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CLINICAL INVESTIGATION

Evaluation of a New Esophageal Stent for the Treatment of Malignant and Benign Esophageal Strictures

Kun Yung Kim[1] · Jiaywei Tsauo[1] · Ho-Young Song[1] · Jung-Hoon Park[1,2] · Eun Jung Jun[1] · Wei-Zhong Zhou[1,3] · Min Tae Kim[1]

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Abstract
Purpose To evaluate the efficacy and safety of the EGIS esophageal stent for treating malignant and benign esophageal strictures.
Materials and Methods Data of 73 patients (mean age 63.0 ± 11.9 years; 66 males) with malignant esophageal stricture and 16 patients (mean age 63.7 ± 9.5 years; 13 males) with benign esophageal stricture who received the EGIS esophageal stent (S&G Biotech, Seongnam, Korea) between October 2010 and April 2016 were obtained from a prospectively maintained electronic database.
Results Technical and clinical success rates were 100% (89/89). Stent malfunction (i.e., tumor/tissue overgrowth, stent migration, and food impaction) occurred in 20.5% (15/73) and 37.5% (6/16) of patients with malignant and benign esophageal strictures, respectively. Stent migration occurred in five (6.8%) and four (25%) patients with malignant and benign esophageal strictures, respectively. The median follow-up durations in patients with malignant and benign esophageal strictures were 130 [interquartile range (IQR) 76–322] days and 486 (IQR 315–736) days, respectively. Recurrent dysphagia occurred in 14.1% (10/73) and 87.5% (14/16) of patients with malignant and benign esophageal strictures, respectively. The median recurrence-free durations in patients with malignant and benign esophageal strictures were 126 (IQR 69–259) days and 100 (IQR 40–182) days, respectively.
Conclusion The EGIS esophageal stent appears to be effective for malignant esophageal strictures, with relatively low rate of stent migration, whereas, for benign esophageal strictures, it seems to be associated with a high rate of recurrent dysphagia, mainly due to stent migration.

Keywords Esophageal neoplasm · Self-expandable metallic stent · Esophageal stricture

Introduction

Self-expanding metallic stent (SEMS) placement is a well-established method for treating esophageal strictures [1]. It is the most widely used approach for the palliative treatment of malignant esophageal strictures, and is also commonly used for the treatment of benign esophageal strictures that are refractory to balloon or bougie dilation [1]. Since Song et al. [2] reported the first fully covered self-expanding metallic stent (FCSEMS) placement in the human esophagus in 1991, their group have developed seven generations of FCSEMSs to overcome limitations related to each generation in treating malignant and benign esophageal strictures [3]. The seventh generation stent (Niti-S Esophageal; Taewoong, Ilsan, Korea) is a braided stent internally covered with a polytetrafluoroethylene (PTFE) membrane; this stent was developed to overcome

Kun Yung Kim and Jiaywei Tsauo have contributed equally to this work.

✉ Ho-Young Song
hysong@amc.seoul.kr

[1] Departments of Radiology and Research Institute of Radiology, Asan Medical Center, University of Ulsan College of Medicine, 88, Olymic-ro 43-gil, Songpa-Gu, Seoul 138-736, Republic of Korea

[2] Biomedical Engineering Center, Asan Institute for Life Sciences, University of Ulsan College of Medicine, Songpa-Gu, Seoul 138-736, Republic of Korea

[3] Department of Radiology, The First Affiliated Hospital of Nanjing Medical University, 300 Guangzhou Road, Nanjing 210029, China

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tumor/tissue ingrowth caused by degradation of the polyurethane covering membrane of previous generation stents [4]. However, the seventh generation stent is associated with a small risk (1%) of tumor/tissue ingrowth caused by detachment of the PTFE membrane [5]. Furthermore, the migration rate (13%) of the seventh generation stent did not markedly improve from those of previous generation stents [6, 7]. Moreover, like any other braided stent, the seventh generation stent has very high axial force, which could lead to pain, foreign body sensation, and recurrent dysphagia from stent abutment, particularly in patients with tortuous anatomy [8]. To overcome these limitations (i.e., membrane detachment, migration, and high axial force), the EGIS esophageal stent (S&G Biotech, Seongnam, Korea) which is externally covered, knitted, and utilize a unique "double-stepped" shoulders design was developed. This stent is commercially available in Korea, Europe, and Japan and is expected to enter clinical trials in both the United States and China in 2017. The purpose of this study was to evaluate the efficacy and safety of the EGIS esophageal stent for treating malignant and benign esophageal strictures.

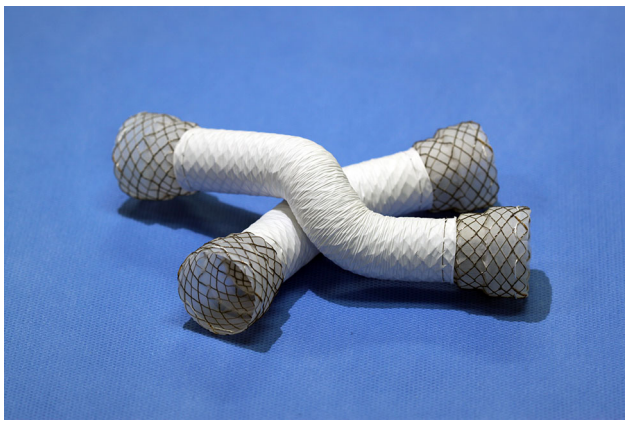

Fig. 1 Photograph of EGIS esophageal stents (S&G Biotech, Seongnam, Korea). The EGIS esophageal stent is knitted from two threads of nitinol wire with a diameter of 0.154 and 0.127 mm, respectively, in a tubular configuration in an interlocking diamond-shaped pattern. The flared ends are coated with silicone, and utilize a unique "double-stepped" shoulders design; the outer shoulders are 24–28 mm in diameter and 13 mm in length, and the inner shoulders are 20–24 mm in diameter and 7 mm in length. The shaft is 16–20 mm in diameter and 4–15 cm in length, and is covered with an ePTFE membrane. The ePTFE membrane is attached to the external surface of the shaft, and is secured with sutures only at its ends. A drawstring made of nylon monofilament is attached to the proximal and distal inner margin of the stent, respectively

Materials and Methods

Patient Population

This retrospective study was approved by our institutional review board, and the requirement for written informed consent was waived. A prospectively maintained departmental electronic database comprising patients that underwent gastrointestinal stent placement was searched to identify eligible patients. The inclusion criterion was patients who received the EGIS esophageal stent for treating benign and malignant esophageal strictures at our institution between October 2010 and April 2016. The exclusion criteria were mildly symptomatic patients whose stricture could allow the passage of an adult endoscope, life expectancy <1 month, multiple small bowel obstructions, and severe vocal cord palsy.

Stent Description

The EGIS esophageal stent is knitted from two threads of nitinol wire with a diameter of 0.154 and 0.127 mm, respectively, in a tubular configuration in an interlocking diamond-shaped pattern (Fig. 1); this construction results in high flexibility, very low axial force, and minimal foreshortening compared with braided stents. The flared ends are coated with silicone to prevent tissue/tumor ingrowth, and utilize a unique "double-stepped" shoulders design to reduce stent migration; the outer shoulders are 24–28 mm in diameter and 13 mm in length, and the inner shoulders are 20–24 mm in diameter and 7 mm in length. The shaft is 16–20 mm in diameter and 4–15 cm in length, and is covered with an expanded PTFE (ePTFE) membrane to prevent tissue/tumor ingrowth. The ePTFE membrane is attached to the external, rather than internal, surface of the shaft to prevent membrane detachment, and is secured with sutures only at its ends so that it does not restrict the movement of the stent structure. A drawstring made of nylon monofilament is attached to the proximal and distal inner margin of the stent, respectively, to facilitate stent removal; pulling on the proximal drawstring collapses the proximal end of the stent, and pulling on the distal drawstring invaginates the stent into itself. The stent is deployed using an 18-Fr 70-cm-long kink-resistant coil braided delivery system.

Stent Placement Technique

After a topical pharyngeal anesthesia was administered using an aerosol spray of lidocaine hydrochloride, an 0.035-in stiff-angled hydrophilic exchange guide wire (Radifocus Guide Wire M; Terumo, Tokyo, Japan) and a 5.4-Fr multifunctional coil catheter (Song-Lim; S&G Biotech) were inserted through the mouth and across the stricture under fluoroscopic guidance. The location and length of the stricture were identified by injection of a limited amount of in (Ultravist 300; Schering Korea,

Ansung, Korea) through the side arm of the catheter. The exchange guide wire was then replaced with a 0.035-in super-stiff guide wire (Amplatz Super Stiff; Boston Scientific, Natick, MA, USA) and the catheter was removed. An EGIS esophageal stent was deployed over the super-stiff guide wire under continuous fluoroscopic monitoring, and an upper gastrointestinal series was performed to confirm good passage of the contrast medium through the stent. After the procedure, patients resumed oral intake of liquids within 24 h and were not permitted any food until an upper gastrointestinal series after 1–3 days showed full stent expansion. When clinically indicated the stent was removed fluoroscopically using a retrieval hook (S&G Biotech) as described previously [9].

Follow-Up

After stent placement, patients were evaluated for obstructive symptoms and oral intake capacity by clinical history and examination at 1 month intervals on an outpatient basis after stent placement; those who could not return for evaluation were followed-up by phone. An upper gastrointestinal series was performed at 1 month to exclude delayed complications. A further upper gastrointestinal series was only performed when clinically necessary.

Data Collection and Definitions

Data on demographics, clinical characteristics, technical success, procedural details, clinical success, complications, reinterventions, survival, and recurrence-free duration were obtained from a prospectively maintained electronic database. Technical success was defined as a successful stent placement at the desired anatomic location and a good passage of contrast medium through the stent. Oral intake status was evaluated by dysphagia score where 0 = normal swallowing, 1 = ability to swallow a semisolid diet, 2 = ability to swallow a soft diet, 3 = ability to swallow liquids only, and 4 = complete dysphagia [7]. Clinical success was defined as improvement of dysphagia score by at least one within 3 days after stent placement. Complications were categorized into major and minor according to the Society of Interventional Radiology clinical practice guidelines [10]. Survival was defined as the interval between stent placement and death. Recurrence-free duration was defined as the interval between stent placement and recurrent dysphagia.

Statistical Analysis

The Student's *t* test was used to compare continuous variables. Time-to-event distributions were estimated using the Kaplan–Meier method and compared using the log-rank test. A two-sided *P* value of <0.05 was considered statistically significance. Statistical analyses were performed using SPSS (ver. 22.0; SPSS, Chicago, IL, USA).

Results

Malignant Esophageal Stricture

A total of 73 patients (mean age 63.0 ± 11.9 years; 66 males and 7 females) with malignant esophageal stricture were included (Fig. 2). Most patients had esophageal (71.2% [52/73]) or gastric (19.2% [14/73]) cancer. Nine (12.3% [9/73]) patients had undergone total gastrectomy with esophagojejunostomy ($n = 8$) or McKeown esophagectomy ($n = 1$). The most common site of stricture was the middle esophagus (43.8% [32/73]) followed by the esophagogastric junction (19.2% [14/73]) and the upper esophagus (17.8% [13/73]). Forty-five (61.6%) patients were receiving either palliative ($n = 36$) or neoadjuvant ($n = 9$) chemo and/or radiation therapy. The demographics and clinical characteristics of the patients are summarized in Table 1.

Technical success was achieved in 100% (73/73) of patients (Fig. 3). Two stents were required to cover the length of the stricture in one (1.4%) patient; the remaining 72 (98.6%) patients required only one stent to cover the length of the stricture. The mean diameter and length of the stents were 16.2 ± 0.6 (range 16–18 mm) and 94.7 ± 23.7 (range 70–150 mm), respectively. All patients had improvement of dysphagia score by at least one within 3 days after stent placement, rendering a clinical success rate of 100% (73/73). The mean dysphagia score significantly improved from 3.3 ± 0.6 before stent placement to 1.1 ± 0.7 after stent placement ($P < 0.001$).

Major complications occurred in 23.3% (17/73) of patients between 0 and 103 days after stent placement (Table 2). Tumor overgrowth occurred in nine (12.3%) patients between 22 and 186 days after stent placement; of these patients, six were treated with fluoroscopic stent placement and three, because of terminal disease, were treated with total parenteral nutrition until death. Stent migration occurred in five (6.8%) patients between 7 and 103 days after stent placement; the migrated stent passed through the rectum spontaneously in three patients and was removed fluoroscopically in two patients (Table 3). All patients with stent migration were receiving palliative chemoradiation therapy and had a decrease in tumor burden; none of these experienced recurrent dysphagia until death. Food impaction occurred in one (1.4%) patient 3 days after stent placement due to non-compliance with food restriction; this patient was treated with fluoroscopic balloon dilation. Aspiration pneumonia occurred in one (1.4%) patient 1 day after stent placement; this patient died 4 days later despite intensive care management. One

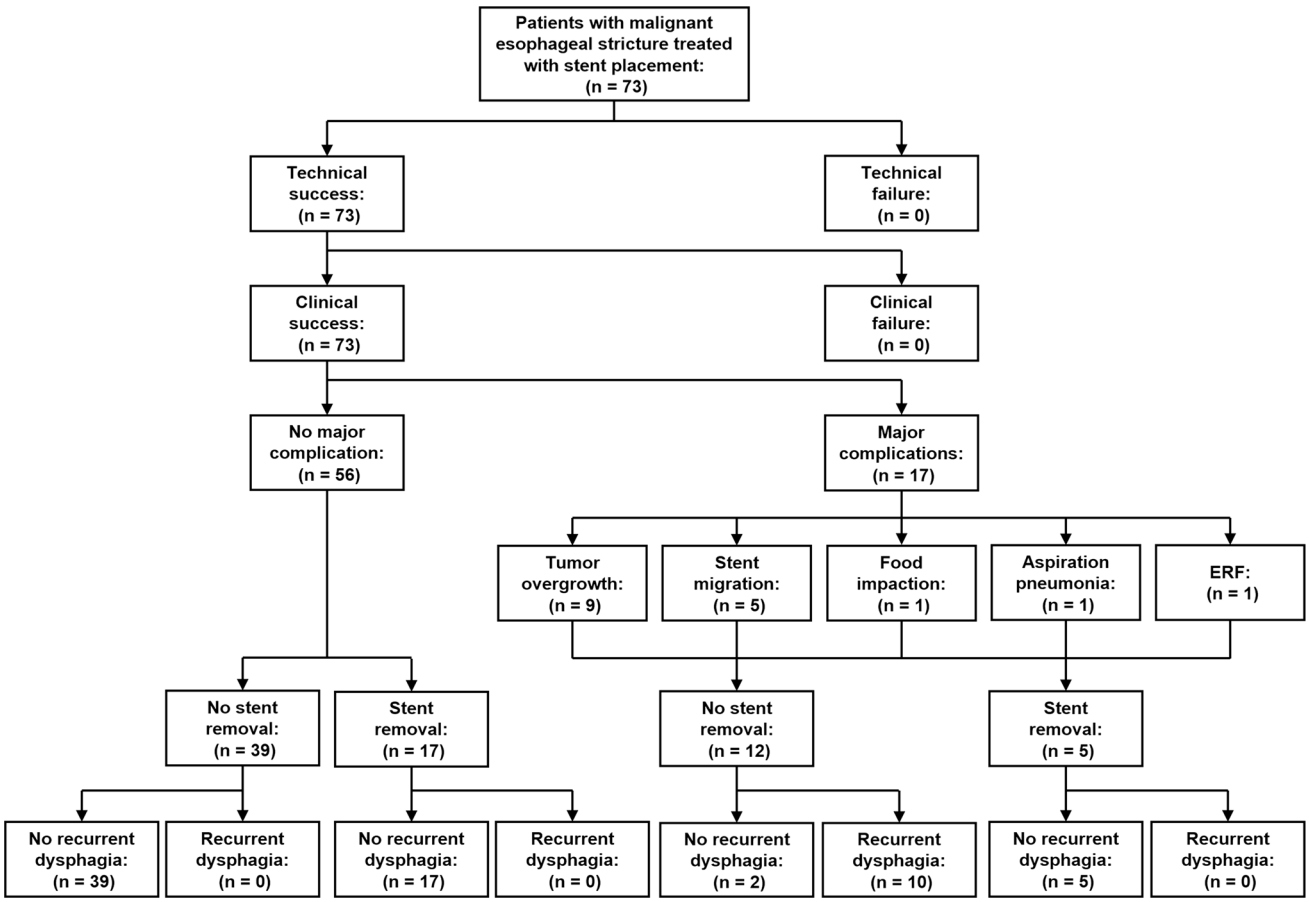

Fig. 2 Flow diagram of outcomes of patients with malignant esophageal stricture treated with stent placement. *ERF* esophagorespiratory fistula

Table 1 Demographics and clinical characteristics of patients with malignant esophageal stricture treated with stent placement

	Patients ($n = 73$)
Age (years)	63.0 ± 11.9
Sex	
Male	66 (90.4)
Female	7 (9.6)
Underlying malignancy	
Esophageal cancer	52 (71.2)
Gastric cancer	14 (19.2)
Metastatic cancer	7 (9.6)
Dysphagia score	3.3 ± 0.6
Site of stricture	
Upper esophagus	13 (17.8)
Middle esophagus	32 (43.8)
Lower esophagus	5 (6.8)
Esophagogastric junction	14 (19.2)
Anastomotic site	9 (12.3)
Length of stricture (cm)	5.9 ± 2.9

Data are presented as mean ± SD or number of patients (percentile)

(1.4%) patients developed esophagorespiratory fistula 87 days after stent placement; this patient was treated by fluoroscopic stent placement to seal of the fistula. Minor complications occurred in 5.4% (4/73) of patients, including mild or moderate pain and gastroesophageal reflux in two (2.7%) patients, respectively; these patients required only nominal therapy.

The median follow-up duration was 130 (interquartile range [IQR], 76–322) days. Two (2.7%) patients were lost to follow-up between 8 and 12 days after stent placement; the remaining 71 (97.3%) patients were followed until death. The median survival was 132 (IQR 77–366) days. The stent was electively removed fluoroscopically between 21 and 126 days after stent placement in 17 (23.3%) patients, including nine (12.3%) patients who were receiving neoadjuvant chemoradiation therapy, and eight (11.0%) patients who were receiving palliative chemo and/or radiation therapy; none of these patients experienced recurrent dysphagia until death. Recurrent dysphagia occurred in 14.1% (10/73) of patients between 3 and 186 days after stent placement due to tumor overgrowth ($n = 9$) and food impaction ($n = 1$).

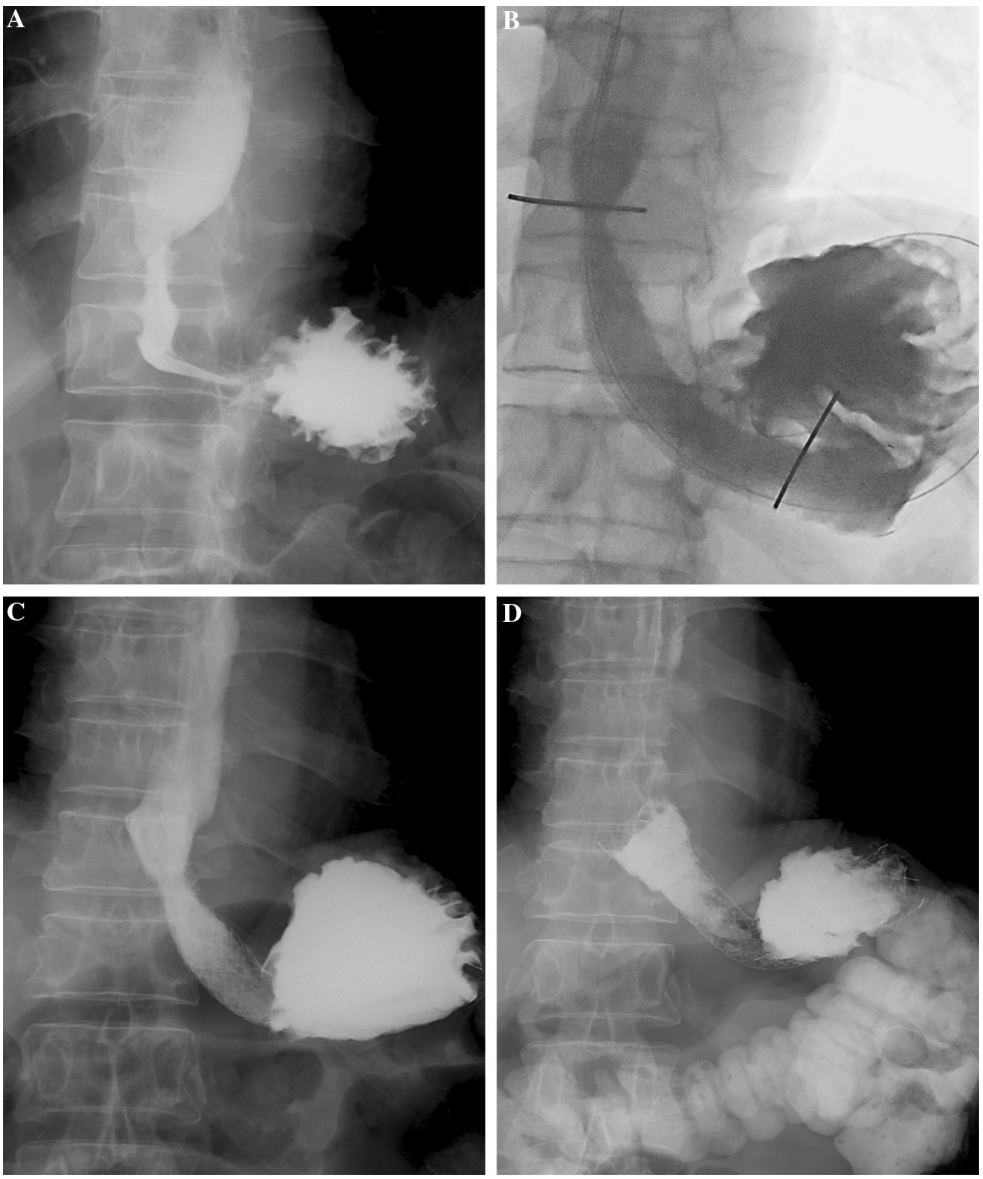

Fig. 3 A 55 year-old man undergoing esophageal stent placement for malignant esophageal stricture secondary to biopsy-proven esophageal squamous-cell carcinoma (T4N3M1). **A** Radiograph shows a torturous stricture at esophagogastric junction. **B** Radiograph shows a 16 mm × 13 cm EGIS esophageal stents (S&G Biotech, Seongnam, Korea) deployed across stricture. **C** Radiograph immediately after stent placement shows a good passage of contrast medium through partially expanded stent. **D** Radiograph 3 days after stent placement shows a good passage of contrast medium through fully expanded stent. The patient's dysphagia score improved by two within 3 days after stent placement, and did not experience recurrent dysphagia until his death 107 days later

Table 2 Major complications and reinterventions after stent placement in patients with malignant esophageal stricture

Complications	Patients ($n = 73$)	Median duration after stent placement (d)	Reinterventions
Tumor overgrowth	9 (12.3)	92 (22–186)	FSP ($n = 6$)
Stent migration	5 (6.8)	39 (7–103)	FSR ($n = 2$)
Food impaction	1 (1.4)	2	FBD ($n = 1$)
Aspiration pneumonia	1 (1.4)	1	
ERF	1 (1.4)	87	FSP ($n = 1$)

Data are presented as number of patients (percentile) or median (interquartile range)

FSP fluoroscopic stent placement, *FSR* fluoroscopic stent removal, *FBD* fluoroscopic balloon dilation, *ERF* esophagorespiratory fistula

Table 3 List of patients with malignant esophageal stricture who had stent migration

Patient no./ age(year)/sex	Underlying malignancy	Stricture		Stent		Dysphagia score		Chemoradiation therapy after stenting	Management of stent migration	Stent dwell time (days)	Recurrence-free duration (days)	Follow-up duration (days)
		Site	Length (cm)	Diameter (mm)	Length (cm)	Before stenting	After stenting					
1/51/M	Esophageal cancer	LE	8	16	13	3	2	+	FSR	7	107	107
2/50/M	Esophageal cancer	LE	5	16	9	3	1	+	None[a]	35	473	473
3/66/M	Esophageal cancer	ME	6	16	10	3	0	+	None[a]	103	406	406
4/65/M	Gastric cancer	AS	5	18	9	4	2	+	None[a]	39	115	115
5/46/F	Lung cancer	ME	6	16	11	3	1	+	FSR	18	237	237

UE upper esophagus, *LE* lower esophagus, *ME* middle esophagus, *FSR* fluoroscopic stent removal

[a] Migrated stent passed through the rectum spontaneously

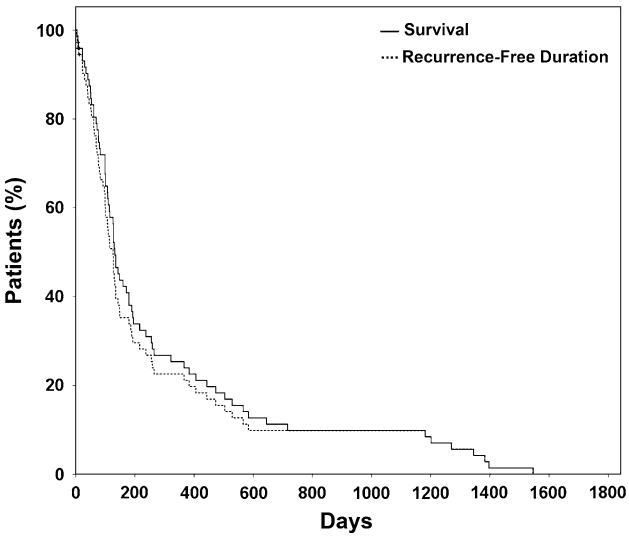

Fig. 4 Kaplan-Meier curves of survival and recurrence-free duration in patients with malignant esophageal stricture treated with stent placement

The median recurrence-free duration was 126 (IQR 69–259) days. Figure 4 shows the Kaplan–Meier curves of survival and recurrence-free duration.

Benign Esophageal Stricture

A total of 16 patients (mean age 63.7 ± 9.5 years; 13 males and 3 females) with benign esophageal stricture were included (Table 4). Most (75.0% [12/16]) patients had post-operative stricture; these patients had undergone McKeown esophagectomy ($n = 4$), total gastrectomy with esophagojejunostomy ($n = 2$) or gastrojejunostomy ($n = 2$), Ivor-Lewis esophagectomy ($n = 1$), total laryngectomy ($n = 2$), or partial gastrectomy ($n = 1$). The mean length of stricture was 4.4 ± 4.6 cm. All patients had a history of one or more balloon dilation.

Technical success was achieved in 100% (16/16) of patients (Fig. 5). One stent (diameter, 16–18 mm; length, 7–15 cm) was placed in each patient. All patients had improvement of dysphagia score by at least one within 3 days after stent placement, rendering a clinical success rate of 100% (16/16). The mean dysphagia score significantly improved from 3.3 ± 0.6 before stent placement to 1.2 ± 0.5 after stent placement ($P < 0.001$).

Major complications occurred in 50.0% (8/16) of patients between 0 and 122 days after stent placement. Stent migration occurred in four (25.0%) patients between 4 and 36 days after stent placement; of these patients, two underwent surgical stent removal because the migrated stent was lodged in the small bowel and two underwent fluoroscopic stent removal. Aspiration pneumonia occurred in one (6.3%) patient 55 days after stent placement; this patient died 3 days later despite intensive care management. One (6.3%)

Table 4 Clinical outcomes of stent placement in patients with benign esophageal stricture

Patient no./ age(year)/sex	Stricture			Stent		Dysphagia score		Complications	Reinterventions	Stent dwell time (days)	Recurrence-free duration (days)	Follow-up duration (days)
	Etiology	Location	Length (cm)	Diameter (mm)	Length (cm)	Before stenting	After stenting					
1/54/M	Post-ESD	LE	2	16	7	2	1	None	FBD	67	182	1722
2/59/F	Post-OP	AS	6	16	7	4	0	None	FSP	111	119	217[a]
3/55/F	Post-OP	AS	2	16	7	3	2	Stent migration	SSR, SC	36	36	1304
4/47/F	Post-OP	AS	3	16	7	3	2	Stent migration	FSR	29	1429	1429
5/64/M	Post-OP	AS	2	16	7	3	1	Stent migration	FSR, FBD	19	40	1288
6/54/M	RI	ME	4	16	9	4	1	None	FBD	28	88	486[a]
7/76/M	RI	LE	10	16	15	4	1	AP	None	58	58	58[b]
8/69/M	Post-Op	AS	5	18	9	3	1	None	PRG	96	120	574
9/75/M	Post-OP	AS	3	16	7	4	1	None	FBD, FSP	112	190	736
10/77/M	Post-OP	AS	7	16	9	3	1	TO	FSR, FBD	122	122	628
11/64/M	Post-OP	AS	6	16	9	3	1	None	FBD	84	100	651
12/61/M	Corrosive	UE	5	16	7	3	1	Food impaction	FSR, FSP	63	63	371
13/51/M	Post-OP	AS	2	16	7	3	1	None	FSR, FBD	40	245	429
14/68/M	Post-OP	AS	7	16	13	4	2	Stent migration	SSR, SC	4	4	357
15/66/M	Post-OP	AS	6	16	7	3	1	None	FSP	224	231	315
16/73/M	Post-OP	AS	1	16	7	3	2	Intractable pain	FSR, PRG	14	17	180

ESD endoscopic submucosal dissection, *RI* radiation-induced, *OP* operation, *UE* upper esophagus, *LE* lower esophagus, *ME* middle esophagus, *AS* anastomotic site, *AP* aspiration pneumonia, *TO* tissue overgrowth, *FSP* fluoroscopic stent placement, *FBD* fluoroscopic balloon dilation, *FSR* fluoroscopic stent removal, *SSR* surgical stent removal, *SC* surgical correction, *PRG* percutaneous radiologic gastrostomy

[a] Patient died of recurrent cancer

[b] Patient died of aspiration pneumonia

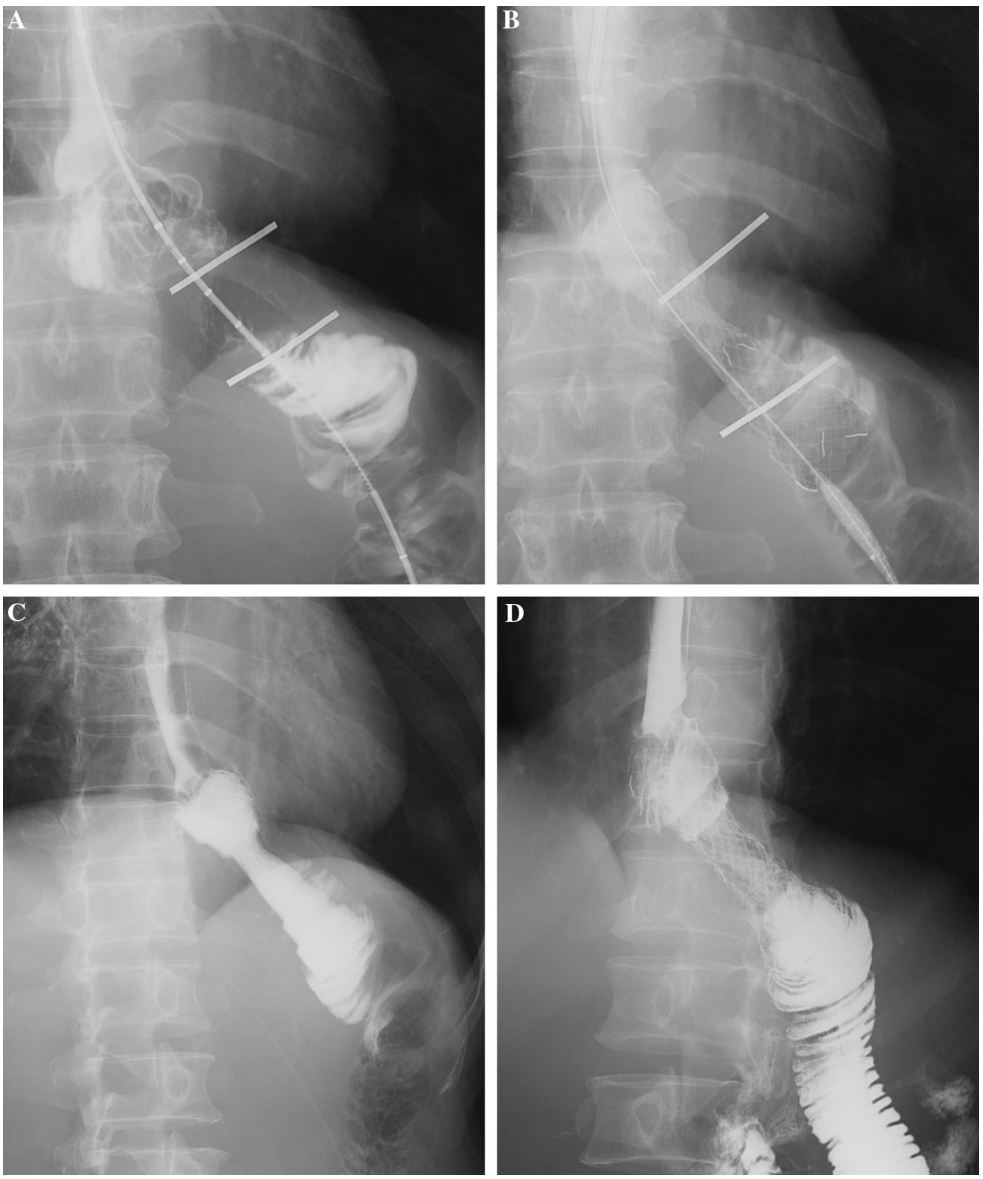

Fig. 5 A 55 year-old woman undergoing esophageal stent placement for biopsy-proven benign esophageal stricture 166 days after total gastrectomy with esophagojejunostomy for advanced gastric cancer **A** Radiograph shows a stricture at anastomotic site. **B** Radiograph shows a 16 mm × 7 cm EGIS esophageal stents (S&G Biotech, Seongnam, Korea) deployed across stricture. **C** Radiograph immediately after stent placement shows a good passage of contrast medium through partially expanded stent. **D** Radiograph 3 days after stent placement shows a good passage of contrast medium through fully expanded stent. The patient's dysphagia score improved by two within 3 days after stent placement, but the stent migration occurred 23 days later; she underwent surgical stent removal because the migrated stent was lodged in the small bowel

patient had proximal tissue overgrowth 122 days after stent placement and underwent fluoroscopic stent removal and balloon dilation. One (6.3%) patient had food impaction 63 days after stent placement and underwent fluoroscopic stent removal. One (6.3%) patient experienced moderate pain immediately after stent placement and underwent fluoroscopic stent removal because pain medications were not effective. There were no minor complications directly related to stent placement.

The median follow-up duration was 486 (IQR 315–736) days. No patients were lost to follow-up. Three (18.8%) patients died because of recurrent cancer ($n = 2$) or aspiration pneumonia ($n = 1$) between 58 and 486 days after stent placement. Eight (50%) patients had the stent electively removed fluoroscopically between 28 and 224 days after stent placement. Seven (43.8%) patients, because of complications, had the stent removed fluoroscopically ($n = 5$) or surgically ($n = 2$) between 2 and 119 days after

stent placement. The median stent dwell time was 58 (IQR 28–96) days.

Recurrent dysphagia occurred in 87.5% (14/16) of patients between 4 and 245 days after stent placement. Eight (50%) patients had recurrent dysphagia between 7 and 205 days after the stent was electively removed; these patients were treated with fluoroscopic balloon dilation ($n = 4$), fluoroscopic stent placement ($n = 3$), or percutaneous radiologic gastrostomy ($n = 1$). Six (37.5%) patients had recurrent dysphagia between 0 and 21 days after the stent was removed due to complications; these patients were treated with surgical correction ($n = 2$), fluoroscopic balloon dilation ($n = 2$), fluoroscopic stent placement ($n = 1$), or percutaneous radiologic gastrostomy ($n = 1$). The median recurrence-free duration was 100 (IQR 40–182) days.

Discussion

It is well-known that FCSEMS placement is an effective and safe method for treating malignant and benign esophageal strictures; however, stent migration is a major limitation of FCSEMSs placement, especially for patients with benign esophageal stricture [11]. In recent years, several FCSEMSs with innovations in designs have been developed with the aim of reducing stent migration. The designs include struts or flip-flop rings on the external surface of the stent to increase affliction to the esophageal wall; however, these designs did not lower the rate of stent migration (14–36%) [12, 13]. In addition, the stent with flip-flop rings appears to be associated with an increased risk (16%) of hemorrhage [13]. One stent with a double-layered configuration (an outer uncovered layer and an inner covered layer) showed low migration rates of 2–3%, but this stent is relatively contraindicated for patients who require stent removal because of its outer uncovered layer [14, 15]. The EGIS esophageal stent was developed for the treatment of both malignant and benign esophageal strictures. In the present study, the rate of stent migration for malignant esophageal stricture was low at 6.8%; this rate is lower than those (8–15%) reported in recent studies of other commercially available FCSEMSs [6, 16–18]. In contrast, the rate of stent migration for benign esophageal stricture in our present study was high at 25.0%; however, such rate remains lower compared to those (29–53%) reported in recent studies for other commercially available FCSEMSs [19–21]. These results may suggest that the EGIS esophageal stent is associated with a relatively low rate of stent migration in patients with malignant and benign esophageal strictures. The most plausible reason for this is most likely due to the "double-step" shoulders design of the EGIS esophageal stent. The additional outer shoulders may increase affixation to the esophageal wall compared to "single-step" shoulders. Because of the seemingly lower rate of stent migration associated with the EGIS esophageal stent, a randomized control trial comparing this stent with another commercially available FCSEMS (Wallflex; Boston Scientific) for treating malignant esophageal stricture has been initiated in the Netherlands (Netherlands Trial Register: NTR4307).

Since the esophagus is a relatively straight tubular structure, the importance of conformability of FCSEMSs has often been overlooked. However, several studies have reported major complications due to poor conformability of the placed stent, including pain, foreign body sensation, and, less often, recurrent dysphagia from stent abutment [4, 7, 8]. In general, braided and laser-cut stents have the highest axial force and therefore, these stents are usually less conformable to tortuous anatomy. The method by which the covering membrane is attached to the stent could also affect the axial force; attaching the covering membrane to the stent by the dipping method or using adhesives usually increases the axial force due to restriction in the movement of the stent structure. The knitted construction of the EGIS esophageal stent generates a much lower axial force than braided and laser-cut stents. In addition, the ePTFE membrane of the EGIS esophageal stent is secured with sutures only at its ends so that it does not restrict the movement of the stent structure. These contributed to the low rate of pain (3.4%), foreign body sensation (0%), and recurrent dysphagia from stent abutment (0%) in our current series.

Tumor/tissue ingrowth is a rare complication of FCSEMS placement, and when it occurs, it is usually caused by degradation or detachment of the covering membrane [3–5]. Polyurethane has commonly been used as the covering membrane of FCSEMSs [22]; however, it is susceptible to the highly acidic gastric fluid and previous studies have shown a degradation rate of 5–8% [3, 4]. PTFE and ePTFE are resistant to almost all types of acids and therefore, these materials are increasingly being used as the covering membrane for FCSEMSs despite of their higher cost [5, 14]. However, tumor/tissue ingrowth caused by membrane detachment remains an unsolved issue and has been reported in up to 9% of cases [15]. A previous study have shown that that externally covered urethral stents could prevent tissue ingrowth caused by membrane detachment compared with internally covered urethral stents (0% vs. 18%; $P = 0.034$) [23]. The ePTFE membrane of the EGIS esophageal stent is attached externally, and indeed, no tumor/tissue ingrowth or detachment membrane occurred in any patients in our current series. This suggests that externally covered esophageal stents could also prevent tumor/tissue ingrowth caused by membrane detachment.

The present study had several limitations of note. First, this was retrospective study and was therefore prone to

selection bias. Second, the sample size of patients with benign esophageal stricture was small, which limits the strength of our results. Last, the lack of control groups treated with other commercially available FCSEMSs limit the conclusions that can be drawn.

In conclusion, the EGIS esophageal stent appears to be effective for malignant esophageal strictures, with relatively low rate of stent migration, whereas, for benign esophageal strictures, it seems to be associated with a high rate of recurrent dysphagia, mainly due to stent migration. Further prospective studies are needed to confirm these findings.

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Compliance with Ethical Standards

Conflict of interest All authors declare that there is no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent This retrospective study was approved by our institutional review board, and the requirement for written informed consent was waived.

References

1. Spaander MC, Baron TH, Siersema PD, Fuccio L, Schumacher B, Escorsell A, et al. Esophageal stenting for benign and malignant disease: European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline. Endoscopy. 2016;48(10):939–48.
2. Song HY, Choi KC, Cho BH, Ahn DS, Kim KS. Esophagogastric neoplasms: palliation with a modified gianturco stent. Radiology. 1991;180(2):349–54.
3. Na HK, Song HY, Kim JH, Park JH, Kang MK, Lee J, et al. How to design the optimal self-expandable oesophageal metallic stents: 22 years of experience in 645 patients with malignant strictures. Eur Radiol. 2013;23(3):786–96.
4. Kim JH, Song HY, Shin JH, Jung HY, Kim SB, Kim JH, et al. Membrane degradation of covered stents in the upper gastrointestinal tract: frequency and clinical significance. J Vasc Interv Radiol. 2008;19(2 Pt 1):220–4.
5. Park JH, Song HY, Kim JH, Jung HY, Kim JH, Kim SB, et al. Polytetrafluoroethylene-covered retrievable expandable nitinol stents for malignant esophageal obstructions: factors influencing the outcome of 270 patients. AJR Am J Roentgenol. 2012;199(6):1380–6.
6. Park JH, Song HY, Shin JH, Cho YC, Kim JH, Kim SH, et al. Migration of retrievable expandable metallic stents inserted for malignant esophageal strictures: incidence, management, and prognostic factors in 332 patients. AJR Am J Roentgenol. 2015;204(5):1109–14.
7. Kim JH, Song HY, Choi EK, Kim KR, Shin JH, Lim JO. Temporary metallic stent placement in the treatment of refractory benign esophageal strictures: results and factors associated with outcome in 55 patients. Eur Radiol. 2009;19(2):384–90.
8. Kim JH, Song HY, Shin JH, Lim JO, Kim KR, Kwon JH, et al. Anastomotic recurrence of gastric cancer after total gastrectomy with esophagojejunostomy: palliation with covered expandable metallic stents. J Vasc Interv Radiol. 2007;18(8):964–9.
9. Song HY, Jung HY, Park SI, Kim SB, Lee DH, Kang SG, et al. Covered retrievable expandable nitinol stents in patients with benign esophageal strictures: initial experience. Radiology. 2000;217(2):551–7.
10. Sacks D, McClenny TE, Cardella JF, Lewis CA. Society of Interventional Radiology clinical practice guidelines. J Vasc Interv Radiol. 2003;14(9 Pt 2):S199–202.
11. Sharma P, Kozarek R. Practice Parameters Committee of American College of G. Role of esophageal stents in benign and malignant diseases. Am J Gastroenterol. 2010;105(2):258–73 **quiz 74**.
12. Uitdehaag MJ, van Hooft JE, Verschuur EM, Repici A, Steyerberg EW, Fockens P, et al. A fully-covered stent (Alimaxx-E) for the palliation of malignant dysphagia: a prospective follow-up study. Gastrointest Endosc. 2009;70(6):1082–9.
13. Uitdehaag MJ, Siersema PD, Spaander MC, Vleggaar FP, Verschuur EM, Steyerberg EW, et al. A new fully covered stent with antimigration properties for the palliation of malignant dysphagia: a prospective cohort study. Gastrointest Endosc. 2010;71(3):600–5.
14. Kim MD, Park SB, Kang DH, Lee JH, Choi CW, Kim HW, et al. Double layered self-expanding metal stents for malignant esophageal obstruction, especially across the gastroesophageal junction. World J Gastroenterol. 2012;18(28):3732–7.
15. Park JG, Jung GS, Oh KS, Park SJ. Double-layered PTFE-covered nitinol stents: experience in 32 patients with malignant esophageal strictures. Cardiovasc Intervent Radiol. 2010;33(4):772–9.
16. Walter D, van den Berg MW, van Hooft JE, Boot H, Scheffer RC, Vleggaar FP, et al. A new fully covered metal stent with antimigration features for the treatment of malignant dysphagia. Endoscopy. 2014;46(12):1101–5.
17. Repici A, Jovani M, Hassan C, Solito B, Di Mitri R, Buffoli F, et al. Management of inoperable malignant oesophageal strictures with fully covered WallFlex((R)) stent: a multicentre prospective study. Dig Liver Dis. 2014;46(12):1093–8.
18. Talreja JP, Eloubeidi MA, Sauer BG, Al-Awabdy BS, Lopes T, Kahaleh M, et al. Fully covered removable nitinol self-expandable metal stents (SEMS) in malignant strictures of the esophagus: a multicenter analysis. Surg Endosc. 2012;26(6):1664–9.
19. Canena JM, Liberato MJ, Rio-Tinto RA, Pinto-Marques PM, Romao CM, Coutinho AV, et al. A comparison of the temporary placement of 3 different self-expanding stents for the treatment of refractory benign esophageal strictures: a prospective multicentre study. BMC Gastroenterol. 2012;12:70.
20. Chaput U, Heresbach D, Audureau E, Vanbiervliet G, Gaudric M, Bichard P, et al. Comparison of a standard fully covered stent with a super-thick silicone-covered stent for the treatment of refractory esophageal benign strictures: a prospective multicenter study. United Europ Gastroenterol J. 2013;1(2):93–102.
21. Dan DT, Gannavarapu B, Lee JG, Chang K, Muthusamy VR. Removable esophageal stents have poor efficacy for the treatment of refractory benign esophageal strictures (RBES). Dis Esophagus. 2014;27(6):511–7.
22. Hindy P, Hong J, Lam-Tsai Y, Gress F. A comprehensive review of esophageal stents. Gastroenterol Hepatology. 2012;8(8):526–34.
23. Na HK, Song HY, Yeo HJ, Park JH, Kim JH, Park H, et al. Retrospective comparison of internally and externally covered retrievable stent placement for patients with benign urethral strictures caused by traumatic injury. AJR Am J Roentgenol. 2012;198(1):W55–61.