Uisng changes in pulmonary mechanics and gas exchange to better define the optimal pulmonary volume in patients ventilated for acute lung injury

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Describe and observe *functional* recruitment as defined by the physiological responses (O2, dynamic compliance, CO2, haemodynamic responses), using these parameters to find the point of the most efficient alveolar minute ventilation at the lowest...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON32764

Source
ToetsingOnline

Brief title
Pulmonary mechanics to better define the optimal pulmonary volume in ALI

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
ARDS, respiratory insufficiency

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: Artificial, Lung Compliance, Respiration, Respiratory Distress Syndrome, Respiratory Mechanics

Outcome measures

Primary outcome

* Comparison of pulmonary physiological, circulatory, and ventilatory

parameters in each patient, enabling correlation between these parameters:

haemodynamic parameters, blood gas analysis including oxygen

saturation, PaO2/ FiO2, v CO2, opening pressure, closing pressure,

oesophageal pressure, plus during CMV we will also measure dynamic

compliance, elastance, respiratory inductance plethysmography and deadspace.

* Correlation of PEEP/MAP and the TPP with currently used markers indicating

achievement optimal lung volume (pO2, p CO2, dynamic compliance, deadspace).

* Comparison of two groups * to compare above parameters between the two

groups of primary and secondary ARDS

Secondary outcome

bloodgasses, hemodynamics

Study description

Background summary

Ventilation strategies in children and neonates vary widely between institution and school of thought. There is increasing evidence in the literature supporting an *open lung ventilation strategy* in both animal models and humans. This concept is based on having a fully recruited *open* lung, protecting the lung from further ventilator induced lung injury (VILI) caused

by repetitive opening and closing of unstable lung units during tidal ventilation (tidal recruitment).
Open lung ventilation is achieved during conventional ventilation by optimizing lung volume (the restitution of functional residual capacity) using positive end expiratory pressure (PEEP), and using smaller tidal volumes (6ml/kg). This approach minimizes tidal recruitment, and has been shown to be associated with lower mortality and barotraumas in patients with acute respiratory distress syndrome (ARDS). The importance of adequate PEEP in preventing VILI is widely accepted, however this should be the lowest level of PEEP that avoids derecruitment and at the same time does not overdistend the lung. The strategy of open lung ventilation is equally effective in both conventional and high frequency oscillatory ventilation (HFOV). Both laboratory experimental studies and clinical experience using high frequency oscillatory ventilation demonstrate that the open lung approach in HFOV is both feasible and safe - even in premature infants.7,1,5,9
Recruitment occurs throughout the respiratory cycle, and both PEEP and PIP (positive inspiratory pressure) contribute. There are a number of methods available to open a derecruited lung. Recruitment manoeuvres (inspiratory cycles with high inspiratory and end expiratory pressure) have been extensively used, and are controversial. Their effect is unclear, and they may cause overdistension and haemodynamic instability1. Sustained PEEP recruitment manoeuvres have also been used without clear effect. In the presence of PEEP sufficiently high to enable open lung ventilation, recruitment manoeuvres have not been shown to be effective in terms of improving oxygenation.
It has been demonstrated that a recruited lung will, due to hysteresis, require less pressure to remain open, than to initially be opened. Because of this, it is necessary to initially use higher pressures to recruit the lung, then to reduce the pressures to find the optimal PEEP in conventional mandatory ventilation [CMV], to prevent end expiratory alveolar collapse. It is increasingly accepted that only the deflation limb of the pressure volume curve provides information about the PEEP required to maintain an *open lung*, and that ventilation on this more compliant deflation limb enables the pressure amplitude to be minimised as much as possible.
In the current literature there are many parameters under study as surrogate markers to indicate that an *open lung* has been achieved. In the laboratory subject, volume pressure curves can help to set the PEEP just above the lower inflection point on the pressure volume curve (using static compliance); however this is difficult to achieve and often dangerous in bedside practice.
In animal and human studies, in addition to clinical parameters (oxygen saturation, end tidal and CO2
elimination (vCO2), blood gasses, PO2/ FiO2 ratio, systemic blood pressure and cardiac output); markers indicating the open lung state include dynamic compliance, elastance, CT scanning, and calculation of dead space - but many of these tools are impractical, or difficult to interpret in clinical bedside practice.
The mechanics of the lung are governed by the lung and chest wall elastance, compliance, and resistance. Each of these three factors varies with lung, chest

wall, and abdominal pathology, which are often significant in patients ventilated in the intensive care unit. Current ventilation strategies are based on measuring only the pressures within the respiratory system, as pressures related to chest wall compliance and resistance are difficult to measure. As the respiratory and chest wall pathologies and pressures are different in each patient and for each illness, it is therefore logical that the PEEP which will be required for each patient will vary.
Studies of open lung ventilation show that the dynamic compliance reaches a maximum just below the PEEP required for open lung ventilation, and that elastance and dead space reaches a mimimum plateau around the PEEP required for open lung ventilation. As these parameters affect the amount of pressure transmitted across the lung, but not the chest wall, the transpulmonary pressure (TPP) would be expected to measure an attenuated increase in pressure over the pressure range where an open lung state is achieved.
The TPP, measured by the airway pressure minus the oesophageal pressure, measures the net result of respiratory and chest wall pressures. It has been extensively studied in respiratory physiology, but has not been studied in optimizing an *open lung* approach to ventilation. The TPP varies with patient effort, increases during the inspiratory and decreases during the expiratory phases in mechanically ventilated paralysed patients. In mechanical ventilation it measures the interaction between the positive airways pressure from the ventilator, the restrictions imposed by inherent pulmonary resistance and compliance, and the chest wall compliance. If an open lung approach is used, where ventilation occurs at the optimal lung volume and compliance, recording the TPP during and after lung recruitment may provide a correlation between optimised *open lung* ventilation, and the attenuation of the increase of the TPP.
The effective use of *open lung ventilation* requires measurable parameters that are reproducible, without risk, and easy to perform and interpret at the bedside. The transpulmonary pressure may fulfil all of these criteria, and as such warrants further study in a clinical trial.

Study objective

Describe and observe *functional* recruitment as defined by the physiological responses (O2, dynamic compliance, CO2, haemodynamic responses), using these parameters to find the point of the most efficient alveolar minute ventilation at the lowest pressure cost
1. To define the transpulmonary pressure at optimal *open lung ventilation* in patients ventilated by CMV and HFOV with Acute Lung Injury (ALI) or ARDS during a descending PEEP trial
2. To correlate the transpulmonary pressure with other possible markers indicating the open lung state (compliance, elastance, deadspace, blood gasses etc)

Secondary objectives

1. To identify whether the TPP needed to optimise lung volumes (to restitute functional residual capacity) is consistent between patients and different lung pathologies (primary versus secondary ALI/ARDS)
2. Document that lung recruitment and an open lung state can be obtained using stepped PEEP increments and then decrements without an inspiratory recruitment manoeuvre in CMV

To test the hypothesis that

3. The TPP can give us a better idea of the optimal lung volume achieved (as measured by the CO2, compliance, oxygenation etc) than simple airway pressures.

Study design

Prospective observational cohort study with a duration of 12 months.

Study burden and risks

Burden and risk for the patient are primarily given by the underlying disease and related standard IC treatment. The studied intervention (daily optimisation of lung volume) is already a standard procedure on our and other IC units. For this study, the different criteria for defining the optimum lung volume, will be measured and compared. The study will therefore not raise axtra risks or burden for the patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. Inclusion criteria
* Mechanically ventilated
* Have lung pathology (either primary or secondary) who fulfil the definition of Acute Lung Injury (ALI) or Acute Respiratory Distress Syndrome (ARDS) -see below
* And their parents agree for them to participate in the study and give given written informed consent

Exclusion criteria

* Children ventilated for an obstructive lung pathology
* Children with raised intracranial pressure or a head injury

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	01-11-2008
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	14-10-2008
Application type:	First submission
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	NL24044.029.08