World Academic Council of Emergency Medicine Experience Document: Implementation of Point-of-Care Thromboelastography at an Academic Emergency and Trauma Center

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Abstract

Background: We aimed to discuss the initial experience of the implementation of point-of-care thromboelastography (POC-TEG) at the Level 1 Trauma Center of an academic health institution in Qatar. Materials and Methods: A TEG protocol was developed and tailored to our hospital requirements and patient population, after an exhausting review of the literature and international published protocols, including a synthesis of a preexisting TEG protocol from our heart hospital. To successfully achieve the incorporation of point-of-care testing (POCT) in our clinical practice, a multidisciplinary organizational and education approach is required. The education and training of the physicians in this POCT modality during the first 3 months period has been described in detail. Results: A TEG protocol has been developed and implemented according to hospital standards. Ten physicians from the department of trauma surgery have been trained over a 3-month period to perform the daily quality control as well as the patient samples in order to provide a 24/7 service. In patients with major trauma, brain injury, bleeding, sepsis, and coagulopathy are the most important determinants of the clinical course and outcomes. Viscoelastic whole-blood assays have already proved their values in cardiac as well as liver surgery. Therefore, this POCT-directed approach would be considered as a part of the goal-directed management in severe polytrauma patients. Conclusions: Our experience shows that implementation of POC-TEG program is feasible and it is a promising tool in the management of major trauma patients with a potential compromised coagulation. However, further prospective research projects and well-trained personnel still warranted.

Keywords: Bleeding, coagulopathy, point-of-care testing, rotational thromboelastography, thromboelastogram, trauma

Introduction

Point-of-care testing (POCT) is worldwide spreading throughout health-care systems. POCT is defined as medical testing at or near the site of a patient by specially trained health-care professionals in order to increase the likelihood of timely diagnosis, monitoring, and treatment.

POCT tests include widely used fast and easy to perform measures such as serum glucose and hemoglobin levels. Other tests include arterial blood gas analysis, activated clotting time, and cardiac markers in more specialized areas, such as intensive care units and cardiac catheterization. Operators of these tests are usually nursing personnel, respiratory therapists, anesthesia, or cardiac catheterization technicians. More complex POCT tests are included, for example whole-blood assays.

Currently, there are two types of whole-blood assays commercially available; thromboelastogram (TEG) and...
rotational thromboelastography (ROTEM). Both have in common, that in the presence of an activator, the viscoelastic changes in the whole-blood sample are measured throughout the entire clotting process. Both systems display graphically the initiation of the coagulation, clot formation, and fibrinolysis.\[1\]

Both tests are usually performed by laboratory personnel.

TEG is not an alternative to the conventional laboratorial coagulation tests such as INR and aPTT; however, it adds more information to guide blood transfusions such as clot strength and fibrinolysis and to differentiate between normocoagulant, hypocoagulant, and hypercoagulant states in septic patients.\[1-2\]

However, a recent systematic review demonstrates that the evidence to show the accuracy of TEG and ROTEM in trauma still needs further evaluation and more research involvement with prospective, randomized controlled trials.\[3,4\]

So far, the use of TEG system in trauma surgery has not been described in the Arab Middle. Herein, we discuss the initial experience for implementation of TEG in the only Level 1 trauma center in Qatar.

**Materials and Methods**

**Protocol development and implementation**

Under the auspices of The World Academic Council of Emergency Medicine and in conjunction with Hamad Trauma Center (HTC), we undertook this pilot project at our center with a vision to develop a Global Trial on point-of-care thromboelastography. The HTC is the only national Level 1 tertiary trauma center in Qatar, with the capability to deliver high-quality, evidence-based advanced treatment needed for polytrauma patients with state-of-the-art life support facilities. The HTC trauma registry is a mature database, that was established in 2007. This trauma registry is compliant with both the National Trauma Data Bank and Trauma Quality Improvement Program (TQIP) of the American College of Surgeons-Committee on Trauma. In HTC, it has been agreed to use a combination of MTP, which had been implemented already in 2010 and TEG-guided therapy. Therefore, the already existing hospital policy for TEG from Qatar’s heart hospital has been taken over from the Heart Hospital as a basis or initial draft which has been immediately modified according to the Danish protocol before implementation. According to this protocol, an action is required in the form of transfusing 1 unit fresh frozen plasma (FFP) when the R-time is between 14–21 min and 2 units when FFP is between 21–28 min, and 4 units FFP when the R-time is prolonged by >28 min. One pooled platelet concentrate is given when the MA is shorter than 48 mm and 2 pooled platelet when MA is <40 mm. Guided by a Danish TEG protocol, the heart hospital protocol was modified concerning the functional fibrinogen level (which is not routinely used in cardiac surgery).

The R-time cutoff in Copenhagen is 10–14 min, treated with 10–20 ml/kg FFP and in a prolongation of >14 min with 30 ml/kg FFP.\[8\]

The range for Kaolin TEG MA is between 45 and 49 mm requiring 1 platelet concentrate or 5 ml/kg. Below 45 mm, 2 platelet concentrates or 10 ml/kg is required.

The TEG treatment algorithm from Copenhagen sets the cut-off value for functional fibrinogen MA is set < 14 mm. Treatment options given are either 20 ml/kg FFP or cryoprecipitate pool (3–4 ml/kg) or fibrinogen concentrate (adults 1–2 g).

The relevant parts of the Danish protocol which have been included in the “Hamad General Hospital (HGH) – Trauma Surgery-TEG Protocol” involved the Kaolin TEG MA as well as the functional fibrinogen MA cut-off values and therapy recommendations [Figure 1]. The HGH-Trauma surgery has developed the TEG-guided blood component therapy algorithm for the management of bleeding and coagulopathy associated with severely injured patients.

TEG operators are usually either trained by a representative from the manufacturer, through self-instruction modules, institutional instructors, or in combination. The minimal requirements in our trauma center are the training provided by a representative from the manufacturer. This is followed by a written test. A general refresher course from the point-of-care team is repeated on a regular basis in a 6-month interval. It is known to be less time-consuming, effective, and consequently less expensive for the institution. However, the regulatory agencies require that the initial training and ongoing competency training to be documented. An alternative approach is an institutional instructor, which is usually more expensive and time-consuming. To increase the quality of service, a synthesis of both approaches has been chosen.

**Results**

In an initial phase, a small number of physicians was selected. This group of physicians included anesthetists as well as...
trauma surgeons with previous knowledge in POCT-TEG. They shared the daily routine operational issues regarding concerning the quality control of the TEG® 5000 system, first the handling of Kaolin samples, and roster preparation concerning the daily TEG quality control as well as ordering the consumables over a period of 3 months.

Subsequently, this group trained other colleagues from trauma surgery and associated anesthetists up to a total of 10 physicians. The total number of 10 has been chosen to make sure that nobody loses his skills due to lack of routine as the quality control in the TEG® 5000 system still is a complex procedure requiring constant training. A number of at least 10 skilled and trained physicians are needed to make sure that a 24/7 service could be provided.

Each new member joining the “TEG-group” has to perform at least 10 supervised and documented TEG Quality Controls (QCs) within a period of 12 weeks. Following that he/she has to undergo a practical test which holds by one of the four team members of the pilot group. This test is performed according to checklist, which has been prepared according to manufacturer standards and agreed on in advance. A similar procedure has been developed for patient samples.

To further raise the standard and quality, the concept of quality assurance for the “TEG in Trauma Surgery at Hamad General Hospital” was guided by the previous experience in performance improvement program and as the European health-care quality manager. Weekly control and monthly statistics concerning the daily quality control have to be performed at a regular basis. A similar PDCA project was started with a respect to the patient samples.

**Discussion**

We describe our TEG model in which the education, training, and service have been developed; without exception, only physician-based consultants, senior consultants, and Trauma Surgery Fellows.

The main difference between TEG and ROTEM is simply technical that in TEG the rotating pin is suspended in a stationary cup, while in ROTEM, the pin is stationary and the cup is rotating. In the TEG system, the coagulation starts the force transmitted to the pin is detected and electronically transmitted to a computer, where it is displayed as a graph. The time until coagulation starts is displayed as “reaction-time” (R-time). This value will be prolonged in the presence of coagulopathy and shortened in patients in a hypercoagulable state. The elapsed time from the beginning of clot formation until a fixed level of clot strength (defined as amplitude of 20 mm) is detected is called K-time. It is a parameter of the speed at which a clot achieves this level of firmness. Fibrinogen deficiency prolongs K-time, whereas increased fibrinogen level or hyperreactive platelets may shorten this parameter. The alpha-angle reflects the speed of fibrin accumulation and polymerization and is closely related to K-time. The “maximum amplitude” (MA) reflects the clot strength. It is mainly represented by fibrinogen and platelets. Finally, the LY-30 represents the percentage of the clot that has dissolved at 30-min time. Figure 2 shows graphical display of a normal TEG (http://teg.haemonetics.com/en-gb/).

TEG-guided transfusion algorithms have successfully been implemented in liver surgery, cardiac surgery, bleeding patients after major surgery, and currently in multisystems injured patients including traumatic brain injury. The use of transfusion algorithms in conjunction with TEG in these subspecialties has been shown to reduce both transfusion requirement as well as blood loss.[6-9]

Prior studies have shown evidence that goal-directed coagulation therapy based on thromboelastographic findings and transfusion algorithms[7,10-12] may be advantageous to the so-called damage control resuscitation with a fixed ratio administration of blood products.[13,14]

A recent meta-analysis assessed the benefits and harms of TEG-guided or thromboelastometry (ROTEM)-guided transfusion in adults and children with bleeding.[15] The authors concluded that there is a growing evidence that application of TEG- or ROTEM-guided transfusion strategies may reduce the need for blood products and improves morbidity in sick patients with considerable bleeding. However, when a new POCT implementation, especially one of the more expensive and complex test is considered, several questions have to be answered. The most important question is whether it is going to change the current practice or not?

By trend, the number of major Level I trauma patients activations is slightly increasing since 2013. Figure 3 shows the total number of Level 1 activation of massive transfusion protocols (MTPs), transfused packed red blood cells (PRBC), FFP, and pooled platelet concentrates in trauma patients per year.

Analysis of the number of major Level 1 activation per year and used blood products in trauma patients revealed the trend of the annual increase since 2013.
Therefore, the implementation of a viscoelastic whole-blood assay in order to control the utilization of blood products by goal-directed use was imperative.

Consecutively, the frequency of potential side effects for patients receiving blood products would automatically decrease. In addition to that, the cost of administering large amount of blood products and the preparation as well as supply with high-quality blood products will be appropriately addressed.

Moreover, reports showed evidence that the use of protocols like MTP, especially in combination with point-of-care-tests such as TEG or ROTEM will decrease the use of blood products and costs. However, the implementation and outcome after TEG may differ from country to country or even from hospital to hospital.

In calculating the cost of running a TEG 5000 properly, several facts have to be taken into consideration. The most important factor in this calculation is the consumables. For the daily quality control, a Level I as well as a Level II control has to be done. End price for one Level I control is 28 US $. In addition, two plain cups are needed, each costs 12 $. Exactly, the same amount has to be spent on Level II control. In the end, the upcoming costs mount up to 103 $/day. In addition, for each kaolin patient sample that is performed, an average cost of 549 $ is generated.

The Transfusion Medicine at Hamad Medical Corporation includes donor collection, component production, patient transfusion, and therapeutic apheresis services in Qatar as the sole provider. Blood components fully comply with the latest Council of Europe (Conformité Européene®) standards and are prepared using the Terumo BCT (https://www.terumobct.com/) Reveos automated component processing system. All components are leukodepleted to <1E6 residual white blood cells. Platelets (both apheresis and pooled) are pathogen-inactivated with riboflavin (Terumo BCT Mirasol) and suspended in platelet additive solution (TSol, Terumo BCT). Plasma is also pathogen-inactivated by the riboflavin system.

Qatar’s blood production is optimized for safety (greatest pathogen reduction after donor infectious disease testing, including nucleic acid test) and speed so that all acceptable components are released in <1-day postcollection. To produce components (i.e., packed RBCs, platelets, and plasma) from one whole-blood donation, it costs in excess of 544 $. Similarly, apheresis derived plasma or platelets from one donor costs in excess of 544 $.

During an activated MTP, blood products are delivered in “shipments” of 6 PRBCs, 6 FFP, and 6 pooled platelets (PLTs). The annual costs for daily quality control of the TEG add up to 57 916 $. With an average production cost of 544 $ per blood product, 69 units of blood products annually must be saved to adjust costs of the quality control to zero.

Most studies concerning the amount of used blood products pre- and post-implementation of TEG or ROTEM have been conducted in the cardiac and liver surgery. For example, Hvas et al. found that the use of PRBCs (31.7% vs. 29.3%) and Factor VIIa had decreased significantly. No difference was found in the use of FFP (24.9% vs. 22.7%) and platelets (25.5% vs. 21.7%), whereas the use of fibrinogen increased (3.6% vs. 11.6%).

Slightly different findings have been reported in 2011 by Gorlinger et al. They found a significant decrease in PRBCs (49.7% vs. 40.4%) as well as FFP (19.4% vs. 11.1%) with a nonsignificant increase in the use of platelets (10% vs. 13%). However, in this study, an increase in the total amount of fibrinogen used was described. In 2006, Anderson et al. described a reduction in PRBC use from 60% to 53%, FFP (17% vs. 12%) and platelets (16% vs. 11%), respectively, in cardiac surgery.

However, in terms of the budget impact, saving is to be expected with the use of TEG. With reduction of utilized blood products, the total number of transfusion-associated side effects will decrease. Accordingly, there will be a decrease in the hospitalization costs. In addition, the reduced total number of blood products will lead to overall reduction in production cost.

A study conducted in a German center for liver transplant, similar to the cardiac surgery setting, found a reduction of cost for blood products of 59% after implementation of ROTEM. Nevertheless, there was a remarkable increase concerning the costs of coagulation factors. However, the overall cost-saving for the hospital during the studied period was 35%. The same study group calculated an overall cost-saving of 6.5% in cardiac surgery before and after implementation of ROTEM. Another group proved in the setting of cardiac surgery an overall cost reduction of 44%.

The comparability of these finding to trauma surgery and Level I trauma patients with activated MTP or transfusion in trauma surgical patients in general is questionable due to the lack of larger qualifying and quantifying studies in this area.
Nevertheless, studies in general surgery, liver transplant, and cardiac surgery showed a reduction of costs between 6.5% and 44%.\(^\text{[17,20]}\)

Usually, the patient population and required tests are known, but who and how many people need to be trained to run the test appropriately and how to monitor their development; still unanswered. Who will hold the Clinical Laboratory Improvement Amendments (CLIA) license for the POCT program and which regulatory guidelines will apply? Last but not least and probably the most important is the question of quality assurance. Transfusion of large amounts of blood products could carry a risk of adverse effects including acute lung inflammation, infections, and increased mortality.\(^\text{[21,22]}\)

Additional challenge during implementation of TEG system is the fact that TEG-based cut-off values are not well validated and are arbitrarily assigned. Furthermore, cut-off values from obstetrics, liver transplant surgery, and cardiac catheterization or surgeries are not necessarily the same as for trauma patients. Accordingly, the developments of unique flowchart or protocol may need to be individualized. The clinical evidence of bleeding or oozing pre-, intra-, and postoperative should be used in accordance with the hospital-specific guidelines, including preexisting MTP, individual experience, and serial measurement of TEG. All these factors in combination with conservative laboratory parameters, including, for example, the usually taken platelet counts, body temperature, and pH status should guide the therapy of a present coagulation disorder.

The key element in implementing a new POCT protocol, independent of hospital or manufacturer requirements, is the “quality control” (QC) program. This may vary by institution, analytic, technology, and regulatory agency. However, at a minimum, the CLIA of 1988 (CLIA ’88).\(^\text{[23]}\) requires that QC should be performed on the day of patient testing. Nevertheless, the frequency of QC testing outlined by the regulatory agencies is the minimum amount of QC testing acceptable. Based on good laboratory practice, the volume of patient testing, experience of testing personnel, and confidence of the laboratory director, some hospitals may choose to perform QC testing more frequently, acknowledging that there will be an increase in the cost of reagents.

**Conclusion**

In patients with major trauma, brain injury, bleeding, sepsis, and coagulopathy are the most important determinants of the clinical course and outcomes. Viscoelastic whole-blood assays have already proved their values in cardiac as well as liver surgery. Therefore, this goal-directed management which has been since several years incorporated as a Grade I C recommendation in the latest edition of the European guideline on management of major bleeding and coagulopathy following trauma should be more frequently considered to be used as goal-directed therapy.\(^\text{[2,24]}\)

TEG is a promising tool in trauma patients with a patient compromised coagulation. However, further prospective research projects and well-trained personnel still warranted.

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**Conflicts of interest**

There are no conflicts of interest.

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