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A New Hemostatic Agent (Ankaferd Blood Stopper®) in Tubeless Percutaneous Nephrolithotomy: A Prospective Randomized Study

Mustafa Okan Istanbulluoğlu, MD,[1] Mehmet Kaynar, MD,[2] Tufan Çiçek, MD,[3] Murat Koşan, MD,[3] Bülent Öztürk, MD,[3] and Hakan Özkardeş, MD[4]

Abstract

Purpose: The present study evaluates the efficiency and reliability of a hemostatic agent ABS (Ankaferd Blood Stopper®) in tubeless percutaneous nephrolithotomy (PCNL).

Patients and Methods: A total of 90 patients were divided into two subgroups. The first group had ABS applied during the intervention, whereas the control group underwent regular tubeless PCNL in this prospective randomized study. Age, stone size, operative time, postoperative hemoglobin change, renal parenchyma thickness, postoperative ureteral catheter removal time, access number, nephroscope time, blood transfusion rate, serum creatinine change, complication rate, visual analogue scale (VAS), and hospitalization time were compared between the two groups.

Results: Preoperative and postoperative data obtained from both groups were compared. No statistically meaningful differences were found related to variables of mean age, stone size, access number, serum creatinine change, operative time, renal parenchyma thickness, VAS scores, and hospitalization period. Whereas the nephroscope time (minutes) was longer in the ABS group (Group 1 [G1]:3, 33 ± 1, 72 *vs* G2:2, 62 ± 1, 43, $P = 0.035$), hemoglobin (Hb) decrease, and urine clarity time were statistically lower compared with the control group. Hb decrease was (mg/dL) (G1: 1.40 ± 1.04 *vs* G2: 1.84 ± 1.15, $P = 0.034$), and urine clarity time was (hour) (G1: 9.60 ± 5.50 *vs* G2: 11.95 ± 4.71, $P = 0.012$), respectively. Complications were encountered in three (6.6%) patients of the ABS group and in four (8.8%) of the control group.

Conclusion: ABS is an efficient and reliable hemostatic agent in tubeless PCNL. Comparative studies are needed, however, with other hemostatic agents that might be applied in tubeless PCNL.

Introduction

Percutaneous nephrolithotomy (PCNL) is a well-established technique for the management of urinary stone disease. Nephrostomy catheters of various diameters are used after standard PCNL operations to provide renal drainage and to tamponade bleeding. In many tubeless PCNL applications, to safeguard against extravasation and hemorrhage, a Double-J or ureteral catheter is used. In stone-free and other cases without serious bleeding and perforation in the collecting system during the operation, totally tubeless PCNL can be safely applied.[1] The aim of various management options of PCNL is to make it more reliable and less morbid, and hence tubeless PCNL might be opted for because it decreases the required hospitalization period and time to return to normal activities, as well as analgesia requirements.[2]

One of the requirements for tubeless PCNL is low bleeding, and therefore various hemostatic agents have been used (fibrin glue, gelatin matrix, oxidized cellulose purified gelatin, etc.) Thus, tubeless PCNL interventions were considered to be more reliable and safe.[3–5]

The present study is about the use of ABS as a hemostatic agent in tubeless PCNL interventions. ABS is a combination of five plant extracts that have been known in Turkish folkloric medicine as hemostatic agents for centuries. The basic action mechanism of ABS is the formation of an encapsulated protein network that provides focal points for vital erythrocyte aggregation.[6] ABS is patented with the number 2007-0-114485, produced by BirgiMefar Group, (www.mefar.com), and marketed all over the world by Ankaferd İlaç Kozmetik A.Ş

In this prospective randomized study, we evaluated the safety and efficacy of ABS as a hemostatic agent in tubeless

[1]Department of Urology, Faculty of Medicine, Mevlana University, Konya, Turkey.
[2]Department of Urology, Konya Education and Research Hospital, Konya, Turkey.
[3]Department of Urology, Konya Medical and Research Center, Başkent University, Konya, Turkey.
[4]Department of Urology, Faculty of Medicine, Başkent University, Ankara, Turkey.

PCNL interventions. To our best knowledge, this is the first study on the use of ABS in urolithiasis.

Patients and Methods

Patients

In this prospective randomized study, we evaluated 90 patients who had undergone PCNL because of renal and/or upper ureter stones. Of these patients, 45 underwent tubeless PCNL with the use of ABS as a hemostatic agent (group 1 [G1]), whereas the remaining ones underwent tubeless PCNL without ABS (group 2 [G2]). The study was approved by the local ethical committee, and patients signed an informed consent form in order to be enrolled in the present study. Before the interventions, complete blood cell count, serum creatinine level, and urine culture were performed. Radiologic evaluation was performed with ultrasonography, intravenous urography (except those with a raised serum creatinine level), and noncontrast CT. Inclusion criteria were stone free or clinically insignificant residual fragments (CIRF) (<4 mm) at the end of the procedure and an intact pelvicaliceal system. Solitary kidney, kidneys with congenital anomalies, patients who underwent bilateral simultaneous PCNL, more than two accesses within a single session, persistent severe hemorrhage, and pelvicaliceal sytem perforation were exclusion criteria in the present study. Prophylactic wide-spectrum antibiotics were administered to patients before the procedure. Patients with bacteriuria were treated according to culture and sensitivity results and underwent tubeless PCNL afterward.

Surgical technique

The appropriate calix was determined approximately before renal access, and parenchyma thickness was measured using noncontrast CT. Under spinal anesthesia, with cystoscopy aid, a 7F ureteral catheter was placed into the ipsilateral ureter and then attached to the urethral Foley catheter. After that, the patient was brought to the prone position. All percutaneous accesses were performed in the prone position. Access to the selected calix was performed with the aid of C-arm fluoroscopy and an 18-gauge needle. After entering the collecting system with a guidewire, dilation was performed using Amplatz dilators, and a 30F Amplatz sheath was placed through which a 26F rigid nephroscope was inserted; stone fragmentation was conducted using a pneumatic lithotripter. At the end of the operation, stone-free patients and patients with CIRF (<4 mm) were determined fluoroscopically and with a flexible scope and in the the postoperative period using plain radiography. The distal end of the ureteral catheters were inserted into the Foley catheters to enable drainage.

All the patients who underwent the above described procedure were randomized into two groups in the operating room on completion using systematic sampling technique. Forty-five patients in G1 were administered ABS tamponade, whereas 45 patients in G2, the control group, were not.

A 4×6 cm sheath sponge soaked with ABS was rolled. To pull the sponge back, the proximal end of the sponge was fixed on No. 1 surgical silk. To determine the position of the rolled sponge, the 2 cm distal end was soaked in dilute urography solution. The prepared sponge was sent with a forceps through the sheath into the kidney. The sponge was visualized with the nephroscope and kept in the kidney for 2 minutes in the parenchyma to enable tamponade (Fig. 1). After 2 minutes, the sponge and the sheath were withdrawn.

In G2, the sheath was kept in the access site like the ABS soaked tamponade for 2 minutes for the sheer tamponade effect of the sheath itself and then withdrawn before the operation was concluded. In both groups, patients' skins were closed with a single silk stitch.

Evaluation

Age, stone size, operative time, postoperative hemoglobin (Hb) change, renal parenchyma thickness, ureteral catheter removal time, access number, blood transfusion rate, creatinine change, complication rate, visual analogue scale (VAS) scores, and hospitalization time of the groups were compared statistically.

In all patients, the Hb level was checked 16 hours after the operation and in doubt regarding hemorrhage or urinoma driven perinephric collection, ultrasonography was performed. Ureteral and Foley catheter removal decision was made based on patients' urine color (light pink-tinged fluid in the urobag). Urine color was observed by the clinical nurse, blind edto both groups, at regular intervals.

Differences in percentages (qualitative variables) were analyzed using the chi-square test. Differences between means were evaluated with the Student t test and Mann-Whitney U test. Statistical analyses were performed using the SPSS 15.0 package program. P value of <0.05 was considered to be statistically significant.

Results

G1 consisted of 29 men and 16 women patients and G2 of 33 men and 12 women. Mean patient age in G1 and G2 was 49, 84±15, 08 (range 21–71) and 49, 86±11, 83 (range 25–76) years, respectively ($P=0.994$). Stone location in G1 was lower calix (n=9), pelvis (n=7), multiple calices (n=16), upper ureter (n=12), and upper calix (n=1) and in G2, lower calix (n=11), pelvis (n=6), multiple calices (n=16), upper ureter (n=10), and upper calix (n=2). Supracostal access (between the 11th and 12th ribs) was performed in seven patients in G1 and in eight patients in G2 (Table 1).

No significant changes were found between the groups in terms of mean stone volume, operative time, mean hospitalization time, access number, renal parenchyma thickness, and VAS scores (Table 2). Hemoglobin drop and hematuria loss and catheter removal times were significantly shorter in G1, however ($P<0.05$). Nephroscope time, however, was significantly longer in G1 ($P<0.05$).

Complications were encountered in G1 in three (6.6%) and in G2 in four (8.8%) patients. One patient with hematuria in G1 received a diagnosis of pseudoaneurysm on renal angiography. Angioembolization was performed to control bleeding. In two patients, a minimal pleural effusion was determined.

Of the four patients in G2, colic emerged in two patients on the third day of the postoperative period. Of these two patients, one was considered to have a blood clot. Conservative treatment was applied in the former and in the latter, a stone was defined in the ureter; ureteroscopy was performed. In another patient of G2, minimal pleural effusion was seen, and in a further one during the second postoperative day, continuing abdominal pain from a perirenal urinoma was

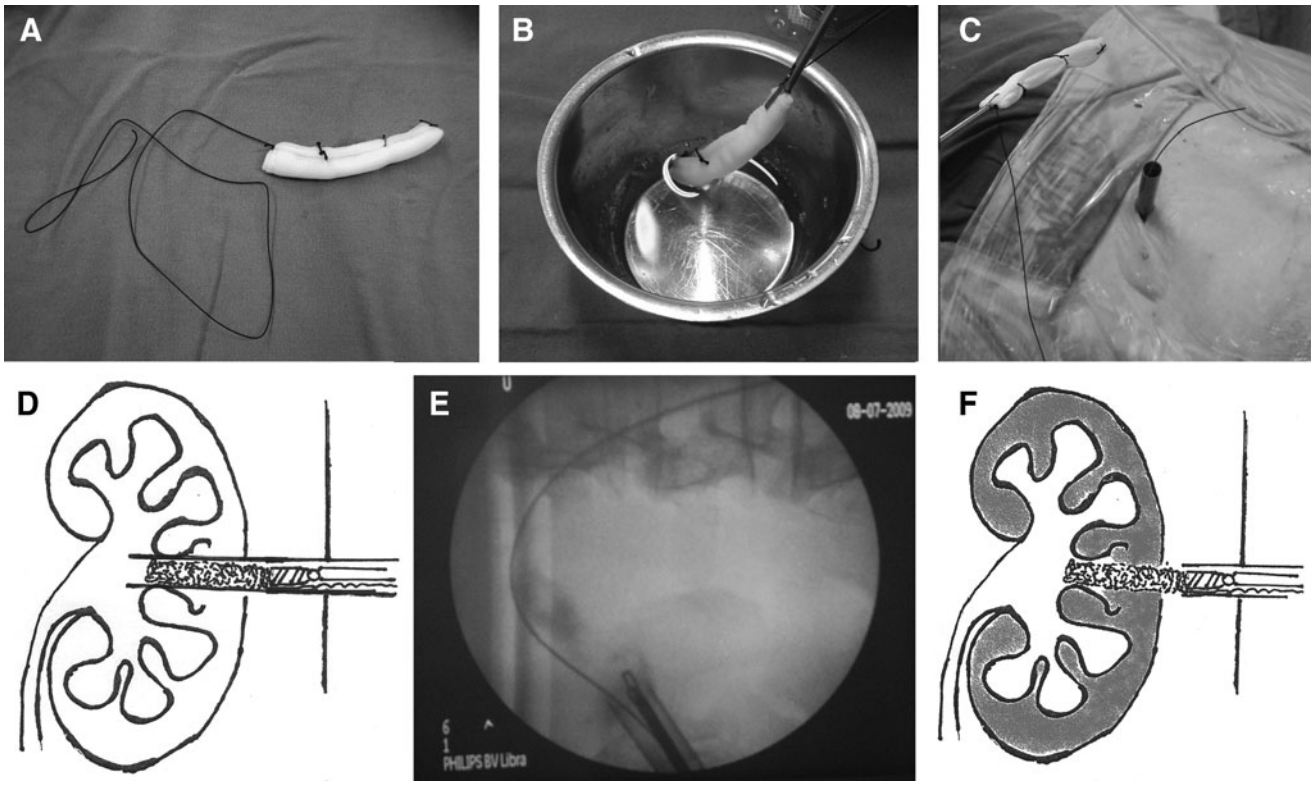

FIG. 1. Enrolled sponge fixed with silk suture **(A)**; Ankaferd Blood Stopper and contrast fluid soak **(B)**; placement into parenchyma through the sheath using forceps **(C)**; nephroscopic and schematic image of the parenchyma with prepared sponge **(D, E, F).**

diagnosed and treated conservatively. Blood transfusion was needed only in the patient with pseudoaneurysm.

Discussion

The European Association of Urology guideline suggests that in uncomplicated cases, tubeless (without nephrostomy tube) or totally tubeless (without nephrostomy tube and without ureteral stent) is a safe alternative with a shorter hospitalization period.[7] Bellman and associates[2] have also determined tubeless percutaneous renal surgery as a safe, efficient, and cost-effective treatment modality because of decreased analgesia requirement, hospital stay, and recovery time.[2]

Many endourologists still consider tubeless PCNL as adventurous and risky, however, and thus hinder its widespread adoption in clinical practice.[8] In particular, some risks, such as urinary leakage and bleeding in the access tract, are considered complex by endourologists and thus they prefer tubeless or totally tubeless PCNL only in painstakingly chosen cases.

In some articles, the advantages and disadvantages of hemostatic agents that have been used after tubeless PCNL to decrease urinary leakage, bleeding, and morbidity are discussed.[9–12]

In the present study, ABS has been used as a hemostatic agent. ABS comprises a standardized mixture of the plants *Thymus vulgaris*, *Glycyrrhiza glabra*, *Vitis vinifera*, *Alpinia officinarum,* and *Urtica dioica.*[6] Each of these plants has some effect

Table 1. Patient Demographics and Operative Data

	Group 1 (n = 45)	*Group 2 (n = 45)*	P *value*
Sex (M/F)	29/16	33/12	
Age ± mean	49.84 ± 15.08	49.86 ± 11.83	0.994
Stone location			
Lower calix	9	11	
Pelvis	7	6	
Multiple calices	16	16	
Upper calix	1	1	
Upper ureter	12	10	
Supracostal access	7	8	
Stone side (rt/lt)	19/26	30/15	
Stone size (mm^2)	604.15 ± 510.07	536.93 ± 448.88	0.345
Access number	1.04 ± 0.20	1.08 ± 0.28	0.404

Table 2. Outcome Measures of Tubeless Percutaneous Nephrolithotomy

	Group 1	*Group 2*	P *value*
Operative time (min)	43.28 ± 30.94	51.82 ± 34.75	0.901
Scope time (min)	3.33 ± 1.72	2.62 ± 1.43	0.035*
Preoperative and postoperative Creatinine change (mg/dL)	1.03 ± 0.35	1.00 ± 0.25	0.685
Hb decrease (mg/dL)	1.40 ± 1.04	1.84 ± 1.15	0.034*
Parenchyma thickness (mm)	16.06 ± 4.19	16.82 ± 4.48	0.403
VAS score	5.00 ± 2.12	5.17 ± 2.21	0.639
Urine color clarity (hour)	9.60 ± 5.50	11.95 ± 4.71	0.012*
Hospitalization (day)	1.39 ± 0.57	1.52 ± 0.62	0.30

*$P < 0.05$ statistical significance level.
Hb = hemoglobin; VAS = visual analogue scale.

on the endothelium, blood cells, angiogenesis, cellular proliferation, vascular dynamics, and cell mediators. ABS represents its unique hemostatic effect by promoting the very rapid (<1 second) formation of a protein network, which acts as an anchor for vital physiologic erythrocyte aggregation mechanism of action independent of clotting factors.[6] ABS, 100 mL, comprises a standardized mixture of plants, including 5 mg *T vulgaris*, 9 mg *G glabra*, 8 mg *V vinifera*, 7 mg *A officinarum*, and 6 mg *U dioica*. It has been used in Turkish traditional medicine as a hemostatic agent in Anatolia for centuries. It has been approved by the Ministry of Health in Turkey and is a licensed hemostatic agent acting as a topical hemostatic agent for mucocutaneous hemorrhages (www.ankaferd.com).

Studies investigating the hemostatic effects and ultrastructural and morphologic analyses have revealed that when ABS was added to plasma or serum, it induced a very rapid formation of a protein network and erythrocyte aggregation without affecting the levels of coagulation factors II, V, VII, VIII, IX, X, XI, and XIII. After ABS addition, plasma fibrinogen activity and antigen levels decreased, in parallel with the prolonged thrombin time. Total protein, albumin, and globulin levels decreased after the addition of ABS as well. These findings suggest that ABS stimulates the formation of an encapsulated protein network that provides focal points for erythrocyte aggregation on contact with blood.[6]

In various studies, the hemostatic effect of ABS has been investigated and used.[13–15] In tonsillectomy,[16] partial nephrectomy,[17] and gastrointestinal bleeding,[18] it has been used safely and efficiently without any reported local adverse effect or systemic toxicity. Because the hemostatic effect of ABS is unrelated to coagulation factors and platelets, it can also be used to control acute bleeding.[6,19]

It is available in different commercial forms such as tampon (2.5 cm × 7 cm-3 mL), (5cm × 7.5cm-10 mL), (20 cm × 20 cm-100 mL), spray 5 mL, 10 mL, 25 mL, 50 mL, and 100 mL, and ampules 24 units × 2 mL per box without any known adverse effects or adverse interactions with drugs used by patients. Moreover, it is also known to be hypoallergenic.

Shah and colleagues[5] used fibrin glue (TISSEEL®) sealant as a hemostatic agent in their study. There was no difference in the hematocrit decrease and blood transfusion requirement in the two groups. The patients who received fibrin glue, however, reported less postoperative pain and needed less analgesia. The underlying cause might be less retroperitoneal blood and urine oozing resulting in less postoperative pain.

In the present study, hemoglobin drop and urine color clarity time were significantly shorter in G1 compared with G2 ($P < 0.05$). Nephroscope time of G1, however, was longer than that of G2. Hb drop and urine color clarity time can be explained with the hemostatic effect of ABS. The reason for the prolonged nephroscope time of G1 is the use of the scope for control during the placement of the ABS soaked sponge into the parenchyma. The prolonged nephroscope time can be considered as the disadvantage of the present study. Therefore, it has to be considered that endoscopy time is not within the nephroscope time. Nephroscope time, in the present study, is the time measured after access to the kidney and thus defines the fluoroscopy time.

The study of Singh and coworkers[4] conducted with absorbable porcine gelatin (SPONGOSTAN™) revealed no statistically significant differences in the control and study group regarding hematocrit drop and time to return to work. Hospitalization, urinary extravasation, and analgesia requirement were, however, significantly lower in the patients who had undergone gelatin sealant assisted tubeless PCNL.

Another study concluded that hemostatic gelatin matrix remained as a fine particulate suspension in both normal and sanguineous urine.[20] Because SPONGOSTAN is totally absorbable in the human body within a long period, 4 to 5 weeks, the Double-J stents were removed after 4 to 6 weeks because of the expectancy that such agents may block and obstruct the pelvicaliceal system, hinder drainage, and trigger even future stone formation. The underlying reason of low urinary extravasation is not clear, because it might be a result of absorbable gelatine hemosealant use or the presence of an ureteral catheter. They found that hospitalization and analgesia requirement was significantly lower. This might be related as in other studies to the lack of nephrostomy tubes.[2,21]

One of the major advantages of our method is the low existence of one of the major complications of PCNL, namely hemorrhage. The lack of a statistically significant VAS in both groups is related to the nonexistence of a nephrostomy tube in both groups. Urinoma was seen in one patient of G2.

Aghamir and colleagues[9] used oxidized cellulose (SURGICEL®) to seal the nephrostomy tract after totally tubeless PCNL; however, sealing the nephrostomy tract with oxidized cellulose after totally tubeless PCNL did not decrease bleeding or extravasation. Because their study was conducted with small groups, larger groups are needed to determine the reliability of the hemostatic effect of oxidized cellulose.

The gel matrix hemostatic sealant (FLOSEAL®)[22,23] was used in tubeless PCNL and mini-PCNL, resulting inreduced postoperative pain and analgesic requirement. The risk of bleeding or urinary leakage was not reduced, however.

In their randomized control study, Cormio and associates[3] defined the efficacy and safety of absorbable equine collagen matrix (TachoSil®). Like in other studies, it was used as a hemosealing agent for the PCNL tract and compared with nephrostomy tube placement. With regard to analgesic requirement, VAS scores, and Hb decrease, there was not any difference in their control and study group. TachoSil, however, provided better tract control (bleeding and urinary leakage) and a shorter hospitalization period compared with nephrostomy tube placement.

In percutaneous nephrolithotomy, parenchyma thickness is among the factors having an impact on bleeding. Atrophic parenchyma is associated with reduced blood loss.[24] Yet, in the above mentioned studies, this issue was not addressed. In the present study, it was measured and compared because of its possible effect on hemorrhage. There was no statistically significant difference regarding parenchyma thickness in G1 and G2, however.

In the present prospective randomized study, there was not a statistically significant difference between G1 and G2 between VAS scores and analgesia requirement. The present study is prospective, because studies randomized at the end of a procedure could introduce selection bias into the study design and will create results favoring one technique over another. Hence, in the present study, patients were randomized and divided as G1 and G2 before the intervention Hb decrease between G1 and G2 were statistically significant. In the other studies, parenchyma thickness was not considered; however, although we considered parenchyma thickness and access number, there was not a statistically significant difference in both groups. We consider that the hemostatic

agents used in other studies might have a sealant or a mechanic tamponade effect on urinary leakage and bleeding until they are absorbed; ABS might, because of its hemostatic effect ,be more suitable in tubeless PCNL.

Conclusion

Hb drop and hematuria, considered to be among the major complications of tubeless PCNL, are decreased with the use of ABS in the present study. Because there were not any differences in the access numbers and parenchyma thickness, among the perioperative hemorrhage factors, was considered as the effect of ABS. The disadvantage of the study was prolonged nephroscope time. Interestingly, compared with other studies, there was not a difference in VAS scores or analgesia requirement and hospitalization period in G1 and G2. It has to be considered that Hb drop and hematuria decrease might be attributed to the hemostatic effect of the sponge as well. Although further studies are needed to compare the efficiency of ABS to other hemostatic agents as well as to the tamponade effect of sponge *per se,* we believe that it is a safe and reliable one in tubeless or totally tubeless PCNL interventions leading to expectations that these procedures might find widespread use among endourologists.

Disclosure Statement

No competing financial interests exist.

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Address correspondence to:
Mehmet Kaynar, MD
Haci Şaban Mah. Meram Yeniyol Caddesi No: 97 PK
42040 Meram-Konya
TÜRKİYE

E-mail: mekaynar@gmail.com

Abbreviations Used

ABS = Ankaferd Blood Stopper
CIRF = clinically insignificant residual fragments
CT = computed tomography
Hb = hemoglobin
PCNL = percutaneous nephrolithotomy
VAS = visual analogue scale