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INVITED REVIEW

The management of the access tract after percutaneous nephrolithotomy

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Abstract
Purpose To describe the evolution of the current technique in percutaneous nephrolithotomy (PCNL) with a special focus on access tract closure techniques.
Methods A systematic review of outcomes and complications of tubeless PCNL was conducted using the MEDLINE and Pubmed databases between 1976 and 2014.
Results During the past decade, PCNL underwent fundamental modifications due to miniaturization of the instruments and advancements in technique. The routine use of the nephrostomy tube after PCNL has been subsequently questioned. Currently, the nephrostomy tube is increasingly omitted, and the access tract is usually sealed by haemostatic agents. An additionally ureteric stent is commonly inserted at the end of the procedure. However, the application of haemostatic sealants increases the immediate costs significantly. Still there are inconsistent data because of small study populations, lack of randomization, retrospective character and further more heterogeneous surgical techniques.
Conclusion The current body of literature does not provide high-level evidence for the preferred treatment of the access tract in PCNL. However, most authors agree that a tract sealing can be omitted without increasing the risk of complication in uncomplicated procedures.

Keywords Tubeless · Percutaneous nephrolithotomy · Haemostatic sealant · Tract sealing · Totally tubeless

Abbreviations

DTPA	Tc 99m technetium diethylenetriaminepentacetic acid
NSD	No significant difference
PCNL	Percutaneous nephrolithotomy
POD	Postoperative day
SWL	Shock wave therapy
URS	Ureterorenoscopy

Introduction

Since its first description by Fernström et al. [1], percutaneous nephrolitholapaxy (PCNL) has become the standard procedure for large renal stones [2] and even for children after shock wave therapy (SWL) or ureterorenoscopy (URS) [3]. Based on this trend, the indication for PCNL has been extended to smaller-sized kidney stones and has lead to an increased application of PCNL in general [2]. During the past decade, the surgical technique as well as the instruments have undergone refinements in an attempt to render the intervention less invasive. One of these modifications refers to the insertion of a nephrostomy tube at the end of the PCNL procedure in order to prevent urinoma and provide renal haemostasis and wound healing. Additionally, the nephrostomy tube guaranteed an easy access for a second look PCNL in case of residual concrements [4, 5]. Bellman first questioned the necessity of a nephrostomy tube after PCNL in 1997 and postulated that a controlled

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renal trauma to the parenchyma and collecting system would heal spontaneously if proper urinary drainage is provided [4]. From this measure to present totally tubeless techniques, various steps had been taken. The present review article summarizes the development of the access tract treatment and gives an overview over clinical trials and commonly used substances to close the percutaneous access tract.

Materials and methods

To evaluate the outcomes and complications of tubeless PCNL, a systematic review of outcomes and complications of tubeless PCNL was conducted using the MEDLINE and Pubmed databases between 1976 and 2014. A special focus was given on the utilization of haemostatic agents for sealing the access tract in PCNL.

The development of tubeless PCNL

Bellman initiated the first prospective study in which the patients underwent PCNL without insertion of a nephrostomy tube [4]. In the first 30 patients, he was able to remove the nephrostomy tube 2–3 h after the operation without any complications. Consequently, the subsequent 20 patients did not receive a nephrostomy tube. In every patient, a ureteral stent was inserted to provide proper drainage of the collecting system. The patients without nephrostomy tube experienced a significant reduction in the use of analgesics and shorter hospital stay and had less costs in comparison with patients for whom a nephrostomy tube was inserted. Moreover, the recovery of the patients was faster. Most importantly, there were no complications in terms of urinoma, haematoma or necessity of blood transfusion.

In spite of these promising results, the fear of continued or prolonged bleeding from the access tract or urine leakage through the tract leads to the idea of closing the tract with heterologous substances. The first attempt of sealing the access tract with a haemostatic agent instead of inserting a nephrostomy tube was introduced by Mikhail et al. [6]. To date, various haemostatic agents have been used for sealing the renal access tract ever since; however, the necessity for the use of these agents is still unclear. In addition to the small body of evidence in clinical use, unfavourable characteristics of some of these agents have been demonstrated in experimental studies [7–9]. Nevertheless, tubeless PCNL—whether the access tract is being sealed or left untreated—is regarded an effective and safe procedure in selected patients after uncomplicated PCNL procedures, consistently leading to decreased length of hospital stay and less requirement for analgesia without increasing complication rates [10, 11].

Totally tubeless percutaneous nephrolithotomy

The early postoperative discomfort after PCNL is putatively caused secondary not only by the nephrostomy tube but also by indwelling ureteral stents [5, 12]. Karami et al. [12] therefore modified the tubeless PCNL technique by simultaneously omitting the nephrostomy tube and the ureteral stent and introduced the so-called totally tubeless PCNL. He performed totally tubeless PCNL in 30 patients. The group was matched with 30 patients who underwent standard PCNL including the placement of a nephrostomy tube and a ureteral stent. The PCNL was performed without significant complications in both groups. However, the length of hospitalization and average analgesic requirement was lower in the experimental group without increasing the complication rate.

Aghamir evaluated totally tubeless PCNL in a prospective randomized trial with 70 enrolled patients [14]. The patients were randomly treated either with totally tubeless PCNL or with standard PCNL. The PCNL was performed using a 30 Fr access sheath; at the end of the procedure, a nephrostomy tube and ureteral stent were placed in every patient. The nephrostomy tube and ureteral stent were randomly removed in the recovery room if active bleeding was excluded. The length of hospitalization and analgesic requirement was significantly lower in the experimental group. The time to normal activity was also significantly faster in the experimental group. There was no difference in transfusion, complication rate, re-treatment or overall stone-free rate between the groups. No major complication occurred in both groups.

A prospective randomized trial with 90 patients compared totally tubeless PCNL versus standard PCNL [15]. Forty-five patients underwent totally tubeless PCNL. The control group with 45 patients underwent standard PCNL with the placement of a nephrostomy tube. The analgesic requirement and the hospitalization length were significantly lower in the experimental group. Complications occurred in two patients (4.5 %) in the experimental group (one retroperitoneal haematoma, one long-lasting colic) and in six patients (13.3 %) in the control group (five prolonged urine drainage, one long-lasting fever).

Kara et al. [20] performed a prospective randomized trial comparing totally tubeless PCNL versus standard PCNL in 60 enrolled patients. The PCNL was performed with a 28 Fr access sheath in both groups. No haemostatic agents were used for tract sealing. The access sheath as well as the ureteral stent was removed in the experimental group at the end of the procedure, whereas in the control group a nephrostomy tube was placed. There was no significant difference in haematocrit drop between the both groups. The length of hospitalization was significantly longer and the analgesic requirement significantly higher in the control

group. No major complications occurred in either of the groups. Two patients in the experimental group developed transient fever (6.6 %) and three patients in the control group (10 %). In both groups, the fever dissolved with conservative treatment; the urine cultures were negative in these patients. There was no sign of urine extravasation in both groups.

Another prospective randomized trial verifying the safety of totally tubeless PCNL was performed by Crook et al. [16]. In total, 50 patients were randomized to totally tubeless PCNL or standard PCNL. The size of the Amplatz sheath was not described. There was no significant difference in haemoglobin drop, creatinine or transfusion rate. The hospitalization was significantly longer in the control group. The analgesic requirement was lower in the experimental group but did not reach statistical significance.

Chang et al. [17] compared totally tubeless PCNL to standard PCNL with the largest number of patients in a prospective randomized trial. In total, 131 patients were enrolled, 68 patients underwent totally tubeless PCNL and 63 patients underwent standard PCNL. The PCNL was performed with a 30-Fr Amplatz sheath in every patient. In the experimental group, bleeding points were cauterized by conventional electric cauterizer after changing the fluid irrigation to distilled water. In analysis, there was no significant difference in haemoglobin decrease, creatinine change, return to normal activity or complications according the Clavien grading system. The length of hospitalization was significantly shorter and the analgesic requirement significantly less in the experimental group. The perfusion rate and glomerular filtration rate assessed by Tc 99m technetium diethylenetriaminepentacetic acid did not reveal a difference between the groups.

A meta-analysis evaluating the safety and efficacy of totally tubeless PCNL in comparison with standard PCNL was performed by Zhong et al. [5]. Included were the five described randomized controlled trials and four clinically controlled trials involving a total of 652 patients (Table 1). The pooled results demonstrated no statistically significant difference in decrease in haemoglobin, fever, transfusion rate, prolonged urinary drainage, second look PCNL or ancillary procedures in comparison with both groups. The length of hospitalization and analgesic requirement were significantly lower in the experimental group.

There is evidence that totally tubeless PCNL significantly reduces the analgesic requirement and contributes to reducing the length of hospitalization without increasing the complication rate in comparison with standard PCNL with the placement of a nephrostomy tube [5, 12–20]. This raises the question whether a haemostatic agent is necessary in addition to seal the access tract regarding the low complication rate published in these data.

Haemostatic agents

In 2003, Mikhail et al. [6] first introduced a haemostatic agent for tract sealing in order to prevent bleeding or urine extravasation after PCNL. In this retrospective non-randomized series, a total of 43 patients who had undergone tubeless PCNL were analysed. The experimental group consisted of 20 patients who received a tract sealing by Tissel® (Baxter) which was applied through the Amplatz sheath. In the control group, neither a nephrostomy tube nor a haemostatic sealant was used in 23 patients. In all patients, a ureteral stent was inserted during the procedure. The patients who received a tract sealing necessitated less analgesics, but the difference was not statistically significant. There was no difference in decrease in haematocrit between the two groups. Three patients in the experimental group required re-hospitalization due to postoperative fever (two patients) or wound seroma (one patient). In the control group, a re-hospitalization was required due to an obstructing ureteral stone (one patient) or ureteropelvic junction obstruction (two patients).

Since then, various haemostatic agents have been used for tract sealing. Choe et al. [21] listed the most common substances used for tract sealing after PCNL. Haemostatic agents lead to accelerated blood clotting. Generally, liquid agents and semi-solid gelatine matrix compounds are distinguished. The liquid products contain all components that are necessary to produce a fibrin clot independent of patient-derived factors. The gelatine matrix in contrary provides a matrix for platelet adhesion and aggregation. It does not provide fibrinogen and therefore depends on patient-derived factors of haemostasis. Therefore, the main difference between the substances is the necessity of a blood source with fibrinogen in order to provide a stable clot by the use of gelatine matrix substances. Furthermore, in contact with water, the gelatine matrix increases its volume between 19 and 400 % compared with the initially applied volume and therefore exerts a compressing effect additionally contributing to immediate haemostasis.

Clinical trials

There are four randomized prospective clinical trials investigating the safety and efficacy of tract closure with haemostatic agents in PCNL in comparison without any tract closure.

Aghamir et al. [22] initiated a randomized prospective pilot study with 20 patients. The inclusion criteria were pelvicaliceal stones >2 cm, lower calix stone >1 cm or failure of shockwave therapy. The size of the Amplatz sheath was not specified. The experimental group received a tract sealing by placing Surgicel® (Ethicon), an oxidized cellulose, under nephroscopy to fill the defect of the renal

Table 1 Safety and efficacy of totally tubeless PCNL in randomized prospective trials

References	PCNL	Study design	Number of patients	Results
Aghamir et al. [14]	30 Fr	Totally tubeless versus nephrostomy tube + ureteral stent	35 versus 35	NSD: transfusion and complication rate, re-treatment, overall stone-free rate SD: lower analgesic requirement and length of hospitalization in the experimental group
Istanbulluoglu et al. [15]	30 Fr	Totally tubeless versus nephrostomy tube	45 versus 45	NSD: haemoglobin decrease, transfusion rate, operating time SD: lower analgesic requirement and length of hospitalization in the experimental group Complication experimental group: 2 patients (4.5 %): 1 retroperitoneal haematoma, 1 long-lasting colic Complications control group: 6 patients (13.3 %): 5 prolonged urinary drainage, 1 long-lasting fever
Kara et al. [20]	28 Fr	Totally tubeless versus nephrostomy tube	35 versus 35	NSD: haematocrit decrease, operating time SD: significant lower analgesic requirement and length of hospitalization in the experimental group Complications experimental group: 2 patients (6.6 %): transient fever 1 Patient (3.3 %): pleural effusion (supracostal access) 1 Patient (3.3 %): pulmonary embolism Complications control group: 3 patients (10 %): transient fever
Crook et al. [16]	Not defined	Totally tubeless versus nephrostomy tube	25 versus 25	NSD: analgesic requirement, haemoglobin decrease, creatinine change SD: shorter length of hospitalization in the experimental group Complications experimental group: 1 Patient (4 %): haemorrhage without necessity of transfusion 2 Patients (8 %): urinary tract infection Complications control group: 3 Patients (12 %): haemorrhage (haemoglobin decrease from 3 to 7.5 mg/dl) without necessity of transfusion 2 Patients (8 %): urinary tract infection 1 patient (4 %): respiratory tract infection
Chang et al. [17]	30 Fr	Totally tubeless versus nephrostomy tube	68 versus 63	NSD: haemoglobin decrease, creatinine change, return to normal activity, complications according Clavien grading system, perfusion and glomerular filtration rate assessed by DTPA, operating time SD: lower analgesic requirement and length of hospitalization in the experimental group Annotation: Electrocauterization with rollerball was performed in experimental group at the end of the procedure

No significant difference (NSD)

Significant difference (SD)

tract. Additionally, pressure dressing with multiple gauzes was done after the tract sealing. In the control group, the Amplatz sheath was removed and only pressure dressing was performed. The degree of bleeding was controlled by haematocrit decrease. In both groups, urine extravasation was determined by the number of wet gauzes as well as perirenal fluid collection in the ultrasonography. A significant drop in haematocrit during the operation was observed in both groups. However, there was no statistical difference in either haematocrit drop or urine extravasation between both groups. Two patients in each group presented with a mild fluid collection around the kidney without necessity of intervention. All patients were dismissed 2 days after the operation without further follow-up.

In another prospective randomized clinical trial, Li et al. [23] randomized 31 patients into three different groups. The patients in the groups underwent either tubeless PCNL with tract closure by Floseal® (Baxter, 10 patients), tubeless PCNL without tract closure (10 patients) or nephrostomy placement after PCNL (11 patients). Inclusion criteria were kidney stones, but the location or size was not defined. PCNL was performed with a conventional 30-Fr Amplatz sheath and a ureteral stent was placed in all patients at the end of the procedure. The follow-up was performed 1 week, 1 month and 3 months after the operation. The health-related quality of life was measured by the standardized quality of life questionnaire SF-36. No statistical difference was found concerning haemoglobin drop, hospital stay, analgesia use,

changes in creatinine or quality of life between the groups. In summary, only the analogue pain scale revealed significant differences between the groups 1 week after the operation. Patients treated with tract closure by Floseal® experienced significantly more pain than the other groups. This difference was not shown at the other time points. Because of the small number of enrolled patients, this study was underpowered to reach true statistical significance.

Shah et al. [24] investigated the efficacy of Tisseel® (Baxter) in tubeless PCNL in a prospective randomized clinical trial. In total, 63 patients were enrolled. Included were all patients with large renal and/or upper ureteral calculi irrespective of stone size and number. The PCNL was performed with a 30-Fr Amplatz sheath, and a ureteral stent was placed in every patient. The patients in the experimental group (32 patients) received a tract sealing by Tisseel® (Baxter), a liquid haemostatic agent with fibrin component, which was applied through the Amplatz sheath. In the control group, the Amplatz sheath was removed and the wound was strapped with a pressure dressing. The patients were not blinded. The follow-up period stretched over 6 weeks and included ultrasonography and plain X-ray. There was no statistical difference in haematocrit drop or requirement for blood transfusions between the two groups. Patients in the experimental group experienced less postoperative pain and required less analgesia. However, this difference was not statistically significant.

For evaluating the efficacy of Spongostan® (Johnson & Johnson) in tubeless PCNL, a prospective randomized trial with 50 enrolled patients was initiated by Sing et al. [25]. Included were patients with a stone burden <2.5 cm^2, short operating time (<1.5 h), minimal intraoperative bleeding and intact pelvicaliceal system. The PCNL was performed with a 24 Fr nephroscope, and a ureteral stent was inserted in every patient. Patients, who met the inclusion criteria, were randomized to tubeless PCNL with Spongostan® (20 patients), whereas in 30 patients a tract sealing was omitted. Follow-up was carried out for three months. There was no statistical difference in haematocrit drop, serum creatinine values and time to return to work between the two groups. The pain score by visual analogue scale and analgesic requirement was significantly lower in the experimental group. There was no necessity for blood transfusion in both groups.

Two recent meta-analyses investigated the role of haemostatic agents in PCNL. Yu et al. [26] included six randomized controlled trails [22–25, 27–29] and two case control studies [6, 30] which compared haemostatic agents with common methods (silk stitch or pressure dressing). There was no significant statistical difference in operation time, blood loss, transfusion rate, fever or complication rate. However, the hospital stay was significantly lower for the haemostatic group compared with control group. Analgesic use or postoperative pain was not investigated in this meta-analysis.

Wang et al. [31] included five prospective randomized studies [23–25, 29, 32] and two retrospective studies [6, 30] which compared haemostatic agents with common methods as well. Studies performed by totally tubeless PCNL were excluded in this meta-analysis. There was no significant statistical difference in haemoglobin drop, analgesic requirements or necessity of blood transfusion between the groups. The hospital stay was significantly lower in the haemostatic agent group.

At this point, no statistical difference concerning urine extravasation, haematocrit drop or blood transfusion requirements has been shown in clinical trials by the use of haemostatic agents in comparison with tubeless PCNL without sealing of the access tract [22–26, 31]. Inconclusive data exist concerning the postoperative pain and analgesic requirements [23–25]. In conclusion, the utilization of haemostatic agents seems to be safe. However, haemostatic agents did not show significant benefit in comparison with the control groups and are probably not mandatory. Furthermore, the utilization of haemostatic agents increases the cost of the procedure significantly (Table 2). For this reason, the argument that the cost of a potential postoperative complication might outweigh the cost of haemostatic sealants might not be valid. Due to limitations of the studies, a clear cut recommendation on the use of haemostatic agents cannot be given and large, randomized controlled studies of sufficient quality are not likely to be conducted in the future.

Experimental trials

There is evidence that the use of haemostatic agents in PCNL can cause alterations of the renal parenchyma. Rigopulous et al. [33] investigated the effect of three different haemostatic agents on the kidney in a porcine study. For this purpose, a renal puncture and dilatation to 30 Fr of the renal tract were performed in 14 pigs (28 renal units). For tract sealing, Helisorb® (Eucare; type 1 absorbable fish origin collagen powder), Tachosil® (Takeda; human fibrinogen- and thrombin-coated sponge) and Floseal® (Baxter) were investigated and compared with a control group without tract sealing. A computed tomography was performed 1, 15, 30 and 40 days postoperatively. On day 40, the animals were killed and the kidneys were resected for further investigation. The histopathological analysis revealed significant alterations of the renal parenchyma up to > 1 cm distant from the access tract if a haemostatic sealant was used. Regardless of which sealant was utilized, the pathologic findings involved chronic and acute inflammation, fibrosis, tubulointerstitial nephritis, foreign body-type reaction, calcification or vascular damage. In comparison,

Table 2 Costs of haemostatic agents

	Substance	Preparation time	Costs
Liquid fibrin compounds	Tisseel (Baxter)	20 min	1 × 2 ml = app. 176,00 €
	Evicel (Johnson and Johnson Medical)	<1 min	1 × 5 ml = app. 510,00 € 1 × 1 ml = app. 106,50 €
Gelatine matrix	Floseal (Baxter)	1–2 min	1 × 5 ml = app. 245,00 €
	Surgiflo (Johnson and Johnson Medical)	30 s	1 × 8 ml with thrombin = app. 280€ 1 × 8 ml without thrombin = app. 132,00€
	Coseal (Baxter)	1–2 min	1 × 4 ml = app. 424,00 €
	Spongostan (Johnson and Johnson Medical)	<1 min	5 × 5×1 (20 Stk.) sponge = app. 108,40 € 6 × 1 g powder = app. 539,70 €

there were no significant microscopic lesions in the control group. Furthermore, in some cases the haemostatic sealants caused obstruction of the collecting system, leading to hydronephrosis or urinoma. In contrast, no evidence of urinoma, haematoma formation or obstruction was noted in the control group [33]. These histological findings support the hypothesis of an inflammatory or allergic reaction discussed in a retrospective PCNL study in which 10 % of the patients developed transient febrile temperatures without elevation of infect parameters after tract sealing with Floseal® [34]. There could also be a correlation with the inflammatory process in the histological findings of Rigopoulos et al. [33].

Uribe et al. [7] investigated the in vitro effect of haemostatic agents in contact with urine. Oxidized regenerated cellulose (Surgicel®, Ethicon), fibrin sealant (Tisseel®, Baxter), gelatine matrix sealant (Floseal®, Bayter) and polyethylene glycol (CoSeal®, Baxter) were examined. The gelatine matrix transformed immediately into a colloidal suspension, which did not change over 5 days. The oxidized regenerated cellulose maintained the solid form and was transformed over 5 days finally to a mucoid substance with visible free-floating fibres. The fibrin sealant as well as the polyethylene glycol formed immediately a solid clot in contact with urine. After 5 days, the fibrin sealant clot transformed into a cohesive mucoid gel. The polyethylene glycol clot did not change and remained solid.

Kim et al. [8] injected haemostatic sealants directly to the collecting system in domestic pigs through a percutaneous nephrostomy before pulling back the tube and sealing the tract. Sixteen kidneys served as control group. The haemostatic sealants were Floseal®, Tisseel®, CoSeal® and BioGlue®. The direct injection of a haemostatic sealant regardless of the substance led to an obstruction of the collecting system in at least half of the injected kidneys. In contrary, none of the control group showed signs of obstruction.

Lipkin et al. [9] evaluated the pathologic findings of Evicel® and Surgiflo® in a porcine model. In a total of 19 kidneys, access was gained and dilated to 30 Fr. Ten kidneys served as a control. An intravenous urography was performed at the first, tenth and 14th postoperative day. The pigs were killed for further pathological investigation. Only on the first postoperative day, two kidneys presented a urine extravasation in the control group. There was no urine extravasation at any other time in the control or experimental group in urography. In histological investigation, all renal tracts were closed in the control and the experimental group with Surgiflo® at day 14. In two kidneys in which Evicel® was utilized, there was a persistence of the substance in the renal tract. Lipkin reasoned an impaired wound healing by the utilization of a fibrin sealant in PCNL.

Summary

In an attempt to minimize the invasiveness of PCNL, the routine insertion of a nephrostomy tube at the end of PCNL is increasingly omitted. In general, "tubeless PCNL" in uncomplicated cases does not lead to an increased complication rate. Although haemostatic sealants are increasingly utilized for tract sealing in order to prevent bleeding and urinoma, the necessity of these sealants has not been demonstrated: four randomized prospective clinical trials presented no difference in complication rate between the experimental and control group. Furthermore, some experimental studies demonstrated obstruction and urine extravasation or even significant alterations of renal parenchyma putatively caused by an inflammatory reaction due to the haemostatic sealant. Additionally, the significant costs of haemostatic agents has to be taken into account. The argument that the expenditure of potential complications might be higher than the routine use of haemostatic agents cannot be justified since current studies do not show an increase in complications without tract treatment.

For these reasons—although the safety and efficacy in totally tubeless PCNL have been demonstrated in various clinical trials and two recent meta-analyses—the general

use of these formulations should be carefully weighed against the potential risks and costs.

Conflict of interest None of the authors has any conflicting interest concerning the contents of this text.

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