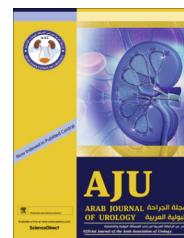




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# Outcome of $\alpha$ -blockers, with or without methylprednisolone combination, in medical expulsive therapy for lower ureteric stones: A prospective randomised study



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## KEYWORDS

$\alpha$ -Blockers;  
Methylprednisolone;  
Ureteric stones;  
Urolithiasis

## ABBREVIATIONS

KUB, plain abdominal radiograph of the kidneys, ureters and bladder;  
MET, medical expulsive therapy;

**Abstract Objectives:** To compare the safety and efficacy of tamsulosin, alfuzosin, and their combinations with methylprednisolone, in the medical management of lower ureteric stones.

**Patients and methods:** Between September 2012 and June 2014, patients diagnosed with a single lower ureteric stone of  $\leq 10$  mm (longest dimension) were enrolled. Patients with urinary tract infection, severe hydronephrosis, pregnancy, hypertension, diabetes, ulcer disease, or renal insufficiency were excluded. According to the medication added to the analgesic anti-inflammatory, patients were stratified into four groups, with 53 patients in each. Group I patients received tamsulosin 0.4 mg and those in Group II received tamsulosin 0.4 mg and methylprednisolone 8 mg. Group III patients received alfuzosin 10 mg and those in Group IV received alfuzosin 10 mg and methylprednisolone 8 mg. Treatment was continued until stone expulsion or to a maximum of 2 weeks. The patients' demographics, stone criteria, and stone-free rates were calculated and analysed.

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SWL, shockwave lithotripsy;  
URS, ureteroscopy

**Results:** The mean (SD) maximum stone dimension was 7.8 (1.5), 8.1 (1.3), 7.9 (1.6) and 8.0 (1.4) mm in Groups I, II, III and IV, respectively. Groups II and IV had significantly higher stone-free rates than Groups I and III ( $P < 0.05$ ), whilst there were no statistically significant differences between Groups I and III or between Groups II and IV. There was no statistical difference among the four groups for the time to stone expulsion. Three patients in Group II and two patients in Group IV developed transient hyperglycaemia, which resolved after cessation of methylprednisolone.

**Conclusions:** The combination of alfuzosin or tamsulosin with methylprednisolone seems to be effective and safe for managing lower ureteric stones of  $< 1$  cm.

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## Introduction

Urolithiasis is an international problem affecting  $\approx 12\%$  of the population. About 70% of stones at the time of diagnosis are located in the lower ureter [1]. Treatment options for ureteric stones range from non-invasive procedures, such as medical expulsive therapy (MET), to more invasive, such as shockwave lithotripsy (SWL) or ureteroscopy (URS) for stone extraction. The rationale of MET is to enhance fluid intake to increase urine volume and hydrostatic pressure, with subsequent increasing ureteric peristaltic activity. Many pharmaceutical agents have been introduced for the medical management of stones, e.g.  $\alpha_1$ -adrenergic receptor blockers, prostaglandin synthesis inhibitors, calcium channel blockers, and steroids [2]. The  $\alpha_1$ -adrenergic receptors are found predominately in the distal ureter. They inhibit smooth muscle contraction with subsequent ureteric relaxation. Corticosteroids are useful for the expulsion of ureteric stones via their anti-oedematous effect by reducing the inflammation of the ureteric mucosa [3]. Numerous reports exist signifying improved spontaneous stone expulsion using alfuzosin [4,5], terazosin [6], naftopidil [7], doxazosin [8], and silodosin [9]. Yilmaz et al. [10] proposed a possible class effect for  $\alpha$ -adrenergic receptor blockers with equal efficacy for all class members. There is insufficient published data on the effect of corticosteroid alone or combined with  $\alpha$ -blockers for MET. In the present study, we aimed to compare the safety and efficacy of tamsulosin, alfuzosin and their combinations with methylprednisolone in the medical management of lower ureteric stones.

## Patients and methods

This prospective randomised study enrolled patients diagnosed with a lower ureteric stone between September 2012 and June 2014, and it was conducted in the Department of Urology, Zagazig University, Egypt. Local Ethics Committee approval and an informed con-

sent from all patients were obtained. Eligible patients were required to have: (i) a single radiopaque stone of  $\leq 10$  mm by plain abdominal radiograph of the kidneys, ureters and bladder (KUB), (ii) the stone located below the sacroiliac joint, and (iii) agree to participate in the study. Patients with UTI, severe hydronephrosis, pregnancy, hypertension, diabetes, ulcer disease, previous pelvic surgery or renal insufficiency (creatinine  $> 1.5$  mg/dL) were excluded from the study. Patients were evaluated by routine laboratory testing (random blood sugar, renal, and liver functions) and blood pressure measurement before starting treatment and at the end of the treatment period.

## Study design

Sample-size was calculated by estimating that the difference in the rate of stone expulsion between  $\alpha$ -blockers and their combination with corticosteroid was 25% based on a prior study [2], and the power of the test to be 80% at a CI of 95%. The calculated sample was 48 in each group. After allowing for a 20% attrition rate, 60 patients were finally enrolled in each group. Patients were randomly divided into four groups by a simple randomisation method (shuffled cards). Group I patients received tamsulosin 0.4 mg daily and those in Group II received tamsulosin 0.4 mg and methylprednisolone 8 mg daily. Group III patients received alfuzosin 10 mg daily and those in Group IV received alfuzosin 10 mg and methylprednisolone 8 mg daily.

## Intervention

Patients received 10 mg ketorolac (oral tablet) twice daily, as well as 75 mg diclofenac sodium (i.m.) as needed for pain. Patients were instructed to accurately report the time of stone expulsion if any. Treatment was evaluated 2 weeks later by KUB for those who did not have clear evidence of complete stone expulsion. Occurrence of and time to stone expulsion were

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