Reduction of Lung Hyperinflation Improves Cardiac Preload, Contractility, and Output in Emphysema: A Prospective Cardiac Magnetic Resonance Study in Patients Who Received Endobronchial Valves

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A single-center, non-randomized, prospective study of the effects of reducing hyperinflation through bronchoscopic lung volume reduction (BLVR) with endobronchial valves on cardiac function and pulmonary artery pressures.

"We found that reduction of hyperinflation using BLVR with endobronchial valves significantly improved cardiac preload, myocardial contractility, and cardiac output, without changes in pulmonary artery pressures."

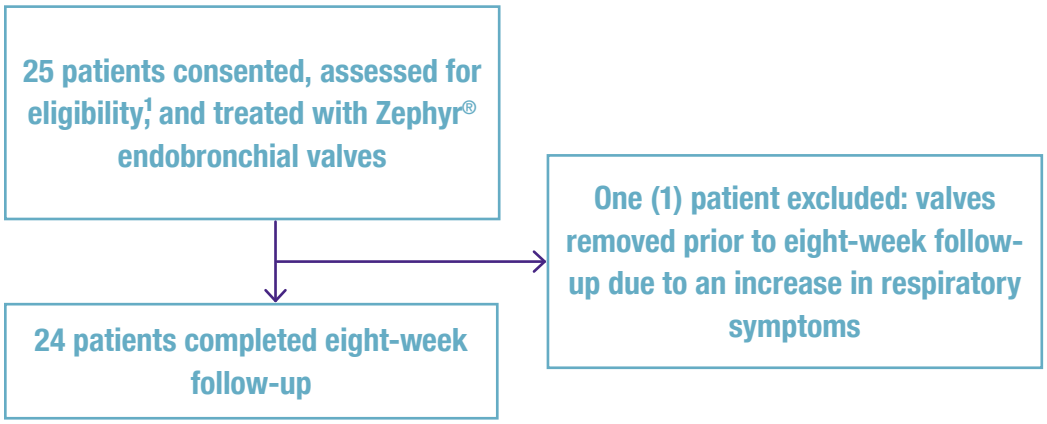
Methods and Endpoints

- First study to extensively assess cardiac function following bronchoscopic lung volume reduction with endobronchial valves
- 24 patients with severe hyperinflation (RV > 175% pred.) and eligible for BLVR were treated with Zephyr® Endobronchial Valves
- Primary endpoint was cardiac preload measured by the right ventricle end-diastolic volume index (RVEDVI) at eight weeks post-BLVR
- Secondary endpoints included indexed end diastolic and end-systolic volumes of the right ventricle, left atrium, and left ventricle, pulmonary artery pressures, cardiac output, ejection fraction, and strain

zephyr® valve

Source: van der Molen MC et al. Am J Respir Crit Care Med. 2022; 206 (6): 704–711.

Study Design



1: FEV1 ≤45% predicted, FEV1/FVC <70%, TLC >100% predicted, residual volume >175% predicted, and >30% emphysematous destruction of the target lobe at -950 Hounsfield units

Results

Primary Endpoint

Significant increases in Right Ventricle End-Diastolic and End-Systolic Volume Indexes (p=0.001 and p=0.024, respectively)

Secondary Endpoint

- Increased Stroke Volume (right ventricle, p=0.026; left atrium, p<0.001; left ventricle, p=0.010)
- Increased Cardiac Output (right ventricle, p=0.018; left ventricle, p=0.007)
- Increased Ejection Fraction (right ventricle, p=NS; left atrium, p=0.013; left ventricle, p=0.032)
- Increased Contractility in all global left ventricle, right ventricle, and left atrium strain measurements
- Increased Peak Flow Velocity (cm/s) in aorta

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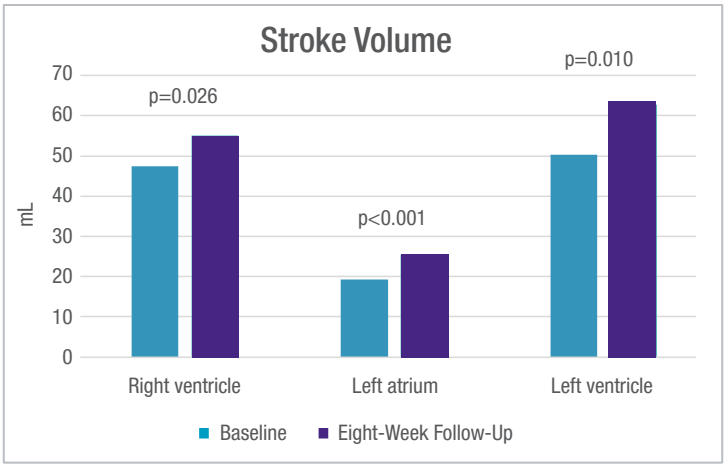

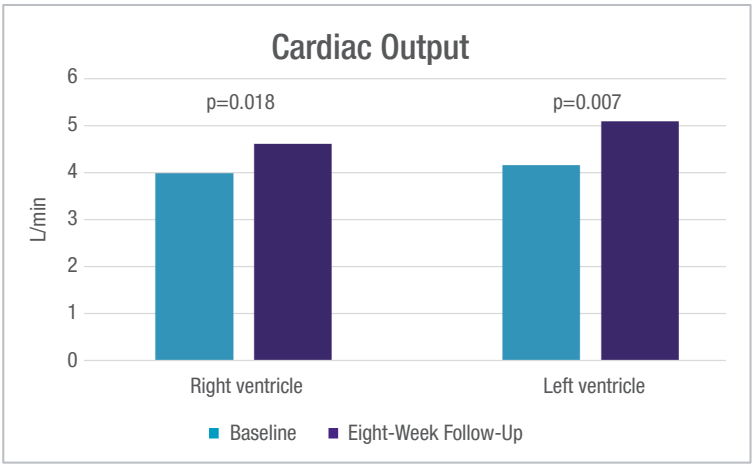

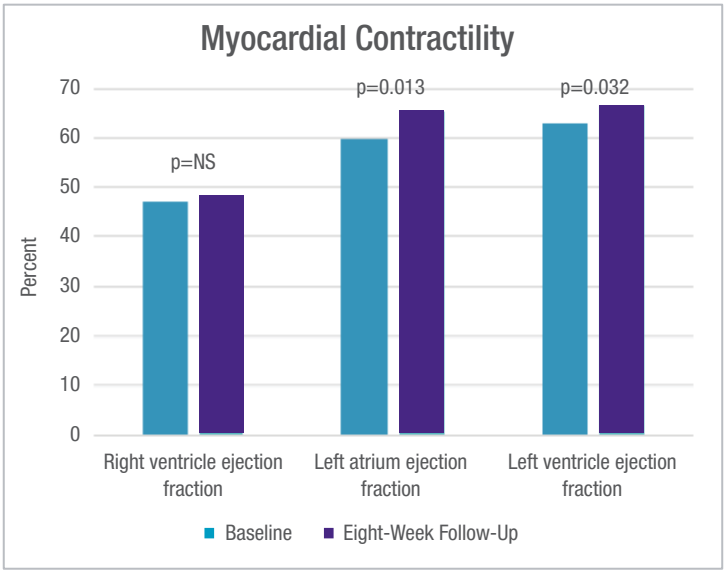

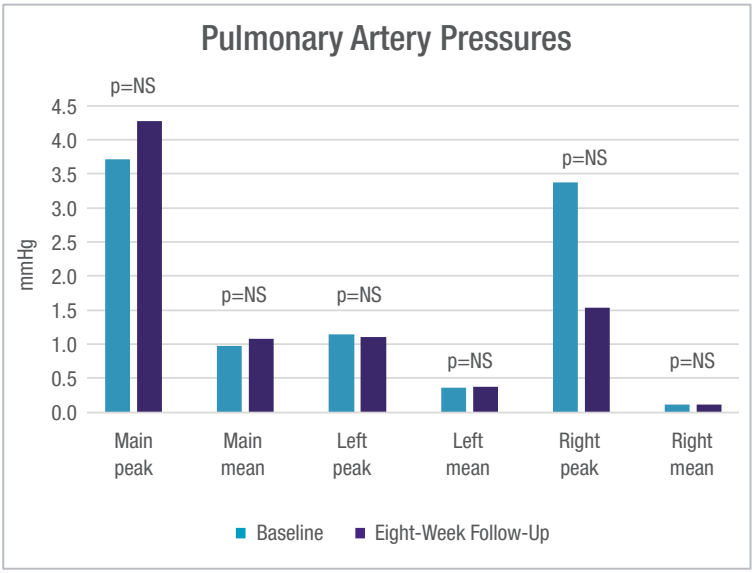

Improvements in Emphysema Clinical Outcomes

Clinically and statistically significant improvements in all clinical outcome measures at eight weeks post-BLVR

Measurement	Baseline	Eight-Week Follow Up	p-value*
Forced Expiratory Volume in 1 Second (FEV_1, L)	0.8 ± 0.19	1.05 ± 0.26	<0.001
Forced Vital Capacity (FVC, L)	2.78 ± 0.81	3.4 ± 0.97	<0.001
Residual Volume (RV, L)	5.29 ± 1.28	4.14 ± 1.09	<0.001
Total Lung Capacity (TLC, L)	8.41 ± 1.72	7.77 ± 1.73	<0.001
RV/TLC (%)#	62.83 ± 6.86	53.25 ± 6.67	<0.001
Inspiratory volume of target lobe (L)	2.14 ± 0.61	0.35 ± 0.68	<0.001
6MWT (meters)	341.8 ± 91.0	400.1 ± 70.5	<0.001
SGRQ Total Score (points)†	54.1 ± 13.9	35.9 ± 14.0	<0.001

RV/TLC = residual-to-total lung capacity ratio; 6-MWT = 6-minute walking distance; SGRQ = St. George's Respiratory Questionnaire.

*Paired sample t-test
#Based on 23 patients with evaluable data.
†Based on 22 patients with evaluable data.

SOURCE: van der Molen MC et al. Am J Respir Crit Care Med. 2022; 206 (6): 704–711.

Conclusion

BLVR with Zephyr® Valves resulted in:

- Target lobe volume reduction with associated improvements in airflow limitation, lung volumes, exercise capacity, and quality of life
- Clinically meaningful improvements in cardiac preload, myocardial contractility, and cardiac output with no changes in pulmonary artery pressures

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.

THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC.

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.

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