New Medications in the Treatment of Peanut Allergy

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Abstract

In the general population, the prevalence of peanut allergy has remained stable at 1.3%. However, in children, the prevalence appears to be increasing. There are no approved treatments for peanut allergy so current treatment involves educating the patient on avoiding products that contain peanut protein. Two drugs that allow controlled desensitization with controlled amounts of peanut protein have reached late stages of development.

Keywords

investigational drugs, formulary management / P & T, drug information, allergy

Epidemiology

An allergy or hypersensitivity to food is an abnormal immunologic reaction to food. Most allergies begin during the first 2 years of life. Parent's perception of food allergies may overestimate the actual presence of an allergy. Researchers surveyed parents of infants and found 14.2% reported food allergies in the first 3 months, but this decreased to 7.2% at 12 months. When tested for food allergies at 12 months, 3.6% of infants were diagnosed with food allergies.[1]

A survey done in 1998 and repeated in 2002 and 2008 found the prevalence of peanut and tree nut allergies in adults to be 1.3%.[2-4] However, the prevalence among children increased from 0.6% in 1997, to 1.2% in 2002 and 2.1% in 2008. Peanut allergy was reported in 0.4% in 1998, 0.8% in 2002, and 1.4% in 2008.[3] It is estimated that 21% of peanut allergy patients may outgrow their allergy.[5]

Current Treatment

There are currently no approved treatments to desensitize patients who are allergic to peanuts. Current management of the allergy is centered on avoidance of peanuts or products that may contain peanuts. This can be a challenge due to cross contact during manufacturing and hidden ingredients. Some nonfood sources such as hair and skin products may also contain peanut protein. Patients with moderate to severe peanut allergies are advised to keep an epinephrine autoinjector for acute systemic reactions. Because 21% of patients may outgrow their allergy, patients are monitored to see whether their tolerance to peanut protein changes. This becomes less likely after age 6.[6] Some physicians will use a desensitization protocol that slowly titrates exposure of peanut protein to increase tolerance.[7]

New Treatment Options

Two drugs that allow controlled desensitization have reached phase III trials (Table 1). Both AR101 and Viaskin Peanut have been designated Fast Track and Breakthrough Therapy status by the Food and Drug Administration (FDA).

AR101 is an oral immunotherapy treatment consisting of a standardized preparation of peanut protein. Patients are initiated on a low dose and titrated to a maintenance dose to desensitize them for peanut protein. The initial dose and each dose titration are given under observation in a physician's office in case rescue medication is needed. Doses are given at home between titrations and after the 300 mg maintenance dose is reached. In a 6-month, 55-patient, phase II trial, 79% of patients treated with AR101 tolerated a 443 mg peanut protein challenge compared with 19% in the placebo group. In addition, 62% were able to tolerate 1043 mg of peanut protein.[9] Aimmune Therapeutics announced that in a 554-patient, phase III trial, 67% of patients who received AR101 were able to tolerate a 600 mg dose of peanut protein compared with 4% with placebo and 50% of patients tolerated 1000 mg of peanut protein.[7]

The Viaskin peanut allergy transdermal patch is an epicutaneous immunotherapy that delivers peanut protein to the immune system through intact skin. The amount of peanut protein exposure is titrated by adjusting the amount of time the patch is left on. For the first week, the patch is worn for 6 hours. The patient wears the patch for 12 hours in the second

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Table 1. New Treatment Options.

Generic name	Sponsor	Drug class	Route of administration
AR101	Aimmune Therapeutics	Peanut allergy desensitization	Oral tablet
Viaskin Peanut	DBV Technologies	Peanut allergy desensitization	Transdermal patch

Note. Information adapted from the Prescribe Right Pharmaceutical Pipeline Tracker database.[8]

week and leaves the patch on for 24 hours beginning in the third week. Each patch is worn for one day and the site is rotated among 6 sites on the upper back each day.[7]

Two phase II trials have been published for the Viaskin peanut patch. Both trials used the amount of peanut protein that could be tolerated before eliciting allergic symptoms as the primary endpoint. In a 12-month, 221-patient, phase II trial, 50% of the patients who received a Viaskin Peanut 250 µg patch tolerated a 1000 mg dose of peanut protein or a 10 times increase from baseline in the amount of peanut protein they could tolerate before the development of clinical symptoms compared with 25% of placebo patients.[10] In a 74-participant, 52-week, phase II trial, 48% of the patients who received a Viaskin Peanut 250 µg patch tolerated a 5044 mg dose of peanut protein or a 10 times increase from baseline in the amount of peanut protein they could tolerate before the development of clinical symptoms compared with 12% of placebo patients.[11]

Data from 2 unpublished Viaskin peanut patch phase III trial have also been presented. DBV Technologies announced that in a 12-month, 356-patient, phase III, trial, 35% of patients who received a Viaskin peanut patch increased the amount peanut protein they tolerated compared with 13% with placebo. However, the lower boundary of the confidence interval did not reach the prespecified level.[7] DBV Technologies also announced that in a 6-month, 393-patient, phase III safety trial, the most common adverse effect with the patch were local application-site reactions. Serious adverse events were similar to placebo.

Author's Note

Information is summarized from selected materials; additional information may be available from other sources. Due to the preapproval nature of the information, non-peer-reviewed data may be utilized. The information provided is meant to provide a way to assess the development status of a new drug and should not be used in making patient care decisions.

Declaration of Conflicting Interests

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References

1. Venter C, Pereira B, Grundy J, et al. Incidence of parentally reported and clinically diagnosed food hypersensitivity in the first year of life. *J Allergy Clin Immunol*. 2006;117(5):1118-1124.
2. Sicherer SH, Muñoz-Furlong A, Burks AW, Sampson HA. Prevalence of peanut and tree nut allergy in the US determined by a random digit dial telephone survey. *J Allergy Clin Immunol*. 1999; 103(4):559-562.
3. Sicherer SH, Muñoz-Furlong A, Sampson HA. Prevalence of peanut and tree nut allergy in the United States determined by means of a random digit dial telephone survey: a 5-year follow-up study. *J Allergy Clin Immunol*. 2003; 112(6):1203-1207.
4. Sicherer SH, Muñoz-Furlong A, Godbold JH, Sampson HA. US prevalence of self-reported peanut, tree nut, and sesame allergy: 11-year follow-up. *J Allergy Clin Immunol*. 2010;125(6):1322-1326.
5. Skolnick HS, Conover-Walker MK, Koerner CB, Sampson HA, Burks W, Wood RA. The natural history of peanut allergy. *J Allergy Clin Immunol*. 2001;107(2):367-374.
6. Stiefel G, Anagnostou K, Boyle RJ, et al. BSACI guideline for the diagnosis and management of peanut and tree nut allergy. *Clin Exp Allergy*. 2017;47(6):719-739.
7. Tilles SA, Petroni D. FDA-approved peanut allergy treatment: the first wave is about to crest. *Ann Allergy Asthma Immunol*. 2018;121(2):145-149. doi:10.1016/j.anai.2018.06.005.
8. Prescribe Right Pharmaceutical Pipeline Tracker. http://www.prescriberight.com/pharmaceutical-pipeline-tracker.html. Published 2018. Accessed May 1, 2018.
9. Bird JA, Spergel JM, Jones SM, et al. Efficacy and safety of AR101 in oral immunotherapy for peanut allergy: results of ARC001, a randomized, double-blind, placebo-controlled phase 2 clinical trial. *J Allergy Clin Immunol Pract*. 2018;6(2):476-485.e3. doi:10.1016/j.jaip.2017.09.016.
10. Sampson HA, Shreffler WG, Yang WH, et al. Effect of varying doses of epicutaneous immunotherapy vs placebo on reaction to peanut protein exposure among patients with peanut sensitivity: a randomized clinical trial. *JAMA*. 2017;318:1798-1809.
11. Jones SM, Sicherer SH, Burks AW, et al. Epicutaneous immunotherapy for the treatment of peanut allergy in children and young adults. *J Allergy Clin Immunol*. 2017;139:1242-1252.