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

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Abstract
Objective To investigate the clinical efficacy of a novel vacuum suction ureteroscopic approach in the treatment of upper ureteral calculi and to compare it with traditional rigid and flexible ureteroscopic approaches.

Subjects and methods 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, the incidence of postoperative complications, 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.

Results All operations were performed successfully, and there were no cases converted to open surgery. Compared with the other 2 groups, the vacuum suction ureteroscopy group had a 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 (\(P<0.05\)) compared with that in the other 2 groups; however, there were no differences in postoperative complications. (\(P>0.05\)).

Conclusion The novel vacuum suction ureteroscopic lithotripsy has significantly improved the stone-free rate especially in complicated cases, compared with that in rigid and flexible approaches; however, the complication and cost were not increased.

Keywords Upper ureteral calculi · Ureteroscopic lithotripsy · Vacuum suction ureteroscopy · Clinical efficacy

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 a 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.
Patients and 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. The choice of the surgical device was mostly made by the surgeons’ preference and also the availability of the device.

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.

The inclusion criteria were as follows: patients with unilateral upper ureteral calculi who were not recommended for ESWL or patients who 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.

Surgical procedures

The new vacuum suction ureteroscope (Fig. 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 ureteroscope and placed near the stones under the guidance of direct vision by the standard ureteroscope, and then the standard ureteroscope 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 the ureteroscope for lithotripsy. After lithotripsy, a 6F D-J tube was indwelled (Video 1).

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 guidewire. After confirming the location, the stones were fragmented with holmium laser; Stone Cone was used in some cases to stop the stone from retrograde-migration and a 6F D-J stent was indwelled after the completion of the operation.

In the flexible ureteroscopy group, patients received general anesthesia, a flexible ureteroscopic access sheath was placed near the stone, and a holmium laser fiber was used to break the stones with the help of flexible ureteroscopy. A stone basket was used in some cases 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 follow-up time is up to 3 months to assess the long-term complication such as ureteral stenosis. The stone-free rate was defined as the absence of residual stones upon CT examination. Complications were assessed using a modified Clavin grading system.

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.

**Results**

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

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 the vacuum suction ureteroscopy group was much lower than that in both the rigid ureteroscopy group and flexible ureteroscopy group (\( P < 0.05 \)). 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 1).

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 2).

**Table 1** Demographic characteristics data of patients according to patients’ group

| Parameter                        | Vacuum suction ureteroscopy group | Flexible ureteroscopy group | Rigid ureteroscopy group | \( F/\chi^2 \) | \( P \) |
|----------------------------------|----------------------------------|-----------------------------|--------------------------|----------------|--------|
| \( N \)                          | 56                               | 54                          | 50                       |                |        |
| Age (years)                      | 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                              | 20.77 ± 3.37                     | 21.91 ± 3.49                | 21.76 ± 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 ± 343.7                   | 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  |

**Table 2** Intraoperative and Postoperative data according to patients’ group

| Parameter                        | Vacuum suction ureteroscopy group | Flexible ureteroscopy group | Rigid ureteroscopy group | \( F/\chi^2 \) | \( P \) |
|----------------------------------|----------------------------------|-----------------------------|--------------------------|----------------|--------|
| \( N \)                          | 56                               | 54                          | 50                       |                |        |
| Operative time                   | 46.4 ± 17.9a                     | 57.3 ± 28.5b                 | 39.1 ± 13.6c             | 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   |
| \( ^{a} \) 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   |
| \( ^{b} \) Stone-free rate at 1 month [\( n \% \)]  | 54 (96.4)b                       | 42 (77.7)b                  | 37 (74.0)b              | 5.48           | 0.01   |

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


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 [6, 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 cones can indeed decrease the risk of stone fragment retrograde repulsion, 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 ensure a clear view of the 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 significantly 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 ureteroscopic 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 a ureteral stricture. For patients who fail to place the sheaths, placing the D-J stent for 2 weeks is suggested. In this study, the sheath was first failed in 3 patients, and the patients were treated 2 weeks after D-J stent placement; however, no ureteral stricture or trauma was found in this study during the follow-up period. 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.

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Authors contributions Protocol/project development: YS. Data collection or management: LWZ. Data analysis: XF. Manuscript writing/editing: LWZ, YS.

Declarations

Conflict of interest The authors declare that there are no conflicts of interest.

Ethics approval The study design was approved by the ShengJing hospital ethics review board. Due to the retrospective nature of the study, the need for informed consent was waived.

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