Comparison of Success Rate in Complete Supine Versus Semi Supine Percutaneous Nephrolithotomy: (The first pilot study in randomized clinical trial)

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Purpose: To compare outcomes and complications of percutaneous nephrolithotomy (PCNL) in the complete supine versus semi supine position in order to select the best position.

Materials and Methods: In this clinical trial, between July 2011 and May 2014, a total of 44 patients who presented for PCNL were prospectively enrolled and randomly divided into 2 groups [complete supine (n=22), and semi supine (n=22)]. The results in both positions were compared regarding the complexity and outcomes. Stone free rate was considered as a main target of the study. However, it was the first study to focus on overlapping the vertebral density during the access.

Results: The two groups were comparable in age, gender, body mass index, and preoperative glomerular filtration rate, hemoglobin and creatinine. The mean operative time was significantly shorter for complete supine versus semi supine (36.68 ± 14.12 min versus 47.50 ± 16.45 min, P = .024). At the angle of 0°, overlapping with the spine occurred in 7 patients (31.8%) in semi supine group and just in 1 patient (4.5%) in complete supine group. Also, overlapping with the edge of bed occurred in 10 cases (45.5%) of complete supine and 1 (4.5%) of semi supine; the differences were statistically significant (P = .023, P = .002, respectively). No significant difference was found between the two groups in terms of stone free rate and complications.

Conclusion: Although, we had to convert two cases from semi supine into the complete supine position but we have demonstrated that PCNL in both positions is safe, effective and suitable for the patients. The stone free rate was similar in both groups. But the complete supine position is associated with a significantly shorter postoperative hospital stay and operative time, which may improve ease and safety of PCNL for patients.

Key words: complexity; fluoroscopy; operative time; percutaneous nephrolithotomy; supine; stone free rate.

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is considered the treatment of choice for most renal stones, especially for large, complex and staghorn calculi. This technique has long been performed in the prone position. But recently, there have been many reports about PCNL in the supine position and complete supine position.⁽¹⁻⁴⁾

Supine position in PCNL is a strong alternative to prone position and is commonly performed in various modification, including the Valdivia, Galdakao-modified Valdivia, modified supine, semi supine and complete supine PCNL (csPCNL).^(1,5)

The supine position as compared to the prone position has numerous advantages such as convenience for patient and surgeon during surgery, low pressure in pyelocalyceal system thus decreasing the migration of residual stones, evacuation of stone fragments, not exposing the surgeon hands to x-ray⁽⁶⁾, rapid access to air way that is important in morbidly obese patients⁽⁵⁾, possibility to perform coincidental the PCNL and ureteroscopy for treatment complex stones^(1,5,7-13), and less bleeding ^(5,14-15), however this method is not familiar to most of the endourologists yet and is neglected by most urologists.^(2,16-17) Some controversial reasons for less trends of urologist to use supine position despite its benefits include: unfamiliar and insufficient training for PCNL in supine position in most educational institutions, reducing the pressure in the collecting system and collapsing the pyelocalyceal system and therefore decreasing operating field⁽¹¹⁾, anteromedial kidney displacement during accessing⁽¹⁸⁾, and overlapping the stone with vertebra in semi supine position.⁽¹⁸⁾

Because of many advantages of supine PCNL, we believe the conflict between supine and prone will terminate in the coming years but the next question will remain as to which kind of supine is appropriate?

In the present clinical trial we compared outcomes and complications of PCNL in the complete supine position versus the semi supine position to choose a better position for patients.

MATERIALS AND METHODS

In this clinical trial, 44 patients were enrolled. In all patients informed consent was taken and then patients were randomly allocated to two groups using random block method (ratio 2:2) from July 2012 to May 2014.

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Characteristics Complete Supine group (N=22) Semi Supine group (N=22)					
			<i>P</i> -Value		
Gender (%)					
Male	8 (36.4)	10 (45.5)	0.380		
Female	14 (63.6)	12 (54.5)			
Mean age ± SD (year)	52.59 ± 11.77	47.55 ± 12.92	0.183		
Mean BMI ± SD	27.41 ± 4.11	27.07 ± 5.18	0.812		
Previous intervention					
ESWL					
Yes	7 (31.8)	6 (27.3)	0.500		
No	15 (68.2)	16 (72.7)			
Open/PCNL					
Yes	9 (40.9)	5 (22.7)	0.166		
No	13 (59.1)	17 (77.3)			
Stone number (%)					
Single	8 (36.4)	9 (40.9)	0.500		
Multiple	14 (63.6)	13 (59.1)			
Stone location (%)					
Only One Calyx	6 (27.3)	2 (9.1)			
Only Pelvis	4 (18.2)	3 (13.6)	4 (18.2)		
Only Upper Ureter	0 (0.0)	1 (4.5)			
Multiple Locations	11 (50.0)	12 (54.5)			
Staghorn	1 (4.5)	4 (18.2)			
Complex stone (%)					
Yes	12 (54.5)	16 (72.7)	0.147		
No	10 (45.5)	6 (27.3)			
Opacity (%)					
Radiopaque	21 (99.5)	22 (100.0)	0.500		
Radiolucent	1 (4.5)	0 (0.0)			
Hydronephrosis (%)					
Yes	16 (72.7)	19 (86.4)	0.228		
No	6 (27.3)	3 (13.6)			
Stone burden ±SD	35.41 ± 10.89	34.23 ± 9.93	0.709		

 Table 1. Demographics of the patients

All patients underwent semi and complete supine PCNL by an expert surgeon.

Group A (22 patients) underwent complete supine position and group B (22 patients) underwent semi supine position (**Figure 1**). Included patients were at least 12 years of age, had single or multiple stones in the upper urinary tract (calyx, the pelvis, upper ureter) with stone burden ≥ 2 cm, lower calyx stones with stone burden ≥ 1.5 cm, SWL-resistant stones ≥ 1 cm. Excluded patients were those with uncontrolled coagulopathy, pregnancy, history of immunosuppression, renal anomalies and untreated UTI (urinary tract infection), upper urinary tract stones with the stone burden ≤ 2 cm, lower calyx stones with stone burden ≤ 1.5 cm and complete staghorn stones.

All PCNLs were performed under fluoroscopic guidance in subcostal access method by a single surgeon who had previous experience of PCNL in the complete supine and semi supine position and general anesthesia was used for all the patients. In complete supine position, patients were located near the edge of the bed, but elevation on the flank and changes in lower limb did not occur. Lower limbs were in full extension and upper limbs were in abduction and extension, as the same technique that the authors described in 2008.⁽¹⁾ In semi supine position, by a 3-liter saline bag, 20-30 degrees elevating on the ipsilateral flank was created, but the position of upper and lower limbs was similar to com-

Characteristics	Complete Supine group (N=22)	Semi Supine group (N=22)	P-Value
Access calyx (%)			
Upper	4 (18.2)	0 (0.0)	
Middle	6 (27.3)	6 (27.3)	0.102
Lower	12 (54.5)	16 (72.7)	
Kidney displacement with 18 gauge needle (mm)	9.55 ± 4.36	10.50 ± 4.51	0.480
Kidney displacement with 9Fr amplatz dilator (mm)	15.14 ± 4.88	17.27 ± 5.40	0.176
Kidney displacement with 28Fr amplatz dilator (mm)	20.05 ± 4.86	22.59 ± 7.51	0.191
FST (Fluoroscopic Screening Time) (second)	86.76 ± 47.42	110.23 ± 49.67	0.121
Access time (second)	133.55 ± 129.37	133.41 ± 175.18	0.707
Operation time (minutes)	36.68 ± 14.12	47.50 ± 16.45	0.024
Post Cr ±SD (mg/dL)*	1.13 ± 0.49	0.979 ± 0.19	0.179
Post GFR ±SD (%)*	73.61 ± 23.07	80.52 ± 19.94	0.294
Post Hb \pm SD (mg/dL)*	$12.62 \pm .94$	12.97 ± 1.59	0.512
Postoperative Hospital stay (days)	1.91 ± 1.23	2.27 ± 0.703	0.057
Stone free rate Yes / No	19 (86.4) / 3 (13.6)	18 (81.8) / 4 (18.2)	0.500
Changing the position	0(0.0)	2(10.0%)	0.221
Tubeless **	22	22	-
Feasibility to get the access	22	22	-

Table 2. Intraoperative and postoperative parameters in 2 groups.

* Post: Post-operative

** Without nephrostomy tube

plete supine position. (Figure 2)

In all PCNLs, the puncture was done between middle and posterior axillary line with an 18 gauge needle in subcostal position. On the base of our previous experiences and other studies this area is safe to enter the kidney.^(2,7,13,19)

Fluoroscopy was used for intraoperative monitoring as well as pneumatic method for lithotripsy. One shot dilation was done to dilate (first by 9 Fr dilator and then 28 Fr Amplatz dilator) and 30 Fr Amplatz sheath was used. Nephrostography was applied before finishing the surgery to diagnose residual stones and extravasation. In the end, all patients in both groups were tubeless. GFR was estimated by the MDRD formula. Hemoglobin and creatinine were assessed the day before surgery and 6 and 24 hours after surgery, respectively. Blood transfusion was administered when hemoglobin dropped to less than 10. Stone free status was considered as residual stone less than 4 mm.

The stone free rate was main target of study to compare the feasibility of semi supine and csPCNL. Other outcomes and complications were measured as a second endpoint of the study.

The assessment of outcomes and complications was done by a blind analyzer. Independent t-test and in case of non-normality the Mann-Whitney test were used to

Table 3: Complications in 2 groups					
Characteristics	Complete Supine group (N=22)	Semi Supine group (N=22)	<i>P</i> -Value		
Complication (%)					
Yes	4 (18.2)	2 (9.1)	0.332		
No	18 (81.8)	20 (90.9)			
Clavien classification					
Grade 0	18 (81.8)	20 (90.9)			
Grade 1	1 (4.5)	1 (4.5)	0.697		
Grade 2	2 (9.1)	1 (4.5)			
Grade 3	1 (4.5)	0 (0.0)			

 Table 3: Complications in 2 groups

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Characteristics	Complete Supine group (N=22)	Semi Supine group (N=22)	P-Value
Overlapping with the spine at the angle of 0° (%)			
Yes	1 (4.5)	7 (31.8)	0.023
No	21 (95.5)	15 (68.2)	
Overlapping with the spine at the angle of 30° (%)			
Yes	2 (9.1)	2 (9.1)	0.697
No	20 (90.1)	20 (90.1)	
Overlapping with the edge of the bed at the angle of 0° (%)			
Yes	10 (45.5)	1 (4.5)	0.002
No	12 (54.5)	21 (95.5)	
Overlapping with the edge of the bed at the angle of 30° (%)			
Yes	0	0	-
No			

Table 4: Overlapping with the spine and the edge of the bed at the angle of 0 and 30 degrees in 2 groups

compare quantitative variables between the two groups, and for qualitative variables, Chi-Square test or Fisher exact test was used. Data were analyzed using SPSS software version 19. The criterion for statistical significance was set to P < 0.05 for all comparisons.

The institutional review board and ethical committee of Guilan University of Medical Sciences approved the protocol of this study. The trial was registered at www.irct. ir with registration number IRCT201405041853N10.

RESULT

Twenty two patients underwent complete supine and another twenty two patients underwent semi supine PCNL. The preoperative parameters of the patients were comparable in both groups, with no statistically significant difference (P > .05). (**Table 1**)

No differences in the history of previous intervention such as ESWL (Extra Shock Wave Lithotripsy), open surgery and PCNL were found between groups.

The demographic data of patients and characteristics of the stones are presented in **Table 1**.

We were able to obtain access in all patients of the two groups. The mean operative time in complete supine group was 36.68 ± 14.12 minutes that in comparison to semi supine group 47.50 ± 16.45 was significantly lower (P = .024). Also, hospitalization after operation in complete supine group was lower than semi supine group (1.91 ± 1.23 , 2.27 ± 0.703 days, respectively). Although there was an obvious difference between semi and csPCNL, it was not statistically significant (P = .057).

Although, shorter time was found toward fluoroscopic screening time in the complete supine group (86.76 ± 47.42 seconds for the complete supine versus 110.23 ± 49.67 seconds for the semi supine), the difference was not statistically significant (P = .121). Stone free status was achieved in 19 patients (86.4%) in complete supine group and in 18 (81.8%) patients in semi supine group, that was nor statistically significant (P = .500).

During the last minutes of the operation in two semi supine cases we had to convert the position into the complete supine to achieve the better stone free rate because of wider space for nephroscop maneuver and lack of vertebral density interfering in csPCNL. The main intraoperative and postoperative parameters are summarized in **Table 2**.

Four patients in complete supine group and 2 patients in semi supine group had complications. Four patients experienced complications in complete supine group: gross hematuria in 1 patient, hemoglobin drop requiring transfusion in 1 patient, gross hematuria and hemoglobin drop requiring transfusion in 1 patient had been reported and 1 patient had all of these complications plus urinary retention with clots. In semi supine group, fever was observed in 1 patient and another patient experienced hemoglobin drop requiring transfusion.

In complete supine group, 3 patients (13.6%) received blood transfusions and 1 patient (4.5%) underwent fluids treatment. In semi supine group, 1 patient (4.5%) was treated conservatively and 1 patient (4.5%) was treated with blood transfusions. No significant differences between patients in the two groups were observed for complications (P = .332).

The complications on the base of Clavien categories (grades 1, 2 and 3) in both groups are shown in Table 3. Overlapping with the spine at the angle of 0° occurred in 7 patients (31.8%) in semi supine group and just in 1 patient (4.5%) in complete supine group, which was statistically significant (P = .023). Two patients in both groups had overlapping with the spine at the angle of 30°. There was significant difference in the overlapping with the edge of the bed at the angle of 0° in two groups (10 patients (45.5%) in group A versus 1 patient (4.5%) in group B; P=.002). No patient in both groups had overlapping with the edge of the bed at the angle of 30°. (Table 4)

DISCUSSION

For many years, PCNL was performed in the prone position. Studies have shown that the supine position is as effective and safe as prone position in PCNL. ^(6,13,14,20) Although, the stone free rates, and rates of complications and transfusion of both methods are equivalent to each other^(19,21) but supine position does not harbor

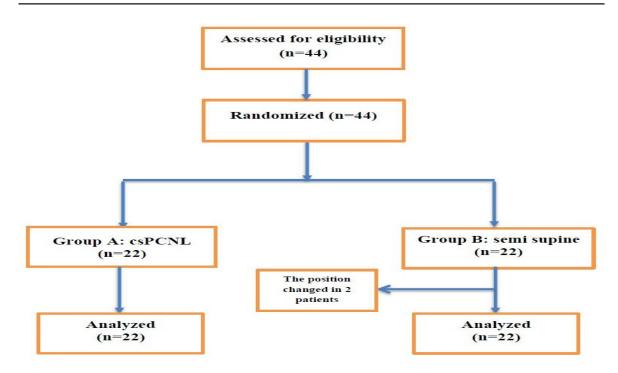


Figure 1: Flow diagram of the study.

some disadvantages of prone position such as necessity to reposition the patient after ureteral catheter insertion, increased risk of pulmonary and anesthetic complications, risk of colonic, central and and peripheral nervous system injuries.^(6,7,13,14,18,20,22,23)

The supine position offers several technical advantages for the surgeon such as evacuation of stone fragments, shorter operation time, feasibility to do cystoscopy or ureteroscopy coincidentally, less patient handling, siting position for the surgeon, easier access to the airway, feasibility to get the access to the upper calyces, and etc. Today, supine position is being performed in various safe and effective types such as: Valdivia, Galdakao-modified Valdivia, and modified supine, semi supine and complete supine.^(1,5-6)

Our results showed that there were no significantly difference between the two study groups in terms of sex, age, body mass index, diabetes and preoperative glomerular filtration rate, creatinine and hemoglobin.

Tubeless PCNL was found a safe and effective procedure with reduced postoperative hospital stay and pain even for staghorn stone and more ease and comfort to the patient.⁽²⁴⁻²⁶⁾ Tubeless PCNL had similar results in csPCNL compared to the prone position^(10,24) so, this method was performed for all patients in this study. We were able to get access in all patients of two groups

in this study, this confirms that PCNL in complete and semi supine position is feasible as other studies mentioned. $^{(1,2,6)}$

In our study, history of SWL and history of open nephrolithotomy or PCNL were evaluated but no significant differences was found between the two studied groups (P = .500, P = .166). Therefore, these factors could have little influence on the outcomes. In another study

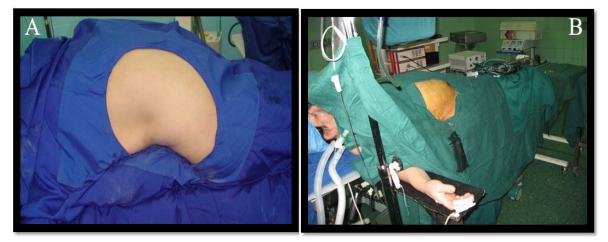


Figure 2: A: semi supine position, B: csPCNL position

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in 2011 by Falahatkar et al., previous open surgery had no effect on kidney stone free rate and complications after the complete supine PCNL.⁽²⁷⁾ Yuruk et al. found that PCNL after failed ESWL is safe and successful but it makes the procedure more difficult with prolonged operative time and fluoroscopic screening time.⁽²⁸⁾ Also, in 2014 Khorrami et al. reported that PCNL can be performed in patients with one or more open stone surgery history successfully without further complications.⁽²⁹⁾ We believe the history of open nephrolithotomy can make the access more difficult. The reasons of this difficulty is the existence of fibrosis and previous sutures along the access pathway.

Mean access time and operative time were 133.55 ± 129.37 seconds and 36.68 ± 14.12 minutes in complete supine group, and 133.41 ± 175.18 seconds and 47.50 ± 16.45 minutes in semi supine group. There was no significant difference in the access time (P=.707) but the duration of operative time was significantly higher in semi supine group (P = .024).

The longer operative time in semi supine position could be related to some factors such as less number of patients, the duration that needed to prepare the position and because of the less experience of the surgeon in this position.

Mean operative time was reported 11.52 ± 44.5 minutes⁽²⁾ in the studies of Xu et al., 123.5 ± 51.2 min by Honzek et al.⁽³⁰⁾ 162.1 minutes by Neto et al.⁽¹⁷⁾ and 65 minutes by Rana et al.⁽²⁶⁾. In two previous studies by Falahatkar et al. the mean operative time of complete supine group were reported 74.7 ± 25.1 minutes and 95.14 ± 26.57 minutes.^(1,10)

Although, two meta-analysis have shown the superiority of supine PCNL regarding operative time^(19,21) but we should mentioned the operative time can be affected by several factors including the position of the patient, stone characteristic, surgeon's experience, migration of stone toward upper calyx and etc.

Stone free rate is one of the most important outcomes of PCNL that is measured by researchers in all studies of this field to evaluates the success rate. Stone free rate has been reported in different studies ranges from 70.2% to 89% for supine position.^(2,5,7,13,26)

We believe that the stone free rate like other outcomes can be affected by several factors such as: stone characteristic, and also the experience of the surgeon.

In two meta-analysis stone free rate in supine position was found the same as prone position [(82.4%) in the supine position versus 82.1% in the prone position) (¹⁹), (83.5% in the supine position versus 81.6% in the prone position) (²¹)] but a meta-analysis in 2014 found significantly lower stone-free rate in the supine position (72.9%) compared to prone position (77.3%).⁽⁴⁾

In this study the stone free rate was 86.4% (19/22) in csPCNL versus 81.8% (18/22) in semi supine group but this difference was not statistically significant (*P* = .500).

The cushion under the patient in some cases of semi supine precluded to have a complete look to calices, as we mentioned it was a difficulty of semi supine position that would need to remove the cushion and consequently to change the position to csPCNL.

Hospital stay after surgery was 1.91 ± 1.23 day in complete supine, and 2.27 ± 0.703 days in semi supine. No statistically significant difference was observed between the two groups (P = .057). In comparison with

other studies such as Honzek et al. $(3.4 \pm 1.9 \text{ days})^{(30)}$, Steele et al. $(3 \text{ days})^{(22)}$, Neto et al. $(4.5 \text{ days})^{(17)}$, Falahatkar et al. $(3.7 \text{ days})^{(6)}$, Rana et al. $(2 \text{ days})^{(12)}$ and Pan et al. $(7.63 \pm 2.39 \text{ days})^{(8)}$ duration of hospitalization after surgery in our study was shorter in both groups.

Although, hospital stay of patients depends on some factors such as bleeding, fever, infection, pain and discomfort, trauma to others organs and etc, but we believe the policy of the surgeon has an important role in this matter, because nowadays surgeons trend to discharge the patients sooner.

According to an article previously published by the authors, the kidney displacement was measured with transparent graph paper (covered in 5 × 5 mm squares) during accessing to target calyx with 18 gauge needle, and dilation by 9 and 28 Fr amplatz dilators.⁽¹⁸⁾ The mean kidney displacements were respectively 9.55 ± 4.36 , 15.14 ± 4.88 and 20.05 ± 4.86 mm in the complete supine group and 10.50 ± 4.51 , 17.27 ± 5.40 and 22.59 ± 7.51 mm semi supine group that was not statistically significant (P = .191, .176 and 480 respectively). In Shoma et al. study, anteromedial kidney displacement in the supine PCNL was more than prone PCNL (11% versus 0%).⁽⁷⁾

In 2011, Falahatkar et al. showed that the mean kidney displacement in the complete supine PCNL in stage 1 and 2 (When the 18 gauge needle and 9Fr dilator had moved the kidney) was significantly lower than prone group. This amount for stage 3 (When the 28Fr Amplatz dilator had moved the kidney) was lower in complete supine group too, however it was not statistically significant.⁽¹⁸⁾

There was a little study to show kidney displacement during the PCNL. However, it seems that the kidney displacement is so different in case by case and the position of the patients is one of the factors that can influence on kidney movement. Nevertheless, the concrete declaration in these field requisites further studies.

Our results showed that there was no significant difference between two groups for overlapping at the angle of 30° with the spine.

Our study has shown that in semi supine position overlapping of kidney with spine might be an important problem and one of the important difficulties in csP-CNL was interfering of the edge of the bed during the access that these difficulties were solved with the increasing of the angle of fluoroscopy. So, this simple but useful maneuver should be in the surgeon's mind during the surgery.

This study was performed in a center which has extensive prior experience in csPCNL. Therefore, the results cannot be simply generalized to other centers. Another limitation of this survey was the small sample size of our study.

CONCLUSIONS

There were some differences between csPCNL and semi supine PCNL in our study. The advantages of csP-CNL were: not using cushion, more simple position, little interference with overlapping with spin density, perhaps shorter operative time and hospital stay, evacuation of stone fragments, proper stone free rate, and no need to convert the position. But there were some disadvantages for csPCNL such as: interfering of bed edge during the access, less familarity to many urologists. Although, in two cases we had to convert the position from the semi supine procedure to complete supine position but our results have clearly shown that complete supine and semi supine PCNL were safe, feasible and also there were a little difference between them. We believe in the future the battle is among modification of supine position for PCNL. So, further prospective studies should be conducted in the future to detect the complexity and benefits of these methods.

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CONFLICT OF INTEREST

The authors declare that they have no competing financial interests in relation to the work described.

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