

Original Article

Comparison of tubeless drainage and nephrostomy tube as a drainage method after percutaneous nephrolithotomy procedure: A prospective study

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Tubeless percutaneous cutaneous nephrolithotomy (PCNL), nephrostomy tube, day care surgery

Abstract

Objective: The standard procedure of PCNL involves insertion of a nephrostomy tube for drainage. The nephrostomy tube also serves as a medium to tamponade bleeding, and in cases where any remnant calculus requires re-exploration, the nephrostomy tube has been proved to be beneficial in providing access. However, presence of a tube may hamper PCNL in cases of day surgery. Tubeless PCNL could be the ideal approach in selecting which patients might be suitable for same day discharge. The objective of this study is to re-explore each drainage technique following PCNL and to compare the safety of these drainage procedures with a clear-cut clinical parameter imposed.

Materials and Methods: Inclusion Criteria: people aged 18 years and above, patients of either gender, all cases of renal calculi who underwent percutaneous nephrolithotomy. Exclusion Criteria: patients who needed more than 2 percutaneous tracts, patients with a solitary kidney or with bilateral renal calculi or with staghorn calculi or patients who had a residual stone after the procedure, patients having congenital renal anomalies, for example horse shoe kidney, mal rotated kidney, duplex moiety, ectopic kidney, patients with pelvis injury and extravasation during surgery. Total sample size was calculated to be 140 (70 in each group). Post operatively, patients in the two groups will be assessed on the following parameters: postoperative pain, analgesic requirement, complications, duration of hospital stay, return to normal activity and mean Hb decrease.

Results: Tubeless PCNL was significantly associated with shorter operative time, shorter hospital stay, faster time to return to normal activity, lower postoperative pain score, lower postoperative analgesia requirements, and lower urine leakage. There were no significant differences in postoperative haemoglobin reduction, stone-free rate, postoperative fever rate, or rate of blood transfusion.

Conclusion: Conclusions made from the outcomes of this study were that in comparison to standard PCNL, use of the tubeless PCNL conferred statistically significant advantages in terms of post-operative pain, morbidity, length of hospital stay and period of convalescence. As tubeless PCNL decreased length patient hospital stay and analgesic requirement this procedure is more efficacious for day care surgery.

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Introduction

Classified as a common urological disease, the prevalence rate for renal stones is notably high. Urinary stones can cause renal function injury, which has a great impact on public health.¹ Various non-invasive, minimally invasive, and invasive methods have been reported as potential treatments for kidney stones, including medicinal treatment, extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), and open renal surgery. Over the past 30 years, the use of PCNL as a minimally invasive method has been an effective treatment for large stones located in the kidney and upper ureter.² In patients with a large kidney stone, PCNL has been recognized as the primary treatment of choice. Over the years, various techniques have been developed to enable the achievement of reliable and safe percutaneous kidney access, leading to enormous popularity of PCNL. The important milestones in the history of percutaneous renal surgery include Goodwin's description of percutaneous nephrostomy in 1955 and Fernstrom and Johannson's first publication of PCNL in 1976.³ Wickham in 1979 described the staged approach, starting with percutaneous nephrostomy under local anesthesia, followed by the dilatation of the tract serially over the next few days, with subsequent stone removal under general anesthesia using a rigid 30° cystoscope. Alken used this technique as a salvage procedure to remove remaining stones after open surgery, through an operatively established nephrostomy tract.⁴

The standard procedure of PCNL involves insertion of a nephrostomy tube for drainage. Apart from drainage, the nephrostomy tube serves as a medium to tamponade bleeding along the PCNL tract. Furthermore, in case of any remnant calculus requiring re-exploration, the nephrostomy tube has been proven to be beneficial in providing access in such cases. However, presence of a nephrostomy tube may hamper PCNL as a day surgery/ ambulatory procedure.⁵ The concept of percutaneous tubeless nephrolithotomy was to no longer insert a nephrostomy tube at the end of the procedure but to drain the renal cavities solely with a ureteral stent. Tubeless PCNL could be the ideal approach in selecting which patients may be suitable for same day discharge.⁶

PCNL includes four steps: access to the kidney, dilatation of the tract (access site), nephroscopy and fragmentation of stones, and

finally insertion of a nephrostomy tube. In tubeless PCNL, the fourth step (i.e., inserting a nephrostomy tube) is not carried out.⁷

The objective of this study is to re-explore each drainage technique following PCNL (tubeless, totally tubeless or nephrostomy tube) and to compare the safety of these drainage procedures with clear-cut clinical parameters imposed.⁸ Judicious application of tubeless PCNL can aid in quick recovery of the patient with the major benefits of shorter hospital stay, lower cost and reduced pain. Nonetheless, the decision to use or not to use a nephrostomy tube after PCNL needs to depend on the surgeon's experience and clinical judgment.⁹

Materials and Methods

Study design

Study design was a comparative and prospective study in a tertiary care hospital. The protocol was approved by the Institutional Ethics Committee of Department of Pharmacology of Mumbai with the study number of IEC/Pharm/RP/292/04/2024, approved August 23, 2024. The duration of the study was 1 year (Fig. 1)

Selection criteria

Inclusion criteria: people aged 18 years and above, patients of either gender, and all cases of renal calculi who underwent percutaneous nephrolithotomy. Renal calculi were defined as calyceal calculi, pelvic calculi, upper ureteric calculi or any of the combination of above, with stone size ranging from 1 cm to 4 cm. Exclusion criteria: patients who needed more than 2 percutaneous tracts, patients with a solitary kidney or with bilateral renal calculi or with staghorn calculi or patients who had a residual stone after the procedure, patients having congenital renal anomalies- horse shoe kidney, mal rotated kidney, duplex moiety, ectopic kidney, and patients with pelvis injury and extravasation during surgery. Pregnant or lactating patients were also excluded from the study.

Sample size

140 participants were selected, out of which 70 underwent tubeless PCNL and 70 standard PCNL (with a nephrostomy tube for drainage). The non-probability purposive sampling method has been used.

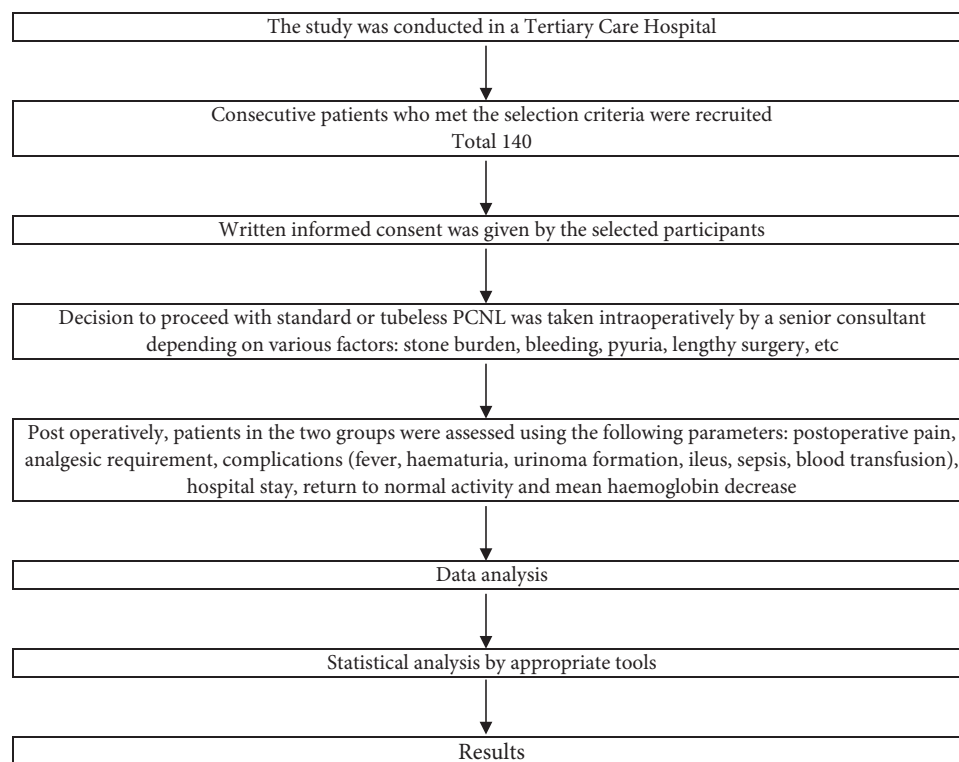


Figure 1. Study flow chart.

Procedure

Criteria for Nephrostomy tube placement. In our study, the decision regarding placement of nephrostomy tube versus tubeless drainage was taken intraoperatively by a senior consultant based on operative findings and patient safety considerations. Use of a nephrostomy tube was preferred in patients with: significant intraoperative bleeding, large stone burden or complex stones, presence of pyuria/infected urine, prolonged operative duration, suspected collecting system injury or extravasation, need for multiple accesses or anticipated second-look procedure tubeless. PCNL was considered only in uncomplicated cases with complete stone clearance, minimal bleeding, single or limited tract access, no collecting system perforation, and hemodynamic stability at the end of procedure.

The tract size was 24 Fr for all cases, and the nephrostomy tube used was of the same calibre and made of biocompatible polyurethane.

Data collection

After getting approval from the IEC, data collection was started after obtaining written informed consent from the study subjects (Annex 3). Information was recorded in a predesigned,

pretested questionnaire. Annex 1 consists of data from the case record forms of participants including age, sex, educational and employment status, religion and estimates of income. Annex 2 is a record of the Visual Analogue Scale (VAS) for pain assessment.

Data analysis

Data was collected and entered in a Microsoft Excel sheet. The collected data was analyzed using appropriate statistical software. Generated data was analyzed as per the aims and objectives of the study using suitable parameters.

Statistical analysis

Both descriptive and inferential statistics were applied. Qualitative data were described in the proportion and percentage. Quantitative data were described as mean $\pm$ SD. Data thus collected were compiled & analyzed in Microsoft excel sheets. For analysis appropriate software will be used. Results are displayed in tabular and graphical format. A p-value less than 0.05 was considered as statistically significant. Other appropriate statistical analysis was then carried out such as a Mann-Whitney U test and a Chi² test.

Results

Age

A Mann-Whitney U test was carried out to compare the results collated between the tubeless and nephrostomy tube groups. For the given data a Mann-Whitney U-Test showed that the difference between tubeless and nephrostomy tube with respect to the dependent variable age (years) was not statistically significant, $U = 2438.5$, $n_1 = 70$, $n_2 = 70$ $p = 0.963$.

Sex

A χ^2 test was performed between sex and drainage. All expected cell frequencies were greater than 5, thus the assumptions for the χ^2 test were met. There was no statistically significant relationship between sex and drainage, $\chi^2(1) = 0.46$, $p = 0.496$, Cramér's $V = 0.06$. The data distribution between tubeless and nephrostomy tube is age and sex matched.

Duration of surgery

A Mann-Whitney U test was conducted to compare scores between the tubeless and nephrostomy tube groups. The data showed that the difference between the two groups with respect to the dependent variable duration of surgery (minutes) was statistically significant, $U = 111.5$, $n_1 = 70$, $n_2 = 70$, $p < 0.001$ (Fig. 2).

Pain (VAS) at 1st hour

A Mann-Whitney U test was conducted to compare scores between the tubeless and nephrostomy tube groups. The data showed that the

difference between the tubeless and nephrostomy tube groups with respect to the dependent variable pain (VAS) at the 1st hour post-operative was statistically significant, $U = 163.5$, $n_1 = 70$, $n_2 = 70$, $p < 0.001$ (Fig. 3).

Pain (VAS) after 24th hours

The mean pain scores after 24th hours were $2.04 (\pm 0.73)$ and $4.8 (\pm 1.39)$ in the tubeless and nephrostomy tube groups respectively. The median pain scores after the 24th hour were 2 and 5 in the tubeless and nephrostomy tube groups respectively. A Mann-Whitney U test was conducted to compare scores between the two groups. The data showed that the difference between tubeless and nephrostomy tube with respect to the dependent variable pain (VAS) after 24 hours was statistically significant, $U = 155.5$, $n_1 = 70$, $n_2 = 70$ $p < 0.001$ (Fig. 4)

Pain (VAS) after 1 month

The mean pain scores after 1 month were $0.06 (\pm 0.29)$ and $2.66 (\pm 1.11)$ in tubeless and nephrostomy tube groups respectively. The median pain scores after 1 month were 0 and 3 in the tubeless and nephrostomy tube groups respectively. A Mann-Whitney U test was conducted to compare scores between the two groups. The data showed that the difference between tubeless and nephrostomy tube with respect to the dependent variable pain (VAS) after 1 month was statistically significant, $U = 98.5$, $n_1 = 70$, $n_2 = 70$ $p < 0.001$ (Fig. 5).

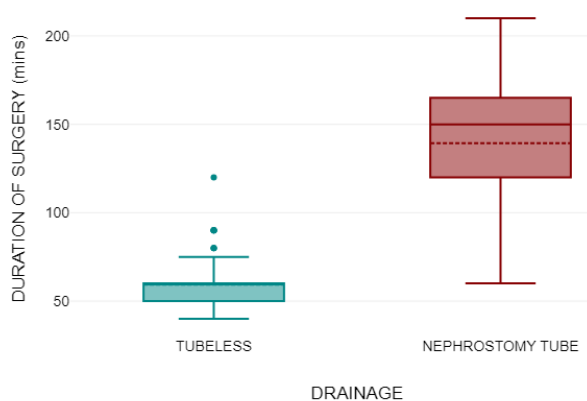


Figure 2. Duration of surgery in comparison to drainage type.

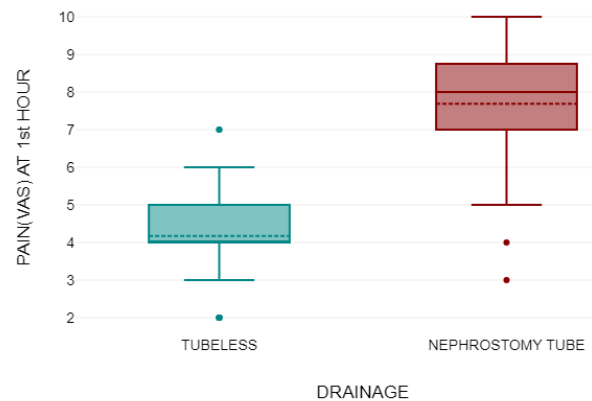


Figure 3. Pain (VAS) at 1st hour in comparison to drainage type.

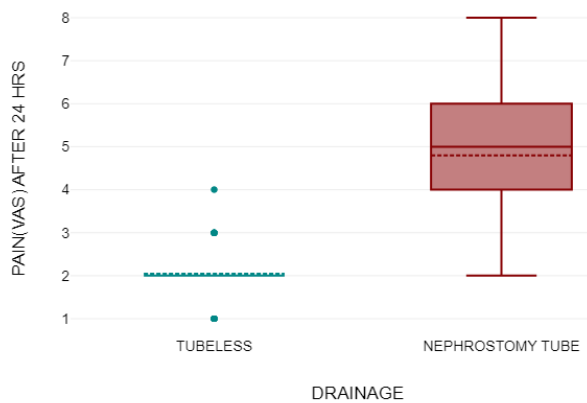


Figure 4. Pain (VAS) after 24th hour in comparison to drainage type.

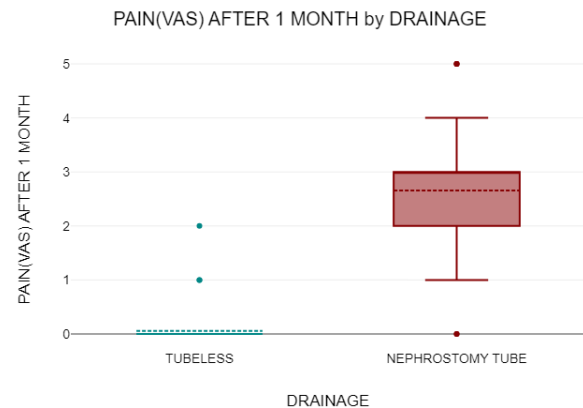


Figure 5. Pain (VAS) after 1 month in comparison to drainage type.

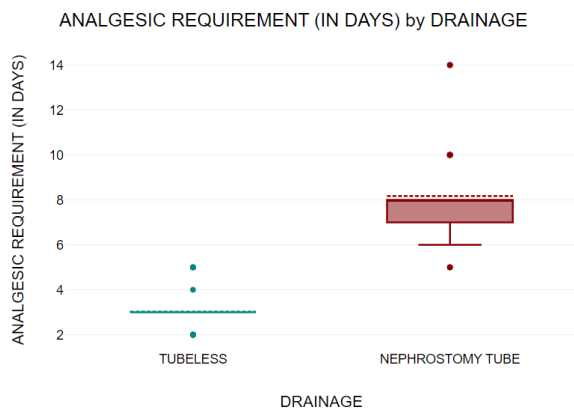


Figure 6. Analgesic requirement in comparison to drainage type.

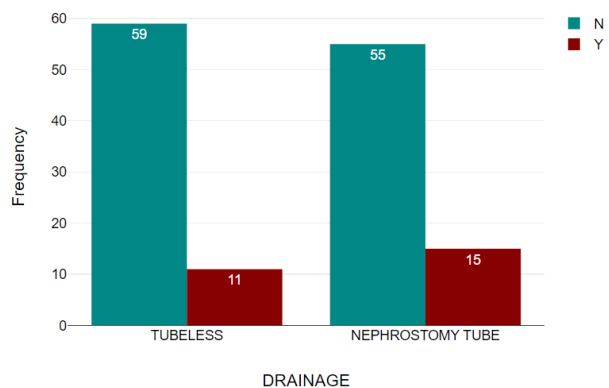


Figure 7. Hematuria in comparison to drainage type.

Analgesic requirement

The mean analgesic requirements were 3.03 (± 0.72) and 8.17 (± 1.93) days in the tubeless and nephrostomy tube respectively. The median analgesic requirements were 3 and 8 days for tubeless and nephrostomy tube groups respectively. A Mann-Whitney U test was conducted to compare scores between the two groups. The data showed that the difference between tubeless and nephrostomy tube with respect to the dependent variable analgesic requirement (days) was statistically significant, $U = 12$, $n_1 = 70$, $n_2 = 70$ $p < 0.001$ (Fig. 6).

Hematuria

Hematuria occurred in 11 and 25 patients in the tubeless and nephrostomy tube groups respectively. A χ^2 test was performed to compare the differences between drainage and hematuria. All expected cell frequencies were greater than 5, thus the assumptions for the χ^2 test were met. There was no statistically significant relationship

between drainage and hematuria, $\chi^2(1) = 0.76$, $p = 0.385$ (Fig. 7).

Urinary leak

Urinary leakage was found in 0 and 30 patients in the tubeless and nephrostomy tube groups respectively. A Fisher's exact test was performed to compare drainage and urinary leakage. There was a statistically significant relationship between drainage and urinary leakage, $p < 0.001$ (Fig. 8).

Urinoma formation

Urinoma formation occurred in 8 and 10 patients in the tubeless and nephrostomy tube groups respectively. A χ^2 test was performed to compare the incidence of drainage and urinoma formation. All expected cell frequencies were greater than 5, thus the assumptions for the χ^2 test were met. There was no statistically significant relationship between drainage and urinoma formation, $\chi^2(1) = 0.26$, $p = 0.614$ (Fig. 9).

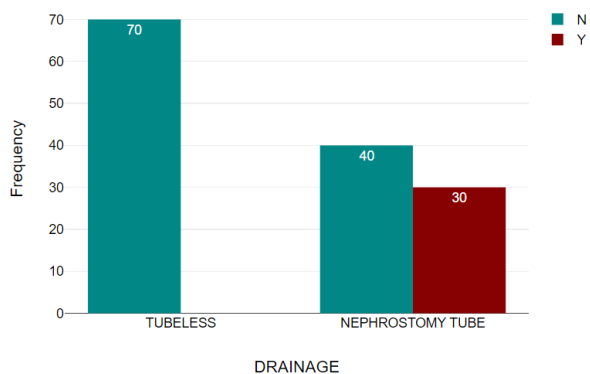


Figure 8. Urinary leakage in comparison to drainage type

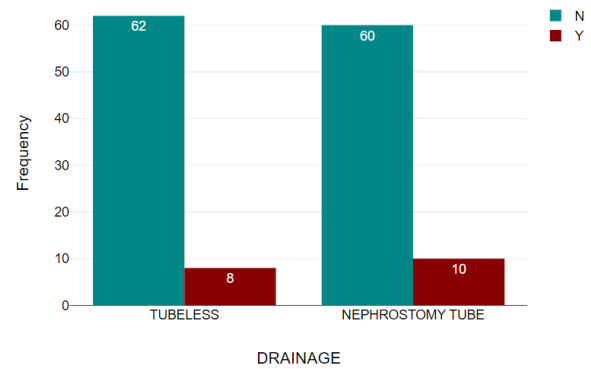


Figure 9. Urinoma formation in comparison to drainage type.

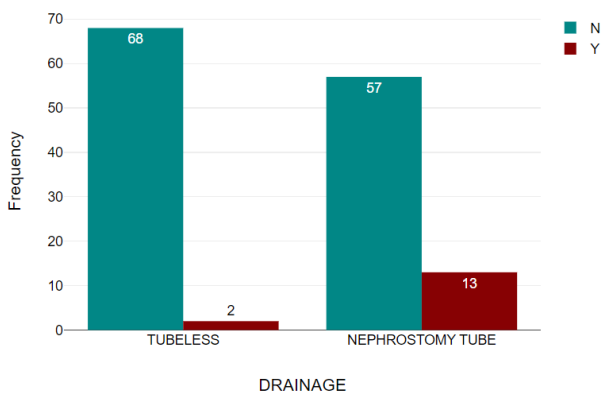


Figure 10. Fever in comparison to drainage type.

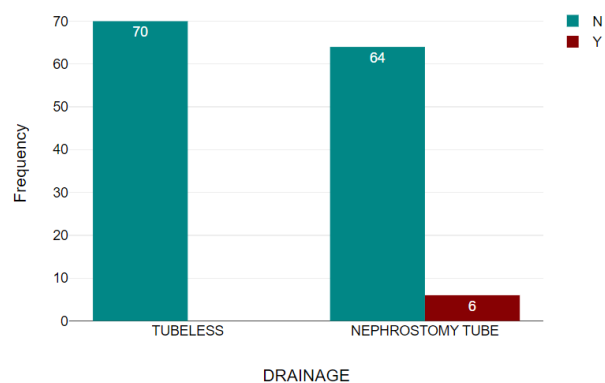


Figure 11. Requirement for blood transfusion in comparison to drainage type.

Urinoma, if suspected, was diagnosed via Ultrasonography. Rarely, in some cases, a CT scan was required.

Fever

Fever occurred in 2 and 13 patients in the tubeless and nephrostomy tube groups respectively. A χ^2 test was performed to compare drainage and fever data. All expected cell frequencies were greater than 5, thus the assumptions for the χ^2 test were met. There was a statistically significant relationship between drainage and fever, $\chi^2(1) = 9.03$, $p = 0.003$ (Fig. 10).

Requirement for blood transfusion by drainage

Blood transfusion was necessitated in 0 and 6 patients in the tubeless and nephrostomy tube groups respectively. A Fishers exact test was performed to compare the type of drainage and the requirement for a blood transfusion. There was a statistically significant relationship between drainage and requirement for blood transfusion, $p = 0.028$ (Fig. 11).

Any other complications

Any other complications occurred in 0 and 3 patients in the tubeless and nephrostomy tube groups respectively. A Fishers exact test was performed to compare these two sets of data. The data showed that there was no statistically significant relationship between drainage and any other complication, $p = 0.245$ (Fig. 12).

Hospital stay

The mean lengths of hospital stay were $1.03 (\pm 0.17)$ and $2.59 (\pm 0.67)$ days in the tubeless and nephrostomy tube groups respectively. The median lengths of hospital stay were 1 and 2.5 days for tubeless and nephrostomy tube groups respectively. A Mann-Whitney U test was conducted to compare the data between the two groups. The results showed that the difference between the two groups with respect to the dependent variable hospital stay (days) was statistically significant, $U = 35$, $n_1 = 70$, $n_2 = 70$, $p < 0.001$ (Fig. 13).

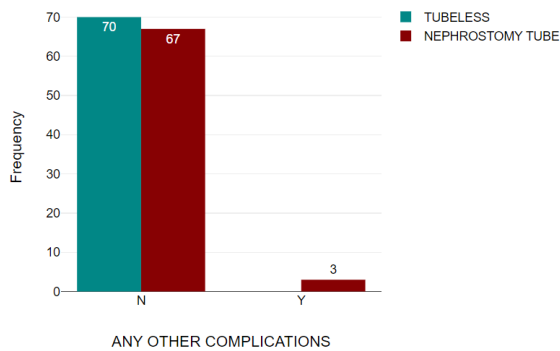


Figure 12. Any other complications in comparison to drainage type.

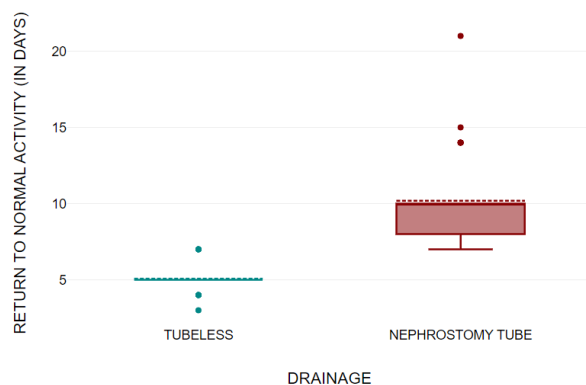


Figure 14. Return to normal activity in comparison to drainage type.

Return to normal activity

The mean lengths of time to return to normal activity were $5.07 (\pm 0.87)$ and $10.19 (\pm 3.05)$ days for tubeless and nephrostomy tube respectively. The median lengths of return to normal activity were 1 and 2.5 days for the tubeless and nephrostomy tube groups respectively. A Mann-Whitney U test was conducted to compare the two groups. The results showed that the difference between the two groups with respect to the dependent variable return to normal activity (days) was statistically significant, $U = 76.5$, $n_1 = 70$, $n_2 = 70$, $p < 0.001$ (Fig. 14).

Discussion

Tirtayasa et al.¹⁰ conducted a comprehensive review on the safety of tubeless drainage and nephrostomy drainage following PCNL in 2016. In this study it was concluded that with similar complication rates between the two procedures, tubeless PCNL was significantly superior to standard PCNL in terms of length of hospital stay, return to normal daily activities, post-operative

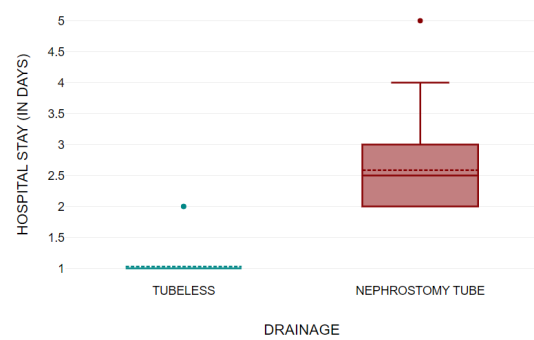


Figure 13. Length of hospital stay in the two types of drainage group.

pain, analgesia requirements and total treatment costs. Thus, the study suggested that in uncomplicated cases, tubeless or totally tubeless PCNL may be considered as a safe alternative.

Xun et al.¹¹ conducted a meta-analysis to compare between the exit strategies for PCNL involving 1,148 patients. The combined results demonstrated that tubeless PCNL was significantly associated with shorter operative time, shorter hospital stay, faster time to return to normal activity, lower postoperative pain score, lower postoperative analgesia requirements, and lower urine leakage. There were no significant differences in postoperative hemoglobin reduction, stone-free rate, postoperative fever rate, or blood transfusion rate. The results of subgroup analysis were consistent with the overall findings.

Gauhar et al.¹² performed a systematic review of randomized trials to summarize the evidence with regard to the safety and stone-free rate after Tubeless PCNL in comparison to standard PCNL. The study concluded that the standout benefits of tubeless PCNL are shorter operative time, shorter hospital stay, and a lower rate of postoperative urinary fistula. However, pain scores, need for readmission, use of analgesia, and complication rates did not differ between the groups, making Tubeless PCNL a safe option and suitable for same day discharge.

Hill et al.¹³ conducted a study to examine differences in postoperative complications and outcomes of tubeless PCNL versus standard PCNL. In comparing tubeless with standard PCNL, there was no difference in readmission rates, or significant Clavien complication rates. Patients undergoing tubeless PCNL experienced higher stone-free rates, but a higher number of patients required postoperative blood transfu-

sion. Thus, the study concluded that the decision to leave a residual nephrostomy tube after PCNL appears unlikely to impact overall complication rates and can be left to the experience and case-based discretion of the surgeon.

Lee et al.¹⁴ performed a systematic review and network meta-analysis to evaluate the feasibility and safety of different PCNL procedures, including total tubeless, tubeless with stent, small-bore tube, and large-bore tube PCNLs. The study concluded that with regard to haemoglobin changes, total tubeless and small-bore PCNLs may be superior to other methods. With regard to hospital stay, total tubeless and tubeless PCNLs with stent may be superior to other procedures.

Our findings were consistent with those reported from previous studies. Tubeless PCNL was significantly associated with shorter operative time, shorter length of hospital stay, faster time to return to normal activity, lower postoperative pain score, lower postoperative analgesia requirements, and lower urine leakage. There were no significant differences in postoperative haemoglobin reduction, stone-free rate, postoperative fever rate, or blood transfusion rate.

Stent syndrome score was not specifically assessed in this study. The study primarily focused on postoperative pain (VAS score), analgesic requirement, complications, hospital stay, and return to normal activity. Although ureteral stent-related symptoms can influence postoperative discomfort in tubeless PCNL, validated stent symptom questionnaires such as the Ureteral Stent Symptom Questionnaire (USSQ) were not included in the study protocol. This can be considered a limitation of the study and an area for future research.

Conclusion

In comparison to standard PCNL, tubeless PCNL significantly reduces postoperative pain, morbidity, hospital stay, and recovery time. This approach reduces the length of hospital stay and analgesic needs, enhancing the feasibility of labelling PCNL as an option for day care surgery.

Conflict of Interest

The authors declared no conflict of interest.

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