THE TRANSFORM STUDY

Published in The American Journal of Respiratory and Critical Care Medicine

A multicenter, multinational randomized controlled trial of Zephyr® Endobronchial Valves (EBV) in patients with heterogenous emphysema and little to no collateral ventilation

"Benefits are in line with those seen with LVRS (lung volume reduction surgery), and the consistent trial results, potential reduction in post-procedure morbidity, and reversibility of the procedure position Zephyr treatment as a viable treatment option in those who remain symptomatic on maximal medical therapy."*

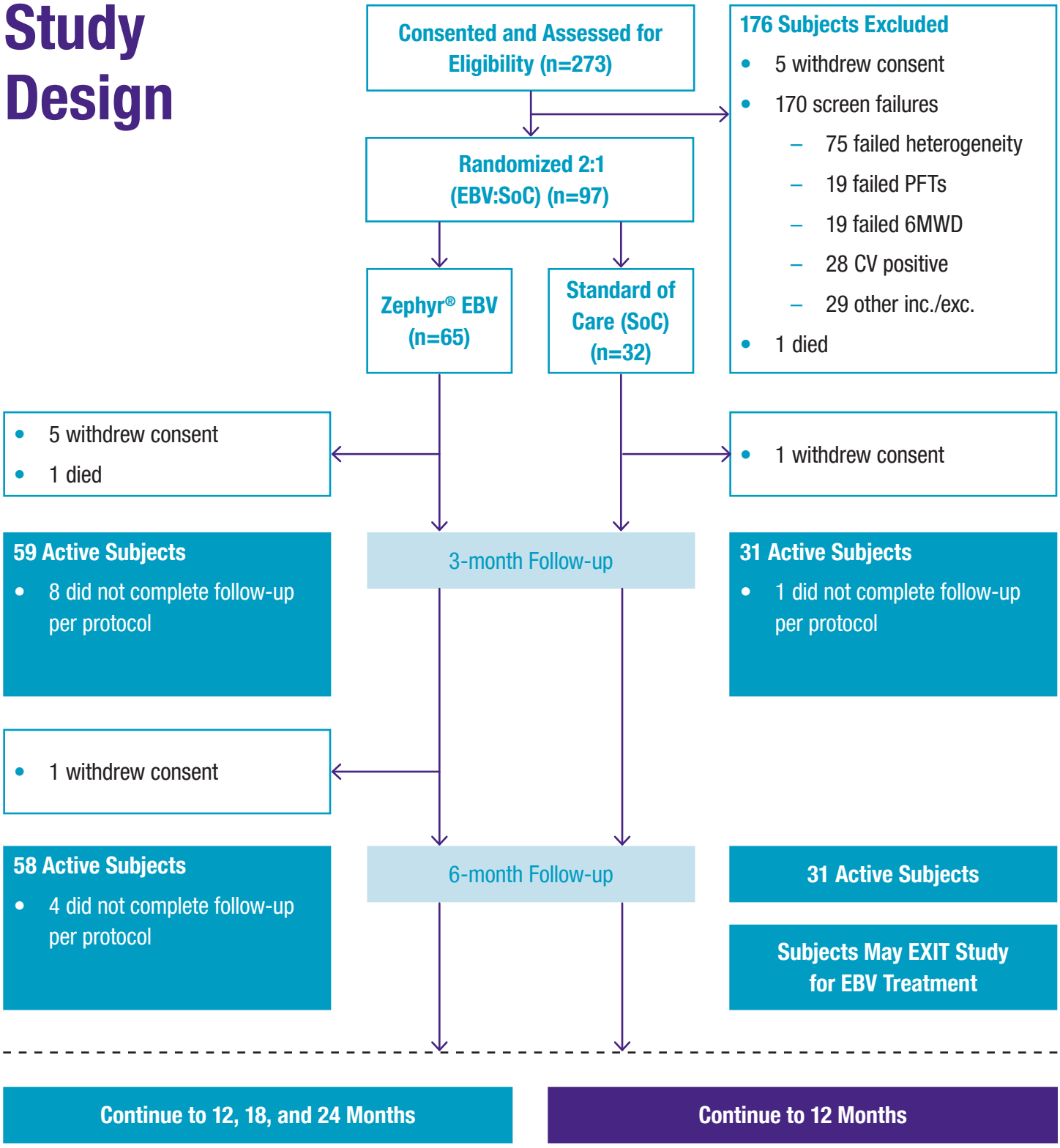
Methods & Endpoints

- 97 patients with heterogeneous emphysema were confirmed with the Chartis® System to be collateral ventilation (CV) negative and likely responders to Zephyr EBV treatment, and randomized 2:1 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.
- Valve position was assessed at 45 days post-implant by CT and repositioned, if necessary.

*SOURCE: Kemp, SV, Slebos, DJ, Kirk, A, Kornaszewska, M, Carron, K, Ek, L and Briault, A. A multicenter randomized controlled trial of Zephyr endobronchial valve treatment in heterogeneous emphysema (TRANSFORM). American journal of respiratory and critical care medicine, 2017;196(12), 1535-1543.

zephyr® valve

Study Design



Reasons for withdrawn consents

- 5 EBV subjects before 3-month visit: 1 difficult anatomy for EBV placement; 1 experienced two pneumothoraces and worsening COPD; 2 for lack of perceived benefit; 1 non-compliant, withdrawn by investigator
- 1 EBV subject between 3- and 6-month visit: Worsening COPD, all valves removed, subject withdrew consent
- 1 SoC subject before 3-month visit: Exited study to pursue EBV treatment outside of the study

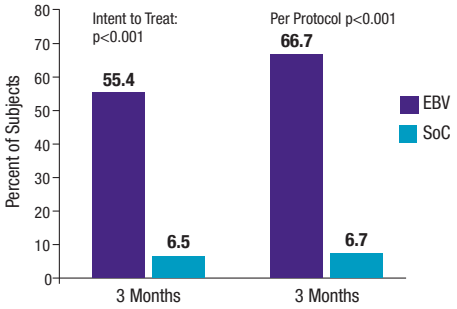
SOURCE: Kemp, SV, Slebos, DJ, Kirk, A, Kornaszewska, M, Carron, K, Ek, L and Briault, A. A multicenter randomized controlled trial of Zephyr endobronchial valve treatment in heterogeneous emphysema (TRANSFORM). American journal of respiratory and critical care medicine, 2017;196(12), 1535-1543.

Results

Primary Endpoint

Percent of subjects achieving a 12% or greater improvement in FEV_1 (L) at 3 months.

Percent of Subjects with FEV_1 Change of ≥ 12%



Secondary Endpoints in the Intent-to-Treat Population

Figure 2a: FEV_1 Improvement (L)

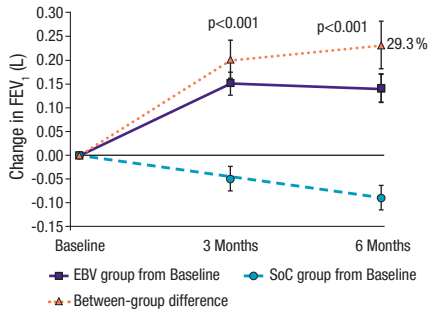


Figure 2b: 6MWD Improvement (meters)

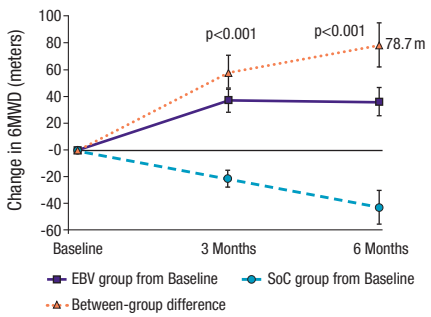


Figure 2c: RV Improvement (L)

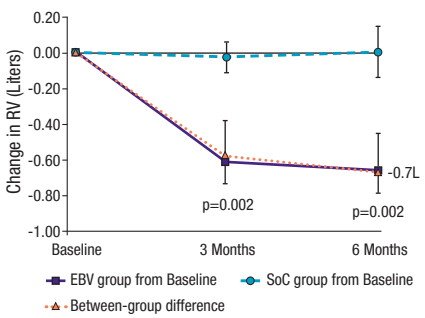


Figure 2d: SGRQ Improvement (points)

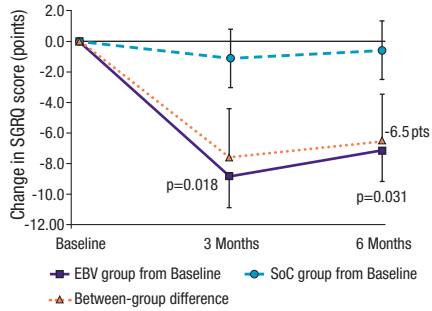
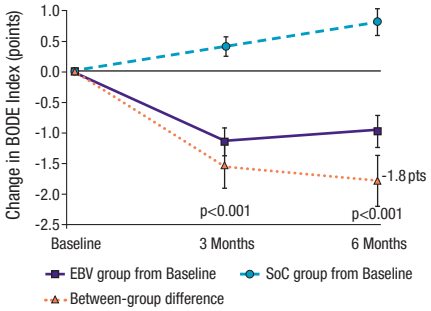


Figure 2e: BODE Improvement (points)



Conclusion

Zephyr® EBV treatment results in clinically meaningful and statistically significant benefits in lung function, dyspnea, exercise tolerance, and quality of life over current standard of care medical therapy when used in hyperinflated subjects with heterogeneous emphysema without collateral ventilation in the target lobe.

Legend to Figure 2: Data presented are mean ± SEM for changes from baseline to 3 and 6 months post bronchoscopy for EBV (■), SoC (●), and difference between EBV and SoC (▲). Figure 2a: FEV_1 (L); Figure 2b: 6-Minute Walk Distance (m); Figure 2c: RV (L); Figure 2d: St. George's Respiratory Questionnaire; and Figure 2e: BODE Index.

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.

pulmonx®

Pulmonx Corporation
700 Chesapeake Drive
Redwood City, CA 94063

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