

Introduction to Lung Transplantation Evaluation

Case related questions.

Scenario:

Mrs. C is a 68-year-old female, lifelong nonsmoker, with a past medical history of idiopathic pulmonary fibrosis. She had the onset of pulmonary symptoms about 6 years ago, first with a mild non-productive cough. She has had slowly progressive exertional dyspnea over the past 3 years, worsening over the past several months. Due to increased symptom burden, she underwent a lung biopsy consistent with Usual Interstitial Pneumonia (UIP). One month ago, she was admitted with pneumonia for 4 days and was discharged on oxygen therapy. She is able to climb one flight of stairs but occasionally has to stop. Since her discharge, she has spent most of the day in a chair using a wheelchair for most activities. She has been told by her primary care physician that she may need a lung transplant.

Question 1:

- A) What are the main indications for lung transplant in the United States?
- B) What is the expected survival for lung transplant recipients?
- C) Are there racial disparities in lung transplantation?

Scenario cont:

Mrs. C is referred for lung transplant evaluation. You have the opportunity to meet her at her first clinic visit. As you might expect, she has many questions.

Question 2: When should patients be referred for lung transplant evaluation?

Scenario cont:

Mrs. C. has a 6 L resting oxygen requirement, an FVC of 53% predicted, and a high-resolution chest CT consistent with a UIP pattern. She reports dyspnea with even mild activity and cannot climb a single flight of stairs. She is anxious and reports worsening depression because it is difficult to leave her home.

Question 3: What are the guidelines for the timing of listing for lung transplantation?

Question 4: Is Mrs. C an appropriate candidate for lung transplantation?

Scenario cont:

Mrs. C. and her family proceed to lung transplant evaluation. She has no obstructive disease on left heart catheterization, normal cardiac function, no pulmonary hypertension, and normal renal and hepatic function. Despite her acute decline over the last few months, she could walk 874 feet on her 6-minute walk test (6MWT), although she required 100% non-rebreather mask (NRB) to maintain an oxygen saturation >87%. The transplant team deemed her to be an appropriate transplant patient and is interested in being actively listed for a transplant.

Question 5: How are lungs allocated in the United States?

Question 6:

- A)** How is the CAS calculated for each listed candidate?
- B)** What are the impacts of the CAS so far?

Introduction to Lung Transplantation Evaluation

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Educational Objectives:

1. Review the basic epidemiology of lung transplantation
2. Review the system for lung allocation in the U.S., the composite allocation score (CAS)
3. Understand the difference between indications for referral for evaluation versus active listing for transplantation
4. Describe the evaluation process for determining transplant eligibility

Scenario:

Mrs. C is a 68-year-old female, lifelong nonsmoker, with a past medical history of idiopathic pulmonary fibrosis. She had the onset of pulmonary symptoms about 6 years ago, first with a mild non-productive cough. She has had slowly progressive exertional dyspnea over the past 3 years, worsening over the past several months. Due to increased symptom burden, she underwent a lung biopsy consistent with Usual Interstitial Pneumonia (UIP). One month ago, she was admitted with pneumonia for 4 days and was discharged on oxygen therapy. She is able to climb one flight of stairs but occasionally has to stop. Since her discharge, she has spent most of the day in a chair using a wheelchair for most activities. She has been told by her primary care physician that she may need a lung transplant.

Question 1:

- A) What are the main indications for lung transplant in the United States?**
B) What is the expected survival for lung transplant recipients?
C) Are there racial disparities in lung transplantation?

In 2022, 2,743 lung transplant procedures were performed in the United States.¹ From 1988-present, 33,743 lung transplants were performed in this country and since 1992, over 65,000 lung transplants have been performed worldwide.² Figure 1 demonstrates that since 2005, fibrotic lung disease has been the most transplanted pulmonary diagnosis in the United States, followed by obstructive lung disease, predominantly Chronic Obstructive Pulmonary Disease (COPD) and alpha-1-antitrypsin deficiency, cystic fibrosis, and pulmonary hypertension.^{1,3}

Figure 1. Pre-transplant Diagnosis Distribution by Location and Era

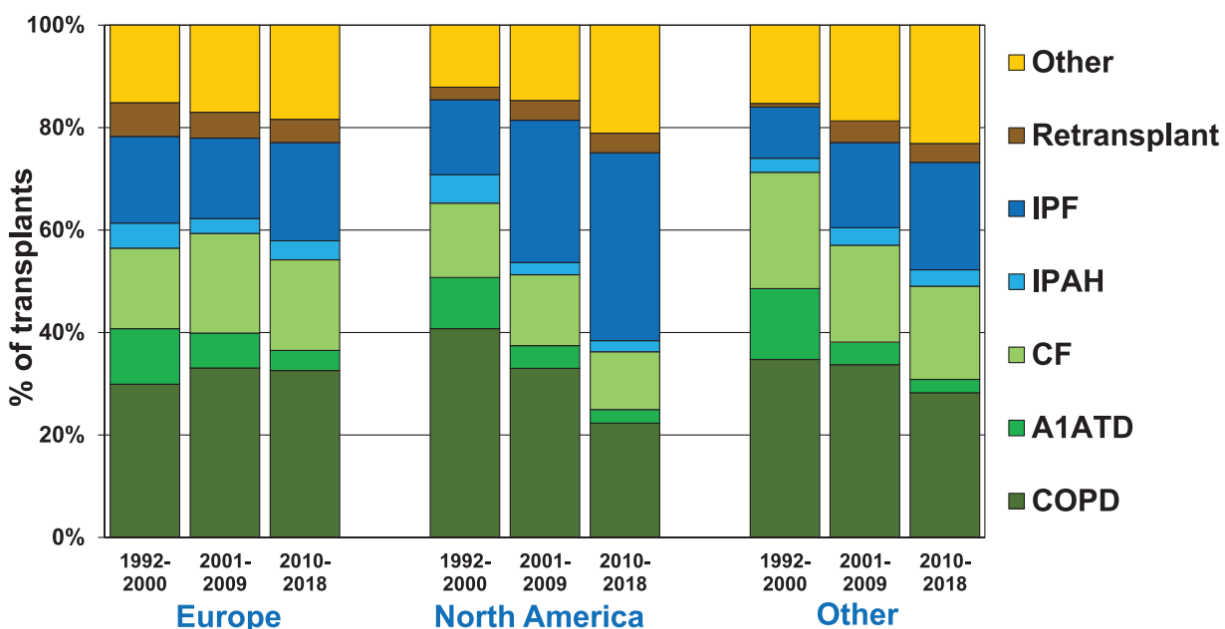


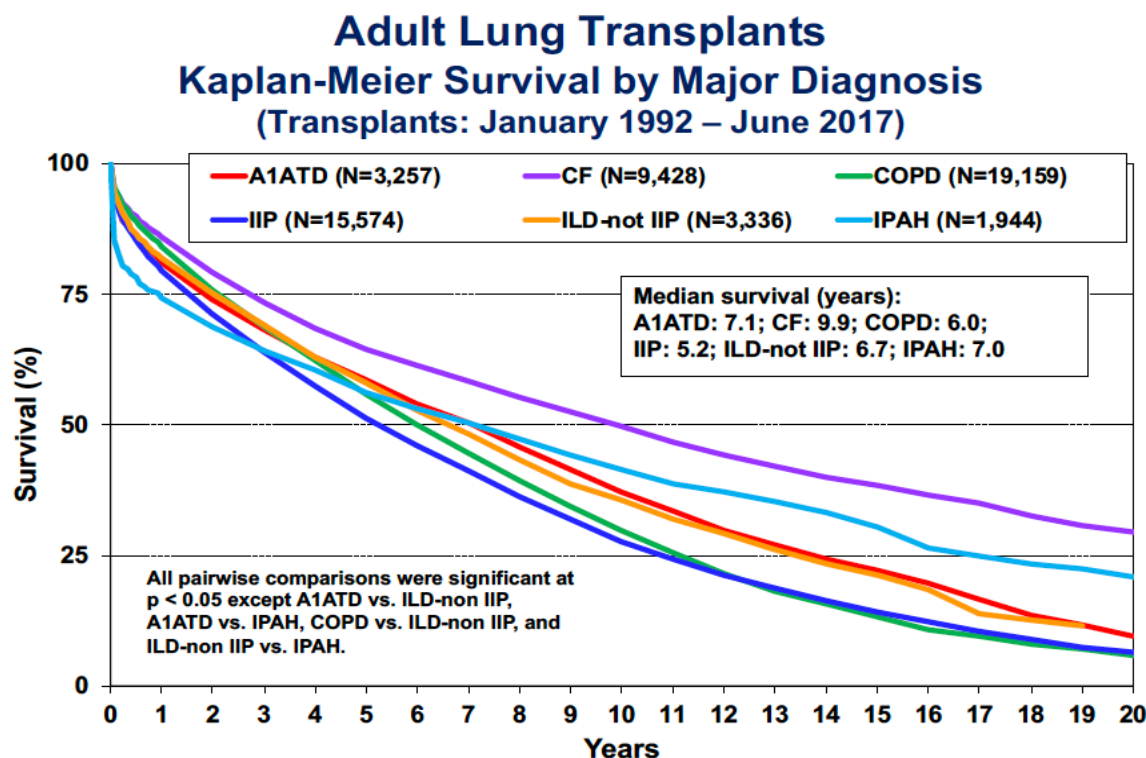
Figure 1 Diagnosis distribution by location and era (transplants: January 1992-June 2018).

Abbreviations: IPF - idiopathic pulmonary fibrosis, IPAH - idiopathic pulmonary arterial hypertension, CF - cystic fibrosis, A1ATD - alpha-1 antitrypsin deficiency, COPD - chronic obstructive pulmonary disease

Borrowed from Perch, M et al. The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation: Thirty-ninth adult lung transplantation report – 2022; Focus on lung transplant recipients with chronic obstructive pulmonary disease. 2022 October; 41(10): 1335-1347.

- A) As illustrated in Figure 2, based on the registry data from the International Society for Heart and Lung Transplantation published in 2019, adults undergoing lung transplantation have a median survival of 6.2 years. For patients who survive the first post-transplant year, median survival increases to 8.3 years. Post-lung transplant survivals vary by type (double vs single) and indication, amongst many other factors including age and ethnicity.^{2,3}

Figure 2. Adult Lung Transplant Survival by Diagnosis



Abbreviations: A1ATD - alpha-1 antitrypsin deficiency, CF - cystic fibrosis, COPD - chronic obstructive pulmonary disease, IIP - idiopathic interstitial pneumonia, ILD - interstitial lung disease, IPAH - idiopathic pulmonary arterial hypertension

Figure from the International Society for Heart and Lung Transplantation registries – 2019, Lung-overall registry. Available at <https://ishltregistries.org/registries/slides.asp> and from JHLT. 2019 Oct; 38(10): 1042-1055.

- B) There is concern for racial disparities in lung transplant candidate referral, selection and transplantation with ongoing research in this area. In 2022, more than 70% of lung transplant recipients were Caucasian.¹ Over time, there has been an increased representation of minority groups listed for lung transplantation. Since 2011, 163.8% Asian, 18.0% Black, and 153.2% more Hispanic candidates, respectively have been listed.” However, frequency of lung transplantation for listed Black candidates is still low at 184.8 transplants per 100 patient-years compared with a range of 223.5-278.2 transplants per 100 patient-years for individuals of other racial groups.¹ No significant racial differences were described in candidates removed from the waitlist.

Post-transplant outcomes also differ based on ethnicity, with survival being greatest in Hispanic individuals followed by Caucasian, Black, Asian, multiracial and Native American individuals.¹

Scenario cont:

Mrs. C is referred for lung transplant evaluation. You have the opportunity to meet her at her first clinic visit. As you might expect, she has many questions.

Question 2: When should patients be referred for lung transplant evaluation?

The purpose of lung transplant evaluation is to evaluate a patient's appropriateness for listing for lung transplantation and to collect detailed data to calculate the lung Composite Allocation Score (CAS). This rigorous evaluation takes time, and in general, patients should be referred earlier when they can undergo extensive testing and potentially modify any factors that will improve their transplant success. These include weight loss for obese patients, completion of pulmonary rehabilitation to improve deconditioning, and obtaining required vaccinations. Referral for evaluation does not necessarily mean a patient will require or be a candidate for lung transplantation.

The decision on the appropriate timing of lung transplant referral depends on the underlying diagnosis. Lung transplant should be considered in those with advanced lung disease on maximal medical therapy with a:

- High risk of death from their underlying disease within 2 years (>50%)
- High likelihood of 5-year post-transplant survival (>80%)⁴

In addition, there are disease-specific guidelines for transplant consideration referral. Please note, there are separate recommendations for listing.

Interstitial lung disease⁴:

- At the time of diagnosis, for those with probable/definite radiographic UIP pattern or histological evidence of UIP
- Any form of pulmonary fibrosis with Forced Vital Capacity (FVC) <80% predicted or Diffusion Capacity of Lung Carbon Monoxide (DLCO) <40% predicted
- Any form of pulmonary fibrosis with the following relative decline in the past 2 years:
 - FVC 10%, DLCO 15%, FVC 5% with worsening respiratory symptoms/radiographic progression
 - Progression of inflammatory ILD on imaging or pulmonary function despite treatment
 - Supplemental oxygen therapy at rest or with exertion
- For inflammatory ILD, failure to improve dyspnea, oxygenation, or lung function after trial of appropriate medical therapy

Cystic Fibrosis^{4,5}:

- Any of the following, despite optimal medical management and trial of elaxacaftor/tezacaftor/ivacaftor if eligible:
 - FEV1 <30% predicted in adults
 - FEV1 <40% predicted and any of the following:
 - 6-minute walk distance <400m
 - PaCO₂ >50mmHg
 - Hypoxemia at rest or with exertion
 - Pulmonary hypertension (Pulmonary Arterial Systolic Pressure (PASP) >35mmHg or right ventricular dysfunction)
 - Worsening nutritional status despite supplementation
 - 2 exacerbations per year requiring IV antibiotics
 - Massive hemoptysis (>240mL) requiring bronchial artery embolization
 - Pneumothorax

- FEV1 < 50% predicted and rapidly declining based on PFTs/symptoms
- Any exacerbation requiring positive pressure ventilation
- Special considerations:
 - Gender: Consideration for early referral for females with CF. This recommendation aims to foster awareness of the increased risk of death for females with CF pre-transplantation
 - Infection/Colonization with multi-drug resistant organisms including *Pseudomonas* and non-tuberculous mycobacterium
 - Patients with *Burkholderia cenocepacia* have increased risk of mortality and should be referred to centers with active research programs for approach to management of recurrent disease
 - Nutritional status and body mass index (ideally >18kg/m²)

The CF Foundation recommends consultation with local and geographically distant transplant centers for individuals with organisms that may pose a risk for transplantation before determining an individual is not a transplant candidate.⁵

COPD⁴:

- BODE score 5-6 with additional factors suggestive of increased mortality
 - Frequent acute exacerbations
 - Increase in BODE score >1 over the past 24 months
 - Pulmonary artery to aorta diameter >1 on CT scan
 - FEV1 20-25% predicted
- Clinical deterioration despite maximal treatment
- Poor quality of life unacceptable to the patient
- Simultaneous transplant and BLVR/LVRS referral

Pulmonary Vascular Disease^{4,6}:

- ESC/ERS intermediate or high risk or REVEAL risk score >8 despite appropriate PAH therapy
- Significant RV dysfunction despite appropriate PAH therapy
- Need for IV or SC prostacyclin therapy
- Progressive disease despite appropriate therapy or recent hospitalization for worsening of PAH.
- Known or suspected high-risk variants, such as pulmonary veno-occlusive disease, pulmonary capillary hemangiomatosis, scleroderma, and large progressive pulmonary artery aneurysms
- Signs of secondary liver or kidney dysfunction due to PAH
- Life-threatening disease complications such as recurrent hemoptysis

Scenario cont:

Mrs. C. has a 6 L resting oxygen requirement, an FVC of 53% predicted, and a high-resolution chest CT consistent with a UIP pattern. She reports dyspnea with even mild activity and cannot climb a single flight of stairs. She is anxious and reports worsening depression because it is difficult to leave her home.

Question 3: What are the guidelines for the timing of listing for lung transplantation?

Similar to the timing of the initial referral, the indications for listing are also disease-specific. It is important to realize that these are overall guidelines and that program-specific and patient-specific factors affect the decision for transplant listing. Not everyone who meets these criteria should undergo lung transplantation. Some disease-specific guidelines for listing are summarized below:

Interstitial Lung Disease⁴:

- Any form of pulmonary fibrosis with a relative decline of one of the following despite appropriate treatment during 6 months of follow-up:
- FVC >10%
- DLCO >15%
- The absolute decline of 5% with radiographic progression
- Desaturation to <88% on a 6-minute walk test or >50m decline in 6-minute walk distance
- Pulmonary hypertension on right heart catheterization or 2-dimensional echocardiogram
- Hospitalization due to respiratory decline, pneumothorax, or acute exacerbation

Cystic Fibrosis⁴: Any of the referral criteria in combination with the following:

- FEV1<25% predicted
- A rapid decline in lung function or progressive symptoms
- Frequent hospitalization
- Any exacerbation requiring mechanical ventilation
- Chronic respiratory failure with hypoxemia or hypercapnia, especially with increasing oxygen requirements or the need for long-term NIPPV
- Pulmonary hypertension
- Worsening nutritional status, particularly with BMI<18kg/m², despite interventions
- Recurrent massive hemoptysis despite bronchial artery embolization
- WHO Functional Class IV

COPD⁴:

- BODE Score 7-1
- FEV1 <20% predicted
- Presence of moderate to severe pulmonary hypertension
- History of severe exacerbations
- Chronic hypercapnia

Pulmonary Vascular Disease⁴:

- ESC/ERS high risk or REVEAL risk score >10 on appropriate PAH therapy, including IV or SC prostacyclin analogues
- Progressive hypoxemia, especially in patients with pulmonary veno-occlusive disease or pulmonary capillary hemangiomatosis
- Progressive, but not end-stage, liver or kidney dysfunction due to PAH
- Life-threatening hemoptysis or pericardial effusion

Question 4: Is Mrs. C an appropriate candidate for lung transplantation?

There are surprisingly few absolute contraindications for lung transplantation, although, as with the timing, there is also no uniform consensus with significant variation across centers. The following are **guidelines** for absolute contraindications for lung transplantation⁴:

- Malignancy with a high rate of recurrence or death (other than non-melanoma skin cancer)
- Acute coronary syndrome within 30 days (excluding demand ischemia)
- Stroke within 30 days
- Active extrapulmonary or disseminated infection
- Active tuberculosis infection
- HIV infection with detectable viral load

- Liver cirrhosis with portal hypertension/synthetic dysfunction
- Acute renal failure with rising creatinine/on hemodialysis and low likelihood of recovery OR GFR <40mL/min/1.73m² unless considered for multi-organ transplant
- Progressive cognitive impairment
- Active substance use/dependence, including current tobacco use, vaping, marijuana smoking, or IV drug use
- Repeated episodes of non-adherence without evidence of improvement
- Lack of patient willingness or acceptance of transplant
- Limited functional status (e.g., non-ambulatory) with poor potential for post-transplant rehabilitation
- Other severe uncontrolled medical conditions are expected to limit survival after the transplant

There is no consistently agreed upon upper age cutoff, but centers become more restrictive with increasing recipient age because of the decreased long-term survival with older recipients, particularly over age 70.⁷

One of the lung transplant evaluation goals is to more accurately assess the risks and benefits of a transplant for an individual potential recipient. This assessment is focused on identifying relative contraindications to lung transplantation. These relative contraindications include⁴:

- Obesity which is associated with increased risk of primary graft dysfunction and decreased survival
- Malnutrition with a BMI <16kg/m²
- Significant extra-pulmonary disease
 - Untreatable hematological disorders
 - Hepatitis B or C with detectable viral load or cirrhosis
 - Left ventricular ejection fraction <40%
- Significant deconditioning
- Active extra-pulmonary collagen vascular disease
- Significant osteoporosis, pain, or narcotic use that may impede the functional ability
- Severe esophageal dysmotility

Other factors also need to be assessed:

- Potential surgical difficulties
 - Prior pleurodesis, median sternotomy, chest wall/spinal deformity, or surgical lung biopsy making native lung extraction more challenging
- Certain infections and colonization⁸
 - *Burkholderia cenocepacia*
 - *Mycobacterium abscessus* and *lomentospora prolificans*
- Need for mechanical ventilation before transplant and the use of extracorporeal membrane oxygenation (ECMO) → Although there is an increased risk of short-term mortality, there has been a significant increase in the use of ECMO as a bridge to transplant for extremely ill but carefully selected recipients
- Lack of social support

Scenario cont:

Mrs. C. and her family proceed to lung transplant evaluation. She has no obstructive disease on left heart catheterization, normal cardiac function, no pulmonary hypertension, and normal renal and hepatic function. Despite her acute decline over the last few months, she could walk 874 feet on her 6-minute walk test (6MWT), although she required 100% non-rebreather mask (NRB) to maintain an oxygen saturation >87%. The transplant team deemed her to be an appropriate transplant patient and is interested in being actively listed for a transplant.

Question 5: How are lungs allocated in the United States?

Before 2005, lungs were assigned within a local organ procurement organization (OPO) and then distributed based on waiting time after matching blood type and body size. This resulted in long average wait times and a preponderance of COPD patients being transplanted. Patients with other diseases (IPF in particular) did not have the survival time to wait for a lung transplant.

In 2005, the Lung Allocation Subcommittee of the Organ Procurement and Transplantation Network (OPTN) implemented the lung allocation score (LAS). The goals of this system were to reduce wait-list mortality, prioritize allocation based on urgency, and maximize the potential benefit of transplant. The LAS summarized the predicted risk of death on the waitlist and one-year survival in the first year after transplant, normalized to 0-100, with higher scores indicating higher priority for lung transplantation. The institution of LAS was integral in decreasing waitlist mortality as patients were no longer listed to accrue time on the waitlist.⁹

In March 2023, the composite allocation score (CAS) was introduced to replace the LAS. As shown in the Table, the CAS score is calculated using patient and organ-specific factors with a continuous framework to allow for distribution of lungs throughout the United States with a goal to reduce waitlist mortality. The CAS ranges from 0 to 100 points (<https://optn.transplant.hrsa.gov/data/allocation-calculators/lung-cas-calculator/>).^{10,11}

Table. The Composite Allocation Score

Attribute	Definition	Maximum Points
Waiting list survival	Expected 1-year waiting list survival	25
Post-Transplant survival	Expected 5-year post-transplant survival	25
Candidate Biology		15
ABO	Based on percentage of compatible donors by blood type	5
cPRA	Based on percentage of compatible donors by cPRA	5
Height	Based on compatible donors by height	5
Patient Access	Total of pediatric and prior living donor points	25
Pediatric	For candidates under 18 years old	20
Prior living donor	For candidates who donated any organ	5
Placement efficiency	Total of travel and proximity efficiency points	10
Travel efficiency	Based on impact of distance on costs of travel	5
Proximity efficiency	Based on impact of distance on other efficiency (time, availability, etc)	5
Total		100

Adapted from: UNOS. Establish Continuous Distribution of Lungs. Accessed July 6, 2023.

<https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-continuous-distribution-of-lungs/?wchannelid=6r36091nxs>.

Question 6:

A) How is the CAS calculated for each listed candidate? B) What are the impacts of the CAS so far?

- A) The lung CAS is unique for each patient with each organ offered, within a potential range of scores. A candidate receives a new CAS score with every organ offer due to fluctuating score values based on proximity and travel efficiency. Similar to the LAS, the patient(s) with the highest CAS have the highest priority for an organ. The goals of the CAS and the continuous allocation framework are to significantly reduce waitlist death, decrease geographic variability in transplant rates, and increase opportunities for pediatric candidates.^{10,11}

The CAS weighs the candidates' expected 1-year waitlist survival equal to their expected 5-year post-transplant survival to determine their medical urgency.^{10,11} This is a change from the LAS where in the 1-year waitlist mortality was weighted twice that of 1-year post-transplant. (OPTN Policy – 10-13) There were initial concerns that the most critically ill patients may garner lower scores under the CAS due to a reduced estimated 5-year post-transplant survival, and a decreased emphasis placed on waitlist mortality.¹³

- B) However, since implementation of the CAS, the lung transplant rate has increased by 16% with a decrease of 29% in the waitlist mortality rate. Additionally, the most medically urgent patients (those with 2.5 or more medical urgency points) had the highest transplant rates and shortest median waiting time for transplantation. A blood type score modification has led to an increase in the transplant rate for candidates with blood type O (previously 218 transplants per patient years, now 263 transplants per 100 patient years).¹³ Ongoing research is needed in the post CAS era to evaluate the effectiveness of the new scoring system.

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Introduction to Lung Transplantation Evaluation

Post-Case Related Questions

1. You see a 60-year-old male with hx of IPF, obesity (BMI 32), chronic pain, and GERD. He is a widow and never fathered any children. He has a history of depression that is well-controlled on an SSRI. He is a former smoker and quit smoking 9 months ago. You are considering referring him for lung transplant evaluation. Which of the following is (are) a potential contra-indication(s) to transplant?
 - a. Recent tobacco use within 1 year
 - b. Obesity
 - c. His depression
 - d. Lack of adequate social support
 - e. Both A and D
 - f. All of the above
2. A 56-year-old female comes to your office for ongoing management of severe COPD. Her FEV1 is 40% predicted, and she requires 2L NC O2 continuously. She is currently on maximum doses of fluticasone-salmeterol, tiotropium, and PRN albuterol and recently completed pulmonary rehabilitation. Her last ABG on room air was 7.35/60/65. Her last CT scan done for lung cancer screening was negative for any lung nodules and showed only apical predominant emphysema. She continued to feel progressively short of breath over the last several years and is more limited in her daily activities. Which of the following is (are) indication(s) to refer this patient for lung transplant evaluation?
 - a. Apical predominant emphysema
 - b. P_{cO_2} of 60
 - c. Progressive dyspnea and decreasing quality of life
 - d. All of the above
 - e. None of the above, refer for LVRS
3. A 65-year-old male with IPF comes to see you for a hospital follow-up. He was recently admitted for acute on chronic dyspnea. His exam is remarkable for a desaturation of 92% on 2L NC. His recent PFTs prior to his hospitalization show a decline in the FVC by 12% compared to the prior 6 months. Echocardiogram obtained during his hospitalization shows a normal ejection fraction of 65% and mild right ventricular dysfunction. Today, he notes his dyspnea is back to baseline. Which of the following are reasons to consider actively listing him for a lung transplant?

- a. His decline in FVC
 - b. HospitalizationHospitalization for respiratory decline
 - c. Mild RV dysfunction on echo
 - d. Would not pursue transplantation evaluation at present due to stable symptoms
 - e. A, B, and C
4. A 59-year-old female presents to establish care in your pulmonary clinic. She has a history of progressive dyspnea over the past six months which she thinks has been in the context of weight gain. Her imaging is notable for a lower lobe predominance fibrotic changes with traction bronchiectasis. She reports her brother has a history of lung disease but is unsure of his diagnosis. He died in his 60s. Which of the following should be included in your work up and management of her disease:
- a) Lung function testing and return to clinic in 3 months
 - b) Lung function testing, referral to pulmonary rehab, and return to clinic in three months
 - c) Lung function testing, referral to hospice given family history
 - d) Lung function testing, referral to pulmonary rehabilitation, concomitant referral to lung transplantation clinic

Introduction to Lung Transplantation Evaluation

Post-Case Related Questions with Answer Key

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 - c. His depression
 - d. Lack of adequate social support
 - e. Both A and D
 - f. All of the above
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 - d. Would not pursue transplantation evaluation at present due to stable symptoms
 - e. **A, B, and C**
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- a) Lung function testing and return to clinic in 3 months
 - b) Lung function testing, referral to pulmonary rehab, and return to clinic in three months
 - c) Lung function testing, referral to hospice given family history
 - d) **Lung function testing, referral to pulmonary rehabilitation, concomitant referral to lung transplantation clinic**