Endoscopic Treatment of Anastomotic Esophageal Stricture. A Randomised Study Comparing Initial Dilation by Electrocautery with Savary Bougies with Electrocautery.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23356

Source
NTR

Brief title
Endoscopic Treatment of Anastomotic Esophageal Stricture. A Randomised Study Comparing Initial Dilation by Electrocautery with Savary Bougies with Electrocautery.

Health condition

English:Anastomotic Esophageal Stricture, Randomised Study, Electrocautery, Savary Bougies, dilatation.
Nederlands: stenose anastomose oesophagus, elektrocoagulatie, Savary Bougies, Gerandomiseerde studie

Sponsors and support

Primary sponsor: Address of correspondence

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Source(s) of monetary or material Support: Non

Intervention

Outcome measures

Primary outcome

This study aims to compare the efficacy of Savary dilation versus endoscopic electrocautery treatment for the treatment of fibrotic anastomotic strictures after esophageal resection. The efficacy of therapy will be evaluated by means of objective and subjective criteria which will be determined both before treatment and during follow-up after treatment.
The objective criteria are obtained by standard items at endoscopy and body weight. Endoscopic evaluation of the stricture will take place at baseline, and will be repeated in case of recurrent or persistent symptoms.

The EORTC health related Quality of Life Questionnaires SF-36, C-30 (version 3) and OES 18 are used to structure a quality of life questionnaire especially focused on benign esophageal stenosis.

Secondary outcome

Is there a difference in the interval of retreatment between electrocautery and Savary bougies, because of stenosis of the anastomosis of the esophagus?

Study description

Background summary

Summary:

Anastomotic strictures are common after esophageal resection. These strictures often need multiple dilation procedures with Savary bougies, and some even fail despite many dilations. Based on the literature and our pilot study of electrocautery therapy of refractory benign esophageal stenosis (Hordijk Marjan L. , Siersema Peter D., Tilanus Hugo W. , Kuipers Ernst J.

Electrocautery therapy for refractory anastomotic strictures of the esophagus. Gastrointest Endosc 2006;63:157-63.), electrocautery treatment is safe, and may provide an excellent alternative for primary treatment of esophageal strictures. A prospective randomized controlled is needed to compare dilation therapy with Savary bouginage with electrocautery therapy for the primary treatment of these strictures.

Study objective

Anastomotic strictures are common after esophageal resection. These strictures often need multiple dilation procedures with Savary bougies, and some even fail despite many dilations. Based on the literature and our pilot study of electrocautery therapy of refractory benign esophageal stenosis (Hordijk Marjan L. , Siersema Peter D., Tilanus Hugo W. , Kuipers Ernst J. Electrocautery therapy for refractory anastomotic strictures of the esophagus. Gastrointest Endosc 2006;63:157-63.), electrocautery treatment is safe, and may provide an excellent alternative for primary treatment of esophageal strictures.
A prospective randomized controlled is needed to compare dilation therapy with Savary bouginage with electrocautery therapy for the primary treatment of these strictures.

Study design

N/A

Intervention

- Upper gastrointestinal endoscopy will be performed. The postoperative stenosis will be inspected and the diameter of the stenosis will be estimated by using the diameter of the endoscope (9.5 mm). These stenoses are usually located at 17 to 20 cm from the incisors.

- For endoscopic bougie dilation of the stricture, a guide wire will be placed in the stomach, followed by removal of the endoscope and passage of Savary Gilliard bougies (Wilson Cook) of increasing diameter over the guidewire according to standard procedures to a diameter of minimal of 16 mm and maximal 19 mm.

- For endoscopic dilation of the strictures with electrocautery, the tip of the endoscope is positioned just proximal from the stenosis, and a needle knife catheter (Wilson Cook, Boston Scientific) is introduced through the working channel. Radial incisions are made in the stenotic ring with the needle knife catheter under direct visualization. The required length of the cut is gauged according to the length of the stricture assumed by the endoscopist in the light of the membranous nature and the caliber of the stricture. The depth of the incision (estimated using the length of the needle knife as a comparator) is not deeper than 4 mm. The length of the incision is dosed to completely remove the rim of the stenosis.

- In case of recurrent stenosis, dilation therapy will be repeated with the same modality as was used at baseline. Recurrent stenosis is defined as no passage or only passage with pressure of the endoscope (diameter 9.5 mm.).

Contacts

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Eligibility criteria

Inclusion criteria

Sixty-two unselected consecutive patients with dysphagia due to a benign anastomotic stricture after transhiatal oesophagectomy with gastric tube reconstruction and cervical anastomosis will be included and randomized to either treatment arm. After informed consent, patients will either undergo dilation with Savary bougies, or primary electocautery.

Exclusion criteria

1. Esophageal dilation with bougies or electrocautery is rarely contraindicated.
Patients should however not be dilated if they recently suffered from acute esophageal perforation.

2. Dilation is relatively contraindicated in the presence of:

a. a bleeding diathesis,

b. severely compromised pulmonary function,

c. severe or unstable cardiac disease, or in

d. patients with large thoracic aortic aneurysms (47).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-06-2004
Enrollment:	62
Type:	Actual

Ethics review

Positive opinion

Date:	12-03-2007
Application type:	First submission

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
NTR-new	NL906
NTR-old	NTR931
Other	: N/A
ISRCTN	ISRCTN81239664

Study results