The role of diaphragm muscle EMG monitoring on respiratory physiology in mechanically ventilated patients with ARDS: a pilot study

Published: 26-08-2010
Last updated: 02-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Muscle disorders
Study type	Observational invasive

Summary

ID

NL-OMON34914

Source
ToetsingOnline

Brief title
Diaphragm muscle EMG during mechanical ventilation

Condition

- Muscle disorders
- Respiratory disorders NEC

Synonym
Acute lung injury; Pneumonia

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: ARDS, Electromyography, Mechanical ventilation, Respiratory muscle

Outcome measures

Primary outcome

• Pressure-time product of the diaphragm (measure for work of breathing)

• Patient-ventilator asynchrony index

Secondary outcome

• Transpulmonary pressure (measure for lung stretch)

• Transdiaphragmatic presure (measure for diaphragm function)

• Oxynation index (arterial oxygen tension / fraction of inspired oxygen)

• Respiratory compliance (tidal volume / plateau pressure - toal PEEP)

• Dead space ventilation

Study description

Background summary

Mechanical ventilation is a life saving intervention in patients with acute respiratory failure. The goal of mechanical ventilation is to increase arterial oxygenation and reduce work of breathing. Modern ICU ventilators allow the physicaibn to choose between several ventilatory modes. Roughly, modes are either controlled or supported. It is assumed that in controlled mechanical ventilation the ventilator performs all the work of breathing, allowing rest of the respiratory muscles. A disadvantage of controlled mechanical ventilation is the development respiratory muscle atrophy due to disuse. In addition, controlled mechanical ventilation may be associated with patient agitation due to asynchrony in respiratory centre and ventilator output ("fighting the ventilator"). In supported ventilation (i.e. pressure support ventilation) the

patient activates the ventilator by creating a negative inspiratory pressure. With activation of the ventilator a preset inspiratory pressure is delivered that unloads the inspiratory muscles. A limitation of this mode is the delay between patient inspiratory effort and initiation of the mechanical supported breath. In addition, several studies have shown wasted respiratory efforts during pressure support ventilation. In wasted efforts, the patient aims to trigger the ventilator, but is unsuccessful, due to muscle weakness or the development of intrinsic PEEP. Wasted efforts increase work of breathing and are associated with patient discomfort (*fighting the ventilator*). Finally, with pressure support ventilation, the support is the same with every breath. This could be considered unphysiological because during normal breathing the tidal volume varies considerably.
NAVA ventilation is a relatively new supported mode of ventilation that was designed to better follow patients physiology of breathing. First, trigger delay is significantly shorter during NAVA compared to pressure support ventilation (Spahija, Crit Care Med, 2010). Second, NAVA has been shown to reduce the number of wasted efforts (Spahija, Crit Care Med, 2010). In addition, this study showed that patients ready to be weaned from mechanical ventilation, had significantly lower work of breathing during NAVA ventilation compared to pressure support ventilation. The effects of different ventilatory modes on work of breathing, oxygenation and patient synchrony has not been studied during the acute phase of ARDS.

Study objective

The objective of this pilot study is to demonstrate that NAVA ventilation is superior compared to pressure support and pressure control ventilation in work of breathing (expressed as pressure-time product) patient ventilator synchrony and other physiological variables such as arterial oxygenation.

Study design

Prospective comparative cross-over study.

Study burden and risks

Two interventions will be performed:

1. Placement of modified nasogastric tube
2. Blood withdrawel from indwelling arterial catheter (total 12 ml in 90 minutes).

All ICU patients have a nasogastric tube for feeding and assessment of gastric retentions. However, to perform physiological measurements a modified tube needs to be inserted. The placement of this modified tube does not impose additional hazards (compared to routine nasogastric tubes). After completion of

the study, this dedicated nasogastric tube does notneed to be replaced, but can be used for feeding and assessment of gastric retentions according to clinical protocols.

The risks of nasogastric tube placement are minimal. Nevertheless, patients with elevated risk for complication of nasogastric tube placemnt are excluded from this study (see exclusion criteria).

To the best of our knowledge no solid studies have been published concerning the complication rate of nasogatric tube placement in ICU patients. From our clinical experience we consider the risks of nasogastric tube placement minimal, especially when *high risk patients* are excluded (upper airway / esophageal pathology, bleeding disorders, hepatic failure). Nasal bleeding is the most frequent complication, though incidence is still low.
As mentioned, nasogastric tube placement is routine care in ICU patients. The dedicated nasogastric tube will be used for clinical purposes after completion of the study.

Blood withdrawel will be performed via the indwelling arterial catheter (routinely available in all ventilated ICU patients). In total, maximal 12 ml of blood will be withdrawn in a time frame of 90 minutes. No complications are to expected from this intervention.

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

• Intubated, mechanically ventilated adult patients
• Meeting criteria for ARDS:
o Acute decrease in the ratio of partial pressure of arterial oxygen to fraction of inspired oxygen to 300 mmHg or less
o Bilateral pulmonary infiltrates on chest radiography consistent with edema
o No clinical evidence of left atrial hypertension
• Mean arterial blood pressure >65 mmHg (with or w/o vasopressors).

Exclusion criteria

• Pregnancy (due to altered position of the diaphragm)
• Increased intracranial pressure, or clinical suspicion of elevated intracranial pressure (i.e. neurotrauma)
• Contra-indication for naso-gastric feeding tube
• Diagnosed neuro-muscular disorder before ICU admission
• Recent (<12 hours) use of muscle relaxants
• Exclusion from sedation interruption protocol as used in our institution
• Open chest or -abdomen
• Inability to obtain informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-01-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	naso-gastric feeding tube with two small thin walled balloons
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-08-2010
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	NL31557.091.10