

Removable, Fully Covered, Self-expandable Metal Stents for the Treatment of Refractory Benign Esophagogastric Anastomotic Strictures

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Abstract The use of metal stents for malignant esophageal strictures for palliation is well accepted. However, utilization of metal stents for benign esophageal diseases has been controversial. Given the availability of removable, fully covered, self-expandable metal stents (RFCSEMSs), this study was undertaken to evaluate the effectiveness and safety of RFCSEMSs in patients with refractory benign esophagogastric anastomotic strictures. Twenty-four patients with RFCSEMSs were enrolled in this study. All patients had undergone endoscopic Savary-Gilliard bougie dilatation five times or more but there was no significant improvement in symptoms. For all 24 patients, the symptom of dysphagia was alleviated significantly while the stent was in place and for a short time after stent removal, and dysphagia scores decreased from 3–4 to 0–1. After 12 months of follow-up, 18 patients were free from dysphagia but the other 6 patients still suffered obvious dysphagia. RFCSEMSs are still not perfect and can induce some complications. The treatment failure rate of restenting was remarkably high after the first failure. Given that effective methods for treating refractory stricture have not been found, RFCSEMSs could be considered

for treating refractory benign esophagogastric anastomotic stricture.

Keywords Esophageal stricture · Esophageal stent · Dysphagia · Esophagectomy · Deglutition · Deglutition disorders

Benign esophagogastric anastomotic strictures occur in 5–46% of patients after esophagectomy for esophageal cancer [1–4]. Various endoscopic dilation techniques have been reported for the treatment of these strictures [1–7]. The success rate of dilation therapy with Savary bougienage (SB), balloons, or Eder-Puestow dilators ranges from 70 to 90% [1–8]. However, stricture recurrence is still common in clinical practice, so consequently patients often require repeated dilation sessions to achieve and maintain a steady state with persistent ability to pass solid foods [1–5]. In one study [9] there was one patient who underwent dilation 46 times.

Therefore, esophageal stents may be another choice for treating refractory benign esophagogastric anastomotic strictures. Stents used to treat esophageal strictures include plastic stents and metal stents. The Polyflex stent (a self-expandable plastic stent; Boston Scientific, Natick, MA) has already been approved for managing benign esophageal strictures [10]. However, it has been reported that the Polyflex stent has a high migration rate of up to 85% [11]. The use of metal stents for palliation of malignant esophageal strictures is well accepted [12, 13] but remains controversial for the treatment of benign diseases. In previous studies, noncovered metal stents were not routinely used for benign esophageal obstruction because of a high incidence of stent-induced trauma leading to fistulization and stent-induced stenosis caused by granulation tissue and

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fibrosis, as well as difficulty in being able to reliably remove the stents [14, 15]. Due to the clinical application of RFCSEMSs, these problems have been resolved in large part.

Given this situation, our hospital deployed removable, fully covered, self-expandable metal stents (RFCSEMSs) to treat refractory benign esophagogastric anastomotic strictures between May 2006 and April 2009, with appreciable long-term therapeutic effect. This article is a retrospective study of the clinical data.

Materials and Methods

Clinical Materials

Twenty-four patients with refractory benign esophagogastric anastomotic stricture were enrolled in this study (Table 1). There were 18 males and 6 females, aged 41–74 years (mean age = 60.5 years). All patients underwent esophagectomy (6 transleft-thoracic esophagectomies, 2 Ivor-Lewis esophagectomies, and 16 Tri-incisional esophagectomies) and postoperative pathological examination confirmed negative margins. Among 24 patients were 22 cases of esophageal cancer, 2 cases of esophagogastric junction cancer, 8 cases of intrathoracic

anastomosis, and 16 cases of cervical anastomosis. All the anastomoses were performed with a mechanical stapler. Anastomotic strictures developed approximately between 1 and 15 months after esophagectomy. All 24 patients were confirmed to be without tumor recurrence of anastomosis by electronic gastroscopy. According to Kochman’s definition of refractory stricture, all patients in our study underwent endoscopic dilatation at least five times but there was no significant improvement in symptoms [16]. The diameter of the anastomosis was dilated up to 15 mm every time. The diameter of the anastomosis measured under endoscopy was 0.1–0.6 cm before stent placement. Informed consent was obtained from all patients for all procedures. In all instances, consent forms, approved by the hospital ethics committee, were signed by the patients. Twenty-nine RFCSEMSs (CZES series, Huai An Sigma Medical Industry CO, Jiangsu Province, PRC) were placed in 24 patients (there were 5 patients who received a second RFCSEMS when they suffered recurrent stricture after removal of the first RFCSEMS).

Dysphagia Scoring System

We employed the scoring system used by Barthel et al. [11] (Table 2) 0 = able to eat solid food without special attention to bite size or chewing; 1 = able to swallow solid food cut into pieces ≤18 mm and thoroughly chewed; 2 = able to swallow semisolid foods (consistency of baby food); 3 = able to swallow liquids only; 4 = unable to swallow liquids or saliva.

Stent Placement and Removal

RFCSEMSs were the CZES series with antireflux function. (The specification and size of the stents used in this study are given in Table 3). All the stents were placed and removed under the gastroscope. The placement method was according to the instruction manual of the stent manufacturer.

Table 1 Characteristics of patients

Characteristics	n (%)
Sex	
Male	18 (75.0)
Female	6 (25.0)
Age (years)	
Mean	60.5
Range	41–74
Location of lesion	
Esophageal carcinoma	22 (91.7)
Carcinoma of the esophagogastric junction	2 (8.3)
Type of esophagectomy	
Transleft-thoracic esophagectomy	6 (25.0)
Ivor-Lewis esophagectomy	2 (8.3)
Tri-incisional esophagectomy	16 (66.7)
Location of anastomosis	
Intrathoracic	8 (33.3)
Cervical	16 (66.7)
Diagnostic time of anastomotic stricture	
≤2 months	4 (16.7)
>2 months	20 (83.3)
Dysphagia score	
3	22 (91.7)
4	2 (8.3)

Table 2 Dysphagia scoring system

Score	Definition
0	Able to eat solid food without special attention to bite size or chewing
1	Able to swallow solid food cut into pieces ≤18 mm ^a and thoroughly chewed
2	Able to swallow semisolid food (consistency of baby food)
3	Able to swallow liquids only
4	Unable to swallow liquids or saliva

^a The diameter of a dime is 18 mm

Table 3 The specification and size (mm) of RFCSEMSs

Parameters of the stents	Basic size	Tolerance
Diameter of the mid-stent	15, 16, 17, 18	+0.5, -1.0
Diameter of the two ends	22, 23, 24, 25	+0.5, -1.0
Length	55, 65, 85, 105, 120	± 1.5

Placement method: (1) Insert the gastroscope by mouth and measure the diameter of the anastomosis (Fig. 1) and the distance between the upper end of the anastomotic stricture and the central incisors. (2) Insert the guide wire via the gastroscopic biopsy hole and cross the stricture segment, then pull back the gastroscope and dilate the stricture segment up to 15 mm under the guidance of the guide wire by Savary-Gillard dilation bougie. (3) Reinsert the gastroscope and cross the anastomosis, measure the distance between the lower end of the stricture segment and the central incisors, calculate the length of the stricture segment, and select the stent with suitable length and diameter. (4) Insert the stent conveyer along the guide wire, lock the conveyer by localizer whose front-end pushes against the dental pad, pull out the fixed pin of the conveyer, use the chest or belly of the operator to push against the localizer, pull back the outer tube, pull out the fixed pin of the stent and release the stent, pull back the conveyer and guide wire. (5) Check the location of the stent by gastroscope (Fig. 2). If the location of stent is not satisfactory, adjust it using the stent retriever or replace it.

Recovery method: (1) Insert the gastroscope and reach the upper end of stent. (2) Insert the retriever via the gastroscopic biopsy hole, beyond the gastroscopic lens about 4–5 cm, and reach the upper end of stent. (3) Draw the sleeve back about 3 cm, expose the hooklet, pull back the steel wire so that the hooklet can slide upward along the inner wall of stent to hook the dark retrieving thread in the

**Fig. 1** Endoscopic view of benign esophagogastric anastomotic stricture before stent placement**Fig. 2** RFCSEMS was placed in proper position to treat a benign esophagogastric anastomotic stricture after esophagectomy

upper end of stent. (4) After hooking the retrieving thread (the stent will be removed along with the steel wire), push the plastic tube downward to press the hooklet and fix the retrieving thread. (5) Retreat the steel wire and the upper end of stent will contract. (6) Pull out the gastroscope and the steel retrieving wire and the stent will be pulled out together.

All patients were followed up by telephone or at the outpatient clinic 3, 6, and 12 months after stent removal. If the patient suffered a relapse of stricture during the follow-up period and had a dysphagia score ≥ 3 grade, we suggested restenting. When restenting was still inefficient or the patient rejected placement of a second stent, we suggested intermittent endoscopic dilation.

Results

We placed and removed 29 RFCSEMSs successfully in 24 patients. The stents were removed within 4–8 weeks after placement. Five patients experienced obvious acid reflux during stent residency, but it could be tolerated with medication. Twenty-one patients complained of chest pain that gradually disappeared within 6 days after stent placement. Stent migration was observed in only one patient but was asymptomatic; the migration was discovered during stent removal. No esophageal rupture or bleeding was found during stent removal. All the retrieved stents were intact and there was no oxidation or breakage. For all 24 patients, the symptom of dysphagia had been alleviated significantly during stent residency and for a short time after stent removal, and dysphagia scores decreased from 3–4 to 0–1. Seven patients suffered recurrent stricture within 3 months after stent removal. The time interval from stent removal to stricture recurrence was 1.5 months

Table 4 Incidence of complications following stent placement

Complication	n (%)
Recurrent stricture	11 (37.9)
Apparent reflux	5 (17.2)
Chest pain	21 (72.4)
Stent migration	1 (3.4)
Bleeding	0 (0.0)
Perforation	0 (0.0)

in three patients, 2 months in three patients, and 2.5 months in one patient. Of these seven patients, two rejected the second stent placement and selected intermittent endoscopic dilation. The other five patients underwent a second stent placement and all stents were removed 8 weeks later. Among these five patients, only one was free of dysphagia by the last follow-up; the restenting failed to treat the dysphagia of the other four patients. After 12 months of follow-up, 18 patients were free from dysphagia, but the other 6 patients still suffered obvious dysphagia. Complications are summarized in Table 4.

Discussion

Removable fully covered self-expandable metal stents (RFCSEMSs) can dilate the anastomotic stricture segment persistently and thus alleviate dysphagia. They can be removed several weeks later to avoid reactive hyperplasia of granulation tissue due to prolonged stimulation. In 2009, a study [17] reported that RFCSEMSs were placed in 31 patients. Stents were embedded in four cases but were easily lifted from the tissue. Severe chest pain or abdominal pain was observed in 23% of the patients. All the stents were successfully retrieved. There were seven patients with refractory benign strictures treated with this method, and the clinical success rate was 29%.

In our study, the success rate of stent placement and removal was 100%. No esophageal rupture or bleeding was found during stent removal. Tissue reaction was slight and stent removal was easy. This kind of esophageal stent was safe and feasible. After 12 months of follow-up, 18 patients were free from dysphagia. The total clinical success rate of this method was 75%. Another study also confirmed the safety of this kind of stent, but only 21% of patients with refractory strictures had successful long-term outcomes without any need for reintervention [18].

Dysphagia scores decreased significantly during stent residency and for a short time after stent removal. The same results were also obtained by Eloubeidi et al. [18]. In our study, seven patients suffered recurrent stricture within 3 months after stent removal. The recurrence of stricture

after stent removal was the most important complication. We placed the stent again in some patients with recurrent stricture, but the final treatment failure rate was as high as 80%. RFCSEMSs could prolong symptom-free duration and therefore reduce the suffering caused by frequent dilation. However, recurrent stricture after stent removal could not be avoided completely. The effectiveness of restenting in patients with recurrent esophagogastric anastomotic stricture is very limited. Therefore, we do not recommend restenting for patients with recurrent stricture after stent removal.

No serious chest pain was recorded in our study. However, slight chest pain was quite common but gradually disappeared within 6 days after stent placement. All stents were removed on schedule. Stent migration was observed in only one patient but was asymptomatic and was discovered during stent removal. In spite of a low incidence of stent migration (1 in 29, 3.4%), we had no preventative measures to avoid it thoroughly.

In our study, only five patients experienced obvious acid reflux during stent residency. This incidence rate was lower than that reported in the literature, largely due to the antireflux function of the stents we used. Laasch et al. [19] compared the open stent with the antireflux stent and reported that the incidence rate of reflux was 96 and 12%, respectively.

With respect to the dwell time of esophageal stent, the majority of doctors consider that 4–8 weeks is appropriate. The main reasons are (1) if the duration is too short, stricture segment cicatricial tissue cannot be organized completely, so recurrent stricture will be prone to occur; (2) if the duration is too long, serious connective tissue proliferation is inevitable and stent removal becomes difficult.

Some patients with refractory benign esophageal anastomotic strictures could be cured with the use of RFCSEMSs. RFCSEMSs have some advantages compared with dilation alone or a permanent stent. Stent placement or removal is not too difficult. However, RFCSEMSs are still not perfect. They can cause certain pain, be a financial burden, and induce some complications. The treatment failure rate of restenting is remarkably high after failure of the first stent. Given that effective methods for treating refractory stricture have not been found, RFCSEMSs could be considered the treatment of choice for refractory benign esophagogastric anastomotic stricture.

This was a retrospective study with a small sample size and did not compare the use of RFCSEMSs with other therapeutic methods. These results may not be able to represent the whole patient experience.

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