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Endobronchial Valves for Emphysema without Interlobar Collateral Ventilation

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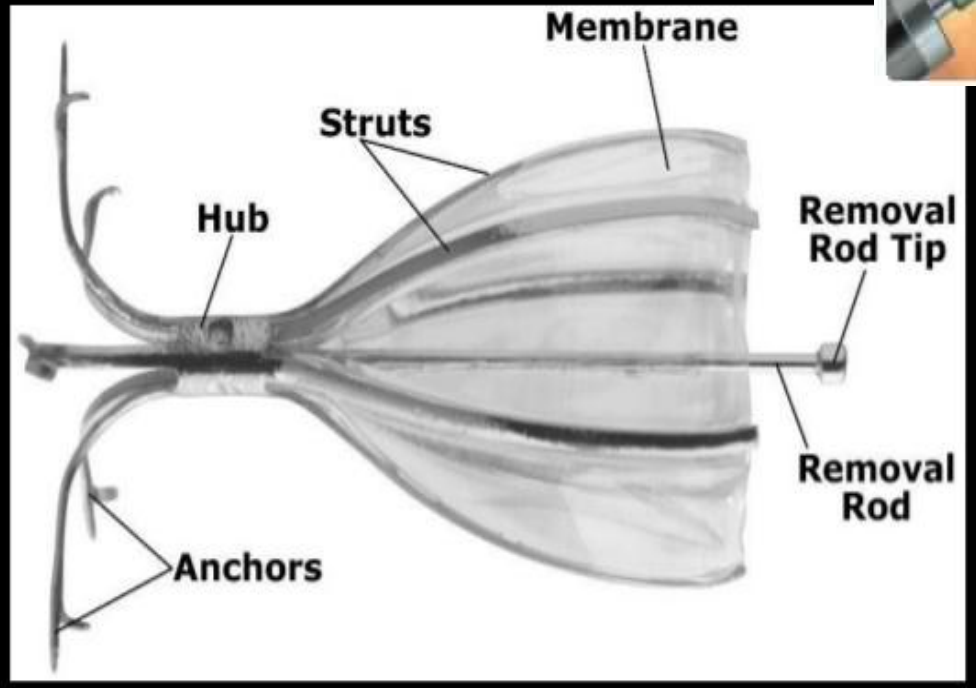
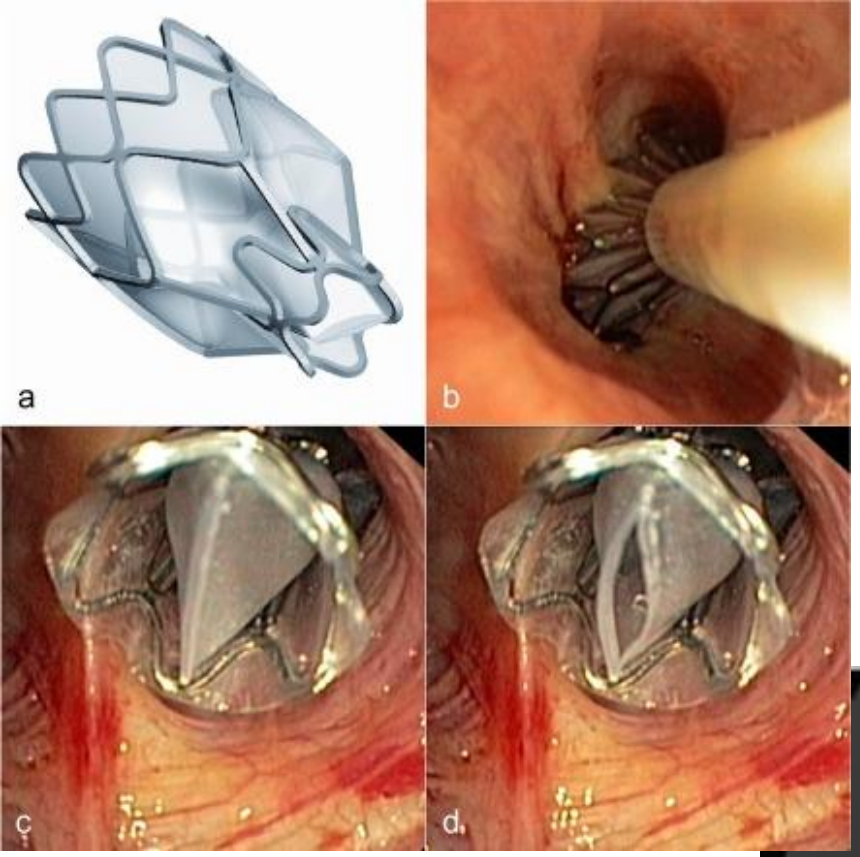
..WHAT IS THE ENDOBRONCHIAL VALVE?

‘’ An **endobronchial valve** is an implantable medical device—a small, one-way valve, which is implanted in an airway in the pulmonary system to treat one of several lung conditions. The one-way endobronchial valve is typically implanted such that when a patient exhales, air is able to flow through the valve and out of the lung compartment that is fed by that airway, but when the patient inhales, the valve closes and blocks air from entering that lung compartment. Thus, an implanted endobronchial valve typically helps a lung compartment to empty itself of air. This has been shown to be beneficial in the treatment of emphysema, where lungs lose their elasticity and thus cannot contract sufficiently to exhale air, leading to air trapping and hyperaeration. When one or more diseased portions of an emphysematous lung are made to deflate and collapse, other healthier portions of the lung have more room in the chest cavity to inhale and exhale, pressure is removed from the diaphragm, and even the heart may function better as the hyper-inflated lung becomes smaller.[1]Endobronchial valves have also been shown to be beneficial in treatment of persistent air leaks in the lungs. It has also been theorized[*by whom?*] that endobronchial valves may be useful for treatment of tuberculosis and its complications… Endobronchial valves are typically implanted using a flexible delivery catheter advanced through a bronchoscope, and thus they are minimally invasive. The valves are also removable if they are not working properly …’’

pulmonX
Interventional Pulmonology

Intra Bronchial Valve (IBV) Spiration

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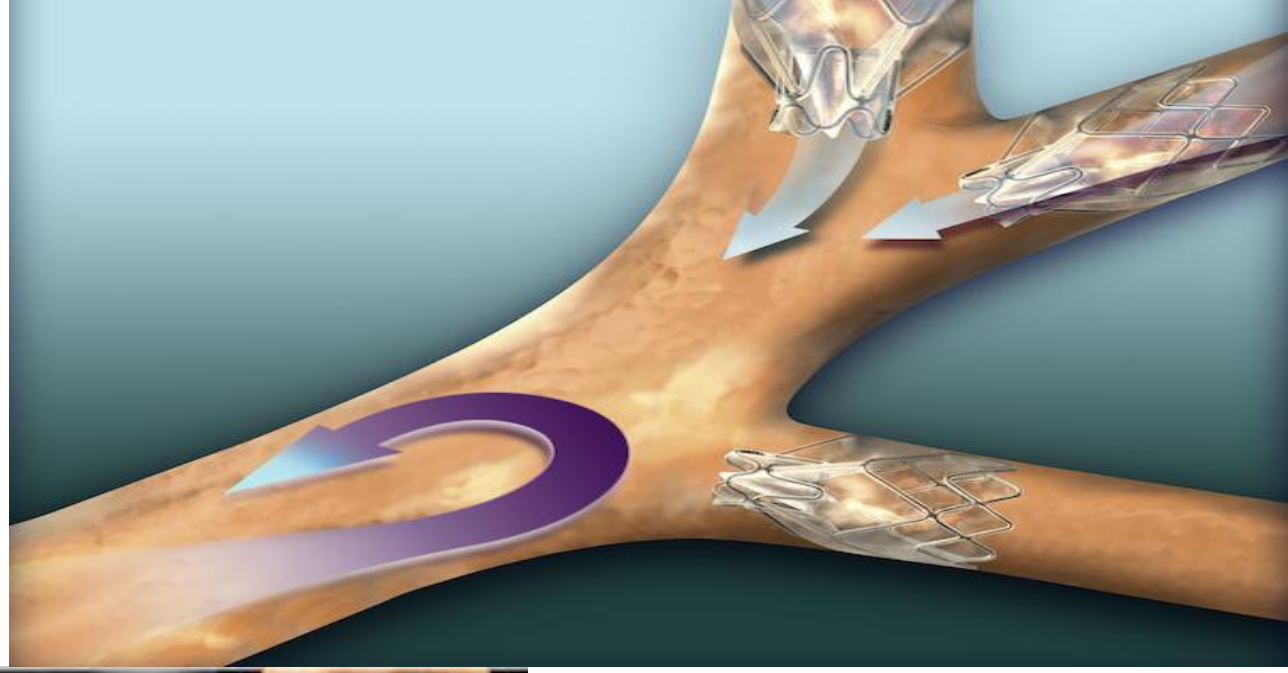
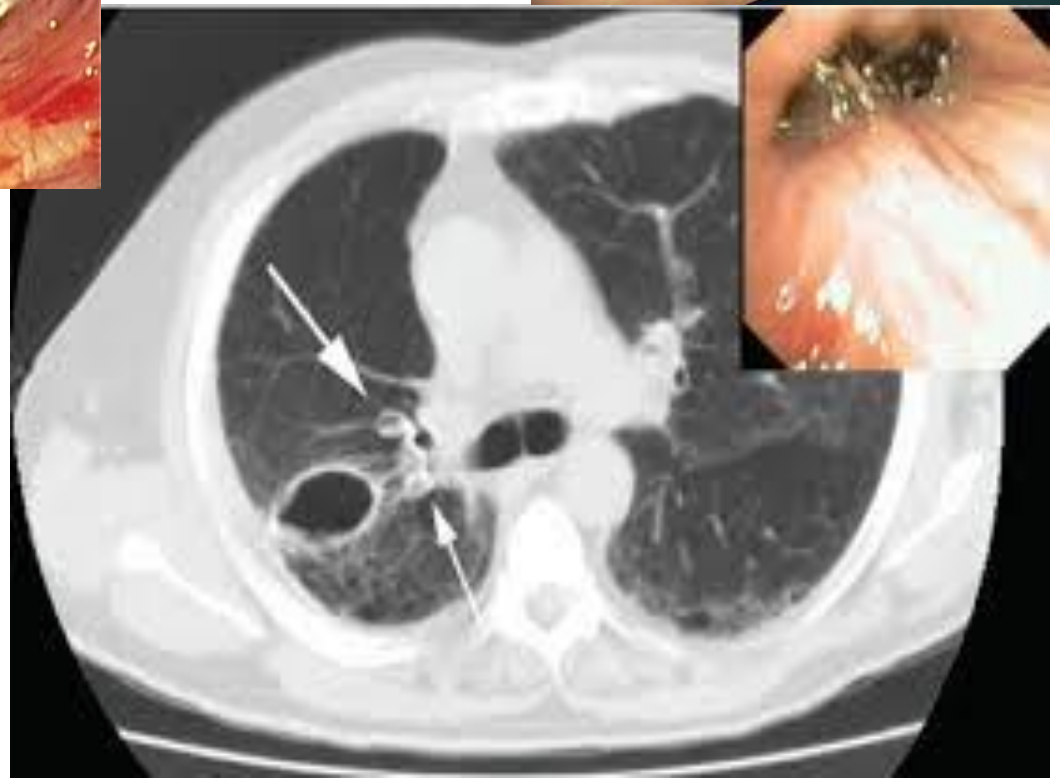
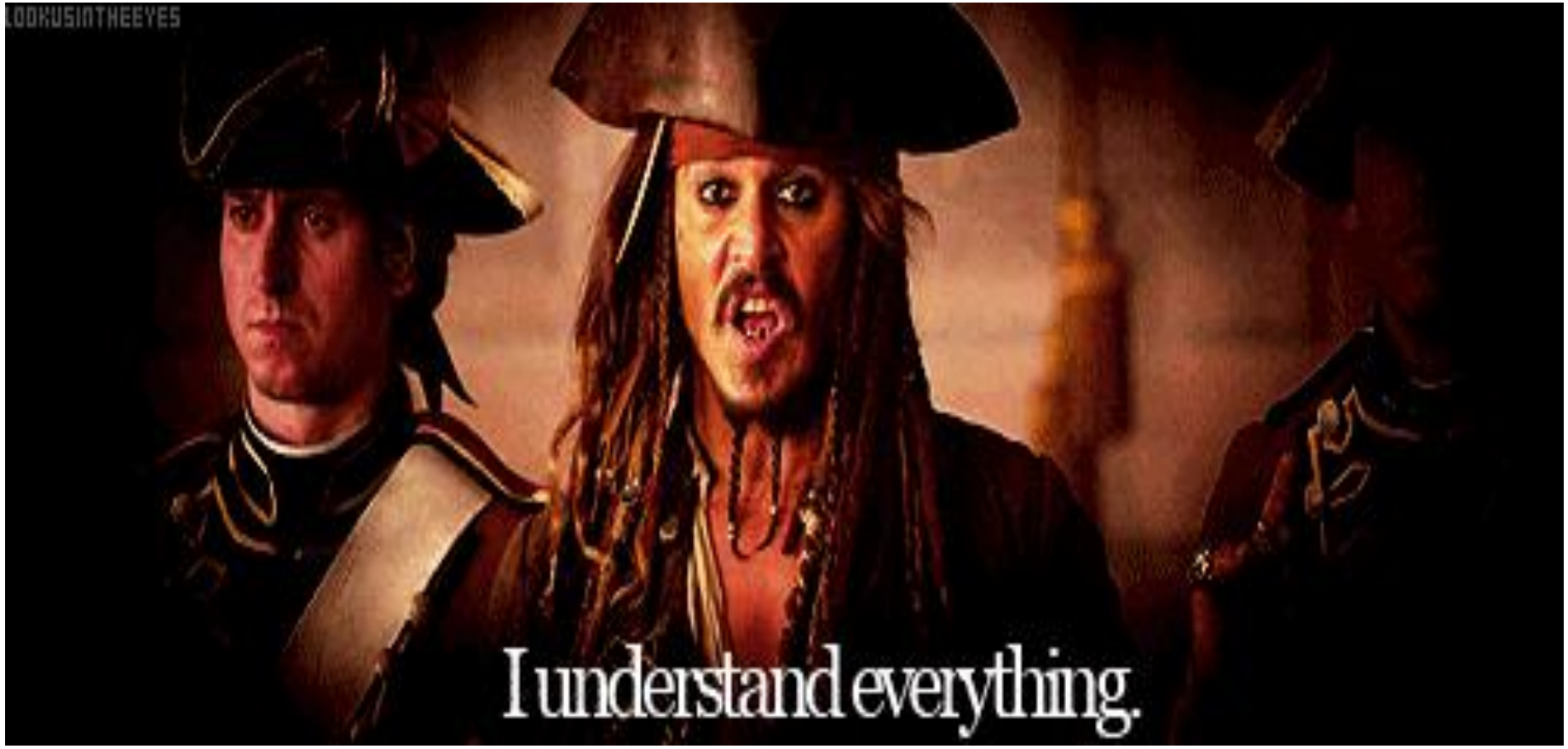
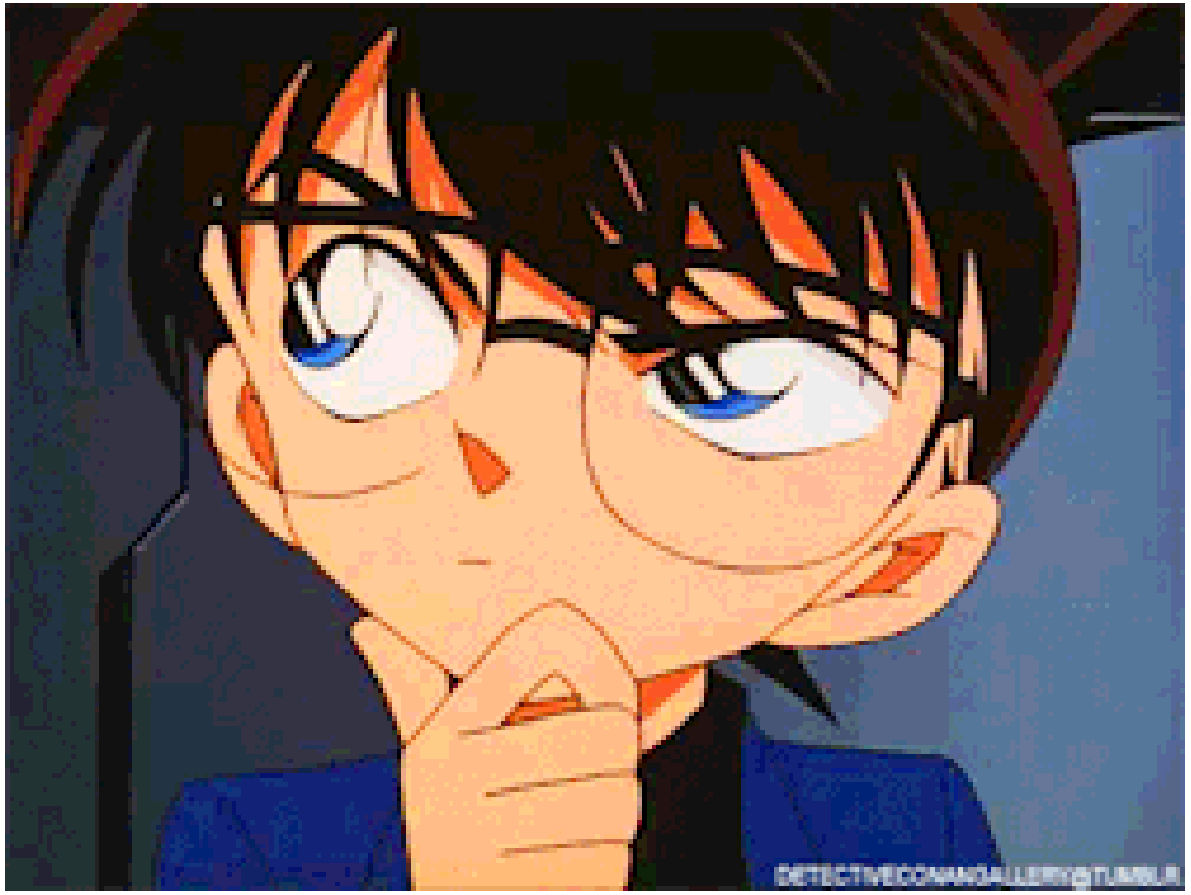





LOOKUSINTHEEYES
I understand everything.

… what about the evidence?



BACKGROUND

Bronchoscopic lung-volume reduction with the use of one-way endobronchial valves is a potential treatment for patients with severe emphysema. To date, the benefits have been modest but have been hypothesized to be much larger in patients without interlobar collateral ventilation than in those with collateral ventilation.

METHODS

We randomly assigned patients with severe emphysema and a confirmed absence of collateral ventilation to bronchoscopic endobronchial-valve treatment (EBV group) or to continued standard medical care (control group) Primary outcomes were ➔ changes from baseline to :

1** 6 months in forced expiratory volume in 1 second (FEV 1),
2** forced vital capacity (FVC),
3** 6-minute walk distance.

Table 1. Baseline Characteristics of the Patients.*

Characteristic	EBV Group (N=34)	Control Group (N=34)
Female sex — no. (%)	18 (53)	28 (82)
Age — yr	58±10	59±8
Body-mass index†	24.1±3.5	24.2±4.0
Cigarette smoking — no. of pack-yr	37±18	35±19
Lung function		
FEV_1		
Liters	0.86±0.30	0.79±0.27
% of predicted value	29±7	29±8
FVC		
Liters	2.80±0.83	2.50±0.90
% of predicted value	78±16	77±20
RV		
Liters	4.64±1.31	4.43±0.72
% of predicted value	216±36	220±32
TLC		
Liters	7.85±1.54	7.31±1.20
% of predicted value	130±13	133±10
Ratio of RV to TLC — %	59±9	61±8
Carbon monoxide diffusing capacity		
Milliters of carbon monoxide/min/mm Hg	10.4±3.2	9.8±2.5
% of predicted value	38.7±9.1	39.0±9.7
Arterial blood gas — mm Hg‡		
Partial pressure of oxygen	69±12	69±9
Partial pressure of carbon dioxide	38±6	38±4
Distance on 6-min walk test — m	372±90	377±84
Quality-of-life scores — no. of points§		
St. George's Respiratory Questionnaire	59.1±13.7	59.3±11.6
Modified Medical Research Council scale	2.7±0.8	2.7±0.6
Clinical COPD Questionnaire	2.9±0.8	2.7±0.6
HRCT findings¶		
Target-lobe volume — ml	1993±742	1716±555
Target-lobe voxels below −950 Hounsfield units — %	47.7±8.2	45.7±7.3
Emphysema distribution — no. (%)		
Homogeneous	18 (53)	18 (53)
Heterogeneous	16 (47)	16 (47)

Table 1. (Continued.)

Characteristic	EBV Group (N=34)	Control Group (N=34)
Medical history — no. (%)		
α_1-Antitrypsin deficiency	4 (12)	3 (9)
Previous pneumothorax	2 (6)	1 (3)
Regular physical activity under professional supervision — no. (%)‖	27 (79)	26 (76)

RESULTS

Eighty-four patients were recruited, of whom 16 were excluded because they had collateral ventilation (13 patients) or because lobar segments were inaccessible to the endobronchial valves (3 patients).

The remaining 68 patients (mean [±SD] age, 59±9 years; 46 were women) were randomly assigned to the EBV group (34 patients) or the control group (34).

At baseline, the FEV1 and FVC were 29±7% and 77±18% of the predicted values, respectively, and the 6-minute walk distance was 374±86 m

Intention-to-treat analyses showed significantly greater improvements in the EBV group than in the control group from baseline to 6 months:

**the increase in FEV was greater in the EBV group than in the control group by 140 ml(95% confidence interval [CI], 55 to 225),

**the increase in FVC was greater by 347 ml (95% CI, 107 to 588),

**the increase in the 6-minute walk distance was greater by 74 m (95% CI, 47 to 100) ($P<0.01$ for all comparisons)

By 6 months, 23 serious adverse events had been reported in the EBV group, as compared with 5 in the control group ($P<0.001$).

One patient in the EBV group died.

Serious treatment- related adverse events in this group included pneumothorax (18% of patients) and events requiring valve replacement (12%) or removal (15%).

Table 2. Mean Change from Baseline to 6 Months of Follow-up in Primary Efficacy Outcomes in the Intention-to-Treat Population.[a]

Variable	EBV Group (N=34)	Control Group (N=34)	Between-Group Difference	P Value
Change in FEV_1				
Milliliters (95% CI)	161 (80 to 242)	21 (−9 to 52)	140 (55 to 225)	0.002
Percentage (95% CI)	20.9 (11.1 to 30.7)	3.1 (−0.4 to 6.6)	17.8 (7.6 to 28.0)	0.001
Response rate — %	59	24	—	0.003
Change in FVC				
Milliliters (95% CI)	416 (201 to 631)	69 (−50 to 187)	347 (107 to 588)	0.005
Percentage (95% CI)	18.3 (9.3 to 27.3)	4.0 (−0.7 to 8.6)	14.4 (4.4 to 24.3)	0.005
Change in distance on 6-min walk test				
Meters (95% CI)	60 (35 to 85)	−14 (−25 to −3)	74 (47 to 100)	<0.001
Percentage (95% CI)	19.6 (10.4 to 28.9)	−3.6 (−6.9 to −0.4)	23.3 (13.6 to 32.9)	<0.001
Response rate — %	59	6	—	<0.001

Table 3. Serious Adverse Events during 6 Months of Follow-up.*

Event	EBV Group (N=34)	Control Group (N=34)	P Value†
	no. (%)		
Total no. of serious events	23	5	<0.001
Pulmonary events:			
Death	1 (3)‡	0	1.00
COPD exacerbation with hospitalization	4 (12)	2 (6)	0.67
Pneumonia	2 (6)	1 (3)	1.00
Pneumothorax	6 (18)	0	0.02
Resolved ≤14 days after onset, without drainage	1 (3)	0	1.00
Resolved ≤14 days after onset, with drainage	2 (6)	0	0.49
Required temporary valve removal	1 (3)§	NA	NA
Required permanent valve removal because of recurrent pneumothorax	1 (3)	NA	NA
Required permanent valve removal, after temporary removal and reimplantation, because of recurrent pneumothorax	1 (3)	NA	NA
Other EBV-related events requiring permanent removal of all valves:			
Torsion of the bronchus	2 (6)¶	NA	NA
Pneumonia distal to valve	1 (3)‖	NA	NA
Increased sputum, dyspnea, or coughing without patient-perceived treatment benefit	2 (6)	NA	NA
Other EBV-related events requiring valve replacement:			
Valve migration	2 (6)	NA	NA
Valve expectoration	0	NA	NA
Valve dislocation due to formation of granulation tissue	1 (3)	NA	NA
Increased sputum, dyspnea, or coughing	1 (3)	NA	NA
Stroke	1 (3)	2 (6)	1.00

CONCLUSION

Endobronchial-valve treatment significantly improved pulmonary function and exercise capacity in patients with severe emphysema characterized by an absence of interlobar collateral ventilation.

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DONE!
THANK YOU FOR YOUR ATTENTION!