CASE STUDY

Biodegradable stent placement before neoadjuvant chemoradiotherapy as a bridge to surgery in patients with locally advanced esophageal cancer

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Dysphagia is the most common presenting symptom in patients with esophageal malignancy and contributes significantly to weight loss and malnourishment. An increasing number of patients with locally advanced esophageal cancer undergo treatment with neoadjuvant chemoradiotherapy (CRT) before surgery because this has been shown to improve survival.[1] Neoadjuvant CRT is, however, associated with acute inflammation and edema of the esophageal mucosa, which could increase symptoms of dysphagia and potentially further jeopardize nutritional status.[2]

There are various options for nutritional support during neoadjuvant CRT, including nasal-enteral tube feeding, laparoscopic jejunostomy, and total parenteral nutrition. None of these options relieves dysphagia. Therefore, based on the good results of self-expandable stent placement in the palliative setting, self-expandable stents were introduced as a bridge to surgery during neoadjuvant treatment. Fully covered, self-expandable, metal and plastic stents (FSEMS and FSEPS) have been used with good results, but this is at the expense of additional endoscopic procedures either to remove a migrated stent or to extract the stent before surgery.[3-6] In addition, SEMSs may hamper dose planning of radiotherapy because of backscatter on CT.[7]

Recently, biodegradable stents have been developed to treat refractory benign esophageal strictures.[8,9] These biodegradable stents have the potential to refute the problems encountered with FSEMSs and FSEPSs; migration is less likely because the stent is uncovered, and removal is not necessary because the stent will be resolved at the time of esophagectomy. The aim of this study was to evaluate safety and efficacy of biodegradable stent placement before neoadjuvant CRT as bridge to surgery in patients with locally advanced esophageal cancer and dysphagia.

PATIENTS AND METHODS

This study was designed as a prospective feasibility study in 2 academic hospitals, the Academic Medical Center in Amsterdam and the University Medical Center Utrecht (registered under number NTR2928 in the Dutch Trial Register). The medical ethics committees of both centers approved the protocol, and written informed consent was obtained from each patient.

Patients

Based on historical data regarding the number of esophageal cancer patients presenting in our centers, we aimed to include 16 patients in 2 years. All consecutive patients with resectable esophageal carcinoma scheduled for neoadjuvant CRT and those with complaints of dysphagia for

Abbreviations: CRT, chemoradiotherapy; FSEMS, fully covered, self-expandable, metal stent; FSEPS, fully covered, self-expandable, plastic stent; SEMS, self-expandable metal stent.

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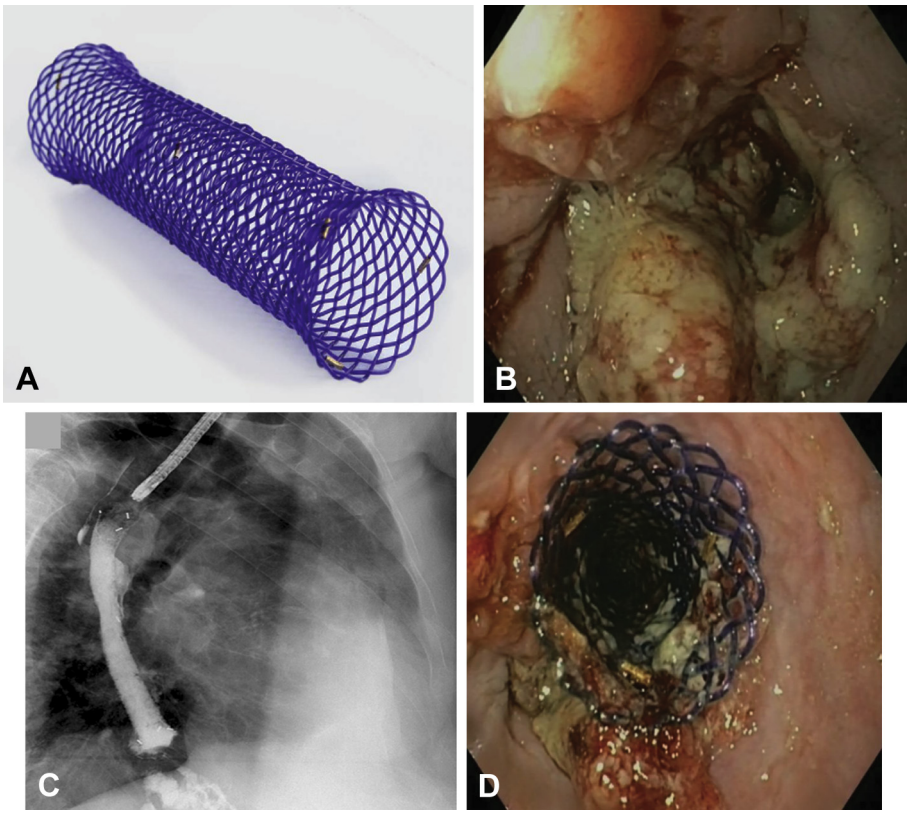

Figure 1. A, Picture of the Ella-SX biodegradable stent. **B,** Obstructing adenocarcinoma in the distal esophagus. **C,** Fluoroscopic control of stent deployment with radiopaque contrast agent. **D,** Endoscopic control of stent position.

solid food (grade ≥ 2 [scale 0-4])[10] were considered for inclusion. Exclusion criteria were as follows: tumor length of >10 cm, tumor growth within 5 cm of the upper esophageal sphincter, tumor extension into the stomach of more than 5 cm, a deep ulcer, a fistula, or no significant stricture.

For safety reasons, a "layered" inclusion scheme was used for the first 5 patients. This dictated that inclusion was open only if the previous patient had completed CRT without the occurrence of any stent-related serious adverse event, and, therefore, there was a waiting period of 5 weeks (ie, CRT duration) after inclusion of 1 of the first 5 patients before a next patient could be included This strategy was chosen because of the high serious adverse event rate in a previous study investigating biodegradable stent placement combined with single-dose brachytherapy for palliation of dysphagia.[11] After these initial 5 patients, inclusion was without restrictions.

All eligible patients who were not included in the study were treated with placement of a nasoduodenal feeding tube in combination with surveillance by a dietician or by dietary surveillance alone, depending on patient nutritional status.

Materials and intervention

The Ella-SX biodegradable stent (Ella-CS; Hradec Kralove, Czech Republic) is Conformité Européenne approved and has an indication for use in benign strictures (peptic, anastomotic, caustic, and post-irradiation) (Fig. 1). The stent is uncovered and available in lengths of 60, 80, and 100 mm, and, for this study, only stents with body diameters of 18 mm and flare diameters of 23 mm were used. Radiopaque markers at both ends and at the middle of the stent enable fluoroscopic visualization. The stent is made of woven polydioxanone monofilaments, and disintegrates 11 to 12 weeks after implantation. The stent is mounted on a delivery system shortly before implantation; the outer diameter of the delivery system is 9.4 mm. Stent placement was done with the patients under conscious or deep sedation. If a pediatric endoscope (Olympus XP-160; Olympus Medical Systems Europe, Hamburg, Germany, or similar) could not pass the stricture, a Savary bougie dilation was performed up to 10 mm to facilitate safe insertion of the delivery system. The length of the stricture was measured endoscopically. The proximal part of the stricture was marked with intramucosal injection of a radiopaque contrast agent to facilitate accurate stent placement under radiologic guidance. A guidewire was positioned, and the delivery device was introduced over the guidewire. The stent was placed with proximal and distal margins of at least 1.5 cm of the stricture. The correct position of the stent was confirmed with fluoroscopy and/or endoscopy (Fig. 1). All patients, with the stent traversing the lower esophageal sphincter, received a proton pump inhibitor after the procedure (omeprazole 40 mg daily).