Tiny, implantable coil promises hope for emphysema patients

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A small, easily implantable device called the Lung Volume Reduction Coil (LVRC) may play a key role in the treatment of two types of emphysema, according to a study conducted in Europe. Results of the study indicate the beneficial effects of the device persist more than a year after initial treatment.

The study will be presented at the ATS 2013 International Conference.

"LVRC treatment results in significant and clinically relevant improvements in lung function, ability to exercise and quality of life for patients with emphysema," said Gaetan Deslee, MD, PhD, professor of respiratory medicine at the University Hospital of Reims, France. "Our study shows the device is effective in treating both homogeneous disease, where emphysema is distributed evenly throughout the lungs, and heterogeneous disease, where emphysema is isolated to specific areas of the lungs."

The coil works by gathering and compressing diseased lung tissue, allowing healthy tissue to function more efficiently. The device is implanted in a simple procedure which does not require a surgical incision. Patients typically are implanted with multiple devices in each affected lung, with each lung being treated in a separate procedure.

The study's researchers gathered and analyzed data from three nearly identical multicenter European studies that analyzed the safety and efficacy of LVRC treatment in 109 patients with severe emphysema who had received two separate coil treatments. In total, 2081 devices were implanted in 218 procedures. In addition, computed tomography (CT) scans were used to determine whether these patients had homogeneous or heterogeneous disease.

Follow-up data were gathered from each patient at six months and 12 months following the procedure on the second lung. To evaluate the effectiveness of the LVRC device, the studies used a validated quality of life survey designed for patients with obstructive airways disease and three other standard measures: the forced expiratory volume or FEV1, which measures the maximum amount of air that can be exhaled in one second; the residual volume or RV, which measures the volume of air remaining in the lungs after a maximal exhalation; and six-minute walking distance or 6WMD, which estimates a person's ability or capacity to exercise.

The study authors found that, at both six months and 12 months following the procedure, values for all four measurements were significantly improved.

"The results clearly demonstrate that a broad population of emphysema patients can achieve clinically and statistically significant improvements in quality of life, exercise capacity and lung function from treatment with LVRC, and that these improvements are sustained at one year from treatment," Dr. Deslee said.

There were few adverse events. Following 218 procedures, there were 13 exacerbations of chronic obstructive pulmonary disease (COPD), nine incidents of pneumonia and nine cases of pneumothorax (deflated lung); in addition, one patient developed a cough containing significant amounts of blood (haemoptysis). All of these events resolved with standard care.

A post-hoc analysis of 53 patients identified as having either homogeneous or heterogeneous disease showed the improvements from LVRC treatment were similar between the groups, an important finding since other minimally-invasive treatment methods have not shown sustained efficacy in the many patients who have diffuse patterns of emphysema, Dr. Deslee noted.

Emphysema and chronic bronchitis are the two primary forms of COPD, recognized worldwide as a
"Emphysema is a progressive disease and there is no known cure," Dr. Deslee said. "Because available drug and behavior-based therapies have only limited effectiveness in relieving the symptoms of the disease, researchers have pinned much hope on the emergence of new medical implants which seek to provide significant and lasting improvements in patients' lung function and ability to perform activities of daily living. To date, many of these technologies have come up short, and data on the sustained effectiveness of new technologies is scarce."

The U.S. Food and Drug Administration (FDA) recently gave its approval for a clinical study evaluating the LVRC in emphysema patients, the first step in making the technology available to emphysema patients in the United States. The LVRC has also been selected by the French Ministry of Health for a national cost-effectiveness study, expected to lead to reimbursement of the treatment for emphysema patients in France.

"A minimally-invasive technology which proves to be effective in treating a large population of emphysema patients could potentially help patients to live healthier lives despite their emphysema," Dr. Deslee said. "Because the disease imposes such an enormous economic and social burden, rapid adoption of such a technology could change the paradigm of emphysema management, evolving the standard of care from today's drug and behavior-based methods to include routine use of treatment procedures to optimize and prolong a patient's overall health."

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