



# TECHNICAL DIFFICULTIES AND PROCEDURAL COMPLICATIONS IN CLOSING MALIGNANT ESOPHAGEAL-RESPIRATORY FISTULAS

Andrei Cozorici<sup>1</sup>, Vlad Porumb<sup>2</sup>, Sorinel Lunca<sup>2</sup>, Ioana Grigoras<sup>3</sup>, Irina Ristescu<sup>3</sup>,  
Iulia Jitaru<sup>3</sup>, Emilia Patrascanu<sup>3</sup>, Laura Gavril<sup>3</sup> and Gabriel Dimofte<sup>2</sup>

<sup>1</sup>Gastroenterology Department, Iasi Regional Institute of Oncology, Iasi, Romania;

<sup>2</sup>Grigore T. Popa University of Medicine and Pharmacy; Faculty of Medicine, Surgery Department 2, Iasi Regional Institute of Oncology, Iasi, Romania;

<sup>3</sup>Iasi University of Medicine and Pharmacy, Faculty of Medicine, Anesthesiology and Intensive Care Department, Iasi Regional Institute of Oncology, Iasi, Romania

**SUMMARY** – The aim of the study was to outline technical difficulties and procedural complications of using partially covered esophageal self-expandable metal stents (SEMSs) in malignant esophageal respiratory fistulas (ERFs) as a palliative treatment option. In this study, 150 patients with malignant dysphagia underwent treatment with SEMSs. A total of 36 ERFs were detected through endoscopic or clinical assessment. Complete fistula sealing with SEMSs was possible in 35 of the 36 patients. The majority of fistulas were diagnosed in male patients with advanced esophageal cancer. All of them presented with prolonged dysphagia and cachexia. Stent migration or tumoral overgrowth was identified in 6 cases with recurrent dysphagia, and required a second stent insertion. SEMSs were highly efficient in 98% of the patients studied with ERFs, with successfully sealed ERFs after the first attempt, with an overall median survival rate of 92 days. The technique of esophageal SEMS placement is simple and can be rapidly mastered. Patients with ERFs have a respiratory shunt that makes intubation difficult and is often avoided. Restoring oral feeding increased the patient quality of life. SEMS placement is generally safe, but has few associated postoperative complications.

**Key words:** *Esophageal respiratory fistulas (ERFs); Covered self-expandable esophageal metal stents; Stenting complications*

## Introduction

Locally advanced esophageal cancer, advanced bronchogenic cancer or mediastinal tumors can become complicated with esophageal-respiratory fistulas (ERFs). ERFs represent a pathology characterized by the presence of an abnormal communication between the respiratory tree and the esophagus. This is caused by growing and local invasion of cancer. The conse-

quences of permanent pulmonary contamination by food containing and digestive secretions can lead to abscess and respiratory failure. Clinical examinations are not sufficient to establish this disease diagnosis. These patients require complementary exams including chest x-ray with or without barium solutions or water-soluble contrast, esophagoscopy, bronchoscopy, and thoracic computed tomography (CT) scans<sup>1-3</sup>.

Radiotherapy-induced necrosis and pressure necrosis secondary to a previously placed self-expandable metal stent (SEMS) may also cause ERFs.

The presence of a fistula leads to aspiration of saliva or food into the respiratory tract and development of pneumonia, often followed by lung abscess. If left un-

Correspondence to: *Assist. Prof. Vlad Porumb, MD, PhD*, Surgery Department 2, Iasi Regional Institute of Oncology, Henri Mathias Berthelot 2-4 Street, Iași 700483, Romania  
E-mail: porumbvlad@ymail.com

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Table 1. Complications related to esophageal self-expandable metal stent placement

Intraprocedural	Early postprocedural	Late postprocedural
<ul style="list-style-type: none"> <li>• Tracheobronchial perforation and pneumothorax</li> <li>• Bleeding</li> <li>• Aspiration</li> <li>• Over sedation</li> <li>• Drug reactions</li> <li>• Stent misplacement</li> <li>• Chest pain</li> <li>• Procedural infection</li> </ul>	<ul style="list-style-type: none"> <li>• Bleeding</li> <li>• Chest pain</li> <li>• Tracheal compression /respiratory arrest</li> <li>• Stent migration</li> </ul>	<ul style="list-style-type: none"> <li>• Bleeding</li> <li>• Recurrent dysphagia</li> <li>• Food impaction</li> <li>• Tumor overgrowth</li> <li>• Tumor ingrowth</li> <li>• Stent migration</li> <li>• Recurrent fistulas</li> <li>• Gastro-esophageal reflux</li> <li>• Halitosis</li> <li>• Infection and septic shock</li> <li>• Small bowel occlusion</li> </ul>

Table 2. Patient characteristics

Age (years)		48-85 (mean 62.4)
Gender		Female, n=4 Male, n=32
Origin of fistulas		Esophageal cancer, n=27 Pulmonary/mediastinal cancer, n=9
Histopathologic type	Esophageal cancer	Squamous cell carcinoma, n=20 Adenocarcinoma, n=5 Signet ring cell carcinoma, n=2
	Bronchogenic cancer	Squamous cell carcinoma, n=2 Adenocarcinoma, n=2 Small cell carcinoma, n=5
Localization of stenosis/fistulas		Upper esophagus, n=6 Middle esophagus, n=26 Lower esophagus, n=4

treated, ERFs are associated with a life expectancy of weeks. A direct consequence is a very poor quality of life of these patients, and the only logical approach is to close this abnormal communication using either esophageal stents, tracheal stents, or both<sup>4-6</sup>.

Self-expandable metal stents allow for immediate closure of fistulas, with major improvement of the quality of life and increase in the overall survival up to 6 months, but the procedure may be associated with several complications (Table 1)<sup>7</sup>. Procedural complications are associated with oversedation, aspiration, drug reactions, and stent misplacement<sup>8,9</sup>. The most common early complications are bleeding, chest pain and tracheal compression, while typical late complications are bleeding, gastroesophageal reflux, recurrent dys-

phagia by tumor overgrowth or stent migration, and recurrent fistula<sup>8,10</sup>. There are few reports of bowel obstruction due to a migrated stent. In most cases, the prevalence of complications ranges from 10% to 30%<sup>11</sup>. Factors associated with a higher incidence of complications are related to tumor size and location, use of concomitant chemotherapy or radiation therapy (that increase the risk of stent migration), and, of course, the characteristics of the prosthesis itself, such as diameter, length and design.

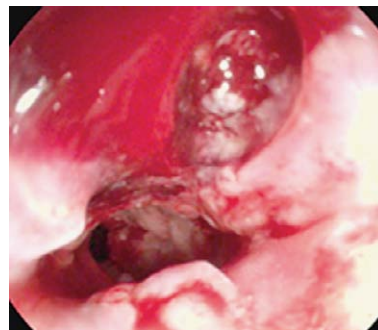
Esophageal-respiratory fistulas are life-threatening situations, thus closure of fistulas is the first aim of palliative treatment, and SEMSs represent the therapeutic gold standard, as shown by clinical experience over the last 30 years<sup>12</sup>.

## Materials and Methods

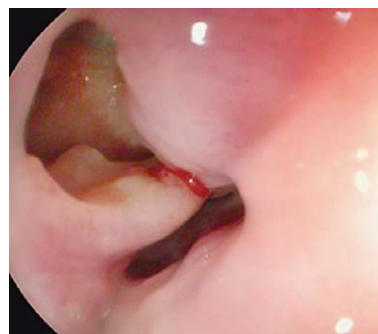
In this study, 150 patients with malignant dysphagia underwent treatment with SEMSs. A total of 36 ERFs were detected, either as clinically manifested fistulas or incidentally during endoscopic assessment. The study was retrospective and patients were followed up in our oncology service, and for those who did not show up for follow up or treatment, we turned to the police digital database to collect the date of death. The mean age of our patients was 62.4 (range 48-85) years; and it was striking that ERFs were mostly encountered in patients of low socioeconomic status. The vast majority of fistulas were detected in men, usually with a long history of dysphagia and significant cachexia. In most cases, the tumor originated in the thoracic esophagus, which is almost always the site of ERFs. Patient characteristics are listed in Table 2.

In all cases, biopsy obtained either during endoscopy or bronchoscopy confirmed the tumor. Before making a therapeutic decision, all patients were assessed by thoracic and abdominal CT scan with intravenous contrast. Even though the CT scan is important in the diagnostic stage, nine patients had subclinical fistulas that were not demonstrated on CT scan. Thus, ERFs are best evaluated by endoscopy just before stent placement (Figs. 1 and 2).

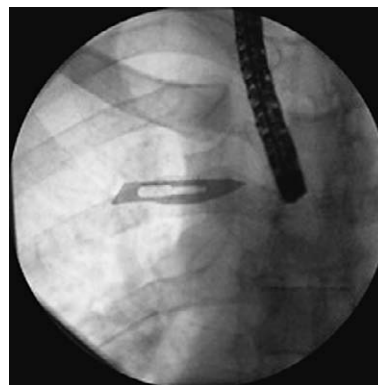
The stenting procedure was similar in all patients. Upper endoscopy was performed first to establish the limits of the esophageal stricture and radio-opaque skin markers were added for better placement (Fig. 3). The upper limit is essential in proximally situated fistulas because stent expansion requires 2 cm of macroscopically normal esophagus for the non-covered proximal part of the stent in order to prevent stent migration, but also to ensure correct coverage of fistulous tract with the covered part of the stent. We used gastroscopes with a diameter of 9.6 mm and 2.8-mm working channel. A metal guidewire was advanced through the malignant stricture under endoscopic and fluoroscopic guidance (Fig. 4). It is important to note that in tight stenosis of the esophagus, the wire frequently passes through the fistula and makes finding the correct esophageal lumen difficult. Misplacement of a stent in the ERF can have dramatic consequences and all precautions should be taken to evaluate the correct position. Partially covered Nitinol stents were used (Ultraflex™, Wallstent™, Boston Scientific, Ni-



*Fig. 1. Esophageal squamous cell carcinoma with esophageal-respiratory fistula.*



*Fig. 2. Bronchogenic squamous cell carcinoma with esophageal-respiratory fistula.*



*Fig. 3. Radio-opaque skin.*

ti-S™ Esophageal Stent, Taewoong Medical, South Korea) with proximal deployment, adding significant advantages for proximal ERFs, as the upper limit can be better positioned in relation to the pharyngo-esophageal junction. The length of the stent was chosen to be by at least 4 cm longer than the malignant stricture, in order to allow for adequate space for expansion of the proximal and distal parts of the stent and provide support against stent migration. We used

stents ranging from 70-180 mm in length and 10-23 mm diameter (Fig. 5). Stents were inserted over the guidewire using the radio-opaque markings for positioning under fluoroscopic guidance (Figs. 4 and 6).

Anesthetic problems were mostly due to the known ERF and changes in pressure balance across the fistula during intubation. Intubation was considered prohibited, mostly in large distal fistulas that cannot be func-



Fig. 4. Radio-opaque guidewire and skin markers.

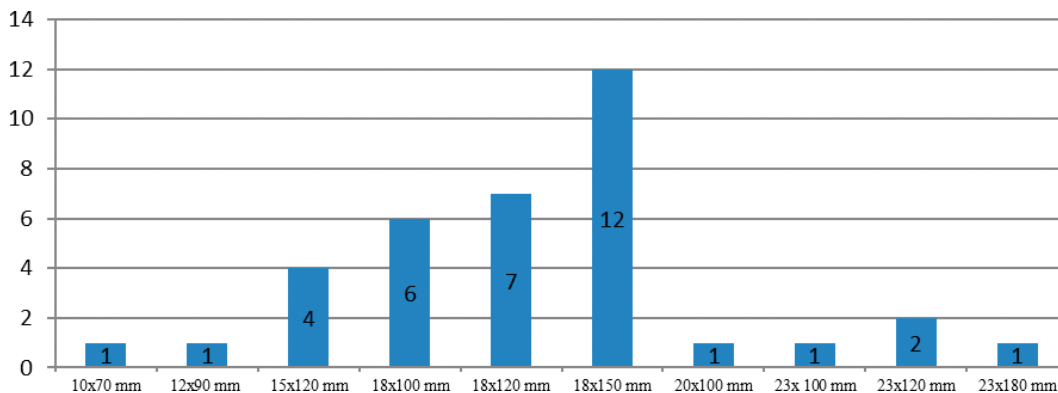


Fig. 5. Stents ranging in length and diameter.

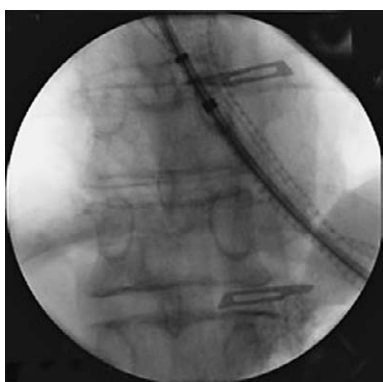


Fig. 6. Complete stent.

tionally isolated with the intubation cannula. We used topical anesthesia with 10% lidocaine and light intravenous sedation with a combination of midazolam and propofol. The procedure needs to be fast and precise to avoid major aspiration into respiratory tract and secondary desaturation.

The study was reviewed and approved by the Ethics Committee of the Iasi Regional Institute of Oncology Review Board. All study participants, or their legal guardians, provided informed written consent prior to study enrolment.

## Results

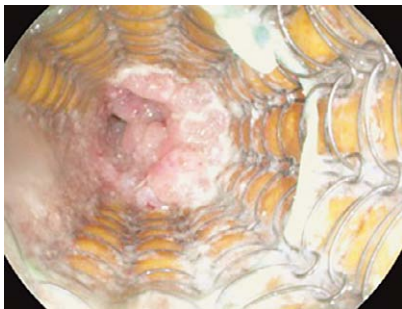
Correct stent positioning was achieved in 98% of patients with ERFs, and in all these cases fistulas were effectively sealed. In one case (2%), the fistula was extremely large and the esophageal lumen could not be identified safely; the gastroscop was only able to pass through the fistula while the guidewire advanced under visual and radiological control was following a trajectory

suggestive of a bronchial tract. Considering the respiratory status of the patient, the procedure was abandoned and the patient underwent surgical gastrostomy.

In two cases, we decided to dilate the stenosis prior to SEMS placement. We used 9-mm Savary bougies under fluoroscopic guidance, in a single step, without associated complications (Fig. 7). We are not in favor of pre-dilatation for two reasons: dilatation increases procedure time and increases the risk of major respiratory complications associated with fistula; and dilatation under light sedation may pose significant discomfort to the patient.



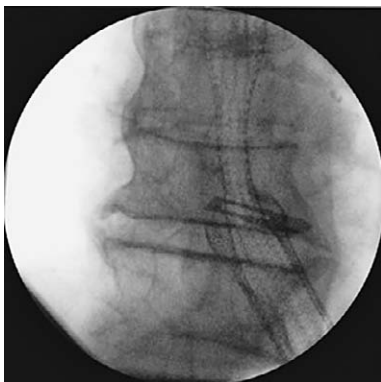
*Fig. 7. Predilation using Savary.*



*Fig. 8. Recurrent dysphagia due to distal tumor.*



*Fig. 9. Gastric migrated stent.*



*Fig. 10. Stent in stent.*

Fistula sealing was achieved in all 35 cases in which the procedure was completed. The position of the stent was not re-evaluated endoscopically as deployment was fluoroscopically confirmed and the covered part overlapped the fistula. Patients were allowed to drink liquids on the same day of the procedure and were recommended to start eating a diet with soft foods the day after the operation. A semisolid diet was advised after stenting and carbohydrate drinks were indicated after meals as these may be helpful in cleaning and we assume help in the prevention of food impaction.

All patients experienced thoracic discomfort after the procedure, requiring pain medication. In severe chest pain, opioids were indicated for short periods of time. In all cases, symptoms were alleviated within 48 hours. There were no postprocedural complications and patients were discharged on postoperative day 2 or 3 but in many patients, respiratory problems required further medical care in respiratory or palliative care units. There were 6 cases of recurrent dysphagia (17.14%) due to tumor overgrowth (Fig. 8) or distal stent migration (Fig. 9). A second stent was placed and oral feeding was restored (Fig. 10). In three patients with SEMS passing across the gastroesophageal junction, gastroesophageal reflux was symptomatic. All were managed with proton pump inhibitors and treatment was continued for symptom control.

Median survival rate was 92 (range, 12-233) days. Life expectancy was influenced by patient medical history and associated comorbidities, with respiratory problems being the most important ones in the immediate postprocedural period. We need to underline that stent placement in patients with ERFs increases the quality of life by simple restoration of swallowing and oral feeding.

## Discussion

Esophageal cancer patients with ERF are not candidates for radiotherapy or major surgical procedures, and the main focus in their management remains palliation. Esophageal stenting combines the benefit of restoration of oral feeding and sealing aero-digestive fistulas. The only surgical alternatives, i.e. esophagostomy or gastrostomy, come with a quality of life that is unacceptable and while allowing enteral nutrition, do not ensure adequate prevention of fluid aspiration in the respiratory tract<sup>13-15</sup>.



Esophageal-respiratory fistulas are generally suspected in cases with a history of coughing, dyspnea and choking associated with oral feeding but in some cases, fistulas are clinically silent. However, the diagnosis is confirmed on endoscopy and, in some instances, on staging CT scans. The ERF can be identified in upper gastrointestinal studies using water-soluble contrast and everybody should be aware of the risks associated with barium passing in the respiratory tract. Severe pulmonary fibrosis and granulomatosis associated with barium usage can alter CT scan interpretation. Furthermore, lung tissue may suffer degradation and if surgery is still an option, technical difficulties may be encountered. Nevertheless, barium meal remains an option when a fistula is not expected. False deglutition with barium aspiration is very common, even more so in old patients, and can mislead the endoscopist in terms of fistula location. Barium meal is typically conclusive in large fistulas but small ERFs may be missed and detected incidentally during the stenting procedure.

Diagnosis of ERF can be suggested by clinical presentation, patients having a history of choking or recurrent respiratory problems. In some cases, respiratory problems are overlooked during initial evaluation of dysphagia or considered outside the esophageal syndrome, with consecutively delayed diagnostics. Contrast media esophageal-gastric studies are still considered by many a standard in the evaluation of dysphagia, hence many ERF cases present with a positive image documenting contrast in the bronchial system. While barium is contraindicated in such cases, patients often present to our department after a fistula was documented in this way, as major dysphagia (often 90% obstruction of esophageal lumen) prevents clinically significant food aspiration. CT scan is, in our experience, less accurate in identifying small ERF while large communications are obviously easy to identify. Our standard procedure is to actively look for fistulas during endoscopic evaluation and very often we identify fistulas of little or no clinical significance.

Anesthesia in patients with ERF poses major problems. Light sedation is generally preferred to orotracheal intubation, as patients with ERFs have a respiratory shunt that has a fragile pressure balance. During normal respiratory movement, the shunt may have minimal significance, but it changes dramatically during positive pressure ventilation, when resistance to air

flow is greater in the respiratory tract than in the digestive tract. Most patients have associated respiratory alterations, due to pneumonia, or lung abscess. While hypoventilation is an issue in favor of orotracheal intubation, fistulas that are situated below the intubation catheter balloon prohibit efficient ventilation and may develop into a life-threatening situation.

The placement of SEMS in ERFs is not a blind procedure<sup>16</sup>; our experience confirms that precise placement is possible and fluoroscopic guidance gives accurate information regarding anatomy and position. Indeed, insufflation is not as effective as in a normal esophagus. Respiratory arrest may be due to failure in sealing the fistula due to stent migration, as suggested by the authors and we agree with the problems associated with positive pressure ventilation<sup>16</sup>. In our experience, stent placement took five to ten minutes and the patients that underwent this procedure suffered minimal discomfort and were exposed to minimal risks.

Prior to stent placement, one should be sure of the macroscopic tumor length and exact position of the fistula. In our series, the stent covered in excess the entire length of the tumor, in such cases, precise location of the fistula being irrelevant. Correct stent placement was confirmed by evaluating the shape of the metal structure, which maintained an hourglass shape in most cases, and our policy is against endoscopic re-evaluation after the procedure, mostly on order to reduce the risk of migration of a stent not fully distended. All patients in the study resumed semi-solid oral feeding, thus confirming the functional result.

In general, esophageal SEMS placement can be performed without procedural complications or technical difficulties<sup>17</sup>. Tumors located less than 2 cm from the upper esophageal sphincter are not a good indication for SEMS as tumor coverage will either be incomplete, or major discomfort will be experienced due to a stent positioned in the lower part of the pharynx. If stenosis is complete, inability to safely pass the guidewire is a contraindication for the procedure. In these cases, tracheal stents should be considered and a surgical alternative for enteral feeding should be recommended.

After the procedure, thoracic pressure or pain is common and expected. We prefer to inform patients that pain is highly probable. Thoracic pain is not considered as a complication unless it requires major pain medication for more than 48 hours. Eroglu *et al.* report an overall complication rate of 31.7%, not including

chest pain<sup>18</sup>. These findings are different from the data collected in our study. Stent migration can be an important complication related to SEMS placement and patients should be informed about this complication<sup>19,20</sup>. Patients who do not comply with the recommended dietary regimen may suffer from early stent migration, precipitated by food impaction. A semisolid diet over the first two to three weeks after stent deployment is recommended, as well as incorporating carbonated beverages during and after each meal.

Chemoradiation changes or strong peristaltic esophageal contractions can be responsible for stent dislodgment. Only one case of stent migration was encountered in our study, but we need to underline that the life expectancy in ERF patients is very short. Removing SEMS endoscopically or even trying to reposition the stent is difficult and rarely attempted. Instead, if the current stent is not well positioned, a second stent may be placed in the desired location. ERFs are life-threatening in patients with limited life expectancy. The median life expectancy in this series was 92 days, similar to other studies that report a median life expectancy of 40 to 110 days<sup>21,22</sup>. Early mortality within the first 30 days was 2.8%, which is in accordance with data cited in the literature<sup>23</sup>. Long-term survival, as well as quality of life may be negatively influenced by recurrent dysphagia as a result of tumor overgrowth. This was observed in 14.28% of patients in this study and was a common complication cited in other studies<sup>24</sup>. Paradoxically, the overall survival rates were highest in these cases (145-233 days), probably due to predominant longitudinal spread along the esophageal wall and a slow growing rate. As a common complication, we will expect it if patients survive long enough and can be easily treated with a second SEMS.

## Conclusions

Esophageal-respiratory fistulas are life-threatening complications of mediastinal tumors, and are associated with severe septic pulmonary complications and short life expectancy. The endoscopic placement of covered esophageal SEMSs is the treatment of choice for malignant ERFs. The overall survival rates after SEMS placement are much higher and improvement in the quality of life is obvious.

The technique of esophageal SEMS placement is simple and can be rapidly performed by any skilled en-

doscopist. Complications include bolus impaction, stent migration, and tumor overgrowth. Restoration of oral feeding is swift and represents the single most important benefit for the patient, for whom dysphagia and food aspiration in the bronchial system add discomfort and life-threatening risks.

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## Sažetak

### TEHNIČKE POTEŠKOĆE I PROCEDURALNE KOMPLIKACIJE ZATVARANJA MALIGNNIH EZOFAGUSNIH RESPIRACIJSKIH FISTULA

*A. Cozorici, V. Porumb, S. Lunca, I. Grigoras, I. Ristescu, I. Jitaru, E. Patrascanu, L. Gavril i G. Dimofte*

Cilj istraživanja bio je utvrditi tehničke poteškoće i proceduralne komplikacije povezane s primjenom djelomice pokrivnih ezofagusnih samoširećih metalnih stentova (*self-expandable metal stent*, SEMS) kod malignih ezofagusnih respiracijskih fistula (ERF) kao opcije palijativne skrbi. U ovom istraživanju je liječenje pomoću SEMS-a primijenjeno u 150 bolesnika s malignom disfagijom. Endoskopskom ili kliničkom procjenom otkriveno je ukupno 36 ERF-a. Potpuno zatvaranje fistule pomoću SEMS-a bilo je moguće u 35 od 36 bolesnika. Većina fistula dijagnosticirana je u muškaraca s uznapredovalim rakom jednjaka. Svi su patili od dugotrajne disfagije i kaheksije. Migriranje stenta ili njegovo prerastanje tumorom utvrđeno je u 6 slučajeva opetovane disfagije i zahtijevalo je uvođenje drugog stenta. SEMS se pokazao visoko učinkovitim u 98% uključenih bolesnika s ERF-om, ERF su uspješno zatvorene u prvom pokušaju, a sveukupni medijan stope preživljenja bio je 92 dana. Tehnika postavljanja ezofagusnog SEMS-a je jednostavna i može se brzo usvojiti. U bolesnika s ERF-om respiracija je skrenuta pa je intubacija teška i često se izbjegava. Ponovno uspostavljanje hranjenja na usta poboljšava bolesnikovu kvalitetu života. Postavljanje SEMS-a uglavnom je sigurno, ali povezano s nekim poslijeoperacijskim komplikacijama.

**Ključne riječi:** *Ezofagusne respiracijske fistule (ERF); Pokriveni samošireći ezofagusni metalni stentovi; Komplikacije postavljanja stenta*