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Omalizumab: a definitive cure for food allergies?

Pills from the literature

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Food allergy is a growing public health concern in industrialized countries. For individuals with food allergies, especially severe ones, inadvertently consuming even a small quantity of the allergenic food can lead to life-threatening and even fatal reactions [1].

Currently, food allergy management involves eliminating the triggering food from the diet and for patients with a history of anaphylaxis also prescribing self-injectable adrenaline. The continuous vigilance regarding diet and the fear of accidentally ingesting the allergenic food can create anxiety and compromise the quality of life of both the patient and their family [1,2].

Various specialized allergy services worldwide now offer oral immunotherapy (OIT), a treatment capable of increasing the tolerated dose of allergenic foods. Although effective, OIT exposes the patient to the risk of allergic reactions, including severe ones, and therefore is not appropriate for all patients. Furthermore, there are no standardized OIT products other than one for peanut allergy, which was recently approved by the U.S. Food and Drug Administration (FDA) for the American market [2].

Small trials have shown that the anti-IgE monoclonal antibody omalizumab can reduce the occurrence and severity of allergic reactions, as well as the time needed to reach the maintenance dose if used in combination with OIT [2]. Recently, it has been demonstrated that monotherapy with omalizumab, which is already approved for patients with severe allergic asthma and chronic spontaneous urticaria [3], may protect individuals with multiple food allergies from severe reactions if they accidentally ingest a small quantity of foods to which they are allergic [4].

In a phase III, double-blind, randomized, placebo-controlled trial published on February 25 in the New England Journal of Medicine, Wood et al. [4] tested omalizumab on 3 adults and 177 children (ranging from 1 year old to 17 years old; median age 7 years) who were severely allergic to peanuts and at least two other foods. Doses and frequency of omalizumab administration were based on patients' weight and baseline total IgE levels. After 16 to 20 weeks of treatment, 67% of those who received omalizumab were able to ingest at least 600 mg of peanut protein (equivalent to approximately to two or three peanuts) in a single dose without experiencing a significant reaction, compared to only 7% of those who received placebo ($p < 0.001$). Furthermore, omalizumab was equally effective in increasing participants' tolerance to other allergenic foods (at least 1000 mg of protein from the respective food), including milk (66% in the active group *vs* 10% in placebo; $p < 0.001$), egg (67% in the active group *vs* 0% in placebo; $p < 0.001$), and cashew (41% in the active group *vs* 3% in placebo; $p < 0.001$). As commonly reported in trials with biologic agents, injection-site reactions were more frequent in the active group. However, no significant adverse effects were observed during the short treatment period with omalizumab [4]. Also, the protective response to peanuts and other foods proved to be durable when omalizumab was continued for another 24 weeks in an open-label extension trial. Based on these results, the FDA approved omalizumab as a treatment for food allergies in the United States [5].

The findings of the study by Wood et al. [4] represent a significant step forward in the treatment of food allergies. Although the drug does not offer a definitive cure for food allergies, it reduces the risk that inadvertently ingesting a small quantity or even traces of the food to which one is strongly allergic could cause anaphylactic reactions and even death. Perhaps the most important limitation of omalizumab is that it does not eliminate food allergies, but it only increases the amount of food a person can consume before experiencing a reaction. Additionally, although omalizumab increases the amount of food needed to trigger a reaction, it is

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unclear whether it can reduce the severity of a reaction if a person accidentally consumes a larger dose of food than the minimum amount tolerated. For this reason, the FDA has approved the drug with the recommendation that individuals using omalizumab for food allergy should continue to avoid the foods to which they are allergic. Also, it should be noted that 14% of peanut-allergic participants treated with omalizumab were not able to tolerate even a small amount of peanut. Understanding why some people do not respond well will be crucial for selecting those who will benefit most from this treatment.

A definitive cure for food allergy is yet to be found. Several therapeutic options for food allergy are currently at various stages of development, including different biologics, pharmacological agents, and various forms of immunotherapy [2]. A better understanding of the immune mechanisms underlying food allergy is pivotal to designing safe and long-term effective therapeutic interventions as well as early preventive strategies.

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PC: drafted the manuscript and revised it for important intellectual content. AM: revised the manuscript for important intellectual content.

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