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ORIGINAL PAPER

Comparative study between Tamsulosin, Silodosin and Tadalafil as a medical expulsive therapy for lower ureteral stones

Mohammad Ahmad Abdelaal, Eman M. El-Dydamony

Department of Urology, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

Summary *Objective: To compare the efficacy of Tamsulosin, Silodosin and Tadalafil as a medical expulsive therapy for treatment of distal ureteral calculi.*

Patients and methods: Over a period of 6 months (January 2022 to June 2022) this prospective randomized study was conducted on 170 patients with distal ureteric stone ≤ 10 mm. Patients were randomly divided into three groups. Patients in group A received Tamsulosin 0.4mg, in group B received Silodosin, and in group C receive Tadalafil 5 mg. Therapy was given for a maximum of 4 weeks. The rate and time of stone expulsion, the analgesic use, attacks of colic and hospital visits for pain, and adverse effects of drugs were recorded.

Results: Among 170 patients who were enrolled in study, 20 were lost to follow-up (7, 8, 5 in group A, B, And C respectively). There was a significant higher stone passage rate in group C than group A and B (90% vs. 70% and 76% respectively; p-value = 0.043) and shorter expulsion time in group C (8.7 ± 3.3 days) vs. group A (12.5 ± 5.2 days) and group B (11.3 ± 4.2 days) with (p-value = 0.001)(highly statistically significant with p-value < 0.001) and increased amount of analgesics required in group A (225 ± 115.7 mg) and group B (163 ± 77.5 mg) when compared with group C (120 ± 55.3 mg).

Conclusion: Tadalafil is more effective than Tamsulosin and Silodosin in treatment of patients with distal ureteric stones ≤ 10 mm as regard stone expulsion rate, expulsion time with decreased number of colicky episodes and side effects.

KEY WORDS: *Ureteral stone; Tamsulosin; Tadalafil; Ssilodosin; Medical expulsive therapy.*

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INTRODUCTION

Medical expulsive therapy (MET) is a non-invasive modality used in treatment of ureteral stones aimed at achieving spontaneous stone expulsion through relaxation of the smooth ureteral muscles and reduction of peristaltic activity (1).

Stone passage is contingent on two principal factors, those involving the stone, and those involving the urinary system. Stone-related factors include stone size, number, and location within the urinary system. Urinary system-related factors include ureteric spasm, mucosal edema or inflammation, and the ureteric anatomy (2).

The objective of MET is to achieve spontaneous stone passage through relaxation of the smooth muscles of the ureter and by reducing peristaltic activity.

There are high densities of the three alpha-1 receptor subtypes (alpha 1a, 1b, and 1d) in the distal third of ureteric smooth muscle. Alpha blocker therapy suppresses basal smooth muscle tone, together with peristaltic frequency and amplitude, while preserving tonic propulsive contractions, resulting in decreased intra-ureteric pressure and greater fluid transport (3). Use of alpha-1 adrenergic receptor blockers thus facilitates stone passage.

Tamsulosin, which exhibits high uroselectivity for alpha-1a and 1d activity, and Silodosin, which is a more selective alpha-1a adrenergic receptor antagonist, are widely employed in research and are of proven efficacy in MET (4). *Phosphodiesterase-5 inhibitors* (PDE-5is) act on the smooth muscle nitric oxide/cyclic guanosine monophosphate signaling pathway and produce ureteral relaxation. The lumen of the ureter is thus dilated, allowing stones to pass spontaneously. Some studies showed that the PDE-5i Tadalafil can effectively treat distal ureteral calculi as MET (5). Although Tadalafil has been employed to treat sexual dysfunction and lower urinary tract symptoms, its application in MET for the treatment of ureteral stones is highly limited. Tamsulosin is the alpha-1 adrenoreceptor antagonist most frequently evaluated for the purpose of MET and is of proven effectiveness (6).

In recent studies, the administration of PDE5-Is alone and in combination with Tamsulosin has led to acceleration of stone passage or even reduction of stone expulsion time and need for analgesics (7).

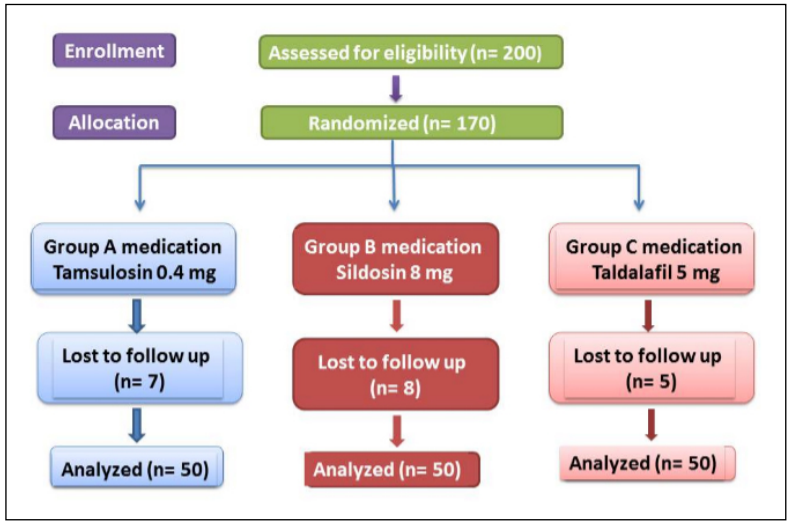
Thus, our main aim of comparing Tamsulosin, Silodosin and Tadalafil, is to determine single best monotherapy as a medical expulsive therapy of distal ureteric stones.

PATIENTS AND METHODS

The study was conducted in the *Department of Urology* at*Al-Zahraa University Hospital*, over a period of 6 months (from Jan 2022 to July 2022). Part of the used methods followed *Gnyawali et al. 2020* (8).

Patients, aged from 20 to 60 years, presented with a single lower ureteric stone from 5 mm to 10 mm in size, diagnosed by *ultrasound* (USG) abdomen/pelvis or *kidney-ureter-bladder* (KUB) X-ray, or *computed tomography* (CT) scan. Patients with the presence of multiple ureteric stones, urinary tract infection or hydronephrosis with complicat-

Figure 1.
Flow chart of the study design study.



ing factors (e.g. sepsis, uncontrollable pain, deterioration of renal function), pregnancy, history of ureteral surgery or previous endoscopic procedures, with kidney or ureteral abnormalities (e.g. single kidney, ureteral malformation), requiring emergency intervention or having allergies to the medications used were not included in the study. Written informed consent was taken from all patients.

Itemized history, clinical examination, routine urine analysis and/or urine culture, serum creatinine, digital KUB X-ray and/or USG abdomen and pelvis, and/or KUB CT were carried out in all patients. The stone size was determined using the largest dimension.

Patients were randomized and divided into three equal groups of 170 as demonstrated in Figure 1. Patients in group A received Tamsulosin 0.4 mg, in group B received Silodosin, and in group C received Tadalafil 5 mg. Therapy was given for a maximum of 4 weeks. All groups received diclofenac (50 mg) on demand. Drugs were continued until stone expulsion or for a period of 4 weeks. In fact, there is no strong evidence that a prolonged period of drug administration will augment the expulsion rate and limiting the period of treatment reduced the noxious influence of obstruction on kidney function. Patients were commanded to drink plenty of fluids and monitor their urine for stone passage using a net.

Patients were assessed by physical examination, serum creatinine, and the same imaging modality by which the stone in the lower ureter were initially diagnosed. In particular in those who either could not retrieve the stone in their urine or retrieved a stone that did not match the size and shape of the stone observed at the beginning of the study. In case of uncertainty, CT KUB was done despite previous imaging modality to confirm stone expulsion. Expulsion of the stone ureter, overall dose of analgesic used, number of colic episodes and emergency room visits, and side effect of drugs were registered. Semi rigid ureteroscopy was done to those who did not pass stones after 4 weeks of follow-up for stone passage.

Ethical approval

The protocol of the current trial was approved by the local ethics committee of the *Faculty of Medicine for Girls Al-Azhar University, Cairo, Egypt* (Study ID 1178).

Written informed consent was obtained from all participants. All procedures were run in compliance with the standards of the Declaration of Helsinki.

Statistics

Data were analyzed using *Statistical Program for Social Science* (SPSS) version 24. Quantitative data were expressed as mean ± SD. Qualitative data were expressed as frequency and percentage. Mean (average) was considered as the central value of a discrete set of numbers, specifically the sum of values divided by the number of values. *Standard deviation* (SD) was the measure of dispersion of a set of values. Differences were considered significant at a P value less than 0.05.

Results

Out of 170 patients, who were randomly assigned into 3 groups. seven patients from Group A, eight patients from Group B and five patients from Group C were lost at follow up for various reasons whereas the remaining 150 patients who met the inclusion criteria completed the study. There were no statistically significant differences in patients' age, gender, and stone size, type or site (Table 1).

There is statistically significant (p-value = 0.043) increased stone expulsion rate in group C (45 patients, 90%) when compared with group A (35 patients, 70%) and group B (38 patients, 76%). Also, there was a statistically significant (p-value = 0.001) longer stone expulsion time in group A (12.5 ± 5.2 days) and group B (11.3 ± 4.2 days) when compared with group C (8.7 ± 3.3 days) (Figure 2). The patients in group C had significantly less episodes of colicky pain than group B (11 patients, 22%) and group A (12 patients, 22%) while in group C (3 patients, 6%) with significantly less number of emergency room visits.

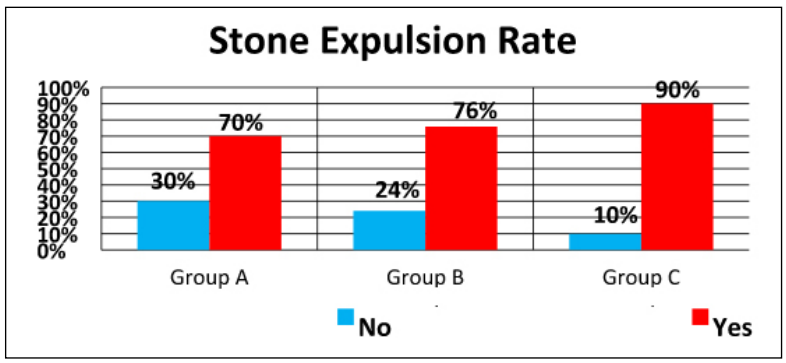
Additionally, the mean requirement of analgesia (diclofenac) was significantly less in group C (120 ± 55.3

Table 1.
Demographic and results.

Parameter	Group A	Group B	Group C	P value
Mean age (years)	38.7	41.3	41.9	0.375
No. of patients (male/female)	35/15	32/18	34/16	0.809
Mean stone size (mm)	6.7± 1.3	6.9± 1.6	6.9 ± 1.5	0.830
Stone type (Radioopaque/Radiolucent)	37/13	40/10	40/10	0.705
Expulsion rate (%)	35/50	38/50	45/50	0.043
Mean expulsion time (days)	12.5 ± 5.2	11.3 ± 4.2	8.7 ± 3.3	0.001
Mean analgesic use (mg)	225 ± 115.7	163 ± 77.5	120 ± 55.3	< 0.001
Percentage of Hospital visits for pain (%)	24%	22%	6%	0.033

Statistical significance was analyzed by Student's t-test and $\chi 2$-test. Values are presented as mean ± standard deviation. Group A: Tamsulosin and Group; B: Silodosin and Group C: Tadalafil.

Figure 2.
Comparisons between studied groups as regard Stone Expulsion Rate.



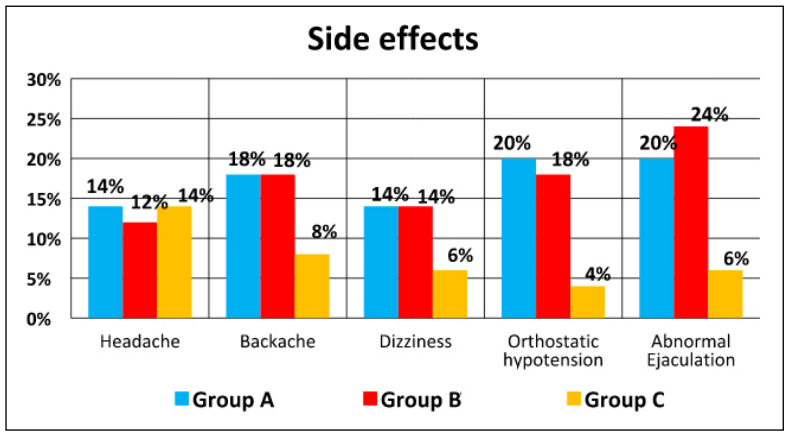
mg) than in group A (225 ± 115.7 mg) or group B (163 ± 77.5 mg). Stone was not expelled even after 4 weeks of MET in 15, 12 and 5 patients in groups A, B and C, respectively. These patients were subsequently treated with ureteroscopic lithotripsy. As regard drug related adverse effects there is no statistically difference between three groups in occurrence of headache, backache or dizziness but there was an increased rate of orthostatic hypotension in group A (10 patients, 20%) and group B (9 patients, 18%) when compared with group C (2 patients, 4%). Also retrograde ejaculation was more reported in group B (12 patients, 24%) and group A (10 patients, 20%) when compared with group C (3 patients, 6%) (Table 2) (Figure 3).

Table 2.
Side effects.

Variable	Group A		Group B		Group C		P value
Headache	7	14%	6	12%	7	14%	0.944 NS
Backache	9	18%	9	18%	4	8%	0.264
Dizziness	7	14%	7	14%	3	6%	0.346
Orthostatic hypotension	10	20%	9	18%	2	4%	0.43 S
Abnormal ejaculation	10	20%	12	24%	3	6%	0.04 S

Statistical Statistical significance was analyzed by the $\chi 2$-test. Group A: Tamsulosin; Group B: Silodosin and Group C: Tadalafil.

Figure 3.
Comparisons between studied groups as regard side effects.



Discussion

Different treatment modalities for lower ureteric stones are available ranging from open surgery to minimally invasive methods. But, all these approaches are associated with complications. So, there has been a paradigm shift in the treatment of lower ureteric stone with a primary focus on medical expulsive therapy (MET) which is a ratified approach to increase the chance of stone passage. In both American and European Guidelines is supported the role of medical expulsive treatment for distal ureteral calculi < 10 mm. In comparison with invasive surgical treatment for ureteric stones, MET has a high safety profile and affordable cost. MET includes various drugs such as alpha adrenoreceptor antagonists, calcium channel blockers and prostaglandin inhibitors.

Phosphodiesterase type 5 inhibitors (PDE5-Is) were more recently approved in the treatment of urinary tract symptoms (9).

However, the most commonly used drugs in MET are still alpha-blockers, among which Tamsulosin is more suitable. The probable mechanism of action of Tamsulosin as a MET is the selective relaxation (repose) of ureteral smooth muscle (10).

Silodosin is a more selective a1A-adrenergic receptor antagonist than Tamsulosin and has a better stone expulsion rate than Tamsulosin (11).

On the other hand, Tadalafil (a PDE5-Is) has been also advocated by many studies for treatment of *lower urinary tract symptoms* (LUTS) secondary to *benign prostatic hyperplasia* (BPH) in recent years. Tadalafil causes the prostate smooth muscle relaxation via the *nitric oxide* (NO)-cyclic guanosine 3', 5'-monophosphate (cGMP) pathway and thereupon improves LUTS and the function of the cavernous muscles in cavernous artery. In recent studies, the administration of PDE5-Is alone and in combination with Tamsulosin has led to acceleration of stone passage or even reduction of stone expulsion time and need for analgesics (12).

According to earlier studies, the expulsion rate of distal ureteric stone by watchful waiting is 25-54% with mean expulsion time > 10 days and is associated with high analgesic requirement even for stones < 5 mm. To improve the expulsion rate and reduce analgesic requirement, medical therapy is considered for distal ureteral stones (13, 14). The present study was thus conducted to determine the best drug for medical expulsive therapy of distal ureteric stones by comparing effect of Tamsulosin, Silodosin and Tadalafil as regard stone expulsion rate, expulsion time, analgesics used, and side effects.

In our study there is a statistically significant (p-value = 0.043) increase of stone expulsion rate in patients on Tadalafil (90%) when compared with cases on Tamsulosin (70%) or Silodosin (76%). Another study conducted by *Puvvada et al.*, in 2016, compared efficacy of Tadalafil and Tamsulosin in expulsion of

lower third ureteric stone. The stone expulsion rate was 84.0% in patients on Tadalafil and 68.0% in patients on Tamsulosin, with Tadalafil showing a significantly higher stone expulsion rate compared with Tamsulosin (P value = 0.0130) (15). In 2019, a similar comparison of Tadalafil and Tamsulosin was done by *Abhishek Laddha et al.* who found that the stone expulsion rate was 58% for the placebo group, 80% for the Tadalafil group and 74% for the Tamsulosin group. Tadalafil was superior to placebo in terms of stone expulsion rate (p-value: 0.017) but comparable to Tamsulosin (p: 0.139) (16). Another study by *Bahadur Kc et al.*, compared Tamsulosin *vs.* Tadalafil as a medical expulsive therapy for distal ureteral stones demonstrating that expulsion rate was significantly higher in the Tadalafil group than in the Tamsulosin group (84.1% *vs.* 61.0%, p = 0.017) (17).

A comparative study made by *Parikh et al.* in 2019 showed that mean expulsion time of calculi was significantly shorter in patients managed by Tadalafil as compared to Tamsulosin (13.1 *vs.* 16.92 days; p < 0.05). Complete expulsion was seen in 86.7% cases on Tadalafil as compared to only 63.3% cases on Tamsulosin (p < 0.05) (18). Rate of expulsion was observed to be significantly shorter with Tadalafil in most of the studies (19-24). *Jayant et al.* in their study compared the stone expulsion rate of Tamsulosin with the Tamsulosin and Tadalafil combination. The expulsion rate was 74.2% *versus* 83.9% (p = 0.349) and 65.5% *vs.* 83.6% (p = 0.031) (25). Similarly, *Hasan et al*. found that Tadalafil had an expulsion rate of 93% compared with 67% for a placebo group (26). In our study we noticed a statistically significant (p-value = 0.001) longer stone expulsion time in cases on Tamsulosin (12.5 ± 5.2 days) and on Silodosin (11.3 ± 4.2 days) when compared with patients on Tadalafil (8.7 ± 3.3 days).

In their study conducted in 2016, *Puvvada et al.*, compared efficacy of Tadalafil *vs.* Tamsulosin in expulsion of lower third ureteric stonea. The mean time for stone expulsion in patients on Tadalafil was 14.7 ± 3.8 days, and in patients on Tamsulosin was 16.8 ± 4.5 days. The time was significantly less in Tadalafil than in Tamsulosin patients (p value = 0.0021) (15).

Kumar et al., in 2018, noticed that the mean expulsion time from the starting of MET was lower for Tamsulosin group (9.38 ± 6.66 days) than for Tadalafil group (9.61 ± 7.47 days), but this difference was not significant (p = 0.78) (19).

Jayant et al., who compared Tamsulosin with the combination of Tamsulosin and Tadalafil, demonstrated a significantly decreased expulsion time (16.7 ± 4.8 *vs.* 14.9 ± 4.4 days, p = 0.003), significantly fewer colicky pain episodes (1.60 ± 1.0 *vs.* 0.45 ± 0.68, p = 0.000), and significantly less analgesic use (2.90 ± 0.90 *vs.* 1.87 ± 0.8, p = 0.000) (25). Colicky pain in ureteral stones occurs owing to an increase in intraureteral pressure above the site of ureteral obstruction.

Kinnman et al. demonstrated that α-blockade relieves ureteric colic by blocking the C-fibers responsible for mediating pain (27). Both drugs are thought to decrease the frequency and amplitude of phasic peristaltic contractions that accompany ureteric obstruction and to decrease the need for analgesia.

In the present study, patients in Tadalafil group showed significantly less episodes of colicky pain (3 patients, 6%) than in Silodosin (11 patients, 22%) and Tamsulosin (12 patients, 22%) with significantly less number of emergency room visits.

Hasan et al. reported a significantly lower pain score of 3.9 versus 7.9 (p < 0.01) and a significantly lower analgesic requirement in the Tadalafil group than in the placebo group (26). Mean number of colicky pain episodes in patients with Tamsulosin was higher in the study done by *Puvvada et al.* which corresponds to the findings observed in the present study suggesting that Tadalafil is also better in controlling pain with lower number of colic episodes and less use of analgesics (15).

However, in 2019, *Li et al.* (28) in a meta-analysis showed that the dosage of analgesia administered in Tadalafil patients was significantly higher than in Tamsulosin patients and the duration of analgesia use in patients who were treated with Tamsulosin plus Tadalafil was significantly lower than in those who received Tamsulosin alone. The average used analgesic dose was reported to be about 200 mg, being 130 mg in *Kumar et al.* (29) and *Kc et al.* (17) studies. In our study the mean requirement of analgesia (diclofenac) was significantly less in patients on Tadalafil (120 ± 55.3 mg) than in patients on Tamsulosin (225 ± 115.7 mg) or Silodosin (163 ± 77.5 mg).

As regard drug related adverse effects there is no statistically difference between three groups in occurrence of headache, backache or dizziness, but there is an increased rate of orthostatic hypotension with Tamsulosin (10 patients, 20%) and Silodosin (9 patients, 18%) when compared with Tadalafil cases (2 patients, 4%). Retrograde ejaculation was also more frequent in Silodosin (12 patients, 24%) and Tamsulosin (10 patients, 20%) when compared with Tadalafil (3 patients, 6%).

In the study by *Kc et al.* (17), the incidence of side effects was similar in both groups and similar results were demonstrated in other studies (25, 29, 30).

Conclusions

Tadalafil is more effective than Tamsulosin and Sildosin in treatment of patients with distal ureteric stones ≤ 10 mm as regard stone expulsion rate, time with decreased number of colicky episodes and side effects.

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Correspondence

Mohammad Ahmad Abdelaal, MD (Corresponding Author)
maal_uro@yahoo.com

Eman M. El-Dydamony, MD
Emanmohamed.8@azhar.edu.eg

377J+VHW, Greek Hospital St, As Sarayat, El Weili, Cairo Governorate 4391050

Conflict of interest: The authors declare no potential conflict of interest.