Minimally Invasive Percutaneous Nephrolithotomy with a Novel Vacuum-assisted Access Sheath for Obstructive Calculous Pyonephrosis: A Randomized Study

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Purpose: To investigate the safety and efficacy of Minimally Invasive Percutaneous Nephrolithotomy (MPCNL) combined with vacuum-assisted access sheath in the treatment of obstructive calculous pyonephrosis.

Materials and Methods: Seventy-six patients with obstructive calculous pyonephrosis, who were planned to receive MPCNL, were randomly divided into two groups. Group A was treated with Amplatz sheath combined with Cyberwand double probe ultrasound lithotripsy, and group B was treated with Vacuum-assisted Access Sheath (VAAS, ClearPetra, Well lead Medical) combined with holmium laser lithotripsy. The primary outcome was the operation success rate. Other perioperative, and postoperative data such as operation time, stone free rate and complications were compared between groups.

Result: Single 20F access sheath was established in all cases. All patients underwent one-stage procedure. Compared with group A, group B had a higher initial stone-free rate (84.2% vs 63.1%, $P = .037$). The operation time of group B was 56.3 ± 19.83 min, significantly shorter than that of group A at 70.4 ± 14.83 min. The complication rate of B group was 15.8%, which was lower than that of group A ($P = .035$). Five patients (15.8 %) of group B had a postoperative fever (>38.5 ºC) (Clavien grade 2) that required additional antibiotics compared with 8 patients (21.1 %) of group A ($P = .361$). There was no blood transfusion in group A, and one case in group B required transfusion.

Conclusion: One-stage MPCNL combined with Vacuum-assisted Access Sheath and holmium laser lithotripsy is a simple, safe, effective, and ergonomically practical method for selected patients with obstructive calculous pyonephrosis.

Keywords: Minimally Invasive Percutaneous Nephrolithotomy; Vacuum-assisted Access Sheath; ultrasound lithotripsy; obstructive calculous pyonephrosis

INTRODUCTION

Obstructive calculous pyonephrosis with evidence of acute infection is a life-threatening disease requiring prompt decompression. In this situation, Minimally Invasive Percutaneous Nephrolithotomy (MPCNL) for complicated stones is more likely to exacerbate infection and urosepsis[(1)]. The simultaneous treatment of complicated stone in an obstructive pyonephrosis case can be of high risk for the patients as well as the surgeons, even if the surgeon is an experienced urologist. First-Stage drainage and second-stage stone management haven been considered as a more practical and irreproachable choice but it is not perfect. It prolongs the hospitalization, extends discomfort from nephrostomy tube retention, and increases the associated cost. Currently, urologists[(2-4)] from different institutions reported that one-staged MPCNL under continuous negative pressure aspiration systems, such as Swiss LithoClast@ Master, Cyberwand and patented suctioning system, has been performed in some of those patients. This maneuvers are highly successful without causing severe complications. However, such devices are either expensive or difficult to assemble.

In this study, we performed one-stage 20F MPCNL with a disposable and straightforward Vacuum-assisted Access Sheath (VAAS, ClearPetra, Well lead Medical, China) as shown in Figures 1 and 2 with suction-evacuation function in obstructive calculous pyonephrosis patients. This sheath differs from the peel-away access sheath by having an oblique egress sluice. It can be connected with a stone collection bottle which next links to a negative pressure aspirator. There is a pressure regulating vent on this sluice that can increase the pressure by pressing the slit. A flexible cap with a central aperture is located at the end of the straight sluice to achieve a closed system when inserting an endoscope through the aperture. Pus or purulent bolts and stone fragments are sucked out either through the space between the

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Table 1. Patients' inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
18-60 years old	Recent untreated UTI
Single Stone diameter< 3cm	Fever
Symptoms and signs were not obvious	Thick or foul pus in the initial aspirated urine
non-acute inflammation stage	Diabetes
Peripheral white blood cells were normal	History of previous kidney surgery and abnormal renal anatomy
Hemoglobin > 90 g/L	
Negative Urine Culture before operation	coagulopathy disorders
Serum procalcitonin < 2 ng/ml	Immunosuppressive diseases
CT value of Hydronephrotic region (HU)> 10	

scope and the sheath or the full working access by withdrawing the endoscope till the red line of the straight sluice. To our knowledge, this is the first report of clinical application of this device in obstructive calculous pyonephrosis.

MATERIALS AND METHODS

Study Population and design

This prospective and randomized trial was reviewed and approved by institutional review committee of Fifth Affiliated Hospital of Guangzhou Medical University (approval code No.20170518). The study design is 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 was registered at http://www.chictr.org.cn/enIndex.aspx (ChiCTR2000029275)

Between July 2017 to June 2018, 1028 patients underwent MPCNL at our center. Patients' inclusion and exclusion criteria were shown in **Table 1**. Written consent was obtained from all patients. Stone size was assessed by its largest diameter preoperatively in contrast CT scan. The CT value (HU) stone density and hydronephrotic region were measured[5]. Of 92 obstructive calculous pyonephrosis patients, 76 that met our criteria were assigned into two groups in a ratio of 1:1 based on the device and technique of MPCNL using the random number table (**Figure 3**). Group A was treated with peel-away access sheath (PAAS, Create Medic, Japan) combined with double probe ultrasound lithotripsy (Cyberwand, Olympus, Japan). Group B was treated with VAAS combined with holmium laser lithotripsy (VersaPulse PowerSuit 100w, Lumenis, Germany). All procedures were performed by one surgeon who has an experience of over 1000 MPCNLs management.

Procedures

All procedures were performed under continuous epidural anesthesia. Patients with negative preoperative urine culture were administrated by parenteral prophylactic antibiotics. Those with positive urine cultures were treated with sensitive antibiotics until the urine cultures were negative. All patients underwent MPCNL in the prone position. Renal puncture of the targeted calyx was performed under fluoroscopic and ultrasonic guidance. Pus or Purulent urine was sent for bacterial culture. Single 20F working access was obtained by one-step dilation in each case. Pus or Purulent bolts are respectively sucked out by Cyberwand in Group A and VAAS in Group B to decompression and having a good vision. Rigid 18Fr nephroscope (Richard Wolf, Germany) and Cyberwand were used in Group A with gravity perfusion. The lithotripsy principle of Cyberwand was described by Krambeck AE[6]. The inner probe vibrates at 21 000 Hz. The outer probe is free to move and is pushed outward by a sliding piston (free mass) driven by the vibration energy of the inner probe[6]. Stone fragmentation occurs both from the conventional high-frequency ultrasonic effect of the inner probe and from the ballistic action of the low-frequency outer probe[6]. The Cyberwand have hollow probes to allow suction capabilities.

In Group B, Rigid 12Fr mini-nephroscope (Richard Wolf, Germany) and VAAS were used with Irrigation Pump (Setting: workflow 200-300 mL/min, pressure 250 mmHg). VAAS was connected with the stone collection bottle, which was connected with the central operating room negative pressure (pressure setting: 0.035 MPa). Lithotripsy was done using 550 um holmium laser end-firing fiber (Lumenis, Germany) with the energy of 40-60 W (2J, 20-30 Hz). The suction method was done during fragments extraction. Small dust is sucked out through the gap between the scope and sheath and then pass through the oblique sluice to the stone collection bottle. When fragments come into the sheath are too large to cross the gap between the scope and the sheath, the urologist can withdraw the endoscope until the red maker to aspirate the fragment though the whole working access sheath. A 6 Fr. D-J was inserted in antegrade fashion, and a balloon nephrostomy tube was inserted at the end of the procedure in both groups.

We would convert to perform nephrostomy if the following intraoperative situation was encountered in patients of both groups.(1) Patients' body temperature was < 36 °C or > 38 °C; (2) Tachycardia was >90 bpm; (3) Respiratory rate > 20 or $PaCO_2$ < 32 mm Hg ; (4) Severe bleeding; (5) suctioning sluice was obstructed by thick pus.

Stone was sent out for analysis. Low dose non-contrasted CT was done on postoperative day one and postoperative 30 days to assess the immediate stone-free rate (ISFR) and Final SFR. Significant residual stones were treated with either shock wave lithotripsy, RIRS, or repeat MPCNL seven to 14 days later. Stone clearance was defined as no visible fragments in CT. The nephrostomy tube was generally removed when the drainage was grossly clear, and the patient was discharged the next day.

Evaluations

The primary outcome was the operation success rate. Other perioperative, and postoperative data such as operation time, stone free rate and complications were compared between both groups. Complications were classified via the modified Clavien system. SPSS 25 was used for data analysis. The measurement data were represented as mean ± standard deviation (x ± s) and

Table 2. Patients and stone characteristics

Variable	Group A	Group B	*P*-value
No. pts	38	38	
Age(year), mean ± SD[a]	40.2 ± 3.2	41.2 ± 2.8	0.2
Sex(M:F)[b]	18/20	16/22	0.65
BMI(kg/cm^2), mean ± SD[a]	23.1 ± 3.5	22.3 ± 4.2	0.12
Stone Size (mm), mean ± SD[a]	20.2 ± 6.5	23.4 ± 7.3	0.28
Side (L/R) [b]	21/17	18/20	0.34
CT Value (HU), mean ± SD[a]			
Stone density	919.45 ± 210.1	969.45 ± 241.4	0.23
Hydronephrotic region	20.21 ± 9.45	23.21 ± 10.47	0.17
Stone Location (n, %) [b]			0.32
Pelvis	14 (36.84 %)	17 (44.74 %)	
Upper pole	8 (21.05 %)	6 (15.79 %)	
Middle Pole	11 (28.94 %)	13 (34.21 %)	
Lower Pole	5 (13.16 %)	2 (5.26 %)	
Hydronephosis (n, %) [b]			0.42
Mild	16 (42.11 %)	14 (36.84 %)	
Moderate	22 (57.89 %)	24 (63.16 %)	
Stone composition (n, %) [b]			0.425
Calcium oxalate monohydrate	23 (60.5 %)	19 (50 %)	
Calcium Phosphate	10 (26.3 %)	8 (21.1 %)	
Uric	3 (7.89 %)	7 (18.5 %)	
Mixed	2 (5.26 %)	4 (10.6 %)	

Abbreviations: BMI, Body Mass Index; HU, Hounsfield Unit.
[a]Continuous variables were compared by independent samples *t*-test
[b]Categorical variables were compared by x^2 test

analyzed using the *t*-test. Count data were analyzed using χ^2 or Fisher's exact test. $P < 0.05$ was judged as a statistically significant difference.

RESULTS

Characteristics of patients and stones were comparable between the two groups (**Table 2**). Costovertebral angle tenderness was found in all patients. No case had fever on preoperative day 3. The HU of the hydronephrotic region in both groups is comparable, and purulent fluid was found in an initial puncture in each case. There were 91.1% and 81.5% of patients with opaque stone in Group A and Group B ($p = .175$) respectively.

All patients were successfully treated with MPCNL in one stage. Intraoperative and postoperative outcomes were showed in Table 3. Patients in group B had high ISFR (84.2 % vs 63.1%, $p = .037$). But there was no significant difference in terms of FSFR. Operative duration was shorter in group B (56.3 ± 19.83 vs 70.4 ± 14.83, $p = .035$). Significant different serum markers on postoperative day 1 was not found in any groups in terms of procalcitonin, hemoglobin, and cystatin C deficit. Positive puncture urine culture were detected in six patients of group B and seven of group A (15.8 % vs 18.4 %, $p = .28$)

The complication per modified Clavien classification was lower in group B (15.8 % vs 23.8%, $p = .035$). Five

Table 3. Intraoperative and postoperative outcomes and complication

Variable	Group A	Group B	*P* value
No. pts	38	38	
ASA score, mean ± SD[a]	1.87 ± 0.58	1.65 ± 0.63	0.15
Positive Urine Culture (Puncture), (n, %) [b]	6 (15.8 %)	7 (18.4 %)	0.28
Stone Free Rate, (n, %)[b]			
Postoperative day 1	24 (63.1 %)	32 (84.2 %)	0.037
Postoperative 30 days	33 (86.8 %)	36 (94.4 %)	0.43
Operative time, min, mean ± SD[a]	70.4 ± 14.83	56.3 ± 19.83	0.035
Postoperative Hospital stay, days, , mean ± SD[a]	3.5 ± 1.3	4.7 ± 2.1	0.36
Puncture calyx, (n, %)[b]			0.09
Upper pole	2(5.26 %)	3(7.89 %)	
Middle Pole	24(63.16 %)	28(73.68 %)	
Lower Pole	12(31.58 %)	7(18.42 %)	
Postoperative day 1 Serum parameters			
Hemoglobin deficit, g/dL, , mean ± SD[a]	5.4 ± 2.3	6.8 ± 2.2	0.07
Procalcitonin, ng/mL, , mean ± SDa	0.86 ± 0.73	0.94 ± 0.83	0.08
Cystatin C deficit, ug/L, , mean ± SD[a]	103.2 ± 66.80	104 ± 63.2	0.102
Modified Clavien-Dindo grade, (n, %) [b]			0.035
Grade 2	8 (21.1 %)	6 (15.8 %)	
Grade 3[a]	1 (2.7 %)		
Fever > 38.5°C, (n, %) [b]	8 (21.1 %)	5 (13.2 %)	0.361
Blood transfusion, (n, %) b	1 (2.7 %)	1	
Nephrostomy tube retention time extend, (n, %) [b]	1 (2.7 %)	1	

[a]Continuous variables were compared by independent samples *t*-test
[b]Categorical variables were compared by x^2 test

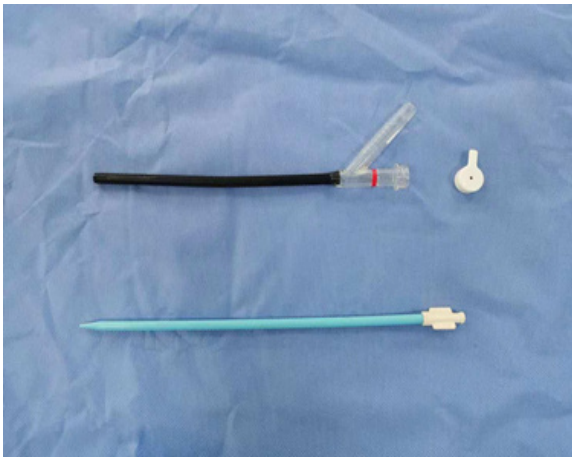

Figure 1. Vacuum-assisted Access Sheath.

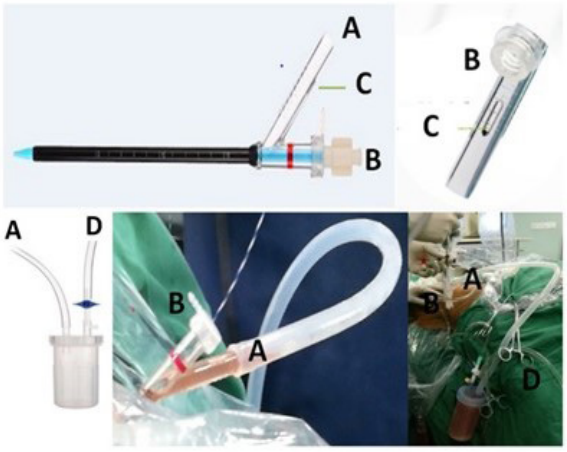

Figure 2. Structure and Connection of Vacuum-assisted Access Sheath (**A.** oblique egress sluice connected with collective bottle; **B.** straight egress sluice with a red line marker and flexible cap; **C.** longitudinal slit shape pressure regulating vent; **D.** connected with aspirator)

patients (15.8 %) of group B had a postoperative fever (>38.5 ºC) (Clavien grade 2) that required additional antibiotics; whereas 8 patients (21.1 %) of group A had fever (P = .361). They were successfully treated without urosepsis occurrence. One patient of group B needed blood transfusion. One patient of group A had nephrostomy tube retention that lasted for one month due to persistent cloudy urine drainage with positive urine culture of Klebsiella pneumoniae and Candida albicans. Nephrectomy was then performed in this case.

DISCUSSION

With the development of MPCNL, the proportion of nephrectomy caused by calculous obstructive pyonephrosis has significantly decreased. At present, one-stage percutaneous nephrostomy and delayed stone management after effective anti-infection administation is the primary option. However, in patients without ongoing UTI and thick or foul pus, Etemadian et al. found that same-day PCNL with 30F Amplatz sheath after aspirating the purulent urine was safe compared with postponed PCNL[7]. Furthermore, thanks to the development of a series of high-efficiency lithotripsy devices with negative pressure function, use of one-stage MPCNL to treat such patients with satisfactory results has been reported by several institutes[2-4].

However, it is not practical for all centers to purchase that particular kind of device due to its high cost. Moreover, it may be too aggressive to some cases with evidence of acute infection. In this study, we only per-

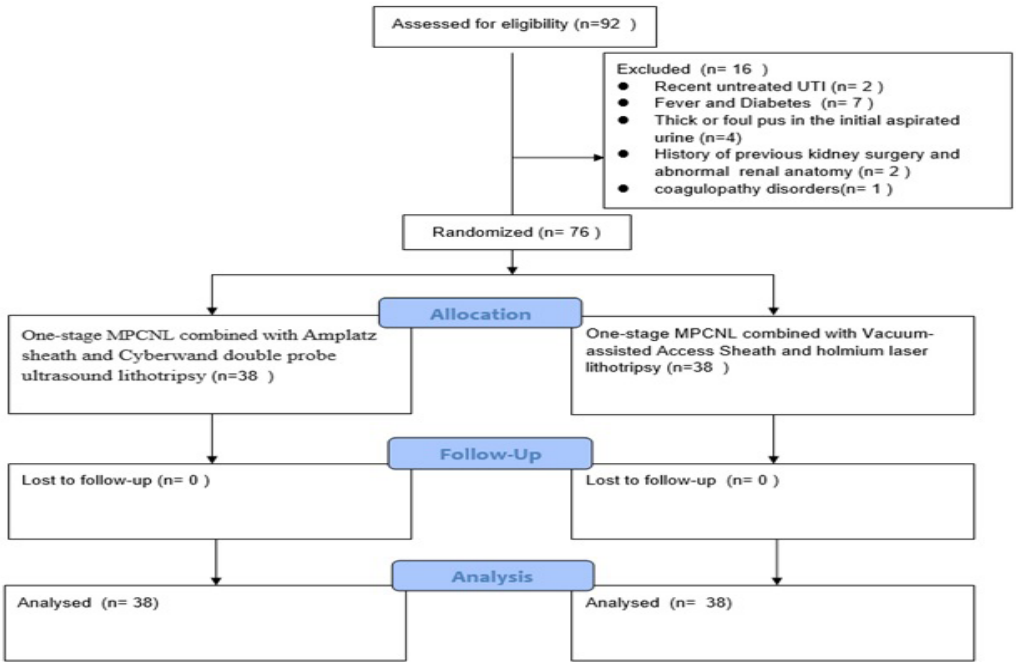

Figure 3. CONSORT Flow Diagram showing the patients inclusive process.

formed one-stage 20F MPCNL with a deposable and straightforward VAAS with suction-evacuation function in obstructive calculous pyonephrosis patients without acute infection. The clinical outcomes are comparable with those using the same size Amplatz sheath combined with Cyberwand double probe ultrasound lithotripsy.

The key to perform one-stage MPCNL safely and effectively on patients with calculous obstructive pyonephrosis is lower intraoperative pelvic pressure and shorter operation time. Zhong et al.[8] showed that each checkpoint of intrapelvic pressure during MPCNL is lower than the limit of renal parenchymal reflux (30mmHg). Patients with pyonephrosis, congestion and edema of tissues were observed and resulted in the increased permeability of blood vessels and lymphatics. The perfusion method of stone extraction during MPCNL may promote the absorption of microbes and associated toxins, resulting in the occurrence of urinary sepsis. Recently, some reports have been published using lithotripsy instruments with aspiration function to treat obstructive pyonephrosis in one-stage with satisfying outcomes. Wang[4] demonstrated that EMS lithotripsy is a safe and effective method to treat obstructive pyonephrosis with conventional PCNL in one-stage. The mean intrapelvic pressure in these cases is below 20 mmHg with the help of its suction methods. Krambeck et al.[6] found that Cyberwand has the same lithotripsy efficiency and clinical effect as EMS lithotripsy. Changing the stone extraction methods from perfusion to aspiration is the key to reduce intraoperative pelvic pressure and operation time.

In this study, we found that the combined use of high power laser effectively reduces stone fragmentation and removal time, despite the deposable and straightforward design of VAAS. Firstly, the VAAS approach provides better passage for large fragments. The maximum internal size fragment probe of Cyberwand is 3.75 mm. Stones were required to be repeatedly fragmented into tiny pieces in size of < 3 mm and then sucked out through the internal space of the probe. However, in VAAS group, more dust fragmented by high power laser could pass through the gap between nephroscope and sheath, and larger fragments could be sucked out through the whole inter size space of the sheath by withdrawing the endoscope. The maximum stone diameter which can go thought the 20F sheath could reach 6.3 mm. Furthermore, high power laser is a powerful lithotripsy energy to fragment all kinds of stone, even for hard stone. Compared with ultrasound lithotripsy, high power laser required more times in the periods of fragmenting stones in El-Nahas's study[9]. In the current study, 91.11% of patients in Group A and 81.5% in Group B had hard stone compositions[10], such as calcium oxalate monohydrate or/and calcium phosphate. Nevertheless, ultrasonic lithotripsy is less effective when dealing with hard stones. Stone fragmentation and removal time for hard stones was longer using ultrasonic lithotripsy even compared to pneumatic lithotripsy[10].

There was no significant difference in terms of postoperative fever in both groups. Postoperative fever is associated with the transient increase and duration of high intrapelvic pressure[8]. The operative time and intrapelvic pressure were well controlled by both methods. Moreover, as our team described in a previous study[11], when some small calyces have stenotic infundibula or the angle between calyx and puncture calyx is inaccessible, the working sheath cannot enter the calyx. We used a 12F mini-nephroscope connected to pressure suction to manage the stone in some case, which can reduce the internal pressure of calyx. Therefore, combined continues suction of VASS and the intermittent suction of 12F nephroscope can minimize intrapelvic pressure as well as the calyx pressure, which was theoretically a double suction method. In this study, the clinical outcome of this method was not significantly better in terms of postoperative fever. However, a higher initial SFR was found in VAAS group. Using a small 12F nephroscope is easier to torque and reach more calyxes for high SFR. The damage of mucosa caused by lithotripsy instruments will lead to an increase of toxin absorption and fever after operation[12]. Cyberwand was previously proven for less damage to renal calyceal mucosa due to its "suspended lithotripsy" effect[13,14]. Similarly, VAAS also has this effect. The balance between continuous perfusion and negative pressure suction results in eddy currents around the stone. A buffer zone is formed between the mucosa and the renal stone. Furthermore, pressing the pressure control vent can increase the power, and then the stone will come into the sheath and be fragmented inside the sheath and away from the mucosa.

Previously, a custom-made 16F metal patented suctioning sheath was reported to treat obstructive pyonephrosis in one-stage MPCNL with a satisfy outcome[3]. In this study, we found that VAAS takes into account the advantages of metal patented suctioning sheath, and has a broader clinical value. VAAS is a disposable consumable material, which avoids reusing consumables and the risk of cross-infection with incomplete disinfection and sterilization. Besides, hydrophilic medical materials can deform elastically and absorb irregular stone fragments and are suitable for one-step dilation to reduce procedural X-ray exposure and operation time.

The primary limitation of this study is that it was a single institution experience with a small sample. Also, we did not measure the intrarenal pelvic pressure because setting up that device will increase the operative room duration and risk of these patients.

CONCLUSIONS

One-staged MPCNL combined with Vacuum-assisted Access Sheath is a simple and safe, effective and ergonomic practical method for some selected patients with obstructive calculous pyonephrosis.

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CONFLICT ON INTEREST

None disclosed.

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