original article

Endobronchial valve vs coil for lung volume reduction in emphysema: results from a tertiary care centre in Turkey

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BACKGROUND: Bronchoscopic lung volume reduction (BLVR) by either the endobronchial valve (EBV) or coil (EBC) procedure is recommended for severe emphysematous patients. BLVR applications generally help healthy lung areas ventilate more comfortably by reducing the hyperinflation and improving the contraction capacity of diaphragm.
OBJECTIVES: Compare our experience with valve and coil BLVR devices.
DESIGN: Retrospective.
SETTING: Single tertiary care centre.
PATIENTS AND METHODS: Demographic data, vital signs, pulmonary function tests (PFTs), the six-minute walking test (6MWT), vital signs, arterial blood gases and complications were recorded.
MAIN OUTCOME MEASURES: Change in PFTs and completion of the 6MWT.
SAMPLE SIZE: 60 Turkish men with a diagnosis of chronic pulmonary lung disease.
RESULTS: Clinical and demographic characteristics were similar in patients who underwent EBV and EBC. Thirty (96.8%) EBV patients and 27 (93.1%) of the EBC patients were able to properly complete the PFT before the procedures, but all complied after the procedures. Significant improvement in PFTs were achieved after the procedure and there were no statistically significant differences in post-procedure performance. For the 6MWT, the completion rate improved from 15 (48.4%) to 19 (61.3%) patients in the EBV patients (P=.125) and from 19 (65.5%) to 21 (72.4%) patients in the EBC patients (P=.500). There was no significant difference in completion rates for the walking test for either group (median 32 meters in EBV patients and 37 meters in EBC patients; P=.652). Vital signs and arterial blood gases were similar in the two groups. The rates of complications were similar in both groups.
CONCLUSION: Endobronchial valves and coils are safe and effective methods for BLVR for patients with severe emphysema.
LIMITATIONS: Relatively small sample, retrospective design, single-centre retrospective study.
CONFLICT OF INTEREST: None.

Chronic obstructive lung disease (COPD) is a disease with irreversible airway obstruction that results in relatively resistant pulmonary symptoms.[1] Pathologically, alveolar wall damage causes irreversible airway obstruction, loss of elastic recoil and therefore, reduced gas exchange areas.[1-3] The emphysematous phenotype of COPD has a prevalence rate of 1.8% worldwide.[2] For terminally emphysemic patients, clinical and life quality are bad.[2,3] Emphysema may have a negative effect on lung functions, such as a decline in forced expiratory volume at first second (FEV1), increase in total lung capacity (TLC), functional residual capacity (FRC) and a decrease in carbon monoxide diffusion capacity (DLCO).[4] Treatments to reduce mortality and symptoms for COPD are smoking cessation,[5] long-term oxygen treatment, bronchodilators and inhalant steroids, pulmonary rehabilitation,[6] bronchoscopic lung volume reduction (BLVR), lung volume reduction surgery (LVRS) and transplantation.[7]

Since 2002, BLRV interventions like the endobronchial valve (EBV) and coil (EBC) have been used to reduce hyperinflation, ameliorate respiratory mechanics, and reduce mortality and morbidity.[8] Studies in the following years have shown that BLVR applications improve health-related quality of life, pulmonary functions and increase exercise capacity in emphysematous patients.[1,9-12]

EBV lung volume reduction provides similar benefits with LVRS but carries fewer risks.[3,13,14] EBCs are devices that are placed bronchoscopically into the subsegmental airways. The coils are made up of shape memory nitinol (a nickel-titanium alloy) wire. Unlike the EBV, EBCs are also effectively used in patients with interlobar collateral-ventilation.[15,16] Both methods have been effective and safe in short- and long-term clinical studies.[17-21] BLVR treatment by either the coil or valve have been recommended by the Global Initiative for Chronic Obstructive Lung Diseases (GOLD).[22] We aimed to evaluate and compare the results of EBV and EBC treatments in our patients with emphysema.

PATIENTS AND METHODS

We retrospectively collected all data on BVLR procedures performed on patients between 1 February 2015 and 1 October 2018 (3 years, 8 months). Informed consent was given by all patients after preoperative evaluation for general anaesthesia. All patients were evaluated with pulmonary function tests (PFTs), arterial blood gas analyses and the six-minute walking test (6MWT) before the procedures and then again after 6 months. Approval was obtained from the Ethics Committee of Afyon University of Health Sciences, dated 2019/11.

Inclusion criteria were age older than 40 years, obstructive pulmonary function test with FEV1 >15% and <50%, pulmonary arterial pressure (PAP) < 55 mm Hg, TLC% >100, $PaCO_2$ <60 mm Hg, residual volume (RV) >175%, dyspnea score ≥2 (evaluated by modified Medical Research Council, mMRC), and the presence of heterogeneous emphysema in candidates for the EBC procedure. Exclusion criteria were the presence of malignant characterized pulmonary nodule, the presence of significant airway pathology, the presence of bronchiectasis in the same lobe, the ability to walk more than 350 meters in the 6MWT, FEV1 <15% and >50%, systolic PAP >55 mm Hg, $PaCO_2$ >60 mm Hg, TLC% <100, RV% >175, dyspnea score <2 (evaluated by modified Medical Research Council, mMRC), previous diagnosis of cancer, the presence of homogeneous emphysema in candidates for the EBC procedure (in that case; we used the ECV procedure), the presence of collateral ventilation for the ECV procedure (when present, the ECV procedure was chosen), or the patient declined to undergo the procedure. Measurements (PFT, arterial blood gases and 6MWT) for all patients were repeated after six months.

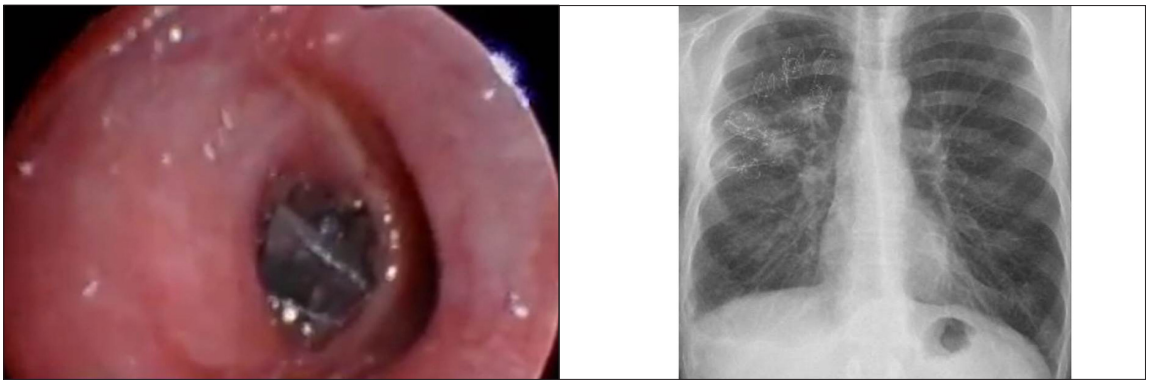

Figure 1. View of the endobronchial valve in the posterior segment of the right upper lobe (left). Endobronchial coils on chest radiograph (right).

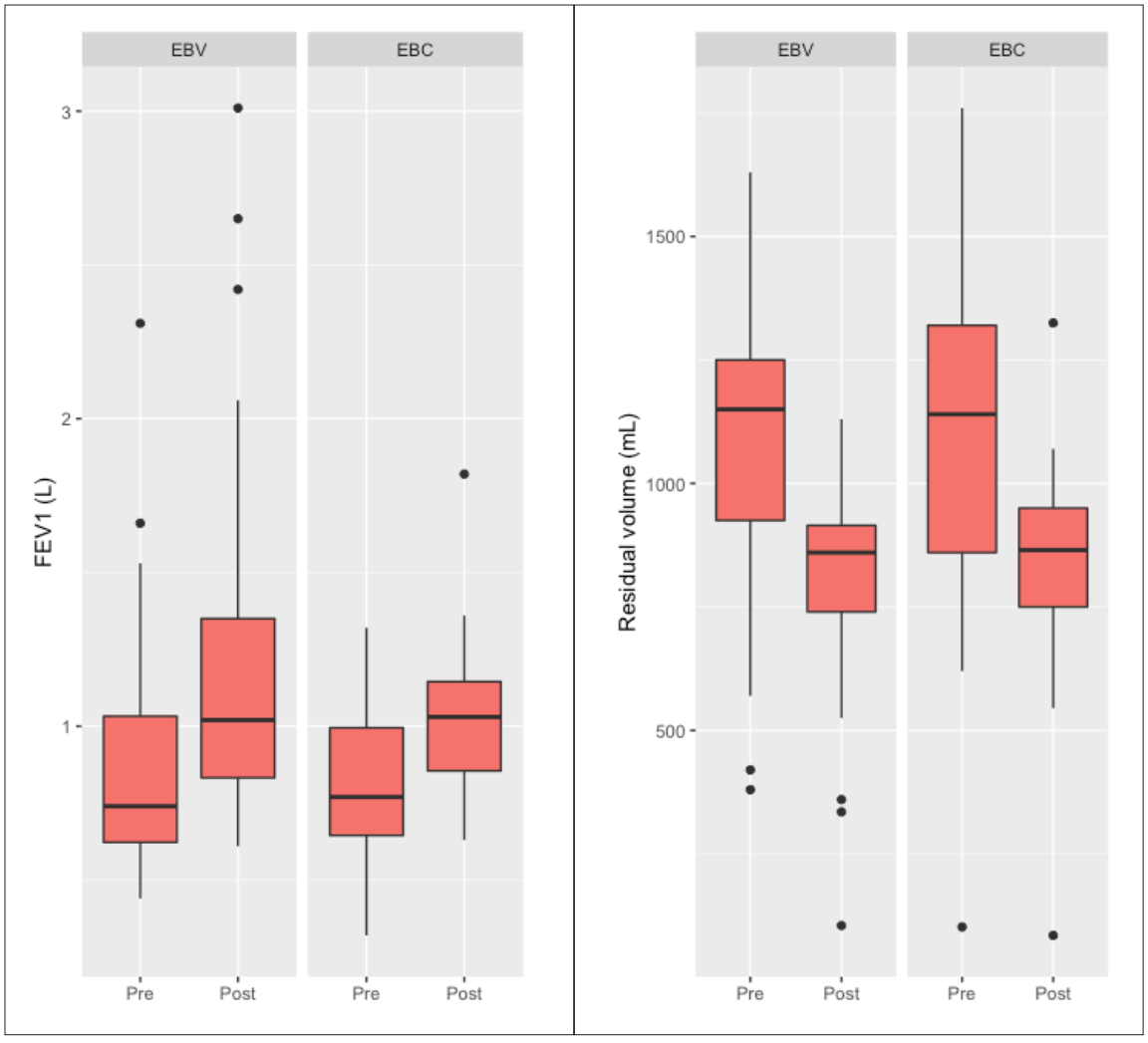

Figure 2. Pre- and post-procedure FEV1 (left) and RV (right) by valve or coil procedure ($P<.01$ and $P<.001$ for pre-to-post changes for FEV1 and RV, respectively) (post values are at 6 months after the procedure).

Endobronchial valve placement

The EBV was placed into the bronchoscopically targeted segmental or subsegmental bronchi. A Chartis catheter was used for cases in which the fissure integrity was not clearly detected in computed tomography (CT) sections. Three to 5 valves were placed in patients who were determined to have no collateral circulation in the targeted lobe. In the presence of collateral circulation with a Chartis catheter, EBC was preferred over EBV.[1,23] Each device is shown in **Figure 1**.

Endobronchial coil placement

Several years after the development of EBV, the coil treatment was developed and applied to heterogeneous emphysematous patients with or without collateral ventilation.[1] The coil was placed into the targeted lobe via fiberoptic bronchoscope through an intubation tube. With experience, we began placing coils into some patients who could tolerate bronchoscopy without intubation. Depending on the number of segments in the targeted lobe, 10 to 15 coils were planted into a patient with one lobe per session. In some cases, the coil was preferable to the valve or vice versa, and then the preferred procedure was used in a second session. Control fiberoptic bronchoscopy was performed for all EBV/EBC patients to confirm the position and function of the EBV/EBC procedures at the third and fourth weeks of the procedures. Both procedures took between 30 minutes to one hour and involved a 1-4 night stay in hospital.

Pulmonary rehabilitation program

Four weeks of a comprehensive pulmonary rehabilitation program were prescribed to all candidate patients in the hospital (2 sessions per week), prior to the procedures. After all the EBV/EBC procedures, 4 weeks of pulmonary rehabilitation were also prescribed for all patients.

Statistical analysis

Statistical evaluation was carried out with IBM SPSS for Windows Version 20.0 (IBM SPSS, Armonk, NY). The Kolmogorov-Smirnov test was used to evaluate the distribution of continuous variables. Categorical variables were expressed as numbers and percentages. Chi-square was used to compare group ratios. When the sample size was less than 5, we used Fisher's exact test to compare group ratios. The McNemar test was used to determine the differences between dependent variables (to compare the completion rate of 6MWT, before and after the procedures). We used the kappa coefficient to measure agreement on completion rates of the 6MWT. Continuous variables are expressed using the median (minimum-maximum) values if they were not normally distributed, and they were expressed using mean and standard deviation (SD) if they were normally distributed. The *t* test was used for all tests of continuous variables when the distribution was normal; otherwise the Mann-Whitney U test was used to compare the two groups. Statistical significance was set at $P<.05$.

Table 1. Clinical and demographic characteristics of the patients (n=60).

Characteristics	Endobronchial valve (n=31)	Endobronchial coil (n=29)	*P* value
Age (years)	64.5 (9.2)	68.0 (7.1)	.07
Smoking status[a]			
Current smoker	17 (54.8)	13 (44.8)	
Ex-smoker	13 (41.9)	13 (44.8)	.480
Non-smoker	1 (3.2)	3 (10.3)	
Height (centimeters)	166.0 (7.2)	166.2 (6.6)	.923
Weight (kg)	65.2 (15.2)	68.9 (14.6)	.344
Body mass index (kg/m^2)	23.6 (4.9)	24.8 (4.4)	.316

Data are number (%) or mean (standard deviation). [a]Fisher's exact test

Table 2. Change in dyspnea score and pulmonary function tests for the two bronchoscopic volume reduction procedures after application (n=60).

Pulmonary function tests	Endobronchial valve (n=31)	Endobronchial coil (n=29)	*P* value
mMRC	-1.0 (-1.0-0)	-1.0 (-2.0-0)	.139
FEV1 (L)	0.25 (-0.18 to 1.35)	0.16 (-0.13 to 0.81)	.198
FEV1 (%)	9.00 (-9.00 to 25.00)	7.00 (-7.00 to 17.00)	.476
FVC (L)	0.31 (-0,95 to 2.00)	0.39 (-0.42 to 1.09)	.497
FVC (%)	7.00 (-10.00 to 24.00)	6.00 (-9.00 to 29.00)	.466
FEV1/FVC	4.50 (-19.00 to 17.00)	1.00 (-27.02 to 27.00)	.298
RV (mL)	-260.50 (-1295.00 to -45.00)	-245.00 (-490.00 to 62.00)	.813

Data are median (min-max) unless indicated otherwise. Statistical comparisons by the Mann-Whitney U test. FEV1: Forced expiratory volume at end of first second, FVC: Forced vital capacity, FEV1/FVC ratio=FEV1%, RV: Residual volume, mMRC: Modified Medical Research Council.

RESULTS

The EBV procedure was applied to 31 patients (51.7%) and the coil to 29 (48.3%) patients (**Table 1**). Clinical and demographic characteristics of the two groups were similar. Thirty (96.8%) EBV patients and 27 (93.1%) EBC patients cooperated with PFT ($P=.606$). In the EBV patients, local anesthesia (oropharyngeal lidocaine) accompanied by midazolam sedation was applied in 24 of these patients. The other 7 underwent fiberoptic bronchoscopy through an intubation tube under general anaesthesia. In the EBC patients, local anesthesia was used initially for most patients receiving the coil treatment. There was an improvement in all PFT results in both groups from before to after the procedures and the differences between the groups after the procedure were not statistically significant (**Table 2, Figure 2**).

In both EBV and EBC patients, there was an increase in the median distance and duration in the 6MWT. In the comparison of the procedures, there were no statistically significant differences in the distance and duration for the 6MWT and vital sign parameters (blood pressure and oxygen saturation) (**Table 3, Figure 3**). For the 6MWT, the completion rate improved from 15 (48.4%) to 19 (61.3%) patients in the 6MWT in the EBV patients ($P=.125$) and from 19 (65.5%) to 21 (72.4%) patients in the EBC patients ($P<.500$). There were no significant differences in completion rates for either study group ($P=.652$). For the EBV the kappa coefficient was 0.744, indicating good agreement between observers ($P<.001$). For the EBC, the kappa coefficient was 0.840, indicating very good agreement ($P<.001$).

In the EBV patients, SBP changed from 119.4 (13.6) to 117.9 (8.3) mm Hg from before to after the procedure ($P=.248$). DBP changed from 82.4 (9.5) to 85.2 (8.1) from before to after. In the EBC patients, SBP changed from 113.6 (17.9) to 114.3 (10.4) mm Hg from before to after the procedure ($P=.841$). Changes in arterial blood gases are shown in **Table 4**.

Local anesthesia was applied to 24 patients (77.4%) EBV patients and general anesthesia was applied to 7 patients (22.6%). For EBC patients, 26 (89.7%) were under local anesthesia and 3 (10.4%) were under general anesthesia (*P*=.204). Anatomical localisations for EBV and EBC applied subjects are given in **Table 5**. The most frequent complications seen after EBV were pneumothorax in 3 patients (9.7%) and cardiac arrhythmia in 2 patients (6.5%). After EBC, 3 patients (10.3%) had pneumonia and 2 (6.9%) patients had COPD exacerbations. All other complications shown in **Table 6**.

DISCUSSION

Airflow limitation is associated with mortality in patients with COPD.[11] An FEV1 less than 15-20% has been suggested as an indicator for lung transplantation.[24] Due to donor insufficiency and advanced age, very few patients are suitable for lung transplantation.[2] Therefore, patients with severe emphysema need different treatment options. Endoscopic valve or coil treatments are suggested treatment options for these patients. EBV treatment is preferred in patients with complete fissure and no collateral ventilation. EBC treatment is preferred in patients whether or not they have an incomplete fissure or collateral ventilation.[25]

Klooster et al reported a 17% increase in FEV1 and a 687 mL decrease in RV in their study, in which they presented 12 months of data for 64 patients treated with EBV.[26] Lee et al recently reported a study which showed a 41.5% increase in FEV1 and a 1960 mL decrease in RV.[27] In a study conducted by the VENT group, on 171 European and 322 American patients who were treated with EBV, an improvement in FEV1 values was presented.[28] Stelvio et al reported a 20.9% improvement in FEV1 in EBV patients with no collateral ventilation.[29] The IMPACT group, which included 93 patients with EBV application, reported a 13.7% increase in FEV1.[30] Three months later, the same group reported a volume reduction of 1195 mL in the target lobe.[31] Slebos et al, at the American Thoracic Society meeting in Washington D.C., presented a study by the IMPACT group on 97 patients and reported that FEV1 increased 32% and RV decreased 14% in their 6-month data on EBV results.[17] Schuhmann et al reported a decrease of more than 350 mL in lung volume as a result of evaluation at month 3 following EBV application.[32] In another study, 20.7% increase in FEV1 was achieved after the EBV procedure.[33]

In 2009, EBC was applied to 16 patients in Holland. Six months after the procedure, a 14.9% increase in FEV1 and 0.411% decrease in RV were achieved.[34] EBC was applied to 46 patients in the RESET study. Three

Table 3. Changes in walking test and other clinical measurements of the effects of the two bronchoscopic volume reduction procedures before and after application (n=60).

	Endobronchial valve (n=31)	Endobronchial coil (n=29)	*P* value
Walking test			
Distance (meters)	32.00 (11.00 to 74.00)	37.00 (-44.00 to 75.00)	.652
Duration (seconds)	11.00 (0.00 to 115.00)	0.00 (0.00 to 90.00)	.128
Pulse rates (bpm)			
Before	14.00 (-2.00 to 28.00)	8.00 (-27.00 to 23.00)	.508
After	8.00 (-1.00 to 28.00)	8.00 (-54.00 to 25.00)	.075
Blood pressure			
Systolic	0.00 (-20.00 to 10.00)	0.00 (-20.00 to 15.00)	.108
Diastolic	5.00 (-5.00 to 20.00)	5.00 (-10.00 to 10.00)	.328
Oxygen saturation, %			
Before	-7.00 (-36.00 to 2.00)	-7.00 (-30.00 to 0.00)	.241
After	-4.00 (-19.00 to 1.00)	-3.00 (-19.00 to -1.00)	.945

Data are median (min-max) unless indicated otherwise. Statistical comparisons by the Mann-Whitney U test.

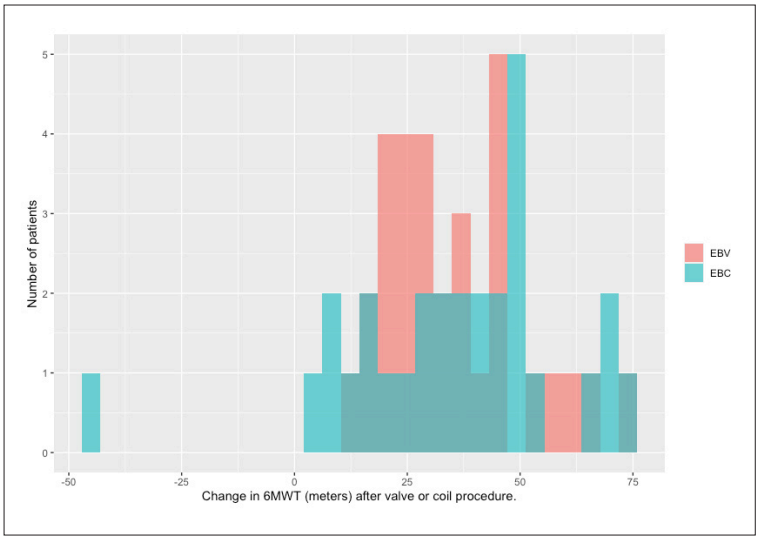

Figure 3. Changes in the six-minute walking test for each patient for the two endobronchial volume reduction procedures after application (*P*=.652).

Table 4. Changes in arterial blood gases before and after application of the two endobronchial volume reduction procedures.

	Endobronchial valve		*P* value	Endobronchial coil		*P* value
	Before	After		Before	After	
pH	7.40 (0.04)	7.39 (0.03)	.182	7.41 (0.04)	7.39 (0.03)	.014
PO_2	53.53 (4.91)	60.51 (4.36)	<.001	54.24 (6.93)	82.49 (12.98)	.182
PCO_2	39.03 (5.25)	39.22 (3.12)	.756	41.38 (6.12)	41.35 (4.39)	.967

Table 5. Anatomical localization for the two bronchoscopic volume reduction procedures (n=60).

Location of the applied procedure	Endobronchial valve (n=31)	Endobronchial coil (n=29)	*P* value
Left			
Upper lobe	8 (80.0)	2 (20.0)	.082
Lower lobe	3 (42.9)	4 (57.1)	.702
Right			
Upper lobe	18 (45.0)	22 (55.0)	.177
Lower lobe	2 (66.7)	1 (33.3)	.999

Data are n (%). Statistical comparisons by Fisher's exact test.

Table 6. Complications following endobronchial volume reduction procedures.

	Total	Endobronchial valve (n=31)	Endobronchial coil (n=29)	*P* value
Cardiac arrhythmia	2 (3.3)	2 (6.5)	0	.492
Hypernatremia	1 (1.7)	1 (3.2)	0	.999
Pneumonia	4 (6.7)	1 (3.2)	3 (10.3)	.346
Pneumothorax	4 (6.7)	3 (9.7)	1 (3.4)	.613
Hemoptysis	1 (1.7)	1 (3.2)	0 (0.0)	.999
Expectoration	1 (1.7)	1 (3.2)	0 (0.0)	.999
Exacerbation of COPD	2 (3.3)	0	2 (6.9)	.229
Death	0	0	0	
Total complications	15 (25)	9 (29)	6 (20.6)	.167

Data are n (%). Statistical comparisons by Fisher's exact test. COPD: Chronic obstructive pulmonary disease.

months after the procedure, a 10.6% increase in FEV1 and a 0.31 L decrease in RV were observed.[9] Klooster et al reported an increase of 18.9% in FEV1 and a decrease of 600 mL in RV.[10] Deslee et al, 12 months after coil treatment, reported an 110 mL increase in FEV1 and a 710 mL decrease in RV.[35] In the REVOLENS study, an increase of 11% in FEV1 and a decrease of 0.37 L in RV was achieved.[36] In the RENEW study performed with 315 patients with the coil procedure, 12 months after procedure, a 7% increase in FEV1 and a decrease of 310 mL in RV were achieved.[37] Simon et al, in their study of the EBC in 2017, reported an increase in FEV1 from 0.5 L to 0.6 L (0.1 L) and a decrease in RV from 6.1 to 5.6.11 Metin et al, reported a 54.0% increase in FEV1 after the valve procedure, and 44% after the coil procedure.[38] In our study, among the patients who underwent EBV, we observed a 380 mL increase in FEV1 (*P*<.001), and 270 mL decrease in RV (*P*<.001). A significant improvement was found in each parameter after application. Among the patients who underwent EBC application before and after the procedure; there was a 260 mL increase in FEV1 and 110 ml in RV. Our results were similar to others in the literature.

In our study, the differences in number of patients who could complete the 6MWT was statistically highly significant for both procedures (*P*<.001). To our knowledge, this is the first study to evaluate completion rates of 6MWT for both procedures in the English literature. Klooster et al presented 6 MWT results of 12-month data of 64 patients with EBV application. They reported that a 61 meter increase was achieved in 6MWT distance (6MWD) after EBV treatment.[26] Lee et al recently reported an increase in 6MWD after EBV treatment.[27] Similarly, in other previous studies, there was an improvement in 6MWD from 39.3 meters to 64 meters after EBV treatment.[17,28,29,31,33,39] In our study, we observed a 35.4 meter (25.7%) increase after EBV treatment.

On the other hand, Selebos et al reported that 6MWD was increased by 84.4 meters after the EBC procedure.[34] In the RESET study, a 63.6 meter increase was achieved in 6MWT 3 months after the EBC procedure.[9] In Klooster et al, 6MWT was increased by 61 meters 6 months after coil treatment.[10] Deslee et al reported an increase of 51.4 meters in 6MWT 12 months after the coil treatment.35 In the REVOLENS study, which applied the coil over 100 patients, an increase of 21 meters in the 6MWT was achieved.[36] In the RENEW study,

performed with 315 EBC patients, an increase of 14.6 meters in 6MWT was achieved 12 months after the procedure.[37] In our study, we achieved an average increase of 35.2 meters (25.2%) in EBC subjects at 6 months. This improvement was similar to others in the literature.

To our knowledge, there are only two studies that have evaluated arterial blood gas analysis prior to endobronchial treatments.[11,27] Post-procedure blood gas values were not available in these studies. In our study; there was a significant improvement in PO_2 value following EBV treatment and improvement in pH after both EBV and EBC treatment. Jorrit et al reported that they performed general anesthesia during their EBC procedure.[40] Valipour et al reported that they performed sedation and general anesthesia during EBV treatment.[30] In our study, 24 patients (77.4%) received only local anesthesia and 7 patients (22.58%) received general anesthesia during EBV treatment. On the other hand, 26 patients (89.7%) received local anesthesia and 3 patients (10.35%) received general anesthesia during the EBC procedure. Although EBC cases are mostly performed under general anesthesia and endotracheal intubation in the current literature, we started to perform the EBC application with sedation without endotracheal intubation without any major complication for our recent cases. Additionally, the rate of the type of anesthesia used in the valve or coil procedure was similar in our study.

Simon et al performed the EBC volume reduction procedure on 21 cases on the right upper lobes (63.6%), to 6 cases on the left upper lobe (18.2%), to 3 cases on the right lower lobe (9.1%), and to 3 cases on the left lower lobe (9.1%).[11] Slebos et al performed EBV on the upper lobe in 55% of cases and to the lower lobe in 45% of cases[17] Lee et al applied EBV to the right middle lobe valve to all cases.[27] Kemp et al applied EBV to 52% of the cases on the left upper lobe, 22% on the left lower lobe, 15% on the right upper lobe, 8% on the right upper and right middle lobe, 3% on the right lower lobe.[41] Yu et al performed all volume reduction procedures to the upper lobe.[42] In our study, we performed EBV on 18 patients (58.1%) to the right upper lobe and 8 patients (25.8%) to the left upper lobe. In the EBC patients, we performed the EBC to mostly 22 patients (75.85%) to the right upper lobe and 4 patients (13.80%) to the left lower lobe.

As to complications, Welling et al reported pneumonia (11.7%), exacerbation of COPD (9.3%), pneumothorax (4.2%), valve migration or shift (1.5%) and mortality (8%) as complications of EBV.[43] Another study by the VENT group found a 4% to 7% complication rates (pneumonia, pneumothorax, hemoptysis, exacerbation of COPD, valve migration, aspiration or expectoration) after EBV treatment.[28] Balkissoon et al reported a 25.3% complication rate. Among these complications were pneumothorax, the most prevalent at 17.3%.[39] Klooster et al reported pneumothorax as a complication in 22% of patients within 6 months follow-up.[26] On the other hand, Lee et al reported no complications after EBV treatment.[27] In our study, pneumothorax was the most prevalent complication in 3 patients (9.7%) followed by cardiac arrhythmia in 2 patients (6.5%) after EBV. None of our patients died during follow-up. Simon et al reported exacerbation of COPD in 41.0%, pneumonia in 14.8%, pneumothorax in 5.7%, and mortality in 3.3% as complications following EBC.[11] Jorrit et al reported COPD exacerbation in 26.42%, pneumonia in 19.28% and pneumothorax in 6.4% after EBC procedure.[40] In our study, we observed 3 patients (10.3%) with pneumonia, 2 patients (6.9%) with COPD exacerbation and 1 patients (3.4%) with pneumothorax as a complication following EBC. As in the EBV procedure, no mortality was seen following EBC. Although similar complications have been reported in the literature, the incidence rates vary. This may depend on the number of patient groups, comorbidities and the experience of the team performing the procedure. To the best of our knowledge, hypernatremia and arrhythmia were not reported in the literature before, so we report these findings as complications for the first time in our study.

The main limitations of this study are its retrospective design and small sample-size. Another limitation is the absence of 9, 12 months or later follow-up results of the patients. Moreover, the absence of comorbidity data for all patients prevented evaluation of potential confounding variables.

In conclusion, endobronchial valves and coils currently appear to be similarly safe and effective bronchoscopic volume reduction procedures. Patient selection is very important. Appropriate patients with no collateral circulation must be chosen for the EBC procedure. In addition, large randomized controlled trials are needed to better define optimal patient selection and find overlooked complications during the endobronchial valve and coil procedures.

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