



NEW INVESTIGATIONAL EMPHYSEMA TREATMENT AVAILABLE AT UVA

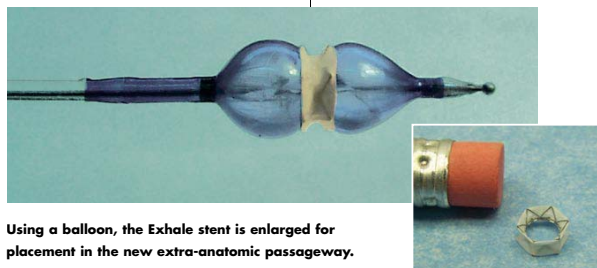
Chronic obstructive pulmonary disease (COPD) is the fourth-leading cause of death in America, according to the American Lung Association. Encompassing emphysema and chronic bronchitis, COPD kills more than 120,000 Americans annually.

But promising research has identified some potential new treatment options for patients suffering from the effects of COPD. UVA's COPD Program is examining the safety and effectiveness of a new emphysema treatment through the Exhale Airway Stents for Emphysema (EASE) trial.

Emphysema causes destruction of lung parenchyma, decreasing the elastic strength of the larger airways and producing an obstruction to complete exhalation and eventual hyperinflation of the lungs. This leads to dyspnea that progressively limits patients' activities.

The Airway Bypass procedure creates a path to allow the gas to exit the lung, reducing hyperinflation, says principal investigator Jonathon Truwit, M.D., the head of UVA's Division of Pulmonary and Critical Care Medicine. Holes are created in the lobar bronchi, Truwit says, followed by insertion of the Exhale drug-eluting stents. Because the lung's small air sacs communicate with each other through a process known as collateral ventilation, says co-investigator Ajeet Vinayak, M.D., an assistant professor of internal medicine at UVA, inserting several stents should translate to substantial reductions in hyperinflation.

One substantial difference between the Airway Bypass and other emphysema treatments, Vinayak says, is that stenting is being considered in patients with diffuse emphysema, while other treatments are indicated or under investigation for emphysema concentrated in the top portions of the lungs.



Using a balloon, the Exhale stent is enlarged for placement in the new extra-anatomic passageway.

To refer a patient for the EASE trial, call UVa Physician Direct at 800-552-3723.

Who is Eligible for the EASE Trial?

ELIGIBILITY CRITERIA INCLUDE

- ▶ High-resolution CT scan evidence of homogenous emphysema
- ▶ Patients who have stopped smoking for eight weeks
- ▶ Post-bronchodilator RV/TLC ratio of > 0.69
- ▶ Forced expiratory volume (FEV1) < 50 percent of predicted and < 1 liter
- ▶ Marked dyspnea, scoring equal or greater than 2 on the modified Medical Research Council scale
- ▶ Patient has undergone pulmonary rehabilitation no less than six weeks prior to the procedure

EXCLUSION CRITERIA INCLUDE

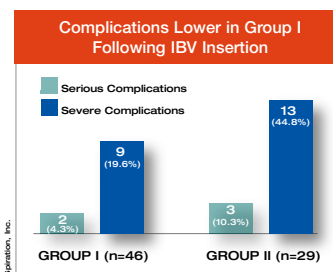
- ▶ FEV1 < 20 percent
- ▶ Diffusing capacity for carbon monoxide < 15 percent of predicted value
- ▶ PCO2 > 50mm Hg
- ▶ Evidence of pulmonary hypertension defined as systolic pressure > 45 mm Hg or mean pressure of > 35 mm Hg
- ▶ Respiratory infections requiring more than three hospitalizations in the past year
- ▶ Inability to walk more than 140 meters in 6 minutes
- ▶ A giant bulla greater than one-third of a single lung's volume
- ▶ Previous lung volume reduction surgery or lobectomy

Emphysema Patients May Benefit From Intra-Bronchial Valve

Emphysema patients at the University of Virginia Health System may benefit from a clinical trial examining a valve system. A preliminary pilot study at UVA and other hospitals found this valve system may help provide noninvasive breathing improvement.

Over 27 months, the trial examined the safety and effectiveness of the Spiration, Inc. Intra-Bronchial Valve (IBV) System. A total of 520 valves were bronchoscopically placed in the upper-lung lobes of 75 patients. Intra-bronchial valves are small umbrella-shaped devices inserted in the bronchial tree to close off targeted airways. The one-way valves allow

secretions and air in unhealthy portions of the lung to escape while redirecting inhaled air to healthy portions of the patient's lung, improving the lung's function.



In an abstract presented to the American College of Chest Physicians, patients were analyzed in two groups: those with valves placed in upper-lobe segments, excluding lingual (Group I) and those with valves placed in upper lobes, including lingual (Group II). Group I patients (46 of the 75 studied) had reduced complications and retained clinical efficacy in comparison to Group II. In patients responding to treatment, 20 percent more ventilation and perfusion was redirected to healthier portions of the lung. Two-thirds of Group I patients had at least a four-point improvement in their SGRQ scores at six months.

"I would say the results are encouraging," says principal investigator Jonathon Truwit, M.D. "The greatest impact has been in the relief of patient symptoms, specifically shortness of breath."

The IBV has not yet been approved by the U.S. Food and Drug Administration to treat emphysema. It is only available as part of the next phase of the clinical trial ongoing at UVA.

To refer a patient for the IBV trial, call UVa Physician Direct at 800-552-3723.

WHEN TO REFER PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE TO UVA

Along with leading-edge treatments, UVA offers a full range of treatments for Chronic Obstructive Pulmonary Disease, which includes emphysema and chronic bronchitis. Patients meeting any of these criteria may benefit from a second-opinion consultation:

- ▶ Conditions refractory to standard therapies
- ▶ Severe dyspnea despite maximum medical therapy
- ▶ High oxygen requirement or desire for transtracheal oxygen
- ▶ Patients needing pulmonary rehabilitation, exercise testing or smoking cessation counseling

HOW CAN UVA HELP COPD PATIENTS?

UVA's COPD Program brings together a specialized team of pulmonary, thoracic surgery, respiratory therapy and transplant experts to partner with referring physicians to develop an individualized treatment plan for each patient. UVA's comprehensive care options include:

- ▶ Comprehensive diagnostics
- ▶ Non-surgical treatment – Medication and oxygen therapy, including transtracheal catheters
- ▶ Surgery – Lung volume reduction surgery and lung transplantation
- ▶ Pulmonary rehabilitation – UVA offers onsite rehabilitation and provides prescriptions for rehabilitation at home
- ▶ Access to clinical trials