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A Comparative Study: Efficacy of Tamsulosin versus Tamsulosin plus Deflazacort in the Treatment of Distal Ureteric Calculi

Dr Roshin Mathew Philip[1], Dr Mahesh Gupta[2], Dr Pooja Gupta[3] , Dr Anu Susan Philip[4]

[1]*MBBS, Post GraduateDepartment of General Surgery, Rama Medical College Hospital and Research Centre, Kanpur, U.P. Pin:209217*
[2]*MS, DMAS, FMAS, FIAGES, Professor and Head Department of General Surgery, Rama Medical College Hospital and Research Centre, Kanpur, U.P. Pin:209217*
[3]*MD MEDICINE, SGL Charitable Hospital Jalandhar*
[4]*MBBS, Amala Medical College Hospital, Thrissur, Kerala.*
Corresponding Author: Dr Roshin Mathew Philip

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ABSTRACT

Background: Urolithiasis, particularly distal ureteric calculi, is a common condition causing severe pain. Medical Expulsive Therapy (MET) using agents like Tamsulosin has shown efficacy, but its combination with anti-inflammatory agents like Deflazacort is less explored.

Objective:This study compares the efficacy of Tamsulosin alone versus Tamsulosin plus Deflazacort in the treatment of distal ureteric calculi.

Materials and Methods: Sixty patients with symptomatic, unilateral, solitary lower ureteral stones (<10 mm) were randomly assigned to two groups: Group 1 received Tamsulosin 0.4 mg daily, and Group 2 received Tamsulosin 0.4 mg plus Deflazacort 30 mg daily, both for 28 days. The primary outcomes were stone expulsion rate and time to expulsion, analyzed using SPSS version 26.

Results: Group 2 had a significantly higher stone expulsion rate (76.6% vs. 56.6%, p=0.041) and a shorter median time to expulsion (75 hours vs. 146 hours, p=0.001) compared to Group 1.

Conclusion: Combining Deflazacort with Tamsulosin enhances stone expulsion rate and reduces time to expulsion, offering a more effective treatment strategy for distal ureteric stones. Further studies with larger sample sizes are recommended to confirm these findings and optimize treatment protocols.

Keywords: Medical Expulsive therapy (MET), Tamsulosin, Deflazacort, expulsion

I. INTRODUCTION

Urolithiasis is a prevalent global condition affecting all racial and ethnic groups, with a higher incidence in poorer countries (22%) compared to wealthier nations (12%) [1]. It predominantly affects individuals aged 15 to 45, especially men [2]. The distal ureter is the most common site for ureteric stones, often causing severe pain [3]. Over the past two decades, Medical Expulsive Therapy (MET) has become a standard treatment, with calcium-channel blockers and alpha-1-adrenergic receptor inhibitors showing promise in facilitating stone passage and reducing pain [4]. Tamsulosin, an alpha-blocker, has demonstrated efficacy in clinical studies, although recent trials have questioned its reliability. Deflazacort, a synthetic glucocorticoid with anti-inflammatory properties, has emerged as a potential adjunct to MET [5]. This study, "Efficacy of Tamsulosin Versus Tamsulosin Plus Deflazacort in the Treatment of Distal Ureteric Calculi," aims to compare these treatments to inform improved therapeutic strategies.

II. MATERIALS AND METHODS

Patients presenting with abdominal colic to the Surgery OPD or Emergency Department at Rama Medical Hospital were systematically evaluated and included if they had symptomatic, unilateral, solitary lower ureteral stones (<10 mm) confirmed by X-ray KUB, USG abdomen, or IVU, with pre-study evaluations including complete hemogram, blood urea, serum creatinine, and urine analysis. Inclusion criteria required stones at or below the ischial spine, while exclusion criteria included active urinary tract infection, fever, renal failure, history of renal surgery, marked hydronephrosis, hypersensitivity to alpha-1 blockers, and pregnancy. Participants were divided into two groups: Group 1 received Tamsulosin 0.4 mg daily for 28 days with high fluid intake and Diclofenac 75 mg as needed, and Group 2 received Tamsulosin 0.4 mg plus Deflazacort 30 mg daily for 28 days with high fluid intake and Diclofenac 75 mg as needed. Follow-up included USG abdomen and X-ray KUB at 2 and 4 weeks, with

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success defined as complete stone passage within 4 weeks. Data were analyzed using SPSS version 26, employing a chi-square test with a significance level of $p < 0.05$.

III. RESULTS

The study comprised of 60 patients. The youngest was of 18 years of age while the oldest was 60 years of age. The mean age was 39.45 +_ 18.74 for group 1 (Tamsulosin) and the mean age of group 2 (tamsulosin + deflazacort) was 38.77±15.45 (Table 1). The median stone size was 5.4±1.21 mm for group 1 and 5.8±0.92 mm for group 2 (Table 2). There were 17 patients with right ureteral calculus and 13 patients with left ureteral calculi. There was an equal distribution of ureteral calculi in both the groups (Table 3). The stone expulsion rate of 56.6% (17 out of 30 patients) was observed for group 1 and 76.6% (23 out of 30 patients) in Group 2. Group 2 showed an advantage in terms of the stone expulsion rate (P= 0.041) as determined by chi- square test. The calculated P value for comparing the median time of expulsion between the 2 groups was 0.001 (table 4). Since this p value is less than the convention threshold of significance (typically =0.05). It signifies group 2 patients receiving tamsulosin and deflazacort experienced a shorter median time of stone expulsion compared to the group 1 who received tamsulosin alone.

Age Group	Group-I(Tamsulosin) n=30		Group- II (Tamsulosin plus Deflazacort) n=30	
	No of cases	Percentage	No of cases	Percentage
18 – 30	06	20.0	07	23.3
31 – 40	15	50.0	16	53.3
41 – 50	07	23.3	05	16.7
51 - 60	02	6.7	02	6.7
Total	**30**	**100.0**	**30**	**100.0**
Mean Age	39.45±18.74		38.77±15.45	
P Value	0.931			

(Table 1: case distribution according to age group)

Characteristic	Group-I(Tamsulosin) n=30	Group- II (Tamsulosin plus Deflazacort) n=30
Median size of the stone in mm	5.4±1.21 mm	5.8±0.92 mm
P Value	**0.098**	

(Table 2: case distribution according to the size of stone)

Stone location Characteristic	Group-I(Tamsulosin) n=30		Group- II (Tamsulosin plus Deflazacort) n=30	
	No of cases	**Percentage**	**No of cases**	**Percentage**
Stone Location(Right)	17	56.7	19	63.3
Stone Location(Left)	13	43.3	11	36.7
Total	**30**	**100.0**	**30**	**100.0**
Statistical Inferences	Chi-square test- 0.27777 p Value-0.598			

(Table 3: case distribution according to the location of stone)

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Characteristic	Group-I(Tamsulosin) n=30	Group- II (Tamsulosin plus Deflazacort) n=30
	Percentage	**Percentage**
Expulsion rate	17(56.6)	23(76.6)
P Value	**0.041**	

(Table 4: Data and results of expulsion rates)

Characteristic	Group-I (Tamsulosin) n=30	Group- II (Tamsulosin plus Deflazacort) n=30
Median time of expulsion in hours	146	75
P Value	**0.001**	

(Table 5: data and results of the median time of expulsion in hours)

IV. DISCUSSION

The study compared two groups of patients with distal ureteric calculi, one receiving Tamsulosin (Group I) and the other receiving Tamsulosin plus Deflazacort (Group II), across various parameters. Both groups had similar age and sex distributions, with no statistically significant differences in mean age (p=0.931) or sex distribution (p=0.592). The median stone sizes were also comparable between the groups (p=0.098, respectively).

Cervenakov et al, concluded the treatment by alpha 1 blockers relieves the lower urinary tract symptoms (LUTS) and helps to accelerate the passing of minor calculi from distal ureter. They concluded that alpha 1 blockers potentiate the spasmoanalgesic action of drugs used in standard methods of treatment.[9]

Symptoms such as pain, nausea, and urgency were reported by all patients, with minor differences between the groups. However, Group II had a significantly higher stone expulsion rate (76.6% vs. 56.6%, p=0.041) and a shorter median time to expulsion (75 hours vs. 146 hours, p=0.001). Overall, adding Deflazacort to Tamsulosin improved the stone expulsion rate and reduced the time to expulsion without significant differences in most other measured outcomes.

V. CONCLUSION

The study findings suggest that the combination therapy of Tamsulosin and Deflazacort significantly improves the expulsion rate and reduces the time to expulsion of distal ureteric stones compared to Tamsulosin alone.Stimulatingalpha-1 adrenergic receptors increases the peristaltic frequency of the urethra, smooth muscle tone, and contractile force resulting in ureteral spasms and decreased ureteral flow [6].The enhanced efficacy of the combination therapy can be attributed to the anti-inflammatory properties of Deflazacort, which likely reduces ureteral edema and facilitates stone passage [7,8]. Additionally, patients in the combination group experienced fewer pain episodes and required less Diclofenac for pain management, indicating better symptomatic relief. These results align with existing literature, supporting corticosteroids in conjunction with alpha-blockers for managing distal ureteric calculi. However, the study also noted a higher incidence of minor adverse effects in the combination group, such as mild gastrointestinal disturbances, which were manageable and did not necessitate treatment discontinuation. Future studies with larger sample sizes and longer follow-up periods are recommended to further validate these findings and optimize the therapeutic protocol for distal ureteric stones.

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Conflict of Interest: None declared

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