Esophageal stent BD-Covered for refractory benign esophageal strictures: a safety and efficacy study

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The main objective of this study is to evaluate, in an exploratory study, the safety and efficacy of implanting the Esophageal Stent BD-Covered (BD-Covered) in patients with refractory benign esophageal strictures, i.e. who has been treated with a...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON45632

Source
ToetsingOnline

Brief title
BD-Covered: safety and efficacy

Condition

- Gastrointestinal stenosis and obstruction

Synonym
esophageal narrowing, esophageal refractory benign stricture

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ELLA-CS

Intervention

Keyword: benign, esophagus, stricture, trial

Outcome measures

Primary outcome

The study has two primary outcome measurements

(i) The efficacy of the device measured by the technical succes of the implantation, i.e. to correct positioning of the stent at the stenosis immediately after the implantation and stent expansion

(ii) Safety of using the medical device, measured by registration of complications - migration, pain, food impaction inside the stent, bleeding from implantation site, esophageal perforation etc.).

Secondary outcome

The study has two secondary objectives:

1. Long-term efficacy (dysphagia) will be measured at baseline and during follow-up at 3 and 6 months with the Ogilvie dysphagia score.

2. Pain during follow-up: the first two weeks pain will be measured daily with a patient diary, using the Visual Analogue Scale (VAS). After this pain will be assessed, using the VAS, during regular controls according to standard care.

3. Bodyweight will be measured at baseline and during follow-up of six months at regular controls according to standard care.

4. The quality of life of the patients will be evaluated by questionnaire (SF-36) during follow-up of six months at regular controls according to

standard care.

5. The presence of hyperplastic reaction will be objectified during regular

endoscopic controls at three and six months follow-up.

Study description

Background summary

A benign esophageal stricture is a narrowing of the esophagus that causes difficulty to swallow, and endoscopically is defined by the inability to cross it with an endoscope of 9 mm of diameter. Clinical symptoms may be dysphagia, odynophagia, weight loss and regurgitation of food.

Benign esophageal strictures are relatively common in clinical practice. In the past, peptic stricture secondary to gastroesophageal reflux, were the most frequent, whereas at present are mainly secondary to caustic ingestion and radiotherapy (1). In recent years they have also been described as a result of advanced endoscopic therapy in the esophagus: endoscopic circumferential mucosal resection and submucosal dissection.

Generally, most benign strictures respond well to endoscopic dilation, but in 25-30% of cases, multiple sessions of dilation are necessary. Moreover, there are also "complex" benign strictures refractory to endoscopic dilatation (2).

Postsurgical stenosis secondary to ingestion of caustic, and those caused by radiation treatments, have a low response rate to endoscopic treatment, where over 40% of cases tend to recur. Additionally, a hypopharyngeal location of a stenosis, regardless of the cause, is usually refractory to endoscopic dilation.

In view of this situation, a definition of "refractory strictures" has been proposed when: 1) absence of inflammatory response or motor disorder at the level of the stenosis is observed; 2) failure to maintain an esophageal diameter * 14mm after 2 dilation sessions conducted at intervals of two weeks; and 3) if there is failure to maintain an esophageal diameter * 14mm 4 weeks after reaching a diameter of 14mm (recurrent stenosis) (3).

Parallel to dilation, other treatments have been proposed, such as steroid injection (triamcinolone) or section of fibrotic ring with needle diathermy, with a very low success rate, leaving as the only option for patients with refractory strictures, the implantation of expandable esophageal stent (EES), since it achieves a sustained expansion of the esophageal lumen (4,5).

Esophageal Stent Types

a) Self-expanding Plastic Stents (SEPS)

The SEPS (Polyflex*) are usually placed under radiological control. Regularly, a SEPS takes a length of 2-4 cm over the stenosis to achieve an extension of 1.2 cm above and below it. These stents have usually slow expansion, reaching their maximum diameter after several hours or days (6). However, the main drawback of these stents is their high rigidity, and is sometimes very difficult to implement, as it requires that the patient place the neck in a hyperextended position. Likewise, the need for a stiff guide wire, increases the risk of esophageal perforation, mainly in angled strictures (7). A systematic review of the recent literature, including 10 studies with a total of 130 patients, shows that the SEPS acquire a 98% of technical success, clinical efficacy of 52%, an early migration rate (<4 weeks) of 24% and a complication rate of 9% (7).

b) Partially covered self-expanding metallic stents (PCSEMS)

Using this type of stent in benign pathology, given the risk of proliferation of granulation tissue at the ends that are not covered (proximal and distal), is inadvisable, making removal difficult. This is why patients with this type of stent present a restenosis rate of 41%, with an incidence of migration of 31%, and the occurrence of complications in 21% of cases (8).

c) Fully covered self-expanding metallic stents (FCSEMS)

The FCSEMS have the advantage that they can be removed after a certain period of time, but leads to an increase in the rate of migration. To try to relieve this problem, there are different types of FCSEMS in the market, so that the endoscopist can choose the most appropriate one for each patient. With this type of stent, a resolution of dysphagia in 29% of cases is achieved, with a migration rate of 36% (9).

d) Uncovered self-expanding biodegradable stent (USEBS)

The USEBS (SX-ELLA Stent Esophageal Degradable BD / BD Stent), ELLA - CS, s.r.o., Hradec Kralove, Czech Republic) are available for clinical use since 2008. The radial force of the stent is maintained for 6-8 weeks after implantation. Degradation of stent occurs in 11-12 weeks. This type of stent achieve a significant improvement of dysphagia in 45% of patients after a follow-up period of 53 weeks, with a migration rate of 9.5% (10, 11).

The main advantage of biodegradable stents is that its removal is not required; furthermore, another advantage is that it can be more effective in resolving the stenosis. In this sense, to try to obtain an increase of the radial force of the BD Stent, and that it can also be effective in esophageal fistulas, that

are occasionally associated with stenosis, were developed the Covered SEBS (Esophageal Stent BD-Covered/ BD-Covered), which supposed a significant improvement in the treatment, with this type of stent.

Study objective

The main objective of this study is to evaluate, in an exploratory study, the safety and efficacy of implanting the Esophageal Stent BD-Covered (BD-Covered) in patients with refractory benign esophageal strictures, i.e. who has been treated with a minimum of 2 and no maximum of esophageal dilation sessions to the minimal diameter of 15 mm, using a balloon dilator or Savary bougie.

Other (secondary) objectives are to assess: the effect of the stent of the study on the quality of life of the subject (Health Questionnaire SF-36), the presence of hyperplastic reaction after implantation of the stent and the functional complications.

Study design

Non-randomized prospective clinical study, in a single centre (Radboudumc), to evaluate the safety and efficacy of endoscopic implantation of a BD-Covered Esophageal Stent (BD-Covered) in patients with refractory benign esophageal strictures.

Intervention

Implantation of the BD-Covered esophageal self expanding stent via an endoscopic procedure

Study burden and risks

Participation in the study does not cause any additional charge to patients. The stent implantation and follow-up are not different from the usual in clinical practice.

The main advantage of the BD-Covered stents is that its removal is not required; Moreover, another advantage is that it can be more effective in resolving the stenosis.

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 esophageal stent, and not different from the complications arising from the use of other expandable stent, migration, perforation and development of hyperplasia/ granulation tissue. However, bleeding and perforation are rare complications.

Risk of esophageal stent implantation:
- Migration of the stent;
- Esophageal perforation;
- Gastrointestinal bleeding;
- Chest Pain;
- Food impaction;
- Bacteremia/ fever.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 8
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 8
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age * 18 years
* Willingness to participate voluntarily in the study and give written informed consent
* Refractory benign esophageal stricture with or without fistulae, i.e. the patient has to be

treated with a minimum of 2 and no maximum of esophageal dilation sessions to the minimal diameter of 15-mm, using a balloon dilator or Savary bougie.
* Ability to undergo periodic endoscopic follow-up

Exclusion criteria

* Pregnancy or breastfeeding
* Simultaneous participation in another clinical study
* Life expectancy of less than 12 months
* Malignant esophageal stricture
* Stenosis after laryngectomy, or if the distance between the upper edge of the stent is less than 2 cm from the upper esophageal sphincter

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Esophageal Covered Self Expandable Biodegradable Covered Stent
Registration:	No

Ethics review

Approved WMO Date:	15-05-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-11-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL59222.091.16