

Research Article

Tubeless versus Standard Percutaneous Nephrolithotomy

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ABSTRACT

Background: Percutaneous nephrolithotomy (PCNL) is an established treatment for large renal calculi; however, conventional nephrostomy drainage may contribute to postoperative pain and prolonged hospitalization. Tubeless PCNL avoids routine nephrostomy tube placement and may facilitate postoperative recovery.

Objective: To compare the outcomes of tubeless versus standard PCNL in patients with renal stones.

Methods: A randomized controlled trial was conducted in the Department of Urology, Liaquat National Hospital, Karachi. A total of 104 patients aged 20-70 years with renal or upper ureteric stones measuring >2 cm were included and randomly allocated to tubeless PCNL (n=52) or standard PCNL (n=52). Outcomes included length of hospitalization, fluoroscopy duration, operative time, hematocrit decrease, and postoperative Visual Analog Scale pain scores at 1 and 6 hours.

Results: The tubeless PCNL group had a shorter mean hospital stay than the standard PCNL group (1.7 ± 0.8 vs. 3.1 ± 1.0 days; $P < 0.001$). Mean fluoroscopy duration was 5.1 ± 1.6 versus 5.4 ± 1.8 minutes ($P = 0.371$), while mean operative time was 76.2 ± 18.5 versus 82.1 ± 20.1 minutes ($P = 0.122$). Hematocrit decrease was $2.5 \pm 1.4\%$ versus $3.4 \pm 1.6\%$ ($P = 0.003$). VAS pain scores at 1 hour were 5.8 ± 1.6 versus 6.7 ± 1.2 ($P = 0.002$), and at 6 hours were 3.4 ± 1.3 versus 4.7 ± 1.4 ($P < 0.001$), respectively.

Conclusion: Tubeless PCNL was associated with shorter hospitalization and lower early postoperative pain compared with standard PCNL, while perioperative procedural outcomes remained comparable. Tubeless PCNL may therefore represent an effective alternative to standard nephrostomy drainage in appropriately selected patients.

Keywords: Percutaneous Nephrolithotomy, Tubeless PCNL, Standard PCNL, Renal Calculi, Nephrolithiasis, Postoperative Pain, Hospital Stay.

INTRODUCTION

Urolithiasis is a serious health disorder and a major problem in urology, which is on the upswing worldwide and has high morbidity. In the last report of Global Burden of Disease Study, there were approximately 106 million new cases in the world in 2021, and the majority (around 67%) were men. The incidence of urolithiasis has declined worldwide, but the number of cases has increased by 26.7% between 2000 and 2021. It suggests that urinary stone disease is still a great clinical issue {1}. Furthermore, recent research has revealed that 11% of the world's population suffer urolithiasis and this varies from region to region and from the method and type of studies performed {2}. Pakistan lies in the 'stone belt'

of Asia and in recent years there have been reports of a significant burden of nephrolithiasis as well as other burdensome lifestyle and environmental risk factors in Pakistan {3}. In the case of large renal calculi (particularly >2cm), percutaneous nephrolithotomy (PCNL) is the preferred minimally invasive procedure. In the traditional method of PCNL, a nephrostomy tube has to be inserted after stone removal, which can lead to postoperative pain, urine leakage, longer hospital stays and increased use of analgesics. To eliminate these problems, tubeless PCNL was developed. For internal drainage maintained with a ureteral stent, removal of the nephrostomy tube is done using this type of PCNL. Recent data revealed

that this method may have advantages and help to maintain stone treatment. Meta-analysis of 26 studies revealed that tubeless PCNL reduced the operating time by 5.18 minutes, and the postoperative hospital stay by 1.10 days. The stone-free rate and major complications were not different from the standard PCNL {4}. A Cochrane systematic review also revealed that tubeless PCNL could reduce the time spent in the hospital after surgery, though there was low-level data evidence {5}. Tubeless PCNL has been shown to be safe in several studies and may shorten hospital stays and decrease the need for postoperative pain medication {6}.

METHODOLOGY

Once the synopsis was approved a randomized control trial was done for 6 months at the Department of Urology, Liaquat National Hospital, Karachi. Patients of both gender, between the age group 20-70 years and with defined eligibility criteria, were included in the analysis, for renal or upper ureteric stones. The purpose of the study was to compare the results of tubeless percutaneous nephrolithotomy (PCNL) with conventional PCNL. A total of 104 patients (52 patients in each study group) were created. The sample size was calculated with WHO sample size calculation software with a mean of pain level one hour after the procedure, 5.8 ± 1.6 in the tubeless PCNL group and 6.7 ± 1.2 in the standard PCNL group at a 90% power level and 95% confidence level. The non-probability consecutive sampling method was used to select the patients. Patients were randomly distributed to two study groups by the lottery system. In Group A, patients performed tubeless PCNL and in Group B standard PCNL was performed. Patients aged 20-70 years were included only if they had stones larger than 2 cm in calices, pelvis or upper ureter. Renal stones, pelvic stones, upper ureteral stones (multiple or single) or 'staghorn' stones were also included. Patients of this study were also included if their hematocrit was less than 36%. Excluded patients were those that had bleeding or perforation of the collecting system, congenital renal anomalies, horseshoe kidney or previous renal surgery. Under C-arm fluoroscopy, an 18 gauge needle was inserted into the kidney, and a 0.038-inch guidewire was introduced into the collecting system and then tract dilatation was performed with Amplatz dilators. An Amplatz sheath was placed into the 28F – 30F. Pneumatic lithotripsy was used for

fragmentation of the stones. An X ray was taken to evaluate stone fragments. If there was no rupture of the renal pelvis, the patients who received tubeless PCNL did not receive a nephrostomy. Ureteral and Foley catheter were withdrawn 4-5 hours after the procedure. Patients were excluded from their study if they had any of the following: residual stones, pelvic rupture, or significant bleeding; and those patients had to have nephrostomy tubes inserted. The fluoroscopy and operative time, as well as length of hospital stay (from the date of admission to the date of discharge) were recorded for each patient. The Visual Analog Scale (VAS) was used to assess postoperative pain at first hour and sixth hour. The independent variable was the type of PCNL (standard vs tubeless). The baseline variables included age, sex, height, weight, BMI, presence of diabetes, and the presence of hypertension, side of surgery, size and location of the stone, as well as the operative side. Outcome variables included hospital stay, fluoroscopy time, operative/procedure time and 1st and 6th hour VAS pain score. The change in hematocrit was also noted as a perioperative factor. The analysis of data collected was done using SPSS version 21. Sex, diabetes mellitus, hypertension, treatment group and stone location were presented as frequencies and percentages. The 57 quantitative variables such as age, height, weight, BMI, length of hospital stay, fluoroscopy duration, decrease in hematocrit of blood during surgery, operative time and pain at 1st and 6th hour (assessed by VAS pain scale) were presented as mean + standard deviation. Student's t-test was performed to compare the results of the tubeless and conventional PCNL groups. After stratification the confounding factors like age, diabetes mellitus, hypertension, obesity (BMI), size and location of stones were evaluated on the outcome and then post-stratification student's t-test was applied. A P value < 0.05 was considered significant. After approval of the synopsis by the College of Physicians and Surgeons Pakistan (CPSP) and clearance by Institutional Ethical Review Committee the study was conducted. Patients were chosen who met the study inclusion criteria. The study was conducted in accordance with the approved research protocol, while maintaining confidentiality.

RESULT

A total of 104 patients were included in the study, with 52 patients allocated to the tubeless

PCNL group and 52 to the standard PCNL group. The baseline demographic and clinical characteristics of the study participants are presented in Table 1. Age, body mass index, sex, diabetes mellitus, hypertension, operative side, and stone size were recorded for both treatment groups. The distribution of stone location was also documented.

The perioperative and postoperative outcomes are presented in Table 2. The assessed

outcomes included length of hospitalization, fluoroscopy duration, operative time, hematocrit decrease, and postoperative pain scores measured using the Visual Analog Scale at 1 and 6 hours. The comparative distribution of the principal perioperative outcomes between the two groups is presented in Figure 1, while the postoperative VAS pain scores at 1 and 6 hours are presented in Figure 2.

Table 1. Baseline Demographic and Clinical Characteristics of the Study Participants

Variable	Tubeless PCNL (n=52)	Standard PCNL (n=52)	P value
Age (years), mean $\pm$ SD	43.2 $\pm$ 8.7	44.1 $\pm$ 9.1	0.607
BMI (kg/m ²), mean $\pm$ SD	26.1 $\pm$ 3.2	26.4 $\pm$ 3.5	0.649
Male, n (%)	38 (73.1)	39 (75.0)	0.820
Female, n (%)	14 (26.9)	13 (25.0)	
Diabetes mellitus, n (%)	8 (15.4)	10 (19.2)	0.612
Hypertension, n (%)	11 (21.2)	12 (23.1)	0.811
Left side, n (%)	27 (51.9)	28 (53.8)	0.846
Right side, n (%)	25 (48.1)	24 (46.2)	
Stone size (mm), mean $\pm$ SD	28.4 $\pm$ 7.1	29.1 $\pm$ 7.6	0.628

Table 2. Perioperative and Postoperative Outcomes

Outcome	Tubeless PCNL (n=52)	Standard PCNL (n=52)	P value
Length of hospitalization (days), mean $\pm$ SD	1.7 $\pm$ 0.8	3.1 $\pm$ 1.0	<0.001
Fluoroscopy duration (min), mean $\pm$ SD	5.1 $\pm$ 1.6	5.4 $\pm$ 1.8	0.371
Operative time (min), mean $\pm$ SD	76.2 $\pm$ 18.5	82.1 $\pm$ 20.1	0.122
Hematocrit decrease, mean $\pm$ SD	2.5 $\pm$ 1.4	3.4 $\pm$ 1.6	0.003
VAS pain score at 1 hour, mean $\pm$ SD	5.8 $\pm$ 1.6	6.7 $\pm$ 1.2	0.002
VAS pain score at 6 hours, mean $\pm$ SD	3.4 $\pm$ 1.3	4.7 $\pm$ 1.4	<0.001

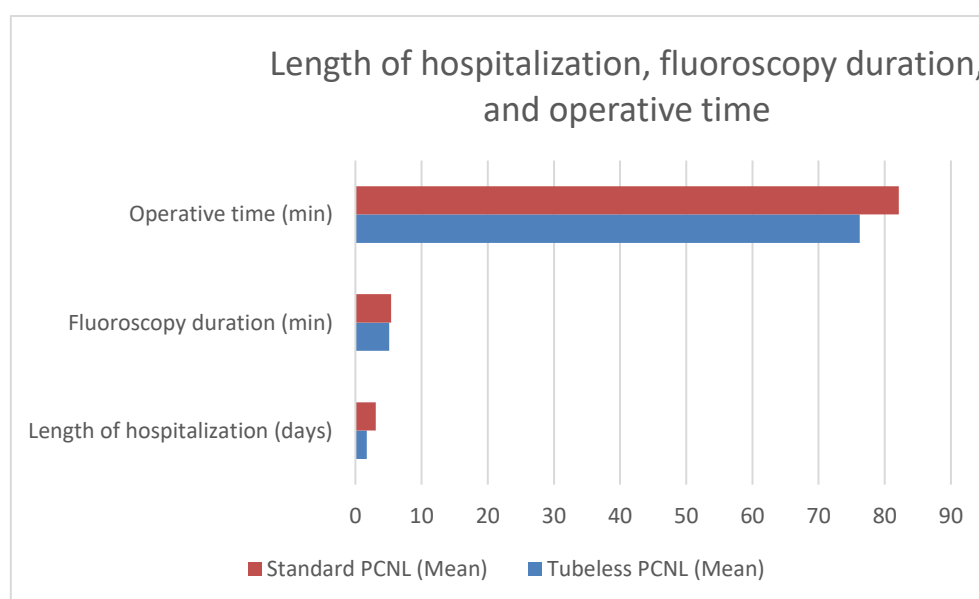


Figure 1: Length of hospitalization, fluoroscopy duration, and operative time

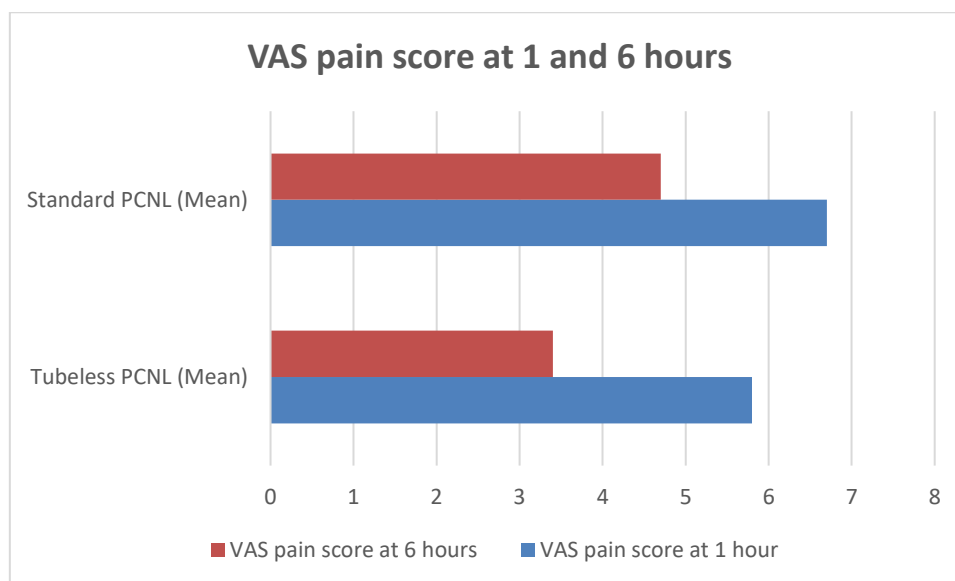


Figure 2: VAS Pain Score at 1 and 6 Hours

DISCUSSION

The present study aimed to compare the tubeless and traditional percutaneous nephrolithotomy (PCNL) in patients suffering from renal stones and showed that tubeless PCNL had better outcomes than the traditional PCNL, with a shorter hospital stay and less early postoperative pain. These results were in line with existing evidence from the modern era showing that a nephrostomy tube is not necessary after an uncomplicated PCNL could aid in better recovery after the procedure without compromising its effectiveness. In a systematic review and meta-analysis of randomized clinical trials (RCTs), the authors found that tubeless PCNL resulted in shorter hospital and operative times than conventional PCNL, but stone-free rates and major complications are similar between the two techniques {7}. The shorter hospital stay with tubeless PCNL was in line with the results of recent systematic reviews. Wilhelm et al. found that tubeless PCNL was associated with a reduction in hospital stay compared with standard tubed PCNL, but the certainty of evidence ranged between very low and moderate certainty {8}. Recently, random studies have shown that totally tubeless PCNL can be safely performed in patients who are well-suited for the procedure {9}. This result is clinically validated for the avoidance of routine nephrostomy drainage if there is good clearance of stone and no major bleeding or injury to the collecting system is seen. The postoperative pain status is a crucial factor for recovery after PCNL. The tubeless technique may result in less pain in the early

postoperative period because the nephrostomy tube is not left in the renal pelvis, and may cause both somatic and visceral pain due to irritation of the renal parenchyma, access tract, skin and surrounding tissues. Modern pain management after PCNL has recognized nephrostomy associated pain as a significant factor of postoperative pain, and has also emphasized that there are tubeless options for minimizing postoperative pain and analgesic needs. {10} Additionally, research on the predictors of pain after PCNL shows that the pain after the procedure is related to patient-related and procedural factors {11}. Post-PCNL pain has also been demonstrated to be a clinically significant outcome that affects early recovery and the need for pain medications {12}. Many procedural factors could affect the difference in the time required to operate and fluoroscope between tubeless and standard PCNL. Both techniques need renal access, tract dilatation, nephroscopy, stone fragmentation and radiological confirmation of stone clearance. Thus, the operative and fluoroscopy times might be better correlated with stone burden, stone location, renal anatomy, ease of access and surgeon experience than with nephrostomy placement. However, new meta-analytic data has indicated that tubeless PCNL might slightly shorten the operating time due to the elimination of nephrostomy tube placement and management {7}. Randomized evidence has also shown that changes to the tubeless technique can be done without significant increases in operative complexity {9}. Peri-operative haematological parameters were also

consistent with the current literature on the safety of tubeless PCNL. A previous meta-analysis of randomized trials revealed no significant difference in reduction of hemoglobin or transfusion rate from the use of nephrostomy drainage, when it was not performed {7}. In recent years, pooled data comparing tubeless and standard PCNL demonstrated that the use of tubeless technique does not increase the clinically relevant bleeding complications, if the patient selection is appropriate {13}. Biological basis is that hemostasis after PCNL is largely dependent on the characteristics of the renal access tract, extent of vascular injury, number of punctures, size of the access tract and intraoperative bleeding and not only on nephrostomy placement. Patient selection is another crucial factor to take into account if a tubeless method is being used. Patients with congenital renal abnormalities, previous operation on one kidney, major bleeding, rupture and residual stones were excluded from the present study protocol, and the nephrostomy drainage was used in case of major bleeding, rupture or residual stones were encountered. This is in line with the more recent evidence which highlights the need for choosing simple cases for tubeless PCNL. There have been recent studies that have evaluated tubeless techniques using a more and more complex stone population; when performed by an experienced surgical team, the tubeless approach may be feasible in highly selected uncomplicated cases, but extended to more complex stone populations as well. {14} However, the choice of nephrostomy drainage should be individualized based on the intra operative data and patient's conditions. Another recent body of evidence have assessed tubeless PCNL in various populations and clinical contexts. New systematic reviews have shown that there are similar efficacy and safety results between tubeless and standard PCNL, with similar stone-free rates and comparable complication rates, and have shown that the tubeless methods have improved recovery outcomes after the procedure {13,15}. These have also been observed in children where tubeless PCNL has been shown to have a good recovery rate without any evidence of decreased efficacy in appropriately selected patients {16}. Together, these results indicate that the benefits for tubeless PCNL are not as much in terms of stone clearance, but in terms of postoperative recovery. One of the salient features of the present study was the randomized controlled design that minimized

the possibility of systematic differences among the treatment groups. The use of predetermined inclusion and exclusion criteria and a uniform operative protocol further enhanced the methodological uniformity. The VAS was utilized to evaluate postoperative pain at predetermined time periods, enabling a systematic evaluation of an important patient-centered outcome. Furthermore, clinically meaningful outcomes such as hospitalization, fluoroscopy time, operation time, hematocrit changes, postoperative pain were compared between the two groups and assessed on the same protocol. Some restrictions should be taken into account. The findings of the study may be applicable to only a single tertiary-care institution. The relatively small sample size could have prevented detection of rare postoperative complications. In addition, the study focused on early peri-operative results and failed to look at longer term measures like stone recurrence, delayed complications, quality of life and long term renal function. Also, the use of non-probability consecutive sampling prior to random allocation could have caused selection bias. Larger multicenter randomized trials with longer follow-up duration should thus be encouraged. The results suggest that tubeless PCNL may be considered as alternatives to the traditional nephrostomy drainage in the well-selected patients from a clinical viewpoint. There is growing evidence today that tubeless and totally tubeless can decrease the workload of a postoperative recovery with satisfactory procedural efficacy and safety {15,17}. Standardized criteria, cost-effectiveness, patient reported outcomes, long term complications and effectiveness of tubeless PCNL in patients with complex and/or high volume stone disease should be the focus of future studies.

CONCLUSION

For renal stones treatment, tubeless percutaneous nephrolithotomy (PCNL) proved to have positive postoperative results when compared to the conventional PCNL. The tubeless technique was found to be correlated with less hospital stay and lower early postoperative pain without affecting the peri-operative procedural results. The results of this study affirm that tubeless PCNL is a safe and practical procedure to avoid the use of nephrostomy tube in suitable patients, provided that there are no significant intraprocedural complications. By preventing routine nephrostomy tube insertion, recovery can occur

sooner after surgery, the patient is more comfortable, and the burden of a long-draining period is minimized. A larger number of patients and longer follow-up in multicenter studies is warranted to further validate its broader clinical applicability.

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