Sonographic assessment of diaphragm function during inspiratory loading.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thoracic disorders (excl lung and pleura)
Study type	Observational invasive

Summary

ID

NL-OMON41151

Source ToetsingOnline

Brief title Sonographic assessment of diaphragm function.

Condition

• Thoracic disorders (excl lung and pleura)

Synonym breathing muscle weakness, diaphragm fatigue

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: Diaphragm function, Inspiratory loading, Sonography

Outcome measures

Primary outcome

Changes in sonographic muscle deformation and velocity (i.e. strain and strain rate) during inspiratory loading.

Secondary outcome

- sonographic fractional thickening of the diaphragm during inspiratory loading
- peak activity of diaphragm electromyography during inspiratory loading
- center frequency of diaphragm electromyography during inspiratory loading
- transdiaphragmatic pressure during inspiratory loading
- transdiaphragmatic twitch pressure before/after inspiratory loading
- tidal volume / minute ventilation during inspiratory loading

Study description

Background summary

In spite of the growing evidence that diaphragm weakness develops in mechanically ventilated patients and contributes to weaning failure, the respiratory muscles are poorly monitored in the ICU. Therefore, diaphragm dysfunction is usually unrecognized and only becomes apparent when a patient fails to wean from mechanical ventilation. An important reason for poor monitoring of the diaphragm is that current state of the art techniques for monitoring are cumbersome in clinical routine due to their invasiveness and susceptibility to interference. An ideal assessment of diaphragm function should be available at bedside, fast and easy to acquire and allow standardized quantification. In contemporary intensive care, sonography is ubiquitously available as a non-invasive diagnostic tool, but current diaphragm sonographic methods sample only a small section of the diaphragm and show a low specificity in identification of weaning failure. A relatively new sonographic approach, known as speckle tracking sonography, is a promising technique already used in cardiac sonography that allows quantification of muscular deformation and displacement.

Study objective

We hypothesize that speckle tracking sonography of the diaphragm is a potential non-invasive method to evaluate diaphragm function.

The objective is to evaluate whether speckle tracking sonography of the diaphragm gives a good representation of diaphragm function in a model of inspiratory loaded breathing.

Study design

Prospective observational study.

Study burden and risks

Placement of the double balloon EMG catheter is not painful, but can be discomfortable for the subject. Also, the presence of the catheter throughout the experiment can cause discomfort for the subject. In contrast to electrical stimulation, magnetic stimulation is not painful, because it does not induce high currents in the skin. Due to this wider field of stimulation,

co-contraction of upper limb muscles may occur with magnetic stimulation of the phrenic nerve. This co-contraction could be encountered as uncomfortable by the subject. Therefore, stimulation intensity is gradually increased to let the subject get acquinted with the stimulus intensity.

Both placement of the esophageal catheter and cervical magnetic stimulation have been performed in previous study carried out by the current investigators. Sonography of the diaphragm induces neglectable load for the subject; the subject will hardly feel the positioning of the measuring instrument.

The risk of complications due to procedures in this study is minimal. Healthy subjects are measured, which makes the risk even less: muscle contractility is not harmed. On the other hand, this research is of great clinical importance. In current clinical practice, there is no quick and noninvasive method available to measure strength or fatigue of the diaphragm, although this is a very important measure during weaning from the ventilator.

When the clinician knows why someone cannot wean from the ventilator, the underlying problem can be solved much more quick and effective and possibly the duration of mechanical ventilation can be decreased.

Both placement of the esophageal catheter and cervical magnetic stimulation have been performed in previous study carried out by the current investigators.

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

- age > 18 year

- informed consent
- body mass index < 25

Exclusion criteria

- pre-existent muscle disease (congenital or acquired) or diseases / disorders know to be associated with myopathy including diabetes and auto-immune diseases

- pre-existent lung disease
- upper airway / esophageal pathology
- recent (< 1 month) nasal bleeding

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- phrenic nerve lesions

- any metals in body (pacemaker, splinters, metal stiches).

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NI

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2014
Enrollment:	15
Туре:	Actual

Ethics review

Approved WMO	
Date:	26-05-2014
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

ССМО

ID NL48872.091.14