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 extend survival in COPD 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).



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

↑ Improved survival found in 4 separate studies

NEW

↑ Preferred treatment over LVRS or continued medical therapy



↑ 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

Fewer complications and comparable benefits to lung volume reduction surgery (LVRS)

CRITERIA TO REFER PATIENT FOR EBV ASSESSMENT

Confirmed diagnosis of COPD

NEW

Non-smoking or willing to guit smoking

Study results added

to 2023 GOLD Report,

and did not appear in

previous reports.

- 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

 Lung volume reduction surgery improves survival in severe emphysema patients with an upper-lobe emphysema and low post-rehabilitation exercise capacity (Evidence A)

Bullectomy

 In selected patients, bullectomy is associated with decreased dyspnea, improved lung function, and exercise tolerance (Evidence C)

Transplantation

• 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

 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 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.
- Senbaklavaci, 0 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.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Important Safety Information: The Pulmonx Zephyr® Endobronchial Valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; those with evidence of active pulmonary infection; known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); known allergies to silicone; or with large bullae encompassing greater than 30% of either lung; Patients who have not quit smoking. The Zephyr Valve should be used with caution and only after careful consideration in treating patients with: Prior lung transplant, LVRS, median sternotomy, or lobectomy; Congestive heart failure or recent myocardial infarction; FEV, <15% of predicted value. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial Valve System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.