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Mini Percutaneous Nephrolithotomy Is a Noninferior Modality to Standard Percutaneous Nephrolithotomy for the Management of 20–40 mm Renal Calculi: A Multicenter Randomized Controlled Trial

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Abstract

Background: High quality of evidence comparing mini percutaneous nephrolithotomy (mPNL) with standard percutaneous nephrolithotomy (sPNL) for the treatment of larger-sized renal stones is lacking.
Objective: To compare the efficacy and safety of mPNL and sPNL for the treatment of 20–40 mm renal stones.
Design, setting, and participants: A parallel, open-label, and noninferior randomized controlled trial was performed at 20 Chinese centers (2016–2019). The inclusion criteria were patients 18–70 yr old, with normal renal function, and 20–40 mm renal stones.
Intervention: Percutaneous nephrolithotomy (NPL) was performed using either 18 F or 24 F percutaneous nephrostomy tracts.
Outcome measurements and statistical analysis: The primary outcome was the one-session stone-free rate (SFR). The secondary outcomes included operating time, visual analog pain scale (VAS) score, blood loss, complications as per the Clavien-Dindo grading system, and length of hospitalization.

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Standard;
Renal stone;
Randomized controlled trial

Results and limitations: The 1980 intention-to-treat patients were randomized. The mPNL group achieved a noninferior one-session SFR to the sPNL group by the one-side noninferiority test (0.5% [difference], $p < 0.001$). The transfusion and embolization rates were comparable; however, the sPNL group had a higher hemoglobin drop (5.2 g/l, $p < 0.001$). The sPNL yielded shorter operating time (–2.2 min, $p = 0.008$) but a higher VAS score (0.8, $p < 0.001$). Patients in the sPNL group also had longer hospitalization (0.6 d, $p < 0.001$). There was no statistically significant difference in fever or urosepsis occurrences. The study's main limitation was that only 18F or 24F tract sizes were used.
Conclusions: Mini PNL achieves noninferior SFR outcomes to sPNL, but with reduced bleeding, less postoperative pain, and shorter hospitalization.
Patient summary: We evaluated the surgical outcomes of percutaneous nephrolithotomy using two different sizes of nephrostomy tracts in a large population. We found that the smaller tract might be a sensible alternative for patients with 20–40 mm renal stones.

1. Introduction

Percutaneous nephrolithotomy (PNL) is the preferred surgical procedure for the treatment of 20–40 mm renal stones, as it has an excellent stone-free rate (SFR) [1]. However, PNL can result in serious morbidities: blood transfusion (7%), sepsis (0.5%), organ injury (0.4%), embolization (0.4%), and death (0.05%) [2]. It has been demonstrated that the large nephrostomy tract (24–30 F), the so-called standard PNL (sPNL), partly contributes to these morbidities [3]. Mini PNL (mPNL; 12–20 F) was initially introduced for pediatric patients. Later, it was applied to the general population to reduce the morbidities [4,5]. Currently, the generally accepted options for treating 20–40 mm renal stones included flexible ureteroscope lithotripsy (fURL) and PNL. Compared with mini percutaneous or micropercutaneous surgery, fURL has a lower SFR and requires staged procedures, but has lower complication rates and shorter hospitalization times [6–8]. With the improvements in nephroscope, lithotripter, nephrostomy sheath, and imaging technique in the past 2 decades, sPNL has been challenged by mPNL. A recent systematic review and meta-analysis reported that mPNL could achieve a comparable SFR, but with a longer operative time. However, mPNL had the advantages of less blood loss and shorter hospitalization. Other complications were similar [1]. However, the quality of evidence in this analysis had certain limitations: there was significant heterogeneity among the included studies, most of the studies were single-arm trials, and this analysis comprised only two small-sized randomized controlled trials (RCTs). Hence, higher-quality evidence is necessary to reach sound conclusions and make suitable recommendations. We conducted a large multicenter RCT to compare the efficacy and safety between sPNL and mPNL.

2. Patients and methods

2.1. Trial design and participants

This is a multicenter, parallel, open-label RCT. Patients were recruited from 20 Chinese tertiary medical centers from January 2016 to August 2019 (ClinicalTrials.gov, NCT02635048). Each participating center performed >500 PNLs per year. Ethics committee approval was obtained at each site, and written informed consent was obtained from each patient. We presented the study following the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

The primary outcome was the one-session SFR, and the secondary outcomes included operating time, visual analog pain scale (VAS) score, blood loss, complications as per the Clavien-Dindo grading system, and length of hospitalization. Patients aged between 18 and 70 yr and with normal serum creatinine (≤133 μmol/l), 20–40 mm renal stones, and American Society of Anesthesiology scores of 1–2 were included. Morbidly obese patients (body mass index ≥40 kg/m^2), patients with congenital abnormalities, patients with histories of renal transplant or urinary diversion, and patients with solitary kidneys, uncorrected coagulopathy, or active urinary tract infections were excluded.

2.2. Randomization and masking

Central randomized allocation was used without stratification. A randomization list was generated by a statistician and securely stored at a password-protected computer of the sponsor's center. Only one protocol-blinded coordinator knew the password and revealed the assignments in sequence to each center. Since the participating centers needed to prepare the appropriate instruments for the allocated procedures, the allocation was revealed 1 d before surgery. Consent forms were signed.

2.3. Procedures and quality control

A uniform operating methodology was established and approved by the principal investigator in each center. Protocol monitoring visits were conducted monthly at all centers.

Intravenous urography and 2 mm noncontrast computed tomography (CT) were performed in all patients. All centers used the same software to measure stone density. All patients had negative urine culture before operation. A single intravenous dose of first/second-generation cephalosporin or ciprofloxacin was administered 30 min before and after each surgery for prophylaxis.

All the procedures were performed by one designated experienced surgeon (≥100 procedures per year in both sPNL and mPNL) per center. Each procedure was completed under general anesthesia and in the prone position. A 5 F open-ended ureteral catheter was first inserted into the renal pelvis. The renal puncture was performed using an 18-gauge needle with fluoroscopic and/or ultrasonic guidance as per the surgeon's preference. The nephrostomy tract was gradually dilated with fascial dilators up to 18 F (mPNL) or 24 F (sPNL). A corresponding peel-away sheath was used (Fig. 1). A 12 F nephroscope (Wolf) was chosen for the mPNL and a 20.8 F one (Wolf) for the sPNL. The stone was fragmented by a pneumatic lithotripter or/and a holmium laser with a 550 μm laser fiber (with energy setting at 30–50 W) and/or an ultrasonic lithotripter (only the sPNL group). The status of residual stones was evaluated routinely by fluoroscopy (radiopaque stone) or ultrasound (radiolucent stone) at the end of the procedure. Then, an immediate second look through the initial tract or another puncture was performed if needed. A 6 F indwelling double-J stent was placed for 4 wk. A 16–18 F nephrostomy tube was inserted and then removed before discharge. Indications for a tubeless procedure were as follows: no visible perforation, no significant bleeding, and complete stone clearance.

2.4. Outcome measures and data collection

Plain kidney-ureter-bladder (KUB) radiograph and renal ultrasound were used to evaluate the residual stones before discharge and during follow-up. If there was a discrepancy between the KUB and ultrasound results, 2 mm noncontrast CT was performed to better assess the presence of residual stones and their clinical management. The residual stones were assessed by two protocol-blinded radiologists. If the largest residual stone was >6 mm, shock wave lithotripsy, retrograde intrarenal surgery, or retrograde ureteroscope lithotripsy was recommended before removing the double-J stent. Residual stones ranging from 4 to 6 mm in size were recommended for conservative treatments [9]. The one-session SFR was defined as the presence of either no residual stone or ≤4 mm asymptomatic, noninfectious, and nonobstructive residual stones [10] at 1 mo after the removal of the double-J stent and without any auxiliary procedures.

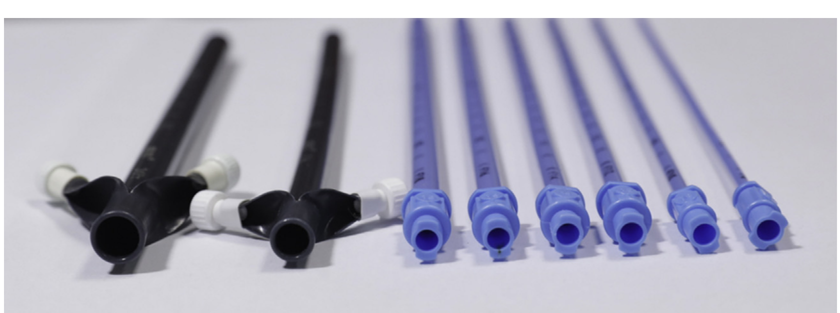
Transfusion was implemented when the hemoglobin was <70 g/l or progressively decreasing after surgery. Indications for angiography and selective angioembolization were continuous significant bleeding and progressive decrease in hemoglobin with hemodynamic instability. VAS was used for quantification of pain at 24 h after surgery [11]. VAS score was evaluated by two protocol-blinded nurses. Patients with a VAS score of >5 were given nonsteroidal anti-inflammatory medication. The stone composition was analyzed using the same infrared spectrometer and methodology [12] in all centers.

Patients' characteristics and clinical outcomes were recorded on a pre-established case report form (Supplementary material). Surgical outcomes were assessed using stone size, tract length, obstruction, number of involved calices, and stone density (STONE) nephrolithometry [13]. The stone size was the largest diameter for a single stone and the summation of the largest diameters for multiple stones. The operating time was defined as the time from a puncture to the placement of the nephrostomy tube or the removal of access sheaths in tubeless cases. Septic shock was identified using the clinical criteria of persisting hypotension requiring vasopressor therapy to maintain the mean artery pressure of ≥65 mmHg and having a serum lactate level of ≥2 mmol/l despite adequate fluid resuscitation [14].

2.5. Statistical analysis

The SFRs of sPNL and mPNL were presumed to be 89% and 83%, respectively, based on previous data [15–19]. Our null hypothesis was that mPNL had an inferior SFR to sPNL; –10% was considered as a noninferior margin. The sample size was calculated with the formulas of a two-sample noninferior test comparing two proportions. The type-1 error (α) was set at 0.05 and the power (1 – β) at 0.8. The sampling ratio was 1. The minimum sample size for each group was 923. The number was increased to 1000 in each group to offset the patient loss to follow-up and withdrawals.

Statistical analysis was performed using SPSS 20.0. Outcomes were analyzed in both intention-to-treat (ITT) and per-protocol (PP) populations. A one-side noninferiority test was used to evaluate whether mPNL had a noninferior one-session SFR to sPNL. Other categorical outcomes (eg, rates of transfusion, embolization and fever, and complication as per Clavien-Dindo grades) were compared using a fisher's exact or chi-square test. The means of continuous



Q1 **Fig. 1 – Fascial dilators and the corresponding peel-away sheaths (18 F and 24 F).**

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outcomes (eg, VAS score, hemoglobin drop, operating time, and length of postoperative hospitalization) were compared using a Student *t* test. Differences between proportions/means and 95% confidence intervals were presented. A *p* value of <0.05 was considered statistically significant.

3. Results

3.1. *Patient recruitment and baseline characteristics*

Of the 2465 patients assessed for eligibility, 2000 underwent randomization. After excluding patients due to canceled surgeries and withdrawn consent, 1980 patients received randomly assigned interventions and formed the ITT population (988 in the sPNL group and 992 in the mPNL group; Fig. 2). Of the ITT population in the sPNL group, five patients were converted to mPNL because the calyceal neck was too narrow or severe bleeding occurred after dilation to 18 F. Besides, 11 patients in the sPNL group and 12 in the mPNL group were converted to second-stage PNLs. Excluding cases lost to follow-up, the PP population included 966 patients in the sPNL group and 978 in the mPNL group. Patient demographics are shown in Table 1.

3.2. *Efficacy*

The mPNL group achieved a noninferior one-session SFR to the sPNL group (ITT: 0.5% [difference], $p <$ 0.001; PP: 0.1% [difference], $p <$ 0.001; Table 2); sPNL yielded shorter operating times than mPNL (ITT: –2.2 min, $p =$ 0.008; PP: –2.3 min, $p =$ 0.007; Table 2).

3.3. *Safety*

Although the sPNL procedure had a significantly higher hemoglobin drop (ITT: 5.2 g/l, $p <$ 0.001; PP: 4.6 g/l, $p <$ 0.001; Table 2), the transfusion and embolization rates of the two groups were comparable. Arterial embolization was required mainly in patients with complicated stones (STONE score ≥10) or in those with more than one

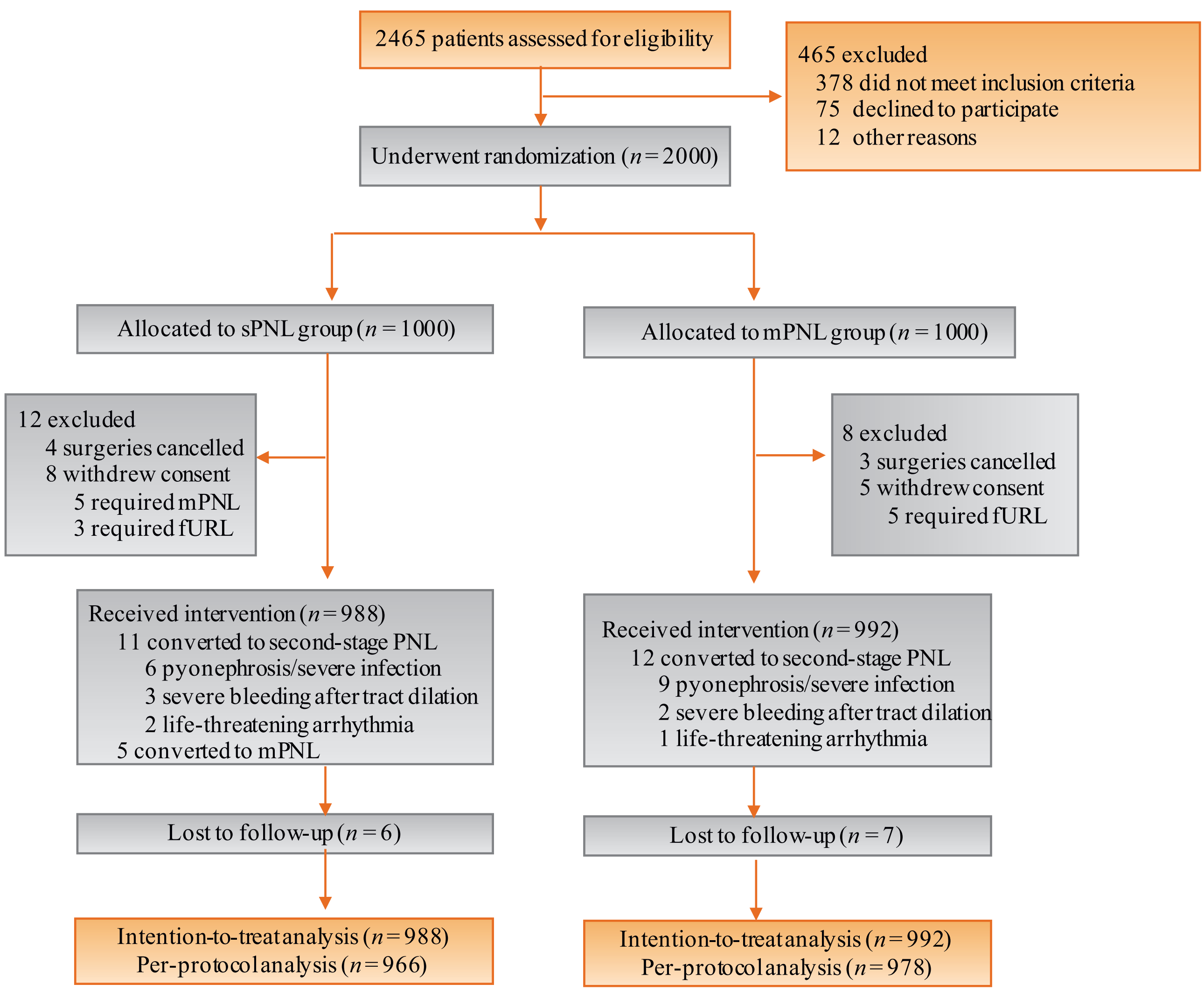

Fig. 2 – Trial profile. fURL = flexible ureteroscope lithotripsy; mPNL = mini percutaneous nephrolithotomy; PNL = percutaneous nephrolithotomy; sPNL = standard percutaneous nephrolithotomy.

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Q2 **Table 1 – Characteristics of the intention-to-treat population at baseline.**

	sPNL (n = 988)	mPNL (n = 992)
Age (yr)	51.0 (44.0, 60.0)	51.0 (43.0, 59.0)
Gender, n (%)		
Male	531 (54)	526 (53)
Female	457 (46)	466 (47)
BMI (kg/m^2)	24.7 (22.7, 26.6)	24.4 (22.3, 26.4)
Stone size (mm)	29.0 (25.0, 35.0)	29.0 (23.0, 35.0)
Stone surface (mm^2)	1122.0 (899.0, 1295.0)	1116.0 (900.0, 1260.0)
Number of stones		
1	878 (89)	856 (86)
≥2	110 (11)	136 (14)
CT value of stone (HU)	1105.1 (880.3, 1275.0)	1086.5 (865.0, 1254.5)
STONE score	7.0 (6.0, 8.0)	7.0 (6.0, 8.0)
Pre-Hb (g/l)	145.0 (134.0, 157.0)	144.0 (133.0, 155.0)
Pre-WBC (μmol/l)	6.4 (5.2, 7.8)	6.6 (5.4, 8.0)
Pre-Cr (μmol/l)	83.0 (71.0, 95.0)	82.3 (70.1, 94.9)
Comorbidity, n (%)	311 (32)	329 (33)
Initial positive urine culture, n (%)	188 (19)	200 (20)
Laterality, n (%)		
Left	501 (51)	492 (50)
Right	487 (49)	500 (50)
Hydronephrosis grade, n (%)		
G0	156 (16)	167 (17)
Mild (G1 or G2)	654 (66)	637 (64)
Moderate (G3)	127 (13)	142 (14)
Severe (G4)	51 (5.0)	46 (5.0)

BMI = body mass index; Cr = creatinine; CT = computed tomography; G0 = grade 0; G1 = grade 1; G2 = grade 2; G3 = grade 3; G4 = grade 4; Hb = hemoglobin; mPNL = mini percutaneous nephrolithotomy; sPNL = standard percutaneous nephrolithotomy; WBC = white blood cell.
Data are presented as median (first quartile, third quartile), or number (proportion).
The formula for calculation of stone surface is that the largest length of stone is multiplied by width.

Table 2 – Primary and secondary outcomes in intention-to-treat and per-protocol population.

	Intention to treat				Per protocol			
	sPNL (n = 988)	mPNL (n = 992)	Difference (95% CI)	p value	sPNL (n = 966)	mPNL (n = 978)	Difference (95% CI)	p value
One-session SFR, N (%)	848 (86)	856 (86)	0.50[a]	<0.001[b]	831 (86)	842 (86)	0.10[a]	<0.001[b]
Transfusion, N (%)	13 (1.3)	11 (1.1)	0.21 (−0.76 to 1.2)	0.7	11 (1.1)	11 (1.1)	0.014 (−0.93 to 0.96)	1
Embolization, N (%)	10 (1.0)	8 (0.81)	0.21 (−0.63 to 1.0)	0.6	9 (0.93)	8 (0.82)	0.11 (−0.72 to 0.94)	0.8
Hemoglobin drop (g/l)	17.0 (10.0, 29.0)	13.0 (5.0, 22.0)	5.2 (3.8–6.6)	<0.001	17.0 (9.0, 28.0)	13.0 (5.0, 22.0)	4.6 (3.2–6.1)	<0.001
Operating time (min)	35.0 (28.0, 48.0)	36.0 (27.0, 51.0)	−2.2 (−3.9 to −0.6)	0.008	35.0 (28.0, 48.0)	37.0 (28.0, 51.0)	−2.3 (−3.9 to −0.60)	0.007
VAS score postop 24 h	6.0 (5.0, 7.0)	5.0 (4.0, 6.0)	0.8 (0.7–1.0)	<0.001	6.0 (5.0, 7.0)	5.0 (4.0, 6.0)	0.8 (0.7–1.0)	<0.001
Analgesics (NSAIDs), N (%)	368 (37)	284 (29)	8.6 (4.5–13)	<0.001	359 (37)	272 (28)	9.4 (5.2–14)	<0.001
Fever (≥38 °C), N (%)	81 (8.2)	97 (9.8)	−1.6 (−4.1 to 0.94)	0.2	79 (8.2)	96 (9.8)	−1.6 (−4.2 to 0.91)	0.2
Septic shock required ICU treatment, N (%)	6 (0.61)	8 (0.81)	−0.20 (−0.94 to 0.54)	0.8	5 (0.52)	8 (0.82)	−0.30 (−1.0 to 0.42)	0.4
Postoperative hospitalization (d)	5.0 (4.0, 7.0)	5.0 (3.0, 6.0)	0.6 (0.4 - 0.8)	<0.001	5.0 (4.0, 7.0)	5.0 (3.0, 6.0)	0.5 (0.3–0.8)	<0.001
Clavien-Dindo, N (%)								
Grade I	409 (41)	385 (39)	–	0.7	406 (42)	377 (39)	–	0.4
Grade II	16 (1.6)	11 (1.1)			16 (1.7)	10 (1.0)		
Grade IIIa	12 (1.2)	11 (1.1)			11 (1.1)	11 (1.1)		
Grade IVa	4 (0.40)	6 (0.60)			3 (0.30)	6 (0.60)		
Grade IVb	2 (0.20)	2 (0.20)			2 (0.20)	2 (0.20)		
Tubeless, N (%)	180 (18)	344 (35)	−16 (−20 to −13)	<0.001	180 (19)	339 (35)	−16 (−20 to −12)	<0.001
Auxiliary procedure (SWL or RIRS or URL), N (%)	63 (6.4)	53 (5.3)	1.0 (−1.0 to 3.1)	0.3	62 (6.4)	51(5.2)	1.2 (−0.88 to 3.3)	0.3

CI = confidence interval; ICU = intensive care unit; mPNL = mini percutaneous nephrolithotomy; NSAID = nonsteroidal anti-inflammatory drug; postop = postoperative; RIRS = retrograde intrarenal surgery; SFR = stone-free rate; sPNL = standard percutaneous nephrolithotomy; SWL = shock wave lithotripsy; URL = ureteroscope lithotripsy; VAS = visual analog pain scale.
Data are presented as median (first quartile, third quartile), or number (proportion).
[a] Difference = P_T – P_S; P_T (proportion of test group): one-session SFR of mPNL; P_S (proportion of standard group): one-session SFR of sPNL.
[b] One-side noninferiority test.

Table 3 – Features of patients requiring embolization.

	sPNL	mPNL
STONE score		
<10	3	3
≥10	7	5
Number of tract		
1	4	3
>1	6	5

mPNL = mini percutaneous nephrolithotomy; sPNL = standard percutaneous nephrolithotomy.

nephrostomy tract (Table 3). In the sPNL group, VAS score was higher (ITT: 0.8, $p < 0.001$; PP: 0.8, $p < 0.001$; Table 2) and more patients needed analgesics (ITT: 8.6%, $p < 0.001$; PP: 9.4%, $p < 0.001$; Table 2). According to the Clavien-Dindo grading system [20], complication rates were comparable between the two groups. Grade I complications accounted for nearly 40%, occurring in patients taking either antipyretic or analgesic medication. Grade II complications occurred in patients requiring transfusions except that three patients required total parenteral nutrition for persistent abdominal distension. Patients with grade IIIa complications included those who underwent arterial embolization or ureteroscopy under local anesthesia. Grade IVa and IVb complications were present in patients who required intensive care unit (ICU) treatment for single or multiple organ failures caused by urosepsis. There was no statistically significant difference in fever and urosepsis (Table 2). The sPNL group had longer hospitalization periods (ITT: 0.6 d, $p < 0.001$; PP: 0.5 d, $p < 0.001$; Table 2).

4. Discussion

There are a rising number of studies debating the merits of minimally invasive PNLs [21]. There are considerable debates regarding the merits of mPNL and sPNL. We aimed to perform a high-quality RCT comparing mPNL and sPNL for the treatment of 20–40 mm renal stones to settle this debate. Since the treatment algorithm was decided according to stone size in the guideline on urolithiasis [22], we used stone size as an inclusion criterion. We measured the largest diameter in both the coronal and the sagittal view on the CT scan to increase accuracy.

Our data demonstrated that mPNL was noninferior to sPNL in the treatment of 20–40 mm stones. The SFR achieved by mPNL was similar to that by sPNL, but with less blood loss, less postoperative pain, and shorter hospitalization. There was no increase in the complication rate with mPNL, albeit a small increase in the operating time. This study reaffirmed the findings of the previous trials [1]. We selected 18 F and 24 F nephrostomy tracts for this study. When tract size increased from 18 F to 24 F, the actual surface area of the tract increased by 77.8%. However, the nephroscope used in sPNL (20.8 F) had a 150% increase relative to mPNL (12 F) in terms of surface area. The space between the tract and the nephroscope was greater in mPNL, which provided better visualization and evacuation of fragments or dust during the procedure. Different lithotripters used between the groups might have caused a bias, because of the different methods of lithotripsy and the different spaces in the working channel of scope after inserting the lithotripter. However, the use of different lithotripsy devices did not result in a difference in the one-session SFR (Supplementary Table 1). We did not routinely use CT to examine the residual stones, even though it has the highest sensitivity and specificity [23]. This was intended to decrease the cost and radiation exposure to the patients. Furthermore, most studies reporting SFRs relied on KUB or multiple modalities, rather than on CT only [24]. In our study, two protocol-blinded radiologists assessed the SFR using KUB and ultrasound; CT was optional.

The main purpose of miniaturized PNL was to offer comparable SFR outcomes with lower morbidity. This study demonstrated that mPNL was associated with a lower hemoglobin drop than sPNL. Further reduction in tract size might even heighten this difference [3]. While there was no statistically significant difference in transfusion and embolization rates, mPNL had a higher tubeless rate owing to less bleeding. The higher tubeless rate might also contribute to the lower postoperative pain and the lower proportion of patients requiring pain medication. In addition, the patients who underwent mPNL had shorter hospitalization periods. In a recent meta-analysis, it was reported that patients recovered faster from the tubeless procedures [25].

Although more than half of the punctures were supracostal (Table 4), no thoracic complications were encountered. Ultrasonic guidance was used for most of these punctures, which might have contributed to the lower incidence [26]. All 10th intercostal rib punctures had nephrostomy tubes placed for 1 wk to safeguard against missed pleural injuries.

As part of Chinese customs, many of our patients chose to be fully recovered and without external tubes before discharge. Consequently, postoperative hospitalization periods in both groups were longer than the published data [8].

4.1. *Strengths and limitations*

The major strength of this study is its large number of participating patients and centers, and the surgeries were performed by only one designated experienced surgeon in each center, leading to a much more reliable comparison.

This study had its limitations. We only selected two tract sizes, 18 F and 24 F, which are most commonly used in China. The central randomized allocation method caused an uneven distribution of cases among the participating centers. This method was practical and used widely in multicenter RCTs with a large number of participants [27]. Auxiliary procedures would incur additional expenses in China; thus, more than half of the patients with residual stones decided to follow them expectantly. With the surgeries performed only by one designated experienced surgeon in each high-volume center, it is uncertain how this study will translate to lower-volume centers with less experienced PNL surgeons. Furthermore, this was a non-

Table 4 – Other variables in intention-to-treat and per-protocol population.

	Intention to treat			Per protocol		
	sPNL (n = 988)	mPNL (n = 992)	p value	sPNL (n = 966)	mPNL (n = 978)	p value
Access under, N (%)						
X-ray	222 (23)	238 (24)	0.7	218 (23)	239 (24)	0.6
Ultrasound	734 (74)	722 (73)		715 (74)	707 (73)	
Combined	32 (3.0)	32 (3.0)		32 (3.0)	32 (3.0)	
Site of puncture, N (%)						
10th intercostal space	15 (2.0)	26 (3.0)	0.4	15 (2.0)	26 (3.0)	0.4
11th intercostal space	520 (53)	517 (52)		505 (52)	509 (52)	
under 12th space	443 (44)	439 (44)		436 (45)	433 (44)	
≥2 sites	10 (1.0)	10 (1.0)		10 (1.0)	10 (1.0)	
Stone composition, N (%)						
Calcium oxalate	748 (76)	747 (75)	0.8	731 (76)	735 (75)	0.9
Uric acid	130 (13)	126 (13)		129 (13)	125 (13)	
Carbonate apatite	75 (7.6)	79 (8.0)		73 (7.6)	79 (8.1)	
Ammonium magnesium phosphate	20 (2.0)	27 (2.7)		19 (2.0)	27 (2.8)	
Others	15 (1.4)	13 (1.3)		14 (1.4)	12 (1.1)	

mPNL = mini percutaneous nephrolithotomy; sPNL = standard percutaneous nephrolithotomy.
Data are presented as number (proportion).

inferior trial, and some centers might need to be equipped with a second set of devices, which might not be sufficient to change the treatment paradigm.

5. Conclusions

This RCT demonstrates that mPNL achieves a noninferior SFR to sPNL, but with the advantages of reduced blood loss, less postoperative pain, and shorter hospitalization. Additionally, mPNL does not cause an increase in the infectious complications. Hence, 18 F mPNL should be considered a sensible alternative to 24 F sPNL for the treatment of 20–40 mm renal stones.

***Author contributions*:** Guohua Zeng and Jean de la Rosette had full access to all the data in the study and took responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: de la Rosette, Zeng.
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Analysis and interpretation of data: Cai, Zhao, Zhu.
Drafting of the manuscript: Cai, Zhao, Zhu.
Critical revision of the manuscript for important intellectual content: de la Rosette, Zeng.
Statistical analysis: Cai, Zhao, Zhu.
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Administrative, technical, or material support: Duan, X. Xu, Mao, X. Li, Nie, Xie, Jiongming Li, Lu, Zou, Mo, C. Li, Jianzhong Li, Wang, Yu, Fei, Gu, Enci Xu, Kong, Wu, Liu.
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Other: None.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.eururo.2020.09.026.

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