Thrombelastography-based monitoring for massive blood loss during pediatric surgery, a pilot study

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We plan a pilot study to obtain normal reference values of TEG parameters during craniofacial surgery. Two machines will be tested: the TEG and the ROTEM.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33804

Source
ToetsingOnline

Brief title
TEG monitoring in children

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
coagulation monitoring, thromboelastography

Health condition

stollingsonderzoek

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: CSL Behring

Intervention

Keyword: children, massive blood loss, TEG

Outcome measures

Primary outcome

TEG data

Secondary outcome

not applicable

Study description

Background summary

The management of massive blood loss in children during trauma or craniofacial surgery is a huge and unsolved problem in pediatric surgery and anesthesia(1). No clear strategies and no evidence-based treatment protocol exist. The classical approach of volume replacement with crystalloid and colloid solutions can seriously alter hemostatic function by diluting clotting factors and further increasing intraoperative bleeding(2, 3). Therefore, it is common practice to use also packed red blood cells (pRBC), fresh frozen plasma (FFP) and concentrated platelets (CP) according to the clinical situation and laboratory parameters. Unfortunately, transfusion of allogenic blood and blood products is associated with a number of serious risks such as transmission of infections, possible immunosuppressance and immunomodulation, transfusion-related lung injury and adverse outcome associated to allogenic transfusion(1, 4). High costs of blood and blood products and an increasing awareness of these risks over the past years have led to develop management strategies to minimize blood loss and to decrease the use of blood products(5). In addition, the ongoing concerns regarding the availability of the national and international blood supply and the remarkable increase in prices of blood products during the past 10 to 15 years due to blood safety measures have further boosted the call for alternative algorithms(6-8). Preoperative assessment of hemostatic parameters has not been successful for identifying patients who are at risk and will bleed excessively(9).

Primary non-syndromic craniosynostosis occurs in 1:2000 births. It affects the child*s morphology and can lead to functional impairments. Primary operative repair of craniosynostosis in infants and young children is recommended. Unfortunately, this procedure can lead to excessive blood loss and is associated with an average loss of 60 to 100 % (!) of the estimated blood volume(10, 11). Therefore, these well-planned operations are a model for excessive acute blood loss especially in children. Our institution performs more than 100 of these craniofacial surgeries per year, which accounts for nearly 90% of such operations in The Netherlands.
Thromboelastography (TEG) is a clinical monitoring method which quantifies the effects of blood loss on blood coagulation(12). It is based on the interaction of platelets and plasma coagulation factors and their ability to form a functional clot and then dissolve the clot through fibrinolysis. Nowadays, two thromboelastographic techniques are available (ROTEM® and TEG®). The efficacy of both techniques has been found to be highly comparable (oral communication April 2008 by Michael Spannagl, Klinikum der Universität München, Germany). However, the feasibility in a pediatric laboratory has to be established. The introduction of TEG has led to a significant decrease in red cell transfusions, use of fresh frozen plasma (FFP) and platelet transfusions in adult surgery and thereby diminishing the risks of infections and immunosuppression and moreover a significant decrease in accompanying costs(4, 13). These data strongly support the evaluation of TEG-guided interventions in children. In the future TEG during pediatric surgery will allow for tailored interventions that will include the transfusion of crystalloid and colloid solutions, pRBC, FFP, and CP, as well as the administration of specific medications like antifibrinolytic agents, concentrates of fibrinogen, or activated recombinant factor VII. Finally, TEG tailored therapy may decrease transfusion related complications in children.
We plan this pilot study to establish pediatric reference values for TEG analysis parameters during craniofacial surgery, and to compare the feasibility of two thromboelastographic techniques in our pediatric laboratory.

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Study objective

We plan a pilot study to obtain normal reference values of TEG parameters during craniofacial surgery. Two machines will be tested: the TEG and the ROTEM.

Study design

We will perform a single-center pilot study to obtain TEG-values in 50 children during surgical repair of primary craniosynostosis. The anesthetic management, fluid replacement and transfusion of blood components will be done according to clinical routine. All children will receive a standardized infusion protocol. During surgery six times 5 ml of blood will be drawn from an in situ infusion line. TEG data will not be used for patiet treatment but only used for this study.

Study burden and risks

no burden and / or risks as the children are under anesthesia.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Fifty children consecutively admitted to our hospital who will undergo elective surgical repair in the Sophia Children*s Hospital from february 2009 until september 2009 will be included in the study.

Exclusion criteria

The only exclusion criterion for enrollment is the refusal to provide consent.

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL23186.078.08