



Efficacy and Safety of Silodosin, Prednisolone or Both for Spontaneous Passage of Lower Ureteric Stones and Renal Colic Control

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Abstract:

Introduction and objectives: Medical expulsive therapy has now become an established modality of treatment for lower ureteric stones and it involves using of different drugs that act on ureter by different mechanisms. Medical expulsive therapy has a proven role to promote stone passage and reduce the need for minimally invasive surgery. Our aim is to compare the safety and efficacy of Silodosin alone, Silodosin with Prednisolone and Prednisolone alone as medical expulsive therapy for distal ureteric stones. **Methods:** Between January 2016 and September 2016, 150 adult patients presenting with distal ureteric stones of size 5 mm to 20 mm were randomized equally to Silodosin with Prednisolone (group A), Silodosin only (group B) and Prednisolone only (group C). Each one was given for a maximum of two weeks. In the group A and group C, 5 mg of Prednisolone was given once daily. Stone expulsion rate, time to stone expulsion, analgesic use, follow-up and endoscopic treatment and adverse effects of drugs were noted. Statistical analyses were done using chi square test, and analysis of variance. **Results:** Stone size has high statistical significance with stone passage, time of expulsion and analgesic requirement between group A and both group B and group C (p-value < 0.001). The mean to expulsion and analgesic use were significantly lower in group A than group B (p value < 0.001), it was statistically significant with group A and C with (p value < 0.001). Regarding stone size: Stone size < 10 mm: 83% (66% passed stone [A: 26.5% , B:30.5%, C:9%])+ 17% not passed [A:2.5%, B:3%, C:11.5%]), Stone size > 10 mm: 17% (5% passed stone [A: 5% , B:0%, C:0%])+ 12% not passed [A:2%, B:3%, C:7%]), The expulsion rates were not statistically different between groups A, B and C. Regarding to the side effects: In group A: 3 patients had gastritis which started after 5 days or more from beginning of the treatment and resolved

completely without any additional treatment in a period less than 2 weeks. Only 1 patient had increase in blood glucose level reaching 180 mg/dl and returned to the baseline 110 mg/dl after 10 days of discontinuation of the treatment, 3 patients had increase blood pressure readings starting after 5 days or more from beginning of the treatment, not exceeding 150/90 mmHg rising from baseline 120/80 mmHg and returned back to baseline in a period less than 10 days after discontinuation of the drug, In group C: 3 patients had gastritis, 1 patient had increase blood pressure, 1 patient had increase in blood glucose level. The most frequent adverse event with Silodosin group was a reduced or absent ejaculation, In group A: 18 patients (8 patients were distressed, 4 patients were not distressed and 6 patients were distressed but can wait for its improvement) and in group B: 19 patients (10 patients were distressed, 4 patients were not distressed and 5 patients were distressed but can wait for its improvement). **Conclusions:** Medical expulsive therapy for the distal ureteric stones using either Silodosin or Silodosin in combination with Prednisolone is safe and efficacious with faster more pain controlling.

Keywords: Lower ureteric stones, Silodosin and Prednisolone.

1. Introduction:

Urinary calculi are the third most common disease affecting the urinary tract, Urolithiasis about 12% of the population ⁽¹⁾, ureteric stones calculate 20% of urolithiasis from which 70% are situated in the lower third of the ureter " distal ureteric stone" ⁽²⁾. Renal stones are most prevalent between age of 20-40 years and 3 times greater in men than women (women excrete more citrate and less calcium than men). ⁽³⁾

Over the last two decades, the management of ureteric stones had changed greatly, especially after the introduction of

shockwave lithotripsy and ureterscope as minimally invasive treatments, however these treatments are expensive and have complications (in ureteroscopy it is about 10-20%, such as ureteric avulsions, perforation and strictures), surgical intervention is needed only with failure of medical treatment or occurrence of complication. ⁽⁴⁾

The choice of treatment between either observation or active management until spontaneous passage is the main problem for the urologist in such cases ⁽⁵⁾ ⁽⁶⁾. The time for stone passage is supposed to be 2 weeks ⁽⁷⁾, but the patient may suffer from recurrent

attacks of renal colic or UTIs, so decision of treatment depends on multiple factors like stone size, its location, severity of obstruction, anatomy of urinary system and patient preference. Regular clinical, laboratory and imaging assessment is important. ⁽⁸⁾

Medical expulsive therapy has now become an established modality of treatment and it involves using of different drugs that act on ureter by different mechanisms. Medical expulsive therapy has a proven role to promote stone passage and reduce the need for minimally invasive surgery. ⁽⁹⁾

The ureter lined by alpha-1 adrenergic receptors that are more populated in its distal third which has an effect on detrusor and ureteric smooth muscle contraction, Blocking of these receptors induces selective relaxation of it that lead to dilatation of ureteric lumen that facilitate ante grade stone propagation. ⁽¹⁰⁾

Both AUA and EAU recommend alpha blockers for treatment of ureteric stones ⁽¹¹⁾. Tamsulosin has equal affinity for both alpha-1A and alpha-1D but Silodosin newly introduced alpha blocker and have much higher selectivity for alpha-1A than alpha-1B. Silodosin has unique properties as, less effect on blood pressure and improving lower urinary tract symptom that associated with benign prostatic hyperplasia, reduce basal tone, peristaltic frequency and reduce colic pain. ^{(12) (13) (14)}

On the other hand, stone formation and its passage in the ureter may lead to inflammation and edema in the mucosa of the ureter so it may interfere with passage of stones and worse patient condition (renal colic, UTIs), so using of anti-inflammatory and anti-edematous treatment like corticosteroids “e.g. Methylprednisolone” supports a significant effect on distal ureteral stone expulsion. ⁽¹⁵⁾

2. Patients and Methods

This is a prospective randomized study in which we divided our cohort into three groups, each group contains 50 patients, using single dose of drug per day before bed time, continued until stone expulsion or for maximum two weeks.

Group A: will receive both drugs, group B: will receive Silodosin (flopalex)(8mg), Group C: will receive Prednisolone (Hostacortine)(5mg).

Failure of treatment include: stone didn't pass after two weeks, or recurrent attacks of renal colic's not controlled by medications and complications due to obstruction.

Inclusion criteria: any patients with lower ureteric stone, Stone size up to 20 mm (length).

Exclusion criteria: Diabetic or hypertensive patient, history of previous ureteric operation,

Stone size > 20 mm (length), Solitary kidney, chronic kidney disease and Pregnancy.

Follow up: Is performed every week by: Asking the patient about stone passage (informed patient to void in a container) then do stone analysis if it passed, Time of stone passage since beginning of treatment, Analgesic requirements, use a pain assessment scale, symptoms and signs related to the side effects of drugs (measurement of blood

pressure, random blood sugar, gastritis and retrograde ejaculation), Radiological assessment with ultrasound, if there is back-pressure, no need to do further CT, if there is no back-pressure, then doctor have to do CT, Labs (kidney function test), urine analysis, urine culture and sensitivity.

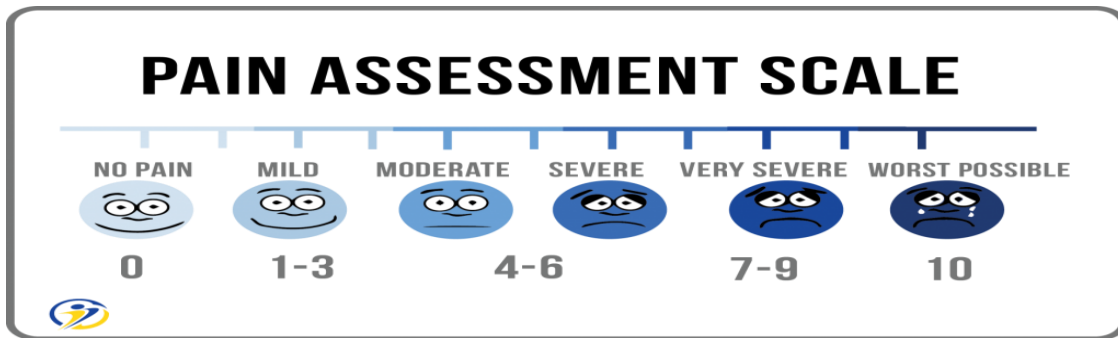


Fig.1

Data was statistically analyzed according to M. Harris and G Taylor (2003), to compute the Statistics which describe data. The analysis of variance was calculated for each character mean by using software program (IBM SPSS version 20).

3. Results:

Stone size has high statistical significance with stone passage, time of expulsion and analgesic requirement between group A and both group B and group C (p-value < 0.001). The mean to expulsion and analgesic use were significantly lower in group A than group B

(p value < 0.001), it was statistically significant with group A and C with (p value < 0.001).

Regarding stone size:

Stone size \leq 10 mm: 83% (66% passed stone [A: 26.5%, B: 30.5%, C: 9%]) + 17% not passed [A: 2.5%, B: 3%, C: 11.5%].

Stone size > 10 mm: 17% (5% passed stone [A: 5% , B:0%, C:0%])+ 12% not passed [A:2%, B:3%, C:7%]).

Regarding to time of expulsion:

In first week: 20 patients with stone size \leq 10 mm (18, 1, 1 patients in groups A, B, C respectively)

In second week: 63 patients with stone size \leq 10 mm and 7patients with stone size >10 mm (23, 37, 10 patients in groups A, B, C respectively)

The expulsion rates were not statistically different between groups A, B and C.

Regarding to analgesic requirement:

100 patients used analgesics (12,43,45 patients in groups A,B,C) , 47 patients passed stones (41 patients with stone size \leq 10 mm and 6 patients with stone size >10 mm and 53 patients not passed the stones (50 patients with stone size \leq 10 mm and 3 patients with stone size >10 mm)

50 patients not used analgesics (12, 43, 45 patients in groups A, B, C)

Regarding to the side effects:

In group A: 3 patients had gastritis which started after 5 days or more from beginning of the treatment and resolved completely without any additional treatment in a period less than 2 weeks. Only 1 patient had increase in blood glucose level reaching 180 mg/dl and returned to

the baseline 110 mg/dl after 10 days of discontinuation of the treatment, 3 patients had increase blood pressure readings starting after 5 days or more from beginning of the treatment, not exceeding 150/90 mmHg rising from baseline 120/80 mmHg and returned back to baseline in a period less than 10 days after discontinuation of the drug.

In group C: 3 patients had gastritis, 1 patient had increase blood pressure, and 1 patient had increase in blood glucose level.

The most frequent adverse event with Silodosin group was a reduced or absent ejaculation, In group A: 18 patients (8 patients were distressed, 4 patients were not distressed and 6 patients were distressed but can wait for its improvement) and in group B: 19 patients (10 patients were distressed, 4 patients were not distressed and 5 patients were distressed but can wait for its improvement).

4. Discussion

Urolithiasis is one of the most common urologic diseases. Among all urinary tract stones, 20% are ureteral stones, of which 70% are found in the lower third of the ureter” distal ureteric stone”.⁽¹⁶⁾

Ureteral stones have a significant impact on patients’ quality of life. Renal colic is common in urological practice, being one of the most

important issues encountered by urologists in emergency clinical settings. It leads to a requirement for analgesia, time off work and, often, repeated hospital admissions for therapeutic interventions.⁽¹⁷⁾

According to EAU Guidelines, in patients with newly diagnosed ureteral stones under 10 mm, and if active removal is not indicated, observation with periodic evaluation is an optional initial treatment. The likelihood of ureteral stone passage varies between 46-85 % for stones under 5 mm and 36- 58% for calculi with a size of 5 to 10 mm.⁽¹⁸⁾ In the past decade, with the introduction of minimally invasive procedure and newer appropriate medical therapy that may be used , so the management of these cases has substantially changed in order to facilitate the stone passage.⁽¹⁹⁾

Medical expulsive therapy developed after an understanding of the various physiologic and pathophysiologic bases for urinary stones and the ureter. The ureter is lined by smooth muscle cells with α -1 adrenergic receptors (α -1A and α -1D), especially in the distal third. Receptor blockade inhibits both basal smooth muscle tone and hyperperistaltic uncoordinated frequency in order to maintain tonic propulsive contractions. Ureteric calculi can induce ureteric spasms that interfere with expulsion; thus, muscle relaxation while maintaining normal peristaltic activity may facilitate passage. Therefore, α -1 adrenergic

receptor antagonists work by creating an increased pressure gradient around the stone, which propels distal ureteral stones out of the ureter.⁽²⁰⁾⁽²¹⁾ According to both AUA and EAU α blockers used in treatment of ureteric stones. Silodosin is newly introduced alpha blocker and has much higher selectivity for α -1A AR with 162 fold than α -1B AR and 56 fold than α -1D AR (so it is selective to α -1A AR) (it is uroselective).⁽²²⁾

Finally, it has been shown that ureteral calculi induce intense inflammatory changes and submucosal edema in proximity to a stone that may worsen ureteric obstruction, thus increasing the risk of impaction and retention. so using of anti-inflammatory and anti-edematous treatment like steroids “e.g. Methylprednisolone” can facilitate stone expulsion by reducing the submucosal edema.⁽²³⁾⁽²⁴⁾

Our analysis found that the combination (Silodosin [8 m] and prednisolone [5mg]) for 2 weeks is superior to controls (Silodosin [8 mg] alone and prednisolone [5mg] alone) in reducing the stone expulsion time and analgesic requirements with The mean duration of analgesic requirement are (6.1 / 8 / 6.8 days) in groups A , B ,C respectively.

The average number of hospital visits for colicky pain was fewer in group A than in both B and C.

Porpiglia et al ⁽²⁵⁾ examined the effects of corticosteroids alone and in conjunction with α -blockers in the expulsion of distal ureteral stones. A total of 111 patients were included in the study. Participants were enrolled in 4 of 4 groups, group A received Tamsulosin [0.4 mg] once daily, group B received Deflazacort [30 mg] once daily, group C received both Tamsulosin [0.4 mg] plus Deflazacort [30 mg] daily, and control group D received only analgesics. **The stone expulsion rates** for the 4 groups were 60%, 37.5%, 84.8%, and 33.3%, respectively, with a **significant difference** observed between group C and the other groups ($p < 0.001$). **The mean analgesic requirement** was 42.5 ± 0.4 mg for group A, 50 ± 0.3 mg for group B, 27.3 ± 0.5 mg for group C, and 81 ± 0.33 mg for group D, with a **significant difference** between group C and the other groups ($p < 0.001$). ⁽²⁵⁾

We agreed with this study in that there was a statistically significance according to **analgesic needed**, between the Group that used combined treatment and both groups that used one drug only with $p\text{-value} \leq 0.001$.

In our study we used Prednisolone [5 mg] which equivalent to 25% of deflazacort [30 mg] that used in above study. ⁽²⁶⁾ Also the our mean stone size (9.46 mm) was more than presented in the above study (5.88 ± 0.23 mm), we used Silodosin (super-selective $\alpha 1a$ -blockers) than

Tamsulosin, smaller dose of corticosteroid that used in our current study ; made exposure to steroid side effects less than in the above study .

Dellabella et al. ⁽²⁷⁾ classified Patients to 2 treatment regimens: group 1 with α -blocker alone (Tamsulosin [0.4 mg]) and group 2 with α -blocker plus corticosteroid (Tamsulosin[0.4] plus Deflazacort [30 mg]) . A total of 45 patients were included in the study. **The median stone size** was comparable between the treatment and control arms, at 6.4 mm and 6.9 mm, respectively. Results revealed no significant difference in **stone expulsion rates**; however, a shorter **stone expulsion time** was noted in the combined α -blocker and corticosteroid group. **The median stone expulsion time** was 120 hours (mean 139.2 ± 113.8) for 27 patients in group 1 and 72 hours (mean 103.3 ± 136.2) for 29 patients in group 2 ($p\text{-value} = 0.036$). ⁽²⁷⁾

We agreed with them in that there was significant difference in the **stone expulsion time** and no significant difference in **the stone expulsion rate** between the combination group and the α -blocker group. Also the our mean stone size (9.46 mm) was more than that presented in the above study (6.9 mm).

Hwang et al ⁽²⁸⁾ reassessed the role of corticosteroids in adjunct to α -blockers in the expulsion of distal ureteral stones <1 cm. Patients were divided into 2 groups: group 1 (analgesic only (control group)) (66 patients)

and group 2 (combination group) (47 patients), Alfuzosin [10mg] and Methylprednisolone [8mg] for 4 weeks. **The average stone size** was 6.15 mm in group 1 and 5.42 mm in group 2. Of the 113 patients, 80 became stone free (70.7%). Group 2 had significantly higher **stone expulsion rates** (82.9 vs. 62.1%, p-value = 0.014), fewer **stone expulsion times** (mean 4.4 vs. 7.3 days, p-value = 0.001), and **mean number of intramuscular analgesic injections** (0.8 vs. 2.1) compared to group 1. ⁽²⁸⁾

We agreed with this study that it was significant in **stone expulsion time** for the group 2 although it depended on stone size < 1 cm (the average stone size was 5.42 mm in group 2),using Alfuzosin (non selective α -blockers) plus Methylprednisolone [8mg] and duration of medication for 4 weeks.

We have more benefits in using silodosin (super-selective α 1a-blockers) and Prednisolone [5mg] (smaller dose) for 2 weeks only; so those situations decreased incidence of side effects of nonselective α -blockers and corticosteroids and less analgesic need , lastly our study included stone size ≥ 20 mm (the average stone size was 9.46 mm).

Waleed Shabana et al ⁽²⁹⁾ assess the safety and efficacy of tamsulin, alfuzosin and their combination with methylprednisolone in lower ureteric stone expulsion .Patients were divided into four group with 53 pt in each. Group 1

received Tamsulosin [0.4 mg], Group 2 received tamsulosin [0.4mg] and corticosteroid [8mg], Group 3 received alfuzosin [10mg] ,Group 4 received alfuzosin [10mg] and corticosteroid [8mg] for 2 weeks with stone size ≤ 1 mm. **The mean (SD) stone size** was 7.8(1.5),8.1(1.3),7.9(1.6),8.0(1.4) mm respectively. Group 2 and 4 had significantly higher **stone expulsion rate** than 1 and 3 (p-value < 0.05). **The stone expulsion time** not significant difference. ⁽²⁹⁾

This study disagreed with our study as there was significant difference in **stone expulsion rate** and no significant difference in **stone expulsion time** . Also the our mean stone size (9.46 mm) was more than that presented in the above study (8.1, 8.0 mm) in Group 2 and Group 4 respectively.

Santosh Kumar et al ⁽³⁰⁾ studied the Efficacy of tamsulosin Versus tamsulosin With tadalafil in combination With Prednisolone for the Medical Expulsive Therapy of Lower Ureteric Stones as Randomized Trial. . He divided Patients as group A were given tamsulosin [0.4 mg] once daily, and those in group B were given tamsulosin [0.4 mg] and tadalafil [10 mg] once daily. In addition, patients in groups A and B received prednisolone [5 mg] once daily for 1 week. In both groups, drugs were continued until stone expulsion or for a maximum of 6 weeks.

The stone expulsion rate was 74.2 % in group A and 83.9 % in group B. Although **the stone expulsion rate** was on the higher in group B, the difference was not statistically significant (p-value =0.349). **The mean stone expulsion time** trended toward a lower value in group B (15.15±5.5 days) than in group A (18.9 ± 8.7 days), but this difference was also not significant (p-value = 0.074). **The average number of hospital visits for colicky pain** were comparatively fewer in group B (0.45±0.67) than in group A (2.90±0.90), and this difference was **highly significant** (p-value =0.000). Also, **the mean analgesic requirement** was **significantly** less in group B (1.87±1.38 times) than in group A (2.90±0.90 times) (p-value <0.0001).⁽³⁰⁾

The above study, showed that the patients who received corticosteroid and α -blockers had shorter **stone expulsion time** and less of **analgesic use** as in our study.

Vijay P Srivastava et al. Studied the effectiveness of α -blockers and corticosteroids in expulsion ureteric stones. Patients were divided in two groups: **Group 1 (tamsulosin Group) & Group 2 (tamsulosin + deflazacort Group)**. He found that the group in Tamsulosin + deflazacort better stone expulsion rate with in shorter period was achieved. There was minimum discomfort to the patients during stone expulsion. Success rate was comparable in both

groups up to 10 mm stone size. There was marked difference in stones bigger than 10 mm (25% and 62.66% in 11-12 mm size, 16.66% and 57.14% in 13-15 mm size and 0.0% and 50% in 16-17 mm size). Tamsulosin (0.4 mg) once daily , till the time stones are expelled or up to 30 days maximum. . Group 2 in addition to the above were given deflazacort (18 mg) once daily for 3 days, (12 mg) OD for 2 days and (6mg) on the 6th day. On 7th day patient was discharged. Treatment was considered successful when stone was expelled within 30 days and patients had fewer and milder symptoms.

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