RESULTS: Ninety-nine of 206 children passed the BM challenge; 107 reacted. Of the 107 who reacted at challenge, 58 required some form of treatment, and 24 required epinephrine. Eighty-eight of the 107 children who did not pass the challenge were instructed to consume some amount of BM. At the time of the last follow-up (median = 49 months), 40% had advanced to direct milk, 27% were eating some form of heated milk, and 33% were avoiding all forms of milk. Of those who had failed the challenge but were instructed to ingest some amount of BM, 29% had progressed to direct milk. Passing the BM challenge was associated with greater odds of advancing to less-heated forms of milk (odds ratio: 4.9; 95% confidence interval: 2.5–9.6). Most who had required treatment during the challenge were still practicing strict avoidance at last follow-up. Thirty-five percent of patients experienced milk reactions during the follow-up period; 77% were mild, but 14% were severe, and there were 7.7% who developed eosinophilic esophagitis.

CONCLUSIONS: Introduction and advancement of BM in patients with milk allergy is associated with higher odds of advancing their level of milk ingestion but is not without risk. Patients need to be counseled about risk as well as ongoing availability of emergency medications.

REVIEWER COMMENTS: Incorporating BM into the diet of patients with milk allergy can be beneficial to allow increased food options. This study demonstrates the importance of performing a BM challenge in patients with milk allergy to determine if BM would be safe to include in the diet. Counseling about the possible risks of BM ingestion is important because reactions to previously tolerated doses and the development of eosinophilic esophagitis are possible.

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AR101 Oral Immunotherapy for Peanut Allergy

Vickery BP, Vereda A, Casale TB, et al. PALISADE Group of Clinical Investigators. *N Engl J Med*. 2018;379(21):1991–2001

PURPOSE OF THE STUDY: To determine if AR101 is a safe and effective treatment to prevent peanut reactions due to accidental exposure.

STUDY POPULATION: Participants (496, 4–17 years old) were randomly assigned 3:1 to receive AR101 (peanut-derived investigational drug) or placebo (oat flour). The majority of the participants had a history of peanut anaphylaxis (72%), asthma (53%), and multiple food allergies (66%). All participants had dose-limiting symptoms at a dose of 100 mg of peanut protein in a double-blind placebo-controlled food challenge at baseline.

METHODS: Participants began a 1-day supervised dose escalation phase from 0.5 to 6 mg. The dose was then increased gradually every 2 weeks from 3 to 300 mg. A maintenance dose of 300 mg was continued for 24 weeks.

RESULTS: A double-blind placebo-controlled food challenge was done at the end of the trial. Among the participants, 250 of the 372 (67.2%) in the active drug group and 5 of 124 (4%) in the placebo group were able to tolerate a dose of 600 mg or more of peanut protein without dose-limiting symptoms. The key secondary endpoints were tolerating 300 mg (76.6%) or 1000 mg (50.3%) compared with those in the placebo group (8.1% and 2.4%, respectively). Severe reactions occurred in 4.3% of the active drug group and 0.8% of the placebo group. Participants in the active treatment group compared with placebo had a higher incidence of gastrointestinal events (85.8% vs 69.4%), respiratory tract events (81.2% vs 71.8%), skin reactions (66.9% vs 55.6%), and immune system concerns (68.9% vs 8.9%). Overall, 43 (11.6%) in the active treatment group and 3 (2.4%) in the placebo group withdrew because of adverse events. Gastrointestinal symptoms causing study withdrawal occurred in 6.5% of the active treatment group and 1.2% of the placebo group. During the course of the trial, 52 participants (14%) in the active drug group and 8 participants (6.5%) in the placebo group were given epinephrine for grade 1 or 2 reactions; of these, the majority (92.7%) was treated with a single dose of epinephrine.

CONCLUSIONS: Overall, 67% of the participants 4 to 17 years old were able to tolerate 600 mg of peanut protein (2 kernels) during the exit food challenge.

REVIEWER COMMENTS: These data are important, and AR101 will give health care providers a standardized way forward to treat this potentially life-threatening condition. It is hopeful that the product will be US Food and Drug Administration approved by the time this synopsis is published.

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Real–World Experience With Peanut Oral Immunotherapy: Lessons Learned From 270 Patients

Wasserman RL, Hague AR, Pence DM, et al. *J Allergy Clin Immunol Pract*. 2019;7(2):418–426.e4

PURPOSE OF THE STUDY: This retrospective record review reports observations on the treatment of 270 patients with peanut allergy with peanut oral immunotherapy (POIT).

STUDY POPULATION: The study included 270 patients between the ages of 4 and 18 years who received POIT in a single practice between 2009 and 2017. A total of 96.7% of patients had a history of an immunoglobulin E–mediated

AR101 Oral Immunotherapy for Peanut Allergy

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