Arab Journal of Urology (2015) 13, 107–111

Arab Journal of Urology
(Official Journal of the Arab Association of Urology)

www.sciencedirect.com

PEDIATRIC UROLOGY
ORIGINAL ARTICLE

Efficacy and safety of tamsulosin as a medical expulsive therapy for stones in children

Hussein A. Aldaqadossi [a,*], **Hossam Shaker** [a], **Mohammed Saifelnasr** [a], **Mohammed Gaber** [b]

[a] *Fayoum Faculty of Medicine, Fayoum, Egypt*
[b] *Tanta Faculty of Medicine, Tanta, Egypt*

Received 12 December 2014, Received in revised form 22 January 2015, Accepted 13 February 2015
Available online 9 March 2015

KEYWORDS

Distal ureteric calculi;
Medical expulsive therapy;
Children;
Tamsulosin

ABBREVIATIONS

MET, medical expulsive therapy;
US, ultrasonography;
BP, blood pressure

Abstract ***Objectives:*** To evaluate the efficacy of tamsulosin for promoting ureteric stone expulsion in children, based on the confirmed efficacy of tamsulosin as a medical expulsive therapy in adults.

Patients and methods: From February 2010 to July 2013, 67 children presenting with a distal ureteric stone of <1 cm as assessed on unenhanced computed tomography were included in the study. The patients were randomised into two groups, with group 1 (33 patients) receiving tamsulosin 0.4 mg and ibuprofen, and group 2 (34) receiving ibuprofen only. They were followed up for 4 weeks. Endoscopic intervention was indicated for patients with uncontrolled pain, recurrent urinary tract infection, hypersensitivity to tamsulosin and failure of stone passage after 4 weeks of conservative treatment.

Results: Sixty-three patients completed the study. There were no statistically significant differences between the groups in patient age, body weight and stone size, the mean (SD) of which was 6.52 (1.8) mm in group 1 vs. 6.47 (1.79) mm in group 2 ($P = 0.9$). The mean (SD) time to stone expulsion in group 1 was 7.7 (1.9) days, vs. 18 (1.73) days in group 2 ($P < 0.001$). The analgesic requirement (mean number of

* Corresponding author at: Fayoum Faculty of Medicine, Kimn Fares, 63514 Fayoum, Egypt. Tel.: +20 1005168856.
E-mail address: aldaqados@yahoo.com (H.A. Aldaqadossi).
Peer review under responsibility of Arab Association of Urology.

Production and hosting by Elsevier

http://dx.doi.org/10.1016/j.aju.2015.02.007

ketorolac injections) in group 1 was significantly less than in group 2, at 0.55 (0.8) vs. 1.8 (1.6) ($P < 0.001$). The stone-free rate was 87% in group 1 and 63% in group 2 ($P = 0.025$).

Conclusions: Tamsulosin used as a medical expulsive therapy for children with ureteric stones is safe and effective, as it facilitates spontaneous expulsion of the stone.

Introduction

Contemporary studies report an increase in the incidence of urolithiasis in children, mostly due to changes in dietary habits, climate changes, and the widespread use of ultrasonography (US) for examination of nonspecific conditions. Generally the incidence of paediatric urolithiasis is 2–3%. Published data on the predominance with gender are variable. Ureteric stones comprise about 20% of diagnosed urinary calculi [1]. Older children usually present with classic symptoms of calculi, such as loin pain, dysuria or haematuria. However, nonspecific symptoms, like irritability, are common in younger children who cannot express themselves [2].

The factors affecting the urologist's decision when recommending treatment for patients with ureteric calculi include the stone location and size, the degree of back-pressure, and associated UTI. Currently, with the development of smaller and more durable endoscopic equipment, the management of ureteric stones in children has developed from open stone surgery to minimally invasive procedures [3]. One approach to the treatment of ureteric calculi is observation, with pharmacotherapy used to relieve any pain. This might be a good choice, as it avoids the risk of anaesthesia and the cost of interventional techniques [4]. Several studies reported that medical expulsive therapy (MET) is effective in promoting the passage of distal ureteric stones in adults.

For this therapy, α-adrenergic blockers are the preferred agent for MET [5]. Tamsulosin was first indicated in children by Donohoe et al. [6] as a therapy for primary bladder neck dysfunction, with no major side-effects. The USA Food and Drug Administration Paediatric Advisory Committee in January 2012 reviewed studies on the use of tamsulosin in children and recommended returning to routine safety monitoring.

The aim of the present study was to evaluate the efficacy of tamsulosin in promoting the spontaneous expulsion of distal ureteric stones in children, based on the confirmed efficacy of tamsulosin as MET in adults.

Patients and methods

From February 2010 to July 2013, 67 children presenting with a distal ureteric stone of < 1 cm, and below the common iliac vessels as assessed by unenhanced CT, were included in the study. All patients were fully evaluated by a detailed history, physical examination, laboratory examinations (urine analysis, blood urea and serum creatinine levels), and radiological tests (a plain abdominal film, urinary tract US, and unenhanced CT of the abdomen and pelvis). The patients were randomised into two groups; group 1 included 33 patients who received tamsulosin 0.4 mg and ibuprofen, and group 2 included 34 patients who received ibuprofen only. The method of randomisation was simple random allocation of the children into the study groups. Patients who could not swallow a tamsulosin capsule were allowed to evacuate the contents into water or juice. Patients were excluded if they had bilateral ureteric stones, multiple stones, marked hydronephrosis, UTI, urinary tract anomalies, voiding dysfunction, and any previous open or endoscopic ureteric surgery.

Tamsulosin was administered using an arbitrary dose of 0.4 mg for patients aged > 5 years and 0.2 mg for younger children. The drug was given at bedtime. We discussed with families the off-label use of tamsulosin and the possible side-effects, e.g., headache, dizziness, rhinitis, back pain, somnolence and sinusitis. The ibuprofen dose was 4–10 mg/kg orally every 6–8 h as needed. In the case of intractable pain, ketorolac 0.5–1 mg/kg was given intramuscularly. The blood pressure (BP) with the child seated was measured before the administration of therapy and at each subsequent visit, to record any change in haemodynamics.

The study was approved by the local ethics committee, and informed consent was obtained from the parents. The guardians of enrolled children were instructed to give their children the study medication, and to filter the child's urine to identify passed stones. Also, they used a diary to record the amount of required analgesics, the number pain attacks, the time of stone expulsion, and any side-effects of study medication.

The patients were assessed clinically every week with a measurement of BP, urine analysis, a plain film if the stone was radio-opaque, and with US if the stone was radiolucent. A radiolucent lower ureteric stone can be assessed by US directly by looking at an acoustic shadow with a negative background, and indirectly by looking at hydronephrosis proximal to the stone. The