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The LIBERATE Study

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

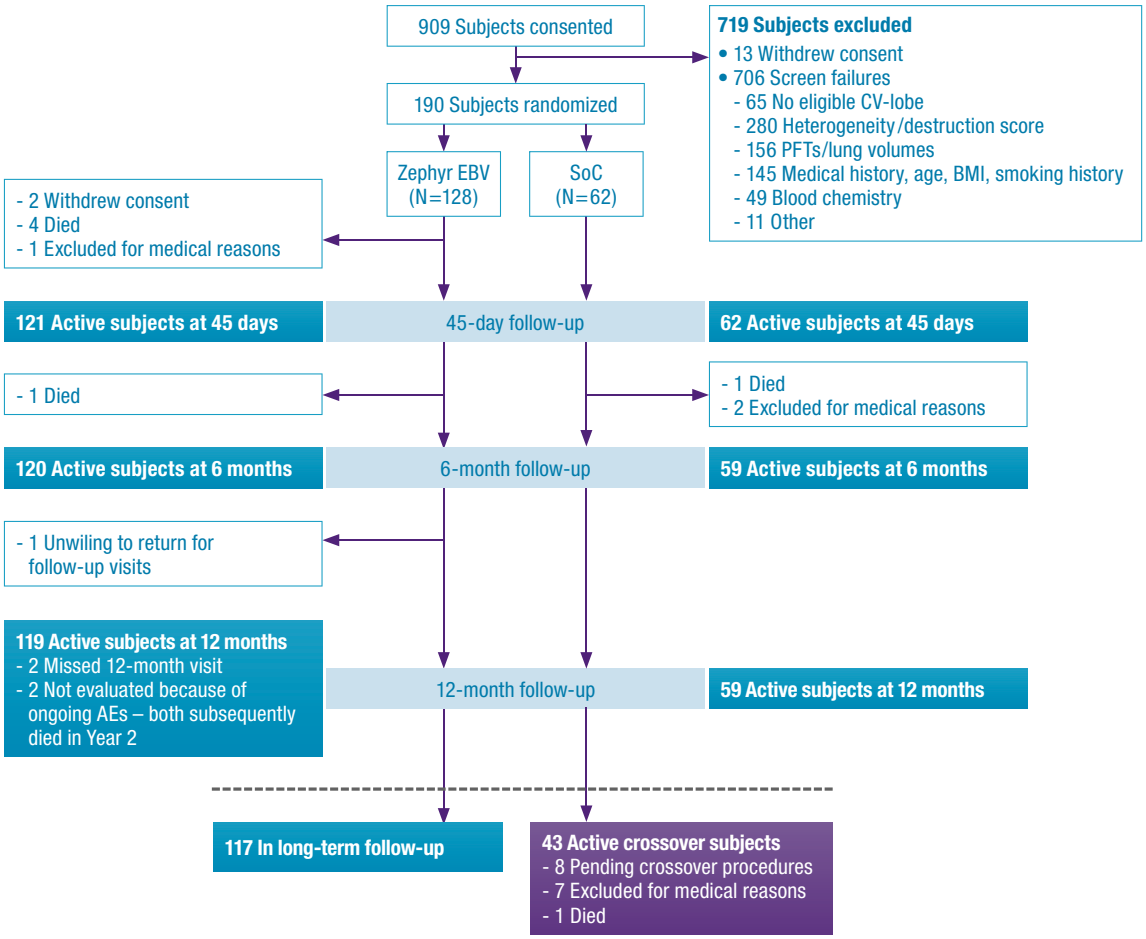
"The benefits are comparable to those seen with LVRS but with a reduction in post-procedure morbidity."

Criner G et al Am J Resp Crit Care Med 2018, in press

METHODS & ENDPOINTS

- First multicenter RCT to evaluate effectiveness and safety of Zephyr® Endobronchial Valves in patients with little or no collateral ventilation (CV) out to 12 months.
- 190 subjects with hyperinflation (RV, 225% pred.; FEV_1, 27% pred.; DLCO, 34% pred.) randomized 2:1 (128 Zephyr EBV: 62 SoC).

STUDY DESIGN

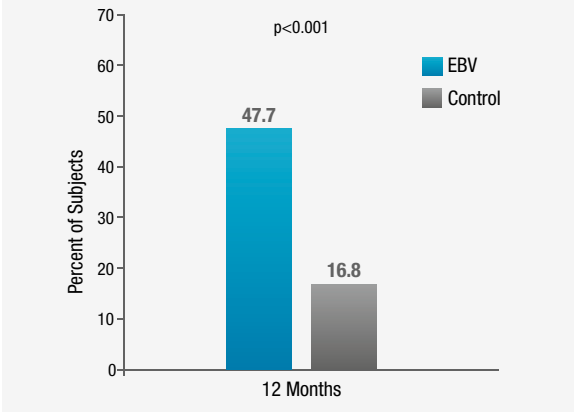


SOURCE: Criner G et al Am J Resp Crit Care Med 2018, in press

RESULTS IN ITT POPULATION

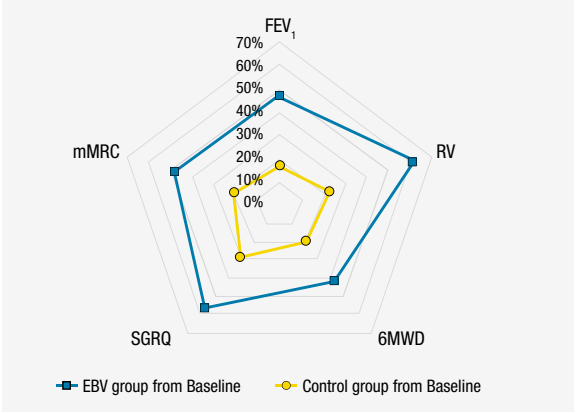
Primary Endpoint Responder Analysis

Percent of Subjects with FEV_1 Change of ≥ 15%



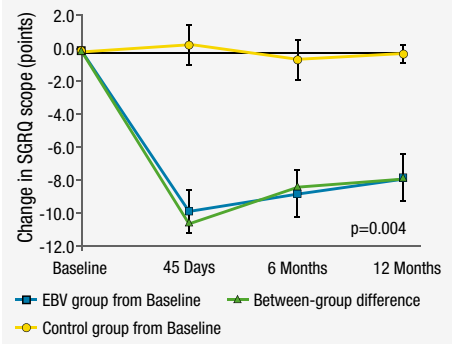
Other Responder Analysis

Proportion of Patients Achieving MCID

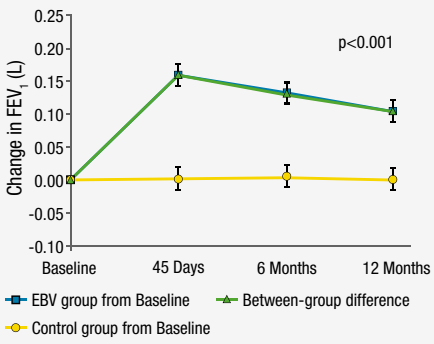


Secondary Endpoints

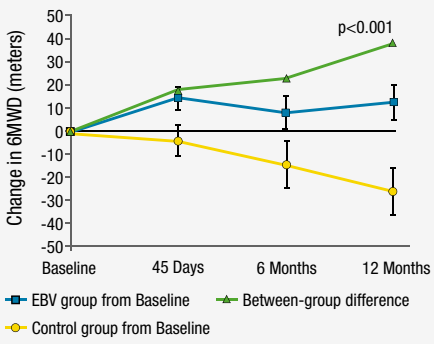
St. George's Resp Questionnaire (points)



FEV_1 (L)



Six-Minute Walk Distance (meters)



Safety: Pulmonary Serious Adverse Events Occurring in at Least 3.0% of Subjects in Either Group

	Treatment Period 0 – 45 Days		Longer-Term Period 46 Days – 1 Year	
	EBV (N=128)	SoC (N=62)	EBV (N=122)	SoC (N=62)
Death	3.1%	0%	0.8%	1.6%
Pneumothorax	26.6%*	0%	6.6%	0%
COPD exacerbation	7.8%	4.8%	23.0%	30.6%
Pneumonia	0.8%	0%	5.7%	8.1%
Respiratory failure	1.6%	0%	0.8%	3.2%

*Statistically different from SoC

- Increased SAE rate with EBV treatment compared to standard of care in the short-term (first 45 days post-procedure)
- Reduced SAE rate long-term (46 days to 12 months) with EBV treatment compared to standard of care
- 5 of the 8 subjects experiencing a pneumothorax in the longer-term period had recently undergone a secondary bronchoscopy for valve replacement and/or removal.

CONCLUSION

Zephyr® Endobronchial Valve treatment in carefully selected patients with little or no collateral ventilation in the target lobe provides clinically meaningful and statistically significant benefits in lung function, exercise tolerance, dyspnea and quality of life over current standard of care medical therapy out to at least 12 months.

SOURCE: Criner G et al Am J Resp Crit Care Med 2018, in press

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