Technical Aspects and Outcomes of Tracheobronchoplasty for Severe Tracheobronchomalacia

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Background. **Tracheobronchomalacia is an underrecognized cause of dyspnea, recurrent respiratory infections, and cough. Surgical stabilization with posterior membranous tracheobronchoplasty has been shown to be effective in selected patients with severe disease. This study examines the technical details and complications of this operation.**

Methods. **A prospectively maintained database of tracheobronchomalacia patients was queried retrospectively to review all consecutive tracheobronchoplasties performed from October 2002 to June 2009. Posterior splinting was performed with polypropylene mesh. Patient demographics, surgical outcomes, and operative data were reviewed.**

Results. **Sixty-three patients underwent surgical correction of tracheal and bilateral bronchial malacia. Twenty-three patients had chronic obstructive pulmonary disease, 18 had asthma, 5 had Mounier-Kuhn syndrome, and 4 had interstitial lung disease. Seven patients had a previous tracheotomy. Operative time was 373 ± 93 minutes. Median length of stay was 8 days (range, 4 to 92 days), of which 3 days (range, 0 to 91 days) were in intensive care. Seventy-five percent of patients were discharged home (28% with visiting nurse follow-up), and 25% went to a rehabilitation facility. Two patients (3.2%) died postoperatively—1 of worsening usual interstitial pneumonia, and the other of massive pulmonary embolism. Complications included a new respiratory infection in 14 patients, pulmonary embolism in 2, and atrial fibrillation in 6. Six patients required reintubation, and 9 received a postoperative tracheotomy; 47 patients required postoperative aspiration bronchoscopy.**

Conclusions. **In experienced hands, tracheobronchoplasty can be performed with a very low mortality rate and an acceptable perioperative complications rate in patients with significant pulmonary comorbidity. Intervention for postoperative respiratory morbidity is often necessary.**

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Adult patients with severe diffuse tracheobronchomalacia (TBM) may present with dyspnea, recurrent infections, intractable cough, and retained secretions [1, 2]. We have previously reported the beneficial effects of internal and external stabilization of TBM for a select group of patients [2, 3]. Although silicone stenting of the collapsing airways is minimally invasive and usually effective, complications are common, and peak at the 3-week mark. Thus, surgical tracheobronchoplasty (TBP) to stabilize the malacic airway is the favored approach in our institution as a long-term solution for appropriate candidates. This operation has historical roots going back more than a half century, and has lately become of more interest as a therapeutic option to treat severe forms of diffuse TBM [3–7].

The purpose of this study was to review our operative experience over the past 7 years to describe the technical details of the operation as modified based on our ongoing experience. In addition, we sought to report the short-term efficacy of the operation in our larger series, and most importantly, to report in transparent fashion the perioperative outcomes, morbidity, and mortality associated with TBP.

Patients and Methods

This study was approved by the Beth Israel Deaconess Medical Center Institutional Review Board. Informed consent for prospective data accrual was obtained from all patients. We retrospectively examined the prospectively maintained database at our institution's Complex Airway Center to identify all patients who were evaluated from October 2002 through June 2009 for severe

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TBM. Severe TBM was defined as complete or near-complete collapse of the trachea and bilateral bronchi, as demonstrated by functional bronchoscopy and dynamic computed tomography scanning. Previous work has shown high concordance of these modalities in detecting and localizing TBM in these patients [3]. The protocols for both dynamic bronchoscopy and computed tomography scanning have been described in prior reports [2, 3, 8, 9]. We then analyzed all consecutive cases of TBP (surgical stabilization of the posterior membrane by prosthetic mesh splinting of the thoracic trachea and bronchi) performed during the study period. Excluded from this analysis were cases of cervical tracheoplasty or resection/reconstruction that were performed for extrathoracic tracheal malacia.

Stenting Trial

As previously described, patients with severe TBM underwent airway stent placement to clarify their candidacy for surgical intervention [2]. Fifty-five percent of patients underwent silicone Y-stenting, representing an evolution of the algorithm from our initial experience in which the most common technique was placement tubular silicone stents in the trachea and left mainstem bronchus of each patient. After a 2-week trial, patients were seen in clinic to review the degree of improvement in symptomatology that resulted from internal stabilization of the airway. Patients who reported marked symptomatic improvement were considered for definitive surgical intervention.

Functional and Symptom Testing

Patients underwent physiologic assessment with pulmonary function testing and a 6-minute walk test. Standardized questionnaires were also administered to determine functional status (Karnofsky Performance Scale); symptomatology (American Thoracic Society Dyspnea Score; Baseline and Transition Dyspnea Indices); and respiratory-impacted quality of life (St. George Respiratory Questionnaire) [10–14]. The administration of these tests to TBM patients has been described previously [2, 3]. Preoperative and 3-month postoperative assessments were performed.

Surgical Technique

We previously have described our technique for TBP in detail [7] (Fig 1). The goal of the procedure is to stabilize the airway by suturing a knitted polypropylene mesh (ref. 0112670; C. R. Bard, Murray Hill, NJ) to the posterior membrane of the trachea and bilateral bronchi. We prefer 4.0 polypropylene sutures (30-inch, RB-1, catalog no. 8557H; Ethicon, Somerville, NJ) to secure the mesh, with each suture passed in partial thickness fashion so as not to enter the airway lumen. Although other groups have utilized absorbable sutures [6], we favor a permanent anchoring of the mesh with polypropylene, although admittedly, this is more preference than science (Fig 2). These anchoring sutures are placed in rows of four across the trachea and larger aspects of the bronchi; rows of three sutures are used in the smaller distal left mainstem bronchus and bronchus intermedius. The rows are spaced approximately 5 to 7 mm apart.

Depending on the amount of lateral migration of the cartilaginous membranous junctions (ie, decreased sagittal:coronal ratio), the mesh is sized to stabilize the airway appropriately. In cases where there is primarily membranous wall intrusion and not much dynamic lateral movement and flattening of the cartilaginous walls, the degree of "cinching" of the airways is less. With tracheomegaly and flattened cartilaginous arches, to restore the coronal diameter, the mesh needs to downsize the transverse diameter more, pulling the cartilaginous-

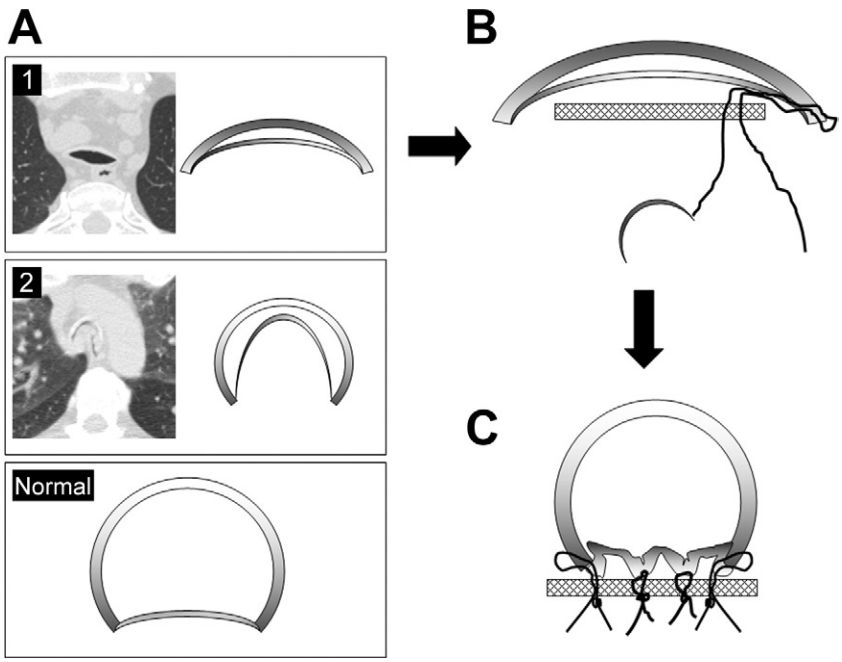

Fig 1. A schematic of malacic airway pathology in cross-section, and correction with tracheobronchoplasty is shown. (A) Airway (1) represents the form of tracheobronchomalacia (TBM) that primarily affects the cartilage, causing lateral migration of the cartilaginous-membranous junction and decreased ratio of sagittal:coronal diameter; a representative computed tomography scan image accompanies the diagram. Airway (2) represents the form of TBM that primarily is manifest by membranous wall intrusion into the lumen of the airway, with relative preservation of coronal diameter; a representative computed tomography scan image accompanies the diagram, and a normal airway cross-section is also depicted. (B) Posterior splinting is depicted. The mesh is represented by the cross-hatched rectangle, and the suture is seen passed in partial-thickness, mattressed fashion through the airway wall. (C) After sutures are tied down, any redundancy of the membranous wall is pleated to the mesh, and the D-shape of the airway is restored. Reprinted from Gangadharan [7].

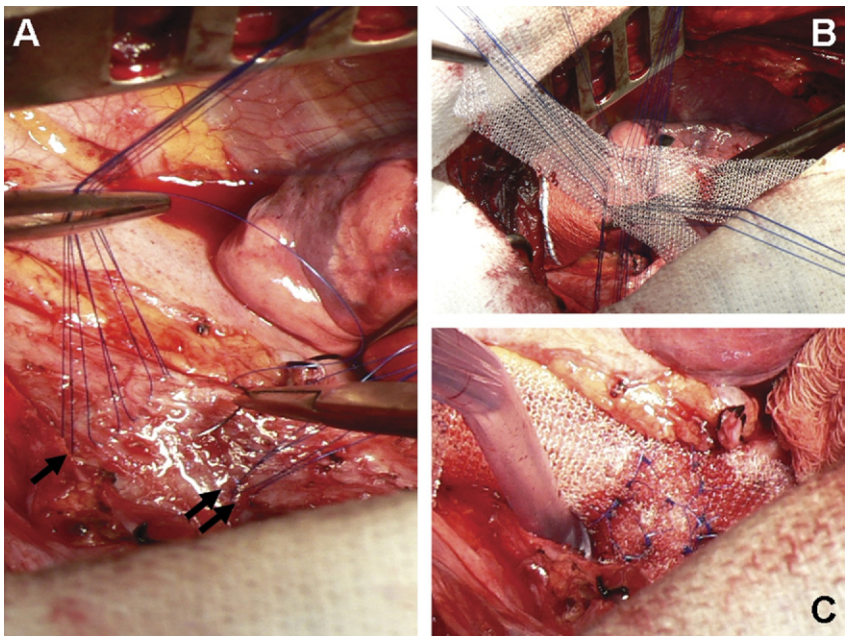

Fig 2. A photograph of tracheobronchoplasty is shown. (A) Partial-thickness sutures are placed in rows across the posterior membrane at the level of the carina. The single arrow marks the row at the distal trachea; double arrows mark the row across the proximal right mainstem bronchus. (B) Polypropylene mesh is parachuted into place after distal trachea and proximal left and right bronchial suture rows have been placed. (C) Appearance after the first rows of sutures are tied and the mesh is anchored to the posterior membrane.

membranous junctions closer in the manner of tension on a bow string.

The thoracic airways are splinted from the thoracic inlet to the distal left mainstem bronchus and distal bronchus intermedius. A completion bronchoscopy is always performed before closure of the chest to aspirate secretions and to verify that the entirety of the thoracic airways to the level of the lobar bronchi are stabilized posteriorly, and no stenosis is noted. Small air leaks at suture holes are rarely observed, and generally will seal with spontaneous breathing. Intraluminal sutures occasionally are seen, and are removed to prevent tracking of bacteria from the airway to the mesh.

Statistics

Wilcoxon signed-rank test was utilized to compare the preoperative and postoperative measurements of lung function, dyspnea, and quality of life scores and 6-minute walk tests as the data were nonparametric. A Bonferroni correction for statistical significance was used as multiple comparisons were performed on this single dataset. As there were five comparisons, a very conservative threshold for statistical significance was set at p less than 0.01 ($p = \alpha/n$) using a standard α error of p less than 0.05.

Results

Of 218 patients referred for evaluation of TBM, 180 were found to have severe TBM on bronchoscopy. Of these, 161 underwent stent trial; 19 patients refused intervention or were deemed to have insufficiently severe symptomatology to warrant intervention. Upon reevaluation, 99 of the stented patients reported marked symptomatic improvement (alleviation of dyspnea, improved secretion clearance, or decreased cough). Sixty-three patients underwent tracheobronchoplasty. There were 28 women (44%) in the cohort, and the mean age was 59 years (±12.5 SD; range, 35 to 82 years). Preoperative comorbidities included respiratory afflictions such as chronic obstructive pulmonary disease in 37%, asthma in 23%, Mounier-Kuhn syndrome in 8%, and interstitial lung disease in 6% (Table 1). Notably, gastroesophageal reflux disease was a comorbid diagnosis in 48% of patients.

The operation time averaged 373 minutes (±93 SD; range, 180 to 635 minutes). The coronal airway dimensions as measured along the posterior wall were as follows (mean ± SD): proximal trachea 2.7 ± 1.0 cm, distal trachea 3.0 ± 1.0 cm, right mainstem bronchus 2.5 ± 0.8 cm, left mainstem bronchus 2.2 ± 0.6 cm, and bronchus intermedius 1.7 ± 0.6 cm. The mesh downsized the airway to the following dimensions: proximal trachea 1.6 ± 0.4 cm, distal trachea 1.7 ± 0.4 cm, right mainstem bronchus 1.5 ± 0.4 cm, left mainstem bronchus 1.4 ± 0.3 cm, and bronchus intermedius 1.1 ± 0.2 cm. Overall, the mean reduction in posterior airway coronal diameter ranged from 32% to 41%.

The median hospital length of stay was 8 days (range, 4 to 92 days), and the median length of intensive care unit stay was 3 days (range, 0 to 91 days). Complications were seen in 38% of patients. There were 2 deaths (3.2%), both during our initial 35-patient experience. One patient succumbed to worsening usual interstitial pneumonia, and the other had a massive pulmonary embolism. During the latter half of the series, there has been no further mortality. Complications included a new postoperative respiratory infection in 14 patients (22%), atrial arrhythmia in 6 (10%), acute renal failure (creatinine >2) in 4 (6%), unplanned return to the intensive care unit in 3 (5%), urinary tract infection in 2 (3%), pulmonary embolism in 2 (3%), myocardial infarction and cardiomyopathy in 1 patient (2%), and wound infection in 1 (2%). Reintubation was necessary in 6 patients (10%). A tracheotomy

Table 1. Preoperative Comorbidities

Comorbidity	Number of Patients
Hypertension	34 (54%)
Gastroesophageal reflux disease	30 (48%)
Chronic obstructive pulmonary disease	23 (37%)
Asthma	18 (29%)
Cardiac (dysrhythmia, coronary artery disease, heart failure)	18 (29%)
Diabetes mellitus	13 (21%)
Previous tracheotomy	7 (11%)
Mounier-Kuhn	5 (8%)
Previous chest surgery	5 (8%)
Interstitial lung disease	4 (6%)

was placed in 9 patients (14%), including 4 tracheotomies intraoperatively immediately after the tracheobronchoplasty was completed in anticipation of the need for frequent aspiration bronchoscopy and tracheal suctioning. Of these patients, 5 were decannulated successfully. One patient still had his tracheotomy at the 3-month postoperative visit and was subsequently lost to follow-up; 1 patient was lost to follow-up immediately after his TBP. The 2 patients who died postoperatively both died with tracheotomies in place. Neither reintubation nor tracheotomy was required in the latter half of the series. There were no reoperations for bleeding.

Not included in the previous calculation of morbidity was the frequency of postoperative bronchoscopy. Some patients underwent routine bronchoscopic evaluation of the airways after TBP, whereas other bronchoscopies were done in response to a specific clinical indication (eg, increased secretions, mucus plugging). Unfortunately, it was not possible to determine from the medical record the indication for bronchoscopy in all cases. Overall, bronchoscopy was performed in the postoperative period in 75% of the patients. The median number of bronchoscopies performed in the patients receiving that intervention was 2 (range, 1 to 32).

More than three quarters of the patients were discharged directly home from the hospital postoperatively; 47% required no assistance, whereas 28% went home with visiting nurse follow-up; and 25% of the patients were discharged to a rehabilitation facility postoperatively.

Thirty-seven patients had complete sets of preoperative and postoperative measurements of forced expiratory volume in 1 second (FEV_1), and no significant difference was demonstrated (preoperative FEV_1 1.62 ± 0.76 mL, postoperative FEV_1 1.66 ± 0.67 mL [mean ± SD]; $p = 0.29$; Table 2). Of this group, 22 of 37 patients had improved FEV_1, with a mean increase of 234 mL (range, 20 to 870 mL). Conversely, 15 of 37 patients demonstrated no improvement or frank worsening of their postoperative FEV_1, with a mean decrease of 235 mL (range, 10 to 1,160 mL; 1 patient also had the exact same FEV_1 values preoperatively and postoperatively).

Significant improvement in patients after TBP was seen in the Karnofsky Performance Scale (preoperatively 62 ± 12 [mean ± SD] versus postoperatively 76 ± 14 [n = 33], $p < 0.001$). Clinically and statistically significant reductions in the American Thoracic Society Dyspnea Score (3.06 ± 0.9 versus 1.65 ± 1.01 [n = 34], $p < 0.001$) and the St. George Respiratory Questionnaire quality of life measure (74 ± 13 versus 46 ± 21 [n = 35], $p < 0.001$) were demonstrated. The 6-minute walk distance also significantly increased postoperatively (987 ± 502 versus 1,187 ± 347 feet [n = 33], $p < 0.005$; Table 2).

All patients in whom baseline dyspnea index was measured had scores of 6 or worse (3.32 ± 1.83 [n = 31]; Fig 3A) The transition dyspnea index was measured postoperatively and demonstrated that 24 of 31 patients reported improvement in their dyspnea after intervention (3.55 ± 5.25 [n = 31]; Fig 3B).

Comment

This study confirms our earlier findings that stabilization of the malacic tracheal and bronchial airway yields significant improvements in short-term (3-month) assessment of quality of life, respiratory symptoms, and functional status in a highly selected group of patients with severe, diffuse TBM [2, 3]. Splinting of the posterior airway membrane to reduce "floppiness" of either the cartilaginous structure, membranous wall, or both, can be done with minimal mortality risk in patients with significant comorbidity utilizing the surgical technique of TBP we have presented. Active management of respiratory events in the postoperative period is important to help ensure good outcomes. It is an arduous operation and recuperation, with an average hospital stay of 8 days. Although nearly 75% of these patients were able to be discharged to their homes, nearly one quarter required a postoperative stint at a rehabilitation facility, which both underscores the magnitude of the recovery from TBP as well as reflects the comorbidities of the patients selected for this operation. A frank discussion of the risks and benefits of operation for this benign condition is imperative. We speculate that is possible that the decreased proportion of patients who respond to stenting and then proceed to tracheoplasty (94% in our earlier series [3]

Table 2. Preoperative and Postoperative Outcome Measures

	Preoperative	Postoperative	*p* Value
FEV_1, n = 37	1.62 ± 0.76	1.66 ± 0.67	0.29
Karnofsky performance scale, n = 33	62 ± 12	76 ± 14	<0.001
ATS dyspnea score, n = 34	3.06 ± 0.9	1.65 ± 1.01	<0.001
SGRQ quality of life measure, n = 35	74 ± 13	46 ± 21	<0.001
Six-minute walk distance, feet, n = 33	987 ± 502	1,187 ± 347	<0.005

Data shown as means ± SD.

ATS = American Thoracic Society; FEV_1 = forced expiratory volume of air in 1 second; SGRQ = St. George Respiratory Questionnaire.

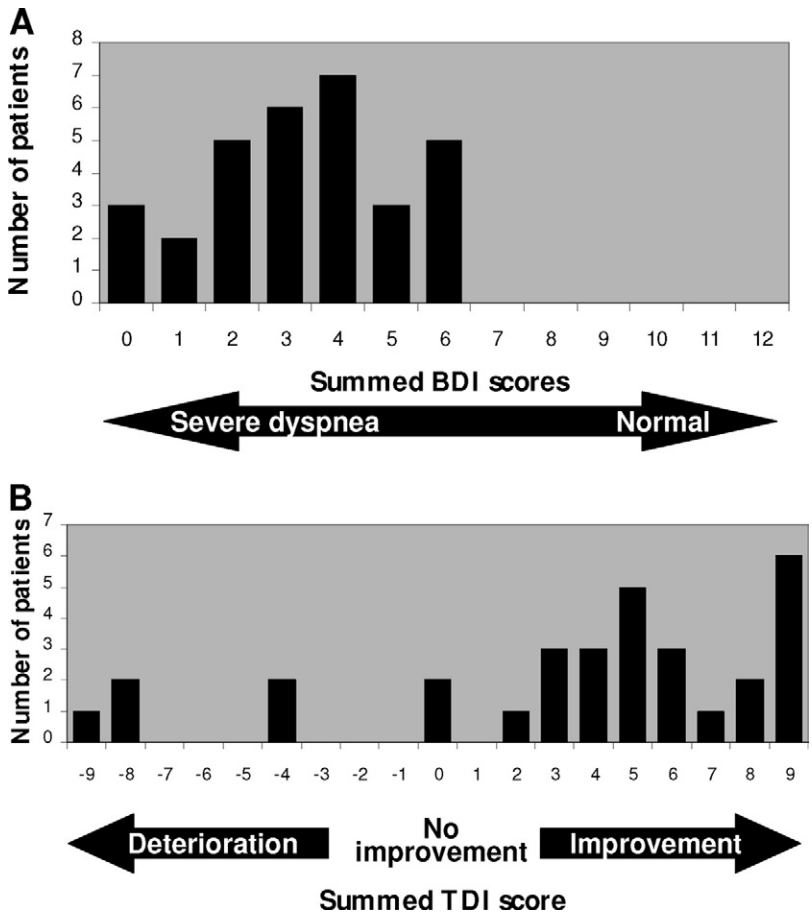

Fig 3. Baseline and transition dyspnea indices are shown. (A) The baseline dyspnea index (BDI) was measured preoperatively. (B) Transition dyspnea index scores were measured postoperatively: zero connotes no change from the intervention, −9 signifies marked deterioration in symptoms after treatment, and +9 signifies marked improvement in symptoms after treatment.

versus 64% in this series) in part reflects this realization both on the part of the clinicians and patients.

Recent work in our institution has demonstrated that even 78% of healthy volunteers may meet standard definitions for TBM (>50% expiratory reduction in cross-sectional airway area) [15]. The mean reduction in tracheal expiratory cross-sectional area was nearly 55% in these study subjects despite the absence of signs or risk factors for TBM. This underscores the importance of careful case selection for TBP, as some degree of dynamic airway collapse can be a normal and expected finding. In our protocol for evaluation and treatment of TBM, only patients with severe cases of collapse (total or near-total) are considered for surgical correction. Moreover, performance of a stent trial before definitive surgical intervention provides an additional level of rigor to ensure that we attempt to operate on patients for whose symptoms their TBM is causative (or strongly contributory) and not simply correlative. One acknowledged shortcoming of this retrospective study is the inability to determine the exact cause of contraction from 99 patients who responded to the stent trial to 63 patients who eventually underwent surgery. It is likely that conservative surgical risk assessment as well as patient preference to avoid surgery account for this drop-off.

Certainly, this study and our institutional protocol in general suffer the weakness of lacking an objective measurement of improvement. While anatomic evidence provided by postoperative bronchoscopy and dynamic computed tomography has shown striking improvement, amelioration of "end-organ" effects such as decreased air trapping have not been demonstrated [16, 17]. With regard to dyspnea, the study did not show that FEV_1 improved after TBP, as might have been expected from increased large airway conductance [18, 19]. Indeed, other investigators have reported improvement in FEV_1 after surgical treatment of TBM in both the pediatric and adult populations [6, 20]. In close examination of these two reports, however, there are findings that might explain the discrepancy between our study and theirs. In the pediatric report, fewer than a third of the patients underwent FEV_1 preoperative and postoperative testing [20]. In a group of children ranging in age from 3 weeks to 5 years, this type of testing might be difficult to obtain, and its validity questionable. The adult tracheobronchoplasty series included only 14 patients, and the mean improvement in FEV_1 was greater than 200 mL in only 5 of these patients [6]. The lack of a clinically significant increase in FEV_1 is consistent with our previous work examining both internal and external stabilization of the malacic airway [2, 3]. In addition, we have also shown that the degree of expiratory tracheal collapse does not correlate with airflow limitation in patients with TBM [8].

Nevertheless, the specter of the "placebo effect" looms

over the subjective index reporting. There are possible confounding effects of the adjuncts to surgical recuperation (eg, a concentrated focus on ambulation and strength training, formal physical or respiratory therapy consultation, or stints in regular or pulmonary rehabilitation facilities) that in and of themselves could result in the improvements seen in this study, including both the subjective indices as well as exercise tolerance. For example, it has been shown that for patients with chronic obstructive pulmonary disease, pulmonary rehabilitation alone may result in significant betterment of 6-minute walk distance, maximal work load, maximal oxygen uptake, and quality of life, but FEV_1 is not increased, in keeping with our results [21]. Despite these concerns, we feel that the demonstrable improvement in anatomy contributes to the subjective improvement in dyspnea. Minimal increases in airflow may result in marked improvement in hyperinflation, dyspnea, and vital capacity, and it has been suggested that stabilization of the central airways might lead to more laminar flow accounting for this finding [18, 22]. This clearly deserves more extensive investigation going forward.

The beneficial effects of this operation are not solely limited to airflow. However, it is difficult to measure objectively the beneficial effects of the operation on secretion retention or orthopnea. The prevalence of respiratory failure as a preoperative presentation of severe TBM is quite low, and therefore, is unlikely to provide much insight into the efficacy of the operation. Future work might be directed at obtaining the follow-up data in regard to cough and prevalence of respiratory infection after TBP. Unfortunately, these variables are prone to bias given their subjective nature. Recognition of other specific objective outcome measures might also improve the application of our institutional protocol, which calls for a stent trial before consideration of TBP. While the majority of patients have been shown to have dyspnea as a presenting symptom, cough and recurrent infections are prevalent as well [3]. These patients might not be expected to report marked subjective improvement after stent placement, and in fact, cough and secretion retention might be exacerbated by the stent, so that moving forward on the basis of a positive stent trial is not possible. More work remains to be done to identify more accurately which of these patients with cough or infection as primary complaints are most likely to benefit from TBP. Overall, our ability to accurately include all patients who are likely to benefit from TBP, and exclude those who will not, is still limited. This is suggested by the finding that both in our earlier work and in this study, the proportion of patients who are diagnosed with severe TBM and then respond positively to a stent trial remains at about 55%.

Future efforts also should be directed at understanding the causes of the varying presentations of TBM. This series demonstrated that 50% of the patients had gastroesophageal reflux disease. This finding corroborates findings in the pediatric population, where it has been shown that a 70% incidence of gastroesophageal reflux disease is found in patients with laryngomalacia and tracheomalacia [23]. Inflammatory processes have been identified on histologic and immunohistochemical examination of malacic airways [24]. Abnormalities of matrix biology [25] and even genetic predispositions [26] also deserve further examination.

In conclusion, despite limitations in the measurement of treatment effects, this series of 63 patients with severe, diffuse TBM demonstrates the beneficial effects of TBP. Although TBP only corrects the anatomy of the central airways, the effects of pathology in the lung or more distal airways did not abrogate the significant improvement in functional status, respiratory-impacted quality of life, exercise tolerance, or symptomatology seen in this carefully selected group of patients. As our experience with the treatment of this multifaceted disease process grows, we hope to refine the assessment tools that will help us understand which patients truly benefit from this highly technical operation. Close coordination of a multidisciplinary team of dedicated radiologists, interventional pulmonologists, and airway surgeons helps ensure optimal selection and treatment of these challenging patients.

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DISCUSSION

DR ROSS M. BREMNER (Phoenix, AZ): The abstract initially suggested that you were going to give us some ideas as to what technical changes or technical details might decrease any sort of complications. I was wondering if you could give us some insight, as this is not a commonly performed procedure for most thoracic surgeons.

Secondly, why don't you see much of a difference in the FEV_1 in these patients? Intuitively, you would think that would improve if you are improving that obstructive element of that severe tracheobronchomalacia.

DR GANGADHARAN: I will address the second question first. I think that is the obvious sticking point with this study and our previous studies with stent and surgical stabilization of the severely malacic airway—namely, that FEV_1 is not seen to improve despite an intuitive expectation that it would. I don't pretend to be a respiratory physiologist, but one thing that has been pointed out to me is that the choke point, or the point where air flow is restricted, can actually occur in these patients before expiratory collapse. So there must be some function in that regard that would prevent FEV_1 from being the perfect metric for improvement. There have been two studies looking at tracheoplasty or tracheobronchoplasty that actually have reported improvement in FEV_1. One was in a pediatric population. The other was the series from the Massachusetts General Hospital of 14 adult patients. In neither of those studies is the improvement striking, meaning in the MGH series, only 5 of the 14 patients actually had an improvement greater than 200 mL of flow, and in the pediatric study, of 33 patients with a mean age of 1.2 years, only 8 patients were measured to have increased FEV_1, while two thirds of the patients were not tested.

In terms of your first question about the technical pearls and pitfalls that we can run into, we don't have the numbers to say that a particular modification might result in a better outcome, but I can tell you that the learning curve of this operation and the particular steps of the operation all require very careful consideration. I think it is the type of operation that is best learned in a mentored setting. These operations span—and you can see the range—from 3 hours, but typically more like 6 to 8 hours, sometimes up to 10 hours in the operating room. The total number of sutures that we place in that back wall is usually about 80 to 100 sutures. So there is quite a lot of technical detail that goes along with it.

DR JOHN P. MAURICE (Newport Beach, CA): I want to commend you on an impressive series you have presented here. The technical achievement that it represents is to be commended.

In the beginning of your presentation when you mentioned that although in your initial series you had a similar proportion of patients diagnosed with TBM and you treated them all with stents, in your current series you have operated on a lesser proportion of those patients. Is it because you have been impressed with the other nonoperative interventions, such as stent development, or have you found that some of these patients can simply be treated well with a temporary stent?

DR GANGADHARAN: I think the decreased proportion of patients who actually are operated on is explained by two things. The first is that I think we are applying our standards more rigorously to this population, and you can afford to do that if your referral base grows and you're seeing more and more of these patients. You can look at these patients as a whole and understand who really is not likely to benefit. So if somebody has an equivocal stent trial, meaning we placed a silicone Y-stent, and they say, "You know, I feel a little bit better," I push them and I say, "Well, what does that mean? What can you do? Can you walk through the grocery store, can you check your mailbox where you hadn't been able to before, or are you just saying that you feel the air moving a little bit easier?" If it's only that they are feeling the air move a little bit easier, in a higher risk patient or somebody in whom the anatomy is not perfect, I'll typically sit back and make them prove that they will actually benefit. I think that's the first thing. You know, the bugaboo here is that dyspnea is easy to evaluate with a stent. If you place a stent and you prop the airway open and people feel better and they breathe better, that's a positive stent trial, but many of the patients are going to have intractable paroxysmal barking cough or recurrent infections as their main presenting complaint, and those patients obviously are not likely to have such a clear-cut benefit from stent trialing, and I think as we parse through these patients a little bit more carefully, that's why we have not offered it to as many of them.

DR ROY THOMAS TEMES (Cleveland, OH): I also found this to be a very fascinating paper.

I have three questions for you. First, you introduced the problem very dramatically with a dynamic bronchoscopy and a dynamic computed tomography (CT) scan. Have postoperative dynamic CT and dynamic bronchoscopy demonstrated resolution of these findings?

Second, it's counterintuitive that patients with a good stenting response undergo stent removal. How do these surgical patients fare compared to those with chronic stents?

Third, in your anatomic picture, the airway and the main stem appear relatively skeletonized. We know vascular compromise may occur if the airway is extensively mobilized. With these large dissections, the presence of a foreign body, and extensive suturing of the airway, have these patients had problems with infection or airway ischemia?

DR GANGADHARAN: Thank you for your questions. I will address them in order. In regard to the first question, whether we have seen improvement in the postoperative studies, we have previously reported the CT signs of improvement after intervention, and it's fairly striking that the patients had a recognizable change in their CT appearance. We also perform bronchoscopy on them, and although it's not reported here, the vast majority of the patients have bronchoscopic evidence of improvement. Now, I will say that that improvement can be mitigated by anatomic constraints. For example, some patients will have TBM beyond the level that is addressed with tracheobronchoplasty and beyond the level that is addressed with a silicone Y-stent, and so they will have persistent malacia in the smaller airways, in the lobar and segmental airways, but nonetheless, the reduction of turbulent flow in the central airways seems to still be beneficial.

To answer your second question about the stenting, as you can see, there is a smaller cohort of patients who have chronic stents left in, and what that requires is very aggressive maintenance. We have also published our results with stents and found that when you leave a stent in for more than 2 weeks, those patients are going to have a complication in upward of 90% of the cases. So they are going to have a stent-related infection, they will plug, they have pneumonias or granulation tissue, and frank obstruction. So we tend not to recommend that in patients who otherwise are reasonable candidates, because surgery provides a better long-term functional result.

In regard to the last question you had on ischemia, the dissection, as you allude to, does take into account that the blood supply is coming in laterally, so we try not to do any type of circumferential dissection. We stop at the cartilaginous-membranous junction just enough to be able to see that junction to place that stitch. With this approach, we have had only 1 patient who has had a stent erosion de novo. This patient was a vasculopathy, and I suspect that even a small amount of dissection was enough to create an ischemic airway. We had another patient who had had previous pediatric tracheal surgery for a TE fistula, and then had been reoperated on twice as an adult for malacia before our performing a tracheobronchoplasty. So that airway had been extensively dissected in the past, and the blood supply was quite tenuous, and that patient actually did have a membranous wall necrosis. But short of that, in most cases, adhering to the principle of staying on the back wall has avoided that type of complication.

DR BRYAN F. MEYERS (St. Louis, MO): I must say I'm stuck at what you described as the "sticking point," which is the fact that there is really no measurable change in their exhaled pulmonary function that would serve as a solid objective measure. One of the problems with expanding this work is the very subjective nature of many steps in the evaluation. You do the bronchoscopy and you're looking at how the airway collapses, and maybe after you look at a bunch of them, you develop a sense of how it's collapsing. Then, when you interview the patient after the stent was placed, you have a sense in talking to them about whether or not their stated improvement is enough or whether they use the right words to make you think that they are safe to go on to surgery. Afterward, they report improvements in subjective things, like quality of life, but don't have any measured improvement of airway function. If you look at the results on your FEV_1, is there any heterogeneity in which there are some who have a great improvement and others who don't improve or actually are worse, or is everyone pretty much the same? I'm concerned that you might be just picking the most suggestible patients or the patients who are most eager to get better, and we have seen with valved airway stents for emphysema and with bronchial thermoplasty for asthma that things that look really good subjectively on a phase II study end up not showing as much promise when you randomize patients and have sham controls, which would be untenable in a 6-hour operation.

DR GANGADHARAN: I think those are great points. I think the subjective nature of the observation is somewhat mitigated by the fact that we're not trying to gauge between 50% airway collapse—which is, as you know, the definition of tracheomalacia. We're not trying to differentiate between 50% and 75%. We're looking at 90%, 95%, 100% collapse. So that's a little bit more obvious to distinguish.

Now, the subjective assessment of whether they had a stent response, you can make that same argument with patients who you are evaluating for a Nissen fundoplication. You talk to them and you say, "Do you feel better when you get on proton pump inhibitors?" If they say yes, then you can talk to them a little bit about what the likelihood would be that they would benefit from an antireflux procedure. So that degree of subjectivity is very common to things that we do for functional benefit. In terms of the air flow itself, I think that we are still stuck looking for the correct outcome measure, because what you have suggested, that there is a placebo effect, that patients want to improve, is certainly one of the weaknesses. And while it's hard to understand that a placebo effect could persist through what is a fairly arduous perioperative course, it certainly could be the case. The other concern that we have is what if the adjunctive measures of postoperative recovery also are improving these patients, meaning we're focusing on getting their strength back, we're focusing on getting them physical therapy, we're focusing on working on their deep breathing, and all those things that actually in and of themselves could make somebody feel better. I think those are all very valid criticisms and certainly need to be addressed in further studies. As you suggest, a randomized trial of tracheobronchoplasty versus sham surgery is untenable, but it could be possible to randomize between rigid bronchoscopy and rigid bronchoscopy plus Y-stent placement. That could address some of the suggestibility and placebo concerns you raise.