Flow versus Volume Controlled Ventilation in intubated obstructive and asthmatic patients

Published: 11-07-2024
Last updated: 27-12-2024

By using advanced respiratory monitoring, we will aim to gain more understanding about the physiological effects and potential benefits of FCV in comparison to VCV in patients with an exacerbation of their asthma or COPD. We hypothesize that FCV in...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON56884

Source
ToetsingOnline

Brief title
FCV vs VCV in obstructive and asthmatic patients

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma/COPD and obstructive pulmonary dissease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Asthma, COPD, FCV, VCV

Outcome measures

Primary outcome

Primary endpoint is the difference in minute volume after 90 minutes on FCV compared to after 90 minutes of VCV.

Secondary outcome

These following secondary study parameters will be measured at baseline (VCV) and thereafter every 30 minutes on FCV and VCV for a total of 180 minutes:

- Dynamic hyperinflation (EILV; End-Inspiratory Lung Volume)
- Vei (volume end-inspiration; estimated by formula: Vei = ((tidal volume x Pplateau)/(Plateau - PEEPtotal))
- Mechanical Power (Joules per minute)
- Dissipated energy (Joules per tidal volume)
- Airway pressures (peak airway pressure, plateau pressure, mean airway pressure, PEEP, intrinsic PEEP, driving pressure)
- Transpulmonary pressures (end-expiratory transpulmonary pressure, end-inspiratory transpulmonary pressure, transpulmonary driving pressure)
- Regional Ventilatory Delay Index (RVDI)
- Global Inhomogenity Index (GI)
- Gas exchange (ventilatory ratio, arterial blood gas measurements)
- Hemodynamic parameters (e.g. mean arterial pressure, heart rate)

Study description

Background summary

Patients with an exacerbation of asthma or chronic obstructive pulmonary disease (COPD) requiring controlled mechanical ventilation (CMV) on the intensive care unit (ICU) have a mortality rate between 10 and 20%. This mortality rate is largely explained by major complications associated with mechanical ventilation e.g., pneumothorax, cardiovascular collapse and pneumonia. Complications are the result of dynamic hyperinflation that forms the cornerstone in the pathophysiology of both diseases. The diameter of the smaller airways decreases because of inflammation, bronchospasm, mucus (asthma) and the loss of elastic recoil by emphysema (COPD). This leads in particular to a high airway resistance during expiration and the residue of tidal volume in the lung when the next inspiration begins. The result is dynamic hyperinflation with a continuously increasing lung volume with high pressures, pneumothorax (barotrauma) and hemodynamic collapse as a result. During CMV (pressure- or volume controlled ventilation; PCV or VCV) only the inspiration is controlled while expiration is passive, possibly leading to airway collapse and further dynamic hyperinflation. Besides, both ventilation modes are accompanied by high flow rates leading to a further increase in airway resistance and ventilation pressures. Flow controlled ventilation (FCV) is a mechanical ventilation method that uses a relatively low and constant flow during both inspiration and expiration, thereby decreasing airway resistance and preventing airway collapse during expiration. Besides, FCV has shown to have a higher ventilation efficiency measured by a decrease in minute volume at stable arterial partial pressures of carbon dioxide (PaCO2). This makes FCV a very interesting ventilation mode in intubated patients with an exacerbation of asthma or COPD, possibly decreasing the amount of dynamic hyperinflation and complications in these patients. Although FCV is widely used for hypoxic respiratory failure on the ICU so far no studies have been performed in asthma or COPD patients. We hypothesize that FCV in intubated patients with an exacerbation of asthma or COPD results in a lower minute volume (MV) and decreased end-inspiratory lung volume (EILV) as a measurement for dynamic hyperinflation compared to VCV.

Study objective

By using advanced respiratory monitoring, we will aim to gain more understanding about the physiological effects and potential benefits of FCV in comparison to VCV in patients with an exacerbation of their asthma or COPD. We hypothesize that FCV in intubated patients with an exacerbation of asthma or COPD results in a lower minute volume (MV) and decreased end-inspiratory lung volume (EILV) as a measurement for dynamic hyperinflation compared to VCV. Insights from this study allow the optimization of personalized lung protective mechanical ventilation.

Study design

Randomized crossover physiological study comparing FCV and VCV.

Intervention

Patients are mechanically ventilated with VCV at baseline. Upon inclusion the EIT-belt and an esophageal balloon are placed to assess the EILV and transpulmonary pressures respectively. Besides, patients are randomized between the sequence of ventilation mode, namely 90 minutes of VCV followed by 90 minutes of FCV or 90 minutes of FCV followed by 90 minutes of VCV. When VCV is switched to FCV the same mechanical ventilator settings are used as in the VCV mode. After half an hour on FCV the PEEP, drivingpressure and flow of FCV are optimized based on the highest compliance and lowest flow matching with a stable PaCO2. VCV is always set according to standard of care. Total time of measurements / study time is 180 minutes.

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 surgery and on the ICU and the patient will be monitored continuously so the clinical team can act directly in case of any adverse event. Lung volume is measured with EIT, a non-invasive, radiation-free monitoring tool. Transpulmonary pressures are measured with an esophageal balloon that is placed in a similar manor as a nasogastric feeding tube. Therefore, overall the risks of this study are limited. Patients could benefit from FCV by its potential to lower the amount of dynamic hyperinflation and thereby the risk of complications during mechanical ventilation. Besides, by recruitment FCV is able to optimize gas exchange, an effect that is expected to continue after the patient is switched back to VCV. FCV can only be applied during controlled mechanical ventilation. Therefore, this study cannot be perfomed in a different setting.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 years or older;
- Provided written informed consent;
- Undergoing controlled mechanical ventilation via an endotracheal tube;
- Reason for intubation being exacerbation of asthma or COPD;
- Intubated <=72 hours

Exclusion criteria

- Severe sputum stasis or production requiring frequent bronchial suctioning (more than 5 times per nurse shift)
- Untreated pneumothorax (i.e. no pleural drainage)
- Hemodynamic instability defined as a mean arterial pressure below 60mmHg not responding to fluids and/or vasopressors or a noradrenalin dose >0.5mcrg/kg/min
- High (>15 mmHg) or instable (an increase in sedation or osmotherapy is required) intracranial pressure
- An inner tube diameter of 6mm or less
- Anticipating withdrawal of life support and/or shift to palliation as the goal of care
- Inability to perform adequate electrical impedance tomography (EIT) measurements with, e.g.:
o Have a thorax circumference inappropriate for EIT-belt
o Thoracic wounds, bandages or deformities preventing adequate fit of EIT-belt
o Recent (<7 days) pulmonary surgery including pneumonectomy, lobectomy or lung

transplantation
o ICD device present (potential interference with proper functioning of the EIT device and ICD device)
o Excessive subcutaneous emphysema
- Contra-indications for nasogastric tube or inability to perform adequate transpulmonary pressure measurements with, e.g.:
o Recent esophageal surgery
o Prior esophagectomy
o Known presence of esophageal varices
o Severe bleeding disorders

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Evone ventilator (FCV) and Evita or Servo i ventilator (VCV)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-07-2024

Application type:	First submission
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
CCMO	NL86078.078.24