

Original Article

Utility of a new portable wireless B-ultrasound probe scanner for percutaneous nephrolithotomy

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Abstract: Objective: We compared the safety and efficacy between a new portable wireless B-ultrasound probe (UProbe-2) and conventional wired B-ultrasound (ALOKA SSD-3500) for puncture guidance in percutaneous nephrolithotomy (PCNL). Methods: Seventy-six patients with unilateral renal calculi and moderate hydronephrosis were randomized to undergo PCNL under the guidance of either wireless or conventional ultrasound. General perioperative conditions, guided puncture time, number of punctures, puncture depth, total operation time, hemoglobin drop, stone clearance rate, postoperative hospital stay, and PCNL complications were compared between two groups by independent samples *t*-test, Mann-Whitney test, *chi*-square test or Fisher's exact probability test. All procedures were conducted by the same surgeons. Results: Most of the technical parameters of UProbe-2 and ALOKA SSD-3500 were similar. However, UProbe-2 was smaller in weight and dimension. UProbe-2 had fewer display modes and quicker image frame. However it required battery to supply electricity and depended on Wi-Fi connection and required Apple iOS or Android-software support system. Baseline data, such as age, sex ratio, body mass index (BMI), kidney position, stone size and degree of hydronephrosis did not differ between two groups (all $P>0.05$). There were no significant differences in guided puncture time, puncture depth, number of needle punctures, and total operation time between two groups (all $P>0.05$). The stone clearance rate, hemoglobin declined, postoperative hospital stay and incidence of postoperative complications were similar between two groups (all $P>0.05$). Conclusion: UProbe-2 portable wireless B-ultrasound probe scanner is as safe and effective as the conventional wired B-ultrasound probe for guiding puncture during PCNL in patients with unilateral renal calculi and moderate hydronephrosis. However, the wireless probe is smaller, lighter and more convenient to use, thus warranting further application, especially in institutions with limited resources.

Keywords: Renal calculi, hydronephrosis, percutaneous nephrolithotomy, ultrasound, portable probe

Introduction

Percutaneous nephrolithotomy (PCNL) is a minimally invasive therapy for the upper urinary calculi first reported in 1976 by Fernstrom [1]. With the development of improved surgical instruments and accumulation of surgical experience, PCNL has become the preferred method for treatment of the upper renal and ureteral calculi with a diameter ≥ 2 cm [2]. Accurate guidance of the puncture to the target calyx is a key step for successful PCNL [3]. Currently, the main imaging modalities for puncture guidance during PCNL are X-ray and ultrasound [4]. As X-ray systems are bulky, require special protection in the operating room, and produce unavoidable radiation exposure to both doctors

and patients, its application is now greatly limited, although X-ray can display the positional relationship between puncture needle and kidney stone in a real-time manner [5]. In contrast, ultrasound can provide real-time guidance and effectively display perirenal tissues and organs to avoid puncture injury, thereby reducing the risk of surgical complications as well as excess radiation exposure [6]. Therefore, ultrasound-guided PCNL is adopted by most hospitals in China [7].

At present, ultrasound is applied using conventional B-ultrasound machines in which the probe is connected to a host (for acquisition control, analysis, and display) through a wire. This system has the following disadvantages (1)

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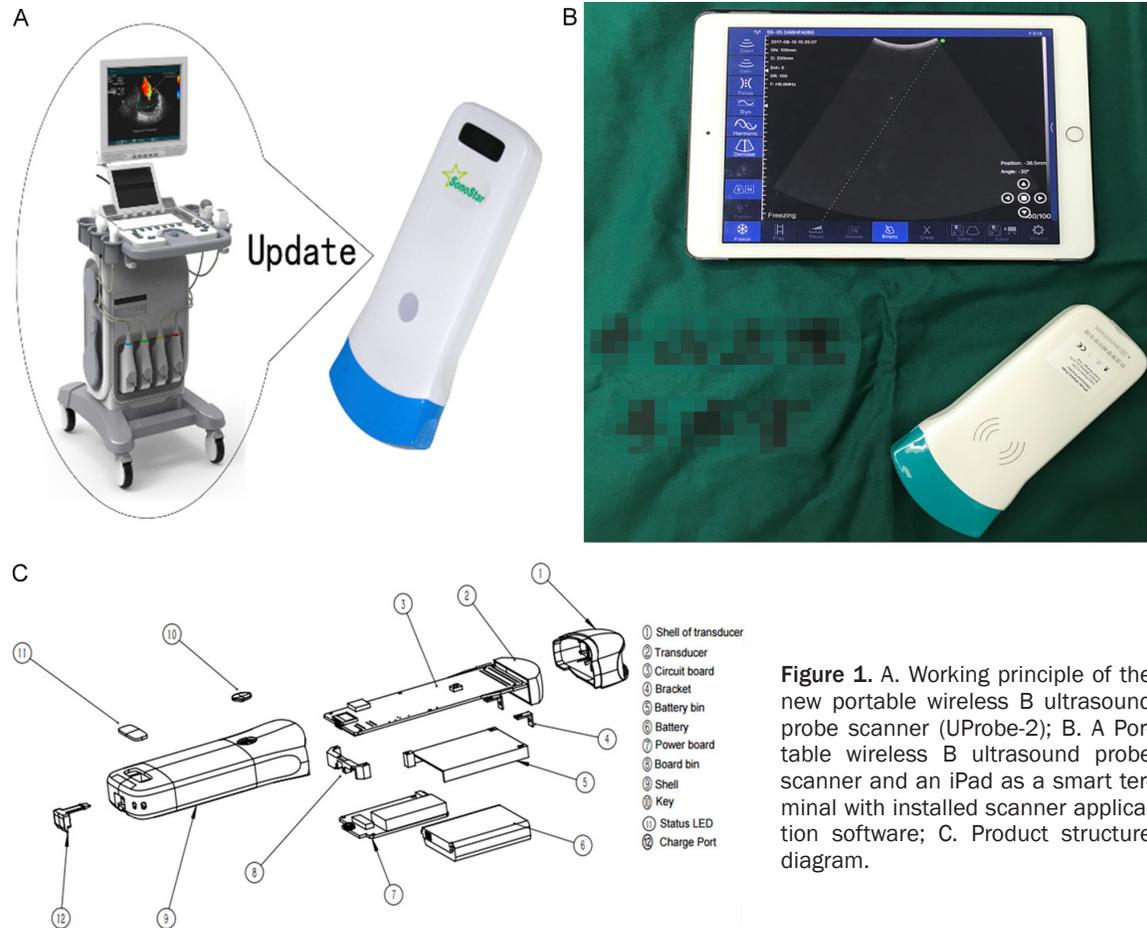


Figure 1. A. Working principle of the new portable wireless B ultrasound probe scanner (UProbe-2); B. A Portable wireless B ultrasound probe scanner and an iPad as a smart terminal with installed scanner application software; C. Product structure diagram.

large size making it inconvenient to move, (2) complicated sterilization procedures for the operating environment, as the connected host must be aseptically isolated with a sterile endoscopic cover, and (3) high cost, requiring the sharing of machines by multiple surgical departments (e.g., urinary surgery, gynecology, hepatobiliary surgery) so that some patients may have to wait for the B-ultrasound machine to continue operation after anesthesia, which greatly impedes surgical efficiency and increases the risk of anesthesia. With the rapid development of intelligent wireless technologies, electronic medical instruments are under constant improvement and innovation [8]. Guangzhou Sono-star Technologies Co., Ltd. has recently developed a wireless portable B-ultrasound machine (UProbe-2) in which the probe contains a small circuit board to replace the host. This highly integrated B-ultrasound probe can connect without a wire to a smart terminal located within 6 meters, such as an iPad tablet or smart phone. The image data can be displayed by real-time Wi-Fi transmission to the

smart terminal. Due to its small size, the probe is very convenient. The 128-array probe with a 32-channel circuit can produce an image almost equal in quality to that of a large B ultrasound machine (Figure 1A-C). We reported the initial clinical experience about using the UProbe-2 ultrasound to guide puncture in PCNL and demonstrated that the puncture performed under the guidance of the wireless US device was feasible [9]. In this article, we further compared the utility and feasibility between this new portable wireless B-ultrasound probe scanner and conventional wired B-ultrasound machine for guiding the percutaneous renal puncture of patients with renal calculi and moderate hydronephrosis.

Materials and methods

Clinical data

From September 2016 to May 2018, 76 patients with unilateral renal calculi and moderate hydronephrosis scheduled for PCNL were



Figure 2. Area for needle puncture marked on the body surface. The area was determined using preoperative CT-guided localization.

enrolled at the Third Affiliated Hospital, Sun Yat-sen University. Inclusion criteria: (1) Adult patients, (2) those with unilateral renal calculi ≥ 2 cm in diameter and (3) separation of renal pelvic sinus echoes by ≥ 2 cm indicative of moderate or severe hydronephrosis as shown by preoperative urinary tract ultrasonography and computer tomography urography (CTU). Exclusion criteria: (1) Those with a history of PCNL, (2) spinal deformity affecting B-ultrasound localization, (3) severe blood coagulation dysfunction, and (4) severe insufficiency of heart, lungs, liver, kidneys or other organs. This study was approved by the ethics committee of the hospital (No. ZDFSYL [2016]2-110), and all patients provided signed informed consents before surgery. Patients were divided into two groups according to a random number table method. Patients in the test group underwent puncture guided by the new portable wireless B-ultrasound probe scanner (UProbe-2), while those in the control group received the same PCNL guided by a conventional large wired B ultrasound machine (ALOKA SSD-3500). Procedures were performed by the same group of surgeons from the Department of Urology. Patients complicated with urinary tract infection received anti-infection treatment before PCNL. Blood glucose and blood pressure were under control in all patients.

Surgical methods

Preoperative localization: The methods for preoperative computed tomography-guided localization, real-time ultrasound localization, and correction to improve the accuracy of guided puncture during surgery were reported as previ-

ously described [10]. Before surgery, a predetermined puncture route was selected according to CT images, and the horizontal distance from the skin puncture point to the midline of the spinous process and its vertical distance to the 12th rib tip was measured. According to the horizontal and vertical distances, the skin puncture point was determined for each patient and used as the center to draw the mark lines inside, outside, and 1.5 cm below it on the body surface. The area surrounding the

lower edge of the 12th rib with a mark line was defined as the area of ultrasound-guided puncture (**Figure 2**).

Technical parameters of UProbe-2 and conventional wired B-ultrasound (ALOKA SSD-3500):

The main technical parameters of the new portable wireless B-ultrasound probe scanner (UProbe-2) and the conventional wired B ultrasound machine (ALOKA SSD-3500) were compared in **Table 1**.

Surgical procedures: For each patient, a tracheal tube was inserted after general anesthesia, and then a 5F ureteral stent catheter was retrograde inserted with the help of ureteroscope to create the ipsilateral artificial hydronephrosis. Next, the patients were placed in a prone position. In the test group, UProbe-2 was disinfected, activated, and installed with a supporting puncture frame. A mobile phone or tablet computer was connected by Wi-Fi to operate the wireless ultrasound software application, the probe was placed in the preoperatively predetermined puncture area and moved slightly to adjust the scanned section to the pre-set level path in a real-time manner, and puncture was performed under probe monitoring (**Figure 3A-C**), the whole process of puncture could be real-time displayed on the screen. In the control group, conventional wired B-ultrasound machine (ALOKA SSD-3500) with a convex W-SHD probe (UST-9123, Hitachi Aloka Medical, Ltd., Japan) was applied to guide puncture by the same procedures (**Figure 4**). In both groups, surgical assistant injected water via the external ureteral stent catheter before puncture to increase hydronephrosis, and

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Table 1. Technical parameters of UProbe-2 wireless B-ultrasound probe scanner and ALOKA SSD-3500 B-ultrasound machine

	UProbe-2	ALOKA SSD-3500
Weight (kg)	0.25	>50
Dimension (cm)	15.6×6.0×2.0	49.0×76.0×135.0
Scanning mode	Electronic array scanning (convex array)	Electronic array scanning (convex array)
Number of array elements in the probe	128 array elements	128 array elements
Number of transmit and receive channels	32-channel circuit	32-channel circuit
Probe frequency	3.5 MHz	3.8 MHz
Scanning depth	200 mm	180 mm
Display mode	B, B/M	B, M, D, D (PW), B/M, B/B, B/D (PW)
Battery use time	3 h	Continuous power supply
Wi-Fi or not	802.11 g/20 MHz/2.4 G/54 Mbps	Wired connection
Software support system	Apple iOS, Android	No
Image frames	12 f/s	20 f/s

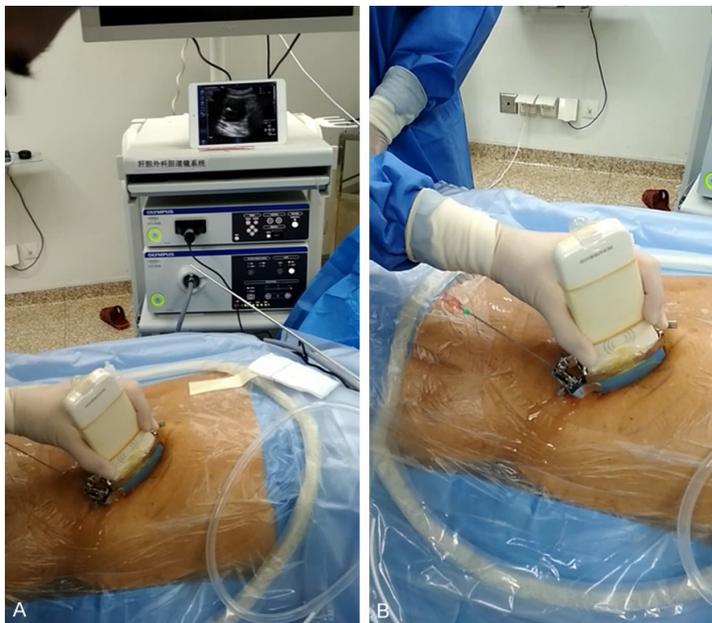


Figure 3. A. In the test group, the wireless probe (UProbe-2) was used to locate the target renal calyx in the pre-operatively predetermined puncture area; B. Clear urine flew out after the target renal calyx was punctured; C. The wireless ultrasound software application was operated by an iPad tablet to display the hydronephrosis image and calyceal puncture approach.

asked the anesthesiologist to briefly stop ventilation at end inspiration and to move the kidney downward as much as possible to prevent respiratory activity from affecting the puncture. Clear urine flowing out after puncture was considered as a successful procedure. Then, a guide wire was inserted into renal collecting system. After puncture needle was removed, percutaneous sheaths were placed one by one to gradually dilate the 18Fr percutaneous renal access sheath, in which a 12Fr percutaneous nephroscope (Richard Wolf GmbH., Knittlingen, Germany) was placed to locate the stones. Then, the stones were fragmented with a holmium laser (Shanghai Ruikeen Laser Technology Co. Ltd., optical fiber: 550 um, light energy: 2J, frequency: 10, power: 20W, Shanghai, China) and flushed out with pulsed water injection using a perfusion pump, while larger stones were removed

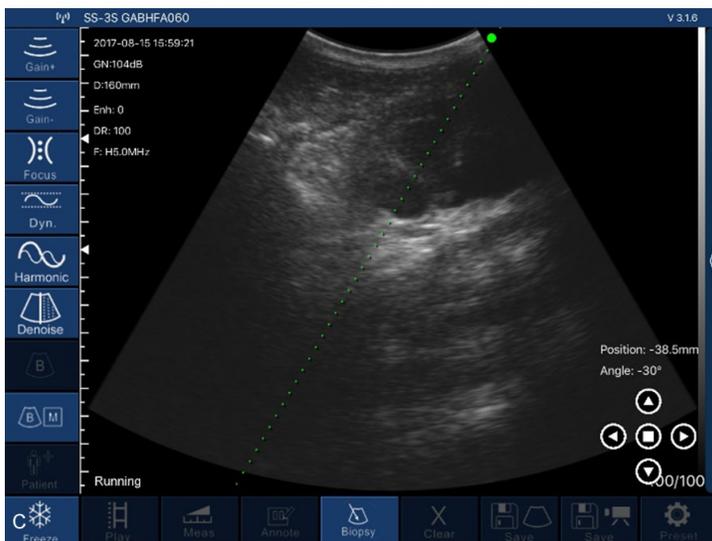




Figure 4. In the control group, a conventional probe was used to locate the target renal calyx in the pre-operatively predetermined puncture area.



Figure 5. In both test and control groups, stones were fragmented using a holmium laser under the 12Fr nephroscope monitor.

with lithotomy forceps (**Figure 5**). Next, the nephroscope was positioned to search for residual stones in renal calyces. Finally, a 5Fr double-J ureteral stent tube was placed antegrade for drainage, and a 16Fr nephrostomy tube was inserted into renal pelvis as a drain. All operations were performed by the same surgeons.

Postoperative management: On Day 2 after PCNL, non-contrast CT and/or plain KUB film were reexamined for the presence of residual stones and the position of the double J ureteral stent tube, and the color of the fistula drainage fluid was observed. Residual stone was defined as ≥ 4 mm on postoperative CT and/or KUB. After confirming that the stones were completely removed and the double J ureteral stent tube was still in place, the nephrostomy tube was removed. Following intestinal gas discharge, diet could be resumed. Postoperative antibiotics were infused intravenously as routine for 3 days. Surgical pain was alleviated using tramadol. At 4 weeks after hospital discharge, the double J ureteral stent tube was removed at Outpatient Department. At 3 months after surgery, urinary tract ultrasonography was performed for reexamination of urinary calculi recurrence and hydronephrosis changes.

Statistical analysis

Data were analyzed using SPSS 23.0 statistical software. Normally distributed measurement data are expressed as mean \pm SD, and group means were compared by independent samples *t*-test. Measurement data with non-normal

distribution are expressed as median (lower quartile-upper quartile), and group medians were compared by Mann-Whitney test. Enumeration data are expressed as ratios and were compared by *chi*-square test or Fisher's exact probability test. A $P < 0.05$ (two tailed) was considered statistically different for all tests.

Results

Perioperative data were statistically compared between two groups (**Table 2**). There were no statistical significance in sex ratio, age, BMI, position of the affected kidney, stone size, and degree of hydronephrosis between two groups (all $P > 0.05$). All procedures were successfully completed, and no patient required open surgery. No severe pleural and intestinal injuries or other complications occurred during or following the procedure. The guided puncture time, number of needle punctures, puncture depth, total operation time, hemoglobin drop, stone clearance rate, and postoperative hospital stay also did not significantly differ between two groups (all $P > 0.05$). One patient experienced severe hematuria after operation in the test group, and relevant symptoms were improved after the fistula tube was clamped and the hemostatic agent was given. One patient in the control group had severe hematuria after surgery, and the symptoms were alleviated after interventional embolization when conservative treatment yielded no efficacy. In the control group, one patient presented with peritoneal extravasation of irrigation fluid, and the symptoms were mitigated after diuresis and peritoneal drainage by puncture and tube placement.

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Table 2. Comparison of preoperative general conditions and perioperative parameters between two groups

	Test group	Control group	P value
Case number	38	38	-
Age (Y)	50.4±11.9	52.8±9.4	0.344 ^a
Sex (M/F)	19/19	24/14	0.247 ^b
BMI (kg/m ²)	23.5 (22, 24.4)	23.4 (22.4, 23.8)	0.582 ^c
Position of the affected kidney (left/right)	21/17	18/20	0.491 ^b
Stone size (mm)	29 (25, 37.8)	30 (24.8, 40)	0.679 ^c
Degree of hydronephrosis (mm)	25 (25, 30)	25 (25, 30)	0.870 ^c
Puncture guiding time (min)	3.4 (2.8, 4.3)	3.6 (3.2, 4)	0.472 ^c
Puncture depth (mm)	65 (60, 80)	65 (55, 80)	0.804 ^c
Number of attempts for successful puncture	1 (1, 1.3)	1 (1, 1.3)	0.950 ^c
Total operation time (min)	60 (50, 70)	62.5 (55, 66.3)	0.282 ^c
Complete stone clearance rate (%)	32/38 (84.2%)	33/38 (86.9%)	0.744 ^b
Hemoglobin drop (g/L)	11.5 (6.8, 19.3)	9.5 (3.8, 16.5)	0.166 ^c
Postoperative hospital stay (d)	4 (3, 5)	4 (3, 6)	0.313 ^c
Complications			
Hematuria	1	1	1.000 ^d
interventional embolization	0	1	1.000 ^e
Fever (≥38.5 °C)	3	4	1.000 ^d
Hypothermia (<36 °C)	4	3	1.000 ^d
Extravasation of irrigation fluid	0	1	1.000 ^e

^aIndependent samples *t*-test; ^bchi-square test; ^cMann-Whitney test; ^dYates' correction; ^eFisher's exact test; BMI: body mass index.

Postoperative fever (≥38.5°C) occurred in 3 patients in the test group and 4 cases in the control group. All cases were improved after anti-inflammatory antibiotics and supportive symptomatic treatment. Hypothermia (<36°C) occurred in 4 cases in the test group and 3 cases in the control group, and all cases were recovered after symptomatic treatment.

Discussion

Ultrasound-guided PCNL is an effective and minimally invasive procedure to clear the upper urinary calculi. Practitioners are constantly improving the precision and safety of needle puncture for ultrasound-guided PCNL [11, 12]. Navigated ultrasound is advantageous in terms of both safety and accuracy of puncture because this modality can display the position of the probe segment relative to the puncture needle in a real-time pattern and facilitate the adjustment of needle angle and depth. However, the large size and high cost of the equipment as well as the skill required to achieve accurate navigation have limited its clinical application [13]. Meantime, ultrasound machines have also been improved for user com-

fort and portability. Clinical trials have reported that handheld ultrasound systems effectively improve operational convenience and comfort, however, they are connected with the host through a wire [14]. The new portable wireless B-ultrasound probe scanner developed by Guangzhou Sono-star Technologies Co., Ltd., has been patented in China (Patent No.: ZL 201520635748.9), and a new patent has been submitted for Europe and the United States (Application No.: PCT/CN2016/096445). UProbe-2 ultrasound machine is priced at about \$2,000 to \$2,500, which is much cheaper than conventional ultrasound machines. Wireless ultrasound software also has the function of puncture guidance. This function combined with the help of a supporting puncture frame ensures that the entire puncture process can be displayed on screen in a real-time manner, thereby improving the accuracy of the puncture process. This novel machine was compared with a conventional large wired B-ultrasound machine during PCNL to further evaluate the safety and effectiveness.

The incidence rate of serious complications of PCNL, including bleeding and adjacent organ

injury, has been reported up to 15-19% [15]. The risk of complications is closely associated with the percutaneous renal puncture approach and access for stone clearance [16]. In the current study, the total incidence of bleeding was 2.6% (2/76), lower than that reported in several previous studies. Such low incidence may be resulted from our preoperative CT-guided localization method, selection of patients with moderate hydronephrosis and usage of a small-tract (18Fr) [17]. We applied preoperative CT to determine the puncture route to initially determine the puncture area on the back skin. Intraoperative ultrasound can quickly scan within the predetermined area, reducing the time and improving the puncture accuracy. Meantime, a side-entry puncture frame and puncture guideline were used for more precise needle insertion. During the entire process, needle access and the needle tip could be displayed on the screen in a real-time manner to ensure that puncture was performed via the predetermined approach, thereby reducing the risk of injury from puncture deviation and deep puncture, improving puncture success rate and reducing the risk of post-puncture bleeding. Using these methods, surgeries were performed successfully in two groups. Indeed, intraoperative puncture time, operation time, stone clearance rate, postoperative hospital stay, and hemoglobin decrease did not significantly differ between the test and control groups. Thus, the portable wireless B-ultrasound probe scanner allowed for guided-puncture accuracy during PCNL for renal calculi with moderate to severe hydronephrosis equivalent to that of a conventional large wired B ultrasound machine. However, the new portable wireless B-ultrasound probe scanner was easier to disinfect and operate.

One patient presented with severe hematuria after operation in the test group, but the patient was improved after the fistula tube was clamped and the hemostatic agent was given. One patient in the control group had severe hematuria after surgery, and relevant symptoms were mitigated after interventional embolization when conservative treatment was not effective. It was concluded that intraoperative bleeding was caused by laceration of the calyceal neck due to an excessively-large angle nephroscope swinging during lithotripsy. Therefore, the puncture approach should be

planned before surgery based on the location and size of stones, and kidney stones should be crushed as gently as possible during surgery. Ultrasound exploration can be performed once again and multiple accesses can be established to remove stones when necessary. If stones are found during postoperative examination, phase II PCNL or ESWL can be performed. One patient in the control group exhibited excessively-high airway pressure and abdominal distention during anesthetic recovery. A large volume of ascites was found by abdominal ultrasound exploration, so abdominal puncture was performed immediately and a drainage tube was placed in the ipsilateral lower abdomen. Then, full dilation, diuresis, positive pressure ventilation, and anti-infection therapy were administered, after which conditions became stable. Extravasation of irrigation fluid in this patient was associated with excessive intraoperative perfusion pressure and long operation time. Therefore, patients' vital signs should be closely monitored, negative pressure suction should be applied appropriately, and the operation time should not be excessively long [18].

In this study, 4 cases in the test group and 2 cases in the control group suffered from postoperative hypothermia, and all patients were improved after providing warming measures. The post-hoc analysis revealed that these patients had a longer operating time and did not use an air blower during the operation to maintain warmth, which probably led to hypothermia. It is generally believed that body temperature is also related to the temperature of the perfusate, and the perfusate in this study was preheated to 37°C before use. Hence, the possibility of this factor was basically ruled out. At present, disposable plastic surgical drapes are widely applied in clinical practice. Compared with surgical drape materials made of traditional fabrics, their warming function may be insufficient, which may be a factor leading to postoperative hypothermia. However, this hypothesis still needs further observation. Fever is a common complication after PCNL. The incidence in this study was 9.2%. It is generally considered that fever is associated with preoperative urinary tract infections and diabetes mellitus [19, 20]. Therefore, all patients should receive routine urine culture before surgery. It is necessary to effectively control the infection and then per-

form surgery. And diabetic patients' blood glucose level should be controlled before surgery.

Although the utility and safety of the portable wireless B-ultrasound probe scanner are equivalent to those of a wired system for puncture guidance during PCNL, it does have several disadvantages, such as inability of color Doppler ultrasound function, inability of real-time display of travel and distribution of large vessels, relatively low probe frequency and low image frame rate compared with the large B-ultrasound machine utilized in this study. To ensure surgical safety, all patients included in this study had renal calculi with moderate hydronephrosis and thin renal cortex. Intrarenal vascular compression was applied to reduce the difficulty of puncture to avoid the risk of bleeding. Preoperative CT-guided localization can effectively reduce the risk of vascular puncture injury. Alternatively, the large B-ultrasound machine is fully functional and can be applied for examinations of other abdominal organs and even cardiac blood flow, although it is large and expensive. However, the wireless B-ultrasound probe scanner has probe frequency and other key parameters sufficient for localization of renal calyceal fornix during PCNL. Nonetheless, multi-center studies with larger sample sizes consisting of patients with different degree of hydronephrosis and renal calculi should be conducted to verify the safety and effectiveness of this wireless B-ultrasound probe scanner.

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Informed consent was obtained from all individual participants included in the study.

Disclosure of conflict of interest

None.

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