Construction of intraoperative pressure-volume loops using transesophageal echocardiography and noninvasive beat-to-beat continuous finger blood pressure monitoring

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Is it possible to reconstruct intraoperative left ventricular end-systolic pressure-volume relations from a combination of non-invasive finger arterial blood pressure measurements and transoesophageal echocardiography in patients undergoing surgery…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON36363

Source
ToetsingOnline

Brief title
LOOPS

Condition

- Other condition

Synonym
Intraoperative cardiac dysfunction / Dysfunction of the heart during surgery

Health condition

Intraoperatieve cardiale dysfunctie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac contractility, Intraoperative monitoring, Left ventricular function, Transoesophageal echocardiography

Outcome measures

Primary outcome

1. Validation of the construction of pressure volume loops and end systolic

pressure volume relation using transoesophageal echocardiography and continuous

non-invasive blood pressure monitoring with the Nexfin

2. Relation between dicrotic notch pressure and beat average pressure

3. Validation of phenylephrine-induced vasoconstriction to use as a loading

intervention to construct the end systolic pressure volume relation from a set

of pressure-volume loops.

Secondary outcome

Not applicable

Study description

Background summary

Methods currently used to monitor cardiac function are invasive and have a risk of complications causing morbidity and mortality. Also, none of the currently used techniques provide direct information on cardiac contractile function. Here we will investigate a method with transoesophageal echocardiography and non-invasive finger arterial blood pressure waveforms to non-invasively

construct pressure-volume loops to describe the end-systolic pressure-volume relations in the heart. This may provide a method to obtain more insight on cardiac contractile function and the interaction of the heart with the vasculature during surgery. This novel method may extend currently available non-invasive intraoperative monitoring standards and contribute to intraoperative therapeutic decision-making. The results of this project may further provide basis for future applications, such as real-time intraoperative PV-loop reconstruction.

Study objective

Is it possible to reconstruct intraoperative left ventricular end-systolic pressure-volume relations from a combination of non-invasive finger arterial blood pressure measurements and transoesophageal echocardiography in patients undergoing surgery?

Study design

Prospective observational clinical trial

Study burden and risks

The study starts and ends in the operating room. Finger blood pressure measurements using Nexfin will not add up to patient discomfort. Transoesophageal echocardiography is standard in cardiac surgery, and is increasingly used in non-cardiac surgery. Echocardiography is performed while patients are under anesthesia, and the burden and risks associated with this procedure are minimal. For the construction of the pressure-volume loops, patients will undergo two loading interventions: vena cava compression and administration of phenylephrine. Vena cava compression decreases preload and blood pressure and may be associated with short-term arrhythmias and decreased coronary perfusion. Phenylephrine is routinely used during anesthesia as vasconstrictor, and is in some cases associated with reflex bradycardia.

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 scheduled for elective:
A. Open abdominal surgery, laparotomy
B. Open cardiac surgery, Coronary Artery Bypass Graft (CABG);A+B:
- Age18-75 years
- informed consent

Exclusion criteria

Group A (open abdominal surgery) specific:
- Known / documented cardiac disease
- ECG / echocardiography abnormalities;Group A+B:
Contraindications for transesophageal echocardiography
Contraindications for arterial line
Contraindications for administration of phenylephrine

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	14-06-2011
Application type:	Amendment
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	NL35259.029.10