



Multisegmented esophageal fully covered self-expandable metal stent for palliation of malignant dysphagia: a prospective, multicenter feasibility and safety study

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Background and Aims: A novel multisegmented esophageal fully covered self-expandable metal stent (FCSEMS) was designed to reduce stent migration, which is seen in up to 30% of patients. The goal of this study was to evaluate the safety and efficacy of the multisegmented FCSEMS.

Methods: This multicenter prospective study aimed to include 30 patients undergoing palliative stent placement. Efficacy, defined as technically successful stent placement and dysphagia scores, and safety, defined as the number of adverse events (AEs) and serious AEs (SAEs), were measured.

Results: The study was prematurely terminated due to safety concerns after including 23 patients (mean \pm standard deviation age, 72 \pm 10 years; 78% male). Stent placement was technically successful in 21 patients (91%), and dysphagia scores had improved in all patients with successful stent placement. SAEs were reported in 16 (70%) patients. Stent-related mortality occurred in 3 patients (13%).

Conclusions: The multisegmented FCSEMS successfully treated malignant dysphagia. The study was prematurely terminated, however, because stent placement was associated with a relatively high SAE rate. (Clinical trial registration number: [NCT04415463](https://clinicaltrials.gov/ct2/show/study/NCT04415463).) (Gastrointest Endosc 2024;99:1027-31.)

More than 50% of patients presenting with esophageal cancer already have unresectable disease at diagnosis.¹ Dysphagia is the predominant symptom and most important cause of reduced quality of life.² Placement of a partially covered self-expandable metal stent (SEMS) or a fully covered SEMS (FCSEMS) is recommended as the palliative modality of choice in patients with a limited life expectancy.³ However, SEMS placement is associated with adverse events (AEs).⁴ Stent migration and retrosternal pain are some of the most common AEs and are seen in up to 30% and 50% of patients,

Abbreviations: AE, adverse event; FCSEMS, fully covered self-expandable metal stent; NRS, numeric rating scale; PPI, proton pump inhibitor; SAE, serious adverse event; SEMS, self-expandable metal stent.



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respectively.⁵ Novel stent designs that both reduce migration rates and decrease retrosternal pain are therefore needed to improve the technical success of stent placement and increase the quality of life of patients undergoing stenting as palliation of malignant dysphagia.

Recently, a multisegmented esophageal fully covered self-expandable metal stent (FCSEMS) (Micro-Tech [Nanjing] Co, Ltd, Nanjing National Hi-Tech, Industrial Development Zone, China) was introduced. Its design is unique in that several segments are independently mobile, which is expected to

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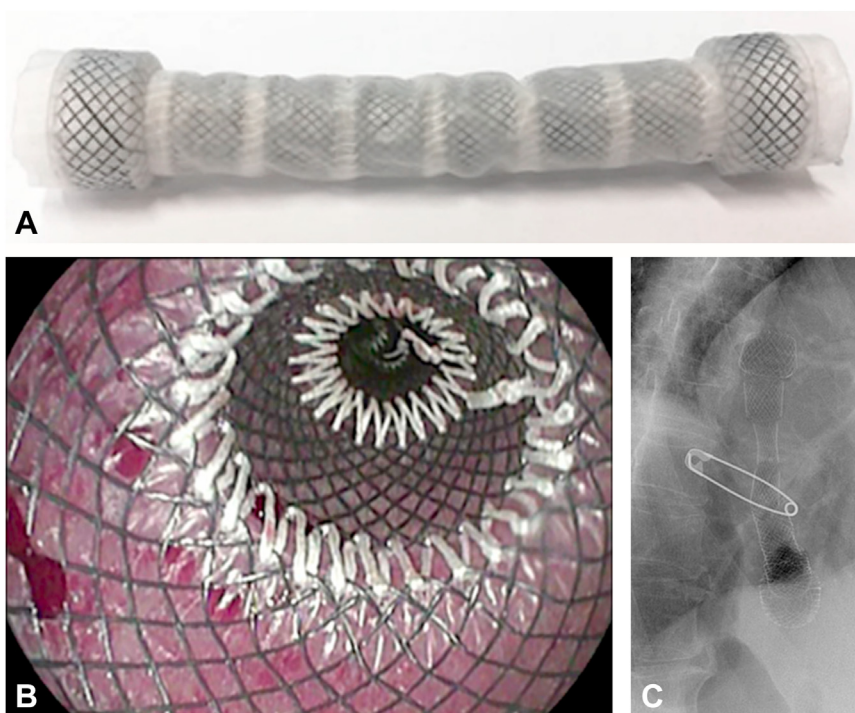


Figure 1. Esophageal multisegmented fully covered self-expandable metal stent.

improve stent adaptation to anatomy and peristalsis of the esophagus. This may reduce retrosternal pain and decrease migration rates while maintaining the favorable characteristics of a fully covered design. The aim of the current study was to assess the safety and efficacy of this multisegmented FCSEMS for palliation of malignant dysphagia.

METHODS

Patients eligible for esophageal stent placement for palliation of malignant dysphagia were screened in 3 centers (Radboud University Medical Center, Nijmegen, and Erasmus Medical Center, Rotterdam, the Netherlands; and Centro Hospitalar São João, Porto, Portugal). All eligible patients who signed informed consent received the multisegmented FCSEMS (Fig. 1). We aimed to enroll a total of 30 patients. Prospective follow-up was performed until death, stent removal, stent migration, second stent placement, or until a maximum of 6 months of follow-up. Appendix 1 (available online at www.giejournal.org) presents details on eligibility criteria, the stent, placement procedure, and follow-up.

The study protocol was approved by the Medical Ethics Committee Oost-Nederland (reference no. NL73180.091.20). The study was registered in an open-access trial database ([ClinicalTrials.gov](https://clinicaltrials.gov): NCT04415463).

Outcomes and definitions

The primary outcomes were efficacy and safety. Efficacy was defined as successful technical stent placement at the required position and by an improved dysphagia score of

at least 1 point according to Ogilvie et al.⁶ Safety was defined as the number of AEs and serious AEs (SAEs), including stent migration. Stent migration was defined as significant displacement (>3 cm) from its original position. AEs were defined as events related to the placement procedure or to the multisegmented stent. AEs could be treated conservatively without the need for repeat endoscopy or hospitalization. SAEs required repeat endoscopy or hospitalization. Retrosternal pain was assessed by using a numeric rating scale (NRS) score ranging from 0 to 10, and it was considered significant in case of a NRS score ≥ 4 . Nausea and/or vomiting was considered an AE in cases in which antiemetics were started. Reflux was considered an AE when proton pump inhibitors (PPIs) were prescribed. The secondary outcome included survival.

Statistical analysis

The Wilcoxon rank sum test and the McNemar test were used to determine differences in, respectively, paired ordinal and paired binary data. A P value $< .05$ was considered statistically significant. All analyses were performed by using SPSS version 27 (IBM SPSS Statistics, IBM Corporation, Armonk, NY, USA).

RESULTS

Following the inclusion of 23 patients, the study was prematurely ended in July 2022 because of safety issues. Appendix 1 describes details on inclusion criteria and

follow-up, and [Supplementary Table 1](#) (available online at www.giejournal.org) presents all baseline characteristics. Median follow-up was 36 days (interquartile range, 6-83 days).

Efficacy

Stent placement was technically successful in 21 (91%) of 23 procedures. In 1 patient, the stent position differed from the intended location due to difficulties in stent release; in another patient, the stent migrated to the mediastinal cavity through a fistula (as discussed in the Safety section). [Supplementary Table 2](#) (available online at www.giejournal.org) presents all technical outcomes. The Ogilvie dysphagia score improved from a median of 3 at baseline to a median of 0 at 14 days after stent placement ($P < .001$). In all patients (100%), the dysphagia score improved with at least 1 point between baseline and day 14 of follow-up ([Supplementary Fig. 1](#), available online at www.giejournal.org).

Safety

All AEs (including SAEs) reported during follow-up are shown in [Table 1](#) and are described in detail in [Appendix 1](#).

A total of 17 SAEs occurred in 16 (70%) of 23 patients. Most SAEs included recurrent dysphagia due to stent occlusion ($n = 4$ [17%]), stent migration ($n = 4$ [17%]), tissue overgrowth ($n = 1$ [4%]), or insufficient stent expansion ($n = 1$ [4%]). Hemorrhage occurred in 2 patients (9%) who both died within 1 month. In 1 patient (4%), the stent caused dyspnea due to compression on the trachea. Severe retrosternal pain requiring one additional endoscopy occurred in 1 patient (4%). Another patient (4%) was admitted and underwent two additional endoscopies because of severe nausea/vomiting. In 1 patient (4%), the stent migrated through a fistula into the mediastinal cavity during placement, leading to placement of a second SEMS ([Supplementary Fig. 2](#), available online at www.giejournal.org), postprocedural pain, and death shortly thereafter.

A total of 17 AEs occurred in 13 (57%) of 23 patients. The most common AE was retrosternal pain with an NRS score ≥ 4 ($n = 11$). Of the 17 patients in whom 2 weeks of follow-up data were available, the percentage of patients with significant retrosternal pain (NRS score ≥ 4) decreased from 53% ($n = 9$) after 1 day to 13% ($n = 2$) after 2 weeks ($P = .039$) ([Supplementary Fig. 3](#), available online at www.giejournal.org). Seventeen patients (74%) used a PPI at baseline. PPIs were initiated during the trial in 3 of 6 patients without a PPI at baseline. Of the 20 patients who did not use antiemetics at baseline, follow-up was available in 14 patients, with 2 (14%) of them starting antiemetics during follow-up. Stent migration without the need for a repeat endoscopy or hospitalization occurred in 1 patient.

Survival

Median survival was 34 days (interquartile range, 9-83 days). Nine patients (39%) died due to tumor progression and 3 (13%) due to a stent-related event following hemorrhage ($n = 2$) or perforation ($n = 1$).

DISCUSSION

This prematurely terminated multicenter prospective study showed that placement of a multisegmented FCSEMS successfully treated malignant dysphagia in all patients. Stent placement was, however, associated with a relatively high rate of SAEs resulting in a stent-related mortality of 13%.

Our SAE rate is higher than observed in a large retrospective cohort study that evaluated placement of various types of partially covered SEMSs and FCSEMSs for malignant dysphagia in daily clinical practice (70% vs 21%, respectively).⁴ Although the prospective follow-up design may have led to a higher SAE rate, there are several reasons that could explain the observed SAE rate. First, some of the SAEs (ie, migration and insufficient stent deployment) may be explained by the design of the stent because it has a relatively low expansion and compression force at a minimum stent diameter, which can lead to insufficient stent deployment. Second, and following the European Society of Gastrointestinal Endoscopy guideline on esophageal stenting for benign and malignant disease, SEMS placement is currently reserved for patients with advanced stages of esophageal cancer with a life expectancy of 6 to 8 weeks.³ This may lead to higher SAE rates because of the already poor medical condition of the patient. An increasing trend in SAEs over time has previously been observed.⁴ Our overall survival rate further supports this hypothesis, as it was shorter than in previous stent studies (median of 34 days vs 80-146 days, respectively).^{7,8} Lastly, up to 80% of our study patients had been treated with chemotherapy and/or radiotherapy before study enrollment, which is considered a risk factor for stent-related AEs and SAEs such as pain due to stent placement and recurrent dysphagia.⁴

The multisegmented SEMS was designed to reduce migration rates and retrosternal pain. Stent migration occurred, however, more often than described in previous studies (22% vs 6%-19% for non-segmented FCSEMSs and 15% for segmented FCSEMSs).^{5,9} As stated earlier, this could be explained by the low axial force of the stent but also, at least partially, by its fully covered design and the distal location of the tumor in more than three-quarters of patients (a well-known risk factor to higher migration rates as the SEMS is often placed across the gastroesophageal junction). Significant retrosternal pain was observed in more patients than was reported in previous studies (65% [$n = 11$ of 17] vs 20%-50%, respectively).^{4,7} Although a large number of patients had undergone prior chemotherapy and/or radiotherapy, which is a risk factor for retrosternal pain, we suspect that the high radial force of the stent may also have contributed.⁴

TABLE 1. AEs during follow-up of all patients treated with the multisegmented fully covered stent for palliation of malignant dysphagia (N = 23)

AE	No. of events in no. of patients (% of n = 23)
Total SAEs	17 in 16 patients (70%)*
No. of endoscopies related to SAEs	18 in 13 patients (57%)
No. of hospitalizations related to SAEs	9 in 9 patients (39%)
SAEs ≤7 days	9 in 9 patients (39%)
Recurrent dysphagia caused by	2
Stent migration	1
Insufficient stent expansion	1
Hemorrhage	2
Fever	1
Migration to mediastinum through fistula	1
Tracheal compression	1
Retrosternal pain (NRS score, ≥4)	1
Severe nausea/vomiting	1
SAEs >7 days	8 in 8 patients (35%)
Recurrent dysphagia caused by	8
Stent occlusion	4
Stent migration	3
Tissue overgrowth	1
Total AEs	17 in 13 patients (57%)
Retrosternal pain (NRS score, ≥4)	11
Reflux	3
Nausea/vomiting	2
Stent migration	1
Outcome of SAEs	
Resolved	12 (52%)
Recovered with minor sequelae†	2 (9%)
Stent-related mortality	3 (13%)

AE, Adverse event; SAE, serious adverse event; NRS, numeric rating scale.

*Fever and insufficient stent expansion occurred in the same patient; further SAEs concerned different patients.

†One patient with external bronchial compression and 1 patient with dysphagia who could not undergo any procedures because of poor clinical condition.

The current study was limited by its size and single-arm design. Because of the lack of a control group with another type of SEMS, a comparison of the multisegmented stent with current stent designs cannot be performed. Although the prospective design of this study might have led to an increased focus on AEs and SAEs compared with retrospective studies, it also strengthens our results as the systematic data collection prevents missing data. Moreover, the multicenter design warrants generalizability of the study results.

In conclusion, this multisegmented FCSEMS showed a remarkably high rate of SAEs and associated mortality. Nevertheless, the malignant dysphagia was effectively treated. Head-to-head trials comparing a further improved design of this multisegmented SEMS versus the existing SEMS are needed to determine the role of this stent for treatment of malignant dysphagia.

DISCLOSURE

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APPENDIX 1

Methods

Eligibility criteria. Patients were eligible in case of malignant dysphagia (grade ≥ 2 according to Ogilvie et al¹) caused by an inoperable malignant obstruction of the esophagus or esophagogastric junction, extrinsic malignant compression, or recurrence of esophageal cancer after esophagectomy. Life expectancy was < 12 months. Exclusion criteria were previous esophageal stent placement, a tumor length > 14 cm, distance between the upper end of the stent and the upper esophageal sphincter < 2 cm, esophageal stricture after laryngectomy, inability to discontinue anticoagulants or high-dose antiplatelet drugs or a known clotting disorder that could not be corrected, and nickel titanium allergy. Because of a serious adverse event (SAE) in the second study patient (details provided in the following Results section), a known or suspected esophageal fistula was added as exclusion criterion.

Stent and placement procedure. The covered self-expandable metal stent (SEMS) delivery system (Micro-Tech [Nanjing] Co, Ltd, Nanjing National Hi-Tech, Industrial Development Zone, China) consists of a multisegmented implantable metallic stent mounted on an inner sheath and constrained by an outer sheath and twisted bundle line. Placement is performed under endoscopic and/or fluoroscopic guidance using the over-the-wire method. Distal release will start after retracting the outer tube and subsequently unwinding the fixation bundle line. The fully covered SEMS (FCSEMS) is made of nitinol wire and has a silicone cover. The flexible multisegmented design is a new aspect aiming to decrease migration rates. Radiopaque marker bands on the inner and outer sheath facilitate radiographic imaging. The stent is available in lengths of 60, 80, 100, 120, and 140 mm; diameters of 18 and 22 mm at its midportion; and 2-sided flanges of 24 or 28 mm, respectively.

The FCSEMS received the CE certificate in 2014 under the Medical Devices Directive. In vitro experiments were performed by the company, which had shown, at minimum stent diameter, a slightly lower expansion and compression force for the multisegmented stent compared with other SEMSs. At the maximum stent diameter, in vitro experiments showed that both the expansion and compression forces of the multisegmented stent was slightly higher compared with those of other SEMSs. These differences in forces were minor, and the performance met clinical usage requirements. After placement, the stent ends should extend the proximal and distal tumor borders with at least 2 cm. An 18 mm diameter stent was used for tumors with the greatest part located above the gastroesophageal junction and the 22 mm diameter stent for tumors with the greatest part located below the gastroesophageal junction. Stents were placed with the

patient under conscious sedation with midazolam and fentanyl or deep sedation with propofol.

Follow-up. Prospective follow-up of patients was performed by telephone interviews at 2 weeks, 4 weeks, and subsequently at 4-week intervals until death, stent removal, stent migration, second stent placement, or until a maximum of 6 months of follow-up. During these interviews, dysphagia, pain, performance status, and AEs were evaluated. Furthermore, all patients recorded retrosternal pain scores in a patient diary daily during the first 2 weeks. Acetaminophen or opiates were prescribed in case of significant retrosternal pain. Hospital admission and/or repeat endoscopy was indicated when patients reported recurrent dysphagia, signs of hemorrhage such as hematemesis, severe nausea and/or vomiting, or significant retrosternal pain refractory to analgesics.

RESULTS

Patients were included at the Erasmus Medical Center ($n = 15$), Radboud University Medical Center ($n = 5$), and Centro Hospitalar São João ($n = 3$) between March 2021 and July 2022. In 2 patients, the distance between the upper end of the stent and the upper esophageal sphincter was < 2 cm; however, the endoscopist judged it technically feasible to position the proximal flange of the stent just below the upper esophageal sphincter, and both patients were therefore included.

Follow-up

Results of the 14-day follow-up assessment were available for 17 (74%) patients. The remaining 6 patients were withdrawn from follow-up within 14 days after stent placement because of stent removal ($n = 2$), stent migration ($n = 2$), or death ($n = 2$). One patient (4%) completed the follow-up of 6 months with the stent in position. A total of 12 patients (52%) were followed up until death, 4 (17%) until stent removal, 4 (17%) until spontaneous stent migration, and 2 (9%) until second stent placement. Nine patients (39%) died due to tumor progression and 3 (13%) due to a stent-related event following hemorrhage ($n = 2$) or perforation ($n = 1$).

Severe AEs

Stent occlusion was treated by endoscopic cleaning ($n = 2$) or stent replacement ($n = 1$) or it was not treated ($n = 1$). Stent migration was treated by stent repositioning ($n = 3$) or second stent placement of a partially covered SEMS (PCSEMS) inside the original stent ($n = 1$). Tissue overgrowth was also treated by placement of a second PCSEMS inside the original stent. Insufficient expansion occurred in a patient who underwent esophagectomy; the stent was placed in this patient directly below the

upper esophageal sphincter despite this being an exclusion criterion, and this was treated by stent removal. One of the 2 patients in whom hemorrhage occurred refused any further intervention and died 4 days after stent placement. In the other patient, no other endoscopic treatment options were available, and the patient died 19 days after stent placement. The patient in whom the stent caused tracheal compression was hospitalized for 8 days. Severe retrosternal pain required 2 repeated endoscopies, including stent removal in 1 patient (4%). Another patient (4%) was admitted for 5 days because of severe nausea/vomiting and underwent 4 additional endoscopies: 1 for diagnosis, 2 for stent repositioning, and 1 for replacement with a new PCSEMS ($n = 1$), respectively, although symptoms persisted despite placement of another type of stent. In 1 patient (4%), the stent migrated through a fistula into the mediastinal cavity during the placement procedure and could not be removed. A second, different type of FCSEMS was placed to close the fistula and treat the patient's dysphagia. However, the patient developed significant retrosternal pain and nausea after the procedure for which intravenous antiemetics and subcutaneous opioids were started. The patient chose best supportive care over surgical stent removal, was discharged after 1 day, and died 6 days later.

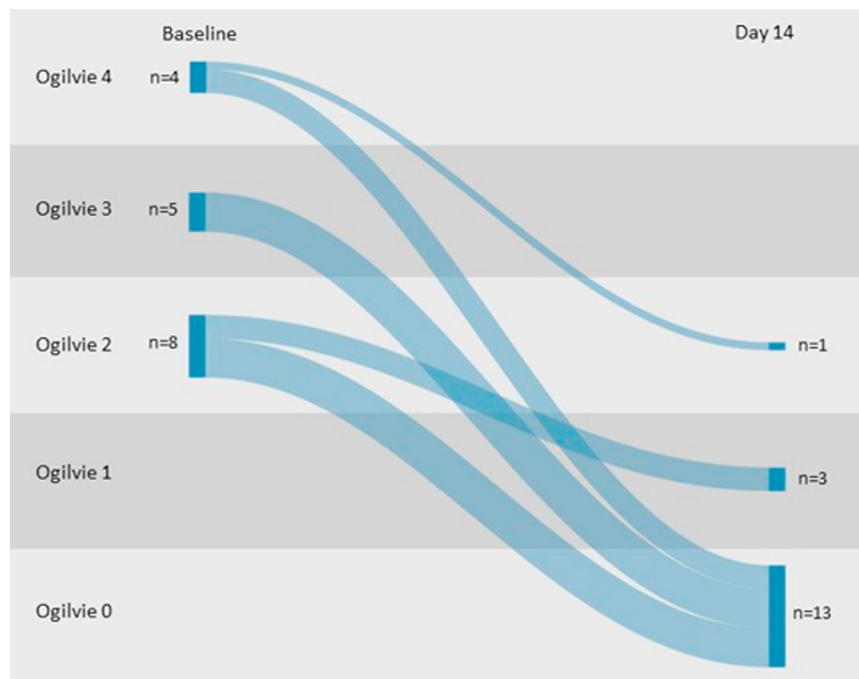
The explanation for the stent migration to the mediastinal cavity is thought to be a combination of patient and stent characteristics. Migration of the stent into the mediastinal cavity occurred shortly after removing the guidewire, likely

due to the negative pressure in the mediastinal cavity created by spontaneous breathing that pulled the stent through a pre-existing fistula, further facilitated by the flexibility of the multisegmented design. To our knowledge, a similar SAE has not been reported previously. As a result, we advised participating centers during the study to exclude patients with a known esophageal fistula to be treated with this multisegmented SEMS. Most SAEs ($n = 12$ of 17 [71%]) were resolved with endoscopic or nonendoscopic means. Two patients recovered but still had minor symptoms due to persistent dysphagia after stent occlusion and tracheal compression. SAEs were observed in 12 (67%) of 18 patients who underwent prior chemotherapy and/or radiation therapy and in 3 (60%) of 5 patients who did not undergo prior chemotherapy or radiation therapy.

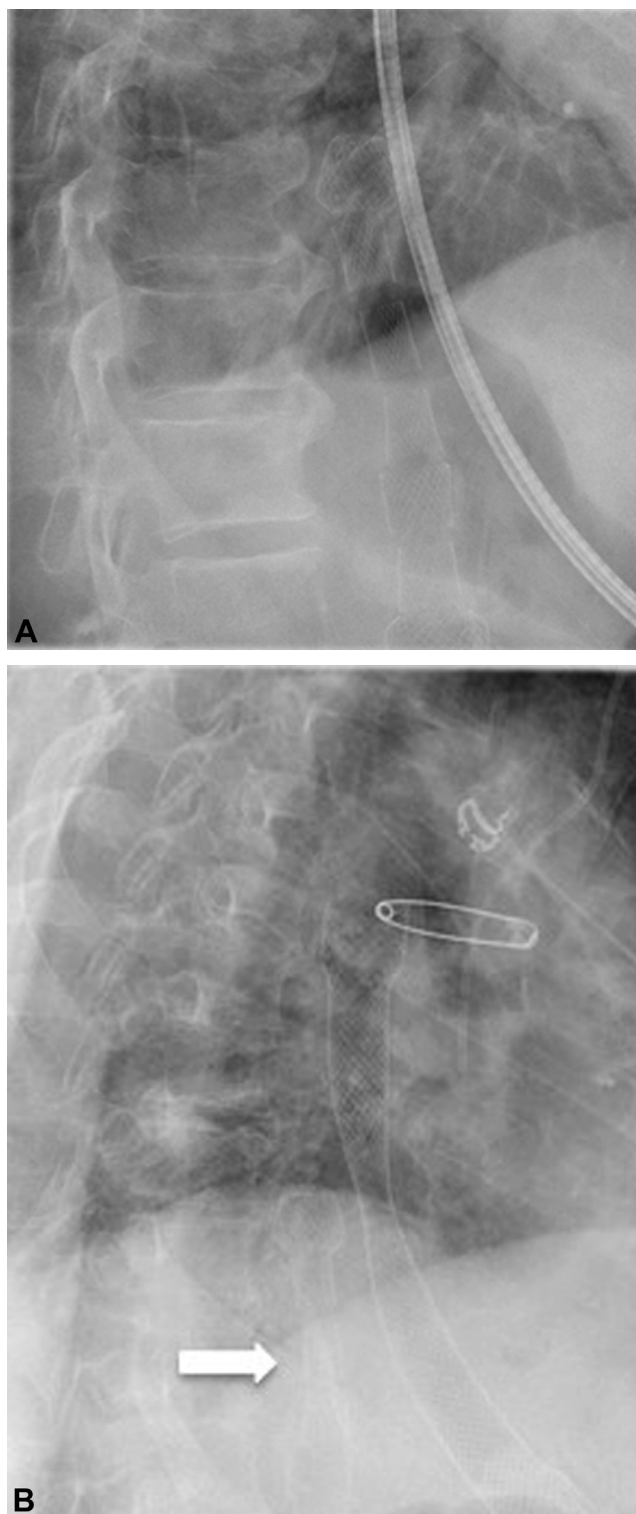
In terms of tumor location, SAEs were seen in 12 (67%) of 18 patients with a tumor location in the distal esophagus or in the cardia, in 1 (50%) of 2 patients with a mid-esophageal tumor location, and in all 3 (100%) patients with a tumor located in the proximal esophagus. When focusing on the stent diameter, AEs occurred both in the 18 mm ($n = 9$ of 11 [82%]) and the 22 mm ($n = 7$ of 12 [58%]) esophageal stent.

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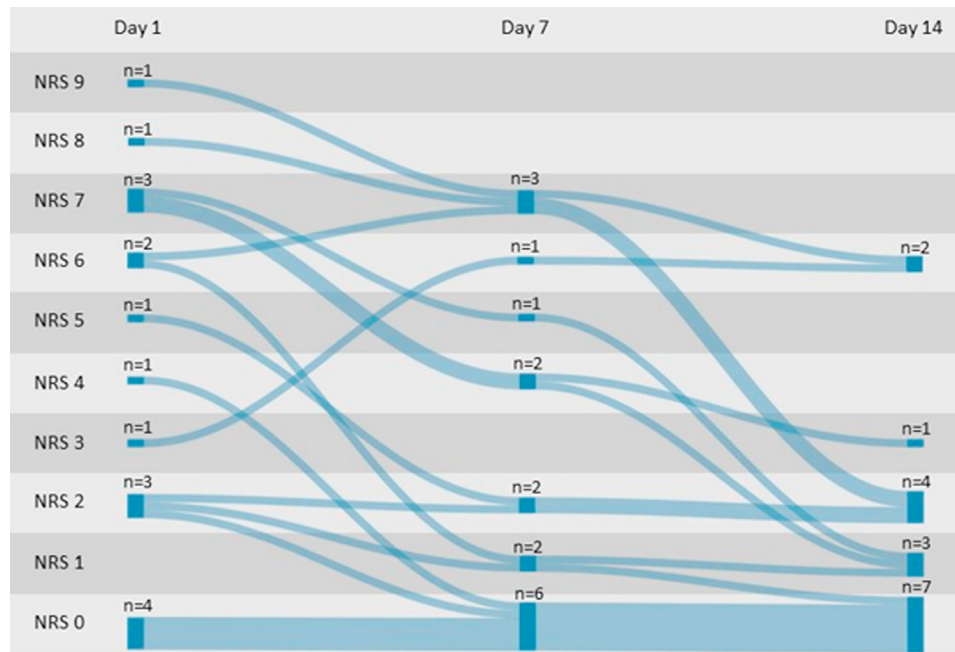
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Supplementary Figure 1. Ogilvie dysphagia score at baseline and day 14 after placement of the multisegmented fully covered self-expandable metal stent (n = 17).



Supplementary Figure 2. **A,** Multisegmented fully covered self-expandable metal stent 120 mm x 18 mm in mediastinum next to gastroscopically placed stent in esophagus. **B,** Multisegmented fully covered self-expandable metal stent 120 mm x 18 mm in mediastinum (left) next to fully covered Wallflex stent 150 mm x 18 mm in esophagus (right).



Supplementary Figure 3. NRS score during the first 2 weeks after placement of the multisegmented FCSEMS (n=17). *NRS*, Numeric rating scale; *FCSEMS*, fully covered self-expandable metal stent.

SUPPLEMENTARY TABLE 1. Baseline characteristics of all patients treated with the multisegmented fully covered stent for palliation of malignant dysphagia (N = 23)

Characteristic	Value
Sex, male	18 (78%)
Age, mean \pm SD, y	72 (10.2)
WHO performance status	
Grade 1	7 (30%)
Grade 2	12 (52%)
Grade 3	4 (17%)
Dysphagia score at baseline	
Grade 2	10 (44%)
Grade 3	7 (30%)
Grade 4	6 (26%)
Previous chemoradiation therapy	
Chemotherapy	4 (17%)
Radiation	2 (9%)
Combination	12 (52%)
None	5 (22%)
Tumor histology	
Adenocarcinoma	14 (61%)
Squamous cell carcinoma	7 (30%)
Other	2 (9%)
Tumor location	
Esophagus	16 (70%)
Cardia	4 (17%)
Anastomotic recurrence	1 (4%)
Extrinsic compression*	2 (9%)
Stricture location	
Proximal esophagus	3 (13%)
Mid esophagus	2 (9%)
Distal esophagus	14 (61%)
Cardia	4 (17%)
Stricture length, mean \pm SD, cm	5.9 (2.3)

SD, Standard deviation; WHO, World Health Organization.

*One patient with subcarinal synovial sarcoma and 1 patient with non-small cell lung cancer.

SUPPLEMENTARY TABLE 2. Technical outcomes of multisegmented fully covered stent placement for palliation of malignant dysphagia (N = 23)

Technical outcome	Value
Patient sedation or anesthesia	
Conscious sedation	20 (87%)
Deep sedation	3 (13%)
Stent length	
100 mm	7 (30%)
120 mm	7 (30%)
140 mm	9 (39%)
Stent diameter	
18 mm	11 (48%)
22 mm	12 (52%)
Placement at required position	19 (83%)
Ease of deployment	
Easy	16 (70%)
Neutral	5 (22%)
Difficult	2 (9%)
Stent placement assisted by	
Fluoroscopy and guidewire	5 (22%)
Guidewire only	1 (4%)
Endoscopic vision	16 (70%)
Endoscopic vision, fluoroscopy, and guidewire	1 (4%)
Overall procedure time, median (IQR), min	20 (16-24)

FCSEMS, Fully covered self-expandable metal stent; IQR, interquartile range.