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Which Is the Preferred Modality of Renal Access for a Trainee Urologist: Ultrasonography or Fluoroscopy? Results of a Prospective Randomized Trial

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Abstract

Background and Purpose: In percutaneous nephrolithotomy (PCNL), placement of the access tract into the kidney is an important aspect of the procedure and is responsible for the steep learning curve associated with the operation. The aim of the current prospective randomized trial was to assess the duration of radiation exposure along with the safety and efficacy of PCNL done by a trainee, utilizing either ultrasonography (US) or fluoroscopic guidance to obtain access.

Patients and Methods: Sixty-four patients with ≤ 3 cm renal calculi undergoing single-tract PCNL by trainee urologists (experience of < 25 PCNL's) were randomized into US- and fluoroscopic-guided access groups (32 in each). In Group 1 (US guided), puncture was done using a 3.5/5 MHz US probe with a puncture attachment, whereas the triangulation technique with biplanar C-arm fluoroscopy was utilized in group 2 (fluoroscopic guided). Patient demographics, stone parameters, intraoperative characteristics, fluoroscopy durations, and postoperative outcomes were analyzed.

Results: Both groups were comparable as far as patient and stone characteristics were concerned. The fluoroscopy exposure during the puncture phase (T2) and overall (T) was significantly lower in the US group at 9.0 ± 20.8 *vs* 43.8 ± 34.8, ($p < 0.0001$) and 204.3 ± 84 *vs* 239.9 ± 77.5, ($p = 0.04$). Six patients in group1 required fluoroscopic adjustment ($p = 0.03$). All other intra- and postoperative parameters were similar in both the groups.

Conclusion: Both ultrasound and fluoroscopic guidance for renal access are equally safe and feasible in the hands of a trainee urologist. Total fluoroscopy duration and exposure time during puncture were both significantly less in the ultrasound group. Expertise in fluoroscopic-guided access is essential for a novice to effectively achieve access in all possible situations.

Introduction

PERCUTANEOUS NEPHROLITHOTOMY (PCNL) was introduced by Fernström and Johansson more than three decades ago and remains till date an important tool in the armamentarium required to treat urolithiasis.[1] It is considered the treatment of choice for renal calculi larger than 2 cm in diameter.[2] With evolution in technique and advances in instrumentation, PCNL has achieved a high success rate with minimal morbidity.[2,3] De la Rosette et al. in a critical review have mentioned that the steep learning curve in PCNL is related most importantly to achieving perfect renal access.[4] They recommend a minimum of 24 PCNLs during the residency phase to attain good surgical proficiency, 60 to achieve competency, and >100 to reach excellence in performing the procedure.[4] Lipkin et al. showed that fluoroscopy during PCNL exposes patients to nearly double the radiation exposure of a noncontrast renal computerized tomography (CT).[5] Whereas real-time ultrasound has multiple advantages as enumerated by Desai such as decreased radiation exposure, linear and shortest access, and avoidance of vascular and adjacent organ injury.[6] Two randomized trials have shown reduction in fluoroscopy duration in the ultrasound group when compared with fluoroscopy.[7,8] No studies have compared the choice of access during the early learning curve of a trainee urologist. The aim of this study was to assess the

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duration of radiation exposure along with the safety and efficacy of PCNL done by a trainee utilizing either ultrasonography (US) or fluoroscopic guidance to obtain renal access.

Patients and Methods

This study was carried out at a high-volume, tertiary referral urology hospital in a stone belt region of Western India after obtaining an approval from the Institutional Review Board and Ethics committee. From March 2013 to March 2014, patients with ≤3 cm renal calculi undergoing single-tract PCNL by trainee urologists were randomized into the US- and fluoroscopic-guided access groups (32 in each group) after obtaining an informed consent (Fig. 1). Utilizing computer-generated random numbers in sets of five, the patients were randomized. Trainee urologists performing the PCNL were residents or fellows who had experience of having performed less than 25 PCNLs. All these novices had a past experience of having performed a minimum of five cases, each utilizing both the techniques to gain access during PCNL. No radiologist was involved in gaining any of the accesses.

A detailed preoperative workup, including a complete medical history and examination, serum creatinine, urine culture, coagulation profile, and computerized tomography-intravenous urography (CT-IVU), was done. Patients with coagulopathy, pregnancy, anomalous kidney, active urinary tract infection, withdrawal of consent, pediatric patients, and those requiring more than one tract were excluded for the study. After general anesthesia, the patient was placed in a lithotomy position for placement of a 5F or 6F ureteral catheter under fluoroscopic control and this time was recorded as T1. Then, in a prone position, bolsters were placed below the lower chest and iliac crest to allow the bowel and viscera to drop down and thereby reducing the probability of visceral injury.

Group 1 (US guided) patients underwent a puncture using a 3.5/5 MHz US probe (Profocus™; B & K Medical) with a puncture attachment. In less hydronephrotic systems, saline was instilled intermittently from the ureteral catheter to keep the pelvicaliceal system (PCS) dilated during the puncture. While advancing the 18-gauge Echo Tip needle (Cook Medical), the dotted puncture line seen was followed all along its course with the respiratory and US probe movement kept at a minimum.[6] Fluoroscopy was used as an adjunct where there was difficulty in gaining access by US alone. After efflux of clear urine and fluoroscopic confirmation of proper access by injecting contrast, a 0.035-inch Glidewire (Terumo) was inserted followed by initial dilatation with a 14F screw dilator. Thereafter, tract dilatation was performed with single-step Amplatz dilatation or Alken serial metal dilatation. Then, Amplatz sheaths ranging from 18F to 28F were placed as deemed appropriate. Using a 14F, 20F, or 24F nephroscope, standard PCNL was performed. Lithotripsy was mostly done using a pneumatic lithotripter (Swiss Lithoclast; EMS Medical systems) or holmium:yttrium-aluminum-garnet (Ho:YAG) laser of 30W (LISA Sphinx; LISA Laser). Fragments were removed with grasping forceps or nitinol baskets.

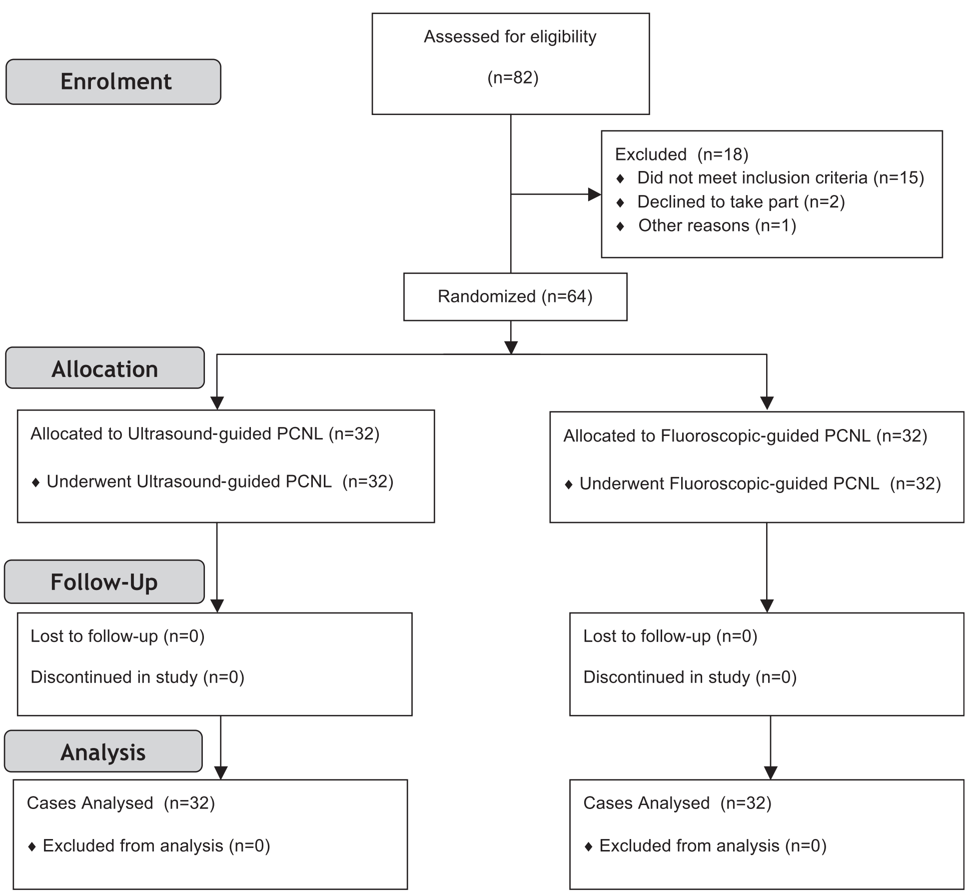

FIG. 1. Consort flow diagram depicting the process of randomization and analysis. PCNL, percutaneous nephrolithotomy.

Table 1. Patient Demographics and Stone Parameters

Parameters	*Ultrasound-guided access*	*Fluoroscopic-guided access*	p-*Value*
Number of patients	32	32	
Age (years)	40.7 ± 11.5	44.5 ± 14.4	0.12
Sex distribution			
Male	25	20	0.27
Female	7	12	
Comorbidity	11 (34.4%)	10 (31.3%)	0.99
Degree of hydronephrosis			
None	6	5	0.96
Mild (< 10 mm)	13	15	
Moderate (10–20 mm)	11	10	
Severe (> 20 mm)	2	2	
Stone laterality			
Left	19	12	0.13
Right	13	20	
Stone size[a] (cm)	2.1 ± 0.5	2.2 ± 0.6	0.24
Hounsfield units	1279 ± 216	1215 ± 276	0.15
Location			
Pelvis	13	11	0.45
Upper calix	3	2	
Middle calix	3	7	
Lower calix	10	10	
Multiple	3	2	

Values are expressed as mean ± standard deviation.
[a]In case of multiple calculi, the sum of the lengths has been provided as the stone size.

In group 2 (fluoroscopy guided) patients, the triangulation technique was utilized with the assistance of biplanar C-arm fluoroscopy to gain access into the appropriate posterior calix after instillation of contrast to opacify the PCS.[9,10] After deciding upon the direction with the C-arm 0° (vertical position), the 18-gauge needle was advanced toward the target calix. Final adjustment to decide the correct depth was done by rotating the C-arm 30° (oblique). US was used as an adjunct if there was trouble in gaining access fluoroscopically. Rest of the procedure was performed as outlined earlier. Stone clearance at the end was judged by a combination of nephroscopy and fluoroscopy. Insertion of a Double-J stent or nephrostomy was decided upon individual case basis by the operating surgeon if there was significant hemorrhage, residual fragments, or PCS injury. Plain radiography of the kidney, ureter, and bladder (KUB) along with US KUB was done on the first postoperative day and at 1 month for assessment of stone-free status. Nephrostomy was removed on the second postoperative day if the patient was stone free and perurethral catheter was removed the next day.

The preoperative, intraoperative, and postoperative data for the two groups were recorded, as shown in Tables 1–3, respectively. Postoperative complications were classified in accordance with the modified Clavien–Dindo classification system.[11] The primary outcome parameters were number of attempts required to achieve effective access, time taken to puncture (P), fluoroscopy duration during puncture (T2), total fluoroscopy time (T), and requirement of the other modality as an adjunct. T2 was defined as the fluoroscopy duration from beginning of the puncture process till the efflux of clear urine. The secondary outcomes were total operative time, intra- and postoperative complications, hemoglobin drop, visual analogue scale (VAS) score and analgesic requirement, hospital stay and stone clearance rates. Statistical analysis was done using the Chi-square test or Fischer exact test for categorical variables and the Student *t*-test for continuous variables with difference considered significant if the *p*-value was less than 0.05.

Results

The patient demographics, degree of hydronephrosis, and stone parameters were comparable in both groups (Table 1). The time taken to achieve effective puncture to target the calix and the number of attempts were similar in both the groups ($p = 0.38$ and 0.33, respectively) (Table 2). The mean duration of fluoroscopy exposure during the puncture phase

Table 2. Intraoperative Parameters

Parameters	*Ultrasound-guided access*	*Fluoroscopic-guided access*	p-*Value*
Time to puncture (P) (second)	152.9 ± 141.3	144.3 ± 48.9	0.38
Number of attempts	1.7 ± 0.9	1.6 ± 0.8	0.33
Fluoroscopy exposure duration (second)			
During ureteral catheterization: T1	24.0 ± 8.5	24.2 ± 8.8	0.47
During puncture: T2	9.0 ± 20.8	43.8 ± 34.8	< 0.0001
During tract dilatation and till end: T3	171.3 ± 79.3	172.7 ± 63.3	0.47
Total: T	204.3 ± 84	239.9 ± 77.5	0.04
Requirement of other modality as adjunct to achieve access	6/32 (18.75%)	0/32 (0%)	0.03
Tract size (in F)	21.9 ± 4.0	23.1 ± 3.6	0.11
Intraoperative complication	2 (6.2%)	1 (3.1%)	0.99
Postoperative nephrostomy	24 (75%)	28 (87.5%)	0.33
Postoperative stent:			
Double-J stent	18	25	0.11
Ureteral catheter	14	7	
Total operative time (minute)	50.3 ± 17.1	49.2 ± 16.8	0.40

Table 3. Postoperative Outcomes

Parameters	*Ultrasound-guided access*	*Fluoroscopic-guided access*	p-*Value*
Patient VAS score			
At 6 hours	3.5 ± 1.6	2.9 ± 1.9	0.08
At 24 hours	2.3 ± 0.9	1.9 ± 1.3	0.11
At 48 hours	0.9 ± 0.8	0.6 ± 0.8	0.08
Analgesic requirement (mg tramadol)	70.3 ± 73.9	81.3 ± 65.7	0.27
Hemoglobin drop (g/dL)	0.8 ± 0.4	0.8 ± 0.7	0.44
Postoperative complications			
Clavien grade I (Fever, hematuria)	2 (6.2%)	3 (9.4%)	0.99
Clavien grade II (Urine leakage)	1 (3.1%)	2 (6.2%)	0.99
Clavien grade III	—	—	—
Clavien grade IV	—	—	—
Hospital stay (days)	2.8 ± 0.9	2.7 ± 1.1	0.36
Stone clearance			
On first postoperative day	31/32 (96.9%)	32/32 (100%)	0.99
At 1 month	32/32 (100%)	32/32 (100%)	—
Auxiliary procedures	0	0	—

VAS = visual analogue scale.

(T2) was significantly lower in group 1 (US) at 9 seconds compared to the 43.8 seconds in group 2 ($p < 0.0001$). This led to a concomitant statistically significant decrease in total fluoroscopy duration (T) as well (204.3 *vs* 239.9 seconds, $p = 0.04$). Six patients in the US group required fluoroscopic adjustment during the puncture, whereas no patients in group 2 required US as an adjunct ($p = 0.03$). Two patients in group 1 and one in group 2 had PCS perforation necessitating a nephrostomy and Double-J stent placement ($p = 0.99$). There was no statistical difference in the total operative time, postoperative complications, hemoglobin drop, VAS score or analgesic requirement, hospital stay or stone clearance rates between both the groups (Tables 2 and 3) ($p > 0.05$).

Discussion

The steep learning curve associated with PCNL is mainly dependent on the ability to obtain an appropriate renal access.[4] In a survey done in the United States by Bird et al., it was found that only 11% of the urologists performing PCNL obtain renal access themselves.[12] Lee et al. noted that training in renal access was the biggest determinant for the future use of percutaneous surgeries in practice.[13] Ninety-two percent of trained urologists did percutaneous renal surgeries compared to 33% in the untrained urologists group ($p < 0.001$).[13] The reasons mentioned in the analysis included deficiency of training, better tools or skills with interventional radiologists, need of additional time, and personal comfort level.[13] Inclusion of other procedures such as percutaneous nephrostomy in a training module can augment the chances of a trainee in obtaining the requisite skills for percutaneous renal access.[4]

At our center, residents routinely perform mentored bedside US. All the novices involved in the study had performed > 30 percutaneous nephrostomies under expert guidance using the US probe with the puncture attachment. They underwent a comprehensive training protocol involving updation of cognitive skills, by observing seniors performing the procedure. Also, exhaustive laboratory training with virtual reality trainers like the PERC Mentor™ (Simbionix) is imparted following a path outlined by Mishra et al.[14] Residents first observe 25 PCNLs, scrub as first assistants in 50, and thereafter perform PCNL under the expert observation of a senior endourology fellow or urology consultant. Stone clearance and complication rates despite being the most pertinent clinical parameters are not considered the best tools to assess the learning curve.[4,15] Total operation time and fluoroscopy exposure durations have been used to evaluate surgical proficiency.[15]

In this study, we used fluoroscopy duration during puncture and overall exposure times as comparative parameters. While the mean time to puncture and total operative times were similar ($p = 0.38$, 0.40), there was significant decrease in the fluoroscopic durations, especially during puncture (T2) (9 *vs* 43.8 seconds, $p < 0.0001$) and overall in total (T) (204.3 *vs* 239.9 seconds, $p = 0.04$) in the US group. This advantage of US-guided puncture can offset the inherent risk of higher radiation hazard that fluoroscopy carries to both the surgeon and staff on a cumulative basis, especially in a high-volume center. Also, with urolithiasis being a recurrent disease, patients are at risk for considerable radiation exposure over their lifetimes. Mancini et al. have determined elevated body–mass index, larger stone bulk, and multiple access tracts as risk factors for increased fluoroscopic exposure and have suggested alternative means to decrease it, namely, narrowing collimation to area of interest, sensible use of magnification, and acquiring as few images as required.[16] The principle of as-low-as-reasonably achievable should be followed maximally.

Ultrasound-guided access has plentiful advantages, namely, reduced radiation, feasibility of use in pregnancy, transplanted and anomalous kidney (ectopic, horseshoe), radiolucent calculus, and obviation of the need to wear a heavy lead apron.[17,18] Despite so many advantages, only a handful of studies have looked at utilizing only US guidance for PCNL.[17–19] All of them showed that totally US-guided PCNL was a safe alternative to the traditional fluoroscopic technique.[17–19] Despite such encouraging reports, fluoroscopy is still the most commonly used technique as shown by the Clinical Research Office of the Endourological Society (CROES) PCNL data, which reveal that 86.3% of patients had fluoroscopic-guided access *vs* 13.7% with US guidance.[20] In the vast majority of cases, US guidance is utilized only during the puncture phase, while rest of the procedure, including tract dilatation, is done under fluoroscopic control. In our study, the fluoroscopic exposure times postpuncture (T2) in the US group were similar to the fluoroscopy group (171.3 *vs* 172.7, $p=0.47$). The true value of the underutilized US technique lies in the possibility of it being used as the sole guidance for performing PCNL in properly selected patients.

Two randomized studies by Basiri et al. and Agarwal et al. comparing US with fluoroscopic-guided PCNL have shown significant reduction in fluoroscopy time during access (41.4 *vs* 57 seconds, $p=0.0001$ and 14.4 *vs* 28.6 seconds, $p<0.01$, respectively).[7,8] The present study also demonstrates a similar decline (9 *vs* 43.8 seconds, $p<0.0001$). It does not show any difference in the time taken to achieve the puncture (152.9 *vs* 144.3 seconds, $p=0.38$), which is unlike what was reported in the Basiri study, where the mean duration of access was higher in the ultrasound group (11 *vs* 5.5 minutes, $p=0.0001$).[8] In contrast the Agarwal group found the time to puncture to be lesser in the US group (1.8 *vs* 3.2 minutes, $p<0.01$).[7] The mean number of punctures required was similar in both the groups in the present study (1.7 *vs* 1.6, $p=0.33$), whereas in the Agarwal study, it was significantly higher in the fluoroscopic group (3.3 *vs* 1.5, $p<0.01$). The overall fewer number of attempts required in both the groups despite the fact that the access was being done by novices could be explained by the systematic dry laboratory training done on virtual reality simulators. This also highlights the future scope for the development of high-fidelity virtual reality simulators for US-guided puncture training.

Effective access was possible in all the patients. In the US group, 6 cases (18.75%) required fluoroscopy as an adjunct, whereas none of the patients in group 2 required US as an adjunct ($p=0.03$). The difficulty in access was due to the absence of hydronephrosis (four) and mild hydronephrosis (two) in patients despite saline instillation to increase PCS dilatation. This finding pinpoints the need to master both the techniques for effective access in all situations. Agarwal et al. do not report any unsuccessful accesses in their US group. They do, however, mention instilling air for better opacification of the posterior calix, because air is visualized as an echogenic shadow easily on US, making targeted puncture effortless.[7]

In our study, none of the intraoperative complications (PCS injury, two [6.2%] in group 1 and one [3.1%] in group 2, $p=0.99$) occurred during puncture or tract dilatation. They occurred during lithotripsy. Although statistically insignificant, the CROES study shows a lower incidence of pelvic perforation in the US group (2.9% *vs* 4%, $p=0.460$).[20] They also reported on univariate analysis that US guidance was associated with lower postoperative hemorrhage (6% *vs* 13.1%, $p=0.001$), although on further multivariate analysis, this difference was correlated to a larger access sheath use and multiple renal punctures ($p=0.005$, $p=0.046$, respectively).[20] Additionally, the blood transfusion rate was lower in the US group (3.8% *vs* 11.1%, $p<0.001$). Kukreja et al. too have noted that US-guided access was associated with significantly lower blood loss.[21] None of our patients in either group required blood transfusion.

In our study, all other intraoperative and postoperative parameters were similar in both the groups ($p>0.05$), and all the patients were stone free at 1 month follow-up. The limitation of this study is the fact that this is a single-center study with small number of patients. The effective radiation dose as a means of comparison was not utilized and no CT scan was done in the follow up due to concerns of the associated radiation hazard and cost involved. This is the first study comparing both the modalities of access in the early learning curve of trainee urologists.

Conclusion

Both ultrasound and fluoroscopic guidance for percutaneous renal access are equally safe and feasible in the hands of a trainee urologist. Total fluoroscopy duration and exposure time during puncture were both significantly less in the ultrasound group. Expertise in fluoroscopic-guided access is essential for a novice to effectively achieve access in all possible situations.

Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

CROES = Clinical Research Office of the Endourological Society
CT = computerized tomography
IVU = intravenous urography
KUB = kidney, ureter, and bladder
PCNL = percutaneous nephrolithotomy
PCS = pelvicaliceal system
US = ultrasonography
VAS = visual analogue scale