Comparison of a solid state versus balloon esophageal catheter for the estimation of pleural pressure in healthy subjects

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To evaluate the accuracy of Pes under different levels of inspiratory loading and positions of the subject, measured with a solid state esophageal catheter compared to those Pes obtained by a standard balloon catheter.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON50537

Source
ToetsingOnline

Brief title
Comparison of a esophageal solid state versus balloon catheter

Condition

- Respiratory disorders NEC

Synonym
N/A

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: balloon catheter, esophagus, pleural pressure, solid state catheter

Outcome measures

Primary outcome

The main study endpoint is the difference in Pes based derived parameters obtained by both types of esophageal catheters during each level of inspiratory loading and position. Pes will be measured as absolute value and relative value. Absolute values are Pes values at end-expiration and at peak inspiration (based on flow recordings), relative Pes is the difference between both absolute values (Pes swings).

Secondary outcome

Not applicable

Study description

Background summary

Measurements of esophageal pressure (Pes) as surrogate for pleural pressure are routinely performed in selected ICU patients to facilitate lung-protective ventilation and assess breathing effort. Pes is clinically measured via an esophageal catheter inserted nasally or orally. Current techniques involve balloon catheters. Unfortunately, the balloon deflates over time, thereby attenuating the pressure signal, leading to underestimated breathing effort of the patient. In turn, this can result in prolonged weaning and increased incidences of ventilator induced lung injury (VILI). Additionally, it is becoming evident that balloons need to be filled with a custom amount of air, as the patient's respiratory mechanics, lung volume and mechanical condition of the balloon all influence its output. Given these possible drawbacks of balloon-catheters, one might consider using a solid state esophageal pressure catheter for the measurement of Pes. Another advantage of a catheter with multiple solid-state sensors is that pressure can be measured at different

locations on the catheter. This may give more information about regional pressures, compared to the single pressure measured with a balloon catheter.

Study objective

To evaluate the accuracy of Pes under different levels of inspiratory loading and positions of the subject, measured with a solid state esophageal catheter compared to those Pes obtained by a standard balloon catheter.

Study design

This is a physiological validation study in healthy subjects.

Study burden and risks

The goal of this study is to improve the technique to measure respiratory parameters, which should improve the respiratory support for patients. We do not expect high risks for participating in this study, as measurements will be performed on healthy subjects. The burden to the subject of placement of the catheters used in this study is similar to the placement of a regular nasogastric feeding tube. From our clinical experience, we consider these risks minimal, especially when *high-risk subjects* are excluded (upper airway / esophageal pathology, nasal bleeding disorders) and insertion performed by well-trained nurses or (technical) physicians. Measurements will take place in a safe environment (research room at the intensive care unit), where potential risks can be anticipated immediately. Therefore, we believe that risks are minimal. All other study procedures involve non-invasive measurements. Subjects have no direct benefits from participating in this study. However, participation will benefit to further knowledge and the possibility of improving monitoring of respiratory mechanics.

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

Signed informed consent
Age * 18 year
Healthy

Exclusion criteria

Pregnancy
Upper airway/esophageal/mouth or face pathology (i.e. recent surgery, esophageal varices, diaphragmatic hernia)
Nasal bleeding within the last < 2 weeks
Use of anticoagulants
Medical history of respiratory or cardiovascular problems (e.g. astma, COPD)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2021
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	intelligent Esophageal Pressure System
Registration:	No

Ethics review

Approved WMO

Date:	22-01-2021
Application type:	First submission
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	NL63194.029.17