



Review

# Airway Stents in Interventional Pulmonology

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**Abstract:** Airway stents, first developed in the 1980s, have become fundamental in managing a multitude of airway pathologies and complications within the field of interventional pulmonology. The primary function of an airway stent is to re-establish airway patency and integrity when obstruction, stenosis, anastomotic dehiscence, or fistulae develop as a result of various malignant or benign conditions. Nevertheless, airway stents are foreign bodies that can result in complications. In this review article, we will discuss airway stents and their ongoing role in the management of several malignant and benign diseases. We will describe indications for airway stenting and review the elements that must be taken into consideration for optimal patient and stent selection. Given the prevalence of data regarding therapeutic bronchoscopy and airway stenting in malignant airway obstruction, much of the discussion in this review will focus on stent placement for that indication. We will also review the data as it pertains to safety, efficacy, and complications after stent placement, and conclude with a discussion of the future applications and research avenues related to airway stents.

**Keywords:** interventional pulmonology; therapeutic bronchoscopy; rigid bronchoscopy; airway stents; self-expandable metallic stents; hybrid stents; silicone stents; malignant airway obstruction

**Citation:** Bashour, S.I.; Lazarus, D.R. Airway Stents in Interventional Pulmonology. *J. Respir.* **2024**, *4*, 62–78. <https://doi.org/10.3390/jor4010006>

Academic Editor: Bruce Fernando Sabath

Received: 30 December 2023

Revised: 7 February 2024

Accepted: 20 February 2024

Published: 1 March 2024



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## 1. Introduction

Airway stents were first developed in the 1980s and have since become pivotal in managing a multitude of malignant and benign airway pathologies. In such conditions, bronchoscopic interventions aim to improve a patient's quality of life and alleviate symptoms when less invasive treatments prove ineffective [1]. The primary function of an airway stent is to re-establish airway patency and integrity when obstruction, stenosis, weakening of the tracheobronchial wall, or fistulae may be present [2]. Several different types of stents are currently available for commercial use. These include devices made of silicone, metallic wire mesh, or a combination of these materials, and are designed with different shapes, diameters, and lengths [3]. Since airway stents are foreign bodies, they are associated with both short and long-term complications. Stent migration, granulation tissue formation, infection, and mucus plugging are commonly encountered [4]. The propensity to develop complications necessitates long-term, close follow-up after stent placement.

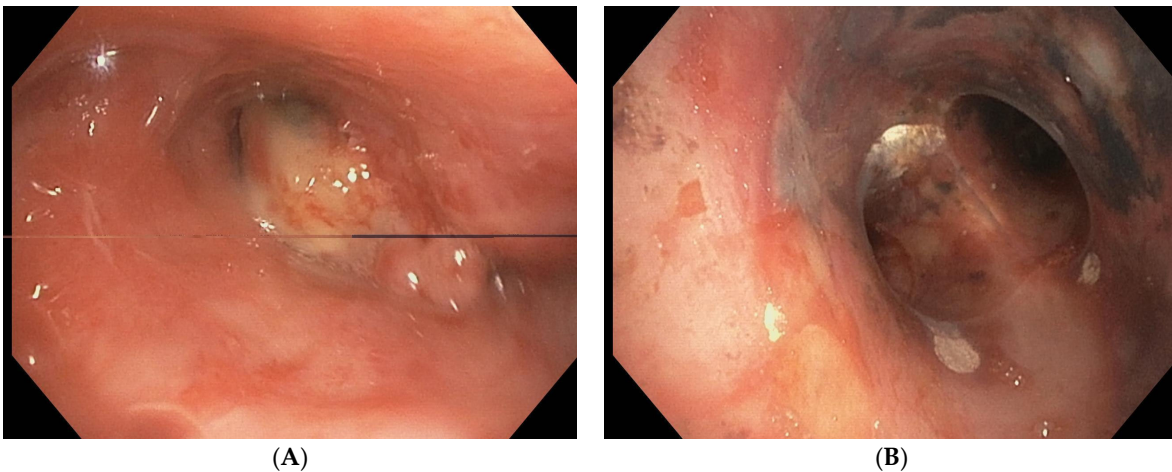
The decision to place an airway stent, and which stent to select, is guided by patient-specific factors, stent-specific factors, the etiology of the presenting symptoms, and the patient's overall clinical condition. In this article we will review airway stents and their ongoing role in the management of several airway diseases within the field of interventional pulmonology. Although we will briefly review stent placement in non-malignant etiologies and in clinical conditions where airway obstruction is not the primary indication, much of the discussion in this review will focus on stent placement for malignant airway obstruction since this is the most well-studied indication. We will discuss the indications for stent placement and the variables that must be taken into consideration

regarding patient and stent selection. We will review the data as it pertains to outcomes after stent placement and conclude with a discussion of the future applications of airway stents.

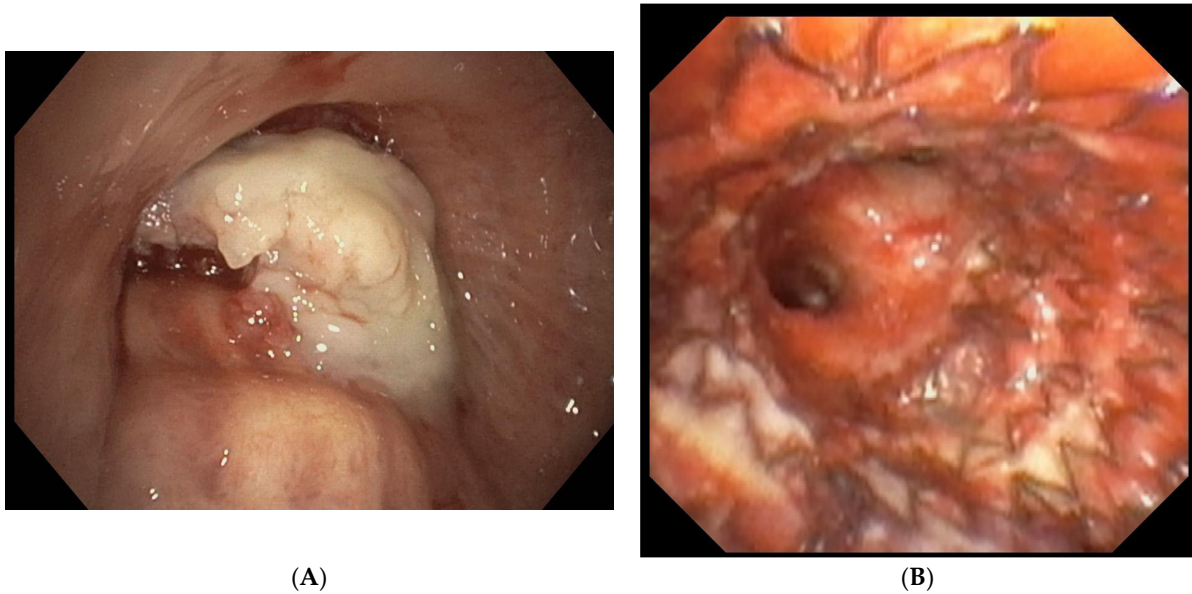
## 2. Indications for Stent Placement

Among the various airway pathologies that may require stent placement, malignant airway obstruction is the most common [5,6]. Most commonly a result of primary lung cancer, airway obstruction can also develop from pulmonary metastases or intrathoracic complications from other malignancies, including lymphoma or breast, esophageal, colon, and renal cell carcinomas [1]. Symptoms ranging from slight dyspnea to severe respiratory distress and asphyxiation have all been reported [7]. One major contributing factor to the symptom burden is the anatomic location of the airway obstruction. Central airway obstruction (CAO) is defined as obstruction within the trachea, bilateral mainstem bronchi, and bronchus intermedius. CAO results in more severe symptoms when compared to obstruction in more distal airways [8]. The degree of narrowing also contributes to the severity of symptoms. For a patient to develop symptoms, the obstruction needs to occlude at least 50% of the diameter of the airway. In the trachea, obstructions resulting in a diameter of 8 mm cause dyspnea with exertion, and obstructions resulting in a diameter of 5 mm or less cause dyspnea at rest [9].

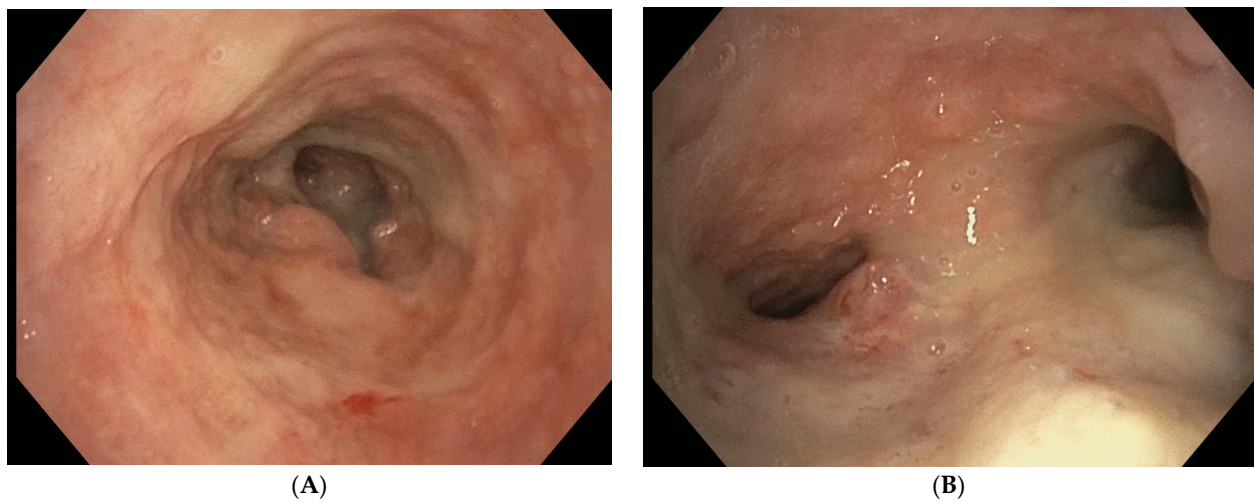
Airway obstruction generally consists of three main types: intrinsic (or endoluminal), extrinsic (or extraluminal), and mixed obstruction [5,6]. For intrinsic obstructions, which are most commonly a result of endoluminal tumor growth, therapeutic bronchoscopic interventions with the application of various ablative therapies can often provide adequate airway recanalization without stent placement [10–12]. Nevertheless, stent placement may be needed if significant residual endoluminal disease remains after ablative intervention (residual disease causing >50% obstruction) or if the underlying pathology recurs. In extrinsic compression, which typically occurs due to external compression of the airway, stent placement is typically needed since there is no endoluminal disease to debulk or ablate to re-establish airway patency. Mixed obstructions, which occur because of a combination of intrinsic and extrinsic compression, typically require a combined approach. This includes various ablative interventions to address the endoluminal component, followed by dilation and stent placement, if needed, to restore airway patency [6]. Figures 1–3 depict examples of airway stenting in malignant airway obstructions.

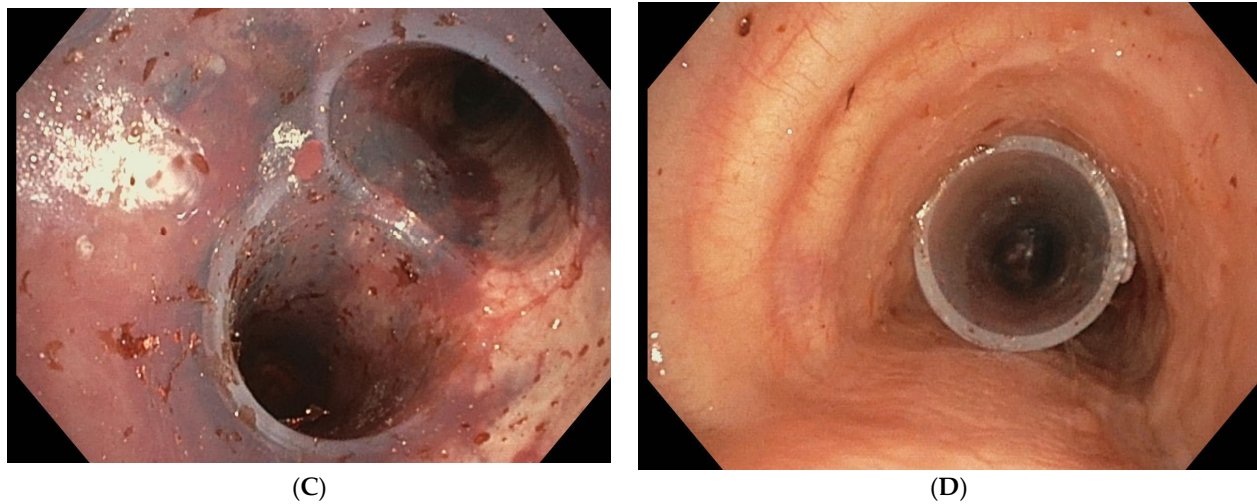


**Figure 1.** A patient with respiratory failure due to central airway obstruction from tumor at the carina: (A) pre-intervention bronchoscopy visualization of tumoral obstruction at the carina; and (B) post-bronchoscopy with obstruction at carina relieved following placement of a silicone Y stent. Images courtesy of Donald R. Lazarus, MD and used with permission.



**Figure 2.** A patient with respiratory failure due to central airway obstruction from tumor obstruction of the left mainstem bronchus: (A) pre-intervention bronchoscopic visualization of left mainstem bronchus obstruction from endobronchial tumor; and (B) following therapeutic bronchoscopy and tumor debulking in the left mainstem bronchus, a fully covered metallic stent was deployed with complete recanalization of the airway. Images courtesy of Donald R. Lazarus, MD and used with permission.





**Figure 3.** A patient with respiratory failure due to central airway obstruction from tumoral involvement of the distal trachea and carina, complicated by respiratory infection: (A) pre-intervention bronchoscopy showing endoluminal tumor within the trachea complicated by respiratory infection; (B) pre-intervention bronchoscopy showing endoluminal tumoral involvement at the carina with mucopurulent secretions secondary to infection; (C) post-bronchoscopy silicone Y stent placed at carina to relieve obstruction following aspiration of mucopurulent secretions; and (D) post-bronchoscopy visualization of proximal trachea and tracheal limb of the Y stent placed to cover the tumoral involvement within the trachea. Images courtesy of Donald R. Lazarus, MD and used with permission.

In addition to malignant airway obstructions and CAO, other airway disorders such as tracheoesophageal fistulae, bronchopleural fistulae, anastomotic dehiscence after lung transplantation or resection, and tracheobronchomalacia have all been managed with airway stenting at various times [13–15]. Post-tracheotomy or post-intubation airway stenosis, as well as post-infectious airway stenosis (particularly due to tuberculosis) have also been reported to be indications for airway stenting in specific clinical scenarios [7,16–21]. Particularly in benign airway disease, however, a multidisciplinary team approach to patient care, with early involvement of surgical specialists, is necessary for optimal disease management. Stent placement has also been used to control airway bleeding. When stenting is needed for this indication, it is often in the setting of diffuse bleeding from large areas of airway tumor involvement [22]. In such a scenario, a stent can tamponade a large area of bleeding mucosa to achieve hemostasis more quickly than standard bronchoscopic interventions for bleeding.

Whether placed for CAO or a different pathology, airway stents are typically reserved for clinical situations in which less invasive measures prove ineffective because stent placement can be challenging, and stents are associated with negative outcomes and complications for many patients. Table 1 represents various points of consideration prior to airway stenting.

**Table 1.** Main points of considerations for airway stenting in patients.

<b>Etiology of obstruction</b>	Malignant airway obstruction	Denotes advanced disease; AS may be indicated for symptom palliation
	Benign airway obstruction	MDT approach for optimal patient care. Early involvement of Thoracic Surgery. AS may be indicated if surgery is not feasible
<b>Anatomic location of obstruction</b>	Central airway involvement	AS more likely to result in significant symptom improvement. AS may be

		indicated at initial presentation based on symptoms and severity
	Distal/lobar airway involvement	AS more challenging and associated with higher rates of complication. Studies show reduced symptom benefit
Type of obstruction	Extrinsic—typically results from external airway compression	AS necessary since no endoluminal disease present to debulk to establish airway patency
	Intrinsic—typically results from endoluminal tumor	Bronchoscopic ablative procedures indicated. AS may not be needed unless residual obstruction >50% of airway lumen
	Mixed (combined extrinsic and intrinsic)	Combined approach, including bronchoscopic ablative procedures, with or without AS
Severity of obstruction	>50% airway lumen obstructed	AS may be necessary
	<50% airway lumen obstructed	AS not likely beneficial with <50% obstruction

Key: AS: Airway Stenting; MDT: Multidisciplinary Team; %: Percent; >: Greater than; <: Less than.

### 3. General Principles in Patient Selection

The decision to place an airway stent must be based on several factors to ensure maximal benefit with minimal harm. Prior to any bronchoscopic intervention, it is of the utmost importance that a detailed evaluation into the cause of a patient’s presenting symptom first be performed. For example, even a patient with an airway obstruction, who presents with shortness of breath, may not benefit from airway stenting if the cause of the shortness of breath is an alternative medical problem, such as an exacerbation of an underlying chronic obstructive pulmonary disease or heart failure. In this scenario, optimizing the underlying medical condition will result in better symptom control than stent placement. In fact, in such situations, stent placement may cause harm. However, if the airway obstruction is severe and a major contributor to the patient’s dyspnea, stent placement should be considered even if other comorbidities are also contributing to the current symptomatology, so long as it can be done safely.

The timing of the intervention is also an important point to consider. When indicated, bronchoscopic intervention should be prompt, but there are times when a period of observation is prudent. For example, stent placement in a patient with a newly diagnosed malignancy and airway obstruction at initial presentation is not generally recommended unless the obstruction is critical. Airway stenting in treatment-naïve patients with malignant endobronchial obstructions is typically avoided, as complication rates are higher and the long-term beneficial effects of stents are less often observed when a stent is placed prior to first-line systemic therapy [23,24]. In such cases, the obstruction may improve with therapy alone if the patient starts systemic therapy in a timely manner. Here, follow-up with the interventional pulmonologist, to ensure that no additional intervention is needed if treatment response is not optimal, may be all that is warranted.

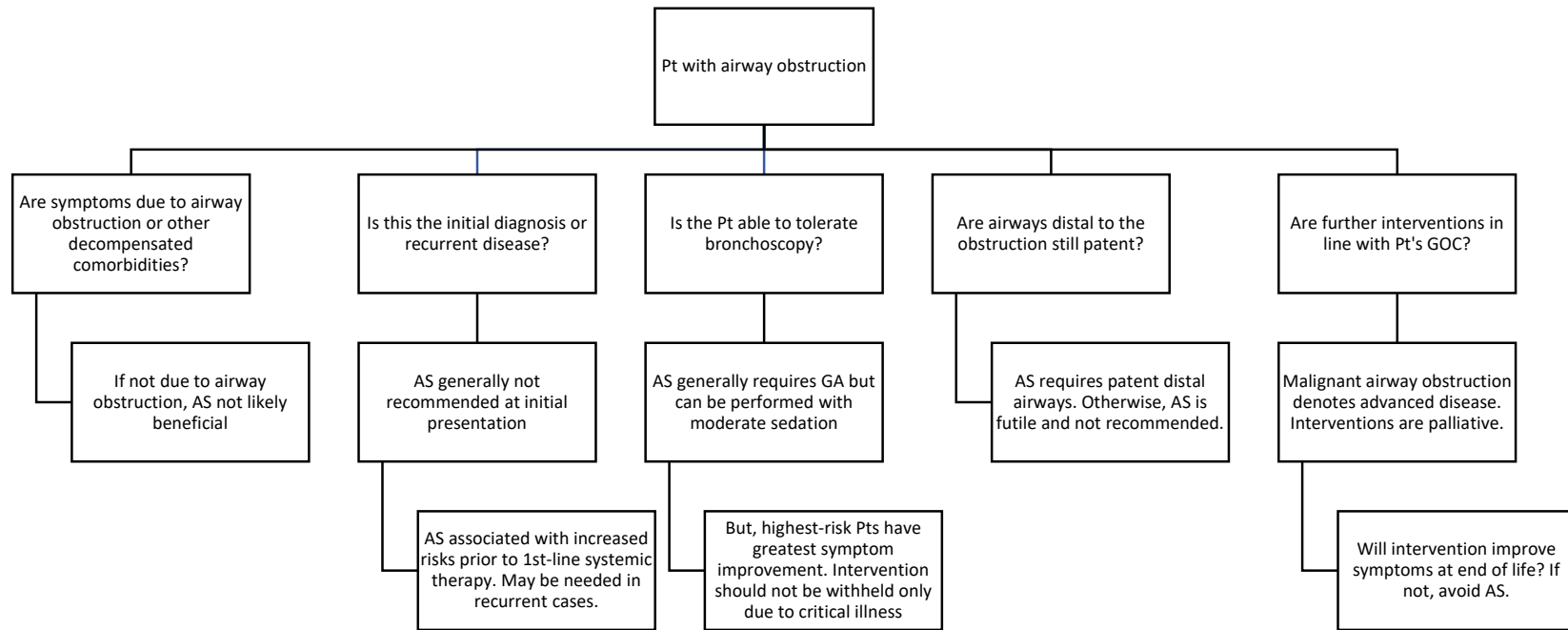
Additionally, the patient’s clinical condition and ability to tolerate the procedure must be evaluated prior to any intervention. Stent placement generally requires bronchoscopic intervention under general anesthesia [25], but many patients requiring airway stents are critically ill or too frail to tolerate such procedures. In such situations, the feasibility of airway stenting under moderate sedation should be considered. It is important to mention, however, that although therapeutic bronchoscopy and airway stenting may pose procedure-related risks, they have also been shown to significantly improve symptoms,

and even liberate critically ill patients from invasive mechanical ventilation [26,27]. In fact, Ost et al. [8] identified that higher-risk patients (those with the highest pre-procedural report of dyspnea and the lowest pre-procedural functional status) had the greatest improvement after therapeutic bronchoscopy for malignant CAO. Therefore, these procedures should not be withheld from patients solely based on a pre-procedural risk assessment, particularly when a significant portion of that risk is related to the critical airway pathology that the therapeutic bronchoscopy is being performed to address, as that would mean withholding bronchoscopic intervention from the patients most likely to have the greatest benefit.

The airways distal to the obstruction must be patent for there to be symptomatic benefits from stent placement for CAO. The placement of a stent in an airway that only leads to a more distal obstruction is futile and will not improve symptoms or be of clinical benefit, and should be avoided. Pre-procedural imaging may illuminate if distal airway patency is likely, but post-obstructive atelectasis may confound imaging assessment. Direct visualization by bronchoscopy is commonly needed to make that final determination. Additionally, the location of the obstruction is an important procedural aspect to consider [28]. Stent placement in smaller, distal airways is more challenging than in larger, central airways. Also, relieving lobar bronchial obstructions results in less symptom improvement than the relief of an obstruction in the central airways [8]. For this reason, airway stenting in a patient with only a lobar bronchial obstruction, where the expectation for meaningful symptom improvement is low, may be deemed to have an unfavorable balance of risk and benefit in many patients.

Lastly, a patient's overall goals of care must be considered prior to any intervention. Patients with malignancy-related indications for airway stenting typically have advanced disease and stent placement in these situations is entirely palliative. Therefore, some patients may decide to focus on more comfort-directed care rather than undergo further invasive procedures. In such a situation, a detailed conversation about goals of care is indicated prior to any therapeutic bronchoscopic intervention or stent placement. To ensure that a patient is making an informed decision, the conversation should include a discussion of the fact that airway stenting in the right setting can provide dramatic symptom palliation, even near the end of life [27,29–32].

Ultimately, several factors need to be taken into account when determining whether airway stenting is the optimal intervention for patients. A patient's symptoms and their causes, procedure timing, location of obstruction, overall clinical condition, and goals of care must all be simultaneously evaluated to make a final decision about whether to proceed with an airway stent procedure. Figure 4 summarizes the patient-related factors that should be taken into consideration prior to bronchoscopic intervention and possible airway stenting.



**Figure 4.** Patient-specific points of consideration to determine if airway stenting is recommended. Key: Pt: Patient; AS: Airway Stenting; GOC: Goals of Care.

#### 4. General Principles in Stent Selection

Airway stents are typically intended to be temporary measures. Whether placed for malignant or benign airway disease, they are meant to stabilize the airway and improve a patient’s symptoms to facilitate additional therapy. Once no longer indicated, stents are ideally removed. However, in cases where patients prove to have progressive or recurrent disease for which airway stenting remains necessary, or in situations where attempts at stent removal pose a significant risk to the patient, keeping the stent in place is possible. As such, careful selection of airway stents is imperative.

The ideal airway stent should have several characteristics [16,33]. First, it should be easy to deploy but also easy to remove when no longer needed. Second, it should be large enough to maintain its position with little to no risk of migration, but simultaneously be small enough to not exert excessive pressure within the airway that may cause tissue ischemia or granulation tissue formation. Third, the stent should be flexible enough to deploy within narrowed airways and accommodate normal physiological airway movement (such as may occur with coughing) but have sufficient radial force to resist airway compression. Lastly, the ideal airway stent should be well-fitted to a patient’s airway and would not impair mucociliary clearance. As such, the more personalized a stent can be, the more likely it is to benefit the patient and be associated with fewer complications (see “Complications” and “Future Applications” for further discussion).

Multiple airway stents are currently available for commercial use. Typically, they are either made of metal or silicone, and further classified based on shape. Each stent has distinct advantages and disadvantages that must be considered at the time of procedure planning to ensure optimal stent selection. In general, metallic stents are easier to place than silicone stents, but can be harder to remove [34]. Metallic stents can be placed using a flexible bronchoscope, while a rigid bronchoscope is required for silicone stent placement. Unlike metallic stents, however, silicone stents can be customized at the time of procedure to attempt to improve outcomes after placement. Table 2 summarizes the main advantages and disadvantages of each stent type. The following sections will include a more in-depth discussion of airway stents and their complications.

**Table 2.** Airway stents and their main advantages and disadvantages.

	Silicone Stent	Self-Expandable Metallic Stent (SEMS)
Advantages	<ul style="list-style-type: none"> <li>• Easier to remove</li> <li>• Available in different shapes (Y, hourglass, and tube) for use in various airway obstructions</li> <li>• Customizable at time of procedure</li> <li>• Y-shaped stent associated with lower rates of migration</li> </ul>	<ul style="list-style-type: none"> <li>• Easier to place (no need for rigid bronchoscope)</li> <li>• Since SEMS are easier to place, can be deployed utilizing moderate sedation over GA if anesthetic risk is prohibitive</li> <li>• Covered and uncovered SEMS are available for use in various airway pathologies</li> </ul>
Disadvantages	<ul style="list-style-type: none"> <li>• More difficult to place; Requires rigid bronchoscope for deployment</li> <li>• Increased rates of granulation tissue formation</li> <li>• Silicone tube stents associated with increased migration risk</li> </ul>	<ul style="list-style-type: none"> <li>• Not customizable at time of procedure</li> <li>• More difficult to remove; Increased complications at time of removal (bleeding)</li> <li>• Covered SEMS will not allow for airway branch ventilation</li> <li>• Uncovered SEMS may allow for tumor ingrowth if used in malignant obstruction</li> <li>• Associated with increased infection risk</li> </ul>

Key: SEMS: Self-expandable metallic stent; GA: General Anesthesia.

##### 4.1. Metallic Stents

Metallic stents were first developed roughly four decades ago. However, reports related to complications and poor outcomes led the Food and Drug Administration (FDA)



to generate a warning against their use in benign airway disease in 2005 [35]. Modern metallic stents are now made of nitinol, a nickel-titanium alloy, which has several properties that make it versatile in medical use. Nitinol stents are temperature-dependent. They are pliable at room temperature but retain their original structure at body temperature once deployed [36]. Shape memory allows the stent to be compressed and stored in a deployment system but then expand after placement in the airway [36]. For this reason, they are called self-expandable metallic stents (SEMS). Lastly, superelasticity allows the stent to resist significant amounts of strain after placement in the airway [6,9,37].

Metallic stents can also be uncovered or covered by a membrane of silicone or polyurethane. Uncovered metallic stents are typically avoided in malignant endobronchial obstruction since tumors can grow through the uncovered portions and re-obstruct the airway. In cases of airway dehiscence after lung transplant, however, uncovered metallic stents may be preferred since they can help to permanently seal the defect by causing granulation tissue formation [38]. Metallic stents that are covered with a silicone membrane are sometimes called hybrid stents. Since tumors cannot grow through the membrane of a covered metallic stent, they are widely used for malignant endobronchial obstructions. However, the membrane can have disadvantages. First, it inhibits mucociliary clearance, which may lead to an accumulation of secretions. Second, any side branches of the airway that the covered stent traverses will also be occluded, even if they were previously patent and not involved by the disease. Several recent studies have evaluated the safety and efficacy of covered metallic stents in both malignant and benign diseases [39–42].

In a review of 50 patients who underwent airway stenting with Bonastents (Thoracent, Huntington, NY, USA), Holden et al. [39] reported that 70% of patients had improvement in respiratory symptoms within 30 days. All stents were placed under general anesthesia via rigid bronchoscopy. The overall complication rate was 54%, at a mean follow-up of over 3 months. Early and late complications (defined as complications that developed in less than vs. greater than 30 days after placement) were also evaluated. Granulation tissue, respiratory infections, mucous plugging, cough, and stent migration were the most common early and late complications. In the first 30 days after stent placement, these complications developed in roughly 8% of patients, but were noted in up to 25% after 30 days. Similarly, Ishida et al. [40] reported on a series of 42 Aero stents (Merit Medical Endotek, South Jordan, UT, USA) placed in 36 patients under general anesthesia via rigid bronchoscopy. In 18 of 23 patients (78%) who required supplemental oxygen prior to intervention (including 5 patients who were mechanically ventilated), the need for oxygen was eliminated completely following intervention. Overall, complications occurred in 33% of cases with stent migration (14%), granulation tissue formation (7%), and mucous plugging (5%) being the most common. Chung et al. [42] evaluated the outcomes of 149 patients who underwent airway stenting with the Ultraflex (Boston Scientific, Marlborough, MA, USA) SEMS. Nearly half of the study population (72 patients) underwent SEMS placement for benign indications (tracheobronchomalacia was the most common benign indication, followed by stenoses from prior intubation and tuberculosis). Seventy-seven patients underwent airway stenting due to a malignant airway obstruction. The Ultraflex SEMS were placed via flexible bronchoscopy using moderate sedation and local anesthesia. Airway stenting in benign disease showed symptom improvement in a greater proportion of patients than in malignant disease (77% vs. 52%) but a significantly higher rate of complications as well (42% vs. 21%). It is postulated that this higher rate of complications in the patients with benign disease may be a result of their longer survival and longer median follow-up times (429 days in the benign disease patients vs. 57 days in the malignant disease patients). Granulation tissue formation was the most common complication in both benign and malignant diseases (19% and 10.5%, respectively). Stent fracture occurred in 16.4% of benign cases, but only 1.1% of malignant cases. Stent migration occurred in both benign and malignant disease in under 10% of cases. Sinha et al. [41] retrospectively analyzed the safety of hybrid stents in post-lung transplant airway

complications. A total of 376 hybrid stents (a combination of Bonastent, Aero, and Atrium iCAST (Atrium Medical, Hudson, NH, USA) SEMS) were placed in 50 patients. All stents were placed and removed under general anesthesia with flexible bronchoscopy. Most patients required a stent for bronchial stenosis (88%) while a minority required airway stenting for anastomotic dehiscence (12%). The most common indications for stent removal were excessive secretions, excessive granulation tissue formation, and stent migration. At the time of stent removal, there were two cases of major bleeding. One resulted in hemorrhagic shock and cardiac arrest, while the other ultimately required a pneumonectomy.

#### 4.2. Silicone Stents

Tracheobronchial silicone stents were first described by Dumon in 1990 [43]. Unlike metallic stents, silicone stents must be deployed using a rigid bronchoscope, but can be customized at the time of procedure [44,45]. For instance, the stent can be cut to a certain length and side holes can be cut out to allow for ventilation of the bypassed normal airway branches. The external surface of silicone stents is lined with studs that anchor them in the airway while simultaneously maintaining a small amount of space between the stent and airway to lessen potential mucosal ischemia and possibly also the stent's impact on mucociliary clearance. Silicone stents can be tube-shaped, Y-shaped, or hourglass in shape. Stenting different types of obstructing lesions is possible when a properly shaped silicone stent is chosen. For example, the Y-stent is commonly used to stent obstructions at the main carina [46] while the hourglass stent, which has a narrowed middle portion and wider distal ends, is useful for tight stenoses of the trachea with less risk of migration since the wider ends of the stent are in contact with normal airways proximal and distal to the stricture.

Several studies have also evaluated the safety and efficacy of silicone stents in both malignant and benign diseases [23,46–49]. Dumon et al. [47] published the largest series on the use of silicone stents across four centers in Europe. One thousand five-hundred and seventy-four stents were placed in 1058 patients over 7 years. All cases involved high-grade stenosis of the tracheobronchial tree resulting from extrinsic compression or airway wall collapse due to loss of cartilaginous support. The mean duration of stenting was 14 months for benign tracheal disease and 4 months for malignant disease. Although symptom-related outcomes were not reported, complication rates were relatively low. The main complications observed were migration (9.5%), granulation tissue formation (7.9%), and obstruction by secretions (3.6%). More recently, Dutau et al. [46] published an analysis of 90 Dumon Y-stents placed in 86 patients with either malignant CAO involving the carina or malignant tracheoesophageal fistulae. There were only two procedure-related adverse events reported. One was coughing following stent placement that lasted one week, and the other was stent migration that required immediate removal. In that analysis, no tool was used to objectively measure the degree of symptom improvement following stent placement, but the authors mention that the remaining patients tolerated the stents well, and all patients experienced subjective symptomatic relief.

Lin et al. [49] published an analysis of the safety and efficacy of the Dumon stent specifically in benign disease. In their study of 99 patients, the majority (57.6%) had post-tuberculosis stenosis, while post-tracheostomy and post-intubation stenoses accounted for 17.2% and 16.2% of patients, respectively; 9.1% of patients had other types of stenosis. The overall complication rate was notably higher in this analysis (91.9%) than previously reported data. This may be due to the nature of stent placement in benign disease but may also be related to variations in post-stent management across providers [50]. Secretion retention was the most common complication (70.7%), while granulation tissue formation occurred in just over two-thirds of patients (67.1%), and stent migration occurred in 12.1%. The overall cure rate was 60.6% (defined as no restenosis during follow-up after stent removal) but it was noted that a markedly lower cure rate was observed in post-tuberculosis stenosis than other types (50.9% vs. 73.8%). The cure rate in stenosis of the left mainstem bronchus was also lower than stenoses at the trachea or right mainstem bronchus (46.5%

vs. 71.4%). Similarly, a recent meta-analysis evaluated the long-term efficacy and safety of the Dumon stent for benign tracheal stenosis [48]. Three-hundred and ninety-five patients across eight studies were included. Silicone stents showed a cure rate of over 40% (defined as the proportion of patients who were able to have their stents removed without symptomatic restenosis in one year). The stability rate of stents (defined as the proportion of patients who maintained stable stent placement) was also roughly 40% in this analysis. As a result, the authors calculated an effective rate of silicone stents (the sum of the curative and stability rates) at over 75%. In terms of complications, stent migration occurred in 25%, and granulation tissue formation occurred in 15.7%.

## 5. Complications

In addition to the studies already mentioned that report complications as part of their overall evaluation of safety and efficacy, several studies have been specifically designed to more robustly examine complications associated with stent placement and therapeutic bronchoscopy [4,24,51]. These will be discussed in this section.

Ost et al. [4] used the American College of Chest Physicians (CHEST) Quality Improvement Registry, Evaluation, and Education (AQuIRE) program registry to conduct a multicenter study of patients undergoing therapeutic bronchoscopy for malignant CAO. In the 1115 procedures performed in 947 patients across 15 centers, roughly one-third involved stent placement (about two-thirds were metallic stents and one-third were silicone). Overall, only 3.9% of patients experienced a complication. Six patients (0.5%) died due to procedural complications. In the highest volume centers (those with data on at least 25 cases), complication rates ranged from 0.9% to 11.7% with significant variation in bronchoscopic practices noted. In this cohort, stent placement occurred in 13% to 69% of procedures. On multivariate analysis, increased complication rates were noted in cases when urgent or emergent procedures were performed, in cases with an American Society of Anesthesiologists (ASA) score >3, in redo therapeutic bronchoscopies, or when moderate sedation was used over deep or general anesthesia. Stents were not associated with an increased risk of complication but were associated with increased risk of death within 30 days of procedure. It is suggested that the association between stent placement and death within 30 days may be a result of confounding, rather than causation, since patients who require stents are more likely to have a higher baseline burden of disease or have evidence of disease progression that requires stent placement—both factors that are associated with higher mortality irrespective of stent placement.

In a comparison of 72 patients with malignant CAO, Grosu et al. [24] evaluated the incidence of lower respiratory tract infection (LRTI) between patients who received a stent and those who did not during therapeutic bronchoscopy. Overall, 23 of 72 patients (32%) developed a LRTI, but by comparing stented to non-stented patients, the incremental risk of infection could also be calculated. Here, the authors found that the risk of infection is increased by 13% per month in stented patients, and that 26% of patients with infections died within 2 weeks of stent placement. Similarly, Ost et al. [51] compared complications across various stent types. One hundred and seventy-two patients in whom 195 stents were placed were evaluated. In the analysis, the majority of stents were Ultraflex SEMS (60%), followed by Dumon silicone stents in 24%, and Aero stents in 16%. The most common complications were infection, migration, granulation tissue formation, and mucus plugging. Seventy-three patients developed 106 LRTI, with a median time to infection of 1 month. Over half of patients with LRTI required hospitalization and nearly one-quarter died within 2 weeks of infection. Interestingly, only the Aero stent was significantly correlated with infection, while only silicone tube stents were significantly correlated with migration (in this subset analysis of migration risk, silicone Y stents were excluded from assessment since they are less likely to migrate overall). Granulation tissue formation was more common in silicone stents as well as in those who developed LRTI. Mucus plugging occurred in nearly one-quarter of cases. A left-sided stent and silicone stents were associated with an increased risk of mucus plugging.

Collectively, these studies show that airway stenting is largely safe, but can be associated with serious complications that detrimentally impact outcomes. As such, a thoughtful approach to bronchoscopic intervention with careful patient and stent selection is crucial.

## 6. Stent Management

Due to the propensity for complications, studies have sought to evaluate various post-stent management strategies that aim to reduce complications and improve patient outcomes. In a retrospective analysis by Lee et al. [52], the utility of routine surveillance bronchoscopies 4–6 weeks after stent placement was evaluated. The study included 134 patients in which 147 stents were placed. The authors found that the symptomatic status of a patient at the time of follow-up bronchoscopy was not associated with stent complications. In fact, 60% of asymptomatic patients in this analysis were found to have stent-related complications after routine surveillance bronchoscopy. This has led to the argument for routine surveillance bronchoscopy in the post-stent care of patients.

Routine surveillance chest imaging with computed tomography (CT) scans has also been compared to surveillance bronchoscopy for the early detection of complications. Djalani et al. [53] found that follow-up CT imaging could identify 97% of stent complications diagnosed in bronchoscopy, providing a possible alternative to surveillance bronchoscopy in the post-stent monitoring of patients.

Importantly, studies continue to show wide variability in provider recommendations and management practices for patients following stent placement [50,54,55]. In the United States, Wayne et al. [50] showed that 74% of providers prescribed medications after stent placement, 50% performed surveillance bronchoscopy, but fewer than 20% performed CT scans in routine follow-ups. In Europe, Virost et al. [55] showed that 70% of providers prescribed saline nebulizers, and nearly two-thirds performed at least one surveillance bronchoscopy. Interestingly, 30% of practitioners in this survey reported performing routine stent replacement at variable times during follow-ups. Such wide variations in practice patterns highlights the need for additional studies to better elucidate the optimal post-stent management strategy.

## 7. When Airway Stenting Is Not the Optimal Initial Strategy

As previously discussed, there are situations in which airway stenting may be feasible but is not an optimal initial management strategy. Particularly in malignant airway disease, these may include patients with lobar (distal) airway obstructions in whom airway stenting is more challenging and less likely to result in symptomatic benefits; patients for whom therapeutic bronchoscopic procedures have been able to relieve endobronchial airway obstructions such that the residual obstruction is <50% of the airway lumen; and in treatment-naïve patients for whom first-line systemic therapies are known to be effective. In such cases, tumor debulking without stent placement (if not otherwise absolutely indicated) is recommended [24,33]. In fact, when approaching such patients, a multidisciplinary team discussion, with early involvement of surgical specialists, radiation oncologists, and oncologists is both recommended and fundamental for optimal patient management.

Primary tracheal tumors are rare conditions but certainly warrant a multidisciplinary approach for optimal patient care. An estimated 10% of primary tracheal tumors are benign, and although bronchoscopic interventions may be sufficient in cases with limited extension, tumors with more widespread tracheal involvement will require definitive surgical resection for optimal long-term disease management [56,57]. Similarly, although the prognosis in malignant primary tracheal tumors is poor, studies have shown that outcomes are improved following surgery as compared to non-surgical treatments. Here, bronchoscopic interventions, combined with adjuvant chemotherapy and radiation, are recommended when patients are determined to not be surgical candidates [57,58].

Benign airway stenoses that may result from prolonged intubation, post-infectious complications (particularly secondary to tuberculosis), and tracheobronchomalacia are further conditions in which the early involvement of surgical colleagues and a multidisciplinary approach will optimize patient care. These conditions pose notable management and therapeutic challenges for medical providers, but surgical intervention is typically the treatment of choice for patients who are deemed appropriate candidates. Here, bronchoscopic interventions are typically reserved for cases where surgery is not feasible [48,59–62]. In fact, studies that have evaluated patient outcomes in benign airway stenoses following bronchoscopic interventions, with or without airway stenting, typically enroll only non-surgical patients or are retrospective analyses since the general consensus is for surgery when feasible [49,60,62]. For tracheobronchomalacia specifically, short-term airway stenting is often performed as a means to determine if a patient will benefit from more definitive surgical intervention, and then referred for surgery pending additional evaluation [63].

Although bronchoscopic intervention and airway stenting is feasible in a myriad of benign and malignant conditions, early involvement of surgical specialists, radiation oncologists, and oncologists is recommended, and a multidisciplinary approach to patient care is fundamental for optimal disease management.

## 8. Future Applications

Given the complications related to airway stents, research into making these foreign bodies better tolerated by patients has been pursued. Biodegradable stents that degrade over time and obviate the need for repeat bronchoscopy solely for stent removal have been developed. However, concerns about restenosis and stent fragmentation and difficulty in predicting the degradation times after stent placement have been reported [64,65]. Drug-eluting airway stents have also been developed. These stents have been coated in chemotherapeutic agents with the aim of treating the underlying tumor at that location or coated in agents like Mitomycin-C to attempt to reduce complication rates [66–68]. Moreover, silver nanoparticles have been combined with alternative agents in drug-eluting stents to create antibacterial devices and reduce the risk of infection [69,70]. Radioactive stents have also been studied to assess their ability in preventing airway restenosis after stent removal [71]. These stents are all actively under investigation but not currently widely used.

There has also been significant interest in the development of patient-specific silicone airway stents using three-dimensional (3D) printing. Since obstructed airways can be tortuous and irregular, commercially available stents do not always fit a given patient's airways well. Three-dimensional-printed patient-specific airway stents have only recently been applied in interventional pulmonology, but preliminary clinical reports indicate promising results [3,72,73]. Gildea et al. [74] used 3D-printed patient-specific airway stents to treat two patients with granulomatosis with polyangiitis. The process by which Gildea et al. produced these 3D-printed patient-specific airway stents was via proprietary software, in which the patient's chest CT was utilized to render a 3D image of their airway. Based on this virtual model of the airway, stent dimensions that included area, diameter, angulation, branching, length, and wall thickness, were determined. Then, a mold for the stent was produced with 3D-printing technology and medical-grade silicone was used to fill the mold. The silicone stent was cleaned, finished for a smooth surface, and sterilized prior to deployment. All in all, the 3D stent manufacturing process required approximately 7 days [74]. Interestingly, at 1-year follow-up, these two patients reported subjective improvement in symptoms and required fewer repeat interventions as compared to the 6 months prior to the 3D-printed stent placement. Similarly, Guibert et al. [75] reported their experience with 3D-printed stents in 10 patients with anatomically complex airway stenoses. At a 3-month follow-up, the reported complication rate was 40%. One patient required stent removal due to intense cough, two patients had stent migration, and one developed mucus-plugging. Overall, the authors reported that 9 out of 10 stents showed great congruence within the airways, and 8 out of 10 stents resulted in significant

improvement in symptoms and quality of life. Such reports have spurred significant interest in the feasibility of novel airway stents that are specifically designed and individually customized for patients, with the hope that complications can be minimized in the future.

## 9. Conclusions

Airway stents are a technology that continues to be a focus of research in interventional pulmonology. They are effective in palliating dyspnea and other symptoms related to airway obstruction, stenosis, and fistulae related to both malignant and benign conditions. Both silicone and self-expandable metallic stents are available and have different properties that influence the choice of stent for a given airway problem. Airway stenting can be associated with complications, and numerous factors must be simultaneously evaluated to ensure proper patient and stent selection. As the field of interventional pulmonology develops, data to help guide this decision-making process are becoming more available, but continued research is needed to develop stents that are better tolerated by patients and to more clearly define optimal post-stent care.

**Author Contributions:** S.I.B. and D.R.L. composed this review manuscript and agree with the submission in its current form. All authors have read and agreed to the published version of the manuscript.

**Funding:** This research received no external funding.

**Institutional Review Board Statement:** Not applicable.

**Informed Consent Statement:** Not applicable.

**Conflicts of Interest:** The authors declare no conflicts of interest.

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