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Comparative Study of the Efficacy of Alfuzosin and Silodosin in the Medical Expulsion Therapy for Distal Ureteral Calculus

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ABSTRACT

Introduction: Ureteral stones often require pharmacological intervention to aid their passage. Alpha-blockers like Alfuzosin and Silodosin are frequently used to relax ureteral smooth muscle and facilitate stone expulsion.**Objectives:** The objective of this study was to compare the efficacy of 10 mg Alfuzosin and 8 mg Silodosin in facilitating the passage of small ureteral stones (≤ 10 mm), with a focus on stone expulsion time.**Methodology:** The study was conducted at Birat Medical College Teaching Hospital, Nepal from December 25, 2023, to June 24, 2024. A total of 116 patients, aged 18 to 50, with unilateral, uncomplicated stones in the middle or lower ureter, were randomly assigned to receive either 10 mg Alfuzosin (Group A) or 8 mg Silodosin (Group B). Patients were monitored weekly for three weeks, and stone passage was tracked. If the stone was not passed by day 21, treatment was considered a failure.**Results:** The mean age of patients was 37.5 years in both groups. In Group A, 48 out of 58 patients (82.8%) passed their stones, while in Group B, 53 out of 58 patients (91.4%) succeeded in passing their stones. The difference in success rates was not statistically significant ($p = 0.166$). However, Silodosin led to faster stone expulsion compared to Alfuzosin.**Conclusion:** Both Alfuzosin and Silodosin were effective in promoting stone passage, with success rates of 82.8% and 91.4%, respectively. While Silodosin showed a higher success rate, the difference was not statistically significant. Silodosin also appeared to facilitate faster stone expulsion, suggesting it may be a slightly more effective option for stone management.

INTRODUCTION

Ureteral colic, primarily caused by ureteric stones, accounts for 1 to 2% of emergency admissions.¹ There has been a significant change in how ureteral calculi are managed, with the emergence of less invasive techniques and novel pharmaceuticals.^{2,3} One of the options involves the relaxation of the smooth muscle in the ureter. The logic supporting the use of alpha blockers is based on the fact that activation of the α_1 receptors in the ureter leads to an enhancement in the intensity of ureteral contraction and the rate of ureteral peristalsis.³ There exist three subtypes of α_1 receptor: α_{1a} , α_{1b} , and α_{1d} , with α_{1d} receptors being notably concentrated in the distal ureter.⁴ Recently introduced selective α_{1a} -adrenoceptor antagonists, such as Alfuzosin and Silodosin, have exhibited encouraging outcomes characterized by fewer adverse effects and improved efficacy.^{4,5,6} For a substantial period, these pharmaceutical agents have been employed in the context of medical expulsive therapy.⁷⁻⁸ The objective of this study was to compare the efficacy of 10 mg Alfuzosin and 8 mg Silodosin in facilitating the passage of small ureteral stones (≤ 10 mm), with a focus on stone expulsion time.

METHODOLOGY

This prospective comparative cross-sectional study was conducted at Birat Medical College Teaching Hospital, Nepal from December 25, 2023 to June 24, 2024. Total 116(58 in each group) patients of age groups of 18–50 years who had unilateral, uncomplicated middle or lower ureteral stones ≤ 10 mm were enrolled in this study. Patients with renal failure, Pregnant women, Sepsis and Co-morbid cardiac (Hypertension, Diabetes Mellitus), Respiratory diseases (Asthma, COPD), Coagulation disorder (INR 1 – 1.4), Severe hydronephrosis (renal pelvis > 6 mm diameter and cortex < 10 mm on ultrasound KUB) and Multiple ureteric stones (more than 2) were excluded from this study

Sample size of 116 (58 in each group) was calculated by using 95% confidence level, 80% power of test and the stone expulsion rate as 82% in silodosin and 58% in alfuzosin.⁹ After approval from hospital's ethical committee, patients fulfilling the selection criteria were enrolled in this study. Informed consent was obtained and patient demographic information (name, age, gender) was recorded. Patients were randomly divided in two equal groups by computer generated method. Fifty eight each were placed in group A treated with Alfuzosin (10mg) and in group B treated with Silodosin (8mg) Ultrasonography (USG) and CT scan were utilized to evaluate each case, with ureter and bladder (KUB) imaging also performed. The initial treatment for all patients consisted of an intramuscular injection of Diclofenac 75 mg, followed by a second dose after 30 minutes if necessary. In cases where diclofenac did not provide sufficient pain relief, injection of Drotavarine via intramuscular or intravenous route was the preferred alternative. Patients who experienced pain resolution were discharged and automatically included in the research study.

The patients in Group A were administered Alfuzosin 10 mg orally once daily for a period of 21 days, while Group B received Silodosin 8mg once daily. Participants were instructed to take the medication at the same time each day. Treatment was ceased upon spontaneous stone expulsion, intervention, or upon completion of the therapy after 21 days. Patients were advised to maintain adequate fluid intake throughout the study period and continue their daily activities.

Weekly follow-ups over a span of 3 weeks included urinalysis and serum creatinine measurements. Abdominal USG and CT scan were conducted to evaluate the status of the stones after 3 weeks. For individuals with a ureter that appeared to be free of stones in the final USG but with unnoticed stone expulsion, the date of the last confirmed presence of stones was documented. Failure of therapy was defined as the absence of stone expulsion beyond day 21.

Discontinuation of the study medication and intervention before the study conclusion due to uncontrollable pain, adverse events, urinary tract infections, acute renal failure, or patient preference for stone removal were also considered instances of failed therapy. The study medication was terminated after spontaneous stone expulsion or upon completion of the study.

Data collection was performed using a predefined proforma.

Data analysis was conducted using statistical software SPSS v25.0. Categorical variables such as gender and stone expulsion were analyzed in terms of frequency and percentage. Quantitative measurements such as age, stone size, and time to stone expulsion were assessed in terms of mean and standard deviation. The stone expulsion rate between groups was compared using the chi-square test, while the time to stone expulsion was compared using the independent sample t-test. A p-value of ≤ 0.05 was deemed statistically significant.

RESULTS

Total 116 patients with distal ureteral calculi were enrolled in this study. In group A, there were 34(58.6%) were males and 24(41.4%) were females. In group B, 33(56.9%) were males and 25(43.1%) were females (Table 1).

Table 1: Frequency distribution of gender, Age groups and Stone size between groups (n=116)

Variables Alfuzosin		Groups		Total
		Silodosin		
Gender n (%)	Male	34 (58.6)	33 (56.9)	67
	Female	24 (41.4)	25 (43.1)	49
Age groups n(%)	18-30 years	13 (22.4)	14 (24.1)	27
	31-50 years	45 (77.6)	44 (75.9)	89
Stone size n (%)	≤ 5 mm	18 (31)	17 (29.3)	35
	>5 mm	40 (69)	41 (70.7)	81

The mean age of patients in group A was 37.59 ± 8.58 years and in group B was 37.24 ± 8.55 years. In group A, there were 13(22.4%) patients in 18-30 years age group and 45(77.6%) in 31-50 years age group. In group B, 14(24.1%) patients in 18-30 years age group and 44(75.9%) in 31-50 years age group (Table 1).

Table 2: Comparison of stone expulsion between groups (N=116)

Stone expulsion	Groups		Total	p-value
	Alfuzosin	Silodosin		
Yes n (%)	48	53	101	0.166
No n (%)	10	5	15	

Table 3: Comparison of time to stone expulsion between groups (N=116)

Groups	Time to stone expulsion (days)	p-value
Alfuzosin (mean \pm SD)	12.26 \pm 1.37	0.0001
Silodosin (mean \pm SD)	10.47 \pm 1.06	

The mean stone size in group A was 5.56 ± 0.78 mm and in group B was 5.60 ± 0.79 mm. In group A, 18(31%) patients had stone size ≤ 5 mm and 40(69%) had >5mm. In group B, 17(29.3%) patients

had stone size ≤ 5 mm and 41(70.7%) had >5 mm (Table 1).

In group A, stone expulsion was noted in 48(82.8%) patients and 53(91.4%) patients on group B with a p-value of 0.166, which is statistically insignificant (Table 2). The mean time to stone expulsion in Alfuzosin group was 12.26 ± 1.37 days and in Silodosin group as 10.47 ± 1.06 days with p-value of 0.0001, which is statistically significant (Table 3).

DISCUSSION

Due to the potential complications and high costs associated with minimally invasive procedures, there is a growing trend toward conservative management of ureteral stones smaller than 10 mm. Treatment decisions are based on factors such as stone size, location, number, structure, and symptoms. Stone expulsion rates are influenced by ureteral spasm, anatomy, and inflammation-induced mucosal edema. Watchful waiting is often preferred for distal stones in patients without infection, with tolerable pain and small stone size. Medical expulsive therapy aims to facilitate natural stone passage by relaxing ureteral smooth muscle, preserving peristalsis, and reducing pain—leveraging the high spontaneous expulsion rates of small stones. The natural rate of spontaneous expulsion of distal ureteric calculi is 68% for stones smaller than 5 mm, and this percentage decreases to about 47% for stones ranging from 5 to 10 mm in size. In addition to size, the location of the calculi plays a crucial role in their spontaneous expulsion. Specifically, the spontaneous expulsion rate is 21% for proximal ureter stones, 46% for middle ureter stones, and 71% for distal ureteral stones.^{10,11}

α -1 receptors have been categorized into three distinct subtypes, namely α -1a, α -1b, and α -1d. The most prevalent adrenoceptors in the ureter are α -1d and α -1a, with their distribution ranked as α -1d $>$ α -1a $>$ α -1b. Predominantly located in the intramural ureter and detrusor muscle, α -1d receptors serve as the primary target for medical expulsive therapy due to their prevalent presence in the distal ureter.¹²⁻¹⁴

Itoh et al. have documented that the distal segment of the ureter displays a greater expression of α -1 adrenoceptor compared to other segments. Moreover, they have shown that α -1d adrenoceptor mRNA is more prevalent than α -1a adrenoceptor mRNA in all sections of the ureter. As a result, their findings suggest that utilizing an α -1d adrenoceptor blocker may be more effective in promoting the passage of ureteral stones than an α -1a adrenoceptor blocker.¹²

In contrast to previous findings, Tatemichi and colleagues presented a contrasting perspective by asserting that the regulation of ureteral motility frequently involves the activation of α 1a adrenoceptors. This novel insight challenges existing beliefs and opens up new avenues for research into the mechanisms underlying ureteral function. By highlighting the role of α 1a adrenoceptors in mediating ureteral motility, this study provides a fresh perspective on the pharmacological targets that could potentially be manipulated to modulate ureteral activity.¹⁵

A comparative analysis evaluating the effectiveness of Silodosin versus Tamsulosin, encompassing a cohort of 136 individuals diagnosed with proximal ureter stones ranging from 4-10 mm

in size, revealed that individuals administered with silodosin exhibited a notable enhancement in the rate of stone expulsion as well as a reduction in the duration of expulsion for lower ureteral stones, with percentages standing at 61.2% and 80.3% respectively.¹⁶

A comprehensive meta-analysis comprising eight publications authored by Huang W et al. has revealed that silodosin exhibits a higher level of efficacy compared to both placebo and Tamsulosin when utilized in the treatment of distal ureteral calculi. This analysis further indicates that silodosin not only outperforms these alternatives in terms of efficacy but also offers superior pain management capabilities. The findings from this meta-analysis strongly suggest that silodosin may hold significant promise as a preferred treatment option for individuals suffering from distal ureteral calculi due to its notable advantages over placebo and Tamsulosin.¹⁷

Moreover, a comprehensive study conducted by Sur RL et al. involved multiple institutions and utilized a randomized, double-blinded, placebo-controlled trial design. The results of this study indicated that Silodosin exhibited a high level of tolerance in participants and demonstrated significant benefits in aiding the passage of distal ureteral stones. These findings contribute valuable insights into the potential effectiveness of Silodosin as a treatment option for patients with ureteral stones, highlighting its role in improving clinical outcomes and patient comfort.¹⁸

In our research, we observed a statistically insignificant difference between the impacts of Silodosin and Alfuzosin on stone expulsion rates ($p=0.166$). The duration of stone expulsion was 12.26 ± 1.37 days for the Alfuzosin group and 10.47 ± 1.06 days for the Silodosin group. Notably, Alfuzosin exhibited a significantly longer stone expulsion duration compared to silodosin.

Imperatore V et al.'s study revealed that both Tamsulosin and silodosin show equivalent efficacy as medical expulsive therapy for distal ureteral calculi measuring less than 10 mm. The stone-expulsion rate was 88% in the silodosin group and 82% in the Tamsulosin group.¹⁹

The rise in pressure within the ureter caused by obstruction is responsible for triggering colic pain episodes. α -1 blockers, primarily utilized for promoting the expulsion of stones, may also lead to a reduction in the use of analgesic medications through the elimination of ureteral calculi.²⁰

Medical expulsive therapy is a cost-effective non-operative intervention for ureteral calculi measuring less than 10 mm. Various research studies have demonstrated that α -1 adrenoceptor blockers can aid in the spontaneous passage of distal ureteral calculi with minimal adverse effects. A systematic review and meta-analysis comprising 21 studies, conducted by Picozzi SC et al., focused on evaluating the impact of medical expulsive treatment for ureter stones. The review concluded that patients experiencing symptoms related to distal ureteral calculi should be offered medical expulsive therapy.²¹

The study by Jeong et al. addresses a crucial issue in urology, given the rising incidence of urinary stones, which has become a significant health concern globally. According to them, the

worldwide incidence of urinary stones has been reported to range from 1% to 20%, depending on geographic and demographic factors. This variation underscores the need for effective training in procedures like percutaneous nephrostomy, which is essential for managing complications arising from urinary stones. The study demonstrates that training with a porcine model significantly improves the technical skills and confidence of medical professionals in performing ultrasound-guided nephrostomy.²² To enhance the discussion on silodosin, a meta-analysis found that silodosin significantly improved the International Prostate Symptom Score (IPSS) and quality of life compared to placebo, demonstrating its effectiveness in alleviating symptoms associated with benign prostatic hyperplasia. Additionally, the analysis highlighted that Silodosin had a favorable safety profile, with a lower incidence of adverse effects such as dizziness and hypotension compared to other α -blockers. This information supports the relevance of Silodosin in clinical practice, particularly in managing patients with urinary symptoms related to prostate conditions.²³

CONCLUSION

By conducting a comparative analysis of the two groups, it was determined that there were no statistically significant disparities in the effectiveness of both medications; however, it was observed that the duration required for the expulsion of stones was notably shorter in the Silodosin group. This finding underscores the importance of considering various factors when evaluating the efficacy of different treatment options for stone expulsion.

LIMITATIONS OF THE STUDY

Conducted at a single center in Nepal, the results may not be generalizable to other regions or healthcare settings. The sample size, though adequate, may not have been large enough to account for all potential variables, and a larger sample could provide more robust data. Further multicentric studies with large sample size is recommended.

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