Bowel plus anastomotic perfusion and oxygenation in colorectal surgery: variables to predict anastomotic leakage?

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Primary objective:1. To investigate a correlation between perfusion measured by the laser-Doppler-spectrophotometry O2C-device and anastomotic leakage in elective colorectal surgery with a primary anastomosis.Secondary objectives: 1. To investigate...

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

Summary

ID

NL-OMON32021

Source
ToetsingOnline

Brief title
Anastomotic perfusion

Condition

- Other condition

Synonym
blood flow, bowel perfusion

Health condition

darmperfusie en naadlekkage

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting Gastrointestinale Chirurgie

Intervention

Keyword: anastomotic leak, colorectal surgery, perfusion

Outcome measures

Primary outcome

Primary study parameters

-oxygen saturation of haemoglobin at anastomosis including systemic saturation

level.

-relative amount of haemoglobin at anastomosis including systemic haemoglobin

level.

-blood flow at anastomosis site.

-blood velocity at anastomosis site.

-functional recovery of perfusion and oxygenation at the anastomosis after

reperfusion.

Primary study outcomes

-clinical signs of anastomotic leakage, objectified by abdominal CT scan.

-stricture at site of anastomosis

Secondary outcome

none applicable

Study description

Background summary

Anastomotic leakage remains a serious complication following colorectal surgery. Its reported prevalence varies widely from 1% to 39%. Inadequate bowel perfusion at the anastomosis is thought to be one of the factors involved causing these anastomotic leaks.

Study objective

Primary objective:
1. To investigate a correlation between perfusion measured by the laser-Doppler-spectrophotometry O2C-device and anastomotic leakage in elective colorectal surgery with a primary anastomosis.

Secondary objectives:
1. To investigate a correlation between the subjective evaluation of bowel viability by the surgeon and the objective perfusion by the laser-Doppler-spectrophotometry O2C-device.

2. To investigate reduction in bowel perfusion measured by the laser-Doppler-spectrophotometry O2C-device at the anticipated site of anastomosis after the colon is mobilized.

3. To investigate whether an inadequate anastomotic perfusion will result in a long-term
morbidity such as incontinence and stricture.

Study design

All patients planned to undergo a left or right hemicolectomy, a sigmoid resection, an anterior resection or a partial small bowel resection at the Vumc will be asked to participate. An informed consent form will be obtained prior to surgery.
Bowel perfusion, in terms of oxygen saturation of haemoglobin, the relative amount of haemoglobin, blood flow and blood velocity, is measured during surgery on the serosa at the anticipated site of anastomosis with the laser-Doppler-spectrophotometry O2C-device: (1) before bowel mobilization, (2) after bowel mobilization and (3) after the anastomosis is made. Parallel to the measurements with the laser-Doplper-spectrophotometry O2C-device blood is drawn for saturation and haemoglobin level measurements. In addition, functional recovery of bowel perfusion and oxygenation in the distal and proximal bowel limb is measured in the following manner: circulation to exactly 5 cm of the distal and proximal bowel is cut off by a non-traumatic surgical clamp,

subsequently after clamp-release (=reperfusion) kinetics and time to full bowel perfusion and oxygenation is measured.
The anastomosis must be tension free. At the time of measurements with the laser-Doppler-spectrophotometry O2C-device the surgeon will be asked to subjectively estimate bowel perfusion in terms of *good, reasonable, moderate or poor perfusion*.
Patients will receive standard post-operative care as described in hospital protocol. Patients are monitored for clinical signs of anastomotic dehiscence, which would subsequently be objectified by abdominal CT scan. In addition, patients will be monitored for stricture of the anastomosis.

Study burden and risks

No substantial risk or burden will be added to patients participating in this study. The laser-Doppler-spectrophotometry O2C-device used in this study is non-invasive and CE-approved, therefore allowed to be operated on humans. All probes used are sterilized as described by the manufacturer and hospital protocol. Predicting anastomotic leakage in patients undergoing colorectal surgery with a primary anastomosis will decrease serious morbidity and even mortality following this type of surgery.

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

1. patients undergoing the following surgery: left or right hemicolectomy, simoid resection, anterior resection or partial small bowel resection with primary anastomosis.
2. age 18 years and older
3. surgery at VU medical center
4. oral and written informed consent

Exclusion criteria

1. no informed consent
2. palliative surgery
3. emergency surgery

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-04-2009
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	31-10-2008
Application type:	First submission
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	NL21628.029.08