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WoundClot® Hemostatic Gauze Reduces Bleeding Time after Arterial Venous Fistula Decannulation

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Keywords

Arteriovenous fistula · Hemodialysis · Hemostasis · Bleeding time · End stage renal disease

Abstract

Introduction: Decannulation of the arteriovenous fistula (AVF) after each hemodialysis session requires a precise compression on the needle puncture site. The objective of our study was to evaluate the bleeding time (BT) needed to achieve hemostasis using WoundClot, an innovative hemostatic gauze, and to assess whether its long-term use can improve AVF preservation. ***Methods:*** This is a prospective single center study. Initially, the time to hemostasis after AVF decannulation was compared between WoundClot and cotton gauze in 24 prevalent hemodialysis patients. Thereafter, the patients continued to use WoundClot for 12 months and were compared to a control group consisting of 25 patients using regular cotton gauze. Follow-up data included parameters of dialysis adequacy, AVF interventions, and thrombotic events. ***Results:*** WoundClot use shortened significantly the time needed for hemostasis. Mean venous BT decreased by 3.99 (±4.6) min and mean arterial BT by 6.38 (±4.8) min when using WoundClot compared to cotton gauze ($p < 0.001$). At the end of the study, dialysis adequacy expressed by spKt/V was higher in the WoundClot group compared to control (1.73 vs. 1.53, respectively, $p = 0.047$). Although patients in WoundClot group had a higher baseline BT, arterial and venous pressures did not differ between the groups after a median follow up of 10.8 months. AVF thrombosis rate was similar between the groups. ***Conclusions:*** WoundClot hemostatic gauze significantly reduced the time required for hemostasis after AVF decannulation and may be associated with better AVF preservation. We suggest using WoundClot for arterial BT longer than 15 min and for venous BT longer than 12.5 min.

Introduction

Arteriovenous fistula (AVF) is the preferred vascular access for hemodialysis due to longer patency and lower complications rate compared to arteriovenous grafts and central vein catheters [1–3]. However, AVF is not free of complications. Aneurysms and thrombosis are some of the drawbacks associated with AVF and are related to significant morbidity [4].

Appropriate management of needle puncture sites after dialysis completion is highly important for access preservation. Hemostasis is best achieved by removing the needles separately and applying direct pressure on the puncture site for at least 10 min [5].

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Occasionally longer time is required to achieve hemostasis, resulting in prolonged sessions and patient's discomfort. Although prolonged bleeding warrants assessment of the access for potential stenosis, a treatable lesion is not always found [6]. It is a fine balance between achieving a comparison firm enough for the hole to clot and yet avoiding an excessive compression that can lead to fistula thrombosis [5].

Devices such as tourniquets or straps used to assist clotting may damage the vascular access and are therefore not recommended [7]. Use of clotting agents to aid this process was scarcely studied in dialysis patients, with only few studies assessing their effectiveness and safety. When used for short term, a designated bandage or hemostatic gauze appeared to be safe [8–11].

WoundClot (WC), manufactured by Core Scientific Creations, is an innovative hemostatic gauze, based on a chemically treated cellulose. When in contact with bleeding, it transforms into a transparent adhesive hydrogel that adheres to the surface as a consequence of its distinct physical, biological, and chemical properties, and promotes formation of a stable clot. WC's distinctive qualities allow it to be applied with minimal compression. Originally manufactured for treatment of uncontrolled bleeding due to trauma, its utilization is expanding [12, 13]. The aim of the present study was to evaluate the impact of using WC on bleeding time (BT) after AVF decannulation and to assess whether its use results in a superior AVF preservation during long-term follow-up, compared to routine practice.

Methods

This is a single center prospective study, conducted at our in-hospital dialysis unit. The study was approved by local Ethics Committee. Informed consent was obtained from all individual participants included in the study.

Prevalent hemodialysis patients using an AVF for dialysis for at least 6 months were considered eligible for the study. Exclusion criteria consisted of a nonmature fistula or access thrombosis requiring emergent angiography in the preceding 3 months. Patients were also excluded if they were unable to sign informed consent or if they were anticipating kidney transplantation within 3 months.

Patients were randomly assigned to the WC group or control. The first aim of the study was to assess the effectiveness of WC gauze in reducing BT, by measuring the time required for hemostasis after needles removal, compared to regular cotton gauze. For this purpose, we measured BT in 3 consecutive HD treatments with WC and in 3 consecutive HD treatments with cotton gauze, only in the WC group.

The second aim was to evaluate whether prolonged use of WC resulted in better preservation of the access. Therefore, patients in the WC group, who used WC at the initial phase, continued to use the hemostatic gauze at the end of each dialysis session during follow-up. The control group continued to use regular cotton gauze. Patients were followed for 1 year or until AVF failure necessitating another dialysis access, patient's decision to withdrawal from the study, transfer to another dialysis unit, kidney transplantation, or death.

Data were collected retrospectively 12 months before entering the study and prospectively during 12 months of follow-up. Data included patients' demographic and baseline characteristics, anticoagulant use (enoxaparin, warfarin, or apixaban. Heparin use solely during dialysis was not considered as chronic anticoagulant use), access location and vintage, dialysis adequacy expressed by single pool Kt/V (spKt/V), arterial and venous pressure, blood flow, and access complications – thrombotic events as well as number of interventional angiography procedures.

Fistula Cannulation

All fistulas were cannulated using the area technique, with 16G rigid sharp metal needles. Our institutional practice is to perform dialysis with a blood flow of 300 mL/min, providing the access permits. Blood flow can be raised to 320–340 mL/min, especially in younger patients.

BT Measurement

Arterial and venous BTs were measured in both groups after decannulation at the end of 3 dialysis sessions while patients were using regular cotton gauze. The minimum time needed to achieve hemostasis was recorded.

In the WC group, at the next dialysis session, WC was used after decannulation for at least half the time needed to achieve hemostasis with cotton gauze (or a minimum of 2 min). Then the nurse checked the gauze to decide whether hemostasis was obtained, and BT was recorded. On subsequent dialysis, it was permitted to reduce compression time by 1 min below the former value to assess hemostasis. In this manner, BT was measured in 3 sequential sessions using WC.

Measurement of Access Function and Dialysis Adequacy

Qb (the blood pump flow delivered to the dialyzer) and arterial and venous pressure in the fistula during dialysis treatment were all obtained retrospectively from the dialysis machine data 3 and 6 months before enrollment on enrollment day and thereafter every 3 months during follow-up. The delivered dialysis dose, reflected by spKt/V, was retrieved from computerized data, measured according to Daugirdas formula [14].

Arteriovenous Access Thrombosis and Angiographic Interventions

Patients were referred to angiographic procedures by the attending nephrologist according to local practice, consisting of clinical indicators for arteriovenous access stenosis or surveillance in formerly stenosed fistulas. Only procedures requiring intervention were recorded. Time to first thrombotic event was documented.

Statistical Analysis

All continuous variables are displayed as means (SD) for normally distributed variables or median (interquartile range [IQR]) for variables with abnormal distribution. Categorical variables are displayed as number (%) of patients within each group. Continuous variables were first tested for normal distribution by using a Kolmogorov-Smirnov test and Q-Q plots, and were compared by

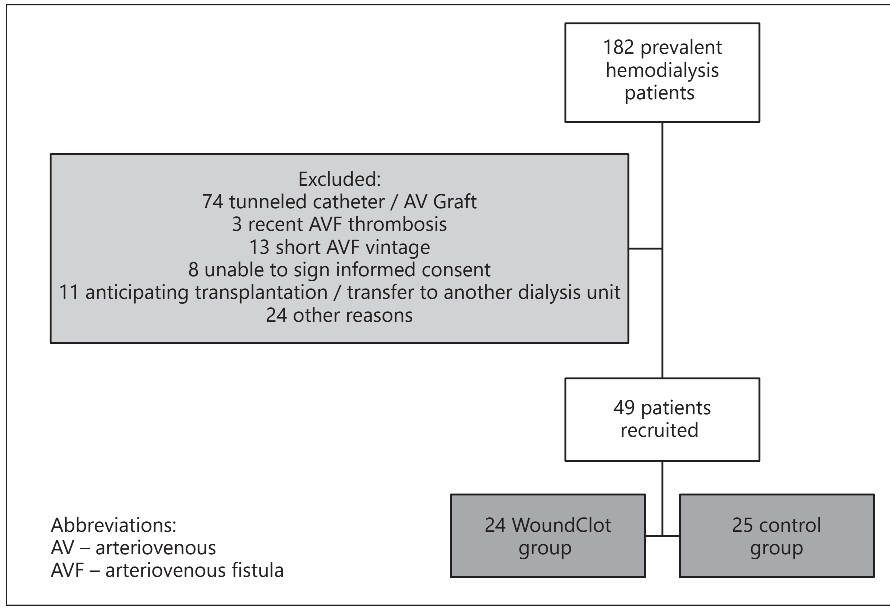

Fig. 1. Study scheme. AVF, arteriovenous fistula; AV, arteriovenous.

a Student's *t* test for normally distributed variables and by the Mann-Whitney U-test for abnormally distributed variables. To assess associations among categorical variables, we used a χ^2-test.

Paired analysis was performed for comparison of difference in venous and arterial BT for cotton and WC gauze. Correlation of parameters to the difference in BT when using cotton versus WC gauze was evaluated with a linear regression model.

Mean arterial and venous BTs, Qb, and spKt/V were calculated for every participant in each gauze type. The evaluation of AVF thrombosis and angiographic intervention during the follow-up period in both groups was performed with Cox regression analysis. The date of visit at which the thrombosis was diagnosed was considered as the time-point for the regression analysis.

p values of <0.05 were considered statistically significant. The IBM SPSS Statistics 24.0 statistical package was used to perform all statistical analyses (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY, USA: IBM Corp.).

Results

Out of 182 prevalent hemodialysis patients, 49 patients were recruited. Twenty-five were assigned to the control group and 24 to WC group (Fig. 1).

Comparison between Groups at Baseline

Participants' baseline demographic, clinical characteristics, and dialysis parameters according to study groups are summarized in Table 1. There were no differences between the groups in AVF vintage, number of angiographies before enrollment, dialysis adequacy, or Qb. There were more brachiocephalic AVFs and a higher baseline mean venous pressure, measured 0–6 months before enrollment, in the WC group. However, mean venous pressure at time zero (on recruitment day) was similar in both groups.

There was a considerable difference in BT using cotton gauze between groups: time to achieve hemostasis was significantly higher in the WC group compared to control for both arterial and venous BT. Use of WC instead of cotton gauze in the WC group reduced BT to values equivalent to control group.

Comparison of BT with Cotton Gauze versus WC

WC use shortened significantly the time needed for hemostasis compared to cotton gauze in 24 patients in the WC group (Fig. 2). Mean venous BT decreased by 3.99 min (±4.6), and mean arterial BT decreased by 6.38 min (±4.8) when using WC compared to cotton gauze.

A longer baseline venous BT was related to a more significant reduction of BT while using WC ($r^2 = 0.156$, $p = 0.05$). Similarly, a longer baseline arterial BT was associated with a greater reduction of BT with WC ($r^2 = 0.791$, $p < 0.001$). There was a significant correlation between the highest percentile of mean venous BT (12.51 min) and arterial BT (15.8 min) with gauze and a reduction of BT with WC (OR = 1.27 (95% CI 1.06–4.14), $p = 0.033$; OR = 1.07 (1.09–1.434) $p = 0.42$ for arterial and venous, respectively).

Comparison between Groups during 1 Year Follow-Up

Median follow-up time was 10.8 months (IQR 2.3–12.0) in the WC group and 11.9 months (IQR 7.2–12.0) in the control group. In the WC group, 11/24 patients

Table 1. Patients' baseline characteristics

Parameter	WC group (*N* = 24)	Control group (*N* = 25)	*p* value
Age, years	65.21 (11.1)	64.18 (18.4)	0.804
Gender, female, %	29.16	28	1.0
AVF type, %			
Radiocephalic	50	80	
Brachiocephalic	45.8	12	0.0378
Other	4.2	8	
AVF vintage, months	54.17 (31.1)	50.3 (36.9)	0.674
No angiographic intervention last 12 months, %	75	72	1.0
Chronic anticoagulation, %	20.0	45.3	0.078
Mean Qb, mL/min	297.1 (12.5)	297.3 (15.5)	0.875
Mean arterial pressure, mm Hg	147.3 (17.4)	148.9 (20.1)	0.762
Mean venous pressure, mm Hg	139.2 (20.7)	127.9 (17.8)	0.049
Mean spKt/V	1.53 (0.28)	1.46 (0.26)	0.411
Qb time 0, mL/min	298.3 (13.1)	295.6 (21.6)	0.597
Arterial pressure time 0, mm Hg	141.5 (23.2)	149.1 (25.4)	0.288
Venous pressure time 0, mm Hg	131.4 (28.3)	124.1 9 (22.2)	0.314
spKt/V time 0	1.63 (0.2)	1.52 (0.3)	0.299
Mean venous BT, cotton gauze, min	10.56 (5.0)	6.1 (2.9)	<0.001
Mean arterial BT, cotton gauze, min	13.06 (7.3)	6.7 (2.9)	<0.001
Median follow-up time, months (IQR)	10.8 (6.7–12.0)	11.9 (7.2–12.0)	0.415

AVF, arteriovenous fistula; BT, bleeding time; WC, WoundClot; Qb, blood pump flow delivered to the dialyzer; spKt/V, single pool Kt/V; IQR, interquartile range.

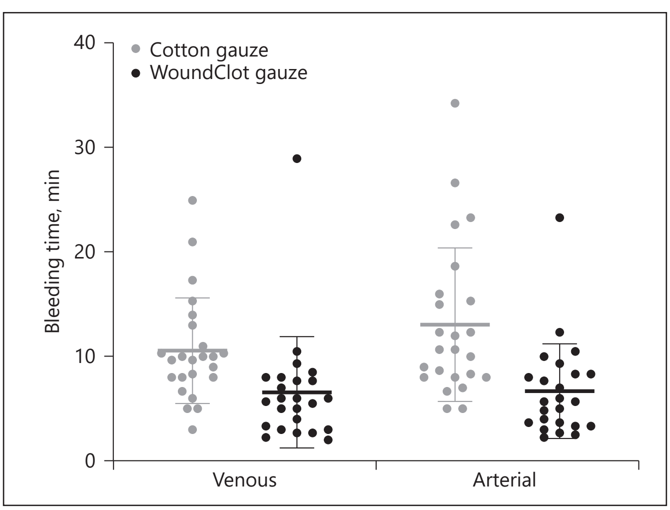

Fig. 2. Venous and arterial BTs (minutes) using WC versus cotton gauze. $p < 0.001$ for both venous and arterial BTs. BT, bleeding time; WC, WoundClot.

completed 12 months of follow-up. Reasons for withdrawal were patient preference (2), side effects (3), AVF thrombosis (2, one of them during an elective surveillance angiography), elective AVF closure due to a bleeding aneurysm (1), death or kidney transplant (2), and transfer to another dialysis unit (3). In the control group, 17/25 completed 12 months of follow-up. Reasons for withdrawal were AVF failure (2), death (4), and kidney transplantation (2).

During the follow-up period, venous and arterial pressures were similar in both groups, as well as Qb. However, spKt/V was significantly higher in the WC group than in control (Table 2). Figure 3 shows hemodialysis parameters before and during the study period for both groups. All parameters revealed a nonsignificant trend.

AVF thrombosis and angiographic intervention rates were similar in both groups (Fig. 4). In the WC group, 12 out of 21 angiographies required intervention (compared to 13 interventional angiographies in 12 months before enrollment), while in the control group intervention was required in 10 out of 13 angiographies (compared to 10 interventions before enrollment).

WC Side Effects

Two patients reported re-bleeding after WC removal at home. One patient had skin lesions that resolved shortly after cessation of WC use.

Table 2. Dialysis parameters in study and control groups during follow-up

Parameter	WC group (N = 24)	Control group (N = 25)	p value
Mean Qb, mL/min	304.1 (7.9)	296.8 (23.9)	0.216
Mean arterial pressure, mm Hg	144.2 (16.3)	145.5 (14.9)	0.773
Mean venous pressure, mm Hg	137.5 (21.1)	131.8 (16.2)	0.337
Mean spKt/V	1.733 (0.33)	1.534 (0.28)	0.047
Thrombosis rate per patient year	0.23 (1.2)	0.34 (1.3)	0.771

Qb, blood pump flow delivered to the dialyzer; spKt/V, single pool Kt/V (delivered dialysis dose); WC, WoundClot.

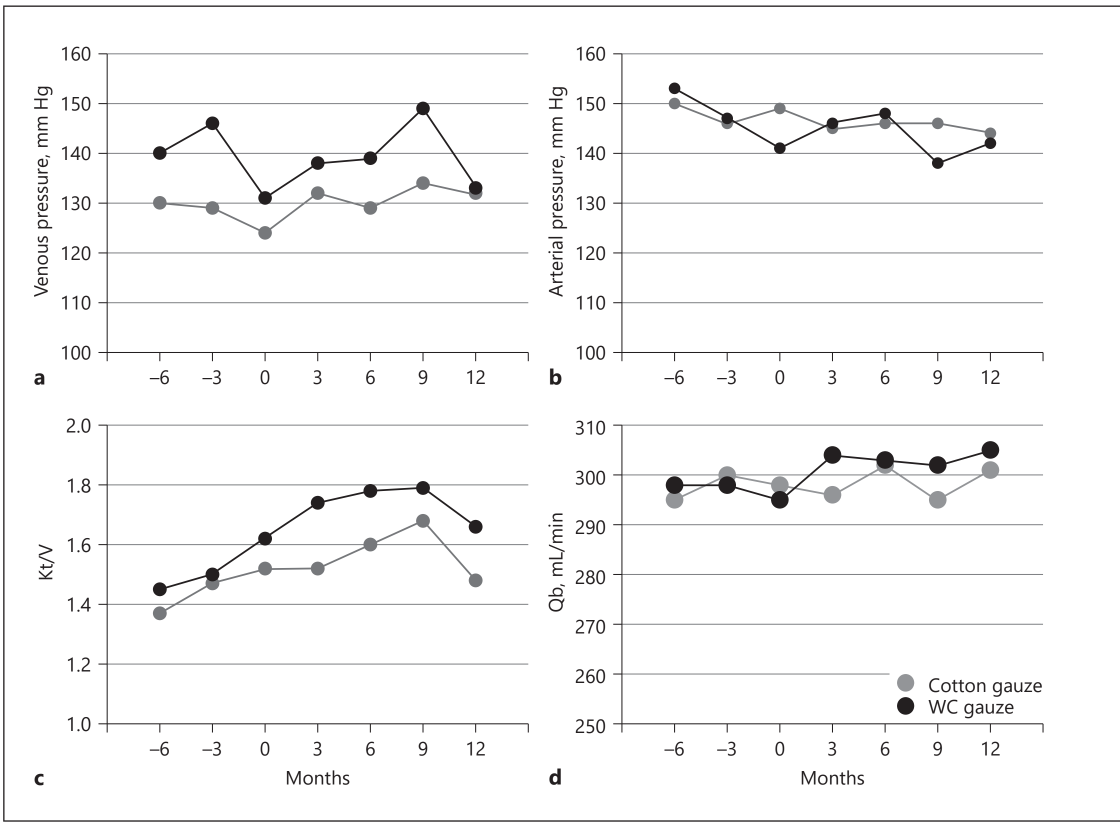

Fig. 3. Change in dialysis parameters according to study groups during follow-up. Time 0 represents study enrollment. Arterial pressure (**a**); venous pressure (**b**); Kt/V (**c**); Qb (**d**). Qb, blood pump flow delivered to the dialyzer; WC, WoundClot.

Discussion

In the current study, we demonstrated that using WC as hemostatic gauze safely decreased the time needed for hemostasis, without evidence of damaging the arteriovenous access. Longer baseline BT was associated with a greater BT reduction. We also observed an improvement in dialysis adequacy (spKt/V) when using WC over the course of 12 months.

Prolonged bleeding after needles withdrawal is one of the clinical indicators of AVF stenosis, necessitating access assessment and intervention [3]. It is associated with anemia and predicts long-term mortality [15, 16]. However, in routine practice, we find ourselves facing patients with prolonged BT in whom there is no culprit that an interventional radiologist can correct. WC application resulted in a significant reduction in time needed for hemostasis. A greater reduction was illustrated in patients with pro-

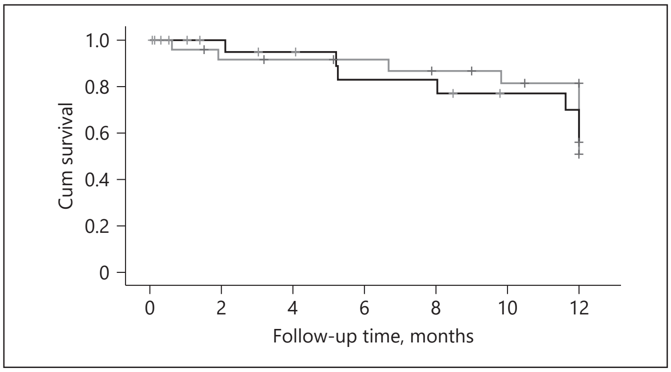

Fig. 4. Time free of AVF thrombosis or angiographic intervention of WC (black) and control (grey) groups. *p* value = 0.435. AVF, arteriovenous fistula; WC, WoundClot.

longed bleeding on baseline. It may therefore serve as an important tool in shortening dialysis time, especially in patients with excessive bleeding. Each twin pack, containing 2 WC gauze for both puncture sites, costs 5 USD. Providing thrice-weekly in-center hemodialysis treatments for patients with ESRD entails a high economic burden, and human resources represent 68% of total costs [17]. Therefore, although WC gauze is more expensive than cotton gauze, it may be translated to lower total costs derived from staff availability, particularly when its use is limited to selected patients. Whereas prolonged bleeding necessitating AVF evaluation is defined above 20 min [18], in clinical practice even 15 min is considered significant and may interrupt the following dialysis shift. Arterial BT above 15 min was in correlation to the 75% percentile in our cohort. Therefore, when considering its advantages versus its cost, we propose to use WC in patients with arterial BT longer than 15 min and venous BT longer than 12.5 min.

Proper needle removal is essential to prevent infiltrations. When reviewing practice guidelines for care of needling sites after decannulating an AVF, there is no recommendation for clotting agents' use [5]. A concern that their application will lead to a clotted skin puncture site while the access may internally bleed may impede their use. Therefore, use of clotting agents was rarely studied in dialysis patients [8, 11, 12]. We demonstrated that long term use of designated hemostatic gauze is safe as it did not result in an increased risk of access loss.

AVF thrombosis results from a triad of endothelial injury, stasis, and hypercoagulability. Among various reasons, the flow through the AVF contributes to thrombosis. Prolonged and enthusiastic compression after needle removal is another contributor to stasis and consequently thrombosis [19, 20]. Our assumption was that reducing the compression time and intensity by using a designated hemostatic gauze would minimize turbulent flow and stasis in the fistula, thereby maintaining the access patent for a longer period. Baseline BT was longer in the WC group and mean venous pressure was higher than in control, both indicators of venous stenosis, predisposing to AVF failure. Hence, although these patients were predisposed to access loss, they exhibited outcomes comparable to the control group, suggesting WC use may result in superior AVF preservation. Additionally, long-term WC use resulted in a better dialysis adequacy, demonstrated by a higher spKt/V. Qb and arterial and venous pressure were similar in both groups, and there was no change in parameters such as dialysis duration and filters type during the study period. Therefore, the finding of a better dialysis adequacy in the WC group may suggest a better AVF preservation although it may also be a sample error.

Fistula thrombosis is a dreadful complication leading to fistula loss. NKF/KDOQI guidelines recommend a center-specific thrombosis rate below 0.25 events per patient year, corresponding with 0.69 events per 1,000 patient days [21]. A systematic review of reported AVF complications observed a median 0.24 thrombotic events rate per 1,000 patient days, lower than the target rate [22]. In our cohort, thrombosis rate was 0.34 events per patient year in control group (corresponding with 0.93 events per 1,000 patient days), compared to 0.23 events per patient year in WC group (0.63 events per 1,000 patient days).

One of the disadvantages of using WC was bleeding after gauze removal at home in 2 participants that led them to withdraw from the study. We overcame this side effect by educating the patients to properly wet the gauze before removing it. In one patient, it caused skin lesions that resolved when he discontinued using WC. We did not observe this side effect in other participants. There were no other side effects and patients were highly satisfied using WC. In fact, all patients in the WC group who completed the study preferred to continue using WC.

The study has several limitations. Being a single center study, it may be subjected to potential bias. Additionally, although AVF vintage was comparable between groups, the groups were not identical regarding AVF location, mean venous pressure before enrollment, and baseline BT. Baseline BT was significantly longer in the WC group, which probably reflects a higher tendency for stenosis in the WC group on baseline. However, using WC significantly reduced BT in this group, a finding that strengthens our conclusion and highlights even further our findings of AVF preservation. Last, a follow-up time of 12 months may not be sufficient to detect dynamics in AVF preservation.

Conclusion

WC hemostatic gauze usage is associated with a significant reduction in time required for hemostasis after AVF needles decannulation and may be associated with better long-term AVF preservation, in particular, in patients with longer baseline BT. We suggest using WC for arterial BT longer than 15 min and for venous BT longer than 12.5 min.

Acknowledgement

We thank Core Scientific Creations for contributing WoundClot gauze throughout the study.

Statement of Ethics

The study was approved by the institute's Ethics Committee. Informed consent was obtained from all individual participants included in the study. No personalized data or identifying information is presented in this work.

Conflict of Interest Statement

All authors declare having no potential conflict of interest. Core Scientific Creations was not involved in study design, patients' enrollment, data acquisition, manuscript drafting, or revision.

Funding Sources

Core Scientific Creations contributed WoundClot gauze throughout the study.

Author Contributions

Kliuk-Ben Bassat O. conceived the study; Romach I., Gorevoy A., Gal-Oz A., and Zubkov A. contributed to study concept and design and acquisition of data; Grupper A. analyzed the data; Kliuk-Ben Bassat O. and Grupper A. contributed to interpretation of data; Kliuk-Ben Bassat O., Romach I., Gorevoy A., Gal-Oz A., and Zubkov A. performed the data collection; Kliuk-Ben Bassat O., Grupper A. and Schwartz D. contributed to drafting of the manuscript. All authors critically reviewed the manuscript and approved it.

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