

A comparison between cardiac output monitoring using (minimally invasive) esophageal Doppler and (noninvasive) thoracic electrical bioimpedance

Submission date 20/09/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/09/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

During major abdominal surgery patients need to be monitored carefully to ensure that tissues have an adequate blood supply (perfusion) and level of oxygen (oxygenation). This requires monitoring of cardiac (heart) output and stroke volume (the volume of blood per beat) to determine the use of fluids and medication to improve blood pressure and flow. During operations the ideal monitor of cardiac output is as minimally invasive as possible. The aim of this study is to investigate a monitor that is non-invasive and compare it to a widely used minimal invasive monitor. The minimal invasive monitor (esophageal Doppler probe) requires an oral or nasal placed catheter (tube), and the non-invasive device (Aesculon) requires only four electrodes placed in the neck and thorax of the patient.

Who can participate?

Patients aged over 18 who are scheduled for elective major abdominal surgery

What does the study involve?

Under anaesthetic, the esophageal Doppler probe and the Aesculon device are placed on the participant. Cardiac output measurements are performed at eight time points: directly after the start of anaesthesia, after skin incision (cutting), during the surgical procedure when the patient is in a stable condition, after skin closure, just before extubation (removal of breathing tube), and 30 and 60 minutes after arrival in the recovery ward.

What are the possible benefits and risks of participating?

There is no interference with standard care and monitoring. The only difference to standard care is the placement of four additional electrodes.

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?
January 2009 to January 2010

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

Who is the main contact?
Mr Boris Cox

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MEC 09-4-052

Study information

Scientific Title
Accuracy, precision and trending ability of electrical cardiometry cardiac output versus esophageal Doppler: a prospective, observational study

Study objectives
The aim of this study is to compare the accuracy, precision and trending ability of cardiac output measurements of a thoracic bioimpedance technique with esophageal Doppler, before, during and after major abdominal surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Prospective observational study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

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

Interventions

Participants are randomly sampled from patients undergoing major abdominal surgery. They receive the standard level of care during surgery. After induction of anesthesia, an esophageal Doppler probe and the Aesculon 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 an esophageal Doppler probe (CardioQTM, Deltex Medical, Chichester, United Kingdom), using the I2C 72-probe for nasal introduction.

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. 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 eight time points: (T1) directly after induction of anesthesia, (T2) after skin incision, during the surgical procedure when the patient was in a stable condition (T3, T4) were performed at a random moment, (T5) after skin closure, (T6) just before extubation, (T7) 30 minutes and (T8) 60 minutes after arrival on the recovery ward.

Intervention Type

Device

Primary outcome(s)

1. Accuracy and precision is measured using Bland Altman analysis by comparing results from the esophageal Doppler to the results of the bioimpedance cardiac output monitor at the eight timepoints. The esophageal Doppler is validated against pulmonary artery catheter, the more or less gold standard of cardiac output measurement. So, the Doppler technique represents the gold standard in this study
2. Trending ability of the techniques is evaluated applying four-quadrant plot and polar plot methodology

Key secondary outcome(s)

Errors in bioimpedance measures are assessed using interruption of the skin's integrity and opening of the abdominal cavity by a surgical incision at the time of surgery

Completion date

07/01/2010

Eligibility

Key inclusion criteria

1. Patients scheduled for elective major abdominal surgery
2. > 18 years old
3. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Nasal, pharyngeal, laryngeal or esophageal pathologies
2. Beeding disorders
3. Cardiac arrhythmias
4. Age < 18 years
5. No informed consent

Date of first enrolment

25/08/2009

Date of final enrolment

06/01/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

Maastricht University Medical Centre

Department of Anesthesiology and Pain Management

MUMC+

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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/or analysed during the current study are/will be available upon request from P.B.W. Cox.

IPD sharing plan summary

Available on request