Bronchoscopic lung volume reduction

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CHAPTER

9

Long-term follow-up after bronchoscopic lung volume reduction treatment with coils in patients with severe emphysema

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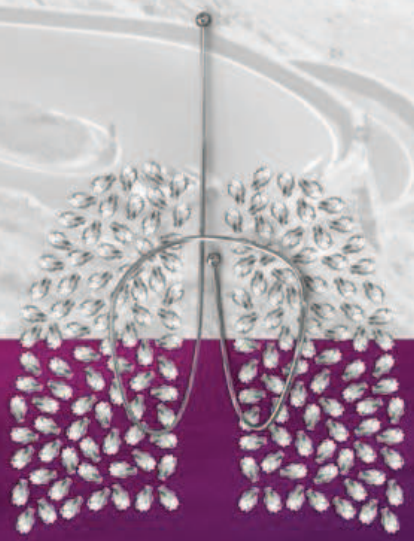

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ABSTRACT

Background
Bronchoscopic lung volume reduction coil treatment has been shown to be safe and clinically effective in patients with severe emphysema in the short term; however, long-term safety and effectiveness has not been evaluated.

Objective
The aim of this study was to investigate the long-term safety and effectiveness of lung volume reduction coil treatment in patients with severe emphysema.

Methods
Thirty-eight patients with severe emphysema (median age is 59 years, forced expiratory volume in 1 second is 27% of predicted value) who were treated in lung volume reduction coil clinical trials were invited for a voluntary annual visit. Safety was evaluated by chest X-ray and recording of adverse events and by efficacy by pulmonary function testing, distance on 6 minute walk test and questionnaires.

Results
Thirty-five patients visited the hospital 1 year, 27 patients 2 years and 22 patients 3 years following coil placement. No coil migrations were observed on X-rays.

At 1-year follow-up, all clinical outcomes significantly improved compared with baseline.

At 2 years, residual volume % of the predicted value, modified Medical Research Council (mMRC) and the St. George's Respiratory Questionnaire score (SGRQ) were still significantly improved.

At 3 years, a significant improvement in mMRC score remained, with 40% of the patients reaching the minimal clinically important difference for distance on the 6 minute walk test, and 59% of the patients reaching the minimal clinically important difference for SGRQ.

Conclusion
Follow-up of the patients treated with lung volume reduction coils in our pilot studies showed that the coil treatment is safe with no late pneumothoraces, coil migrations or unexpected adverse events. Clinical benefit gradually declines over time; at 3 years post-treatment, around 50% of the patients maintained improvement in distance on 6 minute walk test, SGRQ and mMRC.

INTRODUCTION

Bronchoscopic lung volume reduction is a new minimally invasive treatment option for patients with severe emphysema.[1] Bronchoscopic lung volume reduction treatment with one-way endobronchial valves, a 'blocking' device, is an efficacious method in a selected group of patients with absence of collateral ventilation.[2,3] For the majority of patients with severe emphysema, a bronchoscopic lung volume reduction treatment that works independently of collateral ventilation, a 'non-blocking' device, must be used. One of the currently investigated non-blocking devices is the lung volume reduction coil (RePneu, PneumRx, Inc., Mountain View, CA, USA). This nitinol coil is bronchoscopically delivered in both lungs in either upper or lower lobe heterogeneous emphysema or homogeneous emphysema,[4,5] thereby compressing diseased parenchyma and radially suspending airways after placement in the lung.

To date, five studies investigating lung volume reduction coil treatment have been published.[4–8] Four non-randomized studies (N=10, N=11, N=16 and N=60 patients)[4,6–8] and one randomized study (N=24 controls and N=23 treated patients)[5] showed that the procedure is feasible, safe and well tolerated. Significant improvements in quality of life, exercise capacity and pulmonary function were observed.[4,5,7,8] Most studies had relatively short follow-up times: 3 months,[5,6] 6 months[4,8] and one study up to 12 months after treatment.[7] To our knowledge, no study investigated a longer follow-up time after lung volume reduction coil treatment. This longer follow-up time is needed to document both safety and effectiveness of the procedure. In our hospital, we performed two pilot studies investigating bronchoscopic lung volume reduction coil therapy, with treatments in 2009 and 2010.

The aim of this study is to investigate the safety and effectiveness of lung volume reduction treatment with coils 1, 2 and 3 years post-treatment in patients with severe emphysema who participated in pilot trials.

SUMMARY AT A GLANCE

This is the first study to investigate the safety and efficacy of the lung volume reduction coil treatment in the long term. At 3 year of follow-up, this treatment showed no long-term unexpected adverse and device-related events, with clinical benefit gradually declining over time.

METHODS

Study population

Between April 2009 and November 2010, 38 patients were treated with the lung volume reduction coil at our institution, in one of two pilot studies (NCT012209084 and NCT013288997). The inclusion and exclusion criteria for both can be found in box 1. Both studies were approved by the University Medical Center Groningen Medical Ethics Committee, and all participants signed informed consents.

Box 1. Study inclusion and exclusion criteria.

Inclusion criteria

- Patient ≥ 35 years of age*
- FEV_1 ≤ 45% of predicted*
- Total lung capacity >100% of predicted*
- Residual volume > 175% of predicted[2]
- Modified medical research council dyspnea score (mMRC) ≥ 2 on mMRC scale of 0-4*
- Non-smoker for more than eight weeks prior to entering the study*
- High resolution CT scan indicates unilateral or bilateral emphysema[1]
- CT scan indicates bilateral heterogeneous emphysema[2]
- Patient read, understood and signed the informed consent form*

Exclusion criteria

- Change in FEV_1 > 20% post-bronchodilator
- Diffusion capacity < 20% predicted
- A history of recurrent clinically significant respiratory infection
- Uncontrolled pulmonary hypertension defined by right ventricular pressure > 50mmHg
- An inability to walk > 140 meters in 6 minutes
- Evidence of other disease that may compromise survival such as lung cancer, renal failure etc.
- Patient is pregnant or lactating
- An inability to tolerate bronchoscopy under moderate sedation or anesthesia
- Clinically significant bronchiectasisGiant bullar > 1/3 lung volume
- Previous LVR surgery, lung transplant or lobectomy
- Patient has been involved in other pulmonary drug studies with 30 days prior to this study
- Patient is taking >20mg prednisone (or similar steroid) daily
- Any use of clopidogrel or coumarines
- Other disease that would interfere with completion of study, follow-up assessments or that would adversely affect outcomes
- Patient has severe homogeneous emphysema by CT scan

*Applicable for both studies
[1]Applicable for study NCT01220908
[2]Applicable for study NCT01328899

Lung volume reduction coil treatment

The lung volume reduction coil procedure has been described before.[4,6] In brief, the coils (RePneu, PneumRx Inc.) are made of shape-memory nitinol wire, range in length from 70 mm to 200 mm to accommodate airways of different sizes and are designed to compress the lung parenchyma. The coils were bronchoscopically placed under general anesthesia in two sequential procedures using fluoroscopy.

Study design
The follow-up period of both studies were 6 months[4] and 12 months[7] after the second treatment. After completing and exiting the study, patients were invited for a voluntary annual follow-up visit. Patients performed pulmonary function measurements, 6 minute walk test and chest X-ray and completed questionnaires. Patients also had a consultation with a physician who reported the patient's health status during the past year.

Measurements
Spirometry, bodyplethysmography and the 6 minute walk test were performed using ERS/ATS guidelines.[9–11] Health-related quality of life was measured by the SGRQ[12] and dyspnea severity by the mMRC scale.[13]

Safety was measured by recording all adverse events reported by the patients during the yearly follow-up visits. The first X-ray after the treatment and the last performed X-ray at final follow-up visit for all participants were assessed for presence of coil migration (defined as displacement of the original post treatment coil position in the segment), atelectasis and consolidation of tissue around the coils.

Pre-treatment decline in forced expiratory volume in 1 second
All available spirometry results of the pre-treatment years were collected from the patient's own hospital, serving as a reference of the expected decline in lung function of our patients.

Lung transplantation
Two patients underwent a lung transplantation: one patient at 1 year and the second patient at 4 years post-treatment. Both patients gave permission for histopathological examination of the explant. The lung tissue was processed according to routine clinical guidelines for confirmation of disease diagnosis and assessment of any potential concurrent disease. Haematoxylin and eosin stains were made on lung sections after careful removal of the nitinol coils, and representative sections were photographed and unedited used for presentation in this study.

Statistical analysis
Due to non-normally distributed data, Wilcoxon signed rank tests were performed to compare the clinical characteristics at 1-, 2- and 3-year follow-up against baseline and to compare if baseline characteristics differed between responders and non-responders at 3-year follow-up. For the responder analyses, we counted the number of patients who reached the earlier established minimal clinically important difference for FEV_1 (100 ml and 10%[14]), residual volume (400 ml[15]), distance on 6 minute walk test (26 meter[16]), and the SGRQ (4 points[17]). The annual change in post-bronchodilator FEV_1 before the treatment was derived from the slope of the regression line for each patient's individual FEV_1 values measured at their own hospital. We only calculated the annual change in FEV_1 of patients when at least three FEV_1 values were available. Paired sample t-tests were performed to compare the difference in the decline in FEV_1 before and after the treatment. P-values < 0.05 were considered statistically significant. IBM-SPSS Statistics (version 20) was used for statistical analysis (IBM, Armonk, NY, USA).

RESULTS

Patients

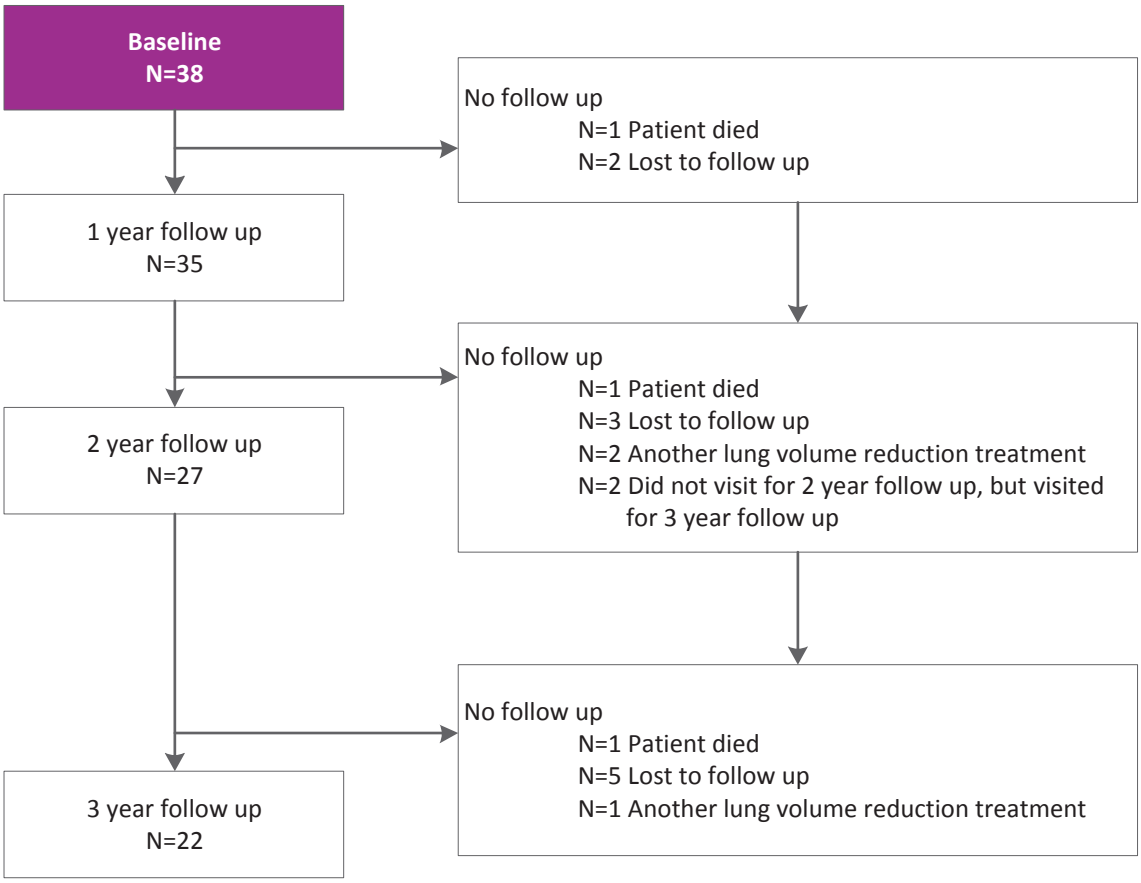
The baseline characteristics of the 38 patients are shown in table 1. One year after the treatment, 35 patients performed follow-up measurements, at 2 years 27 patients and at 3 years 22 patients (figure 1).

Table 1. Baseline characteristics.

Characteristic	Outcome
Female, N (%)	28 (74%)
Age, years	59.2±7.7
BMI, kg/m^2	24.9 (18.6-35.4)
Diagnosis emphysema, years	8.9±3.5
Packyears, years	34.7±11.2
Heterogeneous emphysema, N (%)	35 (92%)
FEV_1, % of predicted value	27 (16-42)
GOLD stage III, N (%)	13 (34%)
GOLD stage IV, N (%)	25 (66%)
FVC, % of predicted value	82±15
RV, % of predicted value	228 (155-341)
Ratio of RV to TLC, %	0.61 (0.50-0.74)
mMRC score, N (%)	3.0 (2.0-4.0)
Distance on 6 minute walk test, meter	326±94
SGRQ total score, points	63.2 (36.9-83.0)

Data are presented as number (%), mean ± standard deviation or median (range). BMI: Body mass index, FEV_1: Forced expiratory volume in 1 second, FVC: Forced vital capacity, RV: Residual volume, TLC: Total lung capacity, mMRC: modified Medical Research Council, SGRQ: St. George's respiratory questionnaire.

Figure 1. Flowchart of study participants.



Safety

The adverse events are shown in table 2. Six patients (16%) died during the 3-year follow-up independent of the treatment. The causes of death are reported in table 2. Two patients had a pneumothorax directly after the coil procedure; however, no long-term pneumothoraces occurred. Of the patients, 74% reported a very mild hemoptysis just post-procedure; only one patient reported spontaneous settling of more severe hemoptysis at 3-year follow-up. On the follow-up chest X-rays, we observed no coil migrations, a segmental atelectasis was visible in 3 patients (8%) and consolidation of tissue around some of the coils in 11 patients (29%) (see figure 2 for the first X-ray post-procedure and the follow-up X-ray at 3-year follow-up of two example patients).

Table 2. Number of reported adverse events.

	Baseline to 1 year FU	**1 year to 2 year FU**	**2 year to 3 year FU**
	N=35	**N=27**	**N=22**
Death*	1 (3%)	3 (8%)	2 (6%)
Pneumothorax	2 (6%)	0 (0%)	0 (0%)
Pneumonia	16 (46%)	2 (7%)	1 (5%)
Hospitalization due to COPD exacerbation	18 (51%)	10 (37%)	8 (36%)
Haemoptysis	0 (0%)	0 (0%)	1 (5%)

Data are presented as number of patients (%). FU: follow-up. *Percentages of patients who died were calculated based on the total number of patients at baseline. Causes of death (N=6, time post-treatment):

1: 20 months (right upper lobe only): pneumonia of the left lung with pseudomonas sepsis.

2: 10 months (right upper lobe only): end-stage COPD, complicated by an osteoporotic Th6 fracture causing immobilization and severe pain.

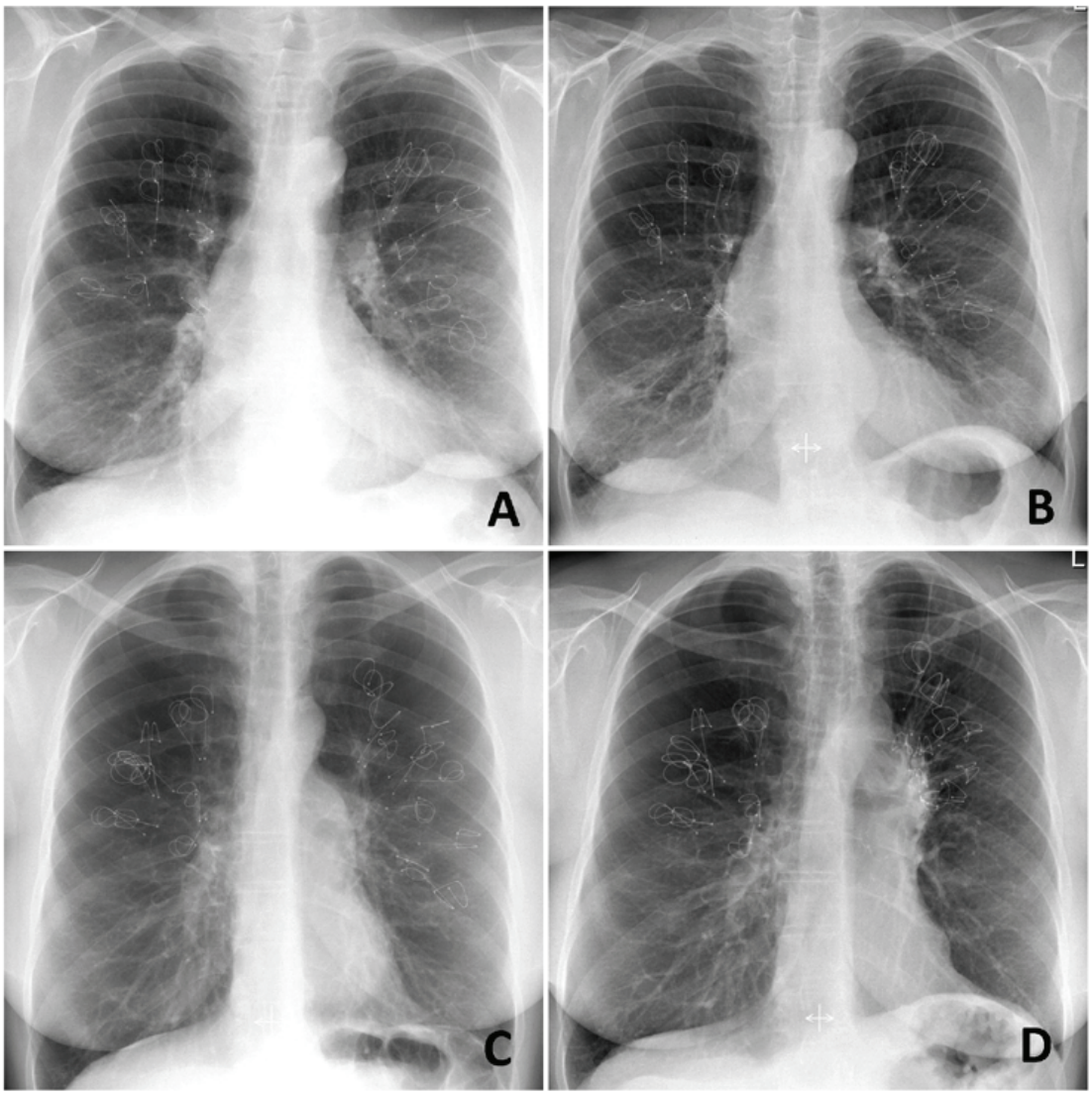
3: 16 months (bilateral upper lobe): end-stage COPD with cor pulmonale.

4: 16 months (bilateral upper lobe): sudden cardiac death not further specified.

5: 38 months (bilateral upper lobe): myocardial infarction.

6: 35 months (bilateral upper lobe): end-stage COPD.

Figure 2. The first X-ray after the procedure and last available follow-up X-ray of two example patients.



(A) Directly after the second procedure in patient 1.
(B) Three years after the procedure in patient 1 without any changes.
(C) Directly after the second procedure in patient 2.
(D) Three years after the procedure in patient 2, showing some 'crowding' of the coils in the left upper lobe resulting in volume reduction and a better left hemidiaphragm position.

Effectiveness

At 1-year follow-up, forced vital capacity, residual volume, ratio of residual volume to total lung capacity, mMRC, distance on 6 minute walk test and SGRQ total score were all significantly improved compared with baseline. At 2-year follow-up, residual volume, mMRC and the SGRQ total score were significantly improved when compared with baseline. At 3-year follow-up, only the mMRC was significantly improved compared with baseline. The other clinical characteristics were not significantly changed at 3 years compared with baseline (table 3).

Table 3. Change in clinical characteristics at 1, 2 and 3 year follow-up.

	1 year FU (N=35)	P value	2 year FU (N=27)	P value	3 year FU (N=22)	P value
FEV_1, Liter	0.2 (-0.2-0.45)	0.171	-0.04 (-0.26-0.36)	0.809	-0.05 (-0.39-0.39)	0.664
FEV_1, % predicted	1 (-6-20)	0.080	-1 (-9-17.)	0.949	0 (-14-19)	0.747
FVC, Liter	0.04 (-0.39-1.13)	0.060	-0.02 (-0.85-1.11)	0.597	0.04 (-0.56-0.91)	0.723
FVC, % predicted	3 (-12-44)	0.014	1 (-25-44)	0.741	6 (-18-38)	0.169
RV, Liter	-0.32 (-1.88-0.68)	<0.001	-0.14 (-1.57-0.92)	0.093	0.07 (-1.67-1.41)	0.629
RV, % predicted	-21 (-91-32)	<0.001	-10 (-83-43)	0.012	-2 (-89-57)	0.509
RV/TLC, %	-3.6 (-21.3-5.7)	<0.001	-0.2 (-18.6-10.3)	0.428	1.5 (-19.0-12.5)	0.664
mMRC, score	0 (-3-2)	0.007	0.0 (-3.0-1.0)	0.007	-0.5 (-3-1)	0.039
6MWD, meter	31 (-110-185)	0.010	-12 (-140-238)	0.696	-32 (-120-177)	0.970
SGRQ,points	-4 (-44-13)	0.005	-8(-40-20)	0.032	-7 (-30-21)	0.101

Data are presented as median (range) in change between follow-up and baseline and P values. Baseline and follow-up measurements were compared with Wilxocon signed-rank test. 6MWD, distance on 6 minute walk test; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; mMRC, modified Medical Research Council; RV, residual volume; SGRQ, St George's Respiratory Questionnaire; TLC, total lung capacity.

The number of patients reaching the MID for FEV_1 ranged from 20–30% (absolute change) to 30–40% (relative change) throughout the 1- to 3-year follow-up. The number of patients reaching the minimal clinically important difference for residual volume decreased during the 1- to 3-year follow-up, from 51% to 19%. The number of patients reaching the minimal clinically important difference for distance on 6 minute walk test decreased during the 1- to 3-year follow-up from 57% to 40%. The number of patients reaching the minimal clinically important difference for SGRQ ranged from 50% to 60% throughout the 1- to 3-year follow-up (table 4). No differences were found in baseline characteristics between patients who reached the minimal clinically important difference for SGRQ or distance on 6 minute walk test at 3-year follow-up

Table 4. Minimal clinically important difference responder analysis.

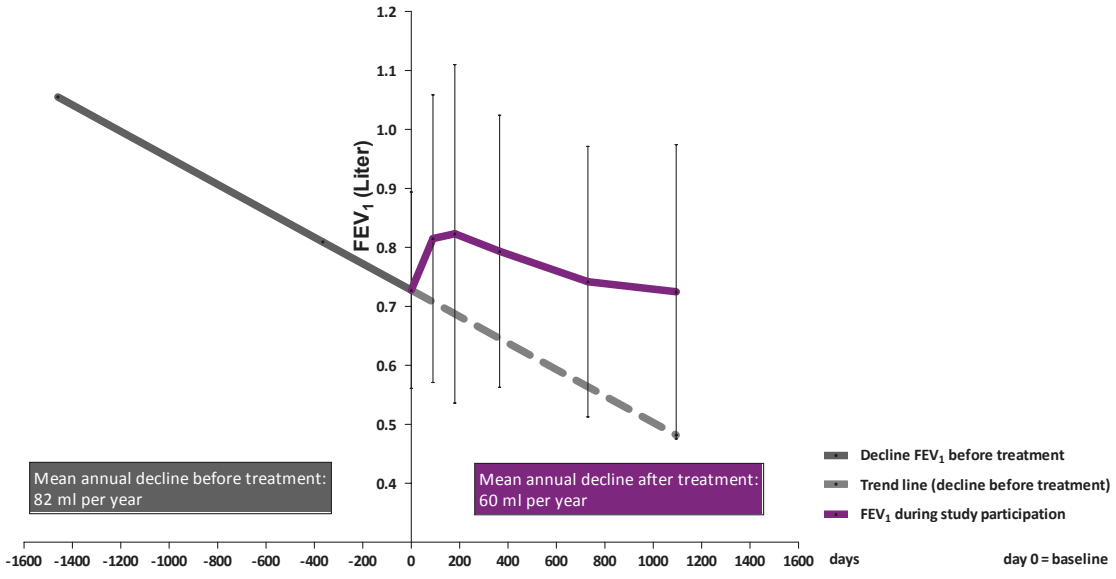
	MCID	6 months (N=35)	1 year (N=35)	2 years (N=27)	3 years (N=22)
Forced expiratory volume in 1-second	**≥ 100 ml**	11 (31%)	8 (23%)	5 (19%)	7 (33%)[2]
Forced expiratory volume in 1-second	**≥ 10%**	17 (49%)	11 (31%)	9 (33%)	8 (38%)[2]
Residual volume	**≤ 400 ml**	18 (51%)	14 (40%)	8 (30%)	4 (19%)[2]
Distance on 6 minute walk test	**≥ 26 meter**	20 (57%)	20 (57%)	7 (27%)[1]	8 (40%)[3]
St. George's respiratory questionnaire	**≤ 4 points**	22 (63%)	18 (51%)	17 (63%)	13 (59%)

Data are presented as N (%). MCID denotes minimal clinically important difference. [1]N=26, [2]N=21, [3]N=20.

Pre-treatment decline in FEV_1

At least three previously performed FEV_1 measurements were available for 30 of the 38 patients (79%). The median number of available measurements was 9 (range 3–23) and the median number of days for the first available measurement before treatment was 1989 days (range: 292–4376). The mean decline in FEV_1 before the lungvolume reduction coil treatment was −0.082 Liter per year (standard deviation: 0.073). This was significantly different compared with the mean decline in FEV_1 during study participation (mean decline: −0.036 Liter per year, P = 0.018). The decline in FEV_1 after more than 6 months of follow-up did not significantly differ compared with the decline before the treatment (mean decline: −0.060 Liter per year, P = 0.45 (figure 3).

Figure 3. Decline in FEV_1 before and after the lung volume reduction coil treatment.



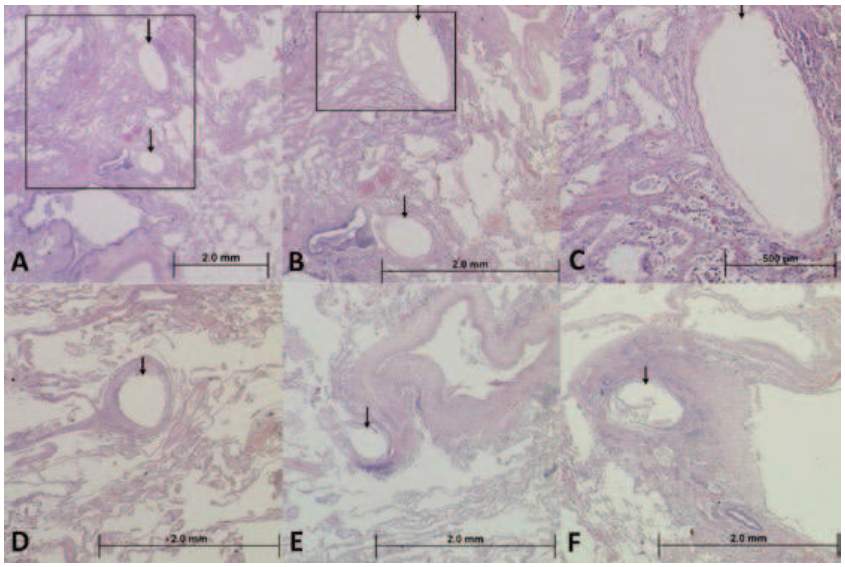
Baseline and post-treatment FEV_1 shown as mean ± standard deviation.

Lung transplant explant evaluation

On gross macroscopic evaluation of the lung explants, the coils could be identified in the main segmental and sub-segmental airways. No vascular disruptions were noticed, nor were there any abscess formations in the coiled regions. Histopathological examination revealed in both patients, besides presence of emphysematous tissue, a thin, compressed capsule of tissue around the imprints of the airways with a slight inflammatory reaction. It was unclear whether these changes represent pre-existing pathology in these patients or if this is associated with device placement.

In the 1-year specimen, the presence of interstitial fibrosis of alveolar septa with the device 'capsule' and the surrounding alveolar parenchyma was visible. In the 4-year specimen, the device imprint in the airways was surrounded by a well-organized fibrous capsule comprised of compressed, concentric rings of stroma, and this was also found in the alveolar parenchyma, where the device imprint was in an area of more dense fibrous tissue. No abundant inflammatory reaction or infection was found in either explant (see figure 4).

Figure 4. Histology of transplanted lungs of two patients.



Photomicrograph, haematoxylin and eosin stain. **(A)** Low power magnification of lung tissue demonstrating two device imprints (arrows) in the alveolar parenchyma. **(B)** Higher magnification of the boxed area in image **(A)** demonstrating the two device imprints in tissue. At this magnification, it is evident that there is a thin, compressed capsule of tissue around the imprints with no other significant inflammatory reaction present. This image also demonstrates the presence of interstitial fibrosis of alveolar septa along the left hand side of the image. **(C)** Higher magnification of the boxed area in image **(B)** demonstrating a closer view of the device capsule and the surrounding alveolar parenchyma. **(D)** Low power magnification of a single device imprint in the alveolar parenchyma (arrow). The imprint is surrounded by a well-organized fibrous capsule comprised of compressed, concentric rings of stroma. Pre-existing emphysema (enlarged alveolar spaces) is also evident in this image. **(E)** Low power magnification of a single device imprint (arrow) in the alveolar parenchyma adjacent to a pulmonary vein. **(F)** Low power magnification of a single device imprint in an area of more dense fibrous tissue. The device capsule contains a mild degree of inflammation. **(A-C)** Patient 1 year after LVR-coil treatment; **(D-F)** patient 4 years after lung volume reduction coil treatment.

DISCUSSION

This was the first study that investigated the long-term safety and effectiveness of bronchoscopic lung volume reduction treatment with nitinol coils. In this trial, we followed our first pilot study patients over the years and showed that the treatment is safe in the long term. After 1 year, the treatment was found to be clinically effective compared with baseline, with a median gradual decline of the clinical benefits over time, with 3-year follow-up approaching similar parameters to the pre-treatment baseline for the overall group and with a responder rate of 59% of the patients reaching minimal clinically important difference for SGRQ and 40% for distance on 6 minute walk test at 3 years.

In the 3-year follow-up of our pilot studies, patients showed that the lung volume reduction coil treatment was safe in the long term. We witnessed no late pneumothoraces, no coil migrations, no major hemoptysis, no major infectious complications or unexpected adverse device events and no treatment-related deaths. The 3-year survival in our group (84%) is in line with survival reports in the literature for comparable patient populations. Lange et al.[18] reported a 74.2% 3-year survival, and a 55–65% 3-year survival is reported when using Collaborative Cohorts to Assess Multicomponent Indices of COPD in Spain, Global Initiative for Chronic Obstructive Lung Disease, or ATS/Body-Mass Index, Airflow Obstruction, Dyspnea, and Exercise Capacity Index in Chronic Obstructive Pulmonary Disease severity criteria.[19]

Evaluation of post-lung transplant-explanted lung tissue showed that the proximal and mid portions of the coils can still be found in the segmental and sub-segmental airways, encapsulated by some fibrotic/organizing reaction, with occasionally the most distal part of the coils being encapsulated in the surrounding lung tissue, but with no signs of serious inflammatory or infectious reactions. These findings indicate that there is tendency of the airways and lung tissue to slowly organize around the coils, which might be due to local tissue stress, compression and micro movements of the coils.

The treatment was beneficial for a large group of patients after 1 year, with overall mean clinical parameters returning to baseline values at 3 years. Unfortunately, we did not have a control group in which we could investigate the natural decline of clinical parameters. However, the National Emphysema Treatment Trial (NETT) study[20] that investigated lung volume reduction surgery in severe emphysema patients with a median follow-up of 4.3 years reported that clinical parameters like SGRQ declined in both the treatment and control group.[20] To estimate the natural rate of functional decline in our patients, we collected all available pre-treatment spirometries. We found that the rate of decline did not change after the lung volume reduction coil treatment but that treatment increased FEV_1 to the extent that return to pre-treatment baseline levels occurred only after approximately 3 years (figure 3). That the rate of decline did not change is unsurprising; two other studies investigating lung volume reduction surgery also showed that the rate of decline after surgery was comparable with the rate of decline before surgery.[21,22]

We believe it is as important to evaluate clinical significance as it is with statistical significance of outcomes from treatment. Therefore, we also investigated whether patients reached the minimal clinically important difference for FEV_1, residual volume, distance on 6 minute walk test and SGRQ at each time point. However, a confounding factor is that most minimal clinically important differences were calculated for short-term changes, ranging from 115 to 616 months post-intervention. A long-term minimal clinically important difference (for example 3 years) could be lower than a minimal clinically important difference for the short term. Therefore, the minimal clinically important differences used in our analyses could underestimate the number of meaningful responders at 3 years. Unfortunately, this is not known and would be interesting to investigate. We did not find any predictive factors to identify responders at 3-year follow-up. However, our sample size was too small to be able to evaluate this in detail. Current ongoing large randomized controlled trials (NCT01608490 and NCT01822795) will possibly give more insight in the best responder profile for this treatment.

Long-term follow-up after bronchoscopic lung volume reduction treatment with coils has not been investigated before. A few other studies investigating other lung volume reduction techniques included at least 12 months follow-up. The NETT study[20] found that 20% of the patients improved more than 8 points on the SGRQ total score 3 years after lung volume reduction surgery (patients who died or were lost to follow-up were considered not improved). When we apply the same rules for improvement, 31% of our patients (N=11) improved more than 8 points after 3 year. As in our study, the NETT study also found a larger improvement in the quality of life in the long term than in exercise capacity. Another study investigated the effect of lung sealant therapy for emphysema in 16 patients two years after the initial treatment.[23] They found a much higher number of patients who reached the minimal clinically important difference for FEV_1 two years after the treatment, which is 50% compared with 19% in our population. Not much literature to date has been published on longer-term follow-up data for bronchoscopic lung volume reduction devices. Three small cohort studies investigated long-term follow-up of endobronchial valve treatment. Venuta et al.[24] showed promising results after 3 and 5 years follow-up. Unfortunately, patient loss to follow-up was not taken into account, and paired statistical analyses were not used, making the result difficult to interpret. A retrospective study by Kotecha et al.[25] showed that 6 out of 16 patients (38%) had sustained long-term improvements in FEV_1 (change > 0), which is comparable with our study (31% at 2-year follow-up: 11 out of 27 patients). Furthermore, Hopkinson et al.[26] showed that the occurrence of atelectasis following endobronchial valve treatment was associated with prolonged survival at 6 years follow-up.

The major disadvantage of our study is the non-controlled design and possible selection bias of patients who volunteered for yearly follow-up visits after participating in one of our pilot studies. Although a large number of patients did visit our hospital yearly, the results at 2 year and 3 year follow-up should be interpreted with caution as patients with worse response could be presumed less likely to return for follow-up. It would be useful to investigate the long-term efficacy and safety of the lung volume reduction coil treatment in a randomized controlled intervention study with long-term follow-up.

Currently, a large (N=315) randomized controlled trial with 5-year follow-up is enrolling patients and will give additional insight into the long-term effectiveness and safety of coil treatment (Lung Volume Reduction Coil Treatment in Patients With Emphysema Study: NCT01608490).

CONCLUSION

Follow-up of our very first pilot patients showed that lung volume reduction coil treatment is safe in the long term, with no late pneumothoraces, coil migrations or unexpected adverse events. Clinical benefit gradually declines over time; at 3 years post-treatment, around 50% of the patients maintained improvement in distance on 6 minute walk test, SGRQ and mMRC.

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