Original Research Article

DOI: http://dx.doi.org/10.18203/2349-2902.isj20203508

Medical expulsive therapy: a cost effective evidence-based definitive treatment for ureteric stones

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Received: 15 July 2020 Revised: 29 July 2020 Accepted: 30 July 2020

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ABSTRACT

Background: The lifetime risk of kidney stones is between 5% and 10% and rates of recurrence are as high as 50%. Majority of the ureteric stones (70%) are found in the lower third of the ureter. Available setup, type, size of the stone, and expertise of the surgeon are the major factors affecting the treatment modality. Medical expulsive therapy has shown promising results in previous studies. Aim of the study was to assess the efficacy of tamsulosin and deflazacort combination therapy for stone expulsion in relation with site and size of stones.

Methods: A total of 97 patients with ureteric calculi of size 10 mm or less attending the urology out-patient department were included. Received medical expulsive therapy using tamsulosin (0.4 mg) and deflazacort (30 mg) for 7 days. Patients were evaluated for stone expulsion on 7th day by non-contrast computed tomography of kidney ureter bladder. Site, side and size of stones were noted.

Results: Ureteric calculi was more prevalent in the age group of 21-30 years 38 (39.2%). Male preponderance was observed (76.28%) with male female ratio being 3.2:1. Lower site 64 (65.97%) ureteric calculi were most common. The majority had a stone size of 4-6 mm (42%). Stones were expelled on 7th day in 69 (71.13%) patients. Expulsion rates were highest for the stone size of 2-4 mm (94.4%) followed by 4-6 mm (88.1%). The highest expulsion rates were observed for Lower ureteric stones (84.4%).

Conclusions: Medical expulsive therapy using tamsulosin and deflazacort is an effective treatment modality for the management of ureteric stones, especially those present in lower ureter and those ≤ 8 mm in size.

Keywords: Lower ureter, Medical expulsive therapy, Stone size, Ureteric calculi, Urolithiasis

INTRODUCTION

The lifetime risk of kidney stones is between 5% and 10% and rates of recurrence are as high as 50%.^{1,2} It is estimated that renal colic affects about 10-20% of men, and 3-5% of women. In India, 12% of the population is expected to have urinary stones, out of which 50% may end up with loss of kidney or renal damage.³ A large number of people, nearly 4-15% of the human populations, are suffering from urinary stones all over the globe.⁴

Multiple modalities are being used for removal of Kidney stones such as medical therapy, ureteroscopy, shock wave lithotripsy, percutaneous nephrostolithotomy, and open/laparoscopic stone removal. Combinations of these modalities are also being used.⁵ The choice of treatment modality is determined by several factors including setup available, type and size of the stone, and expertise of the surgeon.

The possibility of kidney stone passing down the ureter depends on stone dimensions and ureteral conditions.

Though several studies have shown spontaneous passage of the stone which ranges from 71-98% for the stone size <5 mm, for stone having a size between 5-10 mm the rates of spontaneous passage are significantly lower which range from 25-53% only.⁶

Medical expulsive therapy (MET) is an effective conservative treatment option for managing ureteral stones. Alpha-blockers, calcium channel blockers, corticosteroids, and phosphodiesterase-5 (PDE5) inhibitors are some of the agents used under MET. ^{6,7}

Tamsulosin is a selective $\alpha 1$ receptor antagonist whereas deflazacort is a glucocorticoid. Though studies have found that tamsulosin along with deflazacort is a very effective therapy for the expulsion of stones, the data evaluating the use of tamsulosin and deflazacort for stone expulsion is limited in the Indian population. Hence, this study was done to assess the efficacy of MET with tamsulosin and deflazacort in the stone expulsion rate in relation with site and size of stones.

METHODS

This was a prospective study done at L.N. Medical College and Research Center with attached J.K. Hospital, Bhopal from January 2019 to December 2019. All patients with ureteric stone ≤10 mm in size were included in the study. And stone size more than 10 mm, bilateral ureteric stones, impacted stone, UTI or severe hydronephrosis, anatomically abnormal urinary tract, pregnant females, anatomically solitary or solitary functioning kidney, patients in whom steroids were contraindicated. patients not given consent for study were excluded from the study.

Procedure

After informed consent, patients were given tamsulosin 0.4 mg and deflazacort 30 mg for 7 days. They were followed upon 7th day and evaluated for stone expulsion by non-contrast computerized tomography (NCCT)–kidneys ureters bladder. Patient particulars, side, site and size of stones and NCCT findings were noted. Ethical approval was taken from institutional ethics committee.

Statistical analysis

The data analysis was performed using IBM SPSS ver. 20 software. Age of study cohort was expressed as mean and standard deviation whereas categorical data were expressed as numbers and percentages. Categorical data was compared using the Chi-Square test. P-value of <0.05 was considered significant.

RESULTS

A total of 113 patients were enrolled in this study but 16 patients were lost in follow up. Hence, 97 patients were finally included in the study.

The mean age of the study cohort was 32.42±6.12 years. Ureteric calculi were more prevalent in the age group of 21-30 years (n=38) followed by 31-40 years (n=28) and 41-50 years (n=16). No patients in the age between 1-10 years had ureteric calculi in the present study. Ureteric calculi were more prevalent among male 74 (76.28%) populations compared to females 23 (23.71%), with male to female ratio was 3.2:1. Almost equal distribution was recorded for ureteric calculi on both the sides (right side 48 patients, left side 49 patients).

Analysis on the basis of stone size revealed that upto 8 mm size, the expulsion rates were significantly higher, whereas in stones more than 8 mm size, significantly lower rate of expulsion was seen (Table 1).

Table 1: The expulsion rate at different size.

Size of stone (mm)	Expulsion Yes N (%)	Expulsion No N (%)	P value
2-4	17 (94.4)	1 (5.5)	< 0.001
>4-6	37 (88.1)	5 (11.9)	< 0.05
>6-8	12 (63.2)	7 (36.8)	< 0.05
>8-10	3 (16.7)	15 (83.3)	< 0.001

Analyzing the site of stones, it was revealed that lower ureteric calculi were found in 64 (65.97%) patients as compared to the upper 21 (21.64%) and middle ureter 12 (12.34%). Expulsion was significantly more in lower ureteric stone and quite less in upper ureter (Table 2). Overall out of 97 patients, stone expulsion was observed in 69 (71.13%) patients.

Table 2: The expulsion rate at different sites.

Site of stone	Expulsion Yes N (%)	Expulsion No N (%)	P value
Upper ureteric stone	8 (38.1)	13 (61.9)	< 0.05
Middle ureteric stone	7 (58.3)	5 (41.7)	0.286
Lower ureteric stone	54 (84.4)	10 (15.6)	< 0.001

DISCUSSION

Removal with the help of ureteroscopy is the best option for stones in ureter, but it requires anaesthesia and stenting which increases the cost of treatment as well as loss of productive work hours due to hospitalization. ¹² Cases of symptomatic distal ureteric calculus are suitable for expulsion using a proper pharmacological agent.

Previous studies are in agreement with using tamsulosin as an effective measure for the expulsion of stones.⁸⁻¹¹ Also, it is well known that ureteric stone results in edema of the ureter. A pharmacological agent that acts by reducing the edema of the ureter and maintaining the tonicity of the ureter can be used along with the

tamsulosin. The steroid has anti-inflammatory action.¹³ That means a combination of tamsulosin with steroids can be an effective treatment modality for the expulsion of stones. In the present study, we evaluated the role of this combination in the expulsion of stones in 97 patients with calculi of various sizes at different sites in ureter.

Tamsulosin has antagonistic action on alpha-1A and alpha-1D receptors which are mainly present in the distal ureteral tract. Antiedemic effects of deflazacort are also established. Both drugs are well tolerated and have very few side effects. ¹⁴ Kidney stone are quite common and usually affect people who are between 30 and 60 years of age. ³ They affect more men than women. ³ The mean age of this study was 32.42±6.12 years (range: 20-60 years) with male to female ratio was 3.2:1, which was similar to study done by Ramesh et al with mean age 34.94 years (range: 19-62 years). ¹⁵

In a study from Gurugram, Haryana by Sinha et al comparing the effect of tamsulosin alone with tamsulosin and deflazacort combination has shown that results were excellent with the combination therapy recording the expulsion rate of 76% as compared to tamsulosin alone (52%) which are in line with our findings.⁸

In another study by Porpiglia et al comparing the combination (n=33) with tamsulosin (n=30) and deflazacort (n=24) in patients having a stone size of ≥5 mm present in distal location reported that the expulsion rate was 84.8%, 60% and 37.5% respectively which highlight the usefulness of combination therapy.¹⁶ In the present study expulsion rate was 71.13%. Expulsion rate according to the site of the stone was more for lower ureteric stone (84.4%) compared to middle ureteric stone (58.3%) and upper ureteric stone (38.1%). In a study done by Ahmed et al on stones ≤10 mm, 66.66% from upper ureter, 100% from middle ureter and 92.30% from lower ureteric calculus were expelled on tamsulosin therapy.¹⁷ Another study by Coll et al showed that spontaneous expulsion of stones were 48% in proximal, 60% in middle and 75% in distal ureter for various sizes of stones.¹⁸

Dellabella et al also compared the expulsion rates of phloroglucinol, tamsulosin, or nifedipine in 210 symptomatic patients with distal ureteral calculi >4 mm where all the patients received deflazacort. It was found that the expulsion rate was significantly higher in tamsulosin and deflazacort group (97.1%) than in phloroglucinol (64.3%, p<0.0001) or nifedipine (77.1%, p<0.0001). In addition to high expulsion rates with tamsulosin and deflazacort, there was a significantly faster stone passage than the other 2 groups and there was a significantly decreased number of hospitalizations as well as a better decrease in endoscopic procedures performed to remove the stone.9 In comparison, our study showed expulsion of stone size upto 4 mm in 94.5% and 4-8 mm in 80.32%. There was significant non expulsion of stone >8 mm size.

Cross-sectional nature and small sample size were the main limitations of the present study, there is a need for a large clinical trial provide strength to present study findings.

CONCLUSION

It was found that medical expulsive therapy using tamsulosin and deflazacort has good expulsion rates mainly for the lower ureteric stone and stone size upto 8 mm. It is a good therapeutic option due to cost-effectiveness and resuming of early routine work by the patients.

Funding: No funding sources Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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Cite this article as: Ali Q, Khan S, Patel G, Jaiswal K, Krishnanand. Medical expulsive therapy: a cost effective evidence-based definitive treatment for ureteric stones. Int Surg J 2020;7:2879-82.