Evaluation of gastric tube microcirculation with Sidestream Dark Field imaging during minimally invasive esophagectomy and the influence of tissue radiation and the position of the gastric tube in the body on microcirculatory parameters.

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To directly evaluate the gastric tube microcirculation with Dark Sidestream imaging during minimal invasive esophageal resection on several locations, i.e. from best arterial blood supply (antrum) to worst (fundus). Furthermore, to evaluate the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON40730

Source
ToetsingOnline

Brief title
evaluation of the microcirulation during esophagectomy

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
Microcirculation / blood flow

Research involving
Human

Sponsors and support

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

Intervention

Keyword: esophagectomy, irradiation therapy, microcirculation

Outcome measures

Primary outcome

Primary outcome is to directly measure microvascular flow index (MFI) in the

different parts of the gastric tube and changes of MFI duringstandard

anesthesiologic management and changes in positioning of the patient.

Secondary outcome

Secondary parameters measured are: perfused vessel density (n/mm), vessels with

a diameter <25 *m) of total vessel density, proportion of perfused blood

vessels, blood vessel diameters (BVd).

Study description

Background summary

Esophagectomy is a high risk surgical procedure with high peri-operative morbidity and a mortality rate of up to 3-4 % in large centers. Nowadays patients undergo neoadjuvant chemoradiation therapy to improve postoperative survival, but although the majority of operations is performed minimally invasive, the incidence of complications associated with the anastomosis such as leakage (4-26%) and stenosis (12-40%) remains high (1,2).
During oncologic resection and gastric tube formation, multiple arteries are

ligated and blood supply of the gastric tube depends on only one artery. This compromised arterial blood supply but also venous congestion after tube reconstruction has been suggested as causes of early anastomotic complications (leakage) and late anastomotic complications (stenosis). Moreover the anastomosis is made in the fundus where blood flow is most compromised. The fluid status and use of vasopressors might be an influencing factor. In addition, local damage to the tissues because of radiation therapy might aggravate the damage to the microcirculation and thus may increase the risk of leakage and stenosis of the anastomosis. The effect of radiation on microcirculatory parameters has never been studied and might influence microvascularisation of the gastric tube.
Various methods to measure the adequacy of microvascular blood flow in the gastric tube have been tried out peri-operatively through reflection spectrophotometry, laser Doppler flowmetry and Clark-type tissue oxymetry (2). However, these are all indirect methods and the interpretation of the data can be difficult. Originally, sublingual Sidestream Dark Field imaging has been used to visually assess the microcirculation as a surrogate for the microcirculation of other more remote tissues (3-5). However, it is also possible to directly assess the microvascularisation in the target organ. For example, this method has been used safely to examine the bowel mucosa in post cardiac surgery and septic patients and the cortical microcirculation during brain surgery. Therefore it might also be of additional value during gastric tube reconstruction (6-8).
During minimally invasive esophagectomy, the patient is placed in head up positioning to improve visualization of the upper abdomen. Postoperatively patients are bound to stay in 30 degrees head up position to prevent reflux. This positioning however, might affect the blood flow in the gastric tube. Thus far it is unknown if positioning of the patient influences the microcirculation of the gastric tube.

Study objective

To directly evaluate the gastric tube microcirculation with Dark Sidestream imaging during minimal invasive esophageal resection on several locations, i.e. from best arterial blood supply (antrum) to worst (fundus). Furthermore, to evaluate the influence of fluid balance and vasopressor use, tissue radiation and positioning during operation on gastric tube microcirculation

Study design

Single-center pilot observational study

Study burden and risks

Benefits and risks

There is no additional risk related to participation in this trial. Sidestream darkfield imaging has used to measure intestinal perfusion in other investigations (6,7¬). In addition, this method has been used safely to directly measure cortical microcirculation in patients with decompressive craniectomy (8). No side effects of risks were reported. A sterile cover is put over the probe and the probe will not be inserted inside a body cavity. Patients will receive standard care concerning anaesthesia and fluid management. No extra interventions are performed. Each measurement at each location will take about thirty seconds to record, with a maximal total of 10 minutes.

Benefits

This study is observational only. Participating will not give direct benefits to the patient. At this time no intervention or change in surgical or anesthetic management will take place. However, the results might influence the placement of the anastomosis in future populations and give more insight in the etiology of anastomotic failure. In addition, the results might influence anesthesiologic managment concerning the use of vasorpressors and fluids.

Burden

The measurements will cause no damage to the tissues. The probe will be held very lightly on the tisse, as less pressure gives better results. All measurements will be done 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

all patient undergoing an Ivor Lewis or McKeown procedure

Exclusion criteria

Patient refusal, major valve disease

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2014
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	11-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2014
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	NL47619.018.14