The effect of intravenous lidocaine to prevent intracranial pressure increase in endotracheal intubation assessed by optic nerve sheath diameter

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Primary Objective: To investigate the effect on the distention of the ONSD while using lidocaine 1,5 mg/kg IV during endotracheal intubation versus placebo. Secondary Objectives: The secondary objective of this study is to investigate the effect...

Ethical review	Approved WMO
Status	Pending
Health condition type	Injuries NEC
Study type	Interventional

Summary

ID

NL-OMON47899

Source
ToetsingOnline

Brief title
Effect of lidocaine on ICP increase in endotracheal intubation

Condition

- Injuries NEC
- Increased intracranial pressure and hydrocephalus

Synonym
brain pressure, Intracranial pressure

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: Endotracheal intubation, Intracranial pressure, Lidocaine

Outcome measures

Primary outcome

Difference in optic nerve sheet diameter in millimetre before, during and after

intubation between both groups.

Secondary outcome

Time taken for the ONSD to return back to its initial value once the patients

is intubated.

Study description

Background summary

Persistent elevated intracranial pressure (ICP > 20 mmHg) is associated with poor outcome after traumatic brain injury (TBI).[1,4] In the early posttraumatic period there is a high risk of secondary ischemic damage to the brain.
It is therefore necessary that further elevations are prevented and interventions that lower ICP should be initiated as soon as possible to save brain tissue. To evaluate the effect of these strategies ICP should be monitored.[5,6]
Ocular ultrasonography has been investigated to assess elevated ICP. The optic nerve sheath is anatomically continuous with the dura mater, and has a trabeculated arachnoid space through which cerebrospinal fluid (CSF) slowly percolates. Therefore, the optic nerve is subjected to the same pressure changes as the intracranial compartment.[5,7,8] The intra-orbital part of the subarachnoid space is distensible and can therefore inflate when pressure increases.[5,9,10] For this reason, the ONSD as measured by ocular ultrasonography can be considered as a representative for elevated ICP:
Several studies investigated the relationship between ONSD and ICP. [10-20] A

meta-analysis, including 6 studies and 231 patients, showed that ultrasonography of the ONSD is accurate for detection of an elevated ICP.[19-20] The analysis revealed a pooled sensitivity of 0.90 (95% confidence interval 0.80-0.95) and a pooled specificity of 0.85 (95% confidence interval 0.73-0.93).[21] A study investigating the reliability of the sonographic ONSD measurement in ICU patients, whilst manipulating their endotracheal tube, concluded that ONSD and ICP correlate well (R2=0.80). A sensitivity of 94% and specificity of 98% was detected at a cutoff of ONSD >= 5.0 mm, indicating that measuring ONSD is a reliable tool for monitoring ICP.[22] In this study, invasive ICP measuring methods were used.

Patients with traumatic brain injury (TBI) present a particular clinical challenge in prehospital setting, since many airway management techniques potentially increase ICP. Emergency Medical Service (EMS) services in the Netherlands are equipped to perform endotracheal intubation (ETI) or inserting a laryngeal mask airway (LMA) if the airway is not safe. All patients with a Glascow Coma Score (GCS) less than or equal to 8 need to be intubated. Even with a minimal GCS (=3) after TBI, intubation without sedatives and relaxants will trigger laryngeal reflexes that increase ICP.
Coughing and titillation of the laryngeal area causes increased intracranial pressure [23,24].
Adding Lidocaine 1% IV. is used to prevent postoperative cough and sore throat [2]. There is some evidence that giving Lidocaine 1,5 mg/kg BW before intubation might decrease the intracranial response to intubation [3]. Using lidocaine is common practise in ear nose throat (ENT) surgery to prevent from coughing due to irritation of the endotracheal tube. Some of our HEMS physicians use this routinely for anaesthesia induction and intubation of TBI patients for that reason.
The question arises whether the use of lidocaine iv before intubation should become a standard therapy in patients with traumatic brain injury.
To evaluate the effects on ICP in patients without TBI we use the non-invasive ultra-sonographic evaluation of the optical nerve sheath (ONSD). ONSD diameters correlate with ICP changes. [21]

Study objective

Primary Objective:
To investigate the effect on the distention of the ONSD while using lidocaine 1,5 mg/kg IV during endotracheal intubation versus placebo.
Secondary Objectives:
The secondary objective of this study is to investigate the effect size of lidocaine 1,5 mg/kg IV

Study design

We will conduct a double blinded single-centre randomized controlled trial.

Patients undergoing general surgery will be asked to give informed consent to participate. Our study population will be divided in 2 groups. One group of the patients will get an endotracheal tube, the other group will get an endotracheal tube after receiving lidocaine 1,5 mg/kg IV. Lidocaine will be administered 2 minutes before intubation, because than the effect is maximal [25].
Both groups will get standardized anaesthesia to make sure we have one variable.

For the endotracheal tube only group:
opioid (Fentanyl) -> sedative (Propofol) -> muscle relaxant (Rocuronium)
For the endotracheal tube with lidocaine group:
opioid (Fentanyl) -> lidocaine 1,5 mg/kg iv -> sedative (Propofol) -> muscle relaxant (Rocuronium)

The dosage of medication is as followed.
- Fentanyl: 4,0 microgram / kilogram
- Propofol: 2,5 milligram / kilogram
- Rocuronium: 0,6 milligram / kilogram
- Lidocaine: 1,5 milligram / kilogram
See appendix for the leaflets.

Obese patients require special dosing regiments [26]. Therefor we calculate the amount of medication for patients with a BMI greater than or equal to 35 with lean body weight (LBW) and patients with a BMI less than 35 with total body weight (TBW).
LBW is calculated with the formula described by Hume [27]
For men: LBW = (0.32810 × W) + (0.33929 × H) * 29.5336
For women: LBW = (0.29569 × W) + (0.41813 × H) * 43.2933
W = body weight in kilograms and H =body height in centimeters

Patients will randomly assigned to one of the 2 groups using a randomisation list. The ratio will be 1:1. The randomisation list will be made by an independent person, not involved in this research.

Intervention

lidocaine 1,5 mg/kg iv or placebo

Study burden and risks

The technique of OSND-measurement is an accepted technique for an indirect measurement of the intracranial pressure. To our knowledge there are no adverse events associated with applying sterile echo gel to the eyelid. There is also no additional risk regarding the intubation technique because it doesn*t differ from the normal procedure. The burden for the patient is minimal as each measurement will take approximately 2 minutes and no other extra interventions

are needed. The subjects do not benefit from the measurement itself. Perhaps in the near future this non-invasive, in vivo measurement could be used to benefit patients with elevated intracranial pressure. Our results might be food for thoughts to change current protocols.
All drugs used are standard drugs for anesthesia induction. The additional use of lidocaine IV is a commonly used method in daily medical practice. The risk of adverse events is minimal.

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

Patients aged >18 year old, scheduled for elective surgery under general anesthesia with a planned duration of the procedure > 30 min that can be routinely performed with a ETI.

Exclusion criteria

- Surgery of the eye an eye region
- Neurosurgical procedure and neurosurgical procedure in the past
- Neurological disorders
- Bilateral eye trauma
- Glaucoma
- Mentally retarded patients
- Contraindications for the use of lidocaine e.g.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2018
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Lidocaine B. Braun
Generic name:	Lidocaine HCL
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-03-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-08-2018
Application type:	First submission
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
EudraCT	EUCTR2017-000704-26-NL
CCMO	NL60986.078.17