

Fully Covered Alimaxx Esophageal Metal Stents in the Endoscopic Treatment of Benign Esophageal Diseases

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Abstract

Background Expandable esophageal stents are widely used for the palliation of dysphagia in patients with esophageal cancer and are also beginning to be used in patients with benign esophageal diseases such as refractory strictures and fistulas. There is concern regarding the increased risk of migration of the fully covered Alimaxx metal esophageal stent and experience with this stent in benign esophageal pathology has been reported in only a small series of patients.

Aims To evaluate the technical success in placement and removal, efficacy and complications of the Alimaxx esophageal stent for benign esophageal diseases.

Methods Our endoscopy database was retrospectively reviewed from 1/2003 to 2/2009 to identify patients with Alimaxx esophageal stent placement for benign diseases. Chart review was performed for age, gender, indication, site of the lesion, success of placement, outcome, and incidence of complications.

Results Twenty-eight stents were successfully placed in 14 patients with benign esophageal diseases (mean: two stents/patient; range 1–7). Indications included esophageal fistula in seven (50%) and benign strictures in 7/14 (50%). Dysphagia improved in all patients while the fistula resolved in 6/7 (85.8%) patients. Complications related to stents included pain (2/28, 7%), stent related gastric ulcer (1/28, 4%), nausea and vomiting (3/21, 11%) and stent migration (11/28, 39%). All migrated stents were successfully endoscopically retrieved.

Conclusions The fully covered and removable Alimaxx stent is effective in the endoscopic management of benign esophageal strictures or fistulas, despite its relatively high rate of migration. Stent migration was successfully managed endoscopically without complications.

Keywords Alimaxx · Esophageal stent · Esophageal fistula · Esophageal stricture · Completely covered metal stent

Introduction

Endoscopic esophageal stent placement is routinely performed for palliation of malignant dysphagia or for the treatment of benign esophageal diseases such as refractory strictures, perforations, fistulas, and post-operative anastomotic leaks [1, 2]. Self-expandable metal stents (SEMS) have now been developed and are made of stainless-steel or alloys (Nitinol or elgiloy) and may be covered by a plastic membrane or silicone. SEMS can be uncovered (Z-stent, Cook Medical, Winston-Salem, NC) or partially covered (Ultraflex stent and esophageal Wallstent, Boston Scientific, Natick, MA) [3]. A removable completely covered plastic expandable esophageal stent (Polyflex stent, Boston Scientific, Natick, MA) is also available [4].

The Alimaxx stent (Alveolus Inc., Charlotte, NC) is a nitinol stent fully covered with polyurethane to resist tissue ingrowth. However, there is concern about the high rate of stent migration when this completely covered stent is placed for benign esophageal diseases. The aim of this study was to retrospectively review our experience with the Alimaxx esophageal stent in the therapy of benign esophageal pathology.

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Methods

Patients

Our electronic searchable endoscopy database was retrospectively reviewed from 1/2003 to 02/2009 to identify patients who had Alimaxx esophageal stent placement for benign diseases.

Study

This was a retrospective study at a tertiary referral center. The study protocol was approved by the Institutional Review Board at the University of Florida. Chart review was performed for age, gender, indication, site of the lesion, success of placement, outcome, and incidence of complications.

Outcomes

Medical records were reviewed to assess outcomes after esophageal stent placement (i.e., technical success in stent placement and removal, clinical improvement in dysphagia, resolution of stricture or fistula). Improvement was determined by reviewing records of clinical encounters at the University of Florida clinics. Resolution of strictures or fistulas was confirmed from imaging studies (swallow study, CT scan), or endoscopy reports showing resolution of the condition that required stent placement.

Stents

Fully covered Alimaxx esophageal stents (Alveolus Inc., Charlotte, NC) of the following sizes were used: diameter 18 or 22 mm; length 70, 100, or 120 mm. Alimaxx stents were the preferred fully covered stents used at our institution during the study period.

Stent Placement

Upper endoscopy was performed with single-channel gastroduodenoscopes (GIF-160 or H-180, Olympus America, Center Valley, PA) to identify the esophageal lesion that required stent placement. The length of the stent was chosen so as to extend at least 1–2 cm on either side of the proximal and distal extent of the stricture or fistula. Typically, an 18-mm stent was selected for management of strictures while a 22-mm stent was placed for fistulas without an obstruction. This was per the discretion of the endoscopist. Dilation was not routinely performed prior to placement of all stents. Dilation was performed only if the endoscopist felt that the stricture was too tight to allow

passage of the stent delivery system and to allow endoscopic visualization of the distal GI tract, if indicated.

Alimaxx stent placement was then performed as follows: A guidewire was placed through the channel of the endoscope and advanced across the esophageal lesion under endoscopic and fluoroscopic guidance. The endoscope was then withdrawn and the wire left in place. The stent delivery system was then loaded over the guidewire under fluoroscopy. Simultaneous endoscopic visualization was performed in some cases by advancing a standard single channel upper endoscope alongside the stent delivery system. When fluoroscopy was not available, some stents were placed purely under endoscopic guidance using this method (tandem endoscopic guidance with the endoscope alongside the stent delivery system). The stent was then deployed across the lesion.

Stent Removal

Upper endoscopy was repeated in 4–8 weeks for reassessment and stent removal or replacement. If needed, another fully covered stent was placed after removing the first stent. Endoscopy was performed earlier in the event of complications such as stent migration or chest pain. The suture at the proximal end of the stent was grasped with a rat-tooth forceps through the endoscope and the stent removed. Esophageal stenting was continued until symptoms and stricture improved or the fistula healed. Fistula resolution was confirmed with imaging studies (esophagram/CT scan) within 24–48 h after stent placement as required. This was also checked after stent removal (if the fistula was felt to have endoscopically resolved and if a new stent was not placed).

Results

Patients

A total of 14 patients underwent Alimaxx esophageal stent placement (28 stents) for benign esophageal diseases. The mean age of the patients was 62.9 years (range 45–83 years). Of these 14 patients, there were 12 males (85%) and two females (15%) and 57% patients were inpatients while 43% were outpatients. Outpatients were treated as such unless clinical symptoms or complications were noted after EGD requiring admission for further management or 23-h observation.

Stents

A total of 28 stents were placed in 14 patients with six patients requiring more than one stent placed simultaneously

and/or sequentially. Of these 14 patients, eight patients had one stent, two had two stents, three had three, and one patient had seven (a patient with a very long esophageal rupture and esophago-pleural fistula). A total of 43% patients underwent dilation prior to stent placement. Alimaxx stents were placed during serial therapeutic endoscopies. All stents were placed during separate endoscopies except in two patients: one patient with an esophago-pleural fistula had two stents placed during the first endoscopy in order to cover the large fistula, and another patient with a tracheo-esophageal fistula had two simultaneous stents placed during the same session.

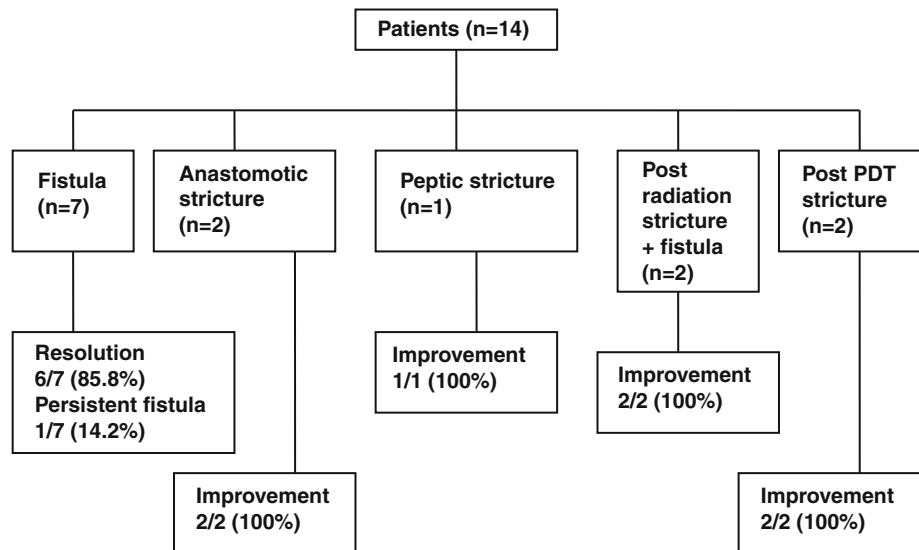
Indications

Stents were placed for esophageal fistulas in 7/14 (50%) patients and for benign strictures in 7/14 (50%) patients including anastomotic stricture in 2/14 (14.28%), peptic stricture in 1/14 (7.14%), radiation stricture and fistula in 2/14 (14.28%), and post-PDT stricture in 2/14 (14.28%) as shown in Table 1. All strictures had previously failed aggressive endoscopic dilation.

Table 1 Indications for Alimaxx stent placement in benign esophageal diseases

Indications	Patients (n = 14)	%
Esophageal fistula	7	50
Anastomotic esophageal stricture	2	14.28
Peptic esophageal stricture	1	7.14
Post radiation stricture + fistula	2	14.28
Post PDT stricture	2	14.28

Fig. 1 Clinical outcomes after Alimaxx stent placement in patients with benign esophageal diseases



Outcomes

Mean follow-up duration was 172 days (range 19–727 days). Technical success was achieved in the placement of all stents. Clinical improvement in dysphagia was seen 7/7 patients (100%) and fistula resolution was observed in 6/7 (85.8%) patients (Fig. 1). The fistula persisted in only 1/7 (14.2%) patients. Dysphagia improved in all patients with strictures (peptic, post-PDT, anastomotic and post-radiation) even though one had traumatic gastric ulceration related to the stent requiring stent removal.

Stent removal was possible and not technically difficulty except in one patient where the stent could not be removed (Alimaxx stent became inexplicably stuck to a Polyflex stent). At the time of follow-up endoscopy for stent removal, the Alimaxx stent was stuck inside the Polyflex stent and could not be removed. Removal was either elective (for stent exchange/insertion of another stent) or due to complications (pain, migration, incomplete expansion). The average time to stent removal was 37 days (range 4–84 days).

Complications

Complications occurred in 15/28 (54%) of the stents placed (Table 2). The most common complication was stent migration in 11/28 (39%) of stents (occurring in 8/14, 57% patients). Average time until migration was 35 days (range of 4–62 days). Stent migration was detected on radiographic imaging and/or endoscopy performed for follow-up or when performed as part of the evaluation if clinical symptoms (pain in neck, chest or abdomen, nausea, vomiting, cough or shortness of breath) developed. Migration was seen in 3/7 (43%) 18-mm stents and in 8/21 (38%) 22-mm diameter stents. All migrated stents migrated

Table 2 Stent-related complications (as percentage of stents and patients)

Complications	Stents (%)	Patients (%)
Pain	2/28 (7)	2/14 (14)
Migration	11/28 (39)	8/14 (57)
Nausea and vomiting	3/28 (11)	3/14 (21)
Gastric ulcer	1/28 (4)	1/14 (7)
Incomplete expansion	1/28 (4)	1/14 (7)
Stuck	1/28 (4)	1/14 (7)

Table 3 Stent migration according to stent size

Stent diameter	Migration
18 mm (<i>n</i> = 7)	3/7 (43%)
22 mm (<i>n</i> = 21)	8/21 (38%)

distally (into the stomach) and management was either repositioning or removal. There was no bleeding, perforation, or bowel obstruction related to stent migration. All migrated stents were successfully endoscopically retrieved with a snare (without an esophageal overtube) and further stent placement was performed as indicated (Table 3).

Severe pain occurred in two patients (14%) after stent placement. In one patient, the stent had migrated, and required repositioning. Stent-related gastric ulcer was noted in the second patient with benign stricture after photodynamic therapy (for Barrett's esophagus with high-grade dysplasia) and the stent was removed 19 days after insertion due to severe pain.

No significant technical difficulties were noted during stent placement. However, in one patient with post-radiation stricture, incomplete expansion of the stent occurred and trial of balloon dilation of the stent 4 days later failed. This stent was therefore removed and another stent placed. No other procedural complications were observed and no patients died from a cause directly related to stent placement. Stents were successfully removed endoscopically in all cases except one. This patient had a persistent fistula after Polyflex stent placement at a referring institution. The Polyflex stent had been placed at an outside referring institution many months prior to the patient getting referred to our center. This Polyflex stent could not be removed as it was firmly embedded in the esophageal wall. An Alimaxx stent was placed at our center partially within the existing Polyflex stent so as to completely cover the persistent fistula. At the time of stent removal (6 weeks after Alimaxx stent placement), the Alimaxx stent was found to be stuck to the Polyflex stent and could not be removed. Follow-up esophagram revealed a stable paraesophageal cavity. This patient did well clinically with the indwelling stents during

a follow-up period of 140 days. Six patients died (mean: 41 days; range: 19–90 days) after stent placement from causes not related to esophageal stent placement. These patients were poor surgical candidates with multiple underlying medical comorbidities. Stent placement was hence considered an appropriate less invasive therapeutic option.

Discussion

Esophageal stents are widely used in the endoscopic management of various malignant and benign esophageal conditions. They can be used for palliation of advanced esophageal cancer and have also shown promising results in benign diseases [5, 6].

The Alimaxx stent (Alveolus Inc., Charlotte, North Carolina, USA) is a metal stent made of nitinol covered with a polyurethane membrane to limit tissue ingrowth and facilitate stent removal if needed. Only a few previous studies have evaluated the Alimaxx stent [7]. In the study by Uitdehaag et al. [8], 45 patients with inoperable esophageal and gastric cancer showed improvement in dysphagia score from a median score of 3–1 after stent placement. A multicenter retrospective study showed improvement in dysphagia with Alimaxx stent placement for all indications [7]. There is very little data regarding the use of these stents purely in benign esophageal diseases [9, 10]. A recent paper by Eloubeidi et al. [11] discussed the feasibility, technique of removal and tissue reaction with the Alimaxx stent. Their study population included patients with both benign and malignant esophageal diseases and palliation of dysphagia was observed to be significantly improved with the Alimaxx stent.

Our study assessed the use of the Alimaxx esophageal stent purely for benign esophageal diseases. Our data shows that this completely covered removable stent is effective in the endoscopic management of benign esophageal strictures, perforations or fistulas, despite its high rate of migration. A strategy of serial endoscopic stent placement and exchanges was effective in treating these benign esophageal conditions. Two overlapping stents were highly efficacious in the endoscopic therapy of large esophageal fistulas. The cost-effectiveness of multiple endoscopy sessions with serial endoscopic stent placement (sometimes more than one overlapping stent placed at one time) has not been evaluated and compared to surgical intervention. However, in patients who are poor surgical candidates due to multiple medical comorbidities or due to prior esophageal surgery and radiation, endoscopic therapy seems a reasonable less-invasive option.

Complications occurred in 54% of the stents in our study, with migration being the most common complication in

39% of all stents placed (occurring in 8/14, 57% patients). In their abstract, Lakhtakia reported stent migration in 4/9 (44%) patients with benign disease [10]. Uitdehaag and colleagues reported stent migration in 16/45 patients (35%) with Alimaxx stent placement for malignant esophageal diseases [8]. In a study of 38 patients with Polyflex stents, a migration rate of 63% was seen [12]. Complication rates ranging from 18 to 48% have been reported in the literature with migration rates of 2–27% after covered stent placement for malignant esophageal diseases [13–15]. A higher migration rate was seen with the Alimaxx stent in our study. When a stent is placed for a benign stricture, gradual dilation of the stricture occurs with time which may make the stent less stable and more liable to migrate. In malignant conditions, tumor growth around the stent may anchor it more to the surrounding tissues making it more stable. This may be the reason for increased stent migration in benign diseases. A future study comparing the incidence of migration of Alimaxx stents to other fully covered stents may be useful. In the study by Uitdehaag et al., increasing the number of antimigration struts on stent from 20 to 45 reduced the rate of migration [8]. In the future, migration rates may thus very well be reduced with modifications that may better anchor these stents in the esophagus.

Our study has various limitations: (1) it is a retrospective study and (2) follow-up is limited. Patients are often referred to our tertiary care facility from neighboring states and hence long-term follow-up is difficult. We measured outcomes based on chart review showing either clinical improvement or radiologic or endoscopic evidence of resolution of the primary pathology that required stent placement. Some studies have previously measured improvement in dysphagia score [8, 11] but since our study was retrospective, an objective dysphagia score could not be obtained in all patients. Outcomes could only be assessed from patient visits to any of the University of Florida clinics. However, fistula resolution was confirmed endoscopically or radiographically.

In conclusion, our data shows the technical success in placement and removal of the Alimaxx esophageal stent and its efficacy in the endoscopic management of benign esophageal strictures or fistulas, despite its relatively high rate of migration. Stent migration was successfully managed endoscopically without complications.

Disclosures/Conflict of interest None.

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