The Effectiveness of a Novel Software Program to Help in ROTEM Interpretation

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ROTEM interpretation among clinicians

Protocol Summary

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University of Utah IRB #:	IRB_00159279
Sponsor:	
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Background and Introduction

The evaluation and treatment of coagulopathy in the perioperative setting is critical to patient morbidity and mortality[1-5]. Historically, the coagulation cascade was evaluated with laboratory studies such as prothrombin time (PT), partial thromboplastin time (aPTT) and platelet count. However, viscoelastic tests such as thromboelastography (TEG®) and rotational thromboelastometry (ROTEM®) have allowed for more specific investigation into clot formation, firmness, strength and lysis[6]. Additionally, thromboelastography can help determine which type of blood product is deficient in this clot formation. This test is commonly used trauma and cardiac surgery [7], but also has applications in obstetrics[8], transplantation[9] and critical care[10]. Utilization of thromboelastometry has been shown in some studies to decrease costs[11] and some blood product administration[12].

Although thromboelastometry can offer valuable information, the biggest challenge of this technology is the ability of clinicians to correctly interpret the data. Especially those practitioners that do not utilize this technology on a regular basis. This may lead to improper administration of blood products which could worsen outcomes.

A novel software was developed at our institution to help clinical providers to interpret rotational thromboelastometry (ROTEM®). There are multiple other thromboelastometry guiding applications currently available including TEG2GO, TEM/TEG Guide, and TICapp, however none have these have been validated with ROTEM.

Hypothesis: Our hypothesis is that a novel software program will improve the accuracy of ROTEM interpretation amongst practicing clinicians with a range of experience in ROTEM interpretation. Furthermore, we hypothesize that diagnostic accuracy will improve more for inexperienced clinicians than those with extensive ROTEM experience.

Purpose and Objectives

The purpose of this study is to assess a novel rotational thromboelastometry (ROTEM®) interpretation software to determine whether its use improves the accuracy of clinician interpretation.

Study Population

Age of Participants: 18+

Sample Size:
At Utah:
All Centers: 100

Inclusion Criteria:
Current residents and attending physicians in the Department of Anesthesiology who have a range of experience and exposure to thromboelastography.

Exclusion Criteria:
Refusal to consent or no longer an active member of the Department of Anesthesiology.

Design

Prospective Biomedical Intervention or Experiment

Study Procedures

Recruitment/Participant Identification Process:
Participants within the Department of Anesthesiology will be sent a email describing the study and with the informed consent document as an attachment to the email. Imbedded in the email will be an individual link to an online survey. Participants will be informed that by clicking the link they have consented to participation in the study. The online survey will include questions on duration of practice, clinical subspecialty if any, duration of experience with ROTEM, and perceived expertise in ROTEM. The participants when then be shown a series of ROTEM images and asked to interpret them. This will be followed by a short tutorial on the novel interpretation application. Finally, the participants will be shown a second series of ROTEM images and asked to interpret them now with the use of the novel interpretation application.

The study team will continually review participant enrollment and the degree of experience of the participants. If there appears to be developing a selection biased towards a certain level of experience the study team will actively seek out and recruit potential participants within the Department of Anesthesiology either by sending a further emails, in person, or through advertisement at faculty meeting or other community events.

If a participant elects not to participate in the study, they may inform the study team and no further attempts at recruitment will be made. Information as to who does and who does not participate in the study will not be communicated to the Department Chair, Vice Chairs, or Residency Directors.

Informed Consent:

Description of location(s) where consent will be obtained:
Consent will be obtained by email. Resident and attending physicians in the Department of Anesthesiology will be recruited via email. The informed consent document will be attached to the email and participants will be informed that by clicking the link to the online survey, they are consenting to participate in the study.

Description of the consent process(es), including the timing of consent:
Consent will be obtained by email. Resident and attending physicians in the Department of Anesthesiology will be recruited via email. The informed consent document will be attached to the email and participants will be informed that by clicking the link to the online survey, they are consenting to participate in the study.

Procedures:

- Currently, ROTEM study results for each patient are printed and uploaded into the medical record.
- We will retrospectively review these ROTEM studies, de-identify them, and upload them to a database. This is covered under IRB 00096411
- An online survey will be developed using these de-identified images to test the ability of clinicians to correctly interpret ROTEM studies.
- Participants within the Department of Anesthesiology will be recruited by email with informed consent and a link to the survey.
- If the clinician participants consent to the study, they will open the link to the survey and will be asked a short series of questions on their clinical practice (years of training, type of clinical practice, and familiarity with ROTEM) and then shown 20 ROTEM images in random order.
- For each ROTEM image they will be asked to choose what intervention should be done (do nothing, give FFP, give platelets, etc...)
- After 20 images have been reviewed, an online version of the novel ROTEM App will be displayed in the survey and a brief tutorial will be given to demonstrate how to use it.
- The participant will then be shown 20 more study ROTEMs in random order and asked to interpret these studies in a manner similar to the beginning of the survey.
- Data will be recorded in RedCap
- A reference standard of correct responses will be created using the responses of two members of the study team who are known experts in ROTEM interpretation. This reference standard will be used to determine the sensitivity/specificity of clinician responses before and after the use of the App.

Procedures performed for research purposes only:

Statistical Methods, Data Analysis and Interpretation

The sensitivity/specificity and diagnostic accuracy of clinicians will be compared before and after the use of novel ROTEM app. The performance of more experienced clinicians will be

compared to those with little to no experience in ROTEM. Analysis will be done using a mixed effects model to account for clustering of measurements within clinician groups. Inter-rater reliability analysis will be done to assess the similarity within clinician groups using the ICC. The reference standard will be established using two cardiac anesthesiologists with specific expertise in ROTEM analysis. ICC will be used to characterize the inter-rater and intra-rater reliability of these experts to create the reference standard.