

# Expandable metal stents as an alternative treatment of cuff-related tracheal stenosis in tracheostomy-dependent ventilated patients: a prospective study of nine cases and description of the complications

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## Abstract

**Background and aims** In long-term intubated patients, cuff-related tracheal injury is occasionally complicated by tracheal stricture. To keep the airway patent, bougienage and deployment of stents are adopted in patients unfit for surgery.

**Materials and methods** Prospectively, nine episodes of cuff-related tracheal stricture in nine tracheostomy-dependent ventilated patients were treated with pre-stenting bougienage, followed by implantation of expandable metal stents (EMS). The primary endpoint of this study was the successful discharge of the patients back to the chronic care unit. The other endpoint was the re-treatment rate.

**Results** The mean age of the nine patients was 61.7 years. The follow-up period was 18.6 months. The first two patients received a bare stent, and the other seven patients received membrane-coated stents. They all recovered well with successful discharge back to the chronic care unit. There were two episodes of granulation formation in one bare-stent patient and in one coated-stent patient, respectively. In another coated-stent patient, complications arose from a broken stent.

**Conclusion** EMS appears to have a role to play in tracheostomy-dependent ventilated patients with benign

tracheal stenoses in whom there are no other reasonable options.

**Keywords** Tracheal stricture · Stent · Stenosis

## Introduction

Cuff-related tracheal stricture, especially complicated by inflammatory granulation, is a major concern in long-term intubated patients. The procedure of tracheal resection and reconstruction is the gold standard for such benign tracheal stenosis [1–3]. In patients unfit for resection surgery, tracheal stents have proved valuable in the management of such benign airway stenosis [4–6]. We report here our prospective study of cuff-related tracheal stricture in nine tracheostomy-dependent ventilated patients, who were all unfit for surgery and were successfully treated with pre-stenting bougienage and implantation of Ultraflex tracheal stents (Boston Scientific, Natick, MA, USA), a design of expandable metal stent (EMS). The purpose of this study was to develop an easy way to treat such patients without the need for specialized tools, such as a LASER or rigid bronchoscope. Therefore, this procedure can be executed in any community hospital.

## Materials and methods

From January 1999 to September 2005, 38 patients were admitted due to cuff-related tracheal disease. In the same time, there were 60 episodes of airway-stent implantation in 52 patients for varied indications. Among these 38 patients, there were nine tracheostomy-dependent ventilated patients

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with cuff-related tracheal stricture who were unfit for resection surgery and who prospectively received EMS after pre-stenting bougienage. The tracheal pre-stenting bougienage was performed through the tracheostomy orifice using commercialized endotracheal tubes (SIMS Portex Limited, UK) of serial sizes as dilators. The minimum size of the endotracheal tube used was a plain type with an internal diameter (I.D.) of 4.0 mm and an outside diameter (O.D.) of 5.3 mm. The largest cuffed endotracheal tube used had an 8.0-mm I.D. (10.7 mm O.D.). During the bougienage procedure, the cuff of the endotracheal tube was removed to avoid injury. The bougienage process could be completed in one or more courses depending on the severity of the stricture. The endotracheal tube with the largest diameter was then kept in situ for several days until the EMS (with the O.D. ranging from 12 to 16 mm depending on the individual condition) was deployed. The primary endpoint of this study was the successful discharge of the patients back to their original ward for long-term care. The other endpoint was the re-treatment rate.

## Results

The mean age of the nine patients was 61.7 years (ranging from 16 to 85 years), and the mean follow-up period was 18.6 months (ranging from 11 to 25 months). All the patients were uneventfully discharged back to the chronic care unit and were alive within the follow-up period. There were two episodes of granulation formation in one bare-stent patient and in one coated-stent patient, respectively. Another coated-stent patient encountered complications due to a broken stent (Table 1). A successful discharge of all patients was fully

attained (100%). The re-treatment rate was 50.0% (one episode/two cases) in the bare-stent cases and 28.6% in the coated-stent cases (two episodes/seven cases).

## Case 1

An 84-year-old female patient was admitted to a local respiratory care ward (RCW) and mechanically ventilated through tracheostomy for 3 months due to congestive heart failure and repeated pneumonia. The progressive difficulty in ventilation was noted for 7 days, with airway pressure up to 55 cmH<sub>2</sub>O. Upon flexible bronchoscopy, a segment of circumferential tracheal stricture was noted 2 cm distal to the tip of the tracheostomy tube. The bronchoscope could not pass through the stenotic segment. She was transferred to our hospital for resuscitation. An emergency tracheal dilatation through the tracheostomy orifice was performed using tracheal tubes of serial sizes with O.D. from 6.0 to 10.0 mm as dilators. The largest tracheal tube was then kept in the tracheal lumen to maintain bougienage and ventilation. The next day, a bare Ultraflex stent (14 mm in diameter and 4 cm in length) was implanted in the stenotic segment. The diameter of the lesion and correspondent normal airway was addressed by bronchoscopy. It was deployed under direct bronchoscope visualization, combined with fluoroscopic confirmation. A regular tracheostomy tube was inserted for mechanical ventilation. Postoperation recovery was initially good, and she was transferred back to the original RCW for further care. Unfortunately, 3 months later, granulation ingrowth through the interstices of the stent complicated her recovery. She suffered from ventilation difficulty and was transferred to our hospital again. This time rigid bronchoscopy was performed to remove the granulation tissue and dilate the

**Table 1** A table of demographics of the patients and results

No.	Age (years)	Sex	Disease <sup>a</sup>	Type of stent	Complication	Follow-up period (months)
1	84	F	Congestive heart failure and pneumonia	Bare 14-4, Coated 14-4	Granulation growth	25
2	73	M	Heart failure and hypoxic encephalopathy	Bare 14-4	None	23
3	16	F	Traumatic hypoxic encephalopathy	Coated 12-4	None	21
4	18	F	Traumatic hypoxic encephalopathy	Coated 14-4	None	19
5	79	F	Cerebral vascular disease, asthma and heart failure	Coated 16-4	Broken stent	18
6	62	F	Cerebral vascular disease	Coated 16-6	None	18
7	84	F	Cerebral vascular disease and heart failure	Coated 16-4	None	18
8	70	F	Cerebral vascular disease, renal failure and pneumonia	Coated 16-4	Edge-granulation	14
9	68	M	Cerebral vascular disease	Coated 16-4	None	11

“Bare 14-4” represents an Ultraflex stent (14 mm in diameter and 4 cm in length) without cover. “Coated 14-4” represents an Ultraflex stent (14 mm in diameter and 4 cm in length) with cover.

F female, M male

<sup>a</sup> “Disease” refers to the original disease.

stenotic segment. A coated Ultraflex stent (14 mm in diameter and 4 cm in length) was expanded inside the previous bare stent under fluoroscopic and bronchoscopic guidance. She recovered well and was transferred back to the RCW for further care. She was still well at her 22-month follow-up evaluation.

#### Case 2

Two months after the first case, a 73-year-old man in the vegetative state was transferred from a local RCW after suffering difficulty in ventilation for 10 days. He was a heart failure patient who had suffered from hypoxic encephalopathy 3 years before and had been maintained by ventilator ever since. The airway pressure was up to 55 cmH<sub>2</sub>O. The flexible bronchoscope revealed a segment of tracheal stricture 1.5 cm distal to the tip of the tracheostomy tube. The regular bronchoscope could not pass through the stenotic segment. An emergency tracheal bougienage was performed via the tracheostomy orifice, using serial sizes of tracheal tubes with O.D. ranging from 5.3 to 10.0 mm. The largest tracheal tube was left in the tracheal lumen to maintain bougienage and ventilation. A bare Ultraflex stent (14 mm in diameter and 4 cm in length) was deployed in the stenotic segment under direct bronchoscopic visualization 2 days later. The diameter of the lesion and correspondent normal airway was addressed by bronchoscopy. A regular tracheostomy tube was inserted for ventilator connection. The postoperation recovery was good, and he was transferred back to the original RCW for further care. During the follow-up examination at 23 months, the stent lumen remained patent.

#### Case 5

A 79-year-old woman in the vegetative state was cared for in a local RCW for 2 years after a cerebral hemorrhage accident. Progressive difficulty in ventilation was noted and became aggravated for 4 days before she was transferred to our hospital. Upon flexible bronchoscopy, a segment of circumferential tracheal stricture 1 cm distal to the tip of the tracheostomy tube was noted. The bronchoscope could barely pass through the stenotic segment. She suffered from an asthma attack at this time. An emergency tracheal bougienage through a tracheostomy orifice was performed, using tracheal tubes of serial sizes with O.D. from 5.3 to 9.3 mm as dilators. The largest tracheal tube was then kept in the tracheal lumen to maintain bougienage and ventilation. Four days later, a coated Ultraflex stent (16 mm in diameter and 4 cm in length) was deployed. This time, the diameter of the lesion and correspondent normal airway was obtained from a computed tomography (CT) scan of the chest and

bronchoscopy evaluation. The stent was deployed under direct bronchoscopic visualization. A regular tracheostomy tube was inserted for ventilation. The asthma improved after medical treatment. She was then transferred back to the original RCW for further care. She remained well until an uncontrolled asthma attacked 18 months later. Bronchoscopy evaluation revealed a broken stent with partial collapse of the trachea. Another coated Ultraflex stent (16 mm in diameter and 4 cm in length) was deployed inside the previous stent. She was then discharged back to the chronic care unit. During the follow-up examination at month, the stent lumen remained patent.

#### Case 8

A 70-year-old woman was cared for in a local RCW for 1 year after a cerebral hemorrhage accident. Progressive difficulty in ventilation was noted and became aggravated for 2 days before she was then transferred to our hospital. Upon flexible bronchoscopy, a segment of circumferential tracheal stricture distal to the tip of the tracheostomy tube was noted. Because of combined renal failure and pneumonia, an aggressive tracheal operation was not favored. An emergency tracheal bougienage through a tracheostomy orifice was performed, using tracheal tubes of serial sizes with O.D. from 5.3 to 10.7 mm as dilators in two separate occasions. The largest tracheal tube was then kept in the tracheal lumen to maintain bougienage and ventilation. Three days later, a coated Ultraflex stent (16 mm in diameter and 4 cm in length) was deployed. A regular tracheostomy tube was inserted for ventilation. The pneumonia improved after medical treatment. She was then transferred back to the original RCW for further care. She remained well until she progressively incurred ventilation difficulty 3 months later. A bronchoscopic evaluation revealed granulation formation around the proximal edge of the stent. The regular tracheostomy tube was replaced with an elongated tracheostomy tube, with the tip of the tube in the stent lumen. She was then discharged back to the chronic care unit. During the follow-up examination at 11 months, the ventilation remained normal with intermittent bloody sputum while changing the tracheostomy tube.

#### Discussion

The reported incidence of tracheal stenosis after tracheostomy and laryngotracheal intubation ranges from 0.6 to 21% [7–9]. For benign tracheal stricture, airway resection and reconstruction provides the most reliable and definitive correction, but not all the patients are suitable for resection [4, 6]. The most common reason for nonsurgical therapy is

the extent of airway damage, and this is uncommon in patients with post-intubation tracheal stenosis. However, even in patients with short segment stenosis, the serious comorbidities of the patients may impede the operation of surgical airway reconstruction. To keep the airway open in such morbid patients, repeated dilatation is necessary. The use of plastic dilators via rigid bronchoscope or bronchoscopic balloon dilatation (BBD) using angioplasty balloon catheters has been reported to be successful in treating benign tracheal stenoses [10]. Repeated bougienage using rigid bronchoscopes of various sizes (small pediatric to large adult) is another option. Nevertheless, a direct dilatation using endotracheal tubes in gradual caliber through the tracheostomy orifice, with or without an introducer, seems easier. In this way, the stenotic segment can safely be dilated in an emergency. Nevertheless, the BBD method remains an option if the stenotic segment is too narrow to allow direct bougienage.

The placement of the elongated tracheostomy tube through the stricture segment has been performed in our earlier cases. However, considering these patients are scheduled to return to a chronic respiratory care ward where a pulmonary specialist is not usually available, the regular placement of an elongated tracheostomy tube is a high risk. The placement of stents was therefore adopted for this prospective study. The placement of the longer tracheostomy tube, acting as an endo-luminal stent, is actually an alternative management method, which was executed in case 8 when there was a complication of edge granulation.

Since 1949, tracheobronchial stents have been used to relieve obstructions. In recent years, the Montgomery silicon T-tubes, first used in 1974, have been most popular in maintaining the airway [11]. The molded Hood stents and studded Dumon stents have external studs to engage the airway and avoid dislodgment. Although silicon tubes can be shaped to conform to the airway anatomy, they are incompatible with the tracheostomy tube inserted within. They also have the disadvantage of stimulating granulation growth along the irritating tip, and they potentially interfere with normal mucociliary clearance and block the luminal patency, resulting in atelectasis and pneumonia [3].

Ultraflex stents, of the expandable metal stent (EMS) design, on the other hand, can allow the tips of the tracheostomy tubes to be partially inserted into the stents. The Ultraflex stents are made of a highly bio-adaptable alloy, which exhibits a low resistance to cough, yet adequate resistance to airway compression. They have an effective internal lumen and do not require hooks to prevent migration. The outward radial force is uniformly applied over the bronchial wall, reducing the risk of mucosal perforation [11]. Originally intended for malig-

nant disease, the EMS can be used in certain benign airway strictures, though there are some complications related to EMS treatment [12]. These complications involve post-stenting granulation obstruction, with the incidence of 15% [13]. It is thought that exuberant bronchial mucosal inflammation will aggravate the occurrence of recurrent obstructing granulation in cases where the EMS has been employed. Therefore, maintaining proper hygiene in the stenting airway is of utmost importance. Another consideration is the appropriate fit between the size of the trachea and the deployed stent to prevent over-irritation of the mucosa. The diameter of the lesion and the correspondent normal airway can be obtained from a CT scan of the chest and bronchoscopy evaluation.

The occurrence of granulation ingrowth in case 1 precipitated the use of a membrane-coated EMS in case 3. Although case 2 remained well without complication during 23 months of follow-up, granulation ingrowth is still a risk if airway inflammation is not kept under control. Therefore, a membrane-coated EMS may be the preferred treatment in cases of benign tracheal stenosis, due to its apparent ability to lower the risk of granulation ingrowth into the stent lumen. The cause of the broken stent in case 8 is unknown. However, re-stenting the airway with or without removal of the broken stent is easy to perform.

## Conclusion

Although expandable metal stents are mainly indicated in malignant-induced airway obstruction, certain benign conditions such as cuff-related stenoses may also demand their use where the complications of granulation or a broken stent are easily controlled. These experiences and follow-ups in nine prospective cases indicate that EMS appears to have a role to play in tracheostomy-dependent ventilated patients with cuff-related tracheal stenoses.

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