Anastomotic Perfusion Pressure Expressed in a Bowel-Arm Index and Gastric Conduit-Arm Index; a New Variable to Predict Anastomotic Leakage.

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A new device has been developed in the VU University Medical Center enabling us to measure perfusion pressure in mmHg in the bowel wall or wall of the gastric conduit. Correlating this measurement to systemic blood pressure in mmHg subsequently…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON39543

Source
ToetsingOnline

Brief title
Anastomotic perfusion pressure measurements

Condition

- Gastrointestinal therapeutic procedures

Synonym
anastomotic leakage, bowel leakage following surgery

Research involving
Human

Sponsors and support

Primary sponsor: Veenhof Medical Divices B.V.

Source(s) of monetary or material Support: pensioenfonds

Intervention

Keyword: Anastomosis, Anastomotic leakage, Bowel resection, Esophageal resection

Outcome measures

Primary outcome

Anastomotic perfusion expressed in a bowel-arm index.

Anastomotic perfusion expressed in a gastric conduit-arm index

Anastomotic dehiscence

Secondary outcome

none

Study description

Background summary

Anastomotic leakage remains a serious complication following colorectal surgery and esophageal resection with gastric conduit. Its reported prevalence varies between 1% and 39%. Currently, before making an anastomosis, viability of the bowel or gastric conduit is estimated by the color of the tissue. This remains very subjective and based on the experience of the surgeon. The aim of this study is to investigate if measurements of perfusion at the site of anastomosis expressed by a bowel-arm index or gastric conduit-arm index can help to predict anastomotic dehiscence.

First a pilot study will be conducted.

Study objective

A new device has been developed in the VU University Medical Center enabling us to measure perfusion pressure in mmHg in the bowel wall or wall of the gastric conduit. Correlating this measurement to systemic blood pressure in mmHg subsequently provides us a bowel-arm index or gastric conduit-arm index. In the future, an anastomosis could subsequently be made where the bowel-arm index in the bowel or gastric conduit-arm index is adequate and thus minimize the chance

of anastomotic leaks.

Study design

All patients undergoing colorectal, small intestinal surgery and esophageal resection in the VU University Medical Center (VUmc), Academic Medical Center (AMC), Zaans Medical Center (ZMC) and Medical Center Alkmaar (MCA), receiving a primary anastomosis will be entered into this prospective study. Patients must be 18 years and older. Informed consent must be obtained from all patients. Patients undergoing palliative treatment or emergency surgery will be excluded from this study. Standard anesthesia is given in all patients included in this study.
Just before performing the anastomosis the bowel perfusion of the bowel wall is measured in mmHg opposite of the mesenterium on both the oral and aboral side of the anastomosis. This is believed to be the site of poorest perfusion in the bowel wall. At the same time the systemic perfusion is measured using an arterial catheter in the radial artery. Bowel perfusion in mmHg is divided by the systemic pressure in mmHg providing us the bowel-arm index. Also the surgeon is asked to subjectively evaluate the bowel perfusion.
In case of esophageal resection, after performing the gastric conduit, just before the anastomosis is made, perfusion of the gastric conduit wall is measured in mmHg opposite of the left gastric artery at the side of the anastomosis. This is believed to be the site of poorest perfusion in the gastric conduit. At the same time the systemic perfusion is measured using an arterial catheter in the radial artery. Gastric conduit perfusion in mmHg is divided by the systemic pressure in mmHg providing us the gastric conduit-arm index. Also the surgeon is asked to subjectively evaluate the gastic conduit perfusion.
Postoperatively patients are clinically followed for signs of anastomotic leakage. Patients with an increase in abdominal pain, leukocyte level and/or C-reactive protein level past postoperative day 3 will be evaluated for anastomotic leakage by CT-scan with oral, rectal and IV contrast. In case of esophageal resection this will be a CT scan of the chest with possibly a gastroscopy. In addition, a CT-scan of the abdomen or thorax will be made at any other postoperative day if deemed necessary by the treating physician.
We will investigate if a threshold in bowel-arm index or gastric conduit-arm index will be able to help predict anastomotic leakage.

First a pilot study will be conducted.

Study burden and risks

No additional risk or burden is expected. The new device only exerts pressure on the bowel wall and wall of the gastric conduit as would a surgical clamp for instance. The perfusion measuring device has a CE approval. No addition out patien clinic visits are planned.

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

Elective bowel resection with primary anastomosis
Elective esophageal resection with gastric conduit reconstruction
Informed consent
Above 18 years of age

Exclusion criteria

No informed consent
Emergency surgery

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2013
Enrollment:	400
Type:	Actual

Medical products/devices used

Generic name:	Bowel perfusion measuring device / Gastric conduit perfusion measuring device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	30-06-2014
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	NL36900.029.11