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Mini Review

Pediatric Rotem Sigma Parameters in Potential Perioperative Hemorrhagic Surgery: An Observational Prospective Pilot Study Protocol

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Abstract

Background: A recent systematic review and meta-analysis was undertaken to determine the impact of transfusion goal directed protocols with viscoelastic methods on postoperative outcome in pediatric hemorrhagic surgery. This trial revealed that fresh frozen plasma transfusion and length of hospital stay were reduced in the group where transfusion was guided with point of care viscoelastic methods. A transfusion goal directed protocol with rotational thromboelastometry sigma is in preparation (ROTEM sigma). Since the actual ROTEM parameters were determined with ROTEM delta, we would like to validate pediatric parameters with ROTEM sigma. Once these parameters are validated in this trial they will be integrated in the pediatric transfusion protocol guided with ROTEM sigma in hemorrhagic surgery.

Objectives: The primary objective is to determine pediatric ROTEM sigma parameters predictive of intraoperative and postoperative transfusion. The secondary objectives are to determine pediatric ROTEM sigma parameters predictive of intraoperative and postoperative blood loss, postoperative length of intensive care stay (LOSICU), length of mechanical ventilation (LMV) and length of hospital stay (LOS).

Methods: Patients aged less than 18 years old admitted for potential hemorrhagic surgery.

The study will be monocentric.

Statistic analysis will be realized with XLSTAT 2018.3 or plus software.

Results are expected end 2021.

Conclusion: This pilot study will determine pediatric ROTEM sigma parameters predictive of intraoperative and postoperative transfusion, blood loss and postoperative LOSICU, LMV and LOS which will be integrated in a transfusion goal directed protocol guided with ROTEM sigma.

Keywords: Transfusion Goal Directed Protocol; ROTEM Sigma; Children; Outcome

Introduction

There is evidence that goal directed transfusion protocols reduce blood product transfusion such as fresh frozen plasma in hemorrhagic surgery in children and adults [1,2]. A recent systematic review and meta-analysis revealed that length of hospital stay (LOS) was reduced in the group were transfusion was guided with viscoelastic methods in pediatric trauma, cardiac, liver transplantation and craniosynostosis surgical patients [1]. Previous studies have demonstrated that transfusion was predictive of adverse postoperative outcome in children in terms of organ dysfunction, length of mechanical ventilation (LMV) and LOS [3].

Viscoelastic point of care devices, namely rotational thromboelastometry (ROTEM) and thromboelastography (TEG) have evolved the last decade in more simplified and more performing devices. We are aiming to develop a transfusion goal directed protocol with point of care device ROTEM sigma. In this protocol, transfusion will be guided with ROTEM sigma with the aim to reduce blood product transfusion in tems of fresh frozen plasma or other blood products derivatives and to reduce LOS. Existing ROTEM pediatric parameters in healthy children were determined with ROTEM delta [4]. We would like to validate pediatric parameters with ROTEM sigma in pediatric potential surgical settings. Once these parameters are validated they will be integrated in a pediatric transfusion goal directed protocol guided with ROTEM sigma.

The primary objective of this study is to determine ROTEM sigma parameters predictive of intraoperative and postoperative blood product transfusion [in terms of fresh frozen plasma (FFP), coagulation factors, platelet (CUP) and red blood cells (PRBC)] in pediatric potential hemorrhagic surgery.

The secondary objectives are to determine ROTEM sigma parameters predictive of intraoperative and postoperative blood loss, postoperative length of mechanical ventilation (LMV), length of stay in the intensive care unit (LOSICU) and LOS in pediatric potential hemorrhagic surgery.

The primary outcome is intraoperative and postoperative blood product transfusion.

The secondary outcomes are intraoperative and postoperative blood loss, postoperative LMV, LOSICU and LOS.

Primary outcome measures are the quantity of intraoperative and postoperative blood product administered. Secondary outcome measures are the quantity of intraoperative and postoperative blood loss, the number of postoperative days spent in the intensive care unit (ICU), under mechanical ventilation and in the conventional hospitalization ward.

This study is part of a Thesis in development [5] which is registered at http://www.theses.fr/s232762.

Methods and Materials

After parents information and approval from the Ethics Committee, patients will be included. Inclusion criteria are patients aged less than 18 years old ; admitted for potential hemorrhagic surgery all specialities included.

Exclusion criteria are patients aged more than 18 years, no potential hemorrhagic surgery, parents or patients refusal.

Patients will be managed as usual according to the local practices or protocols.

ROTEM sigma parameters (EXTEM (α,CT,CFT,A5,A10,MCF,CLI30/60), INTEM (α, CT,CFT,A5,A10,MCF,CLI30/60), FIBTEM (A5,A10,MCF), APTEM (CLI30/60)] will be obtained with whole blood samples and anayzed with ROTEM sigma point of care device preoperatively, intraoperatively and postoperatively.

Intraoperative and postoperative blood product transfusion, blood loss, postoperative number of days spent in the intensive care unit (ICU), under mechanical ventilation (LMV) and spent in the standard hospitalization ward will be registered.

Other variables registered will be age, prematurity, weight, height, gender, surgery, elective or emergency situation, ASA score, existence of a hemorrhagic disorder, hemostatic medication (anticoagulants, antiplatelet drugs, antifibrinolytics or any other drugs interacting with the hemostatic system) duration of surgery and

anesthesia, hemoglobin, platelet, activated thromboplastin, prothrombin time and fibrinogen serum levels.

The number of patients included will be between 500-1000 to have a normally distributed population.

The study will be monocentric.

Statistic analysis will be realized with XLSTAT 2018.3 or plus software. Student's t test or Mann-Whitney test will compare normally distributed variables accordingly. Wilcoxon test or Kruksal-Wallis test will compare non normally distributed variables accordingly.

Normally distributed variables will be expressed in means with standard deviation. Non normally distributed variables will be compared in medians with interquartile range. Fischer's exact test or Chi squarred test will compare categorical variables accordingly. Categorical variables will be expressed in percentages with 95% confidence intervals. To assess for independent predictive factors multivariate analysis will be realized. A p-value equalled to or less than 0.05 will be considered significant.

Results

Are expected end 2021

Conclusion

The results of this pilot study will be integrated in a pediatric transfusion protocol guided by ROTEM sigma in pediatric hemorragic surgery.

Conflicts of Interest

The authors declared non conflict of interest.

Funding

There will be funding.

Bibliography

1. Kumba C., *et al*. "Systematic Review and Meta-analysis of Goal Directed Intra-Operative Transfusion Protocols Guided by Viscoelastic Methods and Perioperative Outcomes in Children". *International Journal of Recent Scientific Research* 10.3 (2019): 31466-31471.
2. Wikkelso A., *et al*. "Thromboelastography (TEG) or thromboelastometry (ROTEM) to monitor haemostatic treat versus usual care in adults or children with bleeding". *Cochrane Database of Systematic Reviews* (2016).
3. Kumba C., *et al*. "Transfusion and Morbi-Mortality Factors: An Observational Descriptive Retrospective Pediatric Cohort Study". *Journal of Anesthesia and Critical Care: Open Access* 8.4 (2017): 00315.
4. Oswald E., *et al*. "Thromboelastometry (ROTEM) in children: age-related reference ranges and correlations with standard coagulation tests". *British Journal of Anaesthesia* 105.6 (2010): 827-835.
5. Kumba C. "Do goal directed therapies improve postoperative outcome in children? (Perioperative goal directed fluid and hemodynamic therapy; Transfusion goal directed therapy using viscoelastic methods and enhanced recovery after surgery and postoperative outcome): A study research protocol". *Acta Scientific Paediatrics* 2.7 (2019) :17-19.