and assist families in understanding the rationale for a particular medication regimen to increase compliance and decrease exacerbations.

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IMMUNOTHERAPY, IMMUNOMODULATION, PREBIOTICS/PROBIOTICS

A Randomized Controlled Study of Peanut Oral Immunotherapy: Clinical Desensitization and Modulation of the Immune Response

Varshney P, Jones SM, Scurlock AM, et al. *J Allergy Clin Immunol.* 2011;127(3):654–660

PURPOSE OF THE STUDY. To determine if peanut oral immunotherapy (OIT) was safe and effective in inducing desensitization in peanut-allergic children. Previous studies on peanut OIT did not include a placebo control.

STUDY POPULATION. Studied were 28 children aged 1 to 16 with peanut allergy defined by clinical history of reaction after ingestion, an elevated peanut immunoglobulin E (IgE) level of >15 kU/L, or an IgE level of >7 kU/L if a significant reaction had occurred within the previous 6 months. All subjects had had a positive skin-prick test result to peanut.

METHODS. Subjects began with an initial dose escalation, with build-up visits every 2 weeks, until a maintenance dose of 4000 mg was reached. Home dosing was continued daily between build-up visits. An oral food challenge (OFC) to peanut occurred around week 48, after at least 1 month of maintenance. Skin-prick testing, cytokine production, and peanut IgG_4 and IgE and T-regulatory cell levels were assessed during treatment.

RESULTS. Peanut OIT significantly increased the amount of peanut tolerated at the OFC compared with placebo (mean: 5000 vs 280 mg, respectively; $P < .001$). Three peanut OIT-treated subjects withdrew because of adverse allergic effects. The peanut-OIT group showed a reduction in skin-test size and interleukin 5 and interleukin 13 levels and increases in peanut IgG_4, and IgE, and T-regulatory cell levels.

CONCLUSIONS. The results of this study clearly showed that peanut OIT induces desensitization as well as marked changes in the immune response in subjects with peanut allergy.

REVIEWER COMMENTS. This study is novel in that it is the first placebo-controlled study of peanut OIT. The study found dramatic efficacy for OIT in inducing desensitization to peanut, as well as concomitant immunologic changes. If OIT is going to become a mainstay of therapy for food allergy, future research will need to address adverse effects of OIT, the optimal duration of OIT, and the efficacy of OIT in inducing long-term tolerance. The sublingual route of immunotherapy for peanut was evaluated in a companion study reported on in the same issue and also showed promise for efficacy and safety (Kim EH, Bird JA, Kulis M, et al. *J Allergy Clin Immunol.* 2011;127[3]:640–646).

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Immunologic Effects of Sublingual Immunotherapy: Clinical Efficacy Is Associated With Modulation of Programmed Cell Death Ligand 1, IL-10, and IgG_4

Piconi S, Trabattoni D, Rainone V, et al. *J Immunol.* 2010;185(12):7723–7730

PURPOSE OF THE STUDY. To evaluate an optimal treatment regimen for sublingual immunotherapy (SLIT) and investigate the underlying mechanism.

STUDY POPULATION. There were 62 Italian patients aged 19 to 60 years enrolled from a clinic in Milano, Italy, between February and September 2009. Inclusion criteria were a clinical history that suggested ragweed sensitization, a positive skin-prick-test result to ragweed pollen, and a clinical report of asthma and/or rhinoconjunctivitis.

METHODS. The patients were randomly assigned to 1 of 4 treatment arms: preseasonal SLIT (5 months); seasonal SLIT (3 months); prolonged SLIT (5 months × 3 years); or no SLIT. Subjects on SLIT were treated with a median Amba1 (major ragweed allergen) dose of 120 mg/day. Clinical outcomes were recorded in daily diaries by the subjects during pollen season. Immunologic outcomes were assessed just before the initiation and completion of the SLIT regimen in the treatment groups and at the beginning and end of the study in the control groups. Clinical efficacy was evaluated with a visual analog scale. Lymphocyte subsets were evaluated by flow cytometry. Peripheral blood mononuclear cells were isolated and incubated with and without Amba1, and their cytokine profiles were analyzed by flow cytometry. Amba1-specific immunoglobulin G_4 (IgG_4) was measured by an enzyme-linked immunosorbent assay.

RESULTS. Clinical outcomes improved in all SLIT regimens compared with controls. This improvement was significantly better in the prolonged-SLIT (5 months × 3 years) compared to the other SLIT regimens. Cytokine analysis of $CD4^+$ T lymphocytes, $CD19^+$ B lymphocytes, and $CD14^+$ monocytes revealed the following: interleukin 4 (IL-4)–producing cells were reduced in all SLIT regimens compared with controls, and IL-10–producing cells were

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