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Endobronchial coils in treatment of advanced emphysema: A single center experience

İleri amfizem tedavisinde endobronşiyal sarmallar: Tek merkez deneyimi

Korkut Bostancı[1], Zeynep Bilgi[1], Hakan Ömercikoğlu[1], Çağatay Çetinkaya[1], Şehnaz Olgun Yıldızeli[2], Mustafa Yüksel[1], Davor Stamenovic[3]

Institution where the research was done:
Marmara University Faculty of Medicine, İstanbul, Turkey

Author Affiliations:
[1]Department of Thoracic Surgery, Marmara University Faculty of Medicine, İstanbul, Turkey
[2]Department of Chest Diseases, Marmara University Faculty of Medicine, İstanbul, Turkey
[3]Department of Thoracic Surgery, St Vicentius Kliniken, Karlsruhe, Germany

ABSTRACT

Background: This study aims to present our experience with endobronchial coils in patients who underwent endobronchial lung volume reduction due to advanced emphysema.

Methods: The study included 46 patients (45 males, 1 female; mean age 61.7±8 years; range, 43 to 80 years) who underwent endobronchial lung volume reduction with endobronchial coils for advanced emphysema. Patients' age, gender, pulmonary function tests, post-treatment morbidity, mortality, pre- and post-treatment (6 months) six-minute walking distance, modified Medical Research Council dyspnea scores, chronic obstructive pulmonary disease assessment test and Hospital Anxiety and Depression Scale scores were recorded.

Results: Patients had an average of 65 pack/year smoking history. An average of 11 (range, 9-15) coils were placed per lobe (right upper lobe=35, left upper lobe=19, right lower lobe=2, left lower lobe=4). Mean follow-up duration was 12.6 months (±5.6 months). Post-treatment forced expiratory volume in one second, residual volume and six-minute walking distance values were improved with statistical significance. Also, significant improvement was seen in quality of life, quantified by modified Medical Research Council, chronic obstructive pulmonary disease assessment test and Hospital Anxiety and Depression Scale scores. While no immediate major postoperative complications occurred, three patients developed chronic obstructive pulmonary disease exacerbation, two developed pneumonia, and one developed recurrence of previous neurologic disorder within 30 days.

Conclusion: Endobronchial coil administration provides lower morbidity and mortality compared to lung volume reduction surgery as well as significant improvement in pulmonary functions and quality of life in selected patients with advanced emphysema.

Keywords: Bronchoscopy; chronic obstructive pulmonary disease; emphysema; lung volume reduction.

ÖZ

Amaç: Bu çalışmada ileri amfizem nedeniyle endobronşiyal akciğer hacim küçültme uygulanan hastalarda endobronşiyal sarmal ile deneyimimiz sunuldu.

Çalışma planı: Çalışmaya ileri amfizem nedeniyle endobronşiyal sarmal ile endobronşiyal akciğer hacim küçültme uygulanan 46 hasta (45 erkek, 1 kadın; ort. yaş 61.7±8 yıl; dağılım, 43-80 yıl) dahil edildi. Hastaların yaşı, cinsiyeti, pulmoner fonksiyon testleri, tedavi sonrası morbiditesi, mortalitesi, tedavi öncesi ve sonrası (6 ay) altı dakika yürüme mesafesi, modifiye Medikal Araştırma Konseyi dispne skorları, kronik obstrüktif akciğer hastalığı değerlendirme testi ve Hastane Anksiyete ve Depresyon Ölçeği skorları kaydedildi.

Bulgular: Hastaların ortalama sigara kullanım öyküleri 65 paket/yıl idi. Lob başına ortalama 11 (dağılım, 9-15) sarmal yerleştirildi (sağ üst lob=35, sol üst lob=19, sağ alt lob=2, sol alt lob=4). Ortalama takip süresi 12.6 ay (±5.6 ay) idi. Tedavi sonrası birinci saniye zorlu ekspirasyon volümü, rezidüel volüm ve altı dakika yürüme mesafesi değerleri istatistiksel olarak anlamlı şekilde düzeldi. Yaşam kalitesinde de modifiye Medikal Araştırma Konseyi, kronik obstrüktif akciğer hastalığı değerlendirme testi ve Hastane Anksiyete ve Depresyon Ölçeği skorlarıyla ölçümlenen belirgin düzelme görüldü. Ameliyatın hemen sonrasında majör komplikasyon yaşanmazken 30 gün içinde üç hastada kronik obstrüktif akciğer hastalığı alevlenmesi, iki hastada pnömoni ve bir hastada önceki nörolojik hastalığın nüksü gelişti.

Sonuç: Endobronşiyal sarmal uygulaması ileri amfizemli seçilmiş hastalarda akciğer hacim küçültme cerrahisi ile karşılaştırıldığında daha düşük morbidite ve mortalite ile beraber pulmoner fonksiyonlarda ve yaşam kalitesinde belirgin düzelme sağlar.

Anahtar sözcükler: Bronkoskopi; kronik obstrüktif akciğer hastalığı; amfizem; akciğer hacim küçültme.

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Correspondence: Korkut Bostancı, MD. Marmara Üniversitesi İstanbul Pendik Eğitim ve Araştırma Hastanesi Göğüs Cerrahisi Anabilim Dalı, 34899 Pendik, İstanbul, Turkey. Tel: +90 532 -324 12 85 e-mail: kbostanci@marmara.edu.tr

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Chronic obstructive pulmonary disease (COPD) is one of the leading causes of death worldwide. With wider availability of healthcare and better overall medical management, an increasing number of patients are being followed-up for advanced COPD and various other comorbidities.[1,2] Medical management is effective for physiological relief and slowing down maladaptive processes; however, there is a significant subset of advanced emphysema patients who report serious dyspnea despite optimal management. Due to very stringent patient selection criteria, high morbidity and limited availability of lung volume reduction surgery (LVRS) and lung transplantation, newer endoscopic treatment modalities are considered "to go" options for palliation and stabilization of advanced emphysema patients.[3,4]

Various endobronchial lung volume reduction (ELVR) techniques have been proposed for endobronchial treatment of advanced emphysema with patient selection criteria mainly derived from LVRS, reporting encouraging results, showing feasibility and safety.[1,2,5-11] Most of the literature to date focuses on endobronchial valves and coils.[6,8-10,12-17] Endobronchial valves were the first reported and investigated solutions, but their effectiveness can be hampered by collateral ventilation of the targeted lobe and patient's individual anatomical limitations regarding large airways.[6,8,12] Up to 67% of advanced emphysema patients are estimated to have collateral ventilation of their targeted lobe, leaving them largely unsuitable for endobronchial valves.

Endobronchial coils were first proposed in 2009, as a solution for collateral ventilation problem in endobronchial valves, with demonstrated clinical safety and moderate clinical improvement.[1,18] Post-marketing studies revealed encouraging results in small case series and a few multi-institutional studies show improved parameters including forced expiratory volume in one second (FEV_1), residual volume (RV), six-minute walk distance (6MWD), modified Medical Research Council (mMRC) dyspnea scores, COPD Assessment Test (CAT) and Hospital Anxiety and Depression Scale (HADS) scores and St. George's Respiratory Questionnaire.[9,10,13-17] Long-term results for most of those studies are expected. Therefore, in this study, we aimed to present our experience with endobronchial coils in patients who underwent ELVR due to advanced emphysema.

PATIENTS AND METHODS

Forty-six patients (45 males, 1 female; mean age 61.7±8 years; range, 43 to 80 years) who underwent ELVR with coils (ELVR-C) were recorded in a prospective database between January 2012 and December 2014 at Marmara University Pendik Hospital, Thoracic Surgery Clinic. The study protocol was approved by the Marmara University Medical Faculty Ethics Committee (No. 09.2015.129). A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Advanced emphysema patients who were judged as candidates were referred to our clinic by treating physicians and were considered for inclusion. Patients having both heterogeneous and homogeneous emphysema were all included in the study. All enrolled patients were in stage 3 or 4 of Global Initiative for Chronic Obstructive Lung Disease, and they were intended to be treated bilaterally. The inclusion and exclusion criteria were similar to those previously reported in the literature.[9,17] Briefly, the inclusion criteria were: *(i)* post-bronchodilator FEV_1 of 15%-45%; *(ii)* RV >175%; *(iii)* 6MWT >140 m; *(iv)* partial pressure of carbon dioxide <55 mmHg; *(v)* bilateral emphysema as detected via computed tomography; and *(vi)* smoking cessation for >8 weeks prior to the primary intervention. The exclusion criteria were: *(i)* post-bronchodilator change in FEV_1 >20%; *(ii)* frequent COPD exacerbation episodes (>2 hospitalizations per year); *(iii)* pulmonary artery pressure >50 mmHg; *(iv)* giant bullae >1/3 of a single lung volume; *(v)* bronchiectasis; *(vi)* lung cancer; or *(vii)* use of an oral anticoagulant.

History, post-bronchodilator pulmonary function tests (Body Box 5500; Medisoft, Sorinnes, Belgium), pre- and post-treatment 6MWD, pre- and post-treatment mMRC scores, CAT and HADS questionnaires were recorded.

Endobronchial lung volume reduction with RePneu coils (PneumRx Inc., Mountain View, California, USA) was performed as previously described.[9,17] All patients were intended to receive 10 coils in the target lobes of each lung in two sequential sessions. Three sizes of coils were available (100 mm, 125 mm, 150 mm) and they were applied under general anesthesia through the working channel of a flexible videobronchoscope passed through the single lumen intubation tube, with fluoroscopic guidance. All cannulated subsegmental airways that were suitable for placement of a coil were treated. The procedural duration, number of coils used during the procedure, and postoperative complications were recorded. Following recovery from anesthesia, patients stayed in the hospital for one night for observation, having a control chest X-ray to rule out any pneumothorax.

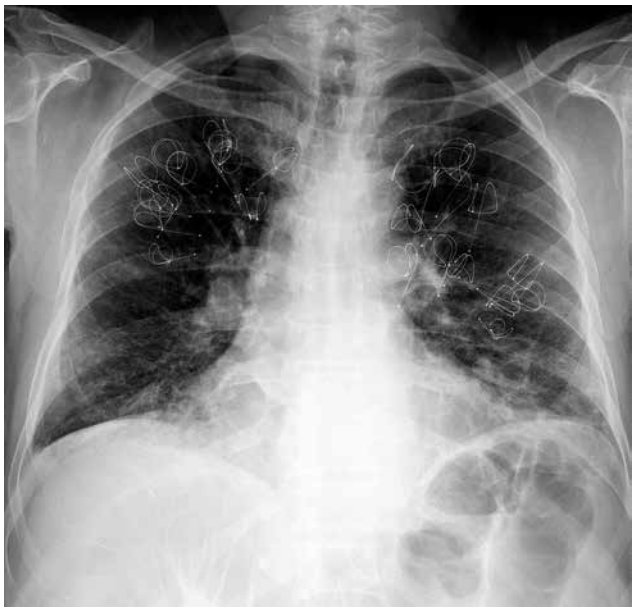

Figure 1. Patient with bilateral endobronchial coils in his upper lobes.

Bilateral treatments were performed as sequential procedures for safety reasons. Contralateral side was treated one to three months after the initial procedure if the patient was medically stable, compliant to the therapy and follow-up (Figure 1).

Patients were followed-up at postoperative first week, first month, sixth month and also referred for further evaluation at our institution's pulmonology department with periodic phone calls. Follow-up quality of life (QoL) questionnaires were gathered.

Statistical analysis

Data were analyzed using the IBM SPSS version 20.0 program (IBM Corp., Armonk, NY, USA). Descriptive statistics were presented as mean and standard deviation. Wilcoxon test and t-test for independent samples were used for recurring data (pre- and postoperative results).

RESULTS

Forty-six patients underwent 60 ELVR-C procedures. Fourteen patients had bilateral treatment. Smoking history varied between 20-150 pack/year (mean 65.8±28.9). Comorbidities and emphysema types and procedure data were summarized in Table 1.

Mean procedural duration was 58 min (range, 30-120 min). There was no adverse events during the procedure, also no failure to extubate or unplanned intubation during the hospital stay of the procedure.

A total number of 662 coils were placed in 60 procedures. In total, an average of 11 (9-15) coils were inserted per lobe (right upper lobe=35, left

Table 1. Demographics, comorbidities, emphysema type and procedure data of patients

	n	%	Mean±SD
Age (year)			61.7±8.0
Gender			
Male	45		
Female	1		
Comorbidities			
Diabetes mellitus	2		
Coronary artery disease	17		
Hypertension	7		
Epilepsy	1		
Smoking (pack year)			65.8±28.9
Emphysema type			
Homogeneous	24	52	
Heterogeneous	22	48	
Laterality of the procedure			
Bilateral	14	30	
Unilateral	32	70	

SD: Standard deviation.

Table 2. Pulmonary functions and exercise capacity in pre-treatment period and six months after last lung volume reduction-coil treatment for patients who were treated either unilaterally or bilaterally

	Pre-treatment	Post-treatment	
	Mean±SD	Mean±SD	*p*
Forced expiratory volume in one second	0.8±0.3	0.9±0.3	0.001
Forced expiratory volume in one second (%)	28.1±9.1	31.9±13.3	0.001
Forced vital capacity	2.1±0.7	2.0±0.7	0.33
Forced vital capacity (%)	57.6±19.4	56.6±21.1	0.37
Residual volume (%)	204.1±25.3	195.1±24.1	0.001
Six-minute walking distance	250±81.9	303.8±104	0.001

SD: Standard deviation.

Table 3. Quality of life scores in pre-treatment period and six months after last lung volume reduction-coil treatment for patients who were treated either unilaterally or bilaterally

	Pre-treatment	Post-treatment	
	Mean±SD	Mean±SD	*p*
Modified Medical Research Council score	3.1±0.8	1.8±1.0	0.001
CAT score	24.5±6.8	17.6±8.4	0.001
Anxiety score	10.1±3.6	6.9±4.7	0.001
Depression score	9.4±3.6	6.8±4.4	0.001

SD: Standard deviation; CAT: Chronic obstructive pulmonary disease assessment test.

upper lobe=19, right lower lobe=2, left lower lobe=4). An average of 10.8 coils were placed per lobe on the first procedure. For the second procedure, 11.4 coils were placed, showing a tendency for increased number of airways successfully cannulated, while this finding did not reach statistical significance. The upper lobes were treated more than the lower lobes (87.5%), while the right upper lobe comprised the most preferred treatment site (58%). Post-treatment FEV_1, RV and 6MWD values were improved with statistical significance (Table 2). There was also a distinct beneficial quality of life effect, quantified by mMRC, CAT and HADS scoring questionnaires (Table 3). Those parameters were found to be changing incrementally during the treatment periods for patients who had bilateral procedures. None of the parameters studied was significantly affected by the emphysema type (homogeneous vs heterogeneous) or the laterality of the procedure (for patient who had unilateral treatment).

There was no 30 or 90-day mortality. Postoperative complications were mild; one patient who had preexisting epilepsy experienced a seizure, three COPD exacerbations and two pneumonia cases were appropriately treated. One patient died at postoperative sixth month due to immediate complications of lung transplant. None of our patients developed pneumothorax during or after the procedure. Two patients died at seventh and eighth months due to COPD exacerbation, pneumonia and sepsis. The last patient's intensive care unit (ICU) stay was complicated due to pneumothorax under mechanical ventilation, which required a chest tube, draining massive air leak.

DISCUSSION

Chronic obstructive lung disease is one of the leading causes of death worldwide. Advances in basic and clinical science lead to an increased understanding of the pathophysiology of the disease and maladaptive changes. Optimal medical management leads to increased survival of COPD patients but does little to alleviate the anatomic changes, thus a decline in life expectancy and QOL is inevitable. Lung volume reduction surgery offers reasonable palliation of those changes with acceptable mortality and morbidity but is only

definitely effective in patients with upper lobe predominant emphysema and low exercise capacity, leaving a larger pool of patients without any option besides medical management.[3,18] For patients with advanced emphysema, there is a great need for a modality of treatment that can significantly improve QoL, without inducing significant morbidity and mortality, and that is potentially available for the majority of patients. Endobronchial lung volume reduction is important in terms of providing improved survival and better QoL for a larger patient pool as it is minimally invasive and has a much better complication profile when compared to LVRS.[1,5,11,18]

Endobronchial lung volume reduction with coils, which is reported to be safe and associated with good results, can be a preferred modality of treatment for patients with advanced heterogeneous and homogeneous emphysema.[9-11,17,18]

The beneficial effect of ELVR-C may arise from the compression of the most damaged areas of the lung due to advanced emphysema and expansion of the relatively healthier parenchyma. Additional benefits may include the reduction in dynamic airway collapse, the reestablishment and improvement of elastic recoil, and the increase in the compliance of the diaphragm and the chest wall.[9,17]

In our study, ELVR-C treatment led to improvements in pulmonary functions, exercise capacity and quality of life at six months after the treatment. Post-treatment FEV_1, RV and 6MWD values were improved with statistical significance, also the mMRC, CAT, and HADS scores.

The RePneu Endobronchial Coils for the Treatment of advanced emphysema with Hyperinflation (RESET) study compared patients treated with coils (2 unilateral and 21 bilateral) with 23 patients who received conservative medical treatment. These patients were followed for up to three months. The RESET study reported an increase of 114.1% in FEV_1 in patients having ELVR-C and 13.5% in those receiving standard medical care, showing a statistically significant difference.[10] Slebos et al.[9] performed 28 ELVR-C procedures in 16 patients (4 unilateral, 12 bilateral) and observed improvements both in FEV_1 and RV after a six-month follow-up. In a multicenter study conducted by Deslee et al.,[19] 34 patients were treated and followed for up to 12 months. Those patients experienced significant improvement in pulmonary functions (both in FEV_1 and RV). Hartman et al.[20] conducted a three-month follow-up study and followed 35 patients for one year, 27 patients for two and 22 patients for three years. The patients showed a significant improvement in FEV_1 at the end of the first year. Forced expiratory volume in one second decreased during the second and third years, respectively, but remained higher than the baseline values. The results in our study are satisfactory both for functional and QoL parameters, and seem to be in parallel with the studies mentioned above.

In our study, postoperative complications were mild and all events resolved with regular medical care, and no noninvasive ventilatory support or ICU admissions were required. Lower morbidity and mortality rates are two of the major advantages of ELVR when compared to LVRS. Being able to treat patients with homogeneous emphysema is another significant advantage of endobronchial coils when compared to not only LVRS but also the other ELVR techniques, such as valves. Our study exhibits that ELVR-C is effective in both types of emphysema, either homogeneous or heterogeneous.

There are currently several ELVR techniques in use, endobronchial one-way valves being the most commonly used in daily practice. These valves, however, were designed for segmental and lobar airway closure, and only work when there is no, or only very limited, collateral ventilation.[21-23] As endobronchial coils reduce the lung volume not by causing atelectasis but by bending the airway and attached parenchyma, their effect is independent of collateral ventilation, thus patients having ELVR-C may have the advantage of experiencing more pronounced benefits even if they have incomplete fissures.[24]

This study has some limitations. The total number of patients and the number of bilaterally treated patients are relatively low, and also the follow-up period can be considered as being short.

In conclusion, endobronchial lung volume reduction with endobronchial coils offers satisfactory advanced emphysema palliation and stabilization for appropriate patients with lower morbidity/mortality than conventional lung volume reduction surgery. Endobronchial coiling provides significant improvement in quality of life and comparable improvements in objective functional measurements.

Declaration of conflicting interests

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