

Insertion of Removable Self-Expanding Metal Stents as a Treatment for Postoperative Leaks and Perforations of the Esophagus and Stomach

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ABSTRACT: **Background:** Esophageal perforations and postoperative esophageal leaks are associated with substantial morbidity and mortality and pose a difficult therapeutic challenge.

Objectives: To evaluate the outcome of removable self-expanding metallic stents (SEMS) as a treatment for postoperative leaks and perforations of the esophagus and stomach.

Methods: We conducted a retrospective study of all patients in one medical center who underwent temporary insertion of a covered plastic stent for postoperative leaks and perforations of the esophagus and stomach from June 2009 to February 2010. Data were retrieved from hospital and outpatient clinical data charts. Data included indication for insertion, post-insertion outcome including stent complications, and follow-up after stent removal.

Results: The indications for stent insertion were postoperative leak in four patients and postoperative esophagopleural fistula in one patient. Three of the patients had a leak at the gastroesophageal junction following laparoscopic sleeve gastrectomy. In all cases the stent insertion was completed successfully. In three patients the stent migrated distally. In two of these three it was repositioned or replaced endoscopically, and in the third it was excreted in the feces. Stents were removed electively after 6 to 7 weeks. All patients recovered fully and were discharged from the hospital.

Conclusions: SEMS insertion may have an important role in the management of postoperative leaks and perforations of the esophagus and stomach and should be considered in such cases.

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metallic stents have become a common palliative treatment for malignant strictures [4,5], improving quality of life in non-operable esophageal cancer patients and reducing complications and length of hospital stay [6]. The development of retrievable devices has extended SEMS indications to the sealing of leaks and perforations in benign cases [7-10]. The mechanism of action is simply a sealing of the leak/fistula opening which allows healing of the perforated site. Preliminary results show low morbidity and mortality rates [1,11]. Nonetheless, the recent guidelines of the American College of Gastroenterology concluded that the quality of evidence for the use of SEMSs in the treatment of esophageal perforations and leaks is very low, and thus the strength of recommendation is still weak [12].

The aim of the present study was to report our experience with removable covered SEMS in cases of postoperative leaks and perforations of the esophagus and stomach.

PATIENTS AND METHODS

We evaluated the indications and the immediate and long-term outcome of patients who underwent insertion of removable stents for postoperative leaks and perforations of the esophagus and stomach between June 2009 and February 2010. The data were retrieved from our hospital computerized patient database, including hospital and outpatient clinical data charts. Data included indications for insertion, post-insertion outcome including stent complications, and follow-up after stent removal.

The procedures were performed after obtaining informed consent from the patient or from three senior doctors in cases where the patient was not able to give his/her consent (intubated and anesthetized patients). Gastroscopy was performed for diagnosis.

STENT PLACEMENT

The SX-ELLA esophageal stent (ELLA-CS, Czech Republic) was inserted in all five patients. Sedation was obtained with

SEMS = self-expanding metal stent

Spontaneous perforation of the esophagus (Boerhaave's syndrome), iatrogenic injury to the esophagus following endoscopies, and postoperative leaks from esophageal and upper stomach anastomosis are life-threatening medical emergencies that present treatment challenges [1-3]. Self-expanding

Table 1. Medical events and management prior to stent insertion

Patient	Age (yrs)	Gender	Medical event	Initial treatment	Indication for stent insertion	Time from initial event to diagnosis of leak/perforation (days)	Time from leak/perforation diagnosis to stent insertion (days)	Length/diameter of stent (mm)
1	82	F	Spontaneous distal esophageal perforation (Boerhaave's syndrome)	Laparotomy, distal closure of GE junction with gastrostomy, jejunostomy, torax drains	Large esophago-pleural fistula with chronic empyema	1	59	110/20 following migration: 150/20
2	39	M	Leak following esophago-gastrectomy for lower esophageal cancer (Ivor-Lewis)	Multiple thorax drains	Continuous leak	5	15	85/25
3	24	M	Leak at the GE junction following sleeve gastrectomy for morbid obesity	First laparotomy with suture repair. Second laparotomy with resection & anastomosis (esophagogastric anastomosis)	Continuous leak	7	16	110/25
4	54	F	Leak at the GE junction following sleeve gastrectomy for morbid obesity	Laparotomy with resection & anastomosis (esophagogastric anastomosis)	Anastomotic fistula	4	10	85 / 20
5	51	F	Leak at the suture line following sleeve gastrectomy for morbid obesity	Laparotomy with suture line repair	Continuous leak	3	18	135/20

GE = gastroesophageal

midazolam and fentanyl or propofol. The circumference of the stent (20 or 25 cm) was determined by estimation of the esophageal diameter. The stents were equipped with an anti-migration segment located between the flared proximal end and the stent body. A guide was inserted under fluoroscopy and the stent inserted on it. Stents were expanded gradually after their placement was assured.

RESULTS

During the 9-month study period SEMs were inserted in five patients. All stents were inserted following failure of an initial medical procedure: surgery in four patients and drainage in the fifth. Demographic and clinical data of the patients, as well as initial treatments, indications for stent treatment, and timing of stent insertion are presented in Table 1. The indication for stent insertion was a postoperative leak in four patients and postoperative esophageal-pleural fistula in one patient. Most of the leak sites were rather small except in one patient in whom a leak comprising one-third of the esophageal circumference was diagnosed. In all cases stents were located in the esophagus extending into the stomach.

A rapid decrease in the amount of discharge from the drains after stent insertion was observed in all patients followed by a gradual decrease in septic parameters and steady recovery.

Stents were removed electively after 6 to 7 weeks. All patients recovered fully and were discharged from the hospital. The outcome of stent insertion is shown in Table 2. Leak occlusion was complete for all patients. The major complication observed was stent migration, occurring in three patients. In two of them, stents were repositioned or replaced endoscopically; in the third, it was excreted in the feces. In patient

Table 2. Patients' outcome following stent insertion

Patient	Complication	Treatment of complication	Hospital stay	Further management	Follow-up after stent removal
1	Distal stent migration	Endoscopic stent reposition	36	Elective removal of stent 6 weeks after insertion; 2nd admission with empyema treated by streptokinase	Full recovery
2	Late stent migration	None	44	None; stent was spontaneously excreted in the feces	Full recovery
3	None	None	80	Elective removal of stent 7 weeks after insertion	Full recovery
4	None	None	53	Elective removal of stent 6 weeks after insertion	Full recovery
5	Distal stent migration	Endoscopic stent reposition	44	Elective removal of stent 6 weeks after insertion	A continuous minor fistula which closed spontaneously, followed by full recovery

1, a stent with greater length and diameter was subsequently inserted. In patient 5, an attempt to anchor the stent to the esophageal mucosa by means of a hemostatic clip was unsuccessful and the stent migrated. The clip was removed and the stent repositioned. There were no documented complaints in any of the patients regarding dysphagia or chest pain.

DISCUSSION

In five patients presenting with esophago/gastric leaks or postoperative fistula formation (following surgery for Boerhaave's syndrome), self-expanding metal stents were suc-

successfully inserted and either retrieved or excreted following full recovery of all patients. In all procedures the stents were inserted a considerable time after onset of the leak following drainage or surgery.

Our results support other reported success rates for SEMS insertion as treatment for both Boerhaave's syndrome and esophageal and upper gastric leaks following surgery. Several studies, albeit with limited numbers of patients, have described the use of stents for postoperative gastroesophageal leaks. Although all the studies were successful in achieving the immediate goal of perforation closure, the final patient outcome varied according to the initial severity of the patients' general condition [7,10,13-15].

The traditional initial management of esophageal leaks and perforations is either surgical intervention or conservative treatment based on the time of diagnosis and the patient's condition [1,16,17]. The potential advantages of stent insertion may be in delayed-diagnosis cases or when surgery has failed. The possibility of inserting stents, with patients under conscious sedation and with direct visualization of the pathology, eliminates the risks associated with anesthesia and avoids extensive or repeated surgical dissection in friable and inflamed tissues [7,12]. Like others, we have demonstrated a successful outcome when stents were inserted several weeks after the medical event or when initial surgical intervention failed.

The size of the leakage site appropriate for stents is an important factor in patient selection. In one patient in our series the leakage was from a hole nearly one-third the circumference of the esophagus. In the other patients the holes were considerably smaller. In the study by Langer et al. [8] the cutoff for stent insertion was one-third the anastomosis circumference.

In three of our patients the stent was inserted due to a leak following sleeve gastrectomy. In all three cases a primary surgical repair had failed. It is important to note that the tubal structure of the stomach that is evident after the surgery enables insertion of a stent also for a suture-line leak. Leakage from the staple line, usually in the esophageal stomach passage, is a common complication of sleeve gastrectomy. The few reports of treatment with self-expanding stents for leakages following sleeve gastrectomy demonstrated high success rates [18,19].

The timing of SEMS insertion is an important consideration, particularly in light of its possible application in both primary and secondary treatment. In the current study, leaks and perforations were diagnosed within one week of the medical event. However, 10 to 59 days elapsed from diagnosis to stent insertion due to the novelty of this procedure for benign cases. This contrasts with the report by Tuebergen et al. [15] of stent insertion following failed primary treatment. There, stents were inserted shortly after the diagnosis of a leak or perforation (median 3 and 5 days for leaks and perforations, respectively). The full recovery in all our patients despite the relatively long delay in treatment attests to the

success of the SEMS. Nevertheless, earlier stent insertion may be advantageous and lead to a faster recovery.

High success rates following SEMS insertion as a primary treatment for leaks with no preceding surgical intervention have also been documented [15,19].

Since the insertion procedure carries a low risk, the characteristics of SEMS devices seem the prime determinant of complication rate. The optimal balance between adhesiveness and retrievability is particularly critical for the use of SEMS in benign esophageal lesions. The ideal stent should enable easy insertion and retrieval or repositioning, low migration rates and minimal complications [12,20]. The major complication that presented in the current study was stent migration in three patients, two of whom required a repeated endoscopy for repositioning or stent replacement. For one patient, the anti-migration device of the SX-ELLA esophageal stent apparently caused severe adhesion in the repeat procedure, resulting in difficult stent retrieval. This device therefore seems only partially effective, with risks of complication. Other studies have reported high migration rates using covered SEMS.

Recently, Blackmon et al. [19] reported stent migration in 43% of procedures (10/23). Reporting migration of seven stents in 5 of 21 patients, Freeman and co-researchers [21] suggested that stent migration can be minimized by slightly oversizing the diameter and significantly oversizing the length of the stent. Leers et al. [14] reported migration in only 2 of 31 patients (3%) following insertion of an SEMS constructed with a large flare to prevent migration.

New techniques for preventing stent migration are being tested. Pexy sealing was tried successfully in 3 of 23 patients who were stented for various reasons [19]. While covered SEMS are known to have a higher migration rate, their ease of removal is an advantage over partially covered stents. Further development of feasible mechanisms to minimize stent migration, while not hampering retrievability, is an important direction for research.

In conclusion, we have demonstrated that SEMS insertion may have an important role in the management of esophago-gastric leaks. Further studies are needed to establish clinical guidelines for SEMS insertion as both a primary and secondary treatment for leaks following esophageal and gastric surgery.

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