

 **TEMPLE HEALTH**

Temple Lung Center

Updates in research & practice

FALL | 2021

LUNG TRANSPLANTATION AND THE COVID-19 PANDEMIC

What you need to know now

FALL 2021

Temple Lung Center

Updates in research & practice

The Temple Lung Center is the nation's first entirely multidisciplinary hub for thoracic medicine and surgery. Bringing together basic science and clinical faculty, collaboration among specialties reinforces Temple's leadership in lung transplantation, thoracic surgery, acute and chronic care of pulmonary diseases, clinical and scientific research, and medical education.

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Lung Transplantation and the COVID-19 Pandemic

What you need to know now

By Sameep Sehgal, MD

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The COVID-19 pandemic has had a profound impact on the lung transplant landscape. Immunosuppressants, comorbidities, and lack of response to vaccines put previous lung transplant recipients at high risk if infected with coronavirus, causing great concern and need for precautions. At the same time, COVID is a catalyst for lung transplantation in a small but growing number of patients. High-volume, experienced transplant centers have resources in place both to help keep transplant patients safe and to perform often-complex post-COVID transplant procedures.

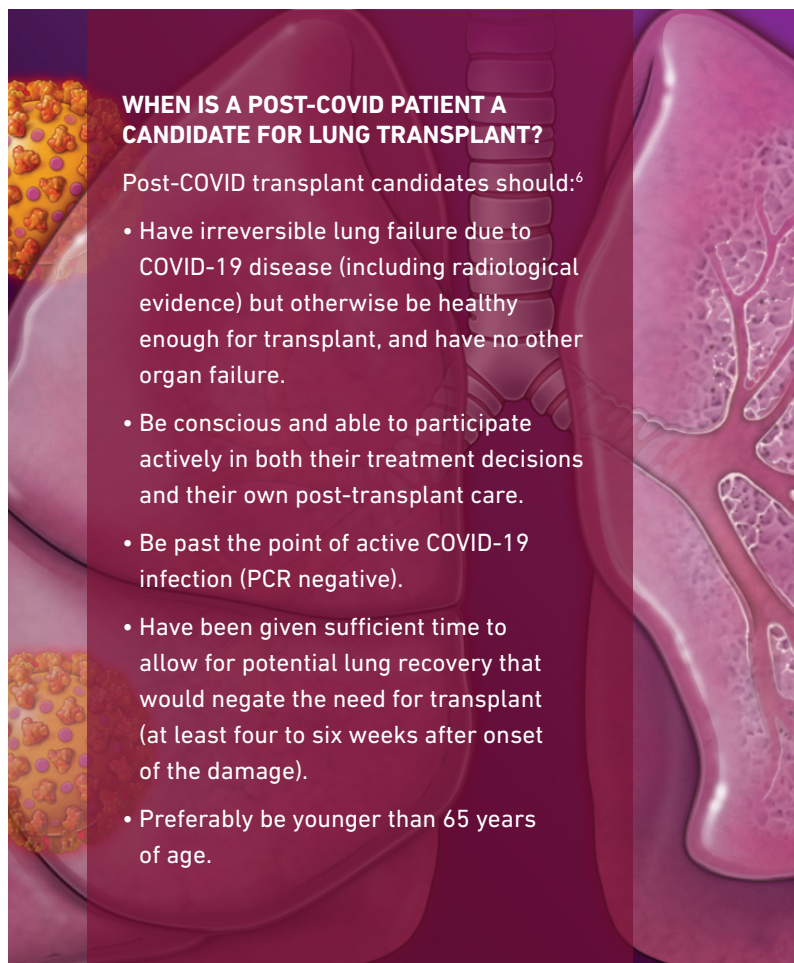
DANGERS OF COVID IN LUNG TRANSPLANT RECIPIENTS

A multi-center study in 2020 found that recipients of solid organ transplants who were later hospitalized for COVID-19 had a high mortality rate—20.5% for all solid organ transplant recipients (SOTR) and approximately 50% for those who'd had lung transplants.¹ The authors found that mortality correlated more with a patient's associated comorbidities than with the intensity of the immunosuppressant medications they received; however, both likely play a role. A larger study (currently in press) that I conducted with colleagues at Temple and multiple other centers found somewhat lower rates—approximately 16% mortality for non-lung SOTR and 24% mortality for lung transplant recipients—but supported the general trend.² Because lung transplant recipients are on high levels of immunosuppressants and often have dangerous comorbidities, and because COVID-19 attacks the lungs primarily (and has the potential to induce graft rejection), this tragic result is not unexpected. My colleagues and I also recently conducted a study suggesting COVID-positive SOTRs are likely to have shorter ICU stays and longer time spent on mechanical ventilation compared with non-SOTR COVID patients—data that may also reflect poorer outcomes among SOTRs.³

The American Society of Transplantation, the International Society of Heart and Lung Transplantation, and others recently issued a statement noting much lower vaccine response rates for SOTRs than for the general population and recommending COVID vaccination pre-transplant if at all possible.⁴ We still encourage post-transplant lung recipients to get vaccinated; however, they should continue to take other precautions to avoid infection, especially if community spread is high.

AVOIDING TRANSPLANT DELAYS

Despite concerns about post-transplant COVID patients, experienced transplant centers such as Temple were able to continue to perform life-saving lung transplants throughout the pandemic while maintaining a high level of patient safety. The United Network for Organ Sharing reported in January 2021 that 2020 was another record year for deceased-donor transplants in the United States, with more than 33,000 performed; the U.S. Department of Health & Human Services' Organ Procurement and Transplantation Network reported 2,539 lung transplants performed in 2020.⁵ Anecdotally, however, we have seen some patients delay transplant evaluation, possibly due



WHEN IS A POST-COVID PATIENT A CANDIDATE FOR LUNG TRANSPLANT?

Post-COVID transplant candidates should:⁶

- Have irreversible lung failure due to COVID-19 disease (including radiological evidence) but otherwise be healthy enough for transplant, and have no other organ failure.
- Be conscious and able to participate actively in both their treatment decisions and their own post-transplant care.
- Be past the point of active COVID-19 infection (PCR negative).
- Have been given sufficient time to allow for potential lung recovery that would negate the need for transplant (at least four to six weeks after onset of the damage).
- Preferably be younger than 65 years of age.

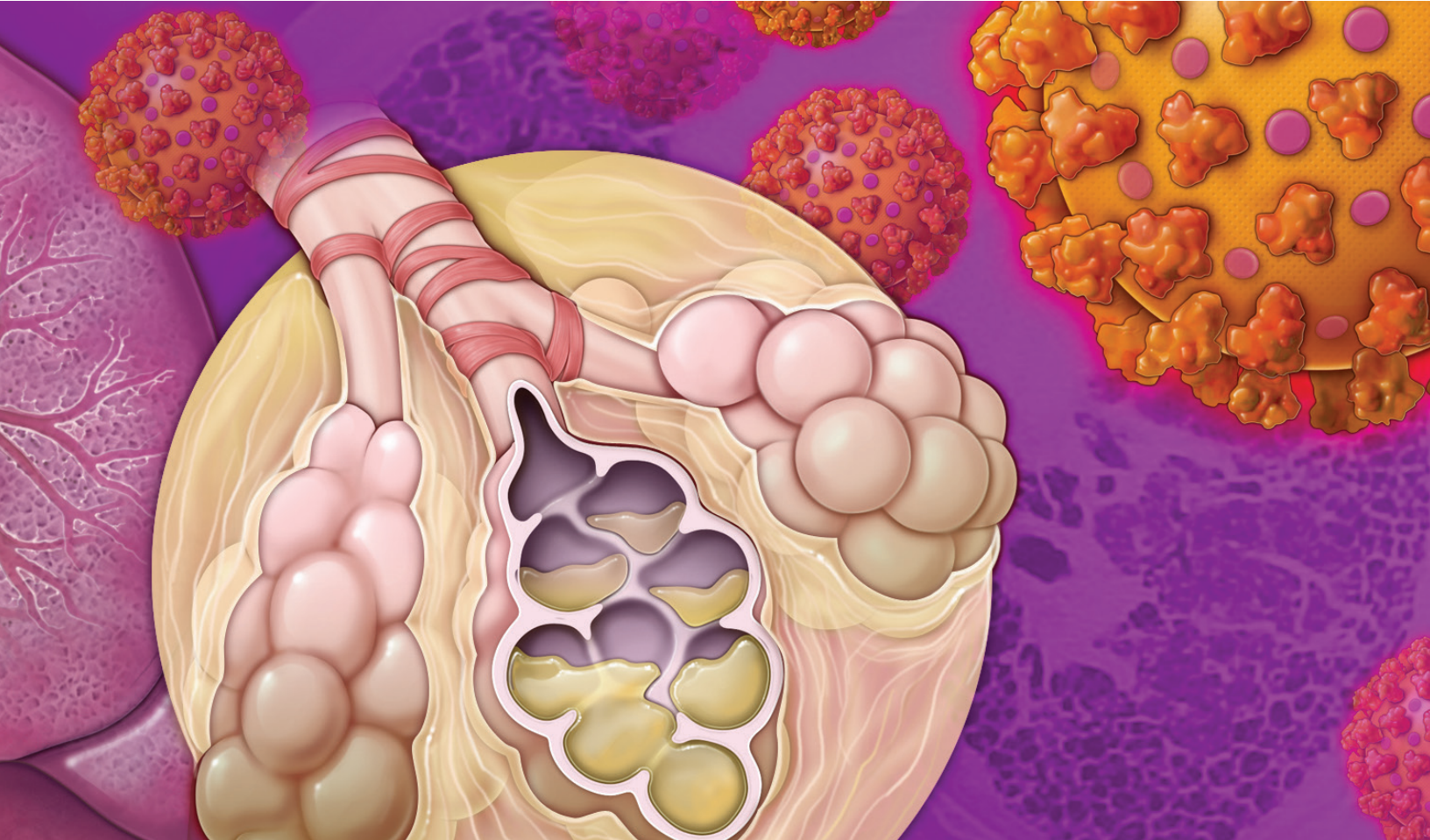
to fear of COVID-19. We urge physicians to encourage timely evaluation and transplantation, as delays can lead to a patient no longer being a good candidate for this life-saving procedure.

TELEMEDICINE: THE NEW NORMAL?

As with many medical disciplines, the pandemic shifted a great deal of transplant evaluation and follow-up care to virtual media. Now that we know we can safely and thoroughly conduct certain transplant follow-up visits via telemedicine, some proportion of these visits—perhaps one-third of those at Temple—will likely remain virtual while the others are returning to an in-person format. Such changes may represent efficiencies for patients and medical systems.

WHEN COVID-19 NECESSITATES LUNG TRANSPLANTATION

In a small number of patients, damage from COVID-19—usually fibrotic scarring—is both permanent and life-threatening. If all other therapies fail, such patients may sometimes be candidates for lung transplantation.



^ Fibrosis in lung tissue

We still lack comprehensive data on post-COVID transplant outcomes, although what we have suggests they are similar to lung transplant outcomes in general. However, the procedure is often complicated, as severe post-COVID patients may be in poor condition due to long ICU stays and comorbidities. For that reason, post-COVID patients should undergo lung transplantation at an experienced, high-volume transplant center with larger donor organ availability.⁶ Temple has performed five lung transplants on post-COVID patients; so far, they are all doing well.

To discuss a case or refer a patient for transplant evaluation, please call the Temple Access Center at **800-TEMPLE-MED (800-836-7536)** with information about the patient's condition and health considerations.

While the COVID-19 pandemic is being brought under control in some locations, its effects will continue to be felt in thoracic medicine and lung transplantation for quite some time.

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Case Study

LEAD PHYSICIAN

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BULLOUS EMPHYSEMA

Surgery and multidisciplinary therapy allow a return to independence

A 59-year-old man presented to the pulmonary clinic at Temple Lung Center for initial evaluation of shortness of breath. He had had minimal contact with healthcare providers over the prior 30 years. He reported a 40 pack-year smoking history and stated that he had quit smoking about one year prior to his presentation. He noted difficulty breathing with minimal exertion and was unable to do his own grocery shopping. He also complained of an associated dry cough and unintentional 35 lb weight loss over about a decade.

DIAGNOSTIC FINDINGS

Initial evaluation included chest X-ray, noncontrast CT of the thorax, 6-minute-walk test, and lung function testing.

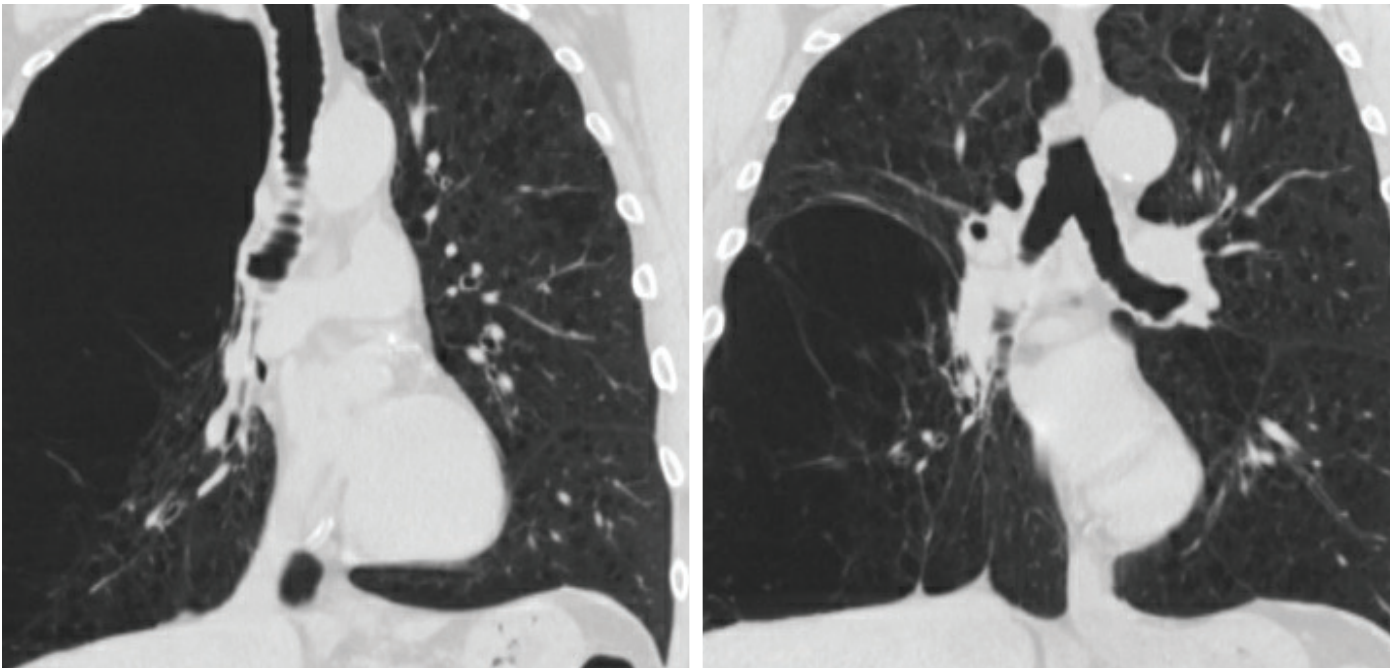
- PFT results:
 - FEV1 was 0.87 L or 24% of predicted
 - FEV1/FVC was 30%
 - Total lung capacity (TLC) was 9.44 L or 132% of predicted
 - Residual volume (RV) was 6.5 L or 281% of predicted
 - DLCO was 23% of predicted
 - 6-minute-walk testing: 313-meter walk distance with a 3 LPM oxygen requirement with exertion
- Imaging: CT thorax showed giant bulla at right lower lobe amidst a background of severe emphysema.

TREATMENT

The patient was started on LAMA/LABA inhaler therapy and referred for pulmonary rehab. He was also sent for evaluation with Thoracic Surgery for possible surgical resection of his right-sided bulla. He participated in pulmonary rehab and was able to remain exacerbation-free with LABA/LAMA therapy, but due to his exercise limitation, the decision was made for him to undergo surgery.

During his surgical workup, he was found to have coronary artery disease. Surgery was delayed, as he required a stent to the right coronary artery. However, a year after his stent placement, he was able to hold antiplatelet therapy in order to have surgical resection of his bulla.

∨ CT scan of thorax showing giant bulla at lower right lung lobe (left) and postoperative improvement of bullous lung disease (right)



OUTCOMES

- Postoperative CT thorax revealed considerable improvement in bullous lung disease and hyperinflation.
- Postoperative PFT
 - FEV1 = 1.6 L (43%)
 - TLC = 8.73 L (122%)
 - RV = 4.86 L (210%)
- Postoperative 6-minute walk: 420-meter walk distance with no exertional oxygen requirement.

- The patient has been able to recover a great deal of independence with the combination of appropriate medical and surgical therapy for his bullous emphysema. He has begun walking for exercise and has been able to complete his own grocery shopping since the operation.

DISCUSSION

With a multidisciplinary approach to managing this patient's severe bullous emphysema, the patient was able to have significant recovery of lung function as well as improved quality of life.

COVID-19: Lessons from the Pandemic

Insights from Temple Health

By Gerard J. Criner, MD, FACP, FACCP

Chair and Professor, Thoracic Medicine and Surgery, Lewis Katz School of Medicine at Temple University

As the COVID-19 pandemic took hold in Philadelphia, Temple physicians had already been in touch with international colleagues for months and knew it was crucial to share what we had learned. We formed the Temple University COVID-19 Research Group with the aim of analyzing and broadcasting key findings coming out of both clinical experiences and pivotal clinical trials taking place at Temple Health. As a high-volume respiratory care center and a prolific clinical research hub, with deep expertise treating high-risk and complex respiratory patients, Temple was primed to help physicians and other health systems worldwide respond to COVID-19.

The research group—an extensive collaboration between researchers and clinicians across multiple departments in the Lewis Katz School of Medicine and Temple University Hospital—made important findings relevant to patient care. More than a year later, we look back on a few highlights of this research effort:

- **Diagnostics:** As hospitals worked to prevent outbreaks at the point of care, the ability to identify COVID patients who tested negative via a nasal or oropharyngeal swab became vital. The Temple COVID-19 Research Group demonstrated that high-resolution computed tomography imaging could fill a pressing need for additional diagnostic methods.¹
- **Cytokine storm:** A report by the Research Group outlined criteria for predicting the onset of cytokine storm (CS)—the dangerous immune response that causes many COVID-19 deaths—among hospitalized COVID patients based on laboratory results. This protocol allowed physicians to intervene earlier to potentially prevent or reduce CS intensity.² Temple researchers also reported the successful first use of etoposide as a salvage therapy in a patient with severe COVID-induced CS that was unresponsive to anti-cytokine or immunomodulation therapies.³
- **Reducing intubation:** Researchers found that using high-flow nasal therapy (HFNT) in COVID patients with moderate to severe respiratory failure reduced the likelihood that they would require invasive mechanical ventilation. There was lower mortality among patients treated with HFNT who did not progress to intubation.⁴ Temple has used HFNT as its primary treatment for patients with COVID-induced moderate or severe hypoxemic respiratory failure, a decision that appears to have contributed to better-than-average outcomes for COVID patients.⁵





- **COVID and COPD:** Examining outcomes from COVID patients at Temple University Hospital, Temple researchers found that patients with emphysema/COPD did not have higher mortality rates or longer hospital stays when compared with similar patients without emphysema/COPD, suggesting that age and other comorbidities play a larger role in negative COVID outcomes. Emphysema/COPD patients were, however, more likely to require admission to the ICU and extra respiratory support.⁶ Another study outlined how COVID-19 interacts with COPD in CT imaging, finding a great deal of variation.⁷
- **COVID and VTE:** Temple published one of the first reported U.S. studies on venous thromboembolism (VTE) rates among COVID-19 patients, finding that progression to invasive mechanical ventilation, D-dimer levels on admission, and mortality were higher among patients with confirmed VTE.⁸

Temple researchers also reported key research findings on COVID-19 and lung transplantation, which you can read about on page 1.

Research-informed treatment influences patient outcomes

Temple's dynamic research program and experience with treating complex respiratory disease appear to have made a difference for our most vulnerable patients during the COVID-19 pandemic. Temple's AAMC Medicare data for January through June of 2020 show:

- 28% lower mortality rate from COVID-19 than national average (15% lower than other Pennsylvania hospitals), and 33% lower patient mortality within 30 days than the national average (32% lower than other Pennsylvania hospitals).
- 9% fewer COVID patients with ICU days than the national rate (28% lower than other Pennsylvania hospitals).
- 21% lower rate of mechanical ventilation than national average.

Temple treated a higher proportion of Medicare patients with COVID (13% compared with an average of 7% locally, 4% statewide, and 3% nationally) and served 33% more dual-eligible, 11% more Hispanic, and 107% more Black Medicare patients with COVID-19 than the national average.

The long haul

COVID-19 remains a disease threat in the United States and worldwide, and Temple is committed to responsive and innovative care for COVID patients. From vaccine trials to monoclonal antibody infusions for high-risk, COVID-positive patients to a post-COVID recovery clinic for patients with persistent post-acute symptoms and for those who require lung transplantation, Temple Health continues to offer necessary and data-driven services that help prevent disease and give patients the best chance for full recovery. ■

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“Breathing Lung”

A New Technology Could Expand Transplant Availability

T

ens of thousands of people in the United States are in need of a lung transplant, and they often must wait for months or years before a donor lung becomes available. The FDA expanded approval of the TransMedics Organ Care System for Lung, or OCS™ Lung, may help increase the pool of available donor lungs for transplant.

Approval under the FDA's expanded criteria means that the OCS Lung System—which keeps lungs perfused in a warm, sterile, portable chamber with nutrient-rich and oxygenated blood—can be used to transport lungs that would otherwise have been deemed unacceptable for transplant. In October, Temple performed Pennsylvania's first post-approval transplant utilizing OCS Lung under these expanded criteria. Five transplants have been performed in total since then; all transplants were successful and the patients are doing well.

Compared with standard cold storage, the OCS Lung System reduces the amount of time that donor lungs are cut off from blood and oxygen support. The lungs are kept “breathing” through a built-in ventilation circuit that allows the medical team to adjust and optimize ventilation throughout the retrieval process without adding extra time. The OCS Lung keeps the donor lungs perfused and ventilated during transport and until they are ready for implantation; it also measures and displays real-time data regarding the health of the organs.

M. Abul Kashem, MD, PhD, research faculty and assistant professor of surgery at Temple's Lewis Katz School of Medicine, is analyzing transplant survival outcomes and assessing the long-term benefits for patients of using the OCS Lung System. “This innovative technology is state-of-the-art in its ability to preserve the health of the organ in such a small chamber and to ventilate in real time before the organ is implanted in patients,” he says. “Our team is looking forward to seeing the results of such device-based lung transplant technology for waiting list patients.”

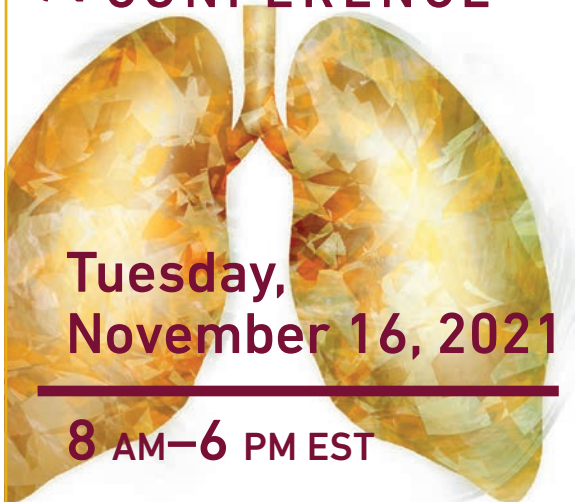
For the past four years, the Temple Lung Center has performed among the highest number of lung transplants of all centers in the United States, yet many more patients remain in need across the country. Technologies like OCS Lung offer the hope that more patients may soon receive this life-saving procedure in time. ■



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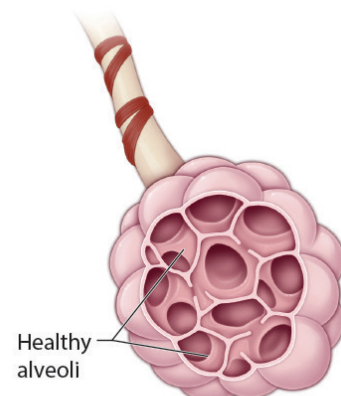
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Alveolar Epithelial Regeneration May Hold Key to Emphysema Treatment

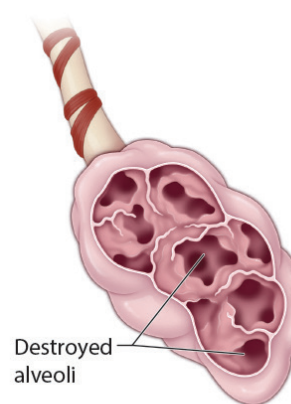
Understanding how alveolar epithelial cells regenerate is crucial for developing new therapeutic strategies for emphysema. Cigarette smoke is the most common risk factor for developing this disease. Beata Kosmider, MS, PhD, at the Center for Inflammation and Lung Research has been awarded a U.S. Department of Defense (DoD) grant to study alveolar type II (ATII) cell injury and repair in emphysema. Dr. Gerard Criner and Dr. Karim Bahmed serve as co-investigators on this project.

Continuous cell replacement and repair are needed to maintain the alveolar epithelium (the barrier between inhaled air and the underlying lung tissue), especially after injury induced by exposure to harmful factors. ATII cells have stem cell potential; when needed, they proliferate and differentiate into alveolar type I (ATI) cells to restore a damaged alveolar surface so that it continues to permit efficient gas exchange. Therefore, ATII cell differentiation to ATI cells is of critical physiologic significance.

Extensive ATII cell apoptosis induced by exposure to cigarette smoke, and not compensated for by cell proliferation, impairs alveolar wall repair and contributes to the development of emphysema. We currently have a poor understanding of the mechanisms that drive ATII cell proliferation, resulting in a lack of strategies to enhance reepithelialization and prevent respiratory disease progression. With the DoD grant, Dr. Kosmider will study the repair of the damaged alveolar epithelium after injury induced by cigarette smoke and in emphysema. Identifying novel regulators of reepithelialization can suggest therapeutic strategies to stimulate lung regeneration in respiratory diseases. ■



Normal



Emphysema

Selected Clinical Trials

COPD:

Mepolizumab as Add-on Treatment IN Participants With COPD Characterized by Frequent Exacerbations and Eosinophil Level (MATINEE)
NCT04133909

Roflumilast or Azithromycin to Prevent COPD Exacerbations (RELIANCE) (RELIANCE)
NCT04069312

Zephyr Valve Registry (ZEVr) (ZEVr)
NCT04186546

Efficacy and Safety of Benralizumab in Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD) With a History of Frequent Exacerbations (RESOLUTE)
NCT04053634

Tezepelumab COPD Exacerbation Study (COURSE)
NCT04039113

Biological Effects of Quercetin in COPD
NCT03989271

Pivotal Study to Assess the Efficacy, Safety and Tolerability of Dupilumab in Patients With Moderate-to-severe COPD With Type 2 Inflammation (BOREAS)
NCT03930732

Evaluation of the Safety and Efficacy of TLD in Patients With COPD (AIRFLOW-3)
NCT03639051

Predicting Sleep, Smoking, and Lung Health Disparities in African American Adults
NCT03534076

RejuvenAir® System Trial for COPD With Chronic Bronchitis (SPRAY-CB)
NCT03893370

Clinical Study of the RheOx Bronchial Rheoplasty System in Treating the Symptoms of Chronic Bronchitis (RheSolve)
NCT04677465

ILD:
Idiopathic Pulmonary Fibrosis and Interstitial Lung Disease Prospective Outcomes Registry (IPF/ILD-PRO)
NCT01915511

Autoantibody Reduction for Acute Exacerbations of Idiopathic Pulmonary Fibrosis (STRIVE-IPF)
NCT03286556

Evaluation of Efficacy and Safety of Pamrevlumab in Patients With Idiopathic Pulmonary Fibrosis
NCT03955146

A Study to Test How Taking BI 1015550 for 12 Weeks Affects Lung Function in People With Idiopathic Pulmonary Fibrosis (IPF)
NCT04419506

GKT137831 in IPF Patients With Idiopathic Pulmonary Fibrosis (GKT137831)
NCT03865927

Prospective Treatment Efficacy in IPF Using Genotype for Nac Selection (PRECISIONS) Trial (PRECISIONS)
NCT04300920

For more information about trials, email breathe@temple.edu or call 215-707-1359

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T.K. Broderic
Manager, Key Accounts at Temple Lung Center
Temple Lung Center
267-608-8433
thomas.broderic@tuhs.temple.edu

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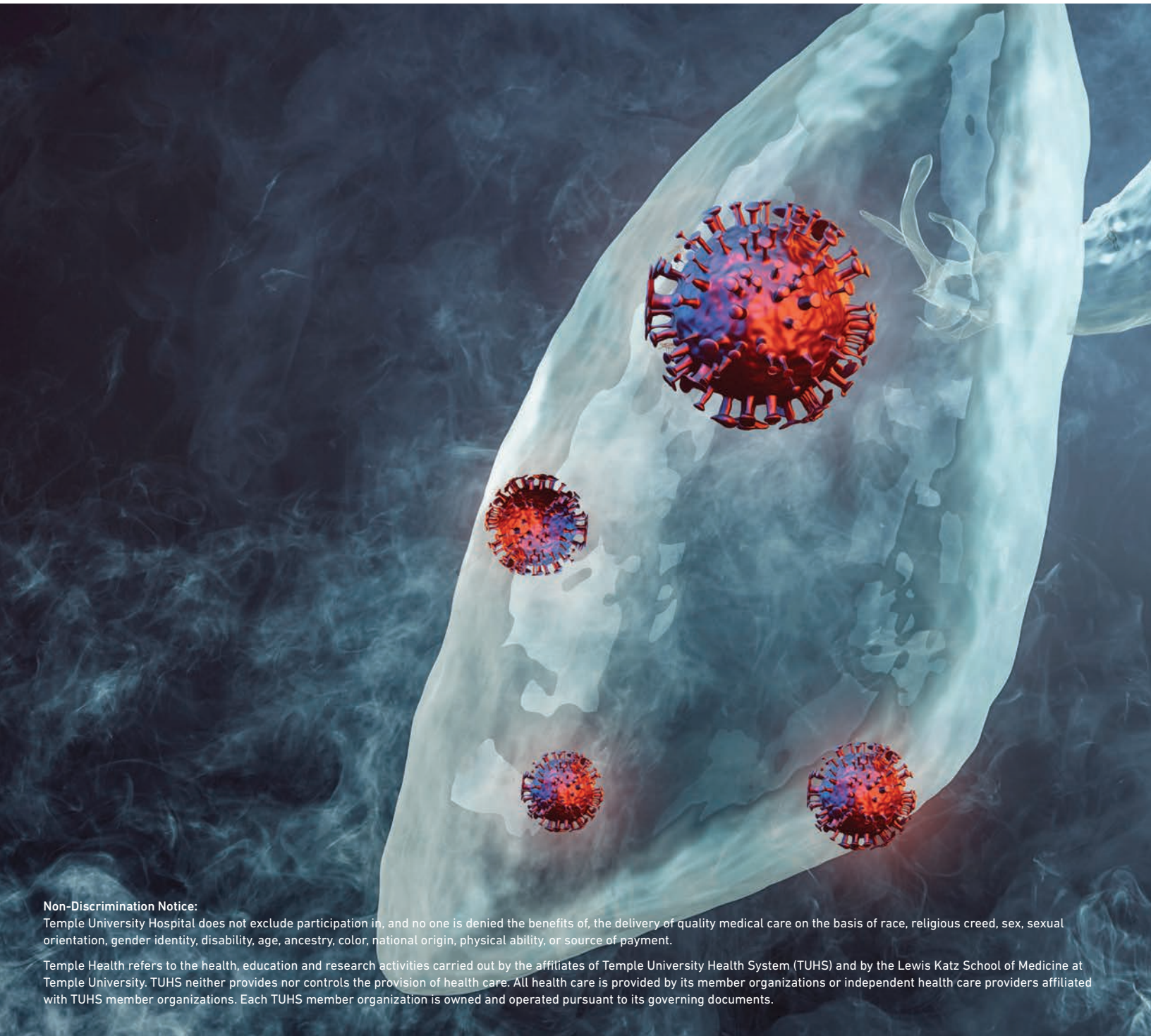
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