

The TRANSFORM Trial

A multicenter, multinational randomized controlled trial of Zephyr® Endobronchial Valves in patients with heterogenous emphysema and 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 EBV® treatment as a viable treatment option in those who remain symptomatic on maximal medical therapy.”

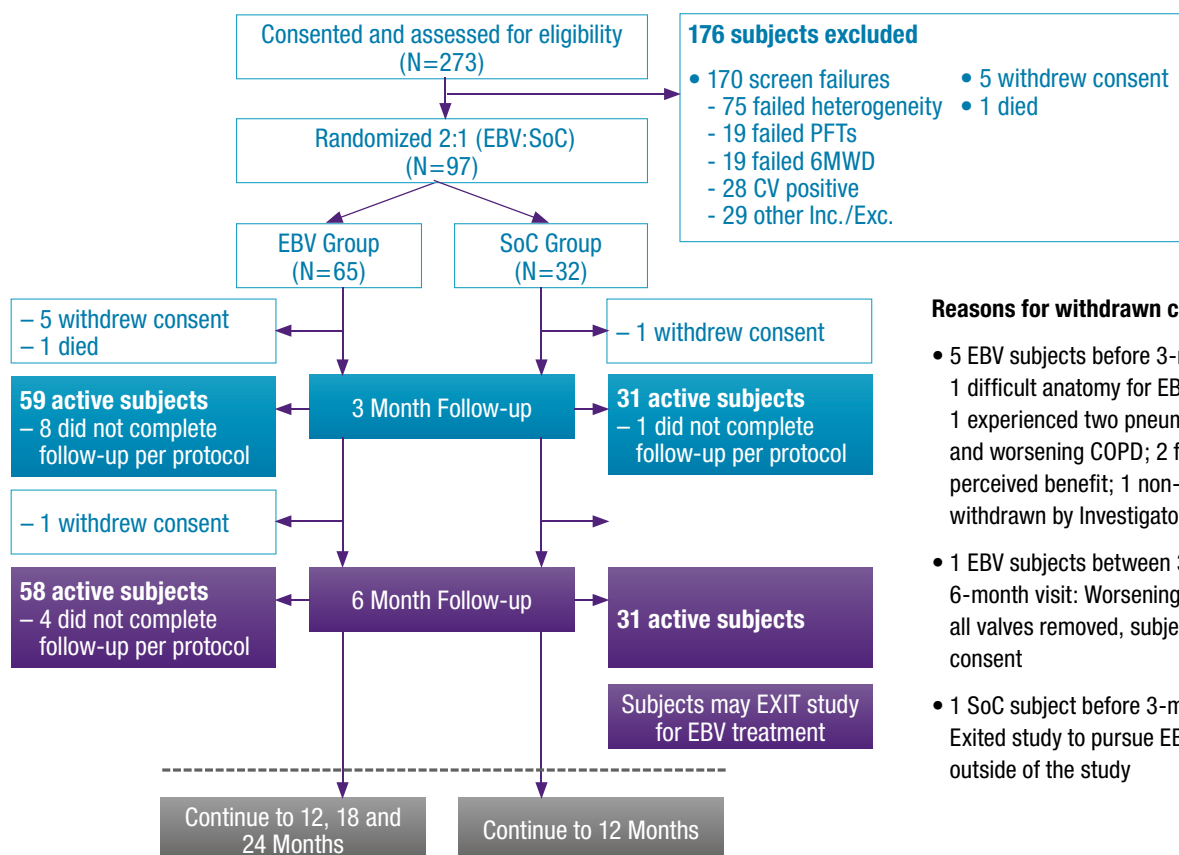


SOURCE: Kemp S et. al. Am J Respir Crit Care Med. 2017

METHODS & ENDPOINTS

- 97 patients with heterogeneous emphysema were confirmed with the Chartis System to be 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.

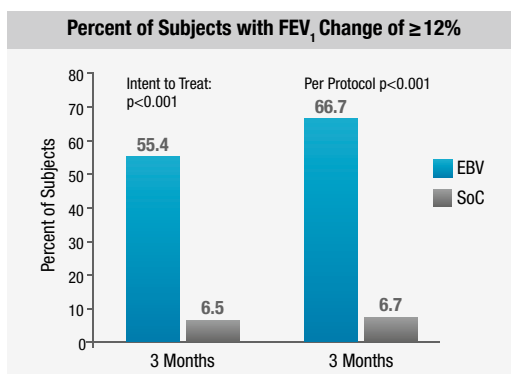
STUDY DESIGN



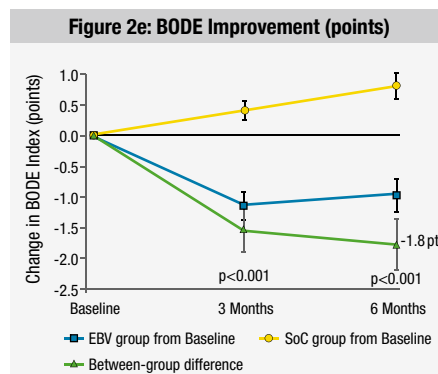
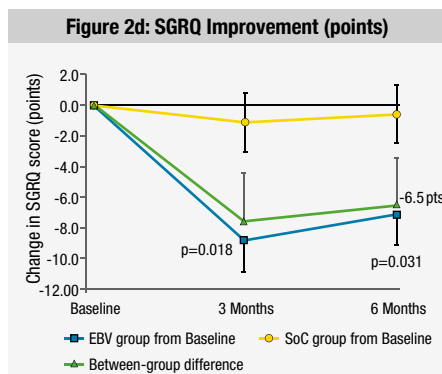
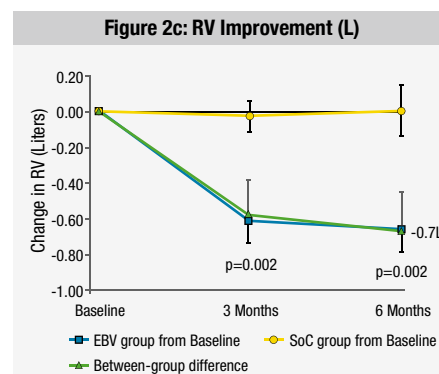
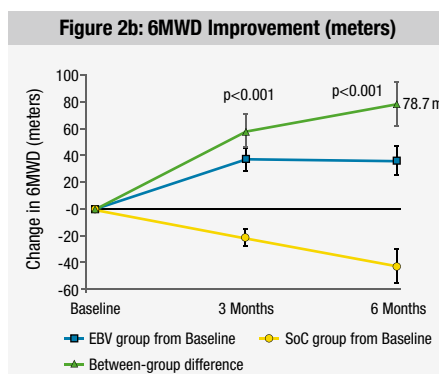
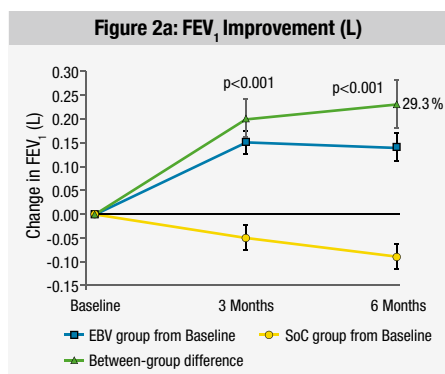
Reasons for withdrawn consents

- 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 subjects 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

Primary Endpoint – Percent of subjects achieving a 12% or greater improvement in FEV₁ (L) at 3 Months



Secondary Endpoint in the Intent to Treat Population



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: FEV₁ (L); Figure 2b: 6-Minute Walk Distance (m); Figure 2c: RV (L); Figure 2d: St. George's Respiratory Questionnaire; and Figure 2e: BODE Index.

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.

SOURCE: Kemp S et. al. Am J Respir Crit Care Med. 2017