Self-Expanding Metal Stents for Endoscopic Treatment of Esophageal Achalasia Unresponsive to Conventional Treatments. Long-Term Results in Eight Patients

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Background and Study Aims: **The successful use of self-expanding metal stents has been demonstrated in the management of malignant esophagocardial strictures. This report assesses the role stents may play in the treatment of esophageal achalasia in selected patients.**

Patients and Methods: **Between September 1996 and December 1997, eight patients (two men, six women; average age 67.6 years) underwent insertion of a self-expanding metal stent for management of achalasia. Previous myotomy and/or balloon dilation or injection of botulinum toxin had failed in all patients. Four nitinol coil stents and five covered Ultraflex stents, 10 cm long, were inserted, being passed through the gastroesophageal junction under mild sedation.**

Results: **Stent placement was successful and uncomplicated in all patients. Early complications were seen in five patients: chest pain (1), gastroesophageal reflux (1), proximal migration (1), and distal migration (2). One patient underwent surgery for stent impaction in the colon. During the follow-up period of 35.5 months, on average (range 29–44 months), four patients experienced complications: chest pain (2), reflux esophagitis (1) and stent migration (1).**

Conclusion: **General use of self-expanding metal stents for esophageal achalasia cannot be recommended.**

Introduction

The placement of self-expanding metal stents (SEMS) for the palliation of malignant dysphagia and esophagorespiratory fistulas is safe and effective [1, 2].

Given the wide availability and user-friendly design of SEMS, it is no surprise that indications for their use continue to expand. In the setting of benign disease, SEMS have been used to treat refractory strictures. Poor candidates for surgery with refractory strictures have generally been considered candidates for SEMS placement to maintain luminal patency. Experience using SEMS in this patient population is extremely limited, with no long-term outcome data.

We proposed, in 1998, for the first time the use of SEMS in patients with long-lasting esophageal achalasia, which was unresponsive to conventional treatments [3]. The present study reports the long-term outcome of stenting with SEMS in these patients.

Patients and Methods

Between September 1996 and December 1997, eight patients (two men, six women; average age 67.6 years) underwent implantation of SEMS for management of esophageal achalasia.

All the patients complained of dysphagia and had lost at least 20% of their normal weight. In addition to the dysphagia, many patients had other symptoms before stent implantation and these are detailed in Table **1**. The mean duration of symptoms was 11.5 years, ranging from 6 to 28 years. All the patients had undergone previous treatments, on one or more occasions. Time to recurrence of symptoms, and particularly to recurrence of dysphagia, ranged from 4 to 80 months (Table **2**).

All the patients had the classical manometric features of achalasia, with a peristalsis and incomplete lower esophageal sphincter (LES) relaxation. In two patients a sigmoid mega-esophagus was seen at barium contrast swallow and in four a rigid stricture of the lower esophagus, extending

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Table 1 Pre-procedure symptoms

Symptoms*	n	%
Dysphagia for solids only	5	62.5
Dysphagia for both solids and liquids	3	37.5
Burning chest pain	2	25.0
Regurgitation	5	62.5
Heartburn	3	37.5
Epigastric pain	4	50.0
Water brash	4	50.0
Gripping chest pain	2	25.0

* Some patients displayed more than one symptom.

Table 2 Patient characteristics and medical history

Sex	Age	Duration of symptoms, years	Previous treatment
M	71	7	SM
F	73	12	I + B
F	42	6	SM + B
M	69	11	B
F	71	9	B
F	68	10	SM
F	87	28	I + B
F	60	9	SM + B

SM, open surgical myotomy; I, botulinum toxin injection, B, balloon dilation.

over 2–3 cm. (Histological and cytological investigations excluded carcinoma). Endoscopy revealed fibrin deposits, liquid and/or solid stasis, and esophagitis in all the patients.

Informed consent was obtained from all patients.

Treatment was carried out on an outpatient basis. Four nitinol coil stents (Instent, Eden, Praire, USA), and four covered Ultraflex stents (Microvasive, Boston Scientific, Natick, Massachusetts, USA), 10 cm long, were placed without dilation and with patients under mild sedation, across the gastroesophageal junction. At 24–36 hours after the implantation procedure, a contrast swallow was performed to confirm correct stent position and esophageal emptying.

Patients were treated with proton pump inhibitor (omeprazole 40 mg/d) and were instructed to elevate the head of the bed and to avoid resting after meals, in order to reduce the risk of reflux and aspiration.

The follow-up study of patients involved a detailed assessment of symptoms and eating habits; contrast barium swallow and upper endoscopy were performed at 1 and 3 months after stent implantation and every 6 months thereafter. Patients were instructed to contact our unit if any complication arose.

Results

Early Outcomes (Within 30 Days)

Stent placement was successful and uncomplicated in all cases. After stent implantation, all the patients had remission of dysphagia and were able to take a normal diet.

Early complications were encountered in five patients. One patient complained of transitory chest pain and nocturnal regurgitation and symptoms of gastroesophageal reflux, requiring medical therapy, were observed in another patient. Proximal migration (Esophacoil) stent occurred in one patient and there were two instances of distal migration (one Esophacoil and one covered Ultraflex), in two patients with sigmoid mega-esophagus. In the first patient mentioned the stent was successfully replaced; in one of the two cases of distal migration, the stent (covered Ultraflex) passed spontaneously per rectum (a new stent was inserted), but in the second, impaction of the stent (Esophacoil) was observed in the right colon. The patient complained of worsening abdominal pain, and she underwent surgery to avoid the risk of perforation. During the surgical procedure, strangulation of colonic tissue between the coil loops of the distal part of the stent was observed.

Late Outcomes (Over 30 Days)

No patients were lost to follow-up. The average duration of follow-up was 35.5 months (range 29 – 44 months). All the patients experienced weight gain. Within 3 months, barium contrast swallow revealed a progressive reduction of esophageal dilation and stasis in all cases. Endoscopy revealed a clean esophagus and absence of liquid or solid stasis.

Late complications occurred in four patients. Chest pain was observed in two patients with Esophacoil stents. Severe esophagitis was observed in one patient with a covered Ultraflex and there was one instance of distal migration in a patient with an Esophacoil stent (Table **3**).

Discussion

In the management of achalasia, three efficacious therapies are now available: pneumatic dilation, surgical myotomy and botulinum toxin injection [4–7]. Percutaneous endoscopic gastrostomy (PEG) can also be used to maintain adequate nutrition.

In many centers, pneumatic dilation is still the first-line intervention for achalasia with open or laparoscopic cardiomyotomy being reserved for those patients who do not respond to this conservative approach. Injection of botulinum toxin has been shown to be a treatment alternative for achalasia, particularly in elderly patients.

Follow-up studies of 5 years or longer have shown that an excellent-to-good outcome occurs in 50–70% of patients following balloon dilation and 70–80% of patients follow-

Table 3 Outcomes

Early results (within 30 days)	
Successful stent insertion	8/8 (100%)
Procedure-related complications	0/8
Early complications	5/8 (62.5%)
Chest pain	1/8
Gastroesophageal reflux	1/8
Proximal migration	1/8
Distal migration	2/8
Surgery for complications	
Stent impaction	1/8 (12.5%)
Mortality	0
Late complications (over 30 days)	4/7 (57.1%)
Reflux esophagitis	1/7
Chest pain	2/7
Distal migration	1/7

ing surgical myotomy. Botulinum toxin injection is shown to have significantly lower long-term efficacy compared with pneumatic dilation and retreatment is frequently necessary [4–7].

Disabling dysphagia occurs in 10–20% of patients following balloon dilation and in 3–5% of patients following surgical myotomy. These patients generally require a new endoscopic treatment or a surgical approach. More troublesome strictures may ultimately require surgical resection of the esophagus [4–7].

Although a surgical esophagectomy for benign disease is less morbid than an esophagectomy for carcinoma, the increase of operative risk with age or serious associated illness justify the search for less invasive nonsurgical techniques.

Recently, we proposed the use of SEMS in patients with long-lasting esophageal achalasia which was unresponsive to conventional treatments [3]. Insertion of a SEMS was selected after failure of conventional treatments such as surgery, balloon dilation or injection therapy, and our idea was that the stent should be used to bypass the fibrotic stricture of the lower third of the esophagus or the high levels of LES pressure. Ease of implantation was also a factor which favoured the use of SEMS.

Although it is clear that implantation of SEMS for the palliation of malignant dysphagia is both safe and effective, their use in benign esophageal disease is extremely controversial. Major concerns have been unknown long-term effects (such as mucosal hyperplasia), safety (such as bleeding, perforation or fistulas), and the permanence factor, as SEMS are generally not removable.

Experience using SEMS to treat benign esophageal obstruction is extremely limited, with no long-term outcome data. A recent review of the literature showed that approximately 80% of patients who underwent implantation of a SEMS for benign disease, experienced a stent-related complication, including new stricture formation (41%), stent migration (31%), chest pain or reflux (21%), tracheoesophageal fistula (6%) and anemia (3%) [8, 9].

In our experience, 62.5% of patients experienced early complications (within 30 days) and 57.1% late complications (over 30 days later). Stent migration was the main early complication in this series (37.5%) because of the difficulty in anchoring the stent, particularly in patients with sigmoid mega-esophagus. The main late complication, however, was chest pain (28.5%) requiring the use of analgesics.

The type of stent inserted (Esophacoil or Utraflex) seems to correlate with complications. The spring design of the Esophacoil stent caused an incarceration of colonic tissue between the coil loops, requiring surgical intervention. Moreover, the high expansile force of this stent, may explain the chest pain experienced by our patients. On the other hand, the Ultraflex stent seems to be well tolerated. The design of the Ultraflex stent may afford the possibility of an improved outcome, given its relatively low expansile force and smooth knitted ends. These factors may decrease the likelihood of ischemic injury, avoiding mucosal hyperplasia, chest pain, delayed perforation, fistulas and hemorrhage.

Conclusion

This report demonstrates the role that the SEMS may play in the treatment of esophageal achalasia. Given the poor results, so far, general use of the SEMS for esophageal achalasia cannot be recommended. In cases of refractory strictures and poor surgical risk, the decision should be based upon individual risk-benefit ratios, assuming a knowledge of the potential complications.

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