Airway Stabilization With Silicone Stents for Treating Adult Tracheobronchomalacia*

A Prospective Observational Study

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Rationale: **It is postulated that in patients with severe tracheobronchomalacia (TBM), airway stabilization with stents may relieve symptoms.**
Objectives: **To evaluate the effect of silicone stents (tracheal, mainstem bronchus, or both) on symptoms, quality of life, lung function, and exercise capacity in these patients.**
Methods: **A prospective observational study in which baseline measurements were compared to those obtained 10 to 14 days after stent placement.**
Measurements and main results: **Of 75 referred patients, 58 had severe disease and underwent therapeutic rigid bronchoscopy with stent placement. Mean age was 69 years (range, 39 to 91 years), 34 were men, 33 had COPD, and 13 had asthma. Almost all patients (n = 57) had dyspnea as a sole symptom or in combination with cough and recurrent infections; four patients required mechanical ventilation for respiratory failure. In 45 of 58 patients, there was reported symptomatic improvement; quality of life scores improved in 19 of 27 patients (p = 0.002); dyspnea scores improved in 22 of 24 patients (p = 0.001); functional status scores improved in 18 of 26 patients (p = 0.002); and mean exercise capacity improved from baseline, although not significantly. The 49 complications included mainly 21 partial stent obstructions, 14 infections, and 10 stent migrations. Most patients with concomitant COPD also improved on most measures.**
Conclusions: **In the short term, airway stabilization with silicone stents in patients with severe TBM can improve respiratory symptoms, quality of life, and functional status. Coexisting COPD is not an absolute contraindication to a stenting trial in this population. Stenting is associated with a high number of short-term and long-term but generally reversible complications.**

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Key words: airway stabilization; bronchoscopy; COPD; stent placement; tracheobronchomalacia

Abbreviations: ATS = American Thoracic Society; BDI = baseline dyspnea index; KPS = Karnofsky performance scale; 6MWT = 6-min walk test; SGRQ = St. George respiratory questionnaire; TBM = tracheobronchomalacia; TDI = transitional dyspnea index

Tracheobronchomalacia (TBM) is an abnormal collapse of the tracheal and bronchial walls. It is characterized by flaccidity of the supporting tracheal and bronchial structures and a significant reduction of airway diameter on expiration seen in the trachea and/or in the mainstem bronchi.[1,2]

The prevalence of TBM in adults is unknown. The incidence may be as high as 23% among patients with COPD undergoing bronchoscopy,[3] and may represent 1% of all patients undergoing bronchoscopy.[4] One study[5] found TBM to be the cause of chronic cough in 14% of nonsmoking patients.

The cause of TBM is often unknown, but it is frequently seen in patients with common respiratory conditions such as chronic bronchitis and emphysema.[6] This pathologic narrowing can produce dynamic outflow obstruction with symptoms such as dyspnea, orthopnea, cough, wheezing, and the in-

ability to clear secretions, predisposing the patient to recurrent infections and wheezing. Some patients may present with stridor, respiratory failure leading to intubation, or immediate respiratory failure after extubation.[7,8]

The severity of TBM is conventionally graded by the degree of airway collapse during forced expiration (intrathoracic malacia) or inspiration (extrathoracic malacia). Based on expert opinion, collapse $< 50\%$ is within normal limits, while 50 to 75% is mild, 75 to 90% is moderate, and 91 to 100% (approximation of posterior membrane to the anterior luminal surface) is severe malacia.

Tracheomalacia has been recognized with increased frequency due to both improved clinical awareness and diagnostic imaging. While most experts still agree that functional bronchoscopy is the "gold standard" for diagnosis, there are no standardized protocols guiding respiratory maneuvers and airway measurements during these procedures. In the past few years, dynamic airway CT has proved to be highly sensitive for the diagnosis of malacia.[9]

Current treatments include techniques that splint the central airways, such as continuous positive airway pressure,[10] silicone airway stents,[11] and surgical tracheobronchoplasty.[12] In patients with severe, symptomatic TBM, stenting may provide symptomatic relief through airway stabilization. Unfortunately, most reports of this approach are anecdotal, and no controlled study has assessed the efficacy of airway stents for treating tracheomalacia.[13,14] This prospective study was designed to evaluate the efficacy of silicone airway stents in improving symptoms, quality of life, lung function, and exercise capacity in patients with severe TBM.

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Materials and Methods

The institutional review board of Beth Israel Deaconess Medical Center approved the protocol and patients gave written informed consent. We conducted a prospective, observational study from January 2002 to September 2006 in all patients referred to our Complex Airway Center for the evaluation of respiratory symptoms presumed to be caused by TBM. All patients who underwent central airway stenting (tracheal, mainstem bronchus, or both) for the treatment of severe TBM ($n = 58$) were considered for evaluation.

Severe TBM was defined by near-total or total airway collapse (with approximation of posterior and anterior luminal surfaces) observed during bronchoscopy. Patients were receiving maximal medical therapy for comorbidities such as obstructive airway disease. Those treatments included inhaled short-acting bronchodilators (β-adrenergic and anticholinergic), long-acting bronchodilators, inhaled corticosteroids, and oral corticosteroids.

Age, sex, comorbidities, and respiratory symptoms were recorded at baseline. All patients underwent dynamic airway CT and functional bronchoscopic assessment. In addition, unselected subsets of patients underwent spirometry testing, 6-min walk test (6MWT), and completed standardized questionnaires including the modified St. George respiratory questionnaire (SGRQ),[15] baseline dyspnea index (BDI)/transitional dyspnea index (TDI),[16] American Thoracic Society (ATS) dyspnea score, and Karnofsky performance scale (KPS).[17]

Silicone stents were placed in all patients to stabilize the airway. Tracheal, bronchial, and bifurcated silicone stents (Dumon tracheal stent size 16, Dumon bronchial stent size 14, and Dumon bifurcated (Y-stent) sizes 14–18; Novatech-Boston Medical Products; Westborough, MA). The degree and location of malacia, the type and location of stent placement, and any complications during stent insertion were also recorded.

At a scheduled follow-up visit 10 to 14 days after the procedure, patients were asked whether symptoms had improved and baseline measurements were repeated. The 2-week window was chosen to minimize confounding factors, such as possible stent complications and any potential long-term impacts of physical conditioning between stent placement and follow-up measurements. Patients were followed up after that for any stent-related complications.

Functional Bronchoscopic Assessments

All bronchoscopies were performed with topical anesthesia and light sedation, which allowed patients to follow commands. The bronchoscope was introduced into the trachea and advanced to approximately 5 cm above the carina. At that point, the patient was instructed to perform a forced expiratory maneuver. This procedure was then repeated at the entrances of the right and left main bronchi. All bronchoscopies were video recorded and reviewed after the procedure to assess the degree of airway collapse before stent placement (Fig 1), as described in detail.[18]

CT of the Airway

All patients underwent CT imaging on a multidetector row, helical CT scanner (LightSpeed; GE Medical Systems; Milwaukee, WI; or Aquilion; Toshiba America Medical Systems; Tustin, CA). Scanners included 4, 8, 16, and 64 detector-row systems.

All patients underwent imaging using a CT central airway protocol,[9] which includes end-inspiratory and dynamic expiratory imaging. Before helical scanning, initial scout topographic images were obtained to determine the area of coverage, which included the trachea and central bronchi, and that corresponded to a

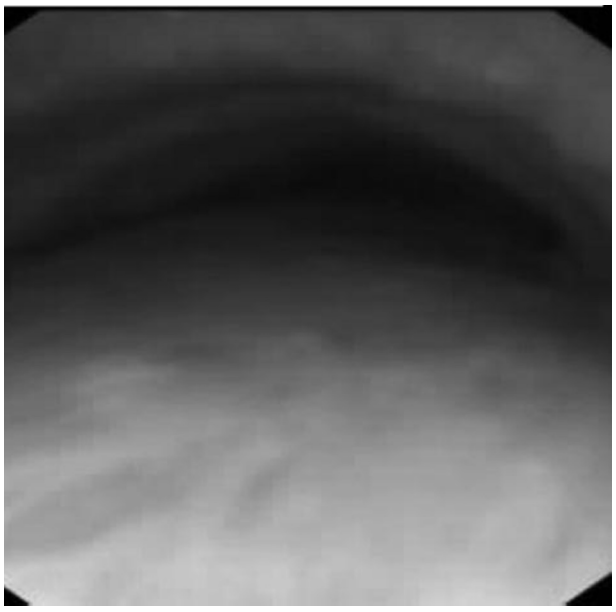

FIGURE 1. Functional bronchoscopy was used to assess airway collapse. During bronchoscopy, patients are instructed to perform a forced expiratory maneuver. At the end of expiration, a picture is taken and the bronchoscopist quantifies the degree of collapse. This patient has approximately 90% collapse of the trachea.

length of approximately 10 to 12 cm. Helical scanning was performed in the craniocaudal dimension during both end-inspiratory and dynamic expiratory phases.

To calculate the percentage of luminal collapse, the estimated dynamic expiratory cross-sectional area was subtracted from the end-inspiratory cross-sectional area, divided by the end-inspiratory cross-sectional area, and then multiplied by 100. Malacia was determined to be present if the percentage of luminal collapse during dynamic expiration was $\geq 50\%$. The distribution of malacia in the trachea and bronchi was also recorded (Fig 2).

Spirometry was performed using the ATS guidelines.[19] FEV_1 was measured at baseline and after stent placement. A change of 0.2 L from baseline was considered clinically important.

The 6MWT, an objective evaluation of functional exercise

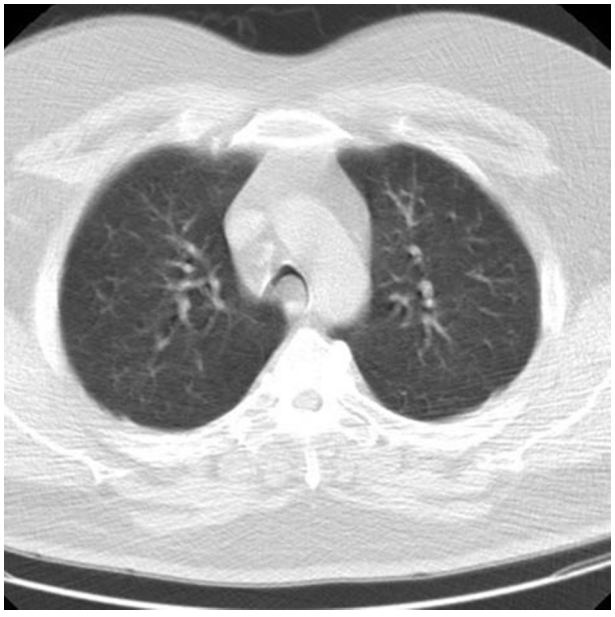

FIGURE 2. Dynamic airway CT showing the degree of malacia in the trachea in the same patient as shown in Figure 1. A 90 to 95% collapse is confirmed with dynamic expiration.

FIGURE 3. A silicone stent in the left main bronchus of a patient with severe TBM. Notice the difference in patency compared to the also affected right mainstem.

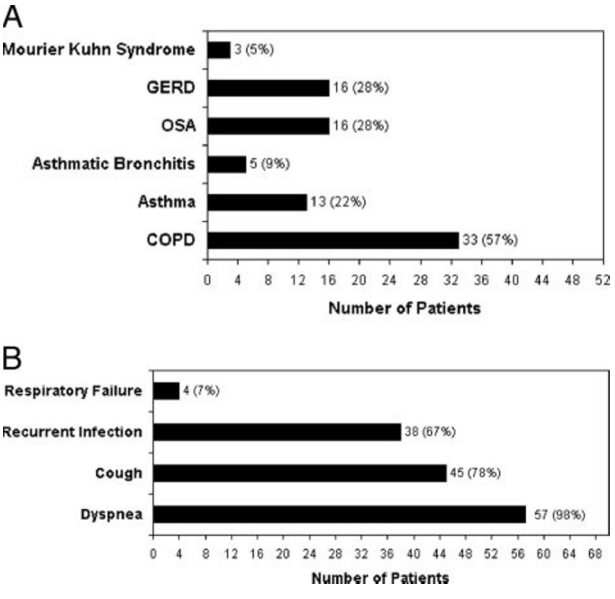

FIGURE 4. *Top*, *A*: comorbidities among 58 patients with severe diffuse TBM. GERD = gastroesophageal reflux disease; OSA = obstructive sleep apnea. *Bottom*, *B*: presenting symptoms among 58 patients with severe diffuse TBM.

Table 1—*Clinical Outcomes of 58 Patients With Severe TBM After Therapeutic Rigid Bronchoscopy and Silicone Stent Placement Under General Anesthesia

Outcome Measures	Baseline Values	Baseline Values§	Follow-up Values	Change	Improved, No./Total	p Value
SGRQ†						
All patients	75 (66, 81)/38	77 (66, 81)/27	61 (32, 71)/27	− 9 (− 43, 0)/27	19/27	0.002
Non-COPD patients	77 (66, 81)/15	77 (72, 81)/9	68 (56, 70)/9	− 9 (− 13, 4)/9	6/9	0.27
COPD patients	73 (66, 84)/23	75 (66, 81)/18	55 (32, 71)/18	− 13.5 (− 43, 0)/18	13/18	0.005
BDI/TDI†						
All patients	3 (2, 5)/41	3 (2, 5)/24	4 (1, 6)/24	NA	22/24	0.001
Non-COPD patients	3 (2, 4.5)/16	4 (2, 6)/7	6 (− 3, 9)/7	NA	6/7	0.34
COPD patients	3 (2, 5)/25	3 (2, 5)/17	4 (1, 6)/17	NA	16/17	< 0.001
ATS dyspnea score†						
All patients	3 (2, 4)/41	3 (2, 4)/29	2 (1, 2)/29	− 1 (− 2, 0)/29	21/29	< 0.001
Non-COPD patients	2.5 (2, 4)/16	2 (2, 4)/9	1 (1, 1)/9	− 1 (− 2, − 1)/9	7/9	0.02
COPD patients	3 (3, 4)/25	3 (3, 4)/20	2 (1, 3)/20	− 1 (− 2.5, 0)/20	14/20	0.002
KPS‡						
All patients	60 (60, 70)/41	65 (60, 70)/26	75 (60, 85)/26	10 (0, 10)/26	18/26	0.002
Non-COPD patients	60 (50, 70)/16	70 (60, 80)/7	80 (70, 90)/7	10 (10, 20)/7	6/7	0.09
COPD patients	60 (60, 70)/25	60 (60, 70)/19	70 (60, 80)/19	10 (0, 10)/19	12/19	0.03
6-min walk distance, ft‡						
All patients	640 (280, 1,200)/36	1,040 (320, 1,200)/17	800 (440, 1,260)/17	60 (− 40, 240)/17	10/17	0.28
Non-COPD patients	1,040 (490, 1,200)/14	1,040 (1,040, 1,120)/5	1,240 (1,000, 1,600)/5	200 (− 40, 240)/5	3/5	0.32
COPD patients	600 (160, 1,200)/22	560 (160, 1,385)/12	623 (280, 1,130)/12	50 (− 77, 220)/12	7/12	0.53
FEV_1, L‡						
All patients	1.3 (1.0, 2.0)/42	1.1 (0.8, 1.8)/10	1.6 (0.7, 1.7)/10	− 0.05 (− 0.1, 0.1)/10	4/10	0.79
Non-COPD patients	1.6 (1.0, 2.2)/15	1.7 (1.2, 2.2)/2	1.6 (1.3, 1.9)/2	− 0.1 (0.2, 0.1)/2	1/2	1.0
COPD patients	1.1 (0.9, 1.7)/27	1.1 (0.7, 1.8)/8	1 (0.8, 1.7)/8	0 (− 0.1, 0.4)/8	3/8	0.81

*Data are presented as median (first and third quartiles)/No. of patients tested unless otherwise indicated. NA = not applicable.
†Higher scores indicate poorer health.
‡Higher scores indicate better health.
§Patients with follow-up.

capacity, was performed according to ATS guidelines.[20] An improvement > 230 feet was considered clinically important.[21]

We used the BDI and the TDI as objective measures of dyspnea. The BDI represents the severity of dyspnea at baseline and is based on three components: functional impairment, magnitude of the task, and the magnitude of the effort. Each component is scored 0 to 4, so the summed scores range from 0 (severe) to 12 (normal). The TDI indicates the change from baseline. The TDI uses the same components as the BDI, but each component is graded from – 3 (major deterioration) to + 3 (major improvement). The summed scores range from – 9 (major deterioration) to + 9 (major improvement).[16]

The ATS dyspnea score, although less well studied, is easy to use and also provides an objective measurement for dyspnea in this population. Scores range from 0 (no dyspnea) to 4 (severe dyspnea).

A modified SGRQ[15] was used to measure the impact of respiratory symptoms on overall health, daily life, and perceived well-being. The questionnaire has been widely used in patients with COPD and asthma. In our study, many patients had COPD, asthma, or both. The questionnaire has three dimensions (symptoms, activities, and impacts). Each dimension describes the respiratory problems encountered by the patient in the preceding 2 weeks (instead of 4 weeks) and is scored from 0 to 100, with higher scores indicating poorer health. Empirical data and interviews with patients indicate that a mean change score of 4 U is associated with a slightly efficacious treatment, 8 U with a moderately efficacious treatment, and 12 U with a highly efficacious treatment.[15,22]

The KPS, which classifies patients by functional impairment, has been used to compare the effectiveness of different therapies and to assess the prognosis of individual oncology, geriatric, and stroke patients.[23,24] Scores range from 0 to 100. The lower the score, the greater the impairment and the worse the prognosis.[25]

Airway Stenting

All airway stents were placed in the operating room with the patient under general IV anesthesia. After anesthesia was induced, a rigid bronchoscope (Bryan-Dumon Series II; Bryan Corporation; Woburn, MA) was introduced, and respiration was maintained through jet ventilation.

After assessing the airways and remeasuring the lengths of the left and right mainstem bronchi, we placed either a Y-shaped stent or multiple stents. Stents were placed in the standard fashion, and a good fit was confirmed visually. All stents were made from silicone to allow easy removal if necessary (Fig 3).

Statistical Methods

Since most outcome data were not normally distributed, baseline and follow-up measurements for all end points were compared with a Wilcoxon signed-rank test. α was set at 0.05, and all tests were two-tailed. Statistical software (SAS, version 9.1.3 for Windows; SAS Institute; Cary, NC) was used for all analyses.

Results

Of 75 patients referred for assessment of TBM during the study period, 58 had severe TBM and

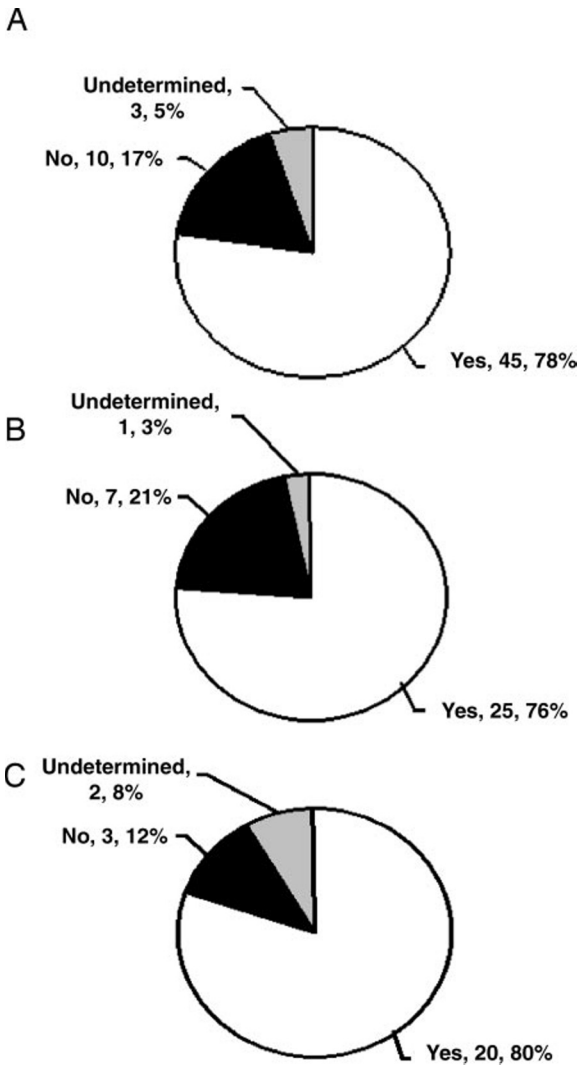

FIGURE 5. Self-reported improvement in symptoms after stent placement in all patients (*top*, *A*), COPD patients (*center*, *B*), and non-COPD patients (*bottom*, *C*).

were able to undergo therapeutic rigid bronchoscopy under general anesthesia. The patients included in this study were on average 69 years old (range, 39 to 91 years), and 34 patients (59%) were men. Among all patients, 33 patients had COPD (57%; median FEV_1, 1.07 L); 13 patients (22%) had asthma; 16 patients (28%) had obstructive sleep apnea; 16 patients (28%) had gastroesophageal reflux disease; and 3 patients (5%) had Mounier Kuhn syndrome, with some patients suffering from more than one (Fig 4, *top*, *A*).

Almost all patients (n = 57, or 98%) had dyspnea as a sole symptom or in combination with cough and recurrent infections. Four patients presented with respiratory failure and required mechanical ventilation (Fig 4, *bottom*, *B*).

Most patients (n = 46, or 80%) had diffuse TBM and were treated with either a combination of a silicone tracheal and left main stent (n = 19) or a Y-stent (n = 27). Six patients each were treated only with bronchial or only with tracheal stents.

The following numbers of subjects had baseline and follow-up data collected for each outcome: SGRQ, n = 38 and n = 27; BDI/TDI, n = 41 and n = 24; ATS dyspnea score, n = 41 and n = 29; KPS, n = 41 and n = 26; 6MWT, n = 36 and n = 17; and FEV_1, n = 42 and n = 10, respectively. For all measures, median baseline values of those patients in whom follow-up was also obtained were comparable to baseline median values for all patients.

SGRQ, BDI/TDI, ATS, and KPS scores improved among both the complete sample with baseline and follow-up measures and the subset of patients with COPD. There were no significant changes in 6MWT results or FEV_1 (Table 1).

On self-reported symptoms, dyspnea improved, secretions cleared, or both, after stent placement in 45 patients. In 10 patients, symptoms were unchanged or worsened after stent placement. In the remaining three patients, changes were equivocal because some symptoms improved while others worsened. Of the 33 patients with COPD, 25 patients reported improved symptoms, 7 reported no improvement, and 1 could not determine whether symptoms had changed. In the 25 non-COPD patients, 20 patients reported improvement of symptoms, 3 reported no improvement, and 2 could not determine whether their symptoms had changed (Fig 5).

Most patients who responded reported improvement immediately after stent placement. All four patients admitted to the hospital with respiratory failure secondary to TBM were weaned off mechanical ventilation after stent placement.

Complications occurred usually within the first 3 months (median, 26 days; range, 3 to 865 days). Of these complications, 44 complications (90%) were related to the stent, 5 to bronchoscopy, and none to anesthesia. Complications included stent obstruction

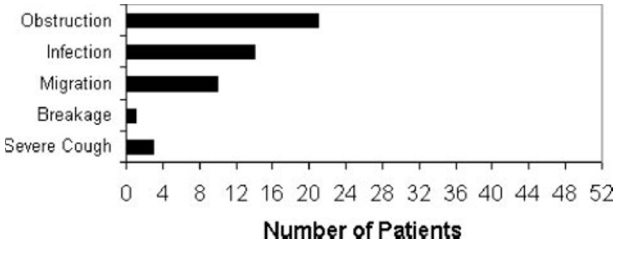

FIGURE 6. Procedure-related complications among patients who underwent rigid bronchoscopy and silicone stent placement.

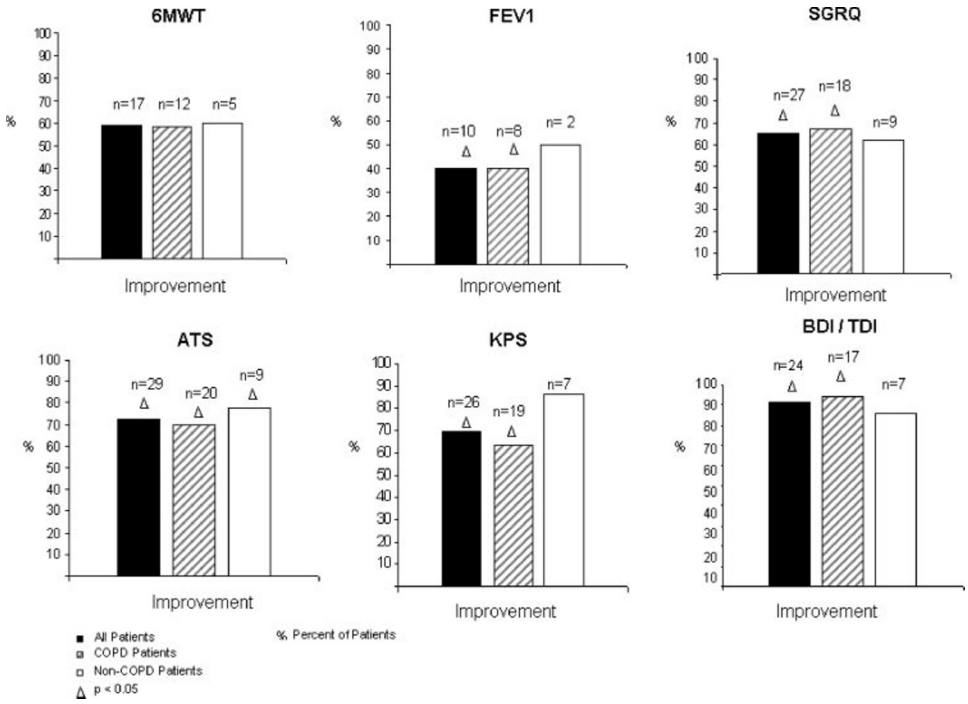

FIGURE 7. Percentage of improved scores after airway stenting among all patients, COPD patients, and non-COPD patients. 6MWT in all patients ($p = 0.28$) [solid bars], COPD patients ($p = 0.53$) [stippled bars], and non-COPD patients ($p = 0.31$) [open bars]. FEV_1 in all patients ($p = 0.79$) [solid bars], COPD patients ($p = 0.81$) [stippled bars], and non-COPD patients ($p = 1.0$) [open bars]. SGRQ in all patients ($p = 0.002$) [solid bars], COPD patients ($p = 0.005$) [stippled bars], and non-COPD patients ($p = 0.27$) [open bars]. ATS dyspnea score in all patients ($p < 0.0001$) [solid bars], COPD patients ($p = 0.002$) [stippled bars], and non-COPD patients ($p = 0.016$) [open bars]. KPS in all patients ($p = 0.002$) [solid bars], COPD patients ($p = 0.03$) [stippled bars], and non-COPD patients ($p = 0.09$) [open bars]. BDI/TDI all patients ($p = 0.001$) [solid bars], COPD patients ($p = 0.0006$) [stippled bars], and non-COPD ($p = 0.36$) [open bars].

secondary to mucous plugging (n = 21), infection (n = 14), stent migration (n = 10), severe cough (n = 3), subglottic edema (n = 3), and stent breakage (n = 1). All complications were treated in standard fashion with mucolytics, cough suppressants, and stent removal or replacement if necessary (Fig 6). Stenting improved the median scores of all clinical end points, and most patients reported improvement (Table 1; Fig 7, 8).

DISCUSSION

There is a need for a higher clinical suspicion and a standardized approach to objectively evaluate for TBM in the patient with dyspnea refractory to traditional therapies. Therapeutic airway stenting is often considered, but evidence for the efficacy of this approach has not been adequately characterized. In this largest prospective study to date, we found that stenting produced statistically significant and clinically important improvement in dyspnea, health-related quality of life, and functional status in a selected patient population with severe TBM. As there were no concurrent changes in medication or physical rehabilitation, we attribute these positive outcomes to the impact of central airway stabilization.

Importantly, 33 of our 58 patients (57%) had COPD. In these patients, TBM is often believed to be an extension of peripheral airway obstruction. In fact, it has been suggested in retrospective, uncontrolled studies[26] that TBM in these patients may not be responsive to aggressive treatment. Our study suggests that COPD patients may benefit from central airway stabilization in severe TBM. Irrespective of any direct impact on flow limitation, TBM in these patients may worsen symptoms by impeding clearance of secretions and/or causing local air irritation resulting in recurrent infections and airway inflammation.

Interestingly, even though some patients had improvement in the 6MWT scores, the improvement was not clinically or statistically significant. We speculate that it is unlikely that patients would undergo

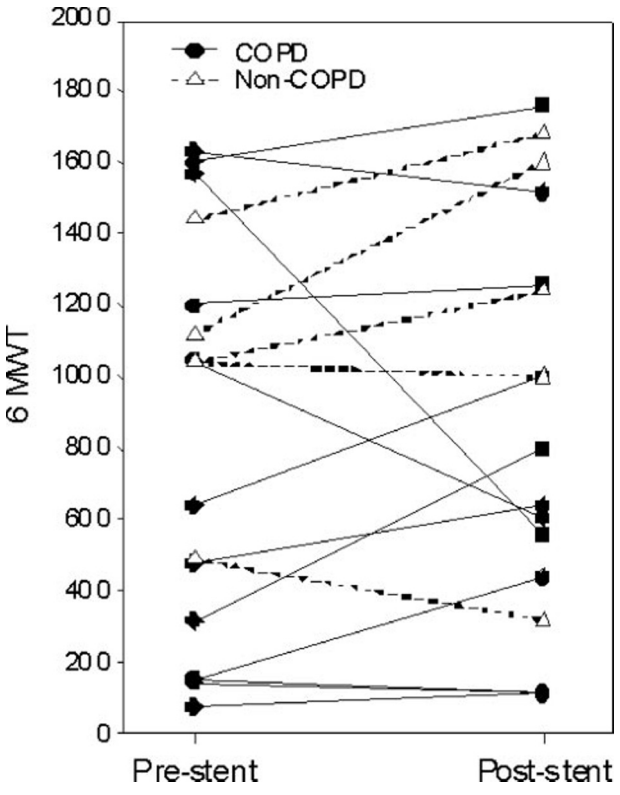

FIGURE 8. Individual values of the changes in the 6-min walk distance before and 2 weeks after stent placement. Distances are expressed in feet.

substantial reconditioning after only 2 weeks of symptomatic improvement, and thus we may have conducted follow-up to soon to see any change. We believe, however, that these patients, who could not undergo a pulmonary rehabilitation program before stenting, are now able to do so and a longer follow-up interval therefore may show improvement in exercise tolerance. Active data collection to address this issue is ongoing.

FEV_1 is frequently used as a surrogate end point for severity of obstructive lung diseases.[27,28] In our study, we found that clinical improvement was not associated with significant changes in FEV_1 in this population. Median FEV_1 decreased by 0.05 L ($p = 0.79$), with first and third quartiles at -0.1 and 0.1, respectively.

On the downside, most complications we observed were related to the stents. Airway stents are often associated with reversible short-term and long-term complications. Complications were common in this study and included obstruction (by mucous plugging), infection, and migration with a peak incidence at 3 weeks. These complications were relatively easily managed by therapeutic suctioning, replacement, or removal of the stent and, if infection was a concern, with a 7- to 10-day antibiotic course. We chose to use silicone stents for a variety of reasons. In case of nonresponsiveness to airway stabilization, these stents are easily removed. Also, as other treatment modalities such as surgical placation are becoming available, permanent stenting may not be desirable. Thirdly, metallic stents in malacia patients are generally fraught with failure and complications and in contrast to silicone stents; their removal is problematic and potentially dangerous. For this reason, the Food and Drug Administration in July 2005 had emitted an alert notice for the use of covered and uncovered metallic stents in benign airway disorders (http://www.fda.gov/cdrh/safety).

There are notable limitations to our approach. Not all stented patients were administered both baseline and follow-up measures. In some cases, patient intake was too rapid to permit baseline assessment, while other patients were unavailable to complete all follow-up testing. There may have been factors related to either the indication for, or success of, treatment that were also associated with availability of pretreatment or posttreatment measures. These factors could bias our findings in favor of positive outcomes. Comparison of baseline measurements obtained on patients who also had follow-up measures, with the total baseline sample reveals no significant differences. This suggests that those available for poststent measurement were comparable to the total baseline sample.

Additionally, there is no control group to compare intervention against standard therapy. Since standard medical therapy for TBM is poorly defined, there was no accepted control condition. Patients were only enrolled after maximal medical therapy for comorbidities was provided.

Finally, neither patients nor providers were blinded to diagnosis or treatment. Although we used well-standardized clinical and research tools for outcome measures, the potential for bias due to observer expectations or placebo effect cannot be ruled out.

CONCLUSIONS

Airway stabilization with silicone stents can improve symptoms in a highly selected patient population with severe TBM. The majority of our patients had marked improvement in dyspnea, health-related quality of life, and functional status in this short-term study. Patients with COPD and severe TBM may also benefit from a stenting trial. Stenting is associated with a high number of short-term and long-term but generally reversible complications. Despite the obvious limitations, we believe the results of this study are compelling: patients with severe TBM

should be considered for airway stabilization, regardless of comorbidities, including COPD. Improvement needs to be carefully documented and in case of unresponsiveness, stents must be removed. Future research should compare stenting to other interventions, such as surgical tracheoplasty, in treating these patients. Additionally, better diagnostic parameters predicting a successful intervention need to be identified. We suggest that evaluation and treatment of tracheomalacia patients be done in experienced centers and all patients be enrolled in prospective outcome databases. A multicenter study with appropriate protocols may be best suited to answer the open questions.

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