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Original Paper

Clinical Outcomes and Patency of Self-expanding Metal Stents in Patients with Malignant Upper Gastrointestinal Obstruction

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Abstract This study was performed to evaluate clinical outcomes and factors associated with patency of self-expanding metal stents (SEMS) in patients with malignant upper gastrointestinal (UGI) obstruction. In 83 patients with malignant UGI obstruction, 118 SEMS placements were performed. Obstruction sites were esophagus/gastro-esophageal junction (GEJ) and gastric outlet (GO) in 41 and 42 patients, respectively. Technical success was achieved in 99.2% and clinical success in 90.5%, with no procedure-related complications. Re-obstruction and migration occurred in 38.1% during a mean follow-up of 137 days; both occurred significantly more often with GO than esophageal/GEJ obstruction (49.2% vs 23.9%). Patency rates of esophageal/GEJ obstruction were 93.5, 78.1 and 67.0% at 30, 90 and 180 days, respectively, and were significantly higher than those of GO obstruction—71.7, 51.8 and 32.5%. Palliative chemotherapy or radiation therapy was not associated with stent patency. Endoscopic SEMS placement is a safe and effective palliative treatment for malignant UGI obstruction, and complications or stent patency differed according to obstruction site.

Keywords Esophageal cancer - Gastric cancer - Malignant obstruction - Self-expanding metal stents - Patency

Introduction

Malignant upper gastrointestinal (GI) obstruction is common in patients with an advanced or inoperable esophageal, gastric, duodenal or pancreato-biliary malignancy. Symptoms of obstruction include dysphagia, early satiety, nausea, vomiting and cachexia, which seriously

impair quality of life. Thus, relief of obstruction to allow enteral feeding is the primary treatment goal in these patients [1–3].

Available therapies for alleviating malignant esophageal obstruction include endoluminal laser therapy, photodynamic therapy, ethanol injection and brachytherapy, but their usage depends on local availability and expertise, and they have little role in the palliation of dysphagia induced by extrinsic causes [4–7]. Surgical bypass is an available option in patients with gastric outlet (GO) obstruction, but this approach may be unsuitable for those with a limited life expectancy because of its significant morbidity and mortality [8, 9].

Self-expanding metal stent (SEMS), which expands radially upon deployment, was initially introduced to gastroenterology to relieve malignant biliary obstruction. It was subsequently used to treat esophageal obstruction and has been widely used in treatment of malignant obstruction of GI tract [1, 10–13]. Moreover, SEMS is particularly useful for patients who cannot tolerate surgery, radiation or chemotherapy due to a poor functional status in advanced metastatic disease or after failure of a previous therapeutic attempt [6].

Although many types of SEMS have been introduced to provide effective treatment alternatives for malignant upper GI obstruction with minimal morbidity, stent re-obstruction by progressive tumor ingrowth or overgrowth and stent migration still pose problems that necessitate additional interventions [5, 14]. Moreover, the long-term stent patency has been reported to be highly variable despite recent technical improvements [4, 14]. The purpose of the present study was to evaluate clinical outcomes, including technical and clinical success rates, and to identify factors associated with long-term patency of SEMS in patients with a malignant upper GI obstruction.

Patients and methods

Patients

The medical records of patients who underwent endoscopic SEMS (M.I. Tech Co., Seoul, Korea) placement to alleviate malignant upper GI obstruction at Seoul National University Hospital between April 2005 and November 2006 were reviewed retrospectively. None of the patients was candidate for curative surgical treatment because of a poor functional status or advanced or metastatic disease. Patients were excluded if they had already undergone palliative surgery or fluoroscopy-guided stent placement, had a tracheo-esophageal fistula or had experienced recurrence at an anastomotic site after curative surgery. Informed consent was obtained from all patients before SEMS placement, and the review of clinical records for the purpose of this study was approved by the ethics committee of the Seoul National University Hospital (IRB No. H-0610-006-185).

Endoscopic SEMS placement

Before stent placement, site, degree and length of obstruction were assessed using a conventional upper GI endoscope, computerized tomography and/or water-soluble contrast fluoroscopic study. Stent type, size and length were chosen according to measured lengths of obstructions. The length of stent was chosen to be at least an additional 2 cm on each side of the obstruction to allow an adequate margin. All procedures were performed under

endoscopic guidance with or without fluorosocopic guidance by one expert endoscopist (Fig. 1). Patients were maintained under conscious sedation with intravenous 0.05 mg/kg midazolam, and the stent was placed using a two-channel endoscope (GIF-260, Olympus, Tokyo, Japan). Covered stents (lengths 12, 16 or 18 cm; diameter 18 mm) and covered stents with an anti-reflux valve (lengths 9, 12 or 16 cm; diameter 18 mm) were primarily used to treat esophageal and GEJ obstructions, respectively. In patients with GO obstruction, covered stents (lengths 9 or 11 cm, diameter 18 mm) were chosen primarily, but an uncovered stent (lengths 11, 12, 16 or 17 cm, diameter 18 mm) was used if a covered stent was not long enough for obstructive lesion or when additional SEMS placement was required due to stent migration.

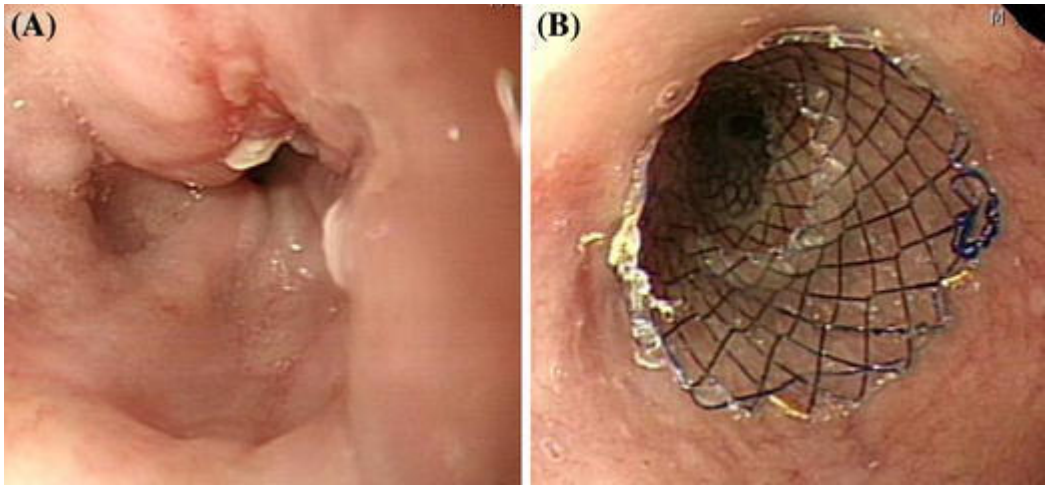

Fig. 1 Self-expanding metal stent (SEMS) placement to palliate dysphagia caused by extrinsic compression of mediastinal lymphadenopathy in an 80-year-old patient with inoperable non-small cell lung cancer. Endoscopic view of extrinsic compression caused by mediastinal lymphadenopathy in the mid-esophagus (**A**), and SEMS (M.I. Tech Co., Seoul, Korea) immediately after successful deployment (**B**).

Clinical outcomes and stent patency

Medical records were reviewed and the following data were collected: age; sex; site of obstruction; diagnosis; stent types; procedure outcomes (technical success and procedure-related complications); clinical outcomes; palliative chemotherapy or radiation therapy after stent placement; complications including tumor overgrowth, ingrowth and stent migration; and time to complication or death. Technical success was defined as proper placement and full expansion of stent across an obstructing lesion, and clinical success as relief of obstructive symptoms and/or an improvement of oral intake [15]. Patients who achieved technical and clinical success were followed to observe complications and survival up to the end of medical records review. Stent patency duration was defined as the time between stent placement and recurrence of obstructive symptoms caused by tumor overgrowth, ingrowth or stent migration, which were confirmed either endoscopically or radiologically. If no stent-related complication was evident during a patient's life, patency duration was considered to equal survival time, but censored. Procedural and clinical outcomes, complications and stent patency were analyzed with respect to patient demographics, obstruction site and stent type.

Statistical analysis

Results were expressed as mean ± standard deviation (SD) or as percentages (no., %). Statistical analysis was performed using the chi-squared test, Student's *t*-test or Fisher's exact test. Stent patency and the patient survival were calculated using Kaplan–Meier method and findings were compared using log rank test. Factors associated with patency duration were assessed using Cox multivariable regression analysis for patients who achieved technical and clinical success. Putative predictors of patency duration were identified according to site of obstruction using the chi-squared test or Fisher's exact test: patient age at time of stent placement, sex, diagnosis, stent type, chemotherapy and/or radiation therapy after stent placement and patient survival. *P* values less than 0.05 were considered statistically significant. All statistical analyses were conducted using SPSS software (version 12.0, SPSS Inc., USA).

Results

Patients' characteristics

A total of 83 patients (71 men, mean age 61.5 years, range 37–84 years) with malignant upper GI obstruction underwent 118 SEMS placements (Table 1). Sites of obstruction were esophagus in 25 patients (30.1%), GEJ in 16 (19.3%) and GO in 42 (50.6%). The causes of the esophageal or GEJ obstruction were esophageal cancer in 27 patients (65.8%), cardiac gastric cancer in 7 (17.1%) and extrinsic compression by lung cancer or malignant mediastinal lymphadenopathy in 7 (17.1%). GO obstructions were caused by gastric cancer in 26 (61.9%), duodenal or pancreato-biliary cancer in 12 (28.6%) and metastatic cancers in 4 (9.5%). The tumor stage was more advanced in patients with GO obstruction than in those with esophageal/GEJ obstruction, although this was not statistically significant. Of patients with esophageal/GEJ and GO obstruction, 6 (14.6%) and 16 (43.2%), respectively, received chemotherapy and/or radiation therapy.

Table 1 Patients' characteristics. *GEJ* gastro-esophageal junction, *GO* gastric outlet, *SD* standard deviation, *PB* pancreato-biliary, *SEMS* self-expanding metal stents

Characteristics	Esophagus/GEJ (no. = 41)	GO (no. = 42)
Age (years, mean ± SD)	62.6 ± 11.1	60.7 ± 10.7
Male, no. (%)	35 (85.4)	35 (83.3)
Diagnosis, no. (%)		
Esophagus	27 (65.8)	0 (0)
Stomach	7 (17.1)	26 (61.9)
Duodenum/PB	0 (0)	12 (28.6)
Others	7 (17.1)	4 (9.5)
Stage, no. (%)		
II or III	12 (29.2)	4 (9.5)
IV	29 (70.8)	38 (90.5)
Covered stent at first placement, no. (%)	41 (100)	24 (57.1)
No. of SEMS placements (%)		

1	31 (75.6)	22 (52.4)
2	10 (24.4)	16 (38.1)
3 or more	0 (0)	4 (9.5)

Technical and clinical outcomes

Successful deployments of SEMS were achieved in 117 (99.2%) of 118 placements. In one patient with GO obstruction due to pancreatic cancer, a guide-wire could not be passed through the obstruction during an attempt at second stent placement after migration, and the patient was recommended to receive a palliative gastrojejunostomy. Clinical successes for the esophageal/GEJ and GO obstruction were achieved in 92% (46/50) and 89.4% (59/66), respectively. There were no procedure-related complications or mortality, but one patient with GEJ obstruction required a palliative operation due to benign gastric ulcer perforation, which was not related to the procedure. Three mortalities occurred due to disease progression within a week, one on the day of stent placement and several days later.

Complications and subsequent interventions

Complications were assessed for 105 SEMS placements in 75 patients who achieved clinical success during a mean follow-up period of 137 days (range 10–428 days) (Table 2). The most common complication was re-obstruction by tumor overgrowth (22 cases; 21.0%), followed by stent migration (11 cases; 10.5%) and tumor ingrowth (5 cases; 4.8%). There was one case of re-obstruction in a patient with esophageal cancer due to food impaction, which was removed endoscopically without placing another stent. One patient with GO obstruction refused further intervention for palliation of obstruction despite obstructive symptom and radiological evidence of re-obstruction 38 days after SEMS placement. The cumulative complication rate was 38.1%, which was significantly higher in patients with GO obstruction than with esophageal or GEJ obstruction (49.2% vs 23.9%, $P = 0.008$).

Table 2 Complications of self-expanding metal stent (SEMS) in relation to obstruction site. *GEJ* gastro-esophageal junction, *GO* gastric outlet, *NS* not significant

Characteristics		**Esophagus/GEJ**	**GO**	***P* value**
		46	**59**	
Complications, no. (%)	Overall	11 (23.9)	29 (49.2)	0.008
	Tumor overgrowth	7 (15.2)	15 (25.4)	0.2
	Tumor ingrowth	0 (0)	5 (8.5)	0.07
	Stent migration	3 (6.5)	8 (13.6)	0.34
	Other	1 (2.2)	1 (1.7)	NS

In patients with esophageal or GEJ obstruction who mainly received covered stents, tumor overgrowth occurred in 7 (15.2%) and migration in 3 (6.5%), but no tumor ingrowth was observed. There was no significant difference between esophageal and GEJ obstruction in terms of tumor overgrowth or stent migration. Although no significant difference in overall complications was found between covered and uncovered stents in patients with GO obstruction, tumor ingrowth tended to occur more frequently in those with uncovered stents, while tumor overgrowth and stent migration were more frequent with covered stents (Table 3).

Table 3 Long-term patency and complications of self-expanding metal stents (SEMS) in patients with gastric outlet (GO) obstruction in relation to stent type

Characteristics		Covered stent	Uncovered stent	*P* value
		26	33	
SEMS, no. (%)	Initial placement	22 (84.6%)	15 (45.5%)	
	Additional placement	4 (14.8%)	18 (54.5%)	
Median patency duration, days		83	108	>0.5
Complications, no. (%)	Overall	15 (57.7)	14 (42.4)	0.24
	Tumor overgrowth	9 (34.6)	6 (18.2)	0.15
	Tumor ingrowth	0 (0)	5 (15.2)	0.06
	Stent migration	6 (23.1)	2 (6.1)	0.12
	Other	0 (0)	1 (3.0)	>0.5

The majority of patients with a complication were managed by placing another SEMS (87.5%). No procedure was attempted in three patients with stent migration because no evidence of obstruction was observed after stent removal. One patient who developed tumor ingrowth after second stent placement was treated by palliative gastrojejunostomy and achieved a satisfactory clinical outcome. In one patient with GO obstruction, a total of five SEMSs were placed due to recurrent migration and overgrowth.

Survival and stent patency

A total of 69 patients (92%) died, with a median survival of 112 days—104 days in patients with esophageal/GEJ and 116 days with GO obstruction (Fig. 2A). Stent patency rates of esophageal/GEJ obstruction were 93.5, 78.1 and 67.0% at 30, 90 and 180 days, respectively, which were significantly higher than those of GO obstruction (71.7, 51.8 and 32.5%; $P = 0.004$). Median stent patency duration in patients with GO obstruction was 107 days (Fig. 2B).

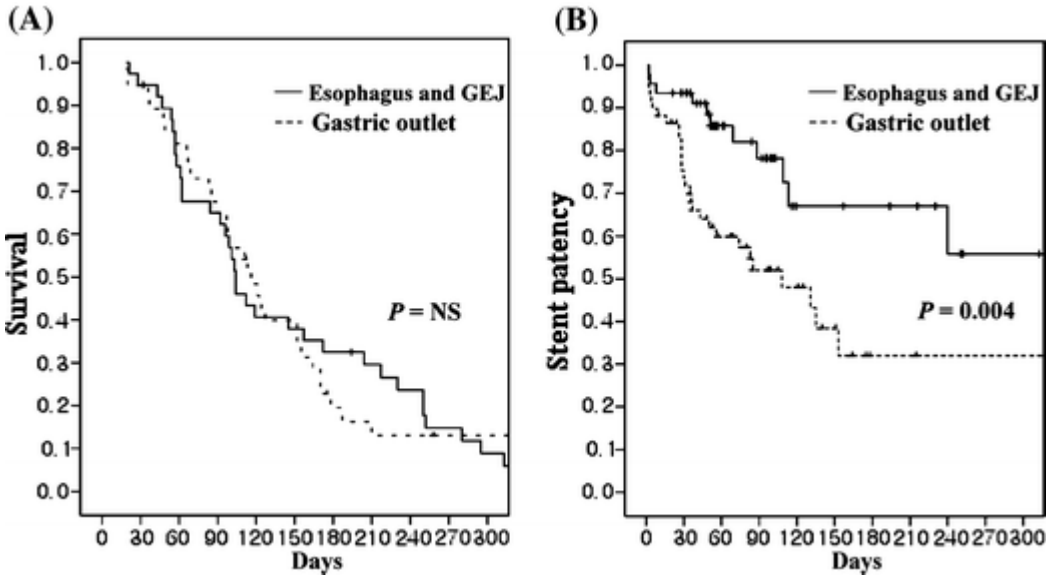

Fig. 2 Kaplan–Meier curve of patient survival (**A**) and stent patency (**B**). Median survivals in patients with esophageal/GEJ and gastric outlet (GO) obstruction were not significantly different in relation to obstruction site. Stent patency rates in patients with esophageal/gastro-esophageal junction (GEJ) obstruction were significantly higher than in those with GO obstruction.

Putative predictors of stent patency were identified by univariable analysis according to site of obstruction and entered into a Cox multivariable regression model (Table 4). There were no significant factors associated with stent patency in patients with esophageal/GEJ and GO obstruction, controlling for patient age and survival.

Table 4 Univariable analysis of complication according to site of obstruction. *GEJ* gastro-esophageal junction, *GO* gastric outlet

Site of obstruction	Variable		Complication, no. (%)		*P* value
			Yes	No	
Esophagus/GEJ (no. = 38)	Age	<60 years	5 (41.7)	7 (58.3)	0.24
		≥60 years	5 (19.2)	21 (80.8)	
	Sex	Male	10 (31.3)	22 (68.7)	0.17
		Female	0 (0)	6 (100)	
	Diagnosis	Esophageal cancer	8 (33.3)	16 (66.7)	0.27
		Others	2 (14.3)	12 (85.7)	
	Palliative therapy	Chemotherapy/radiation therapy	3 (50)	3 (50)	0.32
		No therapy	7 (21.9)	25 (78.1)	

	Survival	<100 days	3 (17.6)	14 (82.4)	0.46
		≥100 days	7 (33.3)	14 (66.7)	
GO (no. = 37)	Age	<60 years	12 (70.6)	5 (29.4)	0.2
		≥60 years	10 (50)	10 (50)	
	Sex	Male	19 (59.4)	13 (40.6)	0.98
		Female	3 (60)	2 (40)	
	Diagnosis	Gastric cancer	14 (60.9)	9 (39.1)	0.82
		Others	8 (57.1)	6 (42.9)	
	Covered stent	Yes	14 (63.6)	8 (36.4)	0.53
		No	8 (53.3)	7 (46.7)	
	Palliative therapy	Chemotherapy	10 (62.5)	6 (37.5)	0.74
		No therapy	12 (57.1)	9 (42.9)	
	Survival	<100 days	5 (31.3)	11 (68.8)	0.002
		≥100 days	17 (81.0)	4 (19.0)	

Discussion

Despite recent advances in early diagnosis and curative treatment, more than 50% of patients with cancer of the esophagus or gastric cardia have incurable disease causing obstruction at presentation [2]. Extrinsic compression of the esophagus due to lung cancer or mediastinal malignancies can also cause troubling symptoms, although it is less common [16–18]. In addition, malignant GO obstruction is a common pre-terminal complication of advanced gastric, pancreato-biliary and metastatic carcinoma [19]. For these patients with limited life expectancy, only palliative treatment is possible to relieve dysphagia and intractable hyperemesis, and to maintain adequate oral nutrition [2, 4, 20]. Thus, the optimal treatment should be safe, effective and cost-effective with minimal morbidity [21, 22].

SEMS placement has become the treatment of choice in patients with dysphagia caused by malignancy [23] and has also been reported to be a safe and effective non-surgical alternative for the palliation of malignant GO obstruction, which quickly restores oral intake and reduces hospital stay and cost [14, 20–22, 24]. The technical success rate for SEMS placement by an expert is close to 100% in patients with a malignant upper GI obstruction, and the clinical success rate exceeds 90% [10, 25]. In the present study, which was not different with respect to obstruction site, comparable results were achieved, with a technical success rate of 99.2%

and a clinical success rate of 90.5%. Moreover, there was no adverse outcome related to either stent itself or procedure.

Many different types of SEMS are available for the treatment of esophageal obstruction, e.g., covered or uncovered with/without an anti-reflux valve to prevent gastro-esophageal reflux in patients with a malignant tumor around the GE junction [26–28]. Covered stents are most commonly used in patients with esophageal obstruction because the cover avoids tumor ingrowth through the stent metal mesh [29]. However, the use of covered stents has been plagued by stent migration. With covered stents placed for the tumors of the distal esophagus or gastric cardia, stent migration is more likely to occur than when stents are placed for more proximally located tumors because the distal portion of stents projects freely into the gastric fundus without fixation to the esophageal wall [2]. Therefore, stent migration has been reported to occur in up to 28% of patients treated with a covered stent [29–31]. However, in the present study, although all patients with esophageal/GEJ obstruction were initially treated with covered stents, the rate of recurrent dysphagia due to stent migration was low (3 of 44, 6.8%) and comparable to that of the double-layered stent which was developed recently to overcome migration (3 of 42, 7%) [32]. Among the stent-migrated patients, 2 patients were successfully treated with another covered or uncovered stent, respectively, and 1 was managed conservatively after extracting the migrated stent.

Recurrent obstructive symptoms or complications necessitating re-intervention have been reported in 20–25% of patients with GO obstruction [14, 15, 33]. However, the cumulative complication rate was 49.2% in the present study, which is higher than that of previous reports, despite our overall technical and clinical success rates being similar to those of meta-analysis [15]. In the present study, stents mainly used in patients with GO obstruction were 18-mm diameter covered stents of shorter length, and this could have predisposed to more complications, such as tumor overgrowth and migration. In addition, a relatively high complication rate may be partly due to the longer patient survival than that observed in the previous report; patients may encounter stent-related problems such as stent obstruction or migration during this longer period [14, 15]. Although tumor ingrowth occurred more frequently with uncovered stents and tumor overgrowth and migration with covered stents, there was no significant difference between the two stent types in terms of overall complications or median patency duration.

Mean or median patient survival has been reported to vary from 10 to 20 weeks in patients who underwent SEMS placement to alleviate malignant esophageal and GEJ obstructions with variable underlying malignancy [34–36]. However, few reports have addressed stent patency duration and factors associated with stent patency. In the present study, the determined stent patency rates were favorable for patients with limited life expectancy after stent placement and were not significantly associated with patients' demographics and palliative therapy after stent placement. Moreover, complications were managed mainly by placing additional SEMS, and no procedure-related complications were encountered.

Median stent patency duration has been reported to range from 5.5 to 8 weeks in patients with malignant GO obstruction and to be 160 days in those with malignant duodenal obstruction, respectively [14, 37, 38]. These variations in stent patency duration may be due to different demographic factors, underlying malignancies and stent types [37]. Some authors have suggested that SEMS could be the best palliative treatment when the life expectancy of patients with GO obstruction is less than 6 months, whereas surgery might provide a better means of palliation when life expectancy exceeds 6 months [10, 15, 39, 40]. The median stent patency time of 107 days in patients with GO obstruction in the present study is comparable to or longer than those previously reported, which implies that SEMS could be

considered initially in patients with a longer life expectancy than the 6 months previously suggested.

Chemotherapy after stent placement could be independently associated with prolonged duration of oral intake, because chemotherapy may stabilize or decrease tumor burden and thereby decrease malignant ingrowth or overgrowth [41]. However, we could not find any association of stent patency with patient demographics, stent type and palliative therapy after stent placement. In the present study, underlying malignancy and primary outcome of interest were different from that the previous study, although median survival and proportion of patients who received chemotherapy or radiation therapy were comparable. Therefore, further prospective randomized trials are needed to determine factors associated with stent patency to identify appropriate individual patient groups for SEMS placement.

Several limitations of the present study should be mentioned. First, its retrospective nature prevented our evaluating symptoms such as pain or gastro-esophageal reflux. Second, our results of median stent patency duration are longer than those reported by other authors, as discussed above, because we assumed that patency equaled survival if no complication became evident, and thus there is a possibility that patency was overestimated.

In conclusion, endoscopic SEMS placement was found to be a safe and effective modality for the palliation of debilitating symptoms caused by malignant upper GI obstruction without any obvious risk of procedure-related complications or mortality. Complications and long-term stent patency were found to be different relative to the obstruction site, but were not associated with patient demographics, stent type or palliative therapy. These aspects require further study with new stent design to overcome complications and improve stent patency, especially for patients with GO obstruction.

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