Original Article

Hemostatic agents for access tract in tubeless percutaneous nephrolithotomy: Is it worth?

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Abstract

Introduction: The role of hemostatic agents as an adjunct for closure of the nephrostomy tract in tubeless percutaneous surgery (tubeless percutaneous nephrolithotomy [tPNL]) has been previously evaluated, observing a potential benefit in terms of reduced bleeding and urinary leakage. We assessed the rate of postoperative complications after the use of hemostatic agents for sealing the nephrostomy tract in patients undergoing tPNL at our institution.

Subjects and Methods: We performed a retrospective analysis of 52 consecutive patients undergoing tPNL at our center between January 2010 and December 2013. No substance was placed within the tract in 25 patients (Group 1). A cylinder of Surgicel® in addition to 1 unit of Gelita® were placed within the access tract in 27 patients (Group 2). We accounted for demographic variables, stone size, operative time, postoperative pain, development of hematoma, postoperative hematocrit drop, urinary leakage, residual lithiasis, and hospital stay length.

Results: Age and sex differed significantly between the two groups ($P = 0.0002$ and $P = 0.048$ respectively). However, there were no significant differences in terms of body mass index and stone burden. No significant differences between groups were found with regards to operative time, postoperative hematocrit drop, postoperative pain and presence of residual lithiasis.

Conclusion: The use of Gelita® and Surgicel® as hemostatic agents in tPNL is safe, but we were not able to demonstrate any significant benefit in terms of postoperative morbidity after comparing the use of these agents in tPNL. We concluded that the uses of hemostatic agents needed to be evaluated in prospective randomized trials to define its benefits.

Key Words: Hemostatics, intraoperative complications, nephrolithotomy, percutaneous nephrostomy, tubeless nephrolithotomy

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INTRODUCTION

Percutaneous nephrolithotomy (PNL) has established itself as the treatment of choice for renal stones >2 cm.[1] Leaving a nephrostomy tube after completion of the procedure has been

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the standard for many reasons: It allows an adequate drainage of the collecting system, hemostasis of the access tract and a pathway for a second look procedure if necessary.[1] However, the use of a nephrostomy tube carries an increase in perioperative morbidity, mainly related to its associated discomfort and pain, increasing postoperative analgesia requirements.[2] In an attempt to reduce this problem, Wickham *et al*.[3] described tubeless PNL (tPNL) in 1984, which consists in omitting the placement of a nephrostomy tube at the end of the intervention. Since then, several modifications to the original technique have been proposed by several groups, including the use of indwelling pigtail catheters, an overnight externalized ureteral catheter or no placement of catheters at all (full tubeless).[4,5]

During the last years, tPNL has shown to be a safe technique in a selected group of patients (single percutaneous access, reduced intraoperative bleeding, indemnity of the collecting system, no significant intraoperative residual lithiasis [≤5 mm] as assessed by fluoroscopy), gaining acceptance among urologists because of its reduced postoperative pain and analgesic requirements and the consequent shorter hospital length of stay.[6,7] However, it is not free from complications. Among them, the most commonly described are perirenal hematomas and urinary leakage through the access tract. In order to prevent them, several authors have shown promising results using hemostatic agents as an adjunct for the closure of the access tract.[8-13] Moreover, the lack of postoperative evaluation with noncontrast computed tomography (CT) in most of these studies has been a major limitation for a proper assessment of results. Recently, two meta-analyses have shown no benefits in the use of hemostatic agents in tPNL in terms of postoperative complications,[14,15] showing that the use of hemostatic agents in tPNL is still controversial. In this context, the objective of our study was to evaluate the rate of postoperative complications after the use of hemostatic agents within the access tract in patients managed with tPNL at our institution.

SUBJECTS AND METHODS

We performed a retrospective analysis of 52 consecutive patients undergoing a tPNL at our center between January 2010 and December 2013, this analysis was approved by our Institutional Review Board. All surgeries were performed by the same surgeon. During that period, the introduction of hemostatic agents in our institution started at June of 2012, then in the first 25 patients no substance was placed within the tract (Group 1) after the introduction of hemostatic agents a cylinder of oxidized regenerated cellulose (Surgicel®, Johnson and Johnson, USA) in addition to 1 unit of matrix of hardened gelatin (Gelita®, B-Braun, Germany) were placed within the access tract in all the subsequent 27 patients (Group 2).

All patients had a negative urine culture prior to the procedure, thus, none of them required preoperative antibiotic treatment. During anesthetic induction, all patients received ceftriaxone 1 g intravenous (IV). Procedures were carried out under general anesthesia in prone-flexed position after initial installation of a 6 Fr ureteral catheter in the lithotomy position. Punction of the collecting system was performed under fluoroscopic guidance. Tract dilation was made in a sequential manner, up to 28 Fr. After insertion of an Amplatz sheath (Cook Urological, Spencer, USA), a 24 Fr nephroscope was used (Karl Storz Endoskope, Germany). Stone disintegration was performed by means of a pneumatic lithotripter (Brok Stone®-600, Digital Precision Systems, Argentina).

Once the procedure was completed, the Amplatz sheath was partially removed under direct visualization up to the renal capsule in Group 2. Then, a 3 cm-cylinder of Gelita® wrapped in Surgicel® was placed under fluoroscopic guidance before removing the Amplatz sheath. In Group 1, the Amplatz sheath was removed immediately after finishing the procedure, and no substance was left within the tract. Skin closure was made with separate stitches of 3–0 silk and a 16 Fr urethrovesical catheter along with the externalized ureteral catheter were left in place overnight. Stone fragments obtained during the surgery were not sent to composition analysis.

A continuous IV infusion of sodium metamizole (4 g) and ketoprofen (300 mg) was administered as initial postoperative analgesia. In those patients allergic to nonsteroidal anti-inflammatory drugs (NSAIDs) or with a history of renal impairment (glomerular filtration rate <60 ml/min), a continuous infusion of tramadol (200 mg) was used. Pain at the puncture site was assessed every 6–8 h by a trained nurse using a visual analog scale (VAS). Patients with VAS ≥4 received a boost of ketorolac 30 mg IV or meperidine 30 mg IV in case of contraindication for NSAIDs. In patients with VAS <4, infusion was suspended and oral acetaminophen 1 g qid was indicated. All patients were controlled on the first postoperative day with a noncontrast CT and a blood hematocrit. On the same day, the urethrovesical catheters along with the ureteral catheter were removed by an attending physician. All patients, regardless of the use of hemostatic agents, received a daily dose of ceftriaxone 1 g IV until removal of the ureteral catheter. Patients who developed hematomas received cefpodoxime 100 mg bid for 10 additional days after hospital discharge.

Clinical data registered included hospital stay length, postoperative hematocrit drop, need for blood transfusion, and the presence of postoperative clinically significant residual lithiasis (≥3 mm),[16] hematomas or urinomas in noncontrast CT.

Statistical analysis was carried out using Stata software version 10.0 (Stata Corp, College Station, TX, USA). Student's *t*-test was carried out to compare variables showing a normal distribution. For variables with nonparametric distribution, Mann–Whitney test was used. Comparison of proportions was performed with the Fisher's exact test. $P < 0.05$ was considered significant for every analysis.

RESULTS

The main preoperative characteristics are listed in Table 1. Age and sex differed significantly between the two groups ($P = 0.0002$ and $P = 0.048$ respectively). There were no significant differences in terms of body mass index, stone size, and preoperative blood hematocrit.

Postoperative outcomes are listed in Table 2, no significant differences between groups were found with regards to operative time, postoperative hematocrit drop, postoperative pain and presence of residual lithiasis. Five patients in each group presented postoperative significant residual lithiasis (as defined above) with an average size of 4 (3–5) mm. All patients were, however, left for conservative management.

Related to postoperative complications, two patients in Group 2 presented a perirenal hematoma (4 cm × 5 cm and 8 cm × 9 cm respectively) while only 1 patient did in Group 1 (6 cm × 5 cm). All patients were managed in a conservative manner (rest, analgesia, daily hematocrit measure during the 1st days and antibiotics). Follow-up with a noncontrast CT was performed after 3 months, showing complete resolution of hematomas in all three cases. Urinomas, another frequent complication described in tPNL, were not observed in all postoperative CTs, no patient developed fever and/or urinary tract infections during the postoperative period. Finally, none of the patients presented urine leakage through the access site.

Table 1: Demographic and clinical characteristics

	No Surgicel® + Gelita® (*n*=25)	Surgicel® + Gelita® (*n*=27)	*P*
Age±SD (years)	50.3±7.9	41.7±7.5	0.0002*
BMI±SD (kg/m^2)	26.6±2.4	25.7±2.3	0.15$^+$
Gender (*n*)			
Female	12	6	0.048§
Male	13	21	0.048§
Stone size±SD (cm^2)	4.7±2.0	4.3±1.8	0.45**
Preoperative hematocrit±SD (%)	38.6±3.4	39.5±2.5	0.24*

*Student's *t*-test for samples with equivalent variances, §Proportion comparison (Z-test). $^+$Nonparametric test of Wilcoxon, **Student's *t*-test. BMI: Body mass index, SD: Standard deviation

Table 2: Postoperative outcomes

	No Surgicel® + Gelita® (*n*=25)	Surgicel® + Gelita® (*n*=27)	*P*
Postoperative hematocrit±SD (%)	35.6±3.7	37.6±3.1	0.16*
Hematocrit drop±SD (%)	2.0±1.7	1.9±1.9	0.45$^+$
Hematoma (*n*)	1	2	0.53§
Residual lithiasis (*n*)	5	5	0.58§
Operative time±SD (min)	112±17.1	107.0±18.2	0.41
Hospital stay length±SD (h)	47.8±5.4	49.3±9.8	0.20$^+$
VAS 24 h±SD	4.2±1.0	4.7±1.4	0.13$^+$
VAS 48 h±SD	2.0±1.0	2.0±0.9	0.87$^+$

*Student's *t*-test for samples with equivalent variances, §Proportion comparison (Z-test), $^+$Nonparametric test of Wilcoxon, **Student's *t*-test. VAS: Visual Analog Scale, SD: Standard deviation

DISCUSSION

This study aimed to assess the role of the simultaneous use of two hemostatic agents (cylinder of Gelita® wrapped in Surgicel®) for the closure of the percutaneous access tract in patients subjected to tPNL. We found no relevant differences between groups in terms of postoperative complications.

Both study groups were comparable in terms of demographic characteristics except for age and gender. However, we believe that these variables had no significant influence on bleeding and urinary leakage since these complications are primarily related to the surgical technique. In fact, age and gender have not been identified as significant risk factors for postoperative bleeding or any other postoperative complication in patients undergoing conventional PNL in large retrospectives studies.[17,18] These facts, although obtained from conventional PNL cohorts, probably applies to our series since several previous reports have established the equivalence of tubeless and conventional PNL in terms of postoperative complications.[19]

Several hemostatic agents are available for use during tPNL. Among them, the most well-known are a type of gelatin and thrombin array (Floseal®), the "fibrin glue" (Tissel®), the oxidized cellulose (Surgicel®) and another array of gelatin (Gelita®).[20] Singh *et al*.[21] described the use of a further type of gelatin array (Spongostan®) for the closure of access tracts in 20 patients in a prospective randomized study of 80 patients. The author showed a significant decrease in the use of postoperative analgesia (evaluated with VAS), length of hospitalization and urinary leakage after use of the sealant. Meanwhile, Shah *et al*.[22] reported no significant differences in terms of postoperative hematocrit drop or the need for blood transfusion in a prospective randomized study of 63 patients subjected to tPNL. In this study, Tissel® was applied in 32 patients, and the tract was abandoned in the remaining group. Significant less pain and analgesia requirements were observed in the Tissel® group (evaluated with VAS). With regards to Surgicel®, Aghamir *et al*.[23] published a prospective randomized trial of 20 patients undergoing full tPNL, using Surgicel® in 10 of them. They

found no significant differences in terms of postoperative hematocrit drop or urine leakage. Two recent meta-analyses have shown that the use of hemostatic agents had benefits in terms of the length of hospital stay, but there were no benefits in terms of blood loss, transfusion rate, fever rate, and complication rates.[14,15]

Surgicel® has been widely used, and its safety and efficacy have been demonstrated in several studies.[24] While it does not have an expansionary effect by its own, the goal of using a cylinder of Gelita® surrounded by Surgicel® in our study was to create a firmer tube for installment within the percutaneous tract, by these means optimizing hemostasis by adding a compressive effect. However, we were not able to see significant differences in terms of postoperative outcomes after using this method. The cost of Surgicel® is significantly lower compared to that of other hemostatic agents (approximately US$ 120). However, we were not able to demonstrate a significant clinical benefit derived from its use.

We acknowledge limitations of our study. Our results were analyzed retrospectively, making selection bias during assignation of patients to each group possible. Furthermore, the number of patients is small, compared to other studies. However, in our favor, all procedures were performed by one surgeon, using the same surgical technique for all patients, and the surveillance protocols were uniform across the period studied. In addition, we must emphasize as the strength of our study the fact that all patients were evaluated with noncontrast CT in the postoperative period. This is a striking difference with previous studies, where either ultrasound or kidneys, ureters, and bladder were the imaging modalities. It is well-known that noncontrast CT is much more sensitive and specific in this scenario, therefore reducing the chance of false-positives/negatives concerning stone-free rates and postoperative morbidities, such as hematomas. Nevertheless, further prospective trials are needed to confirm our findings and for overcoming all of the mentioned limitations.

CONCLUSION

In our experience the use of Gelita® and Surgicel® as hemostatic agents in tPNL is safe, but we were not able to demonstrate any significant benefit in terms of postoperative morbidity after comparing the use of these agents in tPNL. We concluded that the use of hemostatic agents might to be evaluated in more prospective randomized trials to define if these are necessary elements in tPNL.

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Conflicts of interest
There are no conflicts of interest.

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