Blind versus Fluoroscopy-guided Percutaneous Nephrolithotomy: A Randomized Clinical Trial

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Purpose: Due to the negative impact of radiation on the patient and the surgical team during percutaneous nephrolithotomy (PCNL), we aimed to evaluate success rate and complications of blind access for PCNL using lumbar notch landmark and compare with conventional fluoroscopy-guided access.

Materials and Methods: In a clinical trial, 100 patients who were candidate for PCNL, were randomly assigned into blind group (1) and fluoroscopy-guided group (2). In group 1 the lumbar notch was used to guide percutaneous access and in group 2 fluoroscopy performed after needle insertion, Amplatz placement and at the end of surgery. If the access failed, we would repeat puncturing up to 5 times. In group 2, access was achieved using full fluoroscopy guidance. All patients underwent postoperative assessment including kidney-ureter-bladder X-ray and ultrasonography.

Results: Both mean access time and mean operation time were statically similar in group 1 and group 2 (3.3 ± 0.5 vs. 3.6 ± 0.7 min and 35.2 ± 4.6 vs. 38.9 ± 4.1 min, respectively). A successful puncture was achieved in 86% and 94% of the patients in groups 1 and 2, respectively ($P = .18$). Total success rate of procedure was 80% and 88% of the patients in groups 1 and 2, respectively ($P = .27$).

Conclusion: According to this study, it seems that blind access is a safe and effective PCNL method, and we recommend employment of this technique by skilled endourologist in urology centers especially for patient with large hydronephrotic kidney.

Keywords: kidney calculi; surgery; nephrostomy; percutaneous; methods; endoscopy; lithotripsy; adverse effects; postoperative complications; treatment outcome; fluoroscopy; prospective studies.

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) has improved the treatment of kidney calculi since its introduction in late 1970s.[1] Because of its safety and low incidence of complications, now PCNL is the treatment of choice in patients with kidney calculi > 2 cm in diameter and in whom extracorporeal shock wave lithotripsy (SWL) has failed.[2]

Although PCNL under fluoroscopy guidance is the routine approach for accessing the pyelocaliceal system, other methods such as computed tomography-guided (CT-guided) access and especially X-ray free approaches like ultrasonography-guided method have been employed recently in some studies.[3- 7]Because the adverse effects of radiation are not dose dependent and shield protection is not complete, X-ray should be used carefully in medical procedures and eliminate in unnecessary protocols. All occupational personnel should 'achieve as low as reasonably achievable' (ALARA) dose of radiation.[8]

According to our knowledge, there are only few studies reporting blind access to pyelocaliceal system with acceptable safety and efficacy and low radiation hazards to the patient and the surgical team during PCNL.[9-12] This clinical trial is a first study that compares the results and complications of PCNL with blind access under full fluoroscopy evaluation with conventional fluoroscopy-guided approach.

MATERIALS AND METHODS

Study Population

Between January 2005 and October 2010, a total number of 100 patients who were candidate for PCNL enrolled in the study after a routine preoperative evaluation. The inclusion criteria were either pelvic/pyelocaliceal stones larger than 2 cm in diameter or impacted proximal ureteral stones larger than 1 cm. The patients with kidney anomalies, uncontrolled coagulopathies, single caliceal stones without hydronephrosis and previous histories of PCNL or open renal stone surgeries were excluded. The study protocol was explained to each patient and informed consent was obtained. The study was approved by the ethics committee of the Urology and Nephrology Research Center. Preoperative evaluation consisted of tests such as urine analysis, urine culture and renal function tests. Before PCNL, urine cultures were obtained, and if positive, antibiotics were administered. Intravenous urography was the primary imaging modality to determine the size and location of calculi, the anatomy of the upper urinary tract, the degree of hydronephrosis, and the targeted calyx. Prophylactic intravenous antibiotics were administered before surgery. All procedures were performed by a single surgeon who was experienced in PCNL.

Study Design

This was a single center [with balanced randomization (1:1)], parallel-group study conducted in the urology department of Shohadae Tajrish Hospital in Tehran, Iran. Patients were randomly assigned to one of two groups according to the method of treatment: blind (group 1, n = 50) and fluoroscopy-guided (group 2, n = 50) PCNL groups. Simple randomization was carried out using computerized random numbers. Sample size was determined after consideration of type 1 statistical error < 5%; and type 2 statistical error < 20%.

Surgical Technique

After induction of general anesthesia, an open ended 5 French (F) ureteral catheter was inserted in the lithotomic position, and then patient was repositioned into prone position with all pressure points padded.

For patients in group 1, the lumbar notch was used to guide percutaneous access[13] which is bounded by the latissimus dorsi muscle and the 12th rib in the superior, by the sacrospinalis and the quadratus lumborum muscles in the medial, and by the transverses abdominis and the external oblique muscles laterally.[9] An 18-gauge access needle was inserted into the lumbar notch with an angle of 30° to 45° pointed cephalad, and advanced to a depth of nearly 4 to 6 cm under the 12th rib. Correct entrance to the collecting system was assured when urine is withdrawn spontaneously or by syringe aspiration. For patients with a large pelvis and staghorn stones, access was accomplished by touching the stones by the needle. Fluoroscopy was used in this step to assess the position and location of needle in the calyx, and then a guide wire was placed. The depth of insertion measured precisely by ruler for next steps dilatation. The tract dilated by telescopic dilators and then Amplatz sheath (28 to 30 F) inserted. During these steps, sterile water or normal saline was injected into the ureteral catheter to increase the grade of hydronephrosis in order to out flowing of fluid from the end of dilators or Amplatz sheath to prevent over-advance-

Table 1. Demographic and clinical characteristics of study patients.

Variables	Blind	Fluoroscopy-Guided	*P*
Mean age (years)	30.3 ± 6.5	30.4 ± 7.8	.95
Male, no. (%)	31 (62)	32 (64)	.84
Body mass index (kg/m^2)	26.1 ± 4.3	26.7 ± 4.1	.48
Stone diameter (mm)	26.4 ± 5.1	25.8 ± 4.1	.52
Number of stones	1.3 ± 0.7	1.3 ± 0.6	.99
Stone location, no. (%)			
Superior ureter	9 (18)	8 (16)	.69
Pyelocalix	14 (28)	18 (36)	
Pelvic	27 (54)	24 (48)	
Hydronephrosis, no. (%)			
Mild	9 (18)	17 (34)	.18
Moderate	16 (32)	14 (28)	
Severe	25 (50)	19 (38)	
Left side stone, no. (%)	25 (50)	23 (46)	

ment of them. Other fluoroscopy performed to estimate the placement of Amplatz sheath. By using rigid nephroscope and Swiss pneumatic lithotripsy (Swiss Lithoclast; EMS, Angiomed, GmbH & Co., Karlsruhe, Germany), stones were fragmented and extracted by grasping forceps. At the end, nephroscopy followed by a control fluoroscopy were carried out for any residual stone detection and then Amplatz sheets were removed and skin were sutured (tubeless procedure). Maximum of 5 times puncturing was applied in case of no urine drainage, and if it failed, the proper access was performed under fluoroscopic guidance. In group 2, all standard PCNL steps mentioned above including access to the collecting system performed under fluoroscopy guidance.

Outcome Assessment

Due to the difference between two methods, it was not possible to blind the surgical team from knowledge of which procedure a participant received; however, after PCNL operation the patients' evaluator was blind to the method of surgery. Stone free status as the primary outcome measure was used to evaluate the efficacy and residual stone burden was determined by plain abdominal radiographs and renal ultrasound studies routinely obtained 48 hours after treatment. The procedure considered as a failure either in any stone residual fragments detected by these studies or unsuccessful access. Demographic and stones characteristics, degree of hydronephrosis, time to access (from the start of puncturing to complete dilation), number of puncturing attempts, location of access to the system, time of operation (from the induction of anesthesia to last skin suture), hospitalization time, change in hemoglobin level (preoperative and 1 day after surgery) and complications such as bleeding, uro-sepsis and collecting system perforation were compared between the 2 groups.

Statistical Analysis

Data analysis was performed using Student's t test and chi-square test. The statistical package for the social science (SPSS Inc, Chicago, Illinois, USA) version 16 was used for analysis and *P* values lower than .05 were accepted as significant.

RESULTS

After a routine preoperative evaluation, 50 patients in each group were enrolled in this study. Demographic and clinical characteristics of patients in each group are shown in Table 1. A successful access achieved in 43 (86%) and 47 (94%)

Table 2. Intraoperative and postoperative data of study subjects.

Variables	Blind	Fluoroscopy-Guided	*P*
Access, no. (%)			
Direct	2 (4)	0	.30
Middle calyx	37 (74)	41 (82)	
Inferior calyx	11 (22)	9 (18)	
Mean hemoglobin level (mg/dL)			
Before operation	12.8 ± 1.3	12.6 ± 1.1	.40
After operation	11.8 ± 1.2	11.9 ± 1.0	.65
Change	-0.96 ± 0.3	-0.82 ± 0.3	.20
Intraoperative bleeding, no. (%)	2 (4)	1 (2)	NS
Postoperative sepsis, no. (%)	1 (2)	1 (2)	NS
Postoperative bleeding, no. (%)	0.0	0.0	NS
Injury to adjacent organs, no. (%)	0.0	0	NS
Pyelocalyceal system disruption, no. (%)	1 (2)	0.0	NS
Mean access time (minutes)	3.3 ± 0.5	3.6 ± 0.7	.15
Unsuccessful access, no. (%)	7 (14)	3 (6)	.18
Mean operation time (minutes)	35.2 ± 4.6	38.9 ± 4.1	.10
Mean hospital staying (days)	2.7 ± 0.3	2.9 ± 0.3	.14
Success rate, no. (%)	40 (80)	44 (88)	.275

Key: NS, not significant.

patients (94%) in groups 1 and 2, respectively (P = .18). All seven patients in blind group with unsuccessful access underwent fluoroscopy guided PCNL at the same operation time. Also, the three patients with failed access in group 2 successfully managed with fluoroscopic guided PCNL in another session of operation. The average number of percutaneous punctures ± SD needed to find the collecting system was 1.8 ± 0.9/case in group 1 and 1.5 ± 0.7/case in group 2 (P = .11). Both mean access time and mean operation time were statically similar in group 1 and group 2. Success rate of procedure was 80% in group1 and 88% in group 2 (P = .275). When moderate to severe hydronephrosis was present, optimal exposure to ureteropelvic junction was possible even from the lower pole by gently turning the nephroscope and Amplatz sheath.

Intraoperative bleeding occurred in 2 patients (4%) in group 1 and one patient (2%) in group 2, which were controlled by tract dilation with balloon dilator. None of the patients experienced post operative bleeding. Urinary collection developed in one patient in group 1, so the ureteral stent remained for 4 days and the patient discharged without complication. One (2%) patient in each group experienced sepsis which were treated with broad spectrum antibiotics. Details of the treatments in each group are summarized in Table 2. Of patients with failed PCNL, 12 patients underwent classic PCNL and SWL performed in 4 patients.

DISCUSSION

Recently, PCNL considered as a safe and efficient modality for management of various types of renal stone disease.[14] The first step in PCNL is access to the collecting system which is usually achieved using fluoroscopy.[5] Insertion of a nephrostomy tube under fluoroscopy accompanies with a success rate of 90-98%.[5,15]

Many studies have investigated methods for lowering the dose of X-ray used in PCNL, such as PCNL under ultrasonography guidance[15,16] and blind PCNL.[9-12]. This is because of adverse effects of radiation to human tissues. Previous studies have been shown operating room personnel are within safe radiation dose limits during PCNL.[8,17,18] In order to the deleterious effects of radiation on tissue is not dose dependent, surgical team should ALARA dose of radiation.[8]

Chien and Bellman[9] performed blind access nephrostomy in 26 patients with hydronephrosis without any significant complication. In this study nephrostomies were performed on hydronephrotic kidneys, but the degree of hydronephrosis which could affect the success rate, had not been determined. They reported 98% success rate with the mean puncturing attempts of 2.5 per patient. Direct access to the renal pelvis was achieved in 75% of the cases.

McDougall and colleagues[19] suggested blind access in cases with obstruction or stricture of the ureter, abnormal anatomy of the ureteral orifice, or when the required equipment for the standard approach is not available. In their experience, blind access achieved by insertion of a 22 F Chiba needle with a 90° angle, 1 cm to 1.5 cm lateral to lumbar 1 vertebra, for antegrade procedures or contrast medium injection.

In our surgical team's experience on treatment of impacted upper ureteral calculi > 1 cm with blind access PCNL, both success rate of achieving access and procedure were 100% without any major complication.[11] It means that in experienced hand, blind access PCNL could be performed with no need to special instruments, and achieved a high success rate in a short period with minimal morbidity especially in the presence of moderate to severe hydronephrosis. In another study[12] we used blind access for PCNL in 128 patients with staghorn or pyelocaliceal stone with moderate to severe hydronephrosis which resulted in nearly success rate of 90%. Access was accomplished by touching the stones with the needle, in cases with a large pelvis and staghorn stone.

In a clinical trial study, Basiri and colleagues[10] compared blind access with classic fluoroscopic PCNL. The success rate of both achieving access and procedure in blind access group were 62% and 100%, respectively; with no complications of the initial access to the system. The number of puncturing attempts was not different between the 2 groups.

Mousavi-Bahar and colleagues[20] reported success rate of 87% in 62 cases of kidney calculus who underwent blind access PCNL.

In this study, success rate was 80% and 88% and successful access was 86% and 94% in blind and fluoroscopic PCNL, respectively. All seven patients with failed access in blind PCNL group underwent fluoroscopic one at the same operating session with stone clearance of 100%. Our stone free rate was similar to Chien and Bellman's study[9] but it was more than Basiri and colleagues' report.[10] The access rate was comparable in these studies. However, inability to design a double blind clinical trial and low number of cases were the major limitations of our study.

CONCLUSION

It seems that blind access is a safe and effective PCNL method that could be performed by skilled endourologist, especially for patient with large hydronephrotic kidney.

CONFLICT OF INTEREST

None declared.

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Comment on

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I applaud the randomized design, but the authors should include a power analysis of why fifty patients per arm were used. What level of difference did they want to detect and what is the primary end point? Fluoroscopy access was more successful, and the reason it may not be significant is a small sample size. Stone-free rates are best assessed on post-operative computed tomography, not kidney-ureter-bladder X-ray. The stone free rates may not be as good as suggested. Interpolar access is usually only desirable for ureteropelvic junction procedures and often is not a good angle for other stone burdens. In addition these patients had a low body mass index and a small stone burden and I wonder how well this would work with larger patients and a larger stone burden.

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