

Cardiac effects of high thoracic epidural anaesthesia during bicycle exercise: an echocardiographic study

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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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25984

Bron

NTR

Aandoening

Thoracic epidural anaesthesia

Ventricular function

Bicycle ergometry

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)

Overige ondersteuning: Leiden University Medical Center (LUMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate the HTEA effects on systolic and diastolic cardiac function in rest and after

different levels of exercise. Echocardiographic variables:

MV E, MV DT, MV A, MV E/A, MV S', MV A', MV E', TV E, TV A, TV E/A, TV S', TAPSE

Toelichting onderzoek

Achtergrond van het onderzoek

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. 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.

Doel van het onderzoek

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.

Onderzoeksopzet

Eighteen patients scheduled for thoracic surgery (full lateral thoracotomies or pleurodesis by video-assisted thoracoscopic surgery/VATS) under thoracic epidural anaesthesia (TEA) and general anaesthesia will be assigned randomly to one of the two study arms. The randomization will be performed using a computer generating a randomization list. 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 0.75 % 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. Patient and investigators will not be blinded to the epidural study medication.

T0 baseline = before epidural injection of ropivacaine/NaCl

T1 epidural = 30 minutes after epidural injection of ropivacaine/NaCl

T2 exercise = after 3 minutes bicycling with 20 % of maximal workload

T3 exercise = after 3 minutes bicycling with 40 % of maximal workload

T4 exercise = after 3 minutes bicycling with 60 % of maximal workload

T5 recovery = after 10 minutes recovery of exercise test

Onderzoeksproduct en/of interventie

Thoracic epidural anaesthesia

Exercise bicycle/stress testing

Contactpersonen

Publiek

Consultant (cardiothoracic) anaesthesiology

Department of Anaesthesiology

LUMC, P5Q-32

2300 RC
J. Wink
Leiden
The Netherlands
+31 (0)71 5262301

Wetenschappelijk

Consultant (cardiothoracic) anaesthesiology

Department of Anaesthesiology

LUMC, P5Q-32

2300 RC
J. Wink

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Younger than 65 years
- ASA 1 or 2 patients undergoing thoracic surgery under thoracic epidural anaesthesia

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Participation in trial P14.045: "The effect of thoracic epidural anaesthesia with general anaesthesia on mean systemic filling pressure, venous return and cardiac function".

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-11-2014
Aantal proefpersonen:	14
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	06-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4752
NTR-old	NTR4880
Ander register	Medical Ethics Committee LUMC : P14.044

Resultaten