A Safe and Effective Two-Step Tract Dilation Technique in Totally Ultrasound-Guided Percutaneous Nephrolithotomy

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Purpose: To evaluate the safety and efficacy of a radiation-free 2-step tract dilation technique in totally ultrasound-guided percutaneous nephrolithotomy (PCNL).

Materials and Methods: From Oct 2018 to Mar 2020, we prospectively and consecutively enrolled 18 patients with 19 kidney units with urolithiasis. The nephrostomy tracts were established by the following four steps: 1) ultrasound-guided renal puncture, 2) first-stage serial dilation to 16 Fr with Amplatz dilators, 3) introduce the ureteroscope through the 16Fr Amplatz sheath for tract adjustment and confirmation, 4) second-stage dilation with a 24-Fr balloon dilator.

Results: The median age of the patients was 61.5 [54, 66] years, and 11 (61%) were male. The median size of the stones was 3.3 [2.7, 6.2] cm2 with an equal distribution of the laterality(right/left). Successful tract establishment on the first attempt without fluoroscopy was achieved in 18 (95%) operations. The median tract establishment time was 10.2 [9.5, 12.4] mins, and the median operation time was 63.4 [29.2, 81.9] mins. The median decrease in hemoglobin level was 1.0 g/dL [0.5,1.6] and none of the patients required intraoperative or postoperative transfusion. Three of the patients (16%) developed fever postoperatively. Pleural injury occurred in two (11%) patients having supracostal punctures and one required drainage with a pigtail. Stone-free status was achieved in 15 (79%) operations at 3 months postoperatively.

Conclusion: Our experience suggested the radiation-free 2-step tract dilation technique is a safe and effective method for tract development in ultrasound-guided PCNL.

Keywords: percutaneous nephrolithotomy; ultrasound; urolithiasis; fascial dilator; balloon dilator

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) has remained the treatment of choice for large and complex kidney stones, since its introduction in 1970s[1]. To create an access to the collecting system, including the initial renal puncture and subsequent tract dilation, is the crucial part of this surgery which significantly affects the outcome. Traditionally, fluoroscopy has been used to establish the nephrostomy tract and to date it remains the most common image modality for the guidance of PCNL[2]. It facilitates the tract development by providing a clear mapping of the whole collecting system. Besides, almost all kinds of tract dilators, such as Amplatz, balloon, and Alken telescopic metal dilators, are designed to be visible under fluoroscopy, which ensures a successful access to the collecting system. Despite all these advantages, there has been a persistent concern about the patients' and the operators' exposure to the ionizing radiation with fluoroscopic guidance[3].
Ultrasound-guided PCNL has gained popularity in the past few years. It has the merit of reducing or even totally avoiding radiation exposure for patients and operation personnel. Ultrasound-guidance also provides advantages such as visualization of the surrounding structures, prevention of vascular injury by combining Doppler imaging, and no need of wearing lead apron during the operation, etc.[4]. However, although it is usually not difficult to perform renal puncture under ultrasound guidance, the subsequent tract dilation solely by ultrasound is considered challenging and sometimes impossible[5]. This is mainly because of that almost all kinds of dilators are with low echogenicity and bare-

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Table 1. Characteristics of the Study Subjects

Age, year	61.5 [54, 66]
Men, n (%)	11 (61%)
BMI, kg/m2	26.8 [25.5, 30.76]
Comorbidity, n (%)	
Hypertension	9 (50%)
Type II DM	2 (11%)
Smoking, n (%)	11 (61%)
Aspirin used, n (%)	2 (11%)
Stone burden, cm2	3.3 [2.7, 6.2]
Stone laterality, n (%)	
Right	9 (47%)
Left	10 (51%)
Stone position, n (%)	
Upper calyx stone	4 (21%)
Middle calyx stone	6 (32%)
Lower calyx stone	9 (47%)
Ureterovesical junction stone	8 (42%)
Stone complexity, n (%)	
Single stone	1 (5%)
Multiple stone	13 (68%)
Staghorn stone	1 (5%)
Partial staghorn stone	4 (21%)
Calyx puncture location, n (%)	
Upper pole	17 (90%)
Middle pole	0 (0%)
Lower pole	2 (10%)

Table 2. Outcomes of Totally Ultrasound-Guided PCNL

Success tract establishment, n (%)	18 (95%)
Tract establishment time, mins	10.2 [9.5, 12.4]
Operation time, mins	63.4 [29.2, 81.9]
Stone-free status, n (%)	15 (79%)
Total hospital stay, days	4 [3, 7]
Postoperative stay, days	3 [2, 6]
Hb change (g/dL)	-1 [-1.6, -0.5]
Postoperative pyuria, n (%)	8 (42%)
Postoperative fever, n (%)	3 (16%)
Pleural injury, n (%)	2 (11%)
Ancillary procedure, n (%)	3 (16%)

ly visible under ultrasound imaging[6]. In the previous literature, many so-called "ultrasound-guided" PCNLs actually referred to ultrasound-guided renal puncture followed by fluoroscopy-guided tract dilation[7-9]. Even though some authors solely used ultrasound to monitor the advancement of Amplatz, telescopic metal, or balloon dilators[10,11], these generally required an advanced ultrasound technique and were considered limited to experienced hands[12].

To overcome the above challenges during ultrasound-guided tract dilation, we utilized a radiation-free nephrostomy tract establishment technique in the past few years. The dilation was carried out in a 2-step manner, and in between the tract was verified with a ureteroscope. Since it did not require an advanced technique to monitor the dilators' advancement under ultrasound, this method should be much easier for surgeons with any level of ultrasound expertise. The objective of the current study was to evaluate the safety and efficacy of this radiation-free 2-step tract dilation technique in totally ultrasound-guided PCNL.

MATERIALS AND METHODS

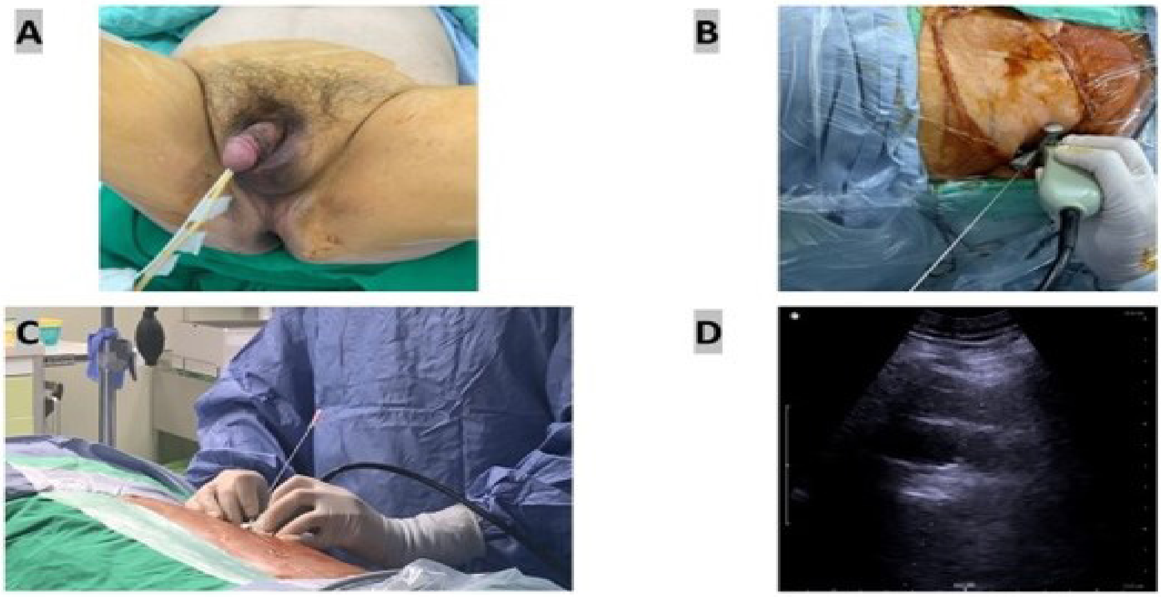
Patient selection

From Oct 2018 to Mar 2020, we consecutively enrolled 18 patients with 19 renal units who underwent PCNL for urolithiasis in our institution. A total of 19 operations were included in the study and the subjects must be at least 18 years old for inclusion. Exclusion criteria included patients with uncontrolled urinary tract infections, pregnancy and bleeding disorders. All the operations were performed by a single surgeon (CHH). The study was approved by Taipei Medical University-Joint Institutional Review Board (N201808062).

Surgical techniques

For each surgical procedure, PCNL was performed under endotracheal general anesthesia with the patient first placed in lithotomy position. Retrograde insertion of a 5-Fr ureteral catheter (PAHSCO, Taiwan) was done with a cystoscope until resistance was felt. According to our experience, the length of the catheter being inserted varied from person to person but was usually around 20 to 25 cm proximal to the ureterovesical junction. Insertion of the ureteral catheter allowed normal saline irrigation via irrigation pump with pressure of 100-200cmH20 to obtain artificial hydronephrosis. The patient was then placed in prone position. Ultrasonography (BK Medical ApS, Mileparken, Herlev, Denmark) was performed to identify the anatomy of the collecting system and stone position. The longitudinal image of the kidney was obtained and the targeted calyx was punctured with a18-Ga/20-cm Chiba needle (Argon Medical Devices, Athens, TX, USA) through a needle-guidance adapter (Bk Medical Ultrasound Transducer Needle Guide Bracket). The route of puncture was determined by the surgeon, and upper calyx was preferentially chosen in this series. The entire needle, including the shaft and the tip, should be monitored by ultrasound in real-time during the entire entry process into the collecting system. Sometimes, the transverse-axis puncture was preferred to avoid rib acoustic shadowing. A 0.035-inch J-tip echogenic guidewire (Boston Scientific, Marlborough, MA, USA) was then inserted into the collecting system through the Chiba needle as long as possible under ultrasound guidance until resistance was felt. The depth of renal puncture was measured with the scale on the Chiba needle. Upon the first step of dilation, the tract was dilated serially with the 8-Fr, 10-Fr, 12-Fr, 14-Fr, and 16-Fr Amplatz Dilators (Boston Scientific, Spencer, IN, USA). All the Amplatz dilators were advanced according to the previously measured depth. A 16-Fr Amplatz Sheath (Boston Scientific, Spencer, IN, USA) was then introduced into the collecting system through the 16-Fr Amplatz dilator.

A semi-rigid 6.0/7.5-Fr ureteroscope (Richard Wolf, Vemon Hills, Illinois, USA) was advanced through the Amplatz sheath to check whether the tract appropriately entered the collecting system. If necessary, the sheath was advanced further along the shaft of the ureteroscope to completely penetrate the renal parenchyma. This ensured the success of the second step of dilation, in which a 24-Fr nephrostomy balloon dilator (UltraxxTM, Cook, Bloomington, IN, USA) was inserted through 16-Fr Amplatz sheath into the collecting system. The depth of the balloon dilator inserted through the 16 Fr. sheath was equal to the depth of the ureteroscope inserted into the collecting system. With the balloon dilator in place, the Amplatz sheath was withdrawn and the balloon was inflated with pressure of 14 atm for 30 sec. A 24-Fr sheath was then advanced through the inflated balloon with the distance according to previously measured inserted depth of the ureteroscope. Once the tract was established, the stones were



Step 1 Create artificial hydronephrosis.
Figure 1:A. Insertion of a ureteral catheter allowed normal saline irrigation via irrigation pump with pressure of 100-200cm$H_2$0 to obtain artificial hydronephrosis. The ureteral catheter was taped to the Foley catheter using surgical tape.
Step 2 Renal puncture with ultrasound. **B,C** The longitudinal image of the kidney was obtained and the targeted calyx was punctured with needle through a needle-guidance adapter.
D. The electronic dotted line on the screen will predict the path of the needle.

fragmented with pneumatic lithotripter (Karl Storz, Tuttlingen, Germany) or holmium laser, and the stone fragments were retrieved with a grasper by 24 Fr. percutaneous universal nephroscope (Richard Wolf, Vemon Hills, Illinois, USA). All the calyces were examined for residual stone fragments before the operation ends. In the end of the surgery, a 6-Fr double-J ureteral stent was placed by nephroscope under direct vision through the sheath in an antegrade manner. The sheath was then removed after a 10 Fr. fascial dilator advanced into the renal pelvis by nephroscope. A nephrostomy tube was inserted through the fascial dilator until the resistance was felt in general. The balloon of the catheter was first inflated with 3cc distilled water and gently pulled out until resistance was felt. Then the catheter was inflated with another 2cc distilled water with a total of 5cc to compress the tract against bleeding.

Data collection

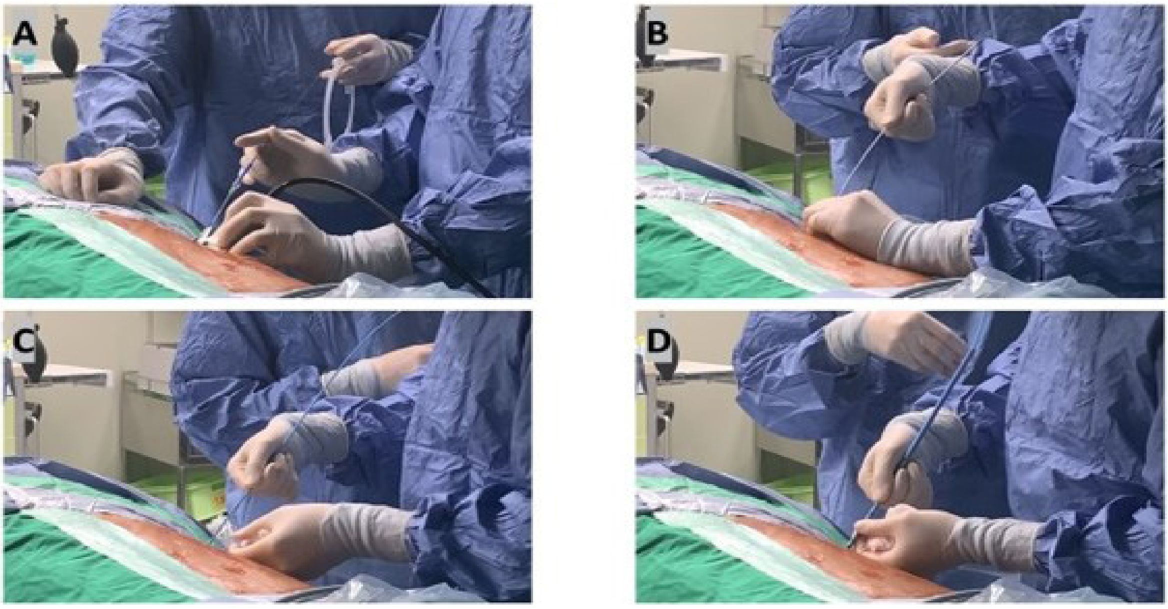
Study subjects' demographics and data regarding the stone, including size, location, and composition, were recorded. The kidney, ureters, bladder (KUB) radiograph was done one week before the surgery in outpatient setting. Stone burden was measured as the maximum diameter on the image. The routine hemogram including CBC/DC, coagulation function (PT/APTT), Urine routine (urine culture if pyuria was noted), and biochemistry test were performed before surgery. The uncorrected coagulopathy was an absolute contraindication to percutaneous surgery. Successful tract establishment was defined as the distal end of the 24-Fr working sheath appropriately placed in the collecting system solely under ultrasound on the first attempt. Cases in which second dilation procedure was required or fluoroscopy was applied at any time of tract establishment were considered as failures. Tract establishment time was calculated from the beginning of renal puncture to the successful placement of the 24-Fr working sheath. Operative time was measured from the retrograde ureteral catheterization to the nephrostomy tube insertion. Any postoperative events and complications were recorded. Stone-free status was defined as no residual fragments greater than 4 mm determined by KUB or CT at 3 months postoperatively.

Statistical analysis

The continuous variables are expressed as the median and [Q1, Q3 (IQR)]; the categorical variables are expressed as count and (percentage). The statistics were carried out with a descriptive study. The analysis was conducted with SPSS 26.0 for Windows (SPSS Inc., USA).

RESULTS

The characteristics of the study subjects are shown in Table 1. The median age of the patients was 61.5 [54, 66] years, and 11 (61%) were male. The median stone size was 3.3 [2.7, 6.2] cm2, and stone was located on the right side in 9 (47%) subjects. Renal access was made on the upper calyx in 17 (90%) operations.
Successful tract establishment on the first attempt was achieved in 18 (95%) operations. In one case (5%), unintentional withdrawal of the guidewire occurred on the first stage of dilation (serial Amplatz), in which we failed to regain an artificial hydronephrosis and fluoroscopy was applied to complete tract establishment. The median tract establishment time was 10.2 [9.5, 12.4] mins. The median operation time was 63.4 [29.2, 81.9]



Step 3 Guidewire access.
Figure 2:A. A 0.035-inch J-tip guidewire was inserted into the collecting system through the Chiba needle.
Step 4 First step of tract dilation (serially with the 8-Fr, 10-Fr, 12-Fr, 14-Fr, and 16-Fr Amplatz Dilators).
B. Dilating with an 8 Fr fascial dilator along the guidewire.**C.** 8-Fr stylet (8/10 Dilator/Sheath Set) was inserted along the guidewire after dilating with 12-Fr fascial dilator. **D.** Dilating with a 16 Fr fascial dilator along the 8-Fr dilator.

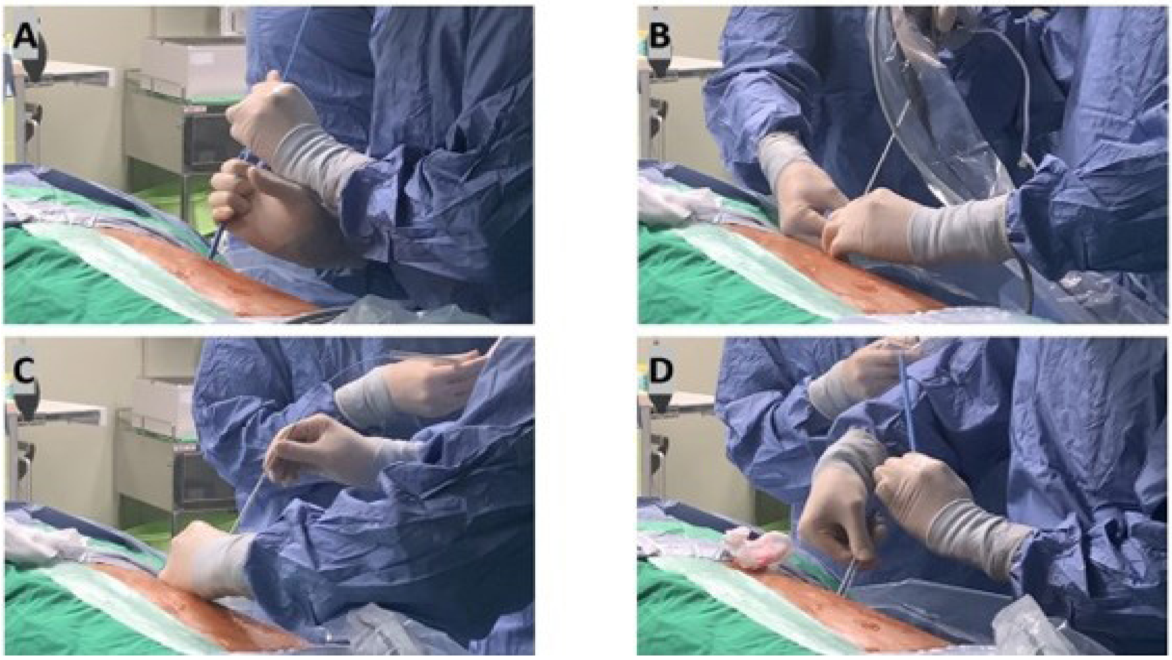
mins. The overall and postoperative hospital stays were 4 [3, 7] days and 3 [2, 6] days, respectively. The median decrease in hemoglobin level was 1.0 g/dL [0.5,1.6] and none of the patients required intraoperative or postoperative transfusion.

Postoperatively, pyuria was noted in eight (42%) operations: the majority was asymptomatic and only three (16%) developed fever. Pleural injury occurred in two (11%) operations with supracostal punctures to gain access to the upper calyx. One was asymptomatic and treated conservatively, while the other patient developed symptoms of cough and chest tightness several hours after the operation. Chest x-ray was done immediately and showed blunting of the left CP angle, which suggested pleural effusion formation, with no evidence of pneumothorax. The chest surgeon was consulted and a pigtail was inserted for drainage under ultrasound guidance successfully. The aspirated fluid was clear and yellowish and hydrothorax was impressed. The symptoms subsided immediately after treatment and the pigtail was then removed after chest x-ray showed complete resolution of the effusion. Among all these PCNL patients, stone-free status was achieved in 15 (79%) operations at 3 months postoperatively. Three (19%) underwent an ancillary procedure of extracorporeal shockwave lithotripsy or retrograde intrarenal surgery (RIRS) and one patient asked for conservative treatment by active imaging surveillance every 3 months.

DISCUSSION

In the current study, we described a technique of radiation-free tract establishment in totally ultrasound-guided PCNL. The collecting system was punctured under real-time ultrasound guidance. Then, the tract was dilated in a 2-step technique. The tract was initially dilated from 8 Fr to 16 Fr with Amplatz fascial dilators. Then, the initially dilated tract was checked and adjusted with a ureteroscope. Finally, the tract was further dilated with a 24-Fr balloon dilator. The results demonstrated that the above technique achieved a high success rate of tract establishment on the first attempt without fluoroscopy. And the time required to establish the tract was consistently short. Compared to ultrasound-guided tract dilation, this method did not require an advanced ultrasound technique and was considered to be easier to carry out.

Several mechanisms contributed to the safety and efficacy of this technique. First, the tips of small-sized Amplatz dilators (8 Fr to 16 Fr) are relatively sharp, which tend to penetrate the kidney parenchyma and enter the collecting system successfully. This largely prevented the status of short dilation. This was supported by those studies of mini-PCNL[13,14], in which the failure rate of serial dilation up to 18 Fr was generally less than 5%. On the contrary, the tips of large-sized Amplatz dilators are relatively blunt and tend to push the kidney away before they enter the collecting system, which causes a status of short dilation[15,16]. Furthermore, we always kept the guidewire straight and dilated the tract with an axis same as the Chiba needle carefully. We ensured the guidewire was movable every time after a dilator was inserted. This largely prevented the status of short dilation and guidewire kinking or slippage. Second, all the small-sized (8-Fr to 16-Fr) Amplatz dilators were advanced at a fixed depth as measured earlier. This avoided the injury to the opposite pelvic membrane in



Step 5 16-Fr tract establishment
Figure 3: A. A 16-Fr Amplatz Sheath was introduced into the collecting system through a 16-Fr Amplatz dilator. **B.** A semi-rigid 6.0/7.5-Fr ureteroscope was advanced through the Amplatz sheath to check whether the tract appropriately entered the collecting system. If necessary, the sheath was advanced further along the shaft of the ureteroscope to completely penetrate the renal parenchyma.
Step 6 24-Fr tract establishment. **C.** 24-Fr nephrostomy balloon dilator was inserted through 16-Fr Amplatz sheath into the collecting system. The Amplatz sheath was withdrawn and the balloon was inflated with a pressure of 14 atm for 30 sec. **D.** A 24-Fr sheath was then advanced through the inflated balloon.

the collecting system. With the above two mechanisms, we could confidently dilate the tract until a diameter of 16 Fr was reached without monitoring by either fluoroscopy or ultrasound. Third, after the tract was initially dilated, we checked the entrance of the 16-Fr tract with a ureteroscope. In our experience, the 16-Fr sheath had been perfectly placed in the collecting system at this step in the majority. Although short dilation did occur in a few cases, it was not difficult to fix by the following procedures: following the guidewire, the ureteroscope was advanced into the collecting system; then the 16-Fr sheath was gently advanced over the shaft of the ureteroscope. The appropriately positioned 16-Fr sheath almost ensured the success of the final dilation with a balloon.

A few authors reported their technique of ultrasound monitoring the dilation process, including balloon dilator[11,17], serial Amplatz dilators[9], one-shot Amplatz dilators[18], or telescopic metal (Alken) dilators[19]. Among these dilators, balloon has been widely used in ultrasound-guided PCNL and has been considered relatively easy to apply under ultrasound guidance[12]. In one study with 138 subjects, totally ultrasound-guided balloon dilation was achieved in 131 (94.9%), and the remaining 7 (5.1%) cases required a switch to fluoroscopy[17]. In another study with 207 cases undergoing ultrasound-guided balloon dilation, the success rate of tract dilation on the first attempt was 88.4%[11]. Short dilation was considered to be the main cause of failure with balloon dilation[15,16]. Obesity was reported to be a predictor of failure for ultrasound-guided balloon dilation[6]. According to previous literature, the success rate of tract dilation was 76.9% in normal weighted and 79.0% in overweighted patients, but only 45.7% in obese subjects[6]. In another study, the presence of staghorn stones, previous ipsilateral open nephrolithotomy, and low pole access independently predicted a failure of tract establishment with balloon, while the presence of hydronephrosis of the target calyx increased the likelihood of success[11]. In general, to monitor these dilators under ultrasound is an advanced technique and is limited to experts and is specially technically challenging in cases without hydronephrosis[16].

Different from the above techniques by using ultrasound to monitor the process of dilation, our method was characterized by checking the initial small-sized dilation with a ureteroscope. This was considered as a 2-step technique in the literature. Wang et al.[11] reported their 2-step dilation technique. The tract was first serially dilated from 8-Fr to 16-Fr with fascial dilators. A 16-Fr peel-away sheath was left to allow the evaluation by ureteroscope. In the second step, a 15-Fr metal dilator was inserted to replace the peel-away sheath, followed by further dilation with 18 to 24-Fr metal dilator. Compared to one-step balloon dilator, their 2-step technique achieved a significantly higher success rate of tract establishment on the first attempt (100% vs 88.6%), and the mean tract establishment time was only 6 minutes[11]. The same technique was also reported by Song et al.[20], who reported a success rate of 84.3% on the first attempt. In another technique of Zhou et al.[5], a 10-Fr fascial dilator was first used to

Step 7 Nephroscopy and stone fragmentation
Figure.4 The stones were fragmented with pneumatic lithotripter or holmium laser, and the stone fragments were retrieved with a grasper under 24 Fr. percutaneous universal nephroscope.

dilate the tract along the guidewire, and a 10-Fr sheath was left in place. A 6-Fr ureteroscope entered the collecting system to adjust the guidewire into the ureter. Then the tract was further dilated with either a balloon dilator or serial fascial dilator (from 12 Fr to 22 Fr). With either type of dilator, the success rate of tract establishment was high and the mean tract establishment time was short (8.9 mins versus 10.1 mins). The success rate and the tract establishment time in our study were comparable to the those of the above studies(5,11,20). Our study generally confirmed that the safety and efficacy of the 2-step technique were at least not inferior to those of fluoroscopy-guided or ultrasound-guided tract dilation. And only basic ultrasound skills were demanded to complete the procedures and the operation was totally radiation-free.

Although, performing totally ultrasound-guided PCNL in pregnancy has been reported previously. They performed three procedures were performed in supine and lateral flank position under spinal anesthesia(21). Our approach was the prone position under general anesthesia so we excluded pregnancy.

The major limitation of the current study was a small case number. However, we believed that the results were still robust enough to support the feasibility of this technique. First, among the 19 consecutive operations, there was only one failure, which was due to an unintentional withdraw of the guidewire. This should not be considered as a failure of the technique itself. Second, the time of tract establishment was consistent and short, suggesting that this technique was easy to perform and was highly reproducible. Third, the overall complication rates, regarding the blood loss, transfusion rate, and fever were generally low and were comparable to those in the literature. There was a relatively higher rate of pleural injury, which was because that upper calyx was the primary target of puncture (supracostal) in the majority of the cases. In our study, more than 90% of the patients have complex renal stones, 13 (68%) with multiple renal stone, 1 (5%) with staghorn stone and 4 (21%) with partial staghorn stones. Upper calyceal puncture provides a direct access to all the calyces and upper ureteral calculi by single tract with higher stone clearance rate. With real-time ultrasound monitoring, the risk of visceral injury by the Chiba needle can be minimized. However, the pleural reflection was difficult to be identified under ultrasound guidance and may be injured during tract dilation due to the shear force or during stone manipulation due to sheath swing. For pleural injury/effusion patients, our protocol of treatment was chest tube(pigtail) insertion in symptomatic patients, oxygen supplementation and combined care with chest surgeon. We closely monitored the patients for signs of clinical deterioration and serial chest X-ray films were taken in the next few days for further evaluation. Chest tubes or pigtails were then removed after the pleural effusion subsided.

CONCLUSIONS

Our experience suggested the radiation-free 2-step tract dilation technique is a safe and effective method for tract development in ultrasound-guided PCNL.

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CONFLICT ON INTEREST

The authors report no conflict of interest.

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