Immunotherapy With a Ragweed-Toll-Like Receptor 9 Agonist Vaccine for Allergic Rhinitis


**PURPOSE OF THE STUDY.** The conjugate compound of the ragweed antigen, Amba1, and an immunostimulatory DNA sequence containing a CpG motif is associated with a suppression of T-helper 2 cellular and cytokine responses via binding to toll-like receptor 9 (TLR9). This study investigated whether Amba1-immunostimulatory oligodeoxyribonucleotide conjugate (AIC) is a safe and effective immunotherapy for ragweed-sensitized patients.

**STUDY POPULATION.** A randomized, double-blind, placebo-controlled, phase 2 clinical trial in which 25 participants with a history of fall allergic rhinitis aged 23 to 60 years were assigned to receive a vaccine containing either AIC or placebo.

**METHODS.** Participants received a total of 6 weekly injections before the ragweed season. The primary clinical end point was the change in albumin level in nasal secretions assessed by a posttreatment nasal allergen challenge. Postchallenge rhinitis symptoms were also scored. Secondary clinical end points included the rhinitis visual analog score, daily nasal symptom diary score, use of relief medication, a rhinoconjunctivitis quality-of-life questionnaire, and skin-test sensitivity. Immunologic evaluation included measuring Amba1- and ragweed-specific immunoglobulin (Ig) G and IgE and cytokine levels.

**RESULTS.** There was no affect on the primary end point with AIC treatment. However, during the 2 posttreatment ragweed seasons, subjects in the group that received AIC had better peak-season rhinitis visual analog scores, peak-season daily nasal-symptom diary scores, and midseason rhinoconjunctivitis quality-of-life scores. Those in the AIC group also had decreased peak-season use of relief medications and antihistamine and decongestant use in the second season posttherapy. AIC was associated with a rise in the Amba1-specific IgE level after treatment but was not associated with an increase in the Amba1-specific IgE level during either posttreatment ragweed season. There were no vaccine-associated serious adverse reactions.

**CONCLUSIONS.** AIC may have a potential therapeutic role in the treatment of ragweed-allergic individuals.

**REVIEWER COMMENTS.** Current allergen immunotherapy involves frequent dosing over 3 to 5 years, which can lead to compliance issues, and may be associated with systemic allergic reactions. The described vaccine is devised to be less likely to trigger allergic reactions during therapy and to enhance nonallergic immune responses to increase efficacy. This study was limited by the small number of patients and the lack of long-term follow-up. However, it suggests that conjugated allergen vaccines may be an option in the future as shorter, safe, and effective immunotherapy regimens that may warrant consideration for use in children.
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