Implementation of Viscoelastic Hemostatic Assay-guided Therapy to Evaluate and Manage Trauma-related Bleeding: A Pilot Study from a Level 1 Trauma Center in Bangkok, Thailand

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ABSTRACT

Objective: To evaluate the effectiveness of viscoelastic hemostatic assay (VHA)-guided therapy for assessing and managing trauma-related bleeding using a multidisciplinary team approach at a level 1 trauma center.

Materials and Methods: This retrospective pilot study included trauma-related hemorrhagic patients who underwent rotational thromboelastometry (ROTEM) during September 2019-May 2020. ROTEM trace results were compared with those of conventional coagulation tests (CCT).

Results: Thirteen patients (median age: 29.1 years; male: 76.92%) were included. The median (range) days of ventilator support, ICU length of stay, and hospital length of stay was 4 [0-65], 5 [1-65], and 6 [1-83], respectively. ROTEM-guided therapy was applied 26 times, and was repeated in 7 cases. Of those, four cases were repeated to correct coagulopathy. The median time-to-confirmed hemostasis for ROTEM was substantially shorter than for CCT (92 minutes [70-110] vs. 287 minutes [204-354], respectively). The coagulation results from 26 ROTEM tests were also compared between those requiring and not requiring a massive transfusion protocol (MTP). MTP with ROTEM-guided therapy was activated in 6/13 cases. Following the resuscitation endpoints in traumatic shock, four of those had their median serum lactate levels decreased from 10.9 d/L (2.1-16.8) to 3.9 d/L (1.7-17.7). ROTEM traces detected cases with low fibrinogen that only required cryoprecipitate transfusion, and red blood cell and fresh frozen plasma use was less in ROTEM than in conventional MTP.

Conclusion: VHA-guided therapy was shown to effectively facilitate goal-directed hemostatic resuscitation and efficient blood product use during resuscitation, definitive treatment, and postoperative intensive care.

Keywords: Implementation; viscoelastic hemostatic assay-guided therapy; trauma-related bleeding; rotational thromboelastometry; trauma-induced coagulopathy (Siriraj Med J 2022; 74: 294-304)

INTRODUCTION

Preventable death due to exsanguination is a leading cause of death in trauma patients. This means that improvements in patient care can improve patient survival.[1] Consistent with this premise, advancements in damage control resuscitation (DCR), including improvements in methods for assessing and managing trauma-related bleeding, have been adopted and implemented with very

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favorable results.[2,3] The DCR concept comprises three aspects, including balanced resuscitation, hemostatic resuscitation, and bleeding control. Hemostatic resuscitation requires advanced understanding of trauma-induced coagulopathy (TIC) that is guided by a goal-directed resuscitation approach.[4-8] This is essentially important because several previous studies reported TIC to be associated with 4- to 6-fold higher mortality.[4,9-13]

Another important death-related factor in hemorrhaging patients is time, including time to hemostasis, time-to-treat, and time to activation of a massive transfusion protocol (MTP).[14] Therefore, a rapid and reliable method is needed that can detect and correct TIC during efforts to achieve surgical control at the bleeding site.[10,15] In a trauma setting, conventional coagulation tests (CCT), such as prothrombin time (PT), activated partial thromboplastin time (APTT), international normalized ratio (INR), platelet count, and fibrinogen level, have limited ability to evaluate for TIC due to their ability to accurately reflect the real physiologic dynamic changes that occur during the coagulation process.[3,16] Moreover, these tests consume too much of the 'golden hour' that is so crucial to patient survival in a trauma setting.[17]

To remedy these treatment-related concerns, technological innovations for detecting coagulopathy were introduced to improve advanced resuscitation. Viscoelastic hemostatic assay (VHA), such as rotational thromboelastometry (ROTEM) (TEM Innovations GmbH, Munich, Germany) and thromboelastography (TEG) (Haemonetics Corp, Niles, IN, USA), is a tool that has the ability to detect and report global hemostasis, including all stages of the coagulation cascade from initiation of clot formation to clot lysis.[3,18] Several clinical trials, reported significant advantages of VHA-guided MTP in trauma patients relative to both decreased mortality and reduced use of blood components during resuscitation.[19-23]

The VHA technique was first introduced by Hellmut Hartert in 1948.[24] During the early period, VHA was used during liver transplantation and cardiac surgery.[3,25-27] It was first applied in trauma care in 1997 to study its ability to detect and improve the management of TIC.[28] VHA-guided MTP was then evaluated their superior benefit than standard MTP for use in trauma patients in 2013.[29] The VHA instrument that is available at our center is a ROTEM sigma machine (TEM Innovations GmbH, Munich, Germany), so this study evaluated the effectiveness of this device compared to conventional MTP. This cartridge-based device delivers dynamic run-through coagulation information in trace, including clot initiation, clot propagation, clot firmness, and clot lysis.

Even though the management of trauma patients in Thailand continues to improve and evolve, certain factors, such as TIC, continue to delay treatment, which reduces the likelihood of a favorable outcome. Moreover, genetic variations may exert variable influence on the pathophysiology of TIC, and data specific to this condition in Thai population remains scarce. Accordingly, the aim of this pilot study was to evaluate the effectiveness of VHA-guided therapy for assessing and managing trauma-related bleeding using a multidisciplinary team approach at our level 1 trauma center, which is a major university-based medical center.

MATERIALS AND METHODS

Study design and patients

This retrospective pilot study included trauma-related hemorrhagic patients who underwent ROTEM testing during September 2019 to May 2020. Patients with trauma-related bleeding caused by penetrating injury or blunt force injury, and patients who required blood transfusion were eligible for inclusion. Our institution's massive transfusion protocol with rotational thrombolelastometry (ROTEM)-guided coagulation management algorithm (Fig 1) was designed and implemented by hematologists and blood bank specialists. ROTEM trace results were compared with those of CCT and interpreted by trained personnel in a multidisciplinary team that included the trauma surgeons, hematologists, and the transfusion team. The primary outcome was 24-hour survival. The secondary outcomes were the number of ventilator days, the number of hospital days, the number of intensive care days, and clinical progression until hospital discharge. Time-to-confirmed hemostasis in this study was defined as the duration from the drawing of the initial blood sample to be sent to the ROTEM machine and the laboratory with subsequent correction of any reported coagulopathy to the time point when repeat results reported the achievement of hemostasis after receiving guided-therapy. The protocol for this study was approved by our center's institutional review board, and written informed consent was not obtained due to our study's anonymous retrospective design.

Brief overview of the use and function of the ROTEM sigma VHA

The ROTEM sigma system is a reagent cartridge-based fully automated system. Blood is added into a cup that is fixed, and a pin is moved by a counterspring (Fig 2). The pin is stabilized by a ball bearing avoid artifacts caused by shock and vibration, which facilitates mobile use of the device. With increasing viscoelastic forces due

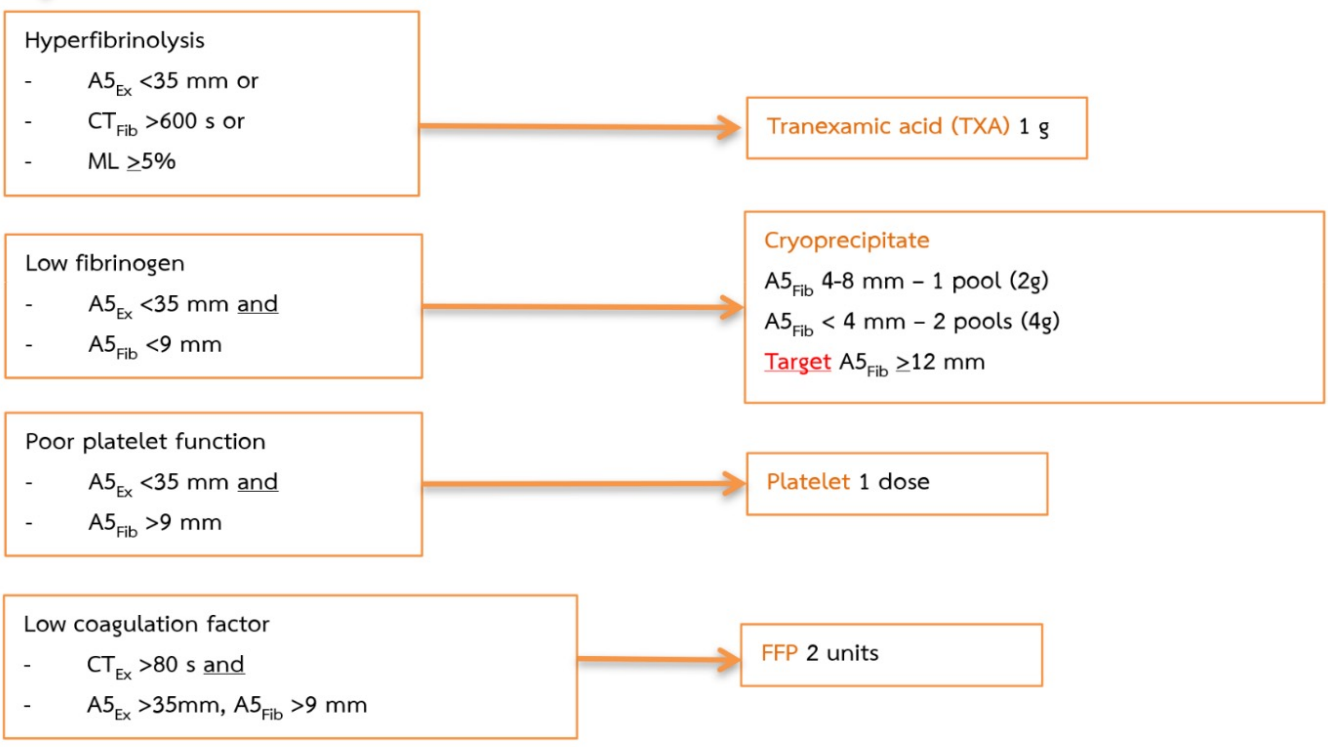

Fig 1. Siriraj massive transfusion protocol with rotational thrombolelastometry (ROTEM)-guided coagulation management algorithm. $A5_{EX}$, clot amplitude 5 min after CT on EXTEM assay; CT_{FIB}, clotting time (CT) on FIBTEM assay; ML, maximum lysis; $A5_{FIB}$, clot amplitude 5 min after CT on FIBTEM assay; CT_{EX}, CT on EXTEM assay; FFP, fresh frozen plasma.

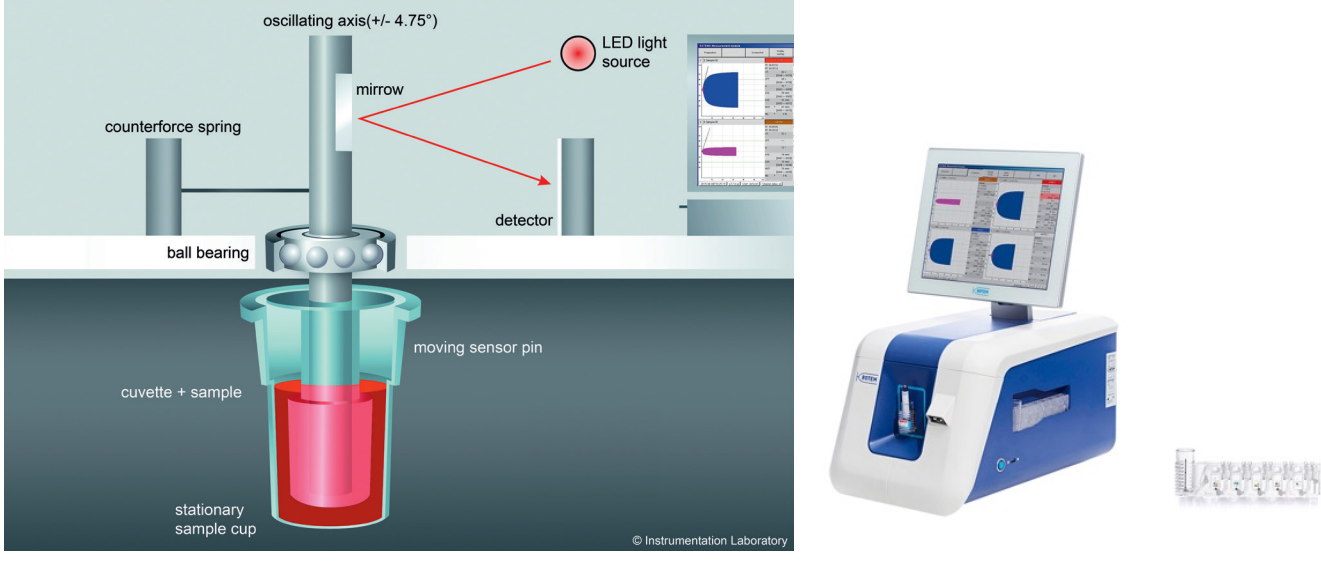

Fig 2. Operational principle of rotational thromboelastometry (ROTEM). (Left image) The ROTEM sigma system is a reagent cartridge-based fully automated system. Blood that is pre-warmed to 37°C is added into a cup that is fixed, and a pin is moved by a counterspring. The pin is stabilized by a ball bearing avoid artifacts caused by shock and vibration, which facilitates mobile use of the device. With increasing viscoelastic forces due to fibrin polymerization and fibrin-platelet interaction, the movement of the pin is reduced, which is detected contact-free by an LED light-mirror-optical detector system. The ROTEM software transforms this signal to a graphical result/signature waveform called a temogram. (Right image) The ROTEM sigma machine. (Figure provided courtesy of TEM Innovations GmbH, Munich, Germany)

to fibrin polymerization and fibrin-platelet interaction, the movement of the pin is reduced, which is detected contact-free by an LED light-mirror-optical detector system. The ROTEM software transforms this signal to a graphical result/signature waveform called a temogram (Fig 3). Clot initiation, propagation, strength, and lysis are displayed in time tracing patterns. The essential initial results for correcting TIC are fibrinolysis, fibrinogen level, platelet quantity, and platelet function because these factors influence initiation and propagation of blood clotting. ROTEM output data can be reliable interpreted within 5 minutes after clotting time (CT) (A5 = amplitude of clot firmness 5 minutes after CT) for fibrinogen polymerization and clot formation. These findings help to determine the stage of the dynamic process of coagulopathy, and facilitate correction via goal-directed therapy.[23,30-32]

Statistical analysis

Descriptive statistics were used to summarize patient demographic and clinical characteristics. Microsoft Excel® spreadsheet and data analysis software was used to manage and analyze the data. The data are presented as number and percentage for categorical variables, and as median and range for continuous data.

RESULTS

Patient characteristics

A total of 13 patients with trauma-related bleeding were included. The median age of patients was 29.1 years (range: 15-75), most were men (10/13, 76.92%), and most had sustained blunt force trauma (11/13, 84.6%). One of the two patients with a penetrating injury was referred to our center with cardiac tamponade and clinically compensated shock at 4 hours after the injury. Three

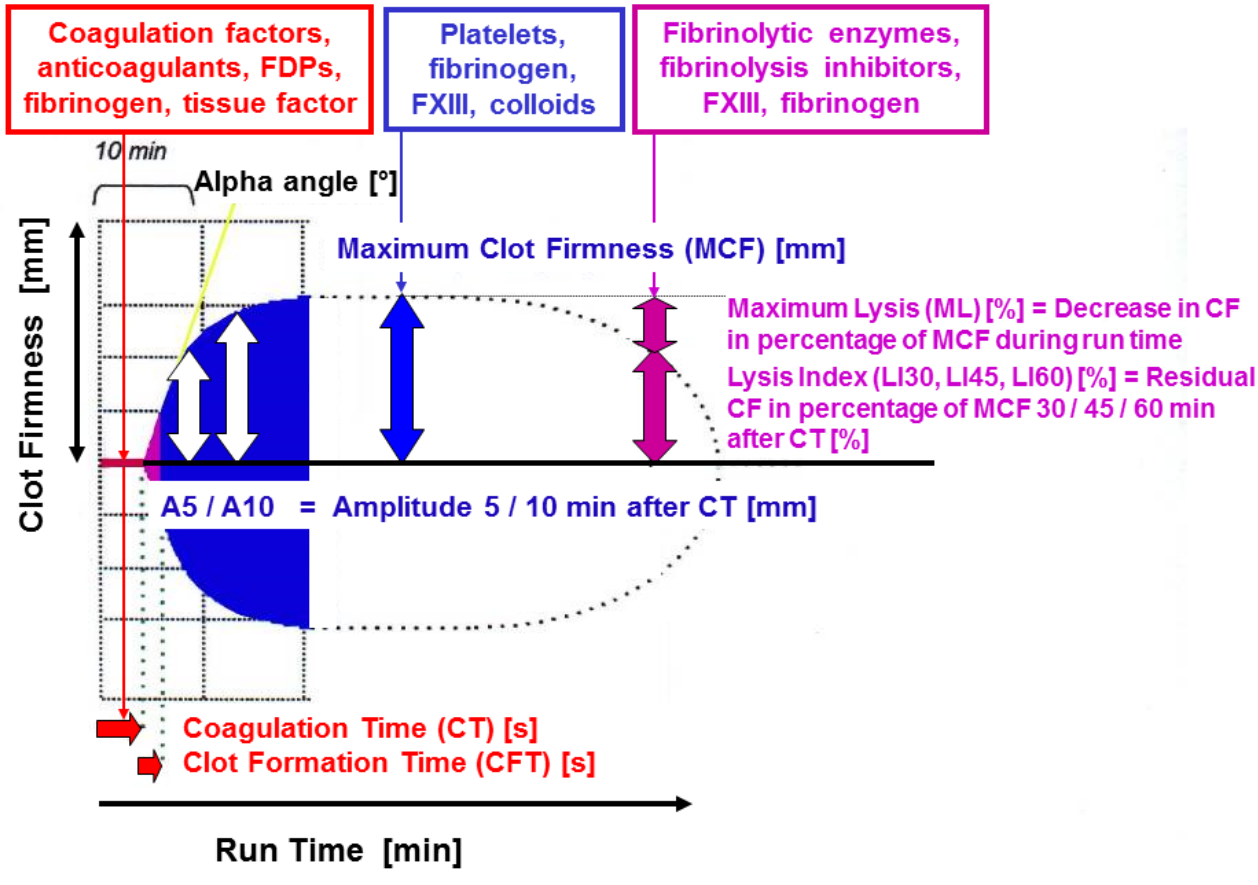

Fig 3. ROTEM traces 4 main clot parameters. **1. Clot initiation**: Coagulation time (CT) is defined as the time from initiation of clot formation to fibrin aggregation **2. Clot propagation:** Clot formation time (CFT) and alpha-angle are used to determine the speed of growth in clot firmness due to fibrin polymerization and fibrin-platelet interaction. **3. Clot strength:** Amplitude (A) 5 minutes (A5) and 10 minutes (A10) after CT and maximal clot firmness (MCF) result from fibrinogen and platelet contribution. We normally used the amplitude at 5 minutes after CT (A5) fibrinogen trace (ROTEM – FIBTEM) as POC for early correction of fibrinogen concentration during resuscitation. [27-29] **4. Clot lysis:** Maximal lysis (ML) and clot lysis index at 30 and 60 minutes after CT (LI30 and LI60, respectively) are related to fibrinolysis. If hyperfibrinolysis is present, antifibrinolytic agents, such as tranexamic acid (TXA) will be administered to correct this pathology that is commonly associated with TIC. [7, 13, 15] (Figure provided courtesy of Dr. Klaus Görlinger, Munich, Germany)

patients were on heparinization, antiplatelet therapy or anticoagulants for post-injury related conditions. Among all cases, the median Injury Severity Score (ISS) was 26 (range: 10-43), and the Revised Trauma Score (RTS) was 7.84 (range: 0-7.84).

Two patients were diagnosed with severe traumatic brain injury (TBI), which was defined as a Glasgow Coma Scale (GCS) score <8, and a head Abbreviated Injury Scale (AIS) score >2. Among all patients, the median systolic blood pressure (SBP) was 118 mmHg (range: 0-154), and the heart rate (HR) was 110 beats per minute (range: 0-158). Patient body temperature data was not recorded in all cases, so that information is not presented here. During critical stage assessment, the median base deficit (BD) was -8.2 mEq/L (range: -16 to 0), and the serum lactate level was 6.5 d/L (range: 1.1-16.8). After VHA-guided therapy, seven patients underwent immediate further surgery in the operating room, and the remaining patients were transferred to the intensive care unit (ICU) (Table 1). In our study group, five cases were transported directly to our trauma center (not transferred from another hospital), and tranexamic acid (TXA) was administrated after drawing the blood sample.

Twelve of 13 patients survived to at least 24 hours after treatment for a survival rate of 92.3%. The one patient who did not survive had sustained an unsurvivable TBI, and also had preexisting terminal cancer. The median number of days of ventilatory support, ICU admission, and length of hospital stay was 4 (range: 0-65), 5 (range: 1-65), and 6 (range: 1-83), respectively.

ROTEM-guided therapy

A total of 26 ROTEM tests were performed among the 13 study participants. The indications for ROTEM activation were, as follows: (1) MTP activation (13 tests in 6 patients), (2) evaluation of clinical correlation (4 tests in 3 patients), and (3) evaluation of efforts to achieve hemostasis (9 tests in 4 patients). These ROTEM tests were performed during hemorrhagic shock in 12 patients. The locations where the decision was made to employ ROTEM-guided therapy were, as follows: resuscitation room (6 cases), ICU (13 cases), and the perioperative care unit (7 cases). Due to the limited number of cartridges available at the beginning of implementation, ROTEM testing was applied more than once in only 7 cases. Of those, four cases had repeat ROTEM testing immediately after blood component transfusion to correct coagulopathy.

TABLE 1. Patient characteristics on admission or during initiation of viscoelastic hemostatic assay (VHA)-guided therapy and patient outcomes (N=13).

Parameters	n (%) or median [range]
Age (years)	29.1 [15-75]
Gender (male)	10 (76.92%)
Type of injury: Blunt force trauma	11 (84.62%)
Severe traumatic brain injury (cases)	2 (15.38%)
Injury Severity Score (ISS)	26 [10-43]
Revised Trauma Score (RTS)	7.84 [0-7.84]
Systolic blood pressure (mmHg)	118 [0-154]
Heart rate (beats per minute)	110 [0-158]
Base deficit (mEq/L)	-8.2 [-16 to 0]
Serum lactate (d/L)	6.5 [1.1-16.8]
Survival rate after 24-hour	12 (92.31%)
Intensive care unit outcomes	
Duration of ventilatory support (days)	4 [0-65]
Intensive care unit admission (days)	5 [1-65]
Length of hospital stay (days)	6 [1-83]

The median time-to-confirmed hemostasis was markedly shorter in the ROTEM group (92 minutes; range: 70-110) than in the CCT group (287 minutes; range: 204-354).

ROTEM trace results and conventional coagulation test results compared between the massive transfusion protocol (MTP) and non-MTP groups are shown in Table 2. An initial study in three cases found normal coagulation status. One case had no further resuscitation plan after a family discussion due to non-survivable TBI with pre-coexisting terminal cancer. The other two cases were reassessed in the ICU after resuscitation, and both were found to have achieved hemostasis. Four cases that were treated according to the ROTEM-guided coagulation management algorithm, demonstrated good response to resuscitation with a median decrease in serum lactate level from 10.9 d/L (range: 2.1-16.8) to 3.9 d/L (range: 1.7-17.7).

Blood and blood component utilization

MTP with ROTEM-guided coagulation management algorithm was activated in 6 of 13 cases (Table 2). Our institutional conventional MTP comprises 3 different sets of blood and blood components. The first set, which is transfused into patients with an unknown ABO blood group, consists of 4 units of group 'O' RBCs, and two units of group "AB" fresh frozen plasma (FFP). This set was transfused into five patients. The second set consists of 4 units of RBCs, 4 units of FFP, and 1 adult dose of platelets. The third set consists of 4 units of RBCs, 4 units of FFP, and 12 units of cryoprecipitate. There were 4 patients who required set 2, and only 1 patient received set 3. The blood package was no longer used after ROTEM results were reported.

This study analyzed the blood and blood components used within 6 hours pre- and post-ROTEM application by categorizing their use into following 3 phases: (1) pre-ROTEM, which was defined as 6 to 1 hour before testing; (2) peri-ROTEM, which was defined as 1 hour before testing to 3 hours after testing; and, (3) post-ROTEM, which was defined as 3 hours to 6 hours after testing. This description of the distribution of blood and blood products makes clearer the benefit of ROTEM testing data and the types of blood products needed during different phases of treatment (Fig 4).

TABLE 2. Indications for rotational thromboelastometry (ROTEM) activation, and ROTEM trace results and conventional coagulation test results compared between the massive transfusion protocol (MTP) and non-MTP groups.

Indications for ROTEM activation	N=13 cases, 26 tests	
Massive transfusion protocol, n	6	
Clinical correlation, n	3	
Evaluation of efforts to achieve hemostasis, n	4	
	MTP (n=6, 13 tests)	**Non-MTP (n=7, 13 tests)**
ROTEM trace results		
Low fibrinogen	6	1
Low coagulation factor	3	4
Poor platelet	1	1
Hyperfibrinolysis	0	1
Normal study	0	3
Conventional coagulation tests when ROTEM was run (data presented as median)		
Fibrinogen level (mg/dL)	186.13	229.64
Platelets (/μL)	171,667	162,667
Prothrombin time (seconds)	16.02	15.08
Activated partial thromboplastin time (seconds)	35.05	28.94

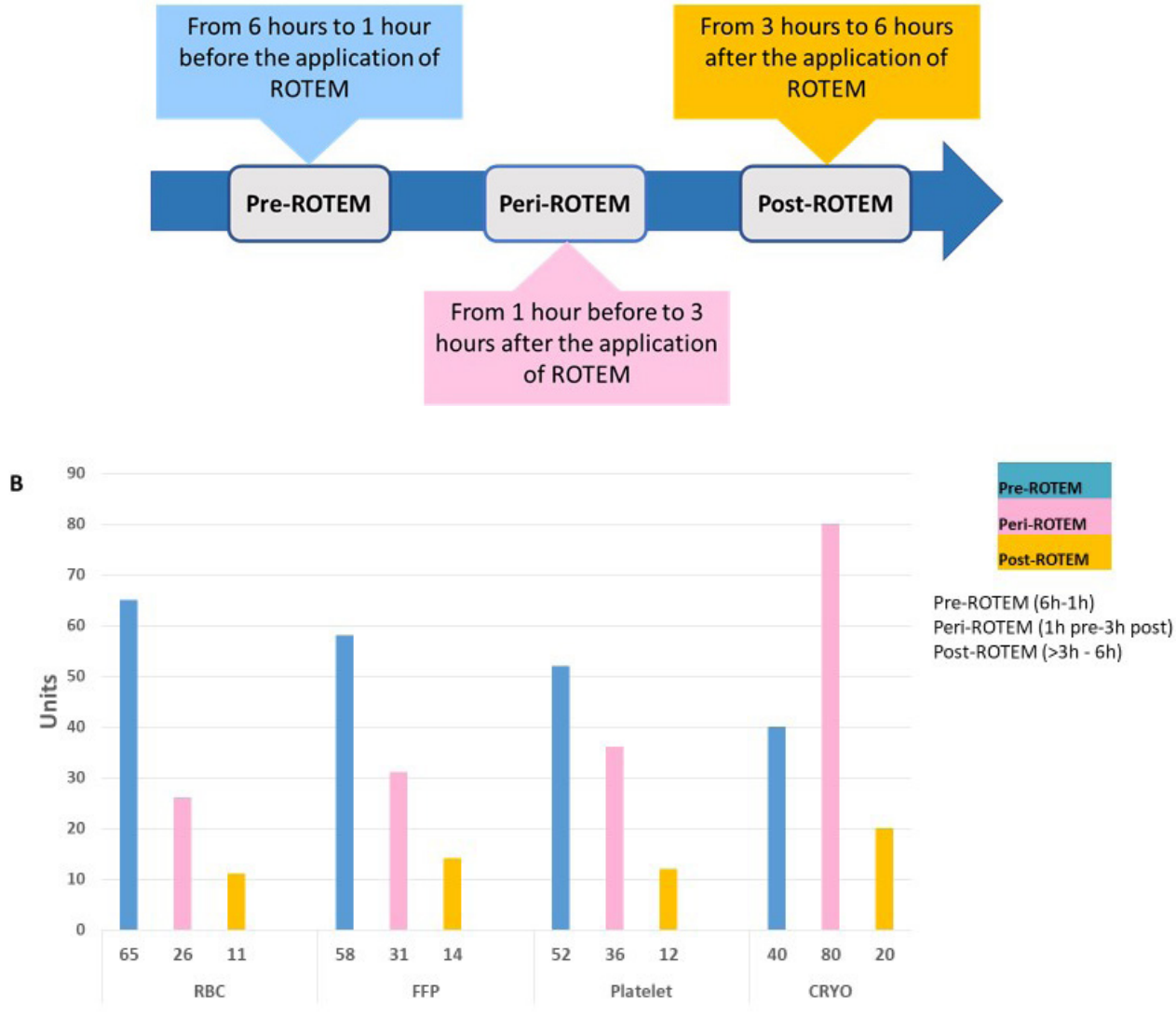

Fig 4. Flow diagram defining the time of evaluation for the before, during, and after phases of rotational thromboelastometry (ROTEM) application (A). Units of blood products given during the before, during, and after phases of ROTEM application among the 13 study patients (B).
Abbreviations: RBC; red blood cell product, FFP; fresh frozen plasma, CRYO; cryoprecipitate

The total number of units of transfused blood products among the 13 patients in this study were, as follows: RBCs 102 units, FFP 103 units, platelets 100 units (25 adult doses), and cryoprecipitate 140 units. A patient who had multiple active conditions, including reoperation for laparotomy and thoracotomy with extracorporeal membrane oxygenation (ECMO) support received a blood transfusion during ROTEM testing that included the following products: RBC 12 units, FFP 14 units, platelet 2 doses, and cryoprecipitate 54 units. Of the four products, RBCs, FFP, and platelets were mainly used during the pre-ROTEM phase for a phase total of 65, 58, and 52 units, respectively. The ratio of MT during the resuscitation phase before applying ROTEM was 1 to 0.9 to 1.12 for FFP, platelets, and RBCs. Cryoprecipitate was given either as part of the 3rd blood product combination MTP set or as needed according to the result of ROTEM testing. The number of units of cryoprecipitate used in the pre-, peri-, and post-ROTEM phases was 40, 80, and 20 units, respectively.

To non-statistically evaluate the benefit of ROTEM-guided therapy as a point-of-care testing (POCT) modality, we evaluated 6 cases that were included in this study that met the activation criteria for conventional MTP. That analysis revealed that we administered 24 units of RBCs and 20 units of FFP less than the number called for using the conventional MTP protocol.

DISCUSSION

Trauma resuscitation in an actively hemorrhagic patient is a challenge, especially in patients with a non-compressible torso hemorrhage (NCTH) because these patients require more time to stabilize, and surgical interventions are commonly needed to control the bleeding. Improved understanding of the pathophysiology of TIC has improved DCR in trauma patients.[2,4-6,9,10,19] The incidence of TIC was reported to range from 25% to 35% in civilian and military trauma-related bleeding patients.[4,9]

Prior to the introduction of VHA-guided therapy, CCT was used for coagulation-guided therapy in patients with TIC; however, these tests are time-consuming and they are limited in their ability to dynamically assess the coagulation cascade.[3,19,28] VHA as a POCT for coagulation assessment was implemented in many countries to overcome these limitations.[5,6,8,10,33,34] Even though there is limited evidence and varied outcomes among studies, several studies reported the benefit of VHA-guided therapy for the management of bleeding in trauma, liver transplantation, cardiothoracic surgery, and obstetric patients.[3,5,8,22,34-36]

Moreover, this technology continues to rapidly evolve and improve. From recent study, the fastest reliable result for the FIBTEM assay was the 5-minute result (the A5 FIBTEM).[30-32]

The benefits of VHA are essential in trauma care, especially during resuscitation and the critical phase, which is associated with many factors that can cause or contribute to TIC. Previous studies that investigated the efficacy of VHA applied in trauma care reported a decrease in mortality from as high as 36% to as low as 17%.[5,18,19,22,23] In the present study, the median ISS among our study subjects was 26, and our 24-hour survival rate was 92.3%. The only death occurred in a patient with non-survivable TBI with coexisting terminal cancer.

TIC incidence

ROTEM analysis of 6 unstable trauma patients upon arrival revealed TIC in all patients (incidence 100%). When comparing between MTP and non-MTP patients, we found a far higher number of patients with low fibrinogen in the MTP group (85.7% vs. 16.67%, respectively), which was defined as a fibrinogen level <200 mg/dL or A5 FIBTEM <9 mm. (Table 2). These results are consistent with the known mechanisms of TIC, especially the importance of fibrinogen concentration, which strongly influences the initial phase of the coagulation cascade. Base on the principle of early fibrinogen and coagulation factor deficiency in TIC, the evolution of VHA as a POCT was developed to deliver faster results so that the speed of care could be accelerated in this vulnerable patient population. These advantages encourage hospitals to provide both VHA-guided therapy and specific coagulation therapy (fibrinogen concentration, prothrombin complex concentrate) to improve patient care to the level currently being provided in several countries around the world.[3,5,8,20,21,37,38]

Interestingly, no patients in the MTP group showed hyperfibrinolysis as a result of ROTEM testing. However, it is possible that cases that were transferred to our trauma center from other hospitals could have received TXA prior to transfer. At present, the CRASH-2 trial and many clinical practice guidelines recommend administration of tranexamic acid (TXA), which is an antifibrinolytic drug, for patients with trauma-related bleeding to correct hyperfibrinolysis in TIC.[4,33,39,40] Our pilot data suggests this as a potentially important topic of further study because TXA administration may help to improve trauma care in developing countries.

ROTEM-related clinical considerations

In addition to the benefits of faster point-of-care testing to determine hemodynamic status, bleeding status, and lactate acidosis or base excess, ROTEM-guided test data also helped us differentiate between medically controllable bleeding and bleeding that required surgical intervention. Two cases that required extensive resuscitation had their treatment plan changed to surgical intervention after our review of ROTEM test results. One patient in our cohort presented with clinically profound shock and was unresponsiveness to resuscitation. Hemorrhagic shock was excluded in that patient after negative result from evaluation by both clinical examination and full-body computed tomography scan. The ROTEM result was also normal, so further investigation revealed a non-survivable TBI with neurogenic shock and no additional strategies for correcting the patient's condition. We also used VHA to evaluate the coagulation status of 3 patients who were on heparinization, antiplatelet therapy or anticoagulants for post-injury related conditions. The first case was on ECMO support for post-traumatic acute respiratory distress syndrome (ARDS), the second had post-vascular bypass with prosthetic graft, and the third was on anticoagulant to treat thrombosis.

Transfusion of blood components

Blood transfusion is one of the mainstay treatments for hemorrhagic trauma patients, especially in those requiring massive transfusion (MT). There are several definitions of MT. MT was defined as a requirement for

more than 4 RBC units or death within the first hour after injury.[5,6] In this study, there were 6 patients who received MT therapy.

Early initiation of blood and blood component transfusion combined with close monitoring of hemostasis is needed to correct TIC. In this study, we evaluated the use of blood and blood components before, during, and after ROTEM measurement. A target MTP ratio of 1:1:1 or 1:1:2 is achieved during the resuscitation process before applying ROTEM. We observed that the use of RBCs, FFP, and platelets was decreased during and after ROTEM testing compared to the pre-ROTEM phase. A previous randomized controlled trial also reported less use of plasma and platelets, but not RBC units, in patients who received MT in the VHA arm.[19] Since the first and second sets of MTP consist of RBC, FFP, and platelet, the higher numbers of blood products used before the application of ROTEM than the post-ROTEM period possibly account for the component consisting in the conventional MTP and a requirement of volume resuscitation in an initial phase. After administration of ROTEM, blood and components would be transfused based on the ROTEM results. This result is in agreement with what we observed that in the VHA arm, the total of 24 units of RBC and 20 units of FFP was spared when compared with the conventional MTP.

In contrast, cryoprecipitate was the only component that was increasingly transfused during the peri-and post-ROTEM phases. The increasing requirement for cryoprecipitate after ROTEM testing suggests that ROTEM is an effective tool for identifying hypofibrinogenemia, and that fibrinogen is an important factor in hemorrhagic trauma patients. This result strongly correlates with the pathophysiology of massive bleeding condition.[5,37,38,41] These results emphasize the importance of fibrinogen level and plasma replacement in an early phase of resuscitation.

Time-to-confirmed hemostasis of coagulation assessment

Time-to-confirmed hemostasis depends on the consistency of VHA-guided initiation, institutional protocol, and team activation. Time-to-confirmed hemostasis in this study was defined as outlined in the Methods section, and included the turnaround time (TAT) duration, which was defined as the time from the blood draw to the reporting of the results. The current European guideline for the management of major bleeding and coagulopathy following trauma states that VHA as a POCT can reduce the TAT by 30-60 minutes when compared to CCT.[5] A multicenter study reported the median TAT in CCT to be 88 minutes with a maximum TAT of up to 235 minutes.[17] The our study found a markedly decreased time-to-confirmed hemostasis between ROTEM and CCT (92 minutes [70-110] vs. 287 minutes [204-354], respectively). Moreover, we are confident that the time-to-confirmed hemostasis by ROTEM can be further decreased once an institutional protocol is established, learned, and refined.

Limitations

This study has some limitations that need to be addresses. First, the inherent weaknesses of the retrospective study design include missing and/or incomplete data, a tendency towards certain types of biases, and an inability to prove causation. For example, body temperature data was not available in all cases, so that data could not be reported in this study. Second, the size of our study population was small because this is a newly implemented technique at our center, and we set forth in this study to evaluate its effectiveness since its introduction. Third, the small number of cases in each group limited our ability to perform sophisticated statistical analyses. However, we analyzed and compared several important related parameters to assess the performance of ROTEM testing compared to non-VHA-guided therapy, and we found marked improvement between techniques for all evaluated parameters. Fourth, since this is a new technique at our center, no standard protocol has been established, which means that heterogeneity in practice management should be assumed. Fifth, since we were limited by the number of available cartridges for VHA testing, repeat ROTEM testing was only performed in 7 of 13 patients. The results of this study suggest the value of full implementation of ROTEM testing in this trauma setting, and that an established ROTEM practice protocol be established within a multidisciplinary team framework. From the beginning of full implementation, a pilot study should be conducted to confirm the results of this study. Our patients and our center will benefit from the improvements in patient survival and more efficient use of blood products that were both demonstrated in this study.

CONCLUSION

The findings of this pilot study strongly suggest the value of VHA-guided therapy for facilitating goal-directed hemostatic resuscitation and efficient blood product use during resuscitation, definitive treatment, and postoperative intensive care. The median time-to-confirmed hemostasis for ROTEM was markedly shorter than for CCT. Among the 6 cases that had MTP activated via ROTEM-guided therapy, four who adhere the protocol had their median lactate levels substantially decreased.

Regarding blood product use, ROTEM detected cases with low fibrinogen that only required cryoprecipitate transfusion, and red blood cell and fresh frozen plasma use was less in ROTEM than in conventional MTP. This point-of-care test platform reduces the time to treat trauma-induced coagulopathy in patients with trauma-related bleeding resulting in improved survival outcome. These results support full implementation of this technique in Thailand to improve survival among patients with trauma-related bleeding.

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This was an unfunded study.

Authors' contributions

TW and JK conceived and designed the study, performed the literature review, collected the data, analyzed and interpreted the data, and drafted the article. KK designed the study and critically reviewed the manuscript. WW and SC collected, analyzed, and interpreted the data. PR and TR critically reviewed the manuscript for important intellectual content. All authors have read and approved the version of the manuscript submitted for journal publication.

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Conflict of interest declaration

All authors declare no personal or professional conflicts of interest, and no financial support from the companies that produce and/or distribute the drugs, devices, or materials described in this report. However, it is herewith declared that laboratory reagents were provided free of charge by TEM International GmbH during the early phase of VHA implementation at our center.

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