Endoscopic evaluation of the paediatric airway after prior prolonged (>24 h) tracheal intubation, a multicenter study.

Published: 22-09-2014
Last updated: 24-04-2024

The first objective of this study is to evaluate by direct laryngo-tracheoscopy the possible role of cuffed versus uncuffed tracheal tubes in producing airway injury in infants and children who were previously more than 24 hours intubated. The...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational invasive

Summary

ID

NL-OMON41240

Source
ToetsingOnline

Brief title
PAAPI (paediatric airway after prolonged intubation)

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
airway injury, narrowing of the airway

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

Intervention

Keyword: complication, cuffed tube, paediatric airway, prolonged intubation

Outcome measures

Primary outcome

Primary outcome parameters are injury or any pathology of the airway caused by cuffed versus uncuffed endotracheal tubes after prolonged tracheal intubation, detected by direct laryngo-tracheoscopy.

Secondary outcome

Secondary outcome parameters are other risk factors which might contribute to airway injury in intubated children. These factors are the brand of the tube, the route of intubation (oral or nasal), and tube size. Further factors are prematurity, age and weight of the patient, the reason for prolonged intubation such as cardiac failure, respiratory failure, sepsis, postoperative ventilation or other, presence of airway infection or shock during intubation. Also adverse events during intubation such as accidental extubation, reintubation, hemodynamic compromise and sepsis will be recorded.

Study description

Background summary

The routine use of cuffed tubes in infants and small children has been extensively discussed because of the potential risk of airway injury (1-3). In the past decade evidence has emerged that cuffed tracheal tubes can be used as safely as uncuffed tubes when comparing post-extubation morbidity as measured by stridor (4-9).Official bodies such as the American Heart Association (AHA) and the International Liaison Committee on Resuscitation (ILCOR) state in their 2005 guidelines for paediatric resuscitation, that the use of cuffed tubes in infants and children is now an accepted alternative to uncuffed tubes (9-12).

So far, only case reports and case series of patients with tracheal intubation injuries, mostly from oversized tracheal tubes, have been published (13, 14). Prolonged tracheal intubation in critically ill patients can cause airway injury (15-17). There has been no significant difference shown in clinical symptoms such as stridor at extubation in paediatric intensive care patients intubated with cuffed or uncuffed tracheal tubes (6). But as mentioned by some authors, stridor at extubation is not a valid outcome measure for assessing airway injury after prolonged tracheal intubation in children. Therefore endoscopic evaluation of those patients is necessary(18).
To date, no large multi-centre endoscopic airway investigations have been performed in small children with previous prolonged tracheal intubation. This would assist in identifying risk factors for airway injury in children and help paediatric anaesthetists and intensivists (19-21) improve the care they give to this vulnerable group of patients. The aim of the study is to systematically evaluate airway injury by rigid endoscopy (laryngotracheoscopy) in children with previous prolonged (> 24h) tracheal intubation with a special focus on whether their trachea was intubated with a cuffed or an uncuffed tracheal tube.

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Study objective

The first objective of this study is to evaluate by direct laryngo-tracheoscopy the possible role of cuffed versus uncuffed tracheal tubes in producing airway injury in infants and children who were previously more than 24 hours intubated.

The second objective is to study the influence of possible risk factors of airway injury: duration of the intubation, tube size, airway infection, shock, sepsis, age, gender and prematurity in infants and children who were previously more than 24 hours intubated.

Study design

In this prospective observational clinical study we will perform a rigid laryngotracheoscopy in those children who had previous prolonged tracheal intubation in our institution and who are now scheduled for elective surgery with mandatory airway instrumentation. Rigid laryngotracheoscopy will be performed by an ENT-surgeon or paediatric anaesthetists within one to five minutes prior to final airway instrumentation in the paralysed paediatric patient. After rigid laryngotracheoscopy, the child*s airway is secured according to institutional guidelines (endotracheal intubation or insertion of

a laryngeal mask). All rigid laryngotracheoscopies are recorded on an electronic storage media, available on the research endoscopy trolley. Each record has a number corresponding with the patient*s data form. An International Study Board Committee (assessor board) will assess the records in a blinded manner using a systematic grading system (See attachment of the study protocol). The study centre number will not be visible to the assessors. The name of the person who performed the laryngotracheoscopy will not be recorded on the study data form, but must be included in the local anaesthesia record.

Study burden and risks

In children, scheduled for elective surgical or diagnostic interventions requiring airway instrumentation, rigid laryngo-tracheoscopy will be added to the usual anaesthetic routine procedures. After induction of general anaesthesia and administering of a muscle relaxant, an ENT-surgeon or paediatric anaesthetist, trained in this procedure, will perform the endoscopy in the preoxygenated, paralysed and conventionally monitored patient (NIBP, ECG, and SpO2) before final airway instrumentation. The rigid endoscope with endoscopy camera attached (outer diameter related to patient*s age) is carefully guided through the larynx down to the carina under monitor vision with electronically recording and then withdrawn from the patient. In case of secretions obstructing the view to interested airway, suction with a soft or rigid suction device is performed and rigid endoscopy repeated.
Maintenance of oxygenation has highest priority; endoscopy will be interrupted as soon as oxygenation (SpO2) starts to decrease. After removing the rigid endoscope from the patient face mask oxygenation is performed and the child*s airway will be secured according to institutional guidelines. The laryngo-tracheoscopy will last approximately 30 seconds. In this time the child will be in apnoe. The whole procedure, including preoxygenation, positioning, preparing the scope and camera will prolong the anesthesia with a few minutes. During this time the child will be ventilated by the attending anesthetist.
Because the patient is paralysed before airway instrumentation the risk for trauma by inadvertent movements is negligible. Laryngo-tracheoscopy will prolong the anaesthetic routine procedure by a few minutes
Beside scientific information, it may be interesting for the medical team and for the parents/patient to know, whether prior intensive care ventilation with tracheal intubation has significantly altered the patient*s airway.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Weitemaweg 12

Rotterdam 3015 CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Weitemaweg 12
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children, aged 1 month to 16 yrs having prior prolonged (>= 24h) tracheal intubation during ICU-stay within the study centre, who are scheduled for elective intervention such as surgery or diagnostics procedures requiring general anaesthesia with airway instrumentation involving muscle paralysis. Children for diagnosis or treatment of stridor are also included
• No known risk for regurgitation
• Written parental consent
• ASA physical status < III

Exclusion criteria

No parental written consent
• Known airway anomalies associated with syndromes or diseases such as TEF and CDH
• Known or suspected difficult intubation
• Emergency surgery or intervention
• Full stomach and/or at risk for regurgitation
• ASA physical status IV and higher
• Patients with current or prior tracheostomy

• Known, suspected or potential cervical spine pathology (e.g. Down*s Syndrome)
• Insufficient clinical details from previous prolonged intubation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-03-2015
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	22-09-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	04-03-2015
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	NL37885.078.13