SHARE study: A randomized controlled trial comparing a semimechanical with a hand sewn cervical anastomosis after esophagectomy with gastric tube reconstruction for cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24371

Source
NTR

Brief title
SHARE

Health condition

Oesophageal cancer, esophagectomy, anastomosis, end-to-end, semi-mechanical, leakage, stenosis

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: Fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Primary endpoint:

Clinical anastomotic leakage defined by neck wound infection and loss of saliva and/or ingested fluids through the wound site, signs of mediastinitis or intrathoracic abcess 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

1. Anastomotic stricture within one year;

2. Number of dilations within one year;

3. Dysphagia score (table 1, score by Sugahara);

4. Quality of life measured by EORTC QLQ C-30 and OES-18.

Questionnaires preoperatively 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 compared 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.

A novel 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 semi-mechanical side-to-side anastomosis is associated with low anastomotic leak rates (5%). Also the percentage of patients with stenosis of the anastomosis is more favourable (10-20%). However, no randomized trial has been conducted which compared this novel semi-mechanical technique with standard techniques.

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 the semi-mechanical with the hand sewn cervical anastomosis after esophagectomy with gastric tube reconstruction for cancer.

Study design

Sugarahara score at 3,6,9 and 12 months after surgery.

QoL EORTC OES 18 en OES 30 preoperative and at 3,6,9 and 12 months postoperative.

Intervention

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 displacement 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 Vshaped 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.”

Contacts

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Eligibility criteria

Inclusion criteria

1. Esophageal resection with stomach tube reconstruction for esophageal carcinoma;

2. Cervical anastomosis;

3. Signed informed consent;

4. Availability for 1 year follow-up in the Erasmus Medical Center;

5. Age over 18 year.

Exclusion criteria

1. Other forms of esophageal reconstruction than a stomach tube;

2. Upper thoracic/cervical esophageal cancer;

3. Classification of American Society of Anaesthesiologists over or equal to 4.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-08-2011
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-08-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35934
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2883
NTR-old	NTR3029
CCMO	NL35746.078.11
OMON	NL-OMON35934

Study results

Summary results
N/A