Title: Endoscopic treatment of benign anastomotic esophagogastric strictures with a biodegradable stent

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Background: Postoperative benign fibrotic strictures of a cervical esophagogastric anastomosis have a reported incidence of 26% to 46%. Factors independently related to development of benign anastomotic strictures are cardiovascular disease, gastric tube compared with colonic interposition, and postoperative anastomotic leakage. These strictures bring about morbidity because of dysphagia and weight loss, leading to a decreased quality of life. Several methods have been described to treat these strictures, including balloon dilation, Savary bougie dilation, and Eder Puestow olive dilation. None of these conventional methods has proved to be superior over others with regard to efficacy and safety. The median number of dilation sessions varies between 2 and 9 per patient when conventional dilation techniques are used to achieve remission. To reduce the number of treatment sessions, dilation has been combined with intralesional steroid injections, revealing a reduction of dilation sessions in uncontrolled series.

Another treatment modality is electrocautery incision of the stricture: a recently published, randomized, controlled trial showed electrocautery incision to be equivalent to Savary bougie dilation in previously untreated anastomotic strictures. Self-expandable metal stents (SEMSs) also have been considered as dilation therapy for the treatment of anastomotic strictures. In several clinical series, however, significant problems were encountered after stent placement. These included difficulty in removing the stent and ingrowth of granulation tissue with subsequent obstruction of the uncovered part of the stent as well as pain. As a consequence, self-expandable plastic stents (SEPSs) were developed to preclude these complications. Although the first results were promising, several studies on SEPSs have by now revealed a long-term clinical success rate of well below 50%, a migration rate of about 50%, and severe complications in 6% of patients.

Building on these techniques, the ideal stent for a benign stricture should not migrate and should overcome ingrowth of granulation tissue, which often occurs after having a stent in situ for a longer period. In this regard, an interesting option could be an uncovered biodegradable stent that dissolves spontaneously after placement.
### Patient(s):
The current study (ESBIO) was designed as a prospective, single-center, feasibility study to evaluate the efficacy and safety of a self-expandable, biodegradable, uncovered stent. The protocol was approved by the Medical Ethical Committee of the Academic Medical Center in Amsterdam. The study was conducted at the Department of Gastroenterology and Hepatology of the Academic Medical Center at the University of Amsterdam. All participants provided written informed consent. From January 2009 to February 2010, consecutive patients older than 18 years of age with an esophagogastric anastomotic stricture, presenting within 6 months after surgery and having dysphagia scores of 2 to 4 were considered for this study. Exclusion criteria were previous endoscopic treatment of the anastomotic stricture, suspicion of malignancy, anastomotic stricture longer than 3 cm, and upper esophageal sphincter within 1.5 cm of the stricture.

### Methods:
In this study, a biodegradable, uncovered, expandable stent (Fig. 1), 60 mm long with a body diameter of 25 mm and a flare diameter of 31 mm, was used (SX-ELLA Biodegradable Esophageal Stent BD, ELLA-CS, Hradec Kralove, Czech Republic). This stent has been Conformité Européenne approved and holds an indication for the use in benign strictures (peptic, anastomotic, caustic, and postirradiation).

### Results:
Between January 2009 and February 2010, 16 patients were screened for inclusion. Six patients did not fulfill all criteria: 1 had a suspicion of malignancy, 1 had an anastomotic stricture longer than 3 cm, 1 had an esophageal sphincter within 1.5 cm of the stricture, and 3 patients did not want to participate. Of the remaining 10 patients (8 men, 2 women; mean age ± standard deviation [SD] 62 ± 6.8 years), 9 had undergone esophagectomy because of esophageal carcinoma and 1 because of Boerhaave's syndrome. Two patients had anastomotic leaks postoperatively.

### Conclusions:
Placement of the SX-ELLA biodegradable esophageal stent in patients with dysphagia caused by benign anastomotic esophageal strictures has promise in regard to efficacy and safety and therefore deserves to be studied in a more rigorous fashion, such as a randomized, prospective trial.