CARDIAC EFFECTS OF HIGH THORACIC EPIDURAL ANAESTHESIA DURING BICYCLE EXERCISE: AN ECHOCARDIOGRAPHIC STUDY

Published: 02-06-2014 Last updated: 20-04-2024

The primary objective of this study consists of:To evaluate the HTEA effects on systolic and diastolic cardiac function in rest and after different levels of exercise.The seconderyobjectives of this study consists of:To assess the difference in...

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

Summary

ID

NL-OMON40956

Source ToetsingOnline

Brief title cardiac effects of HTEA during bicycle exercise

Condition

• Other condition

Synonym cardiac function, epidural anesthesia

Health condition

invloed van sympathicusblokkade door HTEA op de functie van het hart tijdens inspanning

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: bicycle exercise, cardiac effects, echocardiography, HTEA

Outcome measures

Primary outcome

the first primary objective is the expected

change in pulsed tissue Doppler systolic velocities of the mitral annulus (MV

S*) during maximal exercise.

Secondary outcome

CO: Cardiac output

HR: Heart rate

SBP

DBP

MAP

MV A: Peak mitral inflow velocity during atrial contraction phase

MV A*: Mitral annular diastolic velocity during atrial contraction

MV E: Peak mitral inflow velocity during early filling phase

MV E*: Mitral annular diastolic velocity during early filling

MV E/A: Ratio of E to A

MV E DT: Time interval required for the E velocity to decline from its peak to

the baseline

MV S*: Mitral annular systolic velocity

TV A: Peak tricuspid inflow velocity during atrial contraction phase

TV A*: Tricuspid annular diastolic velocity during atrial contraction

TV E: Peaktricuspid inflow velocity during early filling phase

TV E*: Tricuspid annular diastolic velocity during early filling

TV E/A: Ratio of tricuspid E to A

TV S*: Tricuspid annular systolic velocity

Study description

Background summary

Thoracic epidural anaesthesia (TEA) is considered to be the gold standard anesthetic approach in lung surgery and also widely applied in patients undergoing cardiac surgery.

The cardiac sympathetic outflow emerges from C5 to T5 levels, with the main supply to the ventricles from T1 to T4 1. High thoracic epidural anaesthesia(HTEA) results in blockade of these nerves and changes in heart rate, left and right ventricular function and myocardial oxygen demand may occur. Besides excellent postoperative analgesia and prevention of postoperative pulmonary complications, TEA provides cardiac protection 2, may avoid vasoconstriction of atherosclerotic coronary arteries 3 and may increase the diameter of stenoticepicardial coronary arteries in patients with coronary artery disease 4.

There are several studies on the effect of thoracic epidural anaesthesia on left ventricular (LV) function, but the results are controversial 5, 6, 7, 8. These studies were performed in baseline conditions, where cardiac sympathicotonus is low and sympathicolysis by TEA might not be that influential. The influence of upper TEA on circulation during physical exercise has already been tested 9, 10, but these studies used questionable study designs (repeated exercise tests) and the executed echocardiographic exam was very limited. Furthermore, the influence of upper TEA on the performance of the right ventricle (RV) under physical exercise has not been evaluated. Recently, Rex and colleagues 11 demonstrated that in pigs TEA strongly inhibited the positive inotropic response of the RV to acute pulmonary hypertension, suggesting an important role for sympathetic nervous system. Reason for us to conduct a study that non-invasively evaluates the effects of TEA on biventricular systolic and diastolic function during exercise by using

pulsed wave tissue Doppler imaging. Tissue Doppler imaging (TDI) allows for quantitative assessment of LV and RV function by measuring systolic and diastolic velocities of the mitral and tricuspid annulus 12. We hypothesize that the circulatory and cardiac effects of TEA will be most pronounced during circumstances of increased sympathicotonus, which will be induced by an exercise test on a bicycle. Cardiac function will be evaluated non-invasively by trans-thoracic echocardiography (TTE), measuring systolic and diastolic velocities of the mitral and tricuspid annulus by pulsed and colour coded TDI. The increased sympathicotonus induced by bicycle ergometry in this study might mimic conditions of increased sympathicotonus encountered during surgery and acute hemodynamic changes. Therefore, this study might give some insight into the effects of TEA on heart function and circulation during dynamic circumstances such as surgery, making the results clinically relevant.

Study objective

The primary objective of this study consists of: To evaluate the HTEA effects on systolic and diastolic cardiac function in rest and after different levels of exercise.

The seconderyobjectives of this study consists of: To assess the difference in hemodynamic response between bicycling with and without thoracic epidural anaesthesia

Study design

The design is a randomized cross over design with two study arms. We chose this design to increase the power, allowing a smaller patient sample. This design also eliminates the effect of timing of the tests on treatment effects. We assume no carryover effects due to infusion of local anesthetics or due to performing an exercise test.

Eighteen patients scheduled for thoracic surgery (full lateral thoracotomies or pleurodesis by video-assisted thoracoscopic surgery/VATS) under thoracic epidural anaesthesia (TEA) and general anaesthesiawill be assigned randomly to one of the two study arms. The randomization will be performed using a computer. After epidural administration of either NaCl 0,9 % or ropivacaine 0.75 % patients will perform an exercise test on a bicycle. Each patient will perform this exercise test at two different time periods:

Test period 1: Day before surgery. Test period 2: Immediately before surgery.

In study arm A, the patient will receive an epidural dose of 6 ml of NaCl 0.9 % in period 1 and 6 ml of ropivacaine in period 2. In study arm B patients

receive an epidural dose 6 ml of ropivacaine 0.75 % in period 1 and 6 ml of NaCl 0.9% in period 2.

The study will be performed preoperatively in awake patients in the recovery room. An arterial line 20 G will be inserted after local infiltration with lidocaine 1% in the radial or brachial artery to monitor arterial blood pressure (Edward Lifesciences LLC, Irvine, Ca, USA) and CO (Vigileo/FloTrac system (software version 1.01; Edwards Lifesciences, Irvine, CA)). Intravenous access will be established and an infusion of NaCl 0.9 % will be administered at a rate of 5 mL/kg/h 17 starting with the epidural injection of ropivacaine 0.75 % or NaCl 0.9 %. All patients will receive an epidural catheter on the day before surgery. All patients will perform an execise test according to a preset protocol, starting 30 minutes after injection of NaCl 0.9 % (control group) or ropivacaine 0.75 % (epidural group).

TTE examination and hemodynamic measurements will take place before epidural injection, 30 minutes after epidural injection, three times during bicycle ergometry exercise test and 10 minutes after recovery from the exercise test.

After having performed the first test on the day before surgery, patients will return to the ward with an intravenous line and an epidural catheter. The arterial line will be removed before returning to the ward and reinserted before the second test the next day.

All echo data will be stored and analyzed in EchoPAC. Echodata from different workloads and different study arms will be separated and labeled by one researcher and stored under these labels in EchoPac systems. This way, another investigator analyzing the echo data will be blinded to the study arm of the patient, the patient number, the time period and to the workload.

Study burden and risks

RISKS AND ALTERATIONS VS ROUTINE

Thoracic epidural anaesthesia, insertion of an intravenous line and arterial line are all part of normal routine for thoracic surgery. Supine bicycle ergometry is not part of normal routine, but because of the supine positioning during cycling and the patient being relatively young, we don*t expect any additional risk*s or problems related to supine bicycle ergometry. TTE is a noninvasive tool without known side effects. Participation in this study implies extra time of the patients. We expect this study requires an extra 2.5 hours compared to normal routine. To our opinion this study doesn*t add any additional risks compared to normal routine.

The study will be completed when the last TTE exam has been finished. The investigation will not interfere with clinical care in any way. Monitoring, dosage of drugs, sedation, treatment of complications and postoperative care will be treated according to the department*s routine for each specific case. 5 - CARDIAC EFFECTS OF HIGH THORACIC EPIDURAL ANAESTHESIA DURING BICYCLE EXERCISE: A ... 13-05-2025

The anaesthesiologist responsible for the patient during surgery will be informed about the possible existence of dermatomal analgesia (the epidural group) after TEA and will also be informed about problems encountered during the study. After finishing the study, patients with or withoutinsufficient dermatomal analgesia will receive an additional injection of LA through their epidurals as part of the normal analgesic regime for surgery

Contacts

Public Leids Universitair Medisch Centrum

Albinusdreef 2 Leiden 2333 ZA NL **Scientific** Leids Universitair Medisch Centrum

Albinusdreef 2 Leiden 2333 ZA NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Patients younger than 65 years ASA 1 or 2 patients undergoing thoracic surgery under thoracic epidural anaesthesia

Exclusion criteria

Contra-indications for thoracic epidural: * Infection of the skin in the area of the epidural site * A history of neurological diseases * A history of bleeding diathesis * Muscle diseases * Hypersensitive to local anesthetics History of Coronary Artery disease (CAD) Known decreased ejection < 40 % Known severe regurgitation or stenosis of a heart valve (grade 3 or 4) Heart rhythm other than sinus rhythm Existence of diabetes mellitus Use of B-blockers or Calcium-antagonists Pregnancy or lactation Participation in a trial on investigational drugs within 3 months prior to the study

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2015
Enrollment:	18
Туре:	Actual

Ethics review

Approved WMO

Date:	02-06-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-10-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	07-01-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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 CCMO ID NL48088.058.14