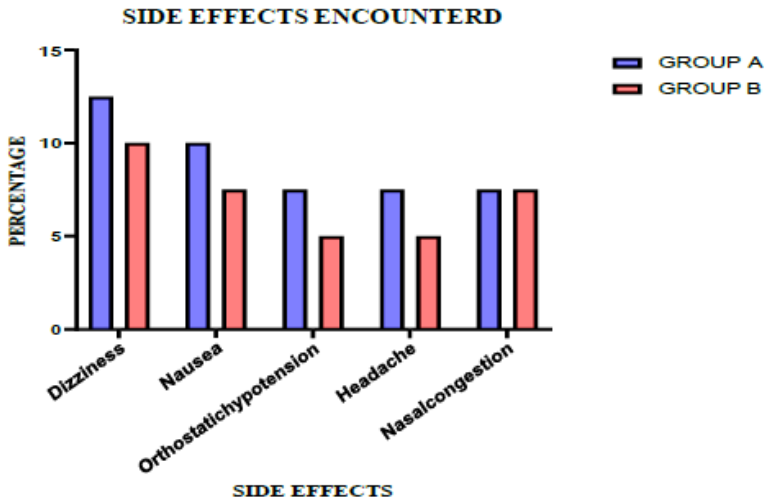

Fig.12: Side effects encountered among the patients

TABLE. 1: Study Outcomes

Outcome	Group A	Group B	P Value
Stone expulsion rate, n (%)	27 (67.5%)	31 (77.5%)	P < 0.017
Mean (SD)stone expulsion time, days	9.0 (3.289)	8.2 (2.828)	P < 0.0375
Pain episodes, N	1.5 (1.2)	1.22 (1.1)	P < 0.023

IV. DISCUSSION

The observed spontaneous stone clearance rates in patients with DUS of 5-7 mm treated with MET were 67.5% and 77.5%, with mean expulsion times ranging between 9.0 days and 8.2 days in Group A and Group B, respectively. Several factors, including stone size, site number, and the presence or absence of ureteric smooth muscle spasm, can affect DUS spontaneous clearance, which is consistent with the findings of **(Coll DM, et al. 2002)** who discovered a direct association between stone size and spontaneous clearance.

In our current study, the stone clearance rate of 5-7mm stone size in patients with DUS was

significantly higher in Group B (silodosin) at 77.5%, which was 31 out of 40 patients passed the stone compared to Group A (tamsulosin), at 67.5%, which was 27 out of 40 patients passed the stone, respectively ($p < 0.017$), which is consistent with **(Gupta S, 2013)** who reported stone clearance rates of 82% and 58%, respectively, for their silodosin and tamsulosin groups, and also with those of **(Kumar S, 2015)** who reported stone clearance rates of 83.3% and 64.4%, respectively, for their silodosin and tamsulosin groups. However, **(Imperatore V, et al. 2014)** found no statistically significant difference in stone clearance rates between silodosin (88%) and tamsulosin (84%), whereas **(Sur RL, et al. 2015)** found a 52% stone clearance rate with silodosin treatment of all ureteric stones (upper, middle, and lower), which may limit overall efficacy because - receptors are more prevalent in thedistal ureter.

The stone expulsion rate in the tamsulosin group was 67.5%, which differs from the findings of **(Al-Ansari A, 2010 Jan)** 41 of 50 (82%) patients in the tamsulosin group passed the stone. **(Yilmaz E, 2005)** discovered that 23out of 29 (79.31%) of the tamsulosin group had expelled the stone. **(Ahmed AF, 2010)** in their study, discoveredthat 25 of 29 (86.20%) patients in the tamsulosin group passed calculus.

The silodosin group had a substantially shorter mean (SD) stone expulsion time than the tamsulosin group, at 8.2(2.828) days versus 8.84 (3.289) days, respectively ($p< 0.0375$). These findings are consistent with those of **(Gupta S, 2013).** Researchers also found that the silodosin group had a considerably lower mean (SD) stone expulsion time than the tamsulosin group, at 12.5 days (3.5) versus 19.5 (7.5) days, respectively. This data supports **(Kumar S, 2015)** The silodosin group reported a time of 14.8 (3.3) days, whereas the tamsulosin group reported a time of 16.5 (4.6) days. However, **(Imperatore V, 2014)** observed a shorter mean stone expulsion time for both silodosin and tamsulosin of 6.7 and 6.5 days, respectively, in agreement with **(Ahmed AF, 2010 Mar)** who reported that the average time for stone expulsion in the tamsulosin group was 7.52 7.0 days, contradicts

(Al-Ansari A, 2010 Jan) who reported that the average time for stone expulsion in the tamsulosin group was 6.4 ± 2.77 days. Our findings contradict those of **(Yilmaz E, 2005)** who found that the average time for stone expulsion in the tamsulosin group is 6.31 ± 0.88, respectively. Similarly, **(Goyal SK, 2018)** concluded that the tamsulosin group had a shorter time to expulsion (9.38 days) than the tadalafil group (9.61 days).

Both medications are safe and well tolerated by patients in terms of safety and side effects. 12.5% of patients reported dizziness, followed by nausea in 10% of patients, nasal congestion, and headache in 7.5% of individuals. Orthostatic hypotension was reported by 7.5% in the tamsulosin group ($P< 0.001$) and 5% in the silodosin group ($P< 0.001$). This difference was not statistically significant. These findings are consistent with those of **(Kumar S, 2015)** who reported orthostatic hypotension in 3.3% and 2% among the silodosin groups, respectively, and 6.6% and 6% of the tamsulosin groups; and are also in consensus with **(Imperatore V, 2014)** that stated a nonsignificant variance in orthostatic hypotension of 2% and 6% in the silodosin and tamsulosin groups.

The current study found a low mean (SD) amount of pain episodes in both groups of 1.22 (1.1) and 1.5 (1.2) ($p =< 0.023$), respectively, in the silodosin and tamsulosin groups, which was not statistically significant. These findings agreed with **(Kumar S, 2015)** who stated a mean (SD) number of pain episodes of 0.8 (0.9) and 1.70 (1.2) in the silodosin and tamsulosin groups, respectively; and also, with **(Imperatore V, 2014)** who reported a non-significant difference of 1.6 (0.4) and 1.7 (0.4), between the silodosin and tamsulosin groups as well.

In conclusion, silodosin is more effective than tamsulosin in terms of stone clearance rate and expulsion time; nevertheless, larger-scale trials are needed to validate its efficacy and safe.

V. CONCLUSION

Our findings indicate that Silodosin has a higher expulsion rate and a shorter expulsion time for stone passage when compared to tamsulosin. In comparison to tamsulosin, silodosin is a better alternative for the management of distal ureteric stones based on expulsion rate and expulsion time. The study also reveals a relationship betweenstone size and expulsion rate, with significant expulsion rates for stones smaller than 5mm. Diabetes and hypertension were discovered to be the most common causes of distal ureteric stones. Both medications were wellaccepted, with few and minor side events, and were discovered to be safer. The amount of side effects observed in both groups was comparable, with the silodosin group experiencing the fewest. Finally, it was determined thatsilodosin was superior than tamsulosin in terms of efficacy and safety for the treatment of distal ureteric stones.

LIMITATIONS

The following are the limitations of our study

- Sample size was limited

- Due to short duration of the study, we are not able to monitor the formation of recurrent stones in the study population
- Cost analysis was not performed

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