

Stents for airway strictures: selection and results

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Abstract: Airway stents can provide effective and timely relief in patients with central airway obstruction. Silicone based stents are the most commonly used airway stents worldwide with a long track record of safety. Metallic stents continue to evolve from the earliest uncovered versions to a variety of newly designed covered stents. Despite the availability of a variety of stent materials and designs, minimal advances have been made towards innovation in stent technology and an ideal stent has unfortunately not yet been developed. Nevertheless, the first generation of biodegradable airway stents are available, work on drug-eluted stents is in the pipeline and three-dimensional printing of a customized airway stent may be the future. In this review, we discuss selection and results for most commonly utilized airway stents.

Keywords: Airway strictures; central airway obstruction; malignant strictures; benign airway stenosis; airway stenting; silicone stents; expandable metal stents

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Introduction

Airway stents have been used for management of tracheobronchial pathologies since the second half of 20th century. A silicone based T-Tube developed by Montgomery in the 1960's is one of the earliest airway stents (1). Dumon followed with the introduction of a 'stand alone' stent (2). Several variations of these polymer-based stents evolved and remained widely utilized until self-expandable metal stents (SEMSs) were introduced in the late 20th century. All currently available airway stents have certain limitations, and stent selection should be catered for specific disease processes. Airway stents remain an important therapeutic option to restore airway patency in selected patients especially in conjunction with other endoscopic modalities. Proper stent selection is crucial and requires consideration of multiple factors including properties, indication, and duration of stent placement. In this review, we discuss selection and results for the most commonly used airway stents.

Indications for airway stents

Major potential indications for airway stenting include:

- (I) Palliation of extrinsic compression and endoluminal intrinsic lesions in malignant airway disease;
- (II) Treatment of benign airway stenosis;
- (III) Treatment of airway fistulas and dehiscence;
- (IV) Management of post lung-transplant (LT) anastomotic complications;
- (V) Management of pediatric airway stenosis.

The two main types of airway stents are silicone stents and metallic stents. Results with their use are discussed below.

Silicone stents

Silicone stents have a long record of safety, are relatively inexpensive and easy to manipulate. They are available in nonexpandable (Dumon, Hood, Dynamic airway) and expandable versions (Polyflex). Dumon and Hood stents are the most commonly used airway stents worldwide and are

developed in two designs: straight and Y-shaped (for carinal stenosis).

Silicone stents for benign airway strictures

Silicone stents have established good efficacy in patients with tracheobronchial strictures, both benign and cancer-related. Earlier reports for their use demonstrated successful airway palliation in 85% to 95% cases, with good tolerance and infrequent complications resulting in their continued use to date (3-7).

The effectiveness of silicone stents has been re-validated in recent works. Jeong *et al.* investigated the utility of silicone stents in 19 patients who developed tracheobronchial stenosis following major thoracic surgery (8). A total of 50 stents were placed (Natural, 33; Y-stent, 13; Dumon, 3; and T-tube, 1) and symptomatic improvement was achieved in all cases. In addition, successful stent removal was possible in 7 (36%) patients within a median duration of 7 months. There was no procedure related mortality. Common complications included restenosis (33%) and stent migration (32%).

Terra *et al.* (9) reported their experience in 92 patients with benign airway strictures using 258 silicone stents (T-tubes, 72%; DUMON, 15%; Polyflex, 12%; and Y-tube, 1%). Interestingly, the authors showed that decannulation was possible in 21% of cases who were considered inoperable before stenting. Mean follow-up after decannulation was 37.4 months. Granulation tissue formation (22%) and stent migration (5%) were the most common complications. Presence of tracheostomy before stenting was the only significant predictor of poor decannulation outcome.

Silicone stents for post-lung transplantation strictures

Silicone stents have demonstrated good efficacy and safety in patients with post-LT anastomotic strictures. Dutau *et al.* examined their utility in 17 patients and observed symptomatic improvement following stent placement in all patients (10). The mean FEV1 increased by 672±496 mL and airway patency was maintained at a mean follow-up of 867 days. Complications occurred in 16 of 23 anastomoses including granulation tissue (n=10), mucus plugging (n=7), stent migration (n=7), and infection (n=4). Successful stent removal was achieved in 16 of 23 anastomoses (69.5%) at a mean of 362±126 days. Similar results were reported by Sundset and colleagues, who described their experience of silicone stent placement in 35 LT patients (11). Symptoms were relieved in all patients and 25 stents were successfully

removed within 6 months (range, 1–22 months). Median FEV₁ was 2.3 liters after stent removal and remained 2.3 liters at 24 months.

Despite proven effectiveness for the treatment of tracheobronchial strictures, there are several limitations with silicone stents such as migration and the need of rigid bronchoscopy for stent placement etc. This has led to development of self-expanding stents most notably SEMS.

Metallic stents

Commonly used metallic stents include uncovered/partially covered (Ultraflex and Wallstent) and covered stents (AERO Stents). They are relatively easy to place using fiber-optic bronchoscopy under fluoroscopic guidance. Covered metallic stents are manufactured with or without a silastic or polyurethane covering to minimize intrinsic tissue growth. Metallic stents have been studied in the management of both benign and malignant airway stenosis.

Metallic stents for malignant strictures

In cancer-related strictures, airway stents can be used either for palliation to maintain airway patency following debulking or as a bridge to other procedures. In addition to providing excellent palliation, timely placement of an expandable metal stent improves survival in patients with malignant stenosis. This was reported by our group in a retrospective analysis of 50 patients with advanced metastatic airway obstruction (12). A total of 72 airway stents were placed. EMSs (Ultraflex and AERO) were inserted for tracheal and bronchial stenosis, while silicone stents (dynamic airway) were deployed for carinal stenosis. Symptomatic improvement was observed in 45 patients (90%). Overall complication rate was 20% (n=10) including mucus plugging (n=2), stent migration (n=2), and tumor ingrowth (n=1). The overall median survival was 117 days with 3-month and 6-month survival rates of 60% and 40%, respectively. Significant survival benefit was observed for patients who had intermediate performance (based on ECOG and MRC) compared with the poor performance group (233 versus 89 days, $P<0.05$).

Metallic stents for benign strictures

Use of metallic stents for benign airway diseases is controversial. Given their ease of insertion compared to silicone stents, metallic stents use gained initial enthusiasm,

with encouraging short-term results. However, long-term results revealed significant complications associated with metallic stents for benign airway diseases that prompted the US Food and Drug Administration (FDA) to release a public health warning against the use of metallic stents in benign airway disease (13). Previous reports comparing the outcomes of metallic stents in benign and malignant strictures have reported a higher incidence of complications in the benign group (14). This has been validated in recent observations as well. Chung and colleagues reported their experience with 211 SEMSs insertion in 149 patients and observed a higher complication rate in the benign group (42.2% *vs.* 21.1%) including granulation tissue formation (19% *vs.* 10.5%) and stent fracture (16.4% *vs.* 1.1%) (15).

Besides a higher complication rate, metallic stents can be difficult to remove. Lunn *et al.* performed stent removal in 25 patients and reported significant complications including retained stent pieces (n=7), mucosal tear (n=4), re-obstruction requiring re-stenting (n=14), need for postoperative mechanical ventilation (n=6) and one tension pneumothorax (16). In the largest series of 55 SEMSs removals by Alazemi and coworkers, it was estimated that stent removal comes with an additional cost of approximately \$11,000 dollars per encounter (17). In addition, there is a concern that EMSs may also limit future therapeutic options in some cases. This was observed in a series of 15 patients, where primary repair was judged to be possible in 10 patients before an EMS placement, yet only 5 patients had a successful repair afterwards (18).

Metallic stents for post-LT strictures

Airway stents have been investigated in the setting of post-LT anastomotic strictures and while some initial reports observed high complication rates, significant benefits have been demonstrated in recent work. Gottlieb and coworkers inserted 111 SEMSs (91% uncovered) in post-LT recipients who developed anastomotic strictures (19). Clinical improvement was seen in 80% cases. Most frequent complications were restenosis (52%), bacterial colonization (40%), mucus plugging (11%) and migration (3%). In multivariate analysis, stent insertion within 3 months postoperative period was independently associated with an increased risk of re-stenosis (HR 3.29; 95% CI: 1.50–7.18; $P=0.003$). In patients who received stent placement, 5-yr survival rate was significantly lower than those who did not undergo stenting (60% versus 76%; $P=0.02$).

Recently, Abdel-Rahman *et al.* evaluated the short-

term and long-term outcomes in 47 post-LT patients (20). The median follow-up was 54 months (range, 1–132 months). Immediate relief was achieved in 95% of patients. Granulation tissue mandating treatment was observed in 65%. Five-year survival rate for patients who underwent stenting was lower compared to those who did not receive stents (55.5% *vs.* 61.1%, $P>0.05$). Overall, the stent group had a significantly increased number of bronchoscopies to manage stent-related problems. They concluded that metal stents can be an acceptable option in this group of patients, but the need for more procedures in the follow-up must be accepted.

Other applications of metal stents include their utility in managing life threatening post-LT anastomotic wound dehiscences (21). Metal stents are frequently associated with granulation tissue formation which can provide a platform for healing of the dehiscence. Ideally, the stent should be removed at 6–8 weeks by the time wound repair is achieved.

Pediatric application of airway stents

Airway stenting may also represent an effective treatment in children with tracheobronchial strictures. Serio *et al.* described the largest cohort of 100 children with severe airway obstruction who underwent stent placement (22). A total of 235 stents were inserted (silicone 112, metallic 120 and biodegradable 3). Silicone stents were mainly placed in the trachea; stainless steel metallic stents were utilized for bronchial lesions. Clinical improvement was reported in eighty patients after stent insertion; furthermore, 17 patients were weaned off mechanical ventilation while 3 showed no significant clinical improvement. Silicone stents were more prone to granulation tissue formation (11.6% *vs.* 0.8%) and dislocation (39.2% *vs.* 4.1%) compared with metallic stents. At a median follow-up of 41.4 months (range, 1.1–145.4 months) complete resolution was registered for 60 (65.9%) patients (silicone 76.6% and metal 72.9%), 17 were still under treatment, 9 lost to follow-up, 8 underwent surgery and 6 died of non-stent related causes. Stent removal was performed in 26 (23%) patients with silicone stents and 6 (5%) patients with metallic stents.

Airway stenting is also potentially useful in the emergency management of pediatric airway pathologies such as congenital tracheal stenosis. Xu *et al.* reported using self-expanding metallic stents in 31 infants with congenital tracheal stenosis without observing any immediate stent-related complication (23). All patients had immediate improvement of respiratory obstruction and successful weaning from the breathing machine.

Granulation tissue was observed in three cases, managed successfully by cryotherapy. In a follow-up up to 24 months, stents remained functional in 29 patients. Only three patients required repeat stent replacement. Stent retrieval was performed in seven cases (range, 0 to 10 months) without any complications. Based on the literature and their own experience, the authors provided the following recommendations for stent removal:

- (I) The stent has been in place for 2–3 months under a good follow-up program;
- (II) The airway remains unobstructed as confirmed by fiber bronchoscopy and CT imaging;
- (III) Absence of dyspnea and ventilatory dysfunction;
- (IV) The stent could be removed by pulling gently using flexible bronchoscopy.

Future perspectives in airway stenting

Biodegradable stents

Biodegradable stents represent a novel alternative in stent technology. They are based on polydioxanone, a material used in sutures. Lischke *et al.* reported the first clinical application of custom made biodegradable polydioxanone stents for the relief of anastomotic stenosis in 6 post-LT patients (24). Stents were inserted using a 13–15F introducer via endotracheal tubes over a guide wire. Airway relief was achieved in all patients. Restenosis occurred in four patients requiring biodegradable stent reinsertion (3–7 stents) with a median duration of 5 months (range, 2–15 months) between resenting. The stents dissolved at an average of 5 months. One patient died during the study period due to pulmonary embolism. All other cases remained clinically well throughout the follow-up period.

The research group of Fuehner recently reported a larger case series with biodegradable stents in post-LT patients (25). They inserted a total of 11 stents. All patients reported immediate relief of their clinical symptoms and patency was achieved in 9 stenoses (82%) at 1 year. Complete degradation was observed at a median of 141 days. Four patients developed in-stent stenosis which was successfully treated with a metallic stent (n=1), argon therapy, and/or balloon dilatation (n=3). Nine patients were treated with topical mitomycin as a result of granulation tissue during follow-up.

Three-dimensional (3D)-printing in airway stenting

Other areas of interest include the possibility of designing customized airway stents. Cheng and colleagues reported

successful insertion of a personalized T-tube designed from a virtual 3D model of the upper airway in a patient with tracheal dehiscence (26). Improvement in symptoms was observed after placement of the T-tube and the patient was able to phonate within 4 days. Follow-up CT scan and bronchoscopy revealed no granulation tissue at 4 weeks. Similarly, Morrison and colleagues reported the clinical application of a custom made 3D printed external airway splint in three infants with severe bronchomalacia (27). The implant was able to provide immediate relief and continues to allow growth of the primary airways.

Commentary

Management of central airway obstruction caused by malignant lesions and benign pathologies is an important clinical problem. Surgical reconstruction remains the preferred approach, but not all patients may be appropriate candidates for surgery. Thus, endoscopic management is important for palliative reasons and for patients deemed inoperable. Airway stents can provide timely and effective relief in these patients and remain an important modality especially in conjunction with other endoscopic therapies such as laser, debridement, photodynamic therapy, mechanical dilatation and cryotherapy.

There are important considerations that must be taken into account regarding the choice of a stent. Both silicone stents and metallic stents have advantages and disadvantages that should be considered before choosing the best stent option for an individual patient. Silicone stents are potentially retrievable and inexpensive. They can be repositioned as many times as needed. However, they are more likely to migrate and interfere with mucociliary clearance. In addition, placement of a silicone stent generally requires rigid bronchoscopy and general anesthesia. Conversely, metallic are technically easier to insert via flexible bronchoscopy under fluoroscopic guidance. They have a more favorable internal-to-external diameter and are less prone to stent migration (however migration does occur). Metallic stents often become embedded in the mucosa and thus are not easily removable. This is an important issue in patients with non-malignant airway strictures who live longer and may require several interventions during the course of their disease.

For malignant airway stenosis, both silicone and metallic stents appear to provide similar efficacy and safety profile (28,29). This is most likely due to the shorter life expectancy of these patients during which long-term complications

of stenting are not observed. In addition, stent removal is generally not a concern in these patients especially when palliation is the ultimate goal. Therefore the choice of a stent is often based on physician's expertise, patient's anatomy and stent availability.

Stent selection in patients with benign strictures is controversial. Significant complications occur with the use of metal stents and their use is strongly discouraged in this group. Silicone stents have shown low complication rates and can ultimately be removed and hence serve as first choice in these patients. Similarly in patients with post-LT strictures, silicone stents should be the first line stent option. We recommend stent removal between 6–12 months after insertion. With regards to the use of SEMSs in these patients, current data is promising with good short-term outcomes. However, due a high long-term complication rate, the need of more follow-up bronchoscopic procedures to manage complications must be accepted (19,20). In addition, Data on removal of SEMS in post-LT patients is very limited. Fruchter *et al.* reported the largest series of six stent removals in 24 patients. The cause of stent removal was excessive granulation tissue formation and stent obstruction. Stents were removed at a median of 30 months (range, 16–48 months) from insertion. No major complications were encountered during stent removal. They concluded that SEMS can be used in selected post-LT patients since their removal could be safely and effectively accomplished if needed (30). A recent area of interest is the use of biodegradable stents in these patients with reasonable initial results (24,25). However, additional data is needed before they can be adopted in the armamentarium of thoracic surgeons and interventional pulmonologists.

In conclusion, airway stenting offers palliation in patients with cancer and a minimally invasive endoscopic option in patients with benign airway disease. Although, there are limitations associated with the use of airway stents, they are generally safe and effective in selected patients. We strongly advocate that stent insertion should only be performed at specialized centers by experienced physicians.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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