New procedure alleviates symptoms in people with severe asthma

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A new drug-free treatment for asthma has been shown to be effective in an international study of patients with severe, uncontrolled asthma. The results showed statistically significant improvements in quality of life and reductions in asthma attacks and emergency room visits for patients who underwent the treatment.

Conducted at 30 sites around the world, including Washington University School of Medicine in St. Louis, the trial tested a procedure designed to reduce the ability of the lung's airways to contract and interfere with breathing. The findings will be presented May 18 at the international conference of the American Thoracic Society in San Diego.

An acute asthma attack is characterized by contraction of muscle tissue in the airway walls in response to irritation, infection or inflammation. Although drugs can lessen the constriction of the breathing passages in many patients, some patients can't control their asthma symptoms even with high doses of medications. The new treatment uses a device to heat the walls of the lung's air passages to reduce the amount of muscle tissue and potentially inhibit narrowing of the airways.

"One of the reasons I find this treatment exciting is that many patients with severe asthma are already taking the best drug therapy we have and are still experiencing debilitating symptoms," says the study's lead U.S. investigator, Mario Castro, M.D., a Washington University pulmonary specialist at Barnes-Jewish Hospital. "This device provides a meaningful new treatment for such patients."

The device is the Alair Bronchial Thermoplasty System, developed by Asthmatx Inc., which funded the study. None of the trial's investigators has financial interest in the company.

The study, the Asthma Intervention Research 2 (AIR2) Trial, a randomized, double-blind, sham-controlled trial, follows the earlier AIR Trial, completed in 2005. AIR compared bronchial thermoplasty to standard medical care for moderate to severe asthma. That trial showed use of the device reduced asthma exacerbations and provided more symptom-free days than standard care.

But past research has shown that almost any medical procedure has the potential for a placebo effect or to cause a benefit not related to actual treatment. So the larger AIR2 trial compared patients who had bronchial thermoplasty with patients who had a sham procedure. In the sham procedure, all the instrumentation looked and sounded the same, but no heat was applied to airway tissue. In all, 297 patients participated in AIR2, two-thirds receiving the bronchial thermoplasty procedure and one-third getting the sham treatment. All patients were followed for one year.

During the post-treatment period, the treated group had an average 32 percent reduction in the rate of severe exacerbations and 84 percent fewer visits to the emergency department for respiratory symptoms compared to the sham group. Further, the treated group missed fewer days of work or school due to asthma symptoms, had more symptom-free days and needed rescue medication (fast-acting bronchodilators) less often than the sham group.

The researchers also determined how well patients responded using a standard quality of life questionnaire, which measured the physical and emotional impact of asthma. For both groups, the quality of life score rose, but the treatment group reported a greater improvement. Starting at

an average score of 4.3 on a scale of one to seven (seven indicating high quality of life), the treated group experienced an average increase of 1.35, while the sham group saw an increase of 1.16. The difference in scores between the groups was statistically significant.

"Although we were expecting the sham group to improve, the amount of their improvement surprised us," says Castro, professor of medicine and pediatrics in the Division of Pulmonary and Critical Care Medicine and director of the Asthma Center and Pulmonary Function Laboratory. "Nevertheless, it was clear that the treatment did benefit most patients who received it."

Patients were sedated during the procedure, which involved inserting the catheter of the Aliar device deep into the main air passages of the lungs. The catheter has an expandable wire array at its tip. When deployed, the wires touch the airway walls and deliver heat. The thermoplasty treatments took place in three sessions, three weeks apart, and each session targeted a different area of the lungs.

During this treatment period, some patients in both groups experienced upper respiratory tract infections and a worsening of asthma symptoms such as wheezing, chest discomfort and cough. The treated group had somewhat more of these side effects during the treatment period but fewer during the post-treatment period compared to the sham group.

"Patients considering the procedure will want to balance the possible risk of adverse events with the potential benefit," Castro says. "There's no one answer for every patient. Each person feels differently about the impact of their asthma and what they might be willing to do to alleviate it. That's going to have to be a personal decision in consultation with their physicians."

The AIR2 trial is no longer recruiting participants, and before the

thermoplasty procedure will be available to patients outside of the trial, the U.S. Food and Drug Administration (FDA) must approve the device for use in the treatment of asthma. Asthmatx has submitted it for FDA review, and a ruling is expected by fall of 2009.

More information: Castro M, et al. for the AIR2 Trial Study Group. Safety and effectiveness of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, sham-controlled trial. Presented at ATS 2009, May 18, 2009.

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