

The Efficacy of Lung Volume Reduction Coil Treatment in Patients with Severe Chronic Obstructive Pulmonary Disease (COPD) Type II Respiratory Failure

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Purpose: Emphysema is a progressive and irreversible disease, proceeding with the decrease in elastic recoil which is connected to tissue damage caused by chronic inflammation. Lung volume reduction coil (LVRC) method in patients with an advanced level of emphysema and irresponsive to medical treatment is shown to provide increase in lung volumes and exercise capacity, decrease in dyspnea, and increase in quality of life. The purpose of this study is to reveal that LVRC treatment is also efficient in severe COPD patients with hypercapnic respiratory failure.

Patients and Methods: Eleven cases with severe COPD and emphysema were included in the study. LVRC treatment method was applied in upper lobes of both lungs in patients with severe COPD ($FEV1 < 45\%$) and Type-2 respiratory insufficiency (PCO_2 55–80 mmHg) who were having medical treatment and CPAP treatment. The patients were followed up for a period of twelve months using arterial blood gas analysis.

Results: Beginning with the first month of the LVRC treatment, PCO_2 levels were found to be significantly decreased in all patients using arterial blood gas analysis.

Conclusion: LVRC method can provide physiological and functional recovery and progress in quality of life in severe COPD cases. It is demonstrated that LVRC treatment caused significant decreases in carbon dioxide levels as well as causing improvement in life quality and respiratory function tests in the patients with hypercapnic respiratory failure.

Keywords: lung volume reduction coil treatment, severe chronic obstructive pulmonary disease, type II respiratory failure

Introduction

Chronic obstructive pulmonary disease (COPD) is one of the major causes of morbidity and mortality worldwide and will be the third main cause of death by 2020.¹ It is estimated that 4.5 million people will die due to the complications caused by COPD until 2030.²

It is characterized by structural changes in lung parenchyma with consecutive reduction of gas exchange surface, loss of elastic recoil and dynamic hyperinflation leading to dyspnea, limited exercise capacity and reduced quality of life. In the advanced stages, it leads to respiratory failure: hypoxemia and eventually chronic hypercapnic respiratory failure. Hyperinflation is a major component in the development of chronic hypercapnic respiratory failure as it is associated with an

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increased ventilatory workload, with key pathophysiological elements being the loss of elastic recoil as well as geometrical changes of diaphragm and thorax compromising the function of the diaphragmatic, intercostal and accessory muscles.³ Correspondingly, increasing dyspnea, decrease in exercise performance, decreases in physical activity and life quality occur in the patients.⁴ The purposes of medical treatment in these patients are to basically ease symptoms and to reduce exacerbations through inhaled bronchodilators, antiinflammatory drugs, appropriate nutrition, rehabilitation and oxygen treatment.⁵ Currently, pharmacologically present treatment options have limited efficacy in the patients with severe COPD. There are invasive surgical procedures such as lung volume reduction surgery and lung transplantation only in a very few patient subgroup with COPD.^{6,7} The benefits of volume reduction surgery performed on the purpose of reducing volume in such group of patients are demonstrated in National Emphysema Treatment Trial:(NETT) study. In addition to it, NETT demonstrates that severe cardiopulmonary complications develop in these patients and same successful results are not achieved in all of the patients with severe emphysema.^{8–11}

Therapeutic interventions applied in patients with emphysematous COPD phenotype in bronchoscopy in recent years have effect by reducing hyperinflation.¹¹ Endobronchial valve (EBV) is the most comprehensively researched technique in bronchoscopic lung volume reduction site. It especially demonstrates significant clinical recoveries in the presence of emphysema and intact fissure mainly in the upper lobe.^{12,13} In addition to it, successful clinical results of EBV treatment are only possible in the patients with no interlobar collateral ventilation and when one-way valves are placed to completely close the whole air route in target lobe, it may be quite difficult due to local anatomy and in technical terms in the absence of important experience with these devices.^{12–15}

It is predicted that only approximately 33% of severe emphysema patients do not have collateral ventilation between target and adjacent lobes and therefore they may potentially be treated by using one-way valves.¹⁵ This situation directly demonstrates requirement for alternative bronchoscopic treatment operating independent from the presence of collateral ventilation. LVRC method is demonstrated to be an effective and reliable treatment method prominently improving pulmonary functions, effort capacity and life quality in the patients with serious emphysema.^{16–19} It is also determined that dependency on oxygen in the patients undergoing oxygen treatment at home due to

hypoxic respiratory failure prominently decreases. This study is performed to determine whether the procedure is effective in severe COPD patients with hypercapnic respiratory failure.

Method

Study Design and Participants

This is a retrospective study. The files of the patients with high PCO₂ values among the ones, who were administered LVRC treatment in Sifa University hospital between August 2014 and August 2015. Respiratory function tests and PCO₂ values performed in the control are recorded. The protocol was approved by Okan University ethics committee (approval number: 102). All participants provided written informed consent, and the study was conducted in accordance with the Declaration of Helsinki.

Patient Selection Criteria

Patients at GOLD stage 3 or 4 and (55–80 mmHg PCO₂ value in arterial blood gas analysis) were eligible to be enrolled in this study. Details of the inclusion and exclusion criteria are listed in Table 1. Patients with homogenous as well as heterogeneous emphysema were eligible. Leading inclusion criteria were a post-bronchodilator forced expiratory volume in one second (FEV1) <45% predicted, total lung capacity (TLC) >100% predicted. Patients were excluded if they had giant bullae >1/3 of lung volume, 6 min walk distance <140 m, or if they had previous LVRS or lung transplantation. The patients with 55–80 mmHg PCO₂ values in arterial blood gas analysis were included in the study.

Procedures

The PneumRx volume reduction coil is an implantable, shape memory Nitinol device. The system (RePneu[®], Lung Volume Reduction Coil System, PneumRx, Inc. Mountain View, CA USA) consists of a cartridge, catheter, guidewire, forceps and coils suitable for single patient use. The system is shown in Figure 1. Three different coil lengths are designed for different airway lengths (100, 125 and 150 mm). The distal and proximal ends of the coil are designed to remain in the sub-segmental airways. In this study, bronchoscopy was performed using a 9.0 mm endotracheal flexible tube and flexible bronchoscope under general anesthesia (BF180; Olympus, 2.8-mm working channel, 6.0-mm outer diameter).

During bronchoscopy, the guidewire is first placed to the desired airway in the fluoroscopic guide. After a catheter is

Table 1 Enrolment Criteria

Inclusion Criteria
Aged ≥ 35 years
A post-bronchodilator forced expiratory volume in the first second (FEV₁) $\leq 45\%$ predicted
High Resolution Computerized Tomography (HRCT) scan indicates homogenous or heterogeneous emphysema
RV $> 175\%$ predicted
Total lung capacity $> 100\%$ predicted
Patient has marked dyspnea score ≥ 2 on modified Medical Research Council scale of 0–4
Pulmonary Hypertension defined by echocardiography < 50 mmHg
Patient has stopped smoking for a minimum of 8 weeks before enrolment
PaCO ₂ 55–80 mmHg
Exclusion Criteria
A change in FEV1 greater than 20% post-bronchodilator
A history of recurrent clinically significant respiratory infection
Giant bullae greater than a third of lung volume
Uncontrolled pulmonary hypertension defined by right ventricular pressure > 50 mm Hg as evidenced by echocardiogram
Evidence of other diseases that can compromise survival—eg, lung cancer or renal failure
Pregnant or lactating
Clinically significant bronchiectasis
Previous lung volume reduction surgery, lung transplant, or lobectomy
Taking greater than 20 mg prednisone (or similar steroid) daily
An inability to walk > 140 meters in 6 mins
On clopidogrel or unable to stop treatment for 1 week before the procedure

passed over the guidewire, it is aligned with the distal end of the guidewire at a distance of 15 mm from the pleura. Airway length is measured by radio-opaque markers to select the coil length. The guidewire is then removed and a flattened LVR coil which was previously placed in a cartridge is pushed forward through the catheter with a biopsy forceps using a fluoroscopic guide. Then, while the LVR coil remains in place, the catheter is removed and the coil returns to its original shape. Finally, the LVR coil is removed from the biopsy forceps. These steps are repeated for each coil to be installed. The radiological view is shown in Figure 2. Patients received a 5-day prednisolone (40 mg once a day) and 5 days of moxifloxacin (500 mg once a day).

Follow-Up

All peri-procedural and in house events were charted. Patients were called to the clinic for follow-up visits, which included physical examination, spirometry, plethysmography, 6 min



Figure 1 The system (RePneu®, Lung Volume Reduction Coil System, PneumRx, Inc. Mountain View, CA USA) consists of a cartridge, catheter, guidewire, forceps and coils suitable for single patient use.

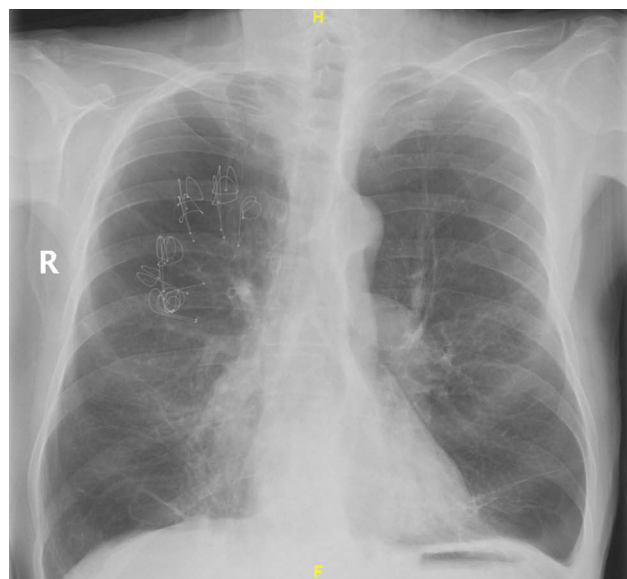


Figure 2 The radiological view.

walk test, CAT dyspnea questionnaire and arterial blood gas measurement. At the physician's discretion, the patient could have a second LVRC treatment, with similar follow-up at 1, 3,

6, 9 and 12 months. Following the final 12-month visit, all patients left the study.

Statistical Analysis

Data were analyzed using a statistical software package. Descriptive data are presented as averages \pm standard deviations (SDs) or medians (ranges). Comparison of before and after results of LVRC treatment was made by Wilcoxon signed ranks test. Changes between the baseline and 1-year data were analyzed. The results were adopted at a 95% confidence interval, and a P value <0.05 was considered to indicate statistical significance.

Results

Eleven (eight heterogeneous and three homogeneous emphysema) patients with severe COPD were included in the study between August 2014 and August 2015. One patient was treated unilaterally and ten were treated bilaterally. The unilaterally treated patient could not be treated because of giant bullae in the other lung. After one month, 10 patients were given second session treatments. Demographic and baseline values of the patients are shown in Tables 2 and 3. An average of 10 (range 8–16) coils were placed in the eligible lung lobe of the patients. A total of 212 coils was used in 21 operations (Table 4). The mean duration of the procedure was 27.14 min (range 12–50 min). Blood gas analysis was performed after 1, 3, 6, 9 and 12 month-follow-up.

Safety

There were no complications related to anesthesia. The average duration of anesthesia lasted 1 hr. No pneumothorax was observed during or after the procedure. Six patients (54.5%)

had minor hemorrhage during the procedure. Light hemorrhage persisted for three days in three patients. During the 1-year follow-up period, pneumonia developed in four patients (36.4%) at 1, 6, 9 and 12 months. Three of these patients were treated as outpatients and one patient was hospitalized. The hospitalized patient was administered with IV antibiotherapy due to pneumonia in the first month of the procedure and with IV 80 mg/day prednisolone against possible pneumonitis for three days. Three patients had COPD exacerbation, one patient had respiratory failure requiring intensive care follow-up. Side effects are shown in Table 5.

Efficacy

When compared to the initial values, LVR coil treatment provided improvement 28 m at 3rd month, 23 m at 6th month and 10 m at 12th month in 6MWT, and a drop value of 27–30 in CAT score. RV and TAC significantly decreased. Although there was a significant increase in FEV1 at 3rd and 6th months, the increase seen at the end of 1 year was not statistically significant (Table 6). PCO₂ values were significantly decreased (Table 7 and Figure 3).

Discussion

Normally working lungs are flexible and as the patient inhales and exhales, they expand and gather back efficiently in order to transfer the air freely from the bronchi to alveoles. Tissue is damaged in the lungs with emphysema and loses the flexibility.²⁰

Improvement in clinical and function parameters observed after LVRC treatment may be associated with volume reduction and parenchyma of the sick lung is compressed by means of flexible characteristic of Nitinol wire, by which spirals are made, and the lung efficiently expands after this procedure by means of recovered mechanic features of remaining tissue. It decreases dynamic hyperinflation occurring potentially in these patients. Air trapping is prevented and carbon dioxide accumulation may be decreased by this way.^{21,22}

Efficacy and reliability of LVRC treatment in the patients with emphysema are demonstrated in the studies performed as of the first pilot publication published in 2011 by Herth et al 11 patients were treated in the study and treatment efficacy is demonstrated by 3 months of follow-up. No justification is made in relation to excluding the patients with high carbon dioxide.¹⁶ We evaluated long-term reliability and improvements of LVRC treatment in 11 patients with hypercapnic respiratory failure with emphysema in our research contrary to the studies

Table 2 Demographics of the Enrolled Patients in This Study

Patient ID	Age	Weight	Height	BMI	Gender
01	78	76	160	29.7	F
02	67	81	158	32.4	F
03	62	83	178	26.2	M
04	73	80	163	30.1	M
05	68	68	179	21.2	M
06	62	80	167	28.7	M
07	59	52	165	19.1	F
08	62	78	176	25.2	M
09	63	75	173	25.1	M
10	65	70	154	29.5	F
11	63	77	164	28.6	M
Average	65.6	74.5	167	26.8	

Abbreviations: M, Male; F, Female.

Table 3 Baseline Measurements Obtained Before Study Intervention

Patient ID	FEV1 (L) % Pred	FVC (L) % Pred	RV (L) % Pred	TLC (L) % Pred	6MWT (m)	CAT Score	PCO ₂ (Baseline)
01	0.77(25)	1.28(32)	7.24(318.3)	8.52(143.1)	200	35	79
02	0.58 (17.3)	2.17(50.3)	6.81(263.8)	8.98(122.9)	170	36	77
03	0.75(22)	2.73(62)	5.37(204.1)	8.1(110.8)	195	38	74
04	0.42(16.8)	0.97(30.2)	5.86(251.2)	6.83(118.2)	165	38	76
05	0.68(26.9)	1.95(65.2)	4.95(240.8)	6.9(119.4)	190	33	67
06	0.40(16.4)	0.76(20.6)	9.49(421.6)	10.3(165.7)	160	35	75
07	0.50(22.1)	1.24(45.2)	4.07(200.7)	5.3(104)	180	38	80
08	0.53(19.1)	1.01(28.2)	9.75(376.4)	10.76(158.2)	176	36	78
09	0.48(16.2)	1.32(35.2)	5.49(208.6)	6.81(117.8)	168	36	76
10	0.42(18.1)	0.64(29.3)	4.68(206.7)	5.32(104.4)	165	34	80
11	0.52(19.2)	1.74(50.2)	5.42(235)	7.16(118.8)	175	34	74
Average	0.55(19.9)	1.43(76.9)	6.28(266.1)	7.72(125.7)	176	35	76

Abbreviations: FEV1, forced expiratory volume in one second; FVC, forced vital capacity; RV, residual volume; TLC, total lung capacity; 6MWT, 6 min walk test; CAT, COPD Assessment Test Questionnaire; Pred, predicted.

Table 4 Data of the Lobes Treated, Average Number of Coils Placed

Number of procedures, n	21
Total coils implanted, n	212
Coils per procedure, n	9.5 ± 1.1 (6–11)
Procedure Time, min	20.8 ± 7.0 (12–50)
Heterogeneous, n	8
Homogeneous, n	3
Right upper, n	11
Right under, n	0
Left upper, n	9
Left under, n	1

performed. We saw that there were also significant improvements in clinic and functional parameters including FEV1, RV, TLC, 6MWD and CAT in this patient group at the end of 12 months of follow-up. However, when evaluated over 12 months, improvement is observed to be in acceptable level in other parameters except for FEV1. Our study could not show significant improvement

in FEV1 apart from other studies performed with 1 year of follow-up period. The reason for it may be associated with the fact that clinic situation depending on PCO₂ highness is severer.

Four studies performed as of 2011 in LVRC treatment are performed as randomized controlled. It was revealed also in these studies that significant improvements occurred in functional and clinic parameters in the groups treated (Table 8). Carbon dioxide highness was not mentioned as an exclusion criteria in none of these studies.^{17,19,23,24} Renew study is the study with the highest patient participation. In sub-group analysis of the study, it was revealed that there were more significant improvements in 6DYT, respiratory function parameters and life quality in the patient group with RV>225. It was mentioned only in expert panel published by Slebos et al that the patients with PCO₂>55 mmHg were excluded from the study.²⁵ Retrospective study of Simon et al is the first study performed in relation to LVRC treatment efficacy in the patients with hypercapnic respiratory failure. The

Table 5 Side Effects Observed During the Study

Side Effect	Post Procedure (n)	1 Month (n)	6 Months (n)	9 Months (n)	12 Months (n)
Hemoptysis	6	0	0	0	0
Pneumothorax	0	0	0	0	0
Pneumonia	0	1	0	1	0
COPD exacerbation	0	0	1	1	1
Thoracic pain	0	0	0	0	0
Pulmonary Embolism	0	0	0	0	0
Respiratory Failure	0	0	0	1	0
Death	0	0	0	0	0

Table 6 Efficacy results at 12th Months

	Initial Value	3rd Month	6th Month	12th Month
6MWT, m	176	+28.72(p<0.003)	+23.18(p<0.003)	+10.54(10–30) (p<0.003)
CAT	35.7	27.55(p<0.003)	28.82(p<0.003)	30.55(28–32)(p<0.003)
FEV1, L	0.55	0.65±0.11(.<0.003)	0.63±0.11(p<0.003)	0.57±0.1(p<0.168)
FEV1%	19.9	23.78±3.56(p<0.003)	22.83±3.79(p<0.003)	20.64±3.17(p<0.168)
RV, L	6.28	−0.42(p<0.003)	−0.38(p<0.003)	−0.02(p<0.004)
TLC, L	7.72	−0.19(p<0.003)	−0.19(p<0.003)	0.08(p<0.002)

Abbreviations: 6MWT, 6 min walk test, CAT, COPD Assessment Test Questionnaire; Pred, predicted, FEV1, forced expiratory volume in one second; RV, residual volume, TLC, total lung capacity.

Table 7 The Significance Decrease in Carbon Dioxide Levels in Follow-Up

Basal Median	1st Month	3rd Month	6th Month	9th Month	12th Month	P
PCO ₂ 76 mmHg	59 (50–63)	58 (52–64)	58 (54–65)	60 (55–70)	62 (59–66)	0.003

Notes: PCO₂; Arterial carbon dioxide gas. The significant decrease in carbon dioxide levels in follow-up (p<0.003).

number of patients is determined as 10 in this study and PCO₂ level is identified as 45–65 mmHg. According to the results, LVRC not only increased respiratory capacity but also provided significant reductions in PCO₂ level.²⁶ The results are also the same in our study. PCO₂ values are higher in our patient group and although the number of the

patients is low, improvements in functional and clinic parameters were still observed after 1 year of follow-up. Probably the number of the patients may be increased in subsequent processes and positive results may be achieved and this patient group may also be included in study inclusion criteria.

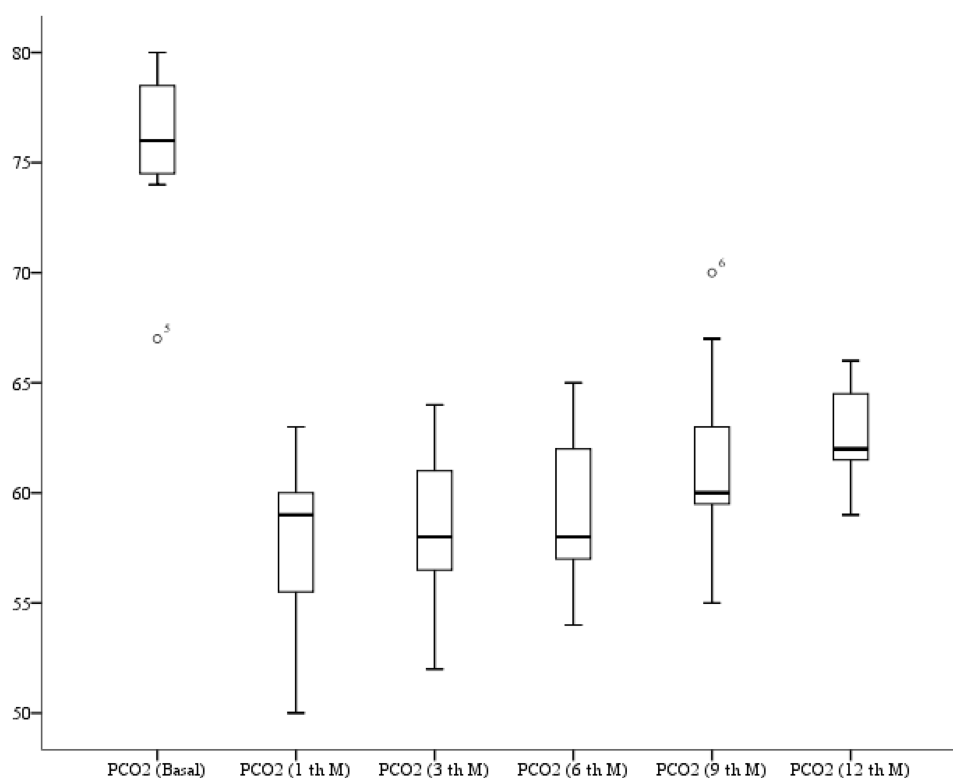
**Figure 3** 1 year PCO₂ follow-up values.

Table 8 Review of Previous LVRC Studies

Author	Year	Patient	Follow-Up Time, M	FEV1	RV	SGRQ	6MWT
Herth et al ¹⁶	2010	11	3	+2.9	%3.3	-6.1	+5.6
Slebos et al ¹⁸	2012	16	6	+14.9%	-11.4%	-14.9	+84.4
RESET study ¹⁹	2013	23	3	-14.1%	-0.51L	-8.6	+51.1
Zoumot et al ²⁴	2015	23	12	+0.2L	-5.2%	-5.8	+14.1
Simon et al ²³	2016	10	36	+0.6L	-5.6%	-	+41
REVOLENS study ¹⁷	2016	50	6	+0.09L	-0.52	-13.4	+18
			12	+0.08L	-0.47	-10.6	-2
RENEV Study ²⁵	2016	158	12	+3.8%	-0.31	-8.9	+10.3

Abbreviations: M, Months; FEV1, forced expiratory volume in 1 s; RV, residual volume; SGRQ, St George's Respiratory Questionnaire total score; 6MWD, 6-min walking distance.

LVRC procedure is a process performed by general anesthesia. Hypercapnic patient group may have been considered as exclusion criteria in the studies due to the fact that it was a patient group, in which the situation due to respiratory depression caused by general anesthesia may get severer. However, we observed as a result of our study that this group of patients may tolerate anesthesia comfortably and no respiratory failure developed after the procedure. Therefore, we consider that LVRC treatment may reliably be performed in hypercapnic respiratory failure group.

In the current multi-center research including 11 centers, no serious side effects were reported during LVR spiral treatment procedure and therefore procedure reliability was proved. Our results prove an acceptable safety profile for LRV spiral treatment and side effect rate was similar to previous reports in relation to LVR spiral treatment.^{16,19} However, pneumonia, pneumothorax and COPD inflammation rates in col treatment group were observed to be higher compared to previous studies and control group in RENEV and REVOLENS studies with widespread patient participation.^{17,24}

Conclusion

It was revealed by the studies performed that LVRC treatment was innovative bronchoscopic technique promising hope for the treatment of patients with severe emphysema.^{16,17,19,24} In patients who qualify, LVRC should be considered the Global Initiative for Obstructive Lung Disease (GOLD) standard.²⁷ We revealed in our research that it was a reliable and efficient treatment method in the emphysema patients with hypercapnic respiratory failure though the number of patients were a few. LVRC treatment may be performed on selected patients with carbon dioxide highness with larger scale studies.

Disclosure

The author reports no conflicts of interest in this work.

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