Lung Volume Reduction with Endobronchial Zephyr Valve

Maggie Yavaraski, PA-S

Background & Purpose

Chronic obstructive pulmonary disease (COPD) is a progressive limitation to airflow at the site of airway pathways such as the bronchioles and the alveoli, COPD is the third leading cause of death in the United States, and worldwide, COPD is the fourth leading cause of death.[1] Patients in advanced stages of emphysema (COPD-e) lung function is significantly impaired, leading to a profound impact on their quality of life.

Lung volume reduction surgery was first introduced to reduce COPD-e symptoms. More recently, Zephyr Valve offers a non-invasive and reversible option to reduce the COPD-e symptoms in patients with severe stage of this disease. This paper aims to evaluate the effectiveness of Zephyr Valve placement, via lung function, in patients with severe COPD-e in one year post Zephyr Valve placement.

PICOT

In patients with severe COPD emphysema, what is the effect of using the Zephyr Valve on improving lung function: TV, TLC, FEV1 compared with lung resection surgery, within one-year post-procedure?

Design & Methods

Keywords: Zephyr Valve, COPD, Emphysema, Exacerbation, Lung function

Inclusion: Studies Zephyr Valve placement versus lung volume reduction surgery and measures lung function, within one year post Zephyr placement. Studies that are published 2018 or later, results in English, full text available, and peer-reviewed.

Exclusion: Studies that did not use Zephyr Valve for treating severe COPD and did not measure lung function. Studies published earlier than 2018, not in full text, not in English, and not peer-reviewed.

Table 1. Summary of Evidence Search:

Database	Yielded	Reviewed	Included in Analysis
Google Scholar	207	10	0
Pub Med	8	3	0
Valpo Summon	46	12	5
Total:	261	25	5

Synthesis of Evidence

Five studies total were used for this research: two retrospective analyses, two randomized control trials, and one multicenter prospective randomized control trial crossover.

Results:

Primary Outcome: Lung Function One Year Post Zephyr Valve

Absolute change in FEV1 8.29±28.42 (41), p 0.069 and RV −460±1,000 (42), p 0.005 at 1 year.[3]

Percent post-bronchodilator FEV1 improvement of ≥15%, which was seen in 47.7% of the Zephyr Valve group and 16.8% of the SoC group with group difference Zephyr-SoC 31.0% (95% CI 18.0 to 43.9) and p-value <0.001.[4]

VC, FEV1, RV, and TLC significantly improved at 6 months and at one year all lung functions except VC and TLC showed significant improvement.[5]

Secondary Outcomes: COPD exacerbation rates, and quality of life and symptomatic scales

COPD exacerbation rates significant decrease from the year before 1.8 ± 2.2 exacerbations p = 0.009. 90% of all patients experienced at least one exacerbation one year before EBV placement, whereas 68.2% of patients experienced at least one exacerbation one year post EBV placement.[6]

Table 2. Changes from Baseline to Six and 12 Months in COPD Validated Measures

Study	6MWD (Meters)	SGRQ (Range: 0-100)	CAT (Range 0-40)	mMRC (Grade 0-4)	BODE (Range 0-10)
Six Months Δ Zephyr valve – SoC					
Eberhardt[3]	28.3±55.3 P 0.016	−7.51±9.56 P <0.001	−0.70±4.51 P 0.468	−0.42±0.81 P 0.019	−0.85±1.39 P 0.006
12 Months Δ Zephyr valve – SoC					
Criner[4]	39.31 (14.64 to 63.98) P 0.002	−7.05 (−11.84 to −2.27) P 0.004	N/A	−0.8 (−1.1 to −0.4) P <0.001	−1.2 (−1.8 to −0.7) P <0.001
Dransfield[7]	39.3 p 0.002	-7.05 p 0.004	Breathlessness: -0.6 p<0.001 Limited activities: -0.7 p <0.001 Confidence -0.7 p0.0224 Energy –0.7 p 0.014	-0.8 p <0.001	N/A
12 Months Zephyr valve group only					
Gompelmann[5]	25.8 ± 82.0 p < 0.05 (paired t test) observed data	N/A	N/A	-0.6 ± 1.4 p < 0.05 (paired t test) observed data	N/A

Best Practice

Discussion:

All studies favored the primary outcome of measuring lung function: post Zephyr Valve after one year and demonstrated long-term benefits beyond two years.[1-2, 3-5,7]

Exacerbation rates were decreased, 6-MWT had significant improvement after 6 months, and SGRQ demonstrated improvement. There were point decreases in the mMRC scale, BODE index, and CAT. The TDI for Zephyr and volume reduction surgery remained similar.[3-7]

Limitations:

The multicenter prospective randomized control trial crossover did not have the standard of care group observed at the 12-month follow up, which prevented an accurate comparison of the Zephyr Valve versus standard of care.[3]

One randomized control trial failed to include strict inclusion and exclusion criteria for participants.[4] One retrospective analysis lacked retention at the one-year mark.[5]

Another randomized control trial relied on patient self-reported exacerbation rates before and after Zephyr placement.[6] Another retrospective analysis had patient self-reporting scales, leading to potential confirmation bias, and no blind randomization.[7]

Further study:

More studies should be done to examine the long-term adverse effects of Zephyr Valve placement, beyond the one-year timeframe.

Conclusion:

In select patients, the utilization of Zephyr outweighs the associated risks as a therapeutic management for severe COPD-e.

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