MINIMAL INVASIVE MONITORING OF VOLUME STATUS IN PATIENTS AFTER MAJOR ABDOMINAL SURGERY.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22383

Source
NTR

Health condition

Major abdominal surgery

Sponsors and support

Primary sponsor: afdeling anesthesiologie van het LUMC
Source(s) of monetary or material Support: Institutional funding

Intervention

Outcome measures

Primary outcome

Cardiac output values (thermodilution, LidCO, Vigileo, Hemosonic).

Secondary outcome

Mean systemic filling pressure, MAP, Pv, CVP, PAP, HR, SVV and PPV.

Study description

Background summary

Determining volume status is important in critically-ill patients. Currently no gold-standard is available to accurately assess a patient's volume status and physicians use clinical signs and hemodynamic parameters (like cardiac output) to estimate volume status.
Currently, the Pulmonary Artery Catheter (PAC) is one of the standards to monitor major abdominal surgery patients. Its use, however, is related to complications upsetting its value in other subpopulations like septic patients. The primary aim of this study is to evaluate the use of less invasive techniques to determine cardiac output (with pulse contour) compared to thermodilution cardiac output measurement with a pulmonary artery catheter. If proven accurate less invasive techniques could replace the PAC in the perioperative monitoring of major abdominal surgery patients.

A second aim of this study is to develop novel techniques to determine mean systemic filling pressure. Mean systemic filling pressure (Pmsf) is the equilibrium pressure in the systemic circulation when there is no flow. Mean systemic filling pressure is thus a measure of volume of the systemic circulation (and thus volume status)[1]. In the operating room and intensive care unit it is not possible to achieve a situation when there is no systemic flow. However, two novel methods can be used to accurately determine Pmsf [2] in heart-beating patients; 1: by arm occlusion or 2: through a ventilator hold maneuver. We hypothesize that a third model can be used; mean systemic filling pressure can be calculated beat-to-beat using cardiac output (CO), stroke volume (SV), central venous pressure (CVP) and mean arterial pressure (MAP) measured during normal ventilation, a single expiratory hold and a single inspiratory hold of 12 seconds. The former two models have been validated in patients after coronary artery by-pass grafting surgery. The two methods to estimate Pmsf have not yet been used in other populations.

Another important issue regarding estimation of volume status is the use of sedative drugs in the ICU and OR and their effects on hemodynamic parameters and their influence on the quality of the measurement of these parameters. In this study we will evaluate the effect of different levels of propofol sedation on Pmsf, venous and arterial resistance and the accuracy of CO measurement with different techniques (for instance pulse contour analysis).

Study objective

Propofol does not change accuracy of pulse contour cardiac output measurements

Study design

11 min after TCI of propofol has achieved a predicted blood concentration of 6 µg•mL-1, again 11 minutes after the propofol target concentration is lowered to achieve a blood concentration of 4 µg•mL-1 using TCI. These steps are repeated at target propofol concentrations of 2 and 1 µg•mL-1. Subsequently measurements are repeated prior to, 30

seconds after start and 2 minutes after returning to baseline conditions for 30° passive leg raising, PEEP +5 cmH2O and PEEP +10cmH2O. Finally, 500 mL of Voluven is administered in 50 mL bolus with intermediate measurements.

Intervention

Propofol administration at different plasma concentrations.

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients requiring mechanical ventilation after elective esophagus resection or Whipple surgery admitted to the post-anaesthesia care unit (PACU) with an indication for pulmonary artery catheter monitoring.

Exclusion criteria

1. Hemodynamic instability with a mean arterial pressure (MAP) < 70 mm Hg, central venous pressure (CVP) >18 mm Hg and/ or a cardiac index < 2.0 L•min-1 or dependence on high dosages of inotropic drugs after admittance to the PACU;

2. Severe arrhythmias;

3. Intra-cardiac shunts;

4. Prior diagnosis of aberrant cardiovascular anatomy;

5. Symptomatic peripheral vascular disease;

6. Symptomatic pulmonary disease;

7. Clinically significant aortic aneurysm;

8. Significant valvular regurgitation.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2010
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-08-2010
Application type:	First submission

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
NTR-new	NL2379
NTR-old	NTR2486
Other	EudraCT / CME / WEC : 2010-019073-15 / P10.67 / 0908;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A