

# Safety and efficacy of percutaneous nephrolithotripsy in comorbid patients: A 3 years prospective observational study

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## Summary

**Purpose:** To report the result of percutaneous nephrolithotripsy (PCNL) via standard nephrostomy tract in a single training institution. The perioperative complications in relation to the comorbid state are particularly assessed.

**Patients and methods:** A prospective interventional study between January 2019 to November 2022, included 210 patients scheduled for PCNL. The average age was  $40.3 \pm 11.8$  years (range 18- 67 years). Patients were categorized into two groups. The first group comprised 146 cases (69.5%) with no associated co-morbidities while the second group 64 (30.5%) had co-morbidities such as obesity in 4 cases (1.9%), hypertension (HTN) in 24 cases (11.4%) cases, diabetes mellitus (DM) in 17 (8.1%) cases, history of recurrent stone surgery in 11 (5.2%) cases and more than one in 8 cases (3.8%). Co-morbidities, stone burden, location of stone, time of surgery, stay in the hospital, further operations, and negative events were among the reported data. Complications and the stone-free rate were the main outcome indicators.

**Results:** Intraoperative complications were reported in 40 (18.8%) patients (18 group 1 and 22 group 2) during PCNL. Bleeding occurred in 22 (10.5%) patients (9 group 1 and 13 group 2), blood transfusions were needed in 4 (1.9%) (2 group 1 and 2 group 2), extravasation was observed in 11 patients (5.2%) (6 group 1 and 5 group 2) and cardiac arrhythmia in 3 (1.4%) (1 group 1 and 2 group 2) patients. Postoperative complications occurred in 61 patients (29%) (24 group 1 and 37 group 2) in the form of fever in 10 patients (4.8 %) (3 group 1 and 7 group 2) and prolonged leakage in 50 patients (23.8%) (21 group 1 and 29 group 2). One patient of group 2 died from postoperative sepsis. Extravasation and postoperative leakage were higher in diabetic patients than in non-diabetics. Stone-free rate was 60.5% (127 of 210). Clinically significant residual fragments (CSRFs) found in 70 cases (33.3%) (33 group 1 and 37 group 2). In 13 cases (6.2%) (5 group 1 and 8 group 2), clinically insignificant residual fragments (CIRFs) were found. In 8 (3 group 1 and 5 group 2) of the 13 cases, spontaneous stone

passage was observed within 4-6 weeks of surgery. Residual stones in three cases (1 group 1 and 2 group 2) were asymptomatic and 4 mm or less, whereas stones increased in two cases of group 2. Among all factors studied, stone burden was significantly correlated to both intraoperative and postoperative complications. The occurrence of postoperative fever increased with large stone burden.

**Conclusions:** PCNL is a therapeutic modality that is effective, feasible, and safe for a wide range of patients with concurrent medical issues. A steep curve is required to reduce intraoperative and postoperative complications.

**KEY WORDS:** Percutaneous nephrolithotripsy; Nephrostomy; Renal stones.

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## INTRODUCTION

Percutaneous nephrolithotomy (PCNL), which completely outperformed open surgical methods for kidney stone treatment, is now the standard therapy method for large stones (1). Complete stone elimination with the fewest complications is the main objective of therapy. Despite recent advancements, complications are still frequent (2). The clinical research office of the endourological society (CROES) recorded complications in approximately one-fifth of the subjects in the PCNL global study (3). In spite of the benefits of smaller incisions, less blood loss, and a quicker time to recover than with open surgery, complications after PCNL are still a serious problem. It has been reported that complications happen in 10.3% to more than 50% of PCNLs (4). Usually, patients with comorbidities and a lower functional level are at a higher risk for surgical complications (5). As per the modified Clavien classification system, perioperative (intraoperative and early postoperative) complications have been divided into

five grades. Grade 1 represents all occurrences that, if left untreated, might resolve spontaneously or require a simple bedside intervention, Grade 2 is assigned when specific medications, such as antibiotics and blood transfusions, were necessary; Grade 3 if endoscopic, surgical, or radiologic intervention was required; Grade 4 in case of organ failures and damage to nearby organs; Grade 5 in case of death (6). To lessen the complications related to PCNL, it's crucial to carefully choose and prepare patients. Renal bleeding is the most concerning PCNL complication, which may be so severe to require a blood transfusion. Early complications of PCNL also include renal vein rupture, ureteral or renal pelvic perforations, duodenal or colonic perforations, injuries to the spleen and liver, sepsis, and retained stones (7). This study aimed to report the outcome of PCNL via standard nephrostomy tract in one training institution. The peri-operative complications in relation to the comorbid state are particularly assessed.

## PATIENTS AND METHOD

Between January 2019 to January 2022, 210 patients from inpatient department of the author's institute who scheduled for PCNL, were enrolled into this prospective observational study. On average, they were  $40.3 \pm 11.8$  years old (range 18-67 years). They were categorized into two groups. The first group included 146 (69.5%) cases with no associated co-morbidities while patients of the second group 64 cases (30.5%) had co-morbidities such as obesity in 4 cases (1.9%), hypertension (HTN) in 24 cases (11.4%), diabetes mellitus (DM) in 17 cases (8.1%), history of recurrent stone surgery in 11 cases (5.2%). Eight cases (3.8%) had more than one complication.

All procedures performed in the study complied with institutional and/or national research council ethical standards as well as the 1964 Declaration of Helsinki and its subsequent amendments or similar ethical standards.

Protocols and written informed consent for all participants were approved by the Research Ethics Committee of Al-Azhar University, Faculty of medicine (Urosurg 2023/0001).

All the patients provided their informed consent that explained nature of procedure, its complications and possible clearance of his stones.

Preoperative workups included a full blood count, platelet count, serum creatinine, hemorrhage and coagulation profiles, and urine culture for all patients. Intravenous urography (IVU), urinary tract ultrasonography, and non-contrast computed tomography (NCCT) were all used in the radiologic assessment of patients. Stone burden has been determined using radiographic examinations, and stones were classified as simple (isolated calyceal stones or isolated renal pelvis stones) or complex (complete or partial staghorn stones, kidney pelvic stones accompanied by calyceal stones), irrespective of size.

Every subject underwent PCNL, which started with a cystoscopy and ureteral catheter insertion, all of the patients under study were placed in the prone position to acquire percutaneous access; then through a Chiba needle, pelvicalyceal system was accessed under fluoroscopy. After a correct calyceal puncture, a 30F Amplatz sheath has been inserted after the tract had been dilated with Alken metal

telescopic dilators. Using a rigid 26-Fr nephroscope, nephroscopy was carried out. When necessary, further tracts were made during the same session to gain access to all stones. A pneumatic Swiss Lithoclast was used to fragment the stone burden. By using antegrade nephrostography and fluoroscopy intraoperatively, the collecting system's integrity and stone removal were verified. At the conclusion of PCNL, a 22-Fr nephrostomy tube has been inserted into the renal pelvis or the affected calyx. If the urine was clear or light pink on the first postsurgical day, the Foley and ureteral catheters have been eliminated. The kidneys, ureters, and bladder were examined with a plain film. The nephrostomy tube was removed on the second postsurgical day after antegrade nephrostography showing that patients had clinically insignificant residual fragments (CIRFs) < 4 mm or no residual stones and drainage of the ureter down to the bladder. If urinary leakage from the tract persisted for more than 24 to 48 hours after the nephrostomy tube was removed, a Double-J catheter was deemed necessary. If a second PCNL session was planned due to remaining stones, the nephrostomy tube was left in place. The PCNL technique was deemed successful when the patient was either stone-free or had CIRFs, which were defined as <4 mm, non-obstructive, non-infectious, and asymptomatic residual fragments.

Statistical analysis: SPSS was used to analyze the data, (version 13.0, SPSS Inc., Chicago, Ill, USA). We compared the two groups using the Student t test, Mann-Whitney U test, and chi-square test. The mean standard deviation was reported for quantitative variables. P values <.05 were deemed significant.

## RESULTS

The study comprised 210 patients treated by PCNL. There were 132 men (group I 84 and group II 48) and 78 women (group I 62 and group II 16). The age was  $40.3 \text{ mean} \pm \text{SD} \pm 12.8$  years;  $40.2 \pm 11.6$  years in group I and  $41.13 \pm 13.2$  years in group II ( $p = 0.77$ ). The average body weight index in groups I and II was  $29.5 \pm 7.1$  and  $30.0 \pm 8.2 \text{ kg/m}^2$ , respectively ( $p = 0.53$ ) (Table 1). Mean stone burden was  $7.5 \pm 5.6 \text{ cm}^2$  (range: 2.5-30  $\text{cm}^2$ );  $7.3 \pm 3.4 \text{ cm}^2$  and  $8.1 \pm 4.8 \text{ cm}^2$  in groups I and II, respectively ( $p = 0.47$ ). Mean follow up was  $41.2 \pm 32.3$  months in group I and  $45.3 \pm 24.3$  months in groups II ( $p = 0.79$ ) (Table 2).

**Table 1.**  
Clinical c of treated patients.

Characteristics	No. (210 cases)	Group I (n = 146)	Group II (n = 64)
Age (mean $\pm$ SD)	40.3 $\pm$ 12.8 yrs	40.2 $\pm$ 11.6	41.13 $\pm$ 13.2
Sex			
Males	132/210 (62.9%)	84	48
Females	78/210 (37.1%)	62	16
Complaint			
Pain	201/210 (95.7%)	141	60
Hematuria	9/210 (4.3%)	5	4
Mean body weight index (kg/m <sup>2</sup> )	29.5 $\pm$ 7.2	29.5 $\pm$ 7.1	30.0 $\pm$ 8.2

**Table 2.**  
Stones characteristics and PCNL access in the two groups.

Stone and access criteria	Group I	Group II
Mean stone burden: $7.5 \pm 5.6 \text{ cm}^2$ (range: 2.5-30 $\text{cm}^2$ )	$7.3 \pm 3.4 \text{ cm}^2$	$8.1 \pm 4.8 \text{ cm}^2$
Classification of stones:		
Simple: 49% (n = 103)	68	35
Complex: 51% (n = 107)	78	29
Mean operation time: $75 \pm 32$ minutes (range 40 to 140)	$70 \pm 20$	$72 \pm 22$
Mean number of percutaneous access no.: $1.1 \pm 0.5$ (range: 1-5)		
Single access: 90% (n = 189)	136	53
Multi-tract accesses: 10% (n = 21)	10	11
Percutaneous access location		
Subcostal access: 98.1% (n = 206)	145	61
Supracostal access: 1.9% (n = 4)	1	3
Overall postsurgical result:		
Mean duration of urethral catheterization: $1.08 \pm 0.2 \text{ d}$ (range: 2-4 d)	$1.3 \pm 0.1 \text{ d}$	$1.4 \pm 0.8 \text{ d}$
Mean time with nephrostomy tube: $2.86 \pm 0.83 \text{ d}$ (range: 3-8 d)	$2.53 \pm 0.71 \text{ d}$	$2.74 \pm 0.22 \text{ d}$
Mean hospital stay was $3.93 \pm 3.17$ days (range: 3-15 d) AKE	$3.88 \pm 2.07 \text{ d}$	$4.03 \pm 3.66 \text{ d}$

One-access subcostal PCNL was performed in 189 (90%) cases (group I 136 and group II 53), while 21 (10%) cases underwent multi-tract PCNL (group I 10 and group II 11). Supracostal approach was indicated in four cases (1.9%) in group I. The average surgical time was  $75.15 \pm 32.75$  mins (range 40 to 140). Nephrostomy tube removal took an average of  $2.86 \pm 0.83$  days (ranging from 3 to 8), and the mean hospital stay was  $3.93 \pm 3.17$  days. No complications occurred intraoperatively in 82.9% (174/210) of the patients, while one or more complications have been noticed in 36 (17.1%) cases during PCNL. Bleeding occurred in 22 (10.5%) patients; transfusions of blood were needed in 4 out of the 22 patients (Table 3) whereas the remaining patients were successfully treated with conservative measures. Postoperative complications occurred in 61 cases (29%). Prolonged leakage following nephrostomy tube removal occurred in 50 (23.8%) patients. Stenting was required in 8 patients (3.8%) because of persistent urine leakage. Fifteen out of the 17 patients with diabetes mellitus developed prolonged leakage after PCNL. In 10 patients (4.8%), there was a transient fever that required antipyretics. Nine out of the ten patients with fever had urosepsis, which was

**Table 3.**  
Intraoperative and postoperative complications.

Intraoperative complications	No. of cases (%)	Group I (n = 146)	Group II (n = 64)
Bleeding	22 (10.5%)	9 (6.2%)	13 (20.3%)
Transfusion	4 (1.9%)	2 (1.4%)	2 (3.1%)
Extravasation	11 (5.2%)	6 (4.1%)	5 (7.8%)
Cardiac arrhythmia	3 (1.4%)	1 (0.7%)	2 (3.1%)
No complications	174 (82.9%)	130 (89%)	44 (68.7%)
<b>Postoperative complications</b>			
Fever	10 (4.8%)	3 (2%)	7 (10.9%)
Leakage	50 (23.8%)	21 (14.4%)	29 (45.3%)
Death	1 (0.4%)	(0.0%)	1 (1.6%)
No complications	149 (71%)	122 (83.6%)	27 (42.2%)
<b>(Either colonic or pleural)</b>			

**Table 4.**  
Overall complications in relation to stone burden.

Stone burden	Complications occurred	No complications
$\leq 3 \text{ cm}^2$	49 (72.1%)	19 (27.9%)
3.1- 5 $\text{cm}^2$	77 (60.6%)	50 (39.4%)
$> 5 \text{ cm}^2$	6 (40%)	9 (60%)

successfully managed with intravenous broad-spectrum antibiotics, but one patient who died from postoperative sepsis (Table 3). No pleural injury neither hydrothorax nor hemothorax and no colonic injury developed in any of our cases.

Complications in relation to stone burden were observed in 49 (72%), 77 (60.6%) and 6 (40%) patients with stone size  $\leq 3 \text{ cm}^2$ , 3.1-5  $\text{cm}^2$  and  $> 5 \text{ cm}^2$  respectively. Conversely, no complications were reported in 19 (27.9%), 50 (39%) and 9 (60%) patients with stone size  $\leq 3 \text{ cm}^2$ , 3.1-5  $\text{cm}^2$  and  $> 5 \text{ cm}^2$  respectively (Table 4). At three months after surgery, the total stone-free rate reached 60.5% (127 of 210). Clinically significant residual fragments were found in 70 cases (33.3%) (33 group 1 and 37 group 2) whereas in 13 cases (6.2%) (5 group 1 and 8 group 2), clinically insignificant residual fragments were found. In 8 (3 group 1 and 5 group 2) of the 13 cases with clinically insignificant fragments, spontaneous stone passage was observed within 4-6 weeks of surgery. Residual stones were asymptomatic and 4 mm or less in three cases (1 group 1 and 2 group 2), whereas stones increased in two cases of group 2.

## DISCUSSION

Despite the high rate of success of PCNL, major risks associated with percutaneous renal surgery involve blood loss requiring transfusion, fever, urinary tract infections, and injury to nearby organs (8, 9). According to *Olbert et al.* (10), there are links between the result of PCNL and patient- and stone-related parameters, including age of the patient, BMI, metabolic syndrome, and type and burden of stone. The PCNL morbidity is significantly influenced by the burden of stones (11).

The most frequent complication in a study by *Lee et al.* (12) on 500 patients who had undergone PCNL was hemorrhage, with a 12% rate of transfusion.

The nephrostomy tract itself is a frequent source of hemorrhage during PCNL (8). The number of serious hemorrhages was recorded as  $< 8\%$  (13). In the majority of such cases, conservative therapy is successful; in the study of *Tefekli et al.* (6) no blood transfusion was required whereas *Mousavi-Bahar et al.* (14) reported a transfusion rate of 0.6%. In our study, the transfusion rate was 1.9% in agreement with *Vorrakitpokatorn et al.* (9), who reported a 1.4% transfusion rate.

Transfusions rates were reported to be 25% in early investigations, but they were significantly reduced due to advances in percutaneous stone removal techniques, and more recent studies have found that they are now between 1% and 2% (15).

Earlier investigations have proposed that diabetes, the

type of stone, and the size of the stone can all predict blood loss in PCNL (16).

The incidence of bleeding complications was found to be 7.0% (109/1555) after telescopic dilatation of the track using large sheaths (27F, 28F, 30F) with 5.9% (208/3533) requiring blood transfusion (17). Obesity is thought to make PCNL more technically challenging, which could increase the chance of complications. However, impact of obesity on PCNL results and complications is not well defined. A negative effect of obesity on complication rate was found in *Bagrodia et al.* (18). In a large recent series, 234 patients were divided into 4 groups based on their BMIs as ideal body weight (< 25 kg/m<sup>2</sup>), overweight (25 to 29.9 kg/m<sup>2</sup>), obese (≥ 30 to 34.9 kg/m<sup>2</sup>), and severely obese (≥ 35 kg/m<sup>2</sup>). After stratification with regard to BMI, no statistically significant difference was observed in length of hospital stay, stone-free rate, rate of complications, or change in hematocrit. This was supported by a more recent study (19), which concluded that BMI was not related to a higher risk of hemorrhage and transfusions.

In our study, the procedures were performed on obliquely prone that we found more suitable for proper puncture of the collecting system. PCNL is most effective when the patient is in the prone position although patient may be placed in any of the following positions: flat prone on a fluoroscopic table, deflected prone on a cushion, oblique prone on a fluoroscopic table, or oblique supine on a fluoroscopic table. The oblique supine position is favored by some urologists because they believe it makes it simpler to access the succeeding PCNL. It must be highlighted that the kidney's axis differs when the patient is lying in an oblique supine position versus a flat prone position (7).

The number and type of access is influenced by the treatment approach and by the stone size and location. Some surgeons favor a standard access via the lower calyx with subsequent ESWL therapy for stones not reachable through this access (20). Others recommend using many tracts (such as the upper pole) in a single session to clear the collecting system (21). Upper pole access offers the best manipulation in cases with stone burdens in the upper and lower calices but involves a slight increase in the rate of complications (i.e., pleural injury). A subcostal technique is usually used, though a supracostal technique is preferred in some cases, like those of proximal ureter stones, superior calyx stones, or staghorn stones. When selecting the supracostal technique, significant chest complication rates of roughly 5% must be taken into account (22). Our policy was to use the subcostal approach. However, supracostal approach was needed in four patients (1.9%) due to stones extending into the upper calyx. We had no complications related to supracostal approach in the four cases. One-access subcostal PCNL was performed in 189 (90%) cases (group I had 136 and group II had 53), while 21 (10%) underwent multi-tract PCNL (group I has 10 and group II has 11).

The average surgical time ranged from 55 to 90 minutes (10) although most studies overlook the variables that influence PCNL's surgical time. In the current study, the average surgical time was 75.15 ± 32.75 minutes (range 40 to 140), which lies in the range described. *Takeuchi et al.* (23) reviewed the clinical records of 1897 patients who underwent PCNL for renal calculi splitting them into

2 groups depending on their median surgical time (group 1: ≤ 60 min; group 2: > 60 min). The average operation time was 64.9 ± 27.6 minutes (with a range of 10-220 minutes).

In the present study intraoperative extravasation occurred in 5.2% (11 cases) and was managed conservatively. The overall incidence of postoperative prolonged leakage was 23.8% although it was significantly higher in group II compared to group I (45.3% versus 14.4%, *p* < 0.045). Fifteen out of the 17 cases with diabetes mellitus developed prolonged leakage after PCNL.

Septicemia can occur as a result of an infection introduced through the renal access tract or because the stones are infected. Individuals with infected urinary stones experience fever more frequently following PCNL than patients with sterile stones (24). Prior to undergoing PCNL, a pyonephrotic kidney must be drained and prophylactic antibiotics must be taken. In the instance of sterile urine, antibiotics could be administered using single-dose or short-course prophylactic procedures without any significant differences between them. There are significant risk factors for postsurgical fever, including the length of the operation and the amount of irrigation fluid used. Additionally, it is critical to avoid an increase in collecting system pressure, and operating times should be kept to a minimum (i.e., < 90 minutes).

The literature reports sepsis rates up to 0.97% (25) although other series (26), reported lower incidence of such complication (0.3%).

In our series, despite proper antibiotic therapy, a diabetic patient with staghorn stone died of urosepsis. He received prophylactic antibiotic, and his preoperative urine culture was negative. The surgical time was 120 minutes.

The total stone-free rate in this study at three months was 60.5% (127 of 210), which was lower than previously reported. *Altunrende F et al.* (27) reported total stone-free rate as 74.5%.

The impact of case volumes on PCNL's efficacy and safety results was recently analyzed in a large database including data from 3933 patients (28). In high-volume centers, stone-free rates were higher (82.5% versus 75.1%; *p* < 0.001). High-volume centers had also a lower rate of complications (15.9% versus 21.7%; *p* = 0.002) and a shorter mean length of stay (3.4 versus 4.9 days). After controlling for stone burden, urine culture status, and the presence of staghorn stones, the stone free rate increased with case volume, while the complication rate and length of stay decreased. Centers that undertook a large number of PCNLs annually had better outcomes and the highest stone free rates have been found in centers with more than 120 cases annually (28).

A study evaluated the natural history of CIRFs (27) in 38 patients who had CIRFs three months following PCNL (22% of the total) and were followed for a minimum of 24 months. During follow-up, 10 (26.3%) patients experienced a symptomatic episode that required medical treatment, whereas the other patients were asymptomatic. According to the radiologic evaluation, the size of the fragments increased in 8 (21.1%) cases while remaining stable or decreasing in 27 (71.1%) cases. A spontaneous stone passage occurred in three (7.9%) of the patients.

In our study, CIRFs were found in 13 cases (6.2%). Eight

of those 13 cases had spontaneous stone passage, whereas the size of the stones increased in two cases, and three had asymptomatic residual stones measuring 4 mm or less. Clinical significant residual fragments (CSRFS) were found in 70 cases (33.3%) and were managed by auxiliary SWL treatment.

According to Margel *et al.* (29), PCNL is time-consuming and may necessitate auxiliary operations in patients who had previous open stone surgery due to scar tissue and anatomic changes in the operated kidney. In contrast, our research found no difference in the rate of complications between patients who had open stone surgery and those who did not, which is consistent with other studies (30).

### Limitation of study

We have relatively high complications rate because our institution is a training center for junior staff and young residents.

### CONCLUSIONS

PCNL represents an efficacious, feasible, and safe treatment modality that can be used in a wide range of patients with concomitant illnesses who need a steep curve for decreasing intraoperative and postoperative complications.

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