The management of post-intubation tracheal stenoses with self-expandable stents: early and long-term results in 11 cases

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Received 6 September 2010; received in revised form 13 December 2010; accepted 14 December 2010; Available online 12 February 2011

Abstract

Objective: The optimal management of post-intubation tracheal stenoses is surgical reconstruction of the airway. Stenting of the trachea using silastic T-tubes or one of the various types of tracheal stents are the alternative ways to surgical reconstruction for the management of post-intubation tracheal stenoses. The early and long-term results of 11 patients with post-intubation tracheal stenosis, who underwent tracheal stenting with self-expandable metallic stents (SEMSs), are presented. Methods: Twelve patients (10 men, mean age: 47.8 ± 20.4 years) with post-intubation tracheal stenosis were referred for tracheal stenting with SEMS (2000–2004). In three cases, the upper tracheal stenosis extended within the subglottic larynx. Stenting was successful in 11 patients, while, in one patient with involvement of the subglottic larynx, the attempt to insert the stent failed. Follow-up time varied from 6 to 96 months, and it was made with virtual and fiberoptic bronchoscopy. Results: Immediate relief of obstructive symptoms was observed in all the 11 patients, where an SEMS was successfully inserted. Stent dislodgement occurred shortly after the procedure in two patients, and it was treated with insertion of a new stent in the first case and a stent-on-stent insertion in the second. Good patency of the stent was observed in three patients for 60–96 months. Three patients with good patency of the stent died from other reasons 24–48 months after stent insertion. Four patients developed obstructive granulation tissue at the ends of the stent after 12–43 months, requiring further treatment with thermal lasers and/or tracheostomy. One patient underwent stent removal and successful laryngotracheal reconstruction 6 months after stent insertion. Conclusions: The application of SEMS in post-intubation tracheal stenoses results in immediate improvement of obstructive symptoms without significant perioperative complications. SEMSs have the potential risks of migration and of granulation tissue formation at the end of the stent. SEMS should be applied only in strictly selected patients with post-intubation tracheal stenosis, who are considered unfit for surgery and/or with limited life expectancy.

Keywords: Airway; Endoscopy/endoscopic procedures; Trachea; Tracheal stents; Tracheal stenosis; Post-intubation tracheal stenosis

1. Introduction

The incidence of tracheal post-intubation stenosis has increased during the past decade because of the increasing number of patients, who require mechanical ventilatory support, and possibly because of the establishment as a routine of percutaneous dilational tracheostomy procedures [1]. Resection of the stenotic segment and tracheal reconstruction is considered the ideal management of post-intubation tracheal stenosis since the development of the techniques for safe tracheal resection and reconstruction from the leading thoracic surgeons in the field, Grillo and Donahue [2] and Pearson [3].

A small subset of patients with post-intubation tracheal stenosis are considered not fit enough to undergo surgical repair of their tracheal stenosis, and alternative techniques have been developed to serve as definitive or temporary solutions, until their medical condition improves, permitting safe surgical repair [4,5]. The available alternative techniques consist of bronchoscopic tracheal stenting or insertion of silastic T-tubes through a tracheostomy. The largest experience worldwide exists with silastic T-tubes, which are tested in large series and are found to be reliable and well tolerated for long time periods. However, T-tubes have the disadvantage of long-lasting tracheostomy that is an embarrassing condition for the majority of patients [6–8].

The experience and the short- and long-term results from the management of benign tracheal stenosis with the application of permanent self-expandable metallic stents (SEMSs) in 11 patients are presented and discussed.
2. Material and methods

2.1. Patients

Twelve patients were referred for stenting of their post-intubation tracheal stenosis between 2000 and 2004. The demographic characteristics of the 12 patients and the cause of prolonged intensive care unit (ICU) stay are presented in Table 1. The 12 patients, who were referred for tracheal stenting, were considered unfit to undergo surgical reconstruction of the airway or to have limited life expectancy due to co-morbidities (Table 1). Most of them also developed multiple organ dysfunction/failure during their ICU stay.

The study was approved by the scientific and ethics committee of AHEPA University Hospital.

2.2. Characteristics of tracheal stenoses

The diagnosis of tracheal stenosis was made by imaging of the larynx and tracheobronchial tree with virtual bronchoscopy and endoscopy. A single tracheal stenosis was found in 11 patients, while a double stenosis, above and beyond a tracheal stoma, was found in one patient. An upper tracheal stenosis involving the subglottic larynx also was found in three out of the 12 cases. Tracheal stenosis was combined with tracheomalacia in one case. The 12 tracheal/laryngotracheal stenoses were structural in nature and their classification, according to the system proposed by Freitag et al.\[9\] for tracheal stenoses and to McCaffrey \[10\] for laryngotracheal stenoses, is presented in Table 2. The elimination of the cross section of the tracheal lumen varied from 50% to 90%.

2.3. Initial management

All the 12 referred patients had a tracheostomy at the time of their referral that was performed for prolonged ventilatory support in 10 cases or shortly after extubation for symptoms of acute airway obstruction shortly after extubation in two cases. In two patients, a silastic T-tube was initially inserted for the management of their tracheal stenosis. The decision to remove the T-tube and to proceed with stenting in these two patients was made to avoid long-lasting or permanent tracheostomy. A previous unsuccessful attempt to destruct the obstructive fibrous tissue with thermal lasers was done in one of the 11 patients. A tracheostomy was performed 10 days later in an emergency setting in the above-mentioned patient for acute airway obstruction.

2.4. Type of stent, technique of stent insertion, and ventilation during the procedure

Nitinol, single strand, self-expanding, distally released, covered stents (UltraflexTM tracheobronchial stent system, Boston Scientific, Galway, Ireland) were used for stenting of the trachea. Selection of the stent’s size was based on virtual and fiberoptic bronchoscopy findings. The covered length of the stent had to completely bridge the airway stricture, while the diameter of the stent was chosen to approximate the size of the normal proximal tracheal lumen. After induction of anesthesia, the ventilation was established through the tracheotomy tube that pre-existing in all the 12 patients. Flexible bronchoscopy through the nose and through the tracheal stoma (after temporal removal of the tracheotomy tube) was then performed to make the exact estimation of the degree and extent of tracheal stenosis. The stenosis was initially dilated with the CRE™ wire-guided balloon dilatational catheter (Boston Scientific, Galway, Ireland). The dilated stenosis balloon was always inserted through the mouth and was advanced through the stenosis under bronchoscopic observation. After the dilation of the stenosis, the stent was inserted within the stricture over the guide wire. Advancement and position of the stent within the tracheal lumen was also observed through the bronchoscope.
Following expansion of the stent, ventilation was re-established via a laryngeal mask until full recovery of the patient, who was then transferred to the cardiothoracic ICU for monitoring.

2.5. Follow-up

A stent was successfully inserted in 11 out of the 12 patients. The 11 patients in whom a stent was successfully inserted had an annual follow-up of the patency of their stented airway by virtual bronchoscopy. Fiberoptic bronchoscopy was applied in patients with complicated clinical course or in those who had abnormal findings in virtual bronchoscopy. Follow-up time varied from 6 to 96 months, and the median follow-up time was 43 months.

3. Results

The cumulative early and late results of tracheal stenting for benign stenoses are presented in Table 3.

3.1. Early results

An SEMS was successfully inserted in 11 patients, while two attempts to insert the stent failed in one patient with tracheal stenosis involving the subglottic larynx. A silastic T-tube was inserted in this patient. The size (diameter/length) of the 11 inserted tracheal stents was: 20 × 40 mm in four patients, 20 × 60 mm in three, 20 × 80 mm in three, and 18 × 60 mm in one patient.

Immediate improvement of the obstructive symptoms was achieved in all the 11 patients. Permanent impairment of the voice (hoarseness) remained after stent insertion in one patient with stenosis involving the subglottic larynx.

Recurrence of obstructive symptoms because of stent migration was observed in two patients, 23 days and 6 months after stent insertion. Re-establishment of the patency of the airway was achieved by removal of the stent and insertion of a new, longer stent in the first case and a stent-in-stent insertion in the second case.

Table 3. Short and long term outcomes (cumulative results) in the twelve patients with post-intubation tracheal stenosis who underwent tracheal stenting using covered Ultraflex SEMS.

<table>
<thead>
<tr>
<th>Short-term outcome</th>
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<tr>
<td>• Failure to insert the stent: 1</td>
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<tr>
<td>• Immediate relief of obstructive symptoms after stent insertion: 11</td>
</tr>
<tr>
<td>• Permanent voice hoarseness after stent insertion: 1</td>
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<tr>
<td>• Recurrent tracheal obstruction due to stent dislodgement: 2</td>
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</tbody>
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<table>
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<tr>
<th>Long-term outcome</th>
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<tr>
<td>• Stent removal and laryngotracheal reconstruction 6 months after stenting: 1</td>
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<tr>
<td>• Good patency of the stented trachea for 60-96 months: 3</td>
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<tr>
<td>• Patients who died 24–48 months after stenting with good patency of their stented trachea: 3</td>
</tr>
<tr>
<td>• Evidence of obstructive granulation tissue formation at the end/s of the stent after 12–43 months: 4</td>
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<tr>
<td>• Episodes of tracheitis and halitosis during the follow-up: 4</td>
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One patient was re-evaluated in another hospital and underwent removal of the tracheal stent and successful laryngotracheal reconstruction, 6 months after tracheal stenting.

3.2. Late results

Good patency of the stented trachea was observed in three patients for 60, 72, and 96 months respectively. All the three patients experienced recurrent episodes of tracheitis that were clinically presented with halitosis and irritating cough. These episodes were successfully treated with the oral administration of clindamycin or doxycyclin.

Three patients died 24, 36, and 48 months after tracheal stenting, without any clinical or imaging finding of airway compromise during the follow-up period. Deaths were clearly unrelated to airway stenting (acute decompensation of heart function in a patient with chronic heart failure, stroke, and multiple sclerosis, respectively).

Symptoms of airway obstruction because of the development of granulation tissue at the end/s of the stent were observed in three patients (Fig. 1). The obstructive granulation tissue became evident 12, 36, 40, and 43 months after stent insertion. Fracture of the stent occurred also in the fourth of the above-mentioned patients, a complication that further aggravated the pre-existing mild symptoms of airway obstruction. Urgent bronchoscopic piecemeal removal of the fractured stent (Fig. 2) was followed by a surgical tracheostomy procedure. In addition, recurrent episodes of tracheitis and halitosis were the main complaints in the above patient during the follow-up period. The critical elimination of tracheal lumen by granulation tissue formation at both ends of the stent in another patient was treated with the creation of tracheostomy and insertion of a permanent tracheostomy.
The patient died 8 months later from diabetic coma.

The attempt made to destruct the obstructive granulation tissue at the end of the stent with thermal lasers was unsuccessful in two of the patients with obstructive symptoms. Flaming of the airway led to a fatal outcome in the first patient. The patient died from pulmonary sepsis in the ICU. Two attempts that were made to destruct the obstructing granulation tissue in the second patient resulted only in temporal improvement of the situation, and he underwent finally a permanent tracheostomy procedure.

4. Discussion

Tracheal stenting for benign airway obstruction has been extensively used in the past with various results of success. Airway stenting is associated with low intra-operative and early postoperative complications rate (up to 4.4% and 8.8%, respectively) [11]. Immediate relief of obstructing symptoms can be achieved in 95% of cases [11–13]. However, the late complication rate was reported to be very high (80%) in the case series published by Wu et al. [11] in 2007. The interesting finding of the above-mentioned study was that the high late complication rate was independent of the type of the tracheal stent used [11]. In addition, according to Merrot et al. [13], the incidence of late complications after tracheal stenting is related to the length of time the stent is present within the tracheobronchial tree than to the type of the prosthesis used. In a recently published study by Galluccio et al. [14], good results were obtained with interventional management of simple and very short (<1 cm) benign airway stenoses. Repeated laser-assisted endoscopic mechanical dilatation of the short stenotic segment and temporal placement of a silicon stent, in case of stenosis recurrence after repeated laser-assisted mechanical dilatation, resulted in cure in 96% of their patients, after a follow-up period ranging from 6 months to 3 years [14].

Ultraflex SEMSs are made of nitinol, a special, highly biocompatible metal alloy of nickel and titanium, where the two elements are present in roughly equal amounts [15]. The nitinol alloy has two unique biomechanical properties, shape memory and superelasticity or pseudoelasticity. The temperature-dependent nitinol stent can be squeezed down more than 'normal' metals (to less than 2-mm diameter) if cooled below 20°C, without breaking or permanently deforming, while it recovers to its original shape at body temperature. Thus, shape memory of nitinol stents allows them to be mounted in very small delivery catheters. In addition, nitinol behaves like a super spring, applying an elastic range more than 10 times greater than a normal spring material because of its superelasticity [15]. Covered stents were developed later as the hybrid of nitinol and polyurethane [15,16].

Uncovered and covered Ultraflex SEMSs were used for the relief of obstructing airway symptoms related to tumoral stenoses, benign stenoses, and strictures. The main advantages of these stents are their easy insertion using both flexible and rigid scopes, and their good adaptation to tortuous airway lesions [15,16]. The use of SEMS for the management of benign airway obstruction still remains questionable. Recently, the food and drug administration (FDA) has launched a public health notification addressing the serious problems, which are connected with the application of SEMS in benign airway stenoses.1

The long-term results of tracheal stenting with Ultraflex SEMS for benign tracheal stenoses were reported in previously published case series including 5–77 patients. Granuloma formation, rupture of the stent due to metal fatigue, and relapse of stenosis due to granuloma formation were the commonly observed late complications in these series, where the follow-up time extended up to 60 months [17–21]. The overall late complication rate in previously published series varied between 25% and 48% [17,18,21]. In our experience, symptomatic obstructive granulation tissue formation was found in 4 out of the 11 patients where a tracheal stent was successfully inserted. Granulation tissue formation is mainly connected with stent’s oversize. The excessive radial pressure along the bronchial mucosa, especially in the presence of mucosal inflammation, is considered to be the main causative factor of granulation tissue formation [20].

Recurrent obstructive symptoms due to distal stent migration occurred in two patients in our series of 11 patients. Stent migration was observed 3 weeks and 6 months after stent insertion. Distal migration of the stent was also observed in 3–12% of patients with benign airway stenoses, who were submitted for airway stenting with Ultraflex SEMS in previously published series. Stent dislodgement occurred exclusively within the first 6 months after stent insertion [5,17,19,21].

Infection of the trachea was also reported in a series of 15 complicated tracheal SEMSs that were referred for removal in the series published by Gaisser et al. [22]. Infectious tracheobronchitis was also a common complication (16%) of SEMS inserted for benign or malignant conditions in a series of 82 patients published by Saad et al. [20]. Majority of their patients, who developed infectious tracheobronchitis, were successfully treated with oral antibiotics [20]. Recurrent

1 http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/UCM021115.
episodes of halitosis and cough, probably due to tracheitis, were also observed in four patients of the present series; and the symptoms subsided with the administration of clindamycin or doxycyclin.

Removal of a covered Ultraflex stent is reported to be easier than the removal of an uncovered Ultraflex stent [15]. In our experience, removal of a covered Ultraflex SEMS after several months can be accomplished only in pieces, and usually requires multiple bronchoscopic interventions. The tracheal wall behind the stent is seriously damaged after stent removal. According to Ranu et al. [23], good tracheal healing should be expected few months after the removal of self-expandable stents.

The application of thermal lasers to destruct the obstructive granulation tissue and to re-establish airway patency has the risk of airway fire. The risk of airway fire is mainly attributed to the high concentration of oxygen used for ventilation of the patient during the procedure [24]. Airway fire is a major hazard of laser therapy in the presence of a covered SEMS within the airway [15]. The polyurethane cover of a SEMS will ignite in the presence of fire, producing polymer dust that will damage the lungs, an event that occurred with fatal outcome in a patient of the present study [24].

The reported indications to proceed with permanent tracheal stenting using SEMS in benign tracheal stenoses are some complex stenoses not amenable to resection, the critically ill patient, the patient who is unfit for surgery and with serious co-morbidities, the patient who declines surgery despite proper consultation, and the patient who has limited life expectancy [4, 17, 18, 20, 21]. However, none of the above-mentioned indications is objective and, consequently, any benign tracheal stenosis should be evaluated individually by a multidisciplinary team including always an experienced surgeon. One patient of the present study, who was initially considered to be unfit for surgery, underwent successful removal of the stent and laryngotracheal reconstruction 6 months later. Gaisser et al. [22] point out that 'tracheal strictures should not declared unresetable unless evaluated by a surgeon experienced in tracheal reconstruction’ because, in experienced hands, tracheal reconstruction has very low mortality (less than 3%) even in patients with advanced emphysema and chronic heart failure, while the results of reconstruction are excellent in more than 90% of patients. In addition, the decision to proceed with stenting in benign stenoses that involve the subglottic area requires special attention. Stenoses of the upper trachea, which involve the subglottic larynx, have the additional risks of failure to insert the stent, of stent migration, of granuloma formation shortly after stent insertion, and of permanent impairment of the voice [20]. In addition, halitosis is a common, embarrassing complication of permanent tracheal stenting with SEMS.

We add to the current body of the literature our experience by using SEMS for the management of benign tracheal stenoses. Despite the relatively small number of patients of the present case series, the follow-up period is quite long and, consequently, conclusions concerning the ‘behavior’ of these stents after many years can be drawn. Patency of the stented trachea was maintained for long periods (5–8 years) in 3 out of the 11 patients, while obstructive granuloma formation at both ends of the stent was observed in four patients. We have to point out that the formation of obstructive granulation tissue is a condition that is difficult to treat.

The recently introduced conical or straight in shape, all covered with polymer, self-expandable metallic stents (Silmet™, Novatech, La Ciotat, France), where the mesh is coated with medical grade silicon, are currently under evaluation for their value in the management of benign airway problems [25]. This innovative stent has the advantage of easy removal and of maintenance of its structure and function if one mesh breaks, due to its polymeric full cover. The polyester cover has also the theoretical advantage of minimal granulation tissue formation. The use of this new generation of SEMS for the definitive management of benign tracheal stenoses needs further evaluation in the future for the possible lack of the known complications of the old generation of SEMS and for their long-term patency.

Permanent tracheal stenting using SEMS is associated with serious late complications and, therefore, their use in benign tracheal stenosis has to be avoided. The application of the new generation, coated with silicon and covered with polyester SEMS for the treatment of post-intubation tracheal stenosis, is promising and currently under evaluation. Tracheal stenting with SEMS should be, at the moment, applied as an alternative to surgical tracheal reconstruction only in strictly selected, unfit for surgery patients with limited life expectancy. Any option to offer tracheal reconstruction has to be thoroughly evaluated by surgeons experienced in laryngotracheal reconstruction, before the final decision to proceed with permanent tracheal stenting using SEMS.

References

Airway stenting for benign tracheal stenosis: what is really behind the choice of the stent?

The study, from Charokopos et al. [1], regarding metallic stenting in benign tracheal stenosis rises some comments. It is always important to recall that airway stenting is indicated as palliation, irrespective of the underlying etiology. Palliation means that it should be considered only after all medical or surgical options have been exhausted. Thus, stenting can be considered as a primary treatment in some cases either as a bridge towards other managements or with a curative intent. "A stent is a foreign body and nobody is perfect," so after placement, one should expect and manage stent-related complications even several times in some patients. In malignancy, the word ‘palliation’ is particularly relevant, as most of the indications rely on palliative care and, the patients unfortunately die before stent-related complications. However, in benign indications, the choice of the stent is essential. Traditionally, airway stents are divided into two categories, the silicone stents, with the Duman stent being the gold standard, and the self-expandable metallic stents (SEMS) with the Ultraflex® (Boston Scientific, Galway, Ireland) as the reference. Both types of stents have their complications. Migration is the main complication for silicone stents, while re-stenosis and rupture are problematic for SEMS. In benign tracheal stenosis, recent articles on SEMS-related complications [2,3] prompted the Food and Drug Administration (FDA), in 2005, to publish recommendations on their use (http://www.fda.gov/cdrh/safety/072905-tracheal.html). It was stated that one should use metallic tracheal stents in patients with benign airway disorders only after thoroughly exploring all other treatment options (such as tracheal surgical procedures or placement of silicone stents). Using metallic tracheal stents as a bridge to other therapies is not recommended, because removal of the metallic stent can result in serious complications. If a metallic tracheal stent is the only option for a patient, insertion should be done by a physician trained or experienced in metallic tracheal stent procedures. If removal is necessary, the procedure should be performed by a physician trained or experienced in removing metallic tracheal stents [4]. So, why some authors continue to prefer SEMS than silicone stenting? Silicone stents are cheaper, easier to remove, do not worsen the primary stenosis and, have shown, in a recent article [5] focusing on benign tracheal stenoses, that, after 18 months of placement, no recurrence in about 70% of cases, 1 year after removal. What is really behind the choice of an SEMS? The main answer relies upon the skills in rigid bronchoscopy. SEMS placement does not need rigid bronchoscopy, while silicone stent placement does. Most of the experts and international guidelines insist on the necessary skills in rigid bronchoscopy for physicians willing to practice interventional bronchoscopy. Stent placement and removal using rigid bronchoscopy is safer and quicker, irrespective of the type of stent. The new all covered SEMS are right now under evaluation in benign indications. Their theoretical advantage is based on the absence of metallic wire directly in contact with the mucosa, avoiding restenosis and allowing easier removal. This could be the future for SEMS but has to be demonstrated.