Single Percutaneous Tract Combined with Flexible Nephroscopy in the Management of Kidney Stones 2-4 cm: Better Options of Treatment Protocols

Xiaobo Zhang[1,2,3], Jie Gu[1,2], Xiong Chen[1,2], Yuanqing Dai[2], Mingquan Chen[1], Sheng Hu[1], Zhenyu Liu[1], Dongjie Li[1,2]*

Purpose: To investigate the safety and efficacy of single percutaneous tract combined with flexible nephroscopy in the Management of 2-4 cm renal calculi.

Materials and Methods: We retrospectively analysed the treatment data of patients with 2-4 cm renal calculi from June 2010 to June 2017. The data included 217 cases of percutaneous nephrolithotomy (PNL), 441 cases of retrograde intrarenal surgery (RIRS) and 217 cases of single-access percutaneous nephrolithotomy combined with flexible nephroscopy (PNCFN). The collected data were analyzed.

Results: A total of 875 cases were studied, with an average age of 42.35 ± 10.29 years. Group PNCFN showed the highest stone-free rates (SFRs)(73.7 vs 66.7 vs 80.2, P = .00), best patient satisfaction (89.84 vs 87.23 vs 92.29, P = .00). The length of stay was shorter in the RIRS group relative to the other two groups (5.22 vs 5.65 vs 3.72, P = .00). Haemoglobin decrease (> 10 g/L) was higher in group PNL than that in group RIRS and group PNCFN (P = .012). Hospitalization fees (RMB) were Increased in group PNCFN compared with that in group PNL and group RIRS (34563.45 vs 21334.69 vs 33343.16, P = .000). Treatment protocols of PNL decreased from 17.51% to 9.22%, those for RIRS from 5.22% to 17.69%, peaking at 2012, PNCFN from 8.29% to 15.67% showed a rapid growth trend.

Conclusion: The percutaneous nephrolithotomy combined with flexible nephroscopy treatment on renal calculi of 2-4 cm was associated with higher stone-free rates and better patient satisfaction than RIRS and PNL.

Keywords: flexible nephroscopy; percutaneous nephrolithotomy; retrograde intrarenal surgery; stone free rate; patient satisfaction

INTRODUCTION

Renal calculi larger than two cm are known for their complexity of clearance, high risk in operation, and high rate of residuals and relapse. Percutaneous Nephrolithotomy (PNL) had been recommended as the first-choice treatment for renal calculi larger than 2 cm[(1)]. The advantages of PNL included higher efficiency and lower rates of residual stones[(2)]. However, single-access PNL cannot effectively deal with parallel calices calculi; multiple-tract PNL in one session is effective while it caused more surgical trauma[(3-5)]. Many researchers have explored RIRS to remove kidney stones 2 cm, reducing operation trauma and shortening length of stay. As RIRS has a lower efficiency than PNL, it takes 1.2 to 1.7 more times of operation and leading to higher expenses to the patients[(6)], the one stage SFR was reported in 72.2% and even lower. Residual stones are related to future stone events and concomitant surgery. Flexible nephroscopy is able to reach more calyces and inspect them for residual fragments, it may reduce the use of the fluoroscopy and detection of the residual stones to improve the efficacy and reduce the morbidity of the procedure[(7,8)].

In current research, with the emergence of new instrument flexible nephroscopy, single-access PNCFN was used to deal with the 2-4 cm renal calculi. This method was expected to have higher calculi removal efficiency, lower risks in operation and a lower rate of residuals. So far, the study of the comparison among PCNL, RIRS and PNCFN in the management of kidney stones 2-4 cm at the same time is lacking. Hence, we compared our clinical experiences and previous clinical cases, where RIRS and PNL were adopted for 2-4 cm renal calculi removal for better reference when selecting treatment protocols.

MATERIALS AND METHODS

Clinical Data

Our study was based on the clinical cases of 2-4 cm renal calculus treatment in our hospital from June 2010 to June 2017. The calculi sizes were measured through CT examination (single calculus 2-4 cm or multiple stones

[1]Xiangya International Medical Center, Department of Geriatrics, Xiangya Hospital, Central South University, Changsha, P. R. China, 410008.
[2]National Clinical Research Center for Geriatric Disorders, Central South University Changsha, P. R. China, 410008.
[3]Urolithiasis Institute of Central South University, Changsha, P. R. China, 410008.
*Correspondence: Department of Geriatrics, Xiangya International Medical Center, Xiangya Hospital, Central South University, Changsha, P. R. China, 410008.
Tel: +86 0731 89753054, E-mail: jerry1375@126.com.
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Table 1. The detailed general patient information.

	PCNL	RIRS	PNCFN	*P* Value
Cases, n 217	441	217	N/A	
Age, years	42.35 ± 11.20	42.62 ± 9.63	41.44 ± 10.36	0.379
BMI (kg/m2)	24.60 ± 3.40	24.99 ± 3.54	24.35 ± 3.37	0.069
Gender (M/F)	100/117	220/221	107/110	0.647
Stone burden (mm)	34.21 ± 4.81	34.57 ± 3.32	34.53 ± 2.86	0.470
Stone location, n(%)				0.000
Upper pole	20(9.22)	34(7.71)	18(8.29)	
Middle pole	37(17.05)	113(25.62)	33(15.21)	
Lower pole	74(34.10)	108(24.49)	84(38.71)	
Renal pelvis	53(24.42)	131(29.70)	41(18.89)	
Multiple stones	33(15.20)	55(12.47)	41(18.89)	
Hydronephrosis, n(%)				0.327
No	58(26.73)	103(23.36)	49(22.58)	
Mild	77(35.48)	140(31.75)	87(40.10)	
Moderate	61(28.11)	152(34.47)	62(28.57)	
Severe	21(9.68)	46(10.43)	19(8.76)	
Urine leukocyte positive, n (%)	51 (23.50)	93 (21.09)	47 (21.66)	0.778
Urine erythrocyte positive, n (%)	24 (11.06)	42 (9.52)	28 (12.9)	0.414
Abnormal serum creatinine, n (%)	18 (8.29)	42 (9.52)	24 (11.06)	0.618

Measurement data between groups were expressed as the mean ± SD ($\bar{x} \pm s$) One-way Analysis of Variance was used to compare the variables in different groups. Counting data were shown as the number and/or percentage (%), using the chi-square test (χ^2). $P < 0.05$ illustrates statistical significance.

2-4 cm combined). The participants were divided into 3 groups according to treatment methodology, including 217 cases of PNL, 441 cases of RIRS and 217 cases of single-channel PNCFN.

All patients were informed about the procedures, and the surgical choice was made by the patient with counselling from the surgeon. All patients received appropriate preoperative antibiotic. The operation time was recorded from insertion of the endoscope to the completion of stent placement. All protocols in the present investigation were reviewed and approved by the ethical review committee of the Xiangya Hospital, Central South University of China. An independent third-party survey center participated in the accurate reporting of patient satisfaction after surgery. All surgeries were completed by the same doctor. We recorded and analyzed patients' general information such as age, gender, the size of the calculi and BMI. The operation time, variation of haemoglobin, the SFRs, complications and length of stay were collected. The length of stay was recorded from admission to discharge.

The inclusion criteria were applicable to all three surgical procedures: 1. age 20-80 years; 2. renal calculi 2~4 cm; 3. serious heart and lung diseases were excluded; 4. systemic haemorrhagic disease was excluded; 5. the ipsilateral GFR was more than 10 ml/min; 6. if both sides met the requirements, bilateral treatment was not included in the study; If staging treatment was performed, the first side of the clinical data was included in the study.

Operation protocol

For the group PNL, operations were performed on patients under general anaesthesia in lithotomy position. A 4 Fr retrograde ureteral catheter was inserted into the surgical side of the ureter with a ureteroscope. Then the position was changed to prone. With the guidance of colour Doppler ultrasound, the puncture point was located at the 11th-12th intercostal between the posterior axillary line and scapular line. The puncture was made through the fornix of calices, and then the tract was dilated to 20 Fr with a balloon or coaxial dilators. A nephrostomy sheath was advanced over the balloon

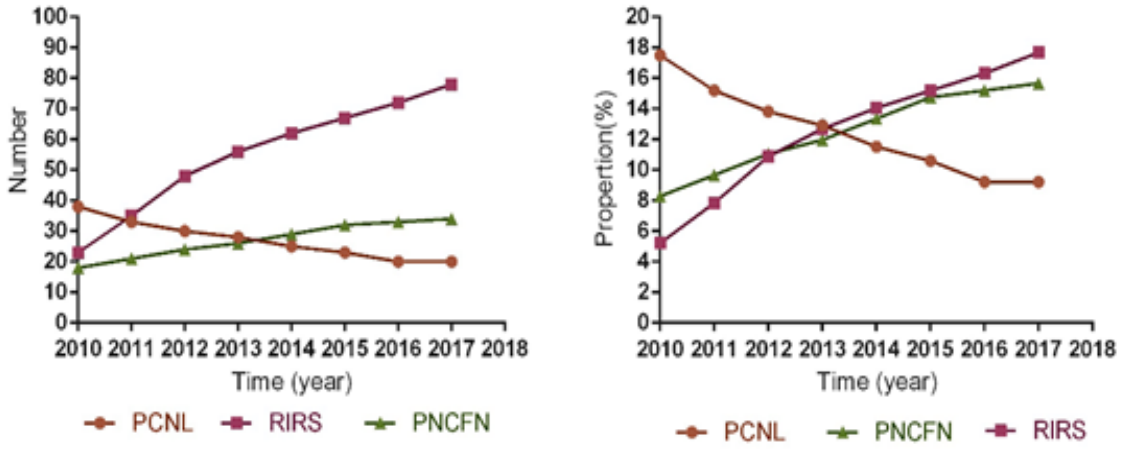

Figure 1. Changes in treatment protocols

Table 2. Comparison of the perioperative related data.

	PCNL	RIRS	PNCFN	*P* Value
stone-free n (%)	160(73.7)	294(66.7)	174(80.2)	0.000
Operation time (min)	104.35 ± 40.65	129.17 ± 41.91	131.88 ± 45.63	0.000
Bleeding (mL)	60.65 ± 40.42	23.86 ± 18.09	54.17 ± 31.81	0.000
Conversion to open surgery n (%)	4(1.8)	2(0.5)	3(1.4)	0.211
Length of stay (d)	5.65 ± 0.74	3.72 ± 1.24	5.22 ± 0.88	0.000
Blood transfusion n (%)	6(2.8)	1(0.2)	4(1.8)	0.188
Complications n (%)	21(9.7)	30(6.8)	11(5.1)	0.165
Unplanned re-operation n (%)	5(2.3)	4(1)	2(0.9)	0.280
Haemoglobin decrease (>10 g/L), n (%)	26 (12.0)	26 (5.9)	24 (11.1)	0.012
Fees (RMB)	21334.69 ± 3006.73	33343.16 ± 3639.04	34563.45 ± 5198.03	0.000
Satisfaction score	89.84 ± 4.37	87.23 ± 5.99	92.29 ± 3.88	0.000

Measurement data between groups were expressed as the mean ± SD ($\bar{x} \pm s$). One-way Analysis of Variance was used to compare the variables in different groups. Counting data were shown as the number and/or percentage (%), using the chi-square test (χ^2). $P < 0.05$ illustrates statistical significance.

and the nephroscope or ureteroscope was placed along the sheath; when the calculi were detected, they were removed with a holmium laser (2.0-2.5 J, 20-25 Hz, 550 μm). A routine postoperative indwelling ureteral stent was placed on the operative side.

For the group RIRS, the operations were performed on patients under general anaesthesia and in the lithotomy position. A 8.0-9.5 Fr ureteroscopy was used to check the surgical side of the ureter up to the pelvis, and a smooth guidewire (0.89 mm, 150 cm, Cook® Medical, America) was placed. Along the guidewire, a ureteral access sheath (12 Fr Cook® Medical) was installed, then an Olympus flexible ureteroscope was used. Every calyx was examined via the flexible ureteroscope, and the calculi were removed with a holmium laser (0.8-1.0 J, 20 Hz, 200 μm). Larger stone fragments were removed using a 1.7 Fr N GageTM nitinol basket (Cook® Medical, Bloomington America). Upon finishing the operation, each calyx was examined again. When the flexible ureteroscope was removed, the whole ureter was checked at the same time, while a routine postoperative indwelling ureteral stent was placed on the operative side.

For the group PNCFN a 20 Fr tunnel was established in the same way as for group PNL. Calculi were removed with a holmium laser (2.0-2.5 J, 20-25 Hz, 550 μm) after the insertion of a nephroscope or ureteroscope. Note that the angle change was avoided in the access to reduce the risk of laceration of calices' necks. When calculi were difficult to reach, flexible nephroscopy with a holmium laser (0.8-1.0 J, 20 Hz, 200 μm) was used to enter the calices through the 20 Fr tunnel and remove the calculi. Upon finishing the operation, each calyx, the pelvis and ureteropelvic junction was examined. and a routine postoperative indwelling ureteral stent was placed on the operative side.

Collected data consisted of patient age, gender, the size of the calculi and BMI. Information about the operation time, variation of haemoglobin, SFRS, complications and length of stay were collected. After 4 weeks, if the non-contrast CT examination indicated no residual calculi or if the residual calculi were less than 4 mm and the patients showed no related symptoms, calculi removal was effectively performed. The ureteral stent was maintained for 4 weeks.

An independent third party (Hualun Consulting Co., Ltd. Hunan) was responsible for the satisfaction survey, which was conducted by telephone one month after discharge. Patient satisfaction is a subjective quantitative score of the medical service. This questionnaire includes six main parts and 15 detailed indicators (**Figure 2**).

Statistical Analysis

The statistical analysis was conducted using SPSS software, version 19.0. Measurement data between groups were expressed as the mean ± SD ($\bar{x} \pm s$), one-way Analysis of Variance was used to compare the variables in different groups. Counting data were shown as the number and/or percentage (%), using the chi-square test (χ^2) to compare the variables in different groups. $P < 0.05$ illustrates statistical significance.

RESULTS

A total of 875 cases was studied, with an average age of 42.25 ± 10.35 years. The general information of the patients in each group is shown in **Table 1**. Among different groups, features such as age, BMI, maximum

Table 3. Comparison of the perioperative data between every two groups.

	PCNL vs RIRS	PCNL vs PNCFN	RIRS vs PNCFN
One-stage stone-free	0.065	0.111	0.000
Operation time	0.000	0.000	0.000
Bleeding	0.000	0.056	0.000
Conversion to open surgery	0.078	0.703	0.181
Length of stay	0.000	0.006	0.000
Blood transfusion	0.099	0.801	0.142
Complications	0.586	0.350	0.685
Unplanned re-operation	0.147	0.253	0.985
Hemoglobin decrease >10 g/L	0.014	0.880	0.021
Hospitalization fees	0.000	0.000	0.001
Patient satisfaction(discharged for one month)	0.000	0.000	0.000

One-way Analysis of Variance was used to compare the measurement variables in different groups. Chi-square test (χ^2) was used to compare the counting variables in different groups.
$P < 0.05$ illustrates statistical significance.

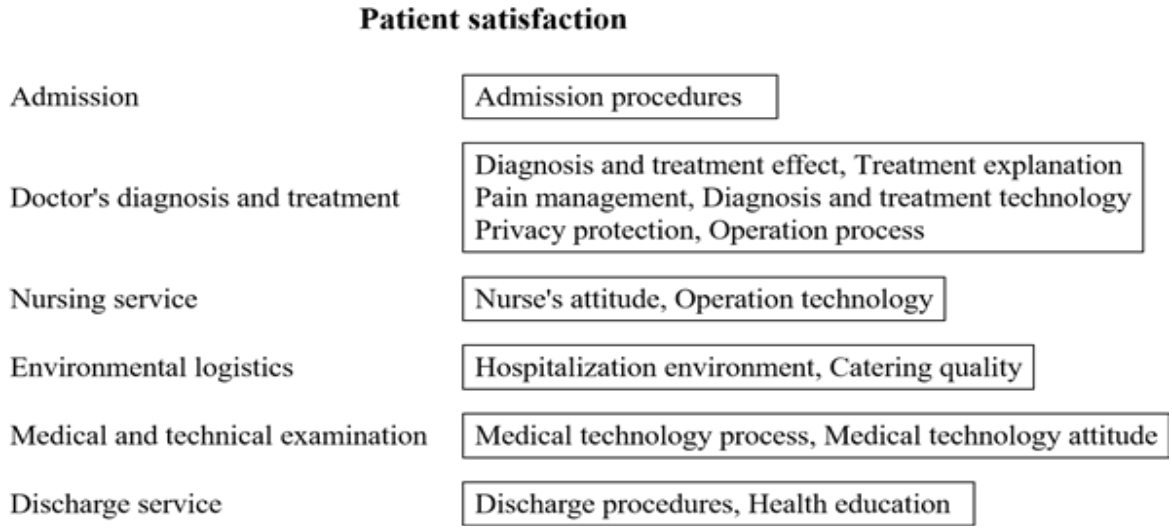

Figure 2. Patient Satisfaction

diameter of calculus, gender proportion, hydronephrosis, rate of urine leukocyte positive, rate of urine erythrocyte positive, and the proportion of abnormal serum creatinine showed no significant differences. The stone locations of lower pole and multiple stones in group PNCFN was higher than that in groups PNL and RIRS (38.71 vs 34.10 vs 24.49%, 18.89 vs 15.20 vs 12.47%). Renal pelvis stones frequency in group PNL, RIRS, PNCFN were 24.42, 29.70, 18.89% respectively.

The perioperative-associated parameters of different groups are shown in **Table 2**. Group PNCFN had higher SFRs (80.2%, $P = .00$), better patient satisfaction (score 92.29, $P = .00$), but a longer operation time (131.88 min, $P = .01$). The length of stay in group PNCFN was shorter than that in group PNL (multiple-tract was performed for 102 (47.0%) cases in the PNL group) but longer than that in group RIRS (average 5.22 vs 5.65 vs 3.72 d, $P < .001$). Haemoglobin decrease (> 10 g/L) was higher in group PNL than those in groups RIRS and PNCFN ($P = .012$). Increased hospitalization fees (RMB) was observed in group PNCFN compared to groups PNL and RIRS (average 34563.45 vs 21334.69 vs 33343.16 RMB, $P < .001$).

The reason for conversion to open surgery in group PCNL was that 2 patients were morbidly obese; 1 case of renal parenchymal laceration by multi-channel; and 1 case of anatomical abnormalities (renal neck stenosis). 1 case of ureteral avulsion injury and 1 case of intraoperative ureteral perforation necessitated conversion in the group RIRS. 1 case of skeletal malformation and 2 case of ureteropelvic junction obstruction in group PNCFN resulted in conversion. The rate of conversion to open surgery, ratio of blood transfusion, incidence of complications and rate of unplanned reoperation displayed no statistically significant differences.

The comparisons of the perioperative data between every two groups are shown in **Table 3**. Compared to group PNL, group PNCFN demonstrated a shorter length of stay ($P = .006$) and a higher patient satisfaction ($P < .001$), but a longer duration of operation ($P < .001$) and a higher hospitalization fees ($P < 0.001$). When comparing groups RIRS and PNCFN, group PNCFN showed higher SFRs ($P < .001$) and patient satisfaction rates ($P < .001$), but greater bleeding ($P < .001$), longer length of stay ($P < .001$), and higher haemoglobin decrease ($P < .001$).

The treatment protocols for 2-4 cm renal calculi are shown in **Figure 1**. The choice of PNL decreased smoothly (17.51% to 9.22%), and RIRS showed a rapid growth trend (5.22% to 17.69%, peaking at 2012). PNCFN continued to increase steadily (8.29% to 15.67%).

DISCUSSION

Guidelines recommend PNL as the first-choice treatment for renal calculi larger than 2 cm[9]. However, parallel calices calculi with the treatment of single-track PNL was difficult. Multiple-access PNL increased complications, such as haemorrhage.[10-12] The advantages of RIRS include utilizing the inherent cavity of the human body, low trauma, fast recovery, and better curative effect[13]. It can significantly reduce the incidence of surgical trauma and complications and shorten the average days of hospitalization[14]. In our study, the average length of stay was 3.72d (RIRS). However, due to the limitation of lithotripsy efficiency, RIRS for renal calculi larger than 2 cm needs to be performed in stages, and the SFR is low. Xiaokun Zhao et al, reported a 92.0% SFR after 3 procedures for RIRS with holmium laser lithotripsy (mean stone burden of 24.5 mm)[15]. In our study, the one-stage SFR was 66.7% (RIRS). Moreover, the success rate of RIRS was largely dependent on the angle between the funnel and the pelvis (infundibulopelvic angle, IPA). Petrisor et al. found that when the IPA was between 30 and 90 degrees, the success rate of RIRS was 74.3%, and when the IPA was less than 30 degrees, the success rate of flexible ureteroscopic lithotripsy became 0% [6].

The EAU and AUA guidelines recommendation is that routine stenting is not necessary before RIRS. However, pre-stenting facilitates RIRS management of stones, improves the SFR, and reduces complications. In our study, if ureteral access is not possible, insertion of a 6 Fr double-J stent 4 weeks before the second attempt offers an alternative to dilation.

Over the last 10 years, living standards and the econ-

omy improved, causing people to be more engaged health and healthcare consumers which lead to a rapid growth of less invasive RIRS (**Figure 1**). However, there remain several controversial issues in the application of flexible ureteroscopy, such as operation indication, operative skills, and cost efficiency. We focus on the hot issues that puzzle clinicians most, and hope our study will be able to help some urologists in clinical practice. Our hospital did not introduce mini-percutaneous nephrolithotomy, super-mini percutaneous nephrolithotomy, or Chinese minimally invasive percutaneous nephrolithotomy, which have improved smaller tracts and are less invasive[16-18].

The use of flexible nephroscopy during PNL was known for its higher SFRs, fewer interventions and minimal bleeding[19]. Improvements in design and novel surgical instruments, such as flexible nephroscope and the introduction of the holmium: YAG laser, increased the SFRs for PNL[20-22]. Williams et al. observed a high SFR and low morbidity rate with staghorn stones following single-access PNL and flexible nephroscopy[23]. Our results showed that there was an 80.2% (174/217) one-stage SFR for PNCFN versus 66.7% (294/441) for RIRS ($P < .001$), indicating that PNCFN was an effective treatment protocol that provided more efficacy in patients with 2-4 cm renal calculi.

Bleeding is a major and troublesome complication of PNL. The volume of blood loss is associated with the number of access points, stone size, and duration of surgery 5,24. In our present study, the mean duration was slightly longer in group PNCFN than that in group PNL (131.88 versus 104.35, $P = .001$) as shown in **Table 2**, whereas the mean bleeding was 54.17 (PNCFN) versus 60.65 ml (PNL), which showed no statistically significant differences ($P = .056$). This result may have been due to the lower number of interventions that were associated with flexible nephroscopy, or the use of a smaller diameter instrument that could reach stones that were inaccessible via rigid nephroscopy (with minimal damage to renal parenchyma)19. Our puncture was made through the fornix of calices. The fornix of the papilla is the preferred site for a puncture to the collecting system[25]. The principle behind this approach relies on the anatomical distribution of the blood vessels within the kidney, it is associated with less haemorrhagic risk [26,27].

The patient satisfaction survey was relevant and meaningful, and assessed patient satisfaction using an independent, third-party survey center to eliminate observer bias[28,29]. Although it is a comprehensive data, there are many influencing factors, however it can reflect the satisfaction to some extent. In our study, the mean score of patient satisfaction was the highest in Group PNCFN 92.29, as represented in **Table 2**, which was higher than 89.84 (PNL) and 87.23 (RIRS), and this result may have been due to the high one-stage SFR (73.7% vs 80.2%), less bleeding (54.17 vs 60.65ml), less complications (11(5.1%) vs 21(9.7%) and the decreased length of stay (5.22 vs 5.65) compared to PNL, although more instruments were used and the expenses were slightly higher than those for PNL. Another crucial factor was that there were no multi-channel cases in Group PNCFN. To our knowledge, our study is the first to report the comparison among PNL, RIRS and PNCFN. There are no assessments of the three protocols based on patient satisfaction by independent investigators.

The complications were low in the three groups, and it showed no statistically significant differences, which may be due to a small sample size. To clarify whether the two were correlated, larger sample sizes are needed to evaluate the long-term outcome of our study. Retrospective design is a drawback of our study, we do agree that prospective and randomized design is needed in the future studies.

When multiple treatment protocols compete in the clinical setting, decisions of the optimal treatment option in an individual patient are mainly dependent on medical factors, including procedural efficacy, success rate and safety. From a broader perspective, these decisions reflect comprehensive factors including the above mentioned factors, as well as doctor`s preference, cost-effectiveness, medical care status, and insurance authorization. Therefore, identifying the changing trends in the numbers or rates of certain treatments is meaningful and may provide a comprehensive assessment of the treatment of kidney stones 2-4 cm that can be used in clinical management. In our study, a single access percutaneous nephrolithotomy combined with flexible nephroscopy was used, which gave full play to the advantages of flexible and rigid nephroscopy. Salient advantages of our PNCFN include one-stage stone-free rate of 80%, length of stay shortened to 5.22 days and improved patient satisfaction. In addition, the cost of the PNCFN was marginally higher than that of the RIRS, which is also in favour of the promotion of the PNCFN surgery in the primary hospitals.

As far as we know, our study is the first to report the comparison among PNL, RIRS, and PNCFN at the same time. There are no assessments of the three protocols based on patient satisfaction by independent investigators in one study. Our study had certain limitations. there may be a choice bias in this study. Fortunately, the study has a large sample size so that this bias is effectively reduced, and **Table 1** shows no significant difference in the baseline data of each group.

CONCLUSIONS

The percutaneous nephrolithotomy combined with flexible nephroscopy treatment on renal calculi of 2-4 cm was associated with higher stone-free rates and better patient satisfaction than RIRS and PNL.

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CONFLICT OF INTEREST

All authors declare that they have no conflict of interest or financial ties to disclose.

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