

Survival in COPD patients treated with bronchoscopic lung volume reduction

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The first study conducted at a single center to compare the survival rate of patients undergoing BLVR with patients who were evaluated for BLVR but did not undergo the procedure

“Bronchoscopically reducing lung volume in patients with severe hyperinflation can lead to a survival benefit for a population with a severely reduced life expectancy.”

Methods:

- Single-center, non-randomized, retrospective analysis of 1,471 patients who were evaluated for BLVR treatment over a 13-year period at University Medical Center Groningen, Groningen, Netherlands
- 483 (33%) underwent BLVR treatment and 988 (67%) were not treated
- 73% of treated patients underwent treatment with Zephyr® Valves, 27% with endobronchial coils, with subgroup analysis performed for patients receiving Zephyr Valves
- Patient survival for the treated and non-treated groups was measured from date of evaluation for BLVR. Follow-up duration ranged from 633 days to 5401 days
- Analysis included all treated patients, regardless of whether they experienced a response (atelectasis) or not

Study Population:

Patients in the BLVR group had a significantly worse COPD functional disease status, as well as a higher degree of co-morbidity

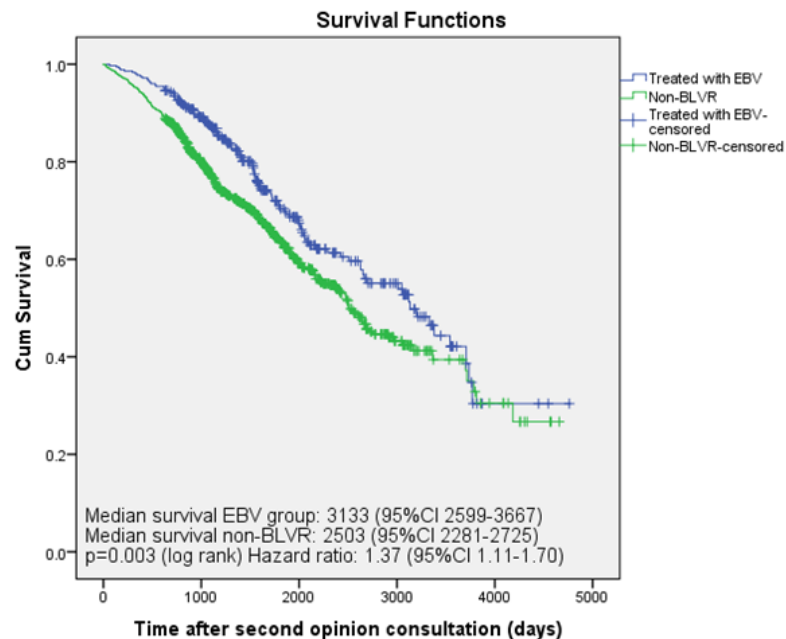
	BLVR GROUP (N=483)	NON-BLVR GROUP (N=988)	P-VALUE
Packyears, years	39 ± 18	40 ± 19	0.179
FEV₁, % of predicted	27.2 ± 7.9	31.8 ± 10.9	<0.001
RV, % of predicted	236.8 ± 41.7	213.4 ± 48.4	<0.001
RV/TLC, %	63.4 ± 7.3	59.6 ± 9.1	<0.001
CAT, total score	21.8 ± 5.6	22.6 ± 6.1	0.049
Emphysema score (-950 HU), %	39.3 ± 7.7	35.6 ± 8.6	<0.001
Air trapping score, %	71.8 ± 6.5	66.5 ± 9.4	<0.001
Comorbidity7 *, yes (%)	63.2%	59.1%	0.229
Comorbidity3 **, yes (%)	27.1%	19.2%	0.007

*Yes, when a patient has one or more of the following 7 comorbidities: cancer, diabetes mellitus, myocardial infarction, a percutaneous coronary intervention, heart failure, hypertension, loss of function or stroke.

**Yes, when a patient has one or more of the following 3 comorbidities: myocardial infarction, a percutaneous coronary intervention or stroke.

Results:

- Median survival of the Zephyr Valve-treated group was 1.7 years longer than the non-treated group ($p < 0.003$)
- Patients in the Zephyr Valve-treated group were 37% less likely to die over the course of the study than non-treated patients
- BLVR treatment was an independent predictor of survival when adjusted for other survival-influencing factors like age, gender, or disease severity



Conclusion:

- This study is the first to compare the survival rate of patients undergoing BLVR with patients who were evaluated for BLVR but were not treated.
- Treatment with Zephyr Valves resulted in a statistically significant increase in survival and reduced risk of death over the study period
- Bronchoscopic lung volume reduction treatment that reduces lung volume in patients with COPD and severe hyperinflation and reduced life expectancy may lead to a survival benefit

United States

Important Safety Information: The Pulmonx Zephyr® Endobronchial Valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; those with evidence of active pulmonary infection; known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); known allergies to silicone; or with large bullae encompassing greater than 30% of either lung; Patients who have not quit smoking. The Zephyr Valve should be used with caution and only after careful consideration in treating patients with: Prior lung transplant, LVRS, median sternotomy, or lobectomy; Congestive heart failure or recent myocardial infarction; FEV1 <15% of predicted value. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial Valve System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

Important Safety Information: The Chartis® System is indicated for use by bronchoscopists during a bronchoscopy in adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD), in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information. The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances. Use is restricted to a trained physician. Prior to use, please reference the Chartis System Instructions for Use/ User Manual for more information on indications, contraindications, warnings, all precautions, and adverse events.

Caution: Federal law restricts this device to sale by or on the order of a physician.

International

Important Safety Information: The Zephyr® Endobronchial Valve is an implantable bronchial valve intended to control airflow in order to improve lung functions in patients with hyperinflation associated with severe emphysema with little to no collateral ventilation, and/or to reduce air leaks. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; Evidence of active pulmonary infection; Patients with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); Patients with known allergies to silicone; Patients who have not quit smoking. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

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Important Safety Information: The Chartis® System is indicated for use by bronchoscopists during a diagnostic bronchoscopy in adult patients with Chronic Obstructive Pulmonary Disease (COPD) and emphysema in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information. The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances. Use is restricted to a trained physician. Prior to use, please reference the Chartis System Instructions for Use/ User Manual for more information on indications, contraindications, warnings, all precautions, and adverse events.

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SOURCES: Eberhardt R, Slebos DJ, Herth FJF, Darwiche K, Wagner M, Ficker JH, Petermann C, Hübner R-H, Stanzel F, Shargill NS, and Valipour A. Endobronchial Valve (Zephyr) Treatment in Homogeneous Emphysema: One-Year Results from the IMPACT Randomized Clinical Trial. *Respiration*, 2021; 100: 1174-1185.
Valipour, A, Slebos, DJ, Herth, F, Darwiche, K, Wagner, M, Ficker, JH, & Eberhardt, R. Endobronchial valve therapy in patients with homogeneous emphysema. Results from the IMPACT study. *Am J Respir Crit Care Med*. 2016;194(9): 1073–1082.