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Intraoperative Patient Selection for Tubeless Percutaneous Nephrolithotomy

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This study was conducted to report our experience of intraoperative patient selection for tubeless percutaneous nephrolithotomy (PCNL) based on a tentative decision-making algorithm. Thirty-four consecutive patients who were scheduled to undergo tubeless PCNL were included and medical records were obtained from a prospectively maintained database for these patients. After completion of PCNL, the nephrostomy site was observed with a safety guidewire in place. If there was no significant bleeding through the tract, tubeless PCNL was performed, and in cases with significant bleeding or other complications, nephrostomy catheter insertion was performed as usual. In 29 cases (85.3%), tubeless PCNL was performed according to our decision-making protocol. Mean stone size was 7.33 ± 9.35 cm^2. Mean hospital stay was 2.61 ± 1.01 days. The difference between preoperative and postoperative hemoglobin was 0.68 ± 1.22 g/dL ($p > 0.05$). Visual analog pain scale scores immediately post-operation, on postoperative day one and on the day of discharge were 4.62 ± 1.80, 3.25 ± 1.68 (postoperative day one *vs.* operative day; $p = 0.001$), and 1.87 ± 0.83 (the day of discharge *vs.* operative day; $p = 0.001$), respectively. The success rate with insignificant remnant stones was 85.2% and complete stone-free rate was 76.5%. In conclusion, tubeless PCNL was performed successfully with low complication rate and reduced pain score through our decision-making algorithm.

Key words: Renal stone – Percutaneous nephrolithotomy – Tubeless – Patient selection

Currently, percutaneous nephrolithotomy (PCNL) is the treatment of choice for large, complex renal stones due to low postoperative morbidity and low complication rate.[1,2] Placement of a nephrostomy catheter is done routinely after PCNL, as it provides proper drainage of urine, prevention of urinary extravasation and tamponade of bleeding.[3,4] In addition, it might be used for a tract for a second-look PCNL.[5]

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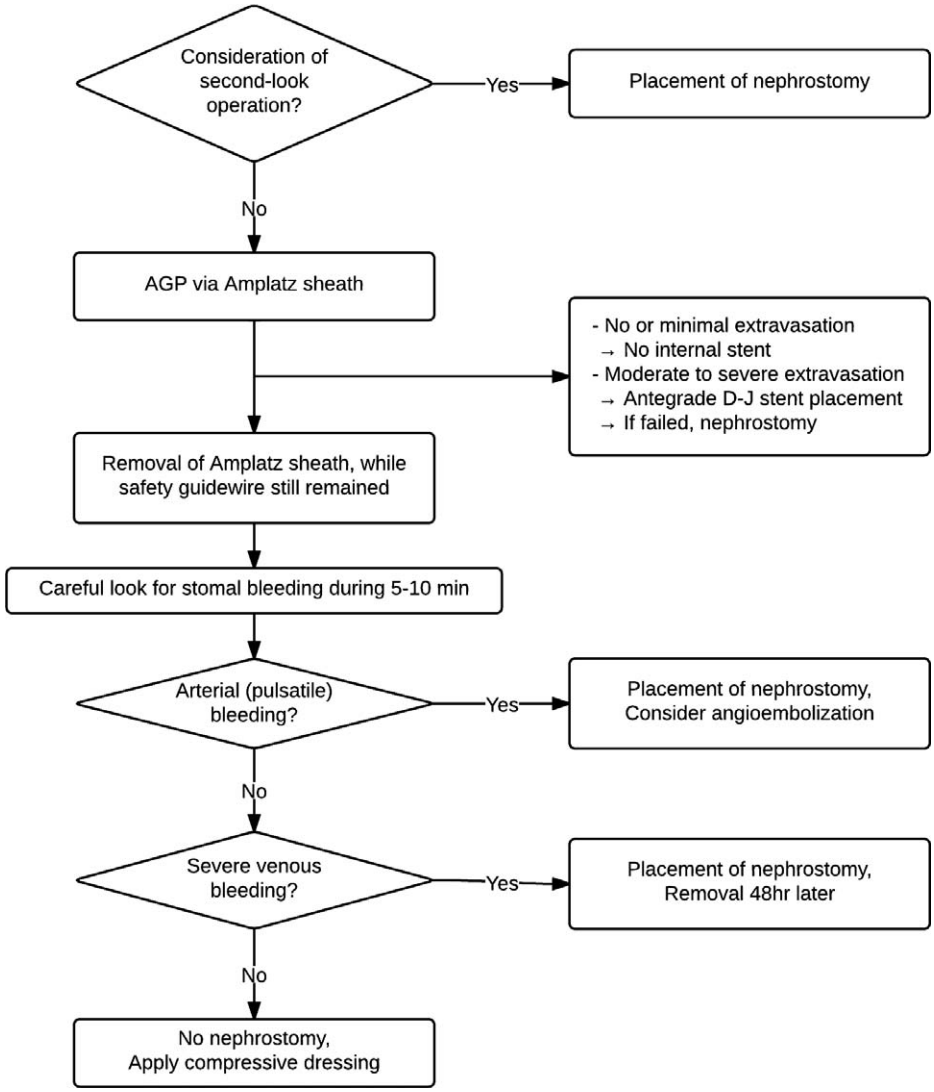

Fig. 1 Decision-making algorithm of intra-operative patient selection for tubeless percutaneous nephrolithotomy. AGP: antegrade pyelography.

Recently, the need for placement of a nephrostomy catheter has been questioned due to an increase in postoperative discomfort, low incidence of second-look operation, and increase in morbidity.[6,7] Tubeless PCNL has been attempted with proper drainage of urine through an indwelling antegrade stent instead of a nephrostomy tube, or alternatively without an internal stent at all.[8] Tubeless PCNL is not yet widespread despite the potential benefits of this approach, because there has been a concern for potentially fatal complications such as massive bleeding without a nephrostomy tube.[9] Several studies have demonstrated the feasibility of tubeless PCNL for the last two decades; however, it has not been determined how to choose patients to undergo either conventional PCNL or tubeless PCNL. Therefore, this study was conducted to report our experience of intraoperative patient selection for tubeless PCNL based on a tentative decision-making algorithm.

Methods

Patients and procedures

From May 2011 to September 2012, 34 consecutive patients who were scheduled to undergo tubeless PCNL were included. Before surgery, the desired calyx was punctured under guidance of fluoroscopy and a guidewire was inserted by an interventional radiologist. After that, PCNL was carried out under

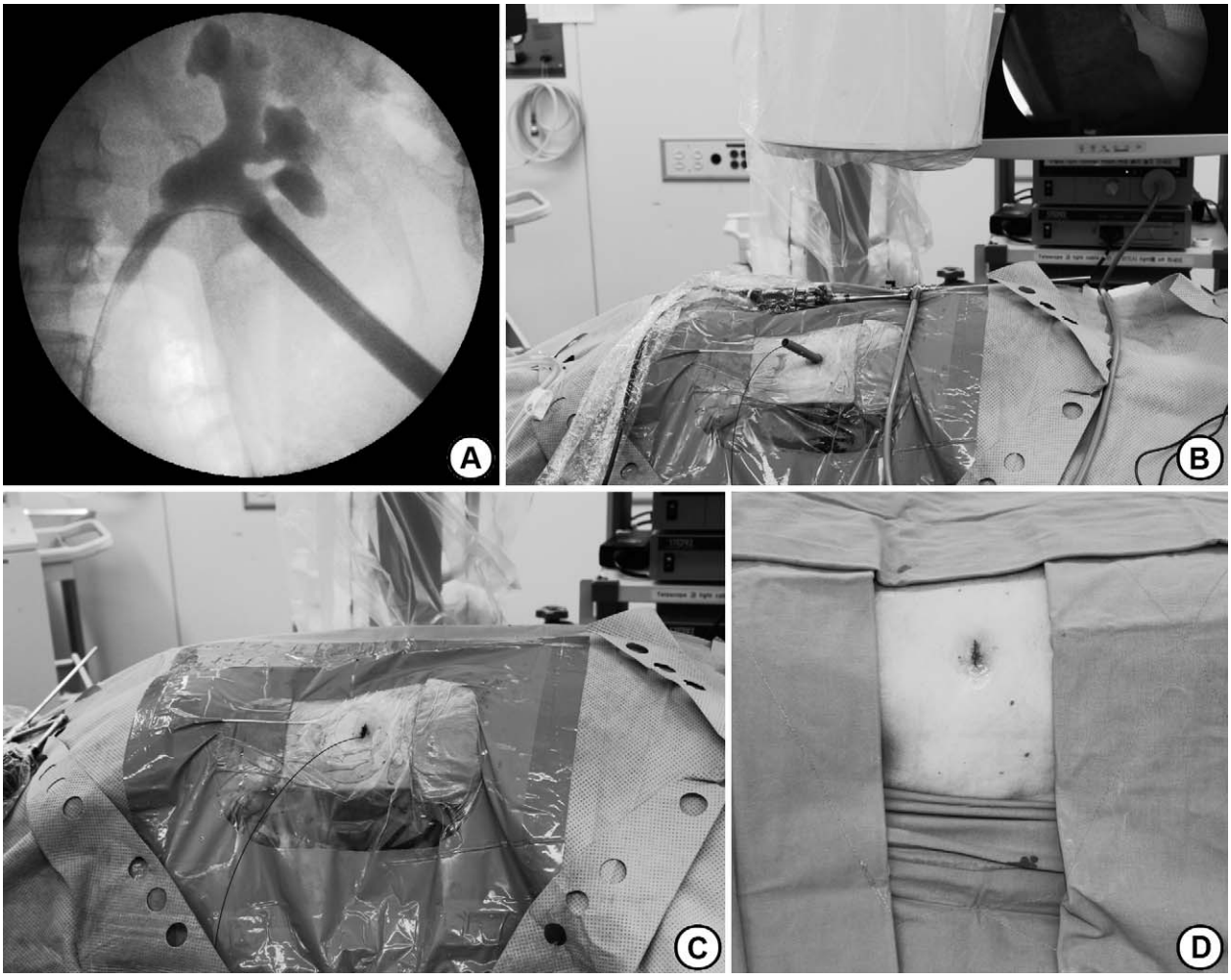

Fig. 2 Intra-operative patient selection for tubeless percutaneous nephrolithotomy (PCNL). After completion of stone removal, antegrade pyelography was performed to identify significant renal pelvic injury (A). After removal of the Amplatz sheath, a nephrostomy site was carefully observed for 5 to 10 minutes with a safety guidewire in place (B, C). When there is no significant bleeding through the nephrostomy site and no significant injury to the renal pelvis and ureter, tubeless PCNL was performed (D).

general anesthesia with endotracheal intubation. The dilatation was performed with a 30 Fr balloon dilator. After Amplatz sheath insertion, the nephroscope was introduced and renal stones were fragmented using LithoClast.

Patients were selected intra-operatively for tubeless PCNL based on our decision-making protocol as follows: after completion of stone removal, antegrade pyelography (AGP) was performed to identify significant renal pelvic injury. After removal of the Amplatz sheath, the nephrostomy site was carefully observed for 5 to 10 minutes while the safety guidewire remained in place. If there was no significant bleeding through nephrostomy site and no significant injury to the renal pelvis and ureter, tubeless PCNL was performed. If there were concerns for either arterial bleeding or massive venous bleeding, a nephrostomy tube was placed via the safety guidewire (Figs. 1 and 2).

Pain was evaluated every 8 hours by a trained nurse using the visual analog scale of pain (VAS). The patients with moderate to severe pain were given tramadol, 50 mg IV, or pethidine, 25 mg IM, if postoperative pain was not controlled with nonsteroidal analgesics. All patients were monitored by checking levels of hemoglobin and serum creatinine pre-operatively and by the seventh postoperative day. Plain X-ray or abdomen-pelvis computed tomography was obtained within 1 to 3 months postoperatively. The patient was discharged when he or she was thought to be free from complications

Table 1 Preoperative clinical data of patients who underwent tubeless percutaneous nephrolithotomy

Variables	*N* (%)
Number of patients	34
Male:Female	21:13
Mean age ± *SD*	53.35 ± 18.00
Mean BMI ± *SD*	21.64 ± 9.93
No. Rt./Lt./Bil.	
Right	17 (50.0)
Left	17 (50.0)
Bilateral	0 (0.0)
Type of stone	
Staghorn stone	9 (26.47)
Upper calyx and pelvic stone	3 (8.82)
Lower calyx and pelvic stone	13 (38.23)
Lower calyceal stone	6 (17.64)
Renal pelvic stone	3 (8.82)
Mean stone size ± *SD* (cm^2)	7.33 ± 9.35

SD, standard deviation; BMI, body mass index.

and when pain was controlled with oral analgesics (VAS score lower than 3).

Good clinical practice protocols

The study was performed in agreement with applicable laws and regulations, good clinical practices, and ethical principles as described in the Declaration of Helsinki. The Institutional Review Board of the hospital approved this study protocol (Approval number: 4-2012-0629).

Statistical analysis

The success rate was defined as the absence of residual stone fragments under conventional X-ray or computed tomography or when clinically insignificant residual fragments (CIRF) were observed. CIRF was defined as residual fragments that were smaller than 4 mm, asymptomatic, nonobstructive, and noninfectious.[10] Perioperative complications were evaluated according to the modified Clavien grading system validated in 2004.[11] The preoperative and postoperative VAS pain scores of all subjects were analyzed by Wilcoxon test. In VAS, the severity of pain is classified according to a 0–10 point scale that indicates the degree of pain, where 0 indicates a complete lack of the pain and 10 indicates the most severe pain. Length of hospital stay was defined as the time interval between the day of surgery and discharge from the hospital. The data were analyzed using Open Office.org Calc (Open Office.org version 3.2.0, Oracle Corp., Redwood Shores, CA, USA) and MedCalc (MedCalc version 11.2.1.0, MedCalc Software, Mariakerke, Belgium). A *P*-value less than 0.05 was considered to be statistically significant.

Results

Following our decision-making protocol, a nephrostomy catheter was inserted in 5 cases (14.7%); significant venous bleeding was suspected in 2 cases, injury of the renal pelvis in 1 case, and second-look operation was considered in 2 cases. In 29 cases (85.3%), PCNL was completed without nephrostomy tube placement. The mean age and body mass index of patients were 53.3 ± 18.0 years and 21.6 ± 9.9 kg/m^2, respectively. Mean stone size was 7.33 ± 9.35 cm^2 (Table 1).

Mean operation time was 89.02 ± 46.31 minutes. Mean hospital stay was 2.61 ± 1.01 days. The difference between preoperative and postoperative hemoglobin was 0.68 ± 1.22 g/dL ($P > 0.05$). Serum creatinine level measured preoperatively, on the day of surgery, and postoperative day one were 1.05 ± 0.68 mg/dL, 1.01 ± 0.69 mg/dL (operative day one *vs*. preoperatively; $P = 0.134$), and 0.99 ± 0.73 mg/dL (postoperative day one *vs*. preoperatively; $P = 0.197$), respectively. Visual analog pain scale on the day of surgery, postoperative day one and the day of discharge were 4.62 ± 1.80, 3.25 ± 1.68 (postoperative day one *versus* operative day; $P = 0.011$), and 1.87 ± 0.83 (the day of discharge *vs*. operative day; $P = 0.001$), respectively.

There were only 4 patients with mild complications according to the Clavien-Dindo classification (Grade I in 2 patients and Grade II in 2 patients). Success rate with CIRF was 85.2% and complete stone-free rate was 76.5% (Table 2). Five patients who have significant residual fragments after PCNL underwent postoperative shock wave lithotripsy, and 4 patients were successfully treated.

Discussion

According to recent studies, there is no significant difference between the complications from standard PCNL and tubeless PCNL.[12] It has been reported that tubeless PCNL was associated with a shorter hospital stay, a faster return to everyday life, less pain, and lower cost.[13] They recommended that a nephrostomy catheter should be placed in certain situations: multiple access, major damage to the collecting system, possibility of a second look operation, severe intraoperative bleeding, compli-

Table 2 Operative and postoperative outcomes of patients who underwent tubeless percutaneous nephrolithotomy

Variables		*P*-value
Mean operative time ± *SD* (min)	89.02 ± 46.31	-
Mean hospital stay ± *SD* (day)	2.61 ± 1.01	-
Mean change of hemoglobin (g/dL)	0.68 ± 1.22	-
Serum creatinine (mg/dL)		
Pre-operatively	1.05 ± 0.68	-
Operation day	1.01 ± 0.69	0.134[a]
Postoperative day 1	0.99 ± 0.73	0.197[a]
Visual analog pain score		
Operation day	4.62 ± 1.80	-
Postoperative day 1	3.25 ± 1.68	0.001[b]
Discharge day	1.87 ± 0.83	<0.001[b]
Clavien-Dindo classification		
Grade I	2	-
Grade II	2	-
Success rate (%)	29/34 (85.2)	-
Stone-free rate (%)	26/34 (76.5)	-

SD, standard deviation.

[a]Versus preoperative mean creatinine; using Wilcoxon signed rank test.

[b]Versus operative day VAS; using Wilcoxon signed rank test.

cated cases and intrathoracic trauma.[14] However, tubeless PCNL has not been in widespread use even considering the potential benefits of this approach, because there are concerns that potentially fatal complications such as massive bleeding without a nephrostomy tube may occur.[9] In the case of major blood vessel damage or severe damage to the collecting system, a nephrostomy catheter should be placed. Several studies have demonstrated the feasibility of tubeless PCNL for the last two decades; however, there are no guidelines for deciding between conventional PCNL and tubeless PCNL. The present study was conducted to report our experience of intraoperative patient selection for tubeless PCNL based on a tentative decision-making protocol. We identified preoperative factors and postoperative outcomes of tubeless PCNL, and focused on the issue of patient selection, which had not been previously examined.

Patients were selected for tubeless PCNL intraoperatively based on our decision-making algorithm, shown in Figure 1. The key point of this algorithm is postoperative AGP and careful observation of the nephrostomy site with a safety guidewire in place after completion of PCNL. Postoperative AGP can show the integrity of the collecting system, and it can be omitted in many cases if there is no suspicion of injury to the collecting system during the operation. Also, the careful observation of the nephrostomy site with a safety guidewire in place can make it easier to determine whether there was significant bleeding within 5 to 10 minutes. According to our decision-making protocol, a nephrostomy catheter was inserted in 5 cases (14.7%), and tubeless PCNL was performed in 29 cases (85.3%) with minimal complications. Peri-operative transfusion was required in only 2 cases (5.8%).

The disadvantages of tubeless PCNL, including the need to place a ureteral stent, should be also considered.[15] The patient must undergo a cystoscopy to remove the ureteral stent, and the placement of a ureteral stent may cause bladder irritation symptoms such as flank pain, gross hematuria, urinary frequency, and urgency. Mishra *et al* demonstrated that early tube removal after PCNL resulted in an equivalent analgesic requirement, decrease in hemoglobin and hospital stay as tubeless PCNL as well as a significantly lower incidence of early hematuria, and better clearance.[16] Meanwhile, totally tubeless PCNL can be feasible and is a more advanced technique compared to early tube removal after PCNL. A meta-analysis by Zhong *et al* showed that totally tubeless PCNL is safe and effective and that it significantly reduced the hospital stay, analgesic requirement, and the time to return to normal activity without increased complications.[17] Because this series consists of our early experiences with tubeless PCNL, we routinely placed a ureteral stent during tubeless PCNL due to safety concerns. However, we believe that there is no need for ureteral stenting if no significant injury to the collecting system is suspected. Therefore, our decision-making algorithm can be also applied for the decision to pursue totally tubeless PCNL.

Omitting the nephrostomy catheter might have potential risks of bleeding and serious complications; therefore, there have been attempts to seal the tract with various alternative methods. Milkahi and his colleagues introduced instillation of a hemostatic agent Tiseel into the nephrostomy tract for the first time.[18] However, they were unable to determine if injection of that agent diminished postoperative bleeding or urinary extravasation following tubeless PCNL. Choi *et al* instilled gel matrix thrombin (Floseal) in the tract whenever persistent bleeding was observed after omitting the nephrostomy catheter.[19] Okeke *et al* explored cryo-ablation of the nephrostomy tract after tubeless PCNL. They inserted a cryoprobe into the access tract and performed a 10-minute freeze-thaw cycle at a temperature of –20′C. This method showed no significant difference in delayed bleeding or urinary

extravasation.[20] Recently, a randomized study by Cormio *et al* showed that TachoSil provided better tract control and a shorter hospital stay than nephrostomy tube placement although it did not reduce pain and analgesic requirements.[21] However, we question whether such agents are needed if surgeons follow our decision-making protocols, because in our series, only 2 patients required perioperative transfusion and our patients had a mean hospital stay of 2.3 days without the use of such sealants.

Tubeless PCNL and totally tubeless PCNL are advocated by leading surgeons in the field of endourology. The future role of tubed PCNL will be in cases of severe intra-operative bleeding, major damage of collecting system, and when there is a possibility of a second-look operation. However, there remain some controversies about the feasibility and efficacy of tubeless PCNL in certain clinical settings. Shoma *et al* suggested that the tubeless approach might not be suitable for patients with chronic kidney disease or those who require a supracostal approach through a prospective randomized study.[9] But Shah *et al* reported a successful outcome using a tubeless technique in a patient with chronic kidney disease. Sofikerim *et al* reported that tubeless PCNL is a safe and effective technique even after supracostal access and is associated with less postoperative pain and a shorter hospital stay.[22] Resorlu *et al* maintained that single or no nephrostomy drainage following multitract PCNL offered the potential advantages of decreased postoperative analgesic requirement, and hospital stay without increasing the complications.[23]

To our knowledge, this is the first proposed decision-making algorithm for intra-operative patient selection for tubeless PCNL and its feasibility through our early experiences. However, there are some limitations regarding selection bias. Most of our cases were relatively simple and had moderate stone burdens, and there were no challenging cases such as those requiring multiple access or supracostal access. In addition, this study was not a randomized controlled trial, and only early experiences were included in the analysis. A large prospective randomized controlled trial is needed to confirm our results using our intraoperative decision-making algorithm for tubeless PCNL.

Conclusions

Tubeless PCNL was successfully performed with a low complication rate and reduced pain score based on our intra-operative decision-making algorithm. A large prospective randomized controlled trial is needed to confirm our successful early experiences.

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