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Proximal Esophageal Stenting: Indications, Risks and Benefits

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INTRODUCTION

For decades, esophageal stents have been a mainstay of treatment for patients with malignant dysphagia.[1,2,3] More recently, self-expanding metal stents (SEMS) have been shown to be a highly successful treatment option in benign esophageal strictures which have failed multiple dilation attempts.[4,5] Inherent potential complications associated with esophageal stenting include migration, pain or globus sensation, hemorrhage, perforation, and airway compromise among others; some of these are common (pain), others rare (airway compromise).

Placement of a SEMS in the proximal esophagus has been associated with higher incidence of complications in some studies.[6,7,8] Furthermore, advanced radiotherapy techniques have been shown to effectively reduce malignant dysphagia, causing some to consider this treatment as first-line therapy over SEMS placement in the upper esophagus in this specific group of patients.[9,10,11] This manuscript will review the role, uses, indications, and adverse events of SEMS in the proximal esophagus.

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Challenges of Proximal Esophageal Stenting

Anatomically, the proximal esophagus is defined as the area of the esophagus between the upper C6 pharyngoesophageal junction and lower T1 vertebrae, approximately 20-22cm proximal from the incisors.[12,13] Practically speaking, the proximal esophagus is visualized rather than measured, and endoscopists will delineate the proximal, mid, and distal esophagus based on endoscopic visualization. Historically, pathology of the proximal esophagus, including tumors, strictures, fistulas, and leaks, has posed a technical challenge to surgeons due to the decreased mobility of this area and the unique anatomic limitations of the thoracic inlet.[14] These structural limitations underpin some of the previously described practical challenges of proper esophageal stent placement in this location.[15,16]

Stenting in the proximal esophagus has inherent risks due to the proximity to the cricopharyngeal sphincter. Respiratory complications including tracheal compression, tracheoesophageal fistula formation (or worsening of an existing fistula), stent migration, and aspiration pneumonia have been implicated.[1,4,5,17,18]

Rates of tracheal compression in patients undergoing proximal esophageal stenting vary. In a series of 442 patients, 40 of which underwent

upper esophageal stenting, 0.9% experienced tracheal compression with half of these patients needing additional airway stenting for symptomatic disease.[19] An association with proximal esophageal stenting and aspiration pneumonia has been shown in some studies, with a proposed mechanism of the proximal flare of the stent impairing swallow function, but incidence rates vary across the literature.[2,7]

Esophagorespiratory fistula formation (ERF) is another potentially serious complication of proximal esophageal stenting. In a study of 442 patients, 5.9% developed ERF after receiving combined-stenting of the esophagus and airway, with 1.8% developing ERF with esophageal stenting only.[8] Proposed efforts to mitigate these risks include pre- and post-procedural bronchoscopy, elevating the head of the bed during the procedure, reducing water flushes, and using techniques to prevent migration including endoscopic clips and suturing.[5,6,20]

BENIGN INDICATIONS FOR PROXIMAL ESOPHAGEAL STENTING

Esophageal Leaks

Esophageal leaks or perforations are commonly iatrogenic, resulting as a consequence of esophagectomy for various indications, both benign and malignant. Stephens et al. documented 89 patients with 5 different types of esophageal leaks treated with esophageal stenting. In the majority of the patients, the esophageal leak was a complication post-esophagectomy. Of those patients's with a proximal esophageal leak, stenting was employed successfully in treating this iatrogenic complication.[4] Esophageal leaks can also, less commonly, form as a complication of previous esophageal stenting. Although some authors have reported success with conservative management and close surveillance of contained esophageal leaks, esophageal stenting is a successful modality in treatment of esophageal leaks.[21,22,23,24]

Benign Strictures

The majority of the published literature describing esophageal stenting for stenosis focuses on palliation in esophageal malignancy. In addition to this well-documented indication, esophageal stenting can be a successful treatment option in benign esophageal strictures. Common causes of benign esophageal strictures include gastroesophageal reflux, injury from esophageal surgery, radiotherapy, and caustic ingestion. In refractory strictures, or in those which fail multiple dilations, stenting is often the treatment of choice.[25,26] In 2010, a meta-analysis including 199 patients from 8 studies demonstrated that placement of self-expanding removable stents significantly improved dysphagia in those who had failed multiple dilations for benign esophageal strictures.[27]

MALIGNANT INDICATIONS FOR PROXIMAL ESOPHAGEAL STENTING

Malignant Strictures

The majority of esophageal malignancies are unresectable at diagnosis.[28] Palliation of symptoms, most commonly dysphagia secondary to malignant esophageal stenosis or obstruction, is a primary treatment goal in these patients (who have an overall 5-year survival rate of 5 to 15%).[29] Placement of SEMS for malignant stenosis of the proximal esophagus is an effective method to relieve dysphagia and improve quality of life. (Figure 1a-c)

Profili et al. described a case series of 10 patients with inoperable proximal esophageal stenosis. Nine of these had malignant stenosis of the upper esophagus. Of the 9 patients with malignant stenosis, 8 were caused by squamous cell carcinoma, with 1 being caused by thyroid cancer. Three of the patients had a very proximal stenosis, involving the hypopharynx and proximal esophagus, with the rest involving proximal esophagus alone. Seven patients had balloon dilation first to facilitate introduction of the delivery system and to have more rapid expansion of the stent. The SEMS was then placed a few days afterward. The rational for delay was to "[shorten] operative time and thus [obtain] a greater patient compliance." Dysphagia score improved immediately with overall clinical success described in 80% and technical success in 90%. The adverse events described in three

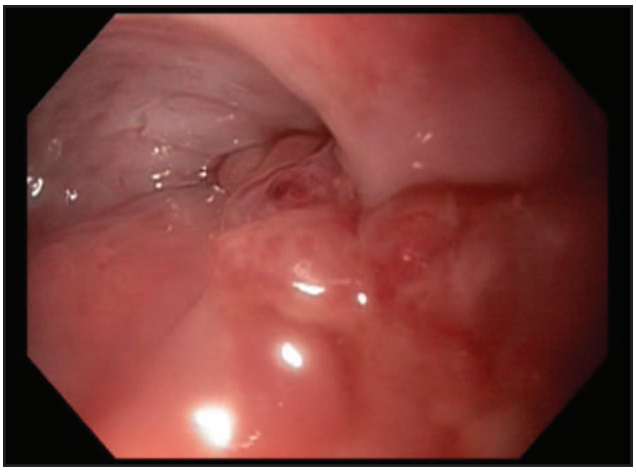

Figure 1a. Esophageal squamous cell cancer located immediately below the GE junction. The patient had metastatic disease.

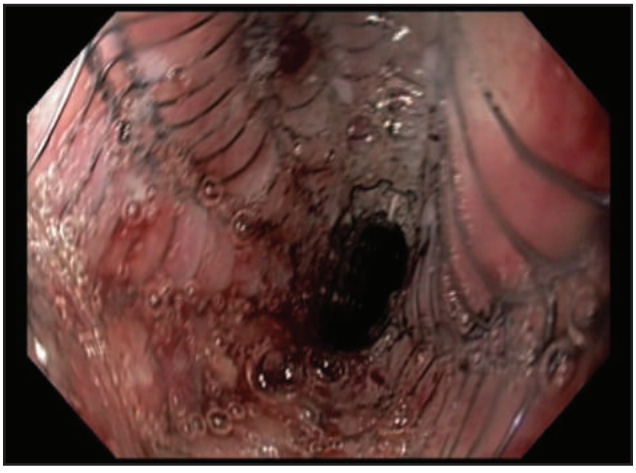

Figure 1b. A partially covered esophageal SEMS after placement across the stricture.

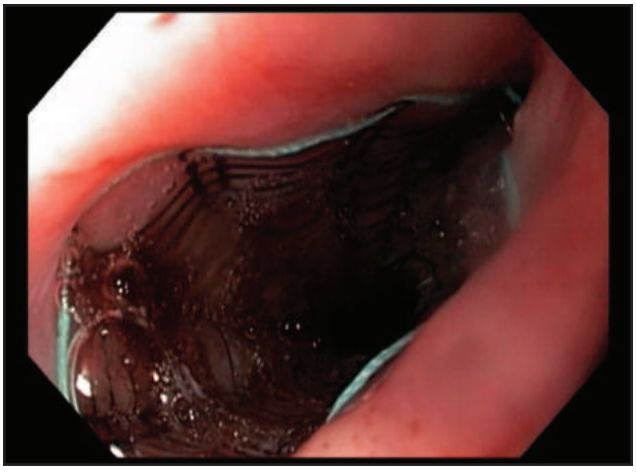

Figure 1c. Note the proximity of the upper esophageal sphincter to the uppermost portion of the stent. The patient tolerated the stent well without pain or aspiration and had improvement in dysphagia.

of their patients respectively included the stent twisting immediately after placement in requiring balloon dilation, distal misplacement of the stent requiring another overlapping stent, and one stent positioned proximal to the epiglottis which interfered with swallowing. All of the patients in the cohort reported a foreign body sensation and mild pain, which resolved within one week without intervention.[30] Verschuur et al. described a larger retrospective series of 104 patients with inoperable, malignant stenosis of the proximal esophagus. In this series, the mean distance from the UES (upper esophageal sphincter) to the upper tumor margin was 4.9 +/- 2.6 cm and 3.1 +/- 2.3cm to the upper stent margin. Of this cohort, 66 patients had primary esophageal carcinoma, and 38 patients had recurrent cancer after esophagectomy. Technical success was achieved in 96% of patients, with a pre-stenting mean dysphagia score of 3 (liquids only) improving to a mean score of 1 (some difficulty with solids). The degree of dysphagia improvement, which was self-reported, did not differ between those with primary esophageal cancer versus those with recurrent cancer after esophagectomy. Also, the proximity of the stented lesion to the UES was not found to be a significant factor in predicting degree of dysphagia relief. Patients who had a malignant stricture within 4 cm of the UES versus those with one within 5 to 8 cm of the UES did not significantly report a difference in dysphagia relief. However, the etiology of the stricture was found to be a predictor of stricture length, as those with primary esophageal cancer were found to have a significantly longer stricture compared with those who had recurrent cancer post-esophagectomy.[31]

Parker et al. performed a case-control study at a single Kenyan hospital in which those with proximal esophageal cancer were matched to random controls with distal esophageal cancer, forming a total of 93 case-control pairs with prospective follow-up for at least one month or until death. The proximal esophageal cancer group was composed of two sub-groups, those with a very proximal tumor, defined as one within 2cm of the UES, and another group including those with lesions within 2.1 to 6cm of the UES. The distal esophageal cancer group was defined as

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those with a tumor greater than 6cm from the UES. The average tumor length was 7.1 cm, with the proximal cancer group having a significantly longer tumor length compared to the distal cancer group. Seven patients with proximal cancer needed placement of 2 nested stents in order to bridge their entire tumor. Those with a very proximal cancer had a pre-stent mean dysphagia score of 3.2 and a post-stent score of 1.7. Those in the other proximal cancer group had a pre-stent dysphagia score of 3.5 and a post-stent score of 1.4. Those with distal esophageal lesions had a pre-stent dysphagia score of 3.3 and a post-stent dysphagia score of 1.5. The reported early complication rate was 6.5% for those in the proximal esophageal cancer group and 9.7% for those with distal esophageal malignancy. The reported late complication rate was 29.2% for those with proximal lesions versus 24.1% for those with distal lesions. Overall, there was no statistically significant difference found between the cases and the controls in overall efficacy of the interventions, complication rates, or survival.[32]

Malignant Esophagorespiratory Fistula

The presence of an esophagorespiratory fistula (ERF) secondary to proximal esophageal malignancy is another indication for stenting. Fistulas can form due to primary tumor involvement or as a consequence of treatments such as chemotherapy, radiation therapy, or a combination thereof. Malignant ERF has been demonstrated to have a higher incidence in the proximal esophagus than the distal esophagus in some studies.[21] Success rates for sealing of malignant ERF with placement of covered stents vary from 70% to 100% in different series, with much of the reported data coming from mixed studies or those involving the middle or distal esophagus.[20] (Figure 2a-c)

In Verschuur et al.'s retrospective analysis of 104 patients with malignant upper esophageal lesions treated by SEMS placement, 24 patients had ERF. Thirteen of these 24 patients had primary esophageal carcinoma, and the remaining 11 had recurrent cancer post-esophagectomy. Four patients received both a tracheal and esophageal stent as the lesion had either invaded the airway or compressed it. Successful sealing of the fistula with stent placement was reported in 19 of these

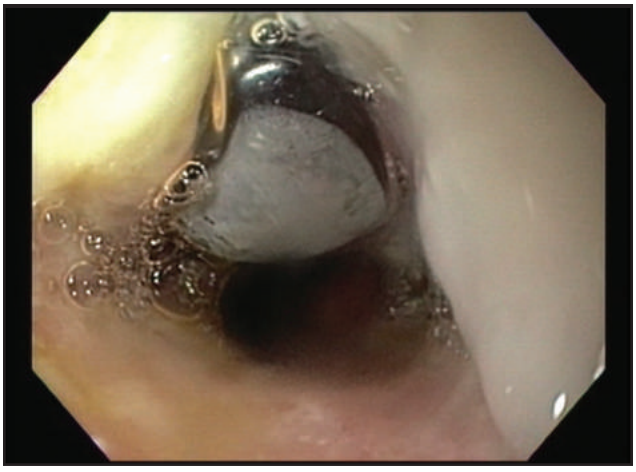

Figure 2a. A tracheoesophageal fistula seen from the esophageal side. Note the balloon on the cuff of the endotracheal tube is visible as it protrudes into the esophageal lumen.

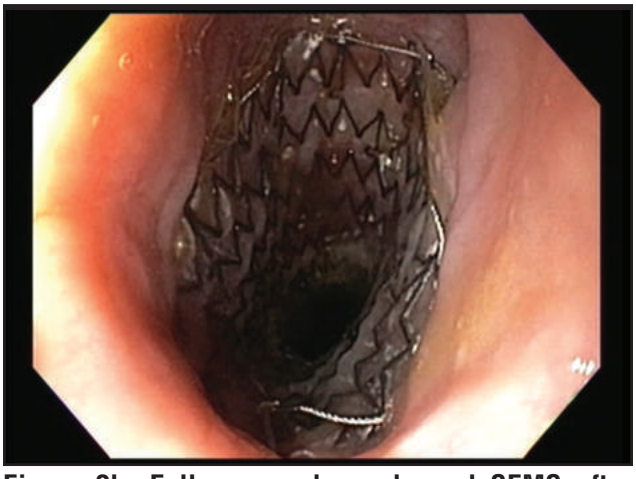

Figure 2b. Fully covered esophageal SEMS after deployment. Not the proximity of the stent to the upper esophageal sphincter.

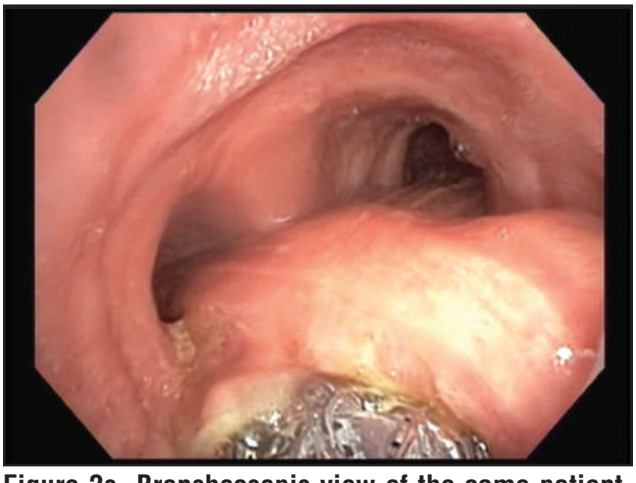

Figure 2c. Bronchoscopic view of the same patient. The esophageal stent is visible through the fistula. The patient also required an airway stent.

24 patients. Of the five patients whose fistula failed to seal, the leakage occurred at 7, 7, 12, 21, and 35 days respectively. Four of these were successfully re-stented, but the fifth patient, who was initially managed conservatively, died from aspiration pneumonia. Overall, their success rate was 79% in sealing malignant fistulas of the proximal esophagus.[20]

RISKS OF PROXIMAL ESOPHAGEAL STENTING

Pain or Globus

Foreign body sensation (globus), which is often perceived in the upper chest or throat, is a commonly reported complication seen after proximal esophageal stenting. In a study examining SEMS stents placed in 442 patients, 40 patients received a stent in the upper esophagus; of these 40 patients, 29 reported experiencing globus. Symptoms in this group resolved completely or partially in 3-7 days. This sensation was only found in those with proximal stenting. Pain also occurred more frequently with those stented in the proximal and middle esophagus.[8] Severe pain can sometimes require stent removal if the patient cannot be made comfortable with pain medications. Bechtler et al. described the use of biliary SEMS in a series of 10 patients with proximal esophageal stenosis with mixed malignant and benign etiology. A total of 3 patients reported post-procedural pain. Two of the patients had mild pain treated with analgesics, but one had severe pain and globus necessitating stent removal the day after implantation. Of note, this patient's stricture was within 10cm of the incisors, the most proximal in the group.[33]

Pain is a complication, which is not limited to upper esophageal stenting. Severe pain is a major complication, which can necessitate stent removal. Siddiqui et al. reported a retrospective study of 55 patients undergoing placement of SEMS for locally advanced esophageal cancer in the middle and distal esophagus. While the vast majority of the complications were minor, two patients had pain severe enough to necessitate removal.[34]

Migration

Migration is a relatively frequent complication in esophageal stenting when fully covered stents are used, regardless of anatomic location. One meta-analysis analyzed migration rates of benign esophageal stenting in 18 studies revealing an overall migration rate of 28.6% with high heterogeneity.[35] Bakken et al.'s study of 56 patients and 104 stents placed found an overall migration rate of 35.6% with proximal stents having a significantly higher rate of migration.[36] Yet not all studies have found anatomic location to be associated with stent migration.

One of the largest studies to investigate migration rates in FCSEMS looked at rates in stents placed in both benign and malignant strictures. In a multicenter, retrospective analysis, Thomas et al. analyzed data from 369 patients in whom 161 had benign strictures and 208 had malignant strictures. In those with benign disease, the total migration rate was 30%, and the clinically relevant migration rate (defined as stent migration requiring replacement) was 17%. In the 28 patients in whom a proximal stent for benign disease was placed the migration rates were 29% and 18%, respectively. In those with malignant strictures, the total migration rate was 23% and the clinically relevant migration rate was 14%. In the 11 patients in whom a proximal stent was placed for malignant disease, the migration rates were 9% and 9%, respectively. In this large analysis, anatomic location of stent placement was not found to be associated with an increased risk of migration. Stent type in the malignant group was found to be significantly associated with migration rate, with the Evolution stent having a higher rate of clinically relevant migration, compared to the Wallflex and Endomaxx stents.[37]

Major Complications

In a randomized trial comparing fully covered versus partially covered SEMS in malignant esophageal strictures, the authors found that proximal stricture location was independently associated with the occurrence of at least one major adverse event, including hemorrhage, pneumonia, stridor, and/or cervical spondylodiscitis.[7] In a study of a total of 104 stents placed for benign esophageal disease, 4 procedures led to acute or subacute airway compromise, with 3 of these occurring in stents placed in the upper esophagus. Of note, 2 of these 3 patients with upper respiratory compromise had received prior radiation therapy.[23]

Verschuur's study of 104 patients with stents placed for malignant stenosis of the upper esophagus

had 22 patients with major complications, including 9 with aspiration pneumonia, 8 with hemorrhage, 7 with fistula formation, and 2 with perforation.[20] Conversely, Gallo et al. described a series of 45 patients, of whom 35 had upper esophageal stenosis, in which very few major complications were seen after stenting. Twenty-two of these patients were treated with SEMS placement. There were two patients who developed severe pain, which required stent removal at 12 and 21 days post-stenting, respectively. No major complications, such as serious hemorrhage, airway compromise, or pneumonia were seen.[38] Parker et al. reported a case-control study comparing stent insertion in patients with proximal esophageal cancer versus matched controls with distal esophageal cancer. Ninety-three patients were included in each group. In the proximal malignancy group the number of patients with a perforation, bleeding, severe chest pain, procedure-related mortality, and 30-day mortality were 1, 1, 3, and 5 respectively. In the distal malignancy group the number of patients with the same complications were 6, 0, 1, 5, and 2 respectively. This study suggested that location of stent placement was not significantly associated with an increased incidence of major complications.[21]

CONCLUSION

Stenting of the proximal esophagus, although technically challenging, can be performed safely and effectively in both benign and malignant disease states. There is not sufficient evidence to preclude the use of proximal esophageal stents from a safety, morbidity, or mortality standpoint. Further investigation with randomized controlled trials and meta-analyses are necessary to investigate the existence of causal relationships between placement of proximal esophageal stents and the adverse events that this procedure has been associated with in the past. ■

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