THE MEDICAL BULLETIN OF
SISLI ETFAL HOSPITAL

DOI: 10.14744/SEMB.2023.06767
Med Bull Sisli Etfal Hosp 2023;57(4):506–512

Original Research

Efficiency and Reliability of Bronchoscopic Lung Volume Reduction Coil Application in Patients with Severe Emphysema

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Abstract

Objectives: In the past years, surgery has been used for the non-medical treatment of severe emphysema. However, in recent years, bronchoscopic lung volume reduction (LVR) treatment has become more preferred because it is less invasive. Bronchoscopic coil treatment is the most frequently applied technique among these methods. The aim of the investigation was to determine the efficacy and safety of bronchoscopic volume reduction coil treatment for patients with severe emphysema.

Methods: The patients who were performed bronchial volume reduction coil treatment between 2015 and 2017 and were followed in our outpatient clinic were retrospectively examined. They were followed for 1 year at quarterly intervals after the procedure. All the safety and efficacy of the patient's records, including the modified Medical Research Council (MRC) dyspnea score, the St. George's Respiratory Questionnaire (SGRQ) quality of life scale, the 6 min walk distance (6-MWT), pulmonary function tests, and adverse events, were evaluated.

Results: Sixteen patients were included in the study. The mean of the preoperative mMRC clinic dyspnea score was 3.38, the mean of the 3rd month's mMRC score was 2.62 (p=0.007), and the mean of the 12th month's mMRC was 2.37 (p=0.003). The preoperative SGRQ quality of life parameter was 71.95±15.7, the 3rd month was 66.7±16.2 (p=0.007), and the 12th month was 62.9±16.4 (p=0.003). Preoperative mean of 6-MWT was 247.25±112.36 m, 3rd month 264.25±95 m (p=0.148), and 12th month 317±122.9 m (p=0.034). Patients' preoperative residual volume was 5.28±1.96 L, 3rd month 4.52±1.35 L (p=0.023), and 12th month 4.545±1.83 L (p=0.163). Patients' preoperative forced expiratory volume in one second, respectively, was 0.79±0.29 L, 3rd month 0.79±0.3 L (p=0.917), and 12th month 0.86±0.3 L (p=0.756).

Conclusion: It seems that bronchoscopic LVR coil treatment, which is an effective and reliable procedure that reduces shortness of breath rather than respiratory function test parameters and improves the quality of daily life, will become even more widespread.

Keywords: Bronchoscopic lung volume reduction treatment, emphysema, endobronchial coil treatment

Please cite this article as "Kayikci H, Cimen P, Katgi N. Efficiency and Reliability of Bronchoscopic Lung Volume Reduction Coil Application in Patients with Severe Emphysema. Med Bull Sisli Etfal Hosp 2023;57(4):506–512".

Chronic Obstructive Pulmonary Disease (COPD) is an important disease worldwide that reduces the quality of life of patients and causes premature death due to severe shortness of breath and respiratory failure.[1] COPD is defined as a completely non-reversible airflow obstruction. There are two separate components called emphysema and chronic bronchitis.[2] Fundamentally, its pathophysiology includes alveolar wall destruction, irreversible airway obstruction, elas-

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Submitted Date: February 08, 2023 **Revised Date:** May 22, 2023 **Accepted Date:** September 07, 2023 **Available Online Date:** December 29, 2023

tic recoil loss, air confinement, and consequently, a reduced gas exchange area.[3] Dynamic hyperinflation develops with exercise, which decreases chest wall compliance and prevents the normal functioning of the respiratory muscles. The work done for breathing has increased. The patient is faced with increased shortness of breath.[4]

According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2020 guidelines, the basis of COPD treatment is smoking cessation. Pharmacological agents are used to decrease symptoms and acute exacerbations and increase exercise capacity. It is important to have influenza and pneumococcal vaccines in order to prevent possible infections. Pulmonary rehabilitation is also among the GOLD 2020 recommendations. Proper nutritional support forms an important part of the treatment. Oxygen therapy improves life expectancy in patients with severe chronic hypoxemia at rest. The application of noninvasive mechanical ventilation at home in patients with severe chronic hypercapnia also decreases the frequency of hospitalization and mortality rate. Volume-reducing surgery or bronchoscopic interventions in selected patients with advanced emphysema who are resistant to all medical support have also taken their place in GOLD 2020.[5]

In patients with emphysema with severe hyperinflation, bronchoscopic coil application is one of the most effective volume-reducing bronchoscopic applications.[6] Patients with a phenotype ranging from centrilobular emphysema to moderate panlobular emphysema are the most suitable candidates for coil therapy.[7] The coil, which is made of nitinol wire with shape memory, is important due to its ability to reduce lung volume despite collateral ventilation without causing blockage.[8] When the coils are placed in the lung parenchyma, they twist around themselves to take on their memorized shape, enveloping and compressing the lung parenchyma. This is the main mechanism to reduce hyperinflation. The tissue tension generated by the same mechanism causes the radial ligaments to strengthen and stretch. This is an auxiliary mechanism that reduces hyperinflation by helping to keep the small airways open.[9]

Bronchoscopic coil application is preferred in patients who cannot undergo volume-reducing surgery due to many reasons, such as advanced age, multiple comorbidities, and who are not suitable for valve treatment due to homogeneous emphysema and collateral ventilation and who are also going towards lung transplantation.[6]

Nowadays, surgical methods are replaced by less invasive bronchoscopic methods, such as lung volume reduction (LVR) coil therapy. It is a good option for treatment for selected COPD patients.[10,11]

In the first randomized controlled trial, it was reported that endobronchial coil application increased the quality of life, exercise capacity, and pulmonary function, and the possible complications were less when compared with other endobronchial volume reduction (EBVR) therapy techniques and volume reduction surgery.[12] In a multicenter meta-analysis, spirometric measurements, lung volumes, the 6 min walking test (6-MWT), and quality of life scales showed significant improvement ($p<0.001$) in the follow-up period at the sixth and 12th months of the endobronchial coil treatment ($p<0.001$).[13]

In our study, we aimed to investigate the efficacy and safety of EBVR coil therapy on pulmonary function tests (PFT), exercise capacity, and quality of life at the 3rd, 6th, and 12th months in COPD patients with advanced emphysema.

Methods

Our study was done in a single center, and the patients with homogeneous or heterogeneous emphysema on thorax high-resolution computed tomography (HRCT) who were performed EBVR coil treatment and were followed between 2015 and 2017 in our clinic were retrospectively evaluated. Our research was approved by the ethics committee of our hospital with the decision dated November 20, 2017 and numbered 7829, and it was conducted in accordance with the Helsinki Declaration. All patients were given detailed information before the procedure, and an informed consent form was taken.

All patients were evaluated with body plethysmography; residual volume (RV), total lung capacity (TLC), and RV/TLC were recorded before the procedure. These values indicate the amount of air trapped in the lung. It is affected by variable parameters such as height, gender, position, body mass, and ethnicity. Values between 80% and 120% are considered normal. Modified Medical Research Council (mMRC) dyspnea score, St George's Respiratory Questionnaire (SGRQ) quality of life scale, 6-MWT, quantitative lung perfusion scintigraphy, and thorax HRCT were performed.

We tried to make our patient selection in accordance with the NETT study criteria as much as possible. To summarize the NETT study criteria: Presence of HRCT-proven bilateral emphysema, stable disease with a maximum of 20 mg prednisone (or equivalent) daily, Forced expiratory volume in 1 second (FEV1) value ≤45% and ≥15% of predicted value, TLC value ≥100% of predicted value, RV value ≥150% of predicted value on PFT, PCO2 ≤60 mm Hg and PO2 ≥45 mm Hg in room air in arterial blood gas, 6-min walk ≥140 meters after rehabilitation, the patient had not smoked for 4 months and had completed a pulmonary rehabilitation program.[14]

Our inclusion criteria for the study were those older than 35 years of age, post-bronchodilator predicted FEV1≤45%,

homogeneous or heterogeneous emphysema on HRCT, RV predicted >175%, TLC >100% predicted, and who had quit smoking 8 weeks ago. Exclusion criteria are pregnancy, lactation, recurrent respiratory tract infection, giant bullae constituting >1/3 of the lung volume, presence of lung cancer, presence of clinically significant bronchiectasis, volume reduction surgery, transplantation or lobectomy, 6-MWT <140 m, history of steroid use 20 mg/ day and those with vessels that visually exceed the size of the adjacent airway.

COPD patients who had homogenous or heterogeneous emphysema in the thorax HRCT of the lungs were included in our study. HRCT was performed with a Hitachi tomography device at 1 mm slice thickness and 1.5 pitch without contrast agent. There are two commonly used methods for quantitative evaluation of emphysema: semiquantitative evaluations made by the observer or quantitative evaluations using computer software programs.[15,16]

In the most commonly used semiquantitative method, the observer evaluates three levels for each lung by evaluating the severity of emphysema at a total of six levels and grading between 0 and 4. There is no emphysema at zero. The rate of emphysematous parenchyma is 1–25% in 1, 26–50% in 2, 51–75% in 3, and 76–100% in 4. The semiquantitative evaluation can be used safely by experienced radiologists or clinicians who are experienced in the lung.[15,17] In our study, HRCT sections were evaluated with radiologists who are specialized in lung.

LVR coil treatment was performed by an experienced pulmonologist under general anesthesia in an operating room, and three types of coil with a length of 100, 125, and 150 mm were used (PneumRx, USA) (Fig. 1). In heterogeneous emphysema, the upper or lower lobe is preferred. The recommended number of coils for the upper lobe is 10–12 and for the lower lobe is 10–14. The optimal area where the coil is to be placed should be four centimeters adjacent to the pleura between the hilum and the pleura (Figs. 2 and 3).

In the follow-up screening, medical history, physical examination, chest X-ray, and PFT were performed at the 1st month. Adverse events, mMRC dyspnea score, SGRQ quality of life scale, and 6-MWT values were recorded at the 3rd, 6th, and 12th months of the patients.

Statistical Analysis

The data obtained in the study were entered into the SPSS 18 program (NY, USA). Non-parametric tests were performed with Wilcoxon mark sequence numbers with initial values at the 3rd, 6th, and 12th months. In all statistical methods, the type one error coefficient was determined as alpha = 0.05. If the p values obtained were <0.05, they were considered statistically significant.

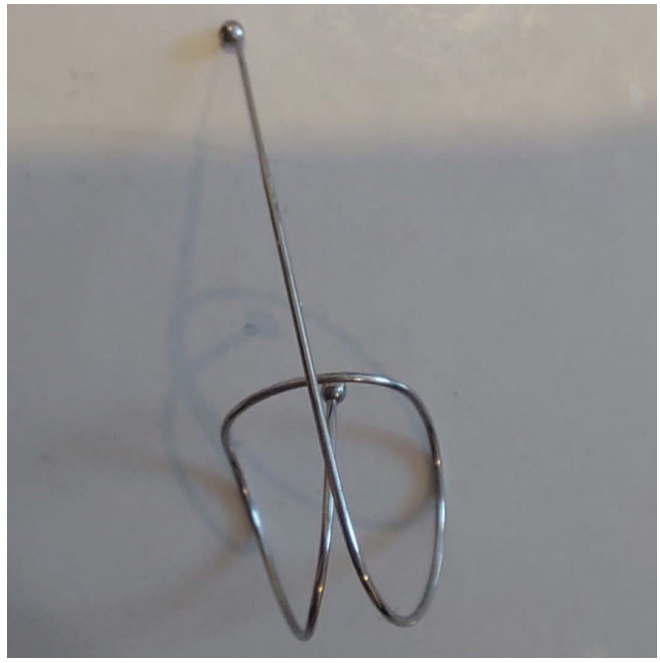

Figure 1. Demonstration of a coil.

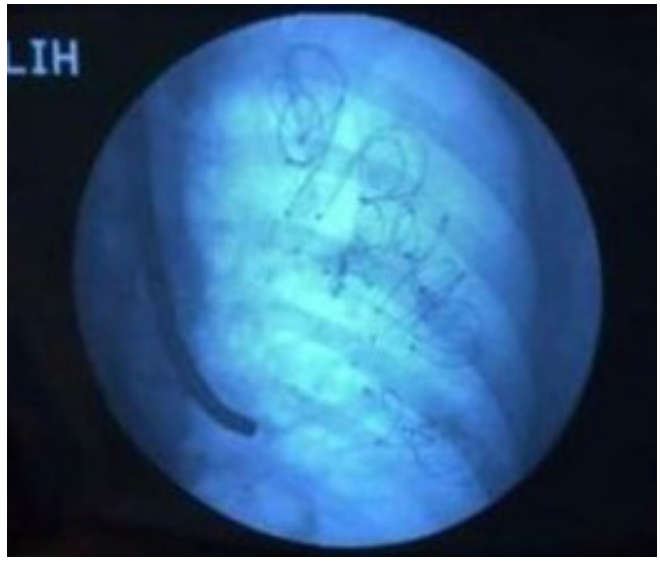

Figure 2. Scopic appereance of coil replacement procedure.

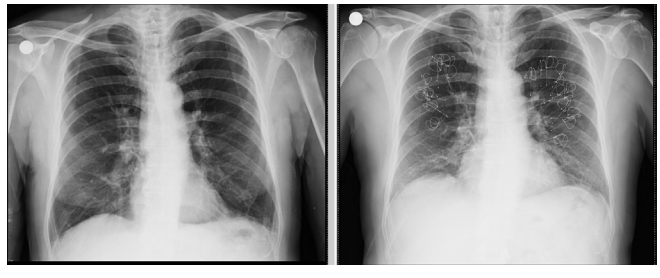

Figure 3. Chest X-ray images of one of the study participants before and after the procedure.

Results

The demographic data of 16 patients who underwent EBVR coil procedures between 2015 and 2017 are given in Table 1. Nine patients underwent bilateral and seven unilateral bronchial volume reduction operations. All of the procedures were applied to the upper lobes of the lung. The mean duration of the second procedure in nine patients who underwent bilateral coiling was 323 (26–782) days.

The average processing time was 50–60 min in a total of 25 procedures. Eight coils (12.5%) were used in two treatments, ten coils (43.8%) in seven treatments, eleven coils (31.3%) in five treatments, and twelve (12.5%) coils in two treatments.

Initial mean FEV1 value was 0.79±0.29L, 3rd month FEV1 value was 0.79±0.24L (p=0.917), 6th month 0.91±0.30L (p=0.063), and 12th month FEV1 value was 0.86±0.30L (p=0.756) (Fig. 4). Although an increase was observed in liters compared to the initial value, no statistically significant difference was found (Table 2).

Baseline RV was 5.28±1.96L, 3rd month RV 4.52±1.35L (p=0.023), 6th month RV 4.55±1.25L (p=0.99), and after 12 months, RV was measured as 4.54±1.83L (p=0.163) (Fig. 5). Although a significant decrease was observed in the 3rd month, a decrease in liters was observed in the 6th and 12th months, but it was not statistically significant (Table 2).

The exercise capacity of the patients was evaluated with 6-MWT. It was calculated as 247±112 m before the procedure, 264±95 m at the 3rd month (p=0.148), 309±117 m at the 6th month (p=0.026), and 317±123 meters at the 12th month (p=0.034). The exercise capacities of the patients increased, and especially a significant improvement was observed in their long-term exercise capacity (Table 2).

SGRQ quality of life was calculated as the total score on the computer using the SGRQ scoring system. Pre-procedural mean value of SGRQ quality of life score was 71.9±15.7, SGRQ score at 3rd month was 66.7±16.2 (p=0.007), 62.4±15.5 (p=0.001) at 6th month, and 62.9±16.4 (p=0.003) at 12th month (Table 2). There was a significant improvement in the SGRQ scores of the patients compared to baseline.

mMRC dyspnea score at baseline was 3.38, median value was 3rd month 2.62, median value was (p=0.007), 6th month mean value was 2.37, median value was 2 (p=0.003), and

Table 1. Characteristics of the patients

Demographic features	Median
Age	62.5 (50–76)
Cigarette pack/years	66 (50–80)
mMRC score	3.38 (3–4)
6-MWT (meter)	200 (142–499)
FEV1, % pred	29 (15–47)
RV, % pred	230.5 (158–474)
SGRQ total score	77.36 (30.76–92.83)
Heterogenous emphysema (n)	13 (81%)
Homogenous emphysema (n)	3 (19%)

mMRC: Medical research council; 6-MWT: 6-minute walking test; FEV1: Forced expiratory volume in 1 second; RV: Residual volume; SGRQ: St George's Respiratory Questionnaire.

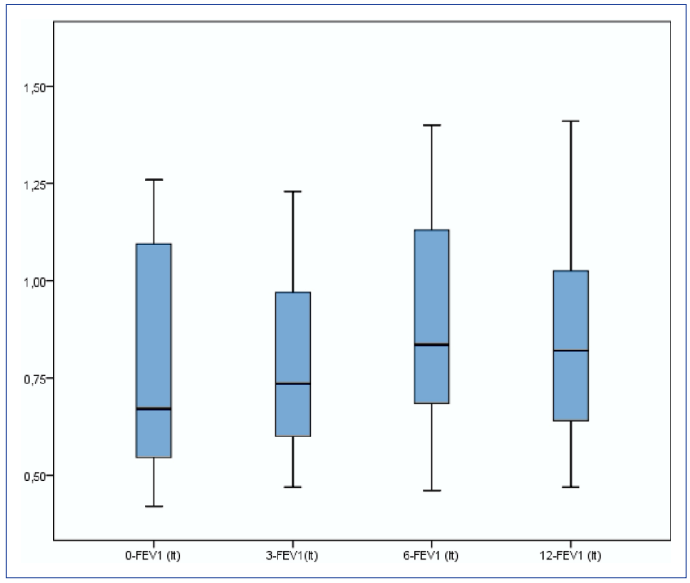

Figure 4. Changes in FEV1 of patients at 1-year follow-up period.
FEV1: Forced expiratory volume in 1 second.

Table 2. Changes of the parameters at 1-year follow-up period

	Baseline Mean	3rd month (p)	6th month (p)	12th month (p)
FEV1 (liters)	0.79±0.29	0.79±0.24 (p=0.917)	0.91±0.0 (p=0.06)	0.86±0.30 (p=0.756)
RV (liters)	5.28±1.96	4.52±1.35 (p=0.023)	4.55±1.25 (p=0.99)	4.54±1.83 (p=0.163)
6-MWT(meter)	247±112	264±95 (p=0.148)	309±117 (p=0.026)	317±123 (p=0.034)
SGRQ total score	71.9±15.7	66.7±16.2 (p=0.007)	62.4±15.5 (p=0.001)	62.9±16.4 (p=0.003)

FEV1: Forced expiratory volume in 1 second; RV: Residual volume; 6-MWT: 6-minute walking test; SGRQ: St George's respiratory questionnaire.

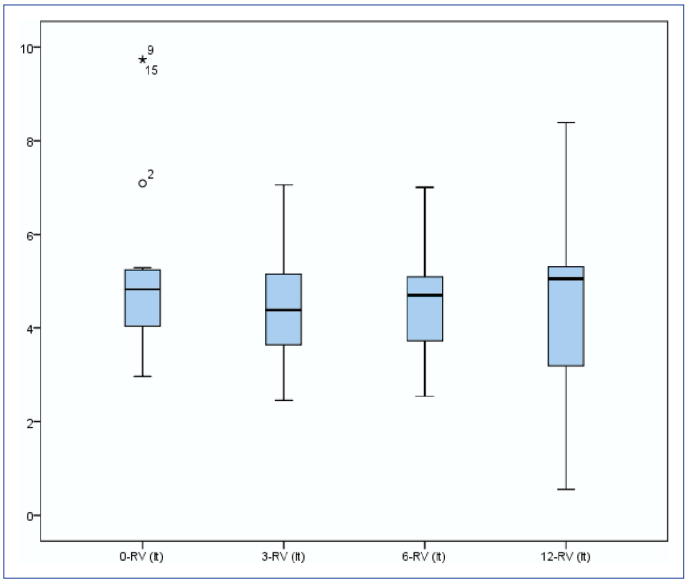

Figure 5. Changes in RV of patients at 1-year follow-up period.
RV: Residual volume.

12th month mean value was 2.37, median value was 2 (p=0.003). There was a significant response in the mMRC dyspnea score of the patients in the follow-up compared to the baseline.

Safety was assessed by adverse events during the follow-up period after the procedure. No perioperative complications were observed. One patient died at 3 months due to pneumosepsis. The most common adverse events after the procedure were acute exacerbations of COPD, pneumonia, and pneumothorax in one patient. Adverse events observed during the 1-year follow-up are shown in Table 3.

Discussion

The treatment choice for COPD was changed after the clarification of the physiopathology of the disease, and respiratory symptom relief therapy was the first treatment. It is known that the current drug therapy is not effective on the mortality and the natural development of the disease, so bronchoscopic interventional therapies have become more popular recently.[18]

In recent studies, it has been proven that coil therapy improves quality of life, reduces hyperinflation, and increases exercise capacity in patients with upper lobe predominant heterogeneous emphysema.[19] Although the benefit is said to be less in severe homogeneous emphysema, it is supported by randomized controlled trial data showing that helix therapy is effective in both groups in patients with heterogeneous and homogeneous emphysema.[12,20] In a study conducted by Klooster et al.[21] in 2014 with 10 patients with homogeneous emphysema, there was a decrease in airway resistance (p=0.009), a decrease in RV (p=0.007), and an increase in 6-MWT (p=0.005) at the end of the 6 month follow-up. and significant improvement in the SGRQ score (p=0.028). In our study, the coil procedure was applied to 17 patients, and four of them were patients with homogeneous emphysema. One of the patients with homogeneous emphysema was not included in the study data because he died due to pneumonia and respiratory failure in the 3rd month. Due to the small number of patients with homogeneous emphysema, a post-procedure comparison of patients with heterogeneous and homogeneous emphysema could not be made.

Patients were selected according to the NETT study's criteria.[14] Patients with FEV1 values in the GOLD 3–4 class and corresponding to group E in the COPD combined assessment modality were included in this study. In a study conducted by Darwiche and Aigner.[22] LVR coil treatment can be applied safely in patients with advanced emphysema (FEV1<20%), and lung functions and exercise capacity can be improved.

The procedure was performed under general anesthesia in operating room conditions. Perioperative and early-postoperative complications were not observed in the patients. The mean hospital stay of patients after the procedure is 1 day, which is similar to that in other centers.[23] In our study, unilateral therapy was applied to seven patients, and bilateral coil therapy was applied to nine patients. The mean time for the second procedure was 323 days for those who underwent bilateral procedures. In a study investigating the efficacy and safety of patients who underwent a second procedure in patients with severe emphysema, the

Table 3. Adverse events after the LVR coil treatment

Adverse events	1st month	3rd month	6th month	12th month
No adverse events	7 (43.7%)	9 (56.3%)	11 (68.8%)	15 (93.8%)
COPD exacerbation	4 (25%)	5(31.3%)	3 (18.8%)	0 (0%)
Pneumonia	4 (25%)	2 (12.5%)	2 (12.5%)	1 (6.3%)
Pneumothorax	1 (6.3%)	0 (0%)	0 (0%)	0 (0%)

COPD: Chronic obstructive pulmonary disease.

second procedure was performed after an average of 1382 (849-1545) days. As a result of the study, it is suggested that performing the secondary procedure approximately 3 years after the initial treatment would be more effective.[23]

In our study, although there was an increase in liters in FEV1 values during the 3rd, 6th, and 12th month follow-up periods, it was not statistically significant. A meta-analysis of 140 patients from 13 centers in Europe showed significant improvement in the FEV1 parameter in patients at 6 and 12 months.[24] In the study conducted by Klooster et al.[21] with 10 patients, although the FEV1 value increased from 0.58 L to 0.69 L (p=0.102), no statistically significant difference was observed, similar to our study. Although an increase in liters was observed in our study, the reason why it was not statistically significant was thought to be related to the low number of patients and the high frequency of adverse events in our cases, as in the study of Klooster et al.[21]

In our study, a decrease was observed compared to the initial RV value after the procedure. While a significant decrease was observed in the RV value, especially at the 3rd month (p=0.023), there was no significant decrease in the 6th month (p=0.99) or 12th month controls (p=0.163). In a study by Kontogianni et al.,[25] significant improvement was observed in RV values at the 3rd and 6th months. In another study with 140 patients, statistically significant improvement in RV was observed at the 6th and 12th month controls.[24] In a study conducted by Gülşen[26] an improvement of 0.42 L (14.5%) was observed in the RV at the 6th month follow-up.

Statistically significant improvement was observed in 6-MWT values at the 6th and 12th months. We think that we did not see a 6-MWT improvement in the 3rd month because the effort capacity was affected due to the side effects that developed in the first 3 months. In the study of Kloth et al.[27] with 30 patients, the initial value of 6-MWT was 290.3±99.18 m, and it was increased to 355.3±94.78 m (p=0.0001). According to the Revolens study, 36 patients showed significant improvement in 6-MWT results at 6th month compared with the untreated group, but no significant improvement in 12th month values.[28] In another randomized controlled trial, significant improvement in 6-MWT results was observed at 3-month follow-up in 46 patients who underwent bilateral coil treatment.[12] As a result of all these studies, although we generally observe positive results in the 1-year follow-up of the patients in the 6-MWT results, there is not enough data on long-term effectiveness, and further studies are needed on the effectiveness in follow-ups over 1 year.

A four-point decrease in SGRQ scores is statistically significant. In our study, we observed a statistically significant improvement in all periods of follow-up. In the study of Klooster et al.[21] with 10 patients with homogeneous emphysema, it was observed that the SGRQ total score decreased from 63 to 48 points (p=0.028). Another study showed a significant decrease in the SGRQ score 6 months after coil therapy.[12] There was a statistically significant improvement in the mMRC clinical dyspnea score in all months. We observed that the EBVR procedure improved patients' symptoms at all follow-up periods.

In our study, the safety of EBVR coil therapy was evaluated by adverse events. Perioperative and early post-operative complications were not observed in the patients. During the follow-ups, the most common complications, especially in the first 3 months, were acute exacerbations of COPD and pneumonia. Only one patient had pneumothorax (6.3%) after the procedure. In a published meta-analysis, 6.4% of patients had pneumothorax requiring a chest tube immediately after coil therapy, similar to our study.[24] Compared to the same meta-analysis, adverse reactions in our study were higher than in the meta-analysis study, but in that meta-analysis, it was observed that the number of patients decreased from 140 to 96 in a 1-year period, and 44 patients were excluded from follow-up. It was thought that the low rate of adverse results might be low due to the lack of information about the clinical processes of the patients who were excluded from follow-up and also we had a small group of patients. The complication directly related to the procedure was pneumothorax. Since the patients selected for the procedure were GOLD E group patients who had frequent exacerbations and had a high frequency of exacerbations and symptoms, it is thought that the high rate of acute exacerbations and pneumonia complications of COPD may not only be due to the procedure but also to the advanced stage of the disease.

The limitation of our study is that it was conducted with a small number of patients.

Conclusion

EBVR coil therapy is an effective and reliable method that provides improvement in clinical recovery rather than respiratory function parameters in patients.

Disclosures

Ethics Committee Approval: Our study approved by the ethics committee of Dr. Suat Seren Chest Diseases and Surgery Training and Research Hospital at the meeting dated 20.11.2017 with the number 7829. The authors have no conflicts of interest and source of funding, including pharmaceutical industry support, that require acknowledgment.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – P.Ç.; Design – P.Ç., H.K., N.K.; Supervision – N.K.; Materials – N.K.; Data collection &/or processing – H.K.; Analysis and/or interpretation – N.K.; Literature search – H.K., P.Ç., N.K.; Writing – H.K., P.Ç., N.K.; Critical Review – N.K.

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