

Comparative Evaluation of Standard versus Totally Tubeless Percutaneous Nephrolithotomy in Renal Stone Treatment

Imran Hyder and Khalid Hussain

ABSTRACT

Objective: To compare the outcomes of standard and totally tubeless percutaneous nephrolithotomy in treating renal stones in terms of postoperative analgesia requirement, operative time and mean duration of hospital stay.

Study Design: Randomized controlled trial

Place and Duration of Study: This study was conducted at the Department of Urology, Nishtar Hospital, Multan, from December 2022 to November 2023.

Methods: A sample size of 88 (44 in each group) were enrolled in the study. Group A was receiving standard percutaneous nephrolithotomy (PCNL), while Group B was receiving the totally tubeless PCNL. Analgesics were administered when the patient reports a VAS pain score above a predefined threshold (e.g., ≥ 4 out of 10). The requirement for postoperative analgesia within a 48-hour period will be recorded.

Results: The mean analgesic requirement of standard PCNL group was greater than totally tubeless PCNL group as 20.79 ± 3.08 mg and 9.71 ± 1.65 mg, respectively. The mean hospitalization time of standard PCNL group was greater than totally tubeless PCNL group 3.31 ± 1.08 days and 1.82 ± 0.54 days.

Conclusion: Totally tubeless PCNL is effective and safe technique, making it a viable option for patients with renal stones. This approach is linked to reduced pain, decreased analgesic requirements, shorter operation times, and decreased hospitalization durations.

Key Words: Renal stones, Tubeless percutaneous nephrolithotomy, Standard nephrolithotomy, Pain, Hospital stay

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INTRODUCTION

Kidney stones are solid deposits of salts and minerals that develop inside the kidneys, often causing severe pain, urinary symptoms, and complications such as infection¹, obstruction, and renal damage approximately 10% of the global population is affected by kidney stones at some point in their lives², with the prevalence increasing over the past several decades. The management of kidney stones has evolved significantly over the years, with a range of treatment options available to patients depending on the size, location, and composition of the stones³.

Department of Urology, Nishtar Medical University & Hospital, Multan.

Correspondence: Dr. Imran Hyder, Associate Professor of Urology Dept., Nishtar Medical University & Hospital, Multan.

Contact No: 0333 4066723

Email: drsalyana@mail.ru

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Number of minimally invasive and non-invasive techniques has been introduced for dealing with kidney stones including lithotripsy like extracorporeal shock wave, open surgery, nephrolithotomy and conservative management^{4,5}. PCNL is a well-established, minimally invasive surgical technique for the treatment of large or complex kidney stones that cannot be effectively managed by conservative or less invasive therapies⁶. While the procedure has a high success rate and is generally well-tolerated, it is not without complications. Postoperative pain, bleeding, and infection are common concerns, as well as the discomfort and inconvenience of managing the nephrostomy tube in the days following surgery⁷. Over the past decade, there has been a growing interest in the development of a less invasive, tubeless variation of the PCNL procedure, known as totally tubeless PCNL (TTPCNL)⁸. In TTPCNL, no nephrostomy tube is placed after the completion of the procedure, and a ureteral stent is inserted instead to maintain renal drainage⁹. Proponents of TTPCNL argue that it reduces postoperative pain, shortens hospital stays, and facilitates a quicker return to normal activities when compared to standard PCNL¹⁰.

METHODS

After taking approval from CPSP, a randomized controlled trial was conducted at Nishtar hospital Multan. After explaining the purpose of study, Informed consent was signed by the patients. A sample size of 88 (44 in each group) is calculated using a 95% confidence interval, power of study 80%, taking number of patients required postoperative analgesia in standard and tubeless procedure as 62.5% and 32.5% respectively.

This sample size was calculated using the online software OpenEpi.com. Patients of age between 18 to 70 years, diagnosis of large kidney stones, defined as stones larger than 2 cm in diameter, stones located in the renal pelvis, calyces and upper ureter on CT scan, failure of conservative treatment or less invasive therapies and patient who has informed consent to participate in the study were included in the study. Analgesics were administered when the patient reports a VAS pain score above a predefined threshold (e.g., ≥ 4 out of 10). The requirement for postoperative analgesia within a 48-hour period will be recorded. It was documented as 'yes' if analgesia was administered based on the visual analogue scale (VAS) score and 'no' if not." The total amount of analgesic medication in milligrams was administered to the patients during 48 hours were documented.

The duration of the procedure was measured in minutes from the initial skin incision to the final skin closure. All the operation was performed by same consultant urologist team, to minimize bias. Pain after procedure was assessed using the visual analogue scale, a validated tool for measuring pain intensity. The VAS is a continuous scale from 0 (no pain) to 10 (worst possible pain). Pain scores were recorded at 6, 24, and 48 hours postoperatively.

Hospitalization time was measured in days from the day of the procedure to the day of discharge. Patients with an active urinary tract infection (more than 10 WBCs on urine analysis) or sepsis (based on q-SOFA criteria, Annexure), patients with bleeding diathesis or coagulopathy (INR more than 1.5), solitary kidney having $GFR < 45 \text{ mL/min/1.73 m}^2$, presence of a renal anomaly or obstruction that may affect the outcome of the procedure (e.g., horseshoe kidney, ureteropelvic junction obstruction, perforation in the collecting system), history of previous open renal surgery or PCNL on the same side, pregnant or lactating women, patients with a known allergy or contraindication to anesthesia or contrast media.

Group A was receiving standard percutaneous nephrolithotomy (PCNL), while Group B was receiving the totally tubeless PCNL. Post-enrollment, random allocation participants were randomly assigned to either Group A or Group B using computer-generated random numbers (Annexure). All patients' were undergoing

preoperative assessment, routine investigations and imaging studies (computed tomography or kidney-ureter-bladder X-ray). Antibiotic prophylaxis was administered according to the hospital protocol. Both groups were undergoing PCNL under general anesthesia, following standard surgical principles. For Group A, a DJ stent or nephrostomy tube was placed at the end of the procedure, whereas in Group B, no nephrostomy tube was placed.

All patients were closely monitored in the post-anesthesia care unit and subsequently transferred to the urology ward. Postoperative pain management was provided as per the hospital's pain management protocol. Patients were assessed for any complications or adverse events during their hospital stay. Operative time was documented during the surgery. Postoperative pain was assessed by postgraduate resident by using the VAS at 6, 24, and 48 hours postoperatively. Analgesic requirement and hospitalization time was recorded in the patient's medical records. Patients were deemed fit for discharge when they exhibit stable vital signs for at least 24 hours, are ambulatory, tolerate oral intake without vomiting, have managed pain controlled by oral analgesics, show no signs of post-operative complications. All the data was recorded on the proforma.

All collected data was entered into a statistical software package, such as SPSS version 26. Continuous variables, such as age, stone size, operative time, change in haemoglobin and pain scores, analgesic requirement, and hospitalization time, was summarized using means and SD. Categorical variables such as sex and stone location were presented as frequencies and percentages.

RESULTS

Overall, 88 patients were included in this study. The study patients were equally divided into two groups as standard PCNL44 (50.0%) and totally tubeless PCNL44 (50.0%). The distribution of age, sex, stone size and stone location of both the study groups were almost equal. Whereas, the mean operative time of standard PCNL and totally tubeless PCNL group was 54.81 ± 5.05 minutes and 50.02 ± 5.09 minutes. (Table. I).

The mean pain score (VAS) at 6 hours of standard PCNL and totally tubeless PCNL group was 8.21 ± 1.26 and 7.68 ± 1.02 , respectively. ($p=0.245$). The mean pain score (VAS) at 24 hours of standard PCNL and totally tubeless PCNL group was 6.44 ± 1.62 and 4.63 ± 0.85 , respectively. ($p < 0.001$). The mean pain score (VAS) at 48 hours of standard PCNL and totally tubeless PCNL group was 4.64 ± 0.68 and 2.54 ± 0.85 , respectively. ($p < 0.001$). (Table. II).

The mean analgesic requirement of standard PCNL group was greater than totally tubeless PCNL group as 20.79 ± 3.08 mg and 9.71 ± 1.65 mg, respectively. The mean hospitalization time of standard PCNL group was

greater than totally tubeless PCNL group 3.31±1.08 days and 1.82±0.54 days,(Table. III).

Table No. 1: Demographics and baseline characteristics of the study groups

Characteristics	Standard PCNL 44 (50.0%)	Totally tubeless PCNL 44 (50.0%)	p-value
Age (years)	51.34±8.44	52.18±8.99	0.652
Sex			
Male	26 (59.1)	24 (54.5)	0.667
Female	18 (40.9)	20 (45.5)	
Stone size (mm)	39.82±3.43	38.66±3.12	0.826
Stone location			
Renal pelvis	8 (18.2)	5 (11.4)	0.713
Middle calyx	11 (25.0)	8 (18.2)	
Lower calyx	9 (20.5)	9 (20.5)	
Upper calyx	7 (15.9)	10 (22.7)	
Upper ureter	9 (20.5)	12 (27.3)	
Operative time (minutes)	54.81±5.05	50.02±5.09	<0.001

Table No. 2: Pain scores distribution of the study groups

Pain score (VAS)	Standard PCNL 44 (50.0%)	Totally tubeless PCNL 44 (50.0%)	p-value
At 6 hours	8.21±1.26	7.68±1.02	0.245
At 24 hours	6.44±1.62	4.63±0.85	<0.001
At 48 hours	4.64±0.68	2.54±0.85	<0.001

Table No. 3: Analgesic requirement and hospitalization distribution of the study groups

	Standard PCNL 44 (50.0%)	Totally tubeless PCNL 44 (50.0%)	p-value
Analgesic requirement (mg)	20.79±3.08	9.71±1.65	<0.001
Hospitalization time (days)	3.31±1.08	1.82±0.54	<0.001

DISCUSSION

In a randomized controlled study conducted by Moosanejadet al¹², 44 patients 24 male, mean age of patients was 50.40±2.02 years. 40 patients underwent standard PCNL. The regular PCNL group had a longer mean operation time 53.37±5.54 min as compare to

tubeless group 50.32±3.83 min. Twenty-five 62.5% standard PCNL patients needed pethidine, compared to 32.5% tubeless PCNL patients. The tubeless PCNL group had a shorter mean hospitalization time 1.25±0.49 days than the regular PCNL group 2.95±1.17 days.

In a study conducted by Sebaey et al¹³, involving 80 patients with a solitary radio-opaque renal stone eligible for PCNL, it was found that the tubeless PCNL group required a statistically significantly lower mean postoperative analgesia dose (43.5mg) compared to the standard PCNL group (48.03mg). Additionally, the tubeless PCNL group exhibited a higher stone-free rate of 90%, while the standard PCNL group had a rate of 82.5%. Another study by Agrawal et al¹⁴ revealed that patients in the Tubeless group have shorter hospital stay (21.6 hours) than controls.

Studies conducted by Thapaet al¹⁵ and Ichaoui et al¹⁶ have compared totally tubeless percutaneous nephrolithotomy to standard PCNL in terms of efficacy, safety, and patient outcomes. However, these studies have yielded mixed results, with some reporting significant benefits of TTPCNL while others have found no significant difference between the two techniques.

In their respective studies, Shenet al¹⁷ and Gonulalan et al¹⁸ observed that patients undergoing surgery with the standard percutaneous nephrolithotomy (PCNL) technique reported heightened pain levels and a greater need for postoperative narcotic analgesics compared to those treated with tubeless method. In our investigation, the omission of catheter of nephrostomy and stent (double J) in TPCNL group appeared to correlate with diminished pain and reduced requirements for analgesics.

In line with the results of this study, Istanbuluoglu et al¹⁹ found no significant differences in blood transfusion, hemoglobin, stone size when comparing totally tubeless percutaneous nephrolithotomy (PCNL) with standard PCNL. In their study, Karami et al²⁰ examined 60 patients, evenly distributed into two groups, and found that 2 (6.6%) individuals in the totally tubeless percutaneous nephrolithotomy (PCNL) group, as well as UTI was diagnosed in 1 patient standard PCNL group.

Wang et al²¹ concluded that tubeless PCNL represents a safe, efficacious, and cost-effective approach for the treatment of renal staghorn calculi. Their findings indicated that this procedure also have association with high stone free rate, low morbidity, a brief hospital stay, and enables an early return to work.

CONCLUSION

Conclusion: PCNL is a safe and effective technique, making it a viable option for patients with staghorn stones. This approach is linked to reduced pain,

decreased analgesic requirements, shorter operation times, and decreased hospitalization durations.

Author's Contribution:

Concept & Design or acquisition of analysis or interpretation of data:	Imran Hyder
Drafting or Revising Critically:	Khalid Hussain
Final Approval of version:	All the above authors
Agreement to accountable for all aspects of work:	All the above authors

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