Electrical Impedance Tomography during Flow Controlled Ventilation in the Intensive Care Unit

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Primary Objective: The primary objective of this study is to assess lung volume measured by EIT and minute ventilation measured by the ventilator during CMV and FCV at the ICU. This will allow for an adequate powercalculation for future studies....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON52522

Source
ToetsingOnline

Brief title
Flow Controlled Ventilation

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Atelectrauma, lung collapse

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: EU-subsidie aangevraagd door Ventinova Medical B.V. ,Ventinova Medical

Intervention

Keyword: Elektrical impedance tomography, Flow controlled ventilation, Mechanical ventilation

Outcome measures

Primary outcome

The main endpoints of this study are lung volume measured by EIT and minute

volume measured by the ventilator during either FCV or CMV at the ICU.

Secondary outcome

Secondary endpoints of this study are a comparison of:

- Airway pressures (peak airway pressure, mean airway pressure, PEEP) between

FCV and CMV.

- Lung aeration score with ultrasound between FCV and CMV

- Hemodynamic parameters (e.g. mean arterial pressure, heart rate, dose of

vasopressors, urine production) between FCV and CMV

- Dissipated energy between FCV and CMV

- Safety of FCV

Study description

Background summary

During controlled mechanical ventilation (CMV) only the inspiration is controlled by either a set driving pressure (Pressure Controlled Ventilation, PCV) or tidal volume (Volume Controlled Ventilation, VCV). The expiration depends on the passive elastic force of the respiratory system and cannot be controlled until airway pressure is equal to the positive end-expiratory pressure (PEEP). Consequentially airway pressure decreases exponentially during expiration. This uncontrolled expiration results in alveolar collapse and significant alveolar heterogeneity, especially in acute respiratory distress syndrome (ARDS).[1] The cyclical opening and collapsing of alveoli is injurious

and contributes significantly to ventilation induced lung injury (VILI).[2] In addition, the mechanical power (or dissipated energy) administered to the lung during CMV is relatively high and potentially injurious.[3]
Flow controlled ventilation (FCV) is a new mechanical ventilation method that uses a constant flow during both inspiration and expiration.[4] FCV results in a linear increase in airway pressure during inspiration and a linear decrease in airway pressure during expiration, as flow is controlled in both phases. In healthy porcine lungs FCV increased the amount of normally aerated lung tissue on CT scan, and decreased the amount of poorly aerated lung tissue as compared to conventional CMV. Thus, FCV improved homogeneity and lung aeration in healthy lungs.[5] In a model for ARDS FCV increased ventilation homogeneity by reducing the amount of atelectasis and improving lung aeration.[6] Both in healthy and ARDS lung FCV resulted in a decrease in minute volume at comparable carbon dioxide levels.[5, 6] In addition, the calculated dissipated energy during FCV is lower as compared to CMV.[4, 7]
FCV is based on an emergency ventilation system (Ventrain; Ventinova Medical B.V., The Netherlands) that restores ventilation through a small bore tracheostomy.[8, 9] The Ventrain working principle was transferred to an automated mechanical ventilator (Evone; Ventinova Medical B.V.). Evone uses an ejector pump and a T-piece to allow both insufflation of oxygen and jet-assisted expiration through a 2.4mm tracheal tube. Occlusion of the ejector pump gas outlet results in inspiration, whereas opening results in expiration by entrainment of air through a long small bore catheter.[10, 11] Because of the small diameter of the tube, FCV has been used during laryngeal surgery providing the surgeon with ample space.[7, 8]
At the moment FCV is mainly used during laryngeal surgery and experience with long term mechanical ventilation (>8 hours) in the Intensive Care Unit (ICU) is limited. The improved ventilation homogeneity, lung aeration and reduced dissipated energy during FCV could be especially beneficial in critically ill patients requiring prolonged mechanical ventilation. This warrants a study with FCV in patients requiring CMV at the ICU. We hypothesize that FCV results in increased lung aeration as compared to PCV or VCV at comparable ventilation settings (i.e. PEEP, peak pressure and FiO2).

Study objective

Primary Objective: The primary objective of this study is to assess lung volume measured by EIT and minute ventilation measured by the ventilator during CMV and FCV at the ICU. This will allow for an adequate powercalculation for future studies.

Secondary Objective(s): The secondary objectives of this study are to assess airway pressures, lung aeration score with ultrasound, dissipated energy, and safety of FCV as compared to conventional CMV modes.

Study design

This is a prospective intervention study comparing CMV and FCV in each patient. ICU patients on CMV are included in this study. All patients are switched to pressure control ventilation if not already in this mode. Lung volume and minute volume during CMV are recorded. Subsequently, FCV is initiated with similar mechanical ventilation settings (PEEP, peak pressure, and FiO2) used at baseline. Lung volume and minute volume during CMV are recorded again. Ventilation settings are adjusted based on peripheral saturation, end-tidal carbon dioxide (etCO2), and arterial blood gases according to standard of care. FCV is continued for 2 to 12 hours, afterwards CMV according to standard of care is continued.

Intervention

All measurements take place on the ICU at the bedside. Patients that require CMV are included in this study following informed consent.

CMV Baseline (standard of care):
Conventional CMV is set according to standard of care and all patients are set on PCV. Lung volume and minute volume are assessed for baseline measurements. Airway pressures in the trachea are measured directly with a probe. This probe is placed within 30 seconds and does not influence respiratory mechanics.

FCV (intervention):
A special connector piece is placed on the standard endotracheal tube and a pressure measurement tube is placed inside the tube for direct tracheal pressure measurement. The patient is then switched to FCV (Evone, Ventinova Medical B.V.). The duration of this procedure is approximately one minute. Initial PEEP, peak pressure, and FiO2 are set according to the last CMV settings. Inspiratory to expiratory ratio is determined by the ventilator. Subsequently, mechanical ventilation settings are guided by peripheral saturation, etCO2, and arterial blood gas. During the first three hours an arterial blood gas sample is taken every hour from the arterial line. Afterwards, arterial blood gases are taken upon indication according to standard of care at the ICU. FCV is continued for 2 to 12 hours. An investigator known with the FCV mode remains available during the study period.

CMV Continued (standard of care):
Conventional CMV is set according to standard of care. Lung volume and minute volume are measured to assess the effects of lung collapse following CMV.

The last 5 patients will not undergo the intervention (FCV) but will only be monitored by EIT on the conventional mechanical ventilation on the ICU (Pressure Controlled Ventilation). This to better interpret the EIT-data on the FCV.

In all patients we strive for a peripheral saturation of 95-100%, a PaO2 <15 kPa, and a PaCO2 of 4.5-6.5 kPa all within normal values according to the

Erasmus MC mechanical ventilation and neurotrauma protocols. In addition, if tidal volumes exceed 10mL/kg predicted body weight, driving pressure (i.e. peak airway pressure) is reduced in order to reduce tidal volume. A tidal volume of 10mL/kg is considered to be acceptable in relatively healthy lungs at the ICU.[16]

Lung volume is monitored by EIT. EIT is a non-invasive, radiation-free, real-time monitoring method to estimate lung volume.[13] EIT measures electrical currents with electrodes similar to electrocardiogram electrodes integrated in an elastic belt on the skin surface. This belt provides us with cross-sectional images of the thorax. An increase in lung volume can be monitored, as an increase in air changes the electrical impedance of the thorax. The ventilation distribution in a 5-10cm thick slice of the thorax can be visualized.[14, 15] At baseline an EIT measurement is performed. Subsequently, all mechanical ventilation parameters and hemodynamic parameters are monitored and recorded continuously.

Study burden and risks

All patients are sedated and on CMV, therefore there will be no discomfort for the patient. FCV has been successfully applied during various kinds of surgery with general anaesthesia. For FCV a small-bore pressure measurement tube is placed inside the standard endotracheal tube, this requires a short disconnection compared to a standard bronchial toilet with a duration of less than a minute. In case of desaturation or any adverse event the small-bore catheter can be removed and standard mechanical ventilation can be applied, restoring the original situation within one minute. An investigator known with the FCV mode remains available during the study period. Lung volume is measured with EIT, a non-invasive, radiation-free monitoring tool. Therefore, the risks of this investigation are limited. Potential benefits seen in preclinical studies are increased lung homogeneity and a decrease in dissipated energy administered to the lung tissue.

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

- The subject is 18 years or older
- Informed consent form is signed by the subject or a legal representative
- Controlled mechanical ventilation via an endotracheal tube

Exclusion criteria

- Severe sputum stasis or production requiring frequent bronchial suctioning (more than 5 times per nurse shift)
- Severe respiratory insufficiency defined as a PaO2 to FiO2 ratio of <100mmHg or moderate to severe ARDS according to the Berlin definition for ARDS
- Untreated pneumothorax (i.e. no pleural drainage)
- Hemodynamic instability defined as a mean arterial pressure below 60mmHg not responding to fluids and/or vasopressors
- Excessive subcutaneous emphysema (prevents proper functioning of the EIT device)
- Thoracic wounds, bandages or other obstruction which prevent proper functioning of the EIT device
- High (>15 mmHg) or instable (requiring more sedation or osmotherapy) intracranial pressure
- An inner tube diameter of 6mm or less

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2022
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Flow controlled ventilation (Evone)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-07-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	01-07-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-02-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT05644418
CCMO	NL68962.078.19