APC-trial: Accuracy, Precison and Concordance of Ventricular Field Recognition in patients after open Abdominal Aortic Aneurysm Repair.

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Aim of the studyIn this prospective, observational trial, we aim to investigate the accuracy, precision and concordance of VFR in patients after open abdominal aortic aneurysm (AAA) repair during their stay in the ICU. CO measurements obtained with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON38733

Source
ToetsingOnline

Brief title
Accuracy of VFR in patients after AAA repair

Condition

- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
Abdominal Aortic Aneurysm, Repair abdominal aorta

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Abdominal Aortic Aneurysm Repair, Cardiac Output, Pulmonary Artery Thermodilution, Ventricular Field Recognition

Outcome measures

Primary outcome

To determine the accuracy, precision and concordance of VFRCO measurements in patients after open AAA repair compared to intermittent thermodilution cardiac output obtained with a PAC.

Secondary outcome

To determine accuracy, precision and concordance of VFRCO measurements in patients after open AAA repair compared to continuous cardiac output obtained with arterial waveform analysis (ProAQT/Pulsioflex).

Study description

Background summary

Cardiac output measurement
Hemodynamic monitoring and therapy in the operating room (OR) and intensive care unit (ICU) is aimed at maintaining adequate oxygen delivery to the tissues (1). Oxygen delivery depends on adequate oxygenation, presence of sufficient haemoglobin concentration and cardiac output (CO). Measurement of CO in the OR and ICU is therefore important, but its widespread use in these settings is hindered by safety considerations and technical limitations.
An ideal CO monitor should be non-invasive, operator-independent, cost-effective, reliable, and providing continuous measurement with a short response time (2). Various efforts have been made to develop this ideal instrument: echocardiography, bioimpedance, transpulmonary thermodilution, and arterial waveform analysis (2). Until now, no single commercially available CO

monitor fulfils all these requirements, and question remains which CO monitor technique should be used when CO measurement is indicated.

Ventricular Field Recognition
Recently, a new, non-invasive, continuous CO monitoring technique has been developed by researchers of the Department of Medical Technology and Clinical Physics of the University Medical Centre in Utrecht: Ventricular Field Recognition (VFR) (3, 4). VFR is based on the finding that, if a weak electric current is applied over the thorax, emptying and filling of the ventricles during the cardiac cycle give rise to two-dimensional spatial patterns of voltage changes on the thoracic skin, which are different from patterns obtained during filling and emptying of the atria (4). Atria and ventricles are differently located inside the human thorax, and hence the atrial epicentre locates differently compared to the ventricular epicentre.
Moreover, a predecessor of this technique was previously investigated in the University Medical Centre under protocol number 00/203. That technique used an identical positioning of the current injecting electrodes, but a different positioning of voltages sensing electrodes. The underlying stroke volume algorithm was quite different. That investigation resulted in a publication in Intensive Care Medicine concluding that a more robust approach for estimating stroke volume index may exclude inconsistencies in the underlying algorithms for estimating stroke volume (5). Therefore, VFR was developed.

Recently, VFR was used in six Dalland pigs, and CO measured with this device (VFRCO) was compared to CO obtained with an invasive ultrasonic flow-probe (FPCO) around the ascending aorta. Variations in CO were achieved by a change in ventricular loading conditions, cardiac pacing and dobutamine administration (3). The results demonstrate that VFRCO was comparable to FPCO in that specific animal model in a wide range of CO measurements. It was postulated that VFR has the potential to become a clinical applicable CO monitor.
In addition, VFR was compared to CO measured at the LVOT with TTE in 7 healthy volunteers, using G-suit inflation and deflation to provoke stroke volume changes (4). In this study, VFR was able to track changes in stroke volume reliably in an in-vitro study and in healthy volunteers.

Study objective

Aim of the study
In this prospective, observational trial, we aim to investigate the accuracy, precision and concordance of VFR in patients after open abdominal aortic aneurysm (AAA) repair during their stay in the ICU. CO measurements obtained with VFR (continuous) are compared to two reference techniques: 1) intermittend thermodilution with a pulmonary artery catheter (TDCO) and 2) continuous arterial waveform analysis CO measured with ProAQT/Pulsioflex (PCO).

Study design

We designed a single-centre, prospective observational trial in 27 patients scheduled for open Abdominal Aortic Aneurysm repair.
In the OR, before induction of anesthesia, a peripheral infusion line (16G) and a radial arterial line (20G) are routinely placed under local anesthesia in these patients. After induction of anesthesia, a pulmonary artery catheter (PAC, 7.5F, CCOmbo CCO/SvO2 catheter, type 744HF75, Edwards Lifesciences, Irvine, CA) is routinely placed for advanced hemodynamic monitoring: cardiac output (TDCO) and central venous oxygen saturation (SvO2). The radial arterial line is routinely placed to monitor arterial blood pressure continuously. Moreover, the arterial line is connected to the ProAQT transducer and the Pulsioflex system (Pulsion, Munich, Germany) providing continuous CO monitoring (PCO). As a result, TDCO and PCO are obtained without the need for additional catheters or deviation from routine care.
After the operation, at arrival in the intensive care unit, current-injecting electrodes will be attached on the neck and on each leg. A set of fourteen voltage-sensing electrodes in a fixed scheme of electrode positions will be attached to the thorax. A continuous harmless, electrical current (2,83 mArms, 55-91 kHz) will be administered inducing voltage changes over the thorax due to cardiac filling and emptying during the cardiac cycle. With these voltage changes, cardiac stroke volume (SV) and hence VFRCO is measured and compared to TDCO and PCO.

Reference CO: the thermodilution technique and ProAQT/Pulsioflex system
TDCO measurement via a PAC is performed in the ICU by five bolus injections of 10 ml of saline 0.9% (7) at room temperature. Each value of TD-CO represents the average of five measurements. Injections will be randomly spread over the respiratory cycle. PCO is continuously measured by connecting the ProAQT sensor to the arterial line. The sensor is fixed at the right atrial level in the intensive care unit.

Measurement of CO: Ventricular Field Recognition
On the neck and each leg, a total of 4 current-feeding electrodes will be attached and connected to a weak and harmless high-frequency AC current source. Furthermore, a set of fourteen voltage-sensing electrodes in a fixed scheme of electrode positions will be attached to the human thorax. A small, harmless, electrical current (2.83 mArms, 55-91 kHz) will be administered continuously, and because of cardiac filling and emptying during the cardiac cycle, voltage changes are measured over the thoracic skin. The voltage differences are processed by the VFR electronics (filters and amplifiers) and digitized using AD-converters. The digital voltage data are then fed into a computer that uses the VFR algorithm (4) to compute Stroke Volume, Cardiac Output and ventricular volume-time curves continuously. The Department of Medical Technology and Clinical Physics of the UMC-Utrecht is the official department within the UMC-Utrecht, which is responsible for the safety of medical equipment. On the basis of this responsibility, the Department of Medical Technology and Clinical Physics of the UMC-Utrecht has performed safety tests on the VFR equipment, and has produced a safety analysis report of the VFR.

Measurement of CO: timing in the intensive care
After the operation, CO is continuously measured with VFR and the ProAQT system. Data of VFR and the ProAQT are automatically stored in a digital patient database. Moreover, at four time points after the operation, CO is additionally measured with the thermodilution technique:
- after arrival in the ICU
- after achieving normothermia in the patient (rectal temperature >36.5º)
- 15-30 minutes after extubation
- the next morning after the operation.
In addition, when the hemodynamic status of the patient desires a fluid challenge, pulmonary artery thermodilution CO will be measured before and immediately after the fluid challenge.

Data collection
A continuous registration of CO measured with VFR is obtained by storing the calculated SV, CO and ventricular volume-time curve data on the hard disk of the on-board computer of the VFR system. A continuous registration of CO measured with Pulsioflex is obtained by connecting the ProAQT sensor to an arterial catheter. This registration is automatically saved in a database. All TDCO measurements required for the study are registered in the digital patient data registry and on a special study record form. The time, at which a TDCO measurement takes place, is registered to allow comparison with the corresponding VFR-derived CO values.
Moreover, continuous measurements of the VFR-system are compared with the continuous measurements obtained with the ProAQT-system.
Data of patients will be anonymously stored according to their sequence in participating in the study: APC1, APC2, *. to APC27.

Study burden and risks

POTENTIAL RISKS: There are no risks known associated with the weak high frequency electric current that is imposed on the patient using non-invasive skin electrodes in VFR. The skin electrodes (commercially available) however are known to potentially cause a light form of irritation of the skin in a small number of patients.

BENEFITS: The measurement of left ventricular stroke volume (SV) and cardiac output (CO) is important in the hemodynamic management of peri-operative and critically ill patients. Pulmonary artery thermodilution CO monitoring using the pulmonary artery catheter has major disadvantages, because pulmonary artery catheterization is time-consuming, and associated with a risk of morbidity and mortality.
Noninvasive ultrasound Doppler techniques to determine CO have been developed, but require skilled operators, and therefore are not suitable for monitoring CO continuously. More recently, esophageal Doppler, Fick principle applied to carbon dioxide, and pulse contour analysis have been identified as key technologies for cardiac output monitoring. Furthermore, recent advances in MRI

show promising results in measuring cardiac output. However, MRI is obviously not suitable for continuous bed-side monitoring.
Thoracic impedance cardiography (ICG) is a non-invasive technique, but conflicting results concerning the validity and reliability of ICG have been reported, varying from satisfactory correlations to poor correlations in comparison to thermodilution CO measurements.
The new VFR technique combines the advantages of ICG (non-invasive, continuous monitoring of stroke volume) with a higher number of independent skin electrodes, advanced electrode placement and improved algorithm for calculating the stroke volume and ventricular volume-time curves.

Contacts

Public
Academisch Medisch Centrum

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Academisch Medisch Centrum

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients scheduled for open Abdominal Aortic Aneurysm repair

Exclusion criteria

- preoperative existing arrhythmias
- valvular heart disease (insufficiency or stenosis grade >= 1)
- intracardiac shunts
- emergency surgery
- age < 18 years
- patients with a contraindication for pulmonary artery catheter insertion

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-06-2013
Enrollment:	27
Type:	Actual

Medical products/devices used

Generic name:	Ventricular Field Recognition device
Registration:	No

Ethics review

Approved WMO Date:	28-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL43176.041.13