Body mass index and microcirculatory behavior in patients undergoing cardiac surgery with cardiopulmonary bypass

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Primary objective: Is there a difference in the change in perfused vessel density between obese and lean subjects after cardiac surgery with cardiopulmonary bypass?Secondary Objectives * Is there a difference in baseline perfused vessel density...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON47560

Source
ToetsingOnline

Brief title
MicrObese

Condition

- Other condition
- Cardiac therapeutic procedures

Synonym
disturbances in perfusion of tissues during surgery, Perioperative disturances in tissue perfusion

Health condition

Perioperatieve complicaties in de doorbloeding van organen

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Body mass index, Cardiac surgery, Microcirculation

Outcome measures

Primary outcome

The primary endpoint is the difference in perfused vessel density before

surgery and immediately after weaning from cardiopulmonary bypass.

Secondary outcome

* Patient demographics

* Proportion of perfused vessels (PPV)

* Perfused vessel density (PVD)

* Microvascular flow index (MFI)

* Perfused boundary region

* Mean arterial pressure

* Glucose levels

* Metabolic parameters (pH, lactate, base excess, pCO2, HCO3)

* Glycocalyx markers (heparan sulphate, syndecan)

* Postoperative complications (ICU stay > 24 hours, mechanical ventilation > 24

hours, pneumonia, CVA/TIA, myocardial infarction, atrial fibrillation), 30-day

mortality

Study description

Background summary

The prevalence of overweight and obesity as defined by a body mass index (BMI) of more than 25 kg/m2 or 30 kg/m2, respectively, has reached epidemic proportions. In the Netherlands 46.5% of men and 41.1% of women were overweight or obese in 2014 (source: CBS). Obese patients are at risk for conditions that increase their likelihood to undergo surgery, such as cardiovascular procedures, but also malignancies, osteoarthritis and gallstones. It is therefore expected that an increasing proportion of the surgical population will be categorized as overweight or obese in the near future. While overweight or mildly obese patients may have better outcomes after surgery, patients with a BMI above 30 kg/m2, patients with central obesity (abdominal fat accumulation) as well as patients with the metabolic syndrome are at higher risk of perioperative complications when compared to lean patients.

The respiratory and cardiovascular physiology of overweight patients is adapted to the altered tissue demands. Due to decreased functional residual capacity, the total lung capacity of overweight patients is impaired, leading to a higher risk for arterial hypoxemia and a higher tendency for desaturation and impaired oxygenation in the perioperative period. In order to maintain an adequate balance in tissue oxygen delivery and demand in overweight patients, an increase in intravascular volume and stroke volume are required. This increases ventricular load, which may lead to left ventricular hypertrophy. Left ventricular hypertrophy may eventually contribute to the development of heart failure, which in itself may increase perioperative risk. The increased activity of the sympathetic nervous system and RAAS-activation further contribute to obesity-related cardiomyopathy. Moreover, increased pulmonary resistance associated with the obstructive sleep apnea syndrome (OSAS) may cause right ventricular strain and failure, eventually leading to biventricular dysfunction. Furthermore, coronary flow reserve is impaired in obese patients with a cardiovascular risk profile,9 which may implicate that during periods of stress, such as the perioperative period, myocardial perfusion and thus cardiac function may fall short with respect to myocardial demands. In conclusion, obesity leads to macrocirculatory changes that may contribute to the development of myocardial dysfunction and increased pulmonary vascular resistance.

Perfusion pressure and microvascular oxygenation serve to maintain adequate vital organ tissue perfusion. Optimization of nutrient and oxygen supply takes place on a microvascular level, and adequate perfusion is vital to maintain organ function. In addition, the microcirculation largely determines vascular resistance and afterload, as in these small arterioles (<150 m in diameter) the largest hydrostatic drop in pressure occurs. Microvascular dysfunction is a characteristic of obesity, which not only alters tissue perfusion but also contributes to the development of hypertension and insulin resistance. Impaired endothelium-dependent vasodilatation has been demonstrated in obese subjects in response to several vasodilators, such as acetylcholine and insulin. Obese subjects also demonstrate a reduction in the number of arterioles and capillaries.14 Both of these characteristics of obesity can contribute to impaired tissue perfusion. In conclusion, obesity is associated with vascular alterations that may lead to hypertension and microvascular dysfunction.

While a substantial part of the surgical population is overweight, the number of studies focusing on macro- and microcirculatory alterations in the perioperative period in these patients is highly limited. Early studies demonstrated a significantly greater depression in cardiac index and stroke work in morbidly obese patients undergoing surgery when compared to lean controls. Moreover, most studies focusing on intraoperative hemodynamics have mainly been performed in morbidly obese patients undergoing bariatric surgery, with specific emphasis on the effect of pneumoperitoneum on system hemodynamics. In one study, morbidly obese patients retained stable blood pressure and cardiac output during the different phases of laparoscopic gastric bypass surgery. In contrast, a later study in morbidly obese patients showed systolic as well as diastolic dysfunction, decreased stroke volume and decreased cardiac output hemodynamics upon insufflation of pneumoperitoneum. In agreement with this, a decrease in cardiac output was observed in obese patients during insufflation of pneumoperitoneum, which was worse in morbidly (average BMI of 45 kg/m2) versus slightly (average BMI of 28 kg/m2) obese patients.

We previously showed that microcirculatory perfusion is disturbed in patients undergoing cardiac surgery with cardiopulmonary bypass, and these alterations continues until 3 days following surgery. Interestingly, this observed decrease in microcirculatory perfusion in was not related to systemic hemodynamic parameters, including mean arterial pressure or cardiac output. The dissociation between cardiac output and microvascular perfusion was further confirmed in patients undergoing abdominal study.

Since obesity is associated with alterations in system hemodynamics as well as microcirculatory perfusion disturbances, the association between macro- and microvascular behavior may be different when compared to lean subjects. Moreover, there is little known about the effects of anesthesia and cardiac surgery with cardiopulmonary bypass on microcirculatory perfusion in these patients.

In this study we aim to investigate whether microcirculatory behavior differs between obese and lean subjects at a resting state before surgery and after surgical stress. Moreover, the relation between systemic hemodynamics and microcirculatory perfusion in obese patients undergoing cardiac surgery with cardiopulmonary bypass will be evaluated, and compared to those in lean patients. In particular, as pathophysiological processes as present during obesity may alter this relation, we hypothesize that obesity is associated with impaired microcirculatory perfusion when compared to lean subjects, and this difference is even enlarged after surgery.

Study objective

Primary objective: Is there a difference in the change in perfused vessel density between obese and lean subjects after cardiac surgery with cardiopulmonary bypass?

Secondary Objectives
* Is there a difference in baseline perfused vessel density between obese and lean subjects?
* Is there a difference in perfused vessel density after cardiopulmonary bypass between obese and lean subjects?
* Is there a different relation between mean arterial blood pressure and microcirculatory perfusion between obese and lean subjects?
* What is the relation between perfusion surrogates such as lactate levels and sublingual microcirculation in lean and obese patients?

Study design

* Single center, prospective observational study.
* Patients with severe obesity (BMI * 32 kg/m2) and lean subjects (BMI < 25 kg/m2) undergoing cardiac surgery with cardiopulmonary bypass.
* Sublingual microcirculation perfusion measurements take place before and during surgery.
* Preoperative HbA1c determination in a blood drop from a finger prick.
* Routine glucose and arterial gas measurements during surgery
* Blood sampling to determine glycocalyx parameters (20 ml).
* The measurements start on the day of surgery and end when patients are admitted to the intensive care unit.

Study burden and risks

There is no advantage for patients to participate in this study. Preoperative HbA1c level will be determined in a blood drop from a finger prick, which may cause discomfort and pain. A total of 20 ml of extra blood will be drawn from an existing intra-arterial line, and this line will also be used for blood pressure measurements. The intra-arterial line is part of routine clinical care in cardiac surgery, and will therefore not add up to patient discomfort in the present study. Microscopic imaging of the microvasculature by means of the GlycoCheck is a noninvasive measurement, and three out of four measurements will be performed while the patient is under anesthesia.

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

* (non-aortic) cardiac surgery
* Adult subjects
* Informed consent
* BMI * 32 kg/m2 or BMI < 25 kg/m2.

Exclusion criteria

* Re-operation
* Aortic surgery
* Emergency operation

* Diabetes mellitus type I and II

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-05-2016
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Sidestream dark field (SDF) imaging camera (Capiscope)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-04-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	10-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO
Date: 10-04-2018

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 12-09-2019

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	NL56951.029.16