Expiratory muscle activity and function in critically ill ventilated patients

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

Summary

ID

NL-OMON50539

Source
ToetsingOnline

Brief title
Expiratory muscles ICU

Condition

- Muscle disorders
- Thoracic disorders (excl lung and pleura)

Synonym
breathing muscle weakness, expiratory muscle dysfunction

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: expiratory muscles, Intensive care unit, mechanical ventilation

Outcome measures

Primary outcome

The primary endpoint is the coordination between the diaphragm and expiratory muscles, quantified with 1) the pressure-time product (PTP) ratio of the expiratory muscles versus total breathing PTP (PTPex/(PTPex +PTPin)), and 2) as the activation pattern of the respiratory muscles using EMG.

More specific:

- Functional coordination will be assessed with the PTP: PTPex = PTP of the expiratory muscles, as derived from Pga recordings during the expiratory phase of breathing (PTPPga,ex).PTPin = PTP of the inspiratory muscles, as derived from Pes recordings and the recoil pressure of the chest wall

- Timing coordination is the temporal phase relationship of sequential onset and offset of different muscles (activation pattern), using the EMG-derived phase angle.

Secondary outcome

Outcomes derived from study procedures:

- Thoracoabdominal synchrony, as derived from respiratory inductance plethysmography bands.

- Electrical activity of the diaphragm as measured with a EAdi catheter (if present) or with surface EMG

- Clinical and physiologically relevant parameters, such as ventilator settings

Study description

Background summary

Cooperation between inspiratory and expiratory muscles exists to maintain adequate alveolar ventilation and such to satisfy the demands of breathing. The diaphragm is the most important respiratory muscle and its capacity is often impaired by ICU-acquired weaknesses. This is associated with adverse outcome, including prolonged duration of mechanical ventilation and higher mortality. In patients with high load of breathing or low inspiratory muscle capacity, expiratory muscles are often recruited. However, the coordination between the inspiratory and expiratory muscles is poorly understood and highly complex, particularly during the expiratory phase of breathing and when the load imposed on the respiratory muscles increases. In addition, the functional effects of expiratory muscle recruitment are poorly understood.

Study objective

The primary objective is to investigate the coordination (functional and timing) between the different respiratory muscles in ICU patients under mechanical ventilation during assisted breathing and during a spontaneous breathing trial. To this end, we 1) quantitate expiratory muscle effort using the expiratory pressure-time-product derived from Pga recordings (PTPex), 2) we define the relationship between PTPex and the total pressure-time-product of the respiratory muscles (PTPtot = PTPex + PTPin) and 3) we define the activation pattern of the respiratory muscles using sEMG.

Secondary objectives are:
- To evaluate the effects of an SBT on expiratory diaphragm activity
- To evaluate the effects of an SBT on thoracoabdominal synchrony as derived from respiratory inductance plethysmography (RIP)
- To evaluate the correlation between PTPex and other parameters such as surface electromyography (sEMG) of the abdominal wall muscles and their derived parameters, RIP-derived endpoints, and clinical respiratory parameters
- To study whether the activation of the abdominal wall muscles and changes in coordination have effects on weaning outcome

Study design

Observational physiological study

Study burden and risks

Placement of balloon catheters is a standard operational procedure in selected ICU patients for the measurements respiratory muscle effort (i.e. severe acute

respiratory distress syndrome, difficult weaning, high risk for ventilator-asynchronies). We will only enroll patients that already have such catheter in situ. As such, there are no additional risks related to the recordings obtained from this catheter.
All study procedures are non-invasive, or study parameters will be obtained from routine care measurements / chart review.
In this study respiratory muscle monitoring procedures will be performed in a structured manner during a period of 1 hour. Respiratory muscle weakness is common in mechanically ventilated patients and is associated with prolonged mechanical ventilation. Studying the effects of critical illness and mechanical ventilation on the expiratory muscles and the coordination between the inspiratory and expiratory muscles is therefore highly needed. Patients have no direct benefit in participating in this study. However, the measurements of esophageal and gastric pressure are available for the clinicians at the bedside and study observations may be used to further optimize ventilator settings.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Informed consent
- Age > 18 years
- Invasive mechanical ventilation in assisted modes
- Dedicated feeding catheter (Nutrivent) in situ for measurements of respiratory mechanics

Exclusion criteria

- Past history of neuromuscular disorders
- BMI > 30 kg/m2
- Drains/wounds limiting placement of EMG electrodes
- Anticipating withdrawal of life support and/or shift to palliation as the goal of care

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-09-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	04-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-12-2020
Application type:	Amendment
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	NL62021.029.17