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Silodosin vs tamsulosin in the management of distal ureteric stones: A prospective randomised study

Hazem Elgalaly, Ahmed Sakr, Amr Fawzi, Emad A. Salem, Esam Desoky, Ashraf Shahin, Mostafa Kamel *

Department of Urology, Zagazig University, Zagazig, Egypt

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KEYWORDS

Silodosin;
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Distal;
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Stone

ABBREVIATIONS

DUS, distal ureteric stones;
KUB, plain abdominal radiograph of the kidneys, ureters and bladder;
MET, medical expulsive therapy;
SWL, shockwave lithotripsy

Abstract ***Objectives:*** To compare the efficacy of silodosin (8 mg) vs tamsulosin (0.4 mg), as a medical expulsive therapy, in the management of distal ureteric stones (DUS) in terms of stone clearance rate and stone expulsion time.

Patients and methods: A prospective randomised study was conducted on 115 patients, aged 21–55 years, who had unilateral DUS of ⩽10 mm. Patients were divided into two groups. Group 1 received silodosin (8 mg) and Group 2 received tamsulosin (0.4 mg) daily for 1 month. The patients were followed-up by ultrasonography, plain abdominal radiograph of the kidneys, ureters and bladder, and computed tomography (in some cases).

Results: There was a significantly higher stone clearance rate of 83% in Group 1 vs 57% in Group 2 ($P = 0.007$). Group 1 also showed a significant advantage for stone expulsion time and analgesic use. Four patients, two in each group, discontinued the treatment in first few days due to side-effects (orthostatic hypotension). No severe complications were recorded during the treatment period. Retrograde ejaculation was recorded in nine and three patients in Groups 1 and 2, respectively.

Conclusion: Our data show that silodosin is more effective than tamsulosin in the management of DUS for stone clearance rates and stone expulsion times. A multicentre study on larger scale is needed to confirm the efficacy and safety of silodosin.

* Corresponding author at: Zagazig University Hospital, Department of Urology, El Mohafza Street, Zagazig, Egypt. Tel./fax: +20 552 300150.
E-mail address: mamar1973@yahoo.com (M. Kamel).
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Introduction

Urolithiasis affects ≈12% of the population globally [1]. Ureteric stones represent ≈20% of urolithiasis cases, from which ≈70% are situated in the lower third of the ureter and termed 'distal ureteric stones' (DUS) [2]. Over the last two decades, the management of ureteric stones had changed greatly, especially after the introduction of shockwave lithotripsy (SWL) and ureteroscopy, as minimally invasive treatments. However, these treatments are expensive and are not risk free. The overall complications after ureteroscopy have been estimated to be 10–20% in different studies, in which major complications, such as ureteric avulsions, perforations and strictures, occurred in 35% of cases [3].

Recently, α-blockers used as medical expulsive therapy (MET) have replaced minimally invasive procedures as the first line of management for small ureteric stones [4,5]. The clinical benefit of α-blockers for treating DUS had been shown in two meta-analysis with a high level of evidence, in which spontaneous stone passage in patients given α-blockers were 52% and 44% greater than those not given such medications [6,7].

Both the AUA [8] and the European Association of Urology (EAU) [9] recommend α-blockers for the treatment of ureteric stones. Recently, the α_{1A}-adrenoceptor subtype has been shown to play the major role in mediating phenylephrine-induced contraction of the human isolated ureter [10]. In the human ureter, silodosin (a selective α_1-adrenoceptor blocker) was found to be more effective than an α_{1D}-adrenoceptor blocker in noradrenaline-induced contraction [11]. However, published data are limited on the use of silodosin as MET for DUS; thus we conducted a prospective randomised study to compare the efficacy and safety of silodosin vs tamsulosin as MET for single, symptomatic, uncomplicated DUS in adults.

The objective of the present study was to compare the efficacy and safety of silodosin (8 mg) vs tamsulosin (0.4 mg) as a MET in the management of DUS in terms of stone clearance rate and stone expulsion time, and adverse effects.

Patients and methods

This prospective randomised study was conducted between March 2014 and September 2014, the cohort comprised 115 adult patients (74 men and 41 women) who presented with a symptomatic, unilateral, single, uncomplicated DUS of ⩽10 mm.

Patients were randomised 1:1, with the first case selected using a sealed envelope method. The sample size was calculated using Epi Info 6 version 6.04d program software (WHO, Geneva, Switzerland) and the difference in stone expulsion time between the two groups was considered as clinical equivalence with a confidence of 95% and power of 80%. The exclusion criteria were: a single kidney, bilateral ureteric stones, renal impairment, UTI, high-grade hydronephrosis (Grades 3 and 4 according to Society of Fetal Ultrasound, SFU), and any history of previous endoscopic or surgical interventions.

All patients were diagnosed by plain abdominal radiograph of the kidneys, ureters and bladder (KUB), ultrasonography, and non-enhanced spiral CT (in some cases). Every patient provided informed written consent after receiving information about the nature of the study, time to study end, adverse effects, and the possibility of intervention if needed. The patients were randomly divided into two groups; Group A (58 patients) received a single dose of silodosin (8 mg) daily, and Group B (57 patients) received a single dose of tamsulosin (0.4 mg) daily. For ureteric colic, diclofenac sodium (50 mg tablet) was prescribed for analgesia. We used a visual analogue scale for pain assessments.

Follow-up was performed every week by asking the patient about stone passage, attacks of renal colic, analgesic requirements, time of stone passage, and symptoms related to side-effects of the drugs. Radiological assessment was done every 2 weeks with plain KUB and ultrasonography for radio-opaque stones, and non-contrast spiral CT for radiolucent stones at the end of the study. All patients were advised to increase water intake and to filter their urine to detect stone expulsion. The primary endpoint was the rate of stone clearance and the secondary endpoint was stone expulsion time. The patients were followed-up until stone passage was confirmed by plain KUB or non-contrast spiral CT or at the end of the study period (4 weeks) and surgical intervention.

Data were checked, entered and analysed using SPSS version 20. Data were presented as the mean (SD) for quantitative variables, and number and percentage for categorical variables; the chi-squared, Fisher's exact test or *t*-test were used when appropriate. The threshold level of significance was fixed at 5% for all the above mentioned tests. The results were considered:

- Significant when the probability of error is $<5\%$ ($P < 0.05$).
- Non-significant when the probability of error is $>5\%$ ($P > 0.05$).
- Highly significant when the probability of error is $<0.1\%$ ($P < 0.001$).

Our study protocol was approved by the Hospital Research and Ethics Committee, and all patients provided an informed written consent for participation.

Results

The patients' ages in both groups ranged between 21 and 55 years. Three patients in group A and one patient