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Clinical Outcomes of Upper Gastrointestinal Stents and Review of Current Literature

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ABSTRACT

Background and Objectives: The self-expandable metal stent (SEMS) is an alternative for several possible surgical and palliative treatments of upper gastrointestinal obstructions that occur in several disease states. The present study was performed to describe a single-center experience with upper gastrointestinal stents.

Methods: All patients at a single center who had an SEMS placed for the treatment of obstruction over a 3-year period were retrospectively evaluated. Pre- and postoperative dysphagia scoring was calculated and used to evaluate postprocedure improvement in quality of life. Procedural success and early and late complication rates were investigated.

Results: A total of 171 endoscopic procedures were performed in 73 patients. Procedural success was 95.8% (n = 69) and dilatation was performed in 80 patients. The rate of perioperative complication was 26% (n = 19). After 1 month, stents were patent in all patients (n = 73). Stent obstruction was noted in 6 patients: 2 each at 2, 7, and 10 months.

Conclusion: SEMS usage for palliative and curative purposes in benign or malignant upper gastrointestinal system obstructions is an efficient and reliable treatment method with advantages, such as shortening hospital stay, decreased pain, cost-effectiveness, and low mortality–morbidity rates when compared to surgical procedures, and a high rate of clinical success.

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INTRODUCTION

Obstructions of the upper gastrointestinal (UGI) tract may present as dysphagia, nausea, vomiting, weight loss, or cachexia, which can seriously impair quality of life, whether the underlying cause is benign or malignant. UGI stents are used especially for esophageal tumors, gastric or periampullary cancers, and extragastrointestinal cancers that invade the GI tract directly or lead to extraluminal compression. They enable the esophageal lumen to remain open and approve quality of life of patients.[1] They may also be used for benign causes, such as anastomotic leak, gastrointestinal fistula, and stricture. Over 50% of the patients with esophageal cancer enter the hospital at advanced stages, survival rates are less than 10%, and average survival rate in inoperable tumors is reported to be between 3 and 6 months.[2–4] In this patient group, the self-expandable metal stent (SEMS) is a reliable alternative method to palliative surgery and endoscopic or oncological procedures, such as feeding gastrostomy, jejunostomy, by-pass surgery, balloon or rigid dilatation, argon plasma coagulation (APC), chemoradiotherapy, ethanol injection, brachytherapy, endoluminal laser ablation, or photodynamic therapy (PDT).[5–8]

Surgical fistulas and perforations after endoscopic procedures result in high rates of mortality and morbidity. Today, the indications for SEMS placement include caustic injury, peptic or radiation-based benign strictures, perforation, anastomotic fistula, and tracheoesophageal fistula and recovery of hemostasis in recurrent and refractory bleeding of esophageal varices.[9,10] Despite the developments in stent technology, this treatment has disadvantages, such as stent obstructions or stent-related complications.[11]

In this study, we sought to evaluate the patients in whom we have placed SEMS in the past 3 years for benign or malignant conditions by recording palliation scores before and after stenting, as well as noting reperformed proce-

dures, complications, safety, and efficacy of the placement procedures. We also provide a review of the literature.

METHODS

This study is a retrospective review of all patients who underwent SEMS in the UGI tract because of benign or malignant lesions at a single center from January 1, 2013 to January 1, 2016. Data regarding patient demographics, procedure indications, technical and clinical success, complications, and surveillance were collected. Patients were excluded if they had tumors or benign obstruction in the distal gastrointestinal (GI) tract. Written informed consent was signed by all patients, and the study was approved by the local ethics committee and performed according to the Declaration of Helsinki.

Stent type and length were chosen based on preoperative clinical, radiologic, fluoroscopic, or endoscopic findings. A 2-cm distance from both ends across the obstructed segment was the preferred length of the stent. Specifically, for cervical esophageal pathologies, shorter proximal flange and obtuse-angled, fully covered (FC)-SEMS were used to improve patient comfort by decreasing the sense of globus and risk of aspiration and fistula.

Stents were deployed over a guidewire under control of endoscopy and fluoroscopy. Dilatation was performed initially with Savary-Gilliard 7- to 9-mm dilators, and the stent was then deployed (Hanarostent Duodenum/Pylorus Lasso, Hanarostent Esophagus TTS; M I Tech Co., Seoul, South Korea). All of the endoscopic procedures were performed by the same endoscopist in patients under sedo-analgesia with 0.05 mg/kg midazolam and 0.5 mg/kg pethidine. Stent positioning was confirmed by X-ray 24 hours after placement. Oral intake was initiated within the first 24 hours with liquids and then progression to semisolids, depending on the patient's tolerance. Covered stents were used for benign obstructions such as stricture or fistula and were removed at the end of the 6th week, whereas uncovered stents were used and stayed for 4 weeks in benign conditions.

Cowling's scoring system was used to evaluate the degree of dysphagia and clinical success[12] before and after stenting (**Table 1**).

Table 1.
Dysphagia Scores of Patients

Score	Patient	Before Stent	After Stent
0	Able to eat normal diet, no dysphagia	0	70
1	Semi-solids only	7	0
2	Liquid diet only	31	0
3	Complete dysphagia	35	3

Statistical Analysis

Statistical analysis was performed with SPSS 17.0 version (IBM, New York, New York, USA). A paired *t* test was used for normally distributed data, whereas Wilcoxon test was preferred for nonnormally distributed data. The χ^2 and Fisher exact tests were used for categorical data and Mann-Whitney U for ordinal data. Statistical significance was set at $P < 0.05$.

RESULTS

Demographics

Over the course of a 3-year period, 171 upper endoscopic procedures were performed in 73 patients. There were 50 men and 23 women, with a mean age of 63.3 years. Demographics of the patients are shown in **Table 2**.

The procedures included 67 dilatations, 72 SEMS insertions, and 18 stent removals. Types of stents used are shown in **Table 3**.

Evaluation using the Cowling dysphagia scale demonstrated a significant improvement in dysphagia symptoms after stenting ($P = .0001$).

Technical and Clinical Outcomes

Technical success was defined as the successful placement of the stent to ensure enough opening, or the occlusion of the fistula tract, depending on the indication for stenting. Clinical success was defined as obtaining alleviation of obstructive symptoms and disappearance of fistula-related symptoms without the need for recurrent procedures.[11,13–15]

Technical success was recorded in 69 of 72 SEMS procedures (95.8%). Although 72 of the patients were unable to take food orally, oral intake was obtained in all the patients for whom technical success was achieved after stenting (n = 69; 95.8%).

One month after the procedure, the stents were patent in all patients (n = 69; 100%). Stent obstruction was noted in a 6 patients: 2 each at 2, 7, and 10 months.

Table 2.
Location and Etiology of Strictures, Procedures, and Related Complications

	Gender		Inoperable	Operable	Stent placement	Dilatation	Perforation	Overgrowth	Migration	Malposition	Failure	Hemorrhage
Middle esophageal cancer	M	8	6	2	8	12	1	1				
	F	9	7	2	5	12						
Distal esophageal cancer	M	12	12		15	1		3				
Esophagogastric junction tumor	M	9	9		9	2	1		1			
	F	4	4		4			1				
Stomach cancer	M	5	4	1	5	2						
	F	3	1	2	2	2			1	1	1	
Lung cancer	M	5	5		7				1	1		
Larynx cancer	M	8		8	4	8		1	1		2	1
	F	1		1	1	1						
Proximal esophageal web	M	1				1						
	F	3				3						
Schatzki's ring	M	1				1						
Caustic esophageal injury	M	1			9	15				1		
HSV esophagitis	F	1			2	5						
Achalasia	F	2				2 BD						
Pyloric stenosis	M	1			1							

Table 3.
Types of Stents

PC	FC	NC	PC+AR	FC+AR
23 (31.9%)	23 (31.9%)	2 (2.7%)	18 (25%)	6 (8.3%)

Data are the number of patients (% of total group).

In 10 patients in whom dilatation was performed for benign causes, an average of 2.3 (range, 1–11) sessions of dilatation were performed with Savary-Gilliard 7, 9, 11, 12.8 mm dilatators. In patients with the history of caustic injury or herpes simplex virus (HSV) esophagitis that dilatations had failed, FC-SEMS was placed and followed up with rigid dilatation sessions.

Clinical Follow-Up

Mean follow-up was 370.3 days (range, 9–1099) and mean duration of hospital stay was 2.4 days (range, 1–4), including the patients with complications. We did not encounter any mortality that was related to the stenting procedure itself.

Four of the patients died during follow-up because of the progression of the primary disease. Causes of death were inoperable gastric cancer (n = 1, on day 574), inoperable lung cancer (n = 1, on day 91), malignant disease of the esophagus (n = 2, on days 80 and 50). Among patients who died during follow-up, mean survival was found to be 165 days (minimum, 50 days; maximum, 574 days).

Complications

Complications that are encountered during the procedure or in the first 24 hours, such as perforation, bleeding, stent migration, are called immediate complications in the literature. In this study, the complications that are encountered between 24 and 72 hours are called early-term complications and migration, perforation, fistula, food impaction, and tumor ingrowth that may be seen after 72 hours are called late-term complications, as described in the previous studies.[16–18]

The rate of postprocedure complications was 26.0% (n = 19). Immediate and early complications related to stenting and dilatation were 9.6% (n = 7). Late complications were observed in 16.4% of the patients (n = 12). All of the complications are shown in **Table 4**.

Table 4.
Complications of UGI Tract Stenting

Complications	Immediate (8.2%)	Early (1.4%)	Late (16.4%)
Perforation	2	0	0
Malposition	3	0	0
Hemorrhage	1	0	0
Food impaction	0	0	1
Migration	0	1	3
Over ingrowth	0	0	6
Fistula	0	0	2
Retrosternal pain*	0	41	0

*Retrosternal pain was not regarded as a complication; thus, it is not included in the calculations. However, for the sake of completeness and to provide complete data to potential researchers, this procedural morbidity was added to the table.

Immediate Complications

Perforation. Perforation occurred at the proximal site of tumor during the stenting of a patient with inoperable distal esophageal tumor. Later, an FC SEMS was placed, including the perforation site. Another perforation that was encountered was in a patient with Schatzki ring, during rigid dilatation with a bougie. Conservative treatment was preferred, and the patient was discharged without any more complications.

Hemorrhage. Hemorrhage occurred during rigid dilatation at the hypopharyngogastrostomy anastomosis line of a patient who had undergone surgery for larynx cancer. After waiting for 5 minutes with and use of an 11 mm dilatation bougie, the hemorrhage stopped spontaneously.

Malposition. The stent opened and was placed below the intended level in 3 patients, including 1 with inoperable gastric cancer, 1 with inoperable lung cancer, and 1 with stricture caused by ingestion of a corrosive substance.

Early-Term Complications

Retrosternal Pain. Twenty-three of the patients with obstructive esophageal tumors (12 mid and 11 distal esophagus), 9 patients with cardia tumors, 2 patients with gastric tumors, 5 patients with pulmonary malignancy, 1 patient with HSV esophagitis, and 1 patient with a history of corrosive substance injury (41 patients total, 56.9%) had

retrosternal pain after stenting, and all of them responded to nonsteroidal anti-inflammatory drug therapy. As retrosternal pain is an expected outcome of esophageal stenting that responds well to symptomatic therapy, it was not regarded as a complication, thus, it is not included in our calculations. However, for the sake of completeness and to provide complete data to potential researchers, this procedural morbidity was added to **Table 4** with other complications, and the details are elaborated.

Stent Migration. In a patient with inoperable cardia tumor, the stent migrated into the stomach on day 3. Later, the FC SEMS was replaced with a partially covered (PC) stent.

Late-Term Complications

In our case series, the rate of late complications was 16.4%. Food impaction occurred in 1 patient, stent migration in 3 patients, stent ingrowth in 6 patients, and tracheoesophageal fistula (TEF) in 2 patients.

Stent Migration. The PC stent that had been placed in a patient with operable gastric tumor and obstruction at the esophagojejunostomy anastomosis migrated on day 10, the FC stent that had been placed in a patient with inoperable lung cancer and TEF migrated at week 6, and the PC stent that had been placed in a patient with laryngectomy migrated at the end of month 1. The last 2 patients were receiving radiotherapy. The overall rate of stent migration in the late term, among patients in whom a stent was successfully placed (n = 69), was 4.3%.

In- or Overgrowth. Obstruction caused by tumor in- or overgrowth occurred in 6 patients (8.7%). Mean duration until obstruction was 178.3 days (range, 80–350) after the procedure. Restenting was performed in all of the patients. In a male patient with an inoperable midesophageal tumor who was receiving chemoradiotherapy, the noncovered (NC) stent obstructed on day 85. Similarly, PC-antireflux (AR) stents became obstructed in 3 male patients with distal esophagus tumors on the days 222, 303, and 350, respectively. In a female patient with inoperable cardiac tumor, a PC-AR stent became obstructed on day 230 and in a male patient with larynx cancer, the FC stent that had been placed for hypopharyngogastrostomy obstruction became obstructed on day 80.

Fistula. In 2 patients with corrosive and HSV esophagitis, TEF was thought to have developed because the patients had discontinued regular follow-up visits. They were treated using covered stents.

Food Impaction. In a patient with a distal esophagus tumor, food impaction was removed with the help of a tetrapod catheter.

DISCUSSION

The rate of esophageal cancer is increasing, and dysphagia is the most common symptom.[19]

At the time of diagnosis more than 50% of esophageal and gastric cancers are at an advanced stage with obstructive symptoms.[20] Although it is relatively rare, mediastinal tumors can lead to obstructive symptoms with extraluminal pressure or direct invasion. Advanced gastric cancers, pancreatobiliary tumors, or metastatic tumors may cause gastric outlet syndrome.[21]

SEMS has been used for palliative reasons in esophageal cancer since 1990.[22] Palliative treatment of inoperable disease seeks to alleviate obstructive symptoms and provide oral intake. In both benign and malignant UGI tract obstructions, treatment with SEMS is thought to be less invasive, effective, and a safer method than surgery and oncological therapies such as photodynamic therapy (PDT), argon plasma coagulation (APC) or brachytherapy. SEMS also decreases the rate of complication and time of hospital stay, and removes the obstruction in a shorter time for a longer period.[23] In recent years SEMS has gained widespread use, owing to its lower rate of morbidity and mortality, when compared to conventional methods.[9,24,25]

The present study describes a single center's experience with SEMS in benign and malignant UGI obstructions. Esophageal cancer was the most common malignancy in our series (n = 29, 46%).

Other studies have demonstrated technical success rates (defined as successful insertion and adequate placement of the stent) of 83 to 100% and clinical success rates (defined as palliation of dysphagia) of 80 to 95%.[11]

In our series, technical success was achieved in 69 of 72 SEMS procedures (95.8%). Before stent placement, all 72 patients were unable to take food orally, oral intake was obtained in all the patients for whom technical success was achieved after stenting (n = 69; 95.8%).

Various complications were encountered in 19 of the patients (26.0%). In our case series, the rate of immediate complications due to stenting and dilatation was found to be 8.2%, that of early-term complications was 1.4%, and the rate of late-term complications was 16.4%.

SEMS usually remain patent between 9 and 23 months after stent placement. Factors such as primary disease, localization, patient condition, presence of concomitant chemotherapy or radiotherapy and the type of stent used have been associated with the length of patency.[26] For esophageal stents, 94% remain patent at 1 month, 78% at 3 months and 67% at 6 month. Similar rates of 71.2, 61, and 33% at 1, 3, and 6 months are reported for stents used for pyloric obstruction.[27,28]

All of the stents in this series were open at the end of month 1. In 6 cases, stents were obstructed by month 10; and the portion of open stents was 91.6%, which makes the procedure very effective for patients with a short life expectancy.

Stent migration is reported to be encountered in 10 to 25% of covered stents and 2 to 5% of uncovered stents.[29,30] Dua et al[25] reported a migration rate of 22% in their series of 40 patients.

Although tumor over- and ingrowth rates of PC and FC SEMS are reported to be less than that of noncovered stents, their migration rates are more, especially at the gastroesophageal junction, because of their limited ability for adhesion.[31] In addition, it is known that short stents and the ones with thinner caliber, may migrate more easily. In our series, stent calibers were the same (20 mm) and we could not evaluate the effect of length because their placement overlapped 2 cm on both ends of the pathologic segment.

The rate of migration in our study was 5.8% (4 cases), including 1 FC at early term and 2 PC, 1 FC at late term, which was evidently less than previous series in the literature.[32] The rate of restenting is reported to be 22 to 50% in the literature.[2,9,33] Successful restenting was performed in all 4 of the patients with stent migration in our study.

In our clinic, we advise removing or restenting at the end of 4 weeks for uncovered SEMS and 4–6 weeks for covered SEMS in patients with benign disease. In our series, mean time for over- or ingrowth was 163 days (minimum, 80 days; maximum, 50 days). Those patients had not come to follow-up at the end of week 6 because of the absence of any symptoms. They were diagnosed with endoscopy, and stents were successfully placed during the same procedure. In addition, one patient with obstructive stricture after corrosive injury and another patient with HSV esophagitis had discontinued regular follow-up visits after insertion of an FC-SEMS and both patients developed TEF. The fistula was repaired immediately after restenting.

Reobstruction usually occurs as a result of tumor overgrowth or food impaction, and its incidence is reported to be between 3 and 15% for covered and 10 and 42% for uncovered stents.[28,34] Stents covered with 5-fluorouracil or paclitaxel (drug-eluting stents) have been introduced to prevent tumor ingrowth in recent studies.[35] Neoadjuvant or palliative chemoradiotherapy is thought to increase the rate of stent migration.[36,37] Obstructions were most common at the distal esophagus in this study and stent migration occurred in 2 patients with inoperable malignancies who were receiving radiotherapy.

Dysphagia, which is caused by benign esophageal strictures after corrosive injury, regresses with a rate of 80 to 90%, but with a recurrence rate of 30 to 60%.[38] Also, recurrent dilatations can lead to increased rates of perforation, fistula, or stricture.[39] For this benign stricture, successful SEMS procedures are recommended instead of dilatation.[40] One patient with strictures in the esophagus and stomach after corrosive injury had declined to return for follow-up examinations and TEF. He was later treated with SEMS and has been under surveillance with regular dilatations for 2.5 years.

One of the most significant complications after UGI tract surgery is anastomosis leak and formation of fistula. These complications usually increase the risk of mortality and morbidity by 10 and 50%, respectively, after UGI tract surgery. The recommended approach is stenting for detachments of 50 to 70% of the anastomosis and surgery for detachments larger than 70%.[41]

Anastomosis strictures are also common complications after UGI tract surgery, with a rate of 5 to 46%.[42] SEMS placement is becoming the preferred method for the management of anastomosis strictures. In our clinic, we prefer inserting SEMS when rigid dilatation does not offer a curable solution.

Iatrogenic esophageal perforations are life-threatening complications with high rates of morbidity and mortality. FC-SEMS placement during the early term and along with minimally invasive drainage is an effective and safe treatment option.[43] In our series, we encountered 2 perforations during stenting. One patient was treated with an FC-SEMS and the other followed conservatively. Procedure related mortality was not seen. One of the most obvious advantages of endoscopic stenting is the ability to immediately detect such complications and perform therapeutic procedures in the same session.

SEMS have been used for the treatment of refractory esophageal varices bleeding, following failure in ligation

and sclerotherapy. They provide hemostasis with rates of 77 and 100% in the literature.[44] Poly-L-lactic acid monofilament structured biodegradable stents have not had complications occurring from displacement of stents,[45] but we do not have experience using them.

In the late term after stenting, food bolus impaction is reported to occur for 7% in the literature.[46] We encountered food bolus impaction in one of our patients (1.4%) who was using dentures because of chewing disfunction and dysphagia in 6 patients (8.7%) caused by tumor overgrowth. These rates are about 12.3% in the literature.[46]

In our study, we determined that stenting can impede the progress of dysphagia symptoms and improve quality of life which is consistent with the literature. The main limitations of our study are its retrospective design and lack of comparison between the results of different procedures such as biodegradable stents, PDT, and brachytherapy.

CONCLUSION

SEMS is an effective and safe palliative or definitive treatment option for the eradication of benign or malignant obstructions, with regard to its advantages, such as decreasing hospital stay, pain, and complication rates. It is also a reliable alternative for conventional surgery. More extended prospective studies are needed with numerous and heterogenous patient groups involving benign and malignant diseases for a full assessment of stent therapy.

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