Semi-mechanical versus hand sewn cervical anastomosis after esophagectomy with gastric tube reconstruction for esophageal cancer; the SHARE study

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The primary objective of this study is to compare a semi-mechanical with a hand sewn cervical anastomosis after esophagectomy with gastric tube reconstruction for cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON35934

Source
ToetsingOnline

Brief title
SMA versus handsewn esophago-gastric anastomosis after esophagectomy

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
esophageal cancer, esophageal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anastomosis, Esophagus, Handsewn, Semi-mechanical

Outcome measures

Primary outcome

Main study parameter/endpoint: clinical anastomotic leakage defined by neck wound infection and loss of saliva and/or fluids through the wound site, signs of mediastinitis or abcess intrathoracic or leakage confirmed by radiological examination (endoscopy or CT with contrast fluids) after clinical suspicion (i.e. leucocytosis, fever, pain), all within 30 days after operation.

Secondary outcome

Secondary study parameters/endpoints: anastomotic stricture within one year, number of dilations within one year, dysphagia score (table 1, score by Sugahara), quality of life measured by EORTC QLQ C-30 and OES-18 questionnaires preoperative and at 3, 6, 9 and 12 months after surgery.

Study description

Background summary

Failure of the anastomosis between the esophagus and stomach tube after radical esophagectomy occurs in about 20% of patients and contributes to the already high morbidity (40-60%) and hospital mortality (3-6%). Anastomotic leakage delays oral intake and prolongs jejunal feeding. It prolongs hospital stay, leads to extra interventions, resulting in increased costs in- and outside the hospital. Anastomotic leakage also leads to a high chance of stenoses of the anastomosis and to 50% of patients need multiple, endoscopicaly guided

dilatations. The optimal technique of joining the esophagus to the stomach tube in the neck is not known due to a lack of randomized trials. Recently we randomised the handsewn end-to-end technique with the end-to-side technique. The end-to-end technique was associated with less leakage (22%) but higher rates of stenosis (40%) were seen.

Recently a semi-mechanical side-to-side anastomosis has been described by Collard. With this technique a wide anastomosis is created with the use of a mechanical stapler device after which the resulting opening is closed by a running suture. The Department of Thoracic Surgery in Leuven, Belgium has popularized this technique.

Retrospective studies suggest that the percentage of anastomotic leakage is low and stenosis is low (5% and 10-20% respectively). It is hypothesised that a semi-mechanical side-to-side anastomosis is associated with lower leaks rates and a lower chance of stenosis. However, no randomized trial has been conducted which compared this novel semi mechanical technique with standard techniques.

A small pilot is performed in our center by our surgeons, 20 patients received the new semi-mechanical anastomosis and were followed for four months. Only one leak was found.

The aim of this study is to compare the semi-mechanical anastomosis and the hand sewn end-to-end anastomosis after esophageal resection and stomach tube reconstruction in patients with esophageal carcinoma.

Study objective

The primary objective of this study is to compare a semi-mechanical with a hand sewn cervical anastomosis after esophagectomy with gastric tube reconstruction for cancer.

Study design

This trial is designed as a single-center patient-blinded, randomised controlled trial. There are two groups, each with 90 patients. To include 90 patients per group, with a mean of 75 esophagectomies per year, the estimated duration of this study will be 3-4 years. Follow up till primary endpoint is 30 days after surgery, but secondary endpoints are until 1 year after surgery, therefore data will be collected in 4-5 years.

Intervention

Protocol oral intake: From day 1-6 posteropatively, patients are only allowed to take sips of water. On day 7 fluids and semisolid food is allowed. In

between day 8 and 10 normal oral intake is continued. Any deviation of this protocol is prohibited, unless there is medical condition which requires prolonged denied oral intake, such as clinical suspicion of leakage.

End-to-end anastomosis: After complete mobilisation of the esophagus the cervical esophagus is transacted at 4 to 5 cm below the upper esophageal sphincter. A 3 cm wide stomach tube is created and the stomach tube is transported by the pre-vertebral route to the neck. A hand-layed single layer continuous esophagal gastrostomy is created with PDS 3/0.

Semi mechanical anastomosis: After complete mobilisation of the esophagus the cervical esophagus is transacted 10 cm below the upper esophageal sphincter in order to create a side-to-side semi mechanical anastomosis as described by Collard; *In the terminalized semimechanical side-to-side suture technique, once the cervical esophagus has been transected and the stomach pulled up to the neck, a small incision is made at the top of the gastric transplant. The posterior wall of the esophageal stump and that of the fundus are placed side by side. The two forks of an stapler are placed across the two opposing walls with the anvil in the gastric lumen and the cartridge of staples in the esophageal lumen. After approximation of the two forks, the trigger of the stapler is squeezed to allow forward dis- placement of the knife and the delivery of three rows of staples on each side. After the two forks have been separated, the stapler is removed and the two stapled wound edges retract laterally on the action of the intra- mural musculature. The medial slit thus becomes a V-shaped opening between the two lumina. The two posterior walls realign themselves by exerting gentle downward traction on the transplant. The anterior walls are sutured to each other using a single-layer running suture technique similar to that used in manual anastomoses.*

Case record forms: In the post operative phase at the daily rounds at the ICU and the surgical ward a standard checklist is used by the attending surgeon, the specialist nurse practitioner or the research fellow to collect data.

The quality of life evaluations: The 5 quality of life of life evaluations are scheduled preoperatively and at 3, 6, 9 and 12 months after operation.

As the sensitivity and specificity of a contrast swallow, a computer tomography with oral contract intake or endoscopy to detect an anastomotic leakage is rather low, no post-operative routine control of the anastomosis is performed. Suspecting a clinical or non-clinical leak, the attending surgeon decides to remain conservative or to choose for one of the above-mentioned options.

Study burden and risks

There is no risk associated with participation in comparison to patients who do not participate in our trial. The burden is that we ask patients to complete a Quality of Life questionnaire 5 times within one year (preoperative and at 3,

6, 9 and 12 months after 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

* Esophageal resection with stomach tube reconstruction for esophageal carcinoma
* Signed informed consent
* Availability for 1 year follow-up in the Erasmus Medical Center
* Age over 18 year

Exclusion criteria

* Other forms of esophageal reconstruction than a stomach tube.
* Classification of American Society of Anaesthesiologists over or equal to 4.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	15-07-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24371
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL35746.078.11
OMON	NL-OMON24371