

Safety and Efficacy of the Tracheobronchial Bonastent: A Single-Center Case Series

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Keywords

Airway obstruction · Airway stent · Rigid bronchoscopy

Abstract

Background: Tracheobronchial stents are widely used devices in interventional pulmonology; however, the current literature on the effectiveness and complication rates of the different types of stents is limited. **Objective:** We report the largest case series of airway Bonastent placement and describe the efficacy and early (<30 days) and late (≥30 days) complication rates. **Methods:** We performed a retrospective review of our prospectively collected database of patients who underwent therapeutic bronchoscopy with stent placement. All adult patients who had a tracheal/bronchial Bonastent placed between July 1, 2017, and July 30, 2019, for any indication at our institution were included. The efficacy as well as intraoperative and short- and long-term complications of Bonastent placement were evaluated. **Results:** Sixty Bonastents were placed in 50 patients. The etiology was malignant in 90% of the cases, while 2 patients had a tracheo-

esophageal fistula. All procedures were performed via rigid bronchoscopy. The most common location for stent placement was the bronchus intermedius, followed by the trachea, in 32 and 30% of the cases, respectively. Seventy percent of the patients (35/50) had improvement of respiratory symptoms within 30 days. Twenty-eight stents (48%) were removed at a mean of 74 days. Seventeen patients (34%) died within 30 days of stent placement. The overall complication rate was 54% (27/50 patients) at a mean follow-up of 111 days. The stent-related complication rate was 23.3% (14/60 cases) within <30 days and 53% (18/34 cases) at ≥30 days. **Conclusions:** The tracheobronchial Bonastent is effective for the treatment of patients with central airway obstruction and tracheoesophageal fistulae with an acceptable safety profile.

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V.K. Holden and D. Ospina-Delgado contributed equally to this work. This study was previously presented as an abstract at the American Thoracic Society International Meeting on May 23, 2018, in San Diego, CA, USA.

Introduction

Tracheobronchial stents are commonly used for the treatment of nonmalignant and malignant central airway obstruction (CAO), tracheoesophageal fistula (TEF), and post-transplant anastomotic dehiscence. Despite a multitude of indications, the most common one is CAO secondary to malignant disease [1]. Of these, the most frequent etiology is lung cancer, but it can also be caused by metastases from other primary tumors or invasion from adjacent organs [2].

There are several methods for improving airway patency in CAO with the overall goals of providing symptomatic relief and preventing postobstructive complications. A multimodal approach, which can include ablative therapies, balloon dilation, and stent placement, is usually employed for immediate effect. Airway stents can be used in both malignant and nonmalignant CAO, with improvement in spirometry, shortness of breath, and quality of life [2, 3]. Fully or partially covered self-expanding metallic airway stents (SEMAS) are most commonly used for malignant CAO [3]; however, stent placement has been associated with an increased 30-day mortality rate and significant morbidity due to stent-related complications such as migration, granulation tissue formation, tumor ingrowth, and mucus plugging [4]. There are multiple SEMAS and silicone stents on the market today. Each has its own specific benefits and disadvantages. We report our experience with a new fully covered SEMAS in a high-volume academic medical center in the USA.

There are several SEMAS available on the market, with a thorough review recently published [5]. The tracheal/bronchial Bonastent (Thoracent Inc., Alpharetta, GA, USA) is a novel fully covered SEMAS approved by the US Food and Drug Administration in October 2014 for strictures caused by malignant neoplasms [6]. The stent is made of nitinol wire and is weaved using a hook and cross-wire design. It is fully covered internally by a silicone membrane, and the flared ends are intended to prevent stent migration. Stent sizes range from 10 × 20 to 20 × 80 mm (diameter × length).

Two recent small case series have described single-center experiences of the Bonastent with favorable results [7, 8]. We present the largest case series to date of tracheal/bronchial Bonastent placement and describe its safety and efficacy.



Fig. 1. Bonastent deployment catheter.

Patients and Methods

Study Design

We performed a retrospective review of our prospectively collected database of patients who underwent therapeutic bronchoscopy with stent placement. All patients aged 18 years or older who had a tracheal/bronchial Bonastent placed between July 1, 2017, and July 30, 2019, for any indication at Beth Israel Deaconess Medical Center, Boston, MA, USA, were included in the study. The efficacy as well as intraoperative and short- and long-term complications of Bonastent placement were evaluated. Patients were identified by review of the operating room procedure logs and Research Electronic Data Capture (REDCap; Vanderbilt University, Nashville, TN, USA) bronchoscopy database. Variables were predefined, and data were extracted from the electronic medical record.

Demographic information and baseline symptoms were collected. A patient-reported measure, the modified Medical Research Council dyspnea scale score, was obtained at baseline and after stent placement as part of routine care. The charts were reviewed for airway characteristics such as etiology, type of lesion, and location. Details on stent placement, removal, size, and location were also studied. Postoperative outcomes, complication rates, and improvement in respiratory symptoms (dyspnea, cough, and stridor) were appraised at <30 days and ≥30 days after stent placement. Complications included development of granulation tissue requiring bronchoscopic intervention, infectious tracheobronchitis or pneumonia, mucous plugging requiring intervention, stent migration, and stent fracture. In addition, the interven-

tional pulmonologists filled out a questionnaire that assessed the ease of deployment after each Bonastent placement for quality assurance purposes. The individual bronchoscopists' survey responses were reviewed.

Operative Technique

Each Bonastent was placed under the direct supervision of one of three interventional pulmonologists (A.C., M.S.P., and A.M.), who have extensive experience with airway stent placement. The procedures were performed in the operating room with the use of general anesthesia and rigid bronchoscopy. Measurements of the target airway were performed based on review of the chest CT and intraoperative bronchoscopic evaluation using an AEROSIZER (Merit Medical, South Jordan, UT, USA) tracheobronchial stent sizing device.

The Bonastent was advanced into the appropriate position in the airway under direct visualization with a flexible bronchoscope. Fluoroscopy was not used. The stent was deployed by pulling back on the release mechanism (Fig. 1). Once the release plunger is past the red line on the deployment catheter, the stent can no longer be recaptured for repositioning.

All patients were started on a standardized mucociliary clearance regimen that consisted of oral guaifenesin extended release 1,200 mg, nebulized 5 mL normal saline, and vibratory positive expiratory pressure device (flutter valve) use twice a day. The patients were subsequently scheduled for a 4- to 6-week clinic follow-up with chest CT. If there were clinical symptoms of a stent-related complication prior to the scheduled follow-up or identified at the time of the imaging study, then the patients were scheduled for bronchoscopy.

Statistical Methods

The data were analyzed using STATA release 14 (StataCorp, College Station, TX, USA). The Shapiro-Wilk test was used to identify normality in the distribution of the data. Continuous variables were analyzed using mean and standard deviation or median and range according to their distribution. Dichotomous variables were analyzed as simple proportions.

Results

Between July 2017 and July 2019, 60 tracheal/bronchial Bonastents were placed in 50 patients, with 27 (54%) of the patients being female. The mean age was 64.9 ± 13.1 years (range, 33–90). All patients except for one had an ASA score of 3 ($n = 32$) or 4 ($n = 17$). The predominant symptom was dyspnea in 42 patients (84%), cough in 41 patients (82%), and stridor in 3 patients (6%). The etiology of the airway disease was malignant CAO in 45 patients (90%), benign disease in 3 patients (6%), and malignant TEF in 2 patients (4%) (Table 1). The type of malignant CAO was mixed in 37 patients (82.2%) and extrinsic in 8 patients (17.8%). One patient had two Bonastents placed during the same procedure. Seven patients had a second procedure for Bonastent replacement due to

Table 1. Patient characteristics ($n = 50$)

Age, years	64.9±13.1
Female gender	27 (54)
Body mass index	25.5±6.3
ASA score 3 or 4	49 (98)
Symptoms	50 (100)
Dyspnea	42 (84)
Cough	41 (82)
Stridor	3 (5)
mMRC dyspnea scale score	3.3±1.2
Etiology of airway disease	
Malignant obstruction	45 (90)
Non-small cell lung cancer	15
Squamous cell carcinoma	11
Metastatic disease	10
Adenocarcinoma	9
Small cell lung cancer	9
Large cell carcinoma	1
Benign disease	3 (6)
Idiopathic tracheal stenosis	1
Malacic stenosis	2
Tracheo-/bronchoesophageal fistula	2 (4)

Values denote mean ± SD or n (%). ASA, American Society of Anesthesiologists; mMRC, modified Medical Research Council.

Table 2. Procedural characteristics ($n = 60$)

Rigid bronchoscopy	60 (100%)
Other endobronchial interventions	47 (78%)
Balloon dilation	35 (58%)
Electrocautery	23 (39%)
Cryotherapy	15 (25%)
Stent location	
Trachea	18 (30%)
Bronchus intermedius	19 (32%)
Left mainstem bronchus	17 (28%)
Right mainstem bronchus	6 (10%)
Stent sizes	
10×30 mm	12
10×40 mm	6
12×30 mm	11
12×40 mm	13
14×30 mm	5
14×40 mm	3
16×40 mm	3
16×60 mm	3
20×40 mm	3
Improper stent deployment	1 (2%)

complex tracheal stenosis with malacia ($n = 1$), persistence of a TEF ($n = 2$), or recurrence of malignant CAO ($n = 4$; 1 squamous cell carcinoma, 1 renal cell carcinoma, and 2 adenocarcinomas). Of the 2 patients with persistent

Table 3. Bronchoscopists' survey (*n* = 60)

	Median Likert score ^a
The Bonastent release mechanism is easy to use	5
The distal and proximal ends of the Bonastent are easily identified on the deployment catheter	5
The Bonastent did not shorten after deployment	4
The diameter of the Bonastent after deployment is accurate compared to the advertised size	4
The Bonastent can be easily readjusted after deployment if needed	4
The level of difficulty of placing a Bonastent is similar to that of placing an Ultraflex stent	5
The Bonastent is easily identifiable on chest X-ray	4

^a 1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree.

TEF, one had three subsequent stent replacements due to extension of the fistula.

All procedures were performed via rigid bronchoscopy with direct visualization of the Bonastent deployment. A multimodal approach was utilized in 78% (*n* = 47) of cases in 42 patients, including use of balloon dilation in 35 cases, electrosurgery in 23 cases, and cryodebridement in 15 cases. The most commonly used stent size was 12 × 40 mm (Table 2). There was 1 improper stent deployment, which occurred with attempt of a 10 × 40 mm Bonastent placement in the left mainstem bronchus. The stent was too proximal and had to be removed. A second attempt was successful. There were no intraoperative episodes of significant hypoxia (SpO₂ <90% for >5 min), bleeding, airway perforation, inadequate stent expansion, or respiratory failure.

The interventional pulmonologists were surveyed after each procedure to assess ease of use and stent characteristics (Table 3). Their responses were based on a 5-point Likert scale. The release mechanism was easy to use, and the distal and proximal ends of the stent were easily identified on the deployment catheter and on the postoperative chest X-ray.

Outcomes

Seventy percent of the patients (35/50) had improvement of respiratory symptoms (dyspnea, cough, or stridor) within 30 days of the procedure, while 64.3% (18/28) had improvement at ≥30 days. When the stent place-

Table 4. Complication rates

	Early (<30 days) complications (<i>n</i> = 60)	Late (≥30 days) complications (<i>n</i> = 34)
Granulation tissue ^a	4 (6.7)	5 (14.7)
Respiratory infection	4 (6.7)	8 (23.5)
Mucous plugging ^a	5 (8.3)	8 (23.5)
Stent migration ^a	3 (5.0)	2 (5.9)
Stent fracture	0	1 (2.9)
Chronic cough	3 (5.0)	5 (14.7)

Values denote *n* (%). ^a Requiring intervention.

ments were analyzed individually, 65% of the cases (39/60) resulted in symptom improvement within 30 days, and 55.9% (19/34) resulted in symptom improvement at ≥30 days. The mean modified Medical Research Council dyspnea scale score was 3.3 ± 1.2 at baseline, 2.7 ± 1 within 30 days, and 2.4 ± 0.7 at ≥30 days. Twenty-eight of the 60 stents (47%) were removed at a mean of 74 ± 69 days after placement. Reasons for removal or revision included: the stent was no longer needed (in 6 cases; 21.4%), progression of TEF (in 4 cases; 14.2%), stent migration (in 4 cases; 14.2%), obstructive granulation tissue (in 3 cases; 10.7%), mucus plugging (in 2 cases; 7.1%), stent fracture or bowing (in 2 cases; 7.1%), respiratory failure (in 2 cases; 7.1%) (tumor ingrowth and tracheostomy placement), development of distal stenosis (in 1 case; 3.6%), lack of improvement in respiratory symptoms (in 1 case; 3.6%), prior to tracheal surgery (in 1 case; 3.6%), or other (in the remaining 2 cases; 7.1%). There was no reported difficulty with stent removal.

Seventeen patients (34%) died within 30 days of stent placement, of which 16 (94.1%) had a malignant CAO and 1 (5.8%) had a tracheo-/bronchoesophageal fistula. The most common cause of death was disease progression (*n* = 10). There was 1 possible stent-related mortality. One patient died 3 days after a Bonastent placement in the mid-trachea for airway obstruction secondary to lung adenocarcinoma. The patient had presented to another hospital with respiratory failure, likely due to mucous plugging. There were no deaths in the group with stent placements for benign disease.

The overall complication rate was 54% (27/50 patients) at a mean follow-up of 111 ± 145 days. The stent-related complication rate was 23.3% (14/60 cases) within 30 days and 52.9% (18/34 cases) at ≥30 days. The rates of individual complications were higher for stents left in



Fig. 2. Bonastent fracture (arrows).

≥ 30 days compared to < 30 days. The most common early complications (< 30 days) were mucous plugging in 8.3% ($n = 5$), granulation tissue formation in 6.7% ($n = 4$), respiratory infection in 6.7% ($n = 4$), stent migration in 5% ($n = 3$), and chronic cough in 5% ($n = 3$) of cases (Table 4). Out of the 14 cases that presented with early complications, 9 (64.3%) required a bronchoscopic intervention. Late complications (≥ 30 days) included mucous plugging in 23.5% ($n = 8$), respiratory infection in 23.5% ($n = 8$), granulation tissue formation in 14.7% ($n = 5$), chronic cough in 14.7% ($n = 5$), and stent migration in 5.9% ($n = 2$) of cases (Table 4). There was 1 case of stent fracture (Fig. 2) in a patient with small cell lung cancer who had the stent in place for 70 days. Of the 18 cases that presented with late complications, 14 (77.8%) required a bronchoscopic intervention.

Discussion

The tracheobronchial Bonastent is a novel fully covered SEMAS having recently become available in the USA; thus, there is limited experience, with only two small case series published. Avsarala et al. [7] reported on 13 Bonastents placed in 11 patients, 6 of whom had post-lung transplant airway stenosis. There were 3 cases of exuberant granulation tissue growing through the silicone covering, 2 instances of stent migration, and 1 stent fracture. The overall clinically significant obstruction rate was 38%. Makkar et al. [8] performed a retrospective chart review of 11 patients who had 13 Bonastents placed predominantly for malignant CAO. Short-term stent-related complications (within 90 days) included obstructive

mucous plugging ($n = 3$) and stent migration ($n = 1$). Four of the 11 patients died within 3 months of stent placement. These studies did not discuss the impact of stenting on patient symptoms or self-reported scores.

In this study, we reported the largest case series of airway Bonastent placement and described its efficacy and early (< 30 days) and late (≥ 30 days) complication rates. Most stent studies are retrospective or small-sized prospective studies with a heterogeneous patient population or variety of stent types used. Studies also differ in their definition of complications. Additionally, there have been no head-to-head comparisons. All of these factors make direct comparisons challenging. The overall stent-related complication rate of 54% in our study is similar in relation to previously published studies and in the context of the previously mentioned limitations [9]. The most common complications were mucous plugging (8.3 vs. 23.5%; early vs. late), infectious tracheobronchitis or pneumonia (6.7 vs. 23.5%), granulation tissue formation (6.7 vs. 14.7%), and chronic cough (5.0 vs. 14.7%).

The 6.7% early complication rate of granulation tissue formation was lower than the reported rate in currently published data on SEMAS. Use of the Ultraflex stent (Boston Scientific, Marlborough, MA, USA) for malignant airway disease had a 10.5% rate of granulation tissue formation, usually detected within the first month [9]. Although the rate increased to 14.7% at ≥ 30 days in our case series, it is still lower than the 19.5% rate at a median of 1.4 months reported in a heterogeneous group of Ultraflex ($n = 118$), AERO ($n = 31$), and Novatech Dumon silicone bronchial and Y-stents ($n = 46$) (Boston Medical Products Inc., Shrewsbury, MA, USA) [10]. Similarly, there was a 14.6% rate of granulation tissue formation in

a cohort of 82 patients who had an Ultraflex (15.5%) or Wallstent (15%) (Boston Scientific) placed [11].

We noted a 23.5% late complication rate of mucous plugging. This is also comparable to prior studies [8, 10, 12]. The smooth internal silicone covering of metallic stents has been shown to have low rates of sputum retention [13]. The rates of respiratory infections in our study were lower than those reported in a mixed stent study by Ost et al. [10] and in an Ultraflex/Wallstent study by Saad et al. [11], which were 37.4 and 15.9%, respectively. Although the flared ends of the Bonastent were intended to prevent stent migration, it occurred as an early complication in 5.0% (3/60) of cases and as a late complication in 5.9% (2/34) of cases. This is similar to other SEMAS [11, 13–15], but much lower than what could be seen with the Polyflex (Boston Scientific) [16] or Wallstent stents [17]. We had only 1 case of in-stent tissue growth, which has been previously described with the Bonastent [7] and covered Ultraflex stents [14]. For the Bonastent, this complication can result from rupture of the silicone membrane that can be spontaneous or iatrogenic at the time of stent reposition.

The overall complication rate increased after 30 days compared to that within 30 days. For this reason, close clinical follow-up with CT scans and early surveillance bronchoscopy should be considered after stent placement – even in the absence of symptoms – due to the high incidence of asymptomatic stent complications [18]. Airway stents should also be removed in a timely fashion when clinically indicated.

Seventy percent of the patients (35/50) in our series achieved improvement of their respiratory symptoms at 30 days. This is higher than the rate of 48% (90/187 patients) who had clinical improvement of dyspnea after undergoing therapeutic bronchoscopy for malignant CAO as reported in the AQuiRE registry [3]. This large, multicenter registry included 1,115 therapeutic procedures in 947 patients with malignant CAO and reported a 14.8% 30-day mortality rate. Death within 30 days of the procedure was associated with stent placement, ASA score >3, and intrinsic or mixed obstruction. The 30-day mortality rate with metal stent placement was 19.5% [4]. In our study, we reported a 34% 30-day mortality rate; however, the majority of our patients had mixed malignant CAO and half of our cohort had an ASA score >3. The great illness severity of our patient population at baseline is likely responsible for the higher rates of symptomatic relief but also poorer prognosis. The most common cause of death was due to disease progression. As with the AQuiRE registry, we noted that patients with

higher baseline dyspnea scores, higher ASA scores, and poorer functional status had greater improvements in health-related quality of life [3]. Potential reasons for lack of improvement in respiratory symptoms were not evaluated in our cohort but are suspected to be multifactorial, such as coexisting pleural effusion or other comorbidities.

Our study is limited in its small number and single-center design. Patients with malignant CAO have a poor prognosis. Thus, the benefits of symptomatic relief have to be weighed against the risks of complications with airway stent placement.

Conclusions

The tracheobronchial Bonastent is an effective alternative for the treatment of patients with symptomatic CAO and TEFs with an acceptable safety profile when placed by an experienced interventional pulmonology team. Future multicenter randomized trials comparing the different types of stents are needed to help improve outcomes and decrease costs.

Statement of Ethics

Written informed consent was waived. The institutional review board of Beth Israel Deaconess Medical Center approved this study protocol (IRB No. 2018P000727).

Disclosure Statement

The authors have no conflicts of interest to declare.

Funding Sources

There was no funding source for this study.

Author Contributions

Conception/design of the work: V.K.H., S.F.-B., F.J.F.H., and A.M. Acquisition, analysis, or interpretation of data for the work: V.K.H., D.O.-D., A.C., M.S.P., M.M.C., D.A.M., and A.M. All authors participated in manuscript writing/revision and final approval of the version to be published and are accountable for all aspects of the work.

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