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Silodosin in the treatment of distal ureteric stones in children: A prospective, randomised, placebo-controlled study

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KEYWORDS

Silodosin;
Distal ureteric stone (DUS);
Children;
Medical expulsive therapy

ABBREVIATIONS

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

Abstract ***Objectives:*** To evaluate the possible role of silodosin (a highly selective α_{1A}-adrenoceptor antagonist) in facilitating the passage of distal ureteric stones (DUS) in children, as the role of α-blockers as medical expulsive therapy is well known in adults.

Patients and methods: In all, 40 paediatric patients (27 boys and 13 girls) diagnosed with unilateral, single, radiopaque DUS of <10 mm were included in the study. Their mean (SD, range) age was 8.1 (2.7, 5–17) years. The patients were randomly divided into two groups: Group A, received silodosin 4 mg as a single bedtime dose; and Group B, received placebo as a single bedtime dose. Ibuprofen was prescribed to both groups on-demand for pain episode relief. Patients were followed up biweekly for 4 weeks. The stone expulsion time and rate, pain episodes, analgesic use, and any adverse effects were recorded.

Results: The mean (SD) stone size in Group A was 6.6 (1.7) mm and in Group B was 6.7 (1.4) mm ($P = 0.4$). Two patients were lost to follow-up (one from each group), and one patient in Group A refused to complete the study. The stone-free rate at end of the 4-week treatment period was 88.8% in Group A vs 73.6% in

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SFR, stone-free rate;
SWL, shockwave lithotripsy;
URS, ureteroscopy

Group B ($P = 0.4$). The mean (SD) stone expulsion time was 7.0 (4.3) vs 10.4 (4.7) days in groups A and B, respectively ($P = 0.02$). The mean (SD) number of pain episodes requiring ibuprofen was 2.3 (1.4) vs 4.7 (2.6) episodes in groups A and B, respectively ($P < 0.001$). Adverse effects (headache and dizziness) were recorded in three patients (16.7%) in Group A, which were mild and none of them discontinued treatment, whilst no adverse effects were recorded in Group B.

Conclusions: The data in the present study show that silodosin can be safely used in the treatment of DUS in children for decreasing time to stone expulsion, pain episodes, and analgesic requirement.

Introduction

The estimated incidence of urolithiasis in children is reported to be between 0.1% and 5% [1–3]. Various factors may contribute to the formation of urinary stones in children including metabolic, environmental, and nutritional factors [4,5].

Ureteric calculi represent ~20% of urinary stones at the time of diagnosis, of which ~70% of the stones are found in the distal third of the ureter [6]. Microscopic haematuria, UTI, and pain are typical presentations in children [7]. The treatment strategy depends on different factors including: stone location, size, and the anatomy of the urinary tract [8].

In recent years, the management of paediatric ureteric stones has shifted from open surgery to minimally invasive procedures, as the entire urinary tract can be accessed by miniature endoscopes and shockwaves. Medical expulsive therapy (MET) may be of benefit in reducing the need for surgical intervention by eliminating pain and/or enhancing stone passage [6,9]. In adults, different drugs have been used to enhance spontaneous stone passage and decrease the time to stone expulsion; however, the use of α-blockers in children has recently expanded to involve treatment of neurogenic bladder, voiding dysfunction, and idiopathic urethritis [6,10,11]. Silodosin, a selective α_{1A}-adrenoceptor antagonist, has been used as MET in adults with distal ureteric stones (DUS) and has achieved a significantly greater stone expulsion rate compared with placebo [12]. In the present study, we aimed to evaluate the possible role of silodosin in facilitating the passage of DUS in paediatric patients.

Patients and methods

The present study was a prospective placebo-controlled randomised study, conducted after obtaining approval from the Ethics Committee in our centre and written informed consent from all patients and/or their guardians. A clear statement was made about silodosin, as a selective α_{1A}-adrenoceptor antagonist, and its off-label use in the treatment of children with DUS, emphasising its possible effects and adverse reactions. In all, 40 paediatric patients (27 boys and 13 girls) who presented with single, radiopaque DUS were included in the present study between September 2014 and October 2015. Inclusion criteria were: age <18 years, single unilateral radiopaque DUS, and largest stone diameter of ≤ 10 mm.

Exclusion criteria were: multiple, bilateral or recurrent stones, radiolucent stone, largest stone diameter >10 mm, UTI or urosepsis, anomalies of the ureter or the kidney, previous urinary tract endoscopy or surgery, marked hydronephrosis, and abnormal renal function. All patients were evaluated by complete history taking and a thorough physical examination. Laboratory investigations included urine analysis and serum creatinine. Radiological assessment with plain abdominal radiograph of the kidneys, ureters and bladder (KUB) and abdomino-pelvic ultrasonography was done.

This single-blinded study included 40 patients with mean (SD, range) age of 8.1 (2.7, 5–17) years. Fig. 1 shows the study flow chart. Treatment was assigned on a randomised basis using the closed envelope randomisation method into two equal groups, i.e. 20 patients in each group. As there were no known published data on the role of silodosin in the treatment of DUS in children, we performed a pilot study prior to the present study, in children who were not included in the present study. The results of the pilot study were used to calculate the sample size by assuming that the mean (SD) stone expulsion time in Group A was 7.2 (2) days and in Group B was 8.6 (0.9) days (pilot data). Using Open Epi 2.3, to detect a 15% difference between the two groups with 80% power and a threshold of significance of 0.05, the sample size was estimated to be 40 patients (20 in each group).

In Group A, children received silodosin 4 mg at bedtime, whilst those in Group B received placebo. Medications (placebo or silodosin) were supplied according to the randomisation list by a registered outpatients-clinic nurse that had a registry for these patients. A pill counter was given to every patient to confirm adequate com-