Clinical Trial/Experimental Study

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Reducing postoperative morbidity of mini-invasive percutaneous nephrolithotomy

Would it help if blood vessels are left unharmed during puncture? A CONSORT-prospective randomized trial

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Abstract

Background: The aim of this study was to provide a randomized controlled trial comparing single B-mode ultrasound guidance and color doppler ultrasound guidance in minimally invasive percutaneous nephrolithotomy.

Methods: Three hundred patients with renal calculus were prospectively randomly assigned into 2 groups. In group 1 (150 patients), minimally invasive percutaneous nephrolithotomy (m-PCNL) were managed with single B-mode ultrasound guidance; In group 2 (150 patients), m-PCNL were managed with color Doppler ultrasound guidance and a needle bracket in order to guide placement at a target location beneath the skin. The characteristics of patients, operation, complications and prognosis, including body temperature, urine culture, and hematologic tests after the operation were recorded and compared.

Results: Our vessel-sparing technique showed a statistically significant decrease in hemoglobin drop, postoperative procalcitonin values, the frequency of postoperative fever, systemic inflammatory response syndrome, and urosepsis ($P < .05$).

Conclusion: Using color Doppler ultrasound in real time and a needle bracket to detect and avoid main renal blood vessels decreased incidences of hemorrhagic complications and postoperative infection.

Abbreviations: CRP = C-reactive protein, CTU = computed tomography urography, KUB = kidney and upper bladder, m-PCNL = mini-invasive percutaneous nephrolithotomy, PCNL = percutaneous nephrolithotomy, PCT = procalcitonin, SFR = stone-free rate, SWL = extracorporeal shock wave lithotripsy, US = ultrasonography, UTI = urinary tract infection.

Keywords: color Doppler ultrasound, kidney stone, m-PCNL, postoperative morbidity

1. Introduction

Stone disease can be found in all countries, with 5% to 15% prevalence rate[1] and around 50% recurrence rate.[2] Also, stone disease is the most common reason for urological care and the primary indication for urological surgery in China, especially in southern regions. Previously, percutaneous nephrolithotomy (PCNL) is widely regarded as an optimal choice for large volume or complex upper urinary tract stone burden.[3] Since its introduction in 1976, the procedure has continued to evolve, with an emphasis on improving postsurgery outcomes and decreasing morbidity in patients, while maintaining a high success rates of stone treatment.[4–7] Recently, minimally invasive PCNL (m-PCNL), a modified PCNL technique of using a small caliber endoscope through a 20-Fr or smaller nephrostomy tract to perform the procedure prevails, has been proved to achieve comparable stone-free rates (SFRs) and fewer complications compared with traditional PCNL.[8,9]

Nevertheless, renal hemorrhage is still one of the most common and intractable complications, which also include postoperative fever and acute renal impairment,[10,11] while modification of the procedure has improved the overall outcome, and several studies found that intraoperative use of color Doppler ultrasound could avoid areas with dense vessels.[12] Therefore, we introduced a vessel-sparing technique to lower the incidences of hemorrhagic and other complications in m-PCNL.

2. Material and methods

2.1. Patient selection

Between August 2012 and February 2014, 300 patients were computer randomized at a 1:1 ratio to either group 1 or group 2 (Fig. 1). Inclusion criteria were as follows: single or multiple stones in the upper urinary tract (calyx, the pelvis, upper ureter); stone burden ≥ 2 cm; SWL-resistant stones ≥ 1 cm. Exclusion

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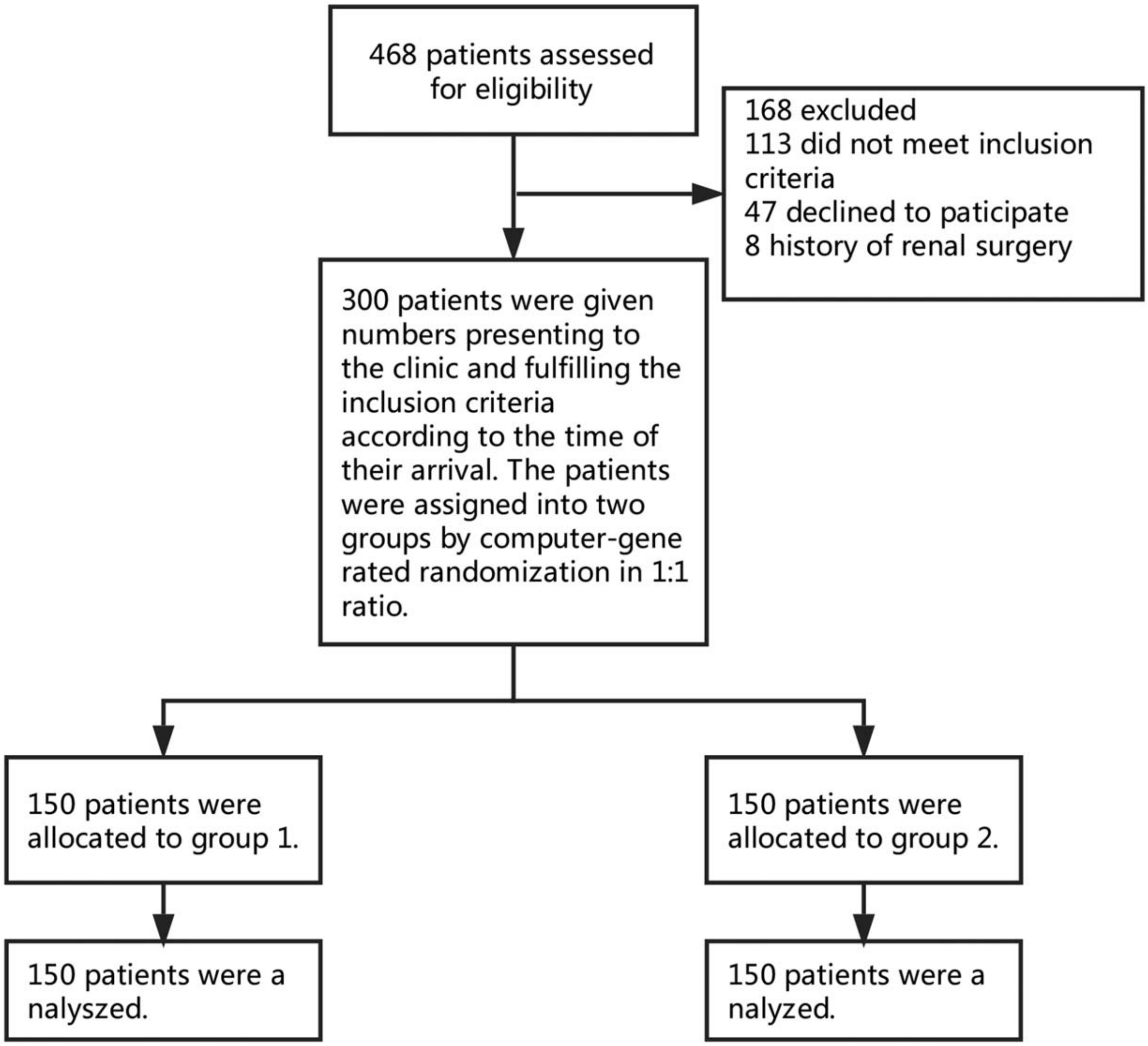


Figure 1. Flow of participants through the study.

criteria included uncontrolled coagulopathy, pregnancy, renal anomalies and untreated UTI (urinary tract infection); stone burden $\leq$ 2 cm; complete staghorn stones. All procedures were performed with general anesthesia using tracheal cannulation by a single surgeon (Y.Z.), who had more than 10 years of experience in PCNL, and had performed 800 PCNL procedures.

2.2. Preoperative examination and preparation

Preoperative radiological evaluation, including routine blood test, inflammation markers, ultrasonography, plain abdominal radiography of the kidneys, ureters, and bladder (KUB) and computed tomography urography, were performed (Fig. 2). The average stone size measured at its maximum diameter on the KUB radiograph was 33.3 mm (range 8–130 mm).

2.3. Surgical procedure

Three hundred patients were prospectively randomized into 2 groups with half of the patients undergoing m-PCNL with B-mode ultrasound guidance and frameless technology in group 1, and another half undergoing m-PCNL with color Doppler ultrasound (Esaote, Genova, Italy, MyLab90) and needle bracket guidance in group 2.

In the lithotomy position, a 6-F open-ended external ureteral catheter was implanted into the target ipsilateral ureteral orifice with cystoscopic guidance. Then, we injected normal saline through the retrograde catheter in order to clarify caliceal anatomy and locate the appropriate site before puncture.

Then, all patients were turned to a prone position. The puncture positions were estimated on the basis of the stone positions. In group 1, only B-mode ultrasound was used to assisted puncture. Whereas in group 2, after being broadly outlined by B-mode ultrasound guidance, the puncture line was followed by color Doppler ultrasound guidance on-screen to avoid vital renal vessels during puncture (Fig. 3). Subsequently, under direct vision of color Doppler ultrasound, we identified a suitable puncture site and ideal angle to avoid the vital vessels. After being guided by an ultrasound needle bracket (Esaote, ABS421), an 18-G coaxial needle was fixed to the echo probe. Then, we aligned and guided the placement of a needle at a target location underneath the skin with color Doppler ultrasound guidance. The needle was inserted into the fornix of the targeted

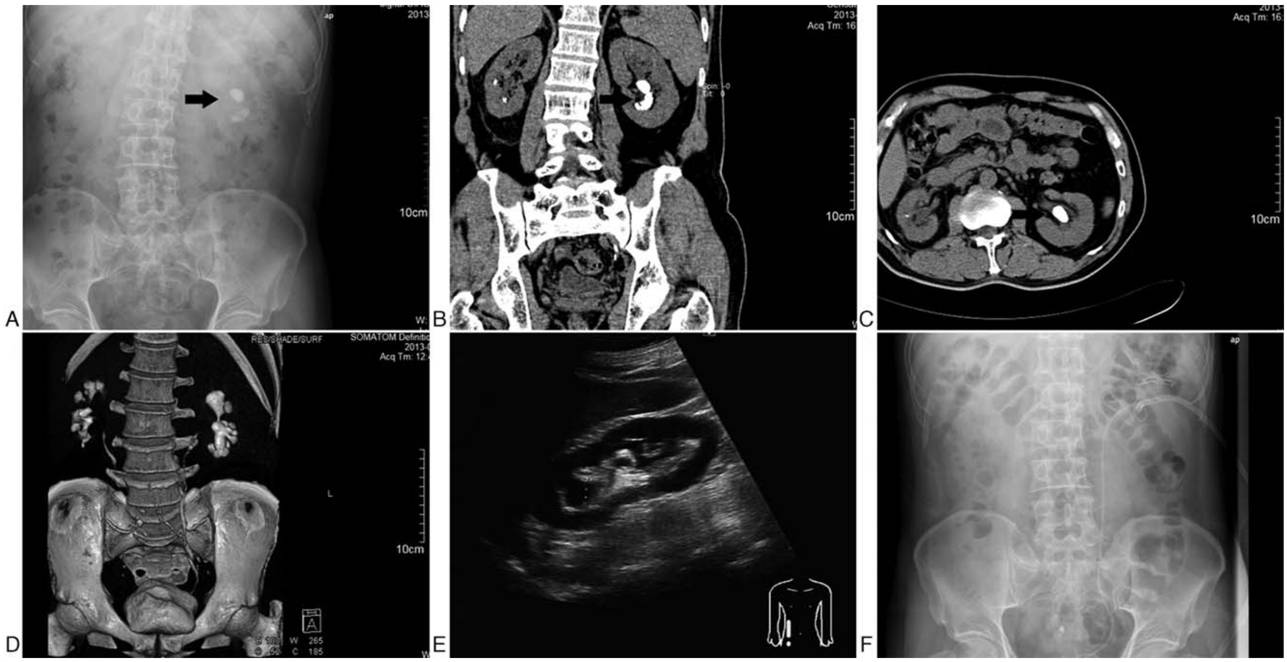


Figure 2. Preoperative and Postoperative imaging examination. (A) Preoperative KUB. (B, C) Preoperative CTU. (D) Preoperative CTU 3-dimensional reconstruction. (E) Preoperative B ultrasound. (F) Postoperative KUB.

calyx (Fig. 4). The upper or middle calyx was preferred because it is convenient for a ureteroscopy to access the ureter and other calices.

In group 1, the puncture was conducted without a needle holder for suitability of trajectory adjustment. By contrast, the puncture needle was held tightly, close to the middle point of the echo probe in group 2. A flexible 0.035-in guidewire was inserted into the renal pelvis through the needle. 8-F and 16-F, and finally 20-F dilators in sequence were used to complete step-wise dilation of the tract. A 20-F working sheath was placed for stone manipulation. The stones were fragmented with Holmium: YAG laser (fiber size 550 μm; Versa Pulse Select, Coherent Corp., Palo Alto, CA) under nephoscopy. The energy of Holmium: YAG laser ranged from 1.0 to 2.0 J, and the frequency ranged from 20 to 30 Hz depending on stone rigidity.

Finally, an ultrasonographic check was performed for slight residual stone fragments. At the end of the procedure, a 6-Fr double-J stent was introduced antegrade into the ureter, and an 18-Fr nephrostomy tube was inserted into each puncture.

2.4. Postoperative treatment

Results from temperature, urine culture, and hematologic tests were collected for evaluation of postoperative infection on the first postoperative morning[13–15]; KUB radiography and ultrasonography were carried out as the evidence of residual stones at the 4th day postoperatively [16] (Fig. 2). Whether the patients would proceed to an SWL (extracorporeal shock wave lithotripsy) or second PCNL depended on size the and location of the residue. One month after surgery, follow-up was scheduled and the double-J stent was extracted in outpatient clinic.

2.5. Statistical analysis

Continuous data were recorded as mean SD if normally distributed or mean rank if not normally distributed. Normally

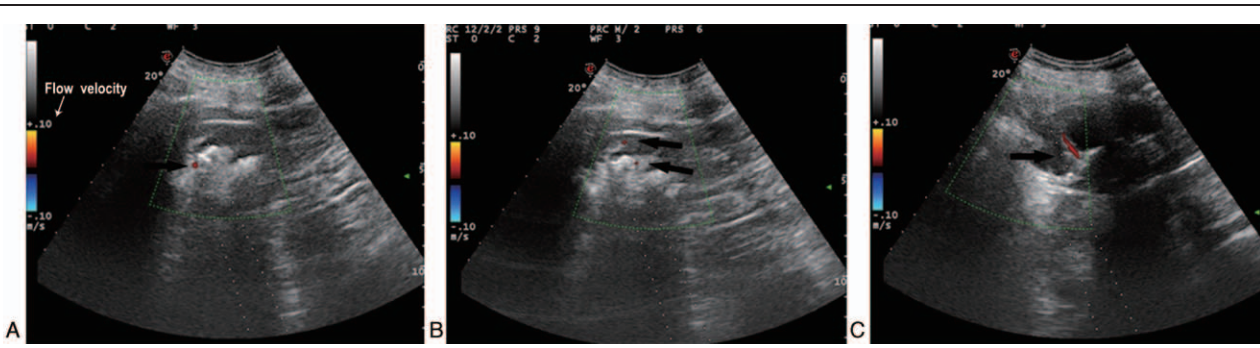
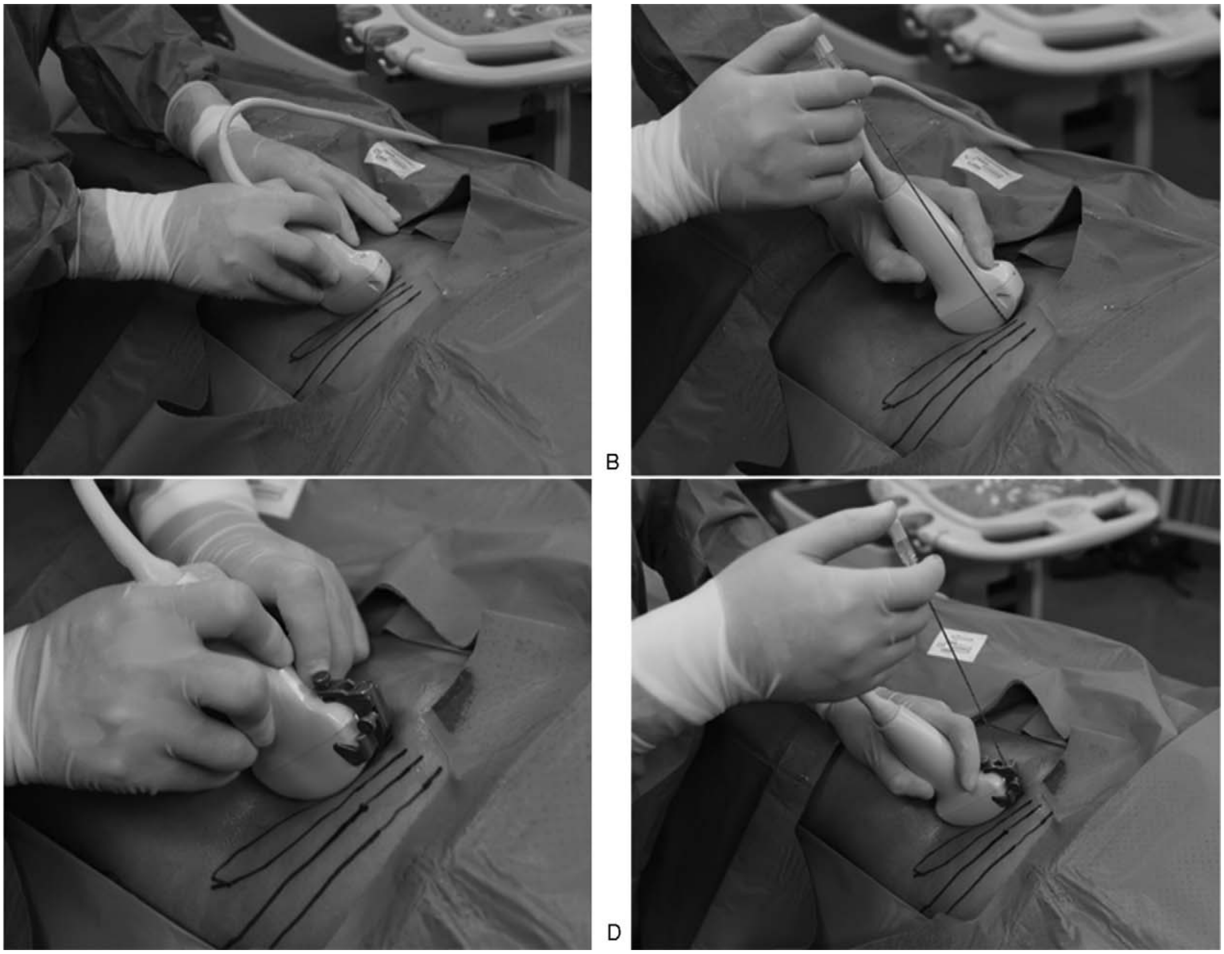


Figure 3. Intraoperative color Doppler ultrasound. (A–C) First, we adjusted the scale value to make the vessels visible whose blood flow velocity was faster than 10 cm/s and the others invisible whose blood flow velocity was slower than 10 cm/s. Then, we identified a suitable puncture site and ideal angle to avoid areas with dense vessels. Finally, during puncture, we kept the needle away from the vessels in real time.



A B C D

Figure 4. Puncture process. (A, B) Puncture process of Group 1. Percutaneous puncture was performed with single B-mode ultrasound guidance. Directly punctured without a needle bracket. (C, D) Puncture process of Group 2. Percutaneous puncture was performed with combined B-mode and color Doppler ultrasound guidance. Using a needle bracket to guide the placement of a needle to a target location.

distributed data were analyzed with Student *t* test, and the Wilcoxon rank sum test was used for non-normally distributed data. Categorical data were analyzed by the Chi-square test or Fisher exact test (proportions), and $P<.05$ was considered statistically significant. Statistical analysis was performed using SPSS 23.0 for Windows (SPSS Inc., Chicago, IL).

3. Result

In all, 300 patients were randomly categorized into this study, including 150 in group 1 and 150 in group 2. Characteristics of the 2 groups are summarized in Table 1. No significant difference was found between the 2 groups, including male: female ratio (90/60 vs 88/62; $P=.814$), age (49.93±13.402 vs 51.76±11.942 years; $P=.213$), body mass index (22.73±2.012 vs 22.58±2.134 kg/m^2; $P=.532$), urinary tract infection (55 vs 45; $P=.221$), stone size (32.88±14.0019 vs 35.24±18.6532 mm; $P=.216$), stone multiplicity ($P=.109$), or S.T.O.N.E[17] score ($P=.08$).

Table 2 summarizes the operative characteristics. There were no significant differences in operative time (108.2±41.462 vs 111.9±43.869 minutes; $P=.453$) and SFR (88.7% vs 88.0%; $P=.857$). However, we found a statistically significant difference in hemoglobin drop (14.037±8.6556 vs 11.038±8.7857 g/L; $P=.003$).

Table 3 summarizes a statistically significant decrease in need for auxiliary procedures in the group 2 ($P=.002$), including embolization, conversion to open surgical hemostasis, and nephrectomy compared with group 1. In group 1, 2 patients (1.3%) needed embolotherapy, 2 (1.3%) needed open surgical

Table 1

Demographic and clinical characteristics of patients.

	Group 1 (n=150)	Group 2 (n=150)	Statistics	*P*
Gender (M/F)	90/60	88/62	0.055*	.814
Age, y	49.93±13.402	51.76±11.942	0.794†	.213
BMI, kg/m^2	22.73±2.012	22.58±2.134	1.125†	.532
UTI, %	55 (36.7%)	45 (30.0%)	1.500*	.221
Stone's size, mm	32.88±14.0019	35.24±18.6532	1.775†	.216
Stone multiplicity			4.425*	.109
Single	49	40		
Multi	74	68		
Staghorn	27	42		
S.T.O.N.E. score	8.03±1.461	7.73±1.501	1.968	.08

Group1: single B-mode ultrasound guidance; Group2: use of Doppler and needle bracket.
BMI=body mass index; UTI=urinary tract infection.
* Pearson Chi-square test.
† *t* test.

Table 2

Operative characteristics.

	Group 1 (n = 150)	Group 2 (n = 150)	Statistics	*P*
Operative time, min	108.2 ± 41.462	111.9 ± 43.869	1.119†	.453
Stone-free rate, %	133 (88.7%)	132 (88.0%)	0.032*	.857
Preoperative hemoglobin, g/L	132.366 ± 17.9129	132.534 ± 17.0198		
Postoperative hemoglobin, g/L	118.442 ± 17.4671	121.496 ± 16.7203		
Hemoglobin drop, g/L	14.037 ± 8.6556	11.038 ± 8.7857	1.030†	0.003

* Pearson Chi-square test.
† Paired *t* test.

hemostasis, and 1 (0.7%) needed nephrectomy. Whereas, no serious hemorrhagic complications in the need for auxiliary procedures were found in group 2. Although transfusion rate had no significantly difference between 2 groups, there was a declining trend in the Doppler group.

There were no statistically significant differences found in the white blood cell count (12.062 ± 4.248 vs 11.576 ± 4.070 109/L; $P = .312$), the C-reactive protein level (108.91 vs 100.79 mg/L; $P = .333$), and the presence of a positive urine culture (5.33% vs 2.67%; $P = .239$); statistically significant differences found in the procalcitonin level (110.19 vs 88.14 ng/mL; $P = .006$), postoperative fever (defined as temperature ≥38°C)[14] (10.00% vs 2.67%; $P = .009$), systemic inflammatory response syndrome (SIRS, 6.67% vs 1.33%; $P = .018$), and urosepsis (4.67% vs 0%; $P = .022$) between the groups (Table 4).

4. Discussion

AUA (American Urological Association) clinical guideline recommended that percutaneous should be a first-line treatment for most patients.[5] Nevertheless, most emerging research indicated the risk of complication in PCNL. Yang et al[13] reported a postoperative complication rate of 12.2% for fever and 27.4% for SIRS in PCNL. Besides according to a study in a large European population, fever developed in 21.0% to 32.1% and transfusion was needed in 11.2% to 17.5%.[18] To minimize the surgical injury of PCNL, a specially designed mini-nephoscopy for m-PCNL in adults was first applied in 2001.[19] However, in the previous studies, there were quite a number of complications occurring in the m-PCNL. Knoll et al[9] reported prolonged postoperative bleeding developed in 4% and fever developed in 12%. Also, 8% fever and mean 0.8 gram% Hemoglobin drop were reported for m-PCNL in the other study.[20]

Urologists who treat urolithiasis have access to advanced techniques and instruments, leading to safer and more effective therapy. A common view is that a safer, more effective, and less harmful procedure is the goal for treating kidney stones. A large number of reports about color Doppler ultrasound have concentrated on its diagnostic or postoperative functions in m-PCNL[12] and PCNL.[21] However, it has not been extensively documented that the wise application of color Doppler ultrasound can avoid renal vessel in percutaneous procedures.

Lu et al[12] reported that a combination of B-mode and color Doppler ultrasound during puncture for m-PCNL decreased the occurrence of hemorrhagic complications. This particular effective in a compensative and solitary kidney.[12] In their comparative study, 2.6% of the patients needed a blood transfusion in the group that used single B-mode ultrasound alone, but none in the group guided by color Doppler ultrasound. However, this study was retrospective rather than prospective. Accordingly, we started a randomized clinical trial. In the study, we evaluated the clinical value of a vessel-sparing puncture approach for m-PCNL in the treatment of symptomatic kidney calculus and noted a statistically significant decrease in blood loss and postoperative infection. There were no serious hemorrhagic complications, 4 patients (3.01%) were suffering from fever, and 2 (1.50%) developing SIRS in group 2. However, 15 (10.00%) had a fever and 10 (6.67%) developed SIRS in group 1. Moreover, the application of a needle-guide bracket improved the stability of ultrasound-guided technique.[22] Our study findings may be attributed to the combined use of m-PCNL and color Doppler ultrasound, resulting in less bleeding and fewer postoperative complications in comparison with prior techniques.

Ogihara et al[23] reported that blood loss and the type of surgery contributed to surgical site infections. In addition,

Table 3

Comparison of embolization, surgical hemostasis, nephrolithotomy, and transfusion.

	Group1 (n = 150)	Group2 (n = 150)	Statistics	*P*
Need for auxiliary procedures, %	10 (6.7%)	0 (0%)	*	.002
Embolization, %	2 (1.3%)	0 (0%)	*	.249
Nephrectomy, %	1 (0.7%)	0 (0%)	*	.500
Conversion to open surgical hemostasis, %	2 (1.3%)	0 (0%)	*	.249
Transfusion rate, %	5 (3.3%)	0 (0%)	*	.060

* Fisher exact test.

Table 4

Comparison of clinical factors associated with postoperative infection.

	Group1 (n = 150)	Group2 (n = 150)	Statistics	*P*
WBC, 10^9/L	12.062 ± 4.248	11.576 ± 4.070	0.918*	.312
PCT, ng/mL ($n_1 = 102$; $n_2 = 96$)	110.19	88.14	2.727†	.006
CRP, mg/L ($n_1 = 113$; $n_2 = 95$)	108.91	100.79	0.969†	.333
Positive urine culture, %	8 (5.33%)	4 (2.67%)	1.389‡	.239
Postoperative fever, %	15 (10.00%)	4 (2.67%)	6.799‡	.009
SIRS, %	10 (6.67%)	2 (1.33%)	5.556‡	.018
urosepsis, %	7 (4.67%)	0 (0%)	5.266§	.022

CRP = C-reactive protein, PCT = procalcitonin, SIRS = systemic inflammatory response syndrome.
* *t* test.
† Nonparametric tests.
‡ Pearson Chi-square test.
§ Continuity correction Chi-square test.

Keoghane et al[24] reported that 23.8% of patients transfused had a postoperative infection, compared with 16.1% of those not transfused among 568 patients after PCNL. Kukreja et al[25] also analyzed the relevance between blood loss and intraoperative complications. They advised that ultrasound-guided access would reduce blood loss, because their study of 236 patients undergoing 301 PCNL procedures certified an association between blood loss and intraoperative complications.[25] In our study, blood vessels were protected from being punctured and exposed directly to the air in order to lower the possibility of infection.

The present study had a short observation and follow-up time. In addition, the exact pathogenesis of postoperative infection after m-PCNL remains unclear. Next task is to develop an experimental animal model of wound and infection.

5. Conclusion

m-PCNL is a viable choice in the treatment of kidney calculi. Differences between surgical procedures designs may be factors that influence the therapeutic outcomes. The results showed that using color Doppler ultrasound and a needle bracket to avoid vital renal vessels during puncture decreased incidences of hemorrhagic complications and postoperative infection.

Author contributions

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Writing – original draft: Congcong Xu.
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