



EFFICACY OF TAMSULOSIN VERSUS TAMSULOSIN WITH DEFLAZACORT AS MEDICAL EXPULSIVE THERAPY IN THE MANAGEMENT OF URETERAL CALCULI.

General Surgery

Dr. Deepak Kumar Kisku*

Associate Professor *Corresponding Author

Dr. Samit Kumar Badhai

Assistant Professor

Dr. Niranjan Maharana

Associate Professor

Dr. Rajat Kumar Patra

Professor

Dr. Sudhir Kumar Panigrahi

Professor

Dr. Aakash Prateek Senior Resident

ABSTRACT

Introduction: Renal and urinary tract stones have troubled mankind since time immemorial. The treatment of kidney and ureteral calculi took a gigantic leap in the last twenty years. While stone passage rates can be favourable with URS and PCNL, there remains room for improvement to avoid surgical morbidity and cost, leaving a role for medical expulsive therapy (MET). **Methods And Materials:** This is a hospital based prospective observational study conducted in the Department of General Surgery, PBMH, Kalinga Institute of Medical Sciences, Bhubaneswar during the period September 2018 to August 2020. An envelope method was used based on the patients attending the Urology/General Surgery OPD or the Emergency department to divide them into 2 groups i.e., group A and group B based on the inclusion and exclusion criteria. Group A patients received Tamsulosin (0.4 mg PO, once daily) Group B patients received Tamsulosin (0.4 mg PO once daily) and Deflazacort (30mg once daily). The above is in addition to antispasmodics/analgesics. A total of 160 patients were enrolled for the study. **Results:** The expulsion rates when compared between the two groups A and B stood at 64% and 72 % respectively which was not statistically significant. Among the patients pooled in the study, there were more with distal than proximal and mid ureteral calculi. In distal ureteral calculi, expulsion rate was found to be higher in Group B patients who received Deflazacort in addition to Tamsulosin than Group A patients who received only Tamsulosin with rates of 76.5% and 69% respectively. **Conclusion:** Ureteral calculi were more noted in the distal third of the ureter than the proximal and mid third. Medical Expulsive Therapy increases stone passage rates in comparison to previous studies. Addition of Deflazacort to Tamsulosin added no extra benefit. Though MET is cost effective compared to surgery, addition of a steroid can be avoided as they are associated with more side effects.

KEYWORDS

Urinary tract stones, Medical therapy, Expulsion rate.

INTRODUCTION:

Urolithiasis are one of the most common diseases of the urinary system and represents a significant public health problem. Incidence of urinary tract stones is between 1% and 20% worldwide and is increasing.^[1,2] Stones of size 5mm or smaller usually pass spontaneously without any intervention. However some calculi may arrest in the ureter producing symptoms such as colicky type of pain, haematuria, burning micturition and features of obstruction and require some form of intervention.

Previously open uretero-lithotomy and blind stone basket manipulation were the mainstay of surgical management, they have now been replaced by superior procedures like ureteroscopy (URS), percutaneous nephrolithotomy (PCNL), extracorporeal shock wave lithotripsy (ESWL). So the options available for treating patients with ureteral stones <10 mm in size: shock wave lithotripsy, medical expulsive therapy (MET), or ureteroscopy. However, shock wave lithotripsy and ureteroscopy are expensive procedures and are not risk free. Consequently, the combination of MET and α -blockers has become the most popular form of treatment over recent years. Both the European Association of Urology and the American Urologic Association recommend that patients with ureteral stones <10 mm in size should receive α -adrenoceptor blockers to assist the passage of stones; these recommendations are based on proposals from previous placebo-controlled trials and meta-analyses.^[3,4]

Medical expulsive therapy (MET) has now become an established method of treatment, and it involves the use of various drugs acting on the ureter by different mechanisms. The ureter is lined by $\alpha 1$ adrenergic receptors, particularly the subtype $\alpha 1D$, which are found more in its distal third, and they play an important role in the lower ureteric physiology through an effect on detrusor and ureteric smooth muscle contraction^[5]. Use of a selective α adrenoceptor blocker for MET is a cost effective approach to treating ureteral stones, based on

the growing body of evidence supporting its efficacy^[6,7]. The present study aims to compare the efficacy and safety of tamsulosin versus tamsulosin with deflazacort as a MET in the management ureteric calculus.

METHODS AND MATERIALS:

This is a hospital based prospective observational study of 160 patients attending the Urology / General Surgery OPD or the Emergency department of PBMH, Kalinga Institute of Medical Sciences, Bhubaneswar during the period September 2018 to August 2020. An envelope method was used based on the patients to divide them into 2 groups i.e., group A and group B based on the inclusion and exclusion criteria. Group A patients received Tamsulosin (0.4 mg PO, once daily) and Group B patients received Tamsulosin (0.4 mg PO once daily) and Deflazacort (30mg once daily). The above is in addition to anti spasmotics / analgesics when necessary.

Inclusion criteria was age between 16-65 years and evidence of presence of calculi of size >5mm and <10mm in proximal, mid, distal ureter as diagnosed by USG (abdomen & pelvis)/NCCT.

Patient were excluded in those cases having ureteral calculi of size < 5mm and >10mm, pregnant women, patients with solitary kidney, presence of UTI with underlying features of urosepsis, patients with obstruction leading to gross hydro or pyonephrosis, conservative management beyond a time period of 28 days, patients with recurrings ever ureteric colic, patients who prefer surgery and patients in whom tamsulosin / deflazacort is contraindicated.

The Patients who fulfilled the above mentioned inclusion and exclusion criteria were enrolled in this study, after an Informed consent. Out of 160 patients enrolled, 10 patients lost to follow up. They were put into two groups as group A patients receiving only Tamsulosin 0.4mg – 75 patients and group B patients receiving

Tamsulosin 0.4mg + Deflazacort 30mg – 75 patients. The patients were followed up weekly for a period of 4 weeks. They were assessed clinically and then subjected to serial imaging to look for any evidence of calculi. Patients not tolerating medical expulsive therapy (MET) were out from the study and were offered alternative treatment options. They definitively were excluded from the study after a period of 4 weeks even if there was an evidence of calculus. The collected data were analyzed statistically, to find the frequency percentage analysis and compare both the surgeries with respect to the above endpoints. The analysis was obtained by using appropriate tests (Chi square test, Fischer test, T test, Paired test). Null Hypothesis was set at p-value: 0.05. Significant p-value <0.05.

RESULTS

Majority of patients in our study belonged to age group of 16-29 yrs with male predominance (65%). In our study we noticed that 29 patients having upper third calculus and 89 patients with lower third ureteral calculus. Calculi are more common in right ureter (58.7%) than left ureter.

Table1: Expulsion Of Stone Based On Location Of The Calculus

Location	Expulsion (Y/N)	Group A Count	Group A % within Group	Group B Count	Group B % within Group	Total Count	Total % Within Group	P Value
Proximal Ureter	NO	3	20.00 %	4	28.60 %	7	24.10 %	0.682
	YES	12	80.00 %	10	71.40 %	22	75.90 %	
	Total	15	100.00 %	14	100.00 %	29	100.00 %	
Mid Ureter	NO	11	61.10 %	6	42.90 %	17	53.10 %	0.305
	YES	7	38.90 %	8	57.10 %	15	46.90 %	
	Total	18	100.00 %	14	100.00 %	32	100.00 %	
Distal Ureter	NO	13	31.00 %	11	23.40 %	24	27.30 %	0.459
	YES	29	69.00 %	36	76.50 %	65	72.70 %	
	Total	42	100.00 %	47	100.00 %	89	100.00 %	
Total	NO	27	36.00 %	21	28.40 %	48	32.20 %	0.32
	YES	48	64.00 %	54	71.60 %	102	67.80 %	
	Total	75	100.00 %	75	100.00 %	150	100.00 %	

Among the patients pooled in the study, there were more with distal than proximal and mid ureteral calculi. In distal ureteral calculi, expulsion rate was found to be higher in Group B patients who received Deflazacort in addition to Tamsulosin than Group A patients who received only Tamsulosin with rates of 76.5% and 69% respectively but insignificant 'p-value' of 0.459.

Table2: Comparison Between The Two Groups With Respect To The Time Taken For Stone Expulsion

Time Of Expulsion	Group A	Group B	P Value
No Expulsion	Count	28	0.438
	% within GROUP	37.3%	
	Count	10	
Expulsion by 1 week	% within GROUP	13.3%	9.3%
	Count	16	
	% within GROUP	21.3%	
By 2 weeks	% within GROUP	17.3%	17.3%
	Count	8	
	% within GROUP	10.7%	
By 3 weeks	% within GROUP	10.7%	20.3%
	Count	75	
	% within GROUP	100.0%	

It was observed that there was expulsion in 13 % of the patients by 1 week, by 2 weeks in 21 %, by 3 weeks in 17 % and by 4 weeks in 10 % of the patients who were grouped in A.

In group B patients expulsion of the stone was seen in 11 % by the end of first week, in 23 % by the end of 2 weeks, in 17 % within 3 weeks and 15 % by the end of four weeks. The comparison between the two groups was not significant with 'p-value' at 0.43.

DISCUSSION

In our present study majority of the patients belonged to the age group of 16 – 29 years which is consistent with SAH Rizvi et al^[8]. The incidence of urinary calculus was higher in males compared to females which was similar to report published by David J. Galvin et al^[9] and Trinchieri et al^[10]. In our study we noticed 19.3% of patients, 21.3% of 32 patients and 59.3% of 89 patients having upper, middle and lower thirds calculus respectively among the total of 150 patients. Miles Fox et al, they observed an incidence of 27 % calculi in upper 1/3 rd of the ureter, 12 % in the middle 1/3rd and 61 % in the lower third of the ureter among 292 patients^[11]. Morse et al^[12] and Rizvi et al^[8] observed similar findings. Our statistical analysis revealed 13.3% expulsion by the end of first week and 21.3 % by the end of second week in patients receiving Tamsulosin. Average was calculated at 2 weeks. The time of expulsion was on an average at 3 weeks for group B patients. Nuraj P and colleagues noted that average time of expulsion at 9.6 (SD ± 7.1 days) days in patients who received Tamsulosin with control group expulsion time at 13.7 days^[13]. De Sio M and co-authors randomized 96 patients in whom they found that the stone passage rate at 2 weeks to be significantly higher in Tamsulosin group.^[14]

The study was conducted by Porpiglia et al^[15] when they randomized 114 patients with distal ureteral stones to four groups as following, only Tamsulosin group, only Deflazacort group, combination group and control group. Combination therapy was noted to be more effective than either tamsulosin or deflazacort alone or placebo. (85% vs. 60%, 38% and 33% respectively, p<0.001). Analgesic requirement was also low in combination group (p<0.001).⁹ But in our study the p-value was insignificant at 0.382 with expulsion rates at 64 % and 72 % suggesting that both the groups had similar effects on the patient.

CONCLUSION

Medical Expulsive Therapy increases stone passage rates and the average time taken for expulsion was noted between 2-3 weeks. Addition of Deflazacort to Tamsulosin added no significant extra benefit in terms of stone expulsion rate. It can be concluded that though Medical Expulsive Therapy is cost effective compared to surgery, addition of a steroid can be avoided as they are associated with more side effects.

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