

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

Gepubliceerd: 18-08-2011 Laatste bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24371

Bron

NTR

Verkorte titel

SHARE

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus Medical Center Rotterdam

Overige ondersteuning: Fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 abscess 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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, endoscopically 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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 esophageal 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."

Contactpersonen

Publiek

Erasmus MC

Department of Surgery, room H874

PO BOX 2040
B.P.L. Wijnhoven
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7040704

Wetenschappelijk

Erasmus MC

Department of Surgery, room H874

PO BOX 2040
B.P.L. Wijnhoven
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7040704

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	14-08-2011
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	18-08-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35934
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A