

Evaluation of the Efficacy of Tamsulosin and Deflazacort versus Tamsulosin Alone in Expulsion of Lower Ureteric Stones in a Tertiary Center

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Abstract

Introduction: Urolithiasis is a very common problem present. About 70% of all ureteric stones are found in the lower third of ureter. Many factors affect the modality of treatment such as setup available, type, size of stone and expertise of the surgeon. Extracorporeal shock wave lithotripsy and ureteroscopy and removal of stone are very effective, but they require the help of anesthetist. Ureter is to be stented, and the stent has to be removed later on. They are very costly and not without complications. Many pharmacological agents have been used for the expulsion of ureteric stones, for example, diclofenac, alkalizers, ketorolac, nifedipine, deflazacort, prazosin, silodosin, and tamsulosin.

Materials and Methods: This prospective observational study was conducted in the Surgery Department at SGT Medical College. A total of 100 patients of distal ureteric stones of sizes 4–10 mm were taken in this study, divided into two groups of 50 patients each. Group I patients were given tamsulosin 0.4 mg and deflazacort 30 mg once in a day, 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 38 (76%) patients, while in Group II, 26 (52%) patients passed stones. This is statistically significant with $P = 0.038$. The median time for stone expulsion was 3 days in Group I and 11 days in Group II with $P = 0.032$.

Conclusion: We have evaluated that medical expulsive therapy using tamsulosin alone is also effective and can be used in patients where steroids are contraindicated, but by adding deflazacort, it becomes very effective for management of distal ureteral calculi.

Key words: Deflazacort, Diclofenac, Expulsion, Pain, Symptoms, Tamsulosin, Urolithiasis

INTRODUCTION

Urolithiasis is a very common problem, present in almost in all geographical areas. It is present in all cultural and racial groups. It has been found out that the risk of urolithiasis is about 12% in the developed world and about 22% in developing countries.^[1] Most common age affected is 15–45 years. Males are involved more commonly than females.^[2] Urolithiasis is a great burden on the society.

A ureteric stone is one that has passed from the kidney into the ureter. The stone is formed by deposition of small grains of solid material in kidney. About 70% of all ureteric stones are found in the lower third of ureter.^[3] A stone passing down the ureter often causes intermittent attacks of ureteric colic. The waves of agonizing loin pain are typically to the groin, external genitalia, and the anterior surface of the thigh. As the stone enters the bladder, the pain can be referred to the tip of the penis.^[4] There are many ways for the treatment of lower ureteric calculi. Many factors affect the modality of treatment such as setup available, type, size of stone and expertise of surgeon. Extracorporeal shock wave lithotripsy and ureteroscopy and removal of stone are very effective, but they require the help of anesthetist. The ureter is to be stented, and the stent has to be removed later on. They are very costly and not without complications. Many pharmacological agents

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have been used for the expulsion of ureteric stones, for example, diclofenac, indomethacin, florglucine, alkalizers, ketorolac, nifedipine, progesterone, deflazacort, prazosin, alfuzosin, silodosin, and tamsulosin.^[5-7]

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of General Surgery at SGT Medical College, SGT University, Budhera, Gurugram, Haryana, India, from July 2017 to November 2018. A total of 100 patients coming to emergency or surgery outpatient department (OPD) complaining of colicky abdominal pain and diagnosed, distal ureteric stones of sizes 4–10 mm were taken in this study. Those patients having stones, of size >10 mm, bilateral stones, impaired kidney functions, urethral stricture, severe hydronephrosis, liver disease, and patients on beta-blockers and patients with pregnancy were excluded from this study. An informed consent, telling the patient and attendant(s) in detail about the nature of research study, was taken. A detailed history with details of pains and other symptoms was taken. Investigations included Hb, BT, CT, complete examination of urine, blood urea, serum creatinine, plain X-ray abdomen and ultrasonography of kidney, and ureter and urinary bladder region were done. For the relief of pain, injection diclofenac sodium 75 mg intramuscularly was given. Once the patient got relief of pain, the patient was sent home. Patients were advised to repeat this injection if pain recurred. Subsequently, patients were advised to attend OPD. 100 patients considered for the study were divided into two groups of 50 patients each, alternatively. Group I (study group) patients were given tamsulosin 0.4 mg once in a day and deflazacort 30 mg once in a day and Group II (controlled group) patients were given tamsulosin 0.4 mg once in a day. Treatment was carried on for 10 days. Patients were asked to note and tell if they passed the stone. Patients were reviewed after 2 weeks and 4 weeks. During follow-ups, X-ray and ultrasonography of kidney, and ureter and urinary bladder regions were done. Liver function tests and kidney function tests were done in all patients to see for any side effects. It was noted that how many times patients had pain, how much analgesics were required. All patients were asked to pass urine through a sieve to note the passage of the stone. Patients were asked in detail about side effects such as dizziness, hypotension, retrograde ejaculation, nasal congestion, nausea, vomiting, diarrhea, constipation and headache.

Study Design

This was a prospective observational study.

Selection of Subjects (Cases)

A total of 100 patients were studied. Informed consent was taken for examination.

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. The analysis was studied using a Chi-square test.

RESULTS

The prospective observational study was performed in the Surgery Department in SGT Medical College, SGT University, Budhera, Gurugram, Haryana, over a period of 1 year and 5 months from July 2017 to November 2018. A total of 100 patients were studied. Informed consent was taken for examination. A detailed history with details of pains and other symptoms was taken. Investigations included Hb, BT, CT, complete examination of urine, blood urea, serum creatinine, plain X-ray abdomen and ultrasonography of kidney, and ureter and urinary bladder region were done. For the relief of pain, injection diclofenac sodium 75 mg intramuscularly was given. Once the patient got relief of pain, the patient was sent home. Patients were advised to repeat this injection if pain recurred. Subsequently, patients were advised to attend OPD. 100 patients considered for the study were divided into two groups of 50 patients each, alternatively. Group I (study group) patients were given tamsulosin 0.4 mg once in a day and deflazacort 30 mg once in a day and Group II (controlled group) patients were given tamsulosin 0.4 mg once in a day. Treatment was carried on for 10 days. Patients were asked to note and tell if they passed the stone.

There were no significant differences among both the groups so far as age (Table 1), sex (Table 2), location of stone (Table 3), and size of stone (Table 4) are considered. All the patients had colicky abdomen pain. Mostly 84% in Group I and 76% in Group II, had pain radiating to groin,

Table 1: Mean age

Characteristic	Group I	Group II	P value
Mean age	33.6	35.7	0.508

Table 2: Sex

Characteristic	Group I	Group II	P value
Sex			
Male	38	41	0.572
Female	12	9	

external genitalia, and the anterior surface of the thigh. Burning micturition, nausea, vomiting, and urgency were present in some patients. Gross hematuria was reported in 2 patients in each Group I and Group II patients (Table 5). Median stone size was 5.8 mm in Group I and 6.3 mm in Group II (Figures 1-3 showing stones of different sizes). Hydroureter was noted in 11 (22%) patients in Group I and 13 (26%) patients in Group II (Table 6). In Group I, the mean number of pain episode was 0.42 ± 0.45 and in Group II the value was 0.57 ± 0.64 (Table 7), which is also not statistically significant. It is clear that the numbers of pain episodes in Group I were lower than that in Group II. However, the numbers of pain episodes were almost similar

in men and women. In Group I, 18 (36%) patients did not require any analgesics after the first dose, 22 (44%) patients required a second dose, in 8 (16%) patients third dose was required, and in 2 patients, >3 doses were required. In Group II, the respective figures were 14 (28%), 24 (48%), 9 (18%), and 3 (6%) (Table 8). In Group I, the stones were

Table 3: Stone location

Characteristic	Group I	Group II	P value
Stone location			
Right	32	29	0.572
Left	18	21	

Table 4: Median size of stone

Characteristic	Group I	Group II	P value
Median size of the stone in mm	5.6	6.1	0.609

Table 5: Symptoms

Symptoms	Group I	Group II	Total
Pain	50	50	100 (100%)
Radiation of pain	42	38	80 (80%)
Nausea	13	15	28 (28%)
Burning of micturition	7	6	13 (13%)
Urgency	6	8	14 (14%)
Hematuria	2	2	4 (4%)

Table 6: Incidence of back pressure changes

Groups	Hydroureter (%)	Hydronephrosis
Group I	11 (22)	Nil
Group II	13 (26)	Nil

Table 7: Incidence of mean pain episode after starting the treatment

Characteristics	Group I	Group II	P value
Mean pain episodes	0.42 ± 0.45	0.57 ± 0.64	0.023

Table 8: Amount of diclofenac used

Amount of diclofenac (in mg)	Group I (%)	Group II (%)
0	18 (36)	14 (28)
150	22 (44)	24 (48)
225	8 (16)	9 (18)
>225	2 (4)	3 (6)

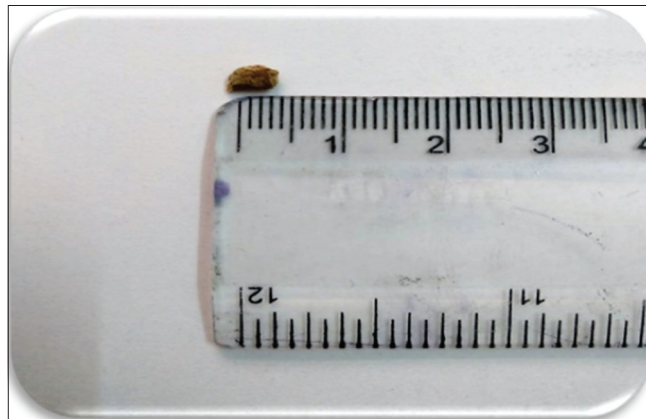


Figure 1: Stone size 3 mm

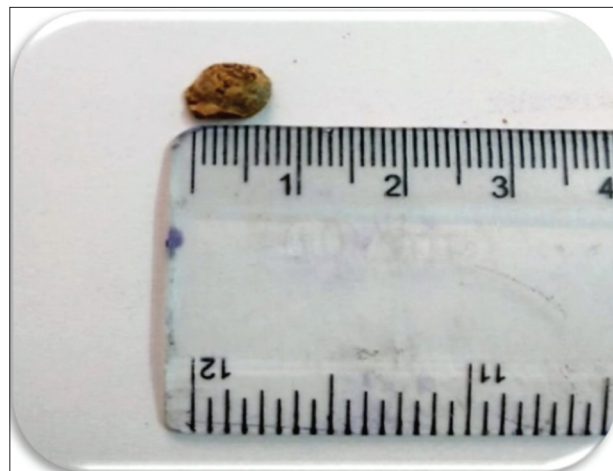


Figure 2: Stone size 7 mm



Figure 3: Stone size 8 mm

expelled in 38 (76%) patients while in Group II, 26 (52%) patients passed stones (Table 9). This is statistically significant with a p value of 0.038 (Table 9). The median time for stone expulsion was 3 days in Group I and 11 days in Group II with $P = 0.032$ (Table 10). So far as side effects are concerned, in Group I, we found retrograde ejaculation in 3 (6%) patients, nausea 6 (12%) patients, dizziness in 4 (8%) patients, headache in 7 (14%) patients, vomiting in 5 (10%) patients, constipation 6 (12%) patients, nasal congestion in 2 (4%) patients, and diarrhea in 1 (2%) patients. In Group II, we found retrograde ejaculation in 2 (4%) patients, nausea 4 (8%) patients, dizziness in 5 (10%) patients, headache in 4 (8%) patients, vomiting in 3 (6%) patients, constipation 0 (0%) patients, nasal congestion in 3 (6%) patients, and diarrhoea in 1 (2%) patients (Table 11). However, the side effects were not significant and therapy was not suspended.

DISCUSSION

We all know that ureteroscopy and removal of stone is the best treatment for the ureteral stone, but this demands anesthesia and stenting, hence there high cost involved with this procedure.^[8] When we come across a symptomatic distal ureteric calculus suitable for expulsion, we are in search of proper pharmacological agent. We are in search of a proper pharmacological agent. The pharmacological agent usually acts by reducing the edema of the ureter and maintaining the tonicity of the ureter.^[9] As we know the fact that a ureteric stone causes edema of the ureter and a steroid has anti-inflammatory action. Hence, it is very clear that if steroid is added, the chances of the expulsion

Table 9: Expulsion rate

Characteristic	Group I	Group II	P value
Expulsion rate	76%	52%	0.038

Table 10: Median time of expulsion

Characteristic	Group I	Group II	P value
Median time of expulsion in hours	72	132	0.043

Table 11: Side effects of therapy

Side effects	Group I (%)	Group II (%)
Retrograde ejaculation	3 (6)	2 (4)
Nausea	6 (12)	4 (8)
Dizziness	4 (8)	5 (10)
Headache	7 (14)	4 (8)
Vomiting	5 (10)	3 (6)
Constipation	6 (12)	0 (0)
Nasal congestion	2 (4)	3 (6)
Diarrhea	1 (2)	1 (2)

of stone are greatly increased. Various studies have shown that α_1 -blockers (tamsulosin along with deflazacort is very effective therapy for the expulsion of stones).^[10-13] This study was conducted on 100 patients divided into two groups of 50 patients each, alternatively. Group I (study group) patients were given tamsulosin 0.4 mg once in a day and deflazacort 30 mg once in a day. Group 2 (controlled group) patients were given tamsulosin 0.4 mg once in a day. Treatment was carried on for 10 days. We selected tamsulosin because it is antagonist to alpha -1A and alpha -1D receptors present in the distal ureteral tract in high concentrations. Deflazacort was selected due to its antiedemic effects. I is also very well tolerated and the side effects also less.^[14,15] The duration of therapy was 10 days only to avoid the side effects of long-term corticosteroid therapy. Further, as per the study of Malin Jr., *et al.*,^[13] it was reported the efficacy of the corticosteroid therapy is more in 1st few days.

In this study first, we found the results of the expulsion of stones by excluding deflazacort. We have found that even without deflazacort the medical expulsive therapy using tamsulosin is also effective and can be used in patients where corticosteroid is contraindicated. However, the results are excellent with the combination therapy of tamsulosin and deflazacort.

So far as side effects are concerned, in Group I, we found retrograde ejaculation in 3 (6%) patients, nausea 6 (12%) patients, dizziness in 4 (8%) patients, headache in 7 (14%) patients, vomiting in 5 (10%) patients, constipation 6 (12%) patients, nasal congestion in 2 (4%) patients, and diarrhea in 1 (2%) patients. In Group II, we found retrograde ejaculation in 2 (4%) patients, nausea 4 (8%) patients, dizziness in 5 (10%) patients, headache in 4 (8%) patients, vomiting in 3 (6%) patients, constipation 0 (0%) patients, nasal congestion in 3 (6%) patients, and diarrhea in 1 (2%) patients. However, the side effects were not significant and therapy was not suspended.

CONCLUSION

We have evaluated that medical expulsive therapy using tamsulosin alone is also effective and can be used in patients where steroids are contraindicated, but by adding deflazacort, it becomes very effective for the management of distal ureteral calculi. Expenditure is very less. Patients can do his routine work with this therapy. Side effects are insignificant.

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