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COMPARISON OF SILODOSIN AND TAMSULOSIN IN THE MEDICAL EXPULSION THERAPY OF MID AND LOWER URETERIC STONES

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ABSTRACT

Background: Medical expulsive therapy (MET), which is widely used to treat ureteric stones, is practiced mainly with alpha-blockers such as silodosin and tamsulosin. However, further work evaluating silodosin as a ureteric stone passage promoter has revealed promising results and has hinted at its merits in efficacy and safety profile over that of alpha blocker tamsulosin. **Objective:** To compare the efficacy and safety of silodosin and tamsulosin in the expulsion management of mid and lower ureteric stones.

Methodology: A total of 100 patients with a mid and a lower ureteric stone were randomly allocated to use either silodosin (8 mg once daily) or tamsulosin (0.4 mg once daily). The stone expulsion rate and mean expulsion time, along with pain episodes, need for additional analgesia, and adverse effects were assessed as main outcomes, while other relevant clinical



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outcomes were regarded as secondary outcomes. SPSS was used for statistical analysis, and a p-value less than 0.05 was considered significant.

Results: Silodosin showed a higher stone expulsion rate as compared to tamsulosin (86% vs 70%), and mean expulsion time was significantly reduced with silodosin (11.2 ± 3.2 vs. 12.9 ± 4.5 days; p = 0.032). The number of pain episodes was lower in the silodosin group (3.5 ± 1.3 vs. 4.2 ± 1.6 ; p = 0.018). Nevertheless, silodosin was associated with a significantly greater incidence of retrograde ejaculation (24% vs.8%, p=0.029) and dry ejaculation (20% vs. 6%, p=0.037).

Conclusion: Silodosin has a higher incidence of ejaculatory dysfunction but is more effective than tamsulosin in reducing the number of pain episodes that occur during the expulsion of ureteric stones. Therapy should be selected for the individual patient according to patient preferences and clinical considerations.

KEYWORDS: Silodosin, Tamsulosin, Ureteric Stones, Medical Expulsive Therapy, Stone Expulsion.

INTRODUCTION

Urolithiasis is the formation of stones within the urinary tract, and it affects millions in the world.[1] Ureteric stones cause a great deal of clinical difficulty because of their symptoms, such as severe pain, hematuria, and obstruction-induced morbidity, including hydronephrosis and urinary tract infection.[2] The three segments of Type I ureteric stones influence their classification: stones occur in either the upper, middle, or lower ureter position.[3] Ureteric stones located in the mid or lower regions create intense suffering in patients, which requires medical intervention when self-passage fails.[4]

Medical expulsion therapy (MET) represents a contemporary approach to treating ureteric stones that helps patients eliminate their stones through a procedure without requiring surgical intervention.[5] The smooth muscle relaxation function of α 1 adrenergic receptor antagonists (α 1-blockers) allows them to block ureter spasms, thus promoting better urine flow.[6] The acceptance of this approach by the medical community remains high mainly because it reduces surgical needs and pain episodes and enhances the quality of life for people with ureteric stones.[7]

The wide acceptance of $\alpha 1$ blocker tamsulosin as a medication stems from its use in treating benign prostatic hyperplasia (BPH) as well as its role in treating ureteric stones.[8] Its $\alpha 1$ A and

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 α 1D receptor selectivity enables tamsulosin to activate a relaxing effect on the lower urinary tract together with the distal ureter, thereby assisting stone passage through the urinary system.[9] The newer silodosin medication shows higher selectivity for α 1A receptors present at the lower ureter and bladder neck area.[10]

The efficiency of silodosin and tansulosin for passing lower and mid-ureter stones has been studied extensively.[11] Although both agents prove effective for stone passage duration and spontaneous stone removal, efficacy studies indicate that silodosin achieved higher expulsion rates due to its specific binding to alA receptors.[12] Silodosin demonstrates limited cardiovascular side effect profiles, along with being a better choice than MET for specific patient needs.[12] The medication seems to lead to retrograde ejaculation, according to certain studies, and this adverse effect would not be suitable for every patient group.[13, 14] Research must compare these variables to determine which pharmaceutical stands best for mid and lower ureteric stone expulsion. Research about tamsulosin and silodosin performance and safety results for mid to lower ureter stone expulsion remains limited to a few specific studies.[12, 15, 16] The therapeutic course between these active substances differs because their distinct receptor selectivity generates different pharmacological properties. An investigation into the effectiveness and safety as well as adverse effects of $\alpha 1$ blockers exists to determine the ideal α l blocker selection process for medical expulsion therapy in settings where patients have mid and lower ureteric stones. This study aims to compare the efficacy and safety of silodosin and tamsulosin in the medical expulsion therapy for mid and lower ureteric stones, its effect on stone expulsion rate, expulsion time, and adverse effects

Materials and Methods

The research investigated silodosin and tamsulosin treatments for expelling stones in mid and lower ureteric regions through a cross-sectional study design. The study was conducted at the Department of Urology at ______ from ______ to ______. The research accepted patients who demonstrated symptoms of stones located in the mid and lower ureter after valid diagnosis through ultrasonography (USG) and non-contrast computed tomography (NCCT). This study comprised 100 participants, out of which 50 patients became part of a silodosin group, while the remaining 50 patients belonged to the tamsulosin group. The researchers applied standard statistics-based techniques to establish a suitable sample size that would permit sufficient power for observing differences between stone elimination percentages between study groups. The research design used data from existing studies

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examining α 1-blockers in medical expulsion therapy (MET) and included an estimated differentiation between the drug expulsion rates.[17] The total participants were selected to achieve 95% confidence alongside an 80% level of power following an anticipated participant exit rate. The study enrolled adult patients whose ages range from 18 to 65 who possess one simple stone that is either radio-opaque or non-opaque with dimensions between 5 and 10 mm located in the mid or lower ureter. The study excluded patients with multiple ureteric stones along with renal insufficiency (serum creatinine exceeding 1.5 mg/dL) in addition to urinary tract infections and severe hydronephrosis and previous ureteric surgery and those with a history of using α -blockers within a month. Patients who have directly related α 1-blocker contraindications, including severe hypotension and documented drug allergy to these medications, were also excluded from the study.

The research study divided participants between two separate groups for evaluation. Patients in the silodosin group took 8 mg of silodosin daily, whereas patients in the tamsulosin group took 0.4 mg of tamsulosin daily.[11] Subjects in both study groups remained properly hydrated while receiving standard pain medication using nonsteroidal anti-inflammatory drugs (NSAIDs) whenever required. The research team checked on patients once per week for four weeks through clinical evaluations and assessments of pain episodes, stone passage status, and adverse effects. Patients reported stone passage to healthcare staff, who then verified the observation through X-ray KUB and ultrasound imaging.

Stone expulsion rate represented the primary outcome measure that needs assessment within four weeks from treatment start. The evaluation contained two secondary measurements consisting of stone expulsion duration and reports of adverse effects such as retrograde ejaculation and dizziness or hypotension. Researchers used SPSS version 26 to process data, which was recorded through structured proforma. The study authors presented demographic and clinical patient data using descriptive statistics. The chi-square test and One-Way ANOVA served as statistical methods to assess the categorical variable differences and numerical value disparities between both groups, respectively. The researchers accepted the findings with p-values below 0.05 as statistically significant.

The Institutional Review Board of ______ provided the ethical approval to proceed with this investigation. All participants were requested to give informed consent, which covers confidentiality and voluntary participation before study enrollment began. Total study information, together with drug-related benefits and potential risks, was explained to patients

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before their participation. All adverse events that occurred during the study period were documented, and the patients received suitable medical assistance.

Results

A total of 100 participants received equal distribution as 50 patients used silodosin and 50 patients utilized tamsulosin. Researchers found no statistically important differences between groups regarding their baseline characteristics, which included age, the distribution of genders, stone dimensions, stone positions, and the presence of hydronephrosis. The research included participants whose mean age reached 38–39 years, and the patient population primarily contained males. Among the participants, silodosin-treated patients had slightly larger stones on average compared to those receiving tamsulosin, although the outcome was not meaningful statistically. The baseline pain scores matched between both groups together with the distribution of stones in the mid and lower ureter, which contributed to an equivalent treatment outcome assessment. (Table 1)

Characteristic	Silodosin Group	Tamsulosin Group	p-value
	(n = 50)	(n = 50)	
Age (years)	38.4 ± 8.5	39.3 ± 9.2	0.613
(Mean ± SD)			
Gender			
Male	34 (68%)	32 (64%)	0.672
Female	16 (32%)	18 (36%)	-
Mean Stone Size (mm)	7.9 ± 1.3	7.7 ± 1.2	0.426
Stone Location (Mid/Lowe	er Ureter)		
Mid Ureter	21 (42%)	19 (38%)	0.683
Lower Ureter	29 (58%)	31 (62%)	
Baseline Pain Score (VAS	6.8 ± 1.4	7.2 ± 1.5	0.171
1-10)			
Hydronephrosis	1		1

Table 1: Baseline Characteristics of Study Participants

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Present	19 (38%)	21 (42%)	0.683	
Absent	31 (62%)	29 (58%)		

The primary treatment outcome, stone expulsion rate, was higher in the silodosin group (86%) compared to the tamsulosin group (70%), approaching statistical significance. Additionally, the mean time to stone expulsion was significantly shorter in the silodosin group, with patients passing stones in approximately 11.2 days on average compared to 12.9 days in the tamsulosin group. Patients receiving silodosin also experienced fewer pain episodes and required less additional analgesia, although the difference in analgesia use did not reach statistical significance. These findings suggest that silodosin may offer superior efficacy in stone expulsion compared to tamsulosin. (Table 2)

Outcome	Silodosin Group	Tamsulosin Group	p-value
	(n = 50)	(n = 50)	
Stone Expulsion Rate (%)	43 (86%)	35 (70%)	0.053
Mean Expulsion Time (days)	11.2 ± 3.2	12.9 ± 4.5	0.032*
Pain Episodes (Mean ± SD)	3.5 ± 1.3	4.2 ± 1.6	0.018*
Use of Additional Analgesia (%)	16 (32%)	23 (46%)	0.151
*P<0.05 is considered significant.	1	1	1

 Table 2: Stone Expulsion and Treatment Outcomes

In terms of adverse effects, both medications were well tolerated, but certain side effects were more prominent in the silodosin group. Retrograde ejaculation and dry ejaculate were significantly more frequent among patients treated with silodosin, occurring in 24% and 20% of cases, respectively, compared to only 8% and 6% in the tamsulosin group. Other side effects, including dizziness, hypotension, headache, and gastrointestinal upset, were reported at similar rates between the two groups, with no significant differences. (Table 3)

Table 3: Adverse Effects in Study Participants

Adverse Effect	Silodosin Group	Tamsulosin Group	p-value
	(n = 50)	(n = 50)	

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Dizziness (%)	7 (14%)	5 (10%)	0.538
Hypotension (%)	5 (10%)	3 (6%)	0.460
Retrograde Ejaculation (%)	12 (24%)	4 (8%)	0.029*
Dry Ejaculate (%)	10 (20%)	3 (6%)	0.037*
Headache (%)	5 (10%)	2 (4%)	0.239
Gastrointestinal Upset (%)	6 (12%)	5 (10%)	0.749

Patient satisfaction levels reflected the overall efficacy of the treatments. A greater proportion of patients in the silodosin group reported being highly satisfied with their treatment (72%) compared to the tamsulosin group (58%). However, the proportion of patients reporting moderate satisfaction or dissatisfaction did not differ significantly between the two groups. Silodosin achieves better patient satisfaction because it successfully expels stones faster but causes more ejaculatory side effects. (Table 4)

 Table 4: Overall Patient Satisfaction with Treatment

Satisfaction Level	Silodosin Group Tamsulosin Group		p-value
	(n = 50)	(n = 50)	
Highly Satisfied	36 (72%)	29 (58%)	0.142
Moderately Satisfied	11 (22%)	15 (30%)	0.361
Not Satisfied	6 (12%)	9 (18%)	0.400

Discussion

This research investigated the performance and security aspects of silodosin compared to tamsulosin in stone expulsion therapy for mid and lower ureteric stones. The stone expulsion rate with silodosin reached 86% while tamsulosin only achieved 70%, and the mean time for stone expulsion was shorter with silodosin. Further analgesics showed less need, but pain episodes required fewer administrations between the treatment groups, although the differences were not found statistically significant. The research established a higher frequency of retrograde ejaculation together with dry ejaculate outcomes in patients receiving silodosin treatment compared to patients medicated with tamsulosin. This study produces data that

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supports current scientific research about the effectiveness comparison between tamsulosin and silodosin for medical expulsive therapy (MET) of urinary tract stones.

Multiple studies have demonstrated that silodosin provides superior outcomes to tamsulosin since it results in higher stone expulsion rates and faster stone passage times. According to a systemic review conducted by Dhinakarbabu N et al. (2024), silodosin produced stone expulsion at a higher rate compared to tamsulosin treatment, which is in accordance with our findings.[15] Our findings show that silodosin treatment resulted in a quicker stone passage duration of 11 ± 3.2 days when compared to tamsulosin. These findings are in accordance with studies by Parvez MM et al. (2023) and Jindan L et al. (2023), who demonstrated enhanced selectivity of silodosin toward the α 1A-adrenergic receptor that prevails in the ureter; thus, it facilitates better ureter dilatation and stone passage.[12, 18]

MET efficacy is based on important parameters such as pain reduction and the need for additional analgesia. Therefore, our findings indicate that patients treated with silodosin were less likely to have pain episodes (mean 3. 5 vs. 4. 2 in tamsulosin group), as reported by Diab T et al. (2024), who showed that silodosin had fewer colic episodes because ureteric relaxation was better.[19] A clinically significant finding (although not statistically significant) was the reduced need for additional analgesia in the silodosin group, as effective pain management is an important goal in the conservative management of ureteric stones.

The adverse effects profile of our study demonstrated a significantly higher incidence of retrograde ejaculation and dry ejaculate in the silodosin group (24% and 20 respectively), which is consistent with the existing literature. La Vignera S et al. (2021), in a meta-analysis, also showed that not only because silodosin is a so highly selective α 1A antagonist, but also due to its relatively higher incidence of ejaculation dysfunction vs. tamsulosin.[20] A study conducted by Ibrahim HM et al. (2023) reported that the rates of dizziness, hypotension, headache, and gastrointestinal upset were higher in the silodosin group.[21]

Our study also has important clinical implications for the medical management of ureteric stones. Silodosin should be regarded as a more effective agent in MET for mid and lower ureteric stones due to its higher stone expulsion rate and shorter expulsion time. Also, its better efficacy in several pain episodes can be considered as a preferable option in providing patients move for better comfort. However, a discussion of the higher incidence of retrograde ejaculation and dry ejaculation should be considered carefully with patients concerned with fertility or sexual function. In clinical practice, they indicate that patients for whom rapid stone



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expulsion is a priority may prefer silodosin compared to tamsulosin, while those wishing to minimize ejaculatory side effects may choose tamsulosin.

Conclusion

The present study shows that silodosin is more suitable than tamsulosin in the management of expulsion of mid and lower ureteric stones, with a higher stone expulsion rate, shorter expulsion time, and fewer pain episodes. Nevertheless, its use is linked with a higher likelihood of retrograde ejaculation and dry ejaculation. Both medications work well for MET, though the choice between them should take into account patient preferences, especially regarding side effects.

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