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Original Article

Evaluating the Safety and Effectiveness of Alpha Blockers in the Treatment of Ureteric Stones: A Prospective Observational Study

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ABSTRACT

Background: Ureteric stones, characterized by the crystallization of mineral particles in stagnant urine, cause considerable discomfort and pain. Alpha-blockers are employed in the management of ureteric stones to alleviate symptoms by dilating the ureter and facilitating stone passage. Alpha-blockers have proven to be effective in improving the clinical outcomes of patients with ureteric stones, with Silodosin, Alfuzosin, and Tamsulosin emerging as promising options. **Aim and Objectives:** This study aims to evaluate the effectiveness and safety of Silodosin, Alfuzosin, and Tamsulosin in treating ureteric stones. It assesses their performance in patients at a Tertiary Care Hospital, aiming to identify the most suitable alpha-blocker for optimum outcomes. **Materials and Methods:** The study involved 60 patients with ureteral stones treated at the Urology Department of Dhiraj Hospital. Patients' responses to a structured questionnaire assessing variables related to ureteric stone development were collected. Physical examinations, along with radiological confirmation through X-ray, Ultrasound (USG), and CT-scan, were conducted. A 15-day follow-up assessed the efficacy of alpha-blockers. Statistical analysis and paired *t*-tests were employed to compare the drugs' effectiveness. **Results:** Silodosin demonstrated the highest stone expulsion rate at 95%, whereas Tamsulosin exhibited a 50% rate, and Alfuzosin recorded a 10% rate. Minimal side effects were observed, such as nausea, vomiting, and diarrhea, which were typical for patients with ureteric stones. **Conclusion:** Silodosin emerged as the most effective alpha blocker for promoting stone expulsion and ameliorating ureteric stone symptoms when compared to Tamsulosin and Alfuzosin. It is considered a pharmacologically superior choice for patients with ureteric stones, making it a valuable option in clinical practice.

Keywords: Ureteric stones, Alpha-blockers, Clinical outcomes, Safety profile.

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INTRODUCTION

Urolithiasis, the formation of urinary stones, exhibits varying prevalence rates across different regions in Asia. In West Asia, Southeast Asia, South Asia, South Korea, and Japan, the prevalence of urolithiasis falls within the range of 5% to 19.1%. In contrast, most parts of East Asia and North Asia tend to have lower prevalence rates, typically between 1% and 8%.[1] Rapid and accurate diagnosis and timely treatment of urolithiasis are of paramount importance. Failure to do so can result in substantial morbidity and, in some cases, even death.[2] The primary constituents of urinary stones are typically calcium oxalate, calcium phosphate, or a combination of both. However, other types, including struvite, cystine, and uric acid stones, may also account for up to 20% of urolithiasis cases.[3] In cases of ureteral stones, these are typically small in size and can sometimes pass spontaneously through the urinary tract, depending on their size and location. However, stones that weigh more than 0.1 grams and have a diameter exceeding 1 cm are less likely to pass on their own and may require medical intervention.[4] Epidemiological research has indicated that the development of urinary calculi is influenced by a multitude of factors, rather than being attributed to a single cause. These factors include sex, ethnicity, age, climatic conditions, and obesity, and they collectively contribute to an individual's risk of developing urinary stones.[5] Among the alpha blockers frequently prescribed for the treatment of urolithiasis, Silodosin stands out as the most effective option for addressing lower ureteric stones.[6] Epidemiological studies have further shown that the prevalence of urolithiasis in economically developed countries ranges from

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4% to 20%.[7] Alpha-blockers are commonly employed to safely facilitate the passage of stones in the treatment of ureteric stones.[8] Non-enhanced CT scans are effective in predicting the passage of ureteral stones, primarily relying on stone size and location as key predictors. This predictive capability aids clinicians in making treatment decisions. Urolithiasis, a common cause of acute flank pain, is becoming more prevalent, driving up healthcare costs. Research suggests that a significant proportion of ureteral stones (75-90%) can pass naturally. In such cases, watchful waiting, with or without Medical Expulsive Therapy (MET), is often the initial approach. For stones not expected to pass, treatments like ESWL, laser lithotripsy, or percutaneous extraction are utilized, though both conservative and invasive approaches carry risks. Predicting spontaneous passage is crucial for appropriate treatment selection, with stone size and location as the primary predictors, and additional factors like hydronephrosis side and grade in specific cases.[9]

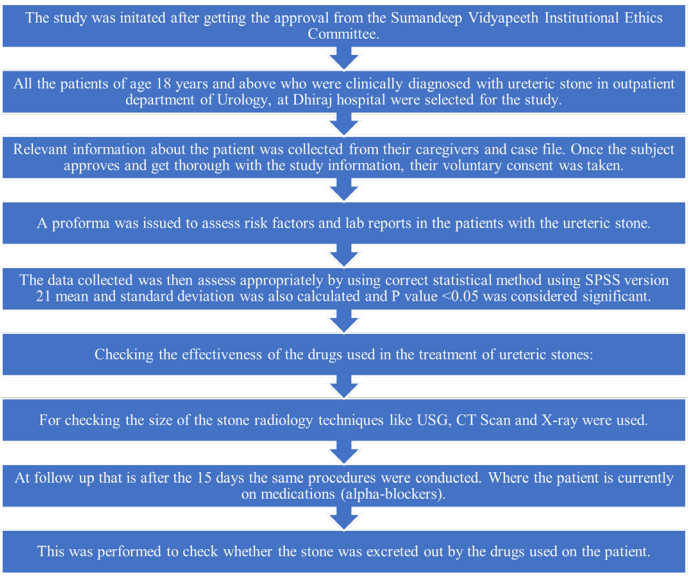
Need of this study

This study addresses the significance of investigating the use of alpha-blockers in treating ureteric stones, which can be painful and potentially harmful if left untreated, leading to complications. The research aims to evaluate the effectiveness of alpha-blockers in stone removal, assess their side effects, and confirm their impact on alleviating symptoms. This study is essential for enhancing our understanding of ureteric stone management and improving patient outcomes and compliance.

MATERIALS AND METHODS

The study utilized a prospective observational design and took place at the outpatient department of Urology in Dhiraj Hospital, with ethical approval from the Sumandeep Vidyapeeth Institutional Ethics Committee (SVIEC/ON/Phar/BNPG21/Nov/22/18). The participants included individuals aged 18 and above with ureteric stones up to 10 mm in size, with exclusion criteria encompassing stones unrelated to the kidney. Data collection involved the preparation of patient information sheets, informed consent forms for both patients and their caregivers, and proforma. Patients were selected based on predefined criteria, and informed consent was obtained after explaining the study. Relevant patient information was collected from caregivers and medical records over four months, aligning with patient visits to the urology department, followed by a two-month data analysis phase. Data collection included assessments of risk factors, laboratory reports, socio-demographic details, daily water intake, diet, smoking, drug history, medical and personal history, and co-morbid conditions. Diagnostic imaging tests, such as Ultrasound (USG), CT scans, and X-rays, were employed to determine stone size, with a follow-up after 15 days to assess the effectiveness of the medications in facilitating stone passage. Data were analyzed using SPSS version 21, involving proportions, chi-square tests, mean and standard deviation calculations, and various visual aids for descriptive analysis, with a statistical significance level set at $p<0.05$.

Flow Chart



RESULTS

Source of water.The study was conducted in the urology department of Dhiraj Hospital, encompassing a total of 144 patients, of whom 60 were diagnosed with urinary stones, accounting for 41.67% of the total patient population. Over the course of four months, patients were continuously screened for data collection. The age distribution of the participants ranged from greater than 18 years, with a mean age of 47.417±13.4785 (Mean±SD). Participants were categorized into six age and gender groups: ≤20 years (n=1, M=1), 21-30 years (n=8, M=3, F=5), 31-40 years (n=10, M=6, F=4), 41-50 years (n=11, M=7, F=4), 51-60 years (n=19, M=15, F=4), 61-70 years (n=11, M=6, F=5), as indicated in Graph 1. In terms of gender distribution, men constituted 63.3% of the total population, while women accounted for 36.67%. The onset of pain was categorized into insidious pain (n=38) at 63.3% and sudden pain (n=22) at 36.7%. Regarding the duration of action, participants were classified into four categories: days (n=6) at 10%, weeks (n=10) at 16.66%, months (n=37) at 61.66%, and years (n=7) at 11.66%. Participants' reported laterality of pain was divided into three categories: Bilateral (n=8) at 13.4%, Left (n=28) at 46.7%, and Right (n=24) at 40%. The radiation of pain was categorized into five groups: No radiation (n=51) at 85%, Groin (n=4) at 6.7%, Penis Scrotum (n=3) at 5%, Thigh (n=1) at 1.7% and Umbilicus (n=1) at 1.7%. Additionally, participants' sources of water were divided into four categories: Bore well (n=19) at 31.7%, Others (n=2) at 3.3%, Tank (n=6) at 10.0%, and Well (n=33) at 55.0% (Table 1) (Graph 1 to 6).

Table 1: Baseline Characteristics.

Age and Gender Distribution				
Age Group	**Gender**		**Total**	**Percentage**
	Female	**Male**		
≤20	0	1	1	1.6%
21 to 30	5	3	8	13.33%
31 to 40	4	6	10	16.67%
41 to 50	4	7	11	18.33%
51 to 60	4	15	19	31%
61 to 70	5	6	11	18.33%
Total	22	38	60	100%

Distribution of Pain Onset		
	Frequency	**Percent**
Insidious	38	63.7
Sudden	22	36.7
Total	60	100

Distribution of Duration of Pain		
Duration	**Frequency**	**Percent**
Days	06	10
Weeks	10	16.6
Months	37	61.66
Years	07	11.66
Total	60	100

Laterality of Pain		
Side	**Frequency**	**Percent**
Bilateral	8	13.4
Left	28	46.7
Right	24	40
Total	60	100

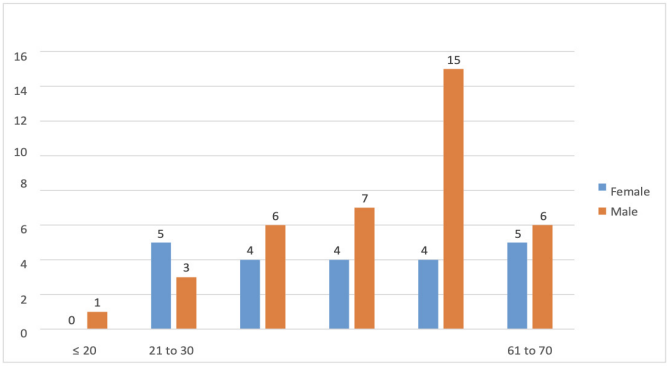
Radiation of Pain		
	Frequency	**Percent**
No Radiation	51	85.0
Groin	4	6.7
Penis Scrotum	3	5.0
Thigh	1	1.7
Umbilicus	1	1.7
Total	60	100

The study assessed the effectiveness of three alpha-blockers, Alfuzosin, Silodosin, and Tamsulosin, in treating ureteric stones. Participants were categorized into three groups based on the medication given and stone size. For Alfuzosin, the mean stone size before treatment was 7.15, with a standard deviation of 2.22542, and after treatment, the mean stone size was 4.55, with a standard deviation of 1.49917, resulting in a mean difference of 2.6±0.72625. For Silodosin, the mean stone size before treatment was 7.175, with a standard deviation of 1.614582, and after treatment, the mean stone size was 3.5, with a standard deviation of 1.627882, resulting in a mean difference of 3.675±0.0133. For Tamsulosin, the mean stone size before treatment was 7.245, with a standard deviation of 1.591689, and after treatment, the mean stone size was 4, with a standard deviation of 1.612452, resulting in a mean difference of 3.245±0.0207. Comparing the mean differences and standard deviations before and after treatment

based on stone size, Silodosin was found to be the most effective alpha-blocker in the study, as it exhibited the largest reduction in stone size in the ureter. Silodosin was also shown to be pharmacologically effective with no reported side effects, making it the most effective and safe drug among the alpha blockers studied for patients with ureteric stones (Table 2).

DISCUSSION

A ureteric stone, also known as a ureteral stone, refers to the presence or the formation of stones within the ureters, which are the slender tubes responsible for transporting urine from the kidneys to the bladder. Approximately 80% of these stones are primarily composed of calcium. It's worth noting that one in every 10 individuals will experience the discomfort of a ureteric stone at some point in their lives. Ensuring patient adherence to prescribed medications and providing thorough counselling are

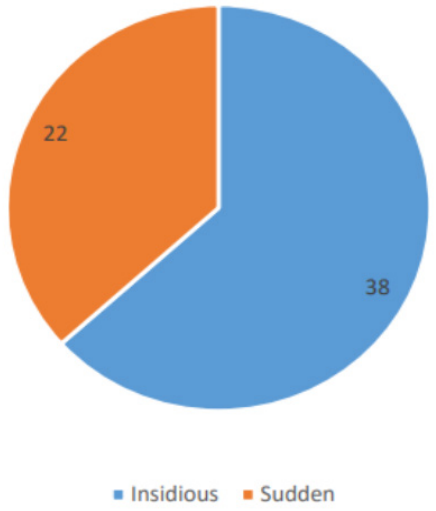


Graph 1: Categories of Age and Gender.

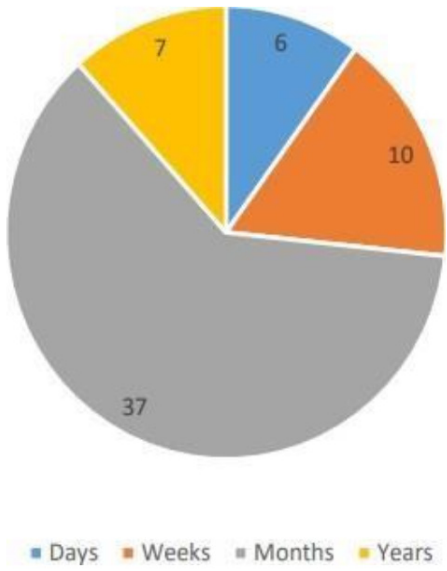
Table 2: Size of Ureteric stone before and after treatment.

Stone Size					
Alfusozin		**Silodosin**		**Tamsulosin**	
Before	**After**	**Before**	**After**	**Before**	**After**
8	5	7	3	8	5
4	4	6	3	8	5
5	4	8	5	4.7	0
10	7	4.4	0	6.7	4
10	6	6	3	7.5	5
9	5	5	0	4	0
9	6	4	0	7	4
9.5	6	7	4	6	3
10	6	5.8	3	5	3
5	4	7.7	4	8	4
6	4	5.9	4	9.7	6
8	5	9	4	8.7	4
4	4	8.8	5	7.8	5
7	3	8	5	5.9	4
8	5	9	5	6	3
3	0	8	4	9.7	6
9	6	8	5	7.2	4
6	4	10	5	9.2	6
4.5	3	7	4	6.8	4
8	4	8.9	4	9	5

Stone Size Descriptive						
	Alfuzosin		**Silodosin**		**Tamsulosin**	
	Before	After	Before	After	Before	After
Mean	7.15	4.55	7.175	3.5	7.245	4
S. D	2.22542	1.49917	1.614582	1.627882	1.591689	1.612452
Mean Difference	2.6		3.675		3.245	
S.D Difference	0.72625		0.0133		0.0207	
Mean±S. D	2.6±0.72625		3.675±0.0133		3.245±0.0207	

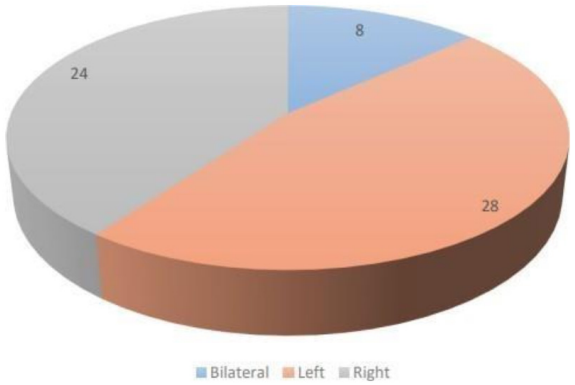


Graph 2: Distribution of Pain Onset.

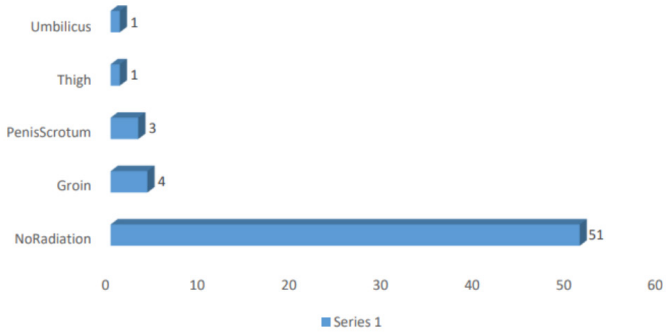


Graph 3: Distribution of Duration of Pain.

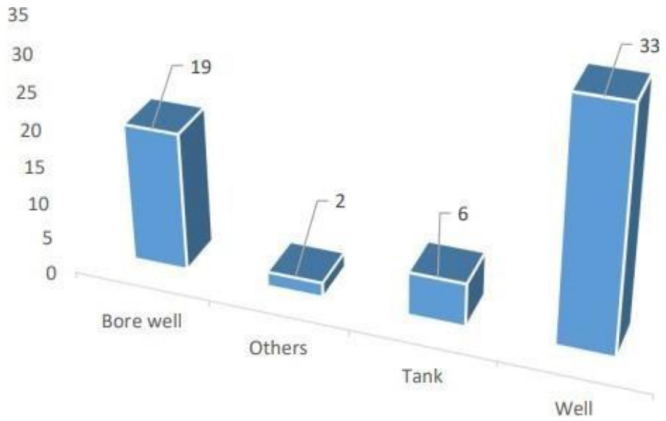
considered vital components in enhancing their overall quality of life. At Dhiraj Hospital, we conducted a prospective observational study to comprehensively assess the clinical presentation, treatment approaches, and the prevalence of ureteric stones. According to epidemiological studies, these calcium stones have been linked to high dietary salt or calcium protein intake, as well as exposure to warm temperatures. It is imperative to effectively manage this debilitating condition to reduce the incidence of associated complications. Achieving a reduction in the severity of the ailment hinges on effective treatment regimens and maintaining a strong system of patient supervision. Our study encompassed a total of 60 patients from the urology department at Dhiraj Hospital, with 63.3% of these patients being male and 36.7% female. In a parallel study conducted in Turkey, involving a total of 193 patients, it was noteworthy that nearly 100% of the participants were male. Historically, ureteric stones have been more commonly observed in men.[10] The study unequivocally demonstrated the safety and efficacy of alpha-blockers in the treatment of ureteric stones. The research involved 143 patients who were categorized into three groups, namely, Tamsulosin, Silodosin, and Alfuzosin. These groups were segregated based on the age range of the participants, which spanned from 19 to 40 years. Within the scope of the study conducted at Dhiraj Hospital, it was observed that the prevalence of ureteric stones varied with age: 1 (1.66%) occurrence in patients below the age of 20, 8 (13.33%) in patients aged between 21 and 30, 10 (16.66%) in patients within the 31 to 40 age bracket, 11 (18.33%) in the 41 to 50 age group, 19 (31.66%) in patients aged 51 to 60, and 11 (18.33%) in patients between the ages of 61 and 70. Notably, in our clinical setting, the age group between 51 and 60 comprised the largest proportion of individuals affected by ureteric stones.[11] In our study, it was observed that 28 patients experienced discomfort attributed to ureteric stones primarily on the left side, while around 24 patients reported pain on the right side. A smaller group of 8 patients mentioned experiencing pain on both sides. This discomfort typically originates in the flank region, which is the area between the hips and the bottom of the ribcage on each side of the spine. While it is possible for discomfort to occur on both sides of the body, it generally affects only one side.[12] During our study at Dhiraj Hospital, ureteric stones were predominantly identified without radiating pain in 51 patients, constituting 85% of the cases. In a smaller subset of patients, 4 individuals (6.7%) reported groin pain, 3 patients (5%) mentioned pain in the penis and scrotum, 1 patient (1.7%) experienced thigh pain, and another 1 patient (1.7%) described umbilicus pain. Notably, among the 60 patients studied, the majority of cases presented with non-radiating flank pain.[13] Diet has emerged as a significant factor in the formation of ureteric stones. According to research conducted at Dhiraj Hospital, individuals adhering to a vegetarian diet were anticipated to exhibit a higher incidence of ureteric stones. This incidence was notably higher when compared to those following a non-vegetarian diet, where 40 patients reported complaints related to ureteric stones.[14] Dietary habits play a pivotal role in the formation of stones, particularly when it comes to those who consume leafy greens, vegetables, peanuts, Swiss chard, and sweet potatoes. These foods are rich in calcium oxalate, which significantly increases the risk of developing calcium oxalate stones in the ureters. In our study involving 60 patients, it was observed that only 1 patient (1.7%) consumed less than or equal to 1.5 L of water per day. A substantial portion of 25 patients (41.7%) consumed at least 2 L of water daily, while 26 patients (43.3%) exceeded their daily intake with at least 3 L of water. Additionally, 8 patients (13.3%) went even further, consuming 4 L or more of water daily. Upon analyzing the data, it becomes evident that patients who consumed at least 2 L of water per day displayed a higher incidence of ureteric



Graph 4: Laterality of Pain.



Graph 5: Radiation of Pain.



Graph 6: Source of water.

stones, implying a potential association between increased water intake and stone formation. The data presented in the graph illustrates a notable correlation between the source of water and the incidence of ureteric stone complaints. Among the patients surveyed, 6 individuals (10%) who primarily used water from a tank as their source reported experiencing ureteric stones. On the other hand, a substantial proportion of 19 patients (31.7%) consuming bore well water, 33 patients (55%) using water from a well, and 2 patients (3.3%) obtaining water from other sources also experienced ureteric stones. Notably, individuals relying on well water appeared to exhibit a higher prevalence of ureteric stones according to our study.

Various studies have indicated a significant risk of kidney or ureteric stone development associated with the consumption of hard well water. Well, water can become contaminated with organic chemicals such as lead, arsenic, and bacteria, further exacerbating the risk. Chronic dehydration is another well-documented risk factor for the formation of ureteric stones. Chronic dehydration results in urine supersaturation, which initiates nucleation, leading to crystal growth and aggregation, ultimately resulting in crystal retention within the body and the eventual formation and growth of stones.[15]

In a pediatric study involving 40 participants aged between 3 and 18 years, the efficacy of alpha-blockers in treating Distal Ureteric Stones was evaluated. The results indicated that Silodosin demonstrated superior efficacy. Additionally, a prospective observational study at Dhiraj Hospital enrolled 60 participants aged 18 years and older to assess the efficacy of alpha-blockers, with Silodosin showing better results.[16,17] A study incorporating 7,077 patients aimed to evaluate the efficacy of three commonly used alpha-blockers for distal ureteric stones. In comparison to a placebo, all treatment groups displayed enhanced stone expulsion rates and reduced stone expulsion times. Silodosin was identified as the most efficacious medical expulsive therapy (MET) for lower ureter stones, followed by Alfuzosin and Tamsulosin. A separate prospective observational study at Dhiraj Hospital, involving 60 patients, also found Silodosin to be more effective than Alfuzosin and Tamsulosin [6,18]

In another study, 134 patients with stone sizes ranging from 4-10 mm were enrolled to compare the efficacy of Tamsulosin and Deflazacort. The results favoured Tamsulosin as the more effective treatment. In a parallel study at Dhiraj Hospital, 60 patients with stone sizes up to 10 mm were included, with the findings indicating greater efficacy of Silodosin.[19,20] A study encompassing 143 patients compared the most frequently used alpha-blockers in the context of distal ureteric calculi and concluded that alpha-blockers are both safe and effective. In a concurrent study involving 60 patients to assess alpha-blocker efficacy, Silodosin outperformed Alfuzosin and Tamsulosin.[11] In one study, the objective was to compare the safety and efficacy of Silodosin (8 mg) versus Tamsulosin (0.4 mg) in 136 patients aged 18 years or older with ureteric stones. The results of this study indicated that Silodosin had a higher stone expulsion rate compared to Tamsulosin. In another study, our aim was to assess the efficacy and safety of Silodosin, Tamsulosin, and Alfuzosin in 60 patients aged over 18 years with ureteric stones. The results of this investigation demonstrated a higher stone expulsion rate for Silodosin when compared to Alfuzosin and Tamsulosin.[21,22] In a larger study, 10,509 patients were enrolled, with 5,787 receiving a placebo and the remainder undergoing treatment with alpha-blockers to evaluate the safety and effectiveness of alpha-blockers for stones with a size of ≤10 mm. The results from this extensive study suggested that alpha-blockers can enhance

the clearance of stones. In our study, we enrolled 60 patients to investigate the efficacy of alpha-blockers for stone sizes up to 10mm, and the findings revealed greater effectiveness of Silodosin when compared to Alfuzosin and Tamsulosin.[8,23]

In the conducted study, the distribution of Hemoglobin (Hb) levels among the patients revealed that 2 patients (3.3%) had Hb levels equal to or less than 10 mg/dL, 49 patients (81.7%) had Hb levels between 11 and 13 mg/dL, and 9 patients (15%) had Hb levels equal to or greater than 14 mg/dL. Notably, patients with Hb levels between 11 and 13 mg/dL showed a higher frequency of ureteric stones, as indicated by our study. Additionally, the Erythrocyte Sedimentation Rate (ESR) data from the study could be categorized as follows: 35 patients (58.3%) had an ESR range between 11 and 15 mm/hr, while 25 patients (41.7%) had an ESR range between 16 and 20 mm/hr. Among the patients, the level of Blood Urea Nitrogen (BUN) was assessed in 53 out of 60 patients, with a mean and standard deviation of (35.55±9.926) from the collected data. The urine test indicated that the amount of urea was less than 15 mg/dL. The study also examined serum creatinine levels in 57 out of 60 patients, which ranged between 0.6 and 13 mg/dL. It was noted that patients with higher serum creatinine levels, indicative of kidney stones, were more likely to have chronic kidney disease and a reduced Glomerular Filtration Rate (GFR). Regarding the location of ureteric stones, the left side was the most common, with 47% of the total patients, followed by bilateral occurrences in 33% of patients, and right-sided occurrences in 20% of patients. The pain associated with ureteric stones can manifest as either intermittent or continuous. The study observed that intermittent pain was predominantly reported by patients with ureteric stones. The size of the stones was determined through diagnostic tests such as X-ray KUB, CT-scan, and Ultrasonography (USG). USG was performed in 32 patients (53.33%), X-ray KUB in 9 patients (15%), and CT-scan in 19 patients (31.67%) among the 60 patients. Based on the data, it is evident that USG is the most useful diagnostic test for patients with ureteric stones at Dhiraj Hospital. Flank pain, characterized by discomfort on either side of the lower back between the pelvic region and the ribs, emerged as the most commonly observed sign and symptom of ureteric stones. Smaller stones tend to have a lower likelihood of becoming lodged in the ureter or other urinary tract organs. These smaller stones can often be passed through the body with mild to moderate symptoms, and many individuals do so painlessly. In contrast, larger stones may induce pain, bleeding, swelling, or infection. However, these symptoms typically do not manifest until the stone has started to traverse the urinary tract. The treatment options for ureteric stones are typically classified into conservative or surgical approaches. In our study, patients were treated with medical interventions involving alpha-blockers. Specifically, 20 patients received Alfuzosin (10 mg), and the mean difference and standard deviation analysis showed a mean±SD of 2.6±0.72625, indicating no significant change in stone size. For patients administered Silodosin (8 mg), the mean±SD of 3.675±0.0133 signified a substantial reduction in stone size, making it an effective treatment option. Tamsulosin (0.4 mg) treatment showed a mean±SD of 3.245±0.0207, suggesting no significant difference in stone size. Consequently, the comparative results suggest that Silodosin (8 mg) is the most efficacious drug for patients with ureteric stones. At Dhiraj Hospital, the treatments administered to patients were found to have no significant adverse drug reactions or side effects. Follow-up data were collected for all patients, and improvements in compliance were noted 15 days after prescribing the medication. Moreover, patients received counselling in their native languages, highlighting the pivotal role of the pharmacist in facilitating effective patient care.

CONCLUSION

In conclusion, the study has revealed several significant findings. Patients in the middle-aged group, particularly those between 51-60 years, demonstrated a higher likelihood of experiencing ureteric stones. Analyzing the pre and post-diagnosis data, stone size differences, and patient symptoms, it is evident that Silodosin outperforms Tamsulosin and Alfuzosin in terms of efficacy in reducing stone size, facilitating stone removal, and improving ureteric stone symptoms. Importantly, this improvement was achieved with no observed side effects and without the need for surgical intervention. Silodosin has proven to be a more pharmacologically effective option for managing ureteric stones and offers a promising approach to enhancing the well-being of patients afflicted with this condition.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

CT-Scan: Computed Tomography Scan; **USG:** Ultrasonography; **SD:** Standard Deviation; **Hb:** Hemoglobin; **ESR:** Erythrocyte Sedimentation Rate; **BUN:** Blood Urea Nitrogen; **GFR:** Glomerular Filtration Rate; **KUB:** Kidneys, Ureters, Bladder (X-ray imaging); **mg/dL:** Milligrams per Deciliter.

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