

Abstract

The Effectiveness And Safety Of Zephyr Endobronchial Valve For
The Treatment Of Heterogeneous Emphysema In China : A
Multi-center Randomized Controlled Clinical Trial

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Objective: To assess the efficacy and safety of Zephyr valve
Endobronchial Valve (EBV) for treating Chinese patients with
severe heterogeneous emphysema without collateral ventilation.

Methods: This prospective, multi-center, randomized controlled
clinical trial enrolled patients from 3 sites from April 2017 to April
2020. Subjects were randomized into an EBV group and
Standard-of-Care (SoC) group. The subjects from the SoC group

received Standard-of-Care and were discharged after post-bronchoscopy; those with EBV underwent placement of Zephyr EBV valves during the same session. The primary outcome was the percentage of subjects who showed improvement in the post-bronchodilator (post-BD) FEV1 of $\geq 15\%$ at 1-year follow-up. Secondary endpoints were: the difference between an absolute change in FEV1, Six-Minute Walk Distance (6MWD), St. George's Respiratory Questionnaire (SGRQ), Chronic Obstructive Pulmonary Disease Assessment Test (CAT), Modified Medical Research Council Dyspnea Scale (mMRC) at 12-months.

Results: A total of 60 subjects (20 EBV, and 40 SoC) were included. At 12-months, 55% EBV and 25% SoC subjects had a $\Delta\text{FEV1} \geq 15\%$ ($p < 0.001$). with a between-group absolute difference of 30.0, RR:2.2 [95% CI: 22.84% to 57.16%; $p < 0.001$; Intention-to-Treat], from baseline to 12-months follow-up difference in FEV1 (0.249L, [95% CI: 0.200 to 0.298]), 6MWD (+154.640meters, [95% CI: 120.463 to 188.817]), mMRC (-0.75 points, [95% CI: -0.287 to -1.213]), SGRQ (-14.125 points, [95% CI: -13.076 to -15.174]), CAT (-9.10 points, [95% CI: -8.24 to -11.35])(all $p < 0.05$)

Conclusions: Compared to Standard-of-Care (SoC), Zephyr valve EBV can improve lung function, dyspnea, quality of life, and exercise capacity for at least 1-year in COPD patients without collateral ventilation.

References:

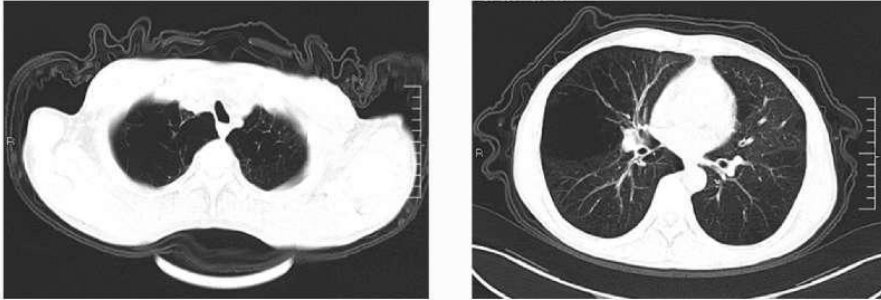
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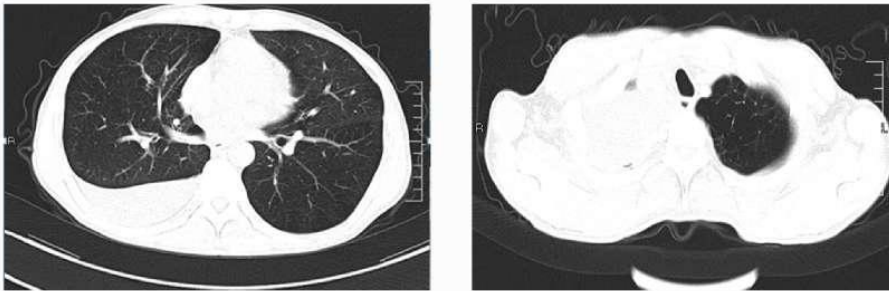
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Conflicts of interest:none

Preoperative of EBV



Postoperative of EBV



Implantment of EBV valve

