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ORIGINAL ARTICLE / ÖZGÜN MAKALE

Outcomes of bronchoscopic lung volume reduction coil treatment in patients with severe emphysema

Ağır amfizemi olan hastalarda bronkoskopik akciğer hacim küçültme koil tedavisinin sonuçları

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ABSTRACT

Background: This study aims to evaluate the outcomes of bronchoscopic lung volume reduction coil treatment in patients with severe emphysema.

Methods: Between February 2016 and March 2019, a total of 20 severe emphysema patients (19 males, 1 female; mean age: 65.2±5.2 years; range, 52 to 73 years) who underwent bronchoscopic lung volume reduction coil treatment were included. Each patient underwent pre- and post-treatment (6 and 12 months) pulmonary function tests, 6-min walking distance, modified Medical Research Council dyspnea scores, and diffusing capacity of the lung for carbon monoxide tests.

Results: An mean number of 12.0±3.8 coils was placed in each lobe. There were significant improvements in the patients' pulmonary function tests and quality of life 12 months after the treatment. There was a significant difference in dyspnea as assessed by the modified Medical Research Council dyspnea scores 12 months after treatment compared to pre-treatment scores ($p<0.05$). There was no change in the pulmonary function tests six months after treatment, while a significant improvement was seen at 12 months ($p<0.05$).

Conclusion: Bronchoscopic lung volume reduction coil treatment seems to be a promising modality for severe emphysema patients with significant improvements in the pulmonary function test results, modified Medical Research Council dyspnea scores, and 6-min walking distance.

Keywords: Bronchoscopic lung volume reduction, chronic obstructive pulmonary disease, coil, emphysema.

ÖZ

Amaç: Bu çalışmada ağır amfizemi olan hastalarda bronkoskopik akciğer hacim küçültme koil tedavisinin sonuçları değerlendirildi.

Çalışma planı: Şubat 2016 - Mart 2019 tarihleri arasında bronkoskopik akciğer hacim küçültme koil tedavisi uygulanan toplam 20 hasta (19 erkek, 1 kadın; ort. yaş: 65.2±5.2 yıl; dağılım, 52-73 yıl) çalışmaya alındı. Her hastaya tedavi öncesi ve sonrası (6 ve 12. aylarda) solunum fonksiyon testleri, 6 dk. yürüme mesafesi, modifiye Medikal Araştırma Kurulu dispne skorları ve akciğerin karbonmonoksit difüzyon kapasitesi testleri yapıldı.

Bulgular: Her loba yerleştirilen ortalama koil sayısı 12.0±3.8 idi. Hastaların solunum fonksiyon testleri ve yaşam kalitesinde tedaviden 12 ay sonra anlamlı iyileşmeler izlendi. Tedavi öncesi skorlara kıyasla, tedaviden sonra 12. ayda modifiye Medikal Araştırma Kurulu dispne skorları ile değerlendirildiği üzere dispne açısından anlamlı bir fark gözlendi ($p<0.05$). Tedaviden altı ay sonra solunum fonksiyon testlerinde bir değişiklik görülmezken, 12. ayda anlamlı bir değişiklik izlendi ($p<0.05$).

Sonuç: Bronkoskopik akciğer hacim küçültme koil tedavisi, solunum fonksiyon test sonuçlarında, modifiye Medikal Araştırma Kurulu dispne skorlarında ve 6 dk. yürüme mesafesinde anlamlı iyileşmeler ile birlikte ağır amfizemi olan hastalar için ümit verici bir yöntem olarak görünmektedir.

Anahtar sözcükler: Bronkoskopik akciğer hacim küçültme, kronik obstrüktif akciğer hastalığı, koil, amfizem.

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Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory disease of the respiratory tract and lungs, and is the third leading cause of death worldwide.[1] It is an irreversible and progressive disease which shares many characteristics of other diseases, such as chronic bronchitis and emphysema.[1] Emphysema is caused by inhalation of cigarette smoke and toxic agents, as well as genetic factors such as α1-antitrypsin deficiency, and is characterized by parenchymal destruction of the lung.[2] Lung parenchymal tissue is destroyed in severe emphysema, leading to decreased lung elasticity, loss of elastic recoil, and collapse of the expiratory airway. These changes result in significant decreases in lung function, exercise capacity, and quality of life of patients.[3]

Treatment options for patients with severe emphysema include smoking cessation, proper nutrition, bronchodilator drugs, vaccines, anti-inflammatory agents, pulmonary rehabilitation, oxygen use, and ventilator support, where necessary. If these treatments fail, surgical interventions, such as lung volume reduction surgery (LVRS) and lung transplantation, can be considered.[3] Although LVRS has been reported to improve lung function, quality of life, and survival in a particular group of patients with advanced heterogeneous upper lobe emphysema, the procedure is associated with significant postoperative complications and high mortality (7.9% after 90 days).[4] The recently developed bronchoscopic lung volume reduction (BLVR) procedures have shown promising results compared to standard medical care, and are safe alternatives to LVRS.[1] Regarding the treatment of severe emphysema, there are several different bronchoscopic treatment alternatives, such as bronchoscopic thermal vapor ablation,[5] lung volume reduction coils,[6] and endobronchial valves.[7] In addition, new airway treatments are being developed, such as metered liquid nitrogen cryospray[8] and denervation of a specific lung lobe.[9] All of these treatments aim to reduce hyperinflation, which causes dyspnea and decreased exercise capacity in emphysema, and to improve exercise performance and quality of life.[7,10]

The aim of BLVR coil (BLVR-C) therapy is for the coils to cause contraction in the destroyed emphysematous lung parenchyma, and to ensure airflow to the healthier parts of the lung. As a result of this contraction, hyperinflation decreases and diaphragmatic efficiency increases. In addition, since the coil can contract the destroyed parenchyma in severe emphysematous segments, elasticity and recoil may be restored to the entire lung.[11] The BLVR-C therapy has been reported to improve the results of some pulmonary function tests, such as residual volume (RV), forced expiratory volume in 1 sec (FEV1), COPD Assessment Test (CAT), modified Medical Research Council (mMRC) dyspnea scores, and 6-min walking distance (6MWD).[12-15] However, there is a limited number of studies reporting long-term results. In the present study, we, therefore, aimed to evaluate the mid- and long-term results of patients treated with BLVR-C.

PATIENTS AND METHODS

This single-center, prospective study was conducted at Kocaeli University, Faculty of Medicine, Department of Thoracic Surgery between February 2016 and March 2019. A total of 20 advanced emphysema patients (19 males, 1 female; mean age: 65.2±5.2 years; age range, 52 to 73 years) who underwent BLVR-C were included in the study. Inclusion and exclusion criteria for this study were similar to those previously reported in the literature.[15] Inclusion criteria were as follows: *(i)* post-bronchodilator FEV1% (15 to 45%) predicted; *(ii)* RV >175% predicted; *(iii)* 6MWD >140 m; *(iv)* partial carbon dioxide pressure (PCO_2) <55 mmHg; *(v)* bilateral emphysema detected by

Figure 1. Chest X-ray showing the bilateral endobronchial coils in upper lobe.

Table 1. Demographic and clinical characteristics of patients

Variables	n	%	Mean±SD	Median	Min-Max
Age (year)			65.2±5.2	66	52-73
Sex					
Male	19	95			
Female	1	5			
Body mass index (kg/m^2)			21.34±5.33	18.87	16.53-39.33
COPD time (year)			9.78±5.89	10	3-30
Coils per procedure			12.0±3.8	11	7-20
Coil 100 mm (n=20)			7.6±3.8	7	2-17
Coil 125 mm (n=16)			5.1±2.4	4.5	1-10
Coil 150 mm (n=1)			-	2	2-2
Coil localization*					
Right upper	14	73.7			
Left upper	4	21.1			
Left under	1	5.3			
Right upper (6th month)	1	5.3			
Left upper (12th month)	1	5.3			
Left under (12th month)	1	5.3			
Comorbidity					
Yes	18	90			
No	2	10			
Comorbidities* (n=18)					
Hypertension	12	66.7			
Gastroesophageal reflux	8	47.1			
Coronary artery disease	6	35.3			
Diabetes mellitus	4	23.5			
Arrhythmia	2	11.8			
Depression	2	11.8			
Atrial fibrillation	1	5.9			
Peptic ulcer	1	5.9			
Mitral stenosis	1	5.9			
Abdominal aortic aneurysm	1	5.9			
Gall stone	1	5.9			
Anxiety	1	5.9			
mMRC*					
Pretreatment (n=20)					
3	5	25			
4	15	75			
6 months (n=18)					
2	2	11.1			
3	15	83.3			
4	1	5.6			
12 months (n=16)					
2	8	50			
3	7	43.7			
4	1	6.3			

SD: Standard deviation; COPD: Chronic obstructive pulmonary disease; mMRC; modified Medical Research Council; * Each category is evaluated within itself.

computed tomography; and *(vi)* no smoking for >8 weeks prior to enrollment. Exclusion criteria were as follows: *(i)* post-bronchodilator change of >20% of FEV1; *(ii)* frequent attacks of COPD exacerbation (>2 hospital admissions per year); *(iii)* pulmonary artery systolic pressure (PASP)

>50 mmHg; *(iv)* bullous lesions more than 4 cm in diameter and take up more than one-third of a single lung; *(v)* bronchiectasis; *(vi)* lung cancer; or *(vii)* use of oral anticoagulants.

Bronchoscopic lung volume reduction with RePneu® coils (PneumRx Inc., Mountain View, CA, USA) was performed as previously described,[15] with the aim of placing 10 coils in each target lobe in the lungs. Three different coil sizes (100 mm, 125 mm, 150 mm) were applied under general anesthesia through the working channel of a flexible video bronchoscope, passing through a single lumen intubation tube with fluoroscopic guidance. Coils were implanted in both lungs of four patients, and in one lung in the other 16 patients (Figure 1). All cannulated lower airways suitable for inserting a coil were treated.

Demographic and clinical characteristics of the patients, baseline, six-month, and 12-month post-bronchodilator pulmonary function tests, pre- and post-treatment 6MWD, mMRC scores, and diffusing capacity of the lungs for carbon monoxide (DLCO) test results were recorded.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were presented in mean ± standard deviation (SD), median (min-max), or number and frequency, where applicable. Descriptive data were presented in mean ± standard error (SE) for mixed effect linear model results. Comparisons of blood values according to measurement times were made with mixed-effect linear models, as there was missing data in the 6- and 12-month measurement values. If a difference was found between the measurements, the data were evaluated with a Bonferroni corrected multiple comparison test. The missing data were estimated with the limited restricted maximum likelihood method. A p value of <0.05 was considered statistically significant.

RESULTS

The demographic and clinical data of the patients are presented in Table 1. Twelve of the patients (66.7%) had hypertension, eight (47.1%) had gastroesophageal reflux, six (35.3%) had coronary artery disease, and four (23.5%) had diabetes mellitus. A total of 205 coils were placed (138 in the upper right lobe, 48 in the upper left lobe, and 19 in the lower left lobe). A mean number of 12.0±3.8 coils was placed in each lobe. No complications were observed during the procedure. However, two patients died from myocardial infarction on Days 7 and 21 following the procedure, respectively and two patients died seven and nine months after the procedure, respectively.

Before treatment, 15 (75%) patients had an mMRC score of 4 and five (25%) had an mMRC score of 3. At 6 and 12 months after the treatment, only one (5.6%) patient had an mMRC score of 4. Fifteen (83.3%) patient had an mMRC score of 3 six months after

Table 2. Pulmonary functions, exercise capacity, 6MWD and DLCO in pre-treatment period and six months and 12 months after lung volume reduction-coil treatment for patients

	Pretreatment		6 month		12 month		Descriptive statistics*	
Variables	$\bar{\chi}$	sh	$\bar{\chi}$	sh	$\bar{\chi}$	sh	F	p
FVC	2.06[ab]	0.13	2.02[a]	0.17	2.29[b]	0.16	**4.851**	**0.023**
FVC%	57.00	3.46	54.70	4.17	62.11	4.26	2.903	0.085
FEV1	0.80[a]	0.05	0.82[ab]	0.07	1.02[b]	0.09	**8.654**	**0.003**
FEV1%	27.74[a]	1.89	28.72[ab]	2.23	33.67[b]	2.84	**5.884**	**0.013**
FEV1/FVC	40.11[a]	2.20	43.70[b]	2.65	43.14[b]	2.28	**5.721**	**0.016**
FEF 25-75	0.38[a]	0.07	0.43[b]	0.08	0.56[b]	0.12	**12.241**	**0.009**
FEF 25-75%	10.63[a]	0.80	12.69[b]	1.10	14.92[b]	1.25	**12.318**	**0.001**
DLCO	1.56	0.21	1.64	0.16	1.86	0.18	3.411	0.057
DLCO%	19.26	3.00	20.39	2.40	22.95	2.68	3.118	0.070
6MWT (m)	208.58[a]	19.87	234.35[b]	20.07	265.46[c]	20.11	24.410	**<0.001**

FVC: Forced vital capacity; FEV1: Forced expiratory volume in 1 sec; FEF: Forced expiratory flow; DLCO: Diffusing capacity of the lungs for carbon monoxide; 6MWT: Six minute walking test; * Mixed-effect linear model results; The a, b, and c superscript show the difference between measurements. Measurements with the same letters are not statistically different from each other.

treatment, and seven (43.7%) had an mMRC score of 3 12 months after treatment.

While there was no change in forced vital capacity (FVC) values six months after treatment, a significant improvement was observed at 12 months (p=0.023). While FEV1 and FEV1% values were similar at six months after treatment compared to pre-treatment values, these values were improved significantly at 12 months (p=0.003 and p=0.013, respectively). Compared to pre-treatment values, FEV1/FVC, forced expiratory flow (FEF) 25-75, FEF 25-75% and 6MWD values improved 6 and 12 months after treatment (p=0.016, p=0.009, p=0.001, and p<0.001, respectively). The differences between the groups for the DLCO and DLCO% values were not significant (p=0.057 and p=0.070, respectively).

DISCUSSION

Emphysema is characterized by a permanent and abnormal expansion of the airways distal to the terminal airways. Tissue damage caused by chronic inflammation in emphysema leads to a decrease in elastic recoil, progressive hyperinflation, and early closure of small airways, all of which may result in insufficient ventilation.[16] As a result, the lung becomes unable to stretch and, thus, cannot function within the rigid rib cage. Exercise capacity decreases, as deep breathing becomes difficult. Breathing itself requires more work and, therefore, the respiratory muscles become tired. The patient's quality of life is impaired due to chronic shortness of breath, and exercise capacity is decreased.[16,17]

A comprehensive approach should be taken for the proper treatment of emphysema, including smoking cessation, optimal nutrition, pulmonary rehabilitation, and vaccination. In addition, pharmacological treatments consisting of beta-2 agonists and anticholinergic agents are practiced almost worldwide.[17] However, patients with severe emphysema do not experience improved breathing, despite their optimal medical treatments (i.e., anticholinergic drugs, beta-2 agonists, long-acting bronchodilators, inhaled steroids, and mucolytics), and there is no improvement in their quality of life.[16,18]

Patients' symptoms, exercise tolerance, and quality of life improve more with surgical treatments (i.e., LVRS) than with medical treatments alone. However, it has been reported that there is an increase in mortality and significant morbidity in patients undergoing LVRS. This has led to the development of minimally invasive lung volume reduction procedures.[11] Innovative therapeutic strategies have been developed in the past decade to reduce lung volume. As a result, emphysema phenotyping is required and emphysema patients require personalized treatments. The gold-standard approach is following a multidisciplinary team to identify which lung volume reduction intervention to apply to each individual patient.[17]

For patients with severe emphysema who do not benefit from medical treatments, bronchoscopic reduction of lung volume may be an appropriate treatment option.[17,19] Different endoscopic lung volume reduction methods have been developed, all of which can be applied for different emphysema phenotypes. Of these, endobronchial one-way valve therapy and endobronchial coil treatment have been the most extensively studied.[2,3,8,20] These treatment methods have been recently adopted in the Global Initiative for Chronic Obstructive Lung Disease (GOLD) recommendations for COPD.[2] The coil treatment aims to increase the true lung volume by compressing the emphysematous lung parenchyma and causing less hyperinflation.[21] In addition, the coils reduce airflow toward targeted segments of the lung, thereby ensuring that the airflow is redistributed to the healthier areas of the lung.[22] Finally, as a result of treating emphysematous areas, the function of the diaphragm increases.[23,24]

In the first pilot study on coil treatment in patients with COPD, 11 patients were treated with six coils per lobe, and both their applicability and safety were evaluated; however, no explanation was given regarding the effectiveness of the coils.[25] In a study conducted using the second-generation of coils, 16 patients were treated, and the safety, feasibility, and effectiveness of the procedure were shown by increasing the number of coils per treated lobe to 10 to 12.[15] At six months after treatment, improvements were observed in the St. George Respiratory Questionnaire (SGRQ), RV, 6MWD, and FEV1. In the Endobronchial Coils for the Treatment of Severe Emphysema with Hyperinflation (RESET) study, which was the first randomized-controlled trial to investigate coils, 23 patients (two unilateral and 21 bilateral) treated with coils were compared with 23 patients who received conservative medical treatment.[14] The results of this study indicated that the improvement in FEV1 three months after the coil treatment increased significantly over the medical treatment group. Similarly, a study conducted in another center reported significant improvements in

the FEV1 (1150 mL), RV (214.5%), 6MWD (148 m), SGRQ (210.5), and CAT score (27.5) of patients six months after BLVR-C treatment.[26] Bostancı et al.[27] reported a significant improvement in FEV1, RV, and 6MVD six months after treatment with BLVR-C, showing a significant improvement in quality of life as measured by mMRC, CAT, and Hospital Anxiety and Depression Scale scores. In a multi-center study in which 34 patients were treated with BLVR-C, there were significant improvements in the respiratory function (both FEV1 and RV) 12 months after treatment.[28] Likewise, Hartman et al.[29] reported a significant improvement in FEV1 12 months after BLVR-C treatment. In the current study, FVC, FEV1, and FEV1% did not improve six months after treatment, while but significant improvements were observed at 12 months. These results are not consistent with the findings of the aforementioned studies, indicating that the values improved at six months.[15,26,27] However, these results are in line with the studies showing that the values improved 12 months after treatment.[29] However, in the current study, mMRC, FEV1/FVC, FEF 25-75, FEF 25-75%, and 6MWD values started to improve at six months after treatment, while getting even better at 12 months. Therefore, we believe that the 12-month results in the current study are satisfactory and seem to be parallel with the results of the studies mentioned above.

Nonetheless, there are some limitations to this study. First, this is an analysis of a small group of patients selected from a single centre. A second limitation is the absence of a control group, the relatively low number of patients receiving bilateral treatment, and the short follow-up period.

In conclusion, our study results showed a significant improvement in the respiratory functions, modified Medical Research Council dyspnea scores, and 6-min walking distance 12 months after bronchoscopic lung volume reduction coil treatment. Based on these findings, the bronchoscopic lung volume reduction coil treatment seems to be promising for severe emphysema patients. However, additional data regarding the efficacy and safety of reducing lung volume in emphysema with this treatment are needed in randomized clinical trials.

Ethics Committee Approval: The study protocol was approved by the Kocaeli University Faculty of Medicine Ethics Committee (date: 03.07.2020, no: 2020/210). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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