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Are single or dual luminal covered expandable metallic stents suitable for esophageal squamous cell carcinoma with esophago-airway fistula?

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Abstract
Background To analyze the outcomes of single or dual luminal self-expandable covered metallic stents (SECMS) for palliative treatment for esophageal cancer with esophago-airway fistula (EAF).
Methods We retrospectively assessed 50 patients who underwent SECMS placement for malignant EAF at our institution between June 2005 and December 2014 to define clinical results of stenting. Treatment provided was classified into initial single airway, single esophageal, or double stent placement. Independent associations between size, location of the EAF, patient's condition, and the risk of migration or reopening with the different types of stenting were examined using logistic regression analysis.
Results The final management of malignant EAF was esophageal stent in 21 patients, airway stent in 13, and dual stents in 16. No patients failed stenting. During a median follow-up of 178 days (range 1–893 days), the fistula reopened in 33 (66 %) of 50 patients. No factors, including fistula size, location, or initial selection of single or dual stenting, were correlated with reopening. Nineteen (57.6 %) of 33 patients needed restenting, and the reopened EAF was sealed off successfully in 52.6 % of new stent placements. The clinical failure of EAF closure was correlated only with proximal dilated esophagus ($p = 0.013$). Mean survival in patients with clinical success of EAF closure was also significantly longer than that in patients with clinical failure (242.0 vs. 80.1 days, $p < 0.001$). KPS ($p = 0.026$), cough ability ($p = 0.004$), successful closure of EAF ($p = 0.001$), and reopening ($p = 0.007$) all had significant effects on survival.
Conclusions We conclude that SECMS is safe and effective in the palliation of esophageal cancer with malignant EAF, especially in patients with an otherwise excellent general condition. Other modalities of management are recommended for malignant EAF with proximal dilation of the esophagus.

Keywords Esophageal squamous cell carcinoma · Esophago-airway fistula · Stent

Abbreviations

EAF	Esophago-airway fistula
KPS	Karnofsky Performance Scale
SECMS	Self-expandable covered metallic stents

Congenital abnormalities, trauma, infection, and tumors are the most common causes of esophago-airway fistula (EAF). This is a rare but life-threatening complication, with mortality rates up to 60 % due to repeated aspiration and poor nutritional intake. Treatment must correct the problem of airway contamination and restore the ability to ingest food. The treatment approach for patients with EAF depends on whether the fistula is benign or malignant in origin [1]. For patients with benign EAF, the treatment is definitive surgical correction. However, most patients with malignant EAF have advanced cancer, with a survival time of only weeks to months, and can only be managed with palliative treatment with esophageal and/or airway stents [1, 2]. Without prompt palliation, death occurs rapidly, with a mean survival time of between 1 and 6 weeks in patients who are treated with supportive care alone. Other

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uncommon treatment options for selected patients with malignant EAF include esophageal exclusion or surgical bypass, and fistula resection and repair [3–6]. The periprocedure mortality rate of stenting for these patients is 15 %, compared to a 29–47 % perioperative mortality for patients undergoing surgery [7].

However, the choice between a single airway stent, single esophageal stent, or dual stent for occlusion of an EAF is still controversial. Among these problems, recurrence of fistula or migration of stents remains the most important adverse event associated with self-expandable covered metallic stents (SECMS), occurring in approximately 10–20 % of patients, even in high-volume units [8, 9]. Moreover, stent- and patient-related problems persist and may require additional interventions for complications [10, 11]. The factors influencing the results of stenting for malignant EAF with different diseases are diverse [12]. Theoretically, dual stenting appears to work better than a single prosthesis both for effectiveness and for safety. Paganin et al. [13] reported that dual stent insertion in EAF may increase the efficiency of EAF closure. However, there were also some reports of unusual complications related to prosthesis placement as a treatment of this condition, such as pressure necrosis [12]. In this retrospective study, we investigated the therapeutic effects of single or dual stents, the preoperative condition of patients, and the size and location of the EAF as factors influencing clinical results in patients suffering from advanced esophageal cancer with malignant EAF managed with covered airway and/or esophageal stent placement.

Materials and methods

Study design and population

We retrospectively reviewed a total of 492 consecutive patients who underwent airway or esophageal SECMS stenting between June 2005 and December 2014 at the National Taiwan University Hospital. All patients with malignant EAF (including major airway fistula above the main bronchus and excluding esophago-pulmonary or esophago-pleural fistulas) secondary to esophageal squamous cell carcinoma were included in this study. Patients with adenocarcinoma were excluded from this study due to differences in the prognosis and survival of these patients. Patients who developed an EAF after undergoing esophagectomy were excluded from this series. All the stenting procedures were performed by two of the co-authors. This study was approved by the National Taiwan University Hospital Institutional Review Board. Medical records were reviewed for demographics, techniques of stent placement, clinical results, occurrences of dysphagia, and coughing associated with eating, fistula reopening, and associated morbidity. Complete survival follow-up was obtained in all patients.

Perioperative evaluation and stenting

Pretreatment evaluations included a complete medical history and physical examination, complete blood count test and biochemistry survey, chest radiography, a contrast study of the upper gastrointestinal tract using a water-soluble contrast medium, and computed tomography of the chest and abdomen. The location and size of the fistula was determined by bronchoscopy and esophagogastroscopy. Distention of the esophagus was defined as vestibule formation corresponding to other parts of the esophagus in the radiographic findings. This distention was best demonstrated by having the breath held during inspiration or through a Valsalva maneuver. In accordance with the basic principles of stenting, airway stenting was typically utilized in cases of EAF due to esophageal cancer with obstruction of the airway lumen, whereas esophageal stenting was employed for malignant EAF with esophageal obstruction, and dual stenting was applied in cases of malignant EAF with obstruction of both the airway and the esophagus. Placement of the esophageal stent (Ultraflex, Boston Scientific Corp, Natick, MA or Niti-S Oesophageal Covered Stent, Taewoong Medical, Korea) and the tracheobronchial stent (Ultraflex, Boston Scientific Corp, Natick, MA) was performed with flexible bronchoscope and esophagogastroscope guidance to determine the level of the EAF under general anesthesia. Propofol was added to deepen the cough reflex throughout the procedure. Prior to stenting, stepwise bougienage was performed for either airway or esophageal obstruction. After endoscopic placement of a 0.035-in. diameter guidewire (Dreamwire Stiff Shaft 0.035 in. × 260 cm; Boston Scientific, Natick, Mass), the stent was placed under endoscopic guidance without fluoroscopic monitoring. The airway SECMS, with a diameter range of 14–20 mm, and the esophageal SECMS, with a diameter range of 20–22 mm, were individually tailored according to the length and location of the fistula. The type, length, and number of fully covered stents used were at the discretion of the attending endoscopist. If airway stenosis with EAF was present, airway stents were inserted first, and in case of esophageal stenosis with EAF, an esophageal stent was inserted for both simultaneously. If the fistula was not satisfactorily closed by the first stent, a second stent was implanted subsequently.

Patients were extubated after completion of the operation and returned to an ordinary ward. A nasogastric tube was placed within the SECMS during the operation and kept in place until fistula occlusion was confirmed by endoscopy and contrast assessment. Upper gastrointestinal

barium study was performed in patients showing a stable condition 5 days after surgery to evaluate the function of the stent and its efficacy for occluding the fistula. This period was selected as the optimal time for the detection of the stent location after swallowing. Patients received intravenous supplemental artificial nourishment postoperatively. Patients who did not improve clinically after stenting or whose leak could not be sealed were evaluated through flexible bronchoscopy without fluoroscopy. Patients resumed oral feeding if no fistula was detected, gradually increasing their oral intake and advancing to an ordinary diet prior to discharge. When the extent of the SECMS is intact, patients can resume swallowing and can therefore be discharged from the hospital early. If leaks are present after stenting, endoscopy has the capacity to determine the viability of the fistula. Patients were then followed up clinically. Clinical improvement was determined by grading food intake capacity on a five-point scale: none, liquid, soft food, most food, or all food. In all patients, recurrence of dysphagia, hemorrhage, and dyspnea were indications for further endoscopy to exclude reopening of the fistula and occlusion of stents.

Statistical analysis

Data are presented as mean or median and range for continuous variables of patient characteristics, and as number and percentage for discrete variables. The differences between each stenting group were examined with Pearson's Chi-square test (Table 1). For categorical data, all associations between the outcomes and the potential predictors (Table 2) were compared using the Chi-square test. Continuous variables were compared using the Wilcoxon rank sum test or the Mann–Whitney *U* test, as appropriate. The significant factors were further analyzed using a logistic regression model, with forward selection of variables to obtain a final multivariable regression model. Survival curves were obtained and compared with log-rank tests and Kaplan–Meier methods. The effects of several risk factors on survival function were further explored with Cox proportional hazards regression. A p value < 0.05 was considered to be statistically significant. Statistical analyses were performed using SPSS version 17 (SPSS Inc., Chicago, IL).

Results

A total of 50 patients (48 men and 2 women, mean age 57.4 + 11.5 years, range 40–89) with endoscopically and radiographically proven malignant EAF were identified and retrospectively enrolled for analysis. Prior to stenting, there were 9 patients (18 %) with dysphagia, 23 (46 %) with aspiration, 10 (20 %) with postprandial cough, 33 (66 %) with pneumonia, and 3 (6 %) who required ventilation support in the intensive care unit. The EAFs were located in the cervical esophagus ($n = 6$, 12 %), upper thoracic esophagus ($n = 12$, 24 %), and middle thoracic esophagus ($n = 32$, 64 %). Assessment of the EAF positions in the airway detected them in the trachea ($n = 40$), left main bronchus ($n = 9$), and right main bronchus ($n = 1$). Thirty-five patients had a normal esophagus, and 15 had stricture and proximal distention. Four patients with EAF due to pressure necrosis caused by an initial esophageal stent placement for esophageal carcinoma were treated with SECMS. Thirty-three (66 %) patients received neo-adjuvant therapy prior to stenting. Among the three categories of stents, i.e., single airway stents, single esophageal stents, and dual stents, there were no differences with respect to age, sex, fistula size, symptoms, Karnofsky Performance Scale (KPS), or previous treatment (Table 1; Fig. 1). Airway stents were inserted in 13 (26 %) patients, esophageal stents in 21 (42 %) patients, and dual stents in 16 (32 %) patients (Fig. 1). Among the 50 patients, fistula closure allowing for significant oral nutrition was obtained in 28 patients before their death. Ventilation was weaned post-stenting in 1 intubated patient. Overall, the KPS increased significantly from a median of 53.2 % to a median of 60.2 % ($p < 0.001$).

Although five patients experienced chest pain after esophageal stenting, none of them required any additional analgesia. One patient had massive hemoptysis after tracheal stenting, and the bleeding was controlled with a second tracheal stenting via endotracheal intubation. Another patient underwent laminectomy due to esophageal stent compression of the vertebrae. Twenty-eight patients had to undergo retreatment due to a reopened EAF (Fig. 1), and 11/21 (52.43 %) of reopened EAF patients ultimately obtained a successful EAF sealing after restenting with an additional overlapping esophageal stent or tracheal stent. Appropriate deployment of a second stent improved the overall success rate and survival in these patients. However, most of the symptoms associated with EAF were pulmonary related (i.e., aspiration and pneumonia). Palliative therapy was also considered as an alternative to inserting additional stents if the initial stenting strategy failed to seal the fistula. A total of 7 patients received palliative treatment (5 gastrostomy and 2 tracheostomy) instead of repeated stenting in order to prevent or decrease pulmonary symptoms due to incomplete EAF sealing (initial clinical failure) with nutritional supplementation from an enteral feeding tube. Three patients experienced EAF reopening but did not receive any further management, such as enterostomy, tracheostomy, or restenting, because their family opted not to proceed due to the terminal stage of their cancer and sepsis.

Table 1 Demographic data of the patients with esophageal cancer and esophago-airway fistula status post-stenting

Characteristics	All ($n = 50$, %)	Final single airway stent ($n = 13$, %)	Final single esophageal stent ($n = 21$, %)	Final dual stent ($n = 16$, %)	p value
Age, mean	57.4 ± 11.5 (40–89)	54.5 ± 9.7	57.8 ± 12.6	59.3 ± 11.6	0.890
Gender, male/female	48/2	13/0	20/1	15/1	0.676
Site of fistula					0.347
Cervical esophagus	6 (12)	1 (7.7)	3 (14.3)	2 (12.5)	
Upper thoracic esophagus	12 (24)	5 (38.5)	2 (9.5)	5 (31.3)	
Middle thoracic esophagus	32 (64)	7 (53.8)	16 (76.2)	9 (56.9)	
Symptoms and signs					
Aspiration	23 (46)	9 (69.2)	7 (33.3)	7 (43.8)	0.122
Dyspnea	9 (18)	2 (15.2)	4 (19.0)	3 (18.8)	0.960
Cough	10 (20)	1 (7.7)	6 (28.6)	3 (18.8)	0.331
Pneumonia	33 (66)	12 (92.3)	12 (57.1)	9 (56.3)	0.066
Ventilator demand	3 (6)	0	3 (14.3)	0	0.110
Dysphagia score					0.325
0	5 (10)	0	2 (9.5)	3 (18.8)	
1	0	0	0	0	
2	10 (20)	4 (30.8)	4 (19.0)	2 (12.5)	
3	26 (52)	5 (38.5)	11 (52.4)	10 (62.5)	
4	4 (8)	4 (30.8)	4 (19.0)	1 (6.3)	
Proximal esophageal distention	15 (30)	4 (30.8)	6 (28.5)	5 (31.3)	0.982
KPS, mean	53.2 ± 13.8	49.2 ± 15.5	55.2 ± 11.7	53.8 ± 15.0	0.527
Previous treatment					0.054
None	17 (34)	1 (7.7)	10 (47.6)	6 (37.5)	
Chemoradiotherapy	33 (66)	12 (92.3)	11 (52.4)	10 (62.5)	

Moreover, an analysis of patient data according to their age, history, degree of dysphagia, preceding albumin, KPS, metastasis, cough, and dyspnea shows that no particular factor contributed to the reopening of EAF with univariate analysis (Table 2). While age ($p = 0.047$) and proximal esophageal distention ($p = 0.006$) were correlated to EAF closure failure in univariate analysis, only proximal esophageal distention ($p = 0.013$) had a statistically significant relationship in multinomial logistic regression analysis (Table 2). Underlying comorbidities and neo-adjuvant therapy were not significantly associated with the risk of fistula recurrence. An intention-to-treat analysis of the various stenting strategies (initial airway/esophageal stenting, then airway/esophageal stenting in cases of reopened EAF) instead of the final stent selection was also not statistically significant ($p = 0.330$) in cases of failure of EAF closure.

All patients died of their malignant disease, and all deaths were unrelated to the stent placement. Mean survival following stenting was 171 days (range 1–893 days), and there were no significant differences in survival time ($p = 0.222$) between the single airway stenting group, single esophageal stenting group, and dual stenting group. Patients with successful sealing of the EAF had better survival (80.1 vs. 242.0 days, $p < 0.001$) (Fig. 2). Multivariate Cox analysis indicated that performance status [adjusted odds ratio (OR) 0.97; $p = 0.026$; 95 % CI 0.95–1.0], cough symptoms (adjusted OR 4.0; $p = 0.004$; 95 % CI 1.5–10.1), and successful sealing of EAF (adjusted OR 6.0; $p = 0.001$; 95 % CI 2.4–14.7) were independent prognostic factors for survival, and the reopening of the EAF (adjusted OR 3.4; $p = 0.007$; 95 % CI 1.4–8.1) was associated with lower survival.

Discussion

For patients with locally advanced esophageal carcinoma, tracheal involvement with fistula is a devastating problem, and further curative resections do not yield satisfactory results. Patients mainly suffer from repeated respiratory infections. Expandable metallic stents are the treatment of choice for patients with malignant EAF [14]. Newer designs and modifications of stents are now available, with delivery systems that have been designed to facilitate using fibroscopy. The procedure is generally technically easy and

Table 2 Univariate analysis of different physiology variables of recurrent esophago-airway fistula (EAF) $n = 50$

Characteristics	Reopening of initial stenting group in EAF ($n = 33$)		Failed closure of final stenting group in EAF ($n = 22$)	
	n (%)	p value	n (%)	p value
Age, mean	57.3 ± 13.1	0.492	55.2 ± 13.0	0.047
Gender, male/female	31/2	0.300	22/0	0.201
Site of fistula				
Cervical esophagus	3 (9.1)	0.291	3 (13.6)	0.814
Upper thoracic esophagus	10 (30.3)		6 (27.3)	
Middle thoracic esophagus	20 (60.6)		13 (59.1)	
Size of fistula, mm	7.9 ± 6.5	0.291	8.4 ± 7.2	0.876
Symptoms and signs				
Aspiration	16 (48.5)	0.623	13 (59.1)	0.100
Dyspnea	6 (18.2)	0.963	4 (18.2)	0.976
Cough	6 (18.2)	0.654	3 (13.6)	0.319
Pneumonia	22 (66.7)	0.890	16 (72.7)	0.373
Preceding albumin, g/dL	3.08 ± 0.47	0.505	3.11 ± 0.54	0.573
Ventilator demand	2 (6.1)	0.980	2 (9.1)	0.415
Dysphagia score	2.7	0.637	3.0	0.418
Proximal esophageal dilation	11 (33.3)	0.474	11 (50)	0.006
KPS	51.5 ± 15.0	0.384	49.1 ± 16.9	0.148
Previous chemoradiotherapy	22 (66.7)	0.890	17 (77.3)	0.136
Metastasis	7 (21.2)	0.765	6 (27.3)	0.254
Initial stenting group				
Airway stent ($n = 20$)	15 (45.5)	0.167		
Esophageal stent ($n = 27$)	15 (45.5)			
Dual stent ($n = 3$)	3 (9.1)			
Final stenting group				
Airway stent ($n = 13$)			7 (31.8)	0.173
Esophageal stent ($n = 21$)			6 (27.3)	
Dual stent ($n = 20$)			9 (40.9)	

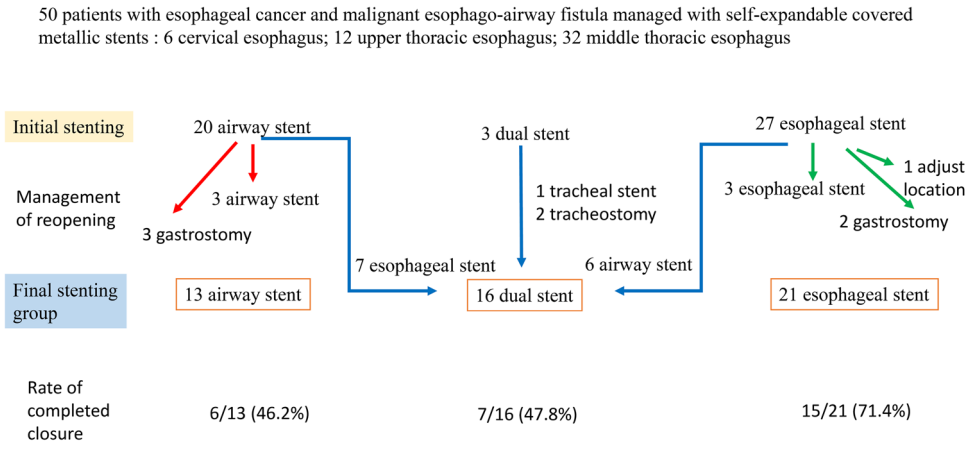

Fig. 1 CONSORT diagram of patients with esophageal cancer and malignant esophago-airway fistula managed with self-expandable covered metallic stents

well tolerated [15]. However, there is insufficient data regarding factors that may affect the success rate and complications of SECMS for malignant EAF. There are no current guidelines focused on stenting for esophageal cancer with malignant EAF. Moreover, any treatment for EAF in end-stage malignant EAF of the esophagus must be

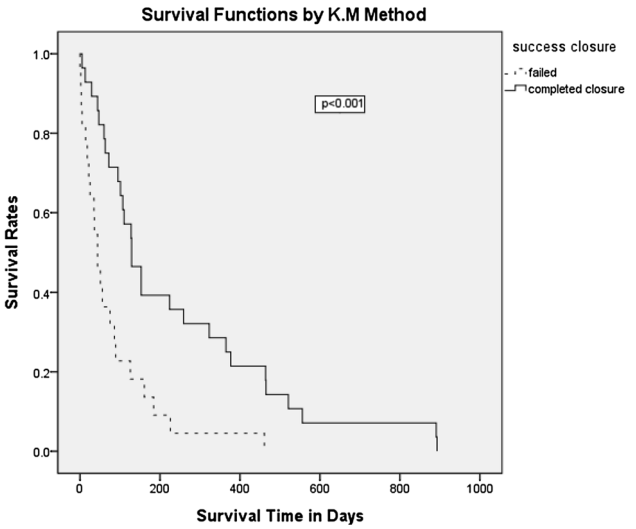

Fig. 2 Proportion of patients surviving with and without successful sealing of esophago-airway fistula managed with self-expandable covered metallic stents was calculated with the Kaplan–Meier method (242.0 vs. 80.1 days; log-rank test, $p < 0.001$; hazard ratio, 5.98; 95 % CI 2.43–14.71).

weighed against the associated morbidity and mortality. Patients are at increased risk of extended hospital stays due to insufficient treatment. Therefore, we retrospectively investigated the different approaches of airway stenting, esophageal stenting, or dual stenting in patients with esophageal cancer and malignant EAF.

Radiographic contrast swallow studies and dual endoscopy are normally used to evaluate the EAF before and after surgery. These examinations provide useful information about the integrity of the EAF, thus allowing timely management to ensure a quick recovery. Successful esophageal stenting improves respiratory symptoms, oral ingestion, and quality of life. In general, depending on the size and location of the tracheal aspect of the fistula, the potential benefits of esophageal stenting are healing without diversion or reconstruction and an early return to an oral diet. Therefore, it is one of the best palliative therapies for patients with malignant EAF. Accurate positioning is crucial in resuming an oral diet. Because insertion of a single stent may be insufficient for palliation, tracheal or dual (tracheal and esophageal) stenting has also been suggested as a valuable therapeutic option. The major concern of this study is that 66 % of patients failed initial stenting, the majority of whom had a single stent placed because the placement of two stents was not statistically predictive of treatment success. The successful sealing rate of EAF was not significantly different between the groups, and there was no significant difference in survival time between the groups. The principle of stenting therefore has to be in accordance with airway stenting for EAF due to airway compression. Lesions in close proximity to the cricopharyngeus can be successfully palliated without significant foreign body sensation in the majority of patients with use of airway stents [16]. For tumors obstructing the airway lumen, the primary goals of management are relief of obstruction of airway and closure of the EAF. Esophageal stenting has been recommended for gastrointestinal obstruction with malignant EAF or for those with EAF at the main carina [12, 17]. Dual stenting could be applied for malignant airway and esophageal obstruction [18]. The most important potential advantage of this management strategy is the reduction in aspiration and the delivery of a patent conduit for early oral feedings. The fistula size and location must be evaluated for the successful management of these patients, but these were not significant factors in successful closure of the EAF. Distention of the proximal esophageal was the only factor that contributed to reopening of EAF after stenting ($p = 0.013$). The self-expanding property of metal stents results in tight sealing of the fistula. However, particular attention has to be paid to patients with a proximally distended esophagus, which resulted into reopening of the EAF due to insufficient attachment between the stent and the fistula. The most likely explanation is that the degree of proximal distention of the esophagus has to be considered in the sealing of the fistula with stents. Overall, interventional treatment was effective for sealing off reopened EAFs in our study (52.43 %). Even so, patients after successful stenting could survive for 8 months or more, which is better than with persistent EAF.

The use of SECMS to treat EAF has a number of drawbacks, including possible migration and high rates of granulation formation, in particular in patients who had a past history of pneumonia [19] [20]. However, granulation formation did not play as important a problem with survival in this study because of the relatively early fatality due to esophageal cancer. Management using mucolytic agents and dilatation as necessary is recommended for stent-related strictures. Four patients with EAF caused by erosion secondary to esophageal stents for esophageal carcinoma were treated with restenting; this did not interfere with the successful sealing of the EAF. We believe that the condition of the EAF patients is important when deciding on management with stenting. Some articles have mentioned the increased risk of severe complications following placement of SECMS in patients with previous chemotherapy and/or radiation therapy [21]. However, 33 patients received radiation and chemotherapy before the fistula developed, which was not associated with an increased risk of life-threatening complications in our study [22]. Patients with high performance ($p = 0.026$) and cough symptoms ($p = 0.004$) showed significantly better expulsion of sputum and positive outcomes after

undergoing stenting. The patients had better survival when they still had good performance status, and they could receive further management such as chemotherapy. When the EAF is extensive and in particular when the patient's condition is deteriorating, avoiding oral intake and providing enteral feedings improves the chance of recovery of general performance and allows for further stenting. There were some critical patients who received a gastrostomy or tracheostomy instead of stenting. In this series, the incidence of persistent leak was an important indicator of poor prognosis ($p < 0.001$) in patients undergoing stenting for malignant EAF. Once a persistent EAF has developed, aspiration pneumonia is common and the overall condition of the patient declines rapidly. Because failed sealing of the EAF is a factor influencing survival in EAF managed with airway and/or esophageal stent insertion, these patients needed other alternative managements (gastrostomy, tracheostomy, etc.), and a newly designed stent with a larger diameter proximal flange for the residual fistula should be used in these cases.

Nevertheless, we acknowledge that our study has several limitations. First, the study did not have the best design possible to study the effects of an intervention on clinical outcomes, because the non-random allocation of patients to each group may have produced an unbalanced distribution of the relevant clinical characteristics. This might have affected the clinical outcomes, although these differences did not show up as significant because of the very limited number of patients. Second, performance status was analyzed, but quality of life after stenting was not. However, SECMS seems to be a useful and easily implemented treatment modality for patients with malignant EAF, which allows for efficient recovery of airway protection and resumption of oral feeds at a relatively low cost, especially when initiated early in the course of the disease. Well-designed prospective clinical trials involving more accurate control of variables are necessary to analyze the effectiveness of SECMS.

Conclusions

Implantation of SECMS proved to be an effective and feasible method of palliating dysphagia and occluding malignant EAF without any major procedure-related complications. Improvements in performance status and successful treatment for malignant EAF may improve survival.

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Compliance with ethical standards

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