Quantitative Assessment of the Safety Benefits Associated with Increasing Clinical Peanut Thresholds Through Immunotherapy

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Rationale: Immunotherapy studies indicate that increase of the threshold to peanut can be achieved in peanut-allergic individuals; however, complete tolerance is rarely achieved. We investigated what level of protection against accidental exposure to undeclared peanut residue in food is provided after partial desensitization.

Method: SAS (version 9.2) was used to run quantitative (probabilistic) risk modeling to determine the percentage of individual eating occasions where a predicted reaction would occur in a peanut allergic individual with a defined threshold dose that would consume cookies containing random selection of a wide distribution of trace concentrations ranging from 1 to 1000 ppm (µg/g) peanut protein. A consumption distribution from 107 cookie categories, based on dietary data recorded in the 2003-2010 National Health and Nutrition Examination Surveys from 11,497 individuals, was used to model potential exposure doses, and a total of 5,000,000 simulations was made.

Results: Peanut-allergic individuals reacting at 1, 3, 10, or 30 mg peanut protein (one tenth of a peanut kernel) before immunotherapy will react in 16.5%, 11.8%, 6.6%, or 2.6% eating occasion, respectively. Successful increase of their threshold dose to 300 mg peanut protein or more during treatment would decrease their risk of an allergic reaction 2,063-fold, 1,475-fold, 825-fold, or 325-fold, respectively, after consumption of a peanut-contaminated cookie.

Conclusion: Reaching a threshold dose of 300 mg peanut protein would be a key milestone in the immunotherapy treatment of highly peanut-sensitive individuals at very high risk of allergic reactions, as they would tolerate most trace levels of undeclared peanut protein in food products.