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COLLEGE OF MEDICINE AND HEALTH SCIENCES
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Outcome and Associated Factors of Two-Step Tract Dilation in a Complete Radiation Free Percutaneous Nephrolithotomy at Tikur Anbessa Specialized Hospital, 2025

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Declaration

I hereby declare that this thesis is my original work and has not been presented for a degree in any other university. All sources of material used in this document have been duly acknowledged and properly cited.

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The undersigned have examined the thesis report entitled **"Outcome and Associated Factors of Two-Step Tract Dilation in a Complete Radiation Free Percutaneous Nephrolithotomy at Tikur Anbessa Specialized Hospital, 2025 "** presented by Dr. Endale Demeke with registration number GSR/3688/13, a candidate for Specialty certificate in urology and hereby certify that it is worthy of acceptance.

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List of abbreviations

ASA-------American Society of Anesthesiology
AUA-------American Urology Association
BMI--------Body Mass Index
CD----------Compact Disk
Cm----------Centimeter
CT----------Computed Tomography
℃----------Degree Centigrade
DJ----------Double J
ESWL-------Extracorporeal Shock Wave Lithotripsy
EUA---------European Urology Association
FG----------Fluoroscope Guided
Fr----------French size
g/dl----------grams per deciliter
HB----------Hemoglobin
Kg/m2--------kilogram per meter square
KUB---------Kidney-Ureter-Bladder
mm----------millimeters
NCCT-------Non-contrast Computed Tomography
PCNL-------Percutaneous Nephrolithotomy
PCS----------Pelvicalyceal System
RCT----------Randomized Controlled Trial
SFR----------Stone Free Rate
SPSS---------Statistical Package for Social Sciences
UG----------Ultrasound Guided
URS---------Ureterorenoscope
USA---------United States of America
US----------Ultrasound

ABSTRACT

Introduction: Percutaneous nephrolithotomy is the treatment of choice for complex renal stones. As fluoroscopy carries a risk of radiation exposure, ultrasound guidance has emerged as an alternative to fluoroscopic guidance.

Objective: To assess the outcome, safety and efficacy of ultrasound-guided percutaneous nephrolithotomy (PCNL) using a two-step tract dilation method.

Methods and Materials: a cross sectional study was done on 130 cases that underwent ultrasound-guided PCNL from January 1 to December 30, 2024. The tract was dilated in a two-step fashion. In step 1, after puncturing the PCS, the tract was dilated to 12 Fr. Then, a 9.5 Fr URS was introduced to evaluate the tract, manipulate the guide wire, and scan the kidney. Finally, in step 2, the tract was dilated to the required size. We evaluated patients' demographic features, stone complexity using the S.T.O.N.E. nephrolithometry score, complications using the Clavien-Dindo grading system, and hospital stay. On postoperative day 1, a KUB was performed to assess stone-free status. Postoperatively, patients were followed up with abdominal ultrasound in the outpatient clinic.

Results: Of the 130 cases, 84 (64.6%) were male, and the mean age at presentation was 39.9 years. About 35(26.9%) of patients had a previous history of open renal surgery. In 80% of patients, the stone complexity score measured by S.T.O.N.E score was between 6 and 8. In 86.9% of patients, only a single tract was used, and the mean total duration of surgery was 100 minutes. The median hospital stay was 2 days. Approximately 77.7% of patients had no complications. The mean hemoglobin drop was 1.69 g/dL, and there was no need for transfusion. Prolonged urine leak was the most common complication (9.2%), and transient elevation of creatinine was seen at 35/77(45%). The early stone-free rate was 75.4%.

Conclusion: Ultrasound-guided PCNL with two-step tract dilation is an effective and safe modality for performing PCNL and holds significant importance in resource-limited areas.

Key words: radiation free, two step, tract dilation, percutaneous nephrolithotomy, renal lithiasis

1 Introduction

1.1 Background of the study

Historically many literatures states that percutaneous nephrolithotomy (PCNL) was introduced in the 1970s as one option of treatment for nephrolithiasis (1). It is a minimally invasive management approach through which access to the renalpelvis is achieved by a needle puncture, and the tract is dilated to the required size under imageguidance (2,3). PCNL is the treatment of choice for large, complex renal stones when otherendourologic stone management techniques fail (4). Both the AUA 2016 and the EAU 2022guidelines recommend PCNL as a primary management modality for large renal stones greaterthan 2 cm (5,6). Because the percutaneous approach to remove renal stones has a better morbidity profile, now a days percutaneous surgery is widely used for large or complex stones(7).

In Ethiopia, PCNL is practiced infrequently. Kifle et al. reported that 6 out of 34 urologists who responded to an online survey practice PCNL (8). In a retrospective study of 202 patients operated on for urolithiasis at St. Paul's Hospital Millennium Medical College, PCNL accounted for 2.5% of all the procedures (9).

PCNL can utilize fluoroscopy and/or ultrasound methods to guide the puncture of the PCS (3,10). However, using fluoroscopy to guide PCNL exposes patients and operating room staff to harmful radiation effects (11). To overcome the limitations of fluoroscopy, urologists have started using ultrasound to guide percutaneous nephrolithotomy in the treatment of renal stones.

1.2 Statement of the problem

Ultrasound-guided PCNL should be practiced as it is associated with a low risk of radiation, less injury to adjacent structures, low cost, and easy accessibility in resource-limited areas. It also provides better visualization of radiolucent stones with non-inferior results compared to fluoroscopy-guided PCNL. Despite these advantages, ultrasound-guided PCNL is still rarely practiced. While extensive studies have been conducted on fluoroscopy-guided PCNL, research on the outcomes and feasibility of completely radiation-free ultrasound-guided PCNL is lacking. In developing countries like Ethiopia, studies on the feasibility of pure ultrasound-guided PCNL remain scarce. Therefore, this study is significant because it will demonstrate the outcomes and safety of two-step tract dilation in completely radiation-free ultrasound-guided PCNL.

1.3 Justification of this study

The motive of this study is the urgent need to assess the effectiveness and associated factors of pure ultrasound-guided PCNL in order to better prevent and treat morbidities and mortalities related to renal stone disease. To the best of our knowledge, there is currently no published study on the outcomes of ultrasound-guided PCNL in this country. This study will provide valuable information about the outcomes and associated factors of pure ultrasound-guided PCNL. Findings from this report will therefore be used as a reference for future researchers regarding ultrasound-guided PCNL. It will also help generate recommendations and policies to change the current practice of PCNL among urologists in our country.

2 LITERATURE REVIEW

A systematic review and meta-analysis conducted at Tehran University, Iran, which included eight randomized clinical trials (RCTs) and eleven observational cohorts comprising 3,016 patients (1,521 UG-PCNL patients), showed no statistically significant difference in primary outcomes such as stone-free rate (SFR), overall complications, duration of surgery, duration of hospitalization, and hemoglobin (Hb) drop. The smallest sample size included was 45 cases. Stone-free rate was defined as no residual stone on follow-up imaging. Secondary outcomes included the need for transfusion, fever, radiation exposure, access time, and number of attempts. In the overall study, no significant differences were observed in the incidence of fever, need for transfusion, and number of attempts. However, results pooled from the RCTs showed a significant reduction in overall complication rate, Hb drop, and need for transfusion. Radiation exposure was higher in fluoroscopy-guided PCNL, and the time to access was shorter in fluoroscopy-guided PCNL (12). Limitations of this study include the heterogeneity of the included studies and differences in patient and operator profiles.

A comparative retrospective study conducted in Indonesia in 2023 compared patients who underwent ultrasound-guided and fluoroscopy-guided PCNL, reporting results from 201 patients (89 UG and 112 FG) (10). Patients with incomplete medical records, uncorrected coagulopathy, congenital kidney anomalies, and those who required intraoperative conversion to open surgery were excluded. The demographic features, such as age, sex, body mass index, preoperative hemoglobin, and stone burden, were similar between the two groups. Preoperative hydronephrosis was identified in 25% of patients in the UG-PCNL group, compared to only 8% in the FG-PCNL group. KUB was used to scan the kidneys postoperatively. A combined DJ stent and nephrostomy were needed in 38.20% of the UG-PCNL group, while only 11.71% of the FGPCNL group required this intervention. There was no statistically significant difference in the stone-free rate (SFR) (79% in the ultrasound-guided PCNL group and 89% in the fluoroscopyguided PCNL group), hospital stay (4 days in the ultrasound group and 3 days in the fluoroscopygroup), or complication rate (no complications in 88.7% of the ultrasound group and 87.5% inthe fluoroscopy group) (10).

Limitations of this study include the high proportion of patients with hydronephrosis in the ultrasound group, the use of KUB to assess residual stones, and its retrospective nature.

A randomized clinical trial conducted in Iran in 2020 involved patients who underwent complete supine PCNL comparing ultrasound-guided and fluoroscopy-guided procedure were Patients with multiple stones in multiple calyxes, staghorn stones (except for non-opaque stones with hydronephrosis), urinary tract anomalies, single kidney, and morbid obesity were excluded.

The mean stone burden was 26.48 in the UG group and 30.44 in the FG group. The stone-free rate (SFR) was 88.5% in the UG group and 75.5% in the FG group. Overall, 7.7% of patients in

the UG group and 24% of patients in the FG group developed grade 1 and 2 complications. Approximately 16% of patients in the FG group needed a transfusion (13). Limitations include the small sample size.

A retrospective comparative study conducted in Iran and published in 2021 examined the results of 70 children (35 patients underwent ultrasound-guided mini-PCNL and 35 patients underwent fluoroscopy-guided mini-PCNL) (14). The tract was dilated up to 18 Fr. The mean stone burden was 15.94 ± 3.69 mm in the ultrasound-guided group and 19.20 ± 7.41 mm in the fluoroscopy guided group. KUB and abdominal ultrasound were used to scan the kidneys. Successful access to the target calyx was 100% in both groups. The stone-free rate (SFR) was 97.1% in the UG group and 94.3% in the FG group, which was not statistically significant. The mean operative time was 69.00 ± 13.33 minutes in the UG group and 63.48 ± 16.90 minutes in the FG group.

Based on this study complication was compared with clavien dindo classification. 31.4% of the FG group versus 11.4% of the UG group. Approximately 11.4% of patients in the FG group experienced intraoperative bleeding, which required transfusions to restore hemodynamic stability. The need for additional surgery was 5.7% in the FG group versus 2.9% in the UG group. Urosepsis occurred in 2.9% of the FG group (14). Limitations of this study include its retrospective nature and the small sample size.

Two groups of of 98 patients who underwent ultrasound-guided PCNL in Israel in 2022, were stratified into two groups, a BMI of < 30 kg/m², with a BMI of > 30 kg/m², with 49 patients in each group (15). The demographic features and stone characteristics were similar in both groups. A flexible nephroscope was used at the end of the procedure. The stone-free rate (SFR) was defined as no residual stone > 4 mm on follow-up after 2 months with low-dose NCCT. The SFR was 87.76% in Group 1 and 73.47% in Group 2, with no statistically significant difference in SFR. There was no significant difference in the complication rate (12%) or the ancillary procedures required to completely remove the stones. Ten ureterorenoscopies (URS) were performed in Group 1, compared to 6 URS and 4 second-look PCNLs in Group 2 to completely remove residual stones (15). The sample size was relatively small.

In 2016 a prospective cohort study done in china on 96 adult patients which showed that ultrasound-guided PCNL is most effective when hydronephrosis is present during puncture and staghorn stones are absent [16]. With an 87.5% stone-free rate, the procedure was completely X-ray free in 16.7% of cases, though fluoroscopy was utilized for access (28.1%), dilation (39.6%), and tube placement (83.3%) [16].

Although using ultrasound guidance for every step of PCNL may not be achievable in all cases, it is generally associated with decreased radiation exposure. A limitation of the study is that there was no control group. Similarly, a prospective observational cohort study of 38 patients who

underwent ultrasound guided PCNL in California, USA, in 2015 showed that the stone-free rate (SFR) was 100%, with a reported grade 2 complication rate of 2.6% (17).

Ultrasound and KUB were used to screen the kidneys 30 days after surgery. Balloon dilation was performed after initial dilation of the tract with a 10 Fr fascial dilator. A flexible nephroscope was used to examine the kidneys for any residual fragments. At the end of the procedure, fluoroscopy was used in all patients to confirm the position of the nephrostomy tube.

Preoperatively, 18 patients presented with hydronephrosis, with a mean BMI of 26.1 kg/m². The procedure averaged 135.4 seconds for PCS access, 11.5 seconds for dilation, and 37.5 seconds for fragmentation, with no cases excluded [17]. Small sample size and a lack of definition for clinically significant fragment size was the limitation of this study.

A 2013 Shenyang-based study analyzed more than 700 individuals undergoing two-stage ultrasound-guided PCNL, assessing outcomes such as procedural success, hospitalization duration, Clavien-Dindo graded complications, stone-free status, and the requirement for follow-up interventions (18). Patients with single calyceal stones >2.0 cm, multiple or staghorn stones, proximal ureteric stones >1.5 cm, and stones refractory toESWL were included in the study. Patients with an ectopic kidney or urosepsis were excluded. Epidural anesthesia was used in 91% of patients. Access to the PCS was 100%. The mean hemoglobin drop was 2.24 g/dL, and the overall stone-free rate at 4 weeks after surgery was 92.6% in patients with a single calculus and 82.9% in patients with staghorn or multiple calculi. Auxiliary treatments, including shockwave lithotripsy in 52 patients, re-PCNL in 41 patients, and ureteroscopy in 18 patients, were performed 1 week after the primary procedure in 15.7% of cases for residual stones >4 mm in size. There were 13.3% grade 1, 2.4% grade 2, and 0.3% grade 3 complications, but no grade 4 or 5 complications were reported. CT scans were performed for every patient to evaluate the stone-free rate at 48 hours and 4 weeks post-procedure.

In this study, the sensitivities of intraoperative ultrasound and flexible nephroscopy for correctly determining stone-free status were 95.3% and 89.1%, respectively (18).

Similarly, a prospective study in Taiwan involving 18 patients who underwent two-step tract dilation in a completely radiation-free PCNL in 2022 showed successful tract establishment on the first attempt without fluoroscopy in 95% of cases. The median tract establishment time and median operation time were 10.2 minutes and 63.4 minutes, respectively. The median decrease in hemoglobin level was 1.0 g/dL, and none of the patients required transfusion. Sixteen percent of patients developed postoperative fever, and pleural injury occurred in two patients (11%) who had supracostal punctures. Three patients (19%) underwent ancillary procedures, and one patient was managed conservatively for a residual stone (4). The stone-free status was 79% at 3 months postoperatively. Patients with uncontrolled urinary tract infections, pregnancy, and bleeding disorders were excluded.

In 2011, researchers in Wuhan, China, performed a retrospective analysis of 262 patients were 83 individuals with complete staghorn stones, 105 with partial staghorn stones, and 74 with renal calculi exceeding 2 cm in diameter. 35 of these patients had history of previous open renal surgeries. The average procedural time—measured from the initial ultrasound penetration to the final fixation of the nephrostomy tube—was 56 minutes. For the team utilized KUB radiographs and ultrasounds, finding an initial SFR of 80.9% at 24 hours, which improved to 92% one month postoperatively. Regarding complications and recovery, 39 patients required auxiliary medical procedures. Blood transfusions were administered to 1.9% of the cohort whose hemoglobin levels fell below 8 g/dL, and 3.1% of patients experienced postoperative fevers exceeding 38.5°C, which were managed via intravenous antibiotics. The average hospital stay following the procedure was 3.8 days (19).

A 2015 study in Shenyang, China, analyzed the learning curve of a novice surgeon performing ultrasound-guided percutaneous nephrolithotomy (PCNL) over 120 cases. Results showed the average operation time decreased from 82.5 minutes in the first 15 cases to 64.7 minutes by cases 46–60, with the surgeon achieving proficiency comparable to a senior surgeon by the 60th case. While the stone-free rate (SFR) showed an upward trend as the surgeon's proficiency grew, the variations between groups—ranging from 60.0% to 93.3% with an average of 75%—were not statistically significant. Furthermore, no major complications were documented throughout the study (20).

Limitations of the study include the novice surgeon’s prior experience in other endourology procedures and training in ultrasound. Additionally, the study was retrospective.

3 OBJECTIVES OF THE STUDY

3.1 General objective

To assess the outcomes and associated factors of two-step tract dilation in completely radiation free percutaneous nephrolithotomy for all patients who underwent the procedure at Tikur Anbessa Specialized Hospital from April to August 2024.

3.2 Specific objectives

- To determine the stone-free rate (SFR) and complications of two-step tract dilation in completely radiation-free percutaneous nephrolithotomy for patients who underwent the procedure.
- To identify factors that affect the stone-free rate (SFR) of two-step tract dilation in completely radiation-free percutaneous nephrolithotomy for patients who underwent the procedure at Tikur Anbessa Specialized Hospital

4 METHODS AND MATERIALS

4.1 Research question

What is the outcome of two-step tract dilation in a complete radiation free percutaneous nephrolithotomy at Tikur Anbessa Specialized Hospital?

4.2 Description of the procedure

- Step 1: After puncturing the PCS, the tract will be dilated serially with 8-Fr, 10-Fr, 12-Fr, 14-Fr, and 16-Fr Amplatz dilators. All the Amplatz dilators will be advanced according to the measured depth of the needle. A semi-rigid ureteroscope will be introduced into the tract to evaluate it, manipulate the guide wire, and assess the renal stone.
- Step 2: Dilation of the tract to the required size.

4.3 Study area and period

This study was conducted in Tikur Anbessa Specialized Hospital in Addis Ababa, Ethiopia from January 1 to December 30, 2024.

4.4 Study design

A cross sectional study design was used.

4.5 Target population

For all patients who are candidates for PCNL in Ethiopia

4.6 Source population

All patients admitted to Tikur Anbessa Specialized Hospital and who underwent ultrasound guided PCNL

4.7 Study population

All patients admitted to Tikur Anbessa Specialized Hospital, who underwent ultrasound guided PCNL and who fulfill the inclusion criteria

4.8 Study subject

Patients who underwent ultrasound guided PCNL and who actually participated in a study

4.9 Study unit

Patient chart

4.10 Sample size calculation

- Sample size is calculated using single population proportion formula taking in to consideration source of population is >10000

$N = Z^2pq/d^2$, where

Z = standard normal variable at 95% Confidence interval, = 1.96

p = proportion based on previous studies, proportion of stone free rate from study conducted in India is 88%, = 0.88 (26).

q = 1-p, which is 1-0.88 = 0.12

d = marginal error at 5% = 0.05

$N = (1.96)^2 (0.88*0.12)/ (0.05)^2$

N = 162

No correction formula was used considering that all renal stone patients in the country are candidates for the PCNL procedure at black lion hospital.

4.11 Inclusion and exclusion criteria

All patients who undergo ultrasound guided PCNL and patients who have follow up imaging within 1 month of the surgery are included in the study.

4.12 Study Variables

- **Dependent variable**
  - Stone free rate
- **Independent variables**
  - Demographic factors(age, sex, BMI, ASA, comorbidities)
  - Stone related factors(no, location, number, S.T.O,N,E score)
  - Patient and procedure related factors(Site of puncture, Tract size, Number of tracts, Time to PCS access, dilate tract, fragment and clear stone)

4.13 Operational definitions

- Time to get ultrasound guided access – the time measured from incision of the skin to efflux of clear urine though the puncture needle.
- Time to dilate tract- the time measured from insertion of guide wire to insertion of working size sheath.
- Time to fragment – the time-measured form starting of stone fragmentation to complete clearance of the stone
- Total duration of surgery – the time measured from starting of cystoscopy guided ureteric catheter insertion to fixation of the nephrostomy tube to the skin.
- Stone free status – no residual stone seen on post-operative KUB and abdominal ultrasound or any stone < 4 mm in largest diameter on NCCT.
- Hospital stay measured from post-operative hospital stay only
- Urine Leak
    - No leak - urine leak < 12 hours
    - Short term leak- leak from 12 to 48 hours.
    - Prolonged urinary leak - leak > 48 hours
- Clavien- Dindo classification: It is a classification used to rank severity of postoperative complications.
    - Minor complications defined as Clavien – Dindo class 2 and 3a complications.
    - Major complications defined as Clavien – Dindo class 3b or 4 complications

4.14 Data collection

A checklist was developed and data was collected using kobotool box.

4.15 Data analysis

The data was analyzed using SPSS version 26 software. The descriptive statistics will be presented with frequency chart and table. Multivariable binary logistic regression model will be used to assess the association between independent variables and the dependent variables.

4.16 Ethical clearance

The study was conducted after ethical approval is granted from the institutional review board.

5 RESULTS

Here in Table 1, the demographic features of the patients are listed. Of the 130 cases, 84(64.6%) were men, and the mean age at presentation was 39.9 years. Most of our patients had a normal BMI; only 17 cases had a BMI of >29.9. Hypertension was the most common comorbidity, occurring in around 40(30.8%) of the cases. Additionally, 35(26.9%) of patients had a previous history of open renal surgery. Most patients had multiple stones, accounting for 68(52.3%). The stones were located in the right kidney, bilateral kidneys, and left kidney in 50(38.5%), 24(18.5%) and 56(43.1%) of cases, respectively. We measured stone complexity using the S.T.O.N.E. nephrolithometry scoring system; with 104(80%) of patients having a score of 6 to 8. Stone factors and operative outcomes are listed in Table 2.

Table 1: Descriptive statistics

Variables		Number, percent, mean, median
Age ,years, mean / **Men**, n		39.9 / 84(64.6%)
ASA class	ASA 1	65(50%)
	ASA 2	58(44.6%)
	ASA 3	7(5.4%)
BMI	<18.5	11 (8.5%)
	18.5-24.9	59(45.4%)
	25-29.9	37(28.5%)
	>29.9	6(4.6%)
Comorbidities	hypertension	40(30.8%)
	Type II DM	16(12.3%)
	CKD	19(14.6%)
	RVI	5(3.8%)
Toxic multinodular goiter		1(1.6%)
Gout/MDD/Tonic clonic seizure		3(2.3%)/2(1.5%)/1(0.8%)
Previous hx of open renal surgery		35(26.9%)
Multiple stone, n		68(52.3%)
Affected kidney	Right	50(38.5%)
	Left	56(43.1%)
	Both	24(18.5%)
Location of stone		
Upper pole		11(8.5%)
Lower pole		26(20%)
Inter pole		10(7.7%)
Pelvis		21(16.2%)
Proximal ureter		10(7.7%)
More than one location		52(40.0%)
S.T.O.N.E. nephrolithometery score		
<6/ 6-8/ >8		9(6.9%)/104(80%)/13(10%)

Entry into the PCS was established through the mid-pole in 41(31.5%), the upper pole in 24(18.5%) the lower pole in 53(40.8%), and multiple sites in 9(6.9%). Successful tract establishment was achieved in 93.75%. We had 4 cases of failed PCNL (3 failed access and 1 tract loss).The first patient is a 17-year-old male with a proximal ureteric stone and severe hydronephrosis. A midpole puncture was made, and tract was established. However, the guide wire slipped, leading to tract loss during manipulation, and the procedure was abandoned. Laparoscopic ureterolithotomy was performed, and the patient was discharged without complications. On follow-up, hydronephrosis increased from moderate to severe, and a CTU is planned. The second patient is a 43-year-old male known for right RVI on medication admitted with the assessment of PUJ stone and moderate hydronephrosis. A midpole puncture was made, and the tract was dilated to 26 Fr. However, during the insertion of the nephroscope, no visible calyces were found, and the tract was distorted. The patient was discharged without complications and readmitted after 3 months, where a successful PCNL was performed by the same surgeon, and he is stone-free on follow-up. The third patient is a 72-year-old female known RVI, chronic kidney disease, hypertension, and diabetes. She was admitted for assessment of a left solitary kidney and obstructive uropathy secondary to a pelvic stone, with no hydronephrosis. The largest stone size was 294 mm^2. An upper pole puncture was made and dilated to 12 Fr. An ureteroscope was introduced, but no stone or PCS was seen. Two additional lower pole punctures were made, but it was not possible to access the PCS. The total duration of surgery was 5 hours. Hemoglobin dropped from 12.9 to 8.8 g/dL, and creatinine rose from 1.4 to 1.7 mg/dL. The patient was discharged on the second postoperative day. The last case is a 36-year-old male patient with stage 4 chronic kidney disease and hypertension who had a successful PCNL on the right kidney for a large pelvic stone. He was admitted for left PCNL for multiple upper pole stones with focal caliectasis. An upper pole and midpole puncture were performed and dilated to 12 Fr. Ureteroscope was introduced, but no stones were seen. The patient developed hydropneumothorax, which was managed with a chest tube. He was discharged after a 3-week hospital stay and he is on conservative management.

Tract size was 12 French in 4 patients and 16 French in another 4 patients, while standard perc was used in (113(86.9%) patients. We used a single tract in 113(86.9%), 2 tracts in 13(10%),

and 3 tracts in 2 patients. The median time to achieve access, time to dilate the tract and time to fragment and remove the stone was 8.2, 11, 28 minutes, and the mean total duration of surgery, and 1060 minutes.

The mean hemoglobin drop was 1.69 ±1.21 g/dL. One patient supplemented with iron syrup, but no transfusion was needed in any patient. Only postoperative hospital stay was measured, with a median hospital stay of 2 days.

Table 2: stone factors and outcome measures

Variables		Number, percent, mean, median
Site of puncture	upper pole	24(18.5%)
	mid pole	41(31.5%)
	lower pole	53(40.8%)
	multiple site	9(6.9%)
Number of tracts used	single tract	114(87.7%)
	two tracts	13(10%)
	three tract	1(0.7%)
Tract size, fr		
Miniperc, 12-16 fr		9(6.9%)
Standard perc,24- 30 fr		113(86.9%)
hemoglobin drop ,g/dl		1.69 ±1.21
stone free rate early complete		98(75.4%)
need for ancillary procedure		
PCNL		7(5.4%)
Laparoscopic		1(0.8%)
Time to get ultrasound guided access(min) median		8.2
Time to dilate tract(min) median		11
Time to fragment(min) median		28
Total duration of surgery(min) mean		100
Duration of nephrostomy (hours), median		26
Post-operative hospital stay (days), median		2

During the postoperative course, a KUB was performed after 24 hours, and the early stone-free rate was 75.4%. Binary logistic regression analysis was performed between the dependant and each independent variable.

- Multiplicity of stone: single stone has odds of 3 more chance of being cleared then multiple stone free
- Degree of hydronephrosis: being mild and moderate hydronephrosis has 69% and 22% likely to achieve SFR as compared to severe hydronephrosis respectively.
- Involvement of a single calyx with stone has 27.6% more chance of being stone free than three calyx.
- But on Multivariate logistic regression analysis however revealed that, mild and moderate hydronephrosis and a single calyx involvement has significant association with stone free rate. Mild and moderate hydronephrosis has 6.3% and 19.4% more likely to achieve SFR as compared to severe hydronephrosis at P-value of 0.004 and 0.016 respectively. Involvement of a single calyx with stone has 16.4% more chance of being stone free than involvement of three calyxes at p- value of 0.03.

A total of 32 patients had stones on the KUB postoperatively. Six patients underwent a second-look PCNL. In one patient, there was a proximal ureteric stone near the PUJ, and an attempt at push-back PCNL was made, but the tract was lost intraoperatively. Laparoscopic ureterolithotomy was performed after a week. The other patients were managed conservatively.

The complication rate was measured using the Clavien-Dindo classification system, and 23.8% of patients experienced complications. Of these, 74% were grade 2 and below. In 6.2% of patients, there was a urine leak that was managed conservatively. out of 77 patients where post op creatinine was determined and 35/77(45)% had a temporary increase in creatinine levels, no change in creatinine level for 14 (10.8%) patients and in 28 out 77(36%) patients there was temporary decrement in creatinine. Two patients developed a renal pelvis perforation (grade 3a) one of them was during retrograde ureteric catheter insertion and the other was during stone fragmentation, both of them were identified intraoperatively. The postoperative stay was uneventful.

Three patients developed grade 3b complications. The first case involved a patient with a right solitary kidney and multiple stones in the lower and mid poles. Intraoperatively, a puncture was made in the midpole, and the midpole stone was removed. During the attempt to remove the lower pole stone, the patient developed bleeding, and the procedure was deferred. Postoperatively, hemoglobin dropped to 8.2 g/dL, and she was managed with Haem-up syrup. The residual stone was managed conservatively. The second patient had left pelvic and multiple lower pole stones and was a known diabetic. A midpole puncture was made, and the pelvic stone was cleared. During the removal of the lower pole stones, the patient experienced aggravated bleeding, and the procedure was deferred. The residual stone was cleared with a second-look PCNL after 1 week. Hemoglobin dropped from 15 to 9.5 g/dL; otherwise, the patient was asymptomatic and discharged home. The third patient developed a tract site TB (GUTB). This patient had a single midpole stone, for which a midpole puncture was performed, but stone removal was incomplete. A second-look PCNL was then done, and the stone was cleared completely. The patient subsequently developed a non-healing wound, and a biopsy was performed, which showed a caseating granulomatous lesion. The patient was then managed with anti-TB treatment.

The grade 4a complication reported involved a 36-year-old male patient with known stage 4 CKD and hypertension, who underwent a successful PCNL on the right kidney for a large pelvic stone. He was admitted for left PCNL for upper pole multiple stones with focal caliectasis. Upper pole and midpole punctures (2 tracts) were performed and dilated to 12 Fr. A URS was introduced, but no stones were seen. The patient developed hydropneumothorax and was managed with a chest tube. He was discharged after 3 weeks, and during follow-up cystoscopy, it was noted that the stent had migrated. It was decided to manage the stones conservatively, and the stent was removed with URS guidance. Finally, there was a 25-year-old female patient who was admitted for the assessment of a right complete staghorn stone. Lower pole and upper pole punctures (2 tracts) were performed, and the stone was cleared. Postoperatively, the patient developed a persistent urine leak for 1 week, pleural effusion, which was managed conservatively, and urosepsis (grade 4b), which was treated with meropenem. Postoperative KUB showed a residual stone, which was managed conservatively and patient was discharged after 12 days.

Table 3: post-op complications (Clavien dindo classification)

Variables	Number, percent, mean, median
Grade 1	
• Fever	7(5.4%)
• transient elevation of creatinine	35/77(45%)
• hydrothoax managed conservatively	1(1.6%)
Grade 2	
• Urine leak stayed more than 12 hours and resolved spontaneously	12(9.2%)
• Wound site infection	1(0.8%)
• Infundibular injury	4(3.2%)
Grade 3a	
• Pelvis perforation	2(1.6%)
Grade 3b	
• Perioperative bleeding requiring quitting the operation	3(2.3%)
• Tract site TB	1(0.8%)
Grade 4a	
• Adjacent organ injury	1(0.8%)
Grade4b	
• Urosepsis	1(0.8%)

We usually remove the stent a month after surgery. We had 2 patients in whom no stenting was performed.

The first patient had an upper pole puncture for a lower pole and pelvic stone, with a tract size of 26 Fr. The stone was cleared, but the PUJ was not visible. Nephrostomy tube was removed on the 5th day and the patient was discharged after 7 days. No complications were observed, except for a temporary rise in creatinine. The patient had a history of PCNL and pyelotomy in the same kidney.

The second patient had a puncture over the lower pole for a relatively large pelvic and lower pole stone. The tract was dilated to 26 Fr, and the stone was cleared completely. The nephrostomy tube was removed after 24 hours, and the patient was discharged on the second day. There were no complications noted.

A nephrostomy tube is left in place as a drainage mechanism for most patients. We had 6 patients for whom a nephrostomy tube was not inserted. These patients underwent tubeless PCNL for relatively small single stones. There were no complications observed, and the patients were discharged on the second postoperative day.

6 DISCUSSION

Since the start of PCNL in 1970, several modifications, such as pulsed mode fluoroscopy, single-shot dilation, and ultrasound-guided access to the PCS, have been made to enhance its safety and effectiveness [17]. Radiation exposure is a primary concern with traditional fluoroscopy-guided PCNL, making ultrasound-guided PCNL increasingly popular due to its ability to completely eliminate radiation risk while achieving comparable outcomes [10]. However, ultrasound is still operator-dependent.

In our study, we presented the technique and outcomes of total radiation-free ultrasound-guided PCNL using a two-step tract dilation technique. After successfully confirming the puncture of the PCS by observing the efflux of clear urine, we dilate the tract in two steps.

First step: The tract was dilated up to 12 Fr using tactile sensation and a depth monitor without ultrasound guidance. We then introduced a 9.5 Fr ureteroscope over the guide wire. The guide wire was manipulated to the proximal ureter or upper calyx, and the general safety of the tract and location of the stone was confirmed.

Second step: The tract was dilated from 16 Fr to 30 Fr without ultrasound guidance, using tactile sensation and the measured length of the puncture needle.

Our study demonstrates a high success rate in developing the tract. Although Amplatz dilators can be difficult to follow with ultrasound, several studies have reported successful dilation using these dilators with only tactile sensation and a depth monitor [18].

There are also other reports that demonstrate the safety and success of the facial dilator tips, especially for smaller sizes of 18 Fr and less, with a first-attempt success tract dilation rate of 95% [19].

Our results show a 93.4% success rate for entering the PCS, which is supported by other studies, such as that of Song Yan et al., where access to the PCS was successful in all cases [20].

The mean total duration of surgery—measured from the start of retrograde stenting to PCN tube fixation—was 100 minutes, which is relatively longer than in most studies. Yan et al. reported

the mean operation time to be 63.4 minutes, while Youmingxu et al. reported a mean operative time of 56 minutes (from ultrasound-guided penetration to nephrostomy tube fixation at the patient's skin) [15].

Despite 86.9% of the patients in our cohort presenting with low-to-moderate stone complexity scores, the recorded **SFR** was 75.4%. This figure is somewhat lower than the 80% or higher benchmarks typically reported in the literature. For instance, research on ultrasound-guided PCNL indicates an SFR of 79% when initial tract establishment fails, rising to 83% when the tract is successfully created on the first try (21).

The SFR is a multifactorial outcome; work by Song Yan highlights that stone burden is a primary determinant, noting success rates of 70.5% for solitary calculi compared to 57.1% for staghorn or multiple stones. Our findings are similar with this trend, demonstrating that patients with a single stone were 3.6 times more likely to achieve a stone-free status than those with multiple calculi (20).

Mohammod et al. from Egypt reported that successful tract establishment was affected by the degree of hydronephrosis, with all the failed tracts (4 patients) occurring in the moderate hydronephrosis group, while all cases with severe hydronephrosis achieved successful tract establishment [22]. In contrast to this study, our report showed that failure to establish the tract was more common in the severe hydronephrosis group (2 of the 4 patients). Moreover, moderate hydronephrosis was associated with a 4.6 times greater likelihood of achieving stone-free status.

In this study, 22.3% of patients had complications, but most of them were Clavien-Dindo grade 1 and 2, which is comparable to other studies. Song Yan et al. reported a 16% complication rate, with no grade 4 or 5 complications [20].

In one study involving 163 total radiation-free PCNL cases, the mean hemoglobin drop was 0.4 ± 2 g/dL for the facial dilator and 0.3 ± 0.8 g/dL for the balloon dilator, with no difference in hemoglobin drop in cases performed by urologists where no transfusion was needed [23]. This is comparable to our results, which showed a mean drop of was 1.69 ±1.21 g/dL with no transfusion required. In a separate analysis of 131 case-controlled randomized trials, researchers observed that the decline in hemoglobin levels was significantly higher in the B-mode ultrasound group (2.33 g/dL) compared to the Doppler group (1.47g/dL). This difference was reflected in the clinical outcomes, as patients in the B-mode group required blood transfusions at a rate of 6.0%, whereas the transfusion rate for those in the Doppler group was only 2.0% [24].

Urine leak was the most common complication noted. We consider a urine leak to be significant if it persists for more than 12 hours, as a leak lasting longer than this can affect outcome

parameters. We recorded a 9.2% incidence of urine leaks. A study by Esam et al. reported that around 36% of patients experienced urine leaks [25].

7 Conclusion

The stone-free rate was found to be 75.4%, which is slightly lower than in most studies. It is a relatively safe procedure, with no complication reported in 77.7% of patients, based on the Clavien-Dindo complication classification. Being single calyx and presence of mild or moderate hydronephrosis were associated positively with stone free rate.

8 Recommendation

- We also recommend to have hospital based standardized peri-operative and follow up protocol to have solid and evidence based data for future works
- Access for fluoroscope to check for some migrated/displaced stones

9 Limitations

Even though majority of the patients were followed with KUB and ultrasound stone-free status was not confirmed with a CT scan. The absence of standardized documentation protocol and poor documentation habit has negative impact on secondary data like ours.

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Annex: Questionnaire format

1. Serial number…….
2. MRN of patients……
3. Gender of patient 1-female 2- male
4. Age of patient……..
5. BMI of patient: 1) <18.5 2) 19.5- 24.9 3) 25-29.9 4) >29.9
6. American Society of Anesthesiologists (ASA) perioperative categorization of a patient's physiological status to help predict operative risk
   1-class I 2- class II 3- class III

7. Hypertension : 0- No 1- yes
8. Type 2 diabets: 0- No 1- yes
9. CKD: 0- No 1- yes
10. Retrovial infection: 0- No 1- yes
11. Toxic multinodular goitor: 0- No 1- yes
12. Gout: 0- No 1- yes
13. MDD: 0- No 1- yes
14. Tonic clonic seizure: 0- No 1- yes
15. Previous history of open renal surgery: 0- No 1- yes
16. Pre-operative hemoglobin……
17. Post-op HG……..
18. Drop in hemoglobin……
19. Pre op creatinine……..
20. Post op creatinine……..
21. Rise in creatinine……..
22. Number of stones 1- single 2- multiple
23. on which side of the kidney the stone is: 1-rt 2- lt 3- both
24. site of stone: 1-upper pole 2-inter pole 3-lower pole 4- -pelvis 5- proximal ureter 6- more than one location
25. largest stone size ……..(in mm)
26. tract length:…….(in mm)
27. degree of hydronephrosis on pre op CT scan: 0- none 1- mild 2- moderate 3- sever

28.Number of calyces involved…….
29.Stone density……
30.S.T.O.N.E score: …….
31.S.T.O.N.E nephrolithomerery score: 1) 5 and below 2) 6-8 3) >8
32.Human power used to position……..
33.Time taken to position pt from supine to prone……
34.Time to get ultrasound guided access……..
35.Time to dilate tract……
36.Time to fragment……..
37.Total duration of surgery……..
38.Any intra op accident……..
39.Site of puncture: 1)upper pole 2) mid pole 3) lower pole 4)multiple
40.Number of tract used……..
41.Diameter of the tract in FR……..
42.Early stone clearance 1)complete 2) incomplete
43.In-patient hospital stay after surgery……..
44.Duration of nephrostomy tube……..
45.Complications noted

1. No complication
2. Fever
3. Urine leak
4. Wound site infection
5. Intraoperative accidents
6. Adjacent organ injury
7. Urosepsis
8. Others
9. Tract site TB
10. Nephrocutaneous fistula

46.Clieven dindo classification- grading of complication

0. No complication
1. 1
2. 2
3. 3a
4. 3b
5. 4a

6. 4b
7. 5

47.Need for ancillary procedures for residual stone

1. No ancillary procedure
2. URS
3. PCNL
4. Exploration
5. Laparoscopic ureterolithotomy

48.Stone free rate after 3 month with abdominal U/S and KUB

1. Noresidual
2. Residual stone

49.Mode of residual check	1) ultrasound	2) CT scan
50.Nephrocutaneous fistula	1) no	2) yes
51.Urine leak	1) no	2) yes
52.Fever	1) no	2) yes
53.Wound site infection	1) no	2) yes
54.Bleeding stopping the procedure	1) no	2) yes
55.Pelvis perforation	1) no	2) yes
56.Adjacent organ injury	1) no	2) yes
57.Urosepsis	1) no	2) yes
58.TRACT site TB	1) no	2) yes
59.Temporary raise in creatinine	1) no	2) yes