

A comparison between cardiac output monitoring using (invasive) pulmonary artery catheter and (noninvasive) thoracic electrical bioimpedance

Submission date 24/05/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/06/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/03/2018	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

During cardiac surgery, patients are monitored to evaluate cardiac function. In patients scheduled for cardiac surgery this usually includes either the use of a pulmonary artery thermodilution catheter (PAC) or endotracheal echocardiography. At the time the study was conducted PAC was the golden standard. Newer devices have come out that need research in order to ensure that they are accurate and precise at measuring cardiac output. The aim of this study is to compare the Aesculon™ bioimpedance electrical cardiometry (Aesc) to the pulmonary artery thermodilution catheter (PAC) technique before, during and after cardiac surgery.

Who can participate?

Adults aged 18 and older who are scheduled for cardiac surgery.

What does the study involve?

Participants who are undergoing cardiac surgery are randomly selected to participate in this study. After induction of anaesthesia, a PAC and the Aesculon™ device are placed on the participant. Participants are measured using the standard pulmonary artery catheter and a thoracic electrical bioimpedance monitor. They have four additional electrodes placed on their neck and chest. Data from the monitors are recorded at certain time points to measure the accuracy and precision of the PAC compared to the Aesc.

What are the possible benefits and risks of participating?

There are no benefits or risks with participating.

Where is the study run from?

Maastricht University Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
November 2008 to November 2010

Who is funding the study?
Maastricht University Medical Centre (Netherlands)

Who is the main contact?
Mr Boris Cox
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MEC 08-4-075

Study information

Scientific Title
Accuracy, precision and trending ability of electrical cardiometry cardiac output versus pulmonary artery thermodilution method: a prospective study

Study objectives
The aim of this study is to compare the accuracy, precision and trending ability of a thoracic bioimpedance technique with pulmonary artery thermodilution before, during and after surgical intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)

Institutional review board of the Maastricht University Medical Center, 15/12/2008, ref: MEC 08-4-075

Primary study design

Observational

Study design

Prospective observational study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Measurement of cardiac output with different devices in patients scheduled for cardiac surgery.

Interventions

After obtaining written informed consent of each patient, participants are randomly sampled from patients undergoing cardiac surgery. They receive the standard level of care during surgery. After induction of anesthesia, a pulmonary artery catheter (PAC) and the AesculonTM device are placed on the participant. The index test is a thoracic electrical bioimpedance cardiac output monitor (Aesculon, Osypka Medical, Berlin, Germany). The reference test was a pulmonary artery catheter (Edwards Life sciences Corporation, Irvine, CA, USA, Continuous Cardiac Output VIP catheter with SvO₂, model 746F8).

The only difference to standard care was the placement of four additional electrocardiography electrodes. Two electrodes are placed in the neck and two are placed at the thoracic level. Only data from standard monitoring and bioimpedance were recorded. There were no benefits or risk for patients taking part in this observational study.

All measurements are performed at certain time points and there was no interference with standard care and monitoring. There was no need for follow up within this study group. Measurements are performed at six time points: after induction and prior to incision (T1), prior to cannulation of the aorta (T2), ten minutes after protamine administration (T3), 30 minutes after arrival in the ICU (T4), 1 hour after extubation (T5), and one day post-operatively at 08.00 AM (T6).

Intervention Type

Device

Primary outcome(s)

1. Accuracy and precision are measured using Bland Altman analysis by comparing results from the clinical gold standard pulmonary artery catheter to the results from the new device, the bioimpedance cardiac output monitor at 6 time points, after induction and prior to incision, prior to cannulation of the aorta, ten minutes after protamine administration, 30 minutes after arrival in the ICU, one hour after extubation, and one day post-operatively.
2. Polar plot methodology was used to objectify trending ability of the new technique (AesculonTM).

Key secondary outcome(s)

Our secondary aim was to assess whether the surgical incision, and therefore the interruption of the continuity of the skin of the thoracic cavity and opening of the cavity itself, could be an important factor in the reported discrepancy between the two instruments.

Completion date

12/11/2010

Eligibility

Key inclusion criteria

1. Scheduled for cardiac surgery
2. No contra-indication for the use of the pulmonary artery thermodilution method
3. Aged 18 and older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Contra indication for the use of the pulmonary artery thermodilution method
2. Under the age of 18

Date of first enrolment

18/02/2009

Date of final enrolment

18/12/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Maastricht University Medical Centre

Department of Anesthesiology and Pain Management

Maastricht University Medical Center+
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6202 AZ

Sponsor information

Organisation

Maastricht Universitair Medisch Centrum

ROR

<https://ror.org/02d9ce178>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Maastricht Universitair Medisch Centrum

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study will be available upon request from Boris Cox at b.cox@mumc.nl

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No