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Original Article

A Randomized Controlled Trial of Ultrasound versus Fluoroscopic Guidance for Percutaneous Nephrolithotomy

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Abstract

Objective: To compare the success rate of ultrasound (US) versus fluoroscopic guidance in entering the target calyx from a proper entry site and in the direction of renal pelvis during percutaneous nephrolithotomy (PCNL), and to determine their relative advantages and disadvantages.

Methods: The present randomized controlled study was conducted between May 2020 and March 2021. Just before PCNL, patients were randomly assigned to undergo either US guidance access (group A) or fluoroscopic guidance access (group B). A needle placed on the patient's flank in the prone position was used to identify the preselected target. The needle was advanced through a needle holder and helped guide percutaneous tract dilation. Data on patient characteristics, tract length, tract access time, and the stone free rate were collected for analysis. Data were analyzed using *t*-test, chi-square test and Fisher's exact test.

Results: There were a total of 40 patients in the trial with 20 patients in each group. There were no statistically significant differences between patients in groups A and B in terms of age, gender, ASA status, BMI, stone size and stone location. The average length of the access tract was 7.7 cm in group A and 7.6 cm. in group B (p = 0.672). The tract access time was 15 minutes in group A and 13 minutes in group B (p = 0.288). The frequencies of location of the access tract at the upper pole in groups A and B were 11 and 12, respectively (p = 0.252). The stone free rate was 45% (9/20) in group A and 55% (11/20) in group B (p = 0.853).

Conclusions: The present study showed that PCNL under US guidance had similar success as PCNL under fluoroscopic guidance. US can be used as an alternative to fluoroscopy in PCNL. The present randomized trial might help convince some endourologists to use US rather than fluoroscopy in their management of renal stones, in order to minimize exposure to ionizing radiation.

Keywords: Ultrasound, Fluoroscopic Guidance, Percutaneous Nephrolithotomy

Introduction

Percutaneous nephrolithotomy (PCNL) is the treatment of choice for staghorn and large renal stones. A perfect percutaneous access tract to the pelvicalyceal system should be made through the tip of renal papilla in the targeted calyx and to be along the axis of the renal calyx.[1-8] It is traditionally guided by fluoroscopy and may pose a radiation risk to patients and staff. The use of ultrasonography in PCNL was first described as early as the 1970's. Although ultrasound (US) guidance renal access for PCNL is a safe, effective, and low-cost procedure, it is underused by urologists.

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The use of fluoroscopy at Suratthani Hospital is limited by the availability of the equipment, which must be shared among all Departments of the Hospital. This was a motivation for the present study. We want to compare the success, the advantages and disadvantages of PCNL under ultrasound guidance to those of PCNL under fluoroscopy, and to determine factors related to difficulty of access.

Patients and Methods

Patients who were admitted for PCNL at Suratthani Hospital by one urologist from May 2020 to March 2021 were enrolled into the study. Inclusion criteria included patients with renal or proximal ureteral stone; large renal stones (2 cm or larger) detected by computerized tomography (non-contrast); and age greater than 18 years. All participants gave informed consent. No participants were excluded from the analysis. Randomization was done using a table of random numbers. Participants were randomized into two groups after induction of anesthesia. Participants in group A underwent PCNL under US guidance. Participants in group B underwent PCNL under fluoroscopic guidance. All operative procedures were performed by one surgeon. All clinical information was collected prospectively. Data were summarized as mean and standard deviation or counts and percentage as appropriate. Quantitative variables were contrasted between groups using unpaired *t*-test while categorical variables were contrasted using chi-square test or Fisher's exact test as appropriate.[9] Statistical significance was defined as a *p*-value less than 0.05. The study was approved by Research Ethics Committee of Suratthani Hospital (no. 54/2563).

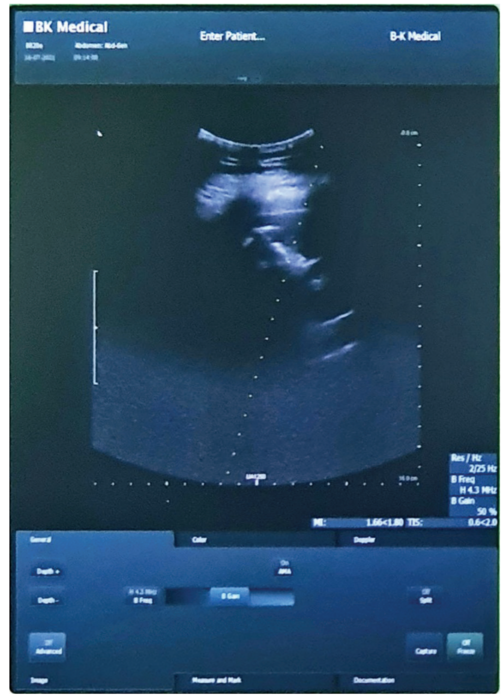

Figure 1 Ultrasonography used for locating the stone and guiding instrumentation.

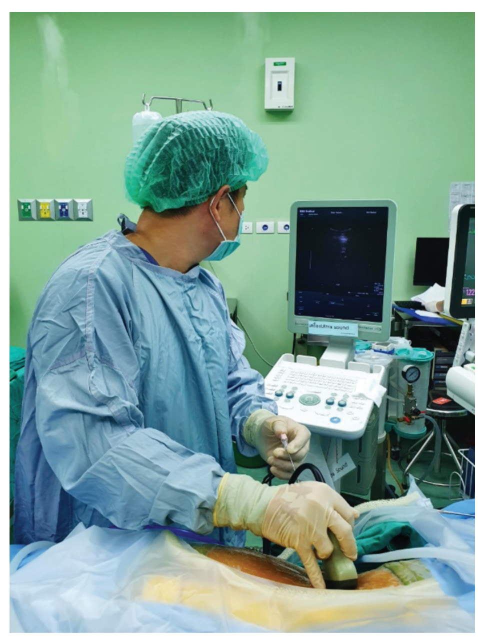

Figure 2 Placing a needle under US guidance

After induction of general anesthesia, an open-ended 5-French ureteral catheter was inserted into the ipsilateral ureter up to approximately 20 centimeters, under cystoscopic guidance, from a lithotomy position with the patient on the operating table. The patient was then moved to a prone position. In group A, percutaneous renal access was obtained under US guidance with a needle guide. We used the US (BK medical Flex Focus 500) to locate the stone as well as to identify an ideally suited posterior calyx for puncture (Figure 1). An 18-gauge needle was advanced under real-time ultrasound monitoring (Figure 2). In group B, we performed all the above steps but with fluoroscopic guidance. Tract access was chosen according to the location of the stone in both groups. In the absence of hydronephrosis, normal saline solution was injected in a retrograde fashion through the ureteral catheter to dilate the collecting system for easier imaging, though this was not routinely done for every patient. Entry into the collecting system was confirmed when either aspiration or efflux of urine through the puncture needle was seen, or when clear visualization of the needle tip within the urinary space or touching the stone can be demonstrated. After entry into the collecting system was confirmed, a J-tip coaxial guide wire was inserted into the renal pelvis or down the proximal ureter. We then sequentially passed a coaxial rod metal dilator, increasing the dilator by 3-French each time, starting from 9-French, and placed a safety wire introducer over the guide wire (Figure 3). The tip of each instrument was marked and visualized using either the US or fluoroscope. The images of instruments entering the collecting system were obtained to prevent perforation. A 30-French Amplatz sheath was advanced over the 27-French metal dilator. After removal of the coaxial rod metal dilator, nephroscopy was performed with a 27-French rigid offset nephroscope. Stone fragmentation was accomplished using an ultrasonic lithotripter. Flexible nephroscopy was performed to look for residual fragments and to perform additional holmium laser lithotripsy. At the end of the procedure, a nephrostomy tube was placed in all patients. The position of the tubes was checked by retrograde injection of saline solution through the ureteral catheter. A 24-French Foley catheter was routinely used for this purpose.

Length of the access tract was measured from the skin to the calyx. Evidence of any residual stone in the urinary tract, and size of residual stones, were assessed by computerized tomographic scan. Access time was measured from the time of US or fluoroscope use until the nephroscope was successfully inserted.

Figure 3 Introducing the safety wire

Results

From May 2020 to March 2021, 40 patients were enrolled into the study. There were 20 participants in group A and 20 participants in group B. Clinical characteristics of participants are shown in Table 1. All characteristics including age, gender, ASA status, and body mass index were similar between groups. Characteristics of the stone including location, side and size were similar as well. Most of the stones were located in the renal pelvis and at the lower pole. Finally, the degree of hydronephrosis was also similar between groups, the most common being grades II and III.

Comparison of outcomes of the operation between the two groups is shown in Table 2. Most of the operation required only one attempt at puncture, and this was similar between groups. Length of the access tract, time to access, and stone free rate were all similar between both groups. The length of the access tract was from 7 to 8 cm, and the access time was less than 15 minutes, on average. The stone-free rate was about 50%.

Discussion

Percutaneous nephrolithotomy (PCNL) is the procedure of choice for patients with large renal stones not amenable to ureteroscopy or shockwave lithotripsy. In the United States of America and around the world, fluoroscopy had been the primary imaging method used to guide percutaneous renal access and establish a working tract for PCNL. However, there are concerns that long-term use of ionizing radiation may increase the incidence of cancer.[11-13] For patients with nephrolithiasis, reducing their exposure to ionizing radiation is important, as these patients are at high risk for cumulative radiation exposure. Surgical staff are at risk for intraoperative radiation exposure as well. While some studies have shown that radiation exposure during PCNL may be relatively low, this might not be so everywhere. The use of radiation protective equipment may not be effective, or unreliable. The surgeon generally receives more ionizing radiation exposure, especially to the legs and eyes.[14,15]

Several methods have been proposed to help reduce radiation exposure during PCNL. One method is to use endoscopic guidance, commonly known as Retrograde Intra Renal Surgery (RIRS).[16] This method can access the renal collecting system by the use of a flexible ureteroscope. After positioning the ureteroscope in the target calyx, fluoroscopy is used to guide a needle into the kidney in an antegrade percutaneous fashion.

Table 1 Clinical characteristics of patients

Characteristics	Ultrasound guidance (N = 20)	Fluoroscope guidance (N = 20)	*p*-value
Age (years): mean (SD)	59.9 (11.6)	58.5 (9.4)	0.677
Gender: number (%)			
Women	7 (35)	9 (45)	0.519
Men	13 (65)	11 (55)	
ASA Status: number (%)			
I	8 (40)	11 (55)	0.342
II	12 (60)	9 (45)	
Body mass index (kg/m2): number (%)			
< 25	13 (65)	14 (70)	0.796*
25 to 29.9	4 (20)	2 (10)	
> 30	3 (15)	4 (20)	
Site of stone: number (%)			
Left	10 (50)	10 (50)	0.999
Right	10 (50)	10 (50)	
Stone size (cm): mean (SD)	3.96 (1.34)	4.03 (1.35)	0.870
Stone location: number (%)			
Renal pelvis/ Lower pole	8 (40)	6 (30)	0.898*
Full staghorn calculus	7 (35)	7 (35)	
Renal pelvis	2 (10)	5 (25)	
Renal pelvis /Upper pole	1 (5)	1 (5)	
Upper /Lower pole	1 (5)	1 (5)	
Renal pelvis /Middle pole	1 (5)	0	
Hydronephrosis grade: number (%)			
II	5 (25)	4 (20)	0.827*
III	11 (55)	13 (65)	
IV	4 (20)	3 (15)	

*Fisher's exact test; ASA: American Society of Anesthesiologists; SD: standard deviation

The needle enters the collecting system under direct vision of the ureteroscope. Although fluoroscopy is still needed for caliceal puncture, compared to standard PCNL this technique may lower fluoroscopic screening time and increase stone clearance.[17,18]

Real-time US is becoming accepted as an imaging modality for directing PCNL in a dilated renal collecting system.[19] The overall success rate is likely comparable to that of standard fluoroscopic PCNL.[20] US is free of ionizing radiation and is highly portable. US can provide additional imaging information as well. It can identify important structures locating between the skin and kidney that might be in the path of the access tract. The depth of penetration of the puncture needle relative to the target calyx can be estimated. The orientation of calyceal anatomy during PCNL can be correctly established. Thus, US can help prevent adjacent and visceral organ injury. In addition, US eliminates the need for a retrograde ureteral catheter if retrograde ureteral catheterization was unsuccessful.[21] US is ideal for patients who are sensitive to radiation exposure, including pediatric and pregnant patients. Finally, US can help visualize non-opaque or semi-opaque stones not seen radiographically, and thus help improve the stone-free rate.[22]

Table 2 Operative outcomes

Outcome	Ultrasound guidance (N = 20)	Fluoroscope guidance (N = 20)	*p*-value
Numbers of puncture attempt: number (%)			
One attempt	14 (70)	13 (65)	0.938
Two attempts	5 (25)	6 (30)	
Three attempts	1 (5)	1 (5)	
Location of tract: number (%)			
Lower pole	1 (5)	4 (20)	0.252*
Lower/ Upper pole	0	1 (5)	
Upper pole	11 (55)	12 (60)	
Middle pole	2 (10)	0	
Upper /Lower pole	4 (20)	1 (5)	
Upper /Middle pole	2 (10)	2 (10)	
Length of tract (cm): mean (SD)	7.7 (0.72)	7.6 (0.76)	0.672
Access time (min): mean (SD)	14.7 (6.3)	12.7 (5.4)	0.288
Residual stone: number (%)			
No residual stone (stone-free)	9 (45)	11 (55)	0.853*
Lower pole, 10 mm	1 (5)	0	
Lower pole, 2 mm	1 (5)	0	
Lower pole, 3 mm	3 (15)	5 (25)	
Lower pole, 4 mm	2 (10)	1 (5)	
Lower pole, 8 mm	1 (5)	0	
Middle pole, 10 mm	1 (5)	1 (5)	
Middle pole, 4 mm	1 (5)	0	
Upper pole, 4 mm	0	1 (5)	
Upper pole, 6 mm	1 (5)	0	
Upper pole, 8 mm	0	1 (5)	

* Fisher's exact test; SD: standard deviation

The disadvantages of US include additional training for the operator to gain the required skills, although successful puncture of the collecting system can be confirmed by the appearance of urine following removal of the needle obturator. There is the difficulty of percutaneous access when there is no or only mild hydronephrosis. But this can be overcome by administration of diuretics or the retrograde injection of saline solution to transiently dilate the calyces. Finally, there is the difficulty of visualizing the guide wire during its manipulation following renal access, as well as the poor echogenicity of the Amplatz dilatator and Amplatz sheath.[23-25]

The success rate in achieving access tract in our study was 100 % for both groups. The ability to gain access to the collecting system under US guidance was similar to that under fluoroscopic guidance. Some studies have shown that the primary stone-free rate with US guided PCNL was from 49% to 79%.[26,27] In the present study the stone-free rate was 45% to 50%, which was similar to those of previous studies, and was not significantly different between US and fluoroscope guidance. The average access time under US guidance was slightly longer than that under fluoroscope guidance, due to cases with difficult dilatation requiring retrograde fluid irrigation to facilitate US visualization, as compared with fluoroscopy which can visualize the process directly. Also, US guidance is more difficult in obese patients, due to the longer length of the access tract. US guidance is sometimes a "blind technique" when compared with fluoroscopy, which is a real-time image guidance.

Finally, higher degree of hydronephrosis is easier for access by US, so if minimal hydronephrosis is present, then more time or more preparation is required for access.

Conclusion

The present randomized controlled study showed that US guidance had similar outcomes as fluoroscope guidance for PCNL. Thus, US is an equally effective alternative to fluoroscopy in PCNL, and will help reduce exposure to radiation.

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