The Upper Airway

A Prospective, Randomized, Double-blind, Placebo-Controlled Multi-centre Study on the Efficacy and Safety of Sublingual Immunotherapy (SLIT) in Children With Seasonal Allergic Rhinoconjunctivitis to Grass Pollen


**PURPOSE OF THE STUDY.** Subcutaneous immunotherapy (SCIT) for seasonal allergic rhinitis is a well-established, effective, and potentially curative therapy. This study evaluated an alternate route for immunotherapy: the oral mucosa and gastrointestinal tract.

**STUDY POPULATION.** Ninety-seven children, aged 3 to 14 years, with seasonal allergic rhinitis and proven sensitivity to grass pollen were studied.

**METHODS.** Sensitivity to grass pollen was confirmed by positive skin-prick test, grass pollen-specific immunoglobulin E, and conjunctival provocation test. Patients were enrolled in a prospective, double-blind trial comparing sublingual immunotherapy (SLIT) to placebo. The treatment duration was 32 months. The primary outcome measure was the change in a multiple-symptom/medication score (which measured eye, nasal, and lung symptoms and rescue-medication use) after treatment. Data collected included patient-reported symptom scores and medication use, total and antigen-specific immunoglobulin E, skin-prick test, conjunctival provocation test, nasal provocation test, spirometry, exhaled nitric-oxide concentration, atopic dermatitis score, and eosinophilic cationic protein in nasal lavage fluid.

**RESULTS.** The multiple-symptom/medication score was significantly reduced by SLIT to 77.3% of the placebo group ($P = .049$). This overall score was affected mainly by a large reduction in rescue-medication usage among those in the treatment group (67% of placebo; $P = .0025$). There was no significant difference in any individual-symptom score.

**CONCLUSION.** SLIT had a positive effect on rescue-medication usage but no significant effect on symptoms alone.

**REVIEWER COMMENTS.** SLIT represents an alternative therapy with multiple potential advantages to SCIT, including the elimination of injections and improved safety profile. Several studies in adults and children have found improvement in symptom scores as well as reductions in medication use to the point where this is now being used in clinical practice in place of SCIT in many European countries. Additional studies, including investigation of optimal dosing and the potential to use multiple allergens, are needed to further define the future role of SLIT in the United States.

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2006-0900K

Justin Skripak, MD
Robert A. Wood, MD
Baltimore, MD

The Safety of Sublingual-Swallow Immunotherapy: An Analysis of Published Studies


**PURPOSE OF THE STUDY.** To perform a meta-analysis of all published controlled studies concerning sublingual-swallow immunotherapy (SLIT) to determine rates of adverse events (AEs).

**STUDY POPULATION.** Subjects were from 25 published studies (primarily European) aged 5 to 60 years (6 studies only enrolled children, 9 only adults, and the remainder a mix of both).

**METHODS.** A systematic Medline review from 1986 to May 2004 was performed. Twenty-five published double-blind, placebo-controlled studies using SLIT that included efficacy and safety data were analyzed. Twelve studies used a high allergen dose (defined as 50–500 times the standard subcutaneous dose), and 13 used a low allergen dose (defined as 1–50 times the subcutaneous dose). AEs were defined as local or systemic: local included oral itching and/or swelling and gastrointestinal complaints, and systemic reactions included skin reactions and ocular, nasal, and chest symptoms. The rates of AEs were compared between the groups. The allergens used in the studies included mites, grasses, trees, and ragweed (single-allergen treatments).

**RESULTS.** Combining the studies, there were a total of 445 subjects (405 placebo) in the high-allergen-dose group and 302 subjects (285 placebo) in the low-allergen-dose group. Children accounted for 103 total active-dose subjects. A total of 904 AEs were reported in the 198 553 active-allergen doses given, with 694 local reactions and 210 systemic reactions, with a rate of 0.15 to 0.2 reactions per patient. There were no reports of anaphylaxis. Overall, subjects in the low-allergen-dose group had significantly more local reactions than those in the high-dose group. However, there was no significant difference in the number of patients with AEs between the high- and low-allergen-dose groups when compared as a ratio of the number of SLIT doses received.

**CONCLUSIONS.** This analysis found that local reactions were common with SLIT but were mild and self-resolved. Systemic reactions occurred rarely and were not dose...
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Pediatrics 2006;118;S22
DOI: 10.1542/peds.2006-0900KK

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