WoundClot® Hemostatic Gauze as a Post-Procedure Treatment in Hemodialysis Therapy for Renal Failure Patients

A Comparative Study

WOUNDCLOT®
Advanced Bleeding Control™

Core Scientific Creations Ltd.
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Introduction

In patients with kidney failure undergoing hemodialysis therapy, a surgically-created vascular access permits the removal and return of blood, facilitating large amounts of blood flow continuously during the treatment in order shorten blood filtration time per session. This access is typically introduced several weeks or months before hemodialysis begins.

The arteriovenous (AV) fistula and the AV graft are types of vascular access primarily intended for long-term use, with a third type of vascular access—the venous catheter— reserved for short-term use.

Although the utilization of surgical arteriovenous fistulae was first described by Brescia and Cimino in 1966,[1] post-puncture bleeding is still routinely controlled via mechanical compression with either standard or specially-designed hemodialysis bandages.

A crucial factor for both dialysis patients and their caregivers is the optimal control of bleeding following needle removal. Persistent anemia is common in these patients, and the puncture site chronic blood loss is a contributing factor. A significant drop in hemoglobin levels has been demonstrated in excessive post-dialysis puncture site bleeding, estimated by the gauze weigh method.[2,3]

Other issues contributing to difficulties in achieving prompt needle-site hemostasis in dialysis patients are the coagulopathies associated with chronic renal failure, the iatrogenic variety due to heparin therapy, and the usage of oral anticoagulant drugs for treating comorbid conditions.

Two randomized control trials, performed to prevent hemodialysis access graft thrombosis using warfarin or clopidogrel plus aspirin, have demonstrated a significant increase in the risk of bleeding, especially with an increase in bleeding from the cannulation site in the clopidogrel plus aspirin group compared to the placebo group.[4,5]

A lengthy delay in hemostasis can result in a significant impact on the patient's life, particularly by extending time to discharge. Furthermore, the nursing workload of the hemodialysis unit is increased, and continues to rise as the number of patients with delayed hemostasis increases, consuming valuable staff usually dedicated to monitoring patient treatments and likely disturbing the overall dialysis schedule organization of the department.

Thrombosis is another problem that can arise in patients with prolonged post-dialysis bleeding. It is an important cause of loss of function of an AV fistula, and occurs adjacent to a stenosis in the region of an anastomosis or fistula vein.[6]

Excessive compression, especially with the use of medical devices such as straps, tourniquets and rigid clamps, may damage vascular access walls and has been claimed to favor late fistula thrombosis.[7] A number of features can help verify suspected possible stenosis: decreased quality of dialysis, puncture problems, such as prolonged bleeding after AV fistula puncture, pain in the area of the fistula and increased venous pressure.

A further complication for chronic dialysis patients is carpal tunnel syndrome (CTS). Pain, burning, tingling and numbness along the median nerve distribution can be exacerbated by activities placing loads on the tendons which traverse the canal.[8] Mechanical as well as vascular factors contribute to the development of CTS in these patients.[9]

Achieving hemostasis with manual compression at the needle withdrawal site, performed by the nurse, technician or the patient, continues to be the standard of care. The compression offers a mechanical arrest of bleeding until a platelet plug and fibrin mesh form through conventional pathways. However, over the long term, with

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therapy sessions 3-4 times per week for months and years, the continued mechanical stress applied to the shunt often result in CTS for these chronic renal patients. Additionally, the incidence of CTS tends to increase with the duration period of dialysis treatments. Sulowicz et al. described the increase tendency to CTS with relation to the dialysis duration in years. Only 1.6% of patients with less than 10 years of dialysis have CTS. The percentage increase to 42.1% and 66.6% in patients with 10-14 years and 15-19 years dialysis respectively. In this study, all patients treated for 20 years or more suffered from CTS.[10]

WoundClot® Hemostatic Gauze is a novel medical device for the control of bleeding without the need of pressure application. WoundClot® has class IIb CE mark and has been cleared by the FDA as a topical dressing for operative, post-operative, and donor-site bleeding surgical wounds since 2014. Due to its unique technology and capabilities for hemostasis achievement with minimal compression, WoundClot® effectively provides relief from clinical complications and an effective bleed-management solution for both the patient and the dialysis unit.

The objective of the present study was to present the effectiveness of WoundClot®, an innovative advanced bleeding control device, in shortening post-puncture bleeding time at arteriovenous fistulas with minimal placement pressure application compared with the standard of care procedures: use of regular gauze with or without a sponge for manual compression.

Materials and Methods

Eighty hemodialysis adults from OLVG hemodialysis department, Netherlands, were enrolled in a post marketing surveillance study. Among the 80 patients, whose mean age was 69.3 (29-94) years, 44 were males, 36 females, and 27 diabetics. 13 patients were treated with vitamin K antagonist and 28 with thrombocyte aggregation inhibitors. The average value of blood flow rate was 1141.7 mL/min and thrombocytes level of 220.8 (x109) with standard deviation of 501 and 64.5 respectively. 80% of the patients had underarm shunts; the remaining 20% had overarm shunts. The average shunt age is 4.9 years with 4.4 standard deviation value. The eldest shunt is 26 years old as reported in Table I.

STUDY OVERVIEW		
Baseline Data	Total value (n=80)	Percentage (%)
Gender (Male/Female) (n,%)	44/36	55/45
Age (years)	69.3 ±14.4 (29-94)	
Age>50 years (yr.) (n,%)	60	75
Dialysis since (yr.)	5.7±5.3 (0-26)	
Diabetes (n,%)	27	34
Vitamin K antagonist (n,%)	13	16
Thrombocytes aggregation inhibitors (n,%)	28	35
Blood flow (mL/min)	1141.7±501 (315-3055)	
Thrombocytes (x109/L)	220.8±64.5 (50-471)	
Shunt location (onderarm/bovenarm) (n,%)	64/16	80/20
Shunt age (yr.)	4.9±4.4 (0-26)	

Table I – Study Overview

1266 puncture sites were recorded – 644 cases were arterial pressure punctures and 622 were under venous pressure. Three methods of hemostatic treatment were evaluated: cotton gauze, cotton gauze with sponge used under compression versus WoundClot®, which was applied externally without pressure application.

The required duration in order to achieve hemostasis was monitored for each of the treatment methods, i.e. gauze, gauze with sponge, and WoundClot®, for either arterial pressure or venous pressure bleeding.

Results and Discussion

Upon operative dialysis treatment, the needle is withdrawn and the puncture site is exposed to arterial or venous pressure. Gauze is the most common method used on the puncture area while the patient, nurse or technician applies manual force at the bleeding site. The sponge, in addition to the gauze, helps to exert more local pressure onto the puncture due to its tendency to expand. WoundClot® has a gauze-like appearance, yet it applies with no pressure onto the open blood vessel. When WoundClot® is exposed to blood, it transforms into a blood-absorbing gel state and promotes coagulation.

Tables II and III summarize the duration for each type of treatment required to achieve hemostasis under arterial or venous flow respectively. Each of the study groups included 211 cases on average (min. of 203 and max. of 220). Each case was monitored for the time required to achieve hemostasis in 5 minutes intervals up to 15 minutes. All cases above 15 minutes counted together.

ARTERIAL PUNCTURE PRESSURE FLOW				
Time to Hemostasis [min]	Gauze	Gauze + Sponge	WoundClot®	TOTAL
5	93 (44%)	119 (54%)	163 (77%)	375
10	70 (33%)	70 (32%)	45 (21%)	185
15	31 (15%)	25 (11%)	3 (1%)	59
>15	17 (8%)	6 (3%)	2 (1%)	25
Total	211	220	213	644

Table II – Distribution of the arterial puncture treatment with respect to the treatment type and the duration to bleeding cessation.

The use of gauze is the most common control method for post-treatment bleeding in the hemodialysis patient. Pressure application onto the gauze resulted in hemostasis in 44% of the cases within the first 5 minutes of treatment. The addition of a sponge resulted in an increase to 54% of the cases within this time frame (Table II).

Achieving hemostasis in puncture under arterial flow is considered be more difficult due to the elevated pressure created in the flow change from the fistula to the artery.

Under venous pressure, 55% and 61% of the cases managed to achieve hemostasis within 5 minutes utilizing gauze or gauze with sponge respectively (Table III).

WoundClot® hemostatic gauze was applied without exerting pressure onto the puncture site, with resultant hemostasis in 77% of the tested arterial cases and 83% of the venous cases within 5 minutes of application. Within 10 minutes, 98% of all cases had managed to achieved hemostasis with WoundClot®, either arterial or venous.

Between 12-19% of the cases required greater than 10 minutes in order to achieve bleeding control with the other two common treatments.

VENOUS PUNCTURE PRESSURE FLOW				
Time to Hemostasis [min]	Gauze	Gauze + Sponge	WoundClot®	TOTAL
5	115 (55%)	123 (60%)	175 (83%)	413
10	64 (31%)	59 (29%)	31 (15%)	154
15	24 (11%)	14 (7%)	2 (1%)	40
>15	6 (3%)	7 (4%)	2 (1%)	15
Total	209	203	210	622

Table III – Distribution of the venous puncture treatment with respect to the treatment type and the duration to cessation of bleeding.

WoundClot® managed to save much time and effort for the patients and the treatment center. For the 423 cases, it required a cumulative total of 3573 minutes to achieve hemostasis using medical gauze treatment and 3293 minutes by adding the sponge.

WoundClot® managed to stop the bleeding of the 423 cases within only 2589 minutes, which equals a saving at least 11.7-16.4 hours of treatment.

Conclusions

WoundClot® was compared to the current standard of care treatment in post-operative hemodialysis procedures for renal failure patients using medical gauze with or without a sponge. WoundClot® demonstrated better performance capabilities in stopping hemorrhage in a shorter time and with much less patient discomfort, with respect to the common treatment methods. The time saving can be extended to several days in years long treatment for the patient as well as for the hemodialysis unit. The effect of the non-compression application of WoundClot® should be evaluated in a long-term study, particularly on the incidence of carpal tunnel syndrome in WoundClot® hemodialysis patients vs. those using the gauze or gauze/sponge compression methods. However, the influence and long-term effects of manual compression on a blood vessel are well documented, as was reviewed briefly in the introduction section.

References

01. Brescia MJ,Cimino JE,Appel K,Hurwich BJ. Chronic hemodialysis using venipuncture and a surgically created arteriovenous fistula. N Engl J Med 1966;275:1089-92.

02. Awobusuyi JO,Mapayi FA,Adedolapo A. Blood loss during vascular access cannulation: quantification using the weighed gauze and drape method. Hemodial Int 2008;12:90-3.

03. Lin CL,Chen HY,Huang SC,Hsu SP,Pai MF,Peng YS,Chiu YL. Increased blood loss from access cannulation site during hemodialysis is associated with anemia and arteriovenous graft use. On line version of record published since the 27 March 2013, before inclusion in an issue of Ther Apher Dial.

04. Crowther MA,Clase CM,Margetts PJ. Low-intensity warfarin is ineffective for the prevention of PTFE graft failure in patients on hemodialysis: a randomized controlled trial. J Am Soc Nephrol 2002;13:2331-7.

05. Kaufman JS,O'Connor TZ,Zhang JH. Veterans Affairs cooperative study group on hemodialysis access graft thrombosis. J Am Soc Nephrol 2003;14:2313-21.

06. Stolic R. Most important chronic complications of arteriovenous fistulas for hemodialysis. Med Princ Pract 2013;22:220-8.

07. Fan PY, Schwab SJ. Vascular access: concepts for the 1990s. J Am Soc Nephrol 1992;3:1-11.

08. Herbert R, Gerr F, Dropkin J. Clinical evaluation and management of work-related carpal tunnel syndrome. Am J Indust Med 37:62-74.

09. Naito M, Ogata K, Goya T. Carpal tunnel syndrome in chronic renal dialysis patients. J Hand Surg 12-B:3;366-74.

10. Kopeć J, Gądek A, Drożdż M, Miśkowiec K, Dutka J, Sydor A, Chowaniec E, Sułowicz W. Carpal tunnel syndrome in hemodialysis patients as a dialysis-related amyloidosis manifestation--incidence, risk factors and results of surgical treatment. Med Sci Monit 2011;17(9):CR505–9. Published online 2011 Sep 1. doi: 10.12659/MSM.881937.

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