

Does Bleeding During Percutaneous Nephrolithotomy Necessitate keeping the Nephrostomy Tube?

A Randomized Controlled Clinical Trial

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Purpose: To compare outcomes in two groups of patients with kept and discarded nephrostomy tube after percutaneous nephrolithotomy (PCNL) complicated with bleeding.

Materials and Methods: Two hundred patients who had undergone PCNL complicated with hemorrhage were recruited in this study. Patients were randomly allocated to two groups: group A, who underwent tubeless PCNL and tract port was packed for 3 to 4 minutes after removing Amplatz sheath, and group B, for whom a 24-F nephrostomy tube was left in place at the end of the procedure. Patients were followed up for 3 months to check if bleeding occurred.

Results: The mean operation time was 68 ± 4.3 minutes in group A and 74 ± 5.6 minutes in group B ($P = .098$). The mean stone size was similar in groups A and B (36.26 ± 5.3 mm versus 35.35 ± 5.85 mm; $P = .613$). The mean hemoglobin drop was 3.65 ± 1.20 g/dL in group A and 3.13 ± 1.06 g/dL in group B. There was no significant difference between the mean of stone-free rate in groups A and B ($92.58\% \pm 5.97$ versus $89.60\% \pm 8.3$; $P = .210$). Patients in group A experienced a significantly less duration of hospitalization than group B (2.42 ± 0.84 days versus 3.70 ± 0.80 days; $P < .001$).

Conclusion: In the absence of clear indication, nephrostomy tube insertion after PCNL does not seem to be beneficial, and its removal does not pose patients at any additional risk.

Keywords: percutaneous nephrolithotomy, hemorrhage, randomized controlled clinical trial, nephrostomy

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INTRODUCTION

Since the first introduction by Fernstrom and Johansson in 1976,⁽¹⁾ percutaneous nephrolithotomy (PCNL) has become an established procedure in large, complex, and shock wave lithotripsy-resistant renal stones. Technical advances and increased operator experience have resulted in considerable refinement of the percutaneous approach to the renal calculi.^(2,3)

As the kidney is an extremely

vascular organ, some degree of bleeding occurs during every PCNL.⁽⁴⁾ Major complications, including bleeding, extravasation, and fever, can be managed conservatively or minimally invasively.⁽⁵⁾ Even for the most experienced urologists, major complications can still occur in 1.1% to 7% of patients undergoing PCNL, and minor complications may occur in 11% to 25% of the patients.^(6,7)

One of the concerns regarding the tubeless PCNL technique is inability to monitor excessive hemorrhage and tract hemostasis.⁽⁸⁾ However, recently, tubeless PCNL has been advocated increasingly in the literature. It has been found to be safe and effective in properly selected patients and has advantages of less postoperative pain and a shorter hospital stay.^(9,10)

This study, to the best of our knowledge, is the first study comparing outcomes of keeping nephrostomy tube with tubeless PCNL complicated with bleeding.

MATERIALS AND METHODS

Patients

Between April 2005 and April 2009, 200 patients who had undergone PCNL and experienced bleeding were studied.

All patients had intravenous urography before the surgery. Patients with pregnancy, abnormal coagulopathy status, recent nonsteroidal anti-inflammatory drugs consumption, and urinary tract infection were excluded from the study. Whereas single kidney, malrotated or horseshoe kidneys, and previous surgery were not exclusion criteria for this study. The study was approved by the regional Medical Ethics Commission, and a written informed consent was obtained from each patient.

The patients were randomly assigned to two groups by a third person who was blinded to the study. Patients in group A underwent tubeless PCNL while in group B, nephrostomy tube was placed after PCNL.

Pre-operative routine evaluations were done for all of the patients. Operation time, hemoglobin drop, stone-free rate, duration of hospital stay, and transfusion rate were recorded. Ultrasonography or computed tomography scan was performed as needed.

Surgical Technique

All of the surgeries were performed by a single team. For all of the patients, a ureteral catheter was inserted in lithotomy position; thereafter, the renal access was achieved under fluoroscopic

guidance preferably through the lower calyx in prone position. Tract dilation was performed in one-shot method and a 30-F Amplatz sheath was inserted. Pneumatic with or without ultrasonic lithotriptors were used for stone fragmentation

If bleeding happened during the surgery, the patient was recruited into the study and at the end of the surgery, they were randomly divided into 2 groups; A and B. In group A, tract port was packed for 3 to 4 minutes after removing Amplatz sheath. In group B, a 24-F nephrostomy tube was left at the end of the procedure.

Postoperative Care

Close observation was performed for all of the patients after the procedure. Serum level of hemoglobin was measured pre-operatively and every 6 hours on the first postoperative day; and if there was not a significant drop, it was measured daily until the patients' discharge. Patients' vital signs were monitored accurately. In group A, Foley and ureteral catheter were removed 24 to 48 hours after the procedure, once the urine was cleared of blood. In group B, nephrostomy tube was removed after 24 to 48 hours, once the urine was cleared, and the Foley and ureteral catheter were removed 6 to 12 hours after leakage from the nephrostomy tract stopped.

After discharge, the patients were followed up for 3 months to check if bleeding recurred. The patients were examined and asked about the bleeding when they have been visited at clinic. We called the patients who did not attend the clinic to ask about bleedings.

Statistical Analysis

Data were analyzed using SPSS (Statistical Package for the Social Sciences, Version 13.0, SPSS Inc, Chicago, Illinois, USA) software. Quantitative variables were compared by Independent Samples *t* test and Mann-Whitney *U* test, and qualitative variables by Chi-square test. To remove the effect of factors affecting duration of hospitalization, linear regression model was employed. In addition, quantitative variables were provided as mean \pm standard deviation (SD), and *P* values less than .05 were considered statistically significant.

RESULTS

Patients consisted of 140 (68.4%) men and 60 (31.6%) women with the mean age of 45.59 ± 12.06 years (range, 22 to 75 years). Most stones were located in the pelvis and/or lower calyces and rarely in the upper pole calyces.

Demographic and clinical characteristics of the two groups are listed in Table 1. There was not any significant difference between two groups ($P = .616$ and $P = .915$). Statistically significant correlations were found between duration of hospitalization and stone-free rate (Spearman $r = -0.578$; $P < .001$), hemoglobin drop and stone size (Spearman $r = 0.458$; $P = .003$), and hemoglobin drop and stone-free rate (Spearman $r = -0.332$; $P = .039$).

More analysis with linear regression model showed that placing nephrostomy tube is

a significant variable to predict duration of hospitalization ($P < .001$). As it is shown in Table 2, rather than placing nephrostomy tube, other variables such as stone-free rate ($P = .004$), blood transfusion ($P = .005$), and hemoglobin drop ($P = .034$) were significant variables to predict duration of hospitalization. We did not encounter severe bleedings requiring cessation of the procedure or change to open surgery in both groups.

One patient in group A, who had prolonged flank pain, developed perirenal urine collection that was confirmed with non contrast computed tomography scan and was treated successfully by percutaneous drainage. Another patient in the same group came back 5 days after discharge (9 days after procedure) because of gross hematuria and was managed successfully with angioembolization. Lost to follow-up in our study was zero.

Table 1. Comparison of the demographic and main variables in groups A and B*

Variable	A (Tubeless PCNL)	B (PCNL + Nephrostomy tube)	P
Age, y	44.58 ± 13.35	46.55 ± 10.94	.616
Gender, %			
Female	31.6	31.6	.915
Male	68.4	68.4	
Operation time, min	68 ± 4.3 (95% CI = 67.16 to 68.84)	74 ± 5.6 (95% CI = 72.9 to 75.1)	.098
Stone size, mm	36.26 ± 5.3 (95% CI = 35.22 to 37.30)	35.35 ± 5.85 (95% CI = 34.21 to 36.49)	.613
Pre-operative hemoglobin, g/dL	14.79 ± 1.24 (95% CI = 14.56 to 15.02)	14.65 ± 1.14 (95% CI = 14.43 to 14.87)	.706
Postoperative hemoglobin, g/dL	11.14 ± 1.21 (95% CI = 10.90 to 11.38)	11.52 ± 1.30 (95% CI = 11.26 to 11.77)	.354
Hemoglobin drop, g/dL	3.65 ± 1.20 (95% CI = 3.41 to 3.88)	3.13 ± 1.06 (95% CI = 2.92 to 3.34)	.158
Transfusion rate, %	25	20	.233
Stone-free rate, %	92.58 ± 5.97 (95% CI = 91.41 to 93.75)	89.60 ± 8.34 (95% CI = 87.96 to 91.23)	.210
Duration of hospitalization, d	2.42 ± 0.84 (95% CI = 2.26 to 2.58)	3.70 ± 0.80 (95% CI = 3.54 to 3.86)	< .001†

*PCNL indicates percutaneous nephrolithotomy; and CI, confidence interval.

†Statistically significant

Table 2. Linear regression model to predict duration of hospitalization ($r^2 = 0.78$)

Variable	Unstandardized Coefficients (Std.Error)	Standardized Coefficients	t	P
Constant	4.66 (1.56)		2.98	.005
Mean stone-free rate	-0.05 (0.01)	-0.32	-3.11	.004
Placement of nephrostomy tube	1.22 (0.17)	0.59	6.94	< .001
Blood transfusion	0.46 (0.15)	0.29	2.98	.005
Mean hemoglobin drop	0.17 (0.08)	0.19	2.20	.034

DISCUSSION

Although percutaneous procedures of the kidney are associated with less morbidity than open surgery, the potential for significant complications still exists. Hemorrhage is the most significant complication of PCNL.⁽⁷⁾ Staghorn stones, large stones, multiple tracts, solitary kidney, and the presence of diabetes mellitus were associated with increased renal hemorrhage during PCNL on multivariate analysis of previous studies.^(11,12) However, a concern of many urologists with the tubeless technique is lack of a tamponade effect in the nephrostomy tract.⁽¹³⁾ Excessively medial punctures, punctures into the kidneys with abnormal anatomy, and renal pelvic perforation are associated with an increased risk of bleeding.^(14,15) Patients on anticoagulant or antiplatelet medications are also more likely to experience bleeding.⁽¹⁴⁾

Current managements for renal bleeding after PCNL include placement of a nephrostomy tube, a Kaye nephrostomy tamponade, balloon catheter, and endovascular embolization and if these measures fail to control the hemorrhage, partial nephrectomy may be required.⁽¹⁶⁾

In the majority of the subjects, the amount of blood loss during percutaneous procedures is not significant enough to require transfusion, and conservative management is generally sufficient. Occasionally, blood transfusion may be warranted depending on baseline hematocrit, presence of comorbidities, and amount of blood loss. Optimal renal access is the most critical factor influencing surgical success and minimizing overall blood loss.⁽¹⁷⁾ The rate of transfusion after percutaneous procedures differs. Segura and colleagues reported need for transfusion in only 3% of their patients,⁽¹⁸⁾ whereas Stroller and associates had a 23% transfusion rate.⁽¹⁹⁾ Their study showed that calculus morphology, its location, composition, or size did not affect total blood loss, nor did the number of fragments or stone-containing calices. Furthermore, factors such as age, hypertension, urinary infection, degree of hydronephrosis, renal insufficiency, puncture site, type of fascial dilation, previous open renal surgery, previous extracorporeal shock wave lithotripsy, or function of the ipsilateral

renal unit did not affect total estimated blood loss as well.⁽²⁰⁾ The only statistically significant risk factors influencing the likelihood of a blood transfusion were pre-operative anemia and total blood loss.

Parenchymal bleeding is usually seen at the site of the nephrostomy tract dilation. Advancement of the distal segment of the working sheath into the collecting system provides effective parenchymal tamponade, allowing the procedure to continue.⁽²¹⁾ Several studies have demonstrated that dilation of the tract using balloon dilating catheters as opposed to Alken metal telescopic dilators or the Teflon-coated Amplatz dilators results in less blood loss.⁽²²⁾ Renal venous laceration is another source of bleeding and is not uncommon and may be also managed conservatively.⁽⁴⁾ The reported incidence of serious arterial injuries ranges from 0.9% to 3% after percutaneous procedures.⁽²³⁾ Martin and coworkers reported a 1% incidence of severe bleeding after PCNL requiring superselective embolization.⁽¹⁵⁾ Arterial bleeding is relatively rare during percutaneous renal surgery, but may be encountered intra-operatively or in the early or late postoperative period. If it occurs during dilation of the tract, the vessel is usually a tiny arteriole and tamponade may be successful.⁽²³⁾

Delayed bleeding after percutaneous procedures is almost always secondary to pseudoaneurysms or arteriovenous fistulas. The key to successful management is renal angiography during active bleeding.⁽²⁴⁾ In our study, one of the patients in the first group came back with gross hematuria 8 days after discharge. She underwent successful angioembolization due to development of pseudoaneurysm.

Percutaneous nephrolithotomy should be performed by an experienced endourologist in patients at risk of severe bleeding.⁽¹²⁾ Kukreja and colleagues described strategies that may reduce blood loss and transfusion rate, including ultrasound-guided access, using Amplatz or balloon dilatation systems, reducing the operation time, and staging the procedure in cases with a large stone burden or intra-operative complications.⁽²⁰⁾

Recent studies have not reported an increased risk of bleeding after tubeless PCNL.^(13,25) In a prospective study, Maheshwari and coworkers demonstrated no significant increase in the postoperative bleeding in 20 patients who underwent a one stage tubeless PCNL.⁽²⁵⁾ Yoon and Bellman reported that with tubeless PCNL, patients experienced less discomfort without increased risk of complications.⁽¹³⁾ They modified their technique of tubeless PCNL with an indwelling double-J stent and brought it out from the flank. They have also found that in more instances, manual pressure and a deep hemostatic suture at the skin incision will adequately control any visible hemorrhage.⁽²⁰⁾

Recent studies have suggested that only a few indications still remain for the standard PCNL technique, including significant collecting system injury, excessive hemorrhage with poor visualization to place an antegrade stent, pyonephrosis necessitating reliable external drainage, or need for second-loop procedure.⁽⁹⁾ In a prospective randomized trial on 202 patients by Agrawal and colleagues, tubeless PCNL was found to have significant advantages over standard PCNL. They reported that the difference in mean blood loss between the two groups was not statistically significant.⁽²⁶⁾ In another study by Giusti and associates comparing tubeless and standard PCNL, hematocrit drop was not significantly different, but duration of hospitalization was significantly less in the tubeless PCNL group,⁽²⁷⁾ which agrees with our findings.

The nephrostomy tube after PCNL was intended both to drain the kidney and tamponade the access tract and establish hemostasis as well; however, there is no evidence to support this assumption.⁽²⁸⁾ Our study is one of the first experiences that questions the traditional role of nephrostomy tube in PCNLs that face bleeding. We expected to face more patients with continuous bleeding or need to angiography in the first group, but it did not occur. This is in favor of the hypothesis that most bleedings are self-limited. We did not encounter any benefit in leaving nephrostomy tube in place after PCNL. We think if bleeding is not brisk

enough to prevent continuation of surgery, self tamponade pyelocalyceal system, tract closure, and conservative management (ie, bed rest, hydration, and blood transfusion if needed) after the procedure would be sufficient to control the bleeding. However, close observation of these patients is very important in the early postoperative period. We demonstrated that these approaches do not increase morbidity, and additionally, do not affect the outcomes of procedure. Moreover, the patients do not have nephrostomy tube discomfort.

CONCLUSION

Previously, it was thought that one of the advantages of placing nephrostomy tube is tract hemostasis, but based on our study, if the bleeding is not too much to prevent the procedure from continuing, leaving nephrostomy tube in place after PCNL in this regard does not seem to be beneficial; and its omission does not put patients at any additional risk. In most subjects, self tamponade pyelocalyceal system, tract closure, and conservative management are enough to control the bleeding. However, we questioned nephrostomy tube role in control of the bleeding associated with PCNL. It seems that studies with more sample sizes are required to validate our results.

CONFLICT OF INTEREST

None declared.

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