Correlation between ACT anD APTT during Transcatheter Aortic Valve Implantation and Chronic Total Occlusion Percutaneous Coronary Interventions

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Primary Objective: The aim of the present study is to find which point-of-care test (ACT or aPTT) is superior in predicting bleeding complications within 24h after both TAVI (Cohort A) and CTO PCI (Cohort B) procedure. Secondary Objective(s): The...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON49477

Source
ToetsingOnline

Brief title
ADAPT TAVI & CTO PCI

Condition

- Cardiac valve disorders

Synonym
Aortic valve stenosis, Chronic total Occlusion

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Deels klinische zorg;deels via de industrie,Roche Diagnostics

Intervention

Keyword: anticoagulation, monitoring, PCI, TAVI

Outcome measures

Primary outcome

The main clinical study endpoints are any bleeding complication within 24 hours

after the TAVI or CTO PCI procedure.

For Cohort A the VARC2 document is used to determine the presence and severity

of vascular and bleeding complications. For Cohort B the BARC criteria are used.

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Secondary outcome

not applicable

Study description

Background summary

The choice of antithrombotic regimen during TAVI and CTO PCI includes the use of unfractionated heparin. Heparin is the preferred anticoagulant drug in these percutaneous cardiac interventions aiming for an ACT > 200sec or 250seconds depending on the procedure.(1) Heparin has a short half-life time and can be neutralized by protamine.(2)
Monitoring the use of unfractionated heparin during TAVI and PCI can be performed with several measurements, like the ACT and aPTT. To measure ACT, an activator is mixed with whole blood to provide a timing of haemostasis. aPTT is a plasma test in which a surface activator is used to measure the time it takes to form a fibrin clot.(2) In nearly every center ACT is the preferred method (3) because of its ease of use and the assumed reliability.(4) ACT-guided heparin regime during TAVI seems effective in minimizing major bleeding events.(5)

There are limited studies focussing on the difference between ACT- and aPTT measurements. The studies which investigated this difference are merely done in patients with continuous heparin infusions, for example in the setting of extracorporeal membrane oxygenation(ECMO). These studies suggest that there is a better correlation between aPTT and dosage heparin than between ACT and heparin. Also, the correlation between ACT and aPTT seems poor.(2, 6)
The accuracy and correlation of ACT with a point-of-care aPTT test for monitoring the anticoagulation effect of unfractionated heparin has so far not been done in the setting of percutaneous interventions. TAVI requires large bore arterial access and is associated with a relevant frequency of access site related bleeding and vascular complications.(7) CTO procedures often require dual arterial access and the use of different strategies with multiple wires which increases the prevalence of vascular complications, including pericardial effusion.(8, 9)
Precise knowledge of actual anticoagulation during an invasive procedure and at the time of access site closure may affect the incidence of TAVI and CTO PCI related bleeding and vascular complications.
Therefore, the aim of the present study is 1) to compare point-of-care ACT with point-of-care aPTT test and conventional aPTT test and 2) to correlate the measured ACT, and point-of-care aPTT with any bleeding and vascular complications during TAVI and CTO PCI.

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Study objective

Primary Objective:
The aim of the present study is to find which point-of-care test (ACT or aPTT) is superior in predicting bleeding complications within 24h after both TAVI (Cohort A) and CTO PCI (Cohort B) procedure.

Secondary Objective(s):
The secondary objective is to find the correlation between the activity of unfractioned heparin, the point-of-care ACT test and the point-of-care aPTT test. The laboratory APTT test and factor anti-Xa assessment will be used to further evaluate the activity of unfractioned heparin.

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Study design

A Single-center, prospective, observational study which will be performed in two cohorts with their own challenges: Cohort A includes patients undergoing a TAVI procedure and Cohort B consist of patients undergoing a CTO PCI.

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Study burden and risks

According to the Dutch Federation of University Medical Centers (NFU) the risk for patients involved in this trial is very limited. Patients participating in this trial only give an extra, small, amount of blood (2.7mL) from an already available intravenous access. The intravenous access is standard of care during both the TAVI and the CTO PCI procedure. Also, the use of heparin is standard of care and the doses of heparin will not be changed due to this study.

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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

Patients accepted for a TAVI procedure to replace the aortic valve.
Patients accepted for PCI procedure of their chronic total occlusion

Exclusion criteria

none

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):	21-07-2021
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	10-09-2020
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	NL73749.078.20