Clinical decision-support with Viscoelastic Haemostatic Assay; towards a more practical guided and proactive use of clotting agents

Published: 23-03-2021
Last updated: 19-08-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON50862

Source
ToetsingOnline

Brief title
VHALID-study

Condition

- Cardiac therapeutic procedures

Synonym
Coagulation, haemorrhage

Research involving
Human

Sponsors and support

Primary sponsor: Intensive Care

Source(s) of monetary or material Support: Ministerie van OC&W,CSL Behring,Werfen

Intervention

Keyword: Machine learning, ROTEM, TEG, VHA-analysis

Outcome measures

Primary outcome

The primary objective of this study is to provide a guideline model through VHA analysis for optimal coagulation management in the OR and/or ICU to reduce blood loss.

Secondary outcome

Patient specific data like demographic information and intermittently recorded pre- intra and postoperative data, will be collected.

Study description

Background summary

Cardiac surgery is frequently associated with blood loss which forms a great challenge to teams in the operation room and intensive care unit. Blood loss and consecutive blood transfusion are associated with increased morbidity, mortality and costs . To reduce the amount of blood transfusions actions like coagulation support, also known as haemostatic resuscitation, are important measures

To improve adequate therapy and save time between blood draw and result, point of care coagulation testing is available in the form of viscoelastic haemostatic assays (VHA). VHA analysis can be executed with several techniques like rotational thromboelastometry® (ROTEM®) and rotational thrombelastography® (TEG®). Both techniques are able to measure the resistance of a blood sample, representing viscoelastic changes .

VHA analysis can be used for quick and accurate assessment of the clot function during cardiac surgery. The use of VHA analysis was validated for haemostasis testing in cardiac surgery by several studies. Standardized implementation of VHA analysis reduced blood transfusion, decreased mortality and was shown to be

cost effective. In a pediatric cardiac surgery setting, the use of VHA analysis decreased mean cardiopulmonary bypass surgery time with 15 minutes.

However, interpretation of VHA is more complex compared to conventional tests and shows a learning curve. Even though VHA analysis is a validated test that improves patient outcome, it is not yet frequently used during (cardiac) surgery. For the interpretation of VHA analysis several flowcharts have been built, suggesting the difficulty of direct VHA analysis interpretation. VHA interpretation can be simplified by creating a model able to interpret the parameters and able to support the physicians in the optimal strategy to correct coagulation and is therefore of interest.

Study objective

The primary objective of this study is to provide a supportive model for optimal coagulation management in the OR and/or ICU to reduce blood loss. This support will be divided into two models to first assess a problem in the coagulation cascade and second, to give guidance about the kind and amount of coagulation therapy necessary.
Both models will be trained on the *gold standard*, stated as the consensus of at least 2 experts on the interpretation of VHA testing and the advice on the kind and amount of coagulation therapy. The gold standard will be based on all VHA analysis, platelet aggregation analysis, and patient/surgery specific data up to that point, like demographics and intermittently recorded pre- intra and postoperative data.

The second objective is to compare the actual choice made by the during surgery/at the ICU with the decision of the expert panel. The products used or ordered within one hour after VHA analysis will be counted as the choice of the physician (who is not a member of the expert team).

Study design

This is a non-randomized prospective data collection study. We evaluate VHA parameters at several time point during and after surgery. Furthermore, demographic data of the patient and the surgical setting are registered. This study is divided into two phases:

Phase 1:
Phase 1 will be a pilot phase, in which 100 patients scheduled for elective cardiac surgery are included. Several models will be created based on VHA parameters, in order to assess the probability whether a supportive model can be created based on the input parameters of 500 patients. This probability will be tested calculating the accuracy of the models. Two supportive models will be created to first interpreted VHA analysis and secondly advise on the optimal coagulation management.

Phase 2:
In case of a go-decision after phase 1, we will increase the patient population with 400 to a total maximum of 500 cardiac surgery patients. With this increase in data, the supportive models will be optimized, resulting in two validated machine learning models for the VHA interpretation and the advice on the optimal coagulation management.

Study burden and risks

Depending on administration of medication or blood products that affect coagulation status , there will be 4 up to 8 time points where blood is withdrawn via standardly used arterial line. Executing VHA analysis at 3 time points is standard of care. In case of an additional need to improve haemostasis, an extra analysis will be performed for clinical reasons. This will result in a low extra burden for participants in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

>= 18 years of age
Planned for cardiac on-pump surgery
Informed consent

Exclusion criteria

- Failed blood sample collection
- No on-pump procedure

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2021
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	23-03-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL75922.018.20