Effectiveness of ROTEM-based Coagulation Surveillance on Reducing Blood Product Utilization During Complex Spine Surgery. A prospective randomized study.

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Purpose of the Study

The Purpose of this study is to evaluate the effectiveness of intra-operative ROTEM-based coagulation surveillance on reducing total blood product use during complex spine surgeries.

Background & Significance

Blood loss is one of the major challenges in complex spine surgeries. Previous reports suggests that multilevel spine surgery is associated with high risk of excessive bleeding (16%), and that 24% of patients undergoing a three-column osteotomy suffer massive blood losses (>4 L). Current measures to address this problem include the use of anti-fibrinolytic agents, Cell Saver® and hypotensive anesthesia. In spite of these measures, the use of blood products continues to be very high. Rotational thrombo-elastometry (ROTEM) has been proven to be effective in reducing blood loss during liver transplant, cardiothoracic surgery and major trauma surgery. However, its application in major spine surgery has not become widespread. Spinal deformity surgery includes large incisions and extensive dissections, as well as major bleeding from epidural plexus and from highly vascularized cancellous vertebral bone. This study will evaluate the effectiveness of intra-operative ROTEM-based coagulation monitoring on reducing total blood product use during complex spine surgeries by comparing with standard-of-care coagulation profile.

Design & Procedures

Major blood loss is one of the most common complications during complex spine surgery cases. This study will evaluate the effectiveness of intra-operative ROTEM-based coagulation surveillance on reducing total blood product use during complex spine surgeries by comparing with standard-of-care coagulation surveillance. The patients will be randomized to the ROTEM coagulation monitoring (+ROT) or to conventional coagulation monitoring (-ROT) groups.

Primary Outcome:

- The total number of units of PRBC transfused during surgery and during the following 48-hour hospital phase of care.
- Estimated blood losses (EBL) during the procedure.

Predictor variables:

- Patients' demographics: including age, sex, smoking history, medical comorbidities, preoperative diagnosis, procedure performed, OR duration, number of levels fused during the procedure, type and number of spine osteotomies during the procedure, the number of levels of decompression, the number of inter-body fusions.
- Baseline laboratory values of the following: PT/INR, aPTT, platelet count, hemoglobin level.

Secondary outcomes:

- The use of Cell Saver® and the amount of recovered blood transfused during the procedure.
- Drain output during the first 24 hours after surgery.

- The amount and type of blood products (PRBC, FFP, Cryoprecipitate, Platelets) transfused during surgery, and during the 48 hours following surgery.
- Laboratory values including hemoglobin, platelets count, PT/INR, aPTT, fibrinogen.
- Serious adverse events during the hospital phase of care.
- Cost analysis of ROTEM samples vs. Blood products.

Selection of Subjects

The subjects will be recruited from the operating room list at Duke University hospital, Durham, NC. Only patients who agree and consent to the study will be included.

Subject Recruitment and Compensation

Inclusion Criteria:

- Age > 18 and < 80 years old.
- Elective spine surgery cases, with a traditional open posterior approach and involving fusion of at least 5 levels.
- Normal coagulation profile (PT/INR, aPTT) and normal platelets count on pre-operative evaluation.
- Preoperative hemoglobin Level >10 g/dl.
- OR time > 4 hours.
- No contraindication for the use of anti-fibrinolytic therapy (Tranaxemic acid).

Exclusion Criteria:

- Age < 18 or age > 80 years old.
- Anterior spine surgeries or posterior spine surgeries involving <5 levels.
- Minimally invasive spine surgeries.
- Patients with known coagulopathies or bleeding tendencies or patients with abnormal coagulation laboratory values at baseline.
- Patients with Hemoglobin level of <10 g/dl on preoperative baseline laboratory values.
- Trauma and Emergency spine surgeries.
- Patients with spine malignancy diagnosis, either primary or metastatic.
- OR time < 4 hours.
- Patients who refuse to use allogenic blood products.
- Patients with contraindications for the use of anti-fibrinolytic therapy.

Randomization:
The patients will be randomized to the ROTEM coagulation monitoring (+ROT) or to conventional coagulation monitoring (-ROT) groups. A sealed envelope randomization will be performed in a 1:1 ratio. The research team members will not be blinded for the randomization results.

There will be no subject compensation for participation in this study.

Study Interventions

Patients undergoing major spine surgery will be assigned to either ROTEM coagulation surveillance (+ROT) or to conventional coagulation surveillance (-ROT) groups. The main outcomes will be the estimated blood loss during the procedure and the amount of units of PRBCs transfused during the procedure and within the first 48 hours after the procedure.

Risk/Benefit Assessment

ROTEM is a test based on a blood-draw. Blood will be drawn for standard-of-care coagulation testing during the surgery from IV's placed prior to or at the beginning of the procedure. The ROTEM will require a small additional sample of peripheral blood (<5mL). The anesthesiologist treating patients in the ROTEM arm of the trial will have this additional information to help guide blood product use during surgery.

Data Analysis & Statistical Considerations

Power analysis:
Sample size was calculated with G-Power v.3.1.9.2 software. Considering that the average use of 5 units PRBCs for complex spine cases is reduced by 1 unit of PRBCs for each case, a sample size of 20 will provide a power P=0.978 with an α=0.007.

Randomization:
A randomization schedule will be generated with the online application www.randomization.com.

Data Analysis:
The t-test will be used to estimate the differences between two independent means for both coagulation surveillance groups (+ROT) and (-ROT).