



Original article

Use of hemostatic sealant in tubeless percutaneous nephrolithotomy: Experience of a single institution from Taiwan



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ARTICLE INFO

Article history:

Received 29 April 2016

Received in revised form

28 September 2016

Accepted 2 November 2016

Available online 19 January 2017

Keywords:

hemostatic sealant

percutaneous nephrolithotomy

tubeless nephrolithotomy

ABSTRACT

Objective: Tubeless percutaneous nephrolithotomy (PCNL) offers several advantages over standard PCNL, including a shorter hospital stay, less analgesic requirement, and less postoperative pain. Using a fibrin sealant to seal the nephrostomy tract had become a widely accepted technique at the conclusion of tubeless PCNL. Our objective is to evaluate the efficacy and safety of tubeless PCNL using hemostatic matrix.

Materials and methods: This is a retrospective review of PCNL database at our hospital between June 2014 and March 2016. During this period, a total of 139 PCNLs were performed, including 41 with tubeless technique with adjunct of hemostatic matrix (FloSeal; Baxter, Deerfield, IL, USA) at the conclusion of the PCNL procedure. The standard PCNL group and the tubeless PCNL group were compared in terms of demographic characteristics, perioperative data, stone characteristics, and complication rate.

Results: Of all 123 patients included in this study, 41 underwent tubeless PCNL. Demographic data of the two groups were comparable except for a higher proportion of male patients in the tubeless PCNL group (73.2% vs. 53.7%). Stone characteristics were also comparable in the two groups. Perioperative variables, including operative time, drop of serum hemoglobin level, and perioperative complication rate, revealed no statistical difference between the two groups. Tubeless PCNL was associated with less postoperative pain, less analgesic requirement, and a shorter hospital stay ($p < 0.01$).

Conclusion: Tubeless PCNL with adjunct use of a hemostatic sealant can be considered as a safe treatment option for renal calculi with favorable outcome, without an increase in complications. Compared with standard PCNL, tubeless PCNL with hemostatic sealant use is associated with less pain, use of fewer narcotic agents, and a shorter hospital stay.

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1. Introduction

Percutaneous nephrolithotomy (PCNL) was first described and performed by Fernstrom and Johansson in 1976,¹ and it became a well-established procedure and standard of care to treat renal calculi greater than 20 mm or smaller calculi refractory to shock wave lithotripsy.² A routine step at the conclusion of standard PCNL is the placement of a large-bore nephrostomy tube in the access tract. The main purpose of the nephrostomy tube is to facilitate collecting system drainage, tamponade the access tract for

hemostasis, and provide repeat access to the collecting system for staged surgery.³ However, growing evidence demonstrated that an indwelling nephrostomy tube is associated with significant postoperative discomfort and morbidities such as pain and a longer hospital stay.^{4–6} In the efforts to reduce the discomforts associated with nephrostomy tube placement, the idea to indwell smaller tubes was successfully introduced without increased morbidities.⁷ Further, the necessity of a nephrostomy tube came into question. In 1984, Wickham et al⁸ first described the tubeless technique in their case series. However, not until 1997, Bellman et al⁹ challenged the requirement of routine nephrostomy tube use and introduced tubeless PCNL, which involved the placement of an internal ureteral stent without any nephrostomy tube. Since the late 2000s, growing evidence demonstrated that the efficacy and safety of tubeless PCNL were comparable with those of standard PCNL. Besides, the

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tubeless technique was considered to have advantages including a shorter hospital stay and less postoperative pain without increased complications.¹⁰ With increasing studies, urologists began to embrace the concept of tubeless PCNL. However, under the concern about complications related to unsealed access tract, few techniques were introduced to facilitate hemostasis in the tubeless technique. The gelatin matrix hemostatic sealant (FloSeal; Baxter Medical, Fremont, CA, USA) had been reported as a safe agent for nephrostomy tract hemostasis. The purpose of this study is to compare the efficacy and safety of standard PCNL and tubeless PCNL with the use of a hemostatic sealant.

2. Materials and methods

Between June 2014 and March 2016, we retrospectively reviewed all PCNLs performed at our institution. The indication of PCNL in our institution is renal calculi greater than 20 mm or smaller calculi refractory to shock wave lithotripsy. For patients with scheduled PCNL, standard PCNL and tubeless PCNL were provided as treatment options. Patients chose either the standard or the tubeless procedure under their discretion and preference after being fully informed of the risks and benefits. Except for a known allergic history to any hemostatic agents and complete staghorn stone, no contraindications or medical conditions precluded the patients from receiving the tubeless procedure. Hence, we excluded patients with complete staghorn stone in this review, as the standard PCNL was the only treatment option.

For this study, medical records of all patients were reviewed. Patient demographics and stone characteristics were recorded. The stone burden was defined by a two-dimensional area (cm²) projected on a preoperative plain abdominal radiograph and was measured by a computer's built-in measuring tool.

2.1. Procedures of standard and tubeless percutaneous lithotomy

All of the nephrostomy access tracts were obtained by urologists under ultrasound guidance. Artificial hydronephrosis was achieved either by a retrograde ureteral catheter with saline infusion or by a double-J stent with water distention of the urinary bladder. The access tract was dilated with the 24 French (Fr) or 30 (Fr) balloon dilator (Cook, Spencer, IN, USA) or Amplatz dilating system. Then a 24 Fr, 26 Fr, or 30 Fr Amplatz working sheath was placed for the remaining procedure.

The method to achieve artificial hydronephrosis and the planned size of renal access tract varied according to stone volume, patients' comorbidities, and surgeon's preference, without unified guidance to choose the techniques. Lithotripsy was performed with a pneumatic lithotripter (Calculusplit; Karl Storz AG, Tuttlingen, Germany), and the stone fragments were extracted by a stone basket and grasper. Fluoroscopic guidance was used depending on the surgeon's preference. There was no definite condition to convert each procedure to the other during the operation despite intraoperative hemorrhage or pelvis perforation. After the stone was disintegrated, the ureteral catheter was replaced by an antegrade ureteral stent. At the conclusion of standard PCNL, a 22 Fr or 24 Fr nephrostomy tube was indwelt, while 5 mL FloSeal (Baxter, Deerfield, IL, USA) was applied into the access tract in the tubeless group.

2.2. Technique of applying gelatin matrix hemostatic sealant

At the conclusion of tubeless PCNL, any significant rupture of the collecting system or bleeding was checked. A 6 Fr Foley catheter was introduced via the working sheath. Under direct vision of endoscopy, the balloon was inflated within the renal pelvis and the working sheath was pulled back to the level of entrance into the

collecting system. The inflated Foley catheter was retracted gently against the inner aspect of the nephrostomy tract to seal the perforated collecting system. The endoscope was withdrawn and 5 mL FloSeal (Baxter, Deerfield, IL, USA) was injected into the renal parenchyma via the long injection tip. The tract was compressed for 2 minutes and then the balloon was deflated to withdraw the Foley catheter. The wound was closed by skin sutures. Details of applying the hemostatic matrix are illustrated in [Figure 1](#).

2.3. Perioperative outcomes and follow-up

Perioperative parameters including stone-free rate, operative time, length of hospital stay, postoperative opioid requirement, and complication rate were analyzed. Stone free was defined as no visible residual fragments in the plain films on Postoperative Day 1. Complete blood cell count and serum chemistry measurements were obtained on Postoperative Day 1. The visual analog scale was assessed at regular times postoperatively at least three times per day. The highest visual analog scale score during hospital stay was recorded. Complications including fever, requirement of blood transfusion, and postoperative emergency room visits were recorded. Other complications requiring invasive intervention was recorded and classified as a Clavien–Dindo Grade III complication. After discharge, all patients had follow-up at 1 week, 4 weeks, and 8–10 weeks postoperatively.

2.4. Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics 22.0 (IBM Corp., Armonk, NY, USA). The Chi-square test was performed to compare categorical variables, and the Mann–Whitney *U* test was used to compare quantitative measurements. A *p* value < 0.05 was considered significant.

3. Results

3.1. Patient demographics and stone characteristics

Within the study period, 139 patients received PCNL. Sixteen patients with staghorn calculi were excluded. Among the 123 patients included in this analysis, 41 received tubeless PCNL, without any conversion to standard PCNL during the operation. Demographic variables and stone characteristics of two groups are shown in [Table 1](#). The median (interquartile range) age of patient was 54 (45–61) years in the tubeless PCNL group and 56 (49–63) years in the standard PCNL group. Tubeless PCNL group had more male patients (73.2% vs. 53.7%, *p* = 0.037) and higher preoperative hemoglobin level [14.30 (13.15–15.40) g/dL vs. 13.40 (11.60–15.42) g/dL, *p* = 0.045]. Other demographics were not statistically different. For stone characteristics, no significant differences existed between the two groups with respect to total stone numbers, percentage of single stone, stone distribution, and stone burden. The standard PCNL group had larger stones with a median stone burden of 3.47 cm², compared with 3.26 cm² in the tubeless PCNL group, although without a statistically significant difference. Both groups used a balloon dilating system in over half of the patients (57.3% vs. 63.4%, *p* = 0.516), and the tubeless group used more 30 Fr sheath as the working sheath (53.7% vs. 36.6%, *p* = 0.071).

3.2. Perioperative data, complications, and outcomes

Perioperative data, complications, and outcomes are presented in [Table 2](#). The two groups had comparative operation time and stone-free rate. For the complication rate, the tubeless group presented with fewer postoperative ER visits (2.4% vs. 8.5%, *p* = 0.27)

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