2017

The Influence on Morbidity and Mortality when Blood Products are Transfused using Conventional Coagulation Tests Versus TEG or ROTEM in Trauma Patients Perioperatively

Teresa Diana Kelley
nonaic49@outlook.com

THE INFLUENCE ON MORBIDITY AND MORTALITY WHEN BLOOD PRODUCTS ARE TRANSFUSED USING CONVENTIONAL COAGULATION TESTS VERSUS TEG OR ROTEM IN TRAUMA PATIENTS PERIOPERATIVELY

A Research Project submitted to
the Graduate College of Business
Marshall University

Final defense submitted in partial fulfillment of requirements for the
Doctorate of Management Practice in Nurse Anesthesia (DMPNA) degree
Conferred by Marshall University (MU) in partnership with the
Charleston Area Medical Center (CAMC) based on a collaborative agreement between the
MU College of Business and the CAMC School of Nurse Anesthesia

By

Teresa Diana Kelley

Marshall University

November 2017

SIGNATURE PAGE

Approved By

Dr. Alberto Coustasse, DrPH, MD, MBA, MPH
Committee Chair, Graduate College of Business, Marshall University

Signature_____ Date_____

Dr. Pricilla Walkup, CRNA, DMP
CAMC School of Nurse Anesthesia

Signature_____ Date_____

Kathy James, CRNA
CAMC Health System, Memorial Hospital

Signature_____ Date_____

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Abstract: Coagulopathy in trauma patients occurs due to tissue injury, hemodilution (dilution of hematocrit and clotting factors), infusion of hypo-coagulable blood products (e.g., packed red blood cells), acidosis, hypothermia, continued blood loss, and depletion of clotting factors. The onset of coagulopathy begins with the initial tissue injury and evolves rapidly. Many factors need consideration when determining resuscitative treatment for the trauma victim. These factors include the amount of time for extraction from the field, transport time to a trauma center, associated weather, and treatment provided in route. This study compared two clinical laboratory pathways (Conventional Coagulation test and Rotational Thromboelastometry [ROTEM] whole blood assay) to determine the influence on morbidity and mortality when trauma patients received blood products perioperatively.

Introduction: Coagulopathy can begin at the point of injury and is called acute coagulopathy of trauma or can be triggered in the presence of low body temperature, dilution, acidosis, and expenditure of clotting factors and is called trauma-induced coagulopathy. Coagulopathy is a critical condition and needs to be diagnosed early. Research on TEG/ROTEM whole blood assays indicates a promising future in the use of these tests and the diagnosis and therapeutic process for trauma patients.

Methodology: A retrospective, case-control investigation was carried out at The Charleston Area Medical Center (CAMC) General Hospital Level 1 Trauma Center in West VA. The hypotheses tested was when ROTEM whole blood assays are used to diagnose and predict the number of blood products needed for patients receiving blunt force trauma or penetration to the abdomen, the morbidity and mortality rate will decrease.

Results: The sample for the Conventional Coagulation Test consisted of 93 patients 18 years or older with an average age of 42. The sample for the TEG/ROTEM whole blood assay consisted of 43 patients 18 years or older with an average age of 44. There was no statistical significance between ROTEM and Conventional tests and ISS, age, BMI, LOS, or the number of blood products given a ($p>0.05$). No statistical significance was found between ROTEM and Conventional tests and gender, AIS, and priority level 1 or 2 with a ($p>0.05$). No statistical significance was found using the Fisher's Exact test comparing ROTEM and Conventional tests and the development of CHF or Pulmonary Edema with a ($p>0.05$). The results indicated that the mortality rate was higher among the ROTEM group and was found to be statistically significant with ($p<0.05$) compared to the Conventional group.

Discussion: CAMC General Hospital began using the ROTEM whole blood assay test on trauma patients in 2014. For this study, there were only 43 ROTEM cases that could be used compared to 100 Conventional Coagulation test cases. Future research should be conducted at CAMC General Hospital on trauma patients receiving blood transfusions and the use of ROTEM whole blood assay tests when more cases are available for comparison.

Conclusion: The working hypothesis for this study was trauma patients who received blood transfusions guided by TEG/ROTEM whole blood assays received fewer blood products and had a decreased morbidity and mortality rate than those who received blood transfusions guided by Conventional Coagulation tests. Although, statistical significance was found between the mortality rate and the case group no significance was found supporting the hypothesis due to the lack of sufficient ROTEM cases.

Key Words: aPTT, Blood Transfusion, Platelets, PT, ROTEM, TEG, Trauma

LIST OF TABLES

INTRODUCTION

Background

Coagulopathy is a condition of decreased clotting factors. In 2016, Chang, Cardenas, Wade, and Holcomb reported that once a traumatic injury has occurred, the endothelium exhibits anticoagulant properties. These features include thrombomodulin, endothelial protein C receptors, and a glycocalyx element. According to Hinsbergh (2011), different factors activate the cells within the endothelium to release these properties such as catecholamines, inflammatory mediators, thrombin, and hypoxia. Cohen et al. (2012) reported that patients with a high Injury Severity Score (ISS) and shock become coagulopathic from the moment of damage. Brohi, Singh, Heron, and Coats (2003) stated an ISS greater than 45 upon admission indicates coagulopathy.

According to Brohi et al. (2008), acute traumatic coagulopathy happens in the early phase of the injury and is due to shock. These authors go on to state shock activates the anticoagulant and fibrinolytic processes causing thrombomodulin to convert thrombin from a coagulant to an anticoagulant and activating protein C in the presence of hypoperfusion. Another study by Brohi, Cohen, and Davenport (2007), trauma-induced coagulopathy is characterized by dysfunction through hemodilution with fluid administration or massive blood transfusion, hypothermia, acidosis, or the consumption of clotting factors. Also, trauma patients commonly have a source of uncontrolled hemorrhaging, and an immediate diagnosis of coagulopathy is necessary to provide appropriate interventions (Schochl, Maegele, Solomon, Gorlinger, and Wolfgang, 2012). Furthermore, once contributing factors have been considered such as extraction from the field, transport time to a trauma center, associated weather, and treatment provided in route, a baseline coagulation analysis must be obtained. Additionally, the conventional coagulation tests give an

analysis of the Prothrombin Time (PT), International Normalized Ratio (INR), and activated Partial Thromboplastin Time (aPTT) and are performed using only plasma (Schochl et al., 2012).

TEG and ROTEM are whole blood viscoelastic tests providing analysis at the initiation of coagulation, the dynamics of clot formation, strength, and breakdown which provides a clear internal view of the patient's medical condition (Schochl et al., 2012).

Literature Review

Conventional Coagulation test:

According to Chowdhury, Saayman, Findlay, and Collins (2004), conventional coagulation laboratory tests have been insufficient to determine the probability of bleeding or predicting low levels of clotting factors. Simmons, Pittet, and Pierce (2014) stated that conventional coagulation tests do not sufficiently evaluate the intricate processes that occur in a patient with Trauma-Induced Coagulopathy (TIC). Furthermore, Conventional Coagulopathy tests are performed on platelet reduced plasma and cannot evaluate the clot strength which can produce negative results. Driessen et al., (2015), reported results from a web-based survey among those attending the 15th European Congress of Trauma and Emergency Surgery in Frankfurt, Germany in May of 2014. According to these authors, the results stated that out of 29% who responded, more than 74% admitted to using the conventional coagulation tests for initial evaluation and continued monitoring of hemorrhaging trauma patients. Chitlur et al. (2011), reported that routine laboratory tests including PT/INR, aPTT, and platelet function were used for analyzing bleeding disorders. Additionally, enhanced knowledge of the clotting cascade provided a better understanding of the function, at the cellular level, of white blood cells, red blood cells, and platelets. Da Luz, Nascimento, and Rizoli (2013) stated that standard

coagulation assays used plasma which did not include platelets or the cellular element and viscoelastic assays such as TEG or ROTEM uses whole blood samples.

Thromboelastography (TEG) and Rotational Thromboelastometry (ROTEM):

According to Ostrowski, Sorensen, Larsen, and Johansson (2011), data indicated that TEG and ROTEM viscoelastic whole blood assays identified and distinguished which type of coagulopathy was present. Furthermore, immediate recognition of coagulopathy is crucial to plan the appropriate transfusion regimen. These authors also reported viscoelastic whole blood assays had been used to direct and monitor transfusion interventions in hemorrhaging trauma patients. Ostrowski et al. (2011), again stated TEG was specifically responsive to shifts in fibrin and platelet function, and it was beneficial to discover changes and defects in the body's blood clotting ability perioperatively. Another study reported Thromboelastography provided immediate results of clot strength and reliable data on coagulation activity and executed target-directed transfusion treatment for trauma patients (Bollinger, Seeberger, and Kenichi, 2012). According to Chitlur et al. (2011), TEG and ROTEM provide a total evaluation of the cellular components starting with the initial clot production and ending with clot lysis. Hoffman and Monroe (2001) stated that hemostasis has three different levels of coagulation. These authors stated the first level is called *initiation* and takes place on the surface of the cells with tissue factor, the second level is *amplification* and occurs on the platelet surface causing platelet adhesion, and the final level is *propagation* where proteases and cofactors combine to generate thrombin. According to Whiting and DiNardo, (2014), the primary clinical purpose for TEG or ROTEM whole blood assays is the prompt return of results which lead to giving fast proper attention to hemostatic deficiencies. Furthermore, TEG parameters include Clotting Index which assesses the initial formation of a clot, Clot Strength, Elasticity, Thrombo-dynamic Potential

Index obtained at maximum amplitude, Clot lysis at 30 and 60 minutes, and Estimated Percent Lysis. Additionally, ROTEM parameters have included INTEM (contact activation), EXTEM (tissue factor activation), APTEM (contains aprotinin for inhibiting fibrinolysis), and FIBTEM (analysis of the fibrinogen contribution to clot strength) (Whiting and DiNardo, 2014).

Significance

Coagulopathy is a serious condition and is diagnosed immediately. Identification of the type of coagulopathy and what interventions are necessary to sustain life are the first steps to recovery. Conventional Coagulation tests utilize a small portion of the coagulation pathway whereas TEG and ROTEM whole blood assays use the initial clot formation and follow through to the breakdown of the clot.

Coagulopathy is evident upon admittance in 25% of patients involved in a traumatic event and contributes to an increase in mortality rate (Brohi et al., 2007). Therefore, comparing the outcomes of conventional coagulation tests to viscoelastic whole blood assays can provide a better understanding of which pathway to utilize in diagnosing coagulopathy and appropriate interventions for trauma patients.

Extensive research has been done on acute and trauma-induced coagulopathy. Research has indicated that the timing of laboratory evaluation is imperative. Coagulopathy presents in the acute phase immediately following a traumatic event due to the activation of protein C and fibrinolysis, or as trauma-induced coagulopathy due to hemodilution, consumption of clotting factors, acidosis, or hypothermia. The present study could enhance medical practice and improve trauma patient outcomes at Charleston Area Medical Center, in West Virginia and other hospitals.

METHODOLOGY

Research Hypothesis

The working hypothesis for this study was trauma patients who received blood transfusions guided by TEG/ROTEM whole blood assays received fewer blood products presented a decreased morbidity and mortality rate than those who received blood transfusions guided by Conventional Coagulation tests.

Research Design and Setting

This study was a retrospective, case-control investigation carried out at The Charleston Area Medical Center (CAMC) General Hospital Level 1 Trauma Center in West Virginia. A chart review of adult trauma patients who received blood products in response to Conventional laboratory assay results or lab results from TEG/ROTEM whole blood assays were compared. The case group consisted of trauma patients that had a TEG/ROTEM whole blood assay test, and the morbidity or mortality that resulted from the interventions provided. The control group consisted of trauma patients that had a Conventional Coagulation test, and the morbidity or mortality rate that resulted from the interventions provided. This study design allowed for the comparison of two laboratory pathways, statistical analysis, and the interventions provided.

Sample Population with Description

The CAMC General Hospital is a level 1 Trauma Center qualified to provide total care for every form of injury (CAMC, 2017). An examination of medical records was performed on 136 priority one and two trauma patients who experienced blunt force trauma or penetration to the abdominal cavity between the dates of January 1, 2006, through August 1, 2016. The medical records were provided through CAMC EMR Sorian (Cerner, 2016).

The patient's sample for this study were identified using the International Classification of Diseases, 9th and 10th revision, Clinical Modification (ICD-9-CM) or (ICD-10-CM) code for blunt force trauma or penetration of the abdominal cavity (Centers for Disease Control and Prevention, 2017).

Inclusion Criteria:

1) Adult male or female patients were18 years of age or older.
2) Patients who were involved in blunt force trauma or penetration to the abdominal cavity and admitted to the CAMC General Hospital Trauma Center Emergency Department.
3) Priority 1 or 2 designated patients. Priority 1 (P1) or Priority 2 (P2) trauma patients were transferred to the highest-level trauma center within 30-minutes or if greater than 30-minutes the patient should be transferred to a nearby facility that was able to resuscitate and stabilize the patient (West Virginia Department of Human Resources, 2017).

Exclusion Criteria:

1) Patients were younger than 18 years of age.
2) Any patient undergoing elective surgery.
3) Any patient considered non-trauma.

Procedures and Protocol

A retrospective, case-control study was performed utilizing patient electronic medical records that experienced a traumatic event producing blunt force trauma or penetration to the abdominal cavity between January 1, 2006 and August 1, 2016. Dependent variables included morbidities (CHF or Pulmonary edema) that developed resulting from the transfusions and the mortality rate. Patient demographic and clinical information was obtained and included: patients who experienced a traumatic event produced by blunt force trauma or penetration to the

abdominal cavity, age, ISS, body mass index (BMI), TEG or ROTEM whole blood assay test results, Conventional Coagulation test results (PT/INR, aPTT, and Platelets), LOS in the hospital, morbidities (CHF or Pulmonary Edema) developed resulting from intervention, and the mortality rate.

The ISS is a structural grading arrangement that supplies a comprehensive score for trauma patients with a combination of injuries (Osler, Nelson, and Bedrick, 1999). Additionally, each injury is given an Abbreviated Injury Scale (AIS) score which includes six body zones (Head, Face, Chest, Abdomen, Extremities). These authors also reported the greatest AIS number for the individual body zones are used and the three most predominantly injured regions scores are squared and totaled to provide an ISS score. Finally, the ISS ranges from 0-75, and if the AIS score is 6 (an un-survivable injury), the ISS score will inevitably be 75 (Osler et al., 1999).

Data Collection

The information gathered for this retrospective case-control investigation came from existing data utilizing the patient's electronic medical records (EMR) (Cerner, 2016). Microsoft Excel was used to organize all data collection. Each patient was given a number, letter, or both categorizing the data as it was collected and safeguarded the patient's identification. This data came from emergency department records, anesthesia records, and from other units at CAMC where patients received care during the hospital stay. The demographic and clinical information obtained was included: patients who received blunt force trauma or penetration to the abdominal cavity, age, ISS, body mass index (BMI), TEG or ROTEM whole blood assay test results, Conventional Coagulation test results (PT/INR, aPTT, and Platelets), length of stay in the hospital, morbidities (CHF or Pulmonary Edema) developed resulting from intervention, and

mortality rate. The BMI was calculated by a person's weight and height and was used as a predictor of body fat composition (CDC, 2011).

Statistical Analysis

The purpose of this study was to compare the outcomes using two laboratory pathways (TEG/ROTEM or Conventional Coagulation) in patients who were involved in a traumatic event that produced blunt force trauma or penetration to the abdominal cavity. Chi-square analysis was done comparing the mortality rate against ROTEM and Conventional Coagulation tests. A t-test was performed and compared means difference between two dependent variables (morbidity and mortality) with ISS, age, BMI, LOS, and the number of blood products given. Three logistic regression tests were performed to determine if there was an association between independent variables ROTEM, age, BMI, gender, ISS with the dependent variables morbidity (CHF and Pulmonary Edema) and mortality. A p-value <0.05 was considered statistically significant. The data was analyzed using SPSS Version 24 (SPSS IBM Company, 2017).

RESULTS

Presentation, Analysis, and Interpretation of the Data

The study sample consisted of 136 patients over the age of 18, presenting to CAMC General Hospital with a trauma injury of blunt force or penetration to the abdomen. The following mean for ISS is 26.29 ± 12.1, BMI 28.68 ± 11, the age of the group was 43.15 ± 17.9, Number of Blood Products Used 20.36 ± 35, and length of stay in the hospital 19.8 ± 24.6 (Table 1). Of the 136 patients, 101 (74.1%) were male, 35 (25.9%) were female, 4 (2.9%) developed CHF, 12 (8.8%) developed pulmonary edema and the mortality rate was 17 (12.5%), (Table 1).

Table 1: Demographic and Clinical Characteristics of Adult Trauma Patients who received Blunt Force Trauma or Penetration to the Abdomen

Variables	Total Sample	Study Groups		Statistical Value
	Total N=136 Mean (SD)	TEG/ROTEM Whole Blood Assay N= 43 (31.6%) Mean (SD)	Conventional Coagulation Test N=93 (68.4%) Mean (SD)	p-Value
ISS	26.29 (12.1)	22.95 (11.5)	27.83 (12.1)	NS
Age (years)	43.15 (18)	44.56 (20)	42.49 (16.9)	NS
BMI (kg/m2)	28.68 (11)	30.12 (17.5)	28.01 (5.9)	NS
Hospital LOS (days)	19.81 (24.64)	18.51 (26.4)	20.41 (23.9)	NS
Number of Blood Products	20.36 (34.94)	28.28 (51.4)	16.70 (23.3)	NS
Mortality (%) 1 - Alive 2 - Dead	 1 – 118 (86.8%) 2 – 17 (12.5%)	 1 – 34 (79.1%) 2 – 9 (20.9%)	 1 – 85 (91.4%) 2 – 8 (8.6%)	 *0.043
CHF (%)	4 (2.9%)	1 (2.3%)	3 (3.2%)	NS
Pulmonary Edema (%)	12 (8.8%)	4 (9.3%)	8 (8.6%)	NS
Gender 1 – Male 2 - Female	 1 – 100 (74.1%) 2 – 35 (25.9%)	 1 – 30 (69.8%) 2 – 13 (30.2%)	 1 – 71 (76.3%) 2 – 22 (23.7%)	 NS
AIS ABD 2 – Moderate 3 – Serious 4 – Severe 5 – Critical	 2 – 46 (33.8%) 3 – 44 (32.4%) 4 – 36 (26.5%) 5 – 10 (7.4%)	 2 – 20 (46.5%) 3 – 11 (25.6%) 4 – 8 (18.6%) 5 – 4 (9.3%)	 2 – 26 (28%) 3 – 33 (35.5%) 4 – 28 (30.1%) 5 – 6 (6.5%)	 NS
Priority 1 and 2	1 – 105 (77.2%) 2 – 31 (22.8%)	1 – 34 (79.1%) 2 – 9 (20.9%)	1 – 71 (76.3%) 2 – 22 (23.7%)	NS

*Indicates Statistical Significance at $p<0.05$, NS = Not Significant ($p> .05$), SD = Standard Deviation, ISS = Injury Severity Score, BMI = Body Mass Index, LOS = Length of Stay, CHF = Congestive Heart Failure, TEG = Thromboelastography, ROTEM = Rotational Thromboelastometry, AIS= Abbreviated Injury Scale

Comparison of the ROTEM whole blood assay (case group) and Conventional Coagulation test (control group) did not show a mean difference between ISS, age, BMI, LOS, or the number of blood products which were not statistically significant ($p>0.05$). Also, comparison of the case group (ROTEM whole blood assay) and control group (Conventional Coagulation test) did not show a statistical significance between gender, AIS, and Priority level

with a (p>0.05). Mortality was associated with a higher percentage in case group (TEG/ROTEM whole blood assay) which was statistically significant (p<0.05), (Table 1).

A Fisher's Exact Test was performed comparing the use of ROTEM and Conventional Coagulation tests with the development of pulmonary edema. The results indicated that 3.8 out of 12 (33%) patients in the case group developed pulmonary edema with no statistical significance (p >0.05), and 8.2 out of 12 (66.7%) developed pulmonary edema in the control group with no statistical significance (p>0.05), (Table 2).

Table 2: Fisher's Exact Test Comparing ROTEM and Conventional Coagulation tests with Pulmonary Edema

			TEG/ROTEM Whole Blood Assa1 (1/0)		
			0	1	Total
Pulmonary Edema	0	Count	85	39	124
		Expected Count	84.8	39.2	124.0
		% within Pulmonary Edema	68.5%	31.5%	100.0%
		% within TEG/ROTEM Whole Blood Assay (1/0)	91.4%	90.7%	91.2%
	1	Count	8	4	12
		Expected Count	8.2	3.8	12.0
		% within Pulmonary Edema	66.7%	33.3%	100.0%
		% within TEG/ROTEM Whole Blood Assay (1/0)	8.6%	9.3%	8.8%
Total		Count	93	43	136
		Expected Count	93.0	43.0	136.0
		% within Pulmonary Edema	68.4%	31.6%	100.0%
		% within TEG/ROTEM Whole Blood Assay (1/0)	100.0%	100.0%	100.0%

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.018*[a]	1	.894		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.018*	1	.894		
Fisher's Exact Test				1.000	.562
Linear-by-Linear Association	.018	1	.894		
N of Valid Cases	136				

A Fisher's Exact Test was performed comparing the use of ROTEM and Conventional Coagulation tests and the development of CHF. The results indicated that of the patients in the case group, only 1 (25%) out of 4 patients developed CHF. The results indicated that 3 out of 4 (75%) patients in the control group developed CHF with no statistical significance ($p>0.05$), (Table 3).

Table 3: Fisher's Exact Test Comparing ROTEM and Conventional Coagulation tests with CHF

			TEG/ROTEM Whole Blood Assay (1/0)		
			0	1	Total
CHF (1/0)	0	Count	90	42	132
		Expected Count	90.3	41.7	132.0
		% within CHF (1/0)	68.2%	31.8%	100.0%
		% within TEG/ROTEM Whole Blood Assay (1/0)	96.8%	97.7%	97.1%
	1	Count	3	1	4
		Expected Count	2.7	1.3	4.0
		% within CHF (1/0)	75.0%	25.0%	100.0%
		% within TEG/ROTEM Whole Blood Assay (1/0)	3.2%	2.3%	2.9%
Total		Count	93	43	136
		Expected Count	93.0	43.0	136.0
		% within CHF (1/0)	68.4%	31.6%	100.0%
		% within TEG/ROTEM Whole Blood Assay (1/0)	100.0%	100.0%	100.0%

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.083[a]	1	.773		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.087	1	.768		
Fisher's Exact Test				1.000	.623
Linear-by-Linear Association	.083	1	.773		
N of Valid Cases	136				

A Pearson Chi-Square test was performed comparing the ROTEM group and the mortality rate. The results indicated that the mortality rate was higher among the ROTEM group 9 (20.9%) compared to 8 (8.6%) in the Conventional group and was found to be statistically significant with ($p<0.05$), (Table 4).

Table 4: Pearson Chi-Square Analysis of the ROTEM (case group) and the Mortality Rate

			TEG/ROTEM Whole Blood Assa1 (1/0)	
			0	1
Mortality (Alive-1 or Dead-2)	1	Count	85	34
		Expected Count	81.4	37.6
		% within Mortality (Alive-1 or Dead-2)	71.4%	28.6%
		% within TEG/ROTEM Whole Blood Assa1 (1/0)	91.4%	79.1%
		Std. Residual	.4	-.6
	2	Count	8	9
		Expected Count	11.6	5.4
		% within Mortality (Alive-1 or Dead-2)	47.1%	52.9%
		% within TEG/ROTEM Whole Blood Assa1 (1/0)	8.6%	20.9%
		Std. Residual	-1.1	1.6
Total		Count	93	43
		Expected Count	93.0	43.0
		% within Mortality (Alive-1 or Dead-2)	68.4%	31.6%
		% within TEG/ROTEM Whole Blood Assa1 (1/0)	100.0%	100.0%

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	4.086[a]	1	.043		
Continuity Correction[b]	3.036	1	.081		
Likelihood Ratio	3.819	1	.051		
Fisher's Exact Test				.054	.044
N of Valid Cases	136				

A t-test analysis was performed comparing the LOS between the ROTEM and Conventional groups with no statistical significance found ($p>0.05$), (Table 5).

Table 5: T-test Analysis comparing LOS between ROTEM and Conventional Coagulation Tests

	TEG/ROTEM Whole Blood Assay (1/0)	N	Mean	Std. Deviation	Std. Error Mean
Length of Stay	0	93	20.41	23.912	2.480
	1	43	18.51	26.419	4.029

The ROTEM group was analyzed with a logistic regression test for the dependent variable Mortality with the independent variables of age, gender, BMI, ISS, and Number of blood products and no statistical significance was found ($p>0.05$), (Table 6).

Table 6: Logistic Regression Analysis Comparing ROTEM with Mortality among Adult Trauma Patients Who Received Blood Products Following a Traumatic Blunt Force or Penetration to the Abdomen

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	Age	.010	.015	.454	1	.501	1.010
	Gender M1 and F2	.578	.579	.997	1	.318	1.782
	BMI	.038	.030	1.645	1	.200	1.039
	Injury Severity Score (ISS)	-.002	.026	.009	1	.926	.998
	TEG/ROTEM Whole Blood Assay	.843	.569	2.193	1	.139	2.323
	Number of Blood Products Used	.005	.007	.589	1	.443	1.005
	Constant	-4.665	1.482	9.915	1	.002	.009

Dependent Variable: Mortality. BMI=Body Mass Index, TEG=Thromboelastography, ROTEM=Rotational Thromboelastometry

The ROTEM group was analyzed with a logistic regression analysis between the dependent variable Morbidity (CHF), and the independent variables that included age, gender, BMI, ISS, and Number of blood products with no statistical significance found ($p>0.05$), (Table 7).

Table 7: Logistic Regression Analysis Comparing ROTEM with Congestive Heart Failure (CHF) among Adult Trauma Patients Who Received Blood Products Following a Traumatic Blunt Force or Penetration to the Abdomen

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	Age	.213	.109	3.823	1	.051	1.237
	Gender M1 and F2	1.572	1.629	.931	1	.335	4.815
	BMI	-.089	.125	.515	1	.473	.915
	Injury Severity Score (ISS)	-.280	.200	1.960	1	.161	.755
	TEG/ROTEM Whole Blood Assay	-2.869	2.130	1.815	1	.178	.057
	Number of Blood Products Used	.034	.034	.993	1	.319	1.034
	Constant	-11.378	6.259	3.305	1	.069	.000

Dependent Variable: Morbidity (CHF). BMI=Body Mass Index, TEG=Thromboelastography, ROTEM=Rotational Thromboelastometry

The ROTEM group was analyzed with a logistic regression analysis between the dependent variable Morbidity (Pulmonary Edema) and the independent variables of age, gender, BMI, ISS, and Number of blood products with no statistical significance found ($p>0.05$), (Table 8).

Table 8: Logistic Regression Analysis Comparing ROTEM with Pulmonary Edema with Adult Trauma Patients Who Received Blood Products Following a Traumatic Blunt Force or Penetration to the Abdomen

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	Age	.009	.018	.277	1	.599	1.009
	Gender M1 and F2	.439	.675	.422	1	.516	1.550
	BMI	.016	.019	.654	1	.419	1.016
	Injury Severity Score (ISS)	.040	.027	2.100	1	.147	1.041
	TEG/ROTEM Whole Blood Assay	.045	.738	.004	1	.951	1.047
	Number of Blood Products Used	.004	.007	.322	1	.571	1.004
	Constant	-5.049	1.572	10.322	1	.001	.006

Dependent Variable: Morbidity (Pulmonary Edema). BMI=Body Mass Index, TEG=Thromboelastography, ROTEM=Rotational Thromboelastometry

DISCUSSION

Discussion of Study Results

It was indicated that TEG/ROTEM are not interrelated with routine coagulation tests (Da Luz et al., 2013). This study also identified that rapid TEG (r-TEG) provides the earliest prediction of blood products to be transfused and can be used as a point of care for the treatment of hemorrhaging trauma patients for faster results. Schochl et al. (2012), reported that whole blood assay tests provided personalized therapy according to the needs of the trauma patient in contrast to the predetermined protocol of dispensing allogeneic blood products. These authors further stated how the individualized care decreased the risks of underestimating or overestimating the number of blood products needed. This present study revealed a statistical significance between the mortality rate and the case group indicating a higher percentage compared to the control group. It is difficult to determine if there is a clinical significance due to the limitations of this study and the lack of sufficient cases to support ROTEM use. For this study, there were only 43 ROTEM cases that could be used compared to 136 Conventional

Coagulation test cases. Therefore, there was not sufficient sample size to support the hypothesis for this study. Research has shown that TEG/ROTEM have been recommended as a point of care test for trauma patients and more facilities need to be trained how to use, calibrate, and understand the specialized variances in performing the test (Da Luz et al., 2013). The use of ROTEM for trauma patients at CAMC General Hospital began in 2014 and, according to research studies, can provide future success in the diagnosis and therapeutic interventions for hemostasis.

Study Limitations

Several limitations were identified in this study. There were not enough ROTEM cases for adequate comparison. Another limitation included unknown preexisting co-morbidities or prescribed medications which could have influenced the treatment and outcome of trauma patients perioperatively. The final limitation was the ROTEM cases included in this study also had a Conventional Coagulation test done, and there was no indication as to which test the interventions were prescribed.

IMPLICATIONS AND RECOMMENDATIONS

A future study comparing ROTEM whole blood assays and Conventional Coagulation laboratory tests should be done when ROTEM has been utilized at CAMC General Hospital for a longer period, and enough ROTEM cases are available for collection. A prospective study could be done as ROTEM whole blood assay is being used for trauma cases to determine if there is clinical significance between the two laboratory pathways and the interventions provided. Another study on ROTEM use could be conducted to include a detailed prediction of the type and number of blood products to be given according to the ROTEM algorithm and the outcomes compared with Conventional Coagulation tests. Finally, a study can be conducted comparing the

timing of the results provided for trauma patients with that of the timing of Conventional Coagulation tests results.

CONCLUSION

In this present study, the use of ROTEM whole blood assay resulting in fewer blood products infused and decreased morbidity and mortality rate could not be determined due to the limited number of ROTEM cases available. Statistical significance was found between the mortality rate and the ROTEM group. The mortality rate among the ROTEM group was found to have a higher percentage and was statistically significant compared to the Conventional group.

REFERENCES

Bollinger, D., Seeberger, M., Kenichi, T. (January 2012). Principles and Practice of Thromboelastography in Clinical Coagulation Management and Transfusion Practice. *Transfusion Medicine Reviews, 26* (1), 1-13.

Brohi, K., Cohen, M., and Davenport, R. (2007). Acute coagulopathy of trauma: mechanism, identification, and effect. *Current Opinion Critical Care, 13*, 680-685.

Brohi, K., Cohen, M., Ganter, M., Schultz, M., Levi, M., Mackersie, R., and Pittet, J. (2008). Acute Coagulopathy of Trauma: Hypoperfusion Induces Systemic Anticoagulation and Hyperfibrinolysis. *The Journal of TRAUMA Injury, Infection, and Critical Care, 64* (5), 1211-1217.

Brohi, Karin, Singh, Jasmin, Heron, Mischa, and Coats, Timothy. (2003). Acute Traumatic Coagulopathy. *The Journal Trauma and Acute Care Surgery, 54* (6), 1127-1130. Retrieved from http://journals.lww.com/jtrauma/Pages/articleviewer.aspx?year=2003&issue=06000&article=00015&type=Fulltext

Centers for Disease Control and Prevention [CDC]. (2011). *Body Mass Index.* Retrieved September 13, 2013 from http://www.cdc.gov/healthyweight/assessing/bmi/

Centers for Disease Control and Prevention [CDC]. (2017). *International Classification of Diseases, Tenth Revision, Classification (ICD-10-CM).* Retrieved November 3, 2017, from www.cdc.gov/Bach's/UCD/icd10cm.htm

Cerner. (2016). *Cerner Sorian Clinicals.* Retrieved November 5, 2017, from http://www.cerner.com/page.aspx?pageid=17179878386&libID=17179878601

Chang, R., Cardenas, J., Wade, C., Holcomb, J. (August 25, 2016). Advances in the understanding of trauma-induced coagulopathy. *Blood, 128* (8), 1043-1049.

Charleston Area Medical Center [CAMC], (2017). *CAMC Health Systems*. Retrieved April 10, 2017 from http://camc.org/Hospitals.

Chitlur, M., Sorensen, B., Rivard, G., Young, G., Ingerslev, J., Othman, M., Nugent, D., Kenet, G., Escobar, M., Lusher, J. (2011). Standardization of Thromboelastography: a report from the TEG-ROTEM working group. *Haemophilia, 17*, 532-537.

Chowdhury, P., Saayman, U., Findlay, and G., Collins, P. (2004). Efficacy of standard dose and 30ml/kg fresh frozen plasma in correcting laboratory parameters of haemostasis in critically ill patients. *British Journal of Haematology, 125,* 69-73.

Cohen, M., Call, M., Nelson, M., Calfee, C., Esmon, C., Brohi, K., and Pittet, J. (February 2012). Critical Role of Activated Protein C in Early Coagulopathy and Later Organ Failure, Infection and Death in Trauma Patients. *Annals of Surgery., 255*(2), 379-385.

Da Luz, L., Nascimento, B., Rizoli, S. (2013). Thrombelastography (TEG): practical considerations on its clinical use in trauma resuscitation. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine, 21* (29), 1-8.

Driessen, A., Schafer, N., Albrecht, V., Schenk, M., Frohlich, M., Sturmer, E., Maegele, M. (2015). Infrastructure and clinical practice for the detection and management of trauma-associated haemorrhage and coagulopathy. *European Journal Emergency Surgery., 41*, 413-420.

Hinsbergh, V. (August 2011). Endothelium-role in regulation of coagulation and inflammation. *Seminars in Immunopathology., 34*, 93-106.

Hoffman, M., and Monroe, D. (2001). A Cell-based Model of Hemostasis. *Thrombosis and*

Haemostasis, 85, 958-965.

Osler, T., Nelson, L., and Bedrick, E. (1999). Injury Severity Scoring. *Journal of Intensive Care Medicine, 14* (1), 9-19. Retrieved from journals.sagepub.com/doi/pdf/10.1177/088506669901400101.

Ostrowski, S., Sorensen, A., Larsen, C., Johansson, P. (2011). Thrombelastography and biomarker profiles in acute coagulopathy of trauma: a prospective study. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine. 19* (64), 1-10.

Schochl, H., Maegele, M., Solomon, C., Gorlinger, K., Wolfgang, V. (2012). Early and individualized goal-directed therapy for trauma-induced coagulopathy. *Journal of Trauma, resuscitation and Emergency Medicine, 20* (15), 1-11

Simmons, J., Pittet, JF., Pierce, B. (2014). Trauma-induced Coagulopathy. *Current Anesthesiology Rep., 4* (3), 189-199.

SPSS IBM Company. (2017). *SPSS Statistics 24.* Retrieved from https://www.ibm.com/analytics/us/en/technology/spss/?source=homepage&hpzone=nav_bar

West Virginia Department of Human Resources. (2017). *Special Operational Policies and Treatment Protocols.* United States: Bureau for Public Health. Retrieved from wvoems.org/media/307834/9103%20field%20trauma%20triage%20rev%20%204_2015.pdf

Whiting, D., and DiNardo, J. (2013). TEG and ROTEM: Technology and clinical applications. *American Journal of Hematology*, *89* (2), 228-232.

APPENDIX A

	Injury Severity Score	BMI	TEG/ROTEM Whole Blood Assay	Conventional Coagulation Test (Y/N)	Length of Stay	CHF(Y/N)	Pulmonary Edema(Y/N)	Mortality (alive or dead)	Age	Number of Blood Products Used
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										

APPENDIX B

New study by expedited review: Approved

July 12, 2017

School of Nurse Anesthesia
3110 MacCorkle Avenue, SE
Charleston, WV 25304

RE: Submission Response for Initial Review Submission Packet 07/12/2017 11:23:07 AM EDT regarding study number 17-354 The Influence on Morbidity and Mortality of Massive Blood Transfusions versus TEG or ROTEM Guided Transfusions in Trauma Patients Perioperatively

Dear Priscilla Walkup:

Your request for expedited approval of the new study listed above has been reviewed. This type of study qualifies for expedited review under FDA and DHHS (OHRP) regulations.

This is to confirm that your application is approved. The following items are approved:

Submission Components			
Form Name	Version	Outcome	
Study Document			
Title	Version #	Version Date	Outcome
Teresa Kelley - #3 after meeting with M. Emmett	Version 1.0	07/09/2017	Approved

The accrual goal is 200. You must submit a request to the IRB to increase enrollment beyond the approved accrual goal.

You are granted permission to conduct your study as described effective immediately. The study is subject to continuing review on or before 07/11/2018, unless closed before that date.

Please note that any changes to the study as approved must be promptly reported and approved prior to implementation. Some changes may be approved by expedited review; others require full board review.

Also, serious and/or unanticipated adverse events must also be reported as required by law and in accordance with CAMC/WVU Charleston Division IRB policies. Contact CAMC / WVU Charleston Division

3110 MacCorkle Ave. SE, Room 3283 Charleston, WV 25304 (304) 388-9970 Fax (304) 388-9976

IRB at (304) 388-9973 or email michael.whitler@camc.org or april.white@camc.org if you have any questions or require further information.

Sincerely,

Atul Singh, DO
Vice-Chair, CAMC/WVU IRB

3110 MacCorkle Ave. SE, Room 3283 Charleston, WV 25304 (304) 388-9970 Fax (304) 388-9976