Role of Tamsulosin Oral Control Absorption System and Alfuzosin in Shock wave Lithotripsy for Renal and Upper Ureteric Calculi

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Abstract: Objectives: - To evaluate the effect of tamsulosin oral controlled absorption system 0.4 mg and alfuzosin 10 mg on clearance of stone fragments after ESWL in renal and upper ureteric calculi. **Patients and Methods: -** A total of 200 patients with single pelvic renal or upper ureteric calculi 20 mm or less were enrolled in this study, underwent ESWL, those patient were divided into 3 groups, group (A) formed of 65 patients received non steroidal anti inflammatory in the form of diclofinac Na 50 mg three times /day on demand with tamsulosin oral controlled absorption system 0.4 mg once daily. Group (B) formed of 66 patients receiving diclofinac Na 50 mg three times /daily on demand with alfuzosin 10 mg at night on bed time. Group (C) formed of 69 patients received diclofinac Na 50 mg three times /daily on demand as controlled group. All groups received 75 mg of diclofinac Na ampule intramuscular on demand. All patients were followed by KUB 2 weeks after each session of ESWL for clearance of stone fragments; all groups are comparable as regard of age, sex mean stone size and stone location. **Results: -** In our study the success rate after the end of study for stone size 10 mm or less was 28/28 patients 100% in group (A), 31/31 patients 100% in group (B) and 28/30 patients 93.3% in group (C). For stone size more than 10 mm, the success rate after 1st session of ESWL was higher in group (A) 26/37 patients 70.27% tamsulosin oral controlled absorption system and group (B) 25/35 patients 71.4% extended release alfuzosin10 mg than group (C) 17/39 patients 35.89% controlled group. The overall success rate at end of study was higher in group (A) 36/37 patients 97.29% and group (B) 33/35 patients 94.28% than group (C) 31/39 patients 79.48%. No sever complication was observed in three groups A,B and C, retrograde ejaculation was 7.69% (5 patients) in group A, orthostatic hypotension did not require suspension of the therapy was 3% (2 patients) in group A and 6% (4 patients) in group B. **Conclusion: -** Medical expulsive therapy (tamsulosin oral controlled absorption system 0.4 mg) and alfuzosin 10 mg after ESWL for renal and ureteral calculi >10 mm increase stone expulsion rate, decrease the time for stone expulsion , amount of analgesia and number of colics episodes ,in contrast, they failed to demonstrate a significant treatment effect after ESWL for stone less than 10 mm.

[Yasser A. Badran, Tamer A. Ali, Mohamed A. Abd Elaal, Mahmud ali, Adil Jamal and Ahmed Farouk Abdulall **Role of Tamsulosin Oral Control Absorption System and Alfuzosin in Shock wave Lithotripsy for Renal and Upper Ureteric Calculi**. *J Am Sci* 2013;9(6):387-393]. (ISSN: 1545-1003). http://www.americanscience.org 46

Keywords: Tamsulosin. ESWL, Stones

1. Introduction

Patients with urinary tract calculi account for 20% of urology inpatients. Urinary tract stone affects 5%-15% of world population and the incidence of this disease is increasing **(Curhan *et al.*, 2007).** Stone size, location, composition and complication are the most determining factors in treatment of urinary stone in addition to patients-dependent factors such as pain tolerance **(James 2007)**.

In patient who has newly diagnosed ureteral stone <10 mm and if active stone removal is not indicated, observation with periodic evaluation is an option for initial treatment. Such patients may be offered appropriate medical therapy to facilitate stone passage during the observation period **(Turk *et al.*, 2010).**

There is growing evidence that medical expulsive therapy accelerate stone passage of ureteral stones and of stone fragments generated with ESWL as well as limits pain **(Turk *et al.*, 2010).** Given that ureteral peristalsis is mediated by alpha adrenergic receptors, it was demonstrated that alpha blockers can increase stone expulsion rate, decrease frequency of colic through relaxing ureteral smooth muscle **(Hollingsworth *et al.*, 2006).**

Several trials have demonstrated increase stone expulsion rates using selective α1a+α1d and non selective adrenoceptors antagonist, were focusing on it is role for distal ureteral calculi **(Zehri *et al.*, 2010 and Ahmed *et al.*, 2010).**

Generally there are few studies evaluating the effect of α blockers on stone fragment after ESWL for renal and ureteral calculi **(Zheng et al. *et al.*, 2010).**

In our study, we are aiming to evaluate the effect of tamsulosin oral controlled absorption system 0.4 mg and alfuzosin 10 mg on clearance of stone fragments after ESWL in renal and ureteric calculi

2. Patients and Method

Our prospective randomized study including 200 patients with single radio-opaque renal or ureteric stone up to 20 mm was selected from outpatient clinic and urology department, Alzahraa university hospital (Egypt) and Soliman Fakeeh Hospital (KSA) over the period from January 2012 to January 2013.

All patients were evaluated by detailed clinical history, general and local examination, complete laboratory assessment including urine analysis, Serum creatinine, liver function tests, complete blood picture, coagulation profile and the followings;

Imaging studies include

Kidney –ureter – bladder (KUB) x-ray for evaluation of stone site, size and density.

Urinary tract ultrasound to detect the degree of dilatation of pelvicalyceal system, actual size and location of stone.

Intravenous urography (IVU): provide useful information about kidney function, location of the stone, pelvicalyceal dilatation and state of ureter (normal, dilated or presence of stricture).

Non contrast spiral CT urinary tract:

Informed consents including the procedure and possible complications were taken from all patients.

The exclusion criteria in our study includes

Pregnancy,age below 18 years old, morbid obesity, uncorrected coagulation profile, uncontrolled urinary tract infection, multiple stones, previous unsuccessful ESWL, impacted ureteric stone (a stone that cannot be bypassed by a wire or catheter, a stone that remains at the same site in the ureter for more than 2 months or arrest of dye at the site of the stone by IVU), concomitant use of calcium channel blocker or alpha one adrenergic antagonist, sever vertebral malformation, aortic and renal artery aneurysm, congenital anomalies of the kidney (as horseshoe kidney), distal stricture to the stone, gastric ulcer disease (to avoid exacerbation of ulcer disease by analgesic), renal insufficiency and hypersensetivity to tamsulosin or alfuzosin.

During ESWL

ESWL was performed at both hospitals using the same model of an electromagnetic lithotripter (SIEMENS) under fluoroscopic guidance about 13.5 KV and a shock rate 60-90/min. The ESWL session was considered complete on satisfactory fragmentation or a maximum of 3500 shocks for renal calculi & about 5000 shocks for ureteric calculi.

During each session, patients received general anesthesia or sedation.

After ESWL

Patients fulfilling the criteria of the study were classified into 3 groups:

Group A

This group including 65 patients (28 patients have stone size less than or equal to 10 mm stone and 37 patients have stone size more than 10 mm) taking morning dose of tamsulosin oral controlled absorption system 0.4 mg once daily post ESWL & continue for 2 weeks after the last session, in addition to Diclofinac Na 50 mg three times daily on demand.

Group B

This group including 66 patients(31 patients have stone size less than or equal to 10 mm stone and 35 patients have stone size more than 10 mm) taking alfuzosin 10 mg at bed time once daily post ESWL & continue for 2 weeks after the last session, in addition to Diclofinac Na 50 mg three time daily on demand.

Group C (Controlled group)

This group includes 69 patients (30 patients have stone size less than or equal to 10 mm and 39 patients have stone size more than 10 mm) taking only Diclofinac Na 50 mg tds on demand post ESWL.

All groups received 75 mg of Diclofenac Na ampules on demand& the drug administration was started immediately after ESWL and was continued for a maximum 4 sessions of ESWL or until success or an alternative treatment was applied for three groups.

Patients of all groups were instructed for the following:

Drink 2 liters of water daily, recording the number of analgesic tablets & ampules taken during the course of treatment and consultation if there is fever, oliguria or any side effect of the drugs.

Follow up:

Follow up of the patients was done by KUB 2 weeks after each session of ESWL for clearance of stone fragments.

The results of both groups were compared to each other as regard expulsion rate, expulsion time, analgesic requirement, and incidence of stienstrasse after ESWL.

The success of our study is defined as stone-free status or presence of clinically insignificant residual fragments (which defined as asymptomatic fragments 3 mm or less in diameter).

Failure was defined as failed ESWL after 4^{th} session or the requirement for auxiliary procedure after any session (any ureteroscopy, percutaneous nephrostomy, or percurtaneous nephrolithotripsy performed for residual calculi or steinstrasse were considered auxiliary procedures.

3. Results

A total numbers of 200 patients met our inclusion criteria randomized into 3 groups (group A Tamsulosin oral controlled absorption system –

group B extended release alfuzosin and group C as controlled group). All patients completed the study.

Table1: Basline patient characteristics

Groups	(A) 65patients	(B) 66 patients	(C) 69 patients	*P* value	
				(A&C)	B &C
Age	23-65 Means ± SD 39.9 ± 11.7	20-60 Means ± SD 38.7 ± 12.03	22-68 Means ± SD 39.7 ± 11.6	> 0.05	> 0.05
Sex male/female	40 Male (61.53%) 25femle (38.46%)	45male (68.18%) 21 female (31.81%)	50 male (72.46%) 19 female (27.53%)	> 0.05	> 0.05
Stone side Right/ Left	36 (55.38%) 29 (44.61%)	30(45.45%) 36(54.54%)	40(57.97%) 42.02%)(29	> 0.05	> 0.05
Stone size	6.5mm-17.5 mm Means ± 12.76± 2.85	6mm-20mm Means ± 11.87 ± 3.61	6.5mm-19mm Means ± 12.79 ± 3.58	> 0.05	> 0.05
Stones ≤ 10mm/ stones >10mm	28 (43%) patients have stones size≤ 10mm/37 (56.9%)patients have stones size >10mm	31(46.96%) patients have stones size≤ 10mm/ 35(53.03%) patients have stones size >10mm	30 (43.47%) patients have stones size≤ 10mm/39(56.52%) patients have stones size >10mm	> 0.05	> 0.05
Stone location Kidney/ureter	35(53.84%)kidney stones /30(46.15%) uretric stones	29(43.93%)kidney stones /37(56.06%)ureteric stones	37 (53.62%)kidney stones / 32(46.37%) ureteric stones	> 0.05	> 0.05

The main age was between 38.7 to 39.9 years , the main stone size was 12.7 ,11.8, 12.8 mm for group A, B and C respectively, regarding to stone location, the renal pelvic stone was 35patients (53.84%), 29 patients (43.93%), 37 patients (53.62%) in group A,B and C respectively, while ureteral calculi was 30paients (46.15%),37 patients (56.06%), 32patients (46.37%) for group A, B, and C respectively. There is no statistically significant difference in three groups as regard the age, sex, the mean stone size and stone location.

Results as regard of stone size ≤ 10mm, there is no statistically difference in group A, B and C As regard of clearance of the stone, stainstrasse after 1st, 2nd and 3rd session of ESWL. As shown in table 2.

Table 2: Results as regard of stone size ≤ 10mm

	Group A (N=28)	Group B (N=31)	Group C (N=30)	*P* value
Stone expulsion after 1st session	21 (75%)	23 (74.19%)	19(63.3%)	> 0.05
Stone expulsion after 2nd session	26 (92.85%)	28 (90.32%)	25(83.3%)	> 0.05
Stone expulsion after 3rd session	28 (100%)	31 (100%)	28 (93.33%)	< 0.01

Table 3: Results as regard of stone size >10mm

	Group A tamsulosin (N=37)	Group B Alfuzosin (N=35)	Group C controlled (N=39)	*P* value A&C	*P* value B&C
Stone expulsion after 1st session of ESWL	26 (70.27%)	25 (71.42%)	17 (35.89%)	< 0.01	< 0.01
Stone expulsion after 2nd session of ESWL	32 (86.4%)	30 (85.71%)	26 (61.65%)	< 0.01	< 0.01
Stone expulsion after 3rd session of ESWL	36 (97.29%)	33 (94.28%)	29 (74.35%)	< 0.01	< 0.01
Stone expulsion after 4th session of ESWL			31 (79.48%)		
Stainstrasse	2 (5.4%)	3 (8.5%)	9 (23.07%)	< 0.01	< 0.01
Mean days to stone expulsion	32 ± 13 days	35 ± 15 days	45 ± 15 days	< 0.01	< 0.05
Numbers of colicky pain	3.5 ± 2.2	3.2 ± 2.2	6.2 ± 2.3	< 0.01	< 0.01
Diclofenac consumption	650- 1100 Means 800 ± 130	700-1200 Means 850 ± 135	800-2650 Means 1470 ± 884	< 0.01	< 0.01

The overall clearance rate was statistically significantly difference between group A, B and C 36 (97.29%), 33 (94.28%) and 31 (79.48%) respectively *P* value was (< 0.01 and < 0.01) statistically difference between group A and C, group B and C respectively. And not statistically difference between group A and B, *P* value was (> 0.05).

The mean expulsion time was 32± 15 days in group A, 35± 17 days in group B and 45 ± 14 days in group (C). The mean expulsion time of group A and B was significantly shorter than group C (*P* value < 0.01 and < 0.05) respectively. The comparison demonstrated no statistical significant difference between both groups A and B (*P* > 0.05).The analgesic requirement in group (A) and (B) was statistically significant lower than the control group (C) (800 mg, 850 mg versus 1470 mg *P* <0.01) respectively. There was a statistically significant difference regarding the mean number of renal colic's episodes between different groups.

The occurrence of stienstrasse at lower ureter was much lower in tamsulosin group (A) 2 (5.4%) and alfuzosin group (B) 3 (8.5%) than the control group 9 (23.07%) (*P* < 0.01).

Table 4: *Side effects observing in patient*

Side effects	Group A	Group B	Group C
Retrograde ejaculation	5 (7.69%)	0%	0%
Orthostatic hypotension	2 (3%)	4(6 %)	0%
Headache	4 (6.1%)	4(6%)	0%
Dizziness	6(9.23%)	5 (7.57%)	0%
Fatigue	3 (4.61%)	6 (9%)	0%
Nausea /vomiting	3 (4.6%)	2(3%)	2(2.89%)

No sever complication was observed in three groups A,B and C, retrograde ejaculation was 7.69% (5 patients) in group A, orthostatic hypotension did not require suspension of the therapy was 3% (2 patients) in group A and 6% (4 patients) in group B.

4. Discussion

Urinary stone disease is one of the most common reasons for patients visiting a urology practice, affecting 5–15% of the population (**Ramello *et al.*, 2000).** Since its introduction in the early 1980, ESWL has become the initial treatment for patients with kidney and ureteric calculi. Even with the refinement of current endourological methods for stone removal, ESWL remains the primary treatment for most patients with uncomplicated calculi (**Preminger *et al.*, 2007).** Accumulated experience has clearly shown that, in addition to efficacy of the lithotripter, the success rate of ESWL depends on the size (volume),number, location and hardness of the stones as well as ureteral peristalsis above the stone, spasm and oedema at location of stone **(logarakis *et al.*, 2000).**

The different subtypes of adrenergic receptors have been pharmacologically identified α1a, α1b and α1d was found in the distal ureter with high density of α1d followed by α1a and α1b **(Hieble *et al.*, 1995; Sigala *et al.*, 2005 and Itoh *et al.*, 2007),** so α adrenoceptor antagonist (α blockers) inhibit contraction of ureteral musculature, reduce basal tone and decrease peristaltic frequency and amplitude and decrease intraluminal pressure (**Sigala *et al.*, 2005).**

Several study demonstrated increased stone expulsion rates for distal ureteral calculi using tamsulosin (selective α1a and α1d adrenoceptors antagonist) and non selective α adrenoceptors antagonist as doxazosin-terazosin and alfuzosin **(Pedro *et al.*, 2008., Alanasri *et al.*, 2010., and Cha *et al.*, 2012).**

Europian urology guidelines 2010 suggest that medical expulsive therapy (MET) for urolithiasis has gained increasing attention in the last years. It seems to expedite and increase stone-free rates, reducing additional analgesic requirements After ESWL for ureteral or renal stones. Our study aimed to evaluate the effect of tamsulosin oral controlled absorption system 0.4 mg and alfuzosin 10 mg on clearance of stone fragments after ESWL in renal and upper ureteric calculi. In our study a total of 200 patients with single pelvic renal or upper ureteric calculi 20 mm or less were included and underwent ESWL, those patient were divided into 3 groups, group (A) formed of 65 patients received non steroidal anti inflammatory in the form of diclofinac Na 50 mg three times / day on demand with tamsulosin oral controlled absorption system 0.4 mg once daily. Group (B) formed of 66 patients receiving diclofinac Na 50 mg three times / day on demand with alfuzosin 10 mg at night on bed time. Group (C) formed of 69 patients received diclofinac Na 50 mg three times / day on demand as controlled group. All groups received 75 mg of diclofinac Na ampule intramuscular on demand. All patients were followed by KUB 2 weeks after each session of ESWL for clearance of stone fragments; all groups are comparable as regard of age, sex mean stone size and stone location.

As regard of overall success rate after the end of study for stone size 10 mm or less.

In our study the success rate was 28/28 patients 100% in group (A), 31/31 patients 100% in group (B) and 28/30 patients 93.3% in group (C). There is no statistically difference in group A, B and C as regard to stone clearance, stainstrasse after 1st, 2nd and 3rd sessions of ESWL for stone less than or equal to 10 mm, these results were

comparable to the results obtained by **Bhagat *et al.*, 2007** who said that no significant difference in clearance rate with stone 6 to 10 mm (P = 0.35) in patients receiving tamsulosin 0.4 mg than control groups, and same result of **Gravina *et al.*, 2005** no significant difference with upper ureteric calculi less than 10 mm in patients receiving tamsulosin than controlled group after ESWL , similar results was found in in **Kupeli *et al.*, 2004** the difference in expulsion rates between treatment (tamsulosin) and controlled group for stone less than 5 mm was not significant.

As regard of our study to stone size more than 10 mm.

The success rate after 1st session of ESWL was higher in group (A) 26/37 patients 70.27% tamsulosin oral controlled absorption system and group (B) 25/35 patients 71.4% extended release alfuzosin10 mg than group (C) 17/39 patients 35.89% controlled group.

The success rate at end of study was higher in group (A) 36/37 patients 97.29% and group (B) 33/35 patients 94.28%than group (C) 31/39 patients 79.48%, these results comparable to the study done by **Kupeli *et al.*, 2004** on 48 patients with lower ureteric stone greater than 5 mm (6 to 15 mm) who underwent ESWL and were randomly assigned into 2 groups; group (A) 24 patients receiving tamsulosin 0.4 mg once daily and group (B) 24 patients as control group , the result was higher in group A (70.8%) than group B (33.3%) and the difference was statically significant (P = 0.019). Same results obtained by **Georgiave *et al.*, 2011**on 248 patients with ureteral and renal calculi who underwent ESWL , the patients were randomized into group (corticosteroid and analgesic) or standard care plus tamsulosin oral controlled absorption system 0.4 mg once daily, the stone clearance rate was significant greater for patients treated with tamsulosin than for slandered care group at 4 weeks (73.4% vs 55.9%) respectively $P < 0.01$ and at 12 weeks (91.3% vs 74.6%) respectively $P < 0.05$, our results comparable to the result of **Hussein *et al.*, 2010** which don on 166 patients underwent ESWL for renal or ureteric stone who divided into group A (N= 83) took tamsulosin 0.4 mg once daily + diclofenac Na on demand and group B (N=83) took only diclofenac Na as needed ,patients were on these regimen for 4 weeks or until stone clearance and were followed up for a maximum of 3 month , the stone clearance rates was significant higher in group A 73% than group B 55 % P= 0.008 . In contrary in a study done by **Osama *et al.*, 2011** on 150 patients who underwent up to four ESWL for renal calculi , patients were randomized into 3 groups of 50 patients each, group A (phloroglucinal 240 mg daily), group B (tamsulosin 0.4 mg once daily plus phloroglucinal) and group C (Doxazosin 4 mg plus phloroglucinal) the treatment continued up to 12 weeks, there were no significant difference between the 3 groups regarding to stone expulsion rates (84%, 92%and 90% respectively).

As regard of stone expulsion time:

In our study the main expulsion time was significantly shorter in group A and B than group C (32 ± 13 days , 35 ±15 days and 45 ±15 days respectively), these result was comparable to result obtained by **Osama *et al.*, 2012** the main expulsion time of tamsulosin and doxazosin was significantly shoreter than control group after ESWL (P value between tamsulosin group and control by **Gerorgiev *et al.*, 2011** tamsulosin oral controlled absorption system was associated with significant lower interval time to eliminate the stone fragments ($P < 0.001$). Our results were comparable to recent pooled analysis studies demonstrated evidence for a higher stone expulsion rate and a reduced time to stone expulsion using α-blocker compared to a standard therapy or placebo control group. Of nine α-blockers trials investigating stone expulsion with mean stone sizes 6-10 mm; only four studies demonstrated a significantly higher expulsion rate in the treatment group. In contrast, regarding α-blocker trials with stone sizes ≥ 11 mm, 19 of 20 studies demonstrated a significant benefit in stone expulsion rates mirrored by an increase of the adjusted risk ratios (ARR) from 0.15 to 0.31. Results might indicate that with decreasing stone size, an additional benefit for medical expulsive therapy is less likely because of the high spontaneous expulsion rate **(Seitz *et al.*, 2009).**

As regard mean analgesic requirement:

In our study there was statistically significant reduction in the analgesic requirement in group (A) and (B) than the control group (C) (800 ± 130 mg, 888 ± 134 mg versus 1470 ± 880 mg P <0.001). 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 **(Sigala *et al.*, 2005)**. This result was comparable to the result obtained by **Gravina *et al.*, 2005** which was 375 mg for tamsulosin group versus 675 mg for the control group (P = 0.001); and the results obtained by **Gupta ., *et al.*, 2008** which was 57 mg for tamsulosin group versus 119 mg for the control group (P = 0.02).and the results obtained by **Hussien *et al.*, 2010** higher number of patients had more frequent attack of colic and used more analgesics in group 1 (control group) than group 2 (tamsulosin group) P = 0.003, 0.001 and 0.002 respectively in 1st , 2nd and 3rd months, **Osama et al., 2011** number of colicky episode significantly

decrease in group B tamsulosin) and group C (doxazosin) than control group A, and significantly decrease use of analgesic 546 ± 194 mg in control group, 311.9 ± 145.5 mg in group B (tamsulosin), and 409.5 ± 197.1 mg in group C (doxazosin).

As regard occurrence of stienstrasse at lower end ureter:

In our study occurrence of stienstrasse at lower ureter was much lower in tamsulosin group A 2 patients (5.4%) and alfuzosin group B 3 patients (8.5%) than the control group C 9 patients (23.07%) (*P* value < 0.01 between group A and C, *P* < 0.01 between group B and C). All patients managed by another session of ESWL & all became stone free. These results are more statistically significant compared to results obtained by **Vineet *et al.*, 2008** in which 4% in group 1 (tamsulosin) and 13% in group 2 (control) developed stienstrasse (*P* = 0.10) and the results obtained by **osama *et al.*, 2011**, the overall rate of occurrence of steinstrasse in his study was 6.6% and 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.

In the study done by **Resim *et al.*, 2005** on 88 patients had steinstrasse in the lower ureter after ESWL were randomly divided into two groups : group 1 (35 patients) control & group 2 (tamsulosin group)(32 patients), both groups received medications for 6 weeks after ESWL. 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. As regard side effect of both alpha blocker tamsolusin oral controlled absorption systeme o.4 mg and alfuzosin 10 mg were tolerable and completely reversible with no significant difference in dizziness , fatigue ,headach and postural hypotension as study of **Cha *et al.*, 2012,** but tamsulosin oral controlled absorption system o.4 mg (selective α blocker) has been linked to higher incidence of retrograde ejaculation than alfuzosin 10 mg (non selective α blocker) as a result of **Agrawal *et al.*, 2009.**

Conclusion:

Medical expulsive therapy (tamsulosin oral controlled absorption system 0.4 mg) and alfuzosin 10 mg after ESWL for renal and ureteral calculi >10 mm increase stone expulsion rate, decrease the time for stone expulsion , amount of analgesia and number of colics episodes ,in contrast, they failed to demonstrate a significant treatment effect after ESWL for stone less than 10 mm.

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