The efficacy of preoperative tamsulosin on ureteral dilatation during ureteroscopy

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Aims and objectives
To estimate the effic acy of preoperative tamsulosin in ureteral dilatation during ureteroscopy compared with placebo confirmed by imaging in adult patients.

Patients and methods
The study was conducted in the period between November 2017 and November 2018 at Assiut Urology and Nephrology Hospital. A total number of 50 patients diagnosed as having distal ureteric stone of large size (>1 cm in length) were included in this study. They were divided into two groups (I and II), with 25 patients in each group. Group I received a tablet of tamsulosin 0.4 mg/day, and group II received placebo. Patients were followed up for 8 weeks.

Results
A total of 50 patients were enrolled. Group I (25 patients) consisted of 17 men and eight women, and group II (25 patients) consisted of 18 men and seven women. The mean age group in tamsulosin group I was 35.5 years, whereas the placebo group II had a mean age of 36.5 years (P=0.950). The mean stone size was 10.5 mm (10, 12 mm) for group I and 10.5 mm (10, 13 mm) for group II. All patients underwent ureteroscopy. Active instrumental ureteral dilatation was always needed in the control group versus 20 (80%) cases of the tamsulosin group (P=0.017). Such difference did not significantly affect the rate of stentless ureteroscopy, which was eight (32%) versus five (20%) cases for tamsulosin and control groups, respectively (P=0.237).

Conclusion
Preoperative tamsulosin seems to be a good aid for ureteral dilatation during ureteroscopy with no effect on the need for ureteral stents. Further studies are needed to confirm the results on a bigger sample size and to outline the time frame during which the drug will give maximum effect.

Keywords:
medical therapy, stones, tamsulosin, ureter

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Introduction

Urolithiasis affects 4–15% of world population, and the incidence of this disease is increasing day by day. Of all the urinary tract stones, 20% are ureteral stones, and 70% of these ureteral stones are found in the distal part of the ureters [1].

At present, multimodalities of treatment are available to the urologists like expectant treatment, noninvasive procedure like extracorporeal shockwave lithotripsy, minimal invasive procedures like ureteroscopy or laparoscopy, and open surgical intervention [2]. The therapeutic potential of α-blockers for ureteral stone disease has been investigated, prompted by the detection of α-receptors in ureteral smooth muscle cells [3].

We chose to focus on tamsulosin because it is the most frequently studied α-blocker, recommended in urology treatment guidelines, and the most common medical expulsive therapy used by emergency physicians [4].

Tamsulosin is a selective antagonist at alpha-1A and alpha-1B-adrenoceptors in the prostate, prostatic capsule, prostatic urethra, and bladder neck. Approximately 70% of the alpha-1-receptors in human prostate are of the alpha-1A subtype. Blockage of these receptors causes relaxation of smooth muscles in the bladder neck and prostate, and thus decreases urinary outflow resistance in men [4].

In this study, we aimed to evaluate the effect of tamsulosin on ureteral dilatation during ureteroscopy and whether it can replace active instrumental dilatation and stent placement or not in a prospective randomized placebo controlled blind setting.

Patients and methods

This study was conducted in the period between November 2017 and November 2018 at Assiut Urology and Nephrology Hospital in an outpatient setting. Any patient with symptomatic large (>1 cm in length) single unilateral lower ureteric stone scheduled for ureteroscopy on our waiting list, age group from 18 to 65 years, have normal renal function, and was compliant with the treatment was included for the study. Patients were excluded if they met any of the following criteria: lower ureteric stones less than 1 cm length, multiple stones within the ureter, distal ureteric obstruction, bilateral ureteric stones, ureteric stones in solitary kidney, pregnant and lactating women, asymptomatic ureteric stones with no hydronephrosis, presence of ipsilateral renal stones, patients with abnormal renal tract anatomy such as duplex system, patients with febrile urinary tract infections, patients with severe hydronephrosis, and contraindication to tamsulosin.

Every case was assessed by ultrasonography, KUB (kidney, ureter, bladder x-ray) radiography, and CTKUB (computerized tomography, kidney, ureter, bladder), in addition, to case history, physical examination, complete blood cell count, routine urinalysis, and serum creatinine measurement.

A total number of 50 patients were included in the study for the management of distal ureteric calculi. They were randomly divided into two groups at a ratio of 1: 1 via closed envelope method, that is, group I (n = 25) received oral tamsulosin 0.4 mg/day and group II (n = 25) received placebo for 2 months (the average waiting time for ureteroscopy operations on our list). Patients were asked to take the study medication once at the same time each day.

Furthermore, they kept a diary to record the frequency of pain attacks, the presence and type of adverse effects thought to be owing to the medication, and noted on every visit. The treatment was discontinued after the spontaneous stone expulsion, intervention, or at the end of the therapy (i.e. after 2 months). They were advised to take plenty of fluids during the study and continue with their daily routine.

The patients were followed-up weekly for 8 weeks, with urinalysis and serum creatinine measurement. Abdominal ultrasonography and radiograph KUB were done to assess the stone status. Discontinuation of study medication and intervention was done before the end of the study owing to uncontrollable pain, adverse events, urinary tract infections, and acute renal failure. All patients signed informed consent, and the study was approved and monitored by the Medical Ethics Committee, Assiut Faculty of Medicine (IRB number: 17100966). The investigators explained the steps and value of the research to all eligible participants. Those who agreed to be included in the study signed fully informed consent.

The study medication was discontinued after spontaneous expulsion and at the end of study. The objective of this trial was evaluating the need for ureteral dilatation and stent placement at scheduled ureteroscopy.

Statistical analysis

Statistical analyses were done using Intercooled STATA (statacorp company in United States America), version 9.2. The two groups were compared regarding patient and stone criteria, and outcomes. Continuous variables were compared using the Mann–Whitney U test with values shown as the median and interquartile range. Categorical variables were compared using the Pearson χ^2 or Fisher exact test. P value less than 0.05 was considered statistically significant.

Results

A total of 50 patients were enrolled. Group I (25 patients) consisted of 17 men and eight women, and group II (25 patients) consisted of 18 men and seven women. The mean age group in tamsulosin group I was 35.5 years, whereas the placebo group II had a mean age of 36.5 years (P = 0.950). The mean stone size was 10.5 mm (10, 12 mm) for group I and 10.5 mm (10, 13 mm) for group II (Table 1).

All patients underwent ureteroscopy. Active instrumental ureteral dilatation was always needed in the control group versus 20 (80%) cases of the tamsulosin group (P = 0.017), as shown in Fig. 1.

Such difference did not significantly affect the rate of stentless ureteroscopy, which was eight (32%) versus five (20%) cases for tamsulosin and control groups, respectively (P = 0.237). Both groups showed a generally decreasing need for analgesic use after the first week of treatment (P = 0.469). No patient needed parenteral analgesic, urgent hospitalization, or intervention during this 2-month period. For both groups of the study, hydronephrosis did not improve by ultrasound during the 2-month period of treatment as compared with the initial ultrasound.

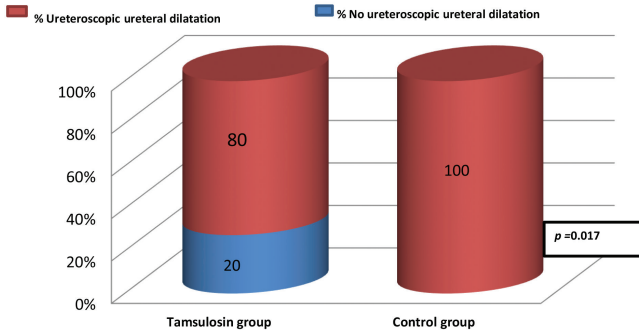
Discussion

The diameter of the ureter is a common obstacle during endoscopy. It is usually unpredictable before

Table 1 Comparison of study groups at initial presentation

Variables	Tamsulosin group (*n*=25)	Control group (*n*=25)	*P*
Age at presentation (years)	35.5 (29.5, 45)	36.5 (29.5, 43)	0.950
Sex: male (%)	68	72	0.805
Laterality: right-sided (%)	52.5	57.5	0.653
Stone length (mm)	10.5 (10, 12)	10.5 (10, 13)	0.467
Stone width (mm)	6 (5.5, 7)	6 (5, 7)	0.241
Radiopaque stone	97.5	97.5	0.999
Stone density (HF units)	975 (752.5, 1204.5)	949.5 (780, 1100)	0.862
Degree of hydronephrosis (HN)			0.379
No HN (%)	20	20	
Mild HN (%)	65	75	
Moderate HN (%)	15	5	

Figure 1



Ureteral dilatation during ureteroscopy.

ureteroscopy whether the ureter will need dilation by balloon or serial dilators or not. Dilatation is a step that may cause ureteral injury and should be avoided if possible. A joint workforce from Duke University, Mainz University, and the University of California evaluated retrospectively the use of balloon dilatation between the years 2000 and 2012 and reported 5% intraoperative and 8% postoperative complications. Half of the intraoperative complications necessitated a second endoscopic intervention [5].

Tamsulosin was evaluated as a stone expulsive agent for the past two decades with mixed results.

In one of the first meta-analyses by Hollingsworth, data from nine studies involving almost 700 patients showed that patients given alpha-blockers had a 54% greater likelihood of spontaneous stone passage compared with those not given the treatment [6]. However, data from a large, double-blind multicenter trial, Spontaneous Urinary Stone Passage Enabled by Drugs (SUSPEND), showed no benefit from active treatment. In the placebo group, 80% of patients did not need further intervention, compared with 81% in the tamsulosin group, with an adjusted risk difference of 1.3% (95% confidence interval: 5.7–8.3; $P = 0.73$) [7].

To the best of our knowledge, the present study is the first RCT (randomized control trial) for large lower ureteral stones more than 1 cm to study another advantage of tamsulosin, which is ureteral dilation and facilitation of ureteroscopy.

We understand that the value of the current result is limited by the small sample size, but the promising results encourage a large scale study that takes also into consideration the cost benefit of not using disposable ureteral dilators and avoidance of possible complications.

Conclusion

Preoperative tamsulosin seems to be a good aid for ureteral dilatation during ureteroscopy with no effect on the need for ureteral stents. Further studies are needed to confirm the results on a bigger sample size and to outline the time frame during which the drug will give maximum effect.

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Conflicts of interest

There are no conflicts of interest.

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