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Metallic Stent and Flexible Bronchoscopy without Fluoroscopy for Acute Respiratory Failure

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Abstract

Stent implantation has been reported to facilitate liberation from mechanical ventilation in patients with respiratory failure due to central airway disease. This retrospective cohort study sought to evaluate the risk and benefit of stent implantation via bronchoscopy without fluoroscopic guidance in mechanically ventilated patients.

From July 2001 to September 2006, 26 patients with acute respiratory failure were recruited for this study. A bronchoscope was inserted through mouth guard into the space between tracheal wall and endotracheal tube. A guidewire was inserted via the flexible bronchoscope to the lesion site. The bronchoscope was reintroduced through the endotracheal tube. Under bronchoscopic visualization, the delivery catheter was advanced over the guidewire to deploy the stent.

These procedures were successfully performed in 26 patients, with 22 stents placed in the trachea and 7 in the main bronchus. Fourteen (53.8%) of the 26 patients became ventilator independent during their ICU stay. Severe pneumonia (7 [58.3%] of 12 patients) was the most common cause for continued ventilator dependence after stenting. Granulation tissue formation was found in seven patients during the follow-up periods.

It is concluded that metallic stents can be safely implanted without fluoroscopic guidance in respiratory failure patients to facilitate ventilator independence.

Introduction

Patients who have symptoms associated with central airway lesions should be treated with a multidisciplinary approach, including surgical, medical, and endoscopic intervention [1–3]. Self-expandable metallic stents (SEMSs) have been widely used to treat patients with benign and malignant airway diseases during the past decade and have been successfully implanted using a flexible bronchoscope while the patient receives conscious sedation and a local anesthetic [4–6]. Because of potentially hazardous complications, the United States Food and Drug Administration has warned that SEMS implantation should be considered only if the patient is not eligible for surgery, rigid bronchoscopy, or silicone stent implantation. For patients who are not candidates for surgery or general anesthesia, SEMS implantation may provide a good alternative [7]. Covered SEMSs have been used to seal off tracheoesophageal fistulas and to avoid aspiration symptoms [8–10].

Among patients with obstruction of the trachea and mainstem bronchi, respiratory failure is one of the most severe complications. Because of advances in endobronchial stents and insertion techniques, interventional bronchoscopic procedures have been reported to facilitate weaning from mechanical ventilation [11–14]. Rigid bronchoscopy under general anesthesia and flexible bronchoscopy under fluoroscopic guidance are the most common methods of stent implantation in mechanically ventilated patients. Some patients, however, are not candidates for surgical intervention or rigid bronchoscopy with a general anesthetic, because of illness

severity and comorbidities or because they refuse surgery. In addition, fluoroscopy requires special facilities that may not be available in every intensive care unit (ICU). Thus, we have developed a modified procedure to implant stents by using flexible bronchoscopy without fluoroscopic guidance in mechanically ventilated patients who are in our ICU.

This study was designed to evaluate the safety, efficacy, and complications of this procedure. Furthermore, the possible causes of failure of the procedure to eliminate the need for a mechanical ventilator were identified.

Materials and Methods

Patient recruitment

From July 2001 to September 2006, 29 tracheobronchial stents were implanted in 26 consecutive patients with respiratory failure associated with central airway obstruction or fistula in an ICU of a tertiary hospital. Informed consent was obtained from each patient or surrogate prior to this procedure. Most of our patients (21/26) had malignant diseases with advanced stage with or without complications. For those with benign lesions, other medical conditions or complications precluded some of them from surgical correction. Because of illness severity, poor surgical risk, or surgical refusal, none of these patients were candidates for surgery or stent implantation under rigid bronchoscopy**.** Patients' baseline characteristics are shown in table 1. Ventilator liberation was defined as successful if reintubation was not required within 48 h after endotracheal extubation.

Bronchoscopic procedure

Ultraflex SEMSs (Boston Scientific, Natick, MA) were used in all patients in this study. All patients underwent SEMS implantation by means of flexible bronchoscopy without fluoroscopic guidance. The length and type of stent to be used (with or without cover) were evaluated by endoscopic examination and chest computed tomography (CT) scan if a CT scan is available before stent implantation. Each patient underwent fiberoptic bronchoscopy as previously described [15]. Briefly, sedation with intravenous midazolam (5 mg) and a local

anesthetic with 2% xylocaine solution were administrated prior to bronchoscopy. The bronchoscope was first inserted through a mouth guard into the space between tracheal wall and endotracheal tube. The bronchoscope was navigated to the proximal end of the lesion (fig. 1). If the lesion was at the level of higher than the tip of endotracheal tube, the endotracheal tube was withdrawn to provide adequate view and space for stent implantation. A guidewire was inserted via the bronchoscope to pass through the lesion (fig. 2). The bronchoscope was withdrawn, leaving the guidewire at the lesion site (fig. 3). The bronchoscope was then reintroduced into the endotracheal tube to inspect the location of the guidewire. Under bronchoscopic visualization, the delivery catheter was advanced over the guidewire to deploy the stent (fig. 4). The delivery catheter, guidewire, and bronchoscope were then withdrawn, leaving the stent in the lesion site (fig. 5). After complement of stent deployment, the bronchoscope was introduced to check the position of the stent. If fine-positioned distally is indicated, we use the biopsy forceps (FB-15C-1, Olympus, Tokyo, Japan) to hold the distal ring of stent and push the stent forward to adjust the position. If fine-positioned proximally is indicated, the biopsy forceps was introduced to hold the proximal ring of the stent and pull backward to adjust the position. The fine-positioned procedures were feasible before full expansion of stents (<24-48 hours of stenting).

The majority of stents could be assessed by direct visualization by bronchoscopy right after the deployment of the stent. For those with larger diameter stents, we used bronchoscope

and guide-wire to determine the location and length of stent. Marked the delivery catheter with the same scale and deployed the stent when it has arrived at the pre-determined level. The position of stent was assessed by bronchoscopy and chest radiological study to ensure the proper position of stent.

Assessment of stent condition

Each patient underwent bronchoscopic examination 1 wk after SEMS implantation, and then every 3–6 mo thereafter to evaluate the position of stent, intactness of stent, granuloma formation, and the alignment of the airway before and after stent implantation. If breathlessness, intractable coughing, increased mucus production, or stent-related symptoms occurred, additional bronchoscopic examination was performed for further assessment.

Statistical analysis

Data were expressed as mean± stand deviation (SD). The factors potentially associated with successful liberation from mechanically ventilator were compared using the Fisher exact test. Odds ratios (OR) and their 95% confidence intervals (CI) were used to assess the difference.

Results

The patients' baseline characteristics are summarized in table 1. All procedures were performed successfully. The procedure time was 24.2±8.8 minutes (mean±SD). During the procedure, 100% of oxygenation and assistant/control mode ventilator support were given to the patients. All the patients were under pulse oximeter and arterial line monitoring for oxygen saturation and blood pressure, respectively. There was no desaturation below 90% or hypotension (systolic blood pressure < 90 mmHg) requiring medical intervention during or after this procedure. Malignant diseases contributed to lesions in 21 of the patients; esophageal cancer was the most common etiology followed by lung cancer and buccal cancer. The locations and causes of central airway lesions are summarized in Table 2. Tracheoesophageal fistula, tumor invasion, and tumor compression were the three most common causes for stent implantation. The 22 tracheal stents ranged in size from 16 mm x 4 cm (n=1), 16 x 8 (n=2), 18 x 4 (n=3), 18 x 6 (n=8), 20 x 6 (n=4) to 20 mm x 8 cm (n=4) and were chosen according to the lesion sizes; two of then were uncovered. The seven main bronchus stents ranged in sized from 10 mm x 4 cm (n=1), 12 x 4 (n=1), 14 x 4 (n=3), 16 x 6 (n=1) to 18 mm x 6 cm (n=1), and all of them were covered.

The time between development of respiratory failure and stent implantation was 3 to 25 d (median 5.5 d). Fourteen patients (53.8%) were successfully liberated from ventilators after stent implantation. Figure 6 shows the proportion of patients remaining on mechanical

ventilation within 30 d after stent implantation. Among the patients who were successfully liberated from ventilators, 13 (92.9%) were liberated from the ventilator within 1 d after stent implantation, and one patient became ventilator independent 8 d after stent implantation. Thirteen of the 14 patients were transferred to a lower level care unit (*e.g.,* ordinary ward or respiratory care center); the time to transfer to lower level care ranged from 1 to 119 d (median 5 d). The overall mortality rate was 57.7%; patients successfully and unsuccessfully liberated were 35.7 and 83.3%, respectively. The median number of survival days for the whole cohort was 30.5 d (3–473 d); the median number of survival days for patients who were ventilator independent and ventilator dependent was 34.5 days (9–473 days) and 21.0 days (3–159 days), respectively.

The factors potentially associated with liberation from mechanically ventilator are listed in table 3. However, none of these factors appeared to be different between patients with ventilator liberation success and those with ventilator liberation failure. The causes of ventilator liberation failure are shown in table 4. Complications related to stent implantation are listed in table 5. Granulation tissue formation was found in seven patients during the follow-up periods of up to 473 d (median 30.5 d). Symptomatic mucus plugging occurred in one patient and was resolved after a subsequent bronchoscopic procedure. Stent migration developed in one patient. The stent was adjusted in second bronchoscopic procedure. An episode of pneumothorax occurred 2 h after stent implantation and resolved spontaneously.

Discussion

The newly developed method of SEMS implantation using flexible bronchoscopy without fluoroscopic guidance was successful in all patients with acute respiratory failure from central airway lesions. The time required for stent implantation was 24.2±8.8 minutes. Successful ventilator liberation rate after stent implantation was 53.8%. Severe pneumonia was the most common cause for ventilator liberation failures. No life-threatening complications developed as a result this procedure.

The average diameter of the adult trachea is more then 20 mm [16]. The inner diameter of an endotracheal tube is 7.5 mm and outer diameter is 10 to 11 mm. When using a 7.26-mm-diameter No. 22Fr delivery catheter and given the elastic character of the trachea, there is enough space for the catheter carrying the stent outside the endotracheal tube. The average time for stent implantation is 24.8 minutes. It also avoids the risks of thoracic surgery and radiation exposure during fluoroscopy. The use of flexible compared with rigid bronchoscopy for airway stent implantation has long been a subject of debate [17,18]. Both techniques have advantages in different respects. Rigid tools provide a wide view for operating space. Silicone and dynamic stents are designed to be implanted using a rigid bronchoscope. Flexible bronchoscopy with fluoroscopic guidance allows more pneumologists to perform stent implantation, thus averting operating room costs and the risks of general anesthetics [4]. Unlike fluoroscopy, our method provides direct visualization of stent deployment, which

decreases the chance of stent malpositioning. The use of our technique will also provide broader accessibility for mechanically ventilated patients who were not suitable for surgery. This method is also a viable alternative when surgical or fluoroscopic equipment is not available.

The easy accessibility of flexible bronchoscopy has made SEMSs more and more popular [7,19,20]. Because of its potential complications and the difficulty in removing Ultraflex SEMSs in patients with benign lesions, the United State Food and Drug Administration has warned that SEMS implantation should be considered only if patients with benign lesions are not candidates for surgery, rigid bronchoscopy, or silicone stent implantation. All the patients in our cohort were in critical condition, therefore; general anesthesia, rigid bronchoscopy, and subsequent silicone stent implantation were not feasible.

Similar to a previous study [12], the ventilator liberation rate in this study is 53.8%. Among the causes of ventilator liberation failure after stenting, severe pneumonia is the most common reason. Pneumonia is a frequent complication in patients with central airway disease due to inadequate drainage of secretions. The implantation of an SEMS should be carefully assessed in these patients, especially if the involved lobes are not directly related to the obstructive airway. By using this new method of stent implantation, a multicenter prospective study is mandatory to investigate the predictor for ventilator liberation failure among the patients with respiratory failure due to central airway disease

In this study, the incidence of granulation tissue formation (26.9%) after stent implantation is similar to a previous report in mechanically ventilated patients [14]. Pneumothorax occurred in one patient after stent implantation but resolved spontaneously. Interventional bronchoscopy has the inherent risk of causing pneumothorax when positive pressure ventilation is used [21]. In addition, the elevated airway pressure caused by the bronchoscope and delivery catheter in the trachea may also contribute to the development of pneumothorax.

In conclusion, this study describes a new method of stent implantation in mechanically ventilated patients with central airway lesions. This method is potentially safe, time saving, and facilitates ventilator independence for the patient. Severe pneumonia may be a negative factor for ventilator discontinuation after airway stenting.

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Legends

FIGURE 1. Tracheal stenosis caused by tumor invasion.

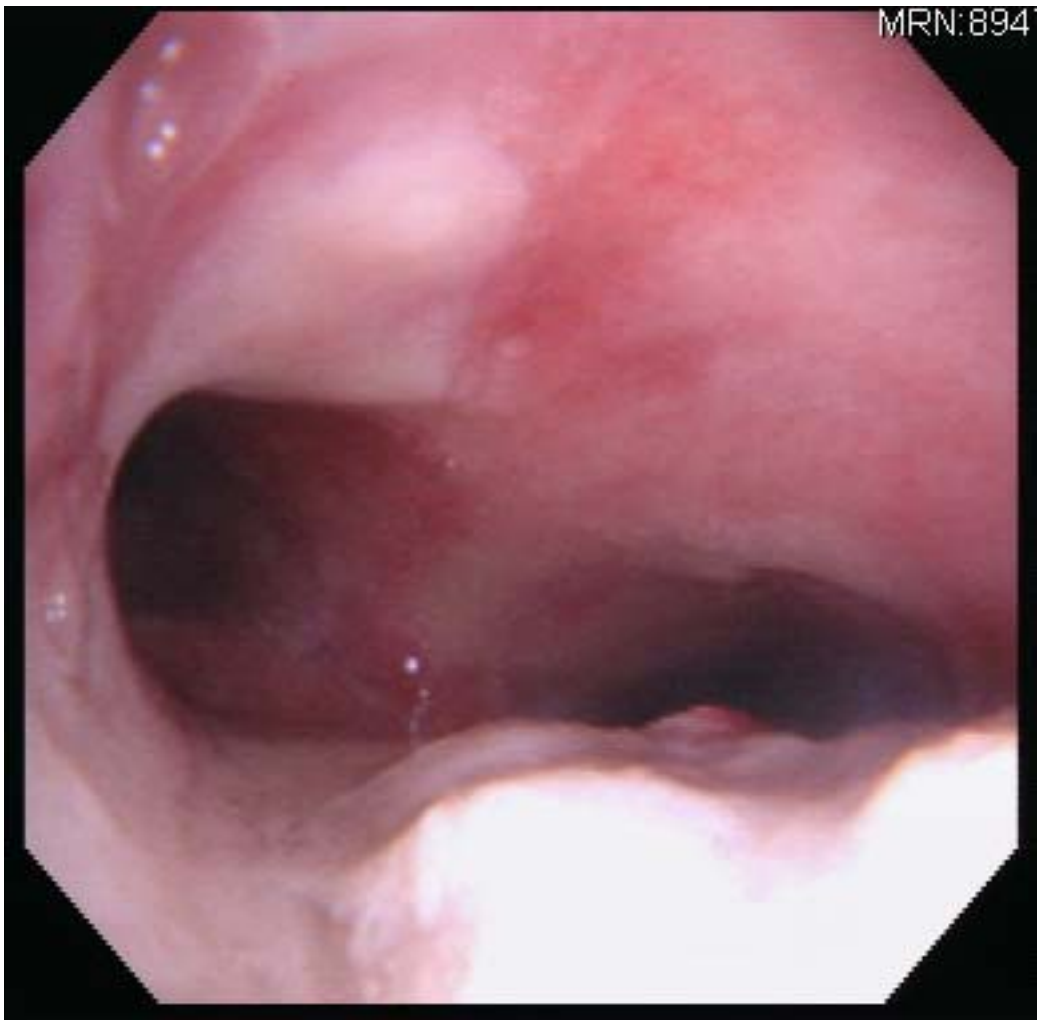


FIGURE 2. The guidewire was inserted via bronchoscope through the lesion outside of the endotracheal tube.

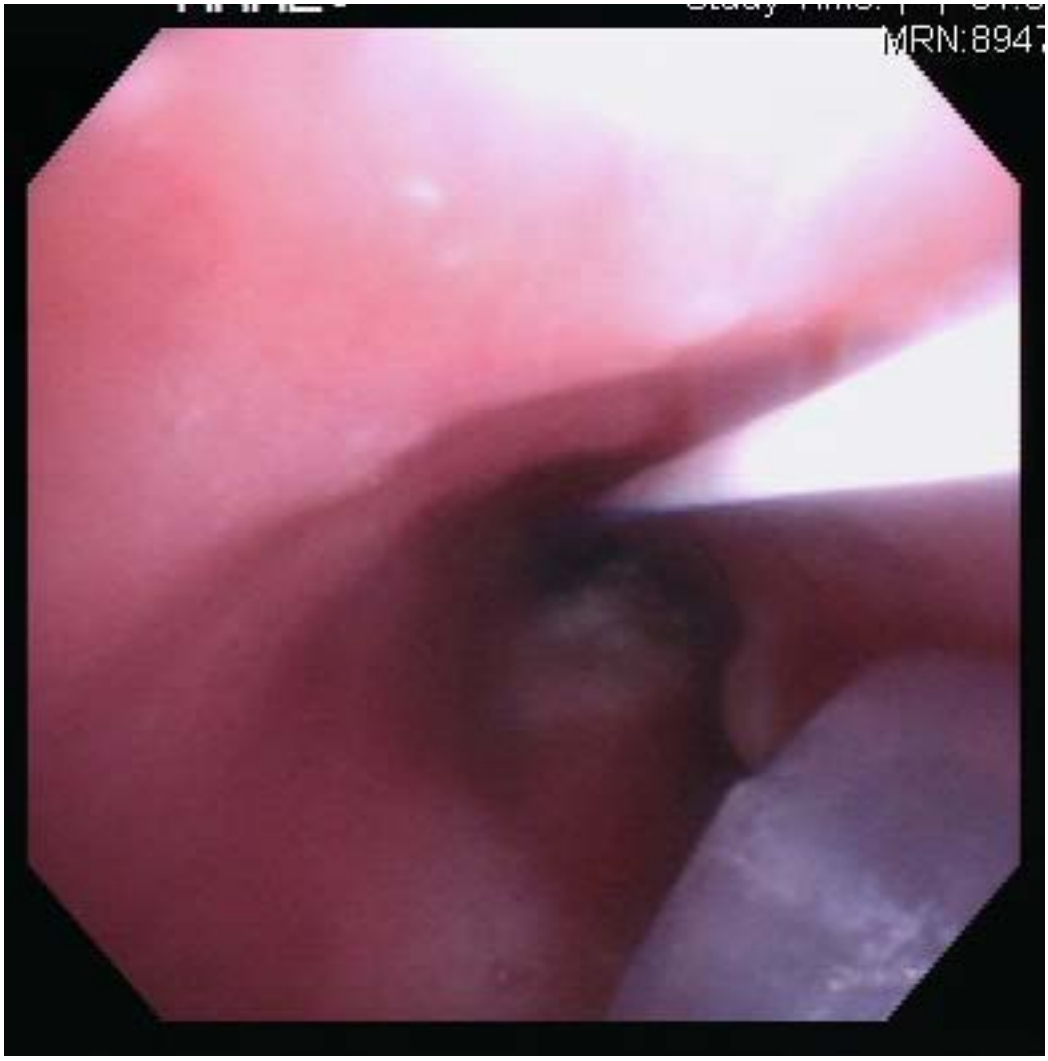


FIGURE 3. The guidewire was left the lesion site.

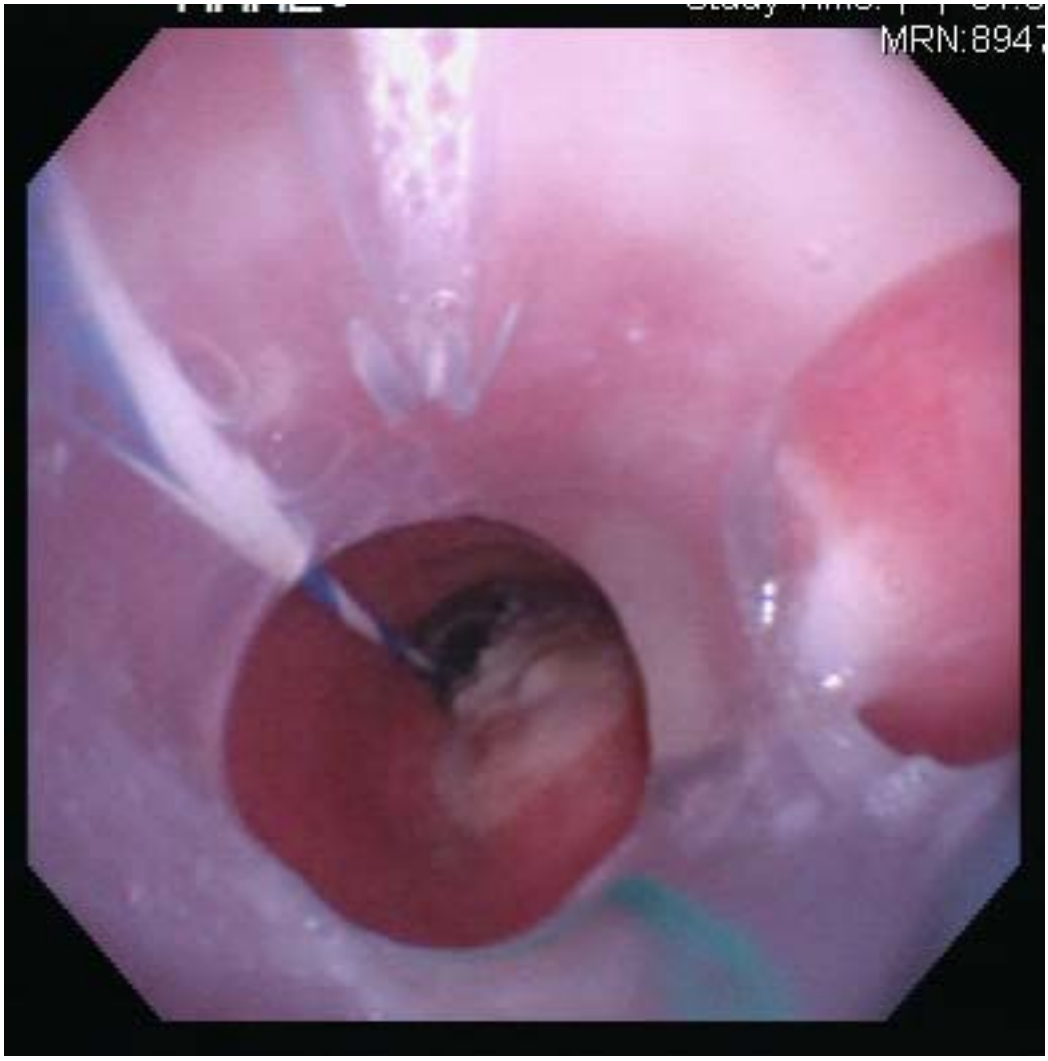


FIGURE 4. The delivery catheter deployed stent under bronchoscopic guidance.

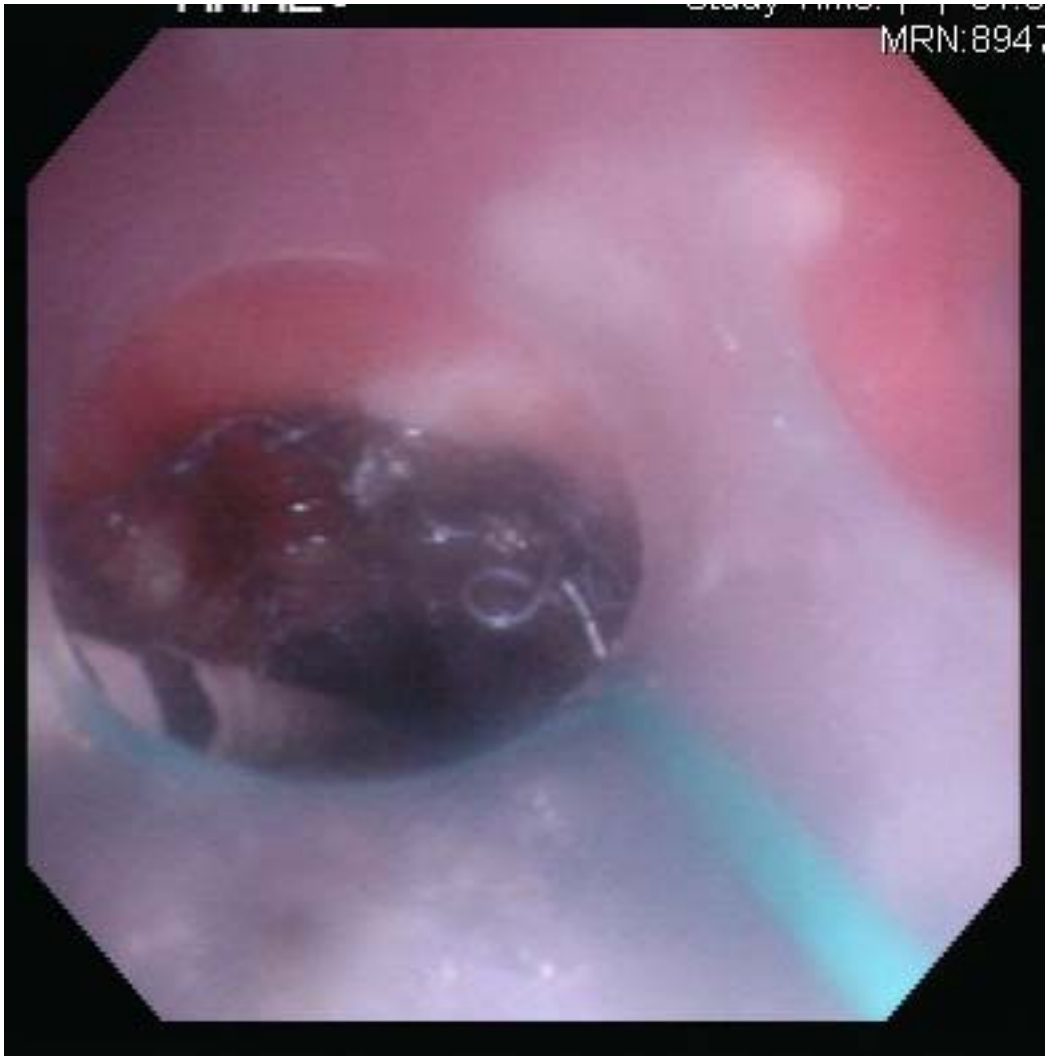


FIGURE 5. An Ultraflex stent was implanted successfully.

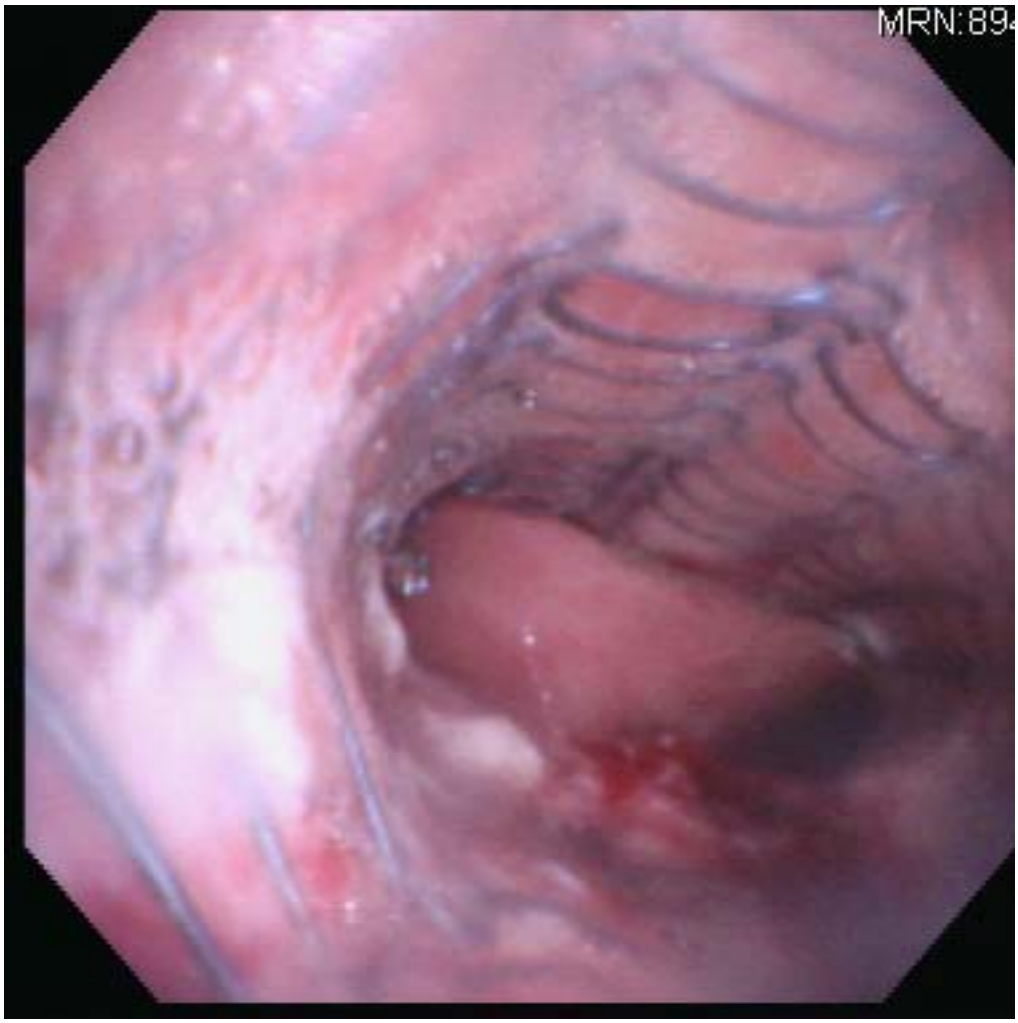
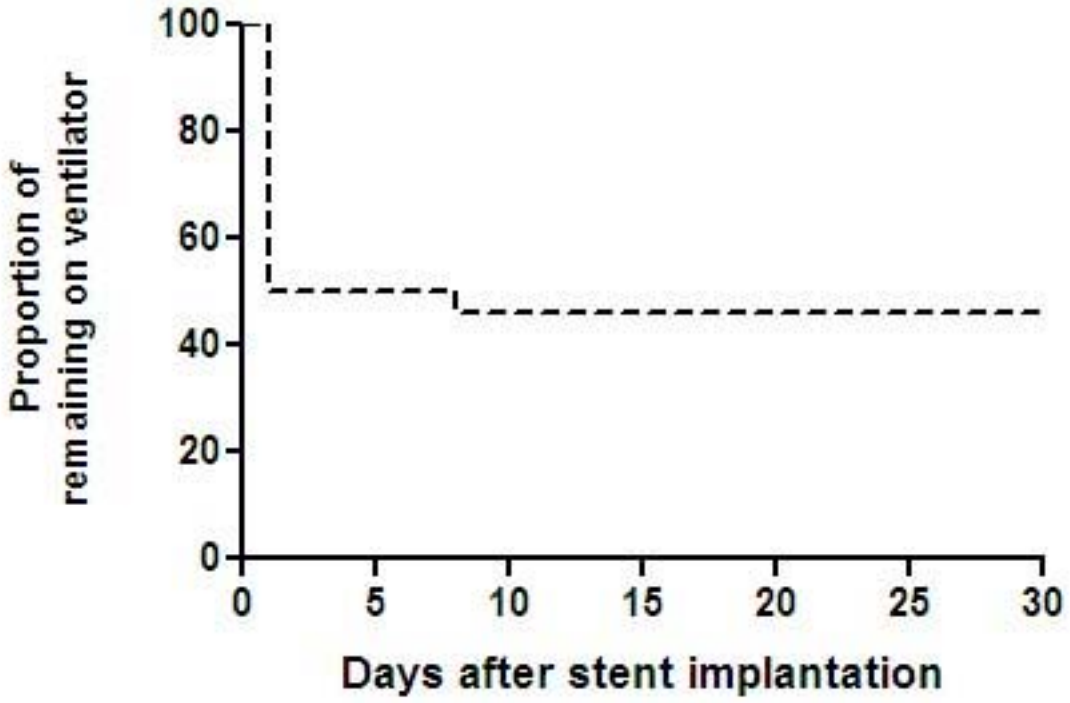


FIGURE 6. The proportion of patients remaining on mechanical ventilation after stent implantation. Fourteen (53.8%) of 26 patients were ventilator independent after stent implantation; 13 of these were free from the ventilatory support within 1 d after stent implantation.


Proportion of remaining on ventilator
100
80
60
40
20
0
0
5
10
15
20
25
30
Days after stent implantation

Tables

Table 1. Baseline characteristics of 26 patients

Age (mean ± SD[a])	63.6 ± 15.8 y
Sex (male/female)	19/7
APACHE II[b] score (mean ± SD[a])	17.4 ± 4.1
Causes of airway lesion, no (%)	
Malignant lesions	21(80.8)
Esophageal cancer	11(42.3)
Lung cancer	5(19.2)
Buccal cancer	2(7.7)
Thyroid cancer	1(3.8)
Mediastinal schwannoma	1(3.8)
Mediastinal carcinoid tumor	1(3.8)
Benign lesions	5(19.2)
Dynamic collapse of right main bronchus	2(7.7)
Postintubation tracheal stenosis	1(3.8)
Tracheal stenosis (unknown origin)	1(3.8)
Tracheoesophageal fistula (unknown origin)	1(3.8)

[a]SD, standard deviation.

[b]APACHE II, Acute Physiology and Chronic Health Evaluation.

Table 2. Locations and causes of central airway lesions

Location	Tumor compression	Tumor invasion	T-E[a] fistula	Dynamic collapse	Tracheal stenosis
Trachea	6	5	6	0	2
Right main bronchus	0	1	0	2	0
Left main bronchus	0	2	2	0	0

[a]T-E fistula, tracheoesophageal fistula.

Table 3. The analysis of factors potentially associated with successful liberation from mechanically ventilator

Factor	**Successful N=14 No. (%)**	**Failed N=12 No. (%)**	**Odds ratio**	**95% Confidence interval**	***P*-value**
Severe pneumonia	5(35.7%)	7(58.3%)	0.40	0.08-7.04	.431
Tracheoesophageal fistula	2(14.3%)	4(33.3%)	0.33	0.05-2.27	.857
Endobronchial tumor invasion	4(28.6%)	4(33.3%)	0.80	0.15-4.25	1.00
External tumor compression	5(35.7%)	2(16.7%)	2.76	0.43-18.05	.391
Lesion located at trachea	12(85.7%)	7(58.3%)	4.29	0.65-28.28	.190

Table 4. Factors associated with failure to liberate from ventilator after stent implantation in the 12 of 26 patients

Variables	No (%)
Severe pneumonia	7(58.3%)
Vocal cord paralysis due to buccal tumor invasion	1(8.3%)
Laryngeal edema	1(8.3%)
Chronic asthma with poor pulmonary function	1(8.3%)
Congestive heart failure	1(8.3%)
Gastrointestinal bleeding with hypovolumic shock	1(8.3%)

Table 5. Complications of stent implantation in 26 patients	
Complication	No (%)
Granulation tissue formation	7(26.9%)
Mucus plugging	1(3.8%)
Pneumothorax	1(3.8%)
Stent migration	1(3.8%)