Comparison of Combined Guidance of Fluoroscopy and Ultrasonography in Total Tubeless Percutaneous Nephrolithotomy with the Standard Method: A Randomized Clinical Trial

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Objective: Utilizing the combination of fluoroscopy and ultrasonography during Percutaneous Nephrolithotomy (PCNL) to minimize radiation exposure.

Methods: In this randomized clinical trial, 118 patients with urinary stones who were candidates for PCNL surgery in the prone position were selected and divided into two groups (with an allocation ratio of 1:1). Cases were grouped according to whether ultrasonography was used for renal tract dilation and Amplatz sheath placement. The number of attempts to establish proper renal access, the time interval between access to the targeted calyx and nephroscope entrance, and the Clavien-Dindo score were collected.

Results: The mean age of all patients was 46.12 ± 11.28 (45.6 ± 11.2 in the total fluoroscopy group and 46.5 ± 11.4 in the combined group) years (20-66). The intergroup differences in the baseline features were not significant. The mean duration of fluoroscopy time was significantly reduced in the combined guidance group (36.22 ± 10.73 vs. 23.05±8.94 seconds, (*P*-value = 0.001). Moreover, the difference in the distribution of Amplatz location on the nephroscopy time was meaningful (*P*-value = 0.016). However, intergroup differences in the number of attempts to successful puncture, length of hospitalization, recovery time, and postoperative complications, including gross hematuria duration, blood loss volume, pack cells requirement, pain score immediately and 6 hours after the surgery, and Clavien-Dindo score were not meaningful.

Conclusion: It can be concluded that the use of ultrasound with X-ray in prone PCNL compared to the use of X-rays alone can significantly reduce the duration of radiation without increasing the risk of intra-operative and postoperative detrimental events.

Keywords: kidney stones; percutaneous nephrolithotomy; fluoroscopy; ultrasonography

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is the preferred treatment of choice for renal calculi (stones >2 cm) and renal calculi larger than 1 cm in the lower renal pole and stones in the upper ureter in case of failed or contraindicated extracorporeal shock wave lithotripsy (ESWL)[1-4]. However, a few issues and drawbacks remained to be discussed regarding the safety of PCNL, particularly fluoroscopy requirement and imposition of radiation exposure, which could result in detrimental outcomes for both the patients and the surgical team[5]. Long-term exposure might put the urologists, operating room personnel, and patients at risk of developing cataracts and various malignancies[6,7]. Ultrasonography is an X-ray-free modality that has been a method of interest respecting its safety in pregnant women, obtaining real-time images of the pelvicalyceal system and neighboring organs, providing better access to renal anomalies (e.g., horseshoe kidney), better demarcation of anterior and posterior calyces, and decreased overall cost[8-10]. However, using ultrasonography requires more experience, and fluoroscopy is highly capable of detecting and localizing radio-opaque stones. Taken together, each of these two modalities is characterized by several pros and cons. Fluoroscopy could provide renal access and calculi localization more accurately, but since the tract dilation step has been assumed to be associated with the highest radiation exposure[11], utilizing ultrasonography is prioritized over fluoroscopy for dilation and even residual stone checking at the end of surgery. Hence their combination seems favorable to be applied. As such, in this randomized clinical trial, we aimed to evaluate the efficacy and safety of adjacent utilization of fluoroscopy and ultrasonography in PCNL.

METHODS

Study Design

The present study adheres to the Consolidated Standards of Reporting Trials (CONSORT) statement[12]. This controlled parallel randomized clinical trial was carried out in Sina Hospital, Tehran University of Medical Sciences, from April 2020 to March 2022. The ethical committee of the Tehran University of Medical Sciences approved this study and sampling was started

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Table 1. Demographic features of patients, Numbers, complexity, locations, and sizes of the stones

Variable		groups	
		X-PCNL	XU-PCNL
Age, mean (SD)		45.6 ± 11.2	46.5 ± 11.4
BMI, mean (SD)		23.8 ± 1.48	24.4 ± 2.0
sex, num (%)	Female	21(35.6%)	24(40.7%)
	male	38(66.4%)	35(59.3%)
Stone number, mean (SD)		2.23 ± 0.79	2.08 ± 0.70
Stone complexity (grade), num (%)	1	5 (8.5%)	9 (15.3%)
	2	48 (81.4%)	40 (67.8%)
	3	0 (0)	2 (3.4%)
	4	6 (10.2%)	8 (13.6%)
Stone location, num (%)	Upper	16 (27.1%)	9 (15.3%)
	Middle	45 (76.3%)	38 (64.4%)
	Lower	36 (61%)	33 (55.9%)
	Pelvic	35 (59.3%)	44 (74.6%)
Stone size (based on location) (cm, mean (SD)	Upper	1.46 ± 0.49	1.17 ± 0.33
	Middle	2.03 ± 0.82	1.75 ± 0.61
	Lower	1.58 ± 0.58	1.40 ± 0.41
	Pelvic	2.80 ± 0.69	2.73 ± 0.76

after receiving the Iranian Registry of Clinical Trials (IRCT20190624043991N1) on 26/07/2019. We performed this trial on adults older than 18 years. Patients scheduled for Percutaneous Nephrolithotomy (PCNL) were randomly assigned to two groups, one going under X-ray-guided PCNL (X-PCNL group) and the other with X-ray and ultrasound guidance, in combination (XU-PCNL group), with an allocation ratio of 1:1. All patients underwent tubeless PCNL. Tubeless PCNL is a safe procedure, with diminished postoperative pain and morbidity. It has been found to be effective even in patients with multiple stones, complex staghorn stones, concurrent obstruction, and various degrees of hydronephrosis.[13]

The study protocol was approved by the ethical committee of the Tehran University of Medical Sciences (ethical code: IR.TUMS.SINAHOSPITAL.REC.1399.023), and written informed consent was obtained from all included participants before enrollment. The design of this study followed the tenets of the Helsinki declaration.

Participants and interventions

Patients older than 18 years old who were willing to participate in the study were considered eligible to be included, while those with the following features were excluded:

Unresolved coagulopathies
Malignant renal tumors
Pregnancy
Active urinary tract infection
Uncontrolled hypertension
Contraindication for general anesthesia
Genitourinary anomalies
The disinclination of the patients to be included in the study
Body mass index (BMI) > 30
Multi-access PCNL

Before the procedure, all patients were assessed by a thorough physical examination, obtaining demographic features (age, sex, and BMI), medical history taking, and laboratory tests encompassing urine analysis, urine culture, complete blood cell count, serum creatinine and urea, and blood group. The size (maximum diameter) and location of the calculi were evaluated using a non-contrast and contrast-enhanced abdominopelvic computed tomography scan. The complexity of stones was evaluated by Guy Stone Score (GSS). It comprises 4 grades: grade I, solitary stone in mid/lower pole or solitary stone in the pelvis with simple anatomy; grade II, solitary stone in upper pole or multiple stones in a patient with simple anatomy or a solitary stone in a patient with abnormal anatomy; grade III, multiple stones in a patient with abnormal anatomy or stones in a caliceal diverticulum or partial staghorn calculus; grade IV, staghorn calculus or any stone in a patient with spina bifida or spinal injury. All patients had at least moderate hydronephrosis. Those who did not meet the eligibility criteria were excluded. Prophylactic antibiotics (ciprofloxacin 400 mg/12 hours, intravenously [IV]) were administered to all patients 24 hours before the surgery. All procedures were performed under general anesthesia. A unified operating method was established for all surgeries that an experienced urologist conducted (defined as a surgeon operating more than 100 surgeries a year). For most patients posterior inferior calyx was the choice of access. Upon the induction of anesthesia, with patients being in the lithotomy position and under a cystoscopy guide, a 5-Fr catheter (later used for contrast infusion) was inserted into the ureter, and then all the patients were turned with careful padding of the pressure points. Under the guidance of the C-arm fluoroscope through the abdominal wall, a pyelogram and subsequent puncture were performed using an access needle guide (18 gauge) with a floppy tip. Then, the needle entry was incised approximately 1 cm with

Table 2. Surgery-associated variables in both target groups

Variable		Groups		*P*-value
		X-PCNL	XU-PCNL	
Length of in-hospital stay (days), mean (SD)		5.18 ± 0.77	4.96 ± 0.81	0.136^{+}
Recovery Time (days)), mean (SD)		8.94 ± 1.19	24.4 ± 2.0	0.118^{+}
Radiation exposure duration (seconds)), mean (SD)		36.22 ± 10.73	23.05 ± 8.94	0.0001^{+}
Number of attempts to successful puncture), mean (SD)		1.66 ± 0.60	1.57 ± 0.64	0.464^{+}
Time from access to nephroscope insertion (minutes)), mean (SD)		9.00 ± 3.17	8.91 ± 3.62 0.893+	
Access Point, num (%)	fornix	49 (83.1%)	49 (83.1%)	1.000^{++}
	Infundibulum	10 (16.9%)	10 (16.9%)	
ntra-operative hemorrhage, num (%)	Yes	6 (10.2%)	1 (1.97%)	0.114^{++}
	No	53 (89.8%)	58 (98.3%)	
Amplatz location on nephroscopy time, num (%)	Outside of the system	3 (5.1%)	0	0.016^{++}
	In the calyx	49 (83.1%)	58 (98.3%)	
	In the cortex	7 (11.9%)	1 (1.7%)	

SD: standard deviation, num: number, $^{+}$: *t*-test, $^{++}$: Chi-squared test

Table 3. postoperative complications classified by the modified Clavien grading system and laboratory findings.

Variable		Groups		*P*-value
		X-PCNL	XU-PCNL	
Gross hematuria duration (Hour), mean (SD)		20.96 ± 9.05	18.24 ± 8.28	0.097[+]
Clavien-Dindo, num (%)	1	53 (89.8%)	55 (93.2%)	0.509[++]
	2	6 (10.2%)	4 (6.8%)	
	3	0 (0)	0 (0)	
	4	0 (0)	0 (0)	
Pain score recovery, mean (SD)		6.15 ± 0.97	5.84 ± 0.90	0.082[+]
Pain score 6 hours after the surgery, mean (SD)		3.25 ± 0.80	3.05 ± 0.68	0.14[+]
Blood loss volume (cc), mean (SD)		366.94 ± 126.49	327.96 ± 130.73	0.12[+]
Pack cells requirement, num (%)	Yes	6 (10.2%)	4 (6.8%)	0.509[++]
	No	55 (93.2%)	53 (89.8%)	
Serum creatinine, mean (SD)	Before surgery	1.1 ± 0.15	1.15 ± 0.35	0.364[+]
	After surgery	1.06 ± 0.14	1.08 ± 0.24	0.633[+]
Hemoglobin, mean (SD)	Before surgery	14.24 ± 1.66	14.54 ± 1.64	0.333+
	After surgery	12.37 ± 1.61	12.62 ± 1.59	0.385[+]
Hematocrit, mean (SD)	Before surgery	42.93 ± 4.65	42.39 ± 4.00	0.509[+]
	After surgery	38.58 ± 3.87	38.31 ± 3.92	0.703[+]

SD: standard deviation, num: number, [+]: *t*-test, [++]: Chi-squared test

the removed needle but preserved guidewire. We used fluoroscopy in both groups similarly for finding proper renal access, considering fluoroscopy's higher efficacy and capability for localizing opaque and non-opaque calculi. Fluoroscopy was continued in the X-PCNL group for the rest of the operation (tract dilation and assessment of possible stone residual fragments).

In contrast, the XU-PCNL group operations were advanced by ultrasonography, following the guidewire insertion (0.038 inches) through the addressed calyx, and an Amplatz of 30 Fr was inserted step by step. Then we performed nephroscopy (Karl Storz®, 26 Fr), and a pneumatic lithotripter (Swiss lithoclast, EMS) was used for stone fragmentation. Finally, fragmented stones were removed with a grasper.

Outcomes

According to the study objectives, a pre-designed checklist was used to gather the following variables in the included patients in both groups. Data related to fluoroscopic screening time, the number of attempts to establish proper renal access, the time interval between access to the targeted calyx and nephroscope entrance, the access, and Amplatz insertion point, and intra-operative hemorrhage (intraoperative hemorrhage is generally defined as blood loss exceeding 1000 mL or requiring a blood transfusion) were precisely measured and recorded. Moreover, the pain scores immediately and 6 hours after the surgery was assessed by visual analog scale (VAS), gross hematuria duration, the need for pack cells infusion, intra-operative bleeding, surgical complications based on the Clavien-Dindo classification, and laboratory findings (serum creatinine, hemoglobin, and hematocrit) before and 24 hours after the procedure.

Sample size and statistical analyses

In this study, based on the study by Falahatkar et al.(14), the sampling was done considering $\alpha = 0.05$, $\beta = 0.2$, P1 = 0.9, P2 = 0.7, and using the following formula:

$N=([P1\ (1-P1)]+[P2\ (1-P2)]\times(Z\ 1-\alpha/2+\ Z\ 1-\beta)^2)/((P1-P2)^2)$

The sample size was estimated to be 59 for each group. Participants were assigned to X-PCNL and XU-PCNL groups via web-based block randomization with block size of six. Descriptive statistics were shown through mean, standard deviation (SD), and percentage. Inter-group analyses were performed using independent T-test and Chi-square, where appropriate. The assumption underlying chi-square test was assessed and wherever violated, the Fisher Exact test was utilized. The per-protocol analysis approach was used. All statistical analyses were implemented in the SPSS software (V.26, IBM) at a significance criterion of 0.05.

RESULTS

Baseline demographic features

The study comprised 118 patients referring to Sina Hospital from April 2020 to March 2022, who were randomly assigned into two groups (59 in each group). The CONSORT diagram in Figure 1 demonstrates the process of participants' inclusion. No pre-operative dilemma occurred in the patients, and all surgeries were performed pre-scheduled. The Normality and homogeneity of variance assumptions were considered for continuous variables and no violations were detected (results not shown). The mean ± SD age and BMI were 46.1 ± 11.2 years (ranging from 20 to 66) and 24.1 ± 1.7 kg/m2, respectively; 73 (61.8 %) were males (male to female ratio of 1.6:1). The mean age, BMI, and sex distribution according to the groups and the performed statistical tests are presented in Table 1. As shown in the table, no significant difference was observed between the two groups regarding demographic characteristics.

Calculi characteristics

The mean ± SD of the stone numbers in all patients was 2.16 ± 0.75. Of whom 25 (21.2%) had upper calyceal, 83 (70.3%) had middle calyceal, 69 (58.5%) had lower calyceal, and 79 (66.9%) had pelvic stones. Eighty-eight (74.6%) participants had stones with grade II complexity. Notably, no significant intergroup differences in stone number, location, size, and complexity were found. These findings are thoroughly presented in **Table 1**.

Surgery-associated variables

In the total of 118 patients, the mean ± SD for the length of hospitalization was 5.07 ± 0.80 days, recovery time after the procedure was 8.77 ± 1.23 days, the radiation exposure duration was 29.63 ± 11.85 seconds, the number of attempts to successful puncture to collecting system was 1.61 ± 0.62 times, for the time from establishing the access to nephroscope insertion was 8.95 ± 3.39 minutes. Furthermore, of all the included ones, 98

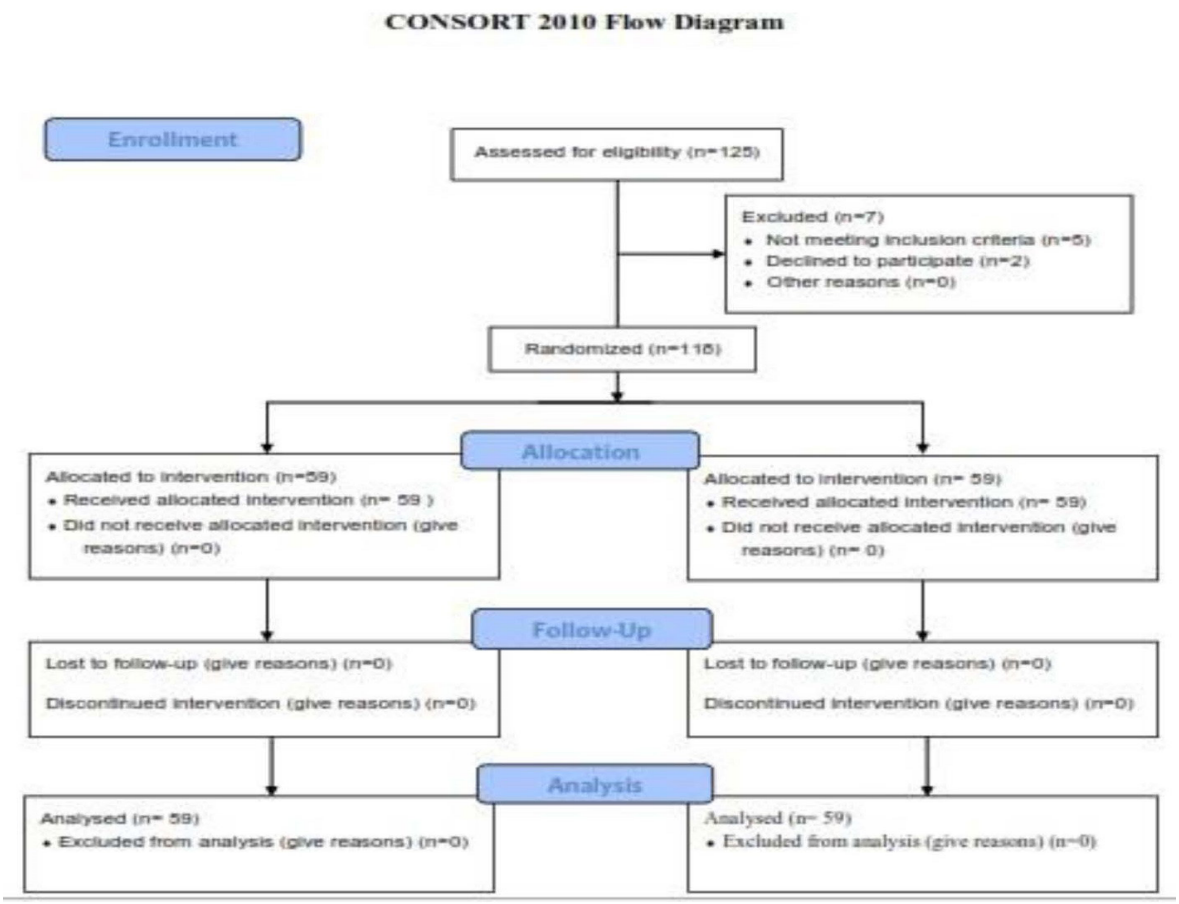

Figure 1. Consort flow diagram of the progress through the phases of a parallel randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis

individuals (83.1%) had fornix access, and intra-operative hemorrhage occurred in 7 (5.9%) patients. Intergroup difference in the mean radiation exposure duration was significant (t-test P-value of 0.0001), similar to the difference in the Amplatz placement location on nephroscopy time (t-test P-value of 0.016). However, the intergroup differences of other variables were not statistically meaningful, as shown comprehensively in **Table 2**.

Postoperative complications

In the total population, the mean ± SD for gross hematuria was 19.57 ± 8.74 hours, for VAS score during the recovery was 6 ± 0.95, for VAS six hours after the procedure was 3.15 ± 0.74, and for blood loss was 347.45 ± 129.56 ml. Furthermore, 108 (91.5%) patients were classified as grade 1 based on the Clavien-Dindo classification, and 10 (8.8%) patients received pack cells. Intergroup differences in none of these outcomes were statistically significant (Chi-squared *P*-value > 0.05). Further data in this regard are presented in Table 3.

Laboratory findings

The mean ± SD for laboratory findings, including serum creatinine, hemoglobin, and hematocrit, were not different between the two groups, either before or after the surgery. However, these variables were significantly lower in both groups after the procedure (*t*-test P-value of 0.007 for creatinine, 0.001 for hemoglobin, and 0.001 for hematocrit). The exact values are further shown in **Table 3**.

DISCUSSION

The pioneering utilization of ultrasonography in PCNL in 1999 by Desai et al.[15] has opened up new horizons for the more widespread use of this modality in Percutaneous Nephrolithotomy (PCNL), and several studies have been carried out in this regard ever since. Cumulative ionizing radiation exposure for surgical teams and patients with recurrent stones who are subjected to recurring PCNL has been the most critical concern (particularly for juveniles) from fluoroscopy. However, fluoroscopy could ensure more accurate renal access. On the other hand, the tract dilation step is assumed to receive nearly half of the intra-operative radiation exposure compared to the access step. Hence, we presumed that adopting fluoroscopy for access and ultrasonography for dilation and residual stone monitoring might be the ideal combination of these imaging methods and conducted this trial. In 2011, Agarwal et al. conducted a similar study but in a reversed manner, as one group went under surgery with total fluoroscopy guidance. In contrast, the other one had ultrasound-guided access adjunct to fluoroscopy for the rest of the procedure. The mean time to successful puncture, duration of radiation exposure, attempts to successfully puncture, and tract formation time in the combined group was significantly lower than that of the total fluoroscopy group[16]. Ilikan et al. assessed these factors in a pediatric population with the same arrangement and classification. The median puncture time, fluoroscopic screening time,

and radiation dose were significantly lower in the combined group, while the complication rates were similar [17]. Zhu et al. conducted a similar but more advanced methodology in adults by randomizing their sample into three groups; total fluoroscopy, total ultrasonography, and combined group (ultrasonography for initial puncture and fluoroscopy for the rest[18]. Accordingly, the fluoroscopy group had the highest proportion of lower pole calyceal punctures and a significant difference in radiation exposure time compared to the combined group. The access failure rate, hospital stay, operative time, and complication rates were similar among the groups. The mean access time for the combined group was significantly higher than the other ones. Aside from these studies, some other studies have been carried out comparing patients going under surgery with whether total ultrasonography or fluoroscopy guidance. For instance, Falahatkar et al. showed the similar stone free rate, complications, operating time, and hospital stay duration in two groups undergoing supine PCNL with the guidance of whether total ultrasonography or fluoroscopy[19].

To summarize, several studies have stated promising findings regarding the ultrasound-guided puncture; as we mentioned earlier, a few of its superiorities over X-ray-guided puncture[20-23]. However, with fluoroscopy, we have a better insight into the anatomic structure of the urinary system; radio-opaque stone visualization requires X-ray radiation. Therefore, their combination might be the ideal method of imaging to perform puncture and further guidewire insertion. Adopting the optimal imaging for tract dilation is the next perplexing issue. Patients and operative room staff are mostly exposed to radiation during this step; thus, obviating the need for X-rays could enhance safety to a large extent, especially in young adults. However, utilizing ultrasonography for this object could be a technical challenge for the surgeons, keeping in mind that the surgeon should simultaneously move the ultrasound probe and pass dilation instruments into the kidney. The surgical team should make a concerted effort to overcome this problem. The poor echogenicity of Amplatz dilators and nephrostomy tubes are the other dilemmas we are faced with following ultrasonography use in PCNL[24, 25]. Future research should try to address these issues to maximize PCNL efficacy and ensure the safety of those in the operating room[26]. Like other studies, the combination of fluoroscopy and ultrasonography was considered, however, in our study fluoroscopy was applied for the first step based on its superiority in renal access and calculi localization, followed by ultrasonography for the dilation step due to fluoroscopy's high radiation exposure in this step. One limitation of this study is that we utilized fluoroscopic screening time to assess the radiation risk instead of dose area product. However, dose area product is a better predictor of radiation risk. The other limitation was the scant follow-up data that disabled us from comparing the risk of stone recurrence between the groups.

CONCLUSIONS

This randomized study revealed utilizing the combination of fluoroscopy and ultrasonography during Percutaneous Nephrolithotomy (PCNL) can significantly reduce the duration of radiation in comparisson with fluoroscopy-guided PCNL. patients in the XU-PCNL group were not different from those in the X-PCNL group regarding intra-operative and postoperative complications. These findings could significantly relieve both patients and surgical team staff. Based on our study's findings, Larger studies can performed to evaluate the cons and pros of the combination method for PCNL.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

CONFLICT OF INTERESTS

All authors claim that there is no competing interest.

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