

COMPARATIVE ANALYSIS OF SILODOSIN MONOTHERAPY VERSUS SILODOSIN + MIRABEGRON ADD-ON THERAPY FOR DISTAL URETERIC STONE BETWEEN 4 TO 10MM

ANÁLISE COMPARATIVA ENTRE A MONOTERAPIA COM SILODOSINA E A TERAPIA COMPLEMENTAR COM SILODOSINA + MIRABEGRON PARA CÁLCULOS URETERAIS DISTAIS COM TAMANHO ENTRE 4 E 10 MM

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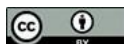
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Abstract

Objective: To compare the efficacy and safety of silodosin monotherapy versus silodosin combined with mirabegron in the management of distal ureteric stones measuring 4–10 mm. **Study Design:** Prospective, randomized controlled trial. **Place and Duration of Study:** Sahiwal Teaching Hospital, Sahiwal, from November 2025 to February 2026. **Methodology:** A total of 40 patients with distal ureteric stones between 4–10 mm were enrolled and randomly divided into two equal groups (n=20 each). Group-A received silodosin 8 mg daily, while Group-B received silodosin 8 mg plus mirabegron 50 mg daily for a maximum duration of four weeks or until spontaneous stone expulsion. The primary outcome was stone expulsion rate. Secondary outcomes included time to stone expulsion,

Resumo

Objetivo: Comparar a eficácia e a segurança da monoterapia com silodosina versus a silodosina combinada com mirabegron no tratamento de cálculos ureterais distais com dimensões entre 4 e 10 mm. **Desenho do estudo:** Ensaio clínico prospectivo, randomizado e controlado. **Local e duração do estudo:** Hospital Universitário de Sahiwal, Sahiwal, de novembro de 2025 a fevereiro de 2026. **Metodologia:** Um total de 40 pacientes com cálculos ureterais distais entre 4 e 10 mm foram incluídos e divididos aleatoriamente em dois grupos iguais (n = 20 cada). O Grupo A recebeu 8 mg de silodosina por dia, enquanto o Grupo B recebeu 8 mg de silodosina mais 50 mg de mirabegron por dia, por um período máximo de quatro semanas ou até a expulsão espontânea do cálculo. O



number of renal colic episodes, additional analgesic requirement, and adverse effects. Data were analyzed using SPSS version 25.0, and p-value <0.05 was considered statistically significant. Results: The stone-free rate was higher in Group-B compared to Group-A (45% vs 25%), but the difference was not statistically significant (p=0.320). Mean stone expulsion time was comparable between Group-A and Group-B (16.40 ± 7.92 days vs 17.22 ± 8.01 days, p=0.857). There were no significant differences in renal colic episodes (2.40 ± 1.98 vs 2.80 ± 1.96, p=0.525) or additional analgesic requirement (2.45 ± 1.61 vs 2.55 ± 1.64, p=0.846). Both treatment regimens were well tolerated, with no significant difference in adverse effects between groups (p=0.266). Conclusion: Silodosin monotherapy and silodosin plus mirabegron combination therapy demonstrated comparable efficacy and safety in the treatment of distal ureteric stones measuring 4–10 mm.

Keywords: Distal Ureteric Stone. Silodosin. Mirabegron. Medical Expulsive Therapy. Stone-Free Rate.

desfecho primário foi a taxa de expulsão de cálculos. Os desfechos secundários incluíram o tempo até a expulsão dos cálculos, o número de episódios de cólica renal, a necessidade de analgésicos adicionais e os efeitos adversos. Os dados foram analisados utilizando o SPSS versão 25.0, e um valor de p <0,05 foi considerado estatisticamente significativo. Resultados: A taxa de ausência de cálculos foi maior no Grupo B em comparação com o Grupo A (45% vs. 25%), mas a diferença não foi estatisticamente significativa (p = 0,320). O tempo médio de expulsão do cálculo foi comparável entre o Grupo A e o Grupo B (16,40 ± 7,92 dias vs. 17,22 ± 8,01 dias, p = 0,857). Não houve diferenças significativas nos episódios de cólica renal (2,40 ± 1,98 vs 2,80 ± 1,96, p=0,525) ou na necessidade adicional de analgésicos (2,45 ± 1,61 vs 2,55 ± 1,64, p=0,846). Ambos os regimes de tratamento foram bem tolerados, sem diferença significativa nos efeitos adversos entre os grupos (p=0,266). Conclusão: A monoterapia com silodosina e a terapia combinada com silodosina e mirabegron demonstraram eficácia e segurança comparáveis no tratamento de cálculos ureterais distais medindo 4–10 mm.

Palavras-chave: Cálculo Ureteral Distal. Silodosina. Mirabegron. Terapia Médica de Expulsão. Taxa de Eliminação de Cálculos.

1 INTRODUCTION

Urolithiasis is a prevalent illness worldwide. with an incidence of approximately 4-15 percent. and it has a significant burden on the health sector [1.2]. In the distal ureter. about 20 percent of urinary stones are found. and 70 percent of them are in the distal ureter [3.4]. Most stones pass spontaneously. but they may cause acute pain (renal colic). for which effective pain relief and better stone-passage techniques are required [4]. The spontaneous expulsion of distal ureteric stones ranges between 25 and 53% of the stones with sizes ranging between 4 and 10 mm. and thus the case can be treated conservatively. The spontaneous passage of ureteric stones is influenced by a number of factors. including stone size. shape. and location. ureteral muscle spasm. a swollen ureteral wall. and anatomical anomalies [5.6]. In most clinical guidelines. the medical expulsive therapy

(MET) is suggested as an option for the treatment of distal ureteral stones with a size of 4-10 mm [7]. MET loosens smooth muscles on the urinary tract thus allowing the stones to pass through. Silodosin is a more selective alpha 1A agonist and is beginning to be used in MET [8]. Silodosin, a selective alpha-blocker, is an effective treatment for lower urinary tract symptoms by relaxing the smooth muscles of the bladder and prostate. The time to stone expulsion is prolonged, and silodosin reduces analgesic consumption [9]. With silodosin, distal ureteral stones of 4 to 10 mm diameter are easier to expel. Nevertheless, the mechanism of action of alpha-blockers may lead to such adverse effects as retrograde ejaculation, nausea, dizziness, and orthostatic hypotension. The necessity, therefore, exists of new, more efficient agents that are less complicated [4]. Beta-3 adrenoreceptors (β 3AR) have also been demonstrated to exist in the ureteral smooth muscle, and are involved in adrenergic stimulation of ureteral relaxation. In addition, urothelium and the interstitial cells, per se, express β 3AR at a higher rate than ureteral smooth muscle. This implies that β 3AR is involved in ureteral dynamics. Mirabegron is a novel selective β 3AR agonist which has just undergone introduction as a MET agent. It is purported to be an effective and safe alternative to the established MET agents, whose mechanisms of action differ [10].

Abdel-Kader and coworkers (2023) conducted a study assessing the efficacy and safety of silodosin and the silodosin + mirabegron combination as MET for stone expulsion in distal ureteric stones <10 mm. The study showed that the rate of stone expulsion in the combination group (94.3) was significantly higher than in the silodosin group (57.1). The average time to stone expulsion in the silodosin group and combination groups was 14 ± 2.3 and 7 ± 2.2 days, respectively. The occurrence of renal colic in combination (7 ± 2.2) was significantly lower than in the silodosin group (14 ± 2.3), indicating the need for fewer analgesics. The combination group had a much higher rate of retrograde ejaculation (84) than the silodosin group (73.9).[4] One of the latest studies by Faridi and colleagues (2024) compared the effectiveness of mirabegron and silodosin as medical expulsive therapy (MET) for the treatment of distal ureteric calculi <10 mm. There was no statistical difference between the two groups in terms of mean age, gender, mean stone size, side or hydronephrosis. There was no statistical difference between the groups (81.03% vs. 82.14% for stone expulsion rate). The silodosin group had shorter stone expulsion time in the first week (25.5% vs 28.2, $p = 0.767$), second week (42.5%

vs 47.8. $p = 0.609$). and fourth week (2.13% vs 4.35. $p = 0.617$). but these differences were not statistically significant. Regarding pain, the rate of renal colic with mirabegron was substantially lower than with silodosin (2.34 ± 0.20 vs. 1.94 ± 0.18 . $p < 0.0001$). It was concluded that in patients with a distal ureter stone (5-10 mm), mirabegron was not superior to silodosin as MET for stone expulsion rate or time, but was significantly lower in the number of renal colic episodes. Research proposed that distal ureter stones can be better treated with mirabegron as a medical expulsive therapy compared to silodosin [11].

2 OBJECTIVE

The objective of the study is to compare the silodosin monotherapy versus silodosin + mirabegron add-on therapy for distal ureteric stone between 4 to 10mm in terms of stone free rate.

3 METHODOLOGY

This prospective, randomized controlled trial was conducted at Sahiwal Teaching Hospital, Sahiwal from November 2025 to February 2026. The study included 40 patients having distal ureteric stones ranging between 4 to 10 mm and divided them in two equal groups of 20 patients each. Group-A was treated to 8 mg of silodosin each day, and Group-B was treated to 8 mg of silodosin on a daily basis with 50 mg of mirabegron. It was estimated that the sample size of 99% confidence and 80% power was based on the already reported silodosin monotherapy stone-free rates of 57.1 percent and silodosin plus mirabegron stone-free of 94.3 percent. In that regard, 20 patients in each group were identified as the required sample size. Eligible patients were selected through the use of simple random sampling. To reduce selection bias, the randomization into two groups was done using a table of random numbers generated by the computer and was prepared by a statistician who did not participate in the research. The study included patients between the ages of 18 and 60 years of either sex who had distal ureteric stones between the sizes of 4 and 10 mm confirmed by imaging. The study excluded patients with one functioning kidney, impaired renal functioning, multiple or bilateral ureteric stones, radiolucent stones, active infection of the urinary tract, uncontrolled hypertension,

pregnancy, previous ureteral surgery, or patients who had complications before four weeks of medical expulsive therapy was administered.

3.1 Data collection

The hospital's ethics committee provided formal consent before the study was initiated, and informed written consent was obtained from all participants. The principles of the Helsinki Declaration were followed regarding confidentiality and privacy. It was designed as a structured pro forma, which was tested before finalization. The principal investigator assessed all patients who came to the hospital with distal ureteric stones. Comprehensive history taking and examination were done, and the variables like age, gender, body mass index, stone laterality, stone size, pre- and post-treatment serum creatinine, stone expulsion status, time to expulsion, the number of renal colic episodes, increased need for analgesics, blood pressure values, and drug-related adverse events were noted. The baseline tests consisted of blood urea, serum creatinine, urine examination, urine culture, KUB X-ray, and non-contrast CT scan. Patients were recommended to use oral ketorolac 30mg for pain episodes and to keep adequate hydration of 2500-3000 ml/day. They were to strain their urine to detect stones. The treatment was continued until spontaneous stone expulsion or for a maximum of 4 weeks. Follow-ups were conducted in the outpatient department weekly, with ultrasonography and KUB X-ray to assess stone status, and clinical outcomes were recorded. The rate of expelling the stones (stone-free rate) was the major study result. Secondary outcomes were time to stone expulsion, renal colic episodes, overall extra analgesic needs, and adverse drug actions. The analysis of all the obtained data was made through SPSS version 25.0. The qualitative variables included gender, laterality, stone expulsion status, renal colic episodes, analgesic requirement, and adverse effects, which were presented in the form of frequencies and percentages. Quantitative variables were age, body mass index, stone size, and pre-treatment creatinine levels, which were presented in the form of mean and standard deviation. The chi-square test was used to assess the relationship between the two treatment groups, and p-values below 0.05 were considered statistically significant. The results were provided in table and graph forms where necessary.

4 RESULTS

Data were collected from 40 patients; the mean age in Group A was 41.75 ± 13.42 years. in Group B 40.55 ± 12.21 years. and the overall mean age was 41.15 ± 12.74 years. The mean BMI was similar between groups (26.14 ± 3.57 kg/m² in Group A vs 26.72 ± 2.75 kg/m² in Group B). with an overall mean of 26.43 ± 3.15 kg/m². The mean stone size was 6.83 ± 1.70 mm in Group A and 7.08 ± 1.72 mm in Group B. indicating balanced stone burden between groups. Pre-treatment creatinine levels were 1.06 ± 0.17 mg/dL in Group A and 1.16 ± 0.17 mg/dL in Group B. while post-treatment values were 0.98 ± 0.18 mg/dL and 1.07 ± 0.14 mg/dL. respectively.

Table 1

Demographic and Baseline Clinical Characteristics

Variable	Group-A (n=20)	Group-B (n=20)	Total (n=40)
Age (years)	41.75 ± 13.42	40.55 ± 12.21	41.15 ± 12.74
BMI (kg/m ²)	26.14 ± 3.57	26.72 ± 2.75	26.43 ± 3.15
Stone Size (mm)	6.83 ± 1.70	7.08 ± 1.72	6.96 ± 1.70
Pre-treatment Creatinine (mg/dL)	1.06 ± 0.17	1.16 ± 0.17	1.11 ± 0.18
Post-treatment Creatinine (mg/dL)	0.98 ± 0.18	1.07 ± 0.14	1.03 ± 0.17

In Group-A. 60% were males and 40% females. compared to 55% males and 45% females in Group-B ($p = 0.749$). Right-sided stones were observed in 55% of Group-A and 50% of Group-B. while left-sided stones were present in 45% and 50%. respectively ($p = 0.749$).

Table 2

Gender and Stone Laterality Distribution

Variable	Group-A (n=20)	Group-B (n=20)	Total (n=40)	p-value
Male	12 (60%)	11 (55%)	23 (57.5%)	0.749
Female	8 (40%)	9 (45%)	17 (42.5%)	
Right-sided stone	11 (55%)	10 (50%)	21 (52.5%)	0.749
Left-sided stone	9 (45%)	10 (50%)	19 (47.5%)	

The stone expulsion rate was higher in Group-B (45%) compared to Group-A (25%); however. this difference was not statistically significant ($p = 0.320$). Overall. 35% of patients achieved spontaneous stone passage. The mean stone expulsion time was comparable between groups (16.40 ± 7.92 days in Group-A vs 17.22 ± 8.01 days in Group-B. $p = 0.857$). Similarly. renal colic episodes were slightly higher in Group-B (2.80 ± 1.96) compared to Group-A (2.40 ± 1.98). but without statistical significance ($p = 0.525$). Additional analgesic requirement was also similar (2.45 ± 1.61 vs 2.55 ± 1.64 ampoules. $p = 0.846$).

Table 3*Primary and Secondary Treatment Outcomes*

Variable	Group-A (n=20)	Group-B (n=20)	Total (n=40)	p-value
Stone Expelled	5 (25%)	9 (45%)	14 (35%)	0.320
Stone Not Expelled	15 (75%)	11 (55%)	26 (65%)	
Stone Expulsion Time (days)	16.40 ± 7.92	17.22 ± 8.01	16.90 ± 7.93	0.857
Renal Colic Episodes	2.40 ± 1.98	2.80 ± 1.96	2.60 ± 1.96	0.525
Extra Analgesic Ampoules	2.45 ± 1.61	2.55 ± 1.64	2.50 ± 1.61	0.846

Adverse effects were distributed comparably between groups ($p = 0.266$). Headache occurred in 20% of Group-A and 5% of Group-B. Dizziness was more common in Group-B (40%) compared to Group-A (20%). Hypotension was slightly higher in Group-A (30%) compared to Group-B (20%). Dry mouth occurred in 20% of Group-A and 10% of Group-B. Notably, 25% of patients in Group-B reported no adverse effects compared to 10% in Group-A.

Table 4*Adverse Effects Profile*

Adverse Effect	Group-A (n=20)	Group-B (n=20)	Total (n=40)	p-value
Headache	4 (20%)	1 (5%)	5 (12.5%)	0.266
Dizziness	4 (20%)	8 (40%)	12 (30%)	
Hypotension	6 (30%)	4 (20%)	10 (25%)	
Dry Mouth	4 (20%)	2 (10%)	6 (15%)	
No Adverse Effect	2 (10%)	5 (25%)	7 (17.5%)	

5 DISCUSSION

The current randomized controlled trial involved the efficacy and safety of silodosin monotherapy versus silodosin with mirabegron in the case of distal ureteric stones 4-10 mm. Baseline age, BMI, stone size, and renal function were statistically similar in both groups and presented internal validity as well as minimum confounding bias. The main effect, that is the rate of stones expelled, was more in the combination group (45% as opposed to 25% in the monotherapy group); but this was not statistically significant ($p = 0.320$). The numerical improvement, though insignificant, is an indication of a potential additive pharmacological effect. Silodosin is a selective blocker of the α_1A -adrenergic receptor which decreases the ureteral α_1A -adrenergic receptor tone of the smooth muscle and allows the passage of stones. Mirabegron is a β_3 -adrenoceptor agonist, which can also intensify relaxation of the ureter by cAMP-dependent mechanisms. Other past studies have shown higher rates of stone-free after combination therapy than those after monotherapy using alpha-blockers and this has been attributed to the dual-pathway modulation of smooth muscle. Nevertheless, the low sample size in the

current research might have limited the statistical power to estimate a significant difference [12].

Concerning secondary outcomes, there were no significant differences in mean stone expulsion time in the two groups (16.40 \pm 7.92 days vs 17.22 \pm 8.01 days, $p = 0.857$). On the same note, episodes of renal colic and other pain relieving needs were not significantly different. These results indicate that the introduction of mirabegron did not significantly speed up the rate at which the stones pass and the load of the pain is taken over during the 4-week follow-up [13]. The research conducted before has indicated shorter expulsion periods and lower analgesic use in combination regimens, but differences in the population of the study, distribution of stone sizes, and course of the treatment could be the reason. Both groups had a stable renal function and there were no clinically significant changes in the pre- and post-treatment creatinine levels. This validates the safety of the two treatment regimens in patients who do not have baseline renal impairment [14-16].

The groups compared in terms of adverse effect profiles ($p = 0.266$). Although dizziness was somewhat more prevalent in the combination group, hypotension was observed to be more in the monotherapy group and there were no severe drug related effects. Notably, a larger percentage of patients in the combination group (25% vs 10%), indicated that they never experienced any adverse effects, which means the tolerability of the combination is acceptable. It has also been shown in the past that mirabegron has no significant effect in increasing hypotensive events because it has selective β_3 activity that leaves vascular β_1 and β_2 receptors intact [17-19]. Bayar and colleagues (2020) conducted a study comparing the effectiveness of silodosin and mirabegron as medical expulsive therapy for ureteric stones in adults. Patients with 4-10 mm ureteral stones were divided into three groups. Group 1 was a control group; group 2 took silodosin 8mg; and group 3 took mirabegron 50mg once a day. It was proven that there was no significant difference in spontaneous expulsion rate between groups. The stone expulsion period was also shorter in the silodosin group (7.1 \pm 4.5 days) than in the control group (12 \pm 8.7 days) in patients with distal localization. In patients whose stones were less than 6 mm, the stone expulsive period was shorter in the silodosin group (5.8 + 4.3) compared to the control group (12.2 \pm 2.8); the analgesic duration was less in the silodosin group (1.4 + 1.3) than in the control group (3.6 \pm 2.8). In any analysis, the stone expulsion interval was

not influenced by mirabegron. The requirement to take analgesics in patients with distal localization or stone size <6 mm was less in the mirabegron group than in the control group. The conclusion was that silodosin or mirabegron does not increase the rate of stone expulsion. Silodosin prolongs stone expulsion time and reduces analgesic requirements for stones less than 6 mm in size [12]. Mirabegron does not alter the stone expulsion interval but reduces analgesic requirements in patients with distal ureteric stones <6 mm [20].

There are several limitations to this study. To start with, the sample size was quite small ($n = 40$), which may have weakened the statistical power to detect meaningful differences between the treatment groups due to numerical differences in stone-free rates. Second, the research was conducted at a single center, which could limit the generalizability of the results to broader populations with diverse demographic or clinical profiles. Third, the follow-up period was only 4 weeks, which may have allowed further observation to yield more information about the delay in stone passage or recurrence. Fourth, blinding was not done, and it can create performance or assessment bias. Also, the imaging modalities used to follow up on the study, including KUB X-ray and ultrasonography, might not have as high a sensitivity as repeat non-contrast CT to ensure complete stone clearance.

6 CONCLUSION

It is concluded that silodosin monotherapy and silodosin combined with mirabegron are both safe and effective options for the management of distal ureteric stones measuring 4–10 mm. Although the combination therapy demonstrated a higher numerical stone-free rate compared to silodosin alone, the difference was not statistically significant. Secondary outcomes, including stone expulsion time, frequency of renal colic episodes, and additional analgesic requirement, were comparable between the two groups. The adverse effect profiles were also similar, indicating good tolerability of both regimens.

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Authors' Contribution

All authors contributed equally to the development of this article.

Data availability

All datasets relevant to this study's findings are fully available within the article.

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