

montelukast, in a population of pediatric patients with mild-to-moderate persistent asthma.

STUDY POPULATION. A total of 154 patients (aged 6–14 years) who participated in the Pediatric Asthma Controller Trial (PACT) were included in the study.

METHODS. This study extracted data from the PACT study, a randomized controlled, double-blind, multicenter trial that studied treatment regimens in children with mild-to-moderate persistent asthma. Both effectiveness and cost measures were used to determine a cost-effectiveness analysis of the 2 controller medications: fluticasone (100 μg twice daily) and montelukast (5 mg daily), given for 48 weeks. Effectiveness measures included (1) asthma-control days (ACDs), (2) improvement in forced expiratory volume in 1 second (FEV_1), and (3) the number of exacerbations avoided. Cost measures were taken from (1) direct costs from a third-party payer's perspective, including the sum of costs from asthma-related medication, emergency department visits, and regular physician's office visits, and (2) societal costs, which were the direct costs plus productivity losses from asthma-related missed school or work. Cost-effectiveness analysis was then used to compare the effectiveness of the different treatments relative to their costs. Cost-effectiveness analysis was also performed for subgroups on the basis of the phenotypic factors of exhaled nitric oxide (eNO) and the provocative concentration that causes a 20% decrease (PC_{20}) in the forced expiratory volume in 1 second (FEV_1).

RESULTS. Of the 154 patients analyzed, 79 received fluticasone and 75 received montelukast. There were no statistical differences in demographics among the participants. When effectiveness measures were compared, fluticasone showed significantly higher effectiveness with respect to ACDs, improvement in FEV_1 , and the number of asthma exacerbations ($P < .01$). Direct costs during the study period were \$759 for fluticasone and \$1189 for montelukast ($P < .001$). Societal costs were \$1075 for fluticasone and \$1673 for montelukast ($P < .001$). Thus, fluticasone was shown to be more cost-effective. In the subgroup analysis, fluticasone was more cost-effective compared with montelukast for the subgroups with high eNO levels ($\text{eNO} \geq 25$ ppb) and more-responsive PC_{20} ($\text{PC}_{20} < 2$ mg/mL).

CONCLUSIONS. In children with mild-to-moderate persistent asthma, fluticasone had lower cost and higher effectiveness when compared with montelukast, especially in patients with more airway inflammation and more responsiveness to methacholine.

REVIEWER COMMENTS. Few evaluations exist for the cost-effectiveness of asthma controller regimens for children. The results of the study were consistent with the National Asthma Education and Prevention Program

guidelines, which recommend inhaled corticosteroid monotherapy as the preferred asthma controller option for mild-to-moderate persistent asthma in children.

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107RRR

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Relationship of Asthma Management, Socioeconomic Status, and Medication Insurance Characteristics to Exacerbation Frequency in Children With Asthma

Ungar WJ, Paterson JM, Gomes T, et al. *Ann Allergy Asthma Immunol.* 2011;106(1):17–23

PURPOSE OF THE STUDY. To identify factors associated with severe asthma exacerbations in children as measured by the number of emergency department (ED) visits and hospitalizations.

STUDY POPULATION. Asthmatic children aged 1 to 18 years were enrolled from specialty and family practice hospital-based outpatient clinics and 2 EDs in Ontario, Canada, from November, 1, 2000, through March 31, 2003.

METHODS. Data regarding demographics, socioeconomic status, drug plan characteristics, health status, health utilization, and symptom data were collected during this retrospective cohort study. These data were compared with data on asthma ED visits and hospitalizations in the full group and a subgroup with prescription drug coverage.

RESULTS. Complete data were available from 490 patients. Fewer exacerbations were associated with medium/high income, older children, recruitment from a physician's office or asthma clinic, and having an action plan. Previous ED visits, pet ownership, nebulizer use, asthma education, and younger age were associated with more exacerbations. A history of food, medication, and insect allergies were associated with 52% more exacerbations. In the drug-plan subgroup, girls had 26% fewer exacerbations, and the rate of asthma exacerbations increased by 14% for every 1% increase in the proportion of income spent on prescription medicines.

CONCLUSIONS. Exacerbations that required urgent care were associated with asthma history, disease-management factors, and socioeconomic status. Because families with drug plans paid a higher proportion of household income for asthma medicines, there was a significant association with more exacerbations.

REVIEWER COMMENTS. This study demonstrates what clinicians see in clinical practice: cost-shifting often leads to rationing and underuse of needed medicines by our patients. We need to assess medication use and educate

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

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107SSS

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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 IgG₄ 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 IgG₄, 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).

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107TTT

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Immunologic Effects of Sublingual Immunotherapy: Clinical Efficacy Is Associated With Modulation of Programmed Cell Death Ligand 1, IL-10, and IgG₄

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 \times 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 G₄ (IgG₄) 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 \times 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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Pediatrics 2011;128;S134

DOI: 10.1542/peds.2011-2107SSS

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Pediatrics 2011;128;S134

DOI: 10.1542/peds.2011-2107SSS

The online version of this article, along with updated information and services, is located on the World Wide Web at:

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