



OPEN Single-access mini-PCNL with flexible cystoscopy vs. multi-access mini-PCNL for complex renal stones in prospective study

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To observe the efficacy and safety of single-access minimally invasive percutaneous nephrolithotomy (MPCNL) combined with flexible cystoscopy and multi-access MPCNL in patients with complex renal stones (CRS). A total of 195 patients with CRS were prospectively randomized into two groups. Ninety-eight in the single-access MPCNL group and 97 cases as control in the multi-access MPCNL group. The stone-free rates (SFRs) at different times were considered as the primary outcome of the study. The secondary end points were operative time, hemoglobin decrease, postoperative hospital stay and operation-related complications. There was no obvious difference between two groups in patients' demographics and preoperative clinical characteristics (All $P > 0.05$). Postoperative data showed that mean decrease in hemoglobin level was less in single-access MPCNL group than that in multi-access MPCNL group ($P < 0.001$). Postoperative hospital stay in single-access MPCNL group was more shortened than that in multi-access MPCNL group ($P < 0.001$). Moreover, the SFRs of the postoperative 2nd day and 4th week in single-access MPCNL group were both significantly higher than those in multi-access MPCNL group (Both $P < 0.05$). However, in terms of the rates of low back pain, perirenal hematoma and renal artery embolization, multi-access MPCNL group were all significantly higher than single-access MPCNL group (All $P < 0.05$). Our study shows that single-access MPCNL and flexible cystoscopy are ideal complementary techniques in the treatment of CRS, satisfying both high SFR and minimized renal injury. This method was safe and reproducible in clinical practice.

Keywords Minimally invasive percutaneous nephrolithotomy, Flexible cystoscopy, Single-access, Multi-access, Complex renal stones, Stone-free rates

Renal stones are a common disease in urology, often accompanied by various discomfort symptoms, such as low back pain, hematuria, vomiting, nausea, fever, etc.¹. Complex renal stones (CRS) are a challenging type in the classification of renal stones, characterized by high stone burden, distribution in various calices, urinary tract infection (UTI) and renal dysfunction, high surgical risk, or high incidence of complications, including multiple stones, staghorn stones, and isolated renal stones^{2–4}. Surgery remains the main treatment for CRS. The traditional surgical method is open nephrolithotomy, which has the disadvantages of large trauma, slow postoperative recovery, and high complications⁵.

Minimally invasive percutaneous nephrolithotomy (MPCNL) is currently the most widely used and has achieved satisfactory therapeutic effects in CRS. Large T⁶ et al. reported that single-access MPCNL for CRS was safe and effective for higher stone-free rates (SFRs) and lower complication rates which were similar with standard PCNL. Meanwhile, Balaji S et al.⁷ considered that multi-access MPCNL was found to be safe, feasible and effective for the management of large burden CRS with respect to stone clearance and morbidity associated with the procedure. It was cost effective and complete stone clearance as a single procedure was higher in comparison to flexible ureteroscopy (FURS) and extracorporeal shock wave lithotripsy (ESWL). Despite the proven advantages of this technique for CRS, it still remains under-utilized for the fear of complications, especially for multi-access MPCNL⁸. Single-access MPCNL is always difficult to remove all stones due to the angle of the renal

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calyx for the CRS. To solve these problems, we find in practice that flexible cystoscopy can compensate some limitations of MPCNL. Firstly, flexible cystoscopy can increase the SFRs of MPCNL by searching residual stones or fragments in locations that are inaccessible by MPCNL, such as beside the MPCNL tract insertion. Secondly, flexible cystoscopy can decrease the possibility of establishing the second or third access tracts. Furthermore, stone fragments broken via flexible cystoscopy are also easily washed out through the MPCNL tract. Therefore, the two procedures can well complement each other in lithotripsy.

Higher SFR and lower surgical complications have always been the pursuit of urologists. Different procedures for lithotripsy will inevitably bring different SFR and operative results, so selecting the optimal surgical modality will be a challenge. However, few studies have focused on the comparison between single-access MPCNL combined with flexible cystoscopy and multi-access MPCNL for CRS. Therefore, we conduct this prospective randomized controlled study to investigate whether patients can benefit more from the combination of single-access MPCNL and flexible cystoscopy than multi-access MPCNL.

Patients and methods

Patients

Patients with CRS referred to our institute between October 2021 to March 2024 were considered for this study. Applying strict inclusion criteria, the patients were randomly assigned to the treatment groups using the envelope method. The study included 195 patients, 98 in the single-access MPCNL group and 97 in the multi-access MPCNL group, based on power analysis performed to estimate the sample size (Fig. 1). The participants' pretreatment evaluation included medical history, physical examination, laboratory investigations (urine analysis, urine culture and/or sensitivity, complete blood count, blood urea nitrogen, serum levels of creatinine, C-reactive protein, and procalcitonin), and radiologic investigations. Patients with a known UTI received antibiotic treatment until infection control was achieved. The protocol for this study has been accepted by the Chinese Clinical Trial Registry (Ethics approval number: ChiCTR2200056402). Meanwhile, The study was approved by the clinical research ethics committee of the Affiliated Jiangning Hospital of Nanjing Medical University (ethics approval number: 202110378). Written informed consent was obtained from all participants. The study followed the principles of the Helsinki Declaration.

Randomization and masking

Parallel randomization was conducted using a stratified approach in our study. Our center enrolled 195 participants, randomized in a 1:1 ratio to either the single-access MPCNL group or the multi-access MPCNL group. Electronic generation of the randomization sequence took place before patient inclusion. Consecutively numbered, sealed envelopes were utilized for random sequence allocation and concealment. After the patients changed their position to prone position and before percutaneous renal puncture, the sealed envelope was opened by a designated nurse, revealing the specific surgical methods. Subsequently, at the conclusion of the procedure, the same individual automatically recorded the operative data.

Perioperative and surgical procedures

All patients underwent a plain preoperative abdominal radiography of the kidneys, ureters, and bladder and unenhanced computed tomography (CT) to assess hydronephrosis and the size, location, and number of the stones. We usually performed preprocedural urine cultures and applied appropriate antibiotic therapy based on the culture-antibiogram test results. The opportunity for operation depended on a downward trend in infection indicators and a negative urine culture. Patients who had negative urine culture took standard peri-operative antibiotic prophylaxis (single shot of cefuroxime 200 mg or levofloxacin 500 mg in cases of allergy) 30 min before intervention. Stone score include stone size (S), tract length (T), obstruction (O), number of involved calices (N), and essence or stone density (E). It was found to predict treatment success and the risk of perioperative complications after PCNL⁹. All procedures were performed by the same urologist in the study. The selection of the surgical method for the enrolled patients was random, excluding any artificial subjective factors.

Multi-access MPCNL

Under general anesthesia, the patient was placed in a lithotomy position. A 6Fr ureteral catheter (Boston Scientific, USA) was inserted into the ureteropelvic junction of the target ureter. The patient was then turned to a prone position and the percutaneous tract was punctured under ultrasonographic guidance with an 18-gauge coaxial needle (Cook Medical, USA). Chief surgeon planned the number of percutaneous renal accesses before surgery and establish upper access firstly to facilitate intraoperative operations. The percutaneous tract was serially dilated using fascial dilators (Cook Medical, USA) of up to 20 Fr. Then a nephroscope (8.5/11 Fr, Suode medical, Hangzhou, China) was inserted into the collecting system to fragment stones within the field of view by a 550 μ m holmium laser fiber with the settings of 40–60 W ((1.6–2) J * (25–30) HZ) based on the hardness of stones. Smaller stone fragments were washed out through the sheath by retrograde irrigation. We always used ultrasound to monitor the clearance of stones in real-time during surgery. The second or third access tracts (18 Fr) would be established to achieve maximum SFR. A 6 Fr double-J stent (Bard, USA) was inserted into the ureter using a loach guidewire (Bard, USA) and nephrostomy tubes (14 Fr) was placed.

Single-access MPCNL combined with flexible cystoscopy

The method of establishing percutaneous renal accesses was similar to that of multi-access MPCNL group, but we will choose a renal calyx that can maximize the clearance of stones. Then the disposable electronic flexible cystoscopy (PC515, Pusen medical, Zhuhai, China) was operated to search and fragment residual stones in the inaccessible locations of nephroscope (mainly beside the PCNL tract insertion) (Fig. 2). At the conclusion of procedure, ultrasound were taken to assess stone clearance. Similarly, a 6 Fr double-J stent and a 14 Fr

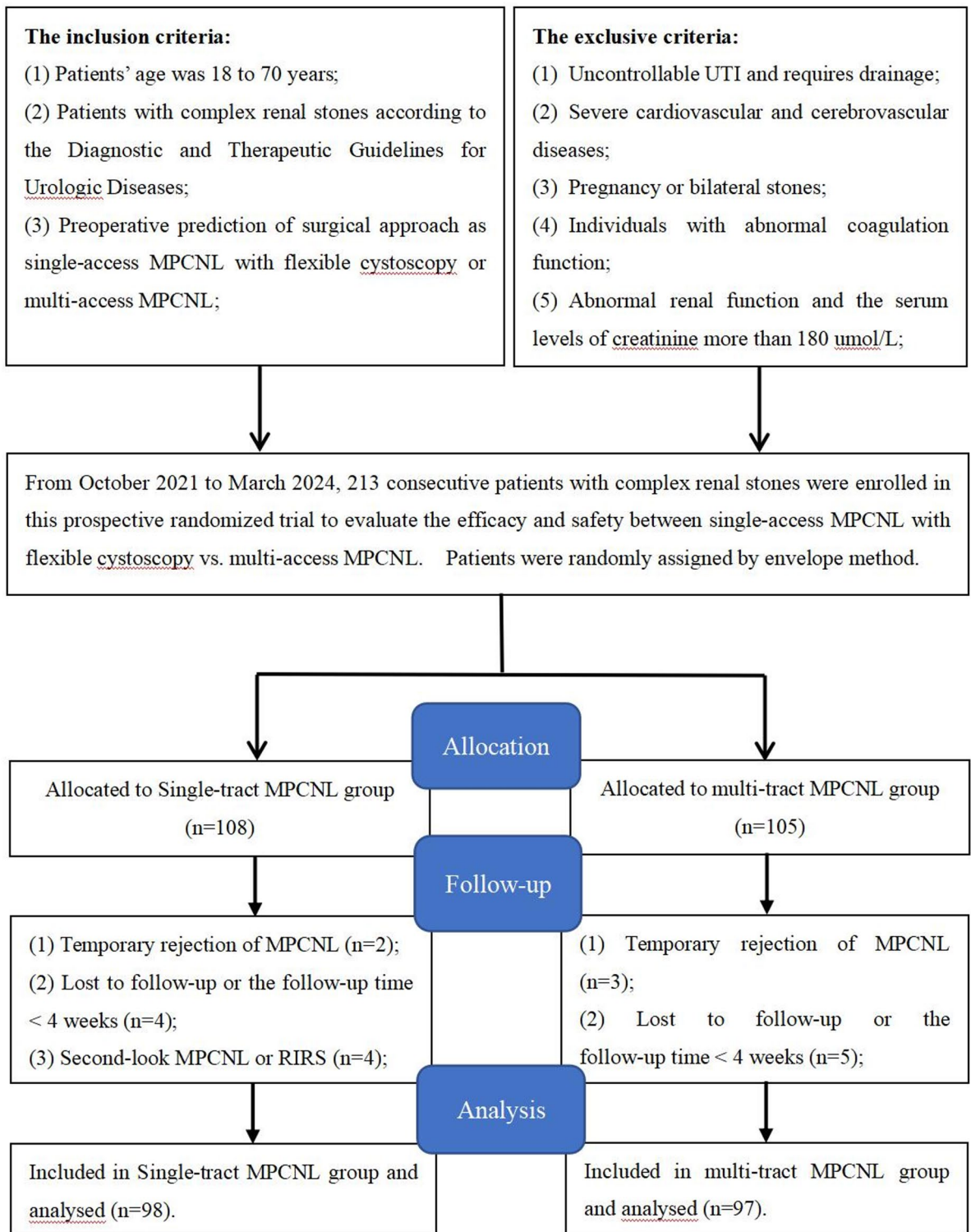


Fig. 1. Flowchart for cases selection.

nephrostomy tube were placed separately. The KUB results of one patient, who has multiple stones, were shown in Fig. 3. During the surgery, a flexible cystoscopy was used to search for residual stones, ultimately achieving complete removal of the stones.

Postoperative follow-up

All patients were checked including complete blood count, routine urinalysis, serum creatinine, procalcitonin and KUB at the postoperative 2nd day and 4th week. If stone composition was pure uric acid or cystine that

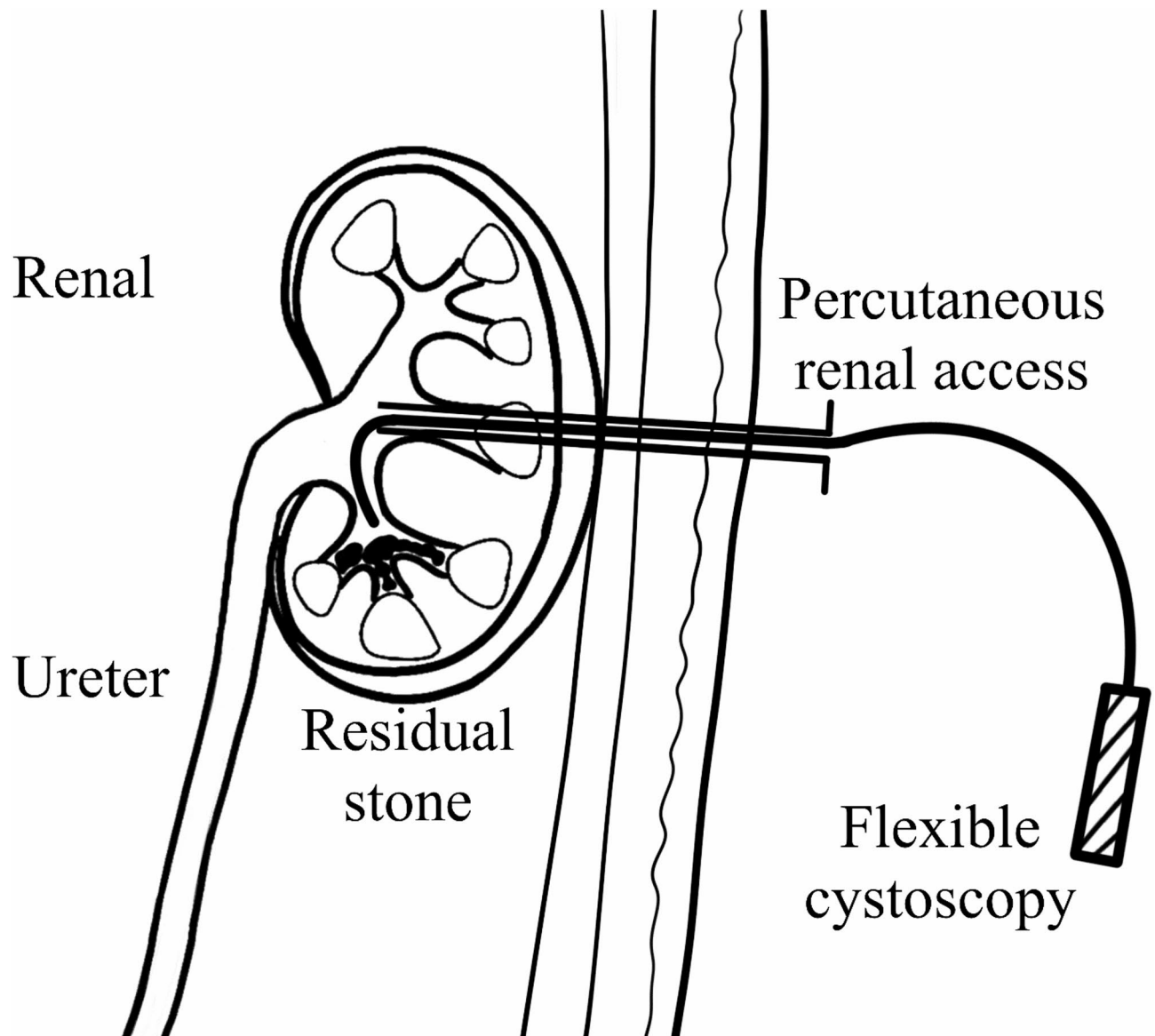


Fig. 2. Diagram for single-access MPCNL combined with flexible cystoscopy.

could not be showed in KUB films, an ultra-low-dose CT examination would be taken to evaluate the residual stones. The stone-free status was defined as no radiological evidence of stone or the presence of ≤ 2 mm asymptomatic fragments in the urinary system^{10,11}. The primary study outcome was the SFRs at the 2nd day postoperatively. The secondary endpoints were SFRs at the 4th week postoperatively, operative time, hemoglobin decrease, postoperative hospital stay and operation-related complications. Postoperative complications were graded according to the modified Clavien classification system as applied to PCNL^{12,13}. If the patient had no residual stones and evidence of bleeding or infection, nephrostomy tube would be removed at the postoperative 3rd day and double-J stent was removed at the postoperative 4th week. Patients with residual stones underwent auxiliary procedures four weeks or more after surgery. These included external physical vibration lithecbole (EPVL), ESWL, or position therapy^{14,15}.

Statistical analysis

IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Continuous variables are presented as means \pm standard deviations. The groups were compared for patient demographics, follow-up, and surgical outcomes using independent samples *t*-test; The Shapiro-Wilk test was used to test the normality of the initial data. A chi-squared test compared the groups for other pre- and postoperative clinical characteristics. A *P*-value < 0.05 was considered statistically significant. The STONE score can vary from a minimum of 3 to a maximum of 12. A score of 3–5 denotes the 'low complex stone', a score of 6–8 denotes 'moderate complex stone', and a score of 9–12 reveals 'the high complex stone'⁹.

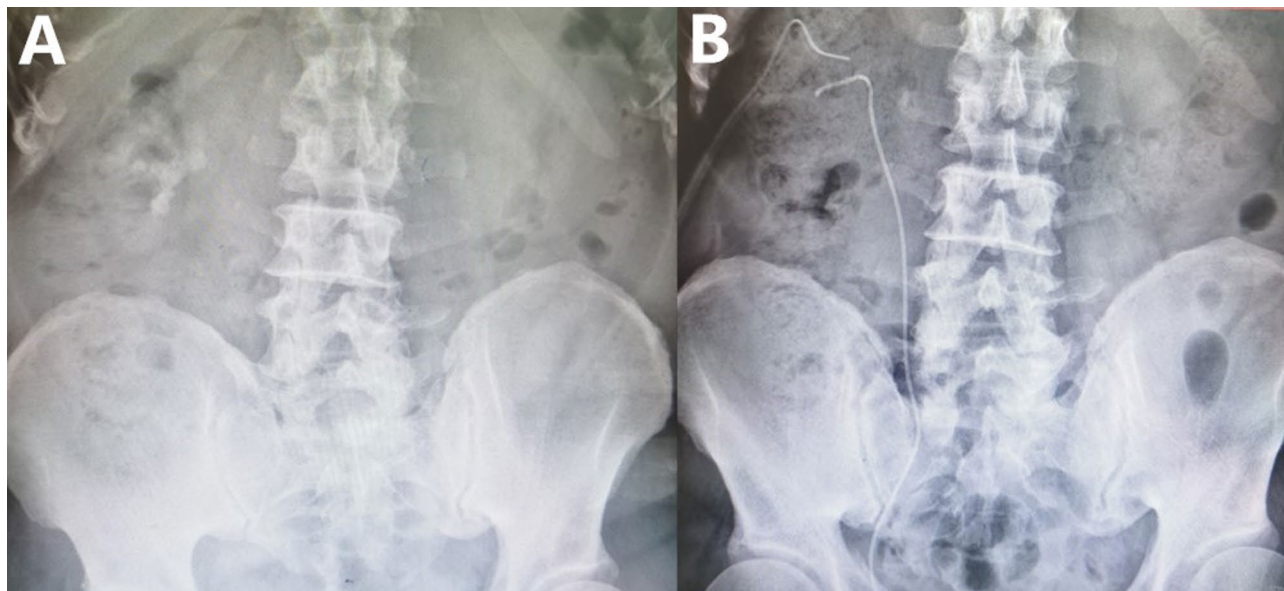


Fig. 3. KUB during the perioperative period (A preoperative; B postoperative).

Variables, mean \pm SD or <i>n</i> (%)	Single-access MPCNL group (<i>n</i> = 98)	Multi-access MPCNL group (<i>n</i> = 97)	<i>P</i> value
Age (years)	43.7 \pm 6.3	44.8 \pm 5.2	0.185
BMI (kg/m ²)	24.3 \pm 3.3	23.7 \pm 2.8	0.173
Gender			
Male	57 (58.2)	52 (53.6)	–
Female	41 (41.8)	45 (46.4)	0.522
Hypertension history	42 (42.9)	36 (37.1)	0.413
Diabetes history	31 (31.6)	26 (26.8)	0.459
STONE score	8.9 \pm 0.8	8.7 \pm 1.1	0.148
Hydronephrosis			
Mild	53 (54.1)	49 (50.5)	0.618
Moderate	34 (34.7)	35 (36.1)	0.839
Severe	11 (11.2)	13 (13.4)	0.644
Urine culture			
Negative	59 (60.2)	63 (64.9)	–
Positive	39 (39.8)	34 (35.1)	0.494
The distribution of stones			
Multiple stones	37 (37.7)	42 (43.3)	–
Staghorn stones	61 (62.3)	55 (56.7)	0.430
Previous surgery ^a			
No	81 (82.6)	84 (86.6)	–
Yes	17 (17.4)	13 (13.4)	0.445

Table 1. Comparisons of patients' demographics and preoperative clinical characteristics between two groups. BMI body mass index, SD standard deviation; ^aPrevious surgery include flexible ureteroscopy lithotripsy, percutaneous nephrolithotomy or open surgery for stone.

Results

Demographics and preoperative clinical characteristics

The 195 patients in this study were randomly assigned to the single-access MPCNL (*n* = 98) or the multi-access MPCNL (*n* = 97) group. The groups were similar in the patients' demographics and preoperative clinical characteristics (Table 1). The mean STONE score was 8.9 in single-access MPCNL group and 8.7 in multi-access MPCNL group, and no significant difference was found (*P* = 0.148). In addition, there was no substantial difference between the two groups in mean age at diagnosis, body mass index, sex ratio, history of hypertension

Variables, mean \pm SD or <i>n</i> (%)	Single-access MPCNL group (<i>n</i> = 98)	Multi-access MPCNL group (<i>n</i> = 97)	<i>P</i> value
Operative time (min)	96.7 \pm 6.2	98.1 \pm 5.9	0.108
Hemoglobin decrease (g/L)	7.3 \pm 4.1	13.4 \pm 3.5	< 0.001
Postoperative hospital stay (days)	4.2 \pm 0.8	5.1 \pm 0.5	< 0.001
Initial SFR (postoperative 2nd day)	87 (88.8)	72 (74.2)	0.009
Total SFR (postoperative 4th week)	93 (94.9)	83 (85.6)	0.028
Complications			
Fever	9 (9.2)	7 (7.2)	0.617
Low back pain	7 (7.1)	18 (18.5)	0.017
Perirenal hematoma	4 (4.1)	13 (13.4)	0.021
Renal artery embolization	0 (0.0)	4 (4.1)	0.042
Urosepsis	2 (2.0)	3 (3.1)	0.642
Stone compositions			
Calcium oxalate	40 (40.8)	37 (38.1)	0.703
Calcium phosphate	28 (28.6)	29 (29.9)	0.839
Struvite or carbonated apatite	23 (23.5)	26 (26.8)	0.591
Uric acid or cysteine	7 (7.1)	5 (5.2)	0.564

Table 2. Comparisons of surgical outcomes and postoperative clinical characteristics between two groups. *SD* standard deviation, *SFR* stone-free rate.

and diabetes, STONE score, degree of hydronephrosis, urine culture, distribution of stones and histories of upper urinary stone operation (all $P > 0.05$).

Postoperative clinical characteristics

Differences in postoperative clinical outcomes between two groups were shown in Table 2. Mean operative time between two groups was similar ($P > 0.05$). Mean decrease in hemoglobin level was less in single-access MPCNL group than that in multi-access MPCNL group (7.3 vs. 13.4 g/L, $P < 0.001$). Meanwhile, postoperative hospital stay in single-access MPCNL group was shorter than that in multi-access MPCNL group (4.2 vs. 5.1 days, $P < 0.001$). Moreover, the SFRs of the postoperative 2nd day and 4th week in single-access MPCNL group were both significantly higher than those in multi-access MPCNL group (88.8% vs. 74.2%, $P = 0.009$; 94.9% vs. 85.6%, $P = 0.028$, respectively). Postoperative complications were classified using the modified Clavien system, including fever ($\geq 38.5^\circ\text{C}$), low back pain, perirenal hematoma and renal artery embolization and urosepsis. In terms of the rates of low back pain, perirenal hematoma and renal artery embolization, multi-access MPCNL group were all significantly higher than single-access MPCNL group (18.5 vs. 7.1%, $P = 0.017$; 13.4 vs. 4.1%, $P = 0.021$; 4.1 vs. 0.0%, $P = 0.042$; respectively). No case needed blood transfusion in single-access MPCNL group and one case needed blood transfusion in multi-access MPCNL group. No significant difference was found between two groups in stone compositions ($P > 0.05$).

Discussion

Currently, various minimally invasive treatment strategies have succeeded in the treatment of renal stones^{16,17}. For the CRS, there is still a need to develop a surgical procedure satisfying both high SFR and minimized renal injury. In the past decade, more and more researches were focusing on multi-access MPCNL for the treatment of CRS^{5,18,19}. Although the surgical method can increase the SFR, it may invisibly increase the occurrence of complications such as renal parenchymal damage and bleeding. However, compared with multi-access MPCNL, single-access MPCNL often requires more operative duration and postoperative ancillary treatments^{20,21}. Furthermore, single-access MPCNL commonly has more blind areas in renal collecting system. So we consider to develop a new hybrid technique, combining single-access MPCNL with flexible cystoscopy, to avoid the shortcomings of multi-access MPCNL and further improve therapeutic outcomes of CRS.

Improving the SFR and reducing the recurrence rate of CRS has always been a key and difficult point in treatment^{22,23}. Given the high risk of stone recurrence, it is imperative to implement effective preventive and therapeutic measures for those identified at high risk^{24,25}. A one-year follow-up analysis pinpointed the treatment regimen, BMI, and STONE score as significant independent risk factors for the recurrence of renal stones²⁶. However, no substantial difference between the two groups in our study was observed in demographics and preoperative clinical characteristics. Then treatment regimen became the key to solving problems. In response to these challenges, our study explored the efficacy of combining MPCNL with flexible cystoscopy for a more comprehensive management of CRS, especially those located in hard-to-reach areas. The introduction of flexible cystoscopy offers a precise method for locating and addressing stones in areas of the renal that are traditionally difficult to reach. Thus, our outcomes showed that the initial and total SFRs in single-access MPCNL group were both significantly higher than those in multi-access MPCNL group (88.8% vs. 74.2%, $P = 0.009$; 94.9% vs. 85.6%, $P = 0.028$, respectively).

Flexible cystoscopy in the hybrid technique can increase intraoperative visual fields to search residual stones and decrease the possibility of establishing multiple percutaneous tracts. Complications in PCNL were directly proportional to the number of percutaneous tracts used for the stone clearance. In a meta-analysis, the

complications of multi-access MPCNL varied from 5 to 44% overall⁷. Gorbachinsky I et al. showed that multi-access PCNL was associated with a significant reduction in the function of the targeted kidney compared to a single access approach²⁷. Another study reported that single-access PCNL provides excellent outcomes in the treatment of CRS, including high SFRs and minimal morbidity⁶. These coincides with our research findings. Our data also showed that multi-access MPCNL group were all significantly higher than single-access MPCNL group (18.5 vs. 7.1%, $P=0.017$; 13.4 vs. 4.1%, $P=0.021$; 4.1 vs. 0.0%, $P=0.042$; respectively) in terms of the rates of low back pain, perirenal hematoma and renal artery embolization.

In addition, for CRS, our study showed that single-access MPCNL was inefficient and safe with the assistance of flexible cystoscopy. Mean decrease in hemoglobin level was less in single-access MPCNL group than that in multi-access MPCNL group (7.3 vs. 13.4 g/L, $P<0.001$). And postoperative hospital stay in single-access MPCNL group was more shorten than that in multi-access MPCNL group (4.2 vs. 5.1 days, $P<0.001$). As was approved by before, this was related to the number of percutaneous tracts established in MPCNL. The mean operative time reached 96.7 min in single-access MPCNL group and was similar between two groups ($P>0.05$).

Finally, there are also some limitations in our study. Firstly, the follow-up is short and may have affected the outcome. Furthermore, the study is based on single center with a small sample size and there may be certain sampling errors. Therefore, large-scale multicenter prospective studies are still needed to further prove the above conclusions. We believe that the ideal procedure will be formulated through a long period of clinical application and observation.

Conclusions

Our study shows that single-access MPCNL and flexible cystoscopy are ideal complementary techniques in the treatment of CRS, satisfying both high SFR and minimized renal injury. This method was safe and reproducible in clinical practice. However, large-scale multicenter prospective studies are still needed to further prove the above conclusions.

Data availability

The datasets generated and/or analysed during the current study are not publicly available due to the nature of this research participants of this study did not agree for their data to be shared publicly, so supporting data is not available, but are available from the corresponding author on reasonable request.

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Author contributions

QL Tang and RZ Tao: Project development. JD Guo and DJ Wang: Data Collection. JY Ji, YY Tu and XZ Zhou: Data analysis and Manuscript writing. All authors reviewed the manuscript.

Declarations

Competing interests

The authors declare no competing interests.

Additional information

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