The pathophysiology of post-extubation dysphagia in ICU patients

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Primary Objective: to determine the pathophysiology of post-extubation dysphagia in ICU patients after prolonged endotracheal intubation using simultaneously recorded flexible endoscopic evaluation of swallowing (FEES), high resolution impedance...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON48639

Source
ToetsingOnline

Brief title
Post-extubation dysphagia

Condition

- Other condition
- Tissue disorders NEC
- Injuries NEC

Synonym
Dysphagia, swallowing disorders

Health condition

slikstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diagnostic methods to assess swallowing function, Dysphagia, Endotracheal intubation, Intensive Care

Outcome measures

Primary outcome

The main study parameter is the underlying pathophysiology of PED, which will

be described qualitatively. Goal is to classify patients into

pathophysiological categories.

Secondary outcome

The secondary outcome parameters are the feasibility of the combination of

techniques and possible interactions.

Study description

Background summary

Mechanical ventilation is a widely used treatment on the intensive care unit (ICU). It is a life-sustaining intervention in patients suffering from acute respiratory failure and in patients who need temporary support after major surgery. About 10% of all extubated patients are reintubated.
An important factor that may contribute to reintubation in these patients is swallowing dysfunction (dysphagia). Oral intake may then result in aspiration and subsequently pneumonia. Dysphagia in ICU patients after endotracheal intubation was found to be associated with an increased reintubation rate, length of hospital stay and mortality. Poor outcomes of dysphagia were also shown in a general population of hospitalized patients: a significant association was found with aspiration pneumonia, length of hospital stay and mortality. Dysphagia has a substantial impact on hospital resources like antibiotic prescription, placement of feeding tubes and hospital and ICU length of stay. Estimated costs are almost 550 million dollars in the USA per year.

Aspiration may be prevented by feeding through a nasogastric feeding tube, and dysphagia may be treated by diet modifications, postural changes, compensatory manoeuvres and training exercises.
Lately, increased attention has been drawn to swallowing dysfunction in ICU patients. Although the exact frequency is unknown, swallowing dysfunction after extubation is common: the frequency ranges from 3 to 62% and the frequency of aspiration from 3 to 56%. These wide ranges are probably due to heterogeneity and bias among studies of dysphagia post-extubation (PED).
The etiology is multifactorial and probably develops via several mechanisms: direct laryngeal trauma of the endotracheal tube, impaired sensibility, impaired swallowing reflex, neuromuscular weakness, discoordination and impaired cognition. However, after prolonged intubation, the pathophysiology of swallowing disorders has never been studied properly. Currently, the mechanism(s) of dysphagia in these patients are unknown, preventing precise recommendations regarding management of PED.
A recent international consensus meeting put dysphagia in ICU patients on the research agenda. The working group of the European Society of Intensive Care Medicine recommends to conduct large prospective studies including both pathophysiology and therapy.
In conclusion, post-extubation dysphagia is associated with poor clinical outcomes but the pathophysiology after prolonged intubation is largely unknown. This pilot study is the first step that aims to fill this knowledge gap to ultimately improve current treatment and prevention of dysphagia and its most important complication aspiration pneumonia.

Study objective

Primary Objective: to determine the pathophysiology of post-extubation dysphagia in ICU patients after prolonged endotracheal intubation using simultaneously recorded flexible endoscopic evaluation of swallowing (FEES), high resolution impedance manometry (HRIM) en electromyography (EMG).

Secondary Objective: to assess the feasibility of combining these techniques (simultaneously recorded FEES, HRIM and EMG) en studying potential interactions in healthy subjects.

Study design

A prospective observational study. The study duration is about 1 hour (and will be performed in patients within 24 hours post-extubation). FEES, HRIM and EMG will be simultaneously recorded. The EMG electrodes will be placed below the chin, the flexible endoscope will be introduced and the manometry catheter will be inserted. During the investigation, the subjects will swallow small sips of saline colored with methylene blue, and possibly thicker liquids and solid food.

Study burden and risks

The burden and risks of the study are considered as low. FEES and manometry are invasive measurements but are widely applied at the outpatient department of the ENT and gastroenterology departments. Most patients are not or mildy uncomfortable during the FEES. Risks are negligible, the techniques are considered to be safe.

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 years
• Informed consent

• Extubated after endotracheal intubation for more than 5 days (> 5 days)
• Between RASS -2 and +2
• Able to sit right up
• No respiratory insufficiency/failure (for this study defined as a SpO2 < 92% with a minimum of 3 L nasal oxygen).

Inclusion criteria of the group of healthy persons:
• Age >= 18 years
• Informed consent

Exclusion criteria

• Pre-existing dysphagia
• Tracheostomy or previous tracheostomy
• History of prior intubation < 3 months ago
• Head/neck surgery, head/neck radiation or head/neck disease
• Pre-existent esophageal disorder
• Coagulopathy (thrombocytes < 50*10^9 /l, or PT/APTT > 1.5 times the reference value, or fibrinogen < 1000 mg/l, or use of therapeutic anticoagulation drugs)
• Allergy for xylometazoline (only if indicated)
• Allergy for methylene blue
• Known pregnancy
• Known G6PD deficiency

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-09-2019
Application type:	Amendment
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	ID
ClinicalTrials.gov	NCT03761823
CCMO	NL62184.091.17