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Viscoelastic Monitoring in Major Hepatic Surgery: An Evidence-Based Practice Project

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DNP Final Scholarly Project Team:

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Abstract

Patients undergoing major hepatic surgery are at high risk for intraoperative transfusion of allogenic blood products. These patients are at increased risk due to pre-existing hepatic pathology, surgical stress, and the complexity of surgical procedures. While blood product transfusion may be necessary to support hemostasis and hemodynamics, it is not without risk. Current literature states that viscoelastic monitoring is superior to traditional laboratory values when guiding transfusion during major hepatic surgery. Viscoelastic monitoring is a term used to describe the measurement of change in viscoelastic properties of whole blood during clot formation. There are two readily available point-of-care types – thromboelastography (TEG) and rotational thromboelastometry (ROTEM). For the purpose of this project, ROTEM will be referred to as viscoelastic monitoring. Although the literature supports the use of viscoelastic monitoring during major hepatic surgery, some facilities' guidelines and policies may not be up-to-date with the most current evidence. The lack of an evidence-based approach to standardize transfusion utilization may lead to misinterpretation of viscoelastic monitoring, which may result in over- or under-resuscitation. This Doctor of Nursing Practice (DNP) project aims to develop an evidence-based practice guideline, utilizing the Rosswurm and Larrabee conceptual model, to assess a need for change, identify gaps in practice, implement the guideline, and evaluate the outcome. Successful implementation and dissemination of this DNP project could lead to changes in the standard of practice, hospital policy, or a revision of current guidelines. The work of this DNP project will be limited to the perioperative setting. Further scholarly work can explore the utility of viscoelastic monitoring in the pre-and postoperative settings.

Keywords: viscoelastic monitoring, major hepatic surgery, coagulation guidelines, transfusion

Introduction

Intraoperative complications from major hepatic surgery are largely due to coagulopathy. Intraoperative coagulopathy consists of many causes, including active hepatic pathophysiology, surgical manipulation resulting in the release of inflammatory mediators, anesthetics, dilutional thrombocytopenia, and dilutional coagulopathy (Oo et al., 2020). Primary hemostasis, coagulation, and fibrinolysis are altered by hepatic disease (Clevenger & Mallett, 2014). Patients are monitored intraoperatively by viscoelastic tests including thromboelastography (TEG) and rotational thromboelastometry (ROTEM). Point-of-care viscoelastic monitoring provides the anesthetist with a comprehensive and real-time assessment of the coagulation process (Clevenger & Mallett, 2014). Centers with limited access to viscoelastic monitoring utilize traditional laboratory testing such as partial thromboplastin clotting time (PTT), activated partial thromboplastin clotting time (aPTT), international normalized ratio (INR) fibrinogen, and platelet count.

Patients undergoing major hepatic surgery are also at significant risk for major bleeding causing intravascular volume shifts and hemodynamic instability. If not detected and assessed early by the surgeon and anesthetist, major bleeding will likely result in allogenic blood product transfusion to replace volume, oxygen-carrying capacity, and depleted coagulation factors. The use of viscoelastic monitoring in conjunction with pharmacologic agents and targeted coagulation replacement to strengthen clots and replenish coagulation factors may decrease the risk of major bleeding or even prevent intraoperative allogenic blood transfusion (Mpaili et al., 2021).

Background

Significance of the Problem to Nurse Anesthesia

Anesthesia providers drive the patient's physiology intraoperatively. They are ultimately responsible for the transfusion and management of blood products. The transfusion of allogeneic blood products during major hepatic surgery, such as lobe resection and transplant is associated with increased morbidity and mortality (Yokoyama et al., 2019). Although intraoperative transfusions may be necessary to support hemodynamics, increase oxygen delivery, and improve hemostasis, transfusion is not without risk. These risks include transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO), hepatic artery thrombosis, acute right ventricular failure, and increased risk of infection (Yokoyama et al., 2019). These complications are acute, life-threatening, and require expert intervention from the anesthetist. To reduce the incidence of complications associated with intraoperative transfusion, the need for transfusion must be mitigated. Alterations in hemostatic balance during hepatic surgery are difficult to predict (Mpaili et al., 2021). Removal of large segments of the liver, decreased hepatic production of clotting factors, vascular clamping, and hemorrhage often lead to major transfusion and a hypocoagulable state (Mpaili et al., 2021). Extensive tissue trauma related to surgical manipulation and reduced synthesis of endogenous anticoagulants can result in a hypercoagulable state (Mpaili et al., 2021). The implementation of viscoelastic monitoring, such as ROTEM and TEG, allows the anesthetist to interpret real-time assessment of clot development, stability, and fibrinolysis (Mpaili et al., 2021). In combination with a vigilant anesthetist, these monitoring systems can reduce intraoperative transfusions and tailor the blood product administration to the patient's physiological needs.

Major Hepatic Surgery

The classification of major hepatic surgery has changed over time as surgical techniques have improved. Morris-Stiff et al. (2016) challenged the current classification of major hepatic resection as the removal of three or more lobes. Hepatic resection, and hepatic surgery in general, have seen significant improvements since the first hepatic resection in 1888 (Morris-Stiff et al., 2016). After the global acceptance of the 1993 Couinaud classification of segmental hepatic anatomy, major resection was classified as three or more segments (Morris-Stiff et al., 2016). A right hemi-hepatectomy involves more segments being excised, but it is far less technically complex than a left trisectionectomy, in which morbidity is known to be considerably greater (Morris-Stiff et al., 2016). Although this classification standardized differentiation between minor and major surgery, it did not account for surgical complexity.

One of the most notable types of major hepatic surgery is orthotopic liver transplantation. Liver transplantation is classified as major hepatic surgery due to patients' complex physiology profiles, multi-system organ dysfunction, and sophisticated hemodynamic and coagulation monitoring (Brezeanu et al., 2020). Liver transplantation is the treatment of choice for end-stage liver disease, which presents with a myriad of physiological derangements (Brezeanu et al., 2020). There are three phases during liver transplantation: the pre-anhepatic phase, the anhepatic phase, and the neo-hepatic phase. The pre-anhepatic phase and the neo-hepatic phases are the two most applicable to this project. The pre-anhepatic phase is defined as the time from skin incision to clamping of the inferior vena cava (IVC), portal vein (PV), and hepatic artery (HA) (Brezeanu et al., 2020). As the liver is being dissected, there is a significant risk of bleeding due to liver failure-induced coagulopathy, dilutional coagulopathy, and bradykinin and prostaglandin

release caused by surgical stress (Brezeanu et al., 2020). The neo-hepatic phase begins at the moment of reperfusion, which can be complicated by post-reperfusion syndrome (PRS) and bleeding from vascular anastomosis of the IVC, HA, and PV (Brezeanu et al., 2020). If blood coagulation status is not monitored closely during these phases of surgery, there is a significant risk of intraoperative mortality (Brezeanu et al., 2020). Liver transplantation requires vigilance and skill from both anesthesia and surgical providers.

Coagulopathy During Hepatic Surgery

End-stage liver disease is associated with many physiological derangements. The most notable of these is coagulopathy due to the imbalance of clotting and bleeding. The liver produces both procoagulant and anticoagulant factors (Forkin et al., 2018). Procoagulants produced by the liver include factors II, V, VII, VIII, X, XI, XII, XIII, and fibrinogen (Brezeanu et al., 2020). Anticoagulants produced by the liver include antithrombin, protein C, and protein S (Forkin et al., 2018). End-stage liver disease impairs the liver's ability to produce these factors, leading to a complex coagulation profile that requires vigilant monitoring by expert providers (Forkin et al., 2018).

Under normal physiologic conditions, platelet aggregation is stimulated by the exposure of von Willebrand Factor (vWF) to damaged vascular endothelium (Forkin et al., 2018). This exposure stimulates the release of adenosine diphosphate and thromboxane A_2 resulting in platelet aggregation (Forkin et al., 2018). Activation of the coagulation cascade leads to the formation of thrombin which converts fibrinogen to fibrin which cross-links to form a mesh barrier over the platelet plug (Forkin et al., 2018). End-stage liver disease resulting in portal hypertension causes congestive splenomegaly that contributes to a quantitative platelet deficiency (Forkin et al., 2018). Cirrhosis increases the production of nitric oxide and

prostacyclin, which are normally released by intact endothelium to prevent platelet aggregation in uninjured vasculature (Forkin et al., 2018). This phenomenon compounds decreased platelet counts with dysfunctional platelet aggregation to further impair coagulation.

Fibrinogen, as previously stated, is an important protein in coagulation and platelet plug stability that is primarily produced in hepatocytes (Forkin et al., 2018). Patients with end-stage liver disease typically present with a reduced amount of fibrinogen (Forkin et al., 2018). Those with cirrhosis and acute live failure have even been shown to have impaired function of the fibrinogen levels that they do have (Forkin et al., 2018). Dysfibrinogenemia is likely attributed to an increase of sialic acid residue on fibrinogen molecules which impairs fibrin polymerization and clot stabilization (Forkin et al., 2018).

The final phase of the coagulation cascade is the dissolution of the clot, known as fibrinolysis. Fibrinolysis relies on the conversion of plasminogen to plasmin by factor XIIa, tissue plasminogen activator (tPA), and urokinase plasminogen activator, which degrades the fibrin mesh and dissolves the clot (Forkin et al., 2018). These activators and inhibitors of fibrinolysis are dysfunctional in end-stage liver disease, which contributes to dysfunctional platelet aggregation, hyperfibrinolysis, and an increased risk of clinically significant bleeding in the intraoperative setting (Forkin et al., 2018). Conversely, the prevention of fibrinolysis is dependent upon thrombin-activatable fibrinolysis inhibitor (TAFI) (Forkin et al., 2018). TAFI levels are typically decreased in end-stage liver disease in proportion to the disease progression due to the liver's eventual inability to adequately synthesize TAFI (Forkin et al., 2018).

Traditional Coagulation Testing

Traditional coagulation tests such as PT, aPTT, and INR have been used as laboratory markers for coagulation status for decades. While they are commonly used, relatively

inexpensive, and less complex, they do not provide a dynamic assessment of coagulation status (Adhikary et al., 2014).

The PT reflects the integrity of the extrinsic and common coagulation pathways by measuring the time taken by the citrated platelet-poor plasma to form a clot in the presence of sufficient concentration of calcium and tissue thromboplastin (Adhikary et al., 2014). The INR was introduced to standardize the PT, as thromboplastin test reagents differ in sensitivity and different laboratories use different reagents (Adhikary et al., 2014).

The aPTT measures the classic intrinsic and common pathways of hemostasis (Adhikary et al., 2014). A sample of plasma is mixed with phospholipid, calcium and a contact activator and the time required for a clot to form is measured in seconds (Adhikary et al., 2014).

Traditional coagulation tests do provide anesthesia providers with important information during major hepatic surgery. Unfortunately, blood samples must be drawn from the patient and then transported to laboratory for testing which requires time. During major hepatic surgery, hemostatic profiles change quickly and traditional tests will be inaccurate by the time they result.

Traditional tests are also skewed by hepatic pathologies and do not provide accurate coagulation assessments (Adhikary et al., 2014). Traditional tests are not able to discriminate between hyper- and hypocoagulability and do not allow for patient-specific transfusions intraoperatively (Mallett, 2015). Traditional coagulation tests should only be used as a last-resort during major hepatic surgery and should not be included in current perioperative guidelines (Oo et al., 2020). Traditional coagulations tests are inferior to viscoelastic monitoring and do not assist anesthesia providers in guiding surgical resuscitation.

Intraoperative Viscoelastic Monitoring

Despite advances in surgical technique and intraoperative hemorrhage, the need for blood transfusions and complex coagulopathy associated with major hepatic surgery still pose a problem for hepatobiliary surgeons and anesthetists. The recent implementation of viscoelastic testing, such as TEG and ROTEM, can help in determining hypo versus hypercoagulable states more accurately than the traditional tests such as INR, PT, aPTT, platelet count, and fibrinogen concentration (Mpaili et al., 2021).

Mallett (2015) assessed the utility of viscoelastic monitoring, both TEG and ROTEM, in patients with liver disease undergoing liver transplantation and their superiority over conventional testing (PT/INR, platelet count, and fibrinogen. Mallett (2015) found that the correlation between PT/INR and reaction and reaction/clotting time (R/CT) on ROTEM is poor. The lack of correlation between PT/INR and R/CT may be explained by several factors. These factors include different activators, specimens (whole blood vs. plasma), and the fact that R/CT, unlike INR, reflects the balance of both pro- and anticoagulant factors (Mallett, 2015). Clot strength is a reflection of platelet-fibrinogen interaction and plug formation (Mallett, 2015). Therefore, adequate clot strength can be achieved even in the presence of a low platelet count (Mallett, 2015). ROTEM is influenced by both fibrinogen levels and platelet count, therefore, making it a more accurate analysis of platelet activity (Mallett, 2015). The Clauss method for the determination of fibrinogen level is the gold standard (Mallett, 2015). Both TEG and ROTEM have assays for monitoring fibrinogen levels and these tests correlate well with the Clauss fibrinogen method (Mallett, 2015).

Viscoelastic Monitoring Effect on Transfusion

Both TEG and ROTEM are superior in assessment of coagulation status and in guiding resuscitation. TEG and ROTEM assess the viscoelastic properties of whole blood, giving a targeted assessment of hemostatic function that encompasses the entire lifespan of clot formation (Clevenger & Mallett, 2014). Since TEG and ROTEM describe the strength and kinetics of clot formation in real-time, transfusion and coagulation management algorithms based on TEG/ROTEM reduce transfusion requirements by differentiating between micro-vascular and surgical bleeding and enabling hemostatic therapy to be tailored to the patient's physiology (Clevenger & Mallett, 2014). Mpaili et al. (2021) also reviewed a small randomized prospective study in liver transplant patients that showed a significant reduction in transfusion in the TEG monitored group versus the conventional testing group, especially in the use of FFP. The trigger threshold for FFP was reached more frequently using INR values compared to R values on TEG (Mpaili et al., 2021). Since both TEG and ROTEM can be run as point-of-care tests in the operating room, transfusion titrations can be made in real-time without the delay of traditional laboratory testing and overall reduce the volume of product transfused (De Pietri et al., 2016).

PICO(T)

In patients undergoing major hepatic surgery (P) would the development and implementation of intraoperative evidence-based practice coagulation guidelines specific to viscoelastic monitoring (I) versus traditional coagulation testing (C) affect blood product utilization management (O) intraoperatively (T)?

Objectives

A project framework to address the need for use of viscoelastic monitoring during major hepatic surgery at the facility of interest. The objectives for this project are as follows:

- Develop evidence-based practice viscoelastic monitoring guidelines for the management of intraoperative coagulation and transfusion management in patients undergoing major hepatic surgery.
- Determine whether current practice standards are in line with evidence-based guidelines.
- Develop a comprehensive plan to implement evidence-based practice guidelines.
- Develop a comprehensive plan on how to adjust guidelines if the outcomes of transfusion management are less than desirable.
- Evaluate the success of the implementation and decide whether to integrate the change into the standard of practice.

Literature Review

Literature Search

A PICOT question directed the literature search for this project. The five components of the PICOT question include population (P), intervention (I), comparison (C), outcome (O), and time (T). The PICOT question for this project is as follows: In patients undergoing major hepatic surgery (P) would the development and implementation of intraoperative evidence-based practice coagulation guidelines (I) versus the traditional approach (C) decrease blood product transfusion (O) intraoperatively (T)?

Databases searched included Cochrane Library, CINAHL (EBSCO), PubMed, and Medline. Search terms included: *hepatic surgery, liver resection, liver transplant, coagulopathy, viscoelastic monitoring, intraoperative resuscitation, coagulation guidelines, hemostatic profile, transfusion, transfusion management, risk factors, and MELD score*. Inclusion and exclusion criteria included: timeline (2014-present), patient population (intraoperative), accessibility to full text, English language, and medical journals. This analysis yielded five studies of varying levels

of evidence and methods which were further analyzed by a literature synthesis table (Appendix A).

Literature Review and Synthesis

The literature search yielded 21 articles that were further analyzed for relevancy to the project topic. This analysis narrowed down the 21 articles to five studies of varying levels of evidence and study methods. The relevant articles chosen for analysis and use for this project included two systematic reviews (Clevenger & Mallett, 2014 and Mpaili et al., 2021), one prospective observational study (Lloyd-Donald et al., 2020), one retrospective observational study (De Pietri et al., 2016) and one evidence-based research article (Forkin et al., 2018). Each article compares the use of viscoelastic monitoring to traditional laboratory testing in the assessment of coagulopathy during major hepatic surgery or in the setting of significant hepatic pathophysiology.

One major theme among the selected articles is that viscoelastic monitoring is quick, accurate, and safe to use (Clevenger & Mallett, 2014; Forkin et al., 2018; Mpaili et al., 2021; Lloyd-Donald et al., 2020; & De Pietri et al., 2016). A barrier to implementation of viscoelastic monitoring described in the literature is the culture of traditionalism in medicine and surgery (Adhikary et al., 2014). This simply means that providers that did not begin their training using viscoelastic monitoring are less likely to implement viscoelastic monitoring because they are wary of change and believe that traditional coagulation testing will still be just as accurate (Bedawy et al., 2012). Clevenger & Mallett (2014), Forkin et al. (2018), Mpaili et al. (2021), Lloyd-Donald et al. (2020), and De Pietri et al. (2016) all conclude that viscoelastic monitoring is superior to traditional coagulation testing. Viscoelastic monitoring can be used point-of-care, provides dynamic assessment of clot strength, and their assays have been CE marked,

International Organization for Standardization (ISO) certified, and approved by the Food and Drug Administration (FDA) (Lloyd-Donald et al., 2020).

In the literature, the impact viscoelastic monitoring has on the reduction of intraoperative allogenic blood transfusion is significant (Clevenger & Mallett, 2014; Forkin et al., 2018; Mpaili et al., 2021; Lloyd-Donald et al., 2020; & De Pietri et al., 2016). During major hepatic surgery there is a significant risk for bleeding due to underlying hepatic pathophysiology and the invasiveness of the procedure. Due to this, allogenic blood transfusions may be necessary. Allogenic blood transfusions are the appropriate treatment for surgical blood loss, but they are not without risk. Clevenger & Mallett (2014), Forkin et al. (2018), Mpaili et al. (2021), Lloyd-Donald et al. (2020), & De Pietri et al. (2016) all show that the use of traditional coagulation testing puts patients at higher risk for allogenic blood transfusion and increased depletion of blood bank storages.

A common conclusion found in the literature is the ease of use of viscoelastic monitoring compared to that of traditional coagulation tests (Clevenger & Mallett, 2014; Forkin et al., 2018; Mpaili et al., 2021; Lloyd-Donald et al., 2020; and De Pietri et al., 2016). Viscoelastic monitoring samples can be drawn from the patient in the OR, placed in the point-of-care analyzer, and the results are obtained as soon as the sample analysis has completed. Traditional coagulation tests require the samples be sent to a laboratory and then results are verbally communicated or updated in the electronic medical record (EMR). Reduction in workflow saves time, resources, and improves efficiency (Clevenger & Mallett, 2014; Forkin et al., 2018; Mpaili et al., 2021; Lloyd-Donald et al., 2020; and De Pietri et al., 2016).

Evidence-Based Practice Model

This project will use the Rosswurm and Larrabee (1999) conceptual model to create change and improve patient outcomes. The purpose of the model is to guide healthcare professionals through a systematic process to implement evidence-based practice (Rosswurm & Larrabee, 1999). The six steps of this model will be applied to this project.

Step 1: Assess the need for change in practice by comparing internal data with external data.

The first step sets the foundation for the purpose of the project. This includes identifying the problem, identifying stakeholders, collecting internal data about the current practice, and comparing the internal data with external data. Identifying the stakeholders will aid in the beginning of a needs assessment which will help determine the guidelines that will make the implementation of the project successful. Development of the PICO(T) question narrowed the literature search and review. Synthesis of this data determined interventions that can create evidence-based change.

Step 2: Link the problem with interventions and outcomes.

The second step required that a problem had been identified so that the selected outcome indicators may be observed with the implementation of the new guidelines.

Step 3: Synthesize best evidence.

A literature search and review will be conducted using the developed PICO(T) question. Review of the evidence related to major variables will be critiqued to assess the feasibility, benefits, and risks of the implementation of the new guidelines.

Step 4: Design a practice change.

The review of literature lead to the development of the evidence-based guidelines that will be implemented. For this DNP project, the practice change is the use of the proposed evidence-based intraoperative viscoelastic monitoring and coagulation guidelines will reduce or negate the need for blood product transfusion intraoperatively for patients undergoing major hepatic surgery.

Step 5: Implement and evaluate the change in practice.

The implementation of the evidence-based guidelines will be more successful if the coordinator is available to closely monitor the process and be available to staff to answer questions. After the guidelines have been in practice for the designated time, the outcomes will be assessed to evaluate the effectiveness of the guidelines. Evaluation of the effectiveness of the guidelines allows the stakeholders to determine if they will adopt, adapt, or reject the guidelines.

Step 6: Integrate and maintain change in practice.

In-service education will be held to inform relevant staff members on changes to practice. The change in practice can then be integrated into standards of care or organizational policy and procedures within the facility. Further monitoring of the change in practice will determine long-term feasibility and effectiveness.

Methods

Setting

The setting for this project is a theoretical level 1 trauma inpatient hospital in the Midwest United States. The theoretical facility already contains the staff, equipment, resources, and infrastructure to implement the proposed guideline. Patients undergoing major hepatic surgery are the primary population. Major hepatic surgery is defined as resection of three or

more lobes, left trisectionectomy, and liver transplantation. Anesthesiologists and CRNAs will be providing anesthetic care through the perioperative period.

Project Implementation

Step 1

The first step is to assess the need for change. This will be done by obtaining the facility's internal data and comparing it to external data. Internal data cannot be collected without stakeholders' assistance and buy-in; therefore, lines of communication must remain open. Key stakeholders that will be vital in collection of data include leaders of the anesthesia department, leaders of the general surgery department, and leaders of transfusion services. Stakeholders that will assist in the development of transfusion and laboratory order sets and review of the guideline will be leaders of the anesthesia department, leaders of transfusion services, leaders of laboratory services, and information technology (IT) associated with the electronic medical record system. Other stakeholders that will assist in the implementation will include individuals in the legal, billing, biomedical engineering, and technical support departments.

Step 2

The clinical problem is coagulopathy associated with patients undergoing major hepatic surgery. The project team leaders and stakeholders will use a gap analysis tool to evaluate if the facility's standard of practice is aligned with current practice recommendations stated in the literature. If the current practice does not meet the standards of best practice, then interventions will be better identified.

A gap analysis tool adopted from the U.S. Department of Health and Human Services Agency for Healthcare Research and Quality will be utilized to compare current practice with stated evidence-based practice.

Table 1

Gap Analysis Tool (U.S. Department of Health and Human Services, 2012)

Best Practice	**Best Practice Strategies**	**How your Practices Differ from Best Practice**	**Barriers to Best Practice Implementation**	**Will Implementation of Best Practice Occur? (Yes/No; Why Not)**
Utilizing intraoperative viscoelastic monitoring to assess coagulopathy and guide transfusion.	Development of guidelines for intraoperative viscoelastic monitoring guidelines for major hepatic surgery.		Financial, technological, educational, cultural, rejection from surgical colleagues	

Step 3

Review and synthesis of current literature and evidence will occur next. This includes applying the best evidence to the facility. The use of viscoelastic monitoring in conjunction with targeted coagulation replacement to strengthen clots and replenish coagulation factors may decrease the risk of major bleeding or even prevent intraoperative allogenic blood transfusion (Mpaili et al., 2021). The project team leaders will also discuss the feasibility of practice change with stakeholders to determine the development of order sets, changes within the electronic medical record, and buy-in from surgical colleagues.

Step 4

The fourth step is to develop a practice change. Communication and collaboration with the stakeholders of the anesthesia department, transfusion services, laboratory services, and IT

services will be critical in reviewing and approving the proposed clinical guideline. The clinical guideline will specifically pertain to ROTEM. Education on the guideline will then begin. Training and education will be facility-specific and should be developed by the anesthesia department, transfusion services, laboratory services, and IT department with advice from project team leaders. Ensuring that the education is internally created by stakeholders is crucial for the acceptance and adherence of staff. After education materials have been created, the project leaders will discuss the need for more laboratory equipment with laboratory services.

After collaboration with IT, a section of the perioperative charting in the electronic medical record will be created for the anesthesia provider to document under. This section will include the surgical procedure, ASA class, if the procedure is emergent or scheduled, if intraoperative ROTEM was drawn, if blood products were administered and if the guidelines were adhered to. If the surgical procedure includes intervention in the liver, ROTEM is drawn, and/or if blood products are administered intraoperatively, the patient's chart will automatically be flagged for review by project team leaders.

Step 5

The fifth step will be the implementation period. After obtaining approval, steps 1-4 will likely take place over a two-to-three-month period. Implementation of the guideline will occur over the next year. Refer to Appendix B to view the guideline. At the one-year mark, outcomes will be evaluated to determine the effectiveness of the guideline and whether the guideline will be revised, accepted, or rejected.

Step 6

Outcomes and data from the intervention will be used to support change and increase buy-in by perioperative staff. Continued evaluation of the guideline will occur over time with a

greater sample size, longer timeline, and improvement in technology. If future data shows changes need to be made to the guidelines, the project team will reconvene and make adjustments accordingly.

Outcome Analysis

Data Collection

Pre-Intervention Data

The outcome analysis plan will begin with step 1 from Rosswurm and Larrabee's (1999) conceptual model. The first step is to assess the need for change. To assess the need for change, baseline data must be obtained. This data will be obtained by doing a retrospective electronic medical record analysis of 50 random patient charts over a period of one year. Data obtained from this retrospective analysis will not contain any personal identification information of patients or staff members. Data that will be recorded will include:

1. Incidence of major hepatic surgery.
2. Incidence of blood transfusions during major hepatic surgery.
3. The amount and types of products transfused during major hepatic surgery.
4. The incidence of antifibrinolytic use (tranexamic acid or aminocaproic acid) during major hepatic surgery.
5. Labs that were drawn intraoperatively during major hepatic surgery.
6. Incidence of use of viscoelastic monitoring during major hepatic surgery.

The baseline data obtained will be compared to the data obtained post-intervention. All data will be recorded on a password-secured laptop on a Microsoft Excel file for ease of organization and future comparison, post-intervention.

Post-Intervention Data

After the implementation of the guideline, data will be obtained through another retrospective electronic medical record analysis of 50 patient charts. Again, data obtained from this retrospective analysis will not contain any personal identification information of patients or staff members. Data that will be recorded will include:

1. Incidence of major hepatic surgery.
2. Incidence of blood transfusions during major hepatic surgery.
3. The amount and types of products transfused during major hepatic surgery.
4. The incidence of antifibrinolytic use (tranexamic acid or aminocaproic acid) during major hepatic surgery.
5. Labs that were drawn intraoperatively during major hepatic surgery.
6. Incidence of use of viscoelastic monitoring during major hepatic surgery.

All data collected will be stored on a password-secured laptop and organized on a Microsoft Excel file to be compared with baseline data.

Data Analysis

Comparison of both pre-and postintervention data will determine effectiveness of the guideline and the adherence by staff. Incidence and volume of blood product transfusion will be compared. The project team will need to communicate with the billing department's stakeholders to assess the guideline's financial impacts on both the facility and the patients. The project team will need communicate with the legal department to assess for the need for and legal intervention over a longer period of time. The project team will also communicate regularly with transfusion services to assess the availability of blood products and to determine if any shortages will affect the outcome of the guideline.

The purpose of the proposed evidence-based guideline is to assess blood product utilization during major hepatic surgery. It is possible that the data analysis will show little or no change in the utilization of blood products. If this is the case, the project team leaders will do another literature review and synthesis and a review of the guidelines will occur. The project team leaders will then decide if revisions will be made to the guideline or if the intervention will be aborted altogether.

Barriers

There are a few barriers that could impede the development and implementation of this project. These barriers include financial, technological, educational, cultural, and rejection from surgical colleagues. Financial barriers would include the availability of TEG or ROTEM machines and laboratory staff available to run and maintain them. In the proposed project site where this project will be implemented in, these machines and personnel are already available. Although they are already available, there is a possibility of an increase in use and request of use of these machines, which may create a need for more equipment and personnel requests. Other financial barriers may include intervention from the billing department in relation to insurance coverage and facility reimbursement. Technological barriers include the inability to create a streamlined section of the perioperative electronic charting system to allow providers to chart information pertaining to the intervention and that would allow the project team to more easily extract data and the development of order sets. Educational barriers include the understanding of the fundamentals of viscoelastic monitoring and coagulopathy. Cultural barriers include anesthesia staff being resistant to change. This may contribute to a lack of adherence to guideline intervention. Surgical staff may also be reluctant or reject this change. Surgical staff may not be educated on the benefits of viscoelastic monitoring and may blame negative patient

outcomes on a change in transfusion management. Barriers will be communicated with stakeholders and their concerns will be seriously addressed so that barriers may be overcome.

Project Facilitators

Primary project facilitators include the anesthesia department leader and champion and the leader of transfusion services. Secondary project facilitators include stakeholders in the billing, legal, laboratory, IT, and ethics departments. If the evidence-based project is successful and the intervention is accepted, the facilitators will be the ones to integrate the guidelines into the standard of practice.

Project Timeline, Budget, and Ethical Considerations

Timeline

Guideline implementation at the described facility would require effort and collaboration from multiple parties. If this project were to be accepted and implemented, the Institutional Review Board approval process would begin after the proposal is complete. This project will take one year to fully implement. It will take one month to communicate with project facilitators and stakeholders to assess current practice utilizing a gap analysis tool. During this time, the retrospective chart review will occur and the pre-intervention data will be organized and recorded which will take a total of two months' time. The implementation of the evidence-based guideline will take six months. Following the intervention of the evidence-based guideline, another retrospective chart review will occur to collect and organize. Once all of the post-intervention data is collected, it will take four months for the project team to assess the data, present the data to stakeholders and facilitators, and make a final written conclusion of the project's results. The project would then be disseminated to the nurse anesthesia faculty, nursing department, and students at Otterbein University.

Budget

The budget for the project will be divided into two categories – direct costs (financial) and indirect (nonfinancial) costs. The financial budget for the implementation of this project at the theoretical facility will be less than $100. The proposed project site is a level 1 trauma center that already has a TEG or ROTEM program in place with the resources necessary to run and maintain them. However, if there were to be increased use of viscoelastic monitoring that would outpace the laboratory's ability to run them in appropriate time frames, the facility may prefer to purchase more machines. This would be a financial decision made by the stakeholders of the theoretical facility and not factored into the budget of this project. Materials used to collect, organize, and record data will be electronic and will not cost the project team or facility any money. Personal costs such as commuting, telecommunications, or the use of personal electronic devices are also not factored into the assessment of the financial budget.

If the project implementation is successful and the facility chooses to adopt and permanently make the guidelines policy, the costs to the facility are expected to increase. The creation of education materials, electronic order sets, increased stock of laboratory equipment, and the possible need for more machines will need to be factored into the total budget and prioritization of expenditures will need to be assessed by the facility. Analyzing the further needs of education, electronic medical records, laboratory equipment, and viscoelastic monitoring machines could be a possible area of future study.

The indirect costs associated with the implementation of the guidelines will include time spent by project leaders implementing the evidence-based project. It is estimated that approximately 60 hours will be spent from step 1 to step 6 of the project implementation. This time will be spent communicating with stakeholders and project facilitators to assess current

practice, obtain pre-intervention data, communicate during the intervention, obtain post-intervention data, communication of the results of the project, writing a final report of the outcomes, and dissemination of the project.

Ethical Considerations

Ethical considerations for this project include protecting the personal identification information of patients and staff members. All data collected will be void of any personal identification information in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and will be stored on a password-secured laptop only accessible by project team leaders. Data shared in the final written report and disseminated to students and faculty of the nursing department at Otterbein University will be void of any personal health information and personal identification information in compliance with HIPAA.

Project Limitations

Although this evidence-based practice project is theoretical, if a facility were to adopt this project and intervention, there are limitations. The major limitation would be the variability in preoperative optimization. Preoperative management strategies are outside the scope of this project. Preoperative optimization is often provider-specific and a preoperative guideline would be needed to standardize this. If some patients are allotted more time and intervention for optimization of hemodynamics and coagulation profiles than others, this could affect the outcome of the intervention.

Areas of Other Interest

The scope of this evidence-based project is limited to the perioperative period. Other areas of future scholarly work should focus on the implementation of viscoelastic monitoring for preoperative optimization and for postoperative management in the ICU. Preoperative

management often affects intraoperative management that affects postoperative management. More study on the pre-and postoperative utilization of viscoelastic monitoring would likely improve patient outcomes and streamline transfusion utilization for healthcare providers.

Another area of future interest could be the implementation of a TEG monitoring guideline for major hepatic surgery. Many institutions have not made the upgrade from TEG to ROTEM and a similar guideline could bridge the gap until the monitoring upgrade is implemented. The framework of the project could be similar to this one. An example of an evidence-based TEG monitoring guideline for major hepatic surgery is referenced in Appendix C.

Conclusion

Patients undergoing major hepatic surgery are at high risk of coagulopathy that may result in the need for blood product transfusion. Evidence within the literature supports the development and implementation of viscoelastic monitoring-focused coagulopathy guidelines to decrease blood product utilization intraoperatively. The purpose of the project is to develop a structured approach, based on Rosswurm and Larrabee's conceptual model, to asses a need for change, review evidence stated in the literature, and incorporate it into an intervention to change practice. Using the methods outlined in this project, project leaders will be able to identify gaps in practice, implement evidence-based practice guidelines, and review the outcomes of the guidelines in clinical practice. Project facilitators and stakeholders will be able to utilize this project to support future improvements in clinical practice.

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Appendix A

Literature Synthesis Table

Citation	Conceptual Framework	Design/Methods	Sample/Setting	Methods	Findings	Level of Evidence
Clevenger & Mallett (2014)	Systematic review of viscoelastic monitoring compared to conventional coagulation tests for transfusion and coagulation management in liver transplantation	Systematic review	9 studies analyzing patients who underwent hepatic resection and received allogenic blood transfusion	Analyzed the studies and compared the volume of transfusion of pRBC, FFP, platelet, and cryoprecipitate during major hepatic surgery	Transfusion management guided by conventional coagulation tests were associated with increased transfusion of all products when compared to viscoelastic monitoring.	Level I
Forkin et al. (2018)	Review of the coagulation profile of end-stage liver disease and considerations for intraoperative management.	Evidence-based research article	Coagulopathy associated with end-stage liver disease and the impact on intraoperative management.	Discusses the complex pathophysiology associated with end-stage liver disease, the utility of viscoelastic monitoring, and how to manage different coagulopathies during major haptic surgery.	End-stage liver disease is a complex and dynamic pathology and may result in hyper- or hypocoagulopathic states. These states change with surgical stimulus and anesthetic administration. Viscoelastic monitoring is useful to anesthesia providers and is more accurate that conventional coagulation testing.	Level V
Lloyd-Donald et al. (2020)	Prospective observational study comparing the	Prospective observational study	34 patients studied on 109 different occasions	Used quantile regression to explore 30 associations	In patients acutely ill with chronic liver disease, TEG shows more	Level II

	use of TEG and conventional coagulation tests in patients with severe liver disease			between TEG parameters and corresponding conventional coagulation tests (CCTs). Then compared TEG and CCT measures of coagulation initiation, clot formation, clot strength, and fibrinolysis.	consistent associations with measure of coagulation than CCTs. CCT results are more affected by chronic liver disease.	
Mpaili et al. (2021)	Systematic review of the utility of viscoelastic coagulation testing during hepatic surgery compared to conventional coagulation tests	Systematic review	12 studies analyzing patients who underwent viscoelastic testing of coagulation during liver surgery	Analyzed the studies and compared detection of normo-, hypo-, and hypercoagulable states.	Conventional coagulation tests overdiagnose hypocoagulation while underdiagnosing hypercoagulation. Viscoelastic monitoring showed to more accurately diagnose the current state of coagulation and its changes.	Level I
De Pietri et al. (2016)	Retrospective observational study on reduced transfusion during orthotopic liver transplant by point-of-care coagulation management and TEG functional fibrinogen	Retrospective observational study	386 consecutive patients undergoing liver transplantation	Single-center, retrospective cohort observational study on implementation of a TEG-based transfusion algorithm	Significant decrease in the use of homologous blood, fresh frozen plasma, and platelets. The use of fibrinogen increased. There were no significant differences in 30-day and 6-month survival between the 2 groups.	Level III

Appendix B

ROTEM Guideline

ROTEM Monitoring for Major Hepatic Surgery	
Issue Date:	**Effective Date:**
Developed/Revised By: Randall Kinietz, SRNA and Brian Garrett, DNP, CRNA	
Reviewed By:	**Date Reviewed:**
Approved By:	
Responsible Providers/Persons: Anesthesia Providers	

Scope – This guideline is in effect for a level 1 trauma center in the Midwest.

Statement of Purpose:
The purpose of this guideline is to assist perioperative staff with a guide for the utilization of intraoperative ROTEM monitoring during major hepatic surgery. Current literature highlights the occurrence of coagulopathy during major hepatic surgery due to baseline hepatic pathology, surgical stress, and procedure complexity. ROTEM provides real-time information on speed and strength of clotting and coagulopathy.

Definitions:
ROTEM

- Clotting Time (CT): Time from start of the measurement until initiation of clotting.
- Clot Formation Time (CFT): Time from initiation of clotting until a clot firmness of 20 mm is detected.
- Maximum Clot Firmness (MCF): Firmness of the clot.
- Lysis Index at 30 Minutes (LI30): Ratio between the clot firmness and the amplitude at 30 minutes.
- Maximum Lysis (ML): Reduction of clot firmness after MCF in relation to MCF.
- Amplitude at 10 Minutes (A10): Amplitude of deflection at 10 minutes.
- EXTEM: Coagulation is activated by a small amount of tissue factor that typically leads to clot formation within 70 seconds.
- FIBTEM: Coagulation is activated as in ETXEM, but with the addition of cytochalasin D the thrombocytes are blocked and the resulting clot is only depending on fibrin formation and polymerization.
- Of note, EXTEM and FIBTEM are reagents added to whole blood to manipulate coagulation.

Guideline:

I. Indications
   a. Request by surgical team
   b. Patient suspected to be in hemorrhagic shock
   c. Initiation of massive transfusion protocol (MTP)

II. Resuscitation/Transfusion
   a. Repeat ROTEM every 30 minutes once drawn or until clinically unnecessary
   b. Transfusions based on recommendation from ROTEM interpretation
   c. The following interpretation is a *guideline* and not a substitute for clinical judgement.

III. Component transfusion based on ROTEM results:

Lab Value	**Product**
CT_{EXTEM} >85	Plasma
$A10_{EXTEM}$ <45 and $A10_{FIBTEM}$ ≥ 10	Platelets
$A10_{EXTEM}$ <45 and $A10_{FIBTEM}$ <10	Cryoprecipitate
ML ≥10	Tranexamic Acid

Appendix C

TEG Guideline

TEG Monitoring for Major Hepatic Surgery	
Issue Date:	**Effective Date:**
Developed/Revised By: Randall Kinietz, SRNA and Brian Garrett, DNP, CRNA	
Reviewed By:	**Date Reviewed:**
Approved By:	
Responsible Providers/Persons: Anesthesia Providers	

Scope – This guideline is in effect for a level 1 trauma center in the Midwest.

Statement of Purpose:
The purpose of this guideline is to assist perioperative staff with a guide for the utilization of intraoperative TEG monitoring during major hepatic surgery. Current literature highlights the occurrence of coagulopathy during major hepatic surgery due to baseline hepatic pathology, surgical stress, and procedure complexity. TEG provides real-time information on speed and strength of clotting and coagulopathy.

Definitions:
TEG

- Citrated Functional Fibrinogen (CFF): Measures fibrinogen contribution to clotting.
- Citrated Kaolin (CK): Used to guide clotting factor requirements.
- Citrated RapidTEG (CRT): Used to guide platelet requirements

Guideline:

I. Indications
   a. Request by surgical team
   b. Patient suspected to be in hemorrhagic shock
   c. Initiation of massive transfusion protocol (MTP)

II. Resuscitation/Transfusion
   a. Repeat TEG every 30 minutes once drawn or until clinically unnecessary
   b. Transfusions based on recommendation from TEG interpretation
   c. The following interpretation is a *guideline* and not a substitute for clinical judgement.

III. Component transfusion based on TEG results:

Lab Value	**Product**
R (CK) >10	Plasma
MA (CFF) <15	Cryoprecipitate
MA (CRT) <50	Platelets
LY30 (CK) >3%	Tranexamic Acid