The Egyptian Journal of Hospital Medicine (July 2022) Vol. 88, Page 3999-4004

Randomized Trial of Stone Fragment Active Retrieval Versus Spontaneous Passage after Pneumatic Lithotripsy of Ureteral Stones

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ABSTRACT

Background: The third-highest rate of all urinary issues is urinary stone illness. Patients with stones less than 5 mm have a 68% spontaneous passage rate, while patients with stones larger than 6 mm have a very low spontaneous passage rate of 5%. The aim of the present study was to assess the difference between complete retrieval of small stone gravels versus spontaneous passage of these gravels after uretroscopic lithotripsy as regard intraoperative and postoperative complications and stone clearance.

Patients and methods: A randomized controlled clinical trial was carried out at Urology department, Al-Azhar University Hospital between February 2021 and August 2021. It included 60 patients with lower ureteric stones admitted to the Urology Department for endoscopic management.

Results: Patients who underwent intraoperative fragment retrieval had significantly longer operative time in comparison to those underwent spontaneous fragment expulsion (57.53 ± 15.13 vs. 34.90 ± 8.14 minute; $p<0.001$). Operative time ranged between 36 and 88 minute in case of fragment retrieval and between 25 and 54 minute in case of spontaneous fragment expulsion. Only 2 (6.7%) patients from those underwent spontaneous fragment expulsion and 5 (16.7%) patients from those underwent intraoperative fragment retrieval developed intraoperative complications with no significant differences ($p=0.21$).

Conclusion: Ureteroscope has been safe and efficient in managing ureteroscopy, leaving gravels 3 mm or less after uretroscopic lithotripsy is associated with mild post-operative symptoms as abdominal pain, burning micturition but less operative time, less complication of anaesthesia, less operative cost less effort from surgeon and less intraoperative complication, so that this method is advisable.

Keywords: Ureteroscopy, Stone fragment active retrieval, Spontaneous passage, Pneumatic lithotripsy, Uretral stones.

INTRODUCTION

Urolithiasis is observed in 12% of the general population. Of all types of urinary system stone, 20% are ureteral stones, and 70% of these are distal ureteral stones [(1)].

Ureteroscopy was developed as an extension of cystoscopy and gradually become the gold standered for the diagnosis and treatment of stone ureter [(2)].

Originally ureteroscopes are produced as rigid instruments for distal ureteric stone management, they had wide working channels, good field of vision, the Semi rigid ureteroscopes have long length, tapered distal tip (e.g., 6.75 to 9.0 Fr) but the working channels are little and narrow, recently flexible uretroscopes had been developed with many advantages and allow to use in intrarenal endoscopies [(2)].

Although the great development of uretroscopic manufacture the ancillary devices and the lithotrepter machine have decreased complication rates of ureteroscopic manipulation of the stone ureter to be considerable and remarkable number observed by all urologists but still many complications have been recorded started from failure to access of the ureteric orifice, trauma, bleeding, perforation, false passage, migration of stone, infection, avulsion of ureter and late stricture ureter formation [(3)].

The aim of the present study was to assess the difference between complete retrieval of small stone gravels versus spontaneous passage of these gravels after pneumatic lithotripsy of uretral stones as regard intraoperative and post-operative complications and stone clearance at the Urology Department of Al-Azhar University Hospital (Assuit).

PATIENTS AND METHODS

This was a randomized controlled clinical trial was carried out at the Urology Department, Al-Azhar University Hospital between February 2021 and August 2021. It included 60 patients with lower ureteric stones admitted to the Urology Department for endoscopic management.

Patients were randomly classified into two groups; **Group I:** We intend to leave gravels less than 3 mm as measured by comparison its size to the guide wire for spontaneous passage to reduce the operative time and intraoperative complications of frequent manipulations, and **Group II:** Patients were subjected to complete retrieval of stones after disintegration regardless the operative time.

Inclusion criteria: (1) Single unilateral ureteric stone. (2) Mild or moderate hydronephrosis and hydroureter. (3) Radio opaque Ureteric stones are equal to 10 mm as measured by CT in its biggest diameter. (4) No distal obstruction or associated pathology. (5) Good renal function in both sides. (6) Fresh or recurrent cases.

Exclusion Criteria: (1) Associated Congenital anomaly. (2) Bilateral stones. (3) Bleeding diathesis. (4)

Received: 17/04/2022
Accepted: 14/06/2022

Patient with previous uretrovesical reimplantation. (5) Evidence of renal pathology on contralateral side.

All cases were subjected to the following:

A. Clinical evaluation in the form of full history taking, general and local examination.

B. Laboratory investigation: *Urine analysis, urine culture and sensitivity, blood urea and serum creatinine and blood sugar, blood coagulation profile and liver function tests.

C. Routine Imaging studies: Plain urinary tract, abdomino-pelvic sonography and CT scan.

D. All patients had informed consent and explanation of the potential complications all received profelactic antibiotics. Overnight fasting, plain film is routine done before and after the operation.

Operative Procedures:

All patients were subjected to spinal anaesthesia, the patients in the lithotomy position, sterilization and towing, and the procedure was started with preliminary urethrocystoscopy (karl stors uretroscope 9Fr) to evaluate the urethral and the bladder and to identify the ureteric orifice.**,** A guide wire 0.038 inch (polytetrafluoroethylene) floppy tip straight negotiate the ureteric orifice under vision , Dilatation of ureteric orifice and intramural part of the ureter was performed by graduated Teflon dilators in 50 patients (83.3%). And the last 10 patients (16.6%) not need any dilatations as the ureteric orifice was wide and the uretroscope passed easily in the intramural portion of the ureter. Under direct vision, Graduated Teflon dilators were passed over guide wire through cystoscope sheath up to 12 Fr then withdrawn with the cystoscope leaving the guide wire in place. Fluoroscopic confirmation of the position of the wire in the renal pelvis obtained.

In this study a semirigid ureteroscope (73cm) (and 9 fr in diameter) karl storz type have been used under direct vision by camera system (storz iada system) and have been introduced beside the safety guide wire, intracorporeal fragmentation of the stone was done by pneumatic lithoclast probe15 beats/second in all cases , we intend to leave gravels less than 3 mm as measured by comparison its size to the guide wire for spontaneous passage to reduce the operative time and intraoperative complications of frequent manipulations in group I, While Patients subjected to complete retrieval of stones after disintegration are classified as group II.

At the end of operation fixing ureteric catheter or the double j or no stenting at all was judged according to the time of manipulation and the presence of evidence of trauma, so that for some patients in both groups double J was fixed and for others ureteric catheter was fixed, and small number of both of them undergo without stenting.

Patients showing no evidence of trauma and complete disintegration of stone had neither need for ureteric catheter nor for double J.

A ureteric catheter was fixed and left in place for 48 hour in 20 patients (33%) and double J stent was fixed in 30 patients (50%) and 10 patients (16%) has no evidence of trauma, and short operative time no stent left behind.

The operative time was measured from beginning of the urethrocystoscopy to the end of the procedure.

At the end of operation Patients are classified into two groups:

Group I: Patients with gravels less than 3 mm as measured by comparison its size to the guide wire for spontaneous passage.

Group II: Patients subjected to complete retrieval of stones after disintegration.

All patients was subjected to medical observation, antibiotics was given after the operation.

Hospitalization was 24-48 hours in most cases except those had got intraoperative complications. Intera-operative complications were measured in both groups early post-operative complications were estimated for all patients.

All patients were subjected to low dose CT film before discharging to estimate residual stones and place of double J stent.

Follow up visits in outpatient clinic for all patients a weak after operation then monthly for 6 months, in each visit patients are subjected to ultrasound, low dose CT film, urine analysis and culture and sensitivity if needed.

Retrieval of double J was done after 2 week except for 5 cases with perforation which removed after 1 month, while ureteric catheter after 48hours.

Ethical approval:

The study was approved by the Ethics Board of Al-Azhar University and an informed written consent was taken from each participant in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

All data are collected and linked to its corresponding group and we use statistical analysis which is SPSS (Statistical Package for Social Sciences, version 20, IBM, and Armonk, New York). Quantitative data with normal distribution are expressed as mean ± standard deviation (SD) and compared with student's t test. Nominal data are given as number (n) and percentage (%). Chi^2 test was implemented on such data. Level of confidence was kept at 95% and hence, P value was considered significant if <0.05.

RESULTS

Age and sex among studied groups:

It was found that both groups had insignificant differences as regard mean age of enrolled patients

(32.80 ± 18.63 vs. 38.63 ± 13.88 years; p=0.10). Majority (21 (70%) of group I and 24 (80%) of group II) was males with no significant difference between both groups (p= 0.27).

Table (1): Comparison between studied groups regarding age and sex.

Variable	Group I (n= 30)	Group II (n= 30)	P value
Age (year) Range	32.80 ± 18.63 18-60	38.63 ± 13.88 18-63	0.10
Sex Male Female	 21 (70%) 9 (30%)	 24 (80%) 6 (20%)	 0.27

Data expressed as number (percentage), mean (SD). P value was significant if <0.05.
Group I included those patients underwent spontaneous fragment expulsion.
Group II included those patients underwent intraoperative fragment retrieval.

Operative time and intraoperative complications in studied groups:

Patients who underwent intraoperative fragment retrieval had significantly longer operative time in comparison to those underwent spontaneous fragment expulsion (57.53 ± 15.13 vs. 34.90 ± 8.14 minute; p<0.001). Operative time ranged between 36 and 88 minute in case of fragment retrieval and between 25 and 54 minute in case of spontaneous fragment expulsion. Only 2 (6.7%) patients from those underwent spontaneous fragment expulsion and 5 (16.7%) patients from those underwent intraoperative fragment retrieval developed intraoperative complications with no significant differences (p= 0.21).

Table (2): Operative time and intraoperative complications in studied groups

Variable	Group I (n= 30)	Group II (n= 30)	P value
Operative (minute) Range	34.90 ± 8.14 25 - 54	57.53 ± 15.13 36 - 88	< **0.001**
Intraoperative complication	2 (6.7%)	5 (16.7%)	0.21

Data expressed as mean (SD). P value was significant if <0.05.

Follow up at 1st week postoperatively in studied groups:

During the follow up at 1st week postoperatively; it was found that patients underwent spontaneous fragment expulsion had significantly higher frequency of burning micturition [20 (66.7%) vs. 12 (40%); p= 0.03], lower abdominal pain [20 (66.7%) vs. 12 (40%); p=0.03] and pyria [20 (66.7%) vs. 12 (40%); p=0.03] in comparison to those underwent intraoperative fragment retrieval. Also, frequency of loin pain [16 (53.3%) vs. 7 (23.3%); p=0.01] and background pressure in ultrasound [16 (53.3%) vs. 7 (23.3%); p=0.01] were significantly higher in group I. Residual stones at 1st week follow up were noticed in 16 (53.3%) patients of group I.

Table (3): Follow up at 1st week postoperatively in studied groups

Variable	Group I (n= 30)	Group II (n= 30)	P value
Burning micturition	20 (66.7%)	12 (40%)	**0.03**
Loin pain	16 (53.3%)	7 (23.3%)	**0.01**
Lower abdomen pain	20 (66.7%)	12 (40%)	**0.03**
Residual stones	16 (53.3%)	0 (0%)	< **0.001**
Pyria	20 (66.7%)	12 (40%)	**0.03**
Backpressure in U/S	16 (53.3%)	7 (23.3%)	**0.01**

Data expressed as number (percentage). P value was significant if <0.05. **U/S:** ultrasound

Follow up at 1st month postoperatively in studied groups:

During the follow up at 1st month postoperatively; none of those underwent intraoperative fragment retrieval developed loin pain, lower abdomen pain, residual stones nor backpressure in ultrasound but four cases of them developed burning micturition and pyuria. In contrast, 16 (53.3%), 11 (36.7%), 14 (46.7%), 9 (30%), 11 (36.7%), and 12 (40%) patients from those underwent spontaneous fragment expulsion had burning micturition, loin pain, lower abdomen pain, residual stones, pyria, and backpressure in ultrasound, respectively.

Table (4): Follow up at 1st month postoperatively in studied groups

Variable	Group I (n= 30)	Group II (n= 30)	P value
Burning micturition	16 (53.3%)	4 (13.3%)	**0.03**
Loin pain	11 (36.7%)	0 (0%)	**<0.001**
Lower abdomen pain	14 (46.7%)	0 (0%)	**<0.001**
Residual stones	9 (30%)	0 (0%)	**<0.001**
Pyria	11 (36.7%)	4 (13.3%)	**0.03**
Backpressure in U/S	12 (40%)	0 (0%)	**<0.001**

Data expressed as number (percentage). P value was significant if < 0.05. **U/S:** ultrasound

Follow up at 2nd month postoperatively in studied groups:

During the follow up at 2nd month postoperatively; none of those underwent intraoperative fragment retrieval developed loin pain, lower abdomen pain, residual stones and backpressure in ultrasound but two cases of them developed burning micturition and pyuria. In contrast, 16 (53.3%), 10 (33.3%), 13 (43.3%), 6 (20%), 8 (26.7%), and 9 (30%) patients from those underwent spontaneous fragment expulsion had burning micturition, loin pain, lower abdomen pain, residual stones, pyria, and backpressure in ultrasound, respectively.

Table (5): Follow up at 2nd month postoperatively in studied groups

Variable	Group I (n= 30)	Group II (n= 30)	P value
Burning micturition	16 (53.3%)	2 (6.7%)	**<0.001**
Loin pain	10 (33.3%)	0 (0%)	**<0.001**
Lower abdomen pain	13 (43.3%)	0 (0%)	**<0.001**
Residual stones	6 (20%)	0 (0%)	**0.01**
Pyria	8 (26.7%)	2 (6.7%)	**0.04**
Backpressure in U/S	9 (30%)	0 (0%)	**<0.001**

Data expressed as number (percentage). P value was significant if <0.05. **U/S:** ultrasound

Follow up at 3rd month postoperatively in studied groups:

During the follow up at 3rd month postoperatively; none of those underwent intraoperative fragment retrieval developed loin pain, lower abdomen pain, residual stones nor backpressure in ultrasound but two cases of developed burning micturition and pyuria. In contrast, 12 (40%), 7 (23.3%), 11(36.7%) and 1(3.3%) patients from those underwent spontaneous fragment expulsion had burning micturition, loin pain, lower abdomen pain, and residual stones respectively.

Table (6): Follow up at 3rd month postoperatively in studied groups

Variable	Group I (n= 30)	Group II (n= 30)	P value
Burning micturition	12 (40%)	2 (6.7%)	**<0.001**
Loin pain	7 (23.3%)	0 (0%)	**<0.001**
Lower abdomen pain	11 (36.7%)	0 (0%)	**<0.001**
Residual stones	1(3.3%)	0 (0%)	**<0.001**
Pyria	0 (0%)	2 (6.7%)	0.55
Backpressure in U/S	1(3.3%)	0 (0%)	---

Data expressed as number (percentage). P value was significant if <0.05. **U/S:** ultrasound

Regarding postoperative complications, there is only one case from group I required re intervention to extract stone residual after failed spontaneous expulsion of stone fragments.

DISCUSSION

The choice of treatment for distal ureteric stones remains one of the most heavily debated subjects in urology. Among the retrospective series, success rates are in general higher with ureteroscopy than with ESWL. Nonetheless, some groups recommend ESWL as first-line therapy as it is less invasive, despite ESWL being associated with inferior stone-free rates. Prospective randomized trials have also evaluated the optimum treatment of distal ureteric stones **(4).**

In our work we favoured the uretroscopy for treatment of distal ureteric stones and we achieved comparable results. On a practical basis, the lower ureter can be accessed almost all the time with a semi-rigid uretroscope. Using pneumatic lithotripter, make ureteroscopy is associated with small stone gravels and fewer secondary interventions. In addition Ureteroscopy has also become less invasive and the risk of complications is lower with modern instruments. Among series published between 1996 and 2021, the overall incidence of ureteroscopic complications for distal stone manipulation was 7%. Furthermore, the incidence of ureteric stricture was < 2% and the incidence of ureteric perforation < 4% in recent studies **(5-6)**.

In our work, the precautions and measures were in consideration to avoid any complications, so that intracorporeal fragmentation of the stone was done by pneumatic lithoclast disintegrations of the stones, and solving any complications intraoperatively by safety positioning guide wire to make the introduction of the uretroscope and their accessories more easy, so that we achieved a good results and reasonable complications.

In comparison of intraoperative complication we found that patients of group II had significantly longer operative time in comparison to those of group I [57.53 ± 15.13 vs. 34.90 ± 8.14 minutes; p<0.001]. Operative time ranged between 36 and 88 minute in case of fragment retrieval and between 25 and 54 minute in case of spontaneous fragment expulsion.

We aim to decrease operative time as we can to decrease the cost of operation, decrease infection rate, decrease complication of prolonged anaesthesia and intraoperative complications.

The total intraoperative complication rate in our patients was 11%, 2 (6.7%) patients from group I and 5 (16.7%) patients from group II.

False passage occurred in 2 patients (3%), ureteral small perforation by pneumatic lithotripsy probe occurred in 5 patients (8%), which is compatible to that reported by **Schuster *et al.*** **(6)** and higher to that reported by **Elashry *et al.*** **(7)** **and Tawfiek E and Bagley** **(8)**.

In the current endourological era, with wide access to newer, smaller semi rigid and flexible instruments

and use of small calibre intracorporeal lithotripsy devices, the complication rate and morbidity of ureteroscopy have been significantly reduced compared with earlier series. Currently, the rates for ureteric perforation and stricture are 2–4% and 0–2%, respectively [110, 111].

During the follow up at 3rd month postoperatively; none of those underwent intraoperative fragment retrieval developed loin pain, lower abdomen pain, residual stones and backpressure in ultrasound but two cases of developed burning micturition and pyuria.

In contrast, 12 (40%), 7 (23.3%), 11(36.7%) and 1(3.3%) patients from those underwent spontaneous fragment expulsion had burning micturition, loin pain, lower abdomen pain, and residual stones respectively.

Regarding postoperative complications, there is only one case from group I required re intervention to extract stone residual after failed spontaneous expulsion of stone fragments.

In a similar study, **Chew *et al.*** [9] examined the natural history, complications and re-intervention rates of residual fragments after ureteroscopy (URS). Among six centres, 232 subjects were found to have residual fragments after URS and were followed for a mean of 16.8 months. Surprisingly, irrespective of their size, residual fragments had a 27% chance of passing spontaneously after URS and 73% remained at follow-up. Even fragments of 4mm or less 28% grew in size, 18% of patients underwent re-intervention and 22% experienced a complication such as emergency department visits and colic pain. These data strongly support the concept that although patients with residual fragment of 4mm or less have a low retreatment risk, they should be closely monitored over the long-term.

Our results are superior to that recorded by **Chew *et al.*** [9] as we only left residual less than 3 mm in size.

In our study at the end of ureteroscopy fixing ureteric catheter and the double j or no stenting at all was judged according to the time of manipulation and the presence of evidence of trauma, so that for some patients in both groups double j was fixed and for others ureteric catheter was fixed, and small number of both of them undergo without stenting.

Patients showing no evidence of trauma and complete disintegration of stone there had neither need for ureteric catheter nor double J.

In this study fixation of ureteral catheter was done and left in place for 48 in 20 patients (33%) and DJ stent was fixed in 30 patients (50%) and 10 patients (16%) has no evidence of trauma, and short operative time no stent left behind.

Routine placement of stent is not preferred by some authors as in those patients who do not require ureteral dilation during ureteroscopic procedures. Ureteral stent placement after ureteroscopy may be avoided in many patients, that reducing operative time, surgical costs, and patient morbidity [5].

In this study stenting was preferred especially in presence of residual stone fragments and with of minor truma at least for short period by uretral catheter. **Hofmann *et al.*** [10] believe Stenting of the ureter for 4 – 6 weeks (average 3 weeks) may prevent ureteral stricture if significant ureteral trauma has occurred during ureteroscopy**.** Other authors such as **Denstedt *et al.*** [11] **and Hosking *et al.*** [12] reported non stented patients had fewer symptoms, short hospital stay and no differences in terms of complications and stone free status.

Our results are compatible to those achieved by **Coll *et al.*** [13] who study the Relationship of spontaneous passage of ureteral calculi to stone size and location as revealed by unenhanced helical CT. and reported that:

Tawfiek and Bagley [8] reported result which are better than our result. They noted 100% success rate with distal ureteric stone extraction with no intraoperative or postoperative complications. This difference in results can be explained that all ureteroscopic procedures were done by the same urologist using basket & forceps intact extraction, EHL, PL. **Peschel *et al.*** [14] reported a complete ureteroscopic stone-free rate in (40 patients) without complications were noted in either group, but the procedure was faster in ureteroscopy and satisfying in all patients. **Pearle *et al.*** [15] prospectively randomized 32 patients with distal stones (diameter <1.5 cm) to ureteroscopy; both treatments cleared the stones completely. Our study is compatible to the studies conducted by **Peschel *et al.*** [14] and **Pearle *et al.*** [15].

CONCLUSION

Ureteroscopy is a common minimally invasive treatment modality utilized in the treatment of ureteral stones. Despite the widespread use of ureteroscopy, there are very few studies regarding the natural history of stone fragments following ureteroscopy. Leaving gravels 3 mm or less after uretroscopic lithotripsy is associated with mild post-operative symptoms as abdominal pain, burning micturition but less operative time, less complication of anaesthesia, less operative cost less effort from surgeon and less intraoperative complication, so that this method is advisable.

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

Sources of funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Author contribution: Authors contributed equally in the study.

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