

# Impacts of Airway Self-expandable Metallic Stent on Ventilator Weaning and Survival of Mechanically Ventilated Patients with Esophageal Cancer and Central Airway Invasion

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## Abstract

**Objective:** This study describes the clinical effects of airway Ultraflex stenting as an alternative method for mechanically ventilated patients with esophageal cancer and central airway invasion. Although these patients have poor prognosis, this method may increase successful weaning to be able to receive the following cancer treatment. **Design:** Retrospective study. **Setting:** Medical intensive care unit (ICU), university hospital. **Patients and interventions:** Sixteen esophageal cancer patients with mechanical ventilation and central airway invasion were admitted to our ICU from 2001 to 2009. They received intervention therapy with Ultraflex stenting for central airway invasion. **Main results:** The mean ventilator day and length of intensive care unit stay of these sixteen patients were 14.4 (range, 1-59) and 16.4 (range, 5-61) days, respectively. Most patients (11/16, 68.7%) were successfully liberated from the ventilator after airway Ultraflex stent implantation. Five patients were finally discharged from hospital and received further treatment including concurrent chemo-radiotherapy (3/16, 18.7%) or palliative radiotherapy (2/16, 12.5%). Although six patients were weaned from mechanical ventilator, they died during their hospitalization because of tumor progression or a new development of sepsis and recurrent respiratory failure. Five patients without weaning from the ventilator died due to severe pneumonia. The mean hospital stay was 36.1 days (range, 5-113) and the mean survival time was 56.1 days (range, 5-183). The ICU survival (10/11, 91% vs. 0/5, 0%;  $p < 0.01$ ) and overall survival (mean: 75.3 days vs. 13.8 days,  $p < 0.01$ ) of patients who were successfully weaned were significantly better than those who were not weaned from their ventilators. **Conclusions:** Airway Ultraflex stenting makes successful withdrawal from mechanical ventilation possible, and can therefore extend survival in critically ill esophageal cancer patients with airway invasion and mechanical ventilation. (J Intern Med Taiwan 2017; 28: 243-251)

**Key Words:** Ultraflex stents, Esophageal cancer, Airway invasion, Respiratory failure, Outcomes

## Introduction

Advanced, unresectable esophageal cancer with airway invasion was referred as a very poor prognosis. Patients with this condition face not only limited life expectancy, but also many potentially debilitating complications<sup>1-3</sup>. For tumors extending into the airway lumen, the primary goals of therapy are palliative relief of the malignant obstruction of the esophageal lumen and central airway and closure of the fistula between the esophagus and central airway. Palliative options include mechanical core-out, dilatation, laser ablation, electrocautery, cryotherapy, photodynamic therapy, and brachytherapy<sup>4</sup>. However, satisfactory results such as patent airway or tracheoesophageal fistula repair may not be immediate or lasting.

In the past decades, endoscopic stenting has gained acceptance as the preferred palliative therapy for airway complications in unresectable esophageal cancer<sup>5</sup>. Stenting is effective for airway stenosis from both extrinsic compression and direct tumor invasion, and has also been shown to be useful in the treatment of tracheoesophageal fistula<sup>6-8</sup>. Among patients with obstruction of the trachea and main stem bronchi with tumor invasion, respiratory failure is one of the most severe complications. Due to advances in airway stents and insertion techniques, interventional bronchoscopic procedures have been reported to facilitate weaning from mechanical ventilation<sup>9,10</sup>. Moreover, covered self-expandable metallic stents (SEMSs) have been used to seal off tracheoesophageal fistulas and to avoid aspiration symptoms<sup>6,11,12</sup>. However, little has been reported about the effect of stent implantation in respiratory failure patients with esophageal cancer complicated with central airway invasion.

The most common methods of stent implantation in mechanically ventilated patients are rigid bronchoscopy under general anesthesia and flexible bronchoscopy under fluoroscopic guidance.

However, some patients are not suitable for surgical intervention or rigid bronchoscopy with a general anesthetic because of the severity of their illness and comorbidities or their refusal to have surgery. In addition, fluoroscopy requires special facilities that may not be available in every intensive care unit (ICU).

We designed this study at the ICU of Chang Gung Memorial Hospital, a university-affiliated hospital in Taiwan. We collected data before and after airway Ultraflex stent implantation among those respiratory failure patients who had esophageal cancer and central airway invasion. We also investigated the outcomes after this stenting that was guided by a flexible bronchoscope inserted through an endotracheal tube.

## Patients and Methods

### Design

This investigation was a retrospective study. Informed consent was obtained from all patients or their representatives prior to stent implantation. The methodology, assurance of patient confidentiality and design of the project were approved by our Institutional Review Board (IRB No.: 99-0337B).

### Patients

From August 2001 to March 2009, 16 respiratory failure patients (mean age  $61.1 \pm 10.1$ , range: 39-77) with esophageal cancer and central airway invasion or tracheoesophageal fistula underwent flexible bronchoscopic airway stent placement were included. Due to illness severity, high surgical risk or surgical refusal, none of these patients were candidates for surgery or stent implantation under rigid bronchoscopy.

### Stent Implantation

All patients in our study received an Ultraflex (Boston Scientific, Natick, MA) self-expandable metallic stent composed entirely of a single strand

of nickel-titanium alloy. The choice of stent length and type (with or without cover) was determined by a previous endoscopic examination (Fig. 1a), chest X-ray (Fig. 2a) and/or chest CT scan. The principles of SEMS implantation and assessment of stent condition through flexible bronchoscopy under sedation and local anesthesia in our institution have been well reported in previous studies<sup>13-15</sup>. Briefly, sedation with intravenous midazolam (5 mg) and a local anesthetic with 2% xylocaine solution is administered prior to bronchoscopy. The bronchoscope is inserted through a mouth guard into the space between the tracheal wall and the endotracheal tube. The bronchoscope is advanced to the proximal end of the lesion (Fig. 1b). A guiding wire is inserted via the bronchoscope and passed through the airway lesion and then the bronchoscope is withdrawn, leaving the guiding wire at the lesion site (Fig. 1c).

The bronchoscope is then reinserted into the endotracheal tube to confirm the location of the guiding wire. Under bronchoscopic visualization, the delivery catheter (Boston Scientific) is advanced over the guiding wire to deploy the stent (Fig. 1d). The delivery catheter, guiding wire and bronchoscope are then withdrawn, leaving the stent in the lesion site (Fig. 1e). After completing stent deployment, the bronchoscope is introduced to check the position of the stent.

#### Assessment of stent condition and complications

After implanting the stent, a follow-up chest X-ray (Fig. 2b) was arranged to confirm its location. A second bronchoscopic study was performed in those patients suspected of having stent complications. The presence of complications such as secretion, migration, tumor ingrowth, new fistula

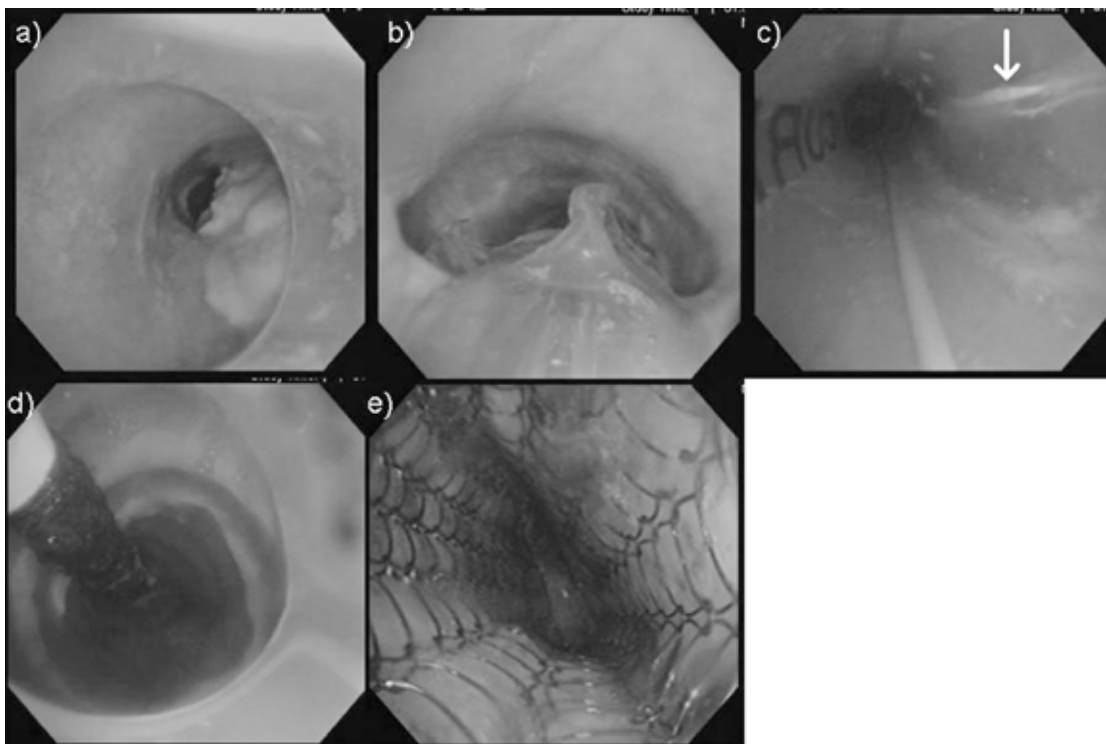


Figure 1. Airway Ultraflex stenting process in a patient with esophageal cancer invading the central airways and respiratory failure: a) Tracheal invasion by esophageal cancer and respiratory failure with endotracheal tube insertion. b) the bronchoscope is inserted into the space between the endotracheal tube and the airway lumen. c) The guiding wire (arrow) is inserted into the trachea lesion, outside the endotracheal tube. d) The stent is deployed by the delivery catheter through the guiding wire under bronchoscopic guidance. e) An Ultraflex stent was successfully placed.

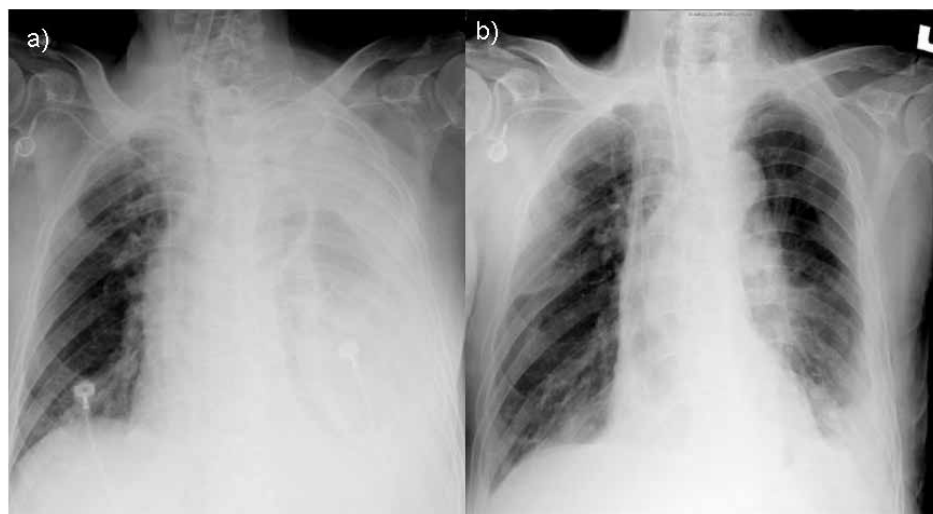


Figure 2. Chest X-rays showing before a) and after b) airway Ultraflex stent implantation in esophageal cancer with respiratory failure. Successful extubation was performed after SEMS implantation.

formation, and pneumothorax were recorded by the follow-up bronchoscopic studies or on chest X-rays. If dyspnea, severe coughing, increased mucus production or other fracture symptoms occurred, an additional bronchoscopy was done. Complication with unknown status was defined as neither follow-up bronchoscopic study nor chest X-ray.

### Statistical Analysis

Descriptive statistics were employed to examine the demographic characteristics of the study population. The ICU survival and overall survival between the weaning success and failure patients were compared using the chi-square test and the two-tailed Student t-test for categorical and continuous variables, respectively.

Kaplan-Meier curve was used to express the time it took until liberation from the ventilator, the length of ICU stay, in-hospital stay, and overall survival after SEMS implantation. All analyses used Prism 5 for Windows (version 5.01, Graphpad Software Inc.).

### Results

From August 2001 to March 2009, 16 respiratory failure patients (mean age  $\pm$  standard deviation,

Table 1. Demography of patients before airway Ultraflex stenting

Age, mean $\pm$ SD (IQR)	61.1 $\pm$ 10.1 years old (13.5)
Male, n (%)	16 (100%)
Pathology	
Squamous cell carcinoma, n (%)	16 (100%)
Esophageal cancer stage	
Stage III, n (%)	13 (81.3%)
Stage IV, n (%)	3 (18.7%)
Esophageal cancer site	
Upper 1/3 of esophagus	4 (25.0%)
Middle 1/3 of esophagus	9 (56.3%)
Lower 1/3 of esophagus	3 (18.7%)
Cancer treatment before stent	
None, n (%)	4 (25.0%)
CCRT, n (%)	8 (50.0%)
Surgery and CCRT, n (%)	4 (25.0%)

SD: standard deviation; IQR: interquartile range; CCRT: concurrent chemo-radiotherapy.

61.1  $\pm$  10.1 years; range, 39-77) with esophageal cancer and central airway invasion received Ultraflex stents in our institute. The demography of these patients when esophageal cancer was diagnosed is listed in Table 1. All these patients were male, and the pathology of their esophageal cancer was all squa-

mous cell carcinoma. Three patients were at stage IV and 13 patients were at stage III when esophageal cancer was diagnosed. Most esophageal cancer invaded the middle esophagus (9/16, 56.3%), and then the upper (4/16, 25.0%) and lower esophagus (3/16, 18.7%) followed sequentially. Eight patients received concurrent chemo-radiotherapy (CCRT) (8/16, 50.0%), 4 patients received esophageal reconstruction and follow-up CCRT (4/16, 25.0%) and 4 patients did not receive treatment for esophageal cancer (4/16, 25.0%).

Information of metallic stents on all the study subjects is listed in Table 2. The indications for stenting in these patients included airway narrowing by tumor invasion (8/16, 50.0%) and tracheoesophageal fistula (8/16, 50.0%). The most implanted site of the airway was the lower trachea (7/16, 43.8%), followed by left main bronchus (5/16, 31.3%) and the middle trachea (4/16, 25.0%). The indications for endotracheal intubation were airway narrowing and aspira-

tion pneumonia due to esophageal cancer invasion and tracheoesophageal fistula, respectively. The duration between diagnosing esophageal cancer and airway Ultraflex stent implantation is listed (mean duration  $\pm$  standard deviation,  $324.8 \pm 286.3$  days; range, 19-939). All stents were covered stents, and the size with outer diameter and length is listed in Table 2.

The outcomes after stent implantation are listed in Table 3. Most patients (11/16, 68.7%) were successfully weaned from their ventilators and 62.5% (10/16) patients survived their period in the ICU after airway Ultraflex stenting. The mean number of days that they were ventilated and in the ICU were 14.4 (range, 1-59) and 16.4 days (range, 5-61), respectively. Six patients were liberated from the ventilator at once after stenting, and the duration from stenting to extubation was  $5.6 \pm 13.9$  days. Five patients could not be liberated from the ventilator because of persistently severe pneumonia (data

Table 2. List of patients who received airway Ultraflex stenting

	Indication of airway Ultraflex stenting	Invasion site	Indication of intubation	Days before SEMS implantation	Stent size (OD x length)	Stent type
Case 1	tumor invasion	LT	airway narrowing	72	20 mm x 8 cm	cover
Case 2	tumor invasion	MT	airway narrowing	19	20 mm x 8 cm	cover
Case 3	tumor invasion	LT	airway narrowing	24	20 mm x 10 cm	cover
Case 4	TE fistula	LT	aspiration pneumonia	154	20 mm x 6 cm	cover
Case 5	TE fistula	LT	aspiration pneumonia	261	20 mm x 8 cm	cover
Case 6	tumor invasion	MT	airway narrowing	939	18 mm x 8 cm	cover
Case 7	TE fistula	MT	aspiration pneumonia	920	18 mm x 6 cm	cover
Case 8	tumor invasion	LT	airway narrowing	305	16 mm x 8 cm	cover
Case 9	tumor invasion	LT	airway narrowing	138	18 mm x 6 cm	cover
Case 10	TE fistula	LT	aspiration pneumonia	440	20 mm x 6 cm	cover
Case 11	TE fistula	LM	aspiration pneumonia	590	18 mm x 6 cm	cover
Case 12	tumor invasion	LM	airway narrowing	184	14 mm x 4 cm	cover
Case 13	TE fistula	LM	aspiration pneumonia	427	16 mm x 6 cm	cover
Case 14	TE fistula	MT	aspiration pneumonia	404	20 mm x 8 cm	cover
Case 15	tumor invasion	LM	airway narrowing	218	14 mm x 4 cm	cover
Case 16	TE fistula	LM	aspiration pneumonia	101	14 mm x 4 cm	cover

TE, tracheoesophageal; LT, lower trachea; MT, middle trachea; LM, left main bronchus; SEMS, self-expandable metallic stent; OD, outer diameter.

not shown). A total of five patients were finally discharged from hospital and they received further treatment including concurrent chemo-radiotherapy (3/16, 18.7%) or palliative radiotherapy (2/16, 12.5%). Six patients died of tumor progression or a new development of sepsis and recurrent respiratory failure during their hospital stay. The mean hospital days were 36.1 (range, 5-113) days and the mean survival days were 56.1 (range, 5-183) days. The complications shown in the follow-up chest X-ray or bronchoscopy included four cases with secretion, three for tumor ingrowth, one for pneumothorax, one for migration and one case with the development of tracheoesophageal fistula. Four patients suffered from rapid progression and no follow-up bronchoscopy was performed. Cases with complication of tumor ingrowth or migration or the development of tracheoesophageal fistula weaned successfully, and one case with pneumothorax and three of four cases

with secretion had failed in weaning.

The ICU survival rate was significantly higher in those patients who were successfully weaned from the ventilator after airway Ultraflex stenting, compared with patients who failed to wean [90.9% (10/11) vs. 0% (0/5),  $p < 0.01$ ]. Those patients who had successful weaning also had longer overall survival days ( $75.3 \pm 52.5$  days) compared with those patients who failed to wean ( $13.8 \pm 11.3$  days) ( $p < 0.05$ ). Figure 3 shows the log rank test analysis of time to liberation from the ventilator, ICU stay, in-hospital stay and overall survival after stenting.

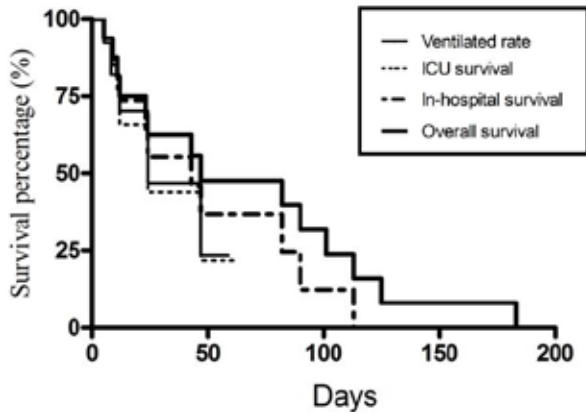
## Discussion

Previous studies have shown that patients with direct airway invasion by esophageal cancer is characterized as a poor prognosis<sup>1-3</sup>. However, there are a few reports<sup>9,10</sup> that describe the outcomes of these patients with respiratory failure and need mechan-

Table 3. Outcomes of patients after airway Ultraflex stenting

	Weaning	MV days	Days between stenting and extubation	ICU outcome	ICU days	In-hospital outcome	Hospital days	Overall survival days	Treatment	Complication
Case 1	-	5	None	M	5	M	5	5	None	Unknown
Case 2	+	1	0	S	5	S	21	101	RTO	Tumor ingrowth
Case 3	+	1	0	S	5	S	22	40	CCRT	None
Case 4	+	6	2	M	11	M	11	7	None	Unknown
Case 5	+	14	2	S	17	S	49	183	CCRT	Tumor ingrowth
Case 6	+	7	0	S	11	M	90	90	None	TE fistula
Case 7	+	11	0	S	11	M	82	82	None	Secretion
Case 8	+	4	0	S	5	S	8	45	RTO	None
Case 9	+	5	0	S	6	S	18	125	CCRT	None
Case 10	-	24	None	M	24	M	24	19	None	Pneumothorax
Case 11	+	15	7	S	20	M	43	37	None	Migration
Case 12	-	8	None	M	9	M	9	5	None	Secretion
Case 13	+	59	47	S	61	M	113	102	None	Tumor ingrowth
Case 14	-	12	None	M	12	M	12	10	None	Secretion
Case 15	-	47	None	M	47	M	47	31	None	Secretion
Case 16	+	12	4	S	14	M	23	16	None	Unknown

MV, mechanical ventilator use; ICU, intensive care unit; "-", weaning failed; "+", weaning succeeded; M, mortality; S, survival; RTO, radiotherapy; CCRT, concurrent chemo-radiotherapy; TE, tracheoesophageal; Unknown complication, defined as neither follow-up bronchoscopic study nor chest X-ray exam.



**K-M curve of ventilated rate, ICU, In-hospital and overall survival after SEMS implantation**

Figure 3. K-M curve: Kaplan-Meier curve; Time to liberation of ventilator, ICU, In-hospital and overall survival after airway Ultraflex stenting was presented. The data was based on log rank test analysis.

ical ventilation. We have shown in this study that airway Ultraflex stent implantation is feasible with a flexible bronchoscope in these subjects even with endotracheal tube insertion.

We report here on 16 attempts of ICU stenting involving the airway and the esophagus in patients with advanced esophageal cancer. Stenting was successfully performed in 16 patients and no patients failed stenting. Eleven patients were successfully liberated from the ventilator, but 5 patients could not be weaned after stenting and developed a poor outcome whereas those who were successfully liberated from the ventilator and ICU developed a better prognosis. Stenting in the involved airway of esophageal cancer has dramatically improved the life quality and outcomes of patients with end-stage esophageal cancer<sup>8-10</sup> after relief of upper airway obstruction or obliteration of tracheoesophageal fistula. While usefulness of airway stent has been published a decade ago in patients with advanced end-stage esophageal cancer with airway involvement, advanced end-stage esophageal cancer with airway involvement and respiratory failure is still a challenging condition for physicians. There are

no current guidelines for ICU airway stent procedures advising for flexible bronchoscopy prior to stent insertion. Recurrent aspiration pneumonia may be induced during airway invasion by esophageal cancer in these respiratory failure patients, which therefore suggests difficult weaning from ventilators and poor prognosis. However, we think the effects of the airway stenting by fiberoptic bronchoscopy such as in our study subjects are so positive that considering stenting should be mandatory to improve patients' outcomes.

This alternative method of airway Ultraflex stenting, using flexible bronchoscopy without fluoroscopic guidance, was successful in all patients in our study. The mean time required for stent implantation was 25 minutes (range, 16-33). Successful ventilator liberation after stent implantation was achieved in 68.7% of our patients. Most patients were rapidly extubated after stenting (six patients extubated at once and 4 patients extubated within 1 week) but 5 patients could not be liberated from the ventilator because of persistently severe pneumonia. In addition, case 13 extubated 47 days after airway stenting; the reason for this delayed extubation was also due to persistently severe pneumonia. There were no appropriate predictors to predict successful weaning after stenting in our study. All three patients without complication weaned from mechanical ventilator successfully. Patients with the complication which could be saved by rescue of stent replacement seemed had better successful weaning compared to those with complication which could not (5/5, 100% vs. 1/5, 20%;  $p = 0.048$ ), and this view of point needed more data to support it. However, no life-threatening complications developed as a result of this procedure. Usually for complication management<sup>16</sup>, we dealt with migration by stent reposition, tumor ingrowth by electrocautery or SEMS removal, and stent fracture by SEMS removal or another SEMS stenting. All three patients without complication received the following esophageal cancer treatment, and only two

of ten patients with complication received it. The use of the present technique also provides broader accessibility for mechanically ventilated patients unsuitable for surgery, and would be a practical alternative when surgical or fluoroscopic equipment is not available. Above all, the improved weaning from the ventilator showed that patients developed better ICU- and overall survival.

The use of silicone stents versus SEMS, stent placement by fiber-optic bronchoscopy versus rigid bronchoscopy, and whether to use double stenting in both the esophagus and airway, remain controversial<sup>7</sup>. However, rigid bronchoscopy under general anesthesia and flexible bronchoscopy under fluoroscopic guidance are the most common methods of stent implantation in mechanically ventilated patients. Despite this, some patients are not suitable for this kind of surgical intervention because of the severity of their illness, comorbidities or a simple refusal to undergo surgery. In addition, fluoroscopy requires special facilities that may not be available in every intensive care unit.

All patients in the present study were in a critical condition; therefore, general anesthesia, rigid bronchoscopy and subsequent silicone stent implantation were not feasible. The alternative method of airway Ultraflex stenting, using flexible bronchoscopy without fluoroscopic guidance, provided these critical patients with alternative treatment to resolve their recurrent aspiration. Once the stent was implanted successfully, we have shown that some of these critical patients could be liberated from their ventilators and further discharged from the ICU and hospital. Thereafter, they could receive further treatment for esophageal cancer including radiotherapy or CCRT, and their overall chances of survival can improve. In conclusion, the current study describes an alternative method of stent implantation in mechanically ventilated patients with esophageal cancer and central airway invasion. Although these patients have a poor prognosis, this method may

facilitate successful withdrawal from mechanical ventilation, hospitalization in an environment with a lower level of care, and may even extend their chances of survival after esophageal cancer treatment.

## Acknowledgement

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## 自張性氣道金屬支架對使用機械式呼吸器的食道癌併中央呼吸道侵犯患者其呼吸器脫離和生存的影響

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### 摘 要

目標：此研究描述在食道癌併中央氣道侵犯且使用機械式呼吸器的患者中，接受氣道極彎支架(Ultraflex stent)置放這種替代性方式有其臨床效果。雖然此族群患者預後不佳，但此方法能讓病人增加脫離呼吸器的機會而接著後續食道癌的治療。設計：回溯性研究。設置及配備：內科加護病房(Intensive care unit, ICU)，大學附屬醫院級。病患和介入性方法：從2001年至2009年間住進加護病房的十六個食道癌併中央氣道侵犯且使用機械式呼吸器的患者，他們因氣道侵犯而接受氣道極彎支架置放。主要結果：十六位患者平均使用呼吸器的時間和加護病房天數分別為14.4天(range, 1-59)和16.4天(range, 5-61)。大部分患者(11/16, 68.7%)在氣道極彎支架置放後，能成功脫離機械式呼吸器。其中五個病人最後順利出院而且接受了後續進一步的治療，包含三個接受同步化療及放射線治療(concurrent chemo-radiotherapy)(3/16, 18.7%)和二個接受姑息性放射線治療(palliative radiotherapy)(2/16, 12.5%)；六個病人在住院期間因為腫瘤進展、新發生的敗血症或反覆的呼吸衰竭而死亡。而五個即使已經接受支架置放仍未能脫離機械式呼吸器患者，則死於肺炎。這十六位患者平均住院天數和平均生存天數分別為36.1天(range, 5-113)和56.1天(range, 5-183)。能夠成功脫離機械式呼吸器者較不能脫離者，其加護病房生存率為佳，分別為91%,10/11 vs. 0%,0/5 ( $p < 0.01$ )，整體平均生存天數也是比較好，分別為75.3 vs. 13.8天( $p < 0.01$ )。結論：在食道癌併呼吸衰竭的重症患者，接受氣道極彎支架置放後是有機會脫離機械式呼吸器的，並且可以延長其存活時間。