

The Leap Study: A Summary



BACKGROUND

- Peanut allergy doubled in the UK from 1.4% to 30% between 2005 and 2015. It is the leading cause of anaphylaxis, develops early and is rarely outgrown.
- Clinical practice guidelines from the UK and US recommended the exclusion of allergenic foods from the diets of infants at high risk for allergy and from the diets of their mothers during pregnancy and lactation.
- Du Toit et al showed that the risk of the development of peanut allergy was 10X among Jewish children in the UK as compared to Israeli children of similar ancestry. In Israel, peanut-based foods are introduced in the diet when infants are approximately 7 months of age, compared to avoidance for 1 year in the UK.
- The study sought to determine whether the early introduction of dietary peanut could serve as an effective primary and secondary strategy for the prevention of peanut allergy.

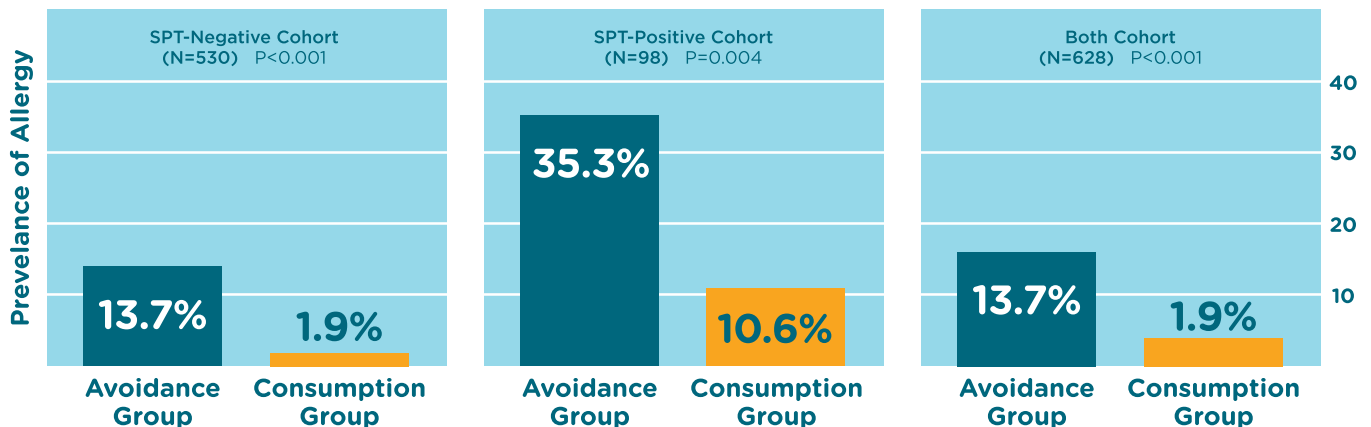
METHODS

- Randomized, open-label, controlled trial of infants 4 months - 11 months of age with severe eczema, egg allergy, or both.
- Participants were stratified into two cohorts based on a skin-prick test for peanut allergy (no wheal vs. 1 to 4mm wheal). Patients with a wheal >4mm were excluded as already having a peanut allergy.
- Participants in each cohort were randomized to peanut avoidance (no peanut) or peanut consumption (2g of peanut 3 times per week) until 60 months. Peanut consumption patients reacting to an oral food challenge were instructed to avoid peanuts. They were included in the ITT analysis but not the per-protocol analysis.

RESULTS

- A comparison of peanut allergy at 60 months based on oral food challenge in both the intention to treat and the per protocol analysis showed an 89% difference in risk.
- Nine participants assigned to peanut consumption discontinued consumption. At month 60, six of these participants had a positive response to the oral food challenge and three had a negative response.

INTENTION-TO-TREAT ANALYSIS



Images and text taken, lightly edited, from:

Du Toit G, Roberts G, Sayre PH, Bahnson HT et al (2015) *Randomized Trial of Peanut Consumption In Infants At Risk for Peanut Allergy*. N Engl J Med 2015; 372:803-813

Summarized by

