Esophageal self-expandable metal stent for malignant strictures: an observational study

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The aim of this study is to evaluate the safety and efficacy of the esophageal partially covered SEMS. We will pay specific attention to recurrent dysphagia rates, migration rates and pain.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Observational invasive

Summary

ID

NL-OMON57002

Source
ToetsingOnline

Brief title
ENTRANCE study

Condition

- Gastrointestinal stenosis and obstruction
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Malignant esophageal stenosis, malignant esophageal stricture

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: Self-expandable metal stent (SEMS)

Outcome measures

Primary outcome

- Safety: Short term (within 7 days after treatment) and long term (after 7 days) major complications and minor complications. Major complications are defined as life threatening and severe complications such as perforation, hemorrhage, fistula formation and severe pain. Minor complications are defined as non-life threatening, moderately severe pain or gastroesophageal reflux and stent migration.

- Efficacy: Consisting of:

• Clinical outcome, measured at baseline and during follow-up until death with the Ogilvie dysphagia score;

•Technical successful placement of the esophageal partially covered SEMS including correct positioning at the stenosis. Technical success is defined as ease of deployment and placement of the stent at the required location.

All primary study parameters will be compared to our historical stent cohort consisting of 997 patients that underwent self-expandable metal stent placement due to an incurable esophageal stricture from July 1994 to May 2017.

Secondary outcome

- Recurrent dysphagia: cause of dysphagia will be registered during follow-up;

- Pain related to esophageal stent during follow-up: the first two weeks pain

will be measured daily with a patient diary, using the Visual Analogue Scale

(VAS). After this, every 4 weeks until death the patient will be contacted with

a telephone interview;

- Overall survival.

All secundary study parameters will be compared to our historic stent cohort

consisting of 997 patients that underwent self-expandable metal stent placement

due to an incurable esophageal stricture from July 1994 to May 2017.

Study description

Background summary

More than 50% of esophageal cancer patients have unresectable disease at presentation (1). Even after curative therapy, about 20% of patients develop dysphagia from recurrent strictures. Dysphagia is the predominant symptom in 70% of esophageal cancer. Complications include high risk of aspiration and reduced patency of the orogastric pathway, which lead to a profound reduction in quality of life. Therefore, palliative therapy has been, and will continue to remain, an important part of the management of esophageal malignancy. The primary goal of palliative treatment in patients with esophageal cancer is to achieve adequate improvement of dysphagia and therefore quality of life, with a reduced need for additional interventions.
Although optimal intervention for treatment of dysphagia has yet to be established, placement of a partially or fully covered self-expandable metal stents (SEMS) is the palliative modality of choice and recommended by the European Society of Gastrointestinal Endoscopy (1). This because of their ability to provide instant, long-lasting relief from dysphagia with minimal morbidity and negligible mortality (2).
The SEMS (Leufen Esophageal aixstent®) has been evaluated for palliation of malignant dysphagia and has been approved with a Conformité Européenne (CE) certificate for the maintenance of esophageal lumen patency in malignant dysphagia.

Since there is limited data on the effectiveness in the clinical context, the aim of this study is to evaluate the safety and efficacy of the esophageal SEMS (Leufen aixstent OES®) compared to our historic stent cohort. We will pay

specific attention to recurrent dysphagia rates, migration rates and pain.

References:
1. Spaander MC, van der Bogt RD, Baron TH, et al. Esophageal stenting for benign and malignant disease: European Society of Gastrointestinal Endoscopy (ESGE) Guideline - Update 2021. Endoscopy. 2021 Jul;53(7):751-762.
2. Juan Carlos Martinez, Matthew M. Puc, and Roderick M. Quiros, Esophageal Stenting in the Setting of Malignancy; ISRN Gastroenterology Volume 2011, Article ID 719575.

Study objective

The aim of this study is to evaluate the safety and efficacy of the esophageal partially covered SEMS. We will pay specific attention to recurrent dysphagia rates, migration rates and pain.

Study design

Single center, prospective, observational clinical study.

Intervention

All patients will be treated with the esophageal self-expandable nitinol stent (Leufen Esophageal aixstent®).

Study burden and risks

- Procedure: gastroscopy with stentplacement
- Follow-up: de first 2 weeks pain will be measured through a daily paindiary using the Visual Analogue Scale (VAS). After 3, 7, 14 and 28 days and hereafter every 4 weeks a telephone interview by the coordinating researcher will be conducted until death to ask for symptoms of dysphagia and pain.

Risk:
The risk classification is determined as negligible based on the guideline of the *Nederlandse Federatie van Universitair Medische Centra*. The risks associated with the participation in the study are similar to the risks of treatment with any esophageal stent, and do not different from the complications arising from the use of other expandable stent; migration, bleeding, perforation and development of hyperplasia/granulation tissue. The Leufen aixstent OES is standard treatment in the Erasmus MC for malignant strictures, meaning that the risks participating patients are exposed to is similar to patients with a malignant stenosis that do not participate.

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

- Patients presenting with dysphagia due to an incurable malignant obstruction of the esophagus or esophagogastric junction including extrinsic malignant compression and recurrence in post-esophagectomy patients;
- Requiring treatment for dysphagia (Ogilvie score of 2-4);
- Life expectancy of less than 12 months;
- Written informed consent;
- Age >= 18 years;

Exclusion criteria

- Stenosis after laryngectomy;

- Distance between the upper edge of the stent less than 2 cm from the upper esophageal sphincter;
- Tumor length of more than 14 cm;
- Previous stent placement for the same condition;
- Inability to discontinue anticoagulants or high-dose antiplatelet drugs at time of the baseline procedure (low-dose aspirin (max. 100 mg/day) may be continued);
- Known clotting disorder that cannot be corrected pre-procedural;
- Esophageal varices;
- Disorders of the physiological swallowing function.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Self-expandable metal stent (Leufen Esophageal aixstent OES)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-09-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL86416.078.24