

2023 GOLD Report: Endobronchial Valve (EBV)

Highlights from “Interventional Therapy in Stable COPD” Chapter (page 82–92)

The 2023 GOLD report summarizes the efficacy of Endobronchial Valves (EBV) to alleviate dyspnea, improve quality of life, and reports on survival data in severe emphysema patients in the “Interventional & Surgical Therapies for COPD” section.

EBV is used in Endoscopic Lung Volume Reduction (ELVR) procedures, also often called Bronchoscopic Lung Volume Reduction (BLVR).



2023 REPORT

NEW

Study results added to 2023 GOLD Report, and did not appear in previous reports.

PATIENT BENEFITS REPORTED IN CLINICAL STUDIES ON ENDOBRONCHIAL VALVE (EBV) TREATMENT (PAGE 85–86)

- ↑ **Improved survival** after successful treatment (4 retrospective studies) **NEW**
- ↑ **Preferred treatment** over LVRS or continued medical therapy **NEW**
- ↑ **Improved FEV₁, 6MWD, and health status** at 6 and 12 months*
- ↓ **Decreased exacerbations**
- ↓ **Decreased respiratory failure episodes**
- ↓ **May delay need for lung transplant** or optimize the patient’s condition if transplant needed **NEW**
- ↓ **Fewer complications and comparable benefits** to lung volume reduction surgery (LVRS)

CRITERIA TO REFER PATIENT FOR EBV ASSESSMENT

- Confirmed diagnosis of COPD
- Non-smoking or willing to quit smoking
- FEV₁ ≤ 50% predicted
- Breathless despite optimal medical management

Complications of the Endobronchial Valve treatment can include but are not limited to pneumothorax, worsening of COPD symptoms, hemoptysis, pneumonia, dyspnea and, in rare cases, death.

*Quality and quantity of data was rated “Evidence Level A”

Endobronchial Valves (EBV) have achieved the highest evidence rating possible under GOLD's standards — Evidence A. In addition, EBV has the highest level of evidence in the Bronchoscopic intervention category, which is the least invasive of all the therapy categories listed in the table below (page 87).

Interventional Therapy in Stable COPD

Lung Volume Reduction Surgery	<ul style="list-style-type: none"> Lung volume reduction surgery improves survival in severe emphysema patients with an upper-lobe emphysema and low post-rehabilitation exercise capacity (Evidence A)
Bullectomy	<ul style="list-style-type: none"> In selected patients, bullectomy is associated with decreased dyspnea, improved lung function, and exercise tolerance (Evidence C)
Transplantation	<ul style="list-style-type: none"> In appropriately selected patients with very severe COPD, lung transplantation has been shown to improve quality of life and functional capacity (Evidence C)
Bronchoscopic Interventions	<ul style="list-style-type: none"> In select patients with advanced emphysema, bronchoscopic interventions reduce end-expiratory lung volume and improve exercise tolerance, health status, and lung function at 6–12 months following treatment. Endobronchial valves (Evidence A); Lung coils (Evidence B); Vapor ablation (Evidence B)
Bronchoscopic Interventions Under Study	<ul style="list-style-type: none"> Phase III trials are currently being conducted to determine the efficacy of treatments for patients with refractory exacerbations and chronic bronchitis using cryospray, rheoplasty, and targeted lung denervation technology

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References

Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Global Initiative for Chronic Obstructive Lung Disease; 2023. Available from: <http://goldcopd.org>.

Key Studies Referenced in GOLD Report on Endobronchial Valves (Bibliography on pages 105–107)

- Klooster, K et al. *N Engl J Med*. 2015; 373(24): 2325–35.
- Criner, GJ et al. *Am J Resp Crit Care Med*. 2018; 198(9): 1151–1164.
- Kemp, SV et al. *Am J Resp Crit Care Med*. 2017; 196(12): 1535–43.
- Valipour, A et al. *Am J Resp Crit Care Med*. 2016; 194(9): 1073–82.
- Criner, GJ et al. *Am J Resp Crit Care Med*. 2019; 200(11): 1354–62.
- van Geffen, WH et al. *Respiration*. 2017; 94(2): 224–31.
- Hopkinson, NS et al. *Eur Respir*. 2011; 37(6): 1346–51.
- Garner, J et al. *Am J Resp Crit Care Med*. 2016; 194(4): 519–21.
- Gompelmann, D et al. *Respiration*. 2019; 97(2): 145–52.
- Hartman, JE et al. *Respir Med*. 2022; 196: 106825.
- Mansfield, C et al. *Chronic Obstr Pulm Dis*. 2018; 6(1): 51–63.
- Naunheim, KS et al. *Ann Thorac Surg*. 2006; 82(2): 431–423.
- DeCamp, MM et al. *Ann Thorac Surg*. 2006; 82(1): 197–206
- Bavaria, JE et al. *J Thorac Cardiovasc Surg*. 1998; 115(1): 9–17.
- Senbakkavaci, O et al. *Eur Cardiothorac Surg*. 2002; 22(3): 363–7.
- Slama, A et al. *J Thorac Dis*. 2018; 10(Suppl 27): S3366–S75.
- Slama, A et al. *Transpl Int*. 2022; 35: 10048.
- Fuehner, T et al. *Respiration*. 2015; 90(3): 243–50.

Important Safety Information: 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 with little to no collateral ventilation, 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.

THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC.