Original Article

The safety and efficacy of ultrasound versus fluoroscopic percutaneous nephrostomy: A prospective randomized study

Ahmed M. Moeen, Mostafa Kamel, Mahmoud Khalil, Fathy G. Elanany, Mohamed Abdel Basir Sayed, Hosny M. Behnsawy

Department of Urology, Assiut University Hospital, Assiut, Egypt

Abstract

Objective: The objective of this study is to compare the outcome of percutaneous nephrostomy by ultrasound (US) versus fluoroscopy including access time, volume of anesthesia required, success rate, and complications.

Methods: One hundred patients were enrolled in a prospective randomized study. Patients were divided into two groups, 50 cases each. Comparing the two groups was done regarding the need for dye, radiation effect, time taken, trial number, rate of complication, volume of anesthesia, and success rate.

Results: Patient demographics were comparable between both groups with no statistically significant difference. According to the modified Clavien–Dindo classification, the complications were Grade I (pain and mild hematuria) in each group. Procedural pain was present in 41 (82%) patients in Group I and in 48 (96%) patients in Group II. It was treated in both groups with a simple analgesic. Mild hematuria was present in 5 (10%) patients in the US group and 13 (26%) in the fluoroscopic group and treated by hemostatic drugs only. There was a statistically significant difference between both groups regarding the volume of required local anesthesia, the trial numbers, the puncture numbers, bleeding, extravasation, and change in the hemoglobin level.

Conclusion: US percutaneous renal access is a safe and effective modality with a high success rate, less operative time, and complication rate. However, a minimum of 50 cases with some pelvicalyceal system dilation may be preliminary requisites to achieve good orientation and competence in achieving safe US percutaneous renal access for future endourological procedures.

Keywords: Fluoroscopy, percutaneous nephrostomy, ultrasound

Address for correspondence: Dr. Ahmed M. Moeen, Department of Urology, Assiut University Hospital, Assiut, Egypt.
E-mail: ahmedmoeen@aun.edu.eg
Received: 17.04.2022, **Accepted:** 04.01.2023, **Published:** 14.02.2023.

INTRODUCTION

Percutaneous nephrostomy (PCN) tube placement is an effective method of temporary or permanent renal drainage. The procedure could be performed either by computed tomography (CT), fluoroscopy, or ultrasound (US).[1,2] The scope of PCN has been expanded. Currently, nonemergent indications such as relieving urinary obstructions, diverting urine for ureteral leak, and accessing the pelvicalyceal system (PCS) for diagnostic and therapeutic procedures outnumber the emergent indications.[3]

Access this article online	
Quick Response Code:	Website: www.urologyannals.com
	DOI: 10.4103/ua.ua_57_22

How to cite this article: Moeen AM, Kamel M, Khalil M, Elanany FG, Sayed MA, Behnasawy HM. The safety and efficacy of ultrasound versus fluoroscopic percutaneous nephrostomy: A prospective randomized study. Urol Ann 2023;15:215-9.

PCN is an invasive procedure with well-defined complications.[4] Improper guidance systems may lead to hazardous results.[5] In earlier series, intravenous (IV) contrast media and fluoroscopy were used to visualize the PCS and guide PCN. A combination of fluoroscopy and US was used as a guidance system for PCN. The advantages of US include nonionizing radiation, lower cost, real time, clear, cross-sectional anatomic details, with a success rate of 96.6%–100%. However, the success rate decreases to about 80% in kidneys with nondilated PCS. Moreover, performing PCN in patients with nondilated PCS results in a six-fold increase in the overall complication rates compared with the dilated system.[2]

Fluoroscopy is the accepted imaging modality for image-guided PCN with a success rate of (92%).[6] However, the adverse effects of radiation are not dose dependent and shield protection is incomplete, so, X-ray should be used carefully.[7]

Herein, the efficacy and safety of US versus fluoroscopic PCN were compared in 100 patients in a prospective randomized study.

PATIENTS AND METHODS

From April 2019 to April 2021, 100 adult patients present with mild-to-moderate renal backpressure as confirmed by US were enrolled in a prospective, randomized comparative study. Patients were randomized into two equal groups, 50 patients each using the closed envelope method. Group I: US-guided nephrostomy and Group II: fluoroscopic-guided nephrostomy.

Patients with an obstructed infected kidney, society of fetal urology grade >4, and with prothrombin concentration >60 were included in the study. On the other side, patients with congenital renal anomalies, for example, ectopic kidney, polycystic, horseshoe, or malrotated kidney, those who underwent renal transplant or urinary diversion, prothrombin concentration <60, and age <18 were excluded.

All patients were subjected to detailed history and physical examination with special emphasis on the absence of respiratory compromise, which will interfere with the prone position, abdominal US and multislice computed tomography (CTKUB), kidney, ureter, and bladder (KUB), and complete laboratory investigation.

Patients were admitted before the procedure at least 6 h for good evaluation, and access to IV line and prophylactic antibiotics were administered 1 h before the procedure. Image guidance was provided by US (Mindray Z6) with convex transducer probe (Mindray 3C5P) with a center frequency of 4–9 MHz. Fluoroscopy (General Electric OEC 9900 Elite C-Arm) with a dose of 0.0029 ± 0.0005 mSv/s was used.

US was done to grade the obstruction and CT to determine the cause of obstruction. Careful patient positioning with adequate padding in the prone position was then performed. Then, PCN was applied as discussed later. The duration, number of trials (in the same puncture), number of puncture sites, the volume of the required local anesthesia, and complications according to the modified Clavien–Dindo classification were recorded. Twenty-four hours postoperatively, US and laboratory examinations were done to be compared with preoperative one.

In the US group, after proper prone positioning, cleaning and draping were done leaving the area between the last rib and the iliac crest pared. The skin was infiltrated with 1% lignocaine (10 and 1 cm on demand) at the point midway between the iliac crest and last rib at the posterior axillary line. Following an incision with a surgical blade (no 11), a puncture needle (18 gauge) was introduced into the dilated PCS by the introducer on the probe of the US to achieve the proper access [Figure 1]. One can appreciate two tactile "pops." The first one corresponds to giving a way of renal capsule/thoracolumbar fascia and the second one is when the needle enters PCS under real-time US by visualizing the echogenic tip of the needle. Then, drainage of urine will confirm that the needle is within the PCS. Finally insertion of a 0.035-inch guidewire over which PCN was introduced and fixed to the skin by 3/0 Vicryl follows.

In the fluoroscopy group, the same steps were applied as previously with the use of a spinal needle first at the point between the last rib and sacrospinalis muscle to inject dye

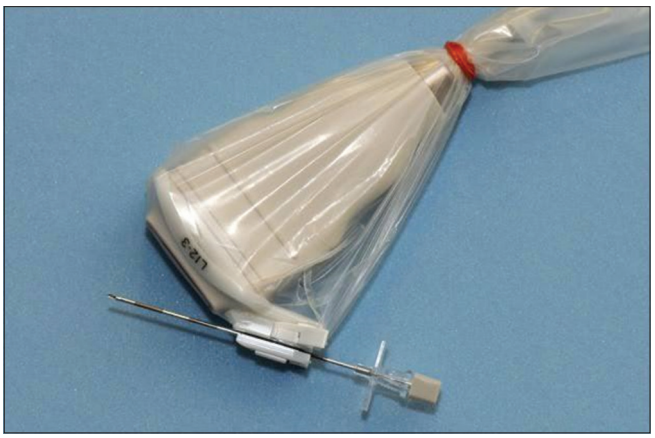

Figure 1: The needle guide mounted to the ultrasound probe

to opacify the PCS. Fluoroscopy was used in two planes, 30° to determine the suitable calyx for entry and 0° to determine the depth of the needle.

Pain during the procedure was graded by the visual analog scale (VAS).[8] Using a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the "no pain" anchor and the patient's mark, providing a range of scores from 0 to 100. A higher score indicates greater pain intensity. Based on the distribution of pain, VAS scores in post-surgical patients were: no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm).[9]

Statistical analysis was done using the Statistical Package for Social Sciences (IBM SPSS Statistics, version 22.0, release 22.0.0.0; IBM Corp), Armonk, New York. The qualitative data were presented as numbers and percentages while quantitative data were presented as mean, standard deviations, and ranges when their distribution was found parametric. The comparison between qualitative data was done using the Chi-square test. Fisher's exact test was used instead of the Chi-square test when the expected count in any cell was <5. The comparison between two independent groups with quantitative data and parametric distribution was done using an independent *t*-test. The comparison between two paired groups with quantitative data and parametric distribution was done using paired *t*-test. The confidence interval was set to 95% and the margin of accepted error was set to 5%. Hence, *P* value was nonsignificant if $P > 0.05$, significant (S) if $P < 0.05$, and highly significant if $P < 0.001$.

RESULTS

Patient demographics were comparable between both groups with no statistically significant difference regarding age, sex, body mass index, previously open, endoscopic surgery or previous PCN placement, and presence of comorbidities such as diabetes mellitus, hypertension, and cardiac problems [Table 1]. The indications of PCN in the current study were drainage of infection in 35% of patients and raised serum creatinine in 65%. The presentation of the patients was pain, tenderness, and fever in case of infection. On the other side, pain, and uremia in 2%, and accidentally discovered in the case of raised serum creatinine. Thirty-three percent of patients had previous open surgery on the same side, 13% had previous PCN placement and 11% had previous endoscopic surgery on the same side.

According to the modified Clavien–Dindo classification, the complications were Grade I in each group. The pain was present in 41 (82%) patients in Group I and in 48 (96%) patients in Group II. It was treated in both groups with a simple analgesic. Mild hematuria was present in 5 (10%) patients in the US group and 13 (26%) in the fluoroscopic group and treated by hemostatic drugs only.

The preoperative parenchymal thickness was 13.8 ± 4 mm in the US and 13.9 ± 2 mm in the fluoroscopy group ($P = 0.8$). The preoperative grade of dilatation was (Grade I in 4%, Grade II in 44%, and Grade III in 52%) in the US group and (Grade II in 56%, Grade III in 44%) in the fluoroscopy group ($P = 0.2$).

There was a statistically significant difference between both groups regarding the volume of required local anesthesia, the trial numbers, the puncture numbers, bleeding, extravasation, and change in the hemoglobin (HB) level

Table 1: The preoperative data of the studied groups

	US group, (*n*=50), *n* (%)	Fluoroscopy group, (*n*=50), *n* (%)	*n*
Sex			
Female	12 (24.0)	6 (12.2)	0.118
Male	38 (76.0)	44 (88.0)	
Age			
Mean±SD	53.48±16.29	58.26±13.95	0.118
Range	24–74	32–88	
BMI			
Mean±SD	25.59±3.31	26.35±4.11	0.313
Range	18.59–35.5	19.57–37.11	
Uremic manifestation	2 (4.0)	-	0.153
Previous open surgery	16 (32.0)	17 (34.0)	0.832
Previous PCN	8 (16.0)	5 (10.0)	0.372
Previous PNL surgery	5 (10.0)	6 (12.0)	0.749
Diabetes mellitus	11 (22.0)	4 (8.0)	0.050
Hypertension	7 (14.0)	7 (14.0)	1.000
Cardiac problems	4 (8.0)	2 (4.0)	0.400

SD: Standard deviation, PCN: Percutaneous nephrostomy tube, BMI: Body mass index, US: Ultrasound, PNL: Percutaneous Nephrolithotomy

Table 2: The operative and postoperative data of the studied groups

	US group (*n*=50), *n* (%)	Fluoroscopy group (*n*=50), *n* (%)	*P*
Operative time (min)	9.2±1.18 (7–12)	12.18±1.75 (10–15)	0.018
Trial number	1.06±0.24 (1–2)	3.28±0.45 (1–4)	0.015
Puncture number	1.2±0.4 (1–2)	1.7±0.81 (1–3)	<0.001
Pain score	1.14±0.756	2.94±1.406	<0.001
Volume of local anesthesia (mL)	10.24±0.87 (10–14)	11.54±2.11 (10–15)	<0.001
Hematuria	5 (10.0)	13 (26)	0.037
Failure of procedure	-	2 (4)	0.153
Extravasation	-	6 (12)	0.012
Slippage of guidewire	6 (12.0)	13 (26)	0.074
Postoperative grade of obstruction (SFU)			
I	50 (100)	48 (96)	0.153
III	-	2 (4.0)	
The percentage of change in HB level, mean (range)	3.00±4.50 (17.90–6.20)	3.00±6.40 (32.30–2.60)	0.043

US: Ultrasound, SFU: Society of fetal urology, HB: Hemoglobin

as shown in Table 2. The two patients in the fluoroscopic group in whom failure of the procedure occurred, they administered IV fluids to fill the PCS and underwent US-guided PCN.

DISCUSSION

PCN is an important method of urinary drainage. The latter could be performed by a variety of methods according to the indication and the general condition of the patients. Internal ureteral stents usually require anesthesia which may be unsuitable in some uremic or septicemic patients and may be associated with a significant mortality rate. However, PCN under US or fluoroscopy could treat the condition with local anesthesia. Hence, it carries less risk if compared to ureteral stenting.[10]

Worldwide, fluoroscopic guidance has been the primary imaging modality of choice used to guide percutaneous renal access and establish a working tract to facilitate intrarenal procedures. Over time, the increased incidence of malignancies due to the long-term cumulative ionizing radiation exposure makes the US more preferable.[11]

Pederson was the first to use the US guidance for PCN, with a success rate of 70%. Afterword, the number of studies has been carried out under US guidance with a success rate ranging between 84% and 100% with no need for dye or radiation effect.[9] This is due to the advent of high-resolution US machines with a better view of the PCS allowing a success rate comparable to fluoroscopic guidance with no radiation hazard.[12-15] US is the preferred option when cystoscopy and/or ureteric catheterization are impossible and for pregnant women who are scheduled for percutaneous nephrolithotomy (PCNL). Guliev reported 318 PCNLs guided by US only with good results.[16] Its success rate in our study was 100% in the US group and 96% in the fluoroscopy group. In addition, the US may be used as a salvage technique in case of difficult access or failure of fluoroscopic guidance as occurred in the two patients in our study. This may be due to the high-quality US used or the dilated PCS.

The operative time may be shorter in the US than in fluoroscopy. A study by Wang 2016, showed that the average time in the US was 6.5 ± 2.8 min that depends on the surgeon experience.[13] The operative time in our study was 9.2 ± 1.2 min in the US group and 12.1 ± 1.7 min in the fluoroscopic group ($P = 0.018$). A study by Skolarikos, *et al*. 2006, showed that the range of trials of US group was 1–2.[17] This was similar to our study which reported a range of trial numbers 1–2 in the US group and 1–4 in the fluoroscopy group ($P = 0.015$). Hence, the US may be better in localization due to the highly better visualization of the hyperechogenicity of the needle when entering the PCS by quality devices. In fluoroscopy, difficulty may be encountered in adjusting the depth of the needle to 0°.

A study by Lodh, 2014, reported that only 10% of patients complain of pain during the US PCN and less local anesthesia was required. This was due to the less number of trials and short operative time.[11] In our study, the volume of local anesthesia required in the US group was 10.24 ± 0.87 ml but in the fluoroscopic group 11.54 ± 2.11 ml ($P < 0.001$).

A study by Skolarikos 2006, showed that significant hematuria that required transfusion is present only in 1.5%. This may due to bleeding tendency or injury during the procedure. Another study by Wang 2016, shows that only 2% of patients with significant blood loss require transfusion. The change in HB level may be due to the dilution effect from fluid given during the procedure.[13,17] In our study, hematuria was present in 10% in the US group and 26% in the fluoroscopy group ($P = 0.037$). No need for a blood transfusion was required in both groups. A significant decrease in HB level was present in 17% in the US group and 32.3% in the fluoroscopic group ($P = 0.043$).

Some technical mishaps during the procedure as slippage of the guidewire were reported between 13% and 18%. This may be due to ineffective assistance or patient irritability. These problems could be minimized by adequate analgesia, anesthesia, and short operative time. This may be in favor of the US as the needle is visualized during entry to PCS.[17,18] In our study, slippage of guidewire occurred in 12% of the US group and 26% in the fluoroscopic group ($P = 0.074$). These technical problems may increase the complication rate as extravasation. A study by Wang, Huan, 2021, showed that extravasation was present in 10.2% of the US group and 12% of the fluoroscopic group.[11] In our study, none of the US group and 12% of the fluoroscopic group developed extravasation ($P = 0.012$). The latter was managed conservatively by US follow-up as the collection did not increase. Hence, every effort should be done to avoid guidewire slippage to minimize the number of PCS punctures with its associated complications. The limitation of our study is the small number of patients.

CONCLUSION

US percutaneous renal access is a safe and effective modality with a high success rate, less operative time, and complication rate. However, a minimum of 50 cases

with some PCS dilation may be preliminary requisites to achieve good orientation and competence in achieving safe US percutaneous renal access for future endourological procedures.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Goodwin WE, Casey WC, Woolf W. Percutaneous trocar (needle) nephrostomy in hydronephrosis. J Am Med Assoc 1955;157:891-4.
2. Pabon-Ramos WM, Dariushnia SR, Walker TG, d'Othée BJ, Ganguli S, Midia M, *et al*. Quality improvement guidelines for percutaneous nephrostomy. J Vasc Interv Radiol 2016;27:410-4.
3. Dagli M, Ramchandani P. Percutaneous nephrostomy: Technical aspects and indications. Semin Intervent Radiol 2011;28:424-37.
4. Degirmenci T, Gunlusoy B, Kozacioglu Z, Arslan M, Ceylan Y, Ors B, *et al*. Utilization of a modified Clavien Classification System in reporting complications after ultrasound-guided percutaneous nephrostomy tube placement: Comparison to standard Society of Interventional Radiology practice guidelines. Urology 2013;81:1161-7.
5. Audenet F, Traxer O, Bensalah K, Rouprêt M. Upper urinary tract instillations in the treatment of urothelial carcinomas: A review of technical constraints and outcomes. World J Urol 2013;31:45-52.
6. Bhatt S, Verma P, Grover RK, Sharma P, Rajaram S. Success, effectiveness, and safety of combined sonographic and fluoroscopic guided percutaneous nephrostomy in malignant ureteral obstruction. Int J Radiol Radiat Ther 2017;3:165-70.
7. Karami H, Mazloomfard MM, Moeini A, Mohammadhosseini M, Rezaei A, Lotfi B. Blind versus fluoroscopy-guided percutaneous nephrolithotomy: A randomized clinical trial. Urol J 2014;11:1386-91.
8. Crichton N. Information point: Visual Analogue Scale (VAS). J Clin Nurs 2001;10:697-706.
9. Weigl K, Forstner T. Design of paper-based visual analogue scale items. Educ Psychol Meas 2021;81:595-611.
10. Liu Q, Zhou L, Cai X, Jin T, Wang K. Fluoroscopy versus ultrasound for image guidance during percutaneous nephrolithotomy: A systematic review and meta-analysis. Urolithiasis 2017;45:481-7.
11. Lodh B, Gupta S, Singh AK, Sinam RS. Ultrasound Guided Direct Percutaneous Nephrostomy (PCN) tube placement: Stepwise report of a new technique with its safety and efficacy evaluation. J Clin Diagn Res 2014;8:84-7.
12. Jensen JA, Nikolov SI, Gammelmark KL, Pedersen MH. Synthetic aperture ultrasound imaging. Ultrasonics 2006;44 Suppl 1:e5-15.
13. Wang H. Ultrasound-Guided Percutaneous Nephrostomy: How to Select Technique? International Journal of Anatomy Radiology and Surgery 2016;5:34-40.
14. Sood G, Sood A, Jindal A, Verma DK, Dhiman DS. Ultrasound guided percutaneous nephrostomy for obstructive uropathy in benign and malignant diseases. Int Braz J Urol 2006;32:281-6.
15. Hongzhang H, Xiaojuan Q, Shengwei Z, Feixiang X, Yujie X, Haibing X, *et al*. Usefulness of real-time three-dimensional ultrasonography in percutaneous nephrostomy: An animal study. BJU Int 2018;122:639-43.
16. Guliev BG. Ultrasound guided percutaneous nephrolithotripsy. Urologiia (Moscow, Russia : 1999) 2014:111-5.
17. Skolarikos A, Alivizatos G, Papatsoris A, Constantinides K, Zerbas A, Deliveliotis C. Ultrasound-guided percutaneous nephrostomy performed by urologists: 10-year experience. Urology 2006;68:495-9.
18. Patel U, Hussain FF. Percutaneous nephrostomy of nondilated renal collecting systems with fluoroscopic guidance: Technique and results. Radiology 2004;233:226-33.