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ORIGINAL ARTICLE

Effectiveness of Silodosin versus Tadalafil as Medical Expulsive Therapy for Lower Ureteric Calculi: A Randomized Controlled Trial

Aquinas Benedict,[1,*] R Vinoth Kumar[2] and Jeyapal Parthiban[3]
[1]*Department of Urology, ACS Medical College and Hospital, Chennai, Tamil Nadu, India*
[2]*Department of Urology, Aarupadai Veedu Medical College and Hospital, Vinayaka Mission's Research Foundation (Deemed to be University), Puducherry, India*
[3]*Department of General Surgery, Aarupadai Veedu Medical College and Hospital, Vinayaka Mission's Research Foundation (Deemed to be University), Puducherry, India*

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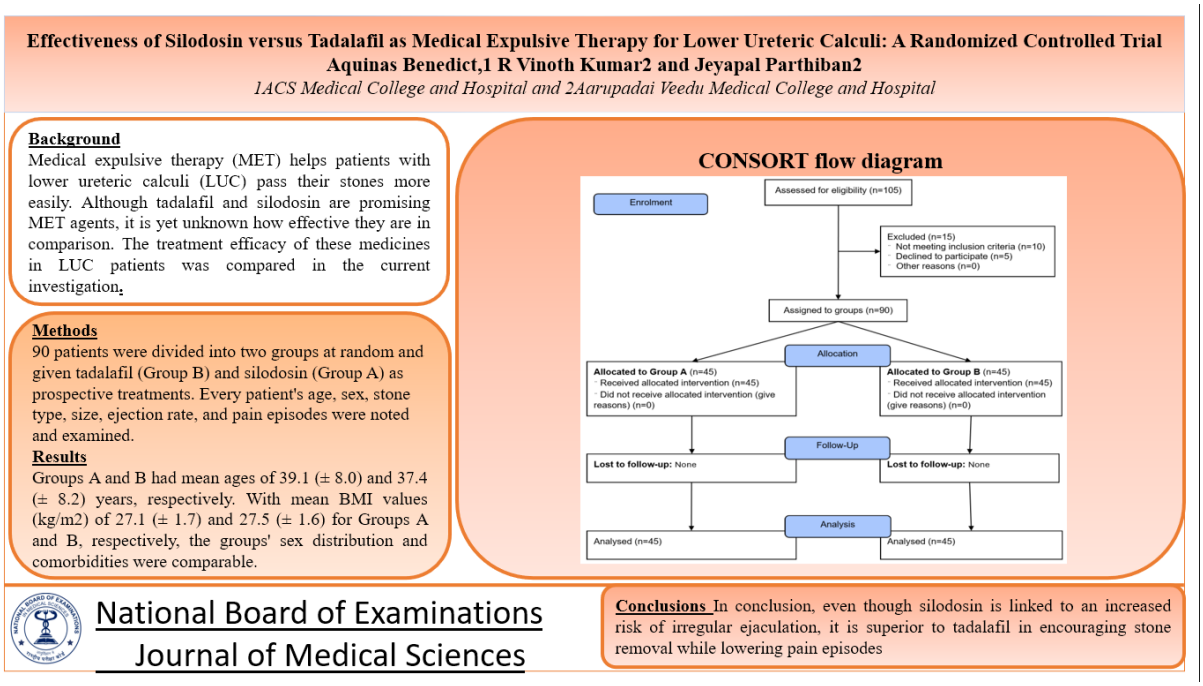
Abstract

Background: Medical expulsive therapy (MET) helps patients with lower ureteric calculi (LUC) pass their stones more easily. Although tadalafil and silodosin are promising MET agents, it is yet unknown how effective they are in comparison. The treatment efficacy of these medicines in LUC patients was compared in the current investigation. **Methods:** 90 patients were divided into two groups at random and given tadalafil (Group B) and silodosin (Group A) as prospective treatments. Every patient's age, sex, stone type, size, ejection rate, and pain episodes were noted and examined. **Results:** Groups A and B had mean ages of 39.1 (± 8.0) and 37.4 (± 8.2) years, respectively. With mean BMI values (kg/m2) of 27.1 (± 1.7) and 27.5 (± 1.6) for Groups A and B, respectively, the groups' sex distribution and comorbidities were comparable. Additionally, the mean stone type (radiopaque: 75.6% vs. 80.0%) and size (7.6 mm vs. 7.8 mm) were comparable. Silodosin treatment, however, resulted in a lower use of analgesics (198.8 mg vs. 247.8 mg, $p < 0.001$), fewer pain episodes (1.1 vs. 2.5, $p < 0.001$), and a greater expulsion rate (80.0% vs. 60.0%) and shorter expulsion duration (14.4 vs. 17.7 days, $p < 0.001$). With the exception of frequent irregular ejaculation with silodosin (17.8% vs. 4.4%), the side effects were comparable. **Conclusion:** In conclusion, even though silodosin is linked to an increased risk of irregular ejaculation, it is superior to tadalafil in encouraging stone removal while lowering pain episodes. Clinical Trial Registration: CTRI/2025/03/082491

Keywords: Ureteric calculi, Medical expulsive therapy, Silodosin, Tadalafil, Stone expulsion rate, Pain management

*Corresponding Author: Aquinas Benedict
Email: aquin87@gmail.com

Graphical Abstract



Introduction

One major source of morbidity is ureteric calculi, also called ureteral stones [1]. Over time, medical expulsive therapy (MET) has become a commonly recognized non-invasive therapeutic option for distal ureteric calculi [2]. MET seeks to enhance patient outcomes, lessen the need for surgical intervention, and promote spontaneous stone passage [3]. Several pharmacological types have been investigated for their potential to improve stone removal, including corticosteroids, nonsteroidal anti-inflammatory medicines (NSAIDs), calcium channel blockers, and adrenergic blockers [2]. The importance of adrenergic blockers, especially alpha-blockers, has grown. Both calcium channel blockers and adrenergic blockers dramatically boosted stone passing rates, according to a research by Hollingsworth et al. [4]. Meta-analyses by the American Urological Association (AUA) and the European Association of Urology (EAU) [2,5,6] later supported this conclusion, showing that adrenergic blockers were better than calcium channel blockers such nifedipine. Alpha-blockers are therefore frequently advised for MET in ureteral stone patients.

Silodosin, a selective alpha-1A adrenergic receptor antagonist, has been extensively studied and found to be one of the most effective alpha-blockers for facilitating ureteral stone passage. Several randomized controlled trials and meta-analyses have supported its use for lower ureteric calculi (LUC) less than 10 mm in size, leading to its endorsement by the EAU and AUA guidelines [7-11]. Tadalafil and other phosphodiesterase type-5 (PDE5) inhibitors may have a role in MET, however this is still unknown. Sildenafil, Vardenafil, and Tadalafil are examples of PDE5 inhibitors that have been demonstrated to have relaxing effects on isolated human ureteral smooth muscle in vitro [2]. Tadalafil has been studied for the treatment of benign prostatic hyperplasia (BPH) and has shown effectiveness in

reducing lower urinary tract symptoms. [12,14] This begs the question of whether tadalafil would be a useful substitute for alpha-blockers, like silodosin, for MET in LUC patients.

PDE5 inhibitors' function in MET is yet unknown, despite alpha-blockers like silodosin having a well-established effect. The current study specifically assessed the efficacy of silodosin versus tadalafil as MET for LUC because prior research has mostly compared the two medications in relation to BPH.

Methodology

Study design

After receiving the required consent from the Institutional Human Ethics Committee, this prospective, randomized controlled experiment was carried out at the tertiary medical center Aarupadai Veedu Medical College and Hospital between July 2023 and December 2024. Patients between the ages of 18 and 60 who had ureteric calculi with a maximum diameter of 5 to 10 mm, as determined by CT-KUB and X-ray KUB, were enrolled in the study after providing informed written consent.

Patients with functional and/or anatomical ureteric abnormalities, multiple and bilateral ureteric stones, pregnant and lactating mothers, history of hypotension, vertigo, dizziness, headache, and cardiac abnormalities were excluded. Patients who were not willing to provide informed written consent were also excluded from the study. Based on the predetermined inclusion and exclusion criteria, 90 patients were included in the study and divided into two groups of 45 patients each. A non-probability sampling technique, purposive sampling/consecutive enumeration, was used to enrol patients in accordance with the specified inclusion and exclusion criteria.

Randomization and Blinding

A computer-generated random number sequence was used to assign participants at random to either the tadalafil (Group B) or silodosin (Group A) groups. To ensure impartial participant distribution, randomization was carried out utilizing the SNOOZE (Sealed Envelope Online Open-Label Enrollment) approach. By distributing individuals equally across the two treatment arms, this technique reduced selection bias. The investigation was carried out as an open-label trial because blinding was not practical due to the nature of the pharmaceutical interventions. For a maximum of four weeks, Group A LUC patients were treated with silodosin 8 mg once daily until the stone was expelled. Tadalafil 5 mg was given once daily to Group B LUC patients until the stones were expelled, or for a maximum of 4 weeks.

Method of data collection

Detailed baseline data were collected for each patient after obtaining their consent, including medical history, vital signs such as Non-Invasive Blood Pressure (NIBP), Heart Rate (HR), and Oxygen Saturation (SpO_2), along with laboratory investigations including Complete Blood Count, Blood Sugar, Blood Urea, and Serum Creatinine. Radiological assessments were conducted using CT-KUB and X-ray KUB, with follow-up imaging performed using ultrasonography KUB as needed. Throughout the study, all patients underwent regular assessments, including physical examinations, blood urea and serum creatinine levels, urine cultures, and repeated radiological investigations as

needed. In addition to the allocated treatment, patients were advised to increase their fluid intake and were prescribed diclofenac 50 mg orally during pain episodes. Patients were followed up for four weeks, during which the primary and secondary endpoints were assessed. The primary endpoint was the stone expulsion rate, while secondary endpoints included stone expulsion time, defined as the number of days from randomization to the confirmed expulsion of the stone, intervention rates, such as the need for ureteroscopy in cases where spontaneous expulsion did not occur, the number of pain episodes experienced by the patient, and adverse effects associated with MET use. Stone expulsion was confirmed using CT-KUB and X-ray KUB imaging. Patients who did not pass the stone spontaneously within the four-week period underwent ureteroscopic lithotripsy for definitive stone removal. Age, gender, body mass index (BMI; kg/m2), silodosin (8 mg once daily), and tadalafil (5 mg once daily) were the independent factors of interest. Stone ejection rate, time to stone expulsion, need for extra intervention, number of pain episodes, and side effects were the dependent variables of interest.

Statistical analysis

The Statistical Package for Social Sciences (SPSS) v23 was used to analyze the collected data. Frequency and percentage were used to describe categorical variables. The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to determine the normality of the data before calculating the mean and standard deviation for continuous variables. The independent t-test for continuous variables and the chi-square test or Fisher's exact test for categorical variables were used to assess statistical significance. The threshold for statistical significance was fixed at $p < 0.05$.

The enrolment of study participants and group allocation is given as a CONSORT flow diagram in Figure 1, and the overall workflow of the study is shown in Figure 2. A total of 105 participants were assessed for eligibility, and 90 were included in the study based on the inclusion and exclusion criteria. The participants were randomly assigned to two groups: Group A (n=45; received silodosin tablets 8 mg once daily) and Group B (n = 45; received tadalafil tablets 5 mg once daily). Table 1 displays the study population's demographic characteristics. Participants in Group B (tadalafil) were 37.4 years old (± 8.2) on average, while those in Group A (silodosin) were 39.1 years old (± 8.0). There was no statistically significant difference in the two groups' mean ages ($p = 0.325$). Compared to 62.2% (n = 28) of the participants in Group B, 46.7% (n = 21) of the participants in Group A were under 40 years old. In contrast, 37.8% (n = 17) of participants in Group B were over 40, but 53.3% (n = 24) of individuals in Group A were. The age distribution between the two groups did not, however, differ statistically significantly ($p = 0.138$). Gender distribution analysis revealed that Group A comprised 68.9% (n = 31) male and 31.1% (n = 14) female participants. Group B comprised 77.8% (n=35) men and 22.2% (n=10) women. The sex distribution difference was not statistically significant, according to statistical analysis ($p = 0.340$). Comorbidities were present in 13.3% (n=6) and 17.8% (n=8) of the patients in Groups A and B, respectively. There was no statistically significant difference in the presence of comorbidities between the two groups ($p = 0.561$). Participants in Group A

(silodosin) had a mean BMI of 27.1 kg/m² (± 1.7), whereas those in Group B (tadalafil) had a mean BMI of 27.5 kg/m² (± 1.6). There was no statistically significant difference in BMI between the two groups (p = 0.254).

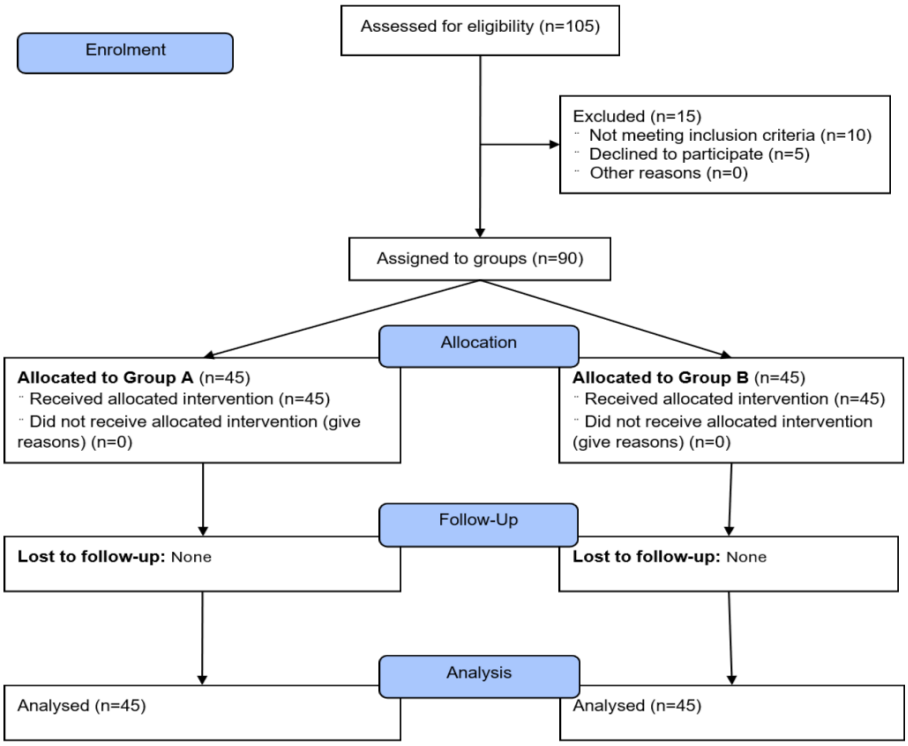


Figure 11. CONSORT flow diagram.

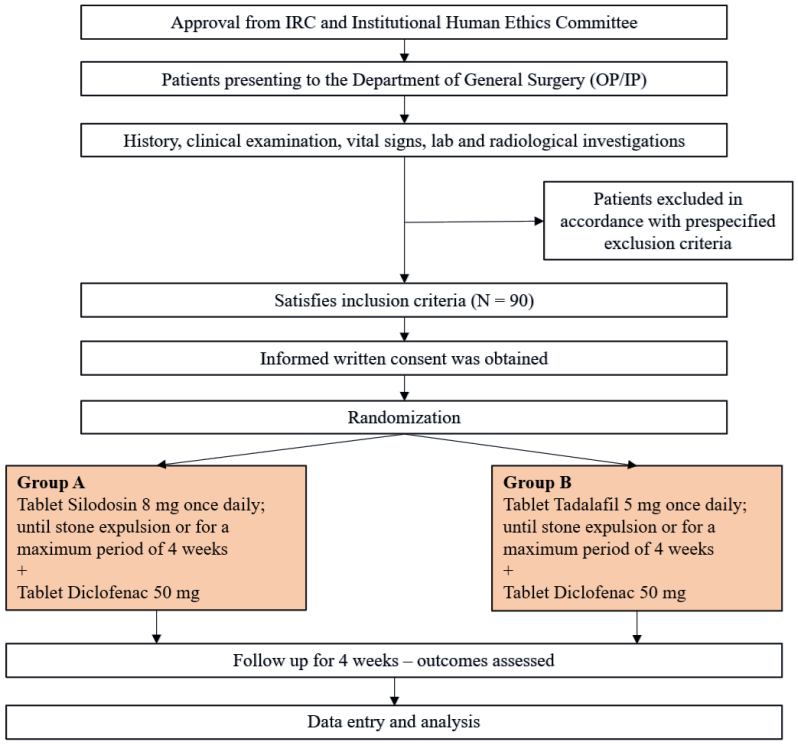


Figure 2. Schematic representation of the workflow.

Results

Table 1. Demographic characteristics of the study population.

Criteria		**Group A (n = 45)**	**Group B (n = 45)**	**P value**
Age (in years), mean ± SD		39.1 ± 8.0	37.4 ± 8.2	0.325
Age (in years), n (%)	≤40	21 (46.7)	28 (62.2)	0.138
	>40	24 (53.3)	17 (37.8)	
Gender, n (%)	Male	31 (68.9)	35 (77.8)	0.340
	Female	14 (31.1)	10 (22.2)	
Comorbidity, n (%)	Present	6 (13.3)	8 (17.8)	0.561
	Absent	39 (86.7)	37 (82.2)	
Body mass index (in kg/m2), mean ± SD		27.1 ± 1.7	27.5 ± 1.6	0.254

Table 2. Comparison of study population by the nature of stone, expulsion, pain episodes and analgesic usage

Criteria		**Group A (n = 45)**	**Group B (n = 45)**	**P value**
Stone size (in mm), mean ± SD		7.6 ± 1.0	7.8 ± 1.0	0.196
Type of stone, n (%)	Radiopaque	34 (75.6)	36 (80.0)	0.612
	Radiolucent	11 (24.4)	9 (20.0)	
Expulsion, n (%)	Yes	36 (80.0)	27 (60.0)	0.038*
	No	9 (20.0)	18 (40.0)	
Expulsion time (in days), mean ± SD		14.4 ± 2.2	17.7 ± 3.4	<0.001*
Number of pain episodes, mean ± SD		1.1 ± 0.9	2.5 ± 1.1	<0.001*
Total analgesic use (in mg), mean ± SD		198.8 ± 42.0	247.8 ± 71.5	<0.001*
*Statistically significant data, $p < 0.001$				

The study population's statistics regarding stone features, ejection, pain episodes, and painkiller use are displayed in Table 2. Group A (silodosin) and Group B (tadalafil) had mean stone sizes of 7.6 mm (± 1.0) and 7.8 mm (± 1.0), respectively, which were not statistically significant (p = 0.196). In terms of stone type, radiopaque stones were found in 75.6% (n = 34) of Group A individuals and radiolucent stones in 24.4% (n = 11) of Group A participants and 20.0% (n = 9) of Group B participants.

The distribution of stone types in the two groups did not differ statistically significantly (p = 0.612). Compared to 60.0% (n = 27) in Group B (tadalafil), 80.0% (n = 36) of participants in Group A (silodosin) were able to successfully evacuate their stones. In contrast, 20.0% (n = 9) of Group A individuals and 40.0% (n = 18) of Group B participants did not have stone-expulsion. There was a statistically significant difference between the two groups' expulsion rates (p = 0.038). Group A's mean expulsion time was 14.4 days ± 2.2, whereas Group B's was 17.7 days ± 3.4. Additionally, the difference in expulsion time was statistically significant (p < 0.001), meaning that silodosin caused a quicker expulsion time than tadalafil. Participants in Group A (silodosin) suffered an average of 1.1 (± 0.9) pain episodes, while those in Group B (tadalafil) experienced an average of 2.5 (± 1.1). The silodosin group experienced fewer pain episodes, as indicated by this statistically significant difference (p < 0.001). In a similar vein, Group A's mean total analgesic consumption (198.8 mg (± 42.0)) was considerably lower than Group B's (247.8 mg (± 71.5)) (p < 0.001). These results imply that compared to individuals receiving tadalafil, those getting silodosin had less pain and needed fewer analgesic dosages.

Table 3: Adverse effect of drug across study population.

Adverse effects, n (%) (numbers not mutually exclusive)	**Group A** **(n = 45)**	**Group B** **(n = 45)**	**P value**
Headache	5 (11.1)	8 (17.8)	0.368
Dizziness	4 (8.9)	10 (22.2)	0.081
Backache	4 (8.9)	9 (20.0)	0.134
Orthostatic hypotension	2 (4.4)	5 (11.1)	0.238
Abnormal ejaculation	8 (17.8)	2 (4.4)	0.044*
*Statistically significant data, p < 0.05			

Both groups experienced adverse pharmacological treatment effects, as seen in Table 3. 11.1% (n = 5) of individuals in Group A (silodosin) and 17.8% (n = 8) in Group B (tadalafil) reported having headaches (p = 0.368). 8.9% (n = 4) of participants in Group A experienced dizziness, compared to 22.2% (n = 10) in Group B (p = 0.081). Backache was reported by 20.0% (n = 9) in Group B and 8.9% (n = 4) in Group A (p = 0.134). 4.4% (n = 2) of patients in Group A and 11.1% (n = 5) in Group B (p = 0.238) had orthostatic hypotension. However, there was a statistically significant difference in the prevalence of aberrant ejaculation, with 17.8% (n = 8) of participants in Group A and only 4.4% (n = 2) in Group B (p = 0.044).

Discussion

The purpose of this study was to evaluate the efficacy of tadalafil and silodosin as medical expulsive therapy for lower ureteric calculi. The baseline characteristics of the study participants were comparable between the two groups, ensuring that any differences in outcomes could be attributed to the medical expulsive therapy rather than confounding factors. There was no discernible difference in the age distribution between the study groups (p = 0.138). According to earlier research, younger individuals typically had higher ureteric stone passing rates because of increased ureteric peristalsis and reduced ureteric wall calcification [15]. However, the current study's lack of substantial age differences guaranteed that age-related factors had no bearing on the two treatments' relative efficacy.

The study groups' male predominance was in line with worldwide epidemiological patterns, and the sex and comorbidity distributions among the groups were likewise not statistically significant. According to studies, urolithiasis is more common in men [16], presumably as a result of hormonal variations, dietary patterns, and metabolic variables that make them more susceptible to the development of stones [17,18]. The male-to-female ratio found in this study shows that urolithiasis is roughly two to three times more common in males than in women, which is consistent with findings from previous studies [19].

There was no discernible difference in the two groups' comorbidity prevalence. Due to changes in urine pH, increased calcium excretion, and decreased citrate levels, comorbid diseases like obesity, diabetes, and metabolic syndrome have been associated with an increased risk of stone development [20]. Comorbidities probably had little effect on stone expulsion since they were equally distributed throughout the groups. Participants in the tadalafil group had a mean BMI of 27.5 kg/m², whereas those in the silodosin group had a mean BMI of 27.1 kg/m². There was no statistically significant difference (p = 0.254). According to earlier studies, metabolic problems including insulin resistance and hypercalciuria are linked to a greater BMI and a higher risk of developing stones [21]. Nevertheless, there is no clear association between BMI and the probability of stone passage, and it does not seem to have a substantial impact on spontaneous stone passage [22].

The two groups' mean stone sizes were similar (p = 0.196). Larger stones (≥10 mm) frequently require surgical care, while smaller stones (<5 mm) are more likely to pass without assistance. Stone size is a crucial factor in determining spontaneous passing [23]. The study's mean

stone size (7.6 mm in Group A and 7.8 mm in Group B) is within the range where MET is often advised, which supports the justification for assessing tadalafil and silodosin in this situation. The distribution of radiopaque and radiolucent stone types was likewise comparable among the groups ($p = 0.612$). While radiolucent stones (24.4% in Group A and 20.0% in Group B) were frequently made of uric acid or cystine, radiopaque stones (about 75.6% of cases in Group A and 80.0% in Group B) were more frequently made of calcium oxalate or phosphate [24]. The same distribution of stone types among the groups guaranteed that the study's confounding factor was not the effect of stone composition on expulsion rates.

The current study's findings show that silodosin is a much better MET for lower ureteric calculi than tadalafil. The silodosin group's expulsion rate (80.0%) was considerably greater than the tadalafil group's (60.0%), indicating that silodosin is more effective at promoting stone passage. This is consistent with previous research demonstrating that silodosin, a highly selective α1A-adrenoceptor antagonist, is superior to non-selective α-blockers or phosphodiesterase inhibitors like tadalafil in terms of relaxing the distal ureter and improving stone ejection. (10–12). Additionally, the silodosin group's stone expulsion time was significantly shorter (14.4 days) than the tadalafil group's (17.7 days). This is clinically significant because prolonged stone retention raises the risk of complications like UTIs, hydronephrosis, and the need for surgery [12]. Silodosin's high selectivity for α1A-adrenergic receptors, which are mostly found in the lower ureter, is responsible for its higher efficacy. This results in maximal ureteric relaxation and reduced resistance to stone passage [25].

One of the most upsetting signs of ureteral calculi is pain. Compared to the tadalafil group (2.5 episodes), the silodosin group had considerably fewer pain episodes (1.1 episodes) ($p < 0.001$). Furthermore, compared to the tadalafil group (247.8 mg), the silodosin group's total analgesic intake was considerably lower (198.8 mg) ($p < 0.001$). This is consistent with earlier research showing that silodosin's strong inhibitory effects on ureteral contractions were linked to fewer bouts of renal colic [9]. The ability of silodosin to diminish intraureteral pressure, which lessens colicky discomfort brought on by sporadic ureteric contractions, is probably the reason for the decreased pain burden in the silodosin group [26]. The main way that the phosphodiesterase-5 inhibitor tadalafil works is by raising the amounts of cyclic guanosine monophosphate (cGMP), which causes smooth muscle relaxation. However, its effects on the ureter are not as strong as those of α1A-selective blockers, which could account for the tadalafil group's higher analgesic needs and more pain episodes [27].

With the exception of aberrant ejaculation, which was considerably more frequent in the silodosin group (17.8% vs. 4.4%, $p = 0.044$), the prevalence of side effects was similar in both groups. Because silodosin has a large affinity for α1A-receptors in the bladder neck and prostate, it has been shown in previous investigations to increase the occurrence of retrograde ejaculation. [7] One well-known adverse effect of selective α1A-adrenoceptor antagonists is retrograde ejaculation, which is usually reversible after stopping the medication. The tadalafil group experienced more adverse effects, such as

headache (11.1% vs. 17.8%, p = 0.368), dizziness (8.9% vs. 22.2%, p = 0.081), backache (8.9% vs. 20.0%, p = 0.134), and orthostatic hypotension (4.4% vs. 11.1%, p = 0.238). However, these differences were not statistically significant. Because tadalafil inhibits phosphodiesterase-5, which causes systemic vascular relaxation, it is known to have negative effects associated to vasodilation. [9,28]. Tadalafil may have a part in ureteral smooth muscle relaxation, but its systemic vasodilatory effects may limit its practical usage as a MET, according to the trend of increased dizziness and hypotension in the tadalafil group.

The current study had a number of shortcomings. First, the results may not be as applicable to other healthcare facilities because the study was limited to a single tertiary healthcare facility. Second, the study was carried out as an open-label experiment, which raises the risk of observer bias when evaluating results like discomfort and side effects. Furthermore, the study did not assess long-term impacts including recurrence rates, quality of life, or the effects of continuous pharmaceutical use; instead, it concentrated exclusively on short-term outcomes like stone ejection rate and time. The subjective evaluation of pain and analgesic use, which may have been impacted by reporting biases and individual pain tolerance, is another drawback. Furthermore, there was no control or standardization of variables that could affect stone ejection, such as food habits, hydration levels, and physical activity. Lastly, the lack of a placebo control group in the trial made it challenging to assess the absolute efficacy of Tadalafil and Silodosin in comparison to no medical expulsive medication. Despite these drawbacks, the study's findings demonstrate that silodosin is more effective than tadalafil at promoting stone expulsion, decreasing pain episodes, and lowering the need for analgesics. Silodosin may be the best choice for MET in patients with lower ureteric calculi because of its quicker expulsion time and greater success rate. Clinicians should be aware of the possibility of abnormal ejaculation, though, as this can be upsetting for certain patients, especially younger ones who are worried about their fertility.

Conclusion

The current study examined the safety and effectiveness of tadalafil and silodosin as medicinal expulsive treatments for lower ureteric calculi. The results show that silodosin is a more successful treatment choice than tadalafil, with a considerably greater stone expulsion rate (80.0% vs. 60.0%) and shorter expulsion duration (14.4 vs. 17.7 days). Furthermore, participants in the silodosin group needed fewer analgesic dosages and had fewer pain episodes, suggesting that it may be beneficial for enhancing patient comfort during the transit of stones. While abnormal ejaculation was far more common in the silodosin group, other side effects did not significantly differ across the groups, despite the fact that both drugs were generally well tolerated.

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

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Human and animal rights

This article does not contain any studies with human participants or animals performed by any of the authors.

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