

Supine versus Prone Percutaneous Nephrolithotomy for Complex Stones: A Multicenter Randomized Controlled Trial

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Study Need and Importance: High-quality evidence comparing supine to prone percutaneous nephrolithotomy (PCNL) for the treatment of complex stones is lacking. This study aimed to compare the outcomes of supine position (SUP) and prone position (PRO) PCNL.

What We Found: A noninferior randomized controlled trial was performed according to the CONSORT (Consolidated Standards for Reporting Trials) criteria (see figure). Overall, 112 patients were randomized, and their demographic characteristics were comparable. The success rates on postoperative day 1 were similar (SUP: 62.5% vs PRO: 57.1%; $p=0.563$). The difference observed (-5.4%) was lower than the pre-defined limit. The final stone-free rates were also similar (SUP: 55.4% vs PRO: 50.0%; $p=0.571$). SUP had a shorter operative time (117.9 ± 39.1 minutes vs 147.6 ± 38.8 minutes; $p < 0.001$). PRO had a higher rate of Clavien ≥ 3 complications (14.3% vs 3.6%; $p=0.045$), leading to a longer hospital stay (median 45.4 hours [30.2–238.2] vs 43.3 hours [20.3–165.0]; $p=0.049$).

Limitations: This study had some limitations, such as patient radiation exposure. The computerized tomography evaluation on postoperative day 1 is controversial because it minimizes the stone-free rate since spontaneous expelling of residual fragments may occur; however, it provides precise information regarding immediate success and complications. Another point is the use of 30Fr access instead of a smaller tract, but this has been the standard technique for complex stones. The relatively small number of patients may also be a point of criticism, especially for secondary outcomes. However, we believe that our study has several strengths that make it important, such as its multicenter randomized design, the few potential bias

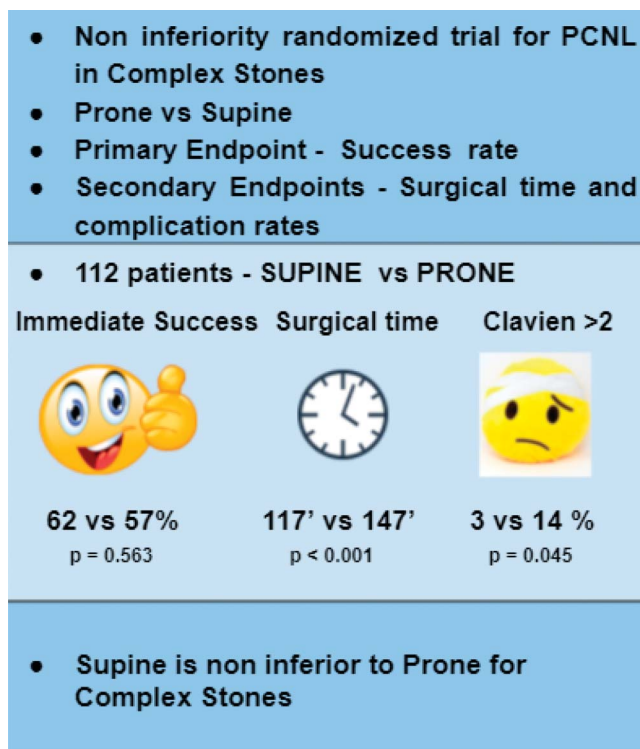


Figure. Visual abstract of study.

sources, a rigorous followup, and the systematic use of computerized tomography scans evaluated by a single blinded radiologist.

Interpretation for Patient Care: Positioning during PCNL for complex kidney stones did not affect the success rates; consequently, both positions may be suitable. However, SUP may be associated with a lower high-grade complication rate.

Supine versus Prone Percutaneous Nephrolithotomy for Complex Stones: A Multicenter Randomized Controlled Trial

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Abbreviations and Acronyms

BMI = body mass index

CT = computerized tomography

GSS = Guy's Stone Score

NCCT = noncontrast computerized tomography

PCNL = percutaneous nephrolithotomy

POD1 = first postoperative day

POD90 = ninetieth postoperative day

PRO = prone position

RF = residual fragment

SFR = stone-free rate

SUP = supine position

Purpose: High-quality evidence comparing supine to prone percutaneous nephrolithotomy (PCNL) for the treatment of complex stones is lacking. This study aimed to compare the outcomes of supine position (SUP) and prone position (PRO) PCNL.

Materials and Methods: A noninferior randomized controlled trial was performed according to the CONSORT (Consolidated Standards for Reporting Trials) criteria. The inclusion criteria were patients over 18 years of age with complex stones. SUP was performed in the Barts flank-free modified position. Except for positioning, all the surgical parameters were identical. The primary outcome was the difference in the success rate on the first postoperative day (POD1) between groups. The secondary outcome was the difference in the stone-free rate (SFR) on the 90th postoperative day (final SFR). A non-inferiority margin of 15% was used. Demographic, operative, and safety variables were compared between the groups. Statistical significance was set at $p < 0.05$.

Results: Overall, 112 patients were randomized and their demographic characteristics were comparable. The success rates on POD1 were similar (SUP: 62.5% vs PRO: 57.1%, $p = 0.563$). The difference observed ($-5.4%$) was lower than the predefined limit. The final SFRs were also similar (SUP: 55.4% vs PRO: 50.0%, $p = 0.571$). SUP had a shorter operative time (mean \pm SD 117.9 \pm 39.1 minutes vs 147.6 \pm 38.8 minutes, $p < 0.001$) and PRO had a higher rate of Clavien ≥ 3 complications (14.3% vs 3.6%, $p = 0.045$).

Conclusions: Positioning during PCNL for complex kidney stones did not impact the success rates; consequently, both positions may be suitable. However, SUP might be associated with a lower high-grade complication rate.

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Conflict of interest: The authors declare that they have no competing interests.

Data sharing policy: REDCap® software.

Ethical approval: All procedures performed in the study were in accordance with the ethical standards of the local research committee and with the 1964 Helsinki Declaration and its later amendments.

Informed consent: Informed consent was obtained from patients preoperatively.

Availability of Data and Material: All data are filed in a database (REDCap® software).

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PERCUTANEOUS nephrolithotomy (PCNL) is the standard treatment for large renal stones, including staghorn stones,^{1–3} and is traditionally performed in the prone position (PRO).⁴ First described in 1976 by Fernström and Johansson,⁵ PRO was followed by the first description of the supine position (SUP) in 1987.⁶ In patients with complex stones, PCNL outcomes are different from those in patients with nonstaghorn stones or simple cases.⁷ The exact role of positioning during surgery in this group of patients has not yet been determined.

According to the CROES (Clinical Research Office of the Endourological Society) study, PRO is the most common technique for the treatment of large stones.⁸ The urological community has recommended PRO with upper calyx access to provide better access to all collecting system;⁴ however, this consensus appears to rely upon expert opinions rather than high-quality-based data. Some systematic reviews presented similar data between both positions; however, data for complex stones are still lacking.^{9–11}

Both techniques are efficient in treating simple cases, but PCNL remains challenging in complex cases and associated with higher complication rates.¹² Nonrandomized studies showed that both techniques have similar safety profiles when treating complex stones,^{13,14} but the question that arises is whether SUP would be as efficient as PRO. In a large observational study, Astroza et al concluded that PRO may offer a higher success rate and that further prospective randomized trials might be necessary to determine the optimal patient position during the management of staghorn stones.¹⁵ While the upper pole seems to be the ideal entrance point for PRO, the lower pole may be more suitable for SUP.¹⁶

The aim of this study was to evaluate the role of positioning in the treatment of patients with complex renal stones by comparing the most widely used technique to supine PCNL.

MATERIALS AND METHODS

We performed a noninferior randomized trial analysis of prospectively collected data, including all consecutive patients (>18 years old) with complex stones (Guy's Stone Score [GSS] of 3 or 4) scheduled for PCNL between May 2018 and June 2019. The exclusion criteria were pregnancy, untreated urinary infection, and uncorrected coagulopathy. Informed consent was obtained, and the study protocol was approved by the local ethics committee (IRB number: 8258117.8.0000.0091) and the national clinical trial registration platform (ReBEC; ensaiosclinicos.gov.br, U1111-1215-4196). We present the study following the CONSORT guidelines (fig. 1).

The primary outcome was the difference in success rate on the first postoperative day (POD1), which was defined as the absence of residual fragments (RFs) >4 mm on noncontrast computerized tomography (NCCT).¹⁷ Secondary outcomes were the differences in final stone-free rate (SFR) without auxiliary procedures, defined as the absence of any stones on the 90th postoperative day (POD90), since it is possible that the RFs visualized on the POD1 NCCT may be eliminated by POD90.

Demographic (sex, age, body mass index [BMI], American Society of Anesthesiologists® score, GSS), operative (number of punctures, supracostal access, urine puncture culture, stone culture, stone analysis, mean operative time, nephroscopy time, hospitalization time), and safety variables (intraoperative and postoperative complications) were recorded. The GSS was determined preoperatively based on computerized tomography (CT) scan findings.^{18,19} The operative time was defined as the time from the beginning of the cystoscopy until the end of the nephrostomy placement, while the nephroscopy time was considered the time between the first and the last insertion of the nephroscope. Hospitalization time was considered to extend from the beginning of anesthesia until hospital discharge. Sepsis was defined as a qSOFA (quick Sepsis-related Organ Failure Assessment) score of 2 or 3. Blood transfusion was considered in patients with signs of refractory hypovolemia. Complications were graded according to the modified Clavien-Dindo classification,¹² and those with Clavien scores ≥ 3 were considered major complications.

Randomization and Procedures

A randomization list was created and stored securely. Only the study coordinator had access to the list. The allocation was revealed immediately before the anesthetic procedure.

Urine culture samples were collected before the procedure. Patients with negative results began prophylactic oral antibiotics (nitrofurantoin) and received a third-generation cephalosporin during the induction of anesthesia. Patients with positive cultures received therapeutic antibiotics 7 days before and during induction according to antibiogram.²⁰ Tranexamic acid was used to prevent bleeding in patients without contraindications (allergy, previous thromboembolic events, creatinine clearance <30 ml/minute, and high risk for thromboembolism).^{21,22}

A uniform operating methodology was established in 2 high-volume centers, and surgeries were performed by 3 surgeons experienced in both positions. SUP was performed in a Barts flank-free modified position²³ with the first entry point preferentially through the lower pole, and PRO was performed in the classic position planned through the upper pole using 30Fr nephrostomy tracts. Surgeons were allowed to decide the most appropriate and safest entry point to achieve stone access with the lowest risk of complications. Excluding positioning, all surgical parameters were the same.

The procedures were performed under general anesthesia and began with cystoscopy and placement of a 6Fr ureteral catheter. Then the PRO cases were turned, while the SUP cases remained in the same position. Ultrasonography was performed before puncture. A retrograde pyelogram and subsequent calyceal puncture were performed

CONSORT 2010 flow diagram

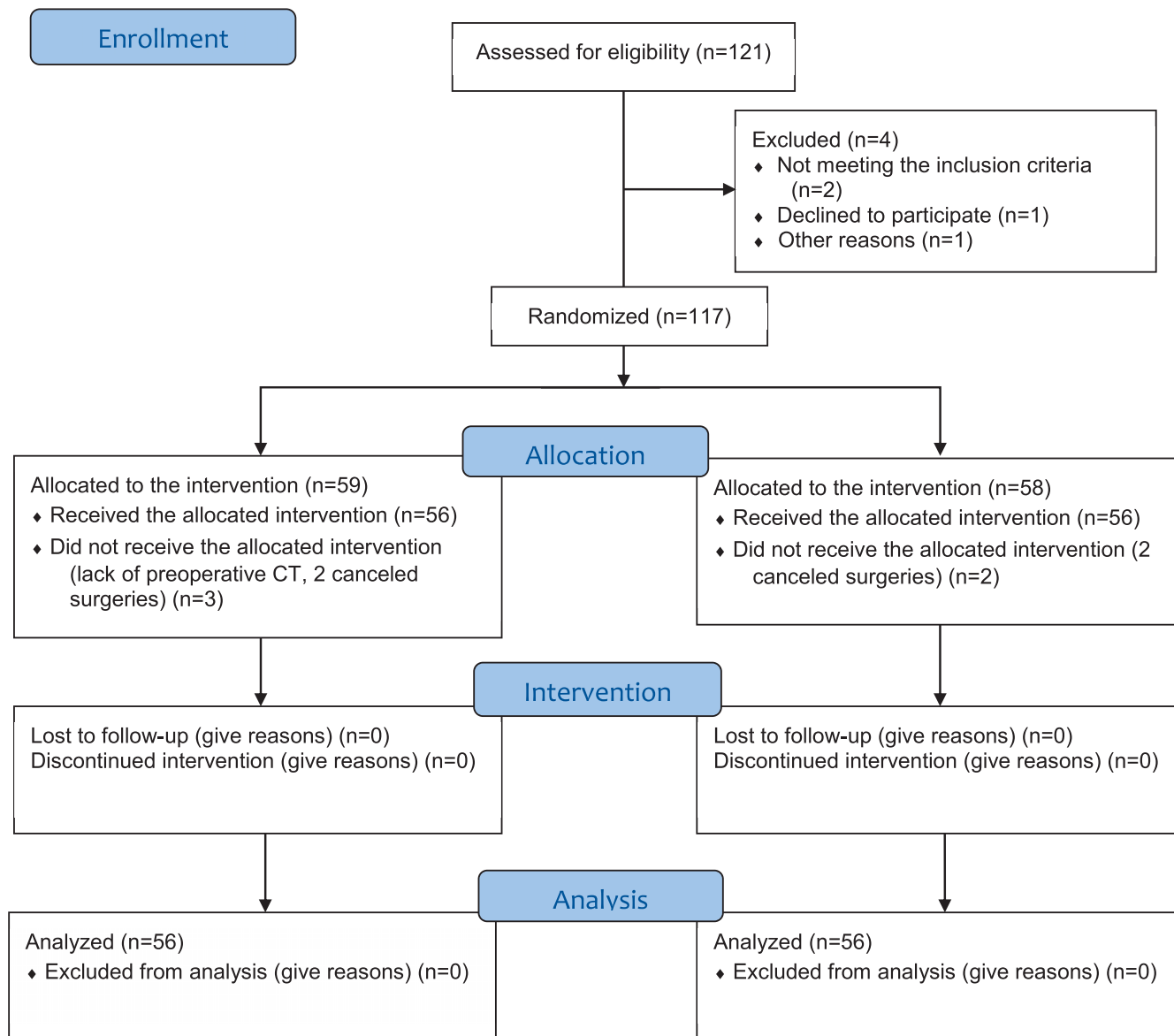


Figure 1. CONSORT (Consolidated Standards for Reporting Trials) flow diagram.

under fluoroscopic guidance. Semirigid plastic dilators (Amplatz dilators[®]) were used to dilate the tract sequentially. Nephroscopy was performed using a 26Fr nephroscope (Karl Storz[®], Tuttlingen, Germany) and stone fragmentation with an ultrasonic lithotripter (Swiss Lithoclast Master[®], EMS, Switzerland).

Intraoperative stone-free status was assessed by fluoroscopy and antegrade flexible nephroscopy.²⁴ Patients with a large stone burden could be staged at the surgeon's discretion, mainly in cases of a low chance of rendering the patient stone-free, significant bleeding or clinical instability. A 16Fr nephrostomy tube and a 4.8Fr × 26 cm

ureteral stent were placed, and ropivacaine 1% (20 ml) was injected into the tracts at the end of the surgery.

Low-dose NCCT and laboratory analyses were performed on POD1 in all cases (regular dose for patients with BMI >30 kg/m²). The nephrostomy tubes were removed before discharge, and the stents after 2 weeks. Another NCCT was performed on POD90 to assess the SFR for patients who had residual stones on the first examination. All CT scans were acquired using a 64-multislice Philips Scanner[®] and evaluated by a single radiologist blinded to the technique. Images were then imported into the software syngo[®].via (Siemens[®]) to

Table 1. Characteristics and demographic variables

	Supine PCNL (SUP)		Prone PCNL (PRO)		p Value
No. pts	56		56		
No. gender (%):					0.343
Male	23	(41.1)	28	(50.0)	
Female	33	(58.9)	28	(50.0)	
Mean yrs age±SD	50.3±12.4		52.0±13.4		0.476
Mean kg/m ² BMI (SD)	27.8±4.5		28.6±4.9		0.37
No. American Society of Anesthesiologists Score (%):					0.901
I	14	(25.0)	12	(21.4)	
II	36	(64.3)	38	(67.9)	
III	6	(10.7)	6	(10.7)	
No. previous stone-related surgery (%)	38 (67.9)		34 (60.7)		0.43
No. GSS (%):					0.225
3	35	(62.5)	41	(73.2)	
4	21	(37.5)	15	(26.8)	
No. laterality (%):					0.186
Rt	32	(57.1)	25	(44.6)	
Lt	24	(42.9)	31	(55.4)	
No. solitary kidney (%)	3 (5.5)		2 (3.6)		0.679
No. neurogenic bladder (%)	4 (7.1)		1 (1.8)		0.364
Mean±SD mm stone size	60.1±25.8		59.3±25.2		0.88
Stone vol (cm ³):					0.078
P50%	6.91		3.96		
P25%–P75%	2.89–11.17		2.40–7.05		
Mean±SD HU stone density	638.7±149.3		641.0±144.2		0.936
Mean±SD gm/dL preop hemoglobin	13.9±1.4		14.2±1.7		0.247
Mean±SD ng/dL preop creatinine	1.18±0.61		1.10±0.42		0.414
No. recurrent urinary tract infection (%)	18 (32.1)		21 (37.5)		0.552

assess stone size (defined as the summation of the largest diameters of all stones), volume, and mean stone density.

Sample Size Calculation and Statistical Analysis

Our null hypothesis was that SUP had an inferior immediate success rate to PRO; –15% was a noninferior margin, considered clinically significant. A 1-sided non-inferior test was used; the sample size was 56 in each group, considering a 10% rate of loss during followup, and a significance level set at 2.5%. The immediate success rates of SUP and PRO for complex stones were assumed to be 38.5% and 27.7%, respectively.¹⁷ Statistical significance was set at $p < 0.05$, and the power at 0.8.

Statistical analysis was performed using STATA®/SE 15.1 (StataCorp LLC, College Station, Texas) for Windows® (Microsoft®, Redmond, Washington). Categorical outcomes were compared using Fisher's exact test or the chi-square test. The means of continuous outcomes were compared using the Student's t-test (normal distribution) or the Mann-Whitney test (non-normal distribution). Differences between proportions, means, and 95% confidence intervals (CIs) are presented.

RESULTS

Of the 121 patients enrolled in the study, 117 received randomly assigned interventions and 56 completed the study in each group (fig. 1). Five patients were excluded after allocation, and none of the patients who underwent surgery were lost to followup. The mean age and BMI were 51.2 ± 12.9

Table 2. Primary outcome and success rates

	Supine PCNL (SUP)	Prone PCNL (PRO)	p Value
No. pts	56	56	
No. immediate success rate (%)	35 (62.5)	32 (57.1)	0.563
95% CI	48.5–75.1	43.2–70.3	
No. final SFR (%)	31 (55.4)	28 (50.0)	0.571
95% CI	41.5–68.6	36.3–63.7	

Immediate success rate: RFs <4 mm on POD1 CT; final SFR: absence of RFs on POD90 CT.

years and 28.2 ± 4.7 kg/m², respectively; 72 patients (64.2%) had previous stone-related surgery, 39 (34.8%) had recurrent urinary infections, and 36 (32.1%) had GSS 4. Preoperative stone size, volume, and mean stone density were similar (table 1).

Primary Outcome

The success rate on POD1 was 59.8% (SUP: 62.5% vs PRO: 57.1%, $p = 0.563$; 95% CI 50.1–69.0). The absolute difference was 5.4% (within the limit of 15%). The 1-sided 95% CI upper level was 9.8% (table 2).

Secondary Outcomes

The SFR on POD1 (no fragments) was 44.6%, which increased to 52.7% according to the POD90 CT findings (table 2). No significant difference was found in final SFR on POD90 (SUP: 55.4% vs PRO: 50.0%, $p = 0.571$; 95% CI –13.1–23.8; table 2).

Operative characteristics, including the number of punctures and the necessity of supracostal access, were comparable. SUP had a higher lower-pole first access (87.3% vs 39.3%, $p < 0.001$). The numbers of patients who needed at least 1 supracostal puncture ($p = 0.563$), stone culture ($p = 0.676$), stone analysis ($p = 0.715$), and urine puncture culture ($p = 0.490$) were similar. SUP had a shorter mean operative time (117.9 ± 39.1 minutes vs 147.6 ± 38.8 minutes, $p < 0.001$). The nephroscopy time was similar (SUP: 67.7 ± 31.9 minutes vs PRO: 65.4 ± 28.8 minutes, $p = 0.685$; table 3).

The overall complication rate was 37.5%. Of these, 8.9% had major complications. The complication rates were similar; however, PRO had a higher rate of Clavien ≥ 3 complications (14.3% vs 3.6%, $p = 0.045$). The sepsis rate was similar between the groups (PRO: 10.7% vs SUP: 3.6%, $p = 0.271$). The hemoglobin drop was also similar (SUP: 1.84 ± 0.13 vs PRO: 1.86 ± 0.15 , $p = 0.832$). Blood transfusion and embolization rates were the same (1.8% in each group). One patient in each group did not receive tranexamic acid, and no thromboembolic events were observed.

When the thoracic complications were analyzed separately, there were no significant differences. We observed similar rates of hydrothorax (5.4% in PRO, $p = 0.243$) and atelectasis (SUP: 3.6% vs PRO: 8.9%,

Table 3. Operative variables

	Supine PCNL (SUP)	Prone PCNL (PRO)	p Value
No. pts	56	56	
No. of punctures:			
P50%	2	1	0.245
P25%–P75%	1–4	1–4	
No. accesses (%):			0.257
1	25 (44.6)	31 (55.4)	
More than 1	31 (55.4)	25 (44.6)	
No. first pole accessed (%):			<0.001
Lower	49 (87.3)	22 (39.3)	
Upper	7 (12.7)	34 (60.7)	
No. supracostal access (%):	32 (57.1)	35 (62.5)	0.563
10th intercostal space	11 (19.6)	5 (8.9)	0.054
11th intercostal space	21 (37.5)	30 (53.6)	
No. staged procedure (%)	5 (8.9)	6 (10.7)	0.877
No. pos urine puncture culture (%)	10 (17.8)	13 (23.2)	0.490
No. pos stone culture (%)	17 (30.4)	15 (26.8)	0.676
Mean±SD mins operative time	117.9±39.1	147.6±38.8	< 0.001
Mean±SD mins nephroscopy time	67.7±31.9	65.4±28.8	0.685
No. stone analysis (%):			
Calcium oxalate	23 (41.1)	22 (39.3)	0.715
Struvite	28 (50.0)	27 (48.2)	
Others	5 (8.9)	7 (12.5)	
Length of hospital stay (hrs)			
P50%	43.3	45.4	0.049
P25%–P75%	42.1–46.2	42.4–66.1	
Min–max	22.7–165.0	30.2–238.2	0.203
Length of hospital stay excluding major complications (hrs):			
P50%	43.3	45.2	
P25%–P75%	42.1–46.2	41.9–51.72	
Min–max	22.7–165.0	30.2–96.2	

p=0.438). Hydrothorax occurred in 3 patients (all undergoing PRO), 2 of whom required thoracic drainage.

PRO had a longer hospital stay, with a median of 45.4 hours (30.2–238.2) vs 43.3 hours (20.3–165.0, p=0.049), not clinically significant. Excluding patients with major complications, the length of hospital stay was similar (SUP: 43.3 hours [22.7–165.0] vs PRO: 45.2 hours [30.2–96.2], p=0.203; table 4).

DISCUSSION

Prone PCNL is a well-established surgery, and it is the most common technique.⁸ Since the initial studies from Valdivia et al,⁶ SUP has been shown to be a good alternative and has gained much attention. However, its use for complex stones is still a matter of debate.²⁵ In the present study, we evaluated, in a prospective and randomized fashion, the impact of patient position on the outcomes of PCNL for complex stones. To define complex stones, we used GSS.¹⁸ Other nomograms have demonstrated similar success, but the GSS has been routinely employed in our cases, mainly because of its ease and speed of application.¹⁹

Table 4. Complications

	Supine PCNL (SUP)	Prone PCNL (PRO)	p Value
No. pts	56	56	
No. overall complication rate (%)	16 (28.6)	26 (46.4)	0.078
No. major complications (%)*	2 (3.6)	8 (14.3)	0.045
No. Clavien-Dindo (%):			
I	10 (17.9)	13 (23.1)	0.490
II	4 (7.1)	5 (8.9)	
III a	1 (1.8)	2 (3.6)	
III b	1 (1.8)	2 (3.6)	
IV a	0	2 (3.6)	
IV b	0	2 (3.6)	
No. thoracic complications (%):†	2 (3.6)	8 (14.3)	0.045
Atelectasis	2 (3.6)	5 (8.9)	0.438
Pleural effusion	0	3 (5.4)	0.243
No. sepsis (%):‡	2 (3.6)	6 (10.7)	0.271
No. septic shock requiring intensive care unit (%)	0	4 (7.1)	0.118
Mean±SD gm/L hemoglobin drop	1.84±0.13	1.86±0.15	0.832
No. blood transfusion (%)	1 (1.8)	1 (1.8)	>0.999
No. embolization (%)	1 (1.8)	1 (1.8)	>0.999

* Clavien ≥3.

† Thoracic complications: pleural effusion or clinically significant atelectasis.

‡ qSOFA ≥2.

Our main findings are the nonsignificant difference in the success rate on POD1 (SUP: 62.5% vs PRO: 57.1%, p=0.563), and no difference in the final SFR on POD90 (SUP: 55.4% vs PRO: 50.0%, p=0.571), suggesting that both techniques are adequate in this setting. To the best of our knowledge, this is the first randomized study to evaluate this specific factor, thereby answering the call of a previous meta-analysis for high quality data on this issue.¹¹ In that meta-analysis, the authors showed a comparable SFR between both positions (SUP: 80% vs PRO: 82%, evaluated by plain x-ray of the kidneys, ureters and bladder).¹¹ Our findings show that neither PRO nor SUP has a significant advantage in terms of SFR.¹ However, our results contrast with those of the CROES study, in which the authors concluded that PRO leads to a better SFR. One major criticism of that study is that cases were not randomized, and that the evaluation of success was not standardized, thus reducing its evidence level.^{8,15}

The success rate (52.7% in a single session) was comparable to that reported in the literature. In a recent trial, success rate for complex stones was 44.4%, showing that there is still room for improvement.²⁶ In the present study, an antegrade flexible nephroscope was used for the final inspection.²⁴ The use of endoscopic combined intrarenal surgery,²⁷ the prone split-leg position technique and the retrograde flexible ureteroscope at the end of surgery²⁸ are alternatives, not used in our cases, proposed to improve the outcomes. Moreover, due to stone complexity, surgeons could opt to stage the cases with a large stone burden before removal of all



Figure 2. CT scan showing relation of ribs to lung and pleura. *A*, medial slice, adjacent to spine. *B*, lateral slice, on tip of 12th rib (arrow).³⁰ This characteristic may explain why there are fewer thoracic lesions in SUP than in PRO even in supracostal cases, since punctures in SUP tend to be more lateral than in PRO.

fragments,²⁶ which occurred in 9.8% of the cases. In these patients, ureteral stents remained until second surgery.

Surgical times were analyzed in a standardized manner, different from other studies that led to misunderstandings. SUP had a lower total operative time (117.9 ± 39.1 minutes vs 147.6 ± 38.8 minutes, $p < 0.001$), but the nephroscopy time was similar (SUP: 67.7 ± 31.9 minutes vs PRO: 65.4 ± 28.8 minutes, $p = 0.685$). These results probably rely on the repositioning of the patient. There were no issues such as tracheal tube dislodgment or clinical instability, showing that the PRO is a safe option when performed properly.

Comparing the complication rates, an overall complication rate of 37.5% and a major complication rate of 8.9% were found, like those in the literature.^{12,15} The most serious complications were septic shock (qSOFA=3) which occurred in 4 patients, all in the PRO group. This finding may be due to the relatively low number of cases but also allows us to

hypothesize a possibly higher intrarenal pressure in PRO, which could lead to an increased pyelovenous reflux. Other authors have presented similar hypotheses regarding a higher incidence of fever; however, this has not yet been proven.^{10,11}

Upper pole access has been recommended when treating complex stones, but this access approach has a higher risk. Conversely, approaching the upper calyx through the lower calyx is feasible in SUP, justifying the choice for a lower pole access.²⁹ The upper calyx approach could be avoided to reduce complications due to the stone position, which occurred in 39.6% of PRO cases, showing that this strategy may not be suitable in all cases. Although the supracostal tract rate in SUP was comparable to that in PRO (57.1% vs 62.5%, $p = 0.563$), SUP apparently led to fewer thoracic complications. The lower thoracic complication rate in SUP may be because the pleura attaches medially to the 12th rib and laterally to the 11th or 10th ribs (fig. 2). In SUP, the puncture is usually more lateral, and may spare pleura from transection.³⁰ Also, thoracic violation could be prevented by the identification of the pleural reflection under ultrasound guidance.

This study had some limitations, such as radiation exposure. The CT evaluation on POD1 is controversial because it minimizes the SFR since spontaneous expelling of RFs may occur; however, it provides precise information regarding immediate success and complications. Another point is the use of 30Fr access instead of a smaller tract, but this has been the standard technique for complex stones. The relatively small number of patients may also be a point of criticism, especially for secondary outcomes. However, we believe that our study has several strengths that make it important, such as its multicenter randomized design, the few potential bias sources, a rigorous followup, and the systematic use of CT scans evaluated by a single blinded radiologist.

Prospective studies with a larger number of patients may be needed to reach definitive conclusions about the safety profile of each position, since our study was powered to evaluate the success rate. However, until large studies are available, our study offers high-level evidence supporting the use of both techniques for complex stones.

CONCLUSIONS

In this randomized study, patient positioning during PCNL for complex kidney stones did not have an impact on success rates. However, SUP might be associated with a lower high-grade complication rate than PRO, but this point warrants further studies.

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EDITORIAL COMMENTS

Although supine PCNL is not a novel approach for treatment of complex stones, the technique is certainly a frequently revisited topic in the endourology community (reference 6 in article). The authors present the first noninferior randomized controlled trial evaluating stone-free status of supine PCNL compared to the more traditional prone. The data highlight that supine PCNL fares no worse for patients with complex stones when it matters—being stone-free. Supine

positioning also notably had shorter operative times as well as lower incidences of Clavien grade ≥ 3 complications, although the latter should be confirmed with larger analysis.

As recent adopters of the supine PCNL at our institution, the emergence of these data support our observed clinical benefits of this approach that I would like to highlight. Sonographic access in supine positioning allows for identification and thus

avoidance of pleura and visceral structures with needle puncture. As upper pole access may be limited due to rib shadowing, interpolar or lower pole calyceal punctures tend to be selected. This may be a foreseeable prerequisite for reliance on flexible nephroscopy for complex stone, but incorporation of thulium mitigates the inefficiency of flexible stone treatment.¹ A more lateral and downward trajectory of the renal sheath associated with supine access encourages drainage of stone fragments and, as the authors postulate, decreases intrarenal pressure which may explain better stone clearance and lowered rate of urinary sepsis. An upright seated posture for supine

PCNL confers better ergonomics enjoyed by both surgeon and trainees. Lastly, familiarity with both supine and prone PCNL allows for flexibility of access when treating the toughest of cases.

Ultimately, the selection of positioning will be based on the surgeon's training and comfort level, but I firmly predict a rising trend of supine PCNL with emergence of strong data as presented by the authors.

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Since its description by Valdivia in 1987 (reference 6 in article), supine PCNL has been gaining more and more interest. According to European Association of Urology guidelines, prone position is preferred for multiple accesses.¹ In particular, complex stones have been considered as a nonideal indication for supine approach due to challenging upper-pole puncture. As for many new techniques, until recently there was a paucity of high-quality noninferiority studies, confirming safety and efficiency of supine PCNL. For example, in a meta-analysis published in 2019, SFR was evaluated with CT only in 4 out of 18 randomized controlled trial studies.² In addition, these studies had some important limitations, such as nonstrict definition of SFR and complex stones as exclusion criterion.

The current study is designed as a randomized 2-center one comparing prone and supine PCNL in patients with complex renal stones, defined as Guy's Stone Score 3–4. The authors showed an equivalent efficiency of prone and supine PCNL with an operative time benefit for the latter. Moreover, there were fewer thoracic complications in the supine group.

However, there are some limitations that should be pointed out. The authors used different definitions for evaluating SFR at different time points. On POD1, stone fragments smaller than 4 mm were defined as “clinically insignificant,” while on POD90 only absence of any residual stones was considered. Though that was explained in the details, it may cause some confusion. Furthermore, all patients were stented during PCNL which is not a standard practice. Since the second stage was not performed until 3 months later, 9.8% of patients had a ureteral stent for quite a long time. In addition, the study is underpowered for evaluating thoracic complications as a secondary end point.

In conclusion, urologists are still recommended to perform PCNL in the position that is most familiar to them, since there is no difference between the 2 positions, even in complex cases.

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REPLY BY AUTHORS

The percutaneous treatment of complex renal stones is a hot topic in endourology and the debate on the

superiority of prone over supine position is still a matter of debate (reference 8 in article). Randomized

controlled trials are always to be welcomed to bring clarity to key unanswered questions.

With this study, we intended to give high-level evidence for this debate. Our paper states the non-inferiority of supine over prone PCNL in terms of success rates for complex stones. The standardization of the procedures and the blindness of the radiologist evaluating their results are some points of strength.

We highlight that both techniques are adequate to treat complex stones. To the best of our knowledge, this is the first randomized study to evaluate this specific factor. Moreover, we also found higher major complication rates on prone position, especially sepsis. This fact led us to hypothesize that prone position

may lead to a higher intrarenal pressure, favoring sepsis.¹ Since our study was not powered to evaluate complications, prospective studies with a larger number of patients are needed to reach definitive conclusions.

Different than the previous studies (reference 8 in article),² we can state that stone-free rates do not favor prone PCNL, and that the choice of patient position could be tailored according to surgeon's preference. However, in high-risk patients, especially to infectious complications, supine may have a safer profile and may be associated to lower sepsis rates.

We sincerely appreciate all the comments made by the authors and the opportunity to clarify some aspects of our paper.

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