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The Efficacy and Safety of Simultaneous Use of Wire Stone Basket and Pneumatic Lithotripter Probe in the Treatment of Ureteral Stones: Randomized Control Trial

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Authors' contributions

This work was carried out in collaboration among all authors. Authors MA, MN and MRF participated in draft, design, analysis, interpretation and writing the manuscript. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: A routine treatment of ureteral stones is using ureteroscopic lithotripsy, a common problem of which is retropulsion of the stone to the renal pelvis and calyces that reduces the rate of lithotripsy's success. In this study, we aim to investigate the safety and success of using wire basket to hold the stones along with pneumatic lithotripstic probe in endoscopic lithotripsy of ureteral stones.
Methods: Patients with ureteral stone were randomly divided to groups A and B. Group A (control) undergone lithotripsy without basket and group B (case) with wire basket along with pneumatic lithotripsy. In addition to demographic and clinical data, rate of success, retropulsion and residual stone with a size of greater than 3 mm were collected, before, during and after lithotripsy. Additionally, the total duration of lithotripsy and ureteral traumatic side effects was also recorded in both groups. All the patients were followed up until their discharge. Data was analyzed using SPPSS ve. 20.
Results: There was no significant difference between groups by the point of demographic data. When compared together, there was no significant difference between the location, side and size of

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the stone and duration of the lithotripsy in both groups. The rate of lithotripsy success was significantly higher in the case group. The incidence of retropulsion and need for a secondary intervention was significantly higher in the control group. We didn't have any ureteral trauma in neither control nor case group.

Conclusion: Based on the results of this study, using wire basked as an anti retropulsion device increases the stone free rate in addition to it's easy applicability, So it can be useful in treatment of ureteral stone.

Keywords: Ureteral stone; stone retropulsion-ureteroscopic; lithotripsy- stone basket.

1. INTRODUCTION

The stone of the urinary tract is common and it has a high cost to healthcare and insurances [1]. The ureter is divided into two segments of proximal and distal, the boundary of which is the narrowing of the ureter on the iliac vessels [2]. Most surgical interventions of urologist are ureter stones. With the advancement of technology today, many ureter stones can be treated with a transurethral lithotripsy by the ureteroscope and it is the first line of treatment in case the lower ureter stone is not excreted on its own and the second line of treatment after extracorporeal shake wave fail in the proximal ureter stones [3]. The main objective in the treatment of ureter stones is achieving maximum stone-free rate with minimal side effects. In the 2007 document, the success rate of treatment in ureteroscopic lithotripsy was reported 81% in proximal ureter stone and 91% in distal ureter stones. ureteroscopy was better than eswl in treatment any size stones in distal ureteral ,as well as for proximal uretral stones greater than 10 m [2].

The pneumatic lithotripters that crush the stone with the projectile mechanism and energy transfer, are effective devices with a high safety margin, low cost and low risk and their success rate have been reported 73 to 100 percent in all types of stones. One of the disadvantages of this type of lithotripter is the high rate of stone retrograde migration, retropulsion, which involves the movement of stone or its fragments to the proximal ureter and the kidney during ureteroscopic lithotripsy, with the thrust of the lithotripter. Stone retropulsion, which is in 2 to 17 percent of cases in ureter stone treatment, has been reported in all lithotripters [4-6]. Desai MR, et al reported 5-40% rates of stone retropulsion during ureteroscopic lithotripsy of proximal and distal ureteral stone cases [7]. Its rate for all types of pneumatic lithotripter is 15 to 48 percent [8-10].Several studies in the treatment of ureter stones have shown that the most common cause of stone removing failure can be attributed to the migration of stone parts [11]. Retropulsion rate is more common in proximal ureter stones and often the failure of lithotripsy is due to inability to recapture the stone in a hydronephrotic ureter [2].

The risk of stone retropulsion or the escaping of the stone is affected by factors such as washing fluid pressure, the energy source type of transurethral lithotripsy, the location and the amount of stone compression in the ureter, and the proximal ureter dilatation severity. The rate of stone migration in pneumatic and electrohydraulic lithotripters is higher than that of a laser lithotripter [11]. Stone upward migration may increase the time of lithotripsy due to time waste of trapping stones fragments that have migrated to the back.

Also, the increment of costs is when it is necessary to change the ureteroscopic technique to the flexible kind to find stone parts or when it is required to do secondary interventions for large retrograded parts, such as inserting a ureteric stent, a shock wave lithotripsy (SWL), and a repeat of ureteroscopy [12].

Different strategies and tools have been designed and developed that are anti-retropulsion and stone- trapping to prevent stone retrograde migration during ureteroscopic lithotripsy. These include the placement of patients in the reverse tredelenburg state and reduction of the flow and washing pressure during lithotripsy.

Different mechanical tools for preventing stone retropulsion include: 1-Lithovac suction device 2-Stone basket 3- N-Trap 4- stone cone 5-Accordion 6-Passport balloon [2,8,11,13-15]. Also, the use of the lubricant gel and back stone gel have been reported and this substance is injected into the proximal part of the stone and prevents stone retropulsion [11].

Because of the convenience and delicate design and the smaller size of the new baskets and lower costs due to the re-usability option and longer durability and limited access to other tools that prevent stone retropulsion and their higher cost and lower durability, we decided to test the simultaneous use of a stone wire basket without a plastic cover with a pneumatic lithotripter probe, to keep the stone in simultaneous lithotripsy.

2. METHODS AND MATERIALS

Patients referred to the Urology Clinic of Baqiyatallah Hospital in 2017 were selected according to their medical history, examination and standard imaging studies, including ultrasound with KUB or IVP or CT scan without contrast, ureter stone with ureteroscopic lithotripsy indications.

Entry Criteria were: 1. Ureteral stones with severe pain symptoms, resistant to supportive and therapeutic treatments. 2. Obstructive ureter stones. 3. Ureter stones that are less likely to be excreted based on size, location, duration of onset of pain and hydronephrosis, 4 bilateral or solitary kidney ureteral stone, Which has impaired renal function. 5. Proximal ureter stones resistant to ESWL due to obesity of the patient or the hardness of the stone, and disfavoring of ESWL by the patient due to its less success rate or the need for secondary intervention. These patients were selected for ureteroscopic lithotripsy. Patients were informed of the study method and that they may be randomly assigned to a group, a control group (without a device), or a group with a wire basket. Disadvantages and benefits of the treatment were explained to them. Patients who agreed entered this study after giving consent.

Exit criteria were: 1. Patients with urinary tract infection and pyonephrosis, 2.lack of proper cardiovascular conditions and lack of cardiac or anesthesia permission,3. patients who didn't consent on ureteroscopic lithotripsy and choosing of ESWL in proximal ureter stones 4.patients with lack of access to stones during ureteroscopy due to ureter stenosis

The necessary tests were performed on patients included in the study. These tests included CBC, BUN, Cr, Na, K, U/A, and U/C, and the demographic and clinical data of patients including age, sex, size, and location of the stones were recorded. The patients were divided into two groups by random allocation, Group A, as the control group, without a wire basket, and Group B with a wire basket in simultaneous use of the pneumatic lithotripter.

The assigner and the patients themselves were not aware of which group they were in. In each group, ureteroscopy was performed using a standard ureteroscope of 9.5 F. After reaching the stone in Group A, it was crushed with the Pneumatic lithotripter probe. During lithotripsy, Minimum flow of water was used and the bed was put in an angular position by raising the patient's head and single direction shots for minimizing stone retropulsion were used.

In the B group the 3F wire basket helical type with 4 wires were passed through the working channel of the urethroscope and were routed to the proximal part of the stone, and the stone was routed into the basket , then it was kept inside the basket , and the probe of the pneumatic lithotripter was also passed through the same working channel and lithotripsy was done. Conditions during lithotripsy were observed just like the control group. Ureteroscopic lithotripsy was performed by a urologist in both groups under similar technical conditions. The findings during and after the completion of the lithotripsy including the success, the duration of the lithotripsy and the traumatic complications of the ureter were recorded in both groups. The success criteria were the conversion of stones into disposable 3 mm and smaller pieces, the absence of ascending stones or parts larger than 3 mm into the kidney and the lack of need for secondary interventions for the remaining pieces.

Patients were followed up during hospitalization in the department of urology which was most often the next day after the operation, and two weeks after being discharged at the clinic for potential complications related to ureteroscopic lithotripsy that may not be detected during or immediately after surgery.

2.1 Data Analysis Methods

Data collected from patients were stored in SPSS software version 20. To compare the quantitative data between the two groups, the parametric test of the Independent sample T was used and the qualitative data were compared between the two groups using Chi-square test and Fisher exact test. Non-parametric Mann-Whitney test was used if the quantitative data distribution was not normal. To determine the parametric and non-parametric quantitative variables, the one-sample K-S statistical test was

used. Finally, a subgroup analysis was performed for both groups to examine the factors influencing the outcome. For all tests, the significance level was considered to be 0.05.

3. RESULTS

A total of 124 patients with an average age of 44.27±13.22 years were studied (Table 1). There was no significant difference in the distribution of gender (male or female), the side of the ureter carrying the stones (left or right) and the location of the stone (proximal or distal) in the two groups. The average of stone size and duration of pneumatic lithotripsy in the two groups did not have a significant difference.

The maximum stone free rate was evaluated in a total of 124 patients in both case group with wire basket and control group without wire basket, and the first was highly successful and had a significant difference with the control group. (Table 2), no ureter trauma was observed in any of the patients. Stone retropulsion was observed in a total of 16 patients in both groups. Significantly stone retropulsion frequency was higher in the control group (Table 3).

The frequency of secondary need for intervention and type of intervention, especially the operation of ESWL, was high in the control group and the difference in the intervention need that was significant in the control group (Table 4). The

Table 1. Stone side and location in two groups

		Control group (N=62)	Case group (N=62)	Total (N=124)
Age	0/666P=	43/76(±12/94)	44/79(±13/58)	44/27(±13/22)
Gender				
Male		41 (%66/1)	50 (%80/6)	91 (%73/4)
Female	0/104P=	21 (%33/9)	12 (%19/4)	33 (%26/6)
Stone side				
right		29 (%46/8)	31 (%50)	60 (%48/4)
left	0/719P=	33 (%53/2)	31 (%50)	64 (%51/6)
Stone location				
Proximal		35 (%56/5)	38 (%61/3)	73 (%58/9)
Distal	0/584P=	27 (%43/5)	24 (%38/7)	51 (%41/1)
Stone Size (mm)	0/375P=	8/806(±3/73)	9/339(±2/88)	9/07(±3/33)
Time (min)	0/572P=	17/44(±4/61)	16/89(±6/06)	17/16(±5/37)

Table 2. Stone free success rate in two groups

Stone free	Control group (N=62)	Case group (N=62)	Total (N=124)
Successful	47 (%75/8)	57 (%91/9)	104 (%83/9)
unsuccesful	15 (%24/2)	5 (%8/1)	20 (%16/1)
P Value	0/015		

Table 3. Frequency of retropulsion in two groups

Retropulsion	Control group (N=62)	Case group (N=62)	Total (N=124)
Has	12 (%19/4)	4 (%6/5)	16 (%12/9)
Doesn't have	50 (%80/6)	58 (%93/5)	108 (%87/1)
P Value	0/032		

Table 4. The frequency of the need for secondary intervention and the type of intervention performed in two groups

Secondary intervention	Control group (N=62)	Case group (N=62)	Total (N=124)
ESWL	5 (%8.1)	0 (%0)	5 (%4)
ESWL + DJ	7 (% 11.3)	2 (%3.2)	9 (%7.3)
Uretroscopy + DJ	3 (%4.8)	3 (%4.8)	6 (%4.8)
No need	47 (%75.8)	57 (%91.9)	104 (%83.9)
P Value	0.033		

Table 5. Investigating the effect of stone location on Stone retropulsion

Stone location		Stone retropulsion		P Value
		Yes	No	
Control group	Proximal	8 (%66.7)	27 (%54)	0/427
	Distal	4 (%33.3)	23 (%46)	
Case group	Proximal	3 (%75)	35 (%60.3)	0/495
	Distal	1 (%25)	23 (%39.7)	

Table 6. Summary of the present study results

	Control group (N=62)	Case group (N=62)	P Value
Age (years)	43.76 ± 12/9	44.79 ± 13.5	0.666
Gender (male / female)	21 /41	12 /50	0.104
Stone location (distal / proximal)	35 /27	38 /24	0.584
The side of the stone (right / left)	33 /29	31 /31	0.719
Stone Size (mm)	8.8 ± 3/7	9.34 ± 2/8	0.375
Lithotripsy duration	17.44 ± 4/6	16.89 ± 6.06	0.572
Success	47 (%75.8)	57 (%91.9)	0.015
Retropulsion	12 (%19.4)	4 (%6.5)	0.032
Secondary intervention			
ESWL	5 (%8.1)	0 (%0)	0.033
ESWL + DJ	7 (%11.3)	2 (%3.2)	
Uretro + DJ	3 (%4.8)	3 (%4.8)	
No need	47 (75.8)	57 (%91.9)	
Ureter trauma	0 (%0)	0 (%0)	-

location of stone in the ureter did not have a significant relationship with the rate of retropulsion in either group. (P> 0.05) (Table 5).

Thus, the available RCTs are inconclusive regarding treatment of non-lower pole stones.

4. DISCUSSION

In this study**,** in total, 16.1% of patients had to undergo a secondary intervention, which included ESWL, ESWL with DJ, and re-ureteroscopy with DJ. The frequency of secondary intervention in the control group was significant, and in general, 19.4% of patients needed ESWL. But in the case group, it was 2.3%. In our center, it is nearly eight years that the method of using a wire basket for holding the stone simultaneously and simultaneous lithotripsy with a pneumatic lithotripter probe in an ureteroscope working channel is used and in our opinion, the duration of operation is reduced and it has reduced the need for secondary interventions, and many times the stones in the renal pelvis have also been treated with this method. This is a unique method, and people who work with it are satisfied with ureter stone treatment, and it is especially highly successful in the treatment of hard stones. By knowing this method, fear of using stone wire baskets fades away. In this method, we did not encounter a single case of traumatic avulsion in more than a thousand patients during this period. The purpose of this study was to prove the success of the treatment and compare the use of this method to the control group without the wire basket. In our study, there were no notable differences among both groups in the case group with the wire basket and the control group without the wire basket in the demographic data. There were also no significant differences between the location and the side of the stone, stone size and lithotripsy duration between the two groups. The success rate of lithotripsy was significantly higher in the case group ($p < 0.05$). Confounding factors were evaluated by subgroup analyzes. Age, sex, and location of the patients' stones had no significant confounding effect on the success of the lithotripsy, its duration and the rate of stone retropulsion. The stone size had a significant confounding effect on the success rate and duration of lithotripsy in both groups ($p < 0.05$). Stone size had a significant effect on stone retropulsion only in the case group. In our study, the frequency of stone retropulsion was remarkably higher in the control group. The need for secondary intervention was considerably higher in the control group than in the case group ($p < 0.05$). The need to perform ESWL and ESWL with DJ was significantly higher in the control

group ($p < 0.05$). Several studies in the treatment of ureteroscopic lithotripsy have shown that the most common cause of failure of lithotripsy can be attributed to stone retropulsion and the movement of stone pieces into the pelvis or kidney calyx during lithotripsy [11]. This can increase costs due to secondary interventions and morbidity [12,16-18].

Knisple, et al. reported stone retropulsion in 40% of proximal ureter stones cases and 5% of cases in distal ureter stones [10]. Ursiny M and Eisner BH, studied the cost-effectiveness of the use of stone retropulsion barrier tools during urethroscopic lithotripsy in 2013 at Harvard University and stated that due to the assessment of these tools' costs and the cost of secondary actions due to stone retropulsion, the use of a barrier tool that prevents stone retropulsion during urethroscopic lithotripsy is more than 6.6% cost-effective [13]. although most of this tools have limitations that prevent their routine use during ureteroscopic lithotripsy treatment [19].

In an RCT study in 2011 at Tanata University of Egypt, Farahat Ya, et al. examined the safety and success of two ureter obstructive tools called N-trap and stone cone for the purpose of preventing stone retropulsion in pneumatic lithotripsy. In this study, stone retropulsion in the stone cone group, was significantly lower than the other two groups [20]

In the two groups of the stone cone and N-trap, the residual stone fragments (mm3), ureter trauma, operation time and ureter stent need were significantly less than the control group. In the stone cone group in comparison with the other two groups, stone removing rate was significantly higher and the need for secondary intervention and ureter trauma was lower.

In this study, no clear ureter trauma was observed in any of the patients. Compared to the aforementioned study the complications of our study were lower, and other results were generally consistent with it and were closer to the results of the stone cone and better than the results of the N-trap [20].

No similar research to this study, i.e., using pneumatic lithotripter with a wire basket in the treatment of ureter stones was found in any scientific database. In one case, Kroczak, et al. used this method in laser lithotripsy in 2018 and had a high success rate in the treatment of ureter stones. Operation time, the possibility of stone retropulsion and the remaining fragments of stone have decreased.

He cites that the disadvantage of this method is the fear of tearing one of the wire basket wires in a laser collision. Though if three wires were still intact, it has been useful in stone lasering, and he reported this method as a unique technique. In the present study, similar to Kroczak's study, the operation time was shorter, and success was higher and the need for a secondary procedure was reduced, and the only difference with the study of Kroczak is the use of pneumatic lithotripter instead of fiber lasers and with this probe, control might be harder with the heavy piston handle and the use of mechanical thrusts, but it's affordable and accessible in comparison to the laser [21]. In another study, wang, et al. in China in 2011 investigated the effect of N-trap on proximal ureter stones treatment. In this RCT study, 113 patients with 57 patients in the control group and 56 in the N-trap group were present. They found that in the control group, stone retropulsion was significantly higher, and the operation duration and the use of sedatives were significantly higher in the N-trap group. There were no notable differences in the frequency of complications in these studies. Longer operation duration can increase the side effects and symptoms of the urinary tract due to UVJ edema or compression of stone fragments in the ureter wall [14].

In this study, although there was no significant difference between the mean lithotripsy duration in the two groups, it was less in the case group than the control group. Due to the fact that the average size of the stone in the case group is higher and the direct and significant relationship between lithotripsy duration and stone size it can concluded that the use of wire baskets has been effective in reducing the duration of lithotripsy.

5. CONCLUSION

The use of wire baskets as a barrier for stone retropulsion simultaneously with the pneumatic lithotripter probe increases the amount of stone removing and decreases stone retropulsion and the need for re-intervention. Using this tool does not have a significant effect on the duration of the lithotripsy process and this technique can be used simply simultaneously with the pneumatic lithotripter probe, which can increase the success of ureter stone treatment, especially proximal ureter stones.

6. SUGGESTIONS

Although the use of this wire basket technique as a barrier tool for stone retropulsion along with the pneumatic lithotripter probe in this study increased the success rate of lithotripsy and didn't have any clear ureter complications, there were no further studies on this subject and experience and the urologist's skill may affect the results, so further studies are needed to determine the success and safety of this technique.

CONSENT

As per international standard or university standard written patient consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocol was approved by the Ethics Committee of Baqiyatallah University of Medical Sciences.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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