

# Thermoplasty May Offer Rx-Free Asthma Option

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SALT LAKE CITY — Bronchial thermoplasty is an innovative outpatient procedure showing considerable promise as a long-term nondrug treatment for asthma, Dr. Michel Laviolette said at the annual meeting of the American College of Chest Physicians.

The investigational procedure, performed through a standard flexible bron-

choscope, resulted in a significant decrease in asthma exacerbations along with improved asthma-related quality of life, compared with state-of-the-art medical management, in the yearlong, randomized, 108-patient, multicenter Asthma Intervention Research (AIR) trial, reported Dr. Laviolette of Laval University, Quebec City.

Bronchial thermoplasty involves use of catheter-delivered radiofrequency energy to thermally ablate airway smooth mus-

cle. During three half-hour sessions, interventional pulmonologists treat all reachable 3- to 10-mm-diameter airways distal to the main stem bronchi, sparing only the right middle lobe.

Because of the encouraging results of the AIR trial, AIR2 is now underway. It is a 300-patient international randomized trial featuring a sham procedure in controls. Asthmatx Inc. is developing bronchial thermoplasty using its Alair catheter system.

Dr. Laviolette explained that AIR trial participants were randomized to standard management with inhaled corticosteroids and long-acting  $\beta$ -agonists, or standard management plus bronchial thermoplasty. All subjects had moderate to severe persistent asthma.

During 1 year of follow-up, the bronchial thermoplasty group experienced a 40% increase in the number of symptom-free days over baseline, which was significantly better than the 13.7% increase in controls. The mean number of puffs of rescue medication required per week dropped by 90% in the thermoplasty group, compared with 10% in controls. Exacerbation rates during a 2-week

**In a yearlong study of 108 patients, thermoplasty led to a significant drop in asthma exacerbations, compared with state-of-the-art drug therapy.**

destabilization period without long-acting  $\beta$ -agonists were 50% lower, compared with baseline in the bronchial thermoplasty group, but not significantly different than at baseline in controls.

In addition, the thermoplasty recipients scored significantly better than did the controls on the Asthma Quality of Life Questionnaire and Asthma Control Questionnaire.

There was no significant difference between the two groups in forced expiratory volume in 1 second ( $FEV_1$ ). However, the patients already had stable asthma at study entry, so one wouldn't expect to see a major increase in  $FEV_1$  over the course of the year, the physician continued.

In terms of safety, bronchial thermoplasty was associated with a transient worsening of asthma symptoms and airway irritation that typically started the day after treatment and resolved within a week.

There were 407 such adverse respiratory events—including dyspnea, cough, wheezing, and night awakening—in the thermoplasty group, compared with 106 such events in controls. Sixty-nine percent of the events were classified as mild and only 3% as severe in nature. There were no lingering or unexpected adverse events; between 1 week and 1 year post treatment, there were three respiratory-related hospitalizations in each study arm.

At the presentation of the study results, audience members were enthusiastic at the prospect of a long-acting nondrug treatment for asthma, although longer-term safety and efficacy data are needed.

When asked how long the benefits would last, Dr. Laviolette replied that in dog studies, a favorable response to the methacholine challenge test is present at 3 years and counting. Follow-up in asthma patients isn't as long yet, but improvement is retained at the 2-year mark.

Dr. Laviolette declared that he has no financial relationship with Asthmatx. ■

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