Utilization Trends of ROTEM Among Trauma Patients At a Level 1 Trauma Center

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Abstract

Background: Trauma-induced coagulopathy (TIC) is a complex process of dysfunctional and/or abnormal clot function occurring in up to 25% of patients presenting with severe bleeding as a result of acute trauma (Veigas et al., 2016). Recent literature reveals that ROTEM-based protocols or algorithms may be superior to traditional approaches aimed at managing severe bleeding and coagulopathy (Shaydakov & Blebea, 2019). The purpose of this retrospective chart review is to retrieve and analyze data regarding the use of ROTEM in relation to a ROTEM-based treatment algorithm and associated guidelines at Legacy Emanuel Medical Center (LEMC), a Level 1 Trauma Center. The overall goal of this project is to provide evidence leading to the optimization of ROTEM utilization among trauma patients.

Local Problem: Data relating to the utilization of ROTEM within the trauma department to include frequency, indications, resulting interventions, and compliance to guidelines has not been collected or analyzed.

Methods: A retrospective chart review was conducted for the period of June 1st to August 31st, 2019. A list of all trauma patients who had a ROTEM completed during their admission was complied. Primary measures were as follows: 1) location of the patient when ROTEM ordered, 2) presumed indication for ROTEM order, 3) abnormal result meeting threshold for intervention on facility ROTEM algorithm, 4) interventions indicated based on ROTEM result, 5) interventions actually employed based on ROTEM result, 6) compliance to facility guideline, and 7) frequency of repeat tests within the same admission.

Interventions: Designated data for each patient was categorically coded and entered into a final results table with applicable subsets included. Frequency distribution and percentages were calculated for each variable and subset. Data was subsequently analyzed.

Results: A total of 85 trauma patients, 9.4%, of all traumas, had a ROTEM ordered during the designated time frame. Of all level one traumas, 45.7% had at least one ROTEM completed. The ED was the most common location of the patient when the sample was obtained and designation of a level one trauma was the most common presumed indication for ordering. Of all 101 samples, 15 had an abnormal value meeting the threshold for intervention. The most common product administered was tranexamic acid (TXA). The most common product indicated by the algorithm was cryoprecipitate. The most frequently observed abnormality was EXTEM maximum clot firmness (MCF). Overall compliance to the ROTEM based treatment algorithm was 53.3%. Retests were completed on 17.6% of patients.

Conclusions: The most impactful data derived from this project was the poor compliance rate to hospital policy and ROTEM based treatment guidelines. While further research is needed at this institution to assess correlation with outcomes and financial implications, the presence of this baseline data set will be instrumental in influencing process improvement regarding ROTEM within the trauma department as well as within the facility.

Utilization Trends of ROTEM Among Trauma Patients At a Level 1 Trauma Center

Problem Description

Background. Trauma-induced coagulopathy (TIC) is a syndrome of disrupted clotting functions precipitated by massive tissue injury and a multitude of trauma-related abnormalities such as hypothermia, acidosis, and hypoperfusion (Veigas, et al., 2016). TIC is characterized by diffuse microvascular bleeding attributed to depleted coagulation factors in combination with an intrinsic, resuscitation-independent disequilibrium of clotting regulatory mechanisms. Ultimately, disruptions of anticoagulation, prothrombotic and fibrinolytic pathways, as well as abnormalities in endothelium and platelet function, may be present (Walsh, et al., 2016). The ensuing result is complicated resuscitation efforts, higher transfusion requirements, organ dysfunction and poorer outcomes, such as higher mortality rates (Veigas, et al., 2016).

TIC is detectable in an estimated 25-35% of patients presenting to the Emergency Department (ED) with severe traumatic injuries and/or hemorrhagic shock (Macdonald & Severn, 2017). Due to the multifactorial nature of TIC and complex clinical picture of trauma inpatients, the risk of or persistence of coagulopathy does not cease following initial resuscitation.

Prompt recognition of coagulopathies and persistent monitoring of patients experiencing/at risk for TIC is imperative as these patients may benefit from a more tailored approach to achieve hemostasis (Abdelfattah & Cripps, 2016). Conventional coagulation tests (CCTs) such as prothrombin time (PT), international normalized ratio (INR), activated partial thromboplastin time (aPTT) and fibrinogen may fail to provide

adequate diagnostic information regarding coagulopathies often present in the setting of traumatic injury (Shaydakov & Blebea, 2019). The unavailability of CCTs as point-of-care (POC) tests also deems their use in emergent situations limited due to delayed result time. Thromboelastography (TEG) and rotational thromboelastometry (ROTEM) are novel modalities that deliver a more comprehensive assessment of clot function and are available as point of care (POC) tests (Shaydakov & Blebea, 2019). TEG and ROTEM have been used extensively in the setting cardiovascular surgery to identify and treat coagulopathies. Comparatively, literature regarding diagnosis and treatment of coagulopathies in the trauma population is not as robust despite the clear potential for use in the trauma setting. However, at least one recent study has demonstrated the ability to effectively diagnose coagulopathy in this population (da Luz et al., 2014). Furthermore, studies evaluating the use of a TEG/ROTEM based algorithm to detect and treat coagulopathy in trauma patients are surfacing and have demonstrated improved outcomes.

Local Significance. Legacy Emanuel is a Level 1 Trauma Center and currently has ROTEM technology available. The current Trauma Program policy regarding specimen collection during a trauma (see Appendix A) requires a ROTEM be collected and processed on all traumas designated as level one. There is a ROTEM based treatment algorithm in place. This algorithm serves as a guide for interpretation of results and appropriate intervention. The algorithm is used in multiple areas of the hospital, encompassing a variety of services. Effectiveness of this protocol at guiding appropriate use, interpretation and ordering interventions based on these results has not been analyzed. Continued assessment of the protocol and utilization strategy is warranted to ensure ROTEM use optimization within the trauma department, as well as within the facility.

Available Knowledge

Case reports detailing successful use of TEG/ROTEM in the trauma population to detect and treat coagulopathies, guide resuscitation efforts and differentiate between surgical bleeding and coagulopathy are abundant. Unfortunately, randomized-controlled trials (RCTs) specific to the trauma population are limited. Studies specific to evaluation of outcomes related to implementation of a TEG/ROTEM based algorithm are available, however similarly infrequent.

One study was identified and deemed to be of particular relevance as it compares outcomes of a TEG/ROTEM based strategy with one using CCTs for massive transfusion in trauma patients. Results demonstrated an overall reduction in blood product administration and improved survival in the TEG/ROTEM algorithm group. Risk of bias and a small sample size were listed as limitations (Gonzalez et al., 2016). Also, Gonzalez et al.'s study did not compare the most common MTP in practice today (ratio-based) but rather a comparison to a similar strategy using CCTs, thus its generalizability is limited. A similar study also comparing a TEG/ROTEM algorithm to use of CCTs was published in 2019. It demonstrated a statistically significant reduction in the number of PRBCs, FFP, and platelets transfused in those treated with TEG/ROTEM as compared to CCTs, however, no statistically significant reduction in mortality, length of stay, or number of ICU days was revealed (Unruh, Reyes, Helmer, & Hahn, 2019).

A study evaluating the use of a ROTEM based algorithm for obstetric bleeding over a four year time period demonstrated improved morbidity indicators, improved mortality and a significant reduction in use of blood products with ROTEM guided correction of coagulopathy as oppose to standard ratio-based resuscitation (McNamara, Kenyon, Smith,

Mallaiah, & Barclay, 2019). This study presents one of the most convincing pieces of evidence in terms of superiority of a TEG/ROTEM algorithm to diagnose and treat coagulopathy in bleeding patients. Once again, generalizability to trauma patients is limited as this study was conducted in obstetric patients only.

One recent systematic review was conducted with the purpose of evaluating the effectiveness of TEG/ROTEM use for diagnosis of coagulopathy, transfusion guidance, and mortality outcomes among patients presenting with severe, traumatic bleeding (da Luz et al., 2014). This study included fifty-five articles, however, none were RCTs. Results indicated that TEG/ROTEM testing is able to diagnose early TIC and may predict transfusion requirements and mortality based on evidence from observational data (da Luz, et al., 2014). Another systematic review, conducted in 2016, produced similar results (Veigas, et al., 2016). This study was also specific to the trauma population and focused solely on ROTEM (as opposed to TEG). Thirteen observational studies met inclusion criteria. The study concluded that EXTEM and FIBTEM clot amplitude components as well as maximal clot firmness could effectively diagnose associated coagulopathy and predict transfusion needs as well as mortality. Both of these systematic reviews had limitations, namely the absence of RCTs. Also mentioned by the authors of both studies was a moderate risk of bias in some of the included studies.

Despite the relative absence of RCTs specific to trauma, a significant body of literature exists regarding TEG/ROTEM use in the cardiac surgery setting. Although this literature is not specific to trauma, its utility in monitoring and managing hemostasis in bleeding patients is relevant. Thus, its mention is justified in this review.

A systematic review evaluating the ability of TEG/ROTEM to monitor hemostatic treatment in bleeding was conducted in 2017 (Wikkelso et al.). This review included studies from a variety of clinical settings, primarily, cardiovascular surgery. Seventeen trials were included in this study, all RCTs. Results were promising in regards to reduction of overall mortality risk as well as reduction of the number of PRBCs, FFP, and platelets utilized in TEG/ROTEM based algorithms as opposed to comparison (Wikkelso et al., 2017).

Rationale

The evidence above strongly suggests that ROTEM has immense potential to effectively diagnosis and treat trauma-related coagulopathies with improved outcomes and reduced use of blood products. Although the absence of a trauma-specific best practice guideline regarding algorithm or protocol implementation is a hindrance, sufficient evidence exists to explore utilization of ROTEM based algorithm in this setting. The facility in which this project took place currently has a ROTEM interpretation algorithm in place (see Appendix B). The purpose of this algorithm is to serve as a guide for ROTEM interpretation and associated intervention. Data related to adherence to this algorithm has not been scrutinized. Furthermore, no data regarding frequency or consistency of ROTEM ordering has been analyzed at this particular facility. In order to determine how to optimize the use of ROTEM within the trauma department at this particular facility, a baseline for its current use must be established. Evaluating ROTEM ordering and intervention trends among providers in the trauma department will guide future process improvement aimed at ensuring optimization of ROTEM use.

Specific Aims

The overall goal of this project was to provide evidence leading to the optimization of ROTEM utilization among trauma patients. The first step of this process is to analyze current data and associated trends. There are several aims directed at accomplishing a thorough data analysis. Primary aims included 1) determining frequency of use in relation to clinical scenario and location, 2) determine which intervention(s) are employed most frequently based on results, and 3) measure compliance to the current guidelines. Particular attention was given to adherence to the current ROTEM ordering protocol among level one trauma patients and adherence to the treatment algorithm. Data derived from these variables will be used to inform future policy or guideline modifications.

Methods

Context

Legacy Emanuel Medical Center (LEMC) is one of two designated Level 1 Trauma Centers in the state of Oregon. The LEMC Trauma Program is verified by the American College of Surgeons in which maintenance of a robust trauma registry is required. The hospital has 554 beds, accommodates a variety of services, and averages more than 150 trauma visits per month (Legacy Health, 2020). This study was conducted via retrospective chart review. IRB approval was obtained from both LEMC and Oregon Health and Science University (OHSU)(STUDY 00021158) prior to start date. Data pertaining to any ROTEM ordered among patients entered into the adult trauma registry was retrieved and analyzed. A period of three months was studied, with dates from June 1st, 2019 to August 31st, 2019. This date range was chosen based on the higher volumes of trauma patients presenting to the Emergency Department (ED) during these months. One full quarter was selected as a timeframe to ensure an adequate representation of data was collected.

Intervention

All trauma patients who had a ROTEM completed, and were admitted during the designated time frame were identified. To accomplish this task, a list of patients who had ROTEM completed during the designated timeframe was cross-referenced with the trauma registry. There were no exclusion criteria for this project. All patients who met the above stipulations were included in data collection. This resulted in a total number of 85 patients. Some patients had multiple ROTEM tests completed, thus the number of samples matching this criteria totaled 101. Each patient's ROTEM result and corresponding electronic medical record (EMR) were analyzed to extract all relevant variables identified under the measures section.

This author was the sole researcher involved in this project, however, the project was well supported by staff from several areas of the hospital. Support provided by the LEMC trauma team providers and administrators, as well as laboratory staff, was integral in the data collection phase of this project as well as in oversight and guidance as needed.

Study of the Intervention

Designated data for each patient and sample was entered into a categorically organized excel spreadsheet. The coding system for each variable is described under measures. Frequency and percentages were subsequently calculated via excel or manual methods and entered into the results table, Table 1 (see Appendix C). Missing data was infrequent, however, also provided a code and accounted for within relevant calculations. All variables were presented independently. Many of these variables were separated into subsets for evaluation. No correlational analysis was performed as the goal of the project was to collect, organize, and quantify data for the purposes for quality improvement.

Measures

Specific measures were chosen based on recommendations from the LEMC trauma team, ease of access to data, and perceived impact the data may have on process improvement. Primary measures were as follows: 1) location of the patient when ROTEM ordered, 2) presumed indication for ROTEM order, 3) abnormal result meeting threshold for intervention on facility ROTEM algorithm, 4) interventions indicated based on ROTEM result, 5) interventions actually employed based on ROTEM result, 6) compliance to facility guideline, and 7) frequency of repeat tests within same admission.

Each of these measures was categorically arranged on Table 1 (see Appendix C) with the associated number and percentage of each specific category. All subsets were also presented with associated frequency and percentage. Additional data collected included trauma level indicator, age, and sex.

Location of the patient (measure one) was extracted from the laboratory ROTEM master list, which divulged location of the patient at the time of ROTEM collection and order. Categories were ED, Neuro-Trauma Intensive Care Unit (NTICU), surgery (operating room), and Trauma Recovery and Acute Care Unit (TRACU).

The indication for ROTEM order (measure two) is labeled “presumed”. This data point was inconsistently located in the EMR and educated medical opinion was utilized to determine why the ROTEM was ordered in certain circumstances. For all patients presenting as a level one trauma in which the ROTEM was ordered immediately, the presumed indication was labeled “Level 1”. The next category included scenarios in which a patient was pathologically bleeding. Most often this was evident in progress notes in which actual or suspected bleeding, without known cause, was being investigated. ROTEM

was frequently listed as an intervention under the assessment and plan portion of the physician notes. In a few instances, abnormally high INR, or the believed presence of anticoagulants in the patient's circulation, appeared to trigger ordering of a ROTEM. This cause was labeled "INR/AC" in the results table. The term "follow-up" was utilized for repeat samples drawn within 12 hours of the initial ROTEM. Clinical deterioration was used as a label in situations such as codes or other non-specific clinical events. The sixth category was "unclear" and accounted for instances in which a ROTEM was ordered and no discernable cause matching any other category could be determined.

For measure number three, all ordered ROTEM results were obtained from the lab results tab in the EMR in the form of a scanned document. EXTEM, INTEM, FIBTEM and APTEM assays were included in all ROTEM samples. Any abnormal result that also met the threshold for intervention on the facility ROTEM algorithm was recorded. Values for each were recorded in the data collection files only if they met the threshold for intervention based on the algorithm. Values that were outside of normal ranges but did not trigger an intervention were not tracked. Similarly, values outside of normal that are not included on the ROTEM algorithm were also not tracked. Table 1 (see Appendix C) presents a detailed list of all tracked values. These values were labeled with an I, E, F, or A (INTEM, EXTEM, FIBTEM, APTEM) followed by the associated abbreviation according to the ROTEM manufacturer. For example, EXTEM maximum clot firmness was labeled "E MCF" under the abnormal results column. Full definition of each abbreviation is listed in the Table 1 legend (see Appendix C).

Measures four and five pertain to interventions triggered and/or employed based on ROTEM results. If an abnormal ROTEM value indicated an intervention was warranted,

it was noted as a "yes" on the excel spreadsheet. The intervention indicated and intervention actually given was subsequently recorded. This allowed tracking of what products are most frequently indicated by ROTEM results, and which products are most frequently administered based on ROTEM results, as well as whether or not the intervention was consistent with the algorithm-based recommendation. Categories of products indicated or given include fibrinogen, cryoprecipitate, tranexamic acid (TXA), platelets, fresh frozen plasma (FFP), and prothrombin complex concentrate (PCC).

Compliance to the ROTEM-based algorithm comprises measure six. Compliance took into account whether there was an intervention completed when indicated and whether or not it was the correct intervention. Dosing of products was tracked however was not included in any of the presented results as each time an intervention was appropriately employed, the dosing was correct. Compliance was only tracked when an abnormal ROTEM result met the threshold for intervention on the algorithm.

The final variable measures the percentage of instances in which a ROTEM is completed during the patient's hospital course. This was extracted from the laboratory master ROTEM list and verified in the patient's EMR. Retest was counted each time ROTEM was repeated at least once during a patient's hospital stay. On two occasions, three ROTEM tests were completed; these were counted only once in the retest data.

The data outlined above was extracted methodically and consistently from each patient chart. Very little missing or unclear data was encountered, thus rendering a high level of data reliability. The exception to this is the "presumed indication" variable in which some degree of subjectivity exists.

Analysis

The primary analysis of this data involved solely descriptive statistical methods. No outcome data was recorded during the course of this project; the primary goal of the project was to establish baseline utilization of ROTEM among trauma patients, and measure adherence to protocol/guidelines.

Both qualitative and quantitative methods were used to analyze data. All variables were collected, organized, and categorized using a word document table and eventually an excel spreadsheet. Numerical calculations describe each variable and categorical subset of data in terms of frequency distribution and percentage. See Table 1 (Appendix C) for additional details.

A number of steps to were taken to ensure the accuracy of statistical data. Initially, review of data in the word table and excel spreadsheet were cross-referenced to ensure consistency. The original master reference of patients (with MRN) was also reviewed to ensure all patients and samples were accounted for following data collection. All variables and subsets were entered into the results table following data coding. Subsequently, numerical and percentage values were calculated by excel formulas as well as manually to ensure accuracy. Retrospective review of all data points to ensure harmony among numerical value and percentages in each subset was also completed. Visual representations of the data are included to aid in detecting variability in results (see Appendix C, Table 1).

Ethical Considerations

This research was retrospective in nature and utilized only patients' EMR. The potential for harm to patients was minimal. One master document containing each

patient's MRN and associated code was stored in accordance with HIPPA specifications on a LEMC password protected computer. The MRN and all other patient protected health information (PHI) were removed from all remaining documents. A word document and excel spreadsheet with the de-identified patient codes were utilized for data collection. No sensitive information was collected.

Results

A few minor adaptations to the initial data analysis were required. Initially, there was intent to measure both location of the patient when the test was ordered as well as what service ordered the ROTEM. Tracking which service the ordering provider originated from was deemed irrelevant due to the inconsistency of providers writing orders in patient charts during different times throughout the course of a trauma admission. Instead, this variable was cut to include only the physical location of the patient at the time the lab was drawn.

In terms of compliance, the original plan was to collect data regarding interventions employed based on results, whether these interventions matched protocol as well as when products were administered that were not indicated by ROTEM results. Unfortunately, tracking when products were administered that were not indicated proved to be exceptionally difficult. In the setting of Mass Transfusion Protocols (MTP), many products are administered regardless of ROTEM result or while ROTEM is being completed. Furthermore, ROTEM was often initially normal then not repeated when the MTP was called, and/or later in the ED course when TIC was demonstrated on repeat CCTs. Adding this data may have skewed compliance results, thus its tracking was aborted early on.

A total of 85 trauma patients, 9.4%, of all traumas, had a ROTEM ordered during the designated time frame. Of these, 69 (81.2%) were designated as level one traumas. These 69 patients represent 45.7% of all level one traumas from June 1st 2019 to August 31st, 2019. With inclusion of repeat testing, a total of 101 samples were processed.

Evaluation of measure one revealed that 72% of the samples were obtained in the ED. Samples sent from surgery accounted for 14.9% and samples from NTICU 11.9%. Only one sample (0.9%) was obtained while the patient was located in the TRACU.

In 64.4% of all samples, the presumptive clinical indication for the ROTEM order was designation as a level one trauma. Actual or suspected bleeding accounted for the next most predominant portion at 19.8%. Follow-up, abnormally high INR and/or presence of anticoagulants, clinical deterioration, and unclear made up the remaining 15.8% of indications.

Out of all 101 ROTEM samples, 15 (14.9%) had an abnormal value(s) significant enough to meet the threshold for intervention. The most frequently observed abnormal result meeting threshold for intervention, according to the facility ROTEM algorithm (Appendix B) was the FIBTEM maximum clot firmness (MCF), which accounted for 50% of abnormalities. Second most prevalent was the EXTEM maximum lysis (ML) (15%). EXTEM MCF, EXTEM clotting time (CT), INTEM CT, and FIBTEM amplitude at 10 minutes (A10) were the remaining abnormalities found in analysis of samples.

No product was administered when indicated by ROTEM algorithm 35% of the time. In the remaining 65%, at least one product(s) was administered when indicated. The correct product was administered 50% of these times.

Fibrinogen or cryoprecipitate were the products most frequently indicated by abnormal ROTEM results (55.6%) with TXA, FFP/PCC, and platelets making up smaller percentages. TXA was the product most frequently administered at 38.5%. Cryoprecipitate accounted for 23.1%. FFP/PCC and fibrinogen were also administered at lower percentages. The patient was taken to surgery on 2 occasions, accounting for 15.4% of interventions.

The overall rate of compliance to the ROTEM based algorithm was 53.3%. The appropriate action was taken based on results in 8 out of 15 instances. More than one ROTEM test was completed in 15 patients, 17.6%. A comprehensive results table detailing all subset numerical values and percentages is listed in Table 1 (see Appendix C).

No associations or correlation between variables were extrapolated as the goal of the project remained to establish data trends regarding utilization of ROTEM and measure compliance to the facility based guideline. There were no unintended consequences related to this project. Missing data was infrequent and associated only with the "presumed indication" variable. This data was coded as "unclear" and included in the calculations above.

Discussion

Summary

The first aim of this project was to establish trends related to ROTEM ordering. Results indicate that 9.4% of all traumas presenting in the designated timeframe had a ROTEM completed during their hospital stay. The Trauma Program policy regarding laboratory specimens to be collected for trauma patients on arrival specifies that all trauma patients designated as level one will have a ROTEM collected and sent to lab. Overall,

45.7% of level one traumas had a ROTEM completed. When level one transfers and ED direct designations are removed, thus isolating this percentage to only level one traumas arriving from the field, a negligible drop to 45.2% is observed. These percentages represent an under-utilization of ROTEM within the trauma population as well as a divergence from policy.

Despite the divergence from policy, the most frequent ordering indication remained designation as a level one trauma. The second most frequent presumed indication was actual or suspected bleeding, which carried a percentage of 19.8%. In the majority of these cases, a ROTEM was ordered to determine whether coagulopathy was contributing to pathologic bleeding. Based on ROTEM results, coagulopathy was corrected as indicated or intervention was pursued in the form of surgical intervention (OR, IR, drains etc.). Patients were located in a variety of physical settings when ROTEM was ordered for this particular indication. The variety of locations suggests providers across multiple services were utilizing ROTEM for diagnosing and treating coagulopathy. This list of services included Trauma Service providers, ED providers, and anesthesia providers. Although it was promising to observe a variety of providers using ROTEM, the overall utilization trend remained low. Variation in use among trauma providers due to differing levels of familiarization with ROTEM and skill in interpretation was likely a significant factor lending to low utilization rates. Another limiting factor to consider is the lack of POC testing at this facility. Specimens must be sent to lab for processing. A special program (separate from the EMR) is used to view results in real time as they populate. This reduces the time necessary to wait for results to be scanned into the EMR however remains a cumbersome approach to quickly obtain and interpret data. Perhaps availability of ROTEM

as a POC would enhance utilization during instances of clinical deterioration. In their systematic review of ROTEM and its use in diagnosis and treatment of TIC, Veigas et al. (2016) cites one of the most significant advantages of ROTEM is its availability as a POC test. Rapid results lead to earlier intervention and consequently, improved outcomes (Veigas, et al., 2016).

The second aim of this project involved determining how ROTEM results were being applied in the clinical setting. Based on data collected pertaining to abnormal values, FIBTEM MCF and EXTEM ML were the values most frequently warranting intervention with product administration. A low FIBTEM MCF relates to a deficit in fibrinogen; the corrective action is administration of fibrinogen (RiaSTAP) or cryoprecipitate. Appropriate action was taken in only 50% of cases. An extended EXTEM ML percentage represents hyperfibrinolysis, in which TXA is indicated. Interestingly, TXA was the most common employed intervention (38.5%), even though it was not the most frequently indicated. TXA was administered 100% of the time when indicated, however, was also administered in cases in which it was not indicated by ROTEM. Based on this data, it appears that using the ROTEM algorithm as a guide for administration of fibrinogen/cryoprecipitate and TXA would yield the highest efficacy.

Finally, a significant portion of effort was dedicated to measuring compliance with facility protocols and guidelines. As mentioned above, adherence to policy regarding specimen collection for level one traumas was 45.7%. This trend was also demonstrated in compliance to the ROTEM-based resuscitation algorithm with a rate of 53.3%. The rate of compliance was characterized by lack of intervention when indicated and also by administering a product not congruent with algorithm indication. Administration of

products when there was a lack of abnormalities meeting algorithm threshold was not tracked, however was observed throughout the course of data collection. Extraneous factors likely had a significant impact on this data. ROTEM represents only one piece of data. Administration of products may have been driven by abnormal CCT results, clinical condition/appearance of the patient, and/or the presence of contraindications. Advanced exploration into these factors is indicated in order to better understand this phenomena.

Interpretation

The results of this project have the potential to impact future facility-wide policy revision and standard of practice. No true best practice guideline has yet been published by an authoritative body in regards to ROTEM based treatment algorithms, however, substantive amounts of literature on the topic suggest numerous associated benefits (Shaydakov & Blebea, 2019). As a Level 1 Trauma Center, LEMC has the responsibility to remain on the forefront of emerging research and trends in order to uphold the state of Oregon's standard to provide the "highest level of definitive, comprehensive care to the injured adult with complex, multi-system trauma" (Oregon.gov, 2020). LEMC has ROTEM technology available and guidelines for use in place. The demonstrated ordering and compliance trends provide evidence that improvements to standard of care expectations and policy revisions may be warranted.

Results of this study were not unanticipated. To date, no data regarding ROTEM at LEMC has been collected or analyzed with the exception of this study. This project satisfies a significant need for organized data in order to drive quality improvement and optimize utilization of ROTEM technology within the trauma department.

Determining correlational associations between variables was not within the scope of the project design. Correlation to outcomes represents an important future need as well as the recommended next step.

No true inferences can be made regarding the compliance rate and cause for divergence. The Level 1 Trauma Policy (see Appendix A) includes a clause allowing for attending-directed cancellation of level one ROTEM order. This represents a factor likely involved, however, a more detailed study is required to make this, or other, correlations.

Further data analysis, correlation with outcomes, and root cause analysis of compliance rates may be necessary in order to implement policy change. Following these steps, changes to policy should be considered. The overall rate of compliance to existing facility guidelines warrants a recommendation for changes aimed at increasing compliance rates. Another suggestion, based on results of this project and current research, pertains to frequency of use. As outlined by Shaydakov & Blebea (2019), ROTEM has demonstrated efficacy in diagnosing coagulopathy as well as predicting transfusion needs. Future aims for policy change should explore the possibility of expanding ROTEM utilization in trauma patients. Finally, evidence supporting the use of ROTEM as a POC for rapid detection of coagulopathy, such as data presented by Veigas, et al. (2016), warrants consideration for adoption of POC testing within this facility.

Limitations

This project had several limitations. While the total number of analyzed samples was within the desirable range, the number of samples with abnormalities in values great enough to meet the threshold for intervention was low. Only 15 samples (14.9%) were considered abnormal. Drawing inferences from this data regarding abnormalities and

interventions employed based on this low number presents a threat to external validity. Data should be interpreted with caution.

Another limitation was the absence of data pertaining to interventions employed when not indicated by ROTEM algorithm. This data was not collected; its absence has been annotated in the above results section as well as in the description of the measures. Future data collection and analysis should include data pertaining to unwarranted interventions.

Values from ROTEM assays were recorded as "abnormal" for the purposes of this project only when they met the threshold for intervention as detailed in the algorithm. Obtaining a baseline regarding abnormal values that did not meet the threshold would assist in designing future algorithm modification, if warranted. To mitigate the risk of misinterpretation of values, the term "abnormal" was accompanied by a phrase pertaining to the algorithm throughout project materials for clarity.

Finally, in regards to measure two, some degree of subjectivity was required to classify the clinical indication for each ROTEM. This presents a risk of bias, warranting caution with interpretation.

Conclusion

Studies demonstrate that TIC is present in 25-35% of trauma patients within the initial phase following injury and may persist throughout hospitalization (Macdonald & Severn, 2017). Current research supports the use of ROTEM in the trauma population for the purposes of diagnosing coagulopathy and guiding transfusion needs (Shaydakov & Blebea, 2019). Although sparse, recent research has supported the use of ROTEM-based algorithms to guide correction of coagulopathy in trauma patients (Unruh, Reyes, Helmer, & Hahn, 2019).

This study was a retrospective chart review evaluating a number of primary measures at a Level 1 Trauma Center, where a ROTEM-based algorithm for use in trauma patients was in place. A specific time period of June 1st to August 31st, 2019 was selected.

The overall goal of this project was to provide evidence leading to the optimization of ROTEM use among trauma patients. The most impactful data derived from this project was the overall compliance rate to hospital policy and ROTEM based treatment guidelines (53.3%), suggesting that use of ROTEM at this facility was inconsistent and divergent from policy.

Several other data trends were established, and included information regarding frequency of ROTEM use, indication for ROTEM use, frequency of interventions based on ROTEM results, and frequency of retesting. While further research is needed at this institution to assess correlation with outcomes, the presence of this baseline data set will be instrumental in influencing process improvement regarding ROTEM within the trauma department as well as within the facility.

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Appendix A
Trauma Laboratory Policy

LEGACY HEALTH
PATIENT CARE
Procedure #: 910.4011
Origination Date: JUN 1994
Last Review Date: MAY 2018
SECTION: TRAUMA SERVICES
TITLE: LABORATORY DATA: INITIAL BASELINE LABS FOR TRAUMA PATIENTS
PURPOSE:
1. To obtain appropriate baseline laboratory data on trauma patients.

RESPONSIBLE STAFF:
Trauma Surgeon (TS) Trauma Resuscitation Nurse (TRN)
Trauma Resident Respiratory Therapist
Trauma Physician Assistant
PROCEDURE:
1. The TRN will draw and process the blood, label the specimens, and send to lab. The initial blood gas specimen is given to the respiratory therapist.

Level 1/Direct to OR – Adult (≥13 years)

Test	Tube Color
ABG/VBG/Lactate	Blood Gas Syringe or Grey
Basic Metabolic Panel	Green or Gold
CBC without Differential	Purple
ETOH Level	Green or Gold
Fibrinogen	Blue
PT/INR	Blue
ROTEM Baseline Panel	Blue**
Type and Cross	Purple
Urine Drug Screen	Urine Cup

Level 1/Direct to OR – Pediatric
(<13 years, use pediatric tubes when appropriate)

Test	Tube Color
ABG/VBG/Lactate*	Blood Gas Syringe or Grey
Basic Metabolic Panel	Green or Gold
CBC without Differential	Purple
Fibrinogen*	Blue
PT/INR*	Blue
ROTEM Baseline Panel*	Blue**
Type and Cross*	Purple

Level 2 – Adult (≥13 years)

Test	Tube Color
Basic Metabolic Panel	Green or Gold
CBC without Differential	Purple
ETOH Level	Green or Gold
Fibrinogen	Blue
Lactate/VBG	Grey or Blood Gas Syringe

PT/INR	Blue
Type and Screen	Purple
Urine Drug Screen	Urine Cup

Level 2 – Adult (≥13 years)

Test	Tube Color
Basic Metabolic Panel	Green or Gold
CBC without Differential	Purple
ETOH Level	Green or Gold
Fibrinogen	Blue
Lactate/VBG	Grey or Blood Gas Syringe
PT/INR	Blue
Type and Screen	Purple
Urine Drug Screen	Urine Cup

Level 2 – Pediatric
(<13 years, use pediatric tubes when appropriate)

Test	Tube Color
Basic Metabolic Panel	Green or Gold
Hematocrit	Purple
Type and Screen*	Purple

Special Considerations
Female of Child Bearing Age (15-44)

Test	Tube
HCG	Green or Gold
Kleihauer–Betke (if patient is known/confirmed as pregnant)	Purple

Suspected Cardiac Injury

Test	Tube
CPK	Green or Gold
Troponin	Green or Gold

Crush Injury

Test	Tube
Serum Myoglobin	Green or Gold
Urine Myoglobin	Urine Cup

*Test may be cancelled at the discretion of the Trauma Surgeon
** ROTEM sample must be sent in a separate tube

2. The initial ABG specimen will be given to the Respiratory Therapist who will analyze the specimen in the operating room stat lab. The results will be given to the Trauma Surgeon and recording nurse.
3. Urine Testing a. The TRN will obtain a urine specimen. 1) If a urinary catheter is inserted, a sterile specimen should be sent.

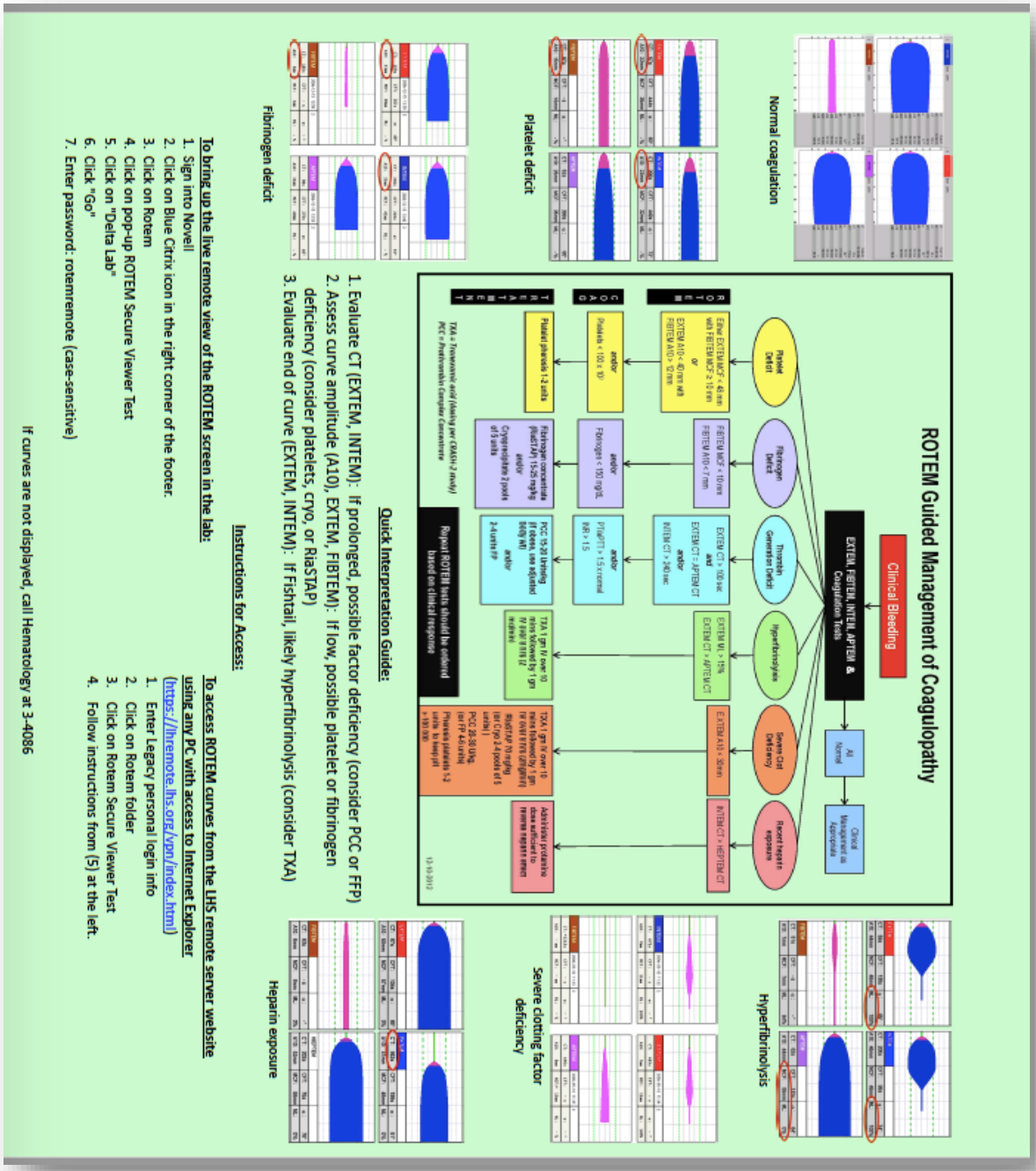
2) If a catheter is not inserted, a clean catch voided specimen is acceptable.

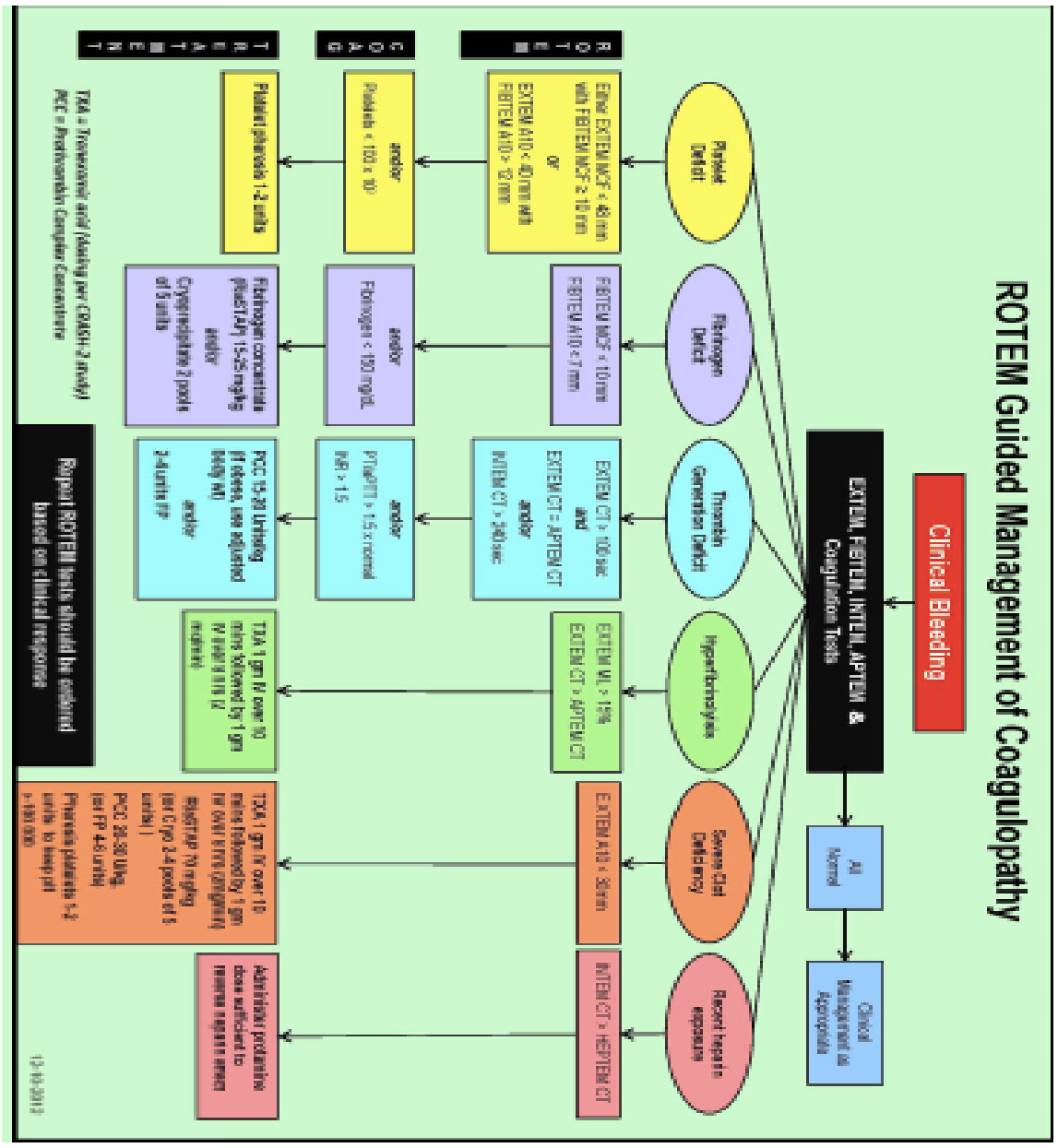
4. Order sets are available in Epic to facilitate ordering of the initial baseline labs for adults in trauma.

DOCUMENTATION:
1. The TRN will document in the medical record per Legacy Health documentation standards.

Key Words: Trauma, labs, specimens, blood, urine, tests
Approval: CSR
NEC
Medical Executive Committees
MQ&C
Originators: Trauma Services

Appendix B
ROTEM Algorithm




ROTEM Guided Management of Coagulopathy
Clinical Bleeding
EXTEM, FIBTEM, INTEM, APTEM & Coagulation Tests
All Normal
Clinical Management as Appropriate
Platelet Deficit
Fibrinogen Deficit
Thrombin Generation Deficit
Hyperfibrinolysis
Severe Clot Deficiency
Recent heparin exposure
ROTEM
Either EXTEM MCF < 49 mm with FIBTEM MCF ≥ 10 mm or EXTEM A10 < 40 mm with FIBTEM A10 > 12 mm
FIBTEM MCF < 10 mm FIBTEM A10 < 7 mm
EXTEM CT > 100 sec and EXTEM CT = APTEM CT and/or INTEM CT > 240 sec
EXTEM ML > 15% EXTEM CT = APTEM CT
EXTEM A10 < 35 mm
INTEM CT = HEPTEM CT
LOCOS
and/or Platelets < 100 x 10⁹
and/or Fibrinogen < 100 mg/dL
and/or PT/aPTT > 1.5 x normal INR > 1.5
TREATMENT
Platelet pheresis 1-2 units
Fibrinogen concentrate (RiaSTAP) 15-25 mg/kg and/or Cryoprecipitate 2 pools of 5 units
PCC 15-30 U/kg (if obese, use adjusted body wt) and/or 2-4 units FP
TXA 1 gm IV over 10 mins followed by 1 gm IV over 8 hrs (if indicated)
TXA 1 gm IV over 10 mins followed by 1 gm IV over 8 hrs (if indicated) RiaSTAP 50 mg/kg (last Cryo 2-4 pools of 5 units) PCC 25-50 U/kg (last FP 4-6 units) Platelets 1-2 units to keep pH > 100 000
Administer protamine dose sufficient to reverse heparin effect
Repeat ROTEM tests should be ordered based on clinical response
TXA = Tranexamic acid (dosing per CRASH-2 study)
PCC = Prothrombin Complex Concentrate

Appendix C
Comprehensive Results

Table 1

Results of data analysis

VARIABLE	TOTAL NUMBER	PERCENTAGE
TRAUMA PATIENTS WITH ROTEM COMPLETED	**85**	**9.4%** *905 total trauma patients
TOTAL NUMBER OF SAMPLES (INCLUDING RETESTS)	**101**	**NA**
FIELD LEVEL 1 PTS WITH ROTEM COMPLETED	**56**	**45.2%** *124 F1
TOTAL LEVEL 1 PTS WITH ROTEM COMPLETED	**69**	**45.7%** *151 Level 1
TRAUMA TYPE	**85 (PATIENTS)**	
• **F1**	56	65.9%
• **TX1**	11	12.9%
• **F2**	10	11.7%
• **TX2**	4	4.7%
• **C**	2	2.4%
• **ED1**	2	2.4%
• **ED2**	0	0%
LOCATION	**101 (SAMPLES)**	
• **ED**	73	72.3%
• **SURGERY**	15	14.9%
• **NTICU**	12	11.9%
• **TRACU**	1	0.9%
CLINICAL INDICATION	**101 (SAMPLES)**	
• **LEVEL 1**	65	64.4%
• **BLEEDING**	20	19.8%
• **FOLLOW-UP**	5	5%
• **INR/AC**	4	4%
• **UNCLEAR**	4	4%
• **CLINICAL DETERIORATION**	3	3%
NUMBER OF ABNORMAL ROTEM TESTS ***abnormal = meets threshold for intervention** ***may be more than one abnormality per test**	**15**	**14.9%** *of total samples

RESULT TRIGGERING INTERVENTION VIA ALGORITHM	**20** *some samples with multiple abnormal values (included)	**NA****
• **F MCF**	10	50%
• **E ML**	3	15%
• **E MCF**	2	10%
• **E CT**	2	10%
• **I CT**	2	10%
• **F A10**	1	5%
INTERVENTION COMPLETED BASED ON ROTEM RESULT	**13** *multiple interventions on two samples	**65%** *intervention completed when triggered
• **TXA**	5	38.5%
• **CRYOPRECIPITATE**	3	23.1%
• **FFP OR PCC**	2	15.4%
• **SURGERY**	2	15.4%
• **FIBRINOGEN**	1	7.7%
• **PLATELETS**	0	0%
NUMBER OF INSTANCES ROTEM TRIGGERED INTERVENTION THAT WAS *NOT* COMPLETED	**7**	**35%**
• **FIBRINOGEN OR CRYOPRECIPITATE**	5	71.4%
• **PLATELETS**	2	28.6%
PRODUCT INDICATED	**18**	**NA****
• **FIBRINOGEN OR** • **CRYOPRECIPITATE**	10	55.6%
• **TXA**	4	22.2%
• **FFP OR FFP**	2	11.1%
• **PLATELETS**	2	11.1%
INSTANCES PRODUCT (BELOW) MATCHED ALGORITHM	**9**	**50%**
• **FIBRINOGEN OR CRYOPRECIPITATE**	4	44.4%
• **TXA**	3	33.3%
• **FFP OR PCC**	2	22.2%
INSTANCES PRODUCT DID NOT MEET ALGORITHM	**9**	**50%**
• **NO INTERVENTION**	7	77.8%
• **DIFFERING INTERVENTION**	2 *TXA	22.2%

CONSISTENCY WITH GUIDELINE	**8** *number of abnormal samples in which appropriate actions were taken	**53.3%** *8/15 (total number of abnormal samples)
AT LEAST ONE RETEST DURING HOSPITAL STAY	**15**	**17.6%**

Note: For NA**: not relevant as they may include multiple abnormal values/products on the same sample. F1= Level 1 from the field. TX1= Level 1 transferred from outside hospital (OSH). F2= Level 2 from the Field. TX2= Level 2 transferred from OSH. C= trauma consulted. ED1= Level 1 called from emergency department. ED2= Level 2 called from emergency department. ED= emergency department. NTICU= neuro-trauma intensive care unit. TRACU= trauma recovery and acute care unit. F MCF= FIBTEM maximum clot firmness. E ML= EXTEM maximum lysis. E MCF= EXTEM maximum clot firmness. E CT= EXTEM clotting time. I CT= INTEM clotting time. F A10= FIBTEM clot amplitude at 10 minutes. TXA= tranexamic acid. FFP= fresh frozen plasma. PCC= prothrombin complex concentrate.