

Editor's Note

Epicutaneous Immunotherapy vs Placebo for Peanut Protein Ingestion Among Peanut-Allergic Children

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Allergy to peanuts is relatively common, and the reactions to exposure can be severe, resulting in anaphylaxis and even death. Avoiding ingestion is the traditional recommendation. However, avoiding peanuts is often difficult because they can

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be hidden in prepared foods or contaminate foods during preparation or processing. Therefore, attention has turned to prevention of peanut allergy. Approaches that have been studied among high-risk children include ingestion of peanut protein at a young age to reduce the risk of developing peanut allergy and desensitization with oral or sublingual immunotherapy. Another approach is epicutaneous immunotherapy—using skin patches containing peanut protein. The theoretical advantages of this approach include ease of use and a lower risk of allergic reactions. Because of the difficulty in managing peanut allergy, the potential severe consequences of a reaction, and the lack of available treatments, the editors considered the phase 3 study of the “peanut patch” reported in this issue—providing data on the effectiveness and adverse events compared with a placebo patch—to be important.

However, the results are not easy to interpret. After 1 year, 35.3% of children who received the peanut patch

were responders vs 13.6% of the placebo group, a statistically significant difference by traditional statistical measures. However, the definition of a clinically significant response, recommended by the Food and Drug Administration and agreed to by the sponsor, was that the lower bound of the 95% CI around the difference should meet or exceed 15%. The lower bound of the 95% CI was 12.4%, meaning the main result did not reach the criterion for a positive trial result.

What should physicians do with these conflicting interpretations of the results? The authors argue that the 15% cutoff was arbitrary, based on convention, and that no thresholds have been set to guide assessment of food allergy immunotherapy. Clinicians will have to determine with patients whether a response of 35.3% with the peanut patch is worthwhile. Other factors that may influence decision making include adverse events, which were common in the study but consisted mostly of local skin reactions to the patch, and adherence, which was high (98.5%). In addition, the effectiveness, adverse events, adherence, and durability of epicutaneous therapy must be weighed against the similar metrics with alternative types of therapy, such as oral immunotherapy.

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