COVER LETTER

Document date: 3/10/2020

Comparison of Blood Product Use and Bleeding Events During and After Endoscopic or Neurosurgical Procedures in Patients with Cirrhosis and Coagulopathy: Rotational Thromboelastometry Versus Conventional Therapy

NCT02457403

Statistical Analysis

Our sample size of thirty-four patients per group was based on a pilot project at OSUWMC that evaluated a total of sixteen patients. The same variables were studied in the pilot project, but no statistically significant results were found. We powered our study for the primary outcome of intraoperative blood loss based on the results of the pilot data.

Patient characteristics and laboratory values were compared between the two groups. Fisher exact tests were used to test for significant differences between the ROTEM and conventional coagulation groups with discrete variables such as race and gender. With continuous variables that were approximately normally distributed (BMI, MELD, and age), two-sample t-tests were used to test for significant differences between groups. Due to the non-normality of all laboratory values and ICU length of stay, nonparametric Wilcoxon rank-sum tests were used to test for significance.

Blood product usage and blood loss during OLT comparing ROTEM guided transfusion therapy versus conventional coagulation therapy were also analyzed. Due to the non-normality of the data, nonparametric Wilcoxon rank-sum tests were used to test for significant differences between the two groups in terms of the use of the 5 different blood products and blood loss. The sum of pRBCs, FFP, platelets, cryoprecipitate, and Cell Saver in units was used as an indicator of total blood product use. Results are expressed as medians and interquartile ranges. A two-tailed P value <0.05 was considered significant.