

ROLE OF DEFLAZACORT AND TAMSULOSIN IN MEDICAL EXPULSIVE THERAPY FOR SYMPTOMATIC LOWER URETERIC STONESK. Sitharamaiah¹, G. Chalapathi², S. Abdul Samad³, C. Surya Prakash Reddy⁴**HOW TO CITE THIS ARTICLE:**

K. Sitharamaiah, G. Chalapathi, S. Abdul Samad, C. Surya Prakash Reddy. "Role of Deflazacort and Tamsulosin in Medical Expulsive Therapy for Symptomatic Lower Ureteric Stones". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 15, February 19; Page: 2499-2504, DOI: 10.14260/jemds/2015/360

ABSTARCT: AIM: To assess the role of corticosteroid deflazacort in combination with alpha blocker tamsulosin in medical management of symptomatic lower ureteric calculus. **INTRODUCTION:** Urinary stone disease is a common condition accounting for 15-20% of our OPD. Ureteric stone with colic is a common Urological emergency, Ureteroscopy with intra corporeal lithotripsy is a proven method of treatment and it is not free of complications. Recently medical expulsive therapy with drugs has been used which reduces the symptoms and helps in stone expulsion. We performed a randomized prospective study to evaluate the role of corticosteroid Deflazacort in combination with alpha blocker Tamsulosin in medical management of symptomatic lower ureteric stones of 5-10mm size. **MATERIALS AND METHODS:** Between 1st january 2014 to 31st december 2014 we enrolled 100 patients of symptomatic lower ureteric calculus of >5mm diameter in this prospective study and divided in to 3 groups. Group A 40 patients received Tamsulosin and Deflazacort, Group B 30 patients received only Tamsulosin and Group C 30 patients received only analgesics. The treatment duration was 30 days. The end point were stone expulsion rate, analgesic consumption and number of URSL and safety. **RESULTS:** All the groups were comparable in terms of age, sex, stone size and stone location. 85 patients completed the study. The rate of stone expulsion for 3 groups were 34/38(89%), 20/25(80%), 10/22(45%) respectively. Statistically significant difference was noted between groups A&B with respect to group C. The mean analgesic consumption was less in group A. No significant side effects were reported with these drugs. **CONCLUSION:** Deflazacort with Tamsulosin combination is proved to be efficient and has to be considered as first line of medical expulsive therapy in the management of symptomatic lower ureteric calculus. In addition Tamsulosin alone can be considered as alternative treatment for those not suitable for steroid therapy.

KEYWORDS: Ureteric calculus, Tamsulosin, Deflazacort, medical expulsive therapy.

INTRODUCTION: Urinary stone disease is a common condition accounting for 15-20% of our OPD. Ureteric stone with colic is a common Urological emergency, Ureteroscopy with intra corporeal lithotripsy is a proven method of treatment and it is not free of complications.¹ On the other hand watchfull waiting approach can be used with good spontaneous expulsion of stones, even this approach has complications like recurrent ureteral colic, infection of urinary tract, hydronephrosis with its ill effects on renal function.^{2,3}

Recently medical expulsive therapy with drugs has been used which reduces the symptoms and helps in stone expulsion.^{4,5, and 6} Some authors reported improved spontaneous expulsion rates using alpha blocker Tamsulosin, on the basis of evidence that alpha 1 receptors are present in ureteral smooth muscle cells, blocking of which improves stone expulsion⁷. Corticosteroid prevents the edematous reaction caused by the stone.⁴

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For this reason we performed a randomized prospective study to evaluate the role of corticosteroid Deflazacort in combination with alpha blocker Tamsulosin in medical management of symptomatic lower Ureteric stones of 5-10mm size.

MATERIALS AND METHODS: We studied 100 patients of ureteric colic with lower ureteric calculus presented to emergency room, from 1st January 2014 to 31st December 2014. Exclusion criteria were past history of spontaneous stone expulsion and past history of stone surgery, fever, gross hydronephrosis, pregnancy, diabetes, renal failure and peptic ulcer. All patients were evaluated by urine analysis, urine culture, serum creatinine, blood sugar estimation, CBP, ultrasound abdomen, plain x-ray KUB, non-contrast CT abdomen in cases where stone is not located with USG and KUB.

100 patients with age group of 18-70yrs were randomized in to 3 groups. Group A -40 patient's received Deflazacort 18 mg per day and Tamsulosin 0.4 mg per day for 15 days. Group B-30 patients received Tamsulosin 0.4 mg od for 15 days. Group C (Control Group)-30 patients received only analgesics on demand. All patients were advised to drink 3-4 ltrs of water per day and inj. Diclofenac 75mg IM on demand. Three urologists participated in the study one was assigned group A therapy, other was assigned group B therapy and third urologist was assigned group C therapy. All patients were advised to come for follow up after 15 days or whenever there is uncontrolled pain or fever or on spontaneous stone passage. Medical treatment was suspended in case of uncontrolled colic, fever, severe hydronephrosis and raised serum creatinine. These patients were subjected to endoscopic treatment (URSL/DJ).

After 15 days all patients were subjected for examination and same diagnostic tests to evaluate the success of the treatment. Non responders with the evidence of stone were subjected for URSL/DJ. If the patient is asymptomatic with evidence of stone after 15 days same treatment was continued for another 15 days.

RESULTS: 100 Patients enrolled, 85 patients completed the study, the age, sex, stone sizes were comparable. 15 patients were lost for the study in first 15 days. Group A consists of 38 patients with overall stone expulsion rate of 89%, Group B 25 patients with overall stone expulsion rate of 80%, Group C 22 patients with overall stone expulsion rate of 45% in 30 days. 10% of patients in Group A, 16% patients in Group B, 40% patients in Group C underwent ureteroscopy because of uncontrollable pain during treatment or on unsuccessful expulsion after 15 days and after 30 days. p value was calculated by EPI INFO 7 statistical package. Statistically significant differences were observed between group A&B compared with group C ($p = 0.00016$). There was no statistically significant differences between group A and B ($p=0.29$). No side effects were observed with drugs. Table 1 and 2 lists the data and the results.

Parameters	Group A	Group B	Group C
	No. 40	No. 30	No. 30
Mean age	39.25 (25-62)	37.66 (18-60)	36.76 (25-70)
Male/Female	34/6	22/8	20/10
Ureteral stone side L/R	18/22	15/15	12/18
Stone Size	7mm(5-10)	7.03(5-10)	7mm(5-10)

Table 1: Clinical parameters of patients

Sl. No.	Parameter	Group A	Group B	Group C	P value
		No. 40	No. 30	No. 30	
1	Expulsion Rate in 15days	84% (32/38)	80% (20/25)	36% (8/22)	Gr.A +B vs C p = 0.00004 (Highly Significant) Gr. A vs B p = 0.66(n s)
2	Spontaneous Expulsion After 15days	33% (2/6)	0% (0/5)	14 % (2/14)	Gr.A+Bvs C P=0.775 (n s) GrA vs B p=0.52 (n s)
3	Overall expulsion up to 30 days	89% (34/38)	80% (20/25)	45% (10/22)	Gr.A+B vs C p=0.00016 (significant) Gr.A vs B p=0.29 (n s)
4	Uretero scopies	10% (4 of 38)	16% (5 of 25)	40% (12 of22)	Gr. A+B vs C p=0.00016 (significant) Gr.A vs B p=0.494 (n s)
5	Lost for study	5% (2 of 40)	17% (5 of 30)	27% (8 of 30)	
6	Analgesic (Average) consumption	25 Mg (0-75 Mg)	50 Mg (0-150Mg)	92 Mg (75-225Mg)	
7	Stone expulsion in < 7 days	75% (24/32)	60% (12/20)	-	
	8-15 days	25% (8/32)	40% (8/20)	100% (8/8)	

Table 2: RESULTS

(Note: n s= not significant)

DISCUSSION: Spontaneous passage of ureteric stone depends on stone size, site, anatomy of ureter and past history of stone passage.⁸The possible causes of stone retention like spasm, edema, infection are modified by the medical treatment. Median probability of stone passage is 68% for stone < 5 mm size and 47% for stones of 5 mm – 10 mm.⁹ Newly diagnosed stones of <10 mm whose symptom are controlled are offered medical therapy which facilitates stone passage and limits pain. Steroids prevent the edematous reaction caused by the stone and aids in stone passage. Deflazacort is a good anti edemic drug, well tolerated with limited side effects.⁴ Alpha blocker Tamsulosin reduces ureteral spasm and relaxes the ureter in the region of and distal to the stone.⁵ This medical expulsive therapy was safe and effective as demonstrated by the increased stone expulsion rate and reduced analgesics consumption when compared to our control group. The medical therapy of

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combination of Deflazacort and Tamsulosin (group A) demonstrated good results in 89% of patients compared to control group C with 45% (89% vs 45%). We do not find any significant difference between group A (Tamsulosin + Deflazacort) and group B (only Tamsulosin). (89% vs 80%). Stone expulsion time was short in group A compare to group C (less than 7days vs morethan 11 days). Analgesic consumption and number of ureteroscopies were also significantly less in group A and B when compare to control group C. No major significant side effects were observed related to use of these drugs. Present study was comparable with Porpiglia. F etall⁴ and Dellabella.M etall⁵.

	Present study	Porpiglia. Fetall ⁴	Dellabella. M etall ⁵
1. Stone size :	5 - 10 mm	5 -8 mm.	5-8 mm
2. Over all stone expulsion rates			
Group A	89% (34/38)	84.8% (28/33)	100%(30/30)
Group B	80% (20/25)	60% (20/33)	
Group C	45% (10/22)	33.3% (8/24)	70%(21/30)

TABLE 3

CONCLUSION: The results of our study indicates that, steroid (deflazacort) with Tamsulosin is proved to be efficient and has to be considered as first line of medical treatment in the management of symptomatic distal ureteric calculi when watchful waiting approach is possible. In addition Tamsulosin alone can be considered as an alternative treatment for those not suitable for steroid therapy.

REFERENCES:

1. Segura, J. W., Preminger, G. M., Assimos, D. G., Dretler, S. P., Kahn, R. I., Lingeman, J. E., Jr. et al: Ureteral Stones Clinical Guidelines Panel summary report on the management of ureteral calculi. J Urol, 158: 1915, 1997.
2. Porpiglia, F., Destefanis, P., Fiori, C. and Fontana, D.: Effectiveness of nifedipine and deflazacort in the management of distal ureteral stones. Urology, 56: 579, 2000.
3. Borghi, L., Meschi, T., Amato, F., Novarini, A., Giannini, A., Quarantelli, C. et al: Nifedipine and methylprednisolone in facilitating ureteral stone passage: a randomized, double blind, placebo-controlled study. J Urol, 152: 1095, 1994.
4. Francesco Porpiglia etal Corticostroids and Tamsulosin in the Medical Expulsive therapy for symptomatic distal ureter stones: Single drug or Association? European urology 50 (2006) 339-344.
5. Marco Dellabella, Giulio Milanese and Giovanni Muzzonigro. Efficacy of Tamsulosin in the medical management of juxta vesical ureteral stones J urology 2003 170: 2202-5.
6. Francesco Porpiglia, Gianpaolo Ghinone, Cristian Fiori, Dario Fontana and Roberto Mario Scarpa. Nefedipine versus Tamsulosin for the managemnet of Lower ureteral stones. J urology 2004; 172: 568-71.
7. Obara, K., Takeda, M., Shimura, H., Kanai, T., Tsutsui, T., Komeyama, T. et al: Alpha-1 adrenoreceptor subtypes in the human ureter. Characterization by RT-PCR and in situ hybridization. J Urol, suppl., 155: 472A, abstract 646, 1996.

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8. Hubner, W. A., Irby, P. and Stoller, M. L.: Natural history and current concepts for the treatment of small ureteral calculi. *EurUrol*, 24: 172, 1993.
9. 2007 AUA Guidelines for the management of Ueteral Calculi.



Fig. 1



Fig. 2

AUTHORS:

1. K. Sitharamaiah
2. G. Chalapathi
3. S. Abdul Samad
4. C. Surya Prakash Reddy

PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Urology, Kurnool Medical College, Kurnool.
2. Assistant Professor, Department of Paediatric Surgery, Kurnool Medical College, Kurnool.
3. Senior Resident, Department of Urology, Kurnool Medical College, Kurnool.

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4. Senior Resident, Department of Urology, Kurnool Medical College, Kurnool.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. K. Sitharamaiah,
Assistant Professor,
Department of Urology,
Kurnool Medical College
Government General Hospital,
Kurnool, Andhra Pradesh.
E-mail: sitharam1986@gmail.com

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