Esophageal Stenting for Leaks and Strictures: A Benign Intervention for a Benign Indication?

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As esophageal stents have evolved in composition, so also have indications for their placement [1]. Stents were available initially only as rigid plastic or rubber stents, used for the treatment of malignant dysphagia. This rigid design resulted in difficult placement and frequent complications. In response to this, self-expanding metal stents (SEMS) were developed. Although better tolerated and easier to place, these stents were plagued by tissue ingrowth through their open mesh. In response to this, a covering membrane was added to stents to minimize tissue ingrowth. While a partially covered stent is sufficient to prevent tumor ingrowth and occlude esophageal fistulas in malignant dysphagia, this design was inadequate for benign indications due to concerns for the stent becoming imbedded at its distal and proximal uncovered ends with in some cases formation of new strictures [2].

More recently, fully covered stents have been available and have been used in a variety of benign indications (Table 1). The most widely studied stent is the Polyflex stent (Boston Scientific, Natick, MA, USA), a self-expanding plastic stent (SEPS) which was introduced in 2001 and remains the only stent with FDA approval for late removability. The Alimaxx-E stent (Merit Endotek, South Jordan, UT, USA), used in the current study by Senousy and colleagues, was introduced in 2005. It is a hybrid fully covered self-expanding metal stent (FCSEMS) constructed of nitinol and fully covered with polyurethane, with 20 outer metal struts to resist migration. Although this FCSEMS is only FDA-approved for immediate removal, the ability to resist tissue ingrowth has led to its use in

benign indications with a delayed removal. More recently, other esophageal FCSEMSs have become available in the United States but none are approved for delayed removal (Table 1).

In this issue, Senousy and colleagues report on their experience using the Alimaxx-E stent for benign esophageal indications. In a retrospective study conducted over a 6-year period, 14 patients were treated in total for esophageal fistulas ($n = 7$) and benign esophageal strictures (BES, $n = 7$) [3]. Given the important clinical differences between these two groups, it is best to consider them separately.

A heterogeneous group of difficult benign strictures were treated in this study, including strictures due to radiation therapy, photodynamic therapy, post-surgical anastomosis, and peptic disease. Impressively, all patients had clinical resolution of their dysphagia after this short-term intervention; however, it is important to note that long-term follow-up in this retrospective study was not standardized. Thus, despite this positive result, a major concern is the durability of this effect, as many of these difficult strictures may recur late after stent removal [4, 5]. In a recently published study of 31 patients with the same FCSEMS placement, stent placement was performed for a refractory BES in 7 patients [6]. With 6 months follow-up after stent placement, stricture resolution was seen in only 29% of patients. A recently published prospective study of 40 patients with rigorous follow-up utilized a SEPS which was removed 4 weeks after initial placement. A similarly poor long-term success rate (30%) was seen at 1 year for these patients with refractory BES [7].

A difficulty in studying interventions for patients with BES is the lack of a uniform definition. Recently, criteria have been proposed to facilitate discussion about management of difficult benign esophageal strictures, and widespread adoption should be considered [8]. In this

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Table 1 Fully covered stents available in the United States

Stent	Manufacturer	Materials	FDA approval for removability
Alimaxx-E	Merit endotek	Nitinol with polyurethane covering	Yes (immediate only)
Evolution stent	Cook medical	Nitinol with silicone covering	No
Niti-S	Taewoong medical	Nitinol with polyurethane covering	No
Polyflex	Boston scientific	Polyester	Yes (immediate and delayed)
WallFlex stent	Boston scientific	Nitinol with silicone covering	No

definition, refractory strictures, those in which a luminal diameter of 14 mm cannot be achieved despite five consecutive endoscopic sessions occurring every 2 weeks, are differentiated from recurrent strictures, in which luminal patency cannot be maintained for 4 weeks *after* target diameter of 14 mm has been achieved. In this current study, the strictures were not defined as refractory or recurrent. Furthermore, the pre-stent endoscopic treatment is unclear, only noting that the strictures “failed aggressive endoscopic dilation.” Thus, it is possible that a subset of these patients would have had resolution of their strictures with more frequent esophageal dilation, incisional therapy, or intralesional steroid injection and thus avoiding the common risks of stent placement including migration and pain. Thus, the high success rate observed in this study must be interpreted in the context of a lack of standardized long-term follow-up, unclear endoscopic therapy prior to stent placement, and small study population.

Due to concurrent medical illness with pulmonary and infectious complications, patients with esophageal perforations and fistulas are often more difficult to treat. Esophageal fistulas may arise as a result of spontaneous (i.e. Boerhaave’s syndrome) or iatrogenic (surgical or endoscopic) perforations, leaks at a surgical anastomosis, or uncommonly due to prolonged endotracheal intubation. In the current study, the etiologies of the esophageal fistulae in the 7 patients treated with stent placement were not described. After esophageal stent placement, fistula resolution was ultimately achieved in 6/7 (85.8%) patients, though some patients required stent replacement on follow-up endoscopies prior to resolution. These positive results are consistent with recently published data from a larger prospective study of 33 patients with esophageal perforation treated with a variety of esophageal stents. Of these patients, 70% survived without the need for esophageal surgery [9]. Similar positive data have recently been published using a well-described surgical population, suggesting a role for stent placement even with a delayed presentation [10]. Fistula closure itself, however, does not obviate the need for surgery. In a prospective study of 19 patients with spontaneous esophageal rupture treated with a SEPS, 17 fistulas resolved after stent placement. However, 9 patients required adjunctive surgical procedures

(decortication or thoracostomy tube placement) at the time of stent placement [11].

In patients with esophageal fistulas, closure of the fistula does not ensure a positive long-term outcome. The very high mortality reported in this study, with 6 patients (42.8%) dying within the first 3 months after the procedure, is suggestive of a very ill population. It is unclear from the data presented whether this mortality was chiefly seen in the patients with esophageal fistulas, but this is most likely [12]. The early mortality also highlights the need for a multidisciplinary approach (endoscopic, surgical, and medical) in this patient population. The high mortality in this study also severely limits the ability to determine the long-term efficacy of the intervention.

A chief concern with the placement of esophageal stents for benign indications is the risk of complications, chief among those being migration. This study does not allay this concern but rather reinforces it. In fact, the majority of patients experienced stent migration. For patients with benign strictures, stent migration may indicate the resolution of the stricture. However, stent migration is particularly troublesome for esophageal fistulas, as migration may occur prior to fistula healing. This high rate of stent migration cannot be attributed solely to the lack of an esophageal stricture, however, as a very high rate (35.5%) of Alimaxx-E stent migration was observed in a previous study of patients with malignant dysphagia [13]. Thus, while the covering membrane facilitates easier stent removal, it also results in an increased risk of migration. Novel methods to prevent stent migration have been described but need further validation prior to widespread use [10, 14, 15]. In this study, repositioning or removal of the migrated stents was performed without difficulty, consistent with the experience of others [13]. Additional severe complications including stent disintegration and fracturing with the Alimaxx stent have been reported in the literature, resulting in a modification of the stent design, but were not seen in this study [6, 16, 17].

As with many retrospective studies, these results ask more questions than they answer. A single critical question remains: what role do esophageal stents have in management of benign esophageal diseases? Combining published literature and anecdotal clinical experience, a preliminary

answer can be formulated. Partially covered SEMS should not be used for BES as tissue ingrowth and new stricture formation commonly occurs. In patients with a true refractory BES, placement of a SEPS or FCSEMS can be considered after appropriate patient counseling. Patients should be aware that post-procedure complications are common including stent migration and chest pain. Furthermore, given the best available literature, it is likely that only a minority of patients will have a long-term benefit. Thus, for this “benign” disease, esophageal stents may be appropriate only when all other therapeutic options have been exhausted. The recent ACG practice guidelines on the use of esophageal stents make reasonable similar recommendations based on the available evidence [18].

In contrast, for patients with esophageal fistulas, esophageal stent placement should be considered part of the management armamentarium in conjunction with minimally invasive surgery in appropriate cases. Both partially covered and fully covered SEMS have been used effectively in this population, and in the urgent setting, using the prosthesis you are comfortable with is appropriate. However, if a partially covered SEMS is used, removal should be performed within 6 weeks to minimize the risks of tissue growth [9]. Although the procedural risks, including stent migration, are also significant in this group, the potential rewards in this very ill population likely exceed these risks. Thus, while an esophageal fistula may be a nonmalignant disease, it is far from “benign,” and esophageal stent placement should be considered early in the evaluation of these patients.

References

1. Schembre D. Advances in esophageal stenting: The evolution of fully covered stents for malignant and benign disease. *Adv Ther.* 27:413–425.
2. Song HY, Park SI, Do YS, Yoon HK, Sung KB, Sohn KH, Min YI: Expandable metallic stent placement in patients with benign esophageal strictures: Results of long-term follow-up. *Radiology.* 1997;203:131–136.
3. Senousy BE, Gupte AR, Draganov PV, Forsmark CE, Wagh MS. Fully covered alimaxx esophageal metal stents in the endoscopic treatment of benign esophageal diseases. *Dig Dis Sci.* 2010. doi: 10.1007/s10620-010-1415-y.
4. Oh YS, Kochman ML, Ahmad NA, Ginsberg GG. Clinical outcomes after self-expanding plastic stent placement for refractory benign esophageal strictures. *Dig Dis Sci.* 55:1344–1348.
5. Holm AN, de la Levy JG, Gostout CJ, Topazian MD, Baron TH: Self-expanding plastic stents in treatment of benign esophageal conditions. *Gastrointest Endosc.* 2008;67:20–25.
6. Eloubeidi MA, Lopes TL: Novel removable internally fully covered self-expanding metal esophageal stent: Feasibility, technique of removal, and tissue response in humans. *Am J Gastroenterol.* 2009;104:1374–1381.
7. Dua KS, Vleggaar FP, Santharam R, Siersema PD: Removable self-expanding plastic esophageal stent as a continuous, non-permanent dilator in treating refractory benign esophageal strictures: A prospective two-center study. *Am J Gastroenterol.* 2008;103:2988–2994.
8. Kochman ML, McClave SA, Boyce HW: The refractory and the recurrent esophageal stricture: A definition. *Gastrointest Endosc.* 2005;62:474–475.
9. van Heel NC, Haringsma J, Spaander MC, Bruno MJ, Kuipers EJ. Short-term esophageal stenting in the management of benign perforations. *Am J Gastroenterol.* 105:1515–1520.
10. Blackmon SH, Santora R, Schwarz P, Barroso A, Dunkin BJ. Utility of removable esophageal covered self-expanding metal stents for leak and fistula management. *Ann Thorac Surg.* 89: 931–936; discussion 936–937.
11. Freeman RK, Van Woerkom JM, Vyverberg A, Ascoti AJ: Esophageal stent placement for the treatment of spontaneous esophageal perforations. *Ann Thorac Surg.* 2009;88:194–198.
12. Attar S, Hankins JR, Suter CM, Coughlin TR, Sequeira A, McLaughlin JS: Esophageal perforation: A therapeutic challenge. *Ann Thorac Surg.* 1990;50:45–49. discussion 50–41.
13. Uitdehaag MJ, van Hooft JE, Verschuur EM, et al. Siersema PD: A fully-covered stent (alimaxx-e) for the palliation of malignant dysphagia: A prospective follow-up study. *Gastrointest Endosc.* 2009;70:1082–1089.
14. Manes G, Corsi F, Pallotta S, Massari A, Foschi D, Trabucchi E: Fixation of a covered self-expandable metal stent by means of a polypectomy snare: An easy method to prevent stent migration. *Dig Liver Dis.* 2008;40:791–793.
15. Kato H, Fukuchi M, Miyazaki T, et al. Kuwano H: Endoscopic clips prevent self-expandable metallic stent migration. *Hepato-gastroenterology.* 2007;54:1388–1390.
16. Berman KH, Rex DK: Alveolus alimaxx-e esophageal stent disintegration and breakage. *Gastrointest Endosc.* 2009;69:980–981.
17. McGrath K. Stents for the long haul: What do we need? *Gastrointest Endosc.* 2009;70:1090–1092.
18. Sharma P, Kozarek R. Role of esophageal stents in benign and malignant diseases. *Am J Gastroenterol.* 105:258–273; quiz 274.