# Airway Stents for Excessive Central Airway Collapse
## *A Randomized Controlled Open-label Trial*

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**Background:** Short-term airway stent placement (stent evaluation) has been employed to evaluate whether patients with excessive central airway collapse (ECAC) will benefit from tracheobronchoplasty. Although retrospective studies have explored the impact of stent placement on ECAC, prospective randomized controlled trials are absent.

**Methods:** This was a randomized open-label trial comparing patients receiving airway stent placement and standard medical treatment (intervention group) versus standard medical treatment alone (control group) for ECAC. At baseline, patients' respiratory symptoms, self-reported measures, and functional capabilities were assessed. Follow-up evaluations occurred 7 to 14 days post-intervention, with an option for the control group to crossover to stent placement. Follow-up evaluations were repeated in the crossover patients.

**Results:** The study enrolled 17 patients in the control group [medical management (MM)] and 14 patients in the intervention group. At follow-up, 15 patients in the MM crossed over to the stent group, resulting in a total of 29 patients in the combined stent group (CSG). Subjectively (shortness of breath and cough), 45% of the CSG exhibited improvement with the intervention compared with just 12% in the MM. The modified St. George Respiratory Questionnaire score in the CSG improved significantly from 61.2 at baseline to 52.5 after stent placement (-8.7, $P = 0.04$). With intervention, the 6-minute walk test in CSG improved significantly from 364 meters to 398 meters (34 m, $P < 0.01$). The MM did not show a significant change in the St. George Respiratory Questionnaire score or 6-minute walk test distance.

**Conclusion:** Short-term airway stent placement in patients with ECAC significantly improves respiratory symptoms, quality of life, and exercise capacity.

**Key Words:** excessive central airway collapse, airway stent, self-reported respiratory symptoms, quality of life, exercise capacity

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Excessive central airway collapse (ECAC), encompassing tracheobronchomalacia (TBM) and excessive dynamic airway collapse (EDAC) is a condition increasingly recognized for causing significant respiratory symptoms such as dyspnea, cough and recurrent respiratory infections.[1–3] While TBM involves the weakening of tracheobronchial cartilaginous structures, EDAC is characterized by the excessive bulging of the posterior airway membrane without cartilage collapse. Although EDAC and TBM have anatomic and pathophysiologic differences, adult crescent-type TBM and EDAC are treated the same under the umbrella of ECAC.

The severity of airway collapse in ECAC is categorized as mild (70% to 79%), moderate (80% to 89%), or severe ($\geq$90%) based on dynamic bronchoscopy or dynamic computed tomography (CT) imaging.[3,4] In patients with $\geq$90% collapse, intervention to stabilize the airway is considered if the patient remains symptomatic despite treatment of coexisting medical conditions.[3,4]

Airway stabilization can be achieved with tracheobronchoplasty (TBP), which consists of surgical stabilization of the airway by suturing a knitted polypropylene mesh to the posterior membrane of the trachea and bilateral bronchi.[5] Short-term airway stent placement (stent evaluation) has been used to determine if a patient with severely symptomatic ECAC could benefit from surgical intervention. This is supported by a recent study affirming that a stent evaluation can serve as a predictor of postoperative outcomes.[6] Currently, there are only retrospective studies assessing the effect of short-term stent evaluation in this group of patients. These trials have shown improvements in dyspnea scores when using the modified Medical Research Council (mMRC), quality of life (QoL) as determined by the Cough-specific Quality-of-Life Questionnaire (CQLQ) and modified St. George Respiratory Questionnaire (SGRQ), and exercise capacity using the 6-minute walk test (6MWT) distance.[7–10] Considering the lack of prospective evidence, this study was designed as a randomized controlled trial to explore the cause-effect relation between interventional

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(stents) and improvements in respiratory symptoms, dyspnea score, QoL, and exercise capacity.

## METHODS

### Study Design

This was a randomized open-label trial performed in a single academic center in the United States. The trial was granted approval by the Institutional Review Board and registered on ClinicalTrials.gov. A random number generator was used to create a random number table for group assignments. These assignments were securely stored in opaque sealed envelopes. The research team determined patient group assignments using these sealed envelopes following a simple randomization sequence. The person enrolling the patients was blind to the order of the envelopes. Patients were then randomly assigned to either the intervention or control group. The intervention group had airway stents placed and received standard medical management. The original plan for the control group involved a sham procedure in addition to standard medical therapy, but this was omitted during the study modification due to the patient's reluctance to enroll in the trial. The study protocol is provided in Supplemental Material 1 (Supplemental Digital Content 1, http://links.lww.com/LBR/A325).

### Patients

Patients 18 years or older were selected from our Chest Disease Center based on the presence of severe symptomatic ECAC, which encompasses TBM (crescent-type only) and EDAC. These individuals had previously received maximum medical therapy for comorbidities, including conditions such as chronic obstructive pulmonary disease (COPD), gastroesophageal reflux disease, vocal cord dysfunction, and asthma, and had undergone pulmonary rehabilitation within the last 2 years. Severe ECAC was defined by luminal collapse during dynamic expiration exceeding 90%.[11] This was established by either a dynamic CT scan or a dynamic flexible bronchoscopy. Dynamic CT scans quantified luminal collapse by calculating the percentage difference between respiratory phases using the formula: [1−(Aee/Aei)],)X100, where "Aee" represents the luminal area at forced-expiration and "Aei" represents the luminal area at end-inspiration.[7,12] The airway was visually assessed through dynamic bronchoscopy for the degree of collapsibility $\geq$90%.[7,13] The specific airway segments evaluated are detailed in Supplemental Material 2 (Supplemental Digital Content 2, http://links.lww.com/LBR/A326). Exclusion criteria of this study were: (1) patients who had not received maximal medical therapy for their respiratory comorbidities, (2) individuals with active respiratory infections, (3) those with uncontrolled cardiac arrhythmias, (4) patients anticipated to not being able to complete initial or follow-up assessments, and (5) those not eligible for stent evaluation or TBP surgery.

### Evaluation and Interventions

Patients in both groups underwent bronchoscopy under minimal sedation using intravenous midazolam and fentanyl to maintain spontaneous respiration. Lidocaine was delivered by atomizer to the posterior oropharynx to suppress the gag reflex. The larynx, vocal cords, aryepiglottic folds, and entire tracheobronchial tree were irrigated with 1% lidocaine in 2 mL aliquots delivered through the bronchoscope during the procedure. To minimize any stenting effect, a bronchoscope with a 4.2 mm outer diameter was utilized. Patients were instructed to take a deep breath, hold it, and then blow it out (forced expiratory maneuver). This maneuver was carried out at 6 specific airway sites, as detailed in Supplemental Material 2 (Supplemental Digital Content 2, http://links.lww.com/LBR/A326). In the same setting, patients in the intervention group underwent rigid bronchoscopy for airway stent placement with either uncovered self-expanding metallic airway stent (USEMAS) or silicone Y-stents. Silicone Y-stents were placed if the airway collapse primarily affected the main carina or when the largest airway diameter exceeded 20 mm, the upper limit of USEMAS' diameter. Otherwise, USEMAS were placed only in the airway portions (trachea/left mainstem/right mainstem) that fulfilled the criteria for severe ECAC. The medical management regimen comprised of mucolytic [nebulizer treatments using albuterol followed by 10% N-acetylcysteine for 15 min twice a day (BID)], expectorant therapy (Guaifenesin 1200 mg BID), codeine as needed, and flutter valve BID. After 7 to 14 days of medical management, patients in the control group were given the option to crossover to the intervention group and undergo stent placement (Fig. 1).

### Outcome

We recorded patients' self-reported respiratory symptoms, self-report measures (SGRQ, CQLQ, mMRC), and functional assessment at baseline and at follow-up visits 7 to 14 days later (Fig. 1). These measurements were also repeated 7 to 14 days in the crossover group after intervention. We used the following minimal clinically significant difference to signify improvement: SGRQ score decrease of 4 points,[14] mMRC score decrease of 1 point,[15] CQLQ score decrease of 10 points,[16] forced expiratory volume in 1 second increase of 10%,[17] and 6MWT distance increase of 30 meters.[18,19] The primary outcome in this study was the change in SGRQ score at baseline compared with follow-up. Secondary outcomes consisted of self-reported respiratory symptoms (dyspnea, cough, and ability to clear secretions), self-report measures (CQLQ and mMRC), functional assessment (spirometry and 6MWT), and a composite treatment success measurement. The composite treatment success measurement (positive stent evaluation) was defined as improvement in 2 or more outcome domains (Table 3).[4]

### Statistical Analyses

We derived our sample size calculation from the SGRQ treatment effect scores in the intervention group from a prior retrospective study on airway stent placement in ECAC.[10] The baseline and follow-up SGQR scores were medians (interquartile ranges) of 77 (66, 81), n = 27 and 61 (32, 71), n = 27, respectively. The original data were obtained, and the values were transformed into means (SD): 74.5 (11.7) and 54.2 (30.5), respectively.[20–22] Applying an alpha level of 5% and a beta level of 20%, our calculations indicated a requirement for a total of 34 patients (17 per group) to detect such a difference. We increased our sample size goal to 50 patients (25 per group) to account for dropouts.

All analyses were performed using IBM SPSS Version 22 with statistical significance set at $P \leq 0.05$. For normally distributed numerical data, the study reported means and SDs. In cases where the data were not normally distributed, medians and interquartile ranges were used as statistical descriptors. A 2-sample $t$ test and Mann-Whitney $U$ (non-normal distribution) were used to test for differences between groups. Comparability of groups was analyzed by paired $t$ tests or Wilcoxon signed-rank test (non-normal


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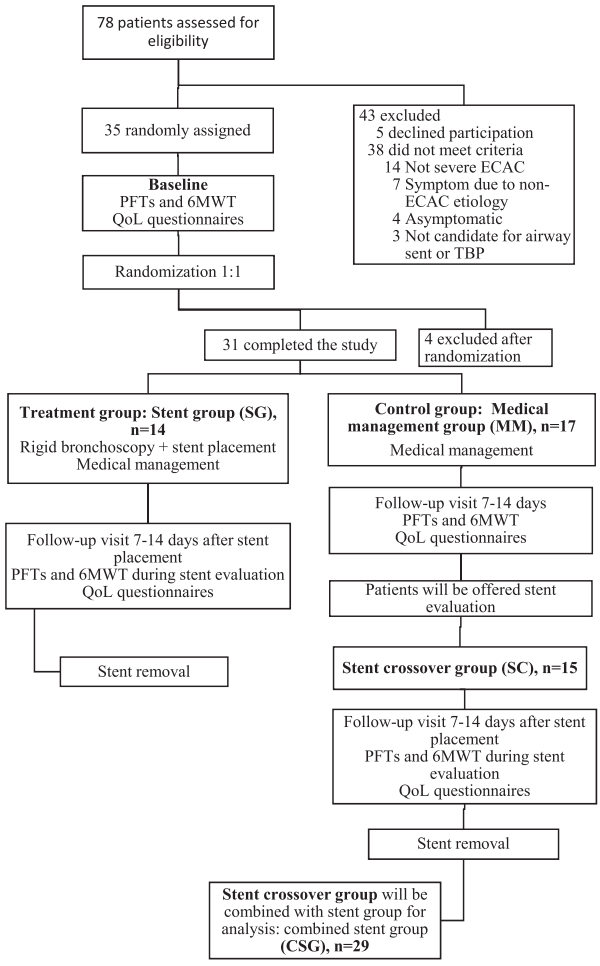


**FIGURE 1.** Consort flowchart. CSG indicates combined stent group; ECAC, excessive central airway collapse; MM, medical management; 6MWT, 6-minute walk test; PFT, pulmonary function test; QoL, quality of life; SC, stent crossover; SG, stent group; TBP, tracheobronchoplasty.

distribution) to compare the groups with respect to changes from baseline in study outcomes. Fisher exact test was used for the comparison of different proportions between groups of categorical variables that met the treatment success criteria.

## RESULTS

In the period spanning from May 2017 to April 2022, our study enrolled 14 patients in the stent group (SG) and 17 patients in the medical management group (MM) (Fig. 1). After 7 to 14 days of medical management, 15 patients in the MM agreed to crossover to the SG. The combined stent group (CSG) had a total of 29 patients. The overall mean age for the 3 groups was 61 years (Table 1). The MM had a higher representation of female patients (88%) compared with the SG, which exhibited a more balanced sex distribution (57%). The ethnic composition of all groups primarily consisted of white patients, with 88% in the MM and 93% in the SG. All groups had a median body mass index above 30. The distribution of comorbidities was similar between the groups, with gastroesophageal reflux disease, COPD, and asthma being present in two-thirds, one-third, and half of the patients, respectively. There were more patients with obstructive sleep apnea in the SG compared with the MM (71% vs 47%). The two most common presenting symptoms were shortness of breath and severe cough (78% to 82%) and (65% to 78%), respectively. Detailed information about the airway distribution of severe ECAC can be found in Supplemental Material 2 (Supplemental Digital Content 2, http://links.lww.com/LBR/A326). The majority of patients in the CSG (76%) and the MM (82%) were EDAC rather than TBM.

The comparison of patient outcome measures between all patients who underwent stent placement CSG and medical management ( is shown in Table 2. Starting with a baseline score of 61.2 in SGRQ, patients in the CSG exhibited a significant reduction to 52.5 at follow-up with stent placement. This represents a statistically and clinically significant reduction of SGRQ score of 8.7, $P = 0.04$. In contrast, the MM showed little change in SGRQ scores, with an increase of 0.7 from 58.7 at baseline to 59.4 at follow-up, which was not statistically significant. The difference in SGRQ score change between the CSG and the MM was statistically significant ($P = 0.05$). The CSG had a 6MWT distance of 364 meters at baseline and 398 meters at follow-up, which represents a statistically and clinically significant improvement by 34 meters, $P < 0.01$ with stent placement. The difference in 6MWT distance between the CSG and the MM was statistically significant ($P = 0.05$). The CSG and MM did not show a significant change in CQLQ, mMRC score, and forced expiratory volume in 1 second with their respective interventions.

The CSG showed significantly more improvement in self-reported respiratory symptoms (subjective domain) compared with the MM (45% vs 12%, $P < 0.01$), which was mainly driven by the improvement in shortness of breath and cough (Table 3). The ability to clear secretions was significantly better in the MM, with 41% of MM patients demonstrating improvement compared with only 10% in the CSG ($P < 0.01$). In terms of subjective-objective domain improvements, a larger proportion of CSG patients (30%) displayed positive changes compared with MM (12%), although this difference was not statistically significant. Similarly, in the objective domain, 72% of CSG patients showed improvements compared with 60% in MM, with no statistically significant differences. Overall, based on the criteria of improvement in at least two out of three domains, 43% of CSG patients achieved treatment success, compared with 15% in MM, although statistical significance was not reached ($P = 0.08$).

USEMAS was the main stent type used which accounted for almost three-quarters of the cases, with the remaining cases involving silicone Y-stents. Stents stayed in place for a median duration of 10 days. Stent placement resulted in 3 episodes (10%) of granulation tissue formation and 3 episodes (10%) of mucus plugging while the stent was in place. There were no complications of stent migration, stent fracture, hemoptysis, or COPD exacerbation in patients with stents placed. The stent evaluation was deemed positive (treatment success) in 12 out of 28 patients, with 92% of these patients subsequently undergoing TBP within a median duration of 10 days after stent removal.

## DISCUSSION

This is the first randomized controlled trial on the use of airway stents in patients with ECAC who remained symptomatic despite MM. Our study showed that a short-term airway stent placement results in improved

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**TABLE 1.** Demographic Profile and Procedure Specifics

| Variable | SG (n = 14) | MM (n = 17) | CSG (n = 29) | *P;* MM vs CSG |
|---|---|---|---|---|
| Mean age, y ± SD | 61 ± 2 | 61 ± 10 | 61 ± 9 | 0.9 |
| Male sex, n (%) | 8 (57) | 2 (12) | 10 (35) | 0.1 |
| Race, n (%) | | | | 0.6 |
| White | 13 (93) | 15 (88) | 26 (90) | — |
| Black | 1 (7) | 0 | 1 (3) | — |
| Hispanic | 0 | 2 (12) | 2 (7) | — |
| BMI* | 35 (30-37) | 30 (26-41) | 31 (26-42) | 0.6 |
| Comorbidities, n (%) | | | | |
| GERD | 9 (64) | 11 (65) | 19 (66) | 0.9 |
| COPD | 4 (29) | 4 (24) | 8 (28) | 0.7 |
| Asthma | 7 (50) | 9 (53) | 15 (52) | 0.9 |
| OSA | 10 (71) | 8 (47) | 18 (62) | 0.3 |
| Symptoms, n (%) | | | | |
| SOB | 11 (78) | 14 (82) | 23 (79) | 1 |
| Severe cough | 11 (78) | 11 (65) | 20 (69) | 0.7 |
| Inability to clear secretions | 5 (36) | 4 (23) | 8 (27) | 1 |
| Recurrent infections | 6 (43) | 8 (47) | 14 (48) | 0.9 |
| Duration (d)* | 7 (5.75-10.50) | — | 10(7-14) | — |
| Type, n (%) | | | | |
| USEMAS | 10 (72) | — | 21 (72) | — |
| Silicone Y-stent | 4 (28) | — | 8 (28) | — |
| Stent complications, n (%) | | | | |
| Granulation tissue formation | 3 (21) | — | 3 (10) | — |
| Mucus plugging | 2 (14) | — | 3 (10) | — |
| Cough | 3 (21) | — | 5 (17) | — |
| Surgery, n (%) | | | | |
| No | 6 (43) | — | 12 (41) | — |
| Yes | 8 (57) | — | 17 (59) | — |
| Time from stent removal to surgery (d)* | 93.5 (23.25-166.25) | — | 85 (43-145) | — |

*Presented as median (25th quartile, 75th quartile).

BMI indicates body mass index; COPD, chronic obstructive pulmonary disease; CSG, combined stent group; GERD, gastroesophageal reflux disease; MM, medical management group; OSA, obstructive sleep apnea; SG, stent group; SOB, shortness of breath; USEMAS, uncovered self-expanding metallic airway stents.

self-reported respiratory symptoms, QoL (SGRQ), and exercise capacity (6MWT) compared with medical therapy alone. Stent placement resulted in minimal complications and uneventful removal.

In prior retrospective studies on the use of airway stents in patients with ECAC, there had been an evolution in the choice of stent types. Initially, studies such as those by Ernst et al[9,10] in 2007 and 2011 were conducted entirely with

**TABLE 2.** Patient Outcome Measures

| Outcomes | n | Baseline (SD) | Follow-Up (SD) | Follow-up and baseline difference (SD) | *P* (baseline vs follow-up) | *P* (difference between groups) |
|---|---|---|---|---|---|---|
| SGRQ | | | | | | |
| CSG | 27 | 61.2 (17.7) | 52.5 (20.3) | −8.7 (21.1) | 0.04 | 0.05 |
| MM | 17 | 58.7 (17.2) | 59.4 (18.1) | 0.7 (9.3) | 0.7 | — |
| CQLQ | | | | | | |
| CSG | 28 | 62.1 (17.1) | 60.8 (16.5) | −1.3 (20.4) | 0.1 | 0.2 |
| MM | 17 | 60.7 (14.8) | 64.3 (15.6) | 3.5 (8.8) | 0.1 | — |
| mMRC | | | | | | |
| CSG | 28 | 2.18 (1.05) | 1.71 (1.24) | −0.46 (1.8) | 0.2* | 0.1† |
| MM | 17 | 2.06 (1.14) | 2.29 (1.10) | 0.23 (1.0) | 0.3* | — |
| 6MWT (meter) | | | | | | |
| CSG | 26 | 364 (103) | 398 (109) | 34 (41) | <0.01 | 0.05 |
| MM | 15 | 351 (120) | 359 (126) | 8 (44) | 0.4 | — |
| FEV1 (liter) | | | | | | |
| CSG | 27 | 1.94 (0.68) | 2.00 (0.72) | 0.06 (0.36) | 0.5* | 0.5† |
| MM | 17 | 1.89 (0.64) | 1.87 (0.75) | −0.02 (0.18) | 0.9* | — |

mMRC and FEV1 are not normality distributed.

Nonparametric test (Wilcoxon signed-ranked test and Mann-Whitney *U*) was used instead.

*Wilcoxon signed-ranked test.

†Mann-Whitney *U* test.

CQLQ indicates Cough-specific Quality-of-Life Questionnaire; CSG, combined stent group; FEV1, forced expiratory volume in 1 second; MM, medical management group; mMRC, modified Medical Research Council; 6MWT, 6-minute walk test; SGRQ, St. George Respiratory Questionnaire.


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**TABLE 3.** Treatment Success Criteria and Outcome

| Domain | CSG; n/N (%) | MM; n/N (%) | *P* |
|---|---|---|---|
| Subjective (2/3) | 13/29 (45) | 2/17 (12) | < 0.01 |
| Improvement in SOB | 15/29 (52) | 5/17 (29) | 0.2 |
| Improvement in cough | 12/29 (41) | 5/17 (29) | 0.5 |
| Improve ability to clear secretions | 3/29 (10) | 7/17 (41) | < 0.01 |
| Subjective/objective (2/3) | 8/27 (30) | 2/17 (12) | 0.2 |
| SGRQ reduced by 4 points | 13/29 (45) | 5/17 (29) | 0.2 |
| CQLQ reduced by 10 points | 7/29 (24) | 1/17 (6) | 0.1 |
| mMRC reduced by 1 point | 11/29 (38) | 2/17 (12) | 0.09 |
| Objective (1/2) | 18/25 (72) | 9/15 (60) | 0.4 |
| FEV1 increased by 0.2 L | 6/29 (21) | 2/17 (12) | 0.3 |
| 6MWT increase by 30 m | 17/29 (59) | 8/17 (47) | 0.7 |
| Treatment success (2/3) | 12/28 (43) | 2/13 (15) | 0.08 |

Fisher exact test was used for the comparison.

CQLQ indicates Cough-specific Quality-of-Life Questionnaire; CSG, combined stent group; FEV1, forced expiratory volume in 1 second; MM, medical management group; mMRC, modified Medical Research Council; 6MWT, 6-minute walk test; SGRQ, St. George Respiratory Questionnaire; SOB, shortness of breath.

silicone stents. However, subsequent research studies by Pan et al[6] in 2023 and Majid et al[7,8] in 2016 and 2023 incorporated the utilization of USEMAS. Despite this heterogeneity, the earliest study by Ernst et al[9,10] in 2007 and 2011 did show a decrease in SGRQ score by about 9 points, which closely aligns with the findings of our study (-8.7 points). While the earlier studies by Ernst and colleagues did not show improvement in 6MWT distance with stent placement, more recent studies, including our own, did show improvement in 6MWT distance. The studies by Majid et al[7,8] in 2016 and 2023 showed a significant improvement in the 6MWT distance of 63 and 105 meters with USEMAS, surpassing the 52m achieved with silicone stents.

The presence of airway stents, particularly silicone stents, has been associated with the exacerbation of cough symptoms in patients, which could potentially elucidate the lack of improvement in the CQLQ score following stent placement.[23] Nonetheless, the studies by Pan et al[6] and Majid et al[7,8] still showed significant improvement in CQLQ scores with both USEMAS and silicone stents. The same studies also showed significant improvement in mMRC score which was not evident in our study. Airway stenting also impedes clearance of secretions as we found in our study.

The use of silicone stents in ECAC has been associated with relatively high rates of mucus plugging of 36% to 66% and a granulation tissue formation rate of up to 33%.[10,24] All 3 episodes of granulation tissue formation in the present study occurred in patients who received silicone Y-stents. Of the 3 episodes of mucus plugging, one occurred in silicone Y-stents (1/8 = 12%) versus 2 episodes in USEMAS (2/21 = 9%). This is consistent with the findings of a comparative study showing the benefit of short-term use of USEMAS over silicone stents in a stent evaluation by having a lower rate of complications, especially mucus plugging.[8] The benefit of USEMAS over silicone stents in this context is attributed to their capacity to preserve the airway's innate mucociliary clearance and superior inner diameter-to-wall thickness ratio.[25] This improved functionality allows the stent evaluation to serve as a better predictor of response to TBP. By reducing complications, USEMAS can ensure that the benefits of airway stabilization are not confounded, making them a valuable choice for stent evaluations in ECAC.

The brief duration of stent placement (median 10 d) in our study has kept the number of complications to a minimum and the removal procedure uneventful. Neoepithelialization can begin as early as 3 to 6 weeks.[26] In a study comprising 90% benign airway disease, metallic stents removed within 30 days were associated with a lower rate of complications and health care utilization as compared with removal after 30 days.[26] Despite the Food and Drug Administration issuing a warning in 2005 against the use of metallic stents in benign airway diseases due to reported complications and removal difficulties,[27] previous research and our study have demonstrated that short-term use of USEMAS for stent evaluations is safe.[7,8] The strategic use of stents for a limited duration appears to minimize risks and ensure a smoother clinical experience, even in the context of the Food and Drug Administration's caution regarding metallic stents in benign airway diseases.

ECAC shares symptomatic similarities with other airway diseases, including COPD. Although subjective, the SGRQ is a validated tool for assessing health impairment in patients with COPD.[14] We recognize that SGRQ's validation within the context of ECAC remains lacking. Given the intricate nature of assessment, clinicians typically employ a multifaceted approach to evaluate intervention outcomes. Thus far, a comprehensive physiological method for measuring clinical responses in patients with ECAC remains elusive, necessitating the integration of various assessment modalities. In this context, the SGRQ emerges as a relatively standardized and objective tool, and it was selected as the primary outcome measure for this study.

The main limitation of our study is the poor recruitment due to the lack of voluntary patient enrollment. Factors identified by the research staff included the perception that participation would delay evaluation for TBP, increased travel expenses and time away from home as many patients come in from out of state, and other subjective factors. The open-label design of the study introduced the possibility of a placebo effect influencing patients' symptom reporting and questionnaire responses. The recruitment process fell short of reaching our intended sample size target due to the recruitment shortcomings mentioned. To address this, we had to combine the group receiving stents with patients from the MM who crossed over and received stents. This combination of groups could potentially re-introduce selection bias, as it is conceivable that some patients opted for stents because they did not experience the desired benefits from medical management.

## CONCLUSIONS

Short-term airway stent placement among patients with ECAC significantly improves self-reported respiratory symptoms, QoL (SGRQ), and exercise capacity (6MWT). Nevertheless, the number of aspects showing improvement in patients with ECAC appears to be lower when compared with prior retrospective studies, particularly concerning CQLQ and mMRC.

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