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Does Imaging Modality Used for Percutaneous Renal Access Make a Difference? A Matched Case Analysis

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Abstract

Objective: To assess perioperative outcomes of percutaneous nephrolithotomy (PCNL) using ultrasound or fluoroscopic guidance for percutaneous access.

Methods: A prospectively collected international Clinical Research Office of the Endourological Society (CROES) database containing 5806 patients treated with PCNL was used for the study. Patients were divided into two groups based on the methods of percutaneous access: ultrasound versus fluoroscopy. Patient characteristics, operative data, and postoperative outcomes were compared.

Results: Percutaneous access was obtained using ultrasound guidance only in 453 patients (13.7%) and fluoroscopic guidance only in 2853 patients (86.3%). Comparisons were performed on a matched sample with 453 patients in each group. Frequency and pattern of Clavien complications did not differ between groups ($p=0.333$). However, postoperative hemorrhage and transfusions were significantly higher in the fluoroscopy group: 6.0 v 13.1% ($p=0.001$) and 3.8 v 11.1% ($p=0.001$), respectively. The mean access sheath size was significantly greater in the fluoroscopy group (22.6 v 29.5F; $p<0.001$). Multivariate analysis showed that when compared with an access sheath ≤ 18 F, larger access sheaths of 24–26F were associated with 3.04 times increased odds of bleeding and access sheaths of 27–30F were associated with 4.91 times increased odds of bleeding ($p<0.05$). Multiple renal punctures were associated with a 2.6 odds of bleeding. There were no significant differences in stone-free rates classified by the imaging method used to check treatment success. However, mean hospitalization was significantly longer in the ultrasound group (5.3 v 3.5 days; $p<0.001$).

Conclusions: On univariate analysis, fluoroscopic-guided percutaneous access was found to be associated with a higher incidence of hemorrhage. However, on multivariate analysis, this was found to be related to a greater access sheath size (≥ 27 F) and multiple punctures. Prospective randomized trials are needed to clarify this issue.

Introduction

ACCURATE AND RELIABLE image guidance is a critical factor for the performance of urological interventions. In percutaneous nephrolithotomy (PCNL), placement of the percutaneous access into the renal collecting system is one of the most critical aspects of the procedure, with ramifications for subsequent efficiency of the procedure and its outcomes.¹ Optimal visualization of the urinary tract, particularly during

the initial placement of needle access, is thus of fundamental importance. Reflecting development of the PCNL technique, which was conceived employing fluoroscopy,² access to the pyelocalyceal system has been performed routinely using fluoroscopic guidance. Other modalities for use during calyceal access are computed tomography (CT),³ especially if there is abnormal calyceal anatomy, and ultrasonography.⁴

Ultrasound has numerous advantages over fluoroscopy, including elimination of radiation exposure to the surgeon,

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operating room staff and patient, avoidance of contrast material administration, lower cost, and ease of use.⁵⁻⁷ The development of high-resolution ultrasound technology has enabled imaging of unenhanced renal and suprarenal tissues and provided real-time control of access puncture between the skin and kidney in PCNL. There are, however, few studies that compare the impact of using ultrasonography or fluoroscopy for guidance in obtaining percutaneous renal access during PCNL. Therefore, the aim of the present study was to assess perioperative and postoperative outcomes of PCNL according to the image modality used for percutaneous access: ultrasound versus fluoroscopy.

Materials and Methods

Between November 2007 and December 2009, the Clinical Research Office of the Endourological Society (CROES) collected prospectively the data on consecutive patients undergoing PCNL in 96 centers on five continents. Preoperative patient and stone characteristics, intraoperative and postoperative outcomes of consecutive patients undergoing PCNL were voluntarily entered by each center for a duration of 1 year. The study organization and methods have been described in detail elsewhere.⁸ Out of the original 5803 patients in the database, information regarding imaging modality used for percutaneous access using either fluoroscopy or US only was available for 3306 patients. Otherwise, there were no other exclusion criteria.

PCNL procedures were performed according to the local clinical guidelines and practices. The standard technique involved using ultrasound and/or fluoroscopy in obtaining percutaneous renal access. After obtaining renal access, the tract was dilated using either balloon dilation, metal telescopic dilation, or Amplatz serial dilation before placement of an access sheath and nephroscope. An intracorporeal lithotripsy device was then introduced through the working channel of the nephroscope and stone fragments were removed using suction, graspers, or basket extraction. At the end of the procedure, the system may be examined with a flexible endoscope. The procedure was considered to have been completed when all removable stones have been taken out. Internal and/or external drain(s) were positioned according to the judgment of the surgeon.

Patient characteristics, perioperative complications, and treatment outcomes were assessed by the treating physician. Postoperative assessment for stone-free was performed by ultrasonography, kidney-ureter-bladder plain film, or computed tomography (CT) scan, based on availability and local clinical practice. Success of treatment was defined as the patient being stone-free within 30 days post-treatment. Perioperative complications of PCNL were classified according to the modified Clavien classification system.^{9,10} The severity of bleeding was based on the clinical judgment of the treating physician, and blood transfusions were performed according to the local practice guidelines.

The propensity score technique was used to create two equal groups (ultrasound and fluoroscopy groups) matched on gender, history of prior PCNL, anticoagulant use, presence of staghorn stone, and the specialist who performed the renal access during the PCNL. The matching variables were based on characteristics with potential effects on treatment outcomes of PCNL. Patient characteristics and perioperative outcomes in the two groups of patients were evaluated. Pro-

portions (%) were used for categorical variables, and means and standard deviations were used for continuous variables.

Multivariate logistic regression analysis was performed to assess bleeding between the two groups adjusting for guidance method, size of access sheath, and the number of punctures performed for renal access.

The level of significance for differences between the two groups was estimated using the chi-square tests and the Mann-Whitney U tests for categorical and continuous variables, respectively, with a cutoff p -value < 0.05 being statistically significant.

Results

This analysis included 3306 patients in the CROES PCNL Global Study database. Fluoroscopy was used to guide renal access in the majority of patients ($n = 2853$; 86.3%), while ultrasound-guided access was used in 453 patients (13.7%).

A matched sample with 453 patients in both the ultrasound group and the fluoroscopy group was produced. The two patient groups were generally well matched in terms of prior treatment, gender, and comorbidities (Table 1). Furthermore, there were no significant differences between the two groups in terms of renal function. Renal anomalies and stone burden were higher in the fluoroscopy group (Tables 1 and 2). However, in the ultrasound group, significantly more patients underwent preoperative evaluation by CT scans compared with the fluoroscopy group (65.9 v 30.9% ; $p < 0.001$) (Table 2).

In the large majority of procedures ($> 96\%$), percutaneous renal access was obtained by urologists in both groups (Table 3). PCNL was performed in the supine position significantly less in the ultrasound group when compared with the fluoroscopy group (6.2 v 15.9% ; $p < 0.001$). There were also

TABLE 1. DISTRIBUTION OF IMAGING METHODS USED TO GUIDE RENAL ACCESS PER COUNTRY

Country	Ultrasound-guided access	Fluoroscopy-guided access
1 Argentina	0	260
2 Belgium	5	0
3 Canada	1	89
4 Chile	1	22
5 China	213	0
6 Czech Rep	0	48
7 France	0	22
8 Germany	3	5
9 Greece	48	111
10 India	97	356
11 Israel	1	92
12 Italy	35	187
13 Japan	29	1
14 Mexico	0	93
15 Netherlands	4	44
16 Portugal	0	19
17 Romania	2	493
18 Spain	2	155
19 Sweden	1	10
20 Thailand	0	8
21 Turkey	0	513
22 United Kingdom	2	76
23 USA	9	249
Total	453	2853

TABLE 2. PATIENT DEMOGRAPHIC AND PREOPERATIVE CLINICAL CHARACTERISTICS

Characteristic	Ultrasound (n = 453)	Fluoroscopy (n = 453)	p- Value
No of centers	31.0	30.0	–
Mean (SD) age (y)	50.2 (13.2)	47.9 (13.3)	0.01
Men/women (%)	62.5/37.5	62.5/37.5	0.945
Comorbidities (%)			
Diabetes mellitus	9.7	10.4	0.816
CVD	16.6	20.6	0.141
Medications (%)			
Anticoagulants	4.0	4.0	0.864
Prednisone	0.9	0.9	1.000
ASA score (%)			
1	63.5	60.4	0.157
2	31.4	31.2	
3	4.6	8.2	
4	0.4	0.2	
Mean (SD) serum creatinine (mg/dl)	1.0 (0.3)	1.0 (0.3)	0.685
Prior renal stone surgery (%)			
PCNL	10.6	10.6	0.914
ESWL	19.9	17.0	0.258
URS	5.8	8.2	0.153
Renal anomalies (%)			
Ectopic	0.2	0.2	0.016
Horseshoe	0.9	2.9	
Malrotation	0.2	1.8	

SD=standard deviation; URS=ureteroscopic laser lithotripsy; PCNL=percutaneous nephrolithotomy; ESWL=extracorporeal shock wave lithotripsy; CVD=cardiovascular disease.

significant differences between the two groups in terms of the puncture site and location of the access tract. For example, patients in the ultrasound group had a significantly less lower calyceal puncture (44.8% *v* 68.1%; $p < 0.001$) and a significantly higher supracostal access (30.2% *v* 14.1%, $p < 0.001$) (Table 3). Balloon dilation was more common in the fluoroscopy group and telescopic dilation was more common in the ultrasound group ($p < 0.001$). In terms of access sheath, the ultrasound group had a significantly smaller access sheath when compared with the fluoroscopy group (22.6 *v* 29.5F; $p < 0.001$). Furthermore, ultrasound-guided PCNL lasted significantly shorter than fluoroscopic-guided PCNL (79.3 *v* 84.6 minutes;

TABLE 3. RENAL STONE CHARACTERISTICS

Characteristic	Ultrasound (n = 453)	Fluoroscopy (n = 453)	p- Value
Diagnosed by preoperative CT (%)	65.9	30.9	<0.001
Staghorn stones (%)	26.5	26.5	1.00
Stone location (%)			
Right kidney	50.4	48.3	0.527
Left kidney	49.6	51.7	
Number of stones (%)			
Single	43.7	32.5	<0.001
Multiple	56.3	67.5	
Mean (SD) stone burden (mm ²)	349.0 (321.8)	456.6 (351.8)	<0.001

CT=computed tomography.

$p = 0.039$). In both groups, a postoperative nephrostomy tube was placed in more than 92%. However, patients in the ultrasound group had a significantly higher placement of antegrade indwelling ureteral stents (67.1% *v* 51.3%; $p < 0.001$).

In terms of complications, hemorrhage and blood transfusions were significantly less in the ultrasound group (6.0 *v* 13.8%; $p = 0.03$) and (3.8 *v* 11.1%; $p = 0.02$), respectively (Table 3). However, on multivariate analysis, when compared with small access sheath of ≤ 18 F, medium access sheaths (24–26F) were associated with a 3.04 times increased risk of hemorrhage ($p = 0.0168$) and the large access sheaths (27–30F) were associated with 4.91 times increased risk of hemorrhage ($p = 0.005$). On multivariate analysis, the method of access (ultrasound *v* fluoroscopy) ceased to be a significant determinant of postoperative hemorrhage ($p = 0.069$). Multiple renal punctures were associated with a higher risk of hemorrhage compared to single renal access punctures ($p = 0.046$). Furthermore, there were no significant differences between the ultrasound and fluoroscopy groups in terms of stone-free rates when categorized according to the imaging modality used to check treatment success (Table 4). Despite the ultrasound group being associated with significantly lower retreatment rates (11.0 *v* 17.5%; $p = 0.002$), it had a significantly longer hospitalization

TABLE 4. OPERATIVE CHARACTERISTICS

Characteristic	Ultrasound (n = 453)	Fluoroscopy (n = 453)	p- Value
Physician performing access procedure (%)			1.00
Urologist	96.5	96.5	
Radiologist	3.5	3.5	
Patient position (%)			
Supine	6.2	15.9	<0.001
Prone	93.8	84.1	
Puncture site (%)			<0.001
Upper calyx	8.9	8.8	
Middle calyx	39.2	11.1	
Lower calyx	44.8	68.1	
Multiple calyces	7.1	11.9	
Location of access tract (%)			<0.001
Above 11th rib	2.2	1.5	
Above 12th rib	30.2	14.1	
Below 12th rib	67.6	84.3	
Dilation method (%)			<0.001
Balloon	9.9	58.7	
Telescopic	90.2	41.2	
Mean (SD) sheath size (F)	22.6 (4.5)	29.5 (3.4)	<0.001
Mean (SD) operating time (minutes)	79.3 (48.8)	84.6 (42.0)	0.08
Postoperative stent placement (%)	67.1	51.3	<0.001
Postoperative nephrostomy (%)	92.9	93.6	0.797
Complications (%)			
Failed access	0.7	2.9	0.020
Pelvic perforation	2.9	4.0	0.460
Hydrothorax	1.3	1.4	0.807
Bleeding	6.0	13.8	<0.001
Blood transfusion	3.8	11.1	<0.001
Colon perforation	0.0	0.0	–
Mean (SD) change in hemoglobin (mg/dL)	3.8 (3.0)	4.2 (3.6)	0.07

(5.3 *v* 3.5 days; $p < 0.001$) (Table 4). There were no significant differences between the two groups in distribution of complications according to the modified Clavien classification.

Discussion

This analysis of the CROES PCNL Global Study database reveals differences in the outcomes of PCNL depending on the use of ultrasound or fluoroscopy to provide imaging guidance during percutaneous renal access (Table 5). Within the clinical centers included in the study, fluoroscopy was generally the preferred method of access guidance. Ultrasound-guided percutaneous access has been shown to have the following advantages: lack of ionizing radiation, shorter procedure time, decreased number of punctures, and avoidance of contrast agent administration.⁵⁻⁷ For surgeons and operating room staff, reduction of radiation exposure is clearly desirable, particularly if the workload is high. However, this requires the urologist to have training to use ultrasound-guided access. More importantly, having access to ultrasound equipment in the operating room is challenging in certain centers.

In addition, this study shows that, despite increasing availability, the use of CT for diagnosis and planning PCNL although widespread was not universal; only one-third of procedures using fluoroscopy-guided access had CT preoperatively. The CROES PCNL Global Study included patients from a varied assortment of clinical centers in Asia, Australia, Europe, North and South America. In low-income countries, intravenous urography (IVU) remains a mainstay in the

evaluation of most urological diseases, whereas in many mid- and high-income countries, CT urography has almost replaced IVU.¹¹ The different pattern of imaging modalities used in the two patient groups might thus reflect local practice and policy.

The higher rate of bleeding with fluoroscopic-guided access found in this analysis appears to support a previous report of this risk association.¹² However, the increased bleeding may be due to the larger mean size of sheaths used in procedures initiated using fluoroscopic guidance. After adjusting for sheath size and number of renal access tracts, there was no statistically significant difference between the rate of bleeding when fluoroscopy or ultrasound was used for guiding PCNL punctures, as found by previously reported comparative studies.^{4,13} Another explanation is, perhaps, the increased bleeding following fluoroscopic-guided access may relate to the longer mean operating time in this group compared with the ultrasound group. Previous smaller studies have identified prolonged operative time as a risk factor for blood loss.^{12,14} In addition, separate analyses of the CROES PCNL Global Study database reported elsewhere have shown that significant increases in bleeding and transfusion requirements in patients undergoing PCNL are associated with a larger sheath size and longer operating times¹⁵ and are more likely with balloon dilation compared with telescopic/serial dilation.¹⁶ Interestingly, there was no significant difference between the two groups in terms of mean change in hemoglobin in the present study. The fluoroscopy group had a higher multiple puncture rate compared to the ultrasound group. This difference may partly explain the higher bleeding rate in the fluoroscopy group. In addition, we noted a higher failed access rate in the fluoroscopy group. Failed access may be associated with a higher bleeding rate and the need to perform secondary punctures. Therefore, several factors may explain the significant differences in blood transfusion rates between the two groups. In low-income countries, one of the common reasons for post-PCNL blood transfusion is preoperative anemia. Indeed, a large proportion of patients included in the present study were coming from low-income countries. Given the similar stone-free rates and complications, the significantly longer hospitalization of patients who received PCNL using ultrasound guidance is unexpected. This may reflect the frequency of postoperative stent placement, which was approximately twofold higher in the ultrasound group, although other factors contribute to the length of and need for postoperative hospitalization. Karami et al compared ultrasound-guided PCNL in the flank position with fluoroscopic-guided PCNL in the prone position and found similar rates of intraoperative bleeding and similar duration of hospitalization.¹³ Another explanation for the difference in hospitalization may be local protocol that operates at individual hospitals, particularly those that perform one type of guidance method only. Finally, it may be of interest to observe that only in the fluoroscopy group, colon perforations were observed. Although not of statistical significance, this is a clinical significant finding. This may be explained by the better ultrasonic visualization of the structures during the puncture to achieve renal access.

One of the major limitations of the present study, common to all prospective multicenter studies, is the lack of uniformity in indications, specific procedural techniques, and postoperative assessment of stone-free rates. However, the CROES PCNL database currently is the only multicenter, prospectively

TABLE 5. POSTOPERATIVE OUTCOMES

Characteristic	Ultrasound (n=453)	Fluoroscopy (n=453)	p- Value
Postoperative fever (%)	12.5	9.7	0.190
Stone-free rate (%)	79.8	73.5	0.030
CT	74.2	63.4	0.719
Ultrasound	87.3	73.8	0.310
KUB X-ray	81.1	74.9	0.080
Retreatment rate (%)	11.0	17.5	0.004
Retreatment method (%)			<0.001
URS	1.3	1.1	
PCNL	6.9	4.4	
ESWL	2.2	11.3	
Other	0.4	0.7	
Mean (SD) length of hospital stay (days)	5.3 (4.2)	3.5 (3.0)	0.041
Complications within 30 days (%)			
Minor (Clavien I and II)	15.2	16.6	0.332
Major (Clavien III–V)	3.3	5.1	
Total complication rate (%)	18.5	21.7	0.266
Clavien categories of complications (%)			0.333
Clavien I	9.9	10.6	
Clavien II	5.3	6.0	
Clavien IIIA	1.8	3.8	
Clavien IIIB	1.1	1.1	
Clavien IVA	0.4	0.0	
Clavien IVB	0.0	0.2	
Clavien V	0.0	0.0	

KUB, kidneys, ureter and bladder.

collected database available for such cross-sectional studies. Another limitation of the present study is the lack of data regarding fluoroscopy time and more importantly radiation exposure during PCNL. Ideally, fluoroscopy times and/or radiation exposures during PCNL would have been collected prospectively and compared between the ultrasound-guided and fluoroscopic-guided PCNLs.

Conclusions

On univariate analysis, fluoroscopic-guided percutaneous access was found to be associated with a higher incidence of hemorrhage. However, on multivariate analysis, this was found to be related to greater access sheath size and multiple renal access. Prospective randomized trials are needed to clarify this issue.

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Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

ASA = American Society of Anesthesiologists
CT = computed tomography
CVD = cardiovascular disease
IVU = intravenous urography
KUB = kidneys, ureters and bladder
PCNL = percutaneous nephrolithotomy
ESWL = extracorporeal shock wave lithotripsy