

Original Article

A comparative study to analyze the efficacy and safety of flexible ureteroscopy combined with holmium laser lithotripsy for residual calculi after percutaneous nephrolithotripsy

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Abstract: A certain proportion of patients with initial Percutaneous nephrolithotripsy (PCNL) management require ancillary procedures to increase the stone-free rate. In this study, we aim to analyze the efficacy and safety of flexible ureteroscopy combined with holmium laser lithotripsy (F-UL) for treatment of residual calculi after PCNL by comparison with extracorporeal shockwave lithotripsy (SWL). Total of 96 patients with residual renal calculi (4 mm to 20 mm) after PCNL was enrolled from May 2010 to March 2013. They were randomly divided into two groups: US Group: patients were treated with F-UL; SWL Group: patients were treated with SWL. Follow-up was made one month and three months after treatment. The mean residual stone size after PCNL was 12.4 ± 4.3 mm in US group compared with 11.9 ± 4.5 in SWL group. The stone-free rate was 84.7% one month after surgical procedure in US group, this rate increased to 91.3% in the third months, while the stone-free rate in SWL group is 64.6% one month after treatment and 72.9% in the third month. For residual stone in lower calyx, the stone-free rate three month after treatment was 90.4% in US group compared to 65.2% in SWL group ($P < 0.05$). The overall complication rate was low in both groups, no severe complication was found. Both F-UL and SWL are safe and effective methods for residual calculi after PCNL, without severe complications. F-UL provided significantly higher stone-free rate compared with SWL, especially for low-pole calculi.

Keywords: Flexible ureteroscopy, holmium laser lithotripsy, percutaneous nephrolithotripsy

Introduction

Nephrolithiasis is a very common disease which affects 5% of the population in the United States [1, 2]. Without treatment, it may finally leads to chronic kidney disease and renal failure. The main treatment option for renal stone includes percutaneous nephrostolithotomy (PCNL), extracorporeal shockwave lithotripsy (SWL) and retrograde intrarenal surgery (RIRS). The European Association of Urology (EAU) and American Urological Association (AUA) guidelines for the management of renal calculi > 20 mm recommend PCNL as the first-line therapy. PCNL is well accepted as the initial treatment for large renal calculi, especially partial and complete staghorn calculi. However, it is reported that the stone-free rate of PCNL monothera-

py was 74%-83% [3, 4]. A certain proportion of patients with PCNL treatment require some other ancillary therapeutic strategies to increase the stone-free rate.

SWL is recommended as the first-line treatment option by EAU and AUA for renal calculi < 20 mm [3]. It is commonly used to treat the residual calculi after PCNL [5]. However, SWL sometimes shows unsatisfied efficacy for stones in lower pole of kidney [6]. Recently years, with the development of the ureterorenoscopy and laser lithotripsy, they were considered as standard therapy for ureteral stone [7]. Modern flexible ureteroscopy are able to visualize the entire intrarenal system in 94-100% of the patients, even the lower calyces of the kidney [8, 9]. An increase in use of retrograde intrarenal surgery

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with flexible ureteroscopy for smaller size (especially size from 15 mm to 20 mm) intrarenal calculi was showed since its better stone-free rate compared to SWL [10, 11].

In this study, 96 patients with residual calculi after PCNL were enrolled from May 2010 to March 2013. They were randomly divided into two groups with flexible ureteroscopy combined with holmium laser lithotripsy (F-UL) and SWL for treatment of residual calculi, respectively. We aim to analyze the efficacy and safety of flexible ureteroscopy combined with holmium laser lithotripsy for treatment of residual calculi after PCNL by comparison with SWL.

Materials and methods

Patients

Total of 96 patients with large renal calculi (> 2 cm) were enrolled in our study from May 2010 to March 2013. All of these patients had undergone PCNL treatment and residual calculi were found by Computed Tomography Urography (CTU) one month after PCNL procedure. For the PCNL procedure, single access was applied to 91 patients and double access was applied for 5 patients. 56 access was located to upper pole of kidney and 45 access was located to middle pole of kidney. Inclusion criteria consisted of the diameter of residual calculi ranged from 4 mm to 20 mm. The patients with anatomic anomalies of the kidney and severe complications after PCNL were excluded. We used random number function for the sample randomization before study. 96 patients were randomly divided into two groups: one group of patients was treated with surgical procedure of flexible ureteroscopy combined with holmium laser lithotripsy (US Group) and the other group was treated with SWL (SWL Group) one month after PCNL treatment. This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of Zhejiang University. Written informed consent was obtained from all participants.

Flexible ureteroscopy procedure

For the US group patients, we performed urinalysis, urine cultures, and sensitivity testing before operation and the antibiotics were given 1 day before the operation, the day of operation

and 2 days after operation. The procedures were performed under general anesthesia. Lithotomy position was used for the surgery on the endoscopy table. All the operations were finished by the same surgeon.

For all of the patients, flexible ureteroscopy (URF-V, OLYPUS) was routinely performed after the dilation of the ureter. A hydrophilic guide-wire was placed to the renal pelvis using a 7.5/8.4F ureteroscopy, which guided the placement of a ureteral access sheath (Flexor 12/14F, Cook). The sheath could facilitate flexible ureteroscopy and allow removal of large stone fragments and keep low intrarenal pressure. The stones were fragmented with holmium laser (Power Suite 100W Plus, Lumenis). The parameters of holmium laser were as following: fiber 200 μm , energy 1.0-1.5 J, power 18 W, aiming beam 80%, frequency 12 Hz. The stones should be fragmented small enough to pass spontaneously [12]. Some stone fragments were evacuated by ureteroscopic stone basket manipulation. In some patients, we relocated stones from low pole to the pelvis or upper pole by basketing to facilitate lithotripsy. After lithotripsy, A Double-J stent was placed. The Double-J stent was routinely removed 1 month after surgical procedure.

Follow-up

The first follow-up was one month later and before remove of Double-J stent, the second follow-up is three months after operation. At each follow-up, urine culture, urinalysis, serum creatinine test and Computed Tomography Urography (CTU) were performed. The stone free is defined as residual fragments < 4 mm.

SWL technique

For the SWL group patients, we used SWL to treat residual calculi one month after PCNL without remove of Double-J stent. The lithotripter we used was MODULARIS Variostar (SIEMENS). The initial voltage was 5 kV for SWL therapy to allow the patient be accustomed to the shocks. The voltage then gradually increased to a maximum of 9 voltages. The mean number of shocks per session was 2000-3500 [13]. The efficacy of the SWL treatment was checked by plain abdominal radiograph and ultrasonic examination. Multiple sessions were applied for the patients with poor efficacy or

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Table 1. Comparison of demographic variables in two groups

Variable	US (n = 46)	SWL (n = 48)	P-value
Age (Years)	42.3 ± 11.5	43.1 ± 12.1	0.743
Height (cm)	169 ± 8	170 ± 7	0.520
Body mass index (kg/m ²)	27.23 ± 4.4	27.48 ± 4.1	0.776
Gender			0.608
Male (%)	32 (69.5)	31 (64.6)	
Female (%)	14 (30.5)	17 (35.4)	
Stone size (mm)	12.4 ± 4.3	11.9 ± 4.5	0.583
Side of stone			
Right (%)	24 (52.2)	22 (45.8)	
Left (%)	22 (47.8)	26 (54.2)	
Position of stone			0.977
Upper calyx (%)	5 (10.8)	6 (12.5)	
Middle calyx (%)	8 (17.4)	7 (14.6)	
Lower calyx (%)	21 (45.7)	23 (47.9)	
Multiple calyces (%)	12 (26.1)	12 (25.0)	
Multiple residual calculi (%)	18 (39.1)	19 (39.6)	0.964
Stone CT Density (HU)	994.0 ± 408.8	990.8 ± 416.2	0.970
Skin to Stone Distance (cm)	6.3 ± 1.5	6.2 ± 1.4	0.761

Table 2. Overall outcome of analysis

	US (n = 46)	SWL (n = 48)	P-value
Mean operative time (min)	83 ± 18.5		
Hospitalization time (days)	2.4 ± 0.8	1.9 ± 0.5	0.0004
The stone-free rate			
Postoperative first month (%)	39 (84.7)	31 (64.6)	0.022
Postoperative third month (%)	42 (91.3)	35 (72.9)	0.021

multiple stones. The during between sessions is 7-14 days. The Double-J stent was routinely removed 1 month after SWL treatment. The follow up of this group of patients is the same as US group described as before.

Data analysis

For the compare of stone free rate and postoperative complications between both group, we used the chi-square test. For the mean of age, height, stone size, hospital stay and operative time, we employed *t* test. SPSS 11.0 was used for statistical analysis and *P* < 0.05 was considered as statistical significance.

Results

The demographic variables of two groups

A total of 96 patients fulfilled the inclusion criteria and involved in our study from May 2010

to March 2013. They were randomly divided into two groups as described above. For the US group of patients, 2 patients failed to perform flexible ureteroscopy because of ureteral stricture, which disabled the placement of ureteral access sheath. Finally, they were switched to PCNL treatment. Thus, a total of 46 patients were successfully performed flexible ureteroscopy and analyzed in this study. For the SWL group, 48 patients underwent SWL treatment. The demographic profiles of the two groups were comparable in (**Table 1**). The mean residual stone size after PCNL was 12.4 ± 4.3 mm in US group compared with 11.9 ± 4.5 in SWL group (*P* = 0.583). The residual stones in 39.1 percentages of patients in US group and 39.6 percentages in SWL group were multiple stones. There was no significant difference between the groups regarding patient sex, age, BMI, mean stone size, position of stone, stone CT density and skin to stone distance. (*P* > 0.05).

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Flexible ureteroscopy combined with holmium laser lithotripsy was successfully performed in all of US group patient. All of them were treated with one session of flexible ureteroscopy, the mean operative time for surgical procedure of F-UL was 83 ± 18.5 minutes. All 48 patients in the SWL group had a mean of number of 2.6 ± 1.1 sessions for stone disintegration and clearance. The mean hospitalization time was 2.4 ± 0.8 days in US group and 1.9 ± 0.5 days in SWL group. The stone-free rate was 84.7% (39/46 patients) one month after F-UL in US group, this rate increased to 91.3% in the third month after surgical procedure, while the stone-free rate in SWL group is 64.6% one month after SWL treatment and 72.9% in the third month after treatment. Statistical analysis demon-

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Table 3. The stone-free rate for stone in different position of renal calyx after three months

Position	US group	SWL group	P-value
Upper calyx (%)	5 (100)	6 (100)	
Middle calyx (%)	8 (100)	6 (85.7)	
Lower calyx (%)	19 (90.4)	15 (65.2)	0.049
Multiple calyces (%)	11 (91.7)	7 (58.3)	0.077

Table 4. Major complications in two groups

Complications	US (n = 46)	SWL (n = 48)	Clavien Classification	P-value
Over all complication rate (%)	8 (17.4)	7 (14.6)	I-II	0.778
Transfusion (%)	0 (0)	0 (0)		
Post procedure hematuria (%)	5 (10.9)	4 (8.3)	I	0.786
Renal hematoma (%)	0 (0)	1 (2.1)	II	
Fever > 38 °C (%)	3 (6.5)	2 (4.2)	II	0.259

strated that the stone free rate 1 month and 3 months after treatment in US group was dramatically higher compared to SWL group ($P < 0.05$, **Table 2**).

The position distribution of residual stones in both groups was described in (**Table 1**). The stone-free rate of different position was summarized in (**Table 3**). For the residual stone in upper calyx and middle calyx, both F-UL and SWL treatment generated very satisfactory stone-free rate. The stone-free rate three months after treatment for residual stone in lower calyx was 90.4% in US group compared to 65.2% in SWL group, the difference is significant ($P < 0.05$). The stone-free rate for residual stone in multiple calyces for US group is higher than SWL group (91.7% vs. 58.3%), the difference is not significant.

The complications of F-UL and SWL treatment

The overall complication rate was low in both groups (**Table 4**). Severe bleeding complication is very rare in both group and no patients need blood transfusion. Post procedure hematuria was the most common complication in both groups, which did not require special treatment. In the SWL group, 1 patient was found renal hematoma after treatment, who was managed conservatively. 6.5% of patient in US group and 4.2% of SWL group patient suffered from urinary infection after treatment and fever over 38°C. All of them were cured by antibacterial therapy. All of the complications were clas-

sified as grade I to grade II based on Clavien System. Overall, our data presented in this study indicated both treatments were safe.

Discussion

The AUA Guideline shows that PCNL should be the first-line treatment for patients with large renal calculi, particularly for the staghorn calculi. It is reported that the overall stone-free rates after PCNL treatment is 74%-83% regardless of stone size or location [3, 4, 7]. A certain part of patients with residual calculi after PCNL require ancillary

procedures. In our study, we employ both F-UL and SWL for the management of residual calculi after PCNL and compare the efficacy and safety. The data indicates that F-UL generated better stone-free rate compared to SWL treatment, without severe complications. Thus, retrograde flexible ureteroscopy represented a leap forward for the treatment of upper urinary calculi.

Guideline states that for the renal calculi > 2 cm, PCNL is recommended as initial treatment, while SWL for the renal calculi < 2 m. With the developments of the flexible ureteroscopes and laser lithotripsy, F-UL became more popular in recent years [3, 12, 14]. Grasso et al. reported that complete ureteroscopic fragmentation was achieved in 76% of renal stone patients and 95% of ureteral stone patients after one session of treatment [15]. After two sessions, completed fragmentation was achieved in 91% of renal stone patients, and the proportion increased to 93% after three sessions. A multi-institutional study analyzed the efficacy and safety of F-UL on management of calculi in an intermediate size ranged from 2 to 3 cm, the result showed that 78% of patients got outpatient surgery and stent was placed in 26% of the patients before surgery. 84% of patients underwent a single F-UL. Residual stone burden of 0-2 mm was showed in 63% patients. The complications rate was 6.7% [16]. However, very few studies report the data of employment of F-UL for treatment of residual calculi after PCNL. Our data presented here that the mean

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residual stone size after PCNL was 12.4 ± 4.3 mm. The stone-free rate was 84.7% (39/46 patients) one month after flexible ureteroscopy procedure and the rate increased to 91.3% in the third month after F-UL. The overall complication rate is 17.4%, all of which was mild. This means F-UL is an effective and safe ancillary treatment for residual stone after PCNL.

Advances in holmium laser lithotripsy dramatically contributes to high success rate of stone fragmentation. The increased flexibility and different sizes of laser fibers facilitate flexible ureteroscopy access of renal pelvis and calyx. The application of an access sheath may facilitate flexible ureteroscope passing the ureter and decrease intrarenal pressures, and also removal of large stone fragments is possible [17-19]. In addition, modern basket and retrieval devices are very useful tools to remove the fragments after lithotripsy and relocate the stone for easier stone fragmentation [20]. All of these strategies in F-UL contributed to better stone-free rate compared to SWL treatment, especially for low-pole stone [7, 21]. El-Nahas AR et al have compared flexible ureterorenoscopy with SWL for the treatment of lower pole stones of 10-20 mm. The matched groups included 37 patients who underwent flexible ureterorenoscopy surgery and 62 patients who underwent SWL. The stone-free rate was significantly better after flexible ureterorenoscopy compared to SWL treatment (86.5% vs 67.7%, $P = 0.038$) [22]. In our study, both F-UL and SWL treatment generated very satisfactory stone-free rate for the residual stone in upper calyx and middle calyx. The stone-free rate for residual stone in lower calyx was 90.4% in US group, which is significantly higher than SWL group (65.2%). The stone-free rate for residual stone in multiple calyces for US group is 91.7% and for SWL group is 58.3%. In our experience, following advantages of F-UL may contribute to better stone-free rate for low calyx compared to SWL. Firstly, holmium laser lithotripsy under flexible ureteroscopy is visual, which could facilitate stone fragmentation and fragment the stones to be much smaller pieces. Secondly, for the stone in lower calyx, we relocate the stones from the lower calyx to upper calyx or renal pelvis to facilitate the lithotripsy, meanwhile it may make the fragments be easier extraction by ureteroscopic stone basket. Thirdly, stricture of

calyx neck was detected in 5 of patients in US group, holmium laser was used for incision of calyx neck, which enabled the flexible ureteroscopy to reach the calyx and then perform lithotripsy. Taken together, flexible ureteroscopy combined with holmium laser lithotripsy is more effective for lower calyx stone.

The treatment costs include the costs of equipment, treatment (personnel, space and time), hospital stay and additional costs due to complications. The cost-effectiveness of both treatments was not studied in this paper since it is difficult to evaluate economics for stone treatment [23, 24].

Ultrasonography shows some advantages compared to CT scan or plain radiography, such as convenience and lack of radiation exposure. However, the recognition of residual stones is limited [25]. Also, it may mistake the multiple fragments as a bigger size single stone and be very hard to evaluate the size of single fragment among multiple residual stones. Continuing improvements in the spatial resolution and speed of newer CT scanners, combined with advanced multiplanar and volume-rendered image reconstruction, have made CTU a comprehensive examination for urological system, CTU was employed to evaluate the residual stone in our follow-up since CT scan present preferable reorganization for residual stones and also the size of fragments could be measured accurately [26]. However, there are some limitations in this study. This research is not a multi-center study and the sample size is relatively small, which require for future further study. Moreover, absence of stone chemical analysis is another limitation for this study.

Conclusions

The above data suggest that both F-UL and SWL are safe and effective methods for residual calculi after PCNL, without severe complications. F-UL provided significantly higher stone-free rate compared with SWL, especially for low-pole calculi. The incidence of complications after F-UL treatment was not significantly more than SWL treatment. Large prospective and multi-center trials comparing the two strategies are needed to further confirm this notion for residual stones after PCNL.

Disclosure of conflict of interest

None.

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Abbreviations

PCNL, percutaneous nephrolithotripsy; SWL, extracorporeal shockwave lithotripsy; F-UL, flexible ureteroscopy combined with holmium laser lithotripsy; RIRS, retrograde intrarenal surgery; BMI, body mass index; CTU, computed tomography urography (CTU).

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