



“STANDARD VERSUS TUBELESS PERCUTANEOUS NEPHROLITHOTOMY: A PROSPECTIVE COMPARATIVE STUDY”.

Urology

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ABSTRACT

Objective: Tubeless PCNL is a modified version of Standard PCNL that uses a double J-stent instead of a nephrostomy tube. A study is being conducted to compare the effectiveness, safety, and benefits of the two procedures. **Material and methods:** 100 patients with stones over 2cm and less than 2 cm after unsuccessful ESWL underwent PCNL. They were divided into two groups - tubeless PCNL and the standard PCNL. **Results:** No significant differences were observed in stone size, clearance, baseline creatinine, puncture site, operative time, hemoglobin drop, or need for transfusion between tubeless and standard PCNL; however, significant differences in the analgesic requirement, complications, and hospital stay were noted. **Conclusion:** In conclusion, compared to Standard PCNL, tubeless PCNL may be a safe, acceptable, and successful treatment for renal calculi in carefully chosen individuals. Even in patients with high renal parameters and those with related comorbid diseases, it is safe in any tract position (upper, middle, or lower).

KEYWORDS

Standard PCNL, Stone, Tubeless PCNL

1. INTRODUCTION

In 1955, Goodwin and colleagues performed the first percutaneous renal surgery on a patient. They reported using a "nephrostomy tube percutaneously" to drain a hydronephrotic kidney^[1]. However, it was not until 1976, when Fernstrom and Johansson established percutaneous access to remove renal stones that the first percutaneous nephrolithotomy (PCNL) was performed^[2].

Standard PCNL requires putting a DJ stent and having postoperative percutaneous drainage. For this purpose, different types of nephrostomy tubes, such as malecot, foley, cope loop, council, and pigtail catheter, with various sizes (20F–32F), have been used^[3]. Lately, there have been attempts to modify standard PCNL by avoiding a nephrostomy tube and only using a double J stent for urine drainage after surgery. This modification is called tubeless PCNL, and it aims to reduce postoperative pain and morbidity caused by nephrostomy tubes^[4].

The introduction and development of tubeless PCNL have been significant in percutaneous nephrolithotomy. This study aims to analyze the evidence-based literature on "nephrostomy-free" or "tubeless" PCNL to evaluate its safety, effectiveness, potential, and advantages over standard PCNL.

2. Patient and methods

One hundred patients with renal calculus with a stone size greater than 2 cm or <2cm with failed ESWL underwent PCNL in South Bihar, India. They were divided into groups A and B, each with 50 patients. Group A consisted of 50 cases of standard PCNL and group B had 50 cases of tubeless PCNL.

The Independent Institutional Ethics Committee approved the study and all patients gave informed consent. (Fig. 1a, 1 b). Patients with sterile urine culture received 1 gram of ceftriaxone on the morning of surgery. Patients with positive urine cultures received sensitive antibiotics three days before and after surgery. Patients underwent PCNL under general anesthesia with a 5-Fr ureteric catheter inserted. Positioning in lithotomy and prone positions allowed for contrast injection and puncture of the calyx.

The puncture site was determined based on its location to ensure complete removal of the stone. An 18-gauge, two-part needle was used to make the PCNL puncture, and a guide wire was then inserted into the system as seen in Fig. 1c.

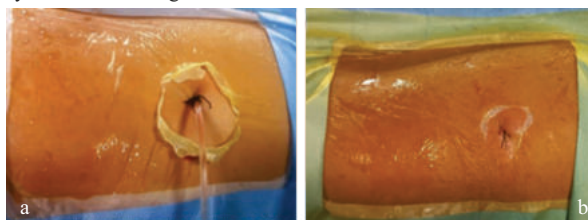


Fig:1 (a) Standard PCNL (b) Tubeless PCNL



Fig 1 (c) Lt. Renal stone with ureteric catheter (d) PCNL puncture (e) Nephroscopy

A guide rod was also inserted, and amplatz dilators were used to widen the tract before the amplatz sheath was applied gradually. Stone fragmentation was performed using a pneumatic lithotripter and a 26-Fr Karl Storz nephroscope (Fig. 1d). After the fragments were retrieved, patients in group A were given an antegrade 5 Fr double J stent along with a 20FR–22FR nephrostomy tube.

Patients in group B were only given a 5 Fr double J stent (Figure 1e). Preoperative factors such as stone size, preoperative creatinine, hemoglobin levels, and comorbidities were noted. The operative time, access route, and the need for blood transfusion were carefully documented during the surgery.



Fig:1 (e) Amplatz sheath with ureteric catheter

After undergoing Standard PCNL, patients had their post-operative X-ray KUB and NCCT KUB (in cases of radiolucent stones) taken before removing their nephrostomy tube. Stones larger than 4 mm were identified as residual calculi. Patients were monitored for parameters such as hemoglobin levels, pain, need for blood transfusions, hospital stay, complications, and additional procedures, if necessary. After one month, the double J stent was removed in both groups, provided there were no remaining stones.

2 a. Data collection

We compared the stone size, serum creatinine level before surgery, operative time, stone clearance, hospital stay, the amount of analgesic needed, and any post-surgery issues like bleeding, infection, or ureteral obstruction. The readmission rate of hospital is also recorded and compared.

2.b Statistical analysis of the study

When dealing with discrete data, proportions are calculated, while mean and standard deviation are computed for continuous data. To compare the proportions of different groups, the chi-square test is used. Any p-values less than 0.001 are considered significant in all analyses. To compare the difference between the two groups an independent sample T-test is used.

3. RESULTS AND OBSERVATION

In both the standard and tubeless PCNL groups more patients were male than female; however, the gender distribution was not statistically significant (As shown in Table-1 and Table -2).

Table1. Age distribution table of Standard vs. Tubeless PCNL patients

Age group(years)	Male		Female	
	Standard PCNL(n)%	Tubeless PCNL(n)%	Standard PCNL(n)%	Tubeless PCNL(n)%
18-35	23(53.4)	20(46.6)	8(40)	12(60)
36-50	10(62.5)	06(37.5)	02(25)	06(75)
51-73	03(60)	02(40)	04(50)	04(50)

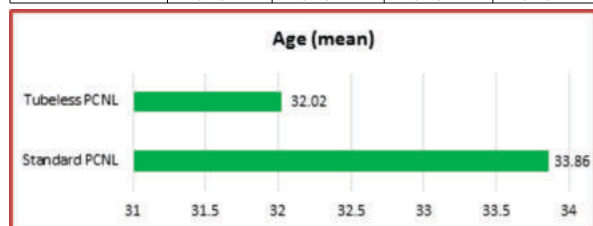


Table 2. Mean age distribution of Standard and Tubeless PCNL patients

Similarly, the mean age distribution, comorbidity in patients, and size of the stone removed in both groups were also insignificant; however standard PCNL removed slight larger stones (1.9-4.5cm) than tubeless PCNL (2.0-4.1cm). Most stones removed in groups A and B were located on the right side, with slightly fewer on the left side. The baseline hemoglobin levels were almost identical in both groups, with group A at 12.744 gm and group B at 12.698 gm. The baseline serum

creatinine level in group A was 0.965 mg/dL, compared to 0.882 mg/dL in group B. The puncture site used in both groups was found to be similar across all locations. Thus, groups A and B observed no significant differences in location, hemoglobin level, creatinine level, or puncture site. The average duration of surgery for Group A was 89.200 ± 17.939 minutes, while for Group B, it was 87.800 ± 18.548 minutes. After the surgery, Group A decreased hemoglobin levels by 1.898 ± 0.856 gm, while Group B showed a decrease of 1.786 ± 0.777 gm. Blood transfusion was required by 14% of patients in Group A and 10% in Group B.

Table-3. Statistical comparison of significance between standard and tubeless PCNL patients with different parameters

Variable		Standard PCNL (n=50)	Tubeless PCNL (n=50)	P-Value	Interpretation
Age	Mean±SD	33.860±13.342	32.02±12.364	0.47	Not significant
Gender	Male Female	35 (70%) 15 (30%)	29 (58%) 21 (42%)	0.213	Not significant
Comorbidity	Hypertension Type-II DM CKD DM+HTN	05 (10%) 02 (4%) 03 (6%) 02 (4%)	04 (8%) 02 (4%) 02 (4%) 03 (6%)		
Stone Size	Mean±SD	2.694±0.647	2.510±0.548	0.1281	Not significant
Stone Location	Right Left	29 (58%) 21 (42%)	27 (54%) 23 (46%)		
Baseline Haemoglobin	Mean±SD	12.744±1.837	12.698±1.744	0.897	Not significant
S. Creatinine (mg/dL)	Mean±SD	0.965±0.436	0.882±0.270	0.2578	Not significant
Puncture site	Lower Calyceal Mild Calyceal Upper Calyceal Supracostal	21 (42%) 19 (38%) 10 (20%) 07 (14%)	23 (46%) 17 (34%) 10 (20%) 05 (10%)		
Operative time	Mean±SD	89.200±17.93	87.80±18.548	0.702	Not significant
Haemoglobin drop	Mean±SD	1.898±0.856	1.786±0.777	0.494	Not significant
Blood Transfusion		07 (14%)	05 (10%)	0.540	Not significant
Analgesic use (mg)	Mean±SD	237.0±39.344	191.0±35.985	<0.0001	Significant
Hospital stay (Days)	Mean±SD	4.920±0.724	3.780±0.815	<0.0001	Significant
Complications	Urosepsis Urine leak Pleural effusion Haematuria	04 (8%) 05 (10%) 02 (4%) 03 (6%)	03 (6%) Nil Nil 04 (8%)	<0.0001	Significant
Stone Clearance	Complete Incomplete	44 (88%) 06 (12%)	44 (88%) 06 (12%)		
Need of ancillary procedure	ESWL-1 Left URSL-1	ESWL-2 Left URSL-3			

Therefore, no significant differences were observed between Group A and Group B concerning the duration of surgery, postoperative hemoglobin levels, and blood transfusion requirements. Patients who underwent standard PCNL reported higher consumption of analgesics at 237.000 ± 39.344 mg compared to those with tubeless PCNL at 191.000 ± 35.985 mg. This difference is significant, with a p-value of less than 0.001. Moreover, when comparing the tubeless PCNL group with the standard PCNL group, a longer hospital stay was observed at 4.920 ± 0.724 compared to 3.780 ± 0.815 , respectively. This difference is also significant, with a p-value of less than 0.001.

Comparing the postoperative complications between the regular PCNL group and the tubeless PCNL group, the tubeless group showed fewer complications ($p < 0.001$). Both groups reported similar stone clearance (88%). Furthermore, 12 % of patients in each group had

residual stones; hence the correlation was not statistically significant. According to statistical analysis, there was no statistically significant difference in the number of ancillary procedures performed between groups A and B. (Table-3)

4. DISCUSSION

Renal stone disease is a commonly diagnosed urological condition that often requires surgical treatment. Percutaneous nephrolithotomy is the preferred method for kidney stone removal due to its safety, and significantly lower morbidity and it allows patients to return to regular activities at sooner rate compared to open stone surgery. Advanced surgical techniques like PCNL aim to minimize nephron loss by avoiding unnecessary tissue handling. Despite significant progress and improvements, some patients still experience complications. While several randomized clinical trials have been conducted to evaluate the safety and efficacy of tubeless PCNL, further research is needed to reach a definitive conclusion.^[5]

The very early findings from nearly 100 patients who had undergone tubeless PCNL were reported by Wickham et al. in 1984, and they concluded that the procedure was safe and effective, requiring a shorter hospital stay of less than 24 hours. According to Bellman et al., less hospitalization time and analgesic usage were among the results of 20 patients with modest stone loads who had PCNL in 1997.^[6]

This study compared patients with renal stone disease who met the inclusion criteria between tubeless PCNL and Standard PCNL.

Tubeless and standard PCNL were done safely in patients with elevated renal parameters; in group A, 6% of patients were known CKD patients. Both groups had similar operative time, group A-89.2 minutes vs. group B-87.8 minutes, and it was not statistically significant compared to studies conducted by *Bhat et al.* (2017) and many randomized clinical trials. The studies conducted by *Akman et al.* (2012)^[7] and *Jones P et al.* (2016)^[8], and *Sairem et al.* (2012)^[9] have confirmed the safety of tubeless PCNL in patients with chronic kidney disease. According to a study published in the British Journal of Clinical Pathology by the University of South Wales in Glasgow, tubeless PCNL was performed safely even in patients with associated ureteric calculi.

This study found that both groups had similar decreases in postoperative hemoglobin levels and the need for blood transfusions. These findings are consistent with previous research conducted by *Tefekli et al.* (2007) and other related clinical trials.^[11-12]

In patients undergoing standard PCNL, it was a common urological symptom to have pain related to the nephrostomy tube. At the same time, the need for postoperative analgesia was found to be less in the tubeless PCNL group, according to our study. The patients of Group A needed tramadol (237.00 ± 39.344) mg as compared to tubeless PCNL (191.00 ± 35.985) mg, and the finding was statistically significant, and also supported by a study of *Madhu S. Agrawal et al. & Kumar S et al.*^[13]

In each group, postoperative complications, including haematuria and sepsis, were almost similar. 10% of patients in the standard PCNL group experienced urine leaks, which resolved with expectant care in 5-7 days. *Ansari et al.* investigated the causes of extended urine leakage and discovered that factors such as residual stones, complicated stones, and complex anatomy contributed to the problem.^[14]

In the study, the patient had a blockage and urine leakage that could have been brought on by postoperative edema or some inadvertent leftover pieces. Compared to the tubeless PCNL group, the standard PCNL group's postoperative hospital stay was more extended. This finding was statistically significant and supported by the studies conducted by *Madhu S. Agrawal et al.* and *Crook et al.* (2008)^[15], which showed similar results. Similar to this study, earlier RCTs demonstrated shorter hospital stays following tubeless PCNL.^[16] The study found that the supracostal puncture was safely performed during tubeless PCNL, and none of the patients in that group experienced any significant issues. According to *Sofikerim M et al.*'s research in 2007^[17], tubeless PCNL was safe and efficient, even after supracostal access, and was linked to reduced postoperative discomfort and shorter hospital stays. Both groups had residual calculi, which is not uncommon. Similarly, *Shah et al.*'s research in 2009^[18] found similar stone-free rates at the 3-month follow-up, and *Giusti et al.*'s findings in 2008^[19] supported these statistics. The need for ancillary operations did not differ statistically substantially between the tubeless and standard

groups. *Shah et al.*^[18] study came to the conclusion that ESWL and conservative management made up the bulk of ancillary treatments, cautious management and wave lithotripsy.

5. CONCLUSION

In carefully selected patients, tubeless PCNL is a safe and effective treatment for renal calculi. It has comparable postoperative complications to standard PCNL with quicker operating times, less discomfort, after surgery, reduced need for painkillers, and shorter hospital stays. It is safe to use in any tract site, including upper, middle, and lower, even in patients with increased renal parameters and comorbid conditions. We suggest that tubeless PCNL to be used for patients with uncomplicated surgical parameters because it has lower morbidity and it allows for an earlier return to routine activities.

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