Validation of clinical applicable techniques for end inspiratory lung volume (Vei) measurement.

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The primary objective of this study is to validate two clinically applicable techniques to measure pulmonary hyperinflation (Vei) in mechanically ventilated patients with airflow obstruction. This will be done by assessing differences between the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON42776

Source
ToetsingOnline

Brief title
Vei measurement

Condition

- Respiratory disorders NEC

Synonym
pulmonary hyperinflation, too high lung volume

Research involving
Human

Sponsors and support

Primary sponsor: Intensive Care
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: end inspiratory lung volume, hyperinflation, obstructive airway diseases

Outcome measures

Primary outcome

The primary study parameter is the difference in degree of pulmonary hyperinflation, expressed as the volume at end inspiration (Vei) between the gold standard and formula (Vei_measurement versus Vei_formula) and between the gold standard and the ventilator (Vei_measurement versus Vei_ventilator).

Secondary outcome

Other study parameters are based on clinical outcome of patients, such as incidence of pneumothorax, days on the ventilator and need for vasopressors.

Study description

Background summary

Chronic pulmonary obstructive disease (COPD) and asthma are characterized by acute or chronic airflow obstruction due to dynamic airway collapse during expiration (in COPD patients) or airway narrowing by bronchospasm or bronchial wall edema. When on the ventilator, in these patients, lung emptying is slow and in the case of a high ventilator respiratory rate or high tidal volume (Vt) the next inspiration may occur before complete lung emptying. This will result in pulmonary hyperinflation, which is defined as additional volume above the relaxing lung volume (functional residual capacity (FRC)) at the end of expiration. Accordingly, the next inspiration occurs at a higher lung volume. This will result in high intrathoracic pressure, increasing the risk of pulmonary barotrauma, in particular pneumothorax, and hemodynamic compromise. Ultimately, respiratory arrest may develop. To limit the risks associated with pulmonary hyperinflation, intensivists will determine the degree of pulmonary hyperinflation by calculation of the pulmonary volume at the end of inspiration (Vei). Previous studies have shown that maintaining Vei below 20 ml/kg predicted bodyweight limits the risks associated with hyperinflation. Many clinical protocols, including the protocol approved by the medical ICU staff of the Radboudumc dictate a strategy to limit pulmonary hyperinflation based on

Vei.
The Vei can be determined in various ways. The first method to determine Vei is to measure the actual expiratory volume (Vei_measurement). While the patient is ventilated in controlled ventilator mode an inspiratory occlusion maneuver is performed using the dedicated knob on the ventilator. Subsequently, the endotracheal tube is occluded while the patient is disconnected from the ventilator. The tube is connected to a dedicated set-up to measure expired volume. This method is considered to be the gold standard to determine Vei. However, a disadvantage is that this method is rather cumbersome to use in clinical practice and requires specific disposables not always readily available at the bedside.
A second method to determine Vei, which is commonly used in clinical practice, is by using the following formula:

Vei = Vt x Pplateau / Pplateau - PEEPtotal (Vei_formula)

The pressures in this formula can be measured by performing occlusion maneuvers as described above. The plateau pressure (Pplateau) is the airway pressure measured during an inspiratory occlusion and the total amount of positive end expiratory pressure (PEEPtotal) is the airway pressure measured during an expiratory occlusion. PEEPtotal is the sum of externally applied PEEP plus the amount of intrinsic PEEP, the latter represents dynamic hyperinflation. The pressures measured are the mean pressures of the alveoli that are open during an occlusion.
A third method to determine Vei is by measuring the expired volume using the flowsensors of the ventilator. In this method, the patient is briefly (max 45 seconds) switched to another ventilation mode, that allows passive exhalation for up to 45 seconds (pressure support ventilation (PSV)). The expired volume is detected by the ventilator and allows calculation of Vei (Vei_ventilator). This method is easy to use in clinical practice, there is no need for additional equipment and there are no additional costs. However, this method has not yet been clinically validated.
The aim of the study is to compare two clinically used methods for measurement of Vei
against the gold standard.

Study objective

The primary objective of this study is to validate two clinically applicable techniques to measure pulmonary hyperinflation (Vei) in mechanically ventilated patients with airflow obstruction. This will be done by assessing differences between the two techniques and the gold standard.

Study design

This study is a single centre non-therapeutic observational study performed in

invasively ventilated patients on the intensive care unit (ICU) with airflow obstruction. The gold standard will be compared with two clinically applicable techniques to determine Vei in each patient. Measurements will take about 15 minutes, a second set of measurements will be performed if values are outside the range dictated by our clinical protocol and after ventilator settings are changed according to the clinical protocol.

Study burden and risks

The Vei is measured in patients to allow safe mechanical ventilation according to the clinical protocol. In case the Vei is outside the range dictated by the clinical protocol, ventilator settings will be modified according to the protocol and Vei will again be measured in various ways. This could be a potential benefit for patient care.

Occlusion manoeuvers:
Occlusion manoeuvers are frequently performed in clinical practice in this patient population to determine the Vei_formula. In this study the time for expiration (Te) will be slightly longer than according to the current clinical protocol (maximum 45 seconds, instead of 20 seconds). However, in clinical practice patients with airflow obstruction ventilated with volume control ventilation (VCV), may be disconnected from mechanical ventilation several times a day for a period up to 1 minute to avoid hyperinflation. So in fact, the study procedures are not importantly different from clinical practice. Risks are negligible and the burden can be considered minimal. For patient safety, measurements will be terminated in case:
• arterial oxygen saturation < 90%
• heart rate > 140/minute or an increase or decrease in heart rate of more than 20%
• systolic blood pressure > 180 mmHg or < 90 mmHg

Blood withdrawal:
Blood will be withdrawn at least once, and in case ventilator settings are changed, twice. Each sample requires 1.0 ml of blood. Blood will be withdrawn from an indwelling arterial catheter already present as part of routine clinical care. Therefore, no adverse events are anticipated from blood withdrawal.

This study can only be performed in invasively ventilated ICU patients. The Vei is already determined several times a day in this population to allow safe mechanical ventilation. In healthy subjects with airflow obstruction dynamic hyperinflation can also occur, but these subjects are not yet respiratory insufficient and thus these subjects have different lung dynamics. Airway collapse could perhaps be simulated, but this is obviously clinically less relevant as it remains a model and cannot reflect the true in vivo situation.

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

- severe airway obstruction due to obstructive airway diseases (COPD and asthma)
- controlled mechanical ventilation
- deep sedation
- arterial catheter

Exclusion criteria

- hypoxemic failure (FiO2 > 70%)
- presence of pneumothorax

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):	18-11-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2015
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	NL53020.091.15