Efficacy and safety of a fully covered esophageal stent: a prospective study

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Self-expandable metal stents (SEMS) are routinely used in the endoscopic management of malignant and benign esophageal pathology. More recently, fully covered self-expandable metal stents (FCSEMS) have become available and have been used for the management of malignant dysphagia as well as benign esophageal diseases such as refractory strictures, perforations, fistulas, and postoperative anastomotic leaks.[1-7] These studies have assessed the use of the Alimaxx (Merit Medical Systems, South Jordan, UT), SX-ELLA (Ella-CS, Hradec Kralove, Czech Republic), and Niti-S stents (Taewoong Medical, Seoul, South Korea). Although fully covered stents are not approved for removability, these recent studies have shown that stent removal is feasible.[2-4] However, these stents are associated with significant complications such as stent migration, pain, and tissue reaction.

The fully covered esophageal Wallflex stent (Boston Scientific, Natick, MA) is a recently introduced self-expandable metal stent made of nitinol covered with silicone. The use of this stent has not been reported except for a retrospective series describing the use of this and other stents in benign esophageal diseases.[8] We therefore conducted a prospective evaluation of the fully covered esophageal Wallflex stent at our tertiary care center.

METHODS

Study

This was a prospective cohort study approved by the Institutional Review Board at the University of Florida. Informed consents for the endoscopy and the study were obtained before the procedure. The aim of this study was to prospectively assess the efficacy and safety of the fully covered esophageal Wallflex stent for malignant and benign esophageal diseases.

Patients and methods

Patients undergoing upper endoscopy from December 2009 to May 2011 for endoscopic stent placement were enrolled in the study. Inclusion criteria were as follows: patients above 18 years of age with esophageal diseases undergoing upper endoscopy for stent placement including (1) malignant or benign strictures requiring endoscopic dilation, (2) fistulas and postoperative anastomotic leaks, and (3) perforations. Refractory and recurrent strictures were defined according to previously published criteria.[9] Refractory strictures included those in which a luminal diameter of 14 mm could not be achieved despite 5 consecutive endoscopic sessions occurring every 2 weeks, whereas recurrent strictures were those in which luminal patency could not be maintained for 4 weeks after a target diameter of 14 mm had been achieved. Exclusion criteria were as follows: (1) patients unfit for sedation or anesthesia, (2) active GI bleeding, (3) hemodynamic instability, and (4) inability to obtain consent.

Clinical, endoscopic, radiologic, and surgical records were maintained as required for clinical care and the study. Dysphagia scores were recorded before and after stent therapy and graded as follows: grade 0, ability to eat a normal diet; grade 1, ability to eat some solid food; grade 2, ability to eat some semisolids only; grade 3, ability to swallow liquids only; grade 4, complete dysphagia (inability to swallow saliva). Patients were followed up at one or more University of Florida clinics (Primary care, Gastroenterology, Pulmonary, Oncology, and Surgery) or as inpatients. The following outcomes were prospectively assessed: (1) improvement in dysphagia score (after stent removal in benign disease and with the stent in place in malignant disease if stents were not removed), (2) stricture or fistula resolution based on endoscopic assessment, radiographic imaging (CT scan with oral contrast or esophagram showing lack of extravasation of contrast), and clinical symptoms/status, (3) adverse events according to the American Society for Gastrointestinal Endoscopy criteria,[10]

Abbreviations: SEMS, self-expandable metal stent; FCEMS, fully covered self-expandable metal stents.

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including (a) symptoms after stent placement including pain (odynophagia, chest pain, abdominal pain), recurrent dysphagia, shortness of breath, nausea, vomiting, coughing, bleeding, perforation, and infection, (b) stent migration (defined as radiographic or endoscopic assessment showing the stent to be in a position different from where it was originally placed), (c) tissue reaction to the stent assessed on subsequent endoscopy, and (d) endoscopic removability.

Stents

Fully covered esophageal Wallflex stents (diameter 18 mm or 22 mm; length 70 mm, 100 mm, 125 mm, or 150 mm) were placed by 4 therapeutic endoscopists at our tertiary care referral center.

Endoscopic stent placement and protocol

Upper endoscopy was performed to identify the esophageal lesion, and the length of the stent was chosen to extend at least 1 to 2 cm on either side of the proximal and distal extents of the stricture or fistula. Typically, an 18-mm stent was selected for management of strictures, whereas a 22-mm stent was placed for fistulas or perforations where there was no esophageal luminal obstruction. This was left to the discretion of the endoscopist. Dilation was performed only if the endoscopist thought 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. A guidewire was then placed across the esophageal lesion under endoscopic and fluoroscopic guidance, and the stent was deployed.

Stent removal

Upper endoscopy was repeated in 6 weeks for reassessment and stent removal or replacement. If necessary, another fully covered stent was placed after removal of the first stent. Endoscopy was performed earlier in the event of complications such as stent migration or symptoms. The suture at the proximal end of the stent was grasped with a rat-toothed forceps, and the stent was removed. Esophageal stenting was continued until symptoms and stricture improved or the fistula or perforation healed. Resolution of the fistula or perforation was confirmed with imaging studies (esophagram/CT scan) within 48 hours after stent placement or removal (if the fistula or perforation was thought to have endoscopically resolved and if a new stent was not placed).

RESULTS

Patients

The study included 20 patients (9 men, 45%; mean age 63.2 years, range 27-82 years) undergoing stent placement for benign or malignant esophageal diseases (Table 1).

Stents

Thirty-one stents were placed in 20 patients; 7 patients required more than 1 stent placed sequentially. Thirteen patients had 1 stent, 5 had 2 stents, 1 patient had 3 stents, and 1 patient with a large esophageal perforation had 5 stents placed during serial endoscopies. Stents were placed in the upper third of the esophagus in 5 patients and across the gastroesophageal junction or anastomosis in 7 patients.

Indications

Stents were placed for esophageal strictures in 5 of 20 (25%) patients (1 radiation, 2 anastomotic, 2 malignant strictures), for fistulas in 7 of 20 (35%) patients (1 radiation, 2 postoperative, 4 malignant fistulas), and for esophageal perforations in 8 of 20 (40%) patients (all benign), as shown in Table 2.

Outcomes

The mean follow-up duration was 114 days (range 30-360 days). Stent placement was technically successful in all cases. Dysphagia score improved from 3 to 1 in 1 of 2 patients with malignant strictures. Benign strictures and dysphagia recurred in all 3 of 3 patients after stent removal, requiring endoscopic dilation. Fistula resolution was observed in 6 of 7 (86%) patients and included 3 of 3 patients with benign fistulas and 3 of 4 patients with malignant fistulas. Perforations resolved in 4 of 8 (50%) patients after stent therapy (all benign indications). Overall response to stent therapy was seen in 11 of 20 (55%) patients: 7 of 14 (50%) for benign indications and 4 of 6 (67%) for malignant diseases, as shown in Table 3.

Stent removal was successful in all patients where it was attempted. The mean time to stent removal was 4.4 weeks, ranging from immediate removal after stent placement in 1 patient to 10 weeks.

Adverse events

Adverse events of any kind (Table 4) occurred in 12 of 20 (60%) patients (mild in 17% and moderate in 83%). Twenty-one of the 31 stents placed (68%) were associated with adverse events: migration in 9 of 31 (29%), pain in 7 of 31 (23%), and tissue reaction in 6 of 31 (19%).

The most common adverse event was stent migration in 8 of 20 (40%) patients (9 of 31 stents, 29%) (migrated distally in 5 patients, migrated proximally in 2, and coughed up in 1). Management of migrated stents was either repositioning (pulled back proximally) or removal/replacement. No bleeding, perforation, or bowel obstruction related to stent migration was observed. All migrated stents were successfully retrieved with an endoscopic forceps or snare. Pain occurred in 6 of 20 (30%) patients (7 of 31, 23% stents) after stent placement. This included 2 patients in whom stent removal was required because of severe throat/chest pain and intolerance to the stent (1 patient required immediate repeated endoscopy because of symptoms in the recovery room, and the stent in the second patient was