Spirometric detection of esophageal intubation

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Determination of the sensitivity and specificity of the algorithm to detect esophageal intubation. (green/red/no light and numerical value of the calculated D-value

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38795

Source
ToetsingOnline

Brief title
Spirometric detection of esophageal intubation

Condition

- Other condition

Synonym
endotracheal intubation, General anesthesia

Health condition

patienten die voor operatie gaan onder algehele narcose

Research involving
Human

Sponsors and support

Primary sponsor: anesthesiologie- onderzoeksbureau
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: esophageal intubation, Spirometric detection

Outcome measures

Primary outcome

Determine the sensitivity/specificity of the fully-automatic device to diagnose

oesophageal intubation based on test ventilations

Secondary outcome

Evaluate the value of the supplementary algorithm to detect tube position

without test ventilation, relying on only pressure waveform analysis during a

conventional *thoracic push*

Study description

Background summary

In endotracheal intubation, it is essential that the trachea is intubated and not the esophagus. In suboptimal situations (outside an operating theatre), malpositioning of the endotracheal tube occurs frequently and is often fatal. The diagnostic tools that are available in the operating theatre are not appropriate for out-of-hospital situations because of several reasons. Moreover, these methods mostly take some time to provide the desired information and don*t have optimal specificity and sensitivity. In order to allow fast diagnosis of this potentially fatal complication, we are developing a fully-automatic detection device to diagnose endotracheal tube malpositioning within 2 seconds.
A high sensitivity/specificity of the algorithm for waveform-analysis was demonstrated in a first study5.
A new device with integrated sensors and microprocessor was developed as a first step to a stand-alone device. This device performs the pressure-registration and the data are sent via Bluetooth to a PC for later analysis. This device was evaluated in intensive care to demonstrate the high sensitivity in patients with pulmonary disease and to demonstrate the feasibility of a battery-powered handheld device for this purpose. These results clearly prove the feasibility and confirm the high sensitivity6.
Now we developed an advanced next generation device, based on the same

electronics as the first stand-alone device, but where the waveform analysis is performed in real-time and a diagnosis is provided immediately. In addition, an extra algorithm is added to the waveform analysis to detect tube location without the need for test ventilation.
A red or green light is activated depending on oesophageal or tracheal tube location. Before it can be reliably used in out-of-hospital emergency situations, a final study in a controlled environment must be performed to evaluate the new electronic system and integrated software. In addition, a higher number of patients needs to be included to more reliably determine sensitivity and specificity.

Study objective

Determination of the sensitivity and specificity of the algorithm to detect esophageal intubation. (green/red/no light and numerical value of the calculated D-value

Study design

interventional study

Intervention

In these patients, automatic pressure waveform is performed during the first three test ventilations after tracheal intubation. After securing of the airway, the oesophagus will also be intubated and three conventional thoracic pushes will be performed. Thereafter, three test ventilations will be performed on both tubes. The sequence (either first 3 times oesophageal followed by 3 times tracheal or conversely) will be determined by randomisation. The responses from the automatic detection device will be recorded. Also all pressure waveforms and computed numbers will automatically be recorded in the internal memory of the device. Thereafter, normal tracheal ventilation will be resumed, any residual gastric air will be evacuated and the oesophageal tube will be removed. Then the procedure can be continued as planned. The whole period of research interventions will take no more than 3 minutes
Main study parameters/endpoints: determination (and automatic recording) of red or green light on the detection device after tracheal and oesophageal test ventilation. Automatic recording of all calculated values by the algorithm and all pressure waveforms during the procedure of test ventilation and thoracic pushes.

Study burden and risks

All measurements will be under anaesthesia. Tracheal ventilation is routine clinical practice. A soft *thoracic push* is harmless and frequently performed for clinical assessment of appropriate tube location in patients where

spirometry is available on the anesthesia ventilator. Test ventilations are also always performed during routine clinical practice. Oesophageal intubation with an endotracheal tube, performed under laryngoscopy by a trained anesthesiologist should be considered harmless. It happens *accidentally* several times a day in any hospital without reported injuries. During the procedure of oesophageal intubation and ventilation, the free airway will already be protected by the tracheal tube with inflated cuff that is already in place. Even during normal clinical practice, manual ventilation using a ventilation mask often causes insufflated gastric air, which is in many cases left *untreated*. In patients included in the study, insufflated gastric air will be removed using a conventional gastric tube.
The total time of the investigational procedure will take maximally 3 minutes in will cause no burden for the patient.

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

- General anesthesia with endotracheal intubation required for the procedure
- Age: 18 years and older
- Total intravenous anesthesia with propofol
(in order guarantee adequate hypnosis during the procedure)

Exclusion criteria

Oesophageal pathology
Patients at risk for desaturation (SpO2 < 95%) if 20 seconds of apnoe is induced after adequate preoxygenation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL45002.042.13