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Research Article

Prospective multicenter study of suctioning MPCNL with the aid of a patented system in treating renal staghorn calculi

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Abstract

Objective: To investigate the safety and efficacy of suctioning minimally invasive percutaneous nephrolithotomy (MPCNL) with the aid of a patented irrigation clearance system in treating renal staghorn calculi.

Methods: From August 2009 to July 2014,4 hospitals had executed prospective multicenter study with a total of 912 cases. The patients were randomly divided into 3 groups: suctioning MPCNL (311 cases); standard percutaneous nephrolithotomy (PCNL, 297 cases); and traditional MPCNL (304 cases). Outcome parameters such as stone free rate, operative time, intrapelvic pressure, and amount of bleeding were compared.

Results: Stone free rate by one surgery using single percutaneous tract in the suctioning MPCNL group were significantly higher while blood loss and intrapelvic pressure were significantly less than that of standard PCNL Group. The operative time, stone free rate by one surgery, stone free rate by one surgery using single percutaneous tract, intrapelvic pressure, and amount of bleeding in the suctioning MPCNL group were better than that of traditional MPCNL Group. The postoperative fever rate was higher in the traditional MPNCL group than that of the standard PCNL and suctioning MPCNL groups.

Conclusion: Suctioning MPCNL using our patented system is safe, effective and better in treating renal staghorn calculi.

Abbreviations: PCNL: percutaneous nephrolithotomy, MPCNL: minimally invasive nephrolithotomy, IVU: Intravenous urography, CT: Computerized tomography, KUB:X-ray of kidneys, ureters, and bladder, EMS: Electro Medical System, SWL: Shock wave lithotripsy

Introduction

Percutaneous nephrolithotomy (PCNL) has become one of the first-line treatments of renal staghorn calculi [1]. In China, the most common two types of PCNL are ultrasonic pneumatic lithotripsy through a standard-sized percutaneous tract (standard PCNL) and minimally invasive PCNL (MPCNL) using a peel-away sheath. Each of these two methods has its advantages and disadvantages. Combining the advantages of the above two kinds of operation, we designed a patented stone-breaking and suctioning system (Patient No.: 200820137434.6, hereinafter referred to as the patented system) to increase the efficacy of stone clearance. From August 2009 to July 2014, we carried out a prospective, randomized, and multicenter study to evaluate the safety and efficacy of MPCNL using the patented system in treating renal staghorn calculi, in 4 different hospitals in China.

Patients and methods

Clinical data

From August 2009 to July 2014, four hospitals in China had executed the prospective multicenter study. A total of 912 patients (542 men and 307 women) were included in our study. Their age ranged from 17 to 68 years with a median age of 43.3. Single-sided 825 cases, double-sided 87 cases. 225 of the 912 patients had no hydro nephrosis. There were 231 patients who were complicated by mild hydro nephrosis, 324 patients were complicated by moderate hydro nephrosis, and 142 patients were complicated by severe hydro nephrosis. The length of stones ranged from 3.0 to 10.1cm with an average length of 5.6cm. There were 258 patients who had a history of kidney surgery. There were 249 patients who were complicated by urinary tract infection. For diagnosis, all patients underwent abdominal plain film exam with/without intravenous urography (IVU). Abdominal CT scan was used to confirm the diagnosis.

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The inclusion standards were as below: 1) The stone was located in the renal pelvis with branch extending to at least two renal calices; 2) Consistent with renal staghorn calculi diagnosis standard and infection was controlled after primary percutaneous nephrostomy drainage to remove renal collecting system empyema. Our exclusion criteria were as below: 1) The patients who had absolute contraindication to operation; 2) patients with recent fever, obvious lumbago, and empyema found in the renal collecting system without drainage to control infection.

Grouping

The patients were randomly divided into three groups: suctioning MPCNL group, patented stone-breaking and suctioning system and 100W holmium laser lithotripsy machine were used to perform MPCNL, a total of 311 cases were included in this group; standard PCNL group, ultrasonic pneumatic lithotripsy was performed through a standard sized percutaneous tract and sheath, a total of 297 cases were included in this group; traditional MPCNL group, MPCNL was performed through a peel-away sheath using a100W holmium laser lithotripsy machine, a total of 304 cases were included in this group.

For all3 groups, surgery took place under continued epidural anesthesia or general anesthesia. A 5F ureteral catheter was then inserted retro gradely into the renal pelvis through cystoscopy or ureteroscopy, and continuous infusion of 0.9% saline at a pressure of 50cmH_2O was used to produce artificial hydronephrosis. After this, a Foley catheter was indwelled; the patient was then changed to prone position. The abdomen was not boosted to prevent the fixation of the kidneys. The direction of percutaneous tract was designed based on preoperative KUB, IVU, and CT images. Ultrasonography-guided percutaneous punctures were made with an 18-gauge coaxial needle into the targeted calyx. The puncture point was in the 11th intercostal space or the 12th subcostal margin, between the posterior axillary line and scapula line. The puncture was judged successful if there was urine overflow or if it touched a stone. Zebra guidewire was inserted and fixed. The puncture needle was then taken out. After a 0.5–0.7 cm skin incision, the dilatation of the percutaneous tract was performed serially over the guidewire with a fascial dilator. The 5F ureteral catheter was connected to an invasive blood pressure monitor for measuring of intrapevic pressure.

For suctioning MPCNL group, as previously described [2-5], a 16F ~ 18F patent metal sheath was placed at the percutaneous access port and was connected to a negative vacuum aspiration machine. A 12F small diameter nephron scope was subsequently inserted through the sheath to observe stones. A holmium laser (100w, Lumenis) was used to break the stones and the vacuum suctioning device was used to clear gravel synchronously (Figure 1). For patients in standard PCNL group, a 24F sheath was placed as the percutaneous access port and was connected to a vacuum suctioning machine, after establishing a percutaneous tract. An EMS system ultrasound was used to break the stones and the vacuum suctioning device was used to clear gravel. For patients in the traditional MPCNL group, a traditional peel-away sheath was placed after the percutaneous tract was expanded gradually to 16F ~ 18F using fascia dilators. No negative pressure suction device was connected. 100W holmium laser was used for lithotripsy and gravel was cleared through flow perfusion or forceps.

For patients who were found to have empyema in the collecting system intraoperatively, we decided on whether to proceed with first-stage lithotripsy based on the following criteria. 1) For patients who had recent fever or obvious lumbago in all three groups, we performed a simple nephrostomy drainage. The patient was regrouped after the infection was controlled. 2) For patients who did not have recent fever or obvious lumbago, we proceeded with first-stage lithotripsy for those who were in the suctioning MPCNL and standard PCNL groups. However, we performed a simple nephrostomy drainage for those who were in the traditional MPCNL group, followed by a second-stage lithotripsy.

After stone clearance in the 3 groups, a 6F double-J stent was indwelled under the guidance of a guidewire followed by a nephrostomy tube placement. Average time in establishing the percutaneous tract, the average stone clearance time (from the beginning of lithotripsy to the end of the nephrostomy tube indwelling), and intraoperative bleeding amount were recorded as data. AKUB was taken 3 to 5 days after surgery, and a CT was performed as necessary, to check for residual stones. If no residual stones > 4mm were present, which was defined as stone-free, the nephrostomy tube was removed and no further treatment was pursued. Otherwise, a SWL treatment or a second-stage percutaneous nephrolithotomy was performed.

Statistics

All data were analyzed using SPSS14. The quantitative variables were represented by $\bar{x}$ ±s and were analyzed by student t test. Count data was analyzed using χ^2 test. P <0.05 was used to indicate statistical significance.

Results

All patients could tolerate the operation. In the suctioning MPCNL group, the stone clearance time was 56±32min, intra pelvic pressure was 1.8±0.9mmHg. There were 182 patients in whom a single percutaneous tract was used. Stone clearance rate by one surgery was 81%. In the standard PCNL group, the stone clearance time was 53+27 min, intra pelvic pressure was 5.8±1.1mmHg. There were 85 patients in whom a single percutaneous tract was used. Stone-free rate by one surgery was 73%. In the traditional MPCNL group, the stone clearance time was 81±41min, intra pelvic pressure was 9.2±5.3mmHg. There were 92 patients in whom a single percutaneous tract was used. Stone-free rate by one surgery was 74% (Tables 1 and 2).

Compared to standard PCNL group, stone free rate by one surgery and stone-free rate by one percutaneous tract were significantly higher in the patented system group (P < 0.05 each) while the amount of bleeding and renal pelvic pressure were significantly less (P < 0.05 each). There was no difference in operation time between the suctioning MPCNL and the standard PCNL groups (P > 0.05). In the meantime, suction MPCNL group was superior to traditional MPCNL

Table 1. Outcome Comparison of suctioning MPCNL, standard PCNL and traditional MPCNL, Part 1.

Group	Case number (n)	Stone clearance time (min)	Bleeding amount（mL）	Intrapelvic pressure (mmHg)	Cases needing IR	Cases with empema (n)
Suctioning MPCN L	311	56+32	153+55	1.8+0.9	2	25
Standard PCNL	297	53+27	216+140	5.8+1.13	2	27
Traditional MPCNL	304	81+41	172+78	9.2+5.3	2	24

IR: Interventional Radiology

Table 2. Outcome Comparison of suctioning MPCNL, standard PCNL and traditional MPCNL, Part 2.

Case	One tract	Two tracts	≥3 tracts	Stone-free rate by one surgery	Cases with postoperative fever	Cases needing tranfusion	Cases needing 2nd stage surgery
(n)	(n)	(n)	(n)	(%)	(n)	(n)	(n)
Suctioning MPCNL	311	182	97	32	81	25	1138
Standard PCNL	297	85	156	56	73	28	1751
Traditional MPCNL	304	92	163	49	74	45	1449

group in average stone clearance time, stone free rate by one surgery and stone-free rate by one percutaneous tract, intra pelvic pressure, and the amount of bleeding ($P < 0.05$ each). Moreover, there was a higher incidence of postoperative fever in the traditional MPCNL group compared to the suctioning MPCNL and standard PCNL groups ($P < 0.05$ each) (Tables 1 and 2).

Discussion

PCNL is an accepted first-line treatment approach for renal staghorn calculi. At present the most common two types are PCNL using a standard sized percutaneous tract and MPCNL [6]. Application of MPCNL using a peel-away sheath is an effective way to treat upper urinary tract calculi. The tract is small, less traumatic, and combined with the high-power holmium laser has the advantages of breaking stones more effectively and producing less bleeding [7]. But because there is no negative pressure suctioning, this technique clears stones away mainly through high pressure perfusion or the use of pliers to remove stone manually. This procedure can lead to intraoperative or postoperative fever, sepsis, or septic shock due to high pressure-induced bacterial endotoxin absorbance in the renal pelvis or perfusion [8]; if the hydro nephrosis is pronounced, high-pressure perfusion makes it difficult to remove the rubble completely, because it moves around inside the renal pelvis. Another disadvantage is a long operation time [9]. This study showed that operation time and rate of postoperative fever in MPCNL group was higher than the other two groups, which is due to stone retrieval method and its relative high intra pelvic pressure.

Standard tract PCNL combined with ultrasonic lithotripsy stone clearance system is an effective way to clear stones, with the function of breaking and aspirating stones at the same time. This can remove stones immediately after they are broken, reduce or avoid the use of high-pressure water or pliers to take out debris and rubble, and shorten operation time. This method can also effectively reduce the intra pelvic pressure, to avoid absorption of toxins and pyrogen during stone breaking and clearance process [10]. The renal parenchyma of patient with renal staghorn calculi is usually thick; the probability of parenchymal vascular injury is increased during the standard PCNL procedure. Also, it is more difficult for a larger endoscope to enter the narrow calyces. Larger devices are also hard to use in a small space, as when removing multiple dispersed kidney stones, usually requiring multiple percutaneous tracts [11]. This study showed that the standard PCNL group had a significantly higher number of percutaneous tract used compared to the other two groups. Due to a higher need for multiple percutaneous tracts to remove stones completely and larger sized percutaneous tract used, standard PCNL group had bleeding more than the other two groups. In order to reduce the bleeding and injury, many scholars adopt standard PCNL combined with MPCNL [12].

Application of the patented stone clearance system in MPCNL represents a small, new, novel MPCNL type, which has adopted advantages for both traditional MPCNL and standard PCNL but avoiding their short comings [10,13]. It is a procedure adding a

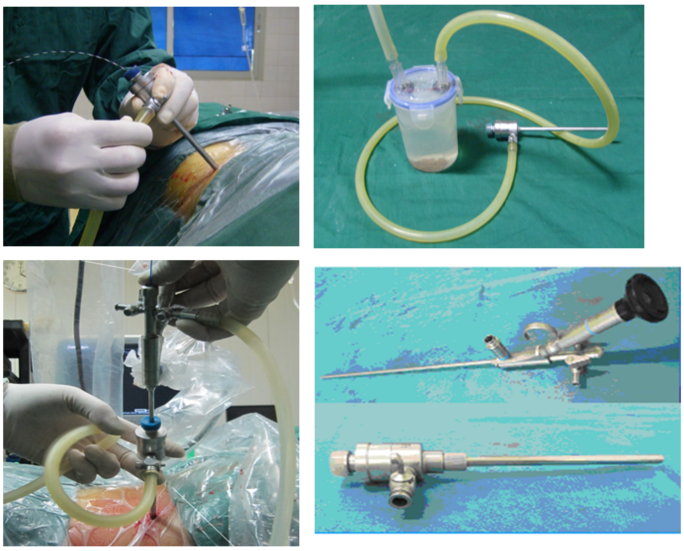

Figure 1. Suctioning lithotripsy sheath was connected with vacuum suctioning device.

Figure 2. Comparison of KUB images before and after suctioning MPCNL using a single percutaneous tract, Case 1.

negative pressure suctioning system to MPCNL, actively aspirate to clear stones. Because the patented sheath is small, and its range of movement is increased, it can easily access most of the renal calices in order to explore and remove stones under direct vision, reducing the number of percutaneous tracts required for staghorn kidney stones, thereby reducing kidney damage. Intraoperatively, kidney parenchyma can be shrunken, the tension in the renal pelvis is decreased, and renal parenchymal compliance is increased, facilitating the movement of the Reno scope to reach more renal calyces. When the angle between the percutaneous tract and renal calyces is less than 90 degrees, the metal sheath can still enter without tearing the kidney. By solely analyzing stones in Figure 2 and Figure 3 from physics standpoint, it would be very difficult to remove the stones in one surgery using one percutaneous tract and a rigid scope. However, when the vacuum suctioning is applied, kidney parenchyma is shrunken, the angle between the original renal calyces and percutaneous changes, the degree of the angle can be increased, so that the Reno scope can access to target renal calices easierly. From our experience, the angle between the percutaneous tract and renal calyx is bigger if we targeting lower calyx to establish percutaneous tract comparing to targeting upper or middle calyx with easier access to each renal calyx (Figure 3).

The metal sheath in our stone clearance system is enabled to have negative pressure suctioning. The intrapelvic pressure can be controlled to low positive or low negative state manually or machinally, or both, which will immobilize the stones in the renal pelvis and calyces during flushing to facilitate the lithotripsy. When there are blood clots attached in the renal collection system, we can use the hard sheath to scrape mucosa gently to suck away the blood clots and expose stone(s). To break stones inside some calyces where the renoscope is not able to reach, we can use the metal sheath to pull out the stones for breaking. If the calyceal neck is narrow, we can use the metal sheath to dilate the neck so that we can perform lithotripsy and stone clearance inside the renal calyx. In contrast, because the peel-away sheath often cannot pull calyceal calculi out due to its softness. Also, standard sized renoscope cannot enter narrowed renal calyces. The ability to pull out the stones and achieve expansion of renal calyceal neck using stone-suctioning lithotripsy is another important reason for its higher stone-free rate by one stage operation and one percutaneous tract.

The pressure in the renal pelvis in the suctioning MPCNL group was lower than that in the other two groups, which is related to vacuum suctioning. In order to facilitate stone breaking and suctioning intraoperatively, we usually adjusted to increase the negative pressure slightly to shrink the kidney to keep a low intra pelvic negative pressure so that the average intrapelvic pressure was low. In addition, we realized that in the stone-suctioning group irrigation amount was greater than the other two groups, the larger irrigation amount could guarantee the intra pelvic pressure would not be too low. Otherwise the amount of bleeding will increase and the clarity of surgical field and operation process will be affected. The sheath was made in metal with decompression threshold, when bubbles were seen in the operative field; a relatively high negative intra pelvic pressure value was indicated, at this time we should reduce the negative pressure appropriately to suck. When outward flush fluid through the pressure threshold was seen, a high intra pelvic pressure was indicated, there may be a pipeline blocking by the gravels, at this time we should clear the obstruction.

Figure 3. Comparison of KUB images before and after suctioning MPCNL using a single percutaneous tract, Case 2.

Renal stone complicated by empyema in the collection system has been regarded as a contraindication to PCNL, which usually needs a nephrostomy to drain the pus before attempting for lithotripsy. However, these purulent liquid is not always infectious and a substantial proportion of purulent urine culture were negative. If the patient has no recent UTI without effective treatment, and no thick or foul-smelling pus, to continue the operation is safe [14]. In our current study, patients with empyema in the collecting system and recent low back pain with fever were all treated initially with first-stage simple nephrostomy without lithotripsy. Because there was no negative pressure suctioning, patients in the traditional MPCNL group were all treated initially with simple nephrostomy. Lithotripsy was performed as a second stage operation later at an appropriate time point. For other patients with empyema in the collecting system but without recent fever and significant low back pain in the standard PCNL and suctioning MPCNL groups, we performed lithotripsy after clearing the purulent material through flushing under a low intra pelvic pressure. The outcome of the surgery was good; we did not see any case complicated by septicemia, which revealed that the safety of the operation was increased by using vacuum suctioning.

Our experience in application of our patented system for MPCNL in treating staghorn renal calculi revealed the following advantages of the system: minimally invasive, safe, high stone-free rate by one surgery, high stone-free rate by one percutaneous tract, short operation time, less number of percutaneous tracts needed, low intrapelvic pressure, and less bleeding. As a safe and highly effective PCNL approach, we think the suctioning MPCNL can become a routine method for the treatment of renal staghorn calculi.

Conflicts of interest

None declared.

Consent

Written informed consent was obtained from the patients for publication of this report and any accompanying images. Copies of the written consent are available for review by the Editor of the journal.

Ethical standard

Ethical and regulatory approvals were sought and obtained from all the 4 participating hospitals

Author contribution

Protocol/project development: Song, Xie, Du, Deng, Yang, Liu (Qigui Liu), Pan, Chen, Ye Data collection or management: Xie, Du, Deng, Qiu, Fan, Zhu, Yang, Liu (Shengfeng Liu), Qin, Liu (Tairong Liu), Peng,Hu, Du,Liu (QiguiLiu), Pan,Chen

Data analysis: Qiu, Xie, Du, Deng, Fan, Zhu, Yang Manuscript writing/editing: Xie, Qiu, Deng, Song, Fan, Zhu, Yang, Du

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