Comparison of a solid state versus balloon esophageal catheter for estimation of pleural pressure in surgical ICU patients

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To evaluate the accuracy of Pes measurement with a solid-state catheter during controlled and assisted ventilation.

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

Summary

ID

NL-OMON53315

Source
ToetsingOnline

Brief title
Esophageal catheter validation

Condition

- Respiratory disorders NEC

Synonym
N/A

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,Gedeeltelijke

financiering door Pulmotech B.V. ,Pulmotech B.V.

Intervention

Keyword: Esophageal pressure, mechanical ventilation, pleural pressure, solid state sensor

Outcome measures

Primary outcome

The main study endpoint is the difference in Pes based derived parameters obtained by both types of esophageal catheters during controlled and assisted mechanical ventilation. 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 mechanically ventilated intensive care patients to facilitate lung-protective ventilation and assess breathing effort. Pes is clinically measured via an esophageal catheter. Current techniques involve balloon catheters. Unfortunately, the balloon has some important limitations including that it could deflate over time, complex positioning/calibration and the need for regularly checking the adequate filling volume and position. Using a solid-state sensor esophageal pressure catheter for the measurement of Pes may overcome these limitations.

Previous older studies have used solid state transducers,but concluded these were not able to meet the requirements.These studies were, however, performed decades ago and/or might have used pressure transducers that were not correctly (temperature) calibrated. The solid-state catheter proposed for this study has

a state-of-the-art pressure transducer, allowing for temperature and ambient pressure calibration.
Bench tests from the manufacturer as well as a previous investigation in healthy volunteers as performed by this research team demonstrated positive results (see IMDD). We now want to further test the accuracy of this solid-state sensor in mechanically ventilated patients.

Study objective

To evaluate the accuracy of Pes measurement with a solid-state catheter during controlled and assisted ventilation.

Study design

This is a physiological validation study, with a duration of 1.5-2hours and performed on a single day.

Study burden and risks

The aim of this study is to improve the technique for the measurements of respiratory parameters, which could optimize mechanical ventilation management of patients. We do not expect high risks for participants in this study. Placement of the catheter may give some discomfort, but this is similar to placing any nasogastric tube. The participant is still sedated at the time of placing the catheter, therefore no discomfort is expected. Risks of this study will be minimal, especially because high-risk participants (with contra-indication for placing a nasogastric catheter) are excluded for participation in the study and the catheter will be inserted by a trained doctor, nurse or technical physician. The measurements will take place in the intensive care unit where vital parameters are continuously monitored and the clinical team (nurse/doctor) is continuously available, so that potential risks can be anticipated immediately. Further observational study measurements are non-invasive. Participants will not directly benefit from this study, but their participation will contribute to more knowledge in the field of esophageal pressure measurements. Insights may lead to future clinical implementation of a catheter that can more accurately measure esophageal pressure, resulting in clinical benefits.

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

- Signed informed consent
- Planned mechanical ventilation in the ICU following cardiothoracic or abdominal surgery
- Age >= 18 year

Exclusion criteria

- Pregnancy
- Contraindications to esophageal catheter placement (e.g., upper airway/esophageal/mouth or face pathology (i.e. recent surgery, esophageal varices, diaphragmatic hernia)
- Nasal bleeding within the last <2 weeks
- Presence of pneumothorax
- Use of anticoagulants that increase the risk of catheter insertion

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-10-2023
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	intelligent Esophageal Pressure System (iEPS)
Registration:	No

Ethics review

Approved WMO Date:	28-04-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	09-11-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	08-02-2024
Application type:	Amendment
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	NL83565.000.22