Deficiencies of Allergen Levels in a Commonly Used Protocol for Peanut Oral Immunotherapy: Proceed with Caution.

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Rationale:

Despite the availability of FDA approved peanut oral immunotherapy (OIT) some allergists use protocols involving different grocery store peanut sources and dosages. Determining allergen profiles of different protocols has not been investigated. Our aim was to evaluate a commonly used peanut OIT protocol by comparing specific allergen content (Arah1, Arah2, Arah3 and Arah6).

Methods:

Peanut flour (n=2) was formulated in solutions ranging from 250mg/mL to 2.5µg/mL peanut protein. Solutions were prepared in distilled water and flavored with Kool-Aid powder per OIT protocol or in a standard extraction buffer: 1xPBS, 2% Tween-20, 1M NaCl (PBS). Cap'n Crunch cereal and PB2 were also analyzed. Arah1, Arah3 and Arah6 were measured using a fluorescent multiplex array. Arah2 was measured by ELISA.

Results:

Extraction of peanut per OIT protocol in distilled water resulted in undetectable or low allergen levels (<10µg/ml) at concentrations <2.5mg/mL. The allergen content of 25-250mg/ml doses was <10-400µg/mL and yielded significantly lower levels of Arah1, Arah3 (11-353-fold) and Arah2, Arah6 (3-6-fold) compared to equivalent solutions prepared in PBS. Allergen profiles of the peanut source materials varied widely in allergen content. Kool-Aid powder appeared to have detrimental effects on the allergens and/or immunoassays.

Conclusions:

Significant variability in peanut allergen composition, concentration and doses were observed when comparing an unapproved OIT protocol with a standard extraction procedure. Extraction of peanut allergens in distilled water is not recommended. Therapeutic preparations used in OIT protocols should be validated for allergen content and compared in clinical trials to strengthen the evidence base for peanut OIT.