Trial demonstrates effectiveness of minimally invasive emphysema treatment

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For patients with severe emphysema, every breath brings equal parts relief and burden. Oxygenated air comes in, but not all the air from the last breath is exhaled. Rather, it becomes trapped in the lungs, caught in large pockets formed by the rupture of the lung's tiny air sacs, known as alveoli.

Surgery to remove small portions of damaged lung tissue helps some patients but is invasive and risky. Now, an effective, but safer option—the Zephyr Endobronchial Valve (Zephyr EBV), an endoscopic lung volume reduction therapy manufactured by California-based Pulmonx Corporation—may provide an alternative. In a Temple-led clinical trial known as LIBERATE, implantation of Zephyr EBV successfully reduced shortness of breath and improved lung function and quality of life, with benefits lasting at least one-year post-intervention.

"The LIBERATE trial was designed to see whether Zephyr EBV was safe and effective over a relatively longer time frame, out to one year," explained Gerard Criner, MD, FACP, FACCP, Chair and Professor of Thoracic Medicine and Surgery at the Lewis Katz School of Medicine (LKSOM) at Temple University and principal investigator of the study. Previous clinical trials were shorter term. They also involved small numbers of patients, whereas LIBERATE included more than 190 subjects. The results of the LIBERATE study were presented May 22 at the ATS 2018 International Conference and were published simultaneously in the *American Journal of Respiratory and Critical Care Medicine*, a journal of the American Thoracic Society.

"We are interested in treatments for emphysema performed with minimally invasive bronchoscopic techniques," Dr. Criner said of his team's interest in pursuing clinical development of the Zephyr valve.

The Zephyr valve can be readily placed in an emphysematous lobe of the lung using a bronchoscope and flexible delivery catheter. Once in place, it functions as a one-way valve, causing the damaged lobe to deflate and preventing further lobar inflation. It thereby reduces hyperinflation, which happens when air becomes trapped in the lungs. Hyperinflation is what makes breathing difficult for emphysema patients.

The Zephyr valve essentially mimics the mechanism of action of lung volume reduction surgery by shrinking the diseased lung region, thereby allowing healthier regions to expand and function with greater efficiency. In the LIBERATE trial, almost half of patients treated with Zephyr EBV experienced improved lung function, compared with just 17 percent of patients treated with current standard medical management approaches for emphysema.

Moreover, while the condition of standard-of-care patients did not change or worsen over time, the patients who responded to Zephyr therapy continued to experience clinical benefits 12 months after receiving treatment. Over the long-term, the frequency of adverse events between the two study groups was comparable.

Key to the success of the LIBERATE trial was proper patient selection. In LIBERATE and smaller previous trials, Zephyr was found to be effective in patients who exhibit little to no collateral ventilation, a phenomenon in which air moves around obstructed lung tissues via channels that bypass the normal airways.

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