International Journal of Current Research and Review
DOI: https://doi.org/10.31782/IJCRR.2022.141601

Research Article

IJCRR
Section: Healthcare

A Comparative Study of Tubeless versus Standard Percutaneous Nephrolithotomy (PCNL) – A Randomized Controlled Study

Ali Nawaz[1*], Singh Akoijam Kaku[2], Somarendra Khumukcham[3]

[1]Senior Resident, Department of Urology RIMS Imphal Manipur, India; [2]Professor, Department of Urology RIMS Imphal Manipur, India; [3]Assitant Professor, Department of Urology RIMS Imphal Manipur, India.

ABSTRACT

Introduction: The tubeless percutaneous nephrolithotomy (PCNL) procedure is defined as nonplacement of double-J stent at the end of procedure. There are numerous advantages of placement of nephrostomy tube as in standard PCNL like adequate renal drainage, tamponade effect for bleeding and relook PCNL.

Aim: This study aims to determine the effectiveness, safety, and morbidity of tubeless PCNL by comparing it to the standard PCNL technique.

Methodology: It was a randomized controlled study conducted over a period of two years from (October 2019 to November 2021). All the patients aged 18-65 years of age with stone size of 1- 2.5cm who underwent PCNL in our department were included. The patients were allocated into two groups Group A (Tubeless PCNL) and group B (Standard PCNL). The randomization was done by block randomization method with sealed envelope system.

Results: The mean age in Group A was 37.94±12.7 years and group B 39.38±11.91 years. The mean stone size in (Group A-20.56±2.87mm, Group B- 21.54±2.63) and both were comparable. The mean operative time in (Group A was 47.68 min±5.27, Group B 49.72min±5.18) with insignificant result. The mean drop in haemoglobin was (Group A- 0.70gm% and Group B- 0.79 gm%) and requirement of blood transfusion was in (Group A- 5(10%) & Group B- 8(16%) patients. The mean analgesia requirement (inj. Tramadol (mg) was 113 mg ±29.68 in Group A and 172 mg ±31.87 in Group B) with significant p value <0.0001. The mean hospital stay was (Group A-3.42±0.72 & Group B-4.2±0.49 days) and the comparison shows significant result p value <0.0001. The stone clearance was more than 90% in both the groups with insignificant result, P value 0.7281.

Conclusion: Tubeless PCNL is an effective alternative procedure with the potential advantages of decreased postoperative pain, analgesia requirement, and hospital stay.

Key Words: Tubeless PCNL, Standard PCNL, Analgesia requirement, Hospital stay, Effectiveness, Safety

INTRODUCTION

Over the past 3 decades, percutaneous nephrolithotomy (PCNL) has evolved considerably, reflecting improvements in technology and surgical skills. There are two modifications trends: first is minimally invasive, namely by narrowing the percutaneous renal puncture passage diameter (mini-PCNL) and second is without using the tube (tubeless PCNL). Tubeless PCNL was introduced by Bellman[1] in 1997 which consisted of performing a PCNL without nephrostomy drainage at the end of the procedure.

Even today, the placement of a nephrostomy at the end of procedure has become the standard approach with the aim to drain urine, serve as haemostatic tamponade for the tract and a quick access if there is need of the relook procedure. However, the tube is always associated with increased morbidity and complications and there is enough existing literature which have confirmed that doing tubeless PCNL is associated with decrease morbidity, early discharge and less complications. So still there is no consensus on the need for post-PCNL drainage and in most of the literature, the choice often depends on the outcomes and difficulties encountered during the procedure and the surgeon's choice.[2] Through this work, we aimed to determine the effectiveness, safety, and morbidity of tubeless PCNL by comparing it to the standard PCNL technique.

Corresponding Author:
Ali Nawaz, Senior Resident, Department of Urology, RIMS Imphal Manipur 795001, India.
Phone: 7889382723, 8506831412; Email: drnawazali37@gmail.com

ISSN: 2231-2196 (Print) **ISSN:** 0975-5241 (Online)

Received: 29.06.2022 **Revised:** 13.07.2022 **Accepted:** 01.08.2022 **Published:** 23.08.2022

MATERIAL AND METHOD

It was a randomized controlled study conducted in the department of urology RIMS Imphal Manipur over a period of two years from (October 2019 to November 2021). The study was taken up after getting clearance from the Research Ethics Board RIMS (Ref. No. A/206/REB-Comm(SP)/RIMS/2015/651/129/2019). All the patients aged 18-65 years of age with stone size of 1- 2.5cm who underwent PCNL in our department were included in our study. The excessive intraoperative bleeding, pelvicalyceal perforations, redo cases and patients with anatomical variation of kidney in size and shape like horseshoe kidney were excluded.

A total of 100 patients were included in our study and each group consist of 50 patients. The sample size was calculated using Clinical calculator[3] with a study power of 90%. The randomization was done by block randomization method with sealed envelope system. We prepared ten randomly generated treatment allocations within sealed opaque envelopes assigning A and B in 5 envelopes each, where A represents tubeless PCNL group and B represents standard PCNL group. Once a patient gave the consent to enter a trial, an envelope was opened and the patient was then offered the allocated group. So, the patients were randomized in a series of blocks of ten.

Procedure:

All the patients underwent PCNL as per the conventional standard procedure.[4] After achieving the complete stone clearance, DJ stent was placed inside the ureter and nephrostomy tube was not kept and PCN puncture site was closed with suture. Whereas in group B, nephrostomy tube was also kept along with DJ stent after achieving the complete stone clearance. The stone characteristics, operation time, requirement of analgesia, drop in haemoglobin/ requirement of blood transfusion, hospital stay, postoperative complications, and requirement of ancillary procedure were recorded and analysed. The stone size was calculated on the basis of CT report given by the radiologist. The operative time was calculated from the beginning of cystoscopy to the removal of amplatz sheath. Body temperature above 101 F after the operation during admission or readmission defined as post operative fever. Foleys catheter was kept in all patients for urinary drainage and removed on 2nd postoperative day.

Follow up: DJ stent was removed after 2 weeks and the patients were followed up again at 1 month with X-ray KUB and checked for need of any ancillary procedures. Stone clearance was decided by doing X-ray/ NCCT KUB at 3 months, reported by an uninformed radiologist and the final results were recorded.

Statistical analysis

All the patient's characteristics were entered in the Microsoft Excel sheet. Descriptive analysis was done in Microsoft Excel 2010. Qualitative data were reported as frequency and percentage whereas the quantitative data were reported as mean with standard deviation. Chi square test and Fischer's exact test were used as a test of significance for comparing the outcome variables and p-value <0.05 was taken as statistically significant.

RESULTS

A total 100 patients were included, and the patients were allocated into two groups Group A (Tubeless PCNL & standard PCNL). The minimum age in group A was 19-year-old with age range of 19-65, mean age of 37.94±12.7 years and the minimum age in group B was 18-year-old with age range of 39.38±11.91. Out of 50 patients, in group A 32(64%) patients were male and 18(36%) patients were female. In group B, out of 50 patients, 29(58%) patients were female, and 21(42%) patients were female. In this study 26(52%) patients had stone on the left side and 24(48%) patients had stone on the right side in group A. In group B, 25(50%) patients had stone on the right side and 25 (50%) had stone on the left side. In group A, the stone size range was between 15-25, mean stone size of 20.56±2.87. (Table 1) In group B, the stone size range was between 16-25, mean stone size of 21.54±2.63. In group A, 32(64%) underwent inferior calyceal puncture, 12(24%) underwent middle calyceal puncture and 6(12%) underwent superior calyceal puncture. The operative time in Group A was between the range of 35- 57 minutes, with a mean of 47.68 min±5.27. In Group B, the operative time was between the ranges of 40- 62 minutes, with a mean of 49.72min±5.18. In group A, the mean drop in haemoglobin was 0.70gm% and in group B was 0.79 gm%. The requirement of blood transfusion was present in 5(10%) patients in group A and in group B, the requirement of blood transfusion was present in 8(16%) patients. In group A, the mean requirement of analgesia requirement (inj. Tramadol (mg) is 113 mg ±29.68. In group B, the mean requirement of analgesia requirement (inj. Tramadol (mg) was 172 mg ±31.87. In group A, the hospital stay was between the range of 3-6days, with a mean of 3.42±0.72days. In group B, the hospital stay was between the range of 4- 6, with a mean of 4.2±0.49days. In group A, 3(6%) patients had haematuria and 3(6%) patients had urosepsis. In group B, 2(4%) patients had haematuria, 3(6%) patients had urosepsis and 2(4%) patients had urinary leakage. In Group A, the stone clearance was seen in 45(90%) patients and in Group B, the stone clearance was seen in 46(92%) patients. In group A, URSL was required in 3(4%) and ESWL in 2(4%) patients. In group B, URSL was required in 2(4%) and ESWL in 2(4%) patients. (Table 1)

DISCUSSION

The age and sex distribution between the two groups were comparable (p value >0.05). The mean size of stone in tubeless PCNL group was 20.56cm±2.87 while in conventional group was 21.54cm ±2.63 and both groups were comparable in term of stone size p-value 0.782.

The mean operative time in tubeless PCNL was 47.68±5.87mintutes and 49.72±5.18 minutes in conventional PCNL groups, however the comparison between the two was statistically insignificant (p value 0.060). Kocakgo H et al.[4] found no significant decrease in the operative time in tubeless group. However, Ramasamy N et al.[5] found statistically significant less operative time in tubeless PCNL.

The mean drop in haemoglobin and requirement of blood transfusion requirement were less in the tubeless PCNL group in our study, however statistically it was insignificant (p value 0.06, Z score 0.89 Significance level 81.38%, Difference 0.06). Chen et al.[6] used fixed effect model for merging 12 RCTs to assess the drop in hemoglobin and the need of blood transfusion and their Pooled estimates of effect sizes showed that the difference of drop in hemoglobin between two groups was not statistically significant (SMD Z -0.04, 95% CI (-0.17, 0.10), P Z 0.59).

In tubeless PCNL the hospital stay was less with a mean of 3.42±0.72 days as compared to the conventional PCNL of 4.2±0.49 days and the difference was statistically significant with p value <0.0001. Agrawal M. et al.[7] in their randomized study found the average hospital stay in the tubeless group was (21.8 ± 3.9 minutes) was significantly shorter than that of the standard PCNL group (54.2 ± 5 minutes) ($p < 0.01$). Xun et al.[8] Wang J et al.[9] in tubeless PCNL is a good option in non-complicated cases, with the advantages of reduced hospital stay and little need for postoperative analgesia. However, Ichaoui et al.[2] in their study, no statistically significant differences were noted for postoperative pain ($p = 0.51$), and duration of hospitalization ($p = 0.16$) and they concluded by saying that longer hospital stays in the standard PCNL group may be the consequence of restricted selection criteria within the tubeless group and here is no reason for nephrostomy catheter placement to delay the patient's discharge when its removal only takes a few minutes.

The analgesia requirement was less in tubeless PCNL as compared to conventional PCNL with a significant p value <0.0001. Chen et al.[6] reported decreased analgesia requirement in the tubeless groups. Xun et al.[8] also reported that tubeless PCNL is a good option in non-complicated cases, with the advantages of reduced hospital stay and little need for postoperative analgesia.

We found that the stone clearance between the two groups were more than 90% and the comparison between the two groups did not turn out to be statistically significant (p value 0.7281). Ramasamy N et al.[5] Ichaoui H et al.[2] also found similar result with no statistically significant result.

The complications in the form of bleeding, postoperative fever and urine leakage were found in both groups however with no significant difference p value 0.3831. In a meta-analysis by Chen et al,[6] showed that advantages of tubeless PCNL being a significantly decreased recurrence of urine leakage, postoperative fever, bleeding requiring blood transfusions.

Candela et al.[10] compared the cost of tubeless procedure with conventional procedure. It was 1638 $ with tubeless and 3750 $ with conventional PCNL. However, in our study we have not evaluated the cost efficacy in our study.

Several retrospective studies have shown that tubeless PCNL can be extended even in patients with multiple, complex and staghorn stones, concurrent UPJ obstruction, solitary kidney, previous ipsilateral open surgery, raised serum creatinine level, with multiple or supracostal tracts, and in patients undergoing bilateral synchronous PCNL.[11,12]Jou et al.[13] performed a retrospective study to assess the outcome and safety of nephrostomy tube-free PCNL (64 procedures in 62 patients) with calculi 3 cm or greater. An 82.8% stone-free rate was reported in this study, and they concluded that with adequate hemostasis, nephrostomy tube free PCNL can be performed in patients with complicated urolithiasis without any increase in morbidity. Falahatkar et al.[14] achieved 88.09% stone-free rate in tubeless PCNL in 42 patients with staghorn stones requiring multiple access tracts and reported it to be a safe procedure with no significant complications.

The tubeless technique has been successful also in obese patients, children,[15] and patients with recurrent stones after open surgery.[16] However, for all these extended indications, the available evidence is insufficient, and needs to be substantiated by prospective randomized trials.

CONCLUSION

Tubeless PCNL can be used with a favorable outcome in selected patients (stone burden ≤2.5 cm, single tract access, no significant residual stones, no significant perforation, minimal bleeding, and no requirement for a secondary procedure), with the potential advantages of decreased postoperative pain, analgesia requirement, and hospital stay.

ACKNOWLEDGMENT

Authors acknowledge the immense help received from the scholars whose articles are cited and included in references of this manuscript. The authors are also grateful to authors / editors / publishers of all those articles, journals and books from where the literature for this article has been reviewed and discussed

Ethical clearance:

The study had conducted after getting appropriate consent from the patients and the study was reviewed and approved by Research Ethic board RIMS. The patients/ participants provided their written informed consent to participate in this study.

Source of funding: Nil

Conflicts of interest: Nil

Authors' contributions:

NA collected the data, analysis, literature review and prepared the manuscript of the study. AKS planned the study, helped in reviewing and supervised the study. KS helped in writing, and editing the manuscript.

REFERENCES

1. Bellman GC. Tubeless percutaneous renal surgery. J Urol 1997; 157:1578-82.
2. Ichirou H, Samet A, Hadjalouane BH. Percutaneous Nephrolithotomy (PCNL): Standard Technique Versus Tubeless - 125 Procedures. Cureus 2019, 11(3): e4251.
3. Rosner B. Fundamentals of Biostatistics. 7th ed. Boston, MA: Brooks/Cole; 2011.
4. Kocakgo H, Adanur S, Ali H, Ozkaya F, Karabulut I. A Comparison of Standard Percutaneous Nephrolithotomy and Tubeless Percutaneous Nephrolithotomy: Does Tubeless Really Superior? A Prospective Randomized Double-Blind Study. New J Urol 2019;14:70-80.
5. Ramasamy N, Balasubramanyan JK: efficacy and safety of standard versus tubeless percutaneous nephrolithotomy- A randomized controlled study. J. evol. med. dent. sci. 2019; 8(25):11-16.
6. Chen ZJ. Comparison of tubeless percutaneous nephrolithotomy and standard percutaneous nephrolithotomy for kidney stones. Asian J Urol (2020) 43, 60-68
7. Madhu S, Agrawal J. A randomized comparison of tubeless and standard percutaneous nephrolithotomy. J Endourol 2008 Mar;22(3):439-42.
8. Xun. Tubeless versus standard percutaneous nephrolithotomy: an updated meta-analysis. BMC Urology 2017;17:102.
9. Wang J. Tubeless vs standard percutaneous nephrolithotomy. BJU 2011;11(3):42-46.
10. Candela J, Davidoff R, Gerspach J, Bellman GC. "Tubeless" percutaneous surgery: A new advance in the technique of percutaneous renal surgery. Tech Urol 1997;3:6-11.
11. Shah HN, Kausik VB, Hegde SS, Shah JN, Bansal MB. Tubeless percutaneous nephrolithotomy: A prospective feasibility study and review of previous reports. BJU Int 2005;96:879-83.
12. Sofer M, Beri A, Friedman A, Aviram G, Mabjeesh NJ, Chen J,. Extending the application of tubeless percutaneous nephrolithotomy. Urology 2007;70:412-7.
13. Jou YC, Cheng MC, Lin CT, Chen PC, Shen JH. Nephrostomy tube-free percutaneous nephrolithotomy for patients with large stones and staghorn stones. Urology 2006;67:30-4.
14. Falahatkar S, Khosropanah I, Roshani A, Neiroomand H, Nikpour S, Nadjafi-Semnani M,. Tubeless Percutaneous Nephrolithotomy for Staghorn Stones. J Endourol 2008;22:1447-52
15. Salem HK, Morsi HA, Omran A, Daw MA. Tubeless percutaneous nephrolithotomy in children. J Pediatr Urol 2007;3:235-8.
16. Shah HN, Mahajan AP, Hegde SS, Bansal M. Tubeless Percutaneous Nephrolithotomy in Patients with Previous Ipsilateral Open Renal Surgery: A Feasibility Study with Review of Literature. J Endourol 2008;22:19-24.

Table 1: Study parameters and comparison between the two groups

Study parameters	Group A (N=50)	Group B (N=50)	Comparison between the two groups (p-value)
Age(years) Mean ±SD	37.94±12.27	39.38±11.91	0.55
Sex distribution Male: Female (%)	32(64%): 18(36%)	29 (58%) :21(42%)	0.54
Stone side Right & left (%)	24(48%) & 52(%)	(50%) & 25(50%)	0.84
Stone size (mm) Mean ±SD*	20.56±2.87	21.54±2.63	0.078
Puncture site distribution (%) Inferior calyx Middle calyx Superior calyx	 32(64%) 12(24%) 6(12%)	 33(66%) 12(24%) 5(10%)	0.948
Operative time (minute), Mean ±SD	47.62±5.27	49.72±5.18	0.068
Drop in Hb (gm%) Mean ±SD	0.70 ±0.25	0.79± 0.32	0.135
Requirement of blood transfusion	5 (10%)	8(16%)	0.135
Analgesia requirement (Inj. tramadol mg)	113mg	172mg	<0.001*

Table 1: ***(Continued)***

Study parameters	Group A (N=50)	Group B (N=50)	Comparison between the two groups (p-value)
Hospital stays (days)	3.42± 0.72	4.2 ±0.49	<0.001*
Complications (%)	6 (12%)	7 (14%)	0.38
Stone clearance (%)	45 (90%)	46 (92%)	0.728
Requirement of ancillary procedures			
ESWL	2(4%)	2 (4%)	
URSL	3 (6%)	4 (8%)	0.36
Total	5 (10%)	6 (12%)	

*Statistically significant, *Standard deviation, ESWL (extracorporeal shock wave lithotripsy), URSL (Ureteroscopic lithotripsy)