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Influence of the inflated cuff balloon of a laryngeal tube on carotid artery blood flow

Submission date
02/07/2017

Recruitment status
No longer recruiting

Registration date
19/07/2017

Overall study status
Completed

Last Edited
21/02/2018

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Endotracheal intubation is a medical procedure in which a tube is placed into the windpipe (trachea) through the mouth or nose. It is accepted as the “gold standard” to maintain an open airway. However, the laryngeal tube (LT) is an alternative technique that is gaining more importance in the daily clinical routine of emergency and intensive care medicine. The advantage of this new airway device is that it can be inserted blindly through the oropharynx (throat) which enables emergency care personnel to secure a patients’ airway even if they are not in regular use of endotracheal intubation. The LT has been successfully tested in several clinical situations. Little is known about the effects of using the LT on the heart and blood vessels. One study measuring carotid artery blood flow in pigs suggests that there is decreased blood flow when an airway device including the LT is used. For the LT, this might be caused by the extensive volume of the cuff balloon decreasing blood flow in the carotid arteries. The aim of this study is to assess the effects of the different airway devices on carotid artery blood flow during general anaesthesia for routine surgery.

Who can participate?
Healthy patients aged 18 or over scheduled for any kind of surgery

What does the study involve?
Participants are randomly allocated to either the endotracheal tube (ET) or laryngeal tube (LT) group. Once the participants have been anesthetized the allocated airway device is used. After securing the airway an ultrasound examination of carotid artery blood flow is carried out. After this has been done, the participant is intubated using the other airway device. After re-intubation, the ultrasound examination is repeated. These measurements are then used to compare the LT with the ET.

What are the possible benefits and risks of participating?
There are no expected benefits for the participants. Participating might result in a slightly increased risk due to one additional intubation procedure.

Where is the study run from?
University Hospital Krems, Karl Landsteiner University of Health Sciences (Austria)

When is the study starting and how long is it expected to run for?
July 2017 to December 2018

Who is funding the study?
Karl Landsteiner University of Health Sciences (Austria)

Who is the main contact?
Dr Raphael van Tulder
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3

Study information

Scientific Title
The influence of the inflated cuff balloon of the laryngeal tube compared to the endotracheal tube on carotid artery blood flow in anaesthetized patients: a randomized cross over study

Acronym
LT-CBF-Study

Study objectives

There is a difference in the peak systolic velocity (measured with carotid ultrasound) in the carotid artery comparing the laryngeal tube versus the endotracheal tube.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics committee of Lower Austria, 06/07/2017

Study design
Prospectively randomized controlled cross over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Emergency medicine, anesthesiology

Interventions
Adult patients scheduled for elective surgery for any reason will be asked to take part in this study. Informed consent will be obtained after intensive education and during regular pre-anaesthesiological education before surgery. In advance of the study all patients will receive a standard carotid ultrasound. The extracranial carotid arteries will be carefully scanned by duplex ultrasound to exclude >25% stenosis, dissections or aneurysms. After ruling out carotid pathologies regular pre-surgery evaluation will be performed according to local standards.

A non-involved statistician will perform 1:1 randomization before the study starts. Concealment will be achieved with sequentially numbered, opaque and sealed envelopes. At the time the patient is brought to the operational room, a member of the study team will open the dedicated envelope. The patient will then be randomized to either the primary endotracheal tube (ET) or laryngeal tube (LT) group. For airway management procedures regular ETs sized 7.5 mm I.D. for female patients and 8.5 mm I.D. for male patients, as well as LTs sized 4 for all patients (of 155-180 cm height) will be used. Both airway devices are CE marked and in regular use for securing the airway under several circumstances.

During the pre-surgery preparation every patient will be monitored with a standard anaesthesia /operational room setting containing peripheral oxygen saturation (SpO2), a 4-lead electrocardiogram (ECG) and a non-invasive arterial blood pressure monitoring. Arterial blood

pressure will then be obtained continuously every minute. Furthermore, a near infrared spectroscopy (NIRS) pulsoxymetry detector will be attached to the forehead of the patient to enable monitoring of the oxygen saturation in the frontal region of the brain throughout the study procedures.
Induction of anaesthesia for surgery will be done according to the local standard operation procedures. No additional medications will be given for this study. Once the patient is anesthetized, according to the randomization either an ET or a LT will be introduced by the attending anaesthetist. Cuff balloons will be filled according to manufacturers recommendation. The pressure of the cuff balloon will be measured and recorded by using a regular cuff pressure manometer. After securing the airway and maintaining anaesthesia the patient will be included to the ultrasound protocol. Ultrasound of the carotid arteries will now be performed. After the ultrasound protocol has been performed, the patient will be re-intubated using the opposite airway device (ET or LT according to the initial airway device), and the ultrasound examination will be performed again for determining differences in carotid artery blood flow. To minimize inter-observer variability the ultrasound protocol will be performed by only one trained radiologist. Ultrasound examinations will be performed as soon as feasible after patients has been monitored, intubated and anaesthetized. Colour flow and spectral Doppler waveform ultrasound images will be obtained from the common carotid arteries. The radiologist performing the ultrasound will be instructed to record blood flow in the carotid arteries using a commercially available portable ultrasound machine. Therefore, a 11- MHz linear array transducer will be placed on the side of the subject's neck in the transverse orientation using visible anatomic landmarks to identify the carotid artery. In the longitudinal orientation, a pulse-wave tracing of the common carotid artery in the longitudinal orientation will be acquired after the smallest possible sample gate was positioned directly over the center of the common carotid artery 2 cm proximal of the carotid bifurcation. The angle between the ultrasound beam and the longitudinal vessel axis will be kept between 45 and 60°. Images will be acquired from the left and right side. All images and video clips will be stored directly on the ultrasound machine for later retrieval. Pulse-wave measurements will be recorded of both (left/right) common carotid arteries determining peak systolic velocity (PSV), end-diastolic velocity (EDV), and mean diastolic velocity (MDV). Then, in patients with LT, PSV, EDV and MDV will be measured three times (next to one another). After changing the LT to the ET, PSV, EDV and MDV measurements will be repeated three times (next to one another). For further analyses the mean of the respective three measurements (PSV, EDV, MDV) will be used. Standardized forms will be used to collect patient data. Only one, trained physician not involved in the clinical care of the patient will acquire all images. Aiming to keep the time period of duplex scans as short as possible, the duration of duplex examinations will be limited to 15 minutes per patient. Duplex clips and images will be stored on the respective duplex ultrasound machine and all analyses will be performed offline.

Intervention Type
Device

Primary outcome measure
Peak systolic velocity, measured using ultrasound 5 min after intubation

Secondary outcome measures
1. Mean diastolic velocity (MDV), measured using ultrasound 5 min after intubation
2. Enddiastolic velocity (EDV), measured using ultrasound 5 min after intubation
3. Oxygen saturation, measured using near infrared spectroscopy (NIRS) pulsoxymetry detector 5 min after intubation

Overall study start date
07/07/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Adult patients with an age of >18 years
2. Informed consent
3. ASA I-II
4. Mallampati Score classification I-II
5. Scheduled for elective surgery for any reason

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Prior intubation or anaesthesia related adverse events
2. >25% stenosis of the extracranial common and internal carotid arteries
3. Carotid dissections
4. Carotid aneurysms
5. Pre-existing surgeries at carotid arteries or in the area of the neck, throat or laryngeal structures
6. Laparoscopic surgery requiring gas inflation of the abdomen
7. Pregnancy
8. Ward of the state/prisoner

Date of first enrolment
24/07/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment

Austria

Study participating centre
University Hospital Krems, Karl Landsteiner University of Health Sciences
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Sponsor information

Organisation
Karl Landsteiner University of Health Sciences

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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/04t79ze18

Funder(s)

Funder type
University/education

Funder Name
Karl Landsteiner University of Health Sciences

Results and Publications

Publication and dissemination plan
Publication is planned within 12-18 months after the study has started.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Raphael van Tulder (raphael.van-tulder@meduniwien.ac.at).

IPD sharing plan summary
Available on request