

A randomized study comparing conventional percutaneous nephrolithotomy versus check pyeloscopic percutaneous nephrolithotomy

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Abstract

Objective: The objective of this study is to compare the advantages of check-pyeloscopic percutaneous nephrolithotomy (CP-PCNL) over conventional PCNL (C-PCNL) in the management of renal calculi.

Materials and Methods: All patients with renal calculi requiring PCNL who attended the department of urology in a tertiary care center from December 2016 to October 2018 were included in the study. The patients were randomized into two groups of 50 each. Each group underwent PCNL in a conventional or check pyeloscopic method, respectively.

Results: A total number of complications were more in C-PCNL group comprising of two pelvic tears, 8 infundibular tears, 1 minor urothelial injury, 2 cases of bleeding lasting for more than 24 hours, while in CP-PCNL group, complications were less (comprising of 1 minor urothelial injury and 1 case of infundibular tear). Statistical analysis was used to compare both the groups, and the results were statistically significant ($P = 0.027$).

Conclusion: Check pyeloscopy at the time of PCNL is a safe, effective, and economical technique. This study shows that the complications such as blood loss, urothelial injury, and postoperative pain are less when check pyeloscopy is done during PCNL.

Keywords: Alken, check pyeloscopy, percutaneous nephrolithotomy

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INTRODUCTION

The incidence of renal calculi has increased across all age groups, sex, and race probably due to lifestyle changes. In 1976, Fernstorm and Johansson reported for the first time, removal of renal stones through percutaneous route. Percutaneous nephrolithotomy (PCNL) is now the gold standard for the management of renal calculus. The advantages of PCNL are mainly because of avoiding the

long incision of open surgery result in lesser morbidity and shorter hospital stay. It scores over extracorporeal shock-wave lithotripsy (ESWL) in a way that stone free rates are much higher in case of PCNL.

PCNL is the preferred technique for treating large stones (>2 cm in diameter) within the kidney and has almost totally replaced open nephrolithotomy. As more and more of

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PCNL are being performed nowadays, the complications also are becoming more common. The bacterial release after fragmentation of the calculi or from surgical manipulation is the basic factors responsible for sepsis-related events.^[1] Other factors can also increase the risk of infection after PCNL.^[2-4] PCNL has three basic steps: first the puncture, second dilatation, and finally stone retrieval. Since most of the PCNLs are performed under fluoroscopic guidance, the dilatation of the nephrostomy tract over the initial puncture guidewire into the collecting system can be judged by fluoroscopic image and efflux of saline during dilatation. However, none of the above methods are accurate in determining whether the dilating tract is under-dilated or over-dilated. Over dilatation of the tract can result in grave complications such as pelvic tear, disruption of the pelvi-ureteric junction, and bleeding. All this can result in longer operative time, greater morbidity, and even mortality. Hence, in order to avoid complications, we identified a safe technique of visually inspecting the tract to confirm entry into collecting system using a small thin ureteroscope. We coined the term “Check Pyeloscopy” for this technique.^[5]

MATERIALS AND METHODS

This study was conducted between December 2016 and October 2018 in a tertiary care hospital where the large number of patients with renal stone disease attend urology department. We included 100 patients with renal calculi in our study. This study was conducted after obtaining approval from the Institutional Ethics Committee. Informed consent was obtained from all the patients who participated in the study.

In conventional PCNL (C-PCNL) under fluoroscopic guidance, the kidney is punctured and dilated up to the desired tract size, whereas in check pyeloscopic PCNL (CP-PCNL) tract is dilated up to a minimum size of 12 Fr and after that the Alken's cannula sheath are placed. The inner cannula is removed. Using a thin ureteroscope (4–5.5fr), a checkscopy is done through the Alken's sheath. Once entry into the collecting system is confirmed, one more safety guidewire is placed into the ureter under direct vision. If the track is found under dilated, ureteroscope is advanced slowly following the guidewire and the sheath re-positioned over it before further dilatation. If the track is found overdilated, ureteroscope is withdrawn outward following the guidewire and the sheath re-positioned into the collecting system before further dilatation. Both these steps were assisted by fluoroscopy to prevent false tracts during visualization. Then, ureteroscope is removed, and a guide rod is placed over the working guidewire through the Alken's sheath into the correct position under fluoroscopic

guidance. The rest of the procedure is similar to a standard PCNL. After fragmentation of stone and clearance, we keep nephrostomy through Amplatz sheath and 6fr DJ stent in all cases. The patient is catheterized with Foley's catheter. In the postoperative period, if there is no fever, bleeding and features of sepsis, PCN tube was removed. The patient is then will be on Urethral Foley for 24 h, if there is no urine leak from PCN tract, Foley is removed and patient discharged. Stent removal is done after 1 month.

Statistical analysis

Statistical analysis was carried out using the SPSS software version 19.0 (IBM SPSS, Chicago, IL, USA) software with regression modules installed. Descriptive analyses were reported as mean and standard deviation of continuous variables. Kolmogorov–Smirnov curve was used to observe for the normal distribution of the data. Mean, median, and standard deviation were used. Complications, blood loss, and postoperative fever were compared in both the groups using the Chi-square test. Pain score, time taken to revert to daily activities, and duration of surgery were compared using the independent *t*-test.

RESULTS

The patient demographics with relation to age, sex, side, and stone burden were comparable and are given in Table 1. All PCNL were done in the prone position. Sub-costal approach was taken in seventy patients. Supra-costal approach was taken in 27 patients. Combined approach was taken in three patients. Lower pole puncture was done in 32 patients; mid-pole puncture was done in 40 patients, and upper pole puncture was done in 20 patients. Direct stone puncture was done in five patients. Multiple punctures were required in three patients [Table 1]. When it comes to the duration of procedure, overall increase in time was found in CP-PCNL group [Figure 1]. Check pyeloscopy time ranged from 4.5 min to 9 min. Time for check pyeloscopy was added in the total duration of surgery in CP-PCNL group. Minimum time for check pyeloscopy was 4.5 min, and maximum time was 9 mins. Mean time was 6.4 + 1.2 min [Table 2].

In 27 cases, under-dilatation was seen in check pyeloscopy, in three cases, overdilatation was seen, and in 20 cases, the sheath was within the system. Intraoperative complications in C-PCNL group occurred in 13 patients, whereas in case of CP-PCNL, it was noted in only two cases [Table 3]. Pain score grading was done based on the Visual Analog Score (VAS). Most of the patients had mild pain (VAS score 0–3). Twenty-six patients (16 in C-PCNL and 10 in CP-PCNL) had moderate pain (VAS score 4–7). One patient

Table 1: Patient Demographics in both groups

	C-PCNL	CP-PCNL
Age in years	21-65 (Mean 42.7+11.4)	26-70 (Mean 42.9+11.5)
Sex Male	34	32
Female	16	18
Side Right	23	22
Left	27	28
Stone Burden Pelvis	37	39
Pure Calyceal	7	6
Partial Staghorn	4	4
Complete Staghorn	2	1
Approach Sub-costal	39	31
Supra-costal	9	18
Combined	2	1
Site of Entry Lower calyx	19	17
Mid calyx	22	18
Upper calyx	6	14
Multiple	2	1

C-PCNL: Conventional Per-Cutaneous Nephrolithotomy, CP-PCNL: Check Pyeloscopic Per-Cutaneous Nephrolithotomy

in C-PCNL had moderate-to-severe pain (VAS score 7–10). Most of the patients required analgesics not more than 4 days. Only nine patients required analgesia for more than 4 days. Most of the patients were discharged within 6 days. Five patients (all in CPCNL group) stayed for 7 days. Two patients (1 in each group) stayed for 8 days [Table 4].

Data analysis

Fifty patients each were included in both the groups. In C-PCNL group, age of the patients was between 21 and 65 years. The mean age in PCNL group was 42.26 +11.4. In CP-PCNL group, the age of the patients was between 26 and 70 years.

The mean age in this group was 42.98 + 11.5. The total number of complications was more in C-PCNL group comprising of 2 pelvic tears, 8 infundibular tears, 1 minor urothelial injury, 2 cases of bleeding lasting for more than 24 h, while in CP-PCNL group, complications were less comprising of 1 minor urothelial injury and 1 case of infundibular tear.

Both the groups were compared for the complications using the Chi-square test, and the result was found to be statistically significant ($P = 0.027$). Bleeding lasting more than 24 h was more in C-PCNL group compared to CP-PCNL group. Even though none of the patients required blood transfusion in the postoperative period in both the groups, it was statistically significant ($P = 0.03$) postoperative fever (>100 F) were seen in 17 patients. Out of these patients, 11 patients were in PCNL group, and rest of the patients were in check-PCNL group. The Chi-square test was used for the comparison of postoperative fever in both the groups. P value was seen to be insignificant.

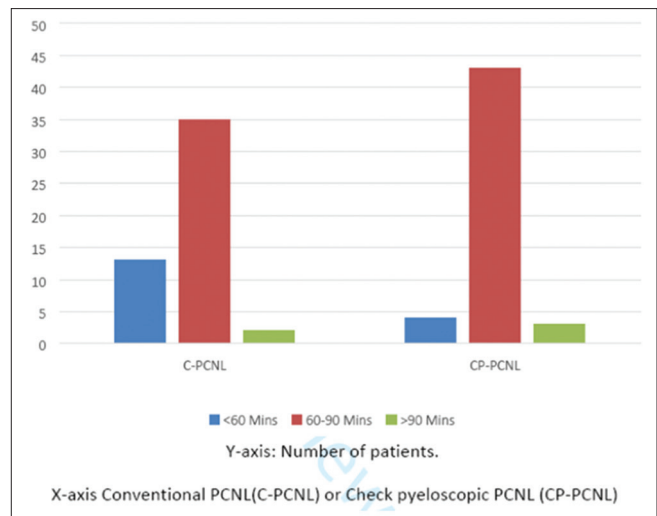


Figure 1: Shows the operative duration of the procedure in both the groups in the bar chart

Duration of surgery (defined as time from prone positioning to insertion of nephrostomy or closure of the incision) was more in CP-PCNL group. Mean duration was 69.14 + 8.6 min in CP-PCNL group, whereas in C-PCNL group, it was 67.45 + 12.6 mins. This did not reach statistically significant value.

Time to return to daily activities was less in CP-PCNL group. Mean duration was 4.86 + 1.2 days in CP-PCNL group, whereas in C-PCNL group, it was 4.53 + .7 days. Descriptive statistics and analysis are given in Table 5 for pain score, duration of procedure, and return to daily activity. These variables were compared in both the groups using the independent t-test. P value in case of pain score was found to significant ($P = 0.000$). Pain was significantly less in CP-PCNL group. P values in case of duration of surgery and time to return to daily activities were found to be insignificant. ($P = 0.44$ and 0.11, respectively).

Persistent PCN site urine leak (>24 h) after the removal of nephrostomy tube was found in patients in both groups and all settled with conservative measures. In C-PCNL group, five patients had urine leak for more than 24 h. All the cases were treated by prolonged catheter drainage and tincture seal of nephrostomy site. Leak stopped in all patients in 2–4 days, and catheter was removed. In CP-PCNL group, four patients had urine leak for more than 24 h, and all patients settled with conservative measures within 2–3 days.

When stone-free rates were compared in both groups at 30 days follow-up in C-PCNL and CP-PCNL groups, it was 85.5% and 87.6%, respectively. This comparison did not reach statistical significance.

Table 2: Time taken for Check pyeloscopy in CP-PCNL group

	PYELOSCOPY TIME								Total
	4.5 MINS	5 MINS	6 MINS	6.5 MINS	7 MINS	7.5 MINS	8 MINS	9 MINS	
CP-PCNL	5	9	8	6	13	1	6	2	50

CP-PCNL: Check Pyeloscopic Per-Cutaneous Nephrolithotomy

Table 3: Major and Minor complications in both the groups

Number of patients	Complications					Total
	None	Bleeding (>24 h)	Minor Urothelial Injury (Mucosal erosion, small puncture rents)	Infundibular tear (exposing fat)	Pelvic tear (exposing peri-pelvic fat)	
In C-PCNL	37	2	1	8	2	50
In CP-PCNL	48	0	1	1	0	50
Total	85	2	2	9	2	100

C-PCNL: Conventional Per-Cutaneous Nephrolithotomy, CP-PCNL: Check Pyeloscopic Per-Cutaneous Nephrolithotomy

Table 4: Comparison of Pain score, analgesic requirement and time to resume daily activity

	Pain score (VAS)			Analgesic Requirement (Days)					Return to daily activity (Days)					
	Mild	Moderate	Severe	Two	Three	Four	Five	Six	Three	Four	Five	Six	Seven	Eight
C-PCNL	33	16	1	4	22	18	2	4	4	15	22	3	5	1
CP-PCNL	40	10	0	11	22	14	2	1	5	19	22	3	0	1

C-PCNL: Conventional Per-Cutaneous Nephrolithotomy, CP-PCNL: Check Pyeloscopic Per-Cutaneous Nephrolithotomy

Table 5: Independent t-test for Pain score, Duration of procedure and Return to daily activities

	Levene's Test for Equality of Variances		t-test for Equality of Means							
	F	Sig.	t	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference		
								Lower	Upper	
Pain score										
Equal variances assumed	0.225	0.636	3.823	98	0.000	0.518	0.135	0.249	0.787	
Equal variances not assumed			3.816	96.449	0.000	0.518	0.136	0.248	0.787	
Duration										
Equal variances assumed	5.964	0.016	-0.781	98	0.437	-1.692	2.167	-5.992	2.608	
Equal variances not assumed			-0.787	88.674	0.434	-1.692	2.151	-5.966	2.582	
Return to daily activities										
Equal variances assumed	2.607	0.110	1.626	98	0.107	0.332	0.204	-0.073	0.738	
Equal variances not assumed			1.640	84.767	0.105	0.332	0.203	-0.071	0.735	

In both the groups, follow-up for residual stones was done at 30 days by computed tomography scan. Clinically, insignificant residual fragments were defined as any fragment less than 4 mm. In the C-PCNL group, eight patients had significant fragments and were treated by ancillary procedures such as ESWL (4), ureteroscopy (3), and redo PCNL (1). In the CP-PCNL group, five patients had significant fragments and were treated by ancillary procedures such as ESWL (4) and ureteroscopy (1). All patients were rendered stone free at 6 months' follow-up in both the groups.

DISCUSSION

The present study is focused on the perioperative and postoperative outcomes of C-PCNL and CP-PCNL. The present study shows that the majority of the patients were between 30 and 50 years of age. The patients had pain as the main symptom which mainly affected the right side of the kidney. This is consistent with the study of Moosanejad

et al. who have shown that the majority of the patients were males (66%) in the age group around 40–50 years.^[6]

In relation to anesthesia, all the patients were subjected to GA. Ureteric catheter positioning was done under fluoroscopic guidance. In all cases, fluoroscopy-guided puncture was done (1 in each group). All the cases were done in the prone position.

The initial punctures for caliceal access were commonly done by bull's eye technique;^[7] however, in a few cases, triangulation technique, gradual descent technique, and ultrasound-guided technique were used.^[7] Subcostal approach was taken in the majority of the cases, whereas in three cases, combined approach was used. In all cases, pneumatic lithotripsy was used.

The total number of complications was more in C-PCNL group comprising two pelvic tears, 8 infundibular tears,

1 minor urothelial injury, 2 cases of bleeding lasting for more than 24 h, while in CP-PCNL group complications were less comprising of 1 minor urothelial injury and 1 case of infundibular tear. The analysis results were statistically significant ($P = 0.027$). This result shows that complications can be avoided or at least reduced by doing check pyeloscopy during PCNL. Over dilatation of the tract can cause pelvic perforation, which in turn leads to serious complications in the form of bleeding, extravasation, and sepsis.

During check pyeloscopy, in cases of over dilatation, Alken's sheath should be withdrawn and correctly placed into the collecting system under ureteroscopic guidance. Complications such as pelvic tear and disruption of the PUJ could be averted in this way.

Bleeding lasting more than 24 h was more in C-PCNL group. This could be explained by the more number of complications such as infundibular tear, pelvic tears, and minor rents in the urothelium. Various studies have shown that larger tract size, renal pelvic perforation, and multiple punctures are associated with high risk of bleeding. In our study, no patient required blood transfusion as all bleeding stopped after 24 h without any intervention. According to previous studies, 1%–12% of patients required blood transfusion.^[8-10]

The duration of the surgery was more in CP-PCNL group compared to C-PCNL group due to the additional time taken for check pyeloscopy. However, the difference in mean values in both the groups did not reach statistical significance. In one study done by Vasudevan *et al.*,^[5] time for check pyeloscopy ranged from 5 to 9 min (mean = 7.2 min), and the mean operative time was lesser than our study (60.9 min). This could be explained by the lesser number of complications, expertise and less bleeding which improves vision resulting in relatively faster surgery.

Postoperative fever (>100 F) was seen in 11 patients in PCNL group and 6 patients in CP-PCNL group. Both the groups were compared for postoperative fever using the Chi-square test, and result was found to be statistically insignificant ($P = 0.183$). AUA and EAU guidelines recommend antibiotic prophylaxis for all patients undergoing PCNL, which has decreased the incidence of postoperative fever following PCNL; however, a few patients do develop fever, sepsis due to bacterial release from the calculus during fragmentation, manipulation, increased duration. The incidence of fever following PCNL

ranges between 2.8% and 32.1%.^[8,10] In the present study, the incidence of fever in CP-PCNL group was 12%, and in C-PCNL group, it was 22%.

Pain is a common complication after surgery. Postoperative pain was calculated by VAS score ranging from 0 to 10. In most of the patients, pain subsided within 4 days. Only 9 patients required analgesia for more than 4 days. Both the groups were compared for postoperative pain score using the independent *t*-test, and the result was statistically significant ($P = 0.000$).

Return to daily activities was compared in both groups. The time taken was lesser in CP-PCNL group which can be attributed to the less number of complications and reduced pain score.

PCNL is time tested and offers a stone-free rates in the range between 70% and 85% in varying studies.^[11] In our study, stone-free rate was in the similar range of 85%. Some patients with residual fragments were treated by ancillary procedures at follow-up and were rendered stone free at 6 months' follow-up.

Since most of our patients were covered by insurance and since ours is a teaching hospital, no extra charge was burdened on the patient for the use of ureteroscopy in CP-PCNL group.

CONCLUSION

Check pyeloscopy during PCNL is a safe, economical, and effective step in reducing the adverse events and complications during the procedure. The incidence of complications such as bleeding, pelvic perforation, PUJ disruption, and postoperative pain can be reduced and in some cases avoided by using this method. This technique is not only helpful in avoiding complications but also increases the success rate by visual confirmation access into the collecting system.

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Conflicts of interest

There are no conflicts of interest.

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