Needles Not the Future Of Immunotherapy

ARTICLES BY
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SAN ANTONIO — Adults with dust-mite allergy respond better to sublingual immunotherapy compared with standard allergy medications, according to Italian researchers.

"The clinical efficacy of sublingual immunotherapy has been previously established in pollen, but not dust-mite allergy," said lead author Carlo Lombardi, M.D., who presented his research at the annual meeting of the American Academy of Allergy, Asthma, and Immunology.

While the effect of sublingual immunotherapy is relatively easy to assess in pollen allergy, its effect on year-round dust-mite allergy has been more difficult to assess, added Giovanni Passalacqua, M.D., a coauthor of the study.

But, over a 3-year study period, the investigators observed a significant reduction in nasal obstruction, itching and cough, and a decreased need for symptom-relief medications in patients treated with sublingual immunotherapy compared with those treated with standard medications for allergic rhinitis and asthma.

The study randomized 68 patients with mild dust-mite rhinitis and/or asthma to standard medication plus sublingual immunotherapy or standard medication plus placebo for 1 year. Drug consumption and allergy symptom scores were tracked through diary cards, and the Short Form-36 Quality of Life Questionnaire.

Compared with patients receiving placebo, patients treated with sublingual immunotherapy experienced a significant reduction in symptoms. The treated group was also significantly less likely to report at least 1 missed day of work due to asthma (25% vs. 43%), said Dr. Lombardi.

There was no change in the quality of life in both groups, he said, adding that at baseline, all patients displayed a normal QOL profile. But sublingual therapy patients reported an overall improvement in their 'change in health status,' " he said.

The study results are "revealing and important to the practice of allergy medicine worldwide," commented Clifford W. Bassett, M.D., medical director of Allergy & Asthma Care of New York.

Although sublingual immunotherapy has been a part of clinical practice in many parts of Europe for the past decade, and in Italy is used more commonly than the subcutaneous route of administration (70% vs 30%), according to Dr. Passalacqua, it remains unapproved by the Food and Drug Administration.

"This and other research is fairly convincing that sublingual immunotherapy is effective when given correctly, at the proper dosage, and the right time. And its safety seems to be quite good from what we've seen so far," said Dr. Bassett. ■

Sublingual Immunotherapy Safe in Children Under 5 Years

SAN ANTONIO — Sublingual immunotherapy is safe and effective in children younger than 5 years—a group considered ideal for early allergy intervention, according to Italian researchers.

"Immunotherapy has been shown to prevent the onset of asthma in allergic patients. ... Therefore, children are optimal candidates," said Giovanni Passalacqua, M.D., professor of allergy and immunology at the University of Genoa, Italy.

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He said concerns about the safety of subcutaneously administered allergy immunotherapy in children make the prospect of sublingual administration particularly appealing.

"Subcutaneous immunotherapy injections can provoke systemic urticaria, angioedema, asthma, or even anaphylaxis—all of which are more difficult to manage in children, compared with adults," he explained.

"This is new information for us, and quite exciting," said Clifford Bassett, M.D., medical director of Allergy & Asthma Care of New York.

Both subcutaneous and sublingual allergy immunotherapy remain unapproved for children by the U.S. Food and Drug Administration.

Speaking at the annual meeting of the American Academy of Allergy, Asthma, and Immunology, Dr. Passalacqua outlined his study, which included 126 children aged 3-5 years, with respiratory allergies.

A total of 76 patients (60%) had rhinitis with asthma, 34 (27%) had rhinitis alone, and 16 (13%) had only asthma.

Immunotherapy was prescribed for dust mites in 62% of participants, grasses in 22%, *Parietaria* species (a nettle of Mediterranean origin) in 12%, *Alternaria* mold species in 2%, and olive in 2%.

All children received sublingual immunotherapy for 2 years, during which time nine instances of side effects were noted in seven patients (5.6%).

Two mild cases of oral itching and one mild case of abdominal pain were resolved by lowering the dose. The remaining six cases involved moderate GI symptoms, also resolved with a lower dose.

Dr. Passalacqua noted that this side effect profile is similar to that reported in adolescent and adult patients.

Although the study was not an efficacy study, he said 70% of the parents noted improvement in their children's allergy symptoms. ■

Penicillin Skin Test Expected to Return to the Market Soon

SAN ANTONIO — A penicillin skin test is expected to return to the market in about 1 year to fill the gap that was left when the original manufacturer, Hollister-Stier, halted production of PrePen in September 2003.

The announcement, which was made at the annual meeting of the American Academy of Asthma, Allergy, and Immunology, is good news for patients, physicians, and the health care system in general, said outgoing AAAAI President Michael Schatz, M.D.

Without the availability of a penicillin skin test, physicians have "stepped back 30 years" in managing the 10% of the population who have a history of penicillin allergy, the most frequently reported drug allergy, said Eric Macy, M.D., chair of the AAAAI's Adverse Reactions to Drugs and Biologicals Committee.

The use of penicillin skin testing can rule out a true penicillin allergy in 90% of this at-risk population, allowing such patients to receive penicillin treatment.

The use of penicillin skin testing can rule out a true penicillin allergy in 90% of this at-risk population, allowing such patients to receive penicillin treatment. But since PrePen became unavailable—followed shortly by the disappearance of its European counterpart—physicians have had no alternative but to treat all of these patients with broad-spectrum alternatives, which are more costly and contribute to antibiotic resistance, Dr. Macy said.

AllerQuest, the newly formed company that will manufacture the as-yet-unnamed test, was formed by four AAAAI members. They will partner with Hanford Pharmaceuticals, the leading manufacturer of generic penicillin and antibiotic products in the United States, said Louis Mendelson, M.D., AllerQuest president and CEO.

PrePen was a major determinant for identification of penicillin allergy, meaning that it picked up about 80% of true allergies. Until now, there has been no commercially available minor determinant to pick up the remaining 20% of true penicillin allergy.

However, AllerQuest plans to produce a commercially available minor determinant, "which will extend the diagnostic accuracy for patients," said Franklin Adkinson Jr., M.D., one of AllerQuest's founding members.

Allergists have been "clamoring" for a penicillin allergy test, Dr. Macy said. "Essentially we have been practicing medicine like we did in 1973," before the introduction of PrePen, he added.

The consequences of not confirming penicillin allergy—morbidity, mortality, and costs—are often underappreciated by physicians, Roland Solensky, M.D., said in a separate presentation during the meeting.

Studies have shown that unconfirmed "penicillin allergy" accounts for between 31% and 51% of vancomycin prescriptions in hospitals. Such prescriptions can increase the risk of vancomycin-resistant enterococci by fivefold, said Dr. Solensky, of Corvallis, Ore.

At Beth Israel Deaconess Medical Center in Boston, a pilot project to skin test patients for penicillin allergy yielded an 86% rate of negative results and resulted in a significant reduction in the use of vancomycin, quinolones, and clindamycin, he said (Am. J. Med. 1999: 107;166-8).

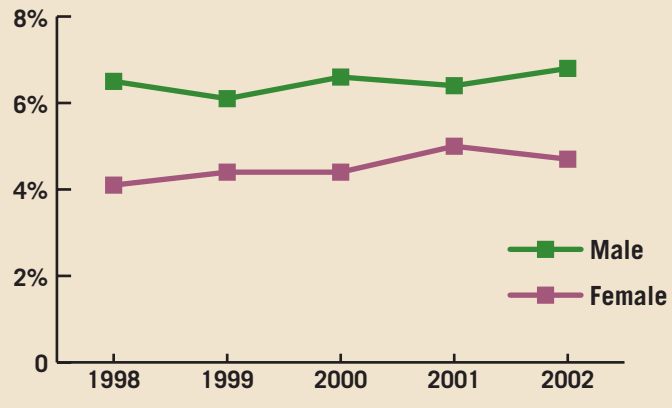
The study showed that after skin testing, the cost of antibiotics was $106 per patient, whereas before skin testing it had been $209.

Similarly, a recent effort to perform penicillin skin testing at the Mayo Clinic resulted in a reduction in vancomycin use from 30% to 3%.

And at the Cleveland Clinic, penicillin skin testing resulted in changes in therapeutic antibiotic use in 82% of patients, with reductions in the use of vancomycin and quinolones (Infect. Control Hosp. Epidemiol. 2003:24:347-50). ■

DATA WATCH

Percentage of Children Aged 0-17 Years With Asthma



Source: Child Trends analysis of National Health Interview Survey data

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