

Efficacy of endoscopic management of leak after foregut surgery with endoscopic covered self-expanding metal stents (SEMS)

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Abstract

Introduction Anastomotic or staple-line leak after foregut surgery presents a formidable management challenge. In recent years, with advancement of endoscopy, self-expanding covered stents have been gaining popularity. In this study, we aimed to determine the safety and effectiveness of self-expanding covered stents in management of leak after foregut surgery.

Methods Consecutive patients who received a fully covered self-expandable metal stent (SEMS) due to an anastomotic leak after upper gastrointestinal surgery between 2009 and 2014 were retrospectively reviewed. Demographic data, stent placement and removal, clinical success, time to resolution, and complications were collected. Predictive factors for clinical success rate were assessed.

Results A total of 20 consecutive patients underwent placement of fully covered SEMS for anastomotic leak, following esophagectomy ($n = 5$), esophageal diverticulectomy ($n = 1$), gastric sleeve ($n = 4$), gastric bypass ($n = 3$), partial gastrectomy ($n = 4$), and total gastrectomy ($n = 3$). All the stents were removed successfully, and clinical resolution was achieved in 18 patients (90 %) after a median of two (range 1–3) procedures and a mean of 6.2 weeks (range 0.4–14). Complications presented in 12 patients (60 %), including stent migration ($n = 8$), mucosal friability ($n = 4$), tissue integration ($n = 2$), and

bleeding ($n = 2$). Two (10 %) patients' treatment was complicated by aorto-esophageal fistula formation resulting in one death. Demographic factors, comorbidities, and type of surgery were not predictive of clinical success rate or time to resolution.

Conclusion SEMS are effective tools for the management of leaks after foregut surgery. The biggest challenge with this approach is stent migration. Caution is warranted due to the risk of fatal complications such as aorto-esophageal fistula formation. No type of surgery or particular patient factor, including age, sex, BMI, albumin, history of radiation, malignancy, and comorbid diabetes or coronary artery disease, appeared to be correlated with success rate. Larger studies are needed to determine factors predictive of clinical success.

Keywords Endoscopic stent · Anastomotic leak · Esophageal leak · Self-expandable metal stent · Leak management · Bariatric surgery

Surgical therapy for obesity as well as both esophageal and gastric malignancy is commonly performed procedures worldwide [1–4]. While there have been improvements in clinical outcomes in recent years, anastomotic and staple-line leaks remain a potentially deadly complication of foregut surgery associated with significant morbidity and mortality and have been reported at rates up to 10 % of the time [5–10]. Leaks are thought to be the result of a variety of etiologies including stapler misfire, wrong staple size for the tissue, tissue trauma, or ischemia due to either tension on the anastomosis or a hematoma [9]. Although primary repair for leaks has been effective historically, it too is associated with significant morbidity and mortality [11–13].

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With recent advancements in endoscopy, the use of fully covered self-expanding metal stents (SEMS) has been gaining popularity as a minimally invasive treatment of gastrointestinal leaks for both malignant [14–17] and benign [9, 18, 19] pathologies. Although SEMS were only FDA approved for malignant stricture, many endoscopists have been pushing the envelope in the past decade and using SEMS to treat anastomotic leaks after foregut surgery. There have been few case series published with small number of patients ranging from 14 to 34 who underwent SEMS placement for leak after foregut surgery [20–23]. The benefits of SEMS include providing a barrier between intraluminal contents and the healing anastomosis to prevent leakage and subsequent infection while simultaneously allowing for oral nutrition. However, the management of leaks with endoscopic stents is not without problems, the most common being stent migration [9, 14, 17, 24, 25]. Other complications include tissue ingrowth, mucosal erosion, and endoscopic complications associated with placement and removal such as perforation.

We reviewed our experience with using SEMS to manage anastomotic leaks after foregut surgery and compared our results to recently published studies. We aimed to determine the safety and effectiveness of SEMS in the treatment of these leaks.

Methods

After obtaining the appropriate institutional IRB approval, we retrospectively identified and reviewed consecutive patients who received SEMS between 2009 and 2014 from our prospective database. Research Electronic Data Capture (REDCap) software was used to collect data prospectively. All stents were placed by surgical endoscopists and gastroenterologists at University Hospitals in Cleveland. Criteria for inclusion were adult patients who received SEMS as treatment for an anastomotic leak from gastrointestinal surgery involving the foregut. Indications for all procedures were for persistent leak or fistulae with consequences of peritonitis, mediastinitis, or malnutrition. Due to this being a retrospective analysis, no specific exclusion criteria were used.

Clinically suspected anastomotic leaks were verified with upper gastrointestinal contrast studies, computed tomography of the chest and abdomen, or endoscopically visualized.

Electronic medical records were reviewed to gather the data. Information on patient demographics including age, body mass index, and gender, as well as on comorbidities including history of ionizing radiation therapy, diabetes mellitus, malignancy, current chemotherapy treatment, and coronary artery disease was obtained. Past surgical history

was reviewed for the cause of the leak, previous intra-abdominal operations and intra-luminal endoscopic procedures. Serum albumin at time of stent placement was obtained. Postoperative details were reviewed including if leak resolution was achieved, duration of stent implantation, number of stents used, number of procedures needed, postoperative complications, and additional non-endoscopic procedures. Data analysis was performed with IBM SPSS ver. 18.0 (IBM Co., Armonk, NY, USA). *T* test and Chi-square were used when appropriate. *P* value less the 0.05 was considered significant.

Results

We identified a total of 20 patients (10 males, 10 females) who were treated with SEMS for an anastomotic or staple-line leak after foregut surgery (Table 1). Mean age was 57 ± 14 years with average body mass index of 37 ± 12 kg/m². The comorbidities of the patients included one (5 %) patient having had a history of ionizing radiation therapy at site of anastomosis, seven patients (33 %) having diabetes mellitus, eight (38 %) having a malignancy, one (5 %) patient treated with chemotherapy within 1 month of stent insertion, and three (15 %) patients having coronary artery disease. Patients had mean albumin of 2.3 ± 0.75 g/dL. Five (25 %) leaks were due to

Table 1 Patient characteristics

Demographics	Mean \pm SD
Age	57 \pm 14 years
Body mass index	37 \pm 12 kg/m ²
Gender (Male/Female)	10/10
Comorbidities	Number (%)
History of ionizing radiation	1 (5 %)
Diabetes mellitus	7 (33 %)
Malignancy	8 (38 %)
Current chemotherapy treatment	1 (5 %)
Coronary artery disease	3 (14 %)
Nutrition status	Mean \pm SD
Albumin	2.3 \pm 0.75 g/dL
Cause of anastomotic leak	Number (%)
Esophagectomy	5 (25 %)
Ivor Lewis	1 (5 %)
Tri-incisional	4 (20 %)
Esophageal diverticulectomy	1 (5 %)
Gastric sleeve	4 (20 %)
Gastric bypass	3 (15 %)
Partial gastrectomy	4 (20 %)
Total gastrectomy	3 (15 %)

esophagectomies with one (5 %) utilizing the Ivor Lewis approach and four (20 %) using the tri-incisional approach, one (5 %) leak was due to esophageal diverticulectomy, four (20 %) leaks were due to gastric sleeves, three (15 %) were due to gastric bypass, four (20 %) were due to partial gastrectomies, and three (15 %) were due to total gastrectomies.

The outcomes and complications of the patients in our cohort are outlined in Table 2. The median time between insertion of the first stent and retrieval of the final stent was 6.2 weeks (range 0.4–14) with resolution of the leak occurring in 18 patients (90 %). Eight patients (40 %) required one endoscopic procedure where a stent was inserted to resolve the leak, 10 patients (50 %) needed two consecutive procedures with stents being placed, and two patients (10 %) required three successive procedures. Two patients (10 %) needed two stents placed simultaneously. There were no major complications during insertion of the stents. Twelve patients (60 %) experienced complications seen during stent removal such as stent migration for eight patients (40 %), friability of the mucosa upon stent removal occurred for four patients (20 %), bleeding in two patients (10 %) which resulted in one death, and tissue integration into the stent occurred in two patients (10 %). There were no leak recurrences after resolution of the initial leak.

Two patients' (10 %) treatment was complicated by aorto-esophageal fistula formation that resulted in demise of one patient. The first patient was a 67-year-old woman being anticoagulated with warfarin [international normalized ratio

(INR) = 2.4] for atrial fibrillation who presented with massive upper gastrointestinal bleeding after a stent was placed for a leak after an esophageal diverticulectomy. Emergent endoscopy revealed active bleeding at the distal end of the stent. It was decided that the stent should be removed after she was more hemodynamically stable. She was resuscitated overnight with significant vasopressor support and a mass transfusion of red blood cells, fresh frozen plasma and platelets. Her INR was normalized to 1.3, and she was brought to the operating room for replacement of the stent. There was no active bleeding when the stent was removed; however, the patient experienced a massive hemorrhage upon removal and expired shortly thereafter. Postmortem autopsy revealed that an aorto-esophageal fistula was the cause of the bleed. The other patient was a 46-year-old woman with end-stage renal disease that was being treated with hemodialysis, diabetes, hypertension, dyslipidemia, as well as multiple other medical problems who received a stent for a perforated marginal ulcer after Roux-en-Y gastric bypass. The stent was removed one month after insertion without initial evidence of bleeding. She returned a few days later with bacteremia and development of aorto-esophageal fistula that initially presented with herald bleed. She underwent emergent aortic endograft placement. She had a long hospital stay and was eventually discharged to a long-term acute care facility. However, she eventually returned to the hospital one month later and died of septic shock secondary to acute cholecystitis despite percutaneous cholecystostomy.

Table 2 Outcomes

Post-endoscopic details	Mean (range)
Time between stent insertion and retrieval	6.2 (0.4–14) weeks
Outcomes	Number (%)
Resolution of leak	18 (90 %)
Number of endoscopic stent insertion procedures	
One	8 (40 %)
Two	10 (50 %)
Three	2 (10 %)
Required two stents placed simultaneously	2 (10 %)
Complications	Number (%)
Complications during stent insertion	0 (0 %)
Complications due to stent	12 (60 %)
Stent Migration	8 (40 %)
Mucosal friability	4 (20 %)
Bleeding	2 (10 %)
Tissue integration	2 (10 %)
Aorto-esophageal fistula	2 (10 %)
Death (stent-related)	1 (5 %)
Recurrence	0 (0 %)

Discussion

Anastomotic and staple-line leaks remain a potentially deadly complication of foregut surgery that are associated with significant morbidity and mortality. Historically, these leaks were treated with primary surgical repair; however, these operations were associated with their own morbidity and mortality. Endoscopic management of anastomotic leaks through the temporary placement of SEMS has become more popular in recent years due to improvements in endoscopic techniques and due to being less invasive than primary surgical repair. There is a paucity of literature regarding the direct comparison between endoscopic and surgical management for gastrointestinal leaks in general, although one recent study reported higher mortality rates in patients treated with stents when compared to those treated with surgery for esophageal perforation [26]. Other recent studies have shown stents to be effective at controlling leaks due to a variety of etiologies in the foregut [8, 14, 16, 17, 24, 27, 28]. Our study provides additional evidence that the use of SEMS is effective in the management of anastomotic leaks after foregut surgery; however, major complications such as aorto-esophageal fistula formation and death can be encountered.

Clinical success was defined as resolution of the anastomotic leak, which was achieved in 18 patients (90 %). Similar success rates have been reported in the literature recently with Fernandez et al. [16] reporting 69 % while using SEMS to treat postsurgical leaks in the esophagus and stomach. Recent pooled analyses of the literature included van Boeckel et al. [14] reporting a rate of 85 % and Van Halsema et al. [18] reporting a rate of 76.8 %. Our success rate, while higher than the averages in the aforementioned pooled analyses, falls within the reported ranges found in the literature. Due to the small size of our cohort, it is difficult to determine any statistically significant differences. We observed no leak recurrences following treatment with SEMS, suggesting that complete closure of the anastomotic dehiscence was achieved. The results of this study provide further evidence that SEMS may be an effective option in the treatment of anastomotic leaks in the foregut.

The mean duration of treatment with SEMS needed for leak resolution in our cohort was 6.2 weeks. This period was similar to those reported in the literature, which ranged from 6 to 10 weeks [14, 18, 25]. These results suggest that 6 weeks may be sufficient for the resolution of an anastomotic leak, but it may be advisable to leave the stent in longer to ensure complete closure of the defect; however, this must be balanced with the increased risk for stent migration, tissue ingrowth, and aorto-esophageal fistula associated with longer durations of stent implantation.

Twelve patients (60 %) in our study required multiple consecutive procedures where stents were inserted in order to resolve the leak, with 10 patients (50 %) needing two total procedures and two (10 %) needing three. These results suggest that overall clinical resolution of leaks may often require multiple stent insertion procedures.

Predicting which patients with anastomotic leaks will benefit from treatment with SEMS helps guide treatment and reduce the morbidity and mortality patients are subjected too with the use of stents. In our sample, no type of surgery or particular patient factor, including age, sex, body mass index, albumin, history of radiation, malignancy, and comorbid diabetes or coronary artery disease, appeared to be correlated with clinical success rate. While we did not discover specific predictive factors, some patients may benefit from conservative treatment instead of SEMS. Al-issa et al. [29] achieved successful resolution of small anastomotic leaks (<1 cm) in their cohort with drainage, antibiotic therapy, and restriction of oral intake. While the number of patients treated this way was small, this is evidence that small leaks can be managed effectively with more conservative management. Ultimately, further investigation is necessary to determine how SEMS compare to this conservative approach in the treatment of small leaks. The lack of a statistically significant association may be the result of our smaller sample size or high success rate. A larger cohort may help discover any statistically significant associations and determine any factors predictive of success.

The most common complication associated with stent use was migration. Migration occurred in eight patients (40 %) included in our cohort, which is comparable to rates found in the literature that range from 17 to 59 % [9, 14, 24, 25]. Each of these patients required repeat endoscopy for removal of the migrated stent and insertion of a new stent in the proper position. It is promising, however, that leak closure was still achieved in all patients whose stents migrated. Mucosal friability and integration of the stent into the mucosa were other complications that were observed in four (20 %) and two (20 %) patients, respectively. These complications have historically been attributed to stents that have been inserted for longer periods and placing stents that are not fully covered [14]. The use of covered SEMS in our study may explain why mucosal friability and tissue integration occurred relatively infrequently.

The mortality rate for stent use in our study was 5 %, which may compare favorably with surgical management where rates ranged from 5 to 50 % [11, 13, 14]. The single mortality in our study involved a patient that developed an aorto-esophageal fistula secondary to SEMS placement. Aorto-esophageal and aorto-enteric fistulas are known

complications of vascular surgery involving the aorta, such as those utilizing endovascular stents, where major hemorrhage is often preceded by a smaller herald bleed [30–32]. The radial traction of the SEMS may erode through the wall of the esophagus or induce inflammation and result in a fistulous tract between the aorta and esophagus. Of the two patients in our cohort whose treatment was complicated by formation of an aorto-esophageal fistula, one developed a small herald bleed prior to the massive hemorrhage that revealed the fistula. Aorto-esophageal fistula is a deadly complication of SEMS use. A high index of suspicion for this complication may be necessary when there is bleeding around the stent placement site. Appropriate workup is needed to assess for aorto-esophageal fistula with emergent vascular management if present. Furthermore, fistula formation secondary to serious mucosal erosion by SEMS has been documented in the literature. One recent study reported major erosions causing tracheo-esophageal fistulas in two out of 23 patients [33], and another described a cohort where stent erosion into pulmonary artery occurred in one of 31 patients that required a major operation [22]. Erosions into major vessels are a dreaded complication; therefore, decision to place SEMS needs to come with careful consideration based on patients' symptoms and risk factors. In the future, better designed stents are needed that rely less on radial traction in order to prevent migration. Optimistically, this may help prevent major complications such as aorto-esophageal fistulas.

Limitations of this study include those inherent to any retrospective analysis such as the lack of randomization and selection bias. Furthermore, the small size of our cohort limits our capacity for statistical analysis and ability to generalize our findings to a larger population. Further prospective studies with larger sample sizes may help determine any true predictors for SEMS success or failure in patients who experienced anastomotic leaks after foregut surgery.

In conclusion, our analysis provides further evidence that the use of SEMS is an effective tool in the management of anastomotic leaks after foregut surgery. While the biggest challenge with this approach was stent migration, clinical resolution was still achieved in each patient where stent migration occurred. Caution is still needed due to the risk of fatal complications such as aorto-esophageal fistula formation.

Compliance with ethical standards

Disclosure Drs. Amir Aryaie, Mojtaba Fayeizadeh have no conflicts of interest of financial ties to disclose. Dr. Jeffrey Marks serves as a consultant for Olympus, GI Supply, US Endoscopy, Apollo Endosurgery, GORE, Boston Scientific, and Merck. Jordan Singer and John Lash have no conflicts of interest or financial ties to disclose.

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