The clinical efficacy of novel vacuum suction ureteroscopic lithotripsy in the treatment of upper ureteral calculi

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Research Article

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Abstract

This study investigated the clinical efficacy of a novel vacuum suction ureteroscopic approach in the treatment of upper ureteral calculi. A total of 160 patients with impacted upper ureteral calculi were included in this study. 50 patients underwent rigid ureteroscopic lithotripsy, 54 patients underwent flexible ureteroscopic lithotripsy, and 56 patients underwent vacuum suction ureteroscopic lithotripsy. The operative time, length of hospitalization, stone-free rate, complication rate and total treatment cost were compared among the three groups. Subgroup analysis was performed based on the stone diameter over and below 1.5 cm. Compared with the other two groups, the vacuum suction ureteroscopy group had higher stone-free rate at 3–5 days (90.0% vs. 61.9% vs. 55.6%, $P < 0.05$) and 1 month (96.4% vs. 77.7% vs. 74.0%, $P < 0.05$) postoperatively. In subgroup analysis, the stone-free rate of the vacuum suction ureteroscopy group was significantly higher when the stone diameter was > 1.5 cm at 1 month postoperatively ($P < 0.05$); however, there were no differences in postoperative complications.($P > 0.05$). In conclusion, the novel vacuum suction ureteroscopic lithotripsy has significantly improved the stone-free rate especially in complicated cases; however the complication and cost was not increased.

Introduction

Ureteral stones are common and the obstruction caused by stones can adversely affect the quality of life of patients [1].There are many options for treatment, such as extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), and retrograde intrarenal surgery (RIRS) [2]. Currently, RIRS is preferred by many clinicians, especially in the management of upper and middle ureteral stones [3].

In general, the absence of residual stones or the presence of stone fragments < 4 mm are clinical indicators of stone-free status. However, even small residual stone fragments can still cause symptoms, such as low back pain, hematuria, and infection. Furthermore, the time required for the complete elimination of stone fragments is variable, so achieving stone-free status in a theoretical sense is of great importance [4]. Ureteroscopic lithotripsy with self-made negative pressure device that can improve the stone-free rate has been reported[5].

Recently, we have performed some ureteroscopic lithotripsy cases with a suction device that can effectively eliminate the stone fragments and reduce the risk of infection. In this study, the clinical efficacy of this new device was evaluated.

Results

160 patients with upper ureteral calculi were included in this study. Their demographic data and clinical characteristics are shown in Table 1.

Table 1
Demographic characteristics data of patients according to patients ‘group

Parameter	Vacuumsuctionureteroscopy group	Flexible ureteroscopy group	Rigid ureteroscopy group	F/χ^2	*P*
n	56	54	50		
Age	53.8 ± 12.1	55.2 ± 10.2	54.3 ± 11.6	0.202	0.817
Gender Male/Female	34/22	37/17	25/25	3.728	0.155
BMI	25.77 ± 3.37	26.91 ± 3.49	26.76 ± 3.40	1.804	0.168
Creatinine	80.06 ± 29.38	85.29 ± 24.09	79.92 ± 31.18	0.628	0.535
Stone duration (month)	2.90 ± 3.44	3.05 ± 3.13	3.61 ± 4.14	0.567	0.568
Stone hardness (1000 HU)	708.59 ± 343.70	684.22 ± 376.30	665.04 ± 309.61	0.213	0.809
Stone diameter (mm)	13.9 + 4.7	12.7 + 5.5	12.48 + 4.9	2.769	0.606
Stone location Left/right	28/28	25/29	23/27	0.217	0.897
Preoperative infection Yes/No	5/40	4/37	4/38	0.727	0.695
SWL history Yes/No	15/41	17/37	12/38	0.751	0.687

The operative time of the rigid ureteroscopy group was significantly shorter than that of the flexible ureteroscopy group and vacuum suction ureteroscopy group ($P < 0.05$). However, there were no differences in postoperative complications ($P > 0.05$).The total treatment cost in vacuum suction ureteroscopy group was much lower than that in both rigid ureteroscopy group and flexible ureteroscopy group($P < 0.05$).

In this study, the sheath placement was first failed in 3 patients, and the patients were treated successfully by the vacuum suction ureteroscopy two week after D-J stent placement; however no ureteral stricture or trauma was found in this study during the follow up period (3 months). The stone-free rate was significantly higher in the vacuum suction ureteroscopy group than that in the other two groups at 3–5 days and 1 month postoperatively ($P < 0.05$) According to the modified Clavin grading system, there were no complications above grade IV in the three groups. There were only two cases with grade I complications (infection and fever) in the vacuum suction ureteroscopy group; four cases with grade I complications (three cases of infection and fever and one case of renal colic that was treated with an analgesic) in the rigid ureteroscopy group; and three cases with grade I complications (infection and fever) in the flexible ureteroscopy group. (Table 2).

Table 2
Intraoperative and Postoperative data according to patients' group

Parameter	Vacuum suction ureteroscopy group	Flexible ureteroscopy group	Rigid ureteroscopy group	F/χ^2	P
n	56	54	50		
Operative time	46.4 ± 17.9^a	57.3 ± 28.5^b	39.1 ± 13.6^c	10.06	0.01
Treatment cost(US. Dollar)	2622.6 ± 794.7	3274.4 ± 903.3	2883.6 ± 1030.7	4.56	0.04
Complication rate (n (%))	2(3.6)	3(5.6)	4(8.0)	3.48	0.18
*Stone-free rate at 3–5 Days (n (%))	$18/20(90.0)^a$	$13/21(61.9)^b$	$10/18(55.6)^b$	8.49	0.00
Stone-free rate at 1 month (n (%))	$54(96.4)^a$	$42(77.7)^b$	$37(74.0)^b$	5.48	0.01

Note: Different a, b and c indicate multiple comparisons among groups that are significantly different; * indicates the stone-free rate of patients was re-examined by CT postoperatively.

In stratified analysis according to the maximum stone diameter (< 1.5 cm and > 1.5 cm), there was no significant difference in the stone-free rate among the three groups at 1 month postoperatively when the stone diameter was < 1.5 cm ($P > 0.05$). When the stone diameter was > 1.5 cm, the stone-free rate of the vacuum suction ureteroscopy group was significantly higher than that of the other two groups at 1 month postoperatively ($P < 0.05$) (Table 3).

Table 3
Comparison of perioperative parameters of stone size stratification, stone-free rate, and postoperative complications

Variables	Stone ≤ 1.5cm			P	Stone > 1.5 cm			P
Sub-Group	Vacuumsuctionureteroscopy group	Flexible ureteroscopy group	Rigid ureteroscopy group		Vacuum suction ureteroscopy group	Flexible ureteroscopy group	Rigid ureteroscopy group	
number	32	30	34		24	24	16	
Operation time	41.7 ± 10.8^a	51.5 ± 24.2^b	34.4 ± 9.7^c	0.001	46.6 ± 11.2	59.1 ± 11.7	45.6 ± 18.6	0.475
Treatment costs	2438.4 ± 749.3	2944.3 ± 880	2585.3 ± 773.3	0.035	2796.3 ± 947.4	3395.1 ± 715.0	2875.1 ± 852.4	0.047
Complication (n(%))	1(3.1)	2(6.67)	2(5.9)	0.680	1(4.1)	1(4.1)	2(12.5)	0.234
Stone-free rate 1month (n(%))	32(100.0)	27(91.7)	29(85.2)	0.257	$22(91.6)^a$	$15(62.5)^b$	$8(50.0)^b$	0.001

Note: Different a, b and c indicate multiple comparisons among groups that were significantly different.

Discussion

The surgical treatment for upper ureteral stones is ureteroscopic lithotripsy and percutaneous nephrolithotomy. Percutaneous nephrolithotomy has a very high stone-free rate, but its complications, including pain, bleeding, and even loss of kidney are not rare [7]. Therefore, ureteroscopic lithotripsy is still regarded as the first-line of treatment by some clinicians [8–10].

Generally, ureteroscopic lithotripsy is safe and effective [8–11]. However, retrograde stone or stone fragments migration is an important factor affecting the success of intraoperative lithotripsy in both rigid and flexible lithotripsy. The use of devices such as stone cone can indeed decrease the risk of stone fragment retrograde retropulsion, but will undoubtedly increase the treatment cost. However, the stone-free rate of most patients immediately after surgery is not high; a long time is needed for the stone residues to pass by themselves. There are two methods for the intraoperative management of calculi by ureteroscopy. The first method (dusting) is to break the calculi into small pieces as tiny as possible, which are slowly discharged postoperatively; the other method is to remove the stone fragments as best as possible by using the stone basket after the stones are fragmented. The former prolongs the lithotripsy time and the latter may inevitably increase the damage to the ureter through the repeated removal of the stone fragments. Although the ureteral access sheath (UAS) may alleviate this damage [12], it is not always satisfactory. Therefore, further studies are needed to improve the initial stone-free rate of ureteroscopic lithotripsy [13].

The novel vacuum suction ureteroscopic approach combines the advantages of ureteroscopy and percutaneous nephrolithotomy. The principle of continuous vacuum suction is basically the same as that of ultrasonic lithotripsy. During the whole process, stones can be continuously drawn and flushed out. However, sometimes stone fragments may get stuck in the sheath while suctioning. If it did happen, it was always safe to break the fragments by laser in the sheath because the metallic sheath can prevent ureteral injury effectively.

By adjusting the vacuum suction device to control the force of suction, the stones are driven and pressed to the tip of the sheath by the vacuum suction force, greatly improving the lithotripsy efficacy and reducing the operative time. Vacuum suction greatly decreased the risk of infection. There is plenty of space between the lithotripsy endoscope(6F) and the working sheath (13F); vacuum suction speeded up the circulation of irrigating water, which helps to ensures the clear view of surgical field and helps to take away the heat generated by the holmium laser [14], thereby reducing thermal injury.

The cost of vacuum suction ureteroscopic lithotripsy was significant lower than that of the other two groups. Devices used to prevent the stone retro-migration or help to clean the stone fragments such as stone cone or stone basket were not used in this group. The working sheath was reusable, which further limited the cost of the procedure. If the stone retro-migration happened, the operation can be easily converted to flexible ureteroscopic lithotripsy by just changing the scope without changing the working sheath.

The stone-free rate of the vacuum suction ureteroscopy group was also much higher than that of the other two groups. In subgroup analysis, we found that the stone-free rate became more significant when the stone diameter was > 1.5 cm, indicating that vacuum suction ureteroscopic lithotripsy would be better in the treatment of larger or complicated stones. In terms of postoperative complications, there was no difference among the three groups.

It is undeniable that this novel vacuum suction ureteroscopy approach has some disadvantages. Firstly, the semi-flexible sheath is made of metallic material, which is possible to cause damage to the ureter, requiring the surgeon to be very familiar with the anatomical structure and to be as gentle as possible, especially in physiological bends. Sheath placement failure may occur in patients with ureteral stricture. For patients who fail to place the sheaths, placing the D-J stent for 2 weeks is suggested. Secondly, although vacuum suction devices can significantly reduce the renal pelvic pressure [15], there is a lack of effective devices to monitor the real-time changes of the suction force and renal pelvic pressure [16]. Therefore, it is necessary for the surgeon to be experienced and to arrive at an effective judgment of the lithotripsy procedure.

In conclusion, vacuum suction ureteroscopy has significantly improved the stone-free rate compared with traditional rigid and flexible approaches. When dealing with large and complicated upper ureteral stones, vacuum suction ureteroscopic lithotripsy is a better option.

Methods

Study Design

The data of 160 patients with upper ureteral stones who were eligible for treatment at our hospital from January 2018 to January 2020 were retrospectively collected in this study. Fifty patients underwent rigid ureteroscopic lithotripsy, 54 patients underwent flexible ureteroscopic lithotripsy, and 56 patients underwent vacuum suction ureteroscopic lithotripsy.

All patients underwent pre-operative CT, urine analysis, urine culture, routine blood analysis, coagulation function tests, and creatinine level. Preoperative prophylactic antibiotic therapy was given to all patients, and sensitive antibiotic was given to patients with positive urine cultures. Stents were preoperatively placed only in patients with obstructing stones and urinary sepsis.

The inclusion criteria were as follows: patients with unilateral upper ureteral calculi who were not recommended for ESWL or patients refused to take ESWL or PCNL. According to Chinese Urology Guidelines, the upper ureter is defined as the imaging segment, which extends from the pelviureteric junction to the upper margin of the sacroiliac joint (or the lower margin of the fourth lumbar vertebra). The exclusion criteria were as follows: patients with a solitary kidney; those who needed concurrent treatment for kidney stones or bilateral ureteral stones; and those who were lost to follow-up.

The study design was approved by the ShengJing hospital ethics review board (NO.2018PS266K). The study was not a clinical trial, the data was retrospectively collected from the hospital database. Due to the retrospective nature of the study, the need for informed consent was waived by China Medical University. The study protocol was done following relevant guidelines.

Surgical procedures

The new vacuum suction ureteroscope (Figure 1) consisted of a standard ureteroscope (9.8F), a lithotripsy endoscope (6F), a standard semi-rigid ureteroscopic access sheath (13F) and a vacuum suction device.

In the vacuum suction ureteroscopy group, patients received general anesthesia and were placed in the lithotomy position. First, the sheath was connected to the standard ureterscope and placed near the stones under the guidance of direct vision by the standard ureterscope, and then the standard ureterscope was withdrawn. The vacuum suction device was connected to the end of the ureteroscopic sheath, the lithotripter (6F) was fixed to the sheath, and a 200-μm holmium laser fiber was inserted into ureterscope for lithotripsy. After lithotripsy, a 6F D-J tube was indwelled. (Video 1).

For patients who failed to place the sheaths, D-J stent were placed first and the patients were treated two week after D-J stent placement.

In the rigid ureteroscopy group, patients received general anesthesia and were placed in the lithotomy position. An 8/9.8F ureteroscope was inserted into the ureter under the guidance of a guide wire. After confirming the location, the stones were fragmented with holmium laser; Stone Cone wasused in some cases to stop the stone from retrograde-migration and a 6F D-J stent was indwelled after the completion of operation.

In the flexible ureteroscopy group, patients received general anesthesia, flexible ureteroscopic access sheath (13F) was placed near the stone, and a holmium laser fiber was used to break the stones with the help of flexible ureteroscopy. Stone basket was used to remove the fragments. A 6F D-J stent was indwelled routinely.

The operative time was defined as the time from the start to the end of anesthesia. Patients were re-examined by CT at 3–5 days postoperatively, and those patients who were not stone free were re-examined by CT to judge the residual stone status at 1 month postoperatively. The double-J stents were usually removed 2 weeks after the operation. The stone-free rate was defined as the absence of residual stones upon CT examination. Complications were assessed using a modified Clavin grading system. All the patients were followed up for 3 months after the operationto determine whether or not they had a post-surgical stricture.

Due to the retrospective nature of the study, the need for informed consent was waived; additionally, the study design was approved by the ShengJing hospital ethics review board. Authors had no access to information that could identify individual participants during or after data collection. All clinical investigations were conducted according to the principles expressed in the Declaration of Helsinki.

Statistical methods

Measurement data were described as mean ± standard deviation (SD), and counting data were expressed as frequency (number). Data were analyzed by SPSS 23.0 software. According to the normality and homogeneity of variance of measurement data, one-way ANOVA was used for comparisons between groups, and the LSD-t test was used for multiple comparisons between groups. In addition, the RxC contingency table chi-square test was used to compare distribution differences of the composition ratio between groups, and the chi-square segmentation method was used for multiple comparisons between groups. *P*-values <0.05 were considered statistically significant.

Declarations

Authors' contributions:

LV Wen Zhang: Data collection, manuscript writing

Yan Song: Study design, supervision

Xiang Fei: Data analysis, manuscript writing

Declarations

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Ethics approval: the study design was approved by the ShengJing hospital ethics review board.

Consent to participate: Due to the retrospective nature of the study, the need for informed consent was waived

Consent for publication: The study was approved by the ShengJing hospital ethics committees for Consent for publication

Availability of data and material: Supporting data can be accessed via the hospital database by contacting the corresponding author upon request.

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Figures

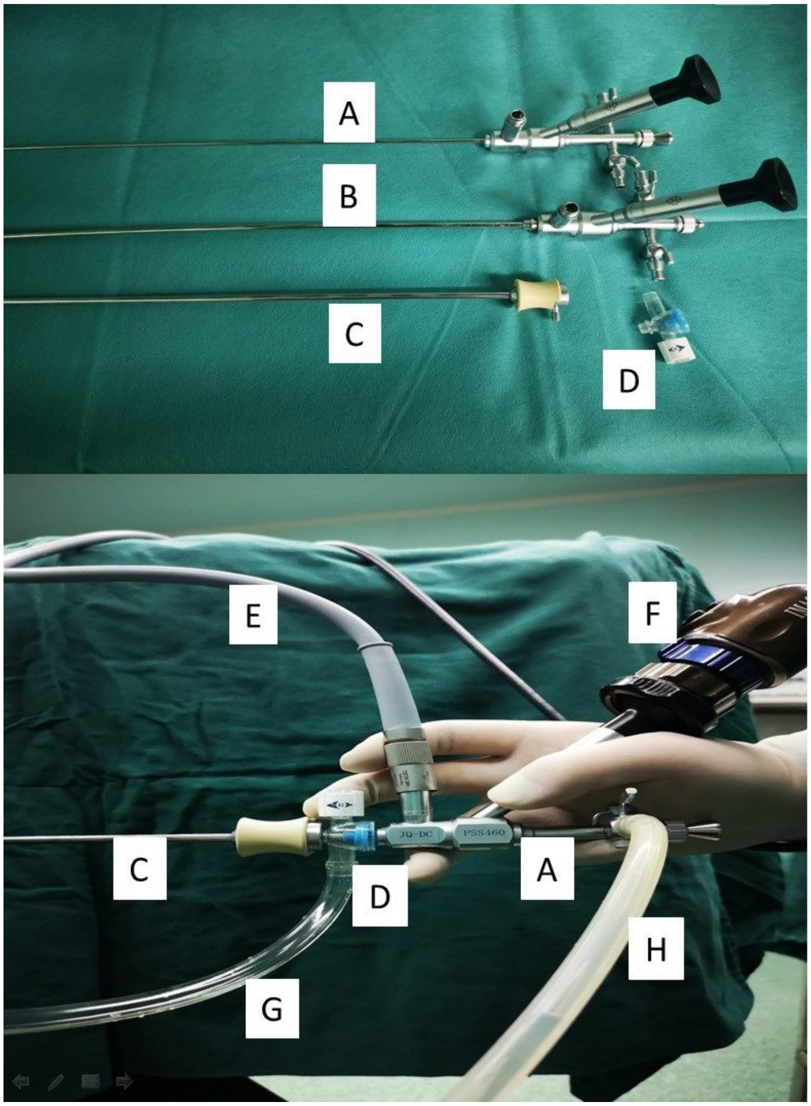

Figure 1

The new vacuum suction ureteroscope (Figure 1) consisted of a standard ureteroscope (9.8F), a lithotripsy endoscope (6F), a standard semi-rigid ureteroscopic access sheath (13F) and a vacuum suction device. A: Vacuum pipe. B: Vacuum suction control. C: Irrigation pipe. D: ureteroscopic access sheath. E: lithotripsy endoscope. F: light. G: Camera.

Supplementary Files

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- Thevacuumsuctionureteroscopiclithotripsy.mp4