Efficacy and safety of a new fully covered self-expandable non-foreshortening metal esophageal stent

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Background: Fully covered esophageal self-expandable metal stents (SEMSs) are potentially removable but can be associated with high migration rates. For precise positioning, non-foreshortening SEMSs are preferred. Recently, a new fully covered non-foreshortening SEMS with anti-migration features was introduced.

Objective: To evaluate the efficacy and safety of this new esophageal SEMS.

Design: Retrospective study.

Setting: Single, tertiary-care center.

Patients: Consecutive patients with malignant and benign strictures with dysphagia grade of ≥ 3 and patients with fistulas/leaks were studied.

Interventions: Stent placement and removal.

Main Outcome Measurements: Technical success in stent deployment/removal, efficacy in relieving dysphagia and sealing fistulas/leaks, and adverse events.

Results: Forty-three stents were placed in 35 patients (mean [$\pm$ standard deviation] age 65 $\pm$ 11 years; 31 male), 24 for malignant and 11 for benign (5 strictures, 6 leaks) indications. Technical success in precise SEMS placement was 100%. The after-stent dysphagia grade improved significantly (at 1 week: 1.5 $\pm$ 0.7; at 4 weeks: 1.2 $\pm$ 0.4; baseline: 3.8 $\pm$ 0.4; $P < .0001$). Twenty stents were removed for clinical indications, with technical success of 100%. All leaks sealed after SEMS placement and did not recur after stent removal. All benign strictures recurred after stent removal. Adverse events included migration (14%), chest pain (11%), and dysphagia from tissue hyperplasia (6%). There was no stent-related mortality.

Limitations: Nonrandomized, single-center study.

Conclusion: The new esophageal SEMS was effective in relieving malignant dysphagia, allowed for precise placement, and was easily removable. It was effective in treating benign esophageal fistulas and leaks. Stent-related adverse events were acceptable. (Gastrointest Endosc 2014;80:577-85.)

Abbreviations: FDA, U.S. Food and Drug Administration; PEG, percutaneous endoscopic gastrostomy; SEMS, self-expandable metal stent; UES, upper esophageal sphincter.

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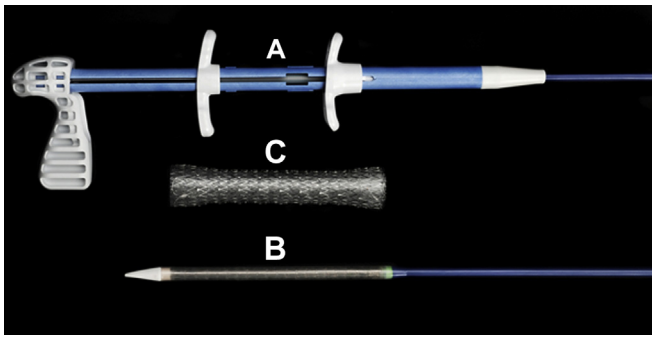

Figure 1. A new non-foreshortening fully covered expandable esophageal stent. **A,** The stent comes preloaded onto a 90-cm long, single-hand, delivery system. The maximum diameter of the delivery system is 8 mm. **B,** Constrained stent. **C,** Expanded stent. The stent is coated with a silicone membrane internally and externally along its entire length.

Take-home Message

- The recently released esophageal self-expandable metal stent was effective in palliating malignant dysphagia. The non-foreshortening feature of this stent allowed for precise placement and its fully covered feature allowed for removability. The stent was also effective in treating benign esophageal conditions, especially fistulas and leaks.
- Adverse events including migration were acceptable.

Esophageal self-expandable metal stents (SEMSs) are commonly used for palliating malignant strictures and fistulas. In addition, an increasing number of patients with refractory benign esophageal strictures and leaks are being managed with SEMSs.[1-8]

SEMSs can vary in design and features. Partially covered SEMSs permit tissue ingrowth, which reduces the risks of migration. Tissue ingrowth can embed the stent, making subsequent removal difficult. Therefore, these stents should not be used for indications in which eventual stent removal is necessary.[9-12] On the other hand, fully covered SEMSs do not allow tissue ingrowth and are being used for treating benign esophageal strictures/leaks.[1,4,6,7] However, these stents can be associated with high migration rates. Most of the fully covered SEMSs available in the United States foreshorten on expansion. The stated length of a foreshortening SEMS is the length after the SEMS has fully expanded; therefore the actual SEMS length may be longer in tight strictures when the stent cannot fully expand and can make precise placement difficult.

A new fully covered non-foreshortening esophageal SEMS (EndoMAXX; Merit Medical Endotek, Salt Lake City, Utah) (Fig. 1) was introduced in 2012. The aim of this study was to evaluate the efficacy and safety of this stent in managing malignant and benign esophageal strictures, fistulas, and leaks.

METHODS

This was a non-randomized study from a single, tertiary-care center. Patients who received a SEMS from October 2011 through April 2013 and who met inclusion criteria were included in the study. Data on patient demographics, prior interventions, indication, procedure, follow-up, reinterventions, outcomes, and adverse events (defined as those requiring hospitalization or unanticipated interventions) were prospectively entered into a clinical database. All adverse events were reviewed by the study faculty and at internal review committee meetings. There were no unexpected adverse events that required reporting to the U.S. Food and Drug Administration (FDA) or the manufacturer. Local institutional review board approval was obtained to retrospectively retrieve and analyze these data.

As per our standard of clinical practice, inclusion criteria included (1) malignant strictures with dysphagia grade of ≥ 3. Dysphagia was graded on a scale of 0 to 4 (0 no dysphagia, 1 dysphagia to solid foods, 2 dysphagia to semisolid foods, 3 dysphagia to liquids, and 4 complete dysphagia).[13] Patients who were receiving chemotherapy with or without radiation were not excluded if they presented with a dysphagia grade ≥ 3. Other inclusion criteria were (2) malignant or benign esophageal fistulas and/or leaks and (3) refractory benign esophageal strictures that fulfilled the criteria as outlined by Kochman et al[14] (inability to achieve an esophageal diameter of 14 mm despite 5 dilatations at 2 weekly intervals or the patient requires ≥ 1 dilatations per month to maintain a diameter of 14 mm).

Exclusion criteria included dysphagia grade ≤ 2 (patient tolerating at least a soft diet at baseline), with severe odynophagia; not willing or able to give consent; not fit for endoscopy; aged <18 years; prior esophageal SEMS placement; or life expectancy <2 weeks.

Stent description

Compared with another non-foreshortening SEMS (Alimaxx-ES; Merit Medical), the EndoMAXX stent is laser cut from a 40% thicker, single, nitinol tube (hence, does not foreshorten compared with woven stents), has anti-migration struts with 350% more surface area and 40% more angle per height, is fully coated with silicone, and has a metal purse-string loop. These features result in additional expansion force and less in-folding, theoretical reduced risks of migration, less degradation of the membrane (compared with the polyurethane coating on the Alimaxx-ES stent),[15] and easy removability. The EndoMAXX comes preloaded on a 90-cm long and 8-mm wide single-hand delivery system (Fig. 1). The delivery system has radiopaque markers for fluoroscopic guidance during deployment but can be deployed under endoscopic guidance by advancing the endoscope parallel to the delivery system (Fig. 2). The stent comes in 19 mm and 23 mm expanded diameters and is available in 70-mm, 100-mm, 120-mm, and 150-mm lengths.