Cardiac sympathetic innervation and coronary blood flow regulation during general anesthesia

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1. Does general anesthesia affect autonomic sympathetic control of coronary blood flow in healthy subjects?2. Does acute inhibition of autonomic sympathetic innervation by means of a thoracic epidural or a thoracic sympathectomy additionally impair...

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

Summary

ID

NL-OMON35529

Source
ToetsingOnline

Brief title
Coronary blood flow regulation during anesthesia

Condition

- Other condition
- Diabetic complications

Synonym
autoregulation disturbances, Diabetic neuropathy

Health condition

anesthesie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: Autoregulation, Cardiac innervation, Cardiovascular autonomic neuropathy, Coronary blood flow

Outcome measures

Primary outcome

Changes in coronary blood flow in the absence or presence of sympathetic

stimulation during sevoflurane anesthesia in patients with and without

cardiovascular sympathetic innervation.

Secondary outcome

Clinical signs of cardiovascular autonomic neuropathy with cardiovascular

reflex tests and heart rate variability.

Study description

Background summary

The central hypothesis in the present project is that general anesthesia may alter autonomic control such that perioperative coronary blood flow (CBF) is significantly disturbed. These disturbances in coronary blood flow may contribute to the development of myocardial ischemia in the perioperative period. Furthermore, patients with an intrinsically altered autonomic sympathetic innervation, like diabetics, are even more prone to develop perioperative disturbances in coronary blood flow. Here we will investigate the direct effects of general and locoregional anesthesia on the CBF. Furthermore, we aim to evaluate whether diabetic subjects and patients undergoing a thoracic sympathectomy show more disturbed CBF responses to anesthesia as compared to healthy subjects.

Study objective

1. Does general anesthesia affect autonomic sympathetic control of coronary blood flow in healthy subjects?
2. Does acute inhibition of autonomic sympathetic innervation by means of a thoracic epidural or a thoracic sympathectomy additionally impair coronary blood flow in healthy, anesthetized subjects?
3. Are patients with an intrinsically impaired autonomic control more prone to develop anesthesia-induced coronary flow disturbances as compared to healthy subjects?

Study design

Open, prospective observational study with invasive measurements

Study burden and risks

Coronary blood flow measurements: Coronary blood flow measurements (CBF) are part of routine clinical care in the department of Cardiology (dr. Otto Kamp). CBF measurements will be performed by non-invasive ultrasound measurements. CBF will be determined by measuring coronary blood flow at resting conditions, during maximal coronary dilatation (by infusing adenosine 140 microgram/kg/min) and during sympathetic stimulation by performing the cold pressure test (immersing the patient*s hand and forearm in ice water). Both adenosine exposure and the cold pressure test may be related to discomfort but with low risk for the patient. Patients will undergo three contrast echo's (pre-, intra- and postoperatively) and patientgroup 2b will undergo a fourth contrast echo 6 weeks postoperatively to study the long term effects of a thoracic sympathectomy. CBF measurements will be performed by an experienced echo technician who performs these measurements routineously. Patients will be informed about the discomfort they may experience by adenosine and the cold pressure test in order to reduce anxiety and stress during the actual measurements. Despite the possible discomfort of CBF measurements we believe that the burden for the subjects is in proportion to the potential value of the present study.

Assessment of autonomic function: All subjects undergo non-invasive cardiovascular reflex tests that are already part of outpatient clinical routine in the department of Endocrinology. The tests will not add up tot patient discomfort, except that for standardization issues and limitations of capacity at the preassessment clinic measurements have to be made at fixed times (morning) and at a separate day in the week before the scheduled surgery. Discomfort from this issue is kept as low as possible by planning coronary flow measurements on the same day.
Blood sampling from an intravenous catheter: In the preoperative phase, blood drawing will be performed by a venapunction. Although venapunction may cause hemorrhages, this risk will be minimized since all blood will be drawn by an experienced physician. Perioperative blood sample drawing from a peripheral

intravenous catheter placement is standard perioperative procedure in all surgical patients, and will therefore not add up to patient discomfort in the present study.

Oral glucose tolerance test: All healthy subjects will undergo a oral glucose tolerance test to exclude the presence of diabetes mellitus or impaired glucose tolerance. Glucose levels will be measured before and 2 hours after ingestion of 75 grams of glucose. This test will not add up to patient discomfort.

Intraoperative and postoperative monitoring. Intraoperative hemodynamic parameters (blood pressure, heart rhythm, BIS monitoring, ventilation, blood oxygen saturation) are part of routine monitoring during anesthesia and will not add up to patient discomfort. Perioperative holter-ECG monitoring will be instituted before anesthesia and be continued in the postoperative phase, but will not add up to patient discomfort.

Thoracic epidural anesthesia: Epidural anesthesia will be instituted before anesthesia conform standard of care, only when epidural analgesia is indicated for the type of surgery.

Sevoflurane anesthesia: The present study requires sevoflurane mask induction of anesthesia, which can be safely be performed in adult patients. Patients will be informed about the procedure and will receive adequate premedication.

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 between 18*75 years
Scheduled for non-cardiac intermediate or high risk surgery
Informed consent
For patient group 2a: indication for thoracic epidural anesthesia
For patient group 2b: undergoing robot assisted thoracic sympathectomy

Exclusion criteria

Known/documented cardiac disease
(Untreated) hypertension
Abnormal ECG or echocardiogram
Peripheral vascular disease
Renal disease requiring hemo- or peritoneal dialysis
Inability to perform transthoracic echocardiography
Medication interfering with presynaptic catecholamine uptake
For patient group 2: contra-indication for thoracic epidural anesthesia (bleeding diasthesis, infection at the puncture site, patient refusal, severe stenotic valvular disease)
Previous allergic reaction to echocardiographic contrast agents
Contraindication for use of echocardiographic contrast agent
Pregnancy
Intracranial neurosurgery
Sympathectomy
Vascular surgery including carotidsurgery

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2009
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL25623.029.08