Pressure distribution in the thorax during mechanical ventilation and its effects on the circulation

Published: 07-08-2009
Last updated: 04-05-2024

The primary objective of the study is to evaluate the indexation of the dynamic parameters for predicting fluid responsiveness at different tidal volumes and to compare the performance of the individual dynamic indices with an integrated parameter....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33072

Source
ToetsingOnline

Brief title
Pressure interactions heart and lung

Condition

- Other condition

Synonym
fluid challenge, volume responsiveness

Health condition

Post-hartchirurgie patienten

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Pre-ejection Period, Pressure distribution, Pulse Pressure Variation, Volume responsiveness

Outcome measures

Primary outcome

The main study endpoint is a new dynamic parameter that is indexed to tidal volume to predict volume responsiveness and decrease the number of unnecessary (and potential harmful) fluid challenges on the ICU.

Secondary outcome

The second study endpoint is a physiological relational model that describes the distribution of breathing pressures during controlled and supported mechanical ventilation at 2 different thorax compliances. The third endpoint is a reliable method for the prediction of volume responsiveness with the combination of the Nexfin (noninvasive CO technique) and the passive leg raising test.

Study description

Background summary

Fluid administration is a daily intervention on the intensive care unit to improve cardiac output and stabilize circulation in critically ill patients. Simultaneously, the volume status of the patient is very difficult to assess. Too little volume leads to inadequate organ perfusion followed by ischemia and organ failure. Too much volume may worsen heart failure and cause pulmonary and peripheral edema and contribute to further tissue injury and organ dysfunction.

Although dynamic indices have been shown to be more accurate predictors of fluid responsiveness, this relevant and complex task is usually guided by static clinical variables and the specialist*s interpretation due to the fact that the interpretation of dynamic parameters is not fully developed and that they are not universally available. This lack of understanding is partially because of the complex interaction with mechanical ventilation. We hypothesize that knowing the distribution of ventilatory pressures will make it possible to index dynamic parameters to tidal volume and improve their predictive value concerning the volume status of the patient.
In addition, it would be of interest to be able to predict fluid responsiveness in a non-invasive way, especially in critically ill patients. Up to now, continuous non-invasive cardiac output monitoring using Nexfin CO in critically ill patients has not been validated and also not tested for its ability to predict fluid responsiveness. The present research proposal evaluates the possibility and accuracy of the model flow analysis obtained by non-invasive finger arterial pressure measurements to determine fluid responsiveness using passive leg raising. It will also be compared to a more invasive method (that is currently used in the clinic) to assess its ability to measure absolute CO levels accurately. It may make it possible to assess fluid responsiveness in a non-invasive and patient friendly way.

Study objective

The primary objective of the study is to evaluate the indexation of the dynamic parameters for predicting fluid responsiveness at different tidal volumes and to compare the performance of the individual dynamic indices with an integrated parameter. The secondary objective of the study is to determine the way (quantitatively) the ventilatory pressures (as a result of the tidal volume) are being distributed along the thorax (esophagus, pleura, pericardium) for a better understanding and interpretation of the measurements of dynamic indices for fluid responsiveness. The tertiary objective is to determine to what extent the Nexfin is able to predict volume responsiveness in combination with a passive leg raising test.

Study design

Prospective interventional trail in patients scheduled for open heart surgery.

Intervention

During surgery, pericardial and pleural drains are routinely placed. For the patients that participate in the present study, these drains will be accompanied by small catheters for pressure measurements. On the Intensive Care Unit the patients are closely monitored and receive regular care from the attending physician who will not be participating in the study, also they receive an esophagus catheter to measure the pressure in the lungs. When the

patient is stable (cardiovascular and respiratory), the patients are ventilated following a specific protocol for a period of 12 minutes. This protocol is repeated with a different compliance of the patients* thorax. This is accomplished by a wide rubber band placed around the thorax of the patient. The band will be adjusted to obtain a decrease of 25-30% in compliance during tidal volumes of 8 ml/kg. The passive leg raising test is performed in case the patient is considered to be fluid responsive according to clinical reasons and fluid resuscitation is started. Clinical reasons and fluid therapy are interpreted and initiated by the attending physician. The measurements performed for the present study will not be available for the attending physician.

Study burden and risks

During surgery, pericardial and pleural drains are routinely placed. For the patients that participate in the present study, these drains will be accompanied by small catheters for pressure measurements. There is no additional risk or discomfort for the patient.
On the intensive care the patients are normally ventilated with tidal volumes between 6-10 ml/kg. For a short period (12 minutes in total), a protocol for mechanical ventilation is used with variable tidal volumes (4-10 ml/kg). Changes in tidal volume for short periods (3 minutes) will not lead to discomfort in sedated patients and do not result in additional risk for the patient. With use of capnography and adjustments of breathing frequency, respiratory minute volume will be kept constant. The esophagus catheter to measure the pressure in the lungs is used on a regular base in the clinic to measure esophageal pressures and does not interfere with regular patient care and also the elastic bands to influence the compliance of the thorax is commonly used in clinical practice (mostly in female patients with large breasts to prevent sternum dehiscence).
The patients do not need to stay in the hospital longer than needed for medical reasons and no extra hospital visit is necessary.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
6525 EZ Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
6525 EZ Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Elective open heart surgery

Exclusion criteria

Significant cardiac arrhythmias, including atrial fibrillation
Hemodynamically instability, as defined by a variation in heart rate, blood pressure and cardiac output of more than 10% during the 15-min period before starting the protocol.
Recent myocardial infarction (<3 mnd, troponine > 50ug/l)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-12-2009
Enrollment:	22
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	07-08-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL28860.091.09