Medscape Medical News

Sublingual Allergy Immunotherapy Gains Ground

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March 21, 2005 (San Antonio) — Sublingual allergy immunotherapy continues to show promise, as investigators document its efficacy against more allergens and its safety in young children, according to a presentation here at the 61st annual meeting of the American Academy of Allergy, Asthma & Immunology.

In one study, patients with mite-induced allergic rhinitis, asthma, or both used fewer drugs and required fewer unscheduled medical appointments after treatment with sublingual immunotherapy than did patients receiving placebo.

"Patients who received the sublingual treatment also reported less allergy-related work absenteeism than did those who received placebo," said principal investigator Carlo Lombardi, MD, during a press briefing. He is a professor of medicine at the University of Genoa in Italy.

The investigators enrolled 68 patients with confirmed mite-induced rhinitis, asthma, or both in a randomized, double-blind, placebo-controlled study. All patients had undergone a baseline assessment for one year prior to enrollment in the study. The patients' average age was 32 years.

During the two-year study period, patients received either standard antihistamine or asthma treatment along with sublingual immunotherapy or placebo. The treatment was given as soluble tablets of monomeric allergoid.

The investigators scored participants' rhinitis and asthma severity on a scale of 0 to 3. The participants recorded their drug consumption for November through February for each year of the study period in a diary, and the investigators conducted an analysis of the cost of both drug consumption and study treatment. In addition, patients filled out the Short Form-36 (SF-36) questionnaire at each observation period to assess their health-related quality of life.

Of the original patients, 56 completed the study. The active and placebo groups had similar discontinuation rates. Dr. Lombardi said that the investigators observed no treatment-related adverse effects during the study period.

The investigators documented a significant reduction in the clinical scores for nasal obstruction, nasal itching, and cough in the treatment group compared with both the placebo group and baseline ($P < 0.5$ for both). In the second year of the study, the treatment group had a 25% reduction in drug consumption compared with baseline, while the placebo group had no change. Therefore, despite the cost of immunotherapy, the investigators found the treatment group's care to be less expensive than that of the placebo group. The analysis of unscheduled medical care showed that 25% of the treatment group required such visits compared with 43% of the placebo

group.

The investigators documented no change in the groups' SF-36 scores on most items compared with baseline. However, Dr. Lombardi stressed that all patients displayed a normal profile at baseline, and he suggested that the patients' disease status was too mild to compromise health-related quality of life. However, the patients in the treatment group were more likely to report a "change in health status," Dr. Lombardi said.

In other research, Giovanni Passalacqua, MD, also a professor of medicine at the University at Genoa, found that the sublingual route of immunotherapy is safe to use in children younger than five years. Because of the reactions that can occur with immunotherapy, it is typically not given to preschool children. In this study involving 126 children (average age, 4.2 years) and 39,000 doses, the investigators documented nine adverse events in seven children: two mild episodes of oral itching and one mild episode of abdominal pain. The remaining six, which consisted of gastrointestinal events, were resolved by reducing the dose.

Dr. Passalacqua said during the same press briefing that the reason that the reactions were so few and mild is not known, but it may be that injected immunotherapy interacts more quickly with mast cells, while the orally absorbed formulation reaches such cells more slowly. This difference may cause the body to have a more severe immune reaction to the injected formulation, he said.

"These and other results are showing that sublingual immunotherapy is effective and safe when given correctly in the right dose at the right time," said Clifford W. Bassett, MD, in an interview seeking outside comment. He is a clinical assistant professor of medicine at the State University of New York in Brooklyn and a clinical instructor at New York University. "These findings are exciting. It should be only a matter of time until the [Food and Drug Administration] receives applications to approve this route of administration in the United States."

AAAAI 61st Annual Meeting: Abstract 828, presented March 20; abstract 1056, presented March 21, 2005.

Reviewed by Gary D. Vogin, MD
