

The Fellows' Challenge

Keeping Up With The Evidence

AABIP/AIPPD Evidence-Based Medicine Series

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Airway Stenting Module

Case Presentation:

Mr. Smith is a 63-year-old man with an 80 pk yr history of smoking and recently diagnosed non-small cell lung cancer who presented to the emergency room with the complaint of worsening shortness of breath. Initial chest x-ray done in the ED showed complete opacification of right hemithorax. A CT chest was done that showed tumor extrinsically compressing the right main stem bronchus. His clinical condition gradually worsened and he was subsequently intubated and transferred to the medical intensive care unit. A bronchoscopy was performed and confirms the finding of near complete obstruction at the level of the right main bronchus from mixed, extrinsic and intrinsic disease. On reviewing his outside records, there was a chest x-ray that was done two weeks ago that showed an aerated right hemithorax with a right hilar mass and a PET scan that showed an FDG-avid right hilar mass with an SUV of 8.6, with no other hypermetabolic activity elsewhere. Interventional Pulmonology was consulted for further management. How do you manage this patient?

Introduction:

Airway stenting has been practiced for several decades and is indicated in a variety of malignant and benign conditions. Airway stents are implanted to maintain patency of the tracheobronchial tree. Stents are considered as a temporizing measure or when there is no surgically curable airway disease. The most common indications for stenting include minimizing extrinsic compression from tumors or lymphadenopathy, maintaining patency after bronchoscopic tumor removal due to intrinsic obstruction, healing airway fistulas and anastomotic dehiscence post lung transplantation and in select cases of benign airway disease. First generation stents were comparatively simplistic and the new generation metallic airway stents are hybrid in nature and made with complex alloys. With improved understanding of stent-airway interactions,

innovations in biomedical engineering, and an improvement in post procedural care, the utility of airway stenting has been increasing with an acceptable safety profile and complications.

Principles of Airway Stents

Ratnovsky A, Regev N, Wald S, Kramer M, Naftali S. Mechanical properties of different airway stents. Med Eng Phys. 2015;37(4):408-415.

The study was conducted to compare different types of stents (silicone, balloon-dilated metal, self-expanding metal, and covered self-expanding metal) in terms of their mechanical properties and the radial forces they exert on the trachea. Mechanical measurements were carried out using a force gauge and specially designed adaptors. The results show a clear correlation between stent diameter and the levels of stress it exerts on the trachea. Metal stents that are covered with less stiff material exert significantly less stress on the trachea and have a low migration risk. Silicone stents produce the lowest levels of stress with high propensity for migration.

Population:

None

Tracheal models were used; basic geometrical model of the trachea consisted of two main layers: smooth muscle and cartilage

Intervention:

Insertion of different types of stents

Comparison:

Compared to different types of airway stents

Outcomes:

- There is a clear correlation between stent diameter (oversizing) and the levels of stress it exerts on the trachea.
- Metal stents covered with less stiff material exert significantly less stress on the trachea while still maintaining strong contact with it.
- The use of such stents may reduce formation of mucosa necrosis and fistulas while still preventing stent migration.
- Silicone stents produce the lowest levels of stress, which may be due to weak contact between the stent and the trachea and can explain their propensity for migration.
- Unexpectedly, stents made of the same materials exerted different stresses due to differences in their structure.

- Stenosis significantly increases stress levels in all stents.

Complications of Airway Stents

Ost DE, Shah AM, Lei X, et al. Respiratory infections increase the risk of granulation tissue formation following airway stenting in patients with malignant airway obstruction. Chest. 2012;141(6):1473-1481.

This is a large retrospective single-center cohort study with 172 patients who underwent airway stent placement for malignant airway obstruction that compared the incidence of complications of different airway stents. They found that Aero stents were associated with an increased risk of infection and Dumon silicone tube stents had an increased risk of migration. Silicone stents and lower respiratory tract infections increased the risk of granulation tissue, and lower respiratory tract infections were associated with decreased survival.

Population:

- Age: 16-84 yrs
- Metastatic lung cancer (41%) and primary lung cancer (59%)
- Excluded if more than one type of stent was in place at the same time

Intervention:

- Ultraflex stents were used in: 118 cases (60 %)
- Aero (Merit Endotek) stents: 31 cases (16 %)
- Dumon silicone bronchial (Novatech) and Y-stents (Boston Medical) were used in 46 cases (24%)

Comparison:

- None

Outcome:

- Aero stents were associated with an increased risk of infection (hazard ratio [HR] = 1.98)
- Dumon silicone tube stents had an increased risk of migration (HR = 3.52)
- Silicone stents (HR = 3.32) and lower respiratory tract infections (HR = 5.69) increased the risk of granulation tissue
- Lower respiratory tract infections were associated with decreased survival (HR = 1.57)

Take home points:

This is the largest retrospective study demonstrating the incidence of complications of different airway stents in malignant airway disease. They found higher respiratory infections in patients with Aero stents and high migration rates in silicone stents, with

low granulation in Ultraflex stents. Stent infection and repetitive motion may be related to the development of granulation tissue.

Grosu HB, Eapen GA, Morice RC, et al. Stents are associated with increased risk of respiratory infections in patients undergoing airway interventions for malignant airways disease. Chest. 2013;144(2):441-449.

This is a retrospective study reporting the incidence of lower respiratory tract infection in patients who had therapeutic bronchoscopy with stent placement for malignant airways disease. The study showed that airway stents were associated with increased risk of infection.

Population:

- 72 patients with malignant central airway disease, 24 had stent placement.
- Mean age 59.4 yrs
- Patients with combined extrinsic and endoluminal tumor: 50%
- Endoluminal tumor:39%
- Extrinsic compression only 4%

Intervention:

Number of stents placed: 29

- Ultraflex stent 15 (52%)
- Aero stent 9 (31%)
- Dumon Stent 1 (3)
- Dumon Y Stent: 3 (10%)
- Polyflex stent 1 (3%)

Outcome:

- Stents were associated with an increased risk of infection (HR 3.76).
- 16% of stent patients will get infected within 30 days of placement.
- The incidence rate of lower respiratory tract infection was 0.0057 infections/per person-day in patients with stents vs 0.0011 without stents.
- Restenosis due to tumor overgrowth was associated with more severe obstruction at baseline (obstruction \geq 50% vs $<$ 50% HR, 13.71).
- 32/72 patients died within 6 months

Take home points:

Therapeutic bronchoscopy with stent placement is associated with increased risk of infection compared to patients who did not have the stent placement in patients with malignant airway disease. If ablative techniques reopen the airway and there is a good chance that the tumor may respond to chemotherapy and/or radiation, a strategy of initially holding off on stenting may be warranted.

Ost DE, Ernst A, Grosu HB, et al. Complications following therapeutic bronchoscopy for malignant central airway obstruction: results of the AQUIRE registry. Chest 2015; 148:450-471.

This was a large multicenter study using results of AQUIRE Registry and reported the complications following therapeutic bronchoscopy for malignant airway obstruction. This study found that there were significant differences among centers. Risk factors for complications were urgent and emergent procedures, American Society of Anesthesiologists (ASA) score > 3, redo therapeutic bronchoscopy and moderate sedation, with a 30-day mortality was 14.8%.

Population:

1,115 patients were included

- 725 (65%) had obstruction at one location only
- 227 (20%) had two locations
- 119 (11%) had three locations
- 35 (3%) had four locations
- 8 (1%) had obstruction at five locations.
- Type(s) of obstruction: 1,041 (93%) patients had only one type of obstruction
- 68 (6%) had two types of obstruction, and 6 (1%) had all three types of obstruction present

Intervention:

Stent placement (wide variation stent usage at centers)

Comparison:

None

Outcome:

- Overall complication rate was 3.9%, but significant variation was found among centers.
- Risk factors for complications were urgent and emergent procedures, American Society of Anesthesiologists (ASA) score > 3, redo therapeutic bronchoscopy, and moderate sedation.
- The 30-day mortality was 14.8%; mortality varied among centers. Risk factors for 30-day mortality included Zubrod score > 1, ASA score > 3, intrinsic or mixed obstruction, and stent placement.

Take home points:

General anesthesia should be considered to perform therapeutic bronchoscopy for malignant central airway obstruction and stent placement was associated with increased 30-day mortality in these patients.

3D Airway Stents

Alraiyes AH, Avasarala SK, Machuzak MS, Gildea TR. 3D printing for airway disease. AME Med J. 2019;

Background/Summary:

With limitations of commercially available stents, alternative methods of airway stent manufacturing such as custom 3D stent printing are being considered. With the right equipment and expertise, 3D printing can allow point-of-care fabrication of customized implants, including airway stents. Very little guidance exists for quality assurance of 3D printed implantable devices. Recently the FDA has cleared patient-specific airway stents.

Lobar and Segmental Stents

Sethi, Sonali Gildea, Thomas R. Almeida, Francisco A. Cicenía, Joseph C. Machuza, Michael S., Clinical Success Stenting Distal Bronchi for "Lobar Salvage" in Bronchial Stenosis, Journal of Bronchology & Interventional Pulmonology, Issue: Volume 25(1), January 2018, p 9-16

This is a retrospective study to assess the feasibility, complications, and long-term impact of using 122 iCAST balloon-expandable stent placement in 38 patients with lobar bronchial stenosis either secondary to malignancy or benign etiologies that was followed for a 3.5 years.

PICO:

Population:

- Mean age 58 years (range, 28 to 76 y)
- 19 women (50%).
- Inoperable lobar bronchial stenosis
- Mixed benign/malignant patients.

Intervention:

iCast balloon expandable stent placement

Comparison:

None

Outcomes:

- Symptomatic improvement in QOL questionnaire was observed in 95% of patients (36/38)
- 76% of patients had radiographic improvement of lobar atelectasis/infiltrates on follow-up chest radiograph.

- 93% (15/16 lung transplant) of these patients showed improvements in their PFT's, with an average improvement in forced expiratory volume (FEV1) of 12.3% (range, 4% to 23%)

Complications:

- Overall complication rate was 20%
- Stent migration (10%)
- Granulation tissue: 5%

Take home point:

Stenting small airways in benign and malignant disease for lobar salvage is safe and effective in improving outcomes with regard to symptoms, radiographic improvement, and pulmonary function tests related to lobar bronchial stenosis.

Tracheobronchial stent in the management of airway complications after lung transplantation

Fernandez-Bussy S, Akindipe O, Kulkarni V, Swafford W, Baz M, Jantz MA. Clinical experience with a new removable tracheobronchial stent in the management of airway complications after lung transplantation. J Heart Lung Transplant. 2009;28(7):683-8.

Background:

This is a retrospective review of 24 consecutive patients requiring tracheobronchial stent placement after lung transplantation. Changes in airway diameter, spirometry and stent-related complications were recorded.

Populations:

- The male/female ratio was 15:9.
- Age 44-68 years with bronchial stenosis, bronchomalacia, bronchial stenosis plus bronchomalacia, and bronchial dehiscence after lung transplants

Intervention:

- Underwent AERO self-expanding hybrid stent placement

Comparison:

None

Outcome:

- Bronchial stenosis decreased from 80% to 20%.
- The mean increase in FVC after stent placement was 0.28 liters (range, 2.52 \pm 0.69-2.80 \pm 0.78 liters; P < 0.0005).

- The mean increase in FEV1 was 0.44 liters (range, 1.35 \mp 0.43-1.79 \mp 0.67 liters; P < 0.00005).
- The average follow-up after stent placement was 232 days.
- 24/49 stents were removed within 14 months for complications.
- Complications: granulation tissue was seen in 20%, stent migration in 18.4% and fracture was seen in 6.1%
- Two patients died 3 months after stent placement from causes unrelated to the stents.

Take home point:

The use of hybrid metal stents provides effective palliation of bronchial stenosis, bronchomalacia, or anastomotic dehiscence in lung transplant patients. The complication rate and cost of the stent is comparable with other types of metallic tracheobronchial stents, with the important advantage of placement and removability using a flexible bronchoscope.

Montgomery T Tubes

Shi S, Chen D, Li X, et al. Outcome and safety of the Montgomery T-tube for laryngotracheal stenosis: a single-center retrospective analysis of 546 cases. ORL J Otorhinolaryngol Relat Spec. 2014;76(6):314-20.

This is a large retrospective study that analyzed the surgical outcomes and safety of patients who underwent Montgomery T tube placement for laryngotracheal stenosis from 1996 to 2010.

Populations:

- 546 pts with laryngotracheal stenosis were included
- Median age: 35 years
- Males: 337 (60.6%) and females: 209 (39.4%).
- Etiologies included: neck trauma in 332 (60.8%), post tracheal intubation in 146 (26.7%), surgical resection of laryngotracheal tumors in 35 (6.4%), chemical burns in 25 (4.6%) and unknown in 8 (1.5%) patients

Intervention:

Underwent Montgomery T-tube stenting

Comparison:

None

Outcome:

- T-tubes were successfully removed in 342 patients at 6-24 months following intubation.

- Initial extubation success rate: 62.3%.
- Laryngotracheal restenosis following extubation occurred in 192 patients, necessitating repeat T-tube placement
- The success rate for the second attempt: 58.9%.
- The overall success rate: 83.3%.
- Complications: Hemoptysis in 8 patients, postoperative infection in 6 patients, wound dehiscence in 3 patients, laryngeal obstruction in 13 patients, aspiration in 12 patients, and postoperative tracheoesophageal fistula in 2 patients.
- Most common complication after Montgomery T-tube stenting in the management of inoperable laryngotracheal stenosis was crusting within the tube

Take home point:

This large clinical series demonstrated the safety and effectiveness of the T-tube for grade 1 and 2 stenosis with stenotic segments of < 6 cm. For segments > 6 cm, tracheal end-to-end anastomosis is not appropriate and long-term placement of a T-tube is recommended.

The Bottom Line

Therapeutic bronchoscopy, including airway stenting, can reestablish airway patency in up to 93% of patients with malignant central airway obstruction. The patients that benefit the most from airway stenting are those with worse baseline dyspnea, poor functional status, central airway obstruction and higher American Society of Anesthesiology score. Early complications associated with stent placement are rare whereas late complications are not infrequent. Stents are a risk factor for lower respiratory tract infection, which, in turn, is a negative prognostic factor in terms of survival. Recent research has seen the development of personalized stents via three-dimensional printing, mini stents for more distal airways, and stents with drug-eluting and biodegradable properties.

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