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COPD III: Advanced Interventions and Transplants

An APCCMPD Ambulatory-Care Curriculum Teaching Script

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COPD III:
Advanced Interventions and Transplants

Scenario 1:

Mr. S is a 62-year-old male with severe COPD and a forced expiratory volume in 1 second (FEV_1) of 38% predicted. You have been following him for several years and have treated him with fluticasone/salmeterol 250/50 1 puff twice daily, tiotropium 18 mcg 1 capsule inhaled daily, and albuterol 2 puffs or a nebulizer treatment every 6 hours as needed. About a year ago, you prescribed roflumilast 500 mcg oral once daily due to a history of several exacerbations in the preceding year and symptoms of chronic bronchitis. He says he initially had some loss of appetite and lost 6 pounds, but he feels better now and denies ongoing side effects. He has not experienced any additional exacerbations since starting the roflumilast, but he still struggles with severe dyspnea despite regular aerobic exercise. He also completed pulmonary rehabilitation 1 year ago after his last exacerbation. A friend told him to ask about lung volume reduction surgery and he wonders if he is a candidate.

Question 1: What patient characteristics are favorable for LVRS? What are the potential risks and benefits?

Scenario 1 (Continued):

On evaluation, Mr. S has an FEV_1 of 38% predicted, TLC 110% predicted, RV 145% predicted, and DLCO 32% predicted. His CT shows severe, relatively homogeneous emphysema. His ABG on room air is 7.32/65/54. Echocardiogram shows normal size and function for both his LV and RV with an estimated PASP of 44 mmHg. You explain that he is not a candidate for LVRS due to homogeneous emphysema, insufficient air-trapping, and significant hypercapnia.

Question 2: What other options for lung volume reduction might be considered for Mr. S?

Question 3: What factors must be weighed when considering BLVR?

Question 4: What are outcomes for BLVR procedures?

Scenario 1 (Continued):

Mr. S has insufficient air trapping to be a good candidate for BLVR with an RV of 145%. His homogenous emphysema and resting PaCO2 of 65 also portend a high risk of a poor outcome. You inform Mr. S that he is not a candidate for BLVR either due to these factors. You recommend an evaluation to qualify him for nocturnal bilevel non-invasive positive pressure ventilation (BPAP) given his chronic hypercapnia, and he qualifies based on a sleep study. You initiate BPAP and uptitrate his inspiratory pressure to 20 cmH_2O with an expiratory pressure of 5 cmH_2O. He feels it helps him rest more comfortably, but over the next 2 years his dyspnea and lung function impairment continue to progress. He asks you if he may be a candidate for lung transplantation.

Question 5: What factors determine when it is appropriate to refer for lung transplant?

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Educational Objectives:

1. Review selection criteria for and outcomes of lung volume reduction surgery (LVRS) and bronchoscopic lung volume reduction (BLVR)
2. Review indications for and outcomes of non-invasive nocturnal ventilation
3. Outline when to consider lung transplantation for chronic obstructive pulmonary disease (COPD)

Scenario 1:

Mr. S is a 62-year-old male with severe COPD and a forced expiratory volume in 1 second (FEV_1) of 38% predicted. You have been following him for several years and have treated him with fluticasone/salmeterol 250/50 1 puff twice daily, tiotropium 18 mcg 1 capsule inhaled daily, and albuterol 2 puffs or a nebulizer treatment every 6 hours as needed. About a year ago, you prescribed roflumilast 500 mcg oral once daily due to a history of several exacerbations in the preceding year and symptoms of chronic bronchitis. He says he initially had some loss of appetite and lost 6 pounds, but he feels better now and denies ongoing side effects. He has not experienced any additional exacerbations since starting the roflumilast, but he still struggles with severe dyspnea despite regular aerobic exercise. He also completed pulmonary rehabilitation 1 year ago after his last exacerbation. A friend told him to ask about lung volume reduction surgery and he wonders if he is a candidate.

Question 1: What patient characteristics are favorable for LVRS? What are the potential risks and benefits?

LVRS involves surgical resection of severely emphysematous lung tissue from one or both upper lung zones. The resection is non-anatomic (i.e. not a lobectomy or segmentectomy). Up to a third of lung tissue may be removed from each lung, and the surgeon will attempt to balance removal of non-functional tissue with preservation of as much functional tissue as possible. Surgical approach for LVRS varies and may be performed via median sternotomy, video-assistant thoracoscopic surgery (VATS), or open thoracotomy.

- **Mechanism:** There are several postulated mechanisms of benefit:
    - First, as the remaining lung stretches to fill the evacuated space in the chest, elastic recoil is increased, thereby increasing stenting forces holding open small airways and reducing small airways resistance allowing for improved expiratory airflow.

- Second, the reduction in overall volume of the chest returns the diaphragm toward a more normal upward resting position, restoring some mechanical advantage.
- Third, resection of dead space in the lung may improve ventilation/perfusion (V/Q) matching, leading to better gas exchange despite the decrease in overall surface area.

- **Patient selection:** Indications for LVRS include severe dyspnea despite aggressive treatment with bronchodilators, oxygen if indicated, and exercise training (preferably pulmonary rehabilitation). Table 1 outlines the additional patient characteristics that are favorable and unfavorable for LVRS in detail.

- **Testing:** To determine candidacy for LVRS, the following tests are required:
  - Full pulmonary function tests with plethysmographic lung volumes (gas dilution methods may significantly underestimate volumes)
  - High-resolution chest computed tomography (CT) without contrast to assess severity and distribution of emphysema
  - Arterial blood gas to exclude significant hypercapnia
  - Transthoracic echocardiogram to exclude significant pulmonary hypertension or left ventricular dysfunction
  - Quantitative V/Q scan can also be helpful to corroborate apical lung destruction (demonstrated by apical hypoperfusion on posterior projections).
  - Cardiopulmonary exercise testing (CPET) by cycle ergometry on 30% oxygen is not strictly necessary but can help to distinguish whether a patient may derive a mortality benefit from the procedure

Table 1. Selection Criteria for Lung Volume Reduction Surgery

Favorable characteristics	Unfavorable characteristics
• Severe, apical predominant emphysema • Severe obstruction (FEV_1 ≤45% pred) • Severe air trapping (ideally RV* >200% pred, TLC* >100%) • Apical hypoperfusion on V/Q (<10% perfusion to upper lung thirds) • Apical air trapping on V/Q (long tracer half life in upper lung thirds) • Low exercise capacity after completion of pulmonary rehab (<25 W on cycle ergometry for women, <40 W for men) • Single organ disease	• Airways disease phenotype (i.e. severe obstruction but only mild emphysema) • Homogenous or basilar predominant emphysema* • Insufficient obstruction (FEV_1 >45% pred) • Insufficient air trapping (RV <150%) • Preserved apical perfusion on V/Q (≥20% perfusion to upper lung thirds) • FEV_1 and DLCO* both <20% predicted ** • Severe comorbid illness • pCO_2 >60 • PASP* >45 (or mean PAP* >35)

**RV indicates residual volume; TLC, total lung capacity; W, watts; DLCO, diffusion capacity of lungs of carbon monoxide; PASP, pulmonary arterial systolic pressure; PAP, pulmonary arterial pressure*
***Higher risk of early mortality.*
Adapted from reference 1.

National Emphysema Treatment Trial (NETT) (NEJM 2003)[1]
Study design: Unblinded, randomized control trial including 1218 subjects with severe COPD comparing LVRS to continued maximal medical management. Baseline assessments and eligibility were determined after completing pulmonary rehab to exclude the effect of exercise conditioning.

Inclusion criteria:

- **Confirmed diagnosis of COPD with**
  - CT scan evidence of bilateral emphysema
  - FEV_1 ≤45% predicted (if age ≥70 years pre-rehabilitation, FEV_1 ≥15% predicted)
  - TLC ≥100% predicted & RV ≥150% predicted
  - Room air resting P_aCO_2 ≤60 mmHg & P_aO_2 ≥45 mmHg
  - Body Mass Index (BMI) ≤31.1 (males) or ≤32.3 (females)
  - Abstinence from tobacco for ≥4 months prior to initial interview and continued abstinence throughout screening

Exclusion criteria:

- FEV_1 ≤20% predicted and either homogeneous disease or DLCO ≤20% predicted (criterion added at interim analysis due to increased mortality)
- CT scan evidence of diffuse emphysema judged unsuitable for LVRS
- Inability to perform valid DLCO maneuver (also added at interim)
- Previous sternotomy or lobectomy, giant bulla, LVRS, or pulmonary nodule requiring surgery
- Pleural or interstitial disease which precludes surgery
- Pulmonary hypertension defined as pulmonary artery systolic ≥45 or mean ≥35 measured by right heart catheterization
- Myocardial infarction within 6 months of baseline
- Congestive heart failure (ejection fraction (EF) <45%)
- Uncontrolled hypertension (systolic >200 mmHg, diastolic >110 mmHg)
- Clinically significant bronchiectasis
- Daily use of prednisone >20 mg
- O_2 requirement >6 L/min
- History of recurrent infections with clinically significant daily sputum production
- Six-minute walk distance <140 m after rehab
- Comorbid disease expected to compromise survival or interfere with the completion of tests, therapy or follow-up over the course of the study

Intervention: LVRS by either VATS or median sternotomy vs. medical management alone.

Primary Outcomes: Survival and maximal exercise capacity.

Results: At an interim analysis, the subgroup with FEV_1 ≤20% predicted and either homogeneous disease or DLCO ≤20% predicted was found to have significantly higher mortality with LVRS and were subsequently excluded from the trial.

Overall mortality was not different between treatment groups, even after excluding high-risk subjects. The LVRS group had a greater chance of a 10 W improvement in exercise capacity (16% vs. 3%, p<0.001).

Among the subgroup of subjects (at least partially conceived *a priori*) with predominantly *upper lobe emphysema* and a *lower exercise capacity* (max workload <25 W for women, <40 W for men), mortality was lower with LVRS (risk ratio for death 0.47, p=0.005). In contrast, those with *non-upper lobe predominant emphysema* and a *higher exercise capacity* demonstrated higher mortality with LVRS (risk ratio for death 2.06, p=0.02). The data for LVRS is shown in figures 1 and 2 for all patients as well as the subgroups.

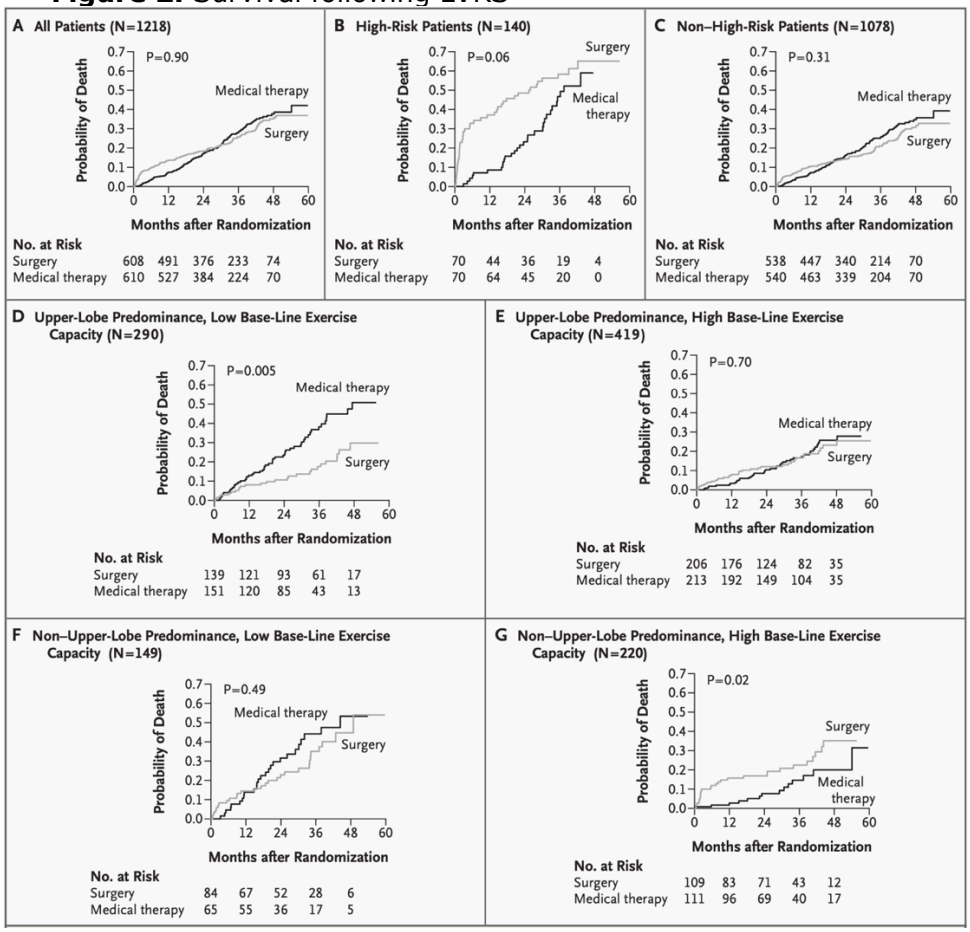
Adverse events: Overall mortality was 5% in LVRS group. Other adverse events included reintubation (22%), air-leak >7 days (~40%), arrhythmias (19%), pneumonia (18%), and failure to wean from mechanical ventilation (tracheostomy required in 8%). MI (1%) and stroke (<1%) were rare.

Figure 1. Improvement in Exercise Capacity and Health-related Quality of Life at 24 Months

Patients	Improvement in Exercise Capacity				Improvement in Health-Related Quality of Life			
	Surgery Group	Medical-Therapy Group	Odds Ratio	P Value	Surgery Group	Medical-Therapy Group	Odds Ratio	P Value
	no./total no. (%)				*no./total no. (%)*			
All patients	54/371 (15)	10/378 (3)	6.27	<0.001	121/371 (33)	34/378 (9)	4.90	<0.001
High-risk†	4/58 (7)	1/48 (2)	3.48	0.37	6/58 (10)	0/48	—	0.03
Other	50/313 (16)	9/330 (3)	6.78	<0.001	115/313 (37)	34/330 (10)	5.06	<0.001
Subgroups‡								
Predominantly upper-lobe emphysema								
Low exercise capacity	25/84 (30)	0/92	—	<0.001	40/84 (48)	9/92 (10)	8.38	<0.001
High exercise capacity	17/115 (15)	4/138 (3)	5.81	0.001	47/115 (41)	15/138 (11)	5.67	<0.001
Predominantly non–upper-lobe emphysema								
Low exercise capacity	6/49 (12)	3/41 (7)	1.77	0.50	18/49 (37)	3/41 (7)	7.35	0.001
High exercise capacity	2/65 (3)	2/59 (3)	0.90	1.00	10/65 (15)	7/59 (12)	1.35	0.61

From the National Emphysema Treatment Trial.[1]

Figure 2. Survival following LVRS



Kaplan-Meier estimates of the probability of death as a function of the number of months after randomization. High-risk patients were defined as having an FEV_1 <20% predicted and either homogenous emphysema or a DLCO <20% predicted.

From the National Emphysema Treatment Trial.[1]

Summary: Removal of emphysematous lung tissue via LVRS in severe emphysema improves physiologic status, leading to improved exercise tolerance and reduced mortality (in the subgroup with upper lobe predominant emphysema and low exercise capacity).

There was an early risk of death in the first three months for those who underwent LVRS, however, long-term outcomes (>36 months) show a benefit of surgery over medical therapy for appropriately chosen candidates in terms of improving lung function, quality of life and exercise capacity.

Candidates likely to garner the most benefit from LVRS are those with apical predominant emphysema and low exercise capacity. Interestingly, although early mortality (<90 day) was increased in the entire homogeneous or basilar predominant group after exclusion of the high risk phenotype (FEV_1 ≤20% predicted and either homogeneous disease or DLCO ≤20% predicted), those with homogeneous disease and a low exercise capacity ultimately did not have higher long-term mortality compared with medical therapy (the survival curves crossed, indicating early mortality in the surgery group followed by a late survival benefit, such that the overall difference was statistically insignificant, with the surgery group technically having the numerically lower mortality). In fact, Medicare approved the procedure for the homogeneous low-exercise group, although not all centers recommend LVRS for this group.

Scenario 1 (Continued):

On evaluation, Mr. S has an FEV_1 of 38% predicted, TLC 110% predicted, RV 145% predicted, and DLCO 32% predicted. His CT shows severe, relatively homogeneous emphysema. His ABG on room air is 7.32/65/54. Echocardiogram shows normal size and function for both his LV and RV with an estimated PASP of 44 mmHg. You explain that he is not a candidate for LVRS due to homogeneous emphysema, insufficient air-trapping, and significant hypercapnia.

Question 2: What other options for lung volume reduction might be considered for Mr. S?

Bronchoscopic lung volume reduction (BLVR) is a non-surgical alternative to LVRS for symptomatic patients with heterogenous emphysema and significant hyperinflation. While several methods for achieving BLVR are under investigation, the best studied (and only FDA-approved) method is endobronchial valve placement. This consists of placing one-way valves in the airways leading to areas of hyperinflated and emphysematous lung. These valves allow for expiration of air, but close during inspiration resulting in collapse of the distal lung tissue, thereby improving hyperinflation. As mentioned in the previous section for LVRS, dyspnea decreases due to improved diaphragm and chest wall mechanics, improved recoil, and in some cases re-expansion of less affected regions of lung.

Question 3: What factors must be weighed when considering BLVR?

BLVR carries a high risk of pneumothorax. As the target lobe collapses, the ipsilateral untreated lobe expands and stretches. As this part of the lung is also typically affected with some degree of emphysema, lung defects (blebs, bullae, etc.) may rupture during rapid expansion. This can result in pneumothorax, a complication of up to 34% of BLVR procedures. Several factors associated with pneumothorax and poor outcomes following

valve placement are listed in Table 2.[2] Consequently, appropriate patient selection is very important.[3,4] Mortality following valve placement is approximately 3%. The Global Initiative for COPD recommends that BLVR selection should occur through a multidisciplinary team approach.[5]

Table 2. Selection Criteria for Bronchoscopic Lung Volume Reduction

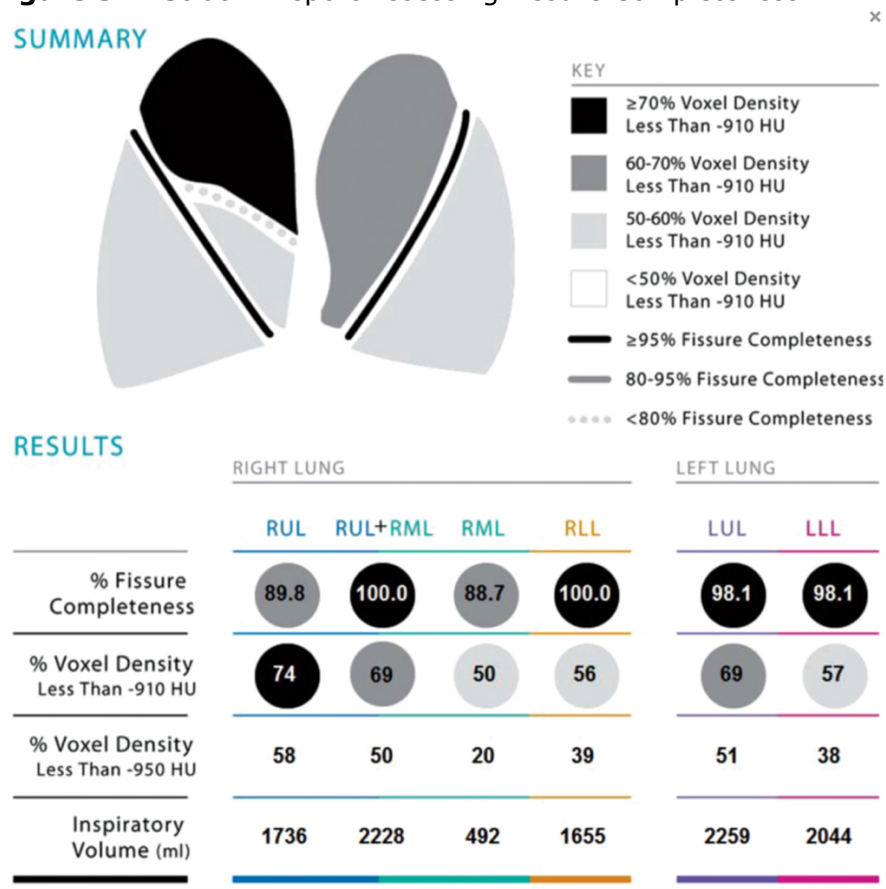
Favorable characteristics	Unfavorable characteristics
• Severe, heterogenous emphysema • Severe obstruction (FEV_1 ≤45% pred) • Severe air trapping (RV >175% pred) • Resting hyperinflation (TLC >100% pred) • 6MWD* <500 m and > 100 m • BMI < 35 • No tobacco use in last 4 months • No evidence of collateral lobar ventilation (Chartis® negative) • Completed pulmonary rehab program within 6 months • modified Medical Research Council (mMRC) Dyspnea Scale grade of at least 2 • On maximal inhaler therapy	• Insufficient obstruction (FEV_1 >45% pred) • Insufficient residual FEV_1 (<15% pred) • Insufficient air trapping (RV <175% pred) • Insufficient diffusion (DLCO <20% pred) • Significant cardiac disease (Reduced EF, recent MI, persistent bradycardia, etc.) • pCO_2 >50 • PASP >45 (or mean PAP >35) • 6MWD of less than 100m • Giant bullae involving >30% of either lung • Daily prednisone of 20mg or more • Active tobacco use

**6MWD indicates walking distance after 6 minutes*
Adapted from references 4, 6-8.

Determining whether collateral ventilation between lobes is present is an essential component of a BLVR evaluation. Airflow from adjacent lobe(s) prevents collapse of the target lobe. This results in a significant number of patients unable to undergo BLVR. Fissure completeness is used to determine the likelihood of collateral ventilation and it should be ≥ 80% for endobronchial valves to be successful.[3]

Fissure completeness can be assessed noninvasively via CT using computer software (StratX® and SeleCT®) that is proprietary for each type of valve. Fissure integrity can also be assessed in the operating room prior to valve placement by occluding the target lobe and measuring if collateral ventilation is present. In addition to measuring fissure completeness, the software utilizes CT densitometry to estimate lobar emphysema involvement. A higher percentage of <-910 Hounsfield units (HU) indicates more extensive emphysematous destruction. An example of a StratX® report is shown below in Figure 3.

Figure 3. A StratX® Report Assessing Fissure Completeness

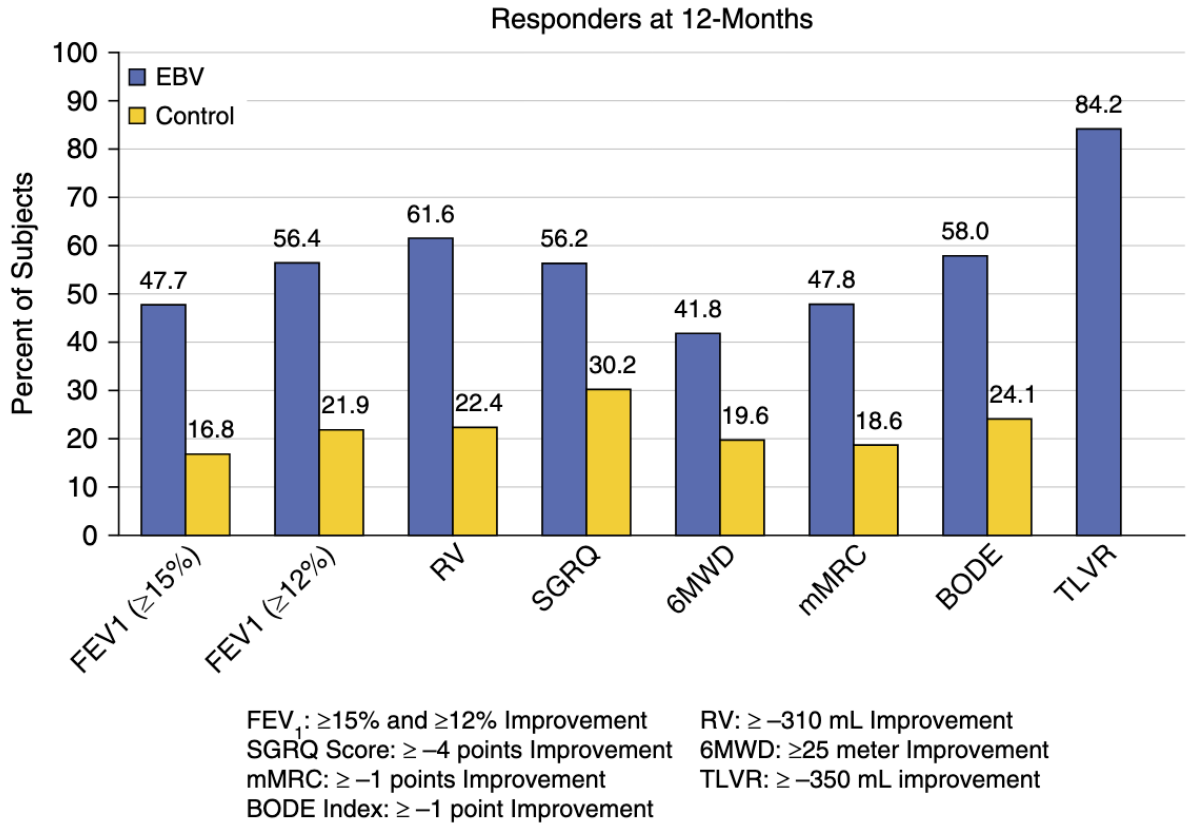


Abbreviations: HU = Hounsfield Units; RUL = Right Upper Lobe; RML = Right Middle Lobe; RLL = Right Lower Lobe; LUL = Left Upper Lobe; LLL = Left Lower Lobe.
Figure source: https://pulmonx.com/stratx/

Question 4: What are outcomes for BLVR procedures?

For suitable patients, outcomes after BLVR are favorable. Four major randomized controlled trials have studied endobronchial valves using two different proprietary valve systems: Zephyr® and Spiration®. The LIBERATE[9] and REACH[10] trials evaluated the Zephyr® valve and the EMPROVE[11] and TRANSFORM[12] trials evaluated the Spiration® valve, each comparing valve placement to standard of care COPD management. These studies have consistently demonstrated improvement in lung function, exercise, and quality of life for patients who received BLVR. Figure 4 shows outcomes from the LIBERATE trial. There is inadequate evidence for BLVR with regard to mortality, however. Some have reported observations of survival benefit in those who experience lobar atelectasis following intervention compared to those who do not.[13] There is also some evidence demonstrating a lower rate of exacerbations in patients who have undergone BLVR achieving lobar atelectasis.[14] The most common adverse event of valve placement is pneumothorax as mentioned above. Valve placement can also be complicated by exacerbations.

Figure 4. Summary of Responders Based on Minimal Clinically Important Difference for Variables Assessed in the LIBERATE Study of Zephyr EBV



Abbreviations: RV = Residual Volume; SGRQ = St George's Respiratory Questionnaire; TLVR = Target Lobar Volume Reduction; BODE index = Body Mass, Obstruction, Dyspnea, Exercise Capacity.
From the LIBERATE trial.[9]

Scenario 1 (Continued):

Mr. S has insufficient air trapping to be a good candidate for BLVR with an RV of 145%. His homogenous emphysema and resting PaCO2 of 65 also portend a high risk of a poor outcome. You inform Mr. S that he is not a candidate for BLVR either due to these factors. You recommend an evaluation to qualify him for nocturnal bilevel non-invasive positive pressure ventilation (BPAP) given his chronic hypercapnia, and he qualifies based on a sleep study. You initiate BPAP and uptitrate his inspiratory pressure to 20 cmH_2O with an expiratory pressure of 5 cmH_2O. He feels it helps him rest more comfortably, but over the next 2 years his dyspnea and lung function impairment continue to progress. He asks you if he may be a candidate for lung transplantation.

Question 5: What factors determine when it is appropriate to refer for lung transplant?

Timing of referral and listing vary among centers, but most adhere to consensus guidelines outlined by the International Society for Heart and Lung Transplantation (IHSLT) to aid in their decision making (see Table 3).[15]

Table 3. Selection Criteria for Referral and Listing for Lung Transplantation in COPD

Timing of Transplant Referral	Timing of Transplant Listing
• BODE index of 5-6 with additional risk factor(s) suggestive of increased morality: 1. Frequent exacerbations, 2. Increase in BODE index of >1 over the past month 3. Pulmonary artery:aorta diameter >1 on CT scan, 4. FEV_1 20-25% • Clinical deterioration despite maximal medical therapy, pulmonary rehabilitation, oxygen, and nocturnal non-invasive positive pressure ventilation (NIPPV) if indicated • Poor quality of life unacceptable to patient • For a candidate appropriate for bronchoscopic or surgical LVRS; simultaneous referral to lung transplant is appropriate	• BODE score of 7-10 • Additional factors which may prompt listing: 1. FEV_1 of <20% 2. Presence of moderate to severe pulmonary hypertension 3. History of severe exacerbations 4. Chronic hypercapnia

Adapted from reference 15.

There are many risk factors for a potentially poor lung transplant outcome. These may change over time. Below you will find a brief list of absolute contraindications to transplant:[15]

- Lack of patient willingness or acceptance of transplant
- Malignancy with high risk of recurrence or death related to cancer
- Glomerular filtration rate <40mL/min/1.73m2 unless being considered for multi-organ transplant
- Acute coronary syndrome or myocardial infarction within 30 days (excluding demand ischemia)
- Stroke within 30 days
- Liver cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant
- Acute liver failure
- Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery
- Septic shock
- Active extrapulmonary or disseminated infection
- Active tuberculosis infection
- HIV with detectable viral load
- Limited functional status (e.g. non-ambulatory) with poor potential for post-transplant rehabilitation
- Progressive cognitive impairment
- Repeated episodes of non-adherence without evidence of improvement (not applicable for pediatric patients)
- Active substance use or dependence including current tobacco use, vaping, marijuana smoking or IV drug use
- Other severe uncontrolled medical condition expected to limit survival after transplant

Patients with COPD may be listed for either single or bilateral lung transplantation. The presence of significant pulmonary hypertension is a relative contraindication, and severe suppurative airways disease is an absolute contraindication to single lung transplantation. Whether to list a COPD patient for single lung transplantation is somewhat controversial. Post single-lung transplant, native lung hyperinflation (enlargement of bullous emphysema of the native lung) can occur, but this does not appear to affect clinical outcomes.

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