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ORIGINAL PAPER

# Tamsulosin and doxazosin as adjunctive therapy following shock-wave lithotripsy of renal calculi: randomized controlled trial

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**Abstract** Alpha-blockers have been established as medical expulsive therapy for urolithiasis. We aimed to assess the effect of tamsulosin and doxazosin as adjunctive therapy following SWL for renal calculi. We prospectively included 150 patients who underwent up to four SWL sessions for renal stones from June 2008 to 2009. Patients were randomized into three groups of 50 patients each, group A (phloroglucinol 240 mg daily), group B (tamsulosin 0.4 mg once daily plus phloroglucinol), and group C (doxazosin 4 mg plus phloroglucinol). The treatment continued up to maximum 12 weeks. Patients were evaluated for stone expulsion, colic attacks, amount of analgesics and side-effects of alpha-blockers. There were no significant differences between the groups regarding stone expulsion rates (84; 92 and 90%, respectively). The mean expulsion time of tamsulosin was significantly shorter than both control group ($p = 0.002$) and doxazosin ($p = 0.026$). Both number of colic episodes and analgesic dosage were significantly lower with tamsulosin as compared to control and doxazosin. Steinstrasse was encountered in 10 (6.7%) patients with no significant difference between the groups. 16 patients on tamsulosin and 21 on doxazosin experienced adverse effects related to postural hypotension. Moreover, 2 (4%) patients in the tamsulosin group reported ejaculatory complaints. In conclusion, adjunction of tamsulosin or doxazosin after SWL for renal calculi decreases the time for stone expulsion, amount of the analgesics and number colic episodes. There was no benefit regarding the overall stone expulsion rate. The side-effects of these agents are common and should be weighted against the benefits of their usage.

**Keywords** Alpha-adrenergic antagonists · Tamsulosin · Doxazosin · Calculi · Lithotripsy

## Introduction

Urolithiasis is a disease that affects 12% of the world population [1]. Shock-wave lithotripsy (SWL) is considered the standard of care for renal calculi less than 20 mm [2]. After application of SWL for renal calculi, the clearance of stone fragments depends on various factors, including stone size, location and renal collecting system anatomy, as well as ureteral edema and spasm [3].

Medical expulsive therapy for urolithiasis has gained increasing attention in the last decade [4]. Various agents have been investigated including calcium channel blockers, alpha-adrenergic antagonists, corticosteroids and smooth muscle relaxants [4, 5]. The goal of medical therapy is to enhance stone expulsion with a parallel decrease in the associated pain. Given that ureteral peristalsis is mediated by alpha-adrenergic receptors, it was demonstrated that alpha-1 blockers can decrease the frequency of colics associated with stone expulsion [6].

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Among all alpha-blockers evaluated, tamsulosin (selective α1A + 1D-adrenoceptor antagonist) seems to be the most effective in facilitating stone passage [4]. Moreover, most of the studies regarding doxazosin, another commonly utilized non selective α1-blocker, were focusing on its role for ureteral stones, and showed significant benefit [4, 7].

Generally, there are few studies evaluating the role of alpha-blockers after SWL for renal calculi. Therefore, it is intuitively difficult to draw a definite conclusion regarding its role as adjunctive therapy following SWL [5, 8].

In this study, we aim to assess the effect of tamsulosin and doxazosin on the outcome of SWL for renal calculi.

## Patients and methods

### Participants

This open-label, randomized, controlled prospective study was performed in an outpatient setting from June 2008 to 2009 in Alexandria University. The study protocol was approved by the local ethics committee. Inclusion criteria encompassed patients over 18 years presenting with a solitary radio-opaque renal stone up to 20 mm in diameter and located in the renal pelvis, middle or upper calices, as assessed on plain abdominal radiography (KUB X-ray) and intravenous urography. All patients were scheduled for SWL therapy.

Exclusion criteria included the presence of concomitant ureteral stones, renal insufficiency (defined as estimated glomerular filtration rate <60 ml/min per 1.73 $m^2$), urinary tract infection, obstructive uropathy or pregnancy. Patients with a history of ureteral surgery, previous unsuccessful SWL, morbid obesity (BMI > 40), severe skeletal malformation, uncorrected coagulopathy, hypersensitivity to tamsulosin or doxazosin; or current use of alpha-blocker or calcium-antagonist, were also excluded.

### Intervention

After informed consent including description of the procedure and the study with the hazards that may be encountered following SWL, all lithotripsy sessions were performed using the Seimens Lithostar® (Siemens Erlangen—Germany). During each SWL session, patients received neuroleptic anesthesia and were treated with up to 3,000 shocks, and a power of 12 ± 2 kV i.e. setting 4 on the machine scale and at 90 shocks per minute. Power was gradually augmented during the initial minute of treatment. Stone fragmentation was monitored fluoroscopically. SWL session was repeated if needed, up to a total of four sessions. The minimum interval between two SWL sessions was 3 weeks.

### Study design

Using a table with random numbers, patients were randomized into three groups. Group A represented the standard therapy and encompassed 50 patients who received 80 mg phloroglucinol (3 tablets daily). In group B, 50 patients received a 0.4 mg morning dose of tamsulosin once daily in association with the standard treatment given in group A. In group C, 50 patients received the same treatment as in group A, associated with an ascending dose of doxazosin; 1 mg for the first 3 days, 2 mg for the next 3 days, and 4 mg once daily thereafter.

In the three groups, the treatment commenced on the first day of SWL and continued until successful stone clearance was achieved or up to a maximum duration of 12 weeks, whichever came first. All patients were instructed to drink around 2 L of water per day and used diclofenac sodium injection (75 mg) on demand for considerable renal colic.

Stone clearance was assessed every 2 weeks after the last SWL session using plain KUB X-ray and urinary ultrasonography. During every follow-up visit, each patient was also assessed for urinary tract infection by urine analysis, renal colics, amount of analgesics that was consumed and the side-effects of the utilized alpha-blockers.

### Study endpoints

The primary endpoint was successful expulsion of stone fragments after SWL. This was defined as those patients who were rendered stone free or had asymptomatic, clinically insignificant residual fragments less than 3 mm at 3 months or earlier after the first SWL treatment, as measured by KUB X-ray and associated with sterile urine.

The secondary endpoints comprised clearance time, number of SWL sessions required for clearance, amount of analgesic consumed, incidence of steinstrasse and adverse effects of medical therapy for patients who received alpha-blocker therapy.

### Statistical analysis

Continuous variables were expressed as mean and standard deviation (SD). Categorical variables were expressed as percentages. The Student's $t$ test was used to compare continuous variables among the three treatment groups; and the $\chi^2$ test was used for categorical variables. All $p$ values less than 0.05 were considered to indicate statistical significance.

## Results

All patients completed their scheduled follow-up period in the study without drop-outs. The three groups were comparable regarding their baseline demographic and clinical characteristics as shown in Table 1. The mean age was 39.7 years. The mean stone size was 15.9, 16.6 and 16.1 mm for groups A, B and C, respectively. Regarding the initial stone location, 26 (52%) of patients in both groups B and C had their stones in the renal pelvis, while 22 (44%) patients in group A presented with a renal pelvis stone (Table 1).

The ultimate stone-free rate was 84% (42/50) for group A, 92% (46/50) for group B, and 90% (45/50) for group C. The difference among the groups regarding stone-free rates did not reach statistical significance (Table 2).

The mean expulsion time was 7.3 ± 2.7 weeks in group A, 5.3 ± 2.6 weeks in group B and 6.8 ± 2.8 weeks in group C. On pairwise comparison between the three groups, the mean expulsion time of group B was significantly shorter than both group A ($p = 0.002$) and group C ($p = 0.026$). The comparison demonstrated no statistical significant difference between both groups A and C ($p = 0.685$) (Table 2).

The mean diclofenac consumption was 546.0 ± 194.0 mg, 311.9 ± 145.5 mg, and 409.5 ± 197.1 mg in the three groups, respectively. A pairwise comparison depicted statistically significant difference between all groups. Similarly, there was a statistically significant difference regarding the mean number of renal colics episodes between different groups (Table 2).

All patients underwent a mean of 2.07 SWL sessions with no statistically significant difference between the three groups. In all, steinstrasse was encountered in 10 (6.7%) patients with no demonstrable statistical significance between the groups.

During the study period, 16 (32%) patients in group B, and 21 (42%) in group C experienced adverse effects related to postural hypotension (dizziness, headache, nausea and vomiting). In addition, 2 (4%) patients in the tamsulosin group reported ejaculatory complaints. These included a notable reduction amount of ejaculate in one patient and absence of antegrade ejaculation in the other patient.

## Discussion

Plenty of factors determine the clearance of stone fragments following SWL for renal calculi. In the kidney, this process is determined by the initial size and location of the stone, pelvi-caliceal configuration and dynamic urinary transport [9]. Regarding clearance from the ureter, it is basically determined by ureteral peristalsis above the stone, spasm and edema at the location of stone [3]. These contributing factors have been targeted by different therapeutic interventions. Some investigators have reported the effectiveness of different medical therapies in enhancing stone expulsion via diminishing the ureteral spasm and peristalsis [6, 7, 10, 11]. Consistently, the European urology guidelines suggest that medical expulsive therapy after SWL for ureteral or renal stones may expedite and increase stone-free rates, reducing additional analgesic requirements [2].

Ureteral relaxation in the region of stone fragment is considered a critical factor promoting stone passage. Therefore, the rationale of using alpha-blockers as medical expulsion therapy is to decrease both the frequency and amplitude of ureteral peristalsis above the stone with reduction in ureteral spasm at stone location. These changes are accompanied by an increase in the intraureteral urine flow and stone expulsion rate as the intraureteral pressure decreases [10, 12].

**Table 1** Baseline patient characteristics

| | Group A (control) ($n = 50$) | Group B (tamsulosin) ($n = 50$) | Group C (doxazocin) ($n = 50$) |
|---|---|---|---|
| Age (years ± SD) | 40.5 ± 11.2 | 39.4 ± 13.1 | 39.2 ± 10.8 |
| Sex | | | |
| Male | 23 (46%) | 25 (50%) | 31 (62%) |
| Female | 27 (54%) | 25 (50%) | 19 (38%) |
| Stone size (mm ± SD) | 15.9 ± 0.3 | 16.6 ± 0.4 | 16.1 ± 0.4 |
| Side | | | |
| Right | 25 (50%) | 25 (50%) | 24 (48%) |
| Left | 25 (50%) | 25 (50%) | 26 (52%) |
| Stone location | | | |
| Pelvis | 22 (44%) | 26 (52%) | 26 (52%) |
| Middle calyx | 17 (34%) | 11 (22%) | 12 (24%) |
| Superior calyx | 11 (22%) | 13 (26%) | 12 (24%) |

**Table 2** Results

| | Group A (control) | Group B (tamsulosin) | Group C (doxazocin) | *p* value | | |
|---|---|---|---|---|---|---|
| | | | | A versus B | A versus C | B versus C |
| Stone free (%) | 42 (84%) | 46 (92%) | 45 (90%) | 0.23 | 0.38 | 0.73 |
| Mean expulsion time (weeks) | 7.3 ± 2.7 | 5.3 ± 2.6 | 6.8 ± 2.8 | 0.002 | 0.685 | 0.026 |
| Steinstrasse | 5 (10%) | 2 (4%) | 3 (6%) | 0.26 | 0.47 | 0.65 |
| Number of SWL sessions | 2.08 ± 0.9 | 2.02 ± 1.0 | 2.12 ± 0.9 | 0.32 | 0.58 | 0.60 |
| Diclofenac consumption (mg) | 546.0 ± 194.0 | 311.9 ± 145.5 | 409.5 ± 197.1 | <0.001 | 0.001 | 0.028 |
| Colic episodes | 5.7 ± 2.0 | 3.0 ± 2.2 | 4.5 ± 2.1 | <0.001 | 0.015 | 0.003 |
| Adverse effects (%) | 0 (0%) | 18 (36%) | 21 (42%) | 0.005 | 0.003 | 0.54 |

Tamsulosin, terazosin, and doxazosin have all been reported to be equally efficacious in ureteral stone expulsion, as well as in reducing the intensity of ureteral colic. Among these agents, tamsulosin has been heavily studied as an adjunct therapy after SWL for ureteral and renal stones [13–16].

The current study aimed in assessing the additive role of tamsulosin and doxazosin when used in conjugation with the standard medical therapy for up to 12 weeks after SWL treatment of renal calculi.

We opted not to include patients with lower pole stones as there is a great controversy about the efficacy of SWL in the treatment of the lower pole calculi and they would probably have gained less benefit from any medical therapy [9].

Our study demonstrated that tamsulosin and doxazosin significantly shortened the time needed for successful stone fragments expulsion and with a significant difference in favor tamsulosin. Conversely, there were no statistically significant differences among the three groups regarding the ultimate stone expulsion rates.

Our results regarding time needed for stone expulsion are consistent with the previous reports on the efficacy of tamsulosin, doxazosin and terazosin in distal ureteral stones. Yilmaz et al. [17] demonstrated a statistically significant advantage of any of these drug groups over the control group, but with no difference between any of these drugs.

On the other hand, out of 11 trials on tamsulosin, 0.4 mg included in a meta-analysis, 6 did not found any benefits for tamsulosin in increasing the expulsion rate [6, 10, 18–21]. However, the overall pooled effect was in favor of tamsulosin (RR = 1.29, 95% CI 1.14, 1.47) [5].

Moreover, the rates for successful stone expulsion in our study were substantially higher when compared with those reported in the same meta-analysis [5]. However, it is worthy to mention that only three of the included trails have focused on renal stones and used a comparable follow-up period [13–15].

In an randomized controlled trial (RCT) on 139 patients, who underwent repeated SWL for renal stones, tamsulosin group had a higher expulsion rate than the control group at 3 weeks ($p = 0.016$), but the difference at 3 months was not statistically significant (94.1 vs. 84.6%, $p = 0.14$) [13]. In the study by Gravina et al. [14] the stone clearance at 3 months was in favor of tamsulosin (78 vs. 60%, $p = 0.04$) following a single session of SWL. Similarly in another study, the expulsion rate at 3 months was significantly higher in tamsulosin group (73 vs. 55%, $p = 0.008$) [15].

Falahatkar et al. [22] conducted a placebo-RCT trial, on 150 patients with one SWL session for renal (90%) or ureteral stones (10%). The overall expulsion rate was 71.4% in the tamsulosin group and 60.5% in the control group, but this difference did not score any statistically significant difference ($p = 0.116$).

In the current study, the patients in tamsulosin and doxazosin groups experienced less attacks of renal colic and intuitively used less analgesic than in the control group. This can be interpreted by the fact that administration of alpha-blockers decreases the frequency of peristaltic contractions accompanying the stone expulsion process. The superiority of tamsulosin regarding decrease of colic episodes may be related to its more selectivity to α1A + 1D-adrenoceptor, which are the most prevalent receptor subtypes in the ureteral wall [23].

In a study on 104 patients with distal ureteral stones, tamsulosin significantly increased the stone expulsion rate from 62 to 80.4% with a parallel decrease in the associated colic episodes and the total amount of analgesic used [24].

Some studies explored the effect of doxazosin on clearance of ureteral stones [17, 25, 26]. Ukhal et al. [25] were the first to report encouraging results regarding raising ureteral stone passage using doxazosin. A recent meta-analysis demonstrated a significant benefit of doxazosin for ureteral stone expulsion (RR 1.45; 95% CI 1.24–1.70) [4]. More recently, an RCT showed that doxazosin 2 mg in association with diclofenac sodium 50 mg significantly

improves stone expulsion and decreases colic frequency and use of analgesia [7].

To our best knowledge, this study is the first report to assess the role of doxazosin in clearance of fragments after SWL of renal stones. Based on our results, doxazosin shortened the time to stone clearance, nevertheless there was no significant differences in the ultimate clearance rate versus control group.

The reported rate of steinstrasse after SWL of renal stones is generally 2–10% depending on the initial stone size [27, 28]. In the present study, the overall rate of occurrence of steinstrasse is 6.6%. The use of tamsulosin or doxazosin did not significantly decrease the risk of steinstrasse. All patients of steinstrasse in the present series required subsequent ureteroscopy. A placement of ureteral stent was required in only four patients and was successfully removed after 3 weeks.

The role of tamsulosin in the clearance of steinstrasse after SWL was studied on 67 patients with a non-significant increase in clearance rate relative to the control group (75 vs. 65.7%. $p > 0.05$) [29]. In contrast, 88 patients with unilateral steinstrasse following SWL were randomized to receive analgesics or tamsulosin (0.4 mg) for a maximum of 4 weeks in addition to analgesic. Stone expulsion rate was significantly higher in the group of tamsulosin (72.7 vs. 56.8%; $p = 0.017$). However, there was no significant difference in stone expulsion time or quantity of analgesics [30].

In the present study, side-effects experienced in both alpha-blocker arms were tolerable and completely reversible. No patient discontinued the medication due to adverse effects.

The potential limitations of our study were its monocentric and non-blinded design. Furthermore, although allowing sufficient evidence of treatment efficacy in terms of stone expulsion and associated pain, the small number of participants might have limited the interpretation of our final conclusions. Symptoms that were utilized as surrogate for alpha-blocker side-effects may be mistaken with those occasionally accompanies renal colic. Lastly, it should be remembered that pain is a complex perceptual experience that remains difficult to quantify. In absence of standardized criteria to measure pain, the utilized number of colic is totally subjective and can be variable according to patients' tolerability and pain threshold.

## Conclusions

Adjunction of tamsulosin or doxazosin after SWL for renal calculi decreases the time for stone expulsion, amount of the analgesics and number colic episodes. However, there was no benefit regarding the overall stone expulsion rate. The side-effects of these agents are common but generally tolerable and should be weighted against the benefits of their usage.

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