Evaluation of the clinical application of TcPCO2 measurements during rigid laryngoscopy or microlaryngeal surgery in children

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The objective of this study is to observe the effect of the planned implementation of transcutaneous carbon dioxide monitoring as standard of care during laryngoscopic and microlaryngeal procedures on the quality of care.

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

Summary

ID

NL-OMON50287

Source
ToetsingOnline

Brief title
TcPCO2 during laryngeal procedures in children

Condition

- Respiratory disorders NEC

Synonym
Upper respiratory tract problems requiring surgery

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,Aanmoedigingsbeurs Ned. Ver. voor Anesthesiologie (¤ 800;-).

Intervention

Keyword: Children, Microlaryngeal surgery, Rigid laryngoscopy, TcPCO2

Outcome measures

Primary outcome

The main study endpoint is the quantification of the effect of the clinical introduction of transcutaneous carbon dioxide monitoring during laryngoscopic and microlaryngeal procedures in children. Therefore, the main study parameter is the cumulative carbon dioxide load / shortage, as a fraction of the monitoring time and will be compared between the *pre* and *post* timeframes.

Secondary outcome

- The effect of adequate carbon dioxide management on the required fraction of inspired oxygen (FiO2) and the resulting SpO2 and cerebral NIRS levels (in patients in which cerebral NIRS measurements were performed).
- The amount of use of different types of ventilation (e.g. manual, jet ventilation, spontaneous breathing) during these procedures in relation to the availability of tcPCO2 monitoring. The timing of the application of these ventilation methods is also compared.
- The influence of patient age on measurements.
- The influence of patient age on the effect of the availability of tcPCO2 monitoring.
- The effects of carbon dioxide management without and with transcutaneous tcPCO2 monitoring on vital parameters such as blood pressure and heart rate.

- The occurrence of skin effects during transcutaneous monitoring.

- The effect of the availability of tcpCO2 monitoring on procedure length and

time required to stabilise the patient between procedure steps.

- The learning curve of anesthesiologists using transcutaneous carbon dioxide

monitoring in terms of changing the timing of the application of different

ventilation methods.

- The consequences of the introduction of transcutaneous monitoring on

clinical

practice as evaluated by a questionnaire.

- Comparison of the transcutaneously measured values to eventual blood gas

samples that are taken as part of clinical care.

- Comparison of the end-tidal CO2 values that are obtained in some instances to

the tcPCO2 values.

Study description

Background summary

ENT (ear, nose, throat) surgeons often perform procedures in the laryngeal area, for example on the vocal cords. Due to the use of endoscopic optics to reach and magnify these small structures that lie deep within the larynx, these minimally invasive procedures are called *laryngoscopies*. Microlarynx surgery is performed using an operating microscope with the patient in suspension during laryngoscopy. During these procedures patients are under general anaesthesia. The success rate of these kinds of procedures depends on the exposure of the larynx during surgery. Therefore endotracheal intubation is unwanted.
As a consequence, less invasive ventilation has to be performed via the rigid bronchoscope or laryngoscope. In patients that have a poor pulmonary status the use of high-frequency jet ventilation is also an option. Some procedures are performed with the patients breathing spontaneously. In children ventilation during these procedures is often particularly difficult because children have

less oxygen buffering capacity than adults and a relatively smaller alveolar surface with which to exchange oxygen and carbon dioxide. Blood oxygen levels can be measured with a pulse oximetry finger clip during the procedure. In patients with an endotracheal tube, the washout of carbon dioxide from the blood by the lungs is usually measured in the expired air. However, the methods for ventilation during rigid laryngoscopy and microlarynx surgery are accompanied by a large amount of air leakage, making these end-tidal carbon dioxide (etCO2) measurements very unreliable at best, and most often simply useless.
More complex laryngoscopic procedures can last over an hour, during which a harmful build-up of blood carbon dioxide, hypercapnia, can occur. These high levels of carbon dioxide cause respiratory acidosis, which in turn is harmful to the entire body metabolism.
Also hypocapnia, low levels of blood carbon dioxide, can occur when the patients is hyperventilated. Hypocapnia can cause vasoconstriction in the brain, which is especially dangerous in young children. To prevent the patient from becoming either hypercapnic or hypocapnic it is important that anesthesiologists can measure the blood CO2 levels of the patient during the procedure.
In neonatology an alternative form of carbon dioxide monitoring is now widely used, called transcutaneous monitoring. By slightly heating the skin to above core body temperatures the peripheral skin blood vessels dilate to such an extent that so much blood flows through these capillary vessels that the production of carbon dioxide by local skin cells does not have a noteworthy influence on the amount of carbon dioxide in the blood at this spot. The heat and vasodilation cause evaporation of carbon dioxide through the skin, which in turn can be measured by a sensor. In this way, a reliable measurement of blood carbon dioxide levels can be attained. While this transcutaneous monitoring technique is widely validated and applied in neonatology and sleep studies in children up to 18 years (and older), it has surprisingly not often found its way into the operating room. In our hospital the decision has been made to use transcutaneous monitoring of carbon dioxide during laryngoscopic procedures for management of ventilation of patients under general anesthesia.

Study objective

The objective of this study is to observe the effect of the planned implementation of transcutaneous carbon dioxide monitoring as standard of care during laryngoscopic and microlaryngeal procedures on the quality of care.

Study design

This controlled intermittent time series evaluates the clinical introduction of transcutaneous carbon dioxide monitoring during laryngoscopic procedures in children. The aim of this study is to quantify the quality of care effect of the introduction of this monitoring modality.

At this moment all laryngoscopic and microlaryngeal procedures in children at our hospital are performed without adequate carbon dioxide monitoring. To be able to compare carbon dioxide management before and after the clinical introduction of transcutaneous carbon dioxide monitoring, during the first group of up to 70 patients of which a target of 60 successfully measured procedures in which monitoring is applied the measured values will not be visible to the anesthesiologist. No alternative method for measuring carbon dioxide during these procedures is present for comparison to post-introduction transcutaneous measurements. During the following 70 patients with a target of 60 successfully measured procedures the measured values will be visible to anesthesiologists. Children of any age up to 18 years are eligible for inclusion in this study. As standard of care, SpO2, electrocardiography, blood pressure and other vital parameters are measured during these procedures.

After inclusion of each of the first group of up to 70 patients with a target of 60 successfully measured patients, transcutaneous monitoring will be applied with the measurements visible to the anesthesiologist. To measure a patient baseline carbon dioxide level, the measurement will preferably be started 30 minutes before the start of the procedure. Return to baseline will be monitored during 30 minutes after the procedure. All temperature settings, sensor site skin inspections and sensor location changes will be performed in concordance with standard of care protocols as used in our neonatal and pediatric intensive care units. Logged data is saved anonymously before it can be extracted for analysis.

Intervention

During the thirty minutes prior to the planned rigid laryngoscopy or microlaryngeal surgery, during the procedure and during the 30 minutes after the procedure transcutaneous CO2 levels will be measured continuously using either an OxiVenT or a V-Sign sensor (SenTec AG, Therwil, Switzerland). This sensor will be placed at a measuring site that is either or both proven to provide good measurements or easiest to manage during such a procedure.

Study burden and risks

Transcutaneous carbon dioxide (and oxygen) sensors locally heat the skin to several degrees above the body temperature, potentially causing discoloration of the skin and can eventually lead to burns when left in place for too long. For standard of care, protocols have been implemented in our neonatal and paediatric intensive care departments to eliminate this risk by regularly changing the measuring site to prevent burns. In practice burns have not been seen in recent years. These standard protocols are adhered to in the operating theatre. Due to the observational nature of this study, there is no influence on the application of transcutaneous monitoring and its clinical indication.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient is up to 18 years of age.
Indication to undergo a rigid laryngoscopic and/or microlaryngeal procedure.
Adequate end-tidal carbon dioxide measurements are unlikely during the planned procedure.

Exclusion criteria

Patient is older than 18 years of age
Procedure is carried out while patient is intubated.

Patient has a tracheal canula

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-01-2019
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	26-10-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-02-2020
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	NL60970.078.17