THE IMPACT STUDY

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The first prospective randomized controlled trial of Zephyr® Endobronchial Valves (EBV) specifically in patients with homogeneous emphysema and little to no collateral ventilation (CV)

"EBV therapy in selected patients with homogeneous emphysema without collateral ventilation results in clinically meaningful benefits of improved lung function, exercise tolerance, and quality of life. Given the very limited treatment options available for this patient population, EBV therapy should be considered in these patients."*

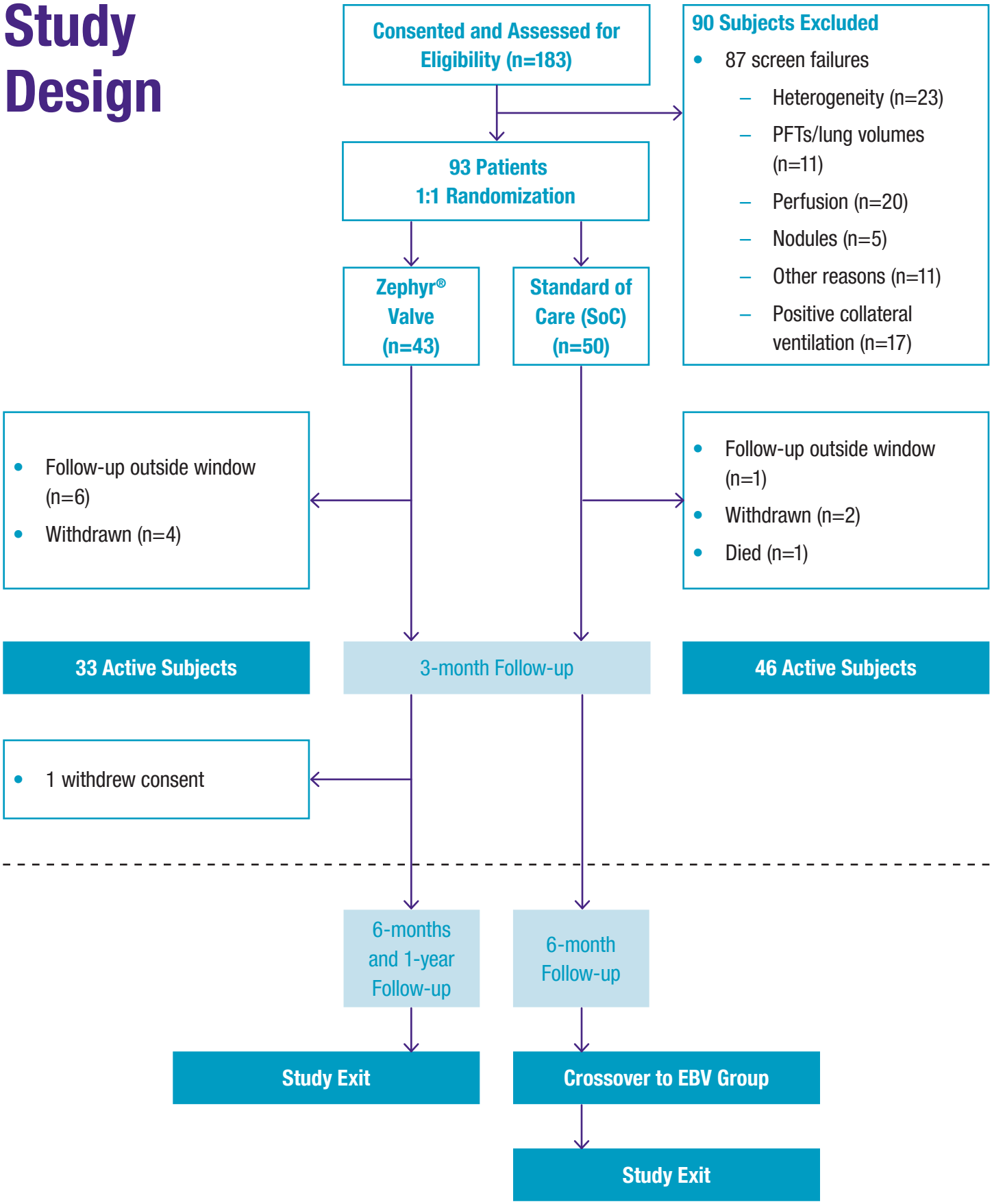
Methods

- 93 patients with homogeneous emphysema were confirmed with the Chartis® System to be CV negative and likely responders to Zephyr EBV treatment and randomized 1:1 to either EBV treatment or medical management.
- For EBV-treated patients, target lobes were selected based on emphysema destruction scores and regional perfusion impairments and were then completely occluded with valves.
- If patients did not feel a benefit, the valve position was assessed at 30 days by CT and repositioned if necessary.

*SOURCE: Valipour, A, Slebos, DJ, Herth, F, Darwiche, K, Wagner, M, Ficker, JH and Eberhardt, R. Endobronchial valve therapy in patients with homogeneous emphysema. Results from the IMPACT Study. American journal of respiratory and critical care medicine, 2016;194(9), 1073-1082.

zephyr® valve

Study Design



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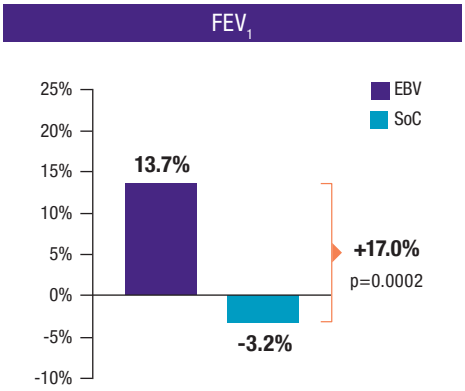
Results

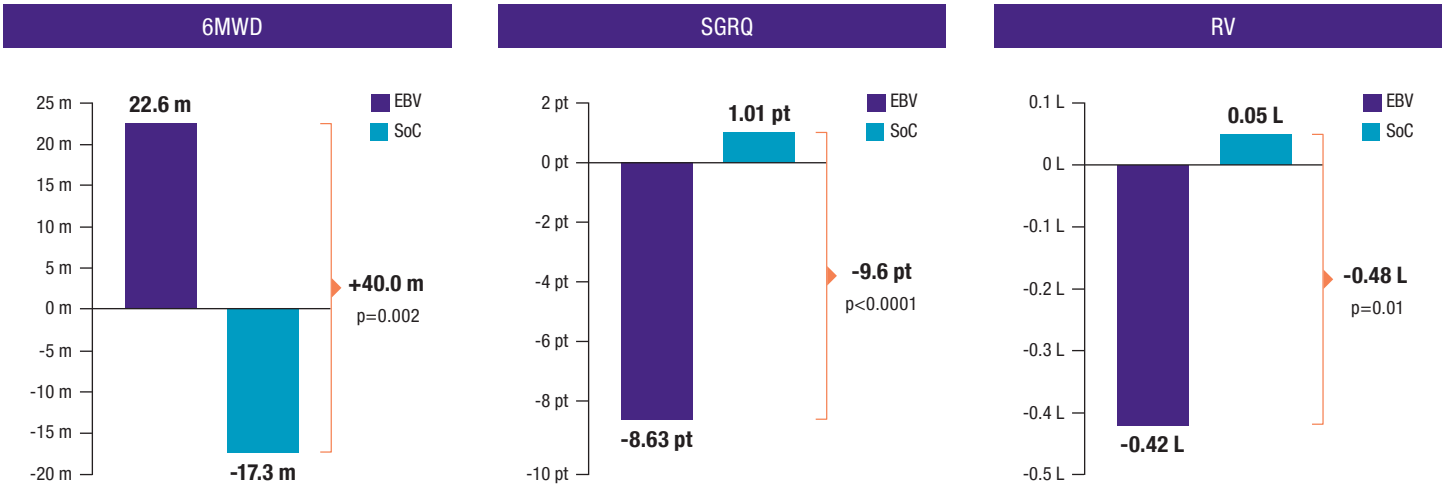
Primary Outcome in the Intention-to-Treat Population

Percent change from baseline to 3 months.



Secondary Outcomes in the Intention-to-Treat Population

Change from baseline to 3 months.



Conclusion

Patients with homogeneous emphysema can achieve clinically meaningful benefits in lung function, exercise tolerance, and quality of life with endobronchial valve treatment when they are pre-selected for absence of collateral ventilation and have complete lobar occlusion.

United States

Brief Statement: 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; Patients with 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; Patients with large bullae encompassing greater than 30% of either lung. 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.

Brief Statement: 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

Brief Statement: 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 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.

Brief Statement: 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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