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Original Article

To Compare the Efficacy of Tamsulosin and Deflazacort Combination with Tamsulosin Alone in Expulsion of Lower Ureteric Stones in a Medical College in South Haryana

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Abstract

Introduction: Men have been suffering from urinary stones since antiquity. Symptomatic ureteric stone is a very common emergency condition faced by general surgeons and urologists. There are many medical and interventional treatments for lower ureteric stones. Removal of stone with ureteroscopy is very effective but this is very costly also. Anesthetist is required; stent is placed in ureter which has to be removed afterward. Stones of size <4 mm will pass hopefully spontaneously. Stones more than 10 mm size will require surgery in general. The expulsion of stones of size 4–10 mm can be tried with the help of pharmacological agents.

Materials and Methods: This prospective observational study was conducted in the Surgery Department at SGT Medical College located in South Haryana. A total of 150 patients of distal ureteric stones of sizes 4–10 mm were taken in this study, divided into two groups of 75 patients each. Group I patients were given tamsulosin 0.4 mg and deflazacort 30 mg once in a day and Group II patients were given tamsulosin 0.4 mg once in a day. Treatment was for 10 days.

Results: In Group I, the stones were expelled in 24 (32%) patients. While in Group II, 11 (14.6%) patients passed stones. This is statistically significant with $P = 0.023$. The median time for stone expulsion was 192 h in Group I and 312 h in Group II with again a significant $P = 0.039$.

Conclusion: We conclude that Group I (tamsulosin + deflazacort) showed a statistically significant advantage in stone expulsion rate than Group II (tamsulosin alone). Group I also showed a statistically significant advantage in stone expulsion time.

Key words: Deflazacort, Diclofenac, Expulsion, Pain, Symptoms, Tamsulosin, Ureteric stones

INTRODUCTION

Men have been suffering from urinary stones since antiquity. English archaeologist E. Smith found a bladder stone in about 5000 years old mummy in Egypt.[1] Even Hippocrates knew the existence of renal stones. He has mentioned about renal stones in his Hippocratic Oath. *"I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work."*[2] Urolithiasis is a problem present in all geographical, racial, and cultural groups. Its risk is about 10–15% in developed world and 20–25% in developing countries.[3] The age group of 20–50 years is most commonly involved. Urolithiasis is more common in men than in women.[4] A ureteric stone is one that has moved down from kidney into the ureter. The stone starts as a tiny grain of solid matter and gets deposited in the kidney. With the passage of time, more and more grains are deposited and the stone increases in size. Most of the stones are eventually carried into the ureter. Among all ureteral stones, about 70% are found in lower one-third of ureter.[5] Symptomatic ureteric stone is a very common emergency condition faced by general

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surgeons and urologists. The pain is very severe. The pain is of colicky type and radiates from loin to groin, often to the tip of the genitalia, i.e. testis in males and labia majora in females. Nausea, vomiting, and sweating are usually due to pain and reflex pylorospasm. Hematuria, dysuria, frequency, and strangury may be present. There may be tenderness in iliac fossa and renal angle, but there is no rebound tenderness. It is difficult to differentiate this pain from the pain of appendicitis, cholecystitis, ovarian, or tubal pathology.[6] A large number of stones of size 2–4 mm will pass spontaneously in about 95% of cases.[7] There are many medical and interventional treatments for lower ureteric stones. Removal of stone with ureteroscopy is very effective but this is very costly also. Anesthetist is required; stent is placed in ureter which has to be removed afterward.[8-11] There are many pharmacological agents such as diclofenac, alkalizers, indomethacin, nifedipine, floroglucin, prazosin, deflazacort, silodosin, tamsulosin, and alfuzosin. We know that stones of size <4 mm will pass spontaneously in most of the cases.[7] Stones more than 10 mm size will require surgery in general. The expulsion of stones of size 4–10 mm can be tried with the help of pharmacological agents.[12] Further, surgery is also modality of choice if the intravenous urography shows deterioration of kidney functions, if there is coexisting infection and if the stone is impacted in ureter with persistent symptoms.[6] The genitourinary system is controlled by the autonomic nervous system (both sympathetic and parasympathetic). Hence, the autonomic nervous system is also responsible for modulating ureteric activity. Within the sympathetic system, alpha-adrenergic fibers are excitatory while beta-adrenergic fibers are inhibitory. Alpha-adrenergic fibers act on alpha-adrenergic receptors which are of three types, (1) alpha-1A, (2) alpha-1B, and (3) alpha-1D adrenergic receptors. Alpha-1A receptors are found in the proximal urethra, prostate, and distal one-third of ureter. Alpha-1B receptors are found more densely in the vascular smooth muscles while alpha-1D receptors are predominantly found in the detrusor and distal one-third of ureter.[13,14] A further study also revealed that alpha-1A and alpha-1D receptors are present more densely in the distal one-third of ureter than other adrenergic receptors.[15] Alpha-adrenergic stimulation induces a positive chronotropic effect, increasing ureteral peristaltic frequency and a positive inotropic effect, increasing muscle tone thus ultimately resulting in ureteral contraction, and decreased volume of urine flow passing through the ureter.[16] Alpha-blockers acting on these receptors relax the ureter and facilitate stone passage.[17]

Most recent alpha-receptor blocker to be used in this regard is tamsulosin which selectively acts on alpha-1A and alpha-1D receptors and these receptors are more abundantly present in lower part of ureter, so tamsulosin is more effective in expulsion of lower ureteric stones. The effect of tamsulosin on the obstructed ureter is to induce and increase in the intraureteral pressure gradient around the stone, that is, an increase in the urine bolus above the stone (and consequently, an increase in intraureteral pressure above the stone) as well as decreased peristalsis below the ureter (and consequently, a decrease in intraureteral pressure below the stone) in association with the decrease in basal and micturition pressures even at the bladder neck. By this mechanism of action, tamsulosin facilitates spontaneous passage of ureteral stone and reduces associated renal colic. Tamsulosin also decreases the frequency of phasic peristaltic contractions in the obstructed ureteral tract, but basal tone is marginally affected.[18] Tamsulosin being highly uroselective has very little activity over alpha-1B adrenergic receptors (the predominant subtype in the vasculature) as compared with other alpha-blockers, so it shows no dilatation of blood vessels, no change in blood pressure and pulse rate, no first-dose hypotension, and no increase in cardiovascular events. The only side effects of tamsulosin are dizziness and retrograde ejaculation.[19]

Stones cause inflammatory reaction and edema of ureteric mucosa.[20] Steroids by their anti-inflammatory action and capacity to decrease edema help to prevent these reactions. Deflazacort is a corticosteroid derived from prednisolone. It has mainly glucocorticoid activity. It is associated with side effects such as gastrointestinal tract disturbances, fluid and electrolyte disturbances, impaired healing, and increased susceptibility to infections, skin stria, and acne on long-term use. When used in combination with alpha antagonists[21,22] or calcium channel blockers,[23] it seems to increase the efficacy of these agents.

A few studies have been conducted in Western countries to find out the efficacy of tamsulosin in combination with deflazacort in expulsion of lower ureteral calculi. However, the results of different authors are at variance. Moreover, the disease spectrum in our country is different from that in developed countries mainly due to delay in diagnosis, delay in investigations, and lack of awareness. Therefore, it has been planned to study the role of tamsulosin and deflazacort combination and tamsulosin alone in expulsion of ureteric stone in Indian population.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of General Surgery at SGT Medical College (which happens to be in South Haryana), SGT University, Budhera, Gurugram, Haryana, India, from January 2018 to September 2019. A total of 150 patients coming to urology

or surgery outpatient department or emergency department with complaints of colicky abdominal pain and diagnosed, distal ureteric stones with the help of plain X-ray abdomen kidney, ureter, and bladder (KUB) or ultrasonography of KUB and of sizes 4–10 mm were considered for this study. Patients with stones, of more than 10 mm size, bilateral stones, impaired renal functions, coexisting infections, urethral stricture, history of ureteric surgery in past, severe hydronephrosis, liver disease, patients on beta-blockers, and patients with pregnancy were excluded from this study. An informed consent about the nature of research study was taken.

Study Design

This was a prospective observational study.

Ethical Considerations

The study was started after taking approval from the Institutional Ethics Committee for Research on Human Subjects. Throughout the study, ethical considerations were followed strictly. Confidentiality was ensured. The data were collected, and entries were made, and analysis was carried out using statistical SPSS version 23 software. Analysis was studied using Chi-square test.

All patients presenting with ureteric colic were given injection hyoscine butyl bromide intravenously and injection diclofenac intramuscularly. In all the cases, clinical history and examination were followed by relevant investigations such as urine complete examination, blood urea, skiagram, and ultrasonography of KUB region. Diagnosis of ureteric stone was made based on typical history of pain and its radiation, urinary symptoms, urine examination, skiagram, and ultrasonography.

These patients were allocated randomly to two groups of 75 each. Alternate patient was allocated to Group I and Group H. Group I (study group) patients were given a combination of tamsulosin 0.4 mg and deflazacort 30 mg and Group II (control group) patients were given tamsulosin 0.4 mg. Duration of treatment was 10 days or for lesser number of days if the stone passed earlier. Patients were prescribed diclofenac (50 mg) tablet as and when required. They were treated in the outpatient department. Patients were instructed to note the day, they pass the stone.

These patients were reassessed on the 3rd, 5th, 10th, and 15th days or telephonically. All patients were asked to pass urine through a sieve to note the passage of the stone. A skiagram and ultrasonography of KUB region was repeated to confirm whether stone had passed or not. The success rate of these two groups was assessed. Statistical analysis was done for expulsion of stone, days taken for expelling the stone, number of pain episodes, and amount of analgesics required during the treatment period.

RESULTS

The present prospective randomized study comprised 150 patients who attended the outpatient Department of Surgery and Urology and Emergency Department of SGT Medical College, SGT University, Budhera, Gurugram, Haryana. The study was conducted over a period of 1 year and 9 months from January 2018 to September 2019. In all the cases, clinical history and examination followed by relevant laboratory investigations such as hemoglobin, total leukocyte count, differential leukocyte count, blood urea, serum creatinine, urine complete examination, USG KUB, and plain X-ray KUB. One hundred and fifty diagnosed cases of lower ureteric stones were enrolled and allocated randomly. Each alternate patient was assigned to Groups I and II. Group I comprised 75 patients who were given tamsulosin 0.4 mg and deflazacort 30 mg once in a day for 10 days. Group II comprised another 75 patients who were given tamsulosin 0.4 mg once in a day for 10 days. All the patients had this treatment at their home. The mean age of the patients in Group I was 31.8 years and Group II was 34.1 years with $P = 0.502$ [Table 1]. Sex distributions revealed that in Group I, there were 76% of male and 24% of female patients. In Group II, there were 81.3% of male and 18.7% of female patients, $P = 0.569$ [Table 2]. Stones were located on the right side in 61.3% and left side in 38.7% in Group I patients. In Group II patients, stones were located on the right side in 57.3% and on the left side in 42.7% with $P = 0.576$ [Table 3]. Median stone size was 5.4 mm in Group I and 6.3 mm in Group II patients with $P = 0.612$ [Table 4]. Pain was present in all the patients. In both the groups, in 78.7% of patients, the pain radiated

Table 1: Mean age in years

Characteristic	Group I	Group II	*P* value
Mean age	31.8	34.1	0.502

Table 2: Sex distributions

Characteristic	Group I (%)	Group II (%)	*P* value
Sex			
Male	57 (76.0)	61 (81.3)	0.569
Female	18 (24.0)	14 (18.7)	

Table 3: Stone location

Characteristic	Group I	Group II	*P* value
Stone location			
Right	46 (61.3)	43 (57.3)	0.576
Left	29 (38.7)	32 (42.7)	

from loin to groin and often to the tip of the genitalia. Burning micturition was present in 20.0% of patients. Nausea, vomiting, and sweating due to pain and reflex spasm occurred in 52.7% of patients. Urinary urgency occurred in 16.0% of patients. Hematuria, dysuria, and strangury occurred in 11.3% of patients. Tenderness in iliac fossa and renal angle without any rebound tenderness occurred in 10.0% of patients [Table 5]. Hydroureter was found in 25.3% in Group I and 22.7% in Group II patients. There was no hydronephrosis in any patients [Table 6]. This study revealed that in 48.0% of patients in Group I and 45.3% in Group II, additional 225 mg diclofenac was used. In 28.0% of patients in Group I and in 30.7% of patients in Group II, more than 225 mg diclofenac was used. In rest of the patients, the amount was 150 mg or no additional diclofenac [Table 7]. The stone expulsion occurred in 24 (32.0%) patients in Group I and 11 (14.6%) patients in Group II with a significant $P = 0.023$ [Table 8]. The stone was expulsed in median 192 h in Group I and 312 h in Group II with a significant $P = 0.039$ [Table 9]. The side effects we observed were nausea and vomiting in 8 (10.7%) patients in Group I and in 11 (14.7) patients in Group II. Headache was in 5 (6.7%) patients in Group I and in 7 (9.3%) patients in Group II. Dizziness was found in 3 (4.0%) patients in Group I and in 4 (5.3%) patients in Group II. Constipation was found in 11 (14.7%) patients in Group I and in 2 (2.7%) patients in Group II. Retrograde ejaculation was found in 4 (5.3%) patients in Group I and in 5 (6.7%) patients in Group II. Nasal congestion was found in 4 (5.3%) patients in Group I and in 2 (2.7%) patients in Group II; diarrhea was found in 3 (4.0%) patients in Group I and in 2 (2.7%) patients in Group II [Table 10]. The side effects were insignificant and the therapy was continued.

Table 4: Median size of stone in mm

Characteristic	Group I	Group II	*P* value
Median size of stone	5.4	6.3	0.612

Table 5: Symptoms

Symptoms	Group I	Group II	Total (%)
Pain	75	75	150 (100)
Radiation of pain	62	56	118 (78.7)
Burning of micturition	18	12	30 (20.0)
Nausea, vomiting, and sweating	38	41	79 (52.7)
Urgency	11	13	24 (16.0)
Hematuria, dysuria, and strangury	8	9	17 (11.3)
Tenderness in iliac fossa and renal angle	7	8	15 (10.0)

Table 6: Incidence of back pressure changes

Groups	Hydroureter (%)	Hydronephrosis
Group I	19 (25.3)	Nil
Group II	17 (22.7)	Nil

Table 7: Amount of additional diclofenac used

Amount of additional diclofenac used (in mg)	Group I	Group II
0	4 (5.3)	2 (2.7)
150	14 (18.7)	16 (21.3)
225	36 (48)	34 (45.3)
>225	21 (28)	23 (30.67)

DISCUSSION

There are different approaches for the treatment of lower ureteric stones. First and foremost is spontaneous expulsion. The second approach is by the use of different pharmacological agents. Still, other approaches are endoscopic removal of stone. Various factors for spontaneous expulsion of ureteric stone are the size of stone, site of stone, and history of spontaneous stone

Table 8: Stone expulsion rate

Characteristic	Group I	Group II	*P* value
Expulsion rate	24 (32.0)	11 (14.6)	0.023

Table 9: Median time of stone expulsion

Characteristic	Group I	Group II	*P* value
Median time of stone expulsion in hours	192	312	0.039

Table 10: Side effects of therapy

Side effects	Group I (%)	Group II (%)
Nausea and vomiting	8 (10.7)	11 (14.7)
Headache	5 (6.7)	7 (9.3)
Dizziness	3 (4.0)	4 (5.3)
Constipation	11 (14.7)	2 (2.7)
Retrograde ejaculation	4 (5.3)	5 (6.7)
Nasal congestion	4 (5.3)	2 (2.7)
Diarrhea	3 (4.0)	2 (2.7)

Table 11: Expulsive rates using tamsulosin+deflazacort

Study	Duration of therapy (in days)	Mean stone size (in mm)	Expulsion rate in parentage
Dellabella *et al.*, 2004	28	6.9	96.7
Porpiglia *et al.*, 2002–2003	28	5.42	85
Porpiglia *et al.*, 2004–2005	10	5.88	84.8
Erkan *et al.*	28	4.10	75.5

expulsion. These factors cannot be modified. The factors which can be modified are the spasm of ureter, its edema, infection, and mechanism responsible for stone retention. The purposes of various pharmacological agents are to control pain, to check modifiable factors and expulsion of stone.

This prospective observational study was conducted in the Department of General Surgery at SGT Medical College, SGT University, Budhera, Gurugram, Haryana, India, from January 2018 to September 2019. A total of 150 patients coming to urology or surgery outpatient department or emergency department were considered. These patients complained of colicky abdominal pain and were diagnosed, distal ureteric stones with the help of plain X-ray abdomen KUB or ultrasonography of KUB. Stones of sizes 4–10 mm were considered for this study. Patients with stones, of more than 10 mm size, bilateral stones, impaired renal functions, coexisting infections, urethral stricture, history of ureteric surgery in the past, severe hydronephrosis, liver disease, patients on beta-blockers, and patients with pregnancy were excluded from this study. An informed consent about the nature of research study was taken.

So far as, age, sex, and site and size of stones are concerned, no statistically significant difference was observed between the two groups. The studies conducted by Dellabella *et al*., in 2002–2003,[24] and Porpiglia *et al*., 2002–2003,[25] report the predominance of lower ureteric stones in male, which is consistent with the study. Dellabella *et al*.[22] observed mean stone size as 6.9 mm and 6.4 mm in Group I and Group II, respectively. In a study by Porpiglia *et al*.,[21] the stone size was 5.88 mm and 5.96 mm in Group I and Group II, respectively. Porpiglia *et al*.[21] noticed that the right-sided ureteric stones were more than left sided. In this study, hydroureter was noted in 25.3% in Group I and 22.7% in Group II. Hydronephrosis was not seen in any patient because patients with hydronephrosis were not considered in this study. In most of the patients, additional diclofenac was used, for example, in Group I, 150 mg additional diclofenac was used in 18.7%, 225 in 48%, and more than 225 mg diclofenac was used in 28%. In only 5.3% of patients, no additional diclofenac was used. Respective figures for Group II are 21.3%, 45.3%, 30.7%, and 2.7%.

The most recent alpha-blocker being used for expulsion of ureteric stone is tamsulosin which selectively acts on alpha-1A and alpha-1D receptors, and these receptors are more abundantly present in lower part of ureter. Tamsulosin decreases the frequency of phasic peristaltic contraction in the obstructed ureteral tract, but basal tone is marginally affected. Several trials have shown the beneficial effects for expulsion of lower ureteral stones with tamsulosin alone or in combination with deflazacort. With tamsulosin alone in Group II, our expulsion rate is 14.6% and median time of stone expulsion is 312 h. In a study by Cervenàkov *et al*.,[26] the stone expulsion rate was 80%, in Autorino *et al*.,[27] 88%, Kaneko *et al*.,[28] 77%, and Griwan *et al*.[29] observed 90% expulsion rate. The cause for higher rate of stone expulsion in above studies and lower rate of stone expulsion in our study is not known. In our study in Group I (tamsulosin with deflazacort), the expulsion rate is 32%. Stone expulsion rate with a combination of tamsulosin and deflazacort in various studies shown in Table 11 varies from 75.5% to 96.7%. Again, we have no explanation, why our rates are low and the above study rates are very high. Mean time of stone expulsion in Group I was 192 h and in Group II 312 h. In a study by Dellabella *et al*., 2004, the mean time of stone expulsion was 72 h in Group I and 168 h in Group II. Only a few patients suffered from the side effects such as nausea, vomiting, headache, dizziness, constipation, retrograde ejaculation, nasal congestion, and diarrhea. The side effects were mild and the therapy was continued.

CONCLUSION

Age: No statistically significant difference was observed in mean age between the two groups. Sex: No significant difference was observed in sex distribution. Lower ureteric stones were more common in males than females. Lower ureteric stones were more common on the right side than the left side. Stone size: No significant difference was observed in stone size. Additional dose of diclofenac required was almost same in both the groups. Group I showed a statistically significant advantage in stone expulsion rate. Group I showed a statistically significant advantage in stone expulsion time.

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