

TEXAS CHILDREN'S HOSPITAL
EVIDENCE-BASED OUTCOMES CENTER
ROTEM-Guided Goal-Directed Therapy for Bleeding after Cardiopulmonary Bypass in Pediatric Heart Surgery
Evidence Summary

Inclusion Criteria

- Pediatric congenital heart patients undergoing cardiac surgery on cardiopulmonary bypass

Exclusion Criteria

- None

Background

Bleeding is a known risk factor for cardiac surgery. Traditional methods of monitoring coagulation in the operating room requires multiple laboratory tests with an approximate turn-around time of 45 - 60 minutes. ⁽¹⁾ Rotational thromboelastometry (ROTEM) and thromboelastography (TEG) are promising new tools utilized in adult cardiac surgery to monitor clot formation. ROTEM and TEG offer timely graphic and numerical results detailing the assessment of the patient's whole blood coagulation profile. ⁽²⁻⁶⁾ Although utilized in adult cardiac surgery, there is limited knowledge on the effectiveness of ROTEM directed transfusion pathways in children.

Critically Analyze the Evidence

The **GRADE criteria** were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. The table below defines how the quality of evidence is rated and how a strong versus a weak recommendation is established.

Recommendation	
STRONG	Desirable effects clearly outweigh undesirable effects or vice versa
WEAK	Desirable effects closely balanced with undesirable effects
Quality	Type of Evidence
High	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
Moderate	Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies
Low	Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence
Very Low	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

PICO Question 1: In pediatric patients with congenital heart disease that are at high risk for post-cardiopulmonary bypass coagulopathy, does the use of a goal-directed transfusion pathway to guide intra-operative blood transfusions decrease the transfusion of blood products post-cardiopulmonary bypass?

Recommendation(s): Strong recommendation with low quality evidence that the use of a goal-directed transfusion algorithm decreases the amount of blood products given after separation from cardiopulmonary bypass. In addition, a ROTEM-guided algorithm can be employed successfully to decrease blood product administration. ^(2,5-13)

It is well documented that blood transfusion is associated with increased morbidity, increased length of stay, increased post-operative ventilator days and increased hospital costs after cardiac surgery. ⁽⁷⁾ There are no existing clinical guidelines or recommendations for the treatment of post-bypass bleeding in pediatric patients. A review of the literature found five studies reporting on the use of transfusion algorithms to treat post-bypass coagulopathy in pediatric cardiac surgery patients. In a prospective study using ROTEM to guide treatment of post-bypass bleeding, Romlin 2011 used a ROTEM-guided algorithm for transfusion. This study confirmed that significantly fewer blood products were administered to patients who received the intervention compared with the control group (44% vs. 80%, p <0.001). ⁽⁵⁾ As a quality improvement initiative, Whitney 2013 measured the impact of a standardized goal-directed transfusion algorithm based on laboratory coagulation tests in pediatric cardiac surgery patients and demonstrated significant reductions in transfusion of packed red blood cells (PRBCs), cryoprecipitate, and total blood products after the algorithm was implemented. ⁽⁸⁾ A 2015 randomized control trial to determine if a ROTEM-based blood transfusion pathway reduced postoperative bleeding in pediatric patients undergoing heart surgery found that patients randomized to the ROTEM-pathway had a decreased amount of postoperative transfusions and no difference noted in intraoperative red blood cell transfusions than the control group; however there was significantly more fresh frozen plasma (FFP) and platelet concentrate administered intraoperatively. ⁽²⁾ Kane 2016

evaluated the use of TEG in pediatric patients undergoing cardiac surgery with cardiopulmonary bypass. The researchers found that patients that underwent cardiopulmonary bypass after the implementation of TEG had a reduction in the use of platelets (1 versus 2.2 units; $p < 0.0001$) and cryoprecipitate (0.7 versus 1.7 units; $p < 0.0001$) units transfused. ⁽⁹⁾ However, a 2010 non-blinded randomized controlled trial of 31 children undergoing surgery for transposition of the great artery or double outlet right ventricle with the use of TEG found no significant difference in the total platelet and total red blood cell usage between groups ($p = 0.984$ and $p = 0.109$, respectively). ⁽¹⁰⁾ Faraoni 2015 reported their experience in the development of a ROTEM-based algorithm. The study retrospectively reviewed the transfusion history of 150 children who underwent elective cardiac surgery with cardiopulmonary bypass in order to refine the algorithm reported in Romlin 2011. ⁽¹¹⁾

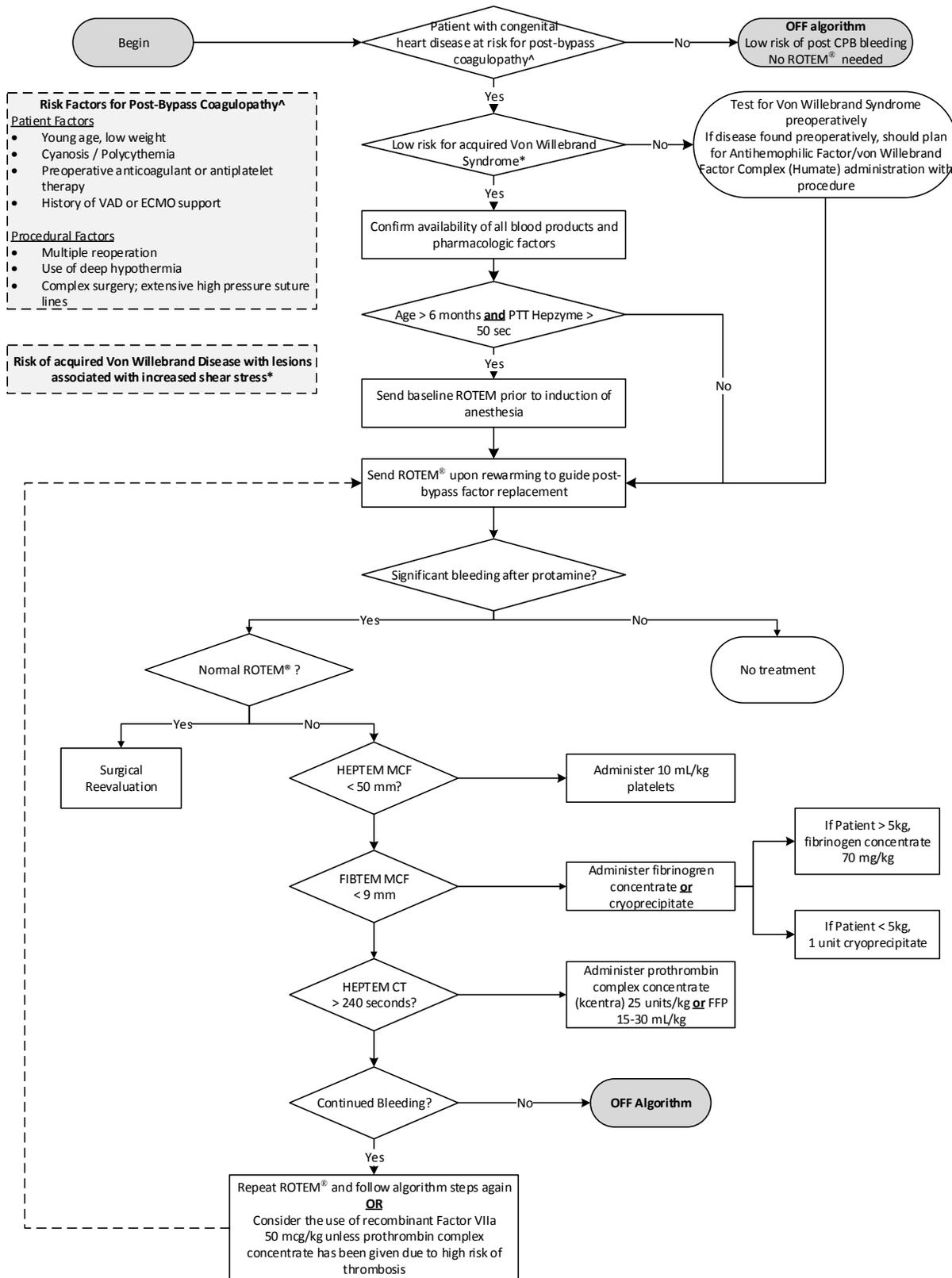
Hass 2014 retrospectively reviewed the effects of a ROTEM-assisted transfusion/coagulation management algorithm in pediatric patients undergoing major craniofacial surgery. Implementation of the algorithm resulted in decreased number of intraoperative transfusions of platelet concentrate (pre-algorithm group 25% compared to post-algorithm group 9%) and total avoidance of FFP transfusions; however, the number of transfusions of fibrinogen concentrate increased over time (pre-algorithm group 61% and post-algorithm group 100%). ⁽¹²⁾ A 2015 retrospective review documented the implementation of a protocol involving a blood sparing technique and the use of TEG in 80 pediatric patients receiving craniofacial surgery. The study concluded that the use of this type of protocol results in decreased intraoperative blood product administration without an effect on postoperative administration. ⁽¹³⁾ The use of TEG- or ROTEM-guided transfusions in adult and pediatric patients with bleeding was found to reduce the proportion of patients in need of pooled red blood cells (RR 0.86, 95% CI 0.79-0.94; $I^2 = 0\%$; 10 studies) and FFP transfusion (RR 0.57, 95% CI 0.33-0.96; $I^2 = 86\%$; 10 studies) in a recent meta-analysis. ⁽⁶⁾

Critical Points of Evidence

Evidence Supports

- Use of a goal-directed transfusion algorithm decreases the amount of blood products given after separation from cardiopulmonary bypass. In addition, a ROTEM-guided algorithm can be employed successfully to decrease blood product administration. ^(2,5-13) – Strong recommendation, low quality evidence

**TCH Evidence-Based Outcomes Center
Clinical Algorithm for ROTEM-guided Goal Directed Therapy for Bleeding after
Cardiopulmonary Bypass (CPB) in Pediatric Heart Surgery**



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Clinical Standards Preparation

This clinical standard was prepared by the Evidence-Based Outcomes Center (EBOC) team in collaboration with content experts at Texas Children's Hospital. Development of this clinical standard supports the TCH Quality and Patient Safety Program initiative to promote clinical standards and outcomes that build a culture of quality and safety within the organization.

ROTEM-Guided Goal Directed Therapy for Bleeding after Cardiopulmonary Bypass in Pediatric Heart Surgery Content Expert Team

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No relevant financial or intellectual conflicts to report.

Development Process

This clinical standard was developed using the process outlined in the EBOC Manual. The literature appraisal documents the following steps:

1. Review Preparation
 - PICO questions established
 - Evidence search confirmed with content experts
2. Review of Existing External Guidelines
 - N/A
3. Literature Review of Relevant Evidence
 - Searched: PubMed, Medline, Cochrane Collaborative
4. Critically Analyze the Evidence
 - One meta-analysis, two randomized controlled trials, and six nonrandomized studies
5. Summarize the Evidence
 - Materials used in the development of the guideline, evidence summary, and order sets are maintained in a ROTEM-Guided Goal Directed Therapy for Bleeding after Cardiopulmonary Bypass in Pediatric Heart Surgery evidence-based review manual within EBOC.

Evaluating the Quality of the Evidence

Published clinical guidelines were evaluated for this review using the **AGREE II** criteria. The summary of these guidelines are included in the literature appraisal. AGREE II criteria evaluate Guideline Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity and Presentation, Applicability, and Editorial Independence using a 4-point Likert scale. The higher the score, the more comprehensive the guideline.

This clinical standard specifically summarizes the evidence *in support of or against* specific interventions and identifies where evidence is *lacking/inconclusive*. The following categories describe how research findings provide support for treatment interventions.

"Evidence Supports" provides evidence to support an intervention

"Evidence Against" provides evidence against an intervention.

"Evidence Lacking/Inconclusive" indicates there is insufficient evidence to support or refute an intervention and no conclusion can be drawn *from the evidence*.

The **GRADE** criteria were utilized to evaluate the body of evidence used to make practice recommendations. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. The literature appraisal reflects the critical points of evidence.

Recommendation	
STRONG	Desirable effects clearly outweigh undesirable effects or vice versa
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Quality	Type of Evidence
High	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
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Recommendations

Practice recommendations were directed by the existing evidence and consensus amongst the content experts. Patient and family preferences were included when possible. The Content Expert Team and EBOC team remain aware of the controversies in ROTEM-guided goal-directed therapy for bleeding after cardiopulmonary bypass in pediatric heart surgery. When evidence is lacking, options in care are provided in the clinical standard and the accompanying order sets (if applicable).

Approval Process

Clinical standards are reviewed and approved by hospital committees as deemed appropriate for its intended use. Clinical standards are reviewed as necessary within EBOC at Texas Children's Hospital. Content Expert Teams are involved with every review and update.

Disclaimer

Practice recommendations are based upon the evidence available at the time the clinical standard was developed. Clinical standards (guidelines, summaries, or pathways) do not set out the standard of care and are not intended to be used to dictate a course of care. Each physician/practitioner must use his or her independent judgment in the management of any specific patient and is responsible, in consultation with the patient and/or the patient's family, to make the ultimate judgment regarding care.

Version History

Date	Comments
Jun 2017	Originally completed
Jan 2020	Reaffirmed