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Beyond the randomized controlled trials: Real-world safety of endobronchial valves for severe emphysema

Chest / 2024

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Article Link: https://pubmed.ncbi.nlm.nih.gov/39181376/

The clinical question

What is the real-world inpatient complication rate after bronchoscopic lung volume reduction with endobronchial valves in the United States?

Take Home Message

In this retrospective cross-sectional study using a real-world cohort from the National Inpatient Sample (NIS) database, the inpatient complication rate after BLVR was similar to those published in randomized controlled trials (RCTs). Although the overall rate of in-hospital complications was 48% in this study, most were minor and in-hospital mortality was less than 2.3%, suggesting that BLVR is a safe intervention for severe emphysema.

Background

Bronchoscopic lung volume reduction (BLVR) with one-way endobronchial valves (EBVs) is a minimally invasive intervention that can improve lung function, quality of life, and exercise tolerance in select patients with severe emphysema. The US Food and Drug Administration (FDA) approved two EBVs for BLVR in 2018 after multiple RCTs demonstrated these benefits with an acceptable safety profile. However, safety outcome data after EBV are limited to the published complication rates from RCTs. Real-world in-hospital safety outcomes in the US are unknown.

Study Design

- **Type of trial:** Retrospective, cross-sectional
- **Setting:** Teaching and non-teaching US hospitals
- **Data source:** National Inpatient Sample (NIS) database
- **Study group:** Adult hospitalizations from 2018 through 2020 with EBV insertion on day 0 or day 1 of admission (n = 467)

- **Primary outcome:** In-hospital complications (pneumothorax, acute respiratory failure, pneumonia, hemoptysis, COPD exacerbation, EBV removal)
- **Secondary Outcomes:** In-hospital mortality, total length of stay (LOS)

Population

Inclusion criteria: All adult hospitalizations (age ≥ 18 years) with a diagnosis of COPD using the International Classification of Diseases, 10th Revision (ICD-10) codes with an EBV insertion on the admission day or day after admission (hospital day 1)

Exclusion criteria: EBV placement after hospital day 1

Baseline characteristics:

- Hospitalizations meeting inclusion criteria: 467
- Sex: 45% female, 55% male
- Race: 85.8% white, 5.6% black, 8.6s% other
- Comorbidities: most common included hypertension (44.5%), hyperlipidemia (32.1%), coronary artery disease (19.9%)
- Primary payer: 72.8% Medicare, 17.8% private, 9.4% Medicaid, self-pay, or no charge
- Hospital bed side: 53.5% small, 28.3% medium, 18.2% large
- Hospital teaching status: 57.0% urban teaching, 23.1% urban non-teaching, 19.9% rural

Outcomes

Primary outcome:

- Any in-hospital complication: 48%
- Pneumothorax: 26.3% (68.3s% required chest tube placement)
- COPD exacerbation: 8.8%
- Pneumonia: 7.3%
- Hemoptysis: 5.3%
- Acute respiratory failure: 19.5%
- EBV removal: 14.8%

There was no significant difference in patient demographics or facility characteristics between hospitalizations with and without complications, though the frequency of hypertension was significantly lower in patients who experienced complications (39.3% vs 49.4%, p = 0.028).

Secondary outcomes:

- In-hospital deaths: < 2.3% (specific number non-reportable per NIS patient privacy policy due to fewer than 11 events)
- Median LOS for all hospitalizations: 2.8 days (interquartile range [IQR], 2.3-4.5)
- Of note, median LOS was significantly longer among those with any in-hospital complication compared to those without (4.0 days [IQR, 2.5-9.1] vs 2.6 days [IQR, 2.1-3.1], p< 0.001).

Commentary

Strengths:

- Largest real-world cohort of US hospitalizations for EBV insertion since FDA approval
- Queried hospitals throughout the US representing a variety of facility sizes, both teaching and non-teaching
- Rates of pneumothorax and EBV removal similar to those reported in EMPROVE and LIBERATE trials, respectively
- Rate of chest tube placement for pneumothorax also similar to prior studies

Limitations:

- Retrospective study
- Dependent on quality of documentation and the billing process with no direct access to individual medical records
- Granular data regarding pneumothorax management (e.g. duration of chest tube, rate of persistent air leak) not reported
- May underestimate short-term complication rate since only in-hospital events were included
- Longitudinal information not available due to limitations on NIS data
- Repeated inpatient encounters for the same patient may have been captured more than once

Funding

None declared.

Suggested Reading

Criner GJ, Delage A, Voelker K, Hogarth DK, Majid A, Zgoda M, et al. Improving lung function in severe heterogenous emphysema with the Spiration valve system (EMPROVE). A multicenter, open label randomized controlled clinical trial. Am J Respir Crit Care Med. 2019 Dec 1;200(11):1354–62.

Criner GJ, Sue R, Wright S, Dransfield M, Rivas-Perez H, Wiese T, et al. A multicenter randomized controlled trial of Zephyr endobronchial valve treatment in heterogeneous emphysema (LIBERATE). Am J Respir Crit Care Med. 2018 Nov 1;198(9):1151–64.

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Article Citation

Costa Filho FF, Buckley JD, Furlan A, Campbell S, Hickok K, Kroth PJ. Inpatient complication rates of bronchoscopic lung volume reduction in the United States. Chest. 2025 Feb;167(2):436–43.

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