

## Characteristics and Rates of In-Home, Dose-Related Adverse Events During Peanut Sublingual Immunotherapy

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### RATIONALE:

- A recent phase 2 study of peanut sublingual immunotherapy (SLIT) showed that 67% of subjects were successfully desensitized to 750 mg of peanut protein, demonstrating promise as a treatment for peanut allergy.
- However, SLIT is limited by adverse events (AEs), which are understudied.

### METHODS

- Retrospective pooled cohort analysis of two peanut SLIT trials
  - N = 48; 2000 mcg/d peanut protein 3-5 years (extension)
  - N= 53; 4000 mcg/d for 48 months
- AEs abstracted from daily diaries
- Bivariate analyses

### GRADING OF ADVERSE EVENTS

- Events at least possibly related to SLIT
- Self-reported grading on a 3-point scale: mild (1), moderate (2), or severe (3)
- Systemic reaction: An AE involving
  - wheezing
  - severe angioedema
  - whole body hives (severe)
  - cough (moderate or severe)
  - repeated vomiting (moderate or severe)
- involved at least two body systems (excluding transient oropharyngeal)
- Assumption: All systemic reactions should require epinephrine.

### POPULATION

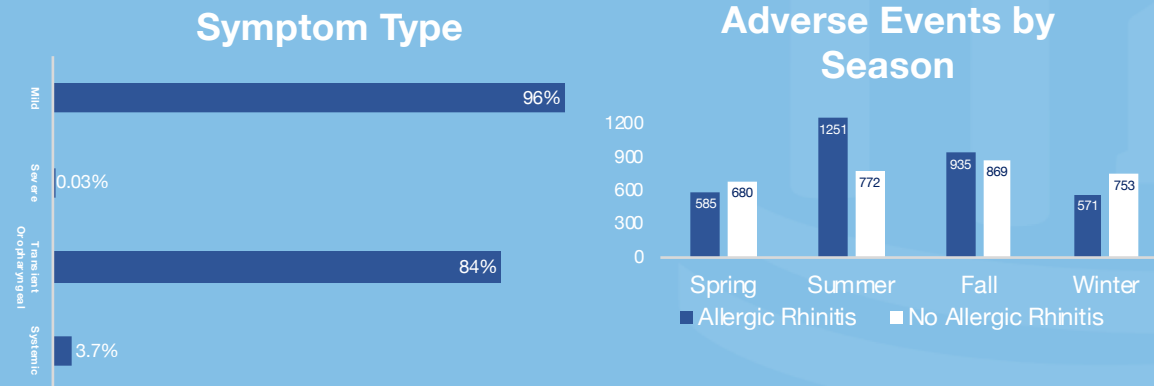
- Median age 6.7 years (IQR 2.3-11.8 )
- 64% Male
- Median SPT 13.5 mm (IQR 9.75 - 18.5)
- Median peanut IgE 84.7 kU/dL (IQR 28.9 - 228.5)



Poster #448



While peanut sublingual immunotherapy is overall well tolerated, systemic reactions occur and are undertreated. Those with allergic rhinitis may experience more adverse events in the summer.



### RESULTS

- Of 101 participants, 86% experienced 6377 possibly- or likely-related SLIT dosing-related AEs
- 14% of participants accounted for 75% of all AEs

ADVERSE EVENT CHARACTERISTICS	N (%)
Mild	6122 (96%)
Severe	2 (0.03%)
Transient Oropharyngeal	6357 (84%)
Mucocutaneous	673 (11%)
Respiratory	38 (0.6%)
Gastrointestinal	327 (5.1%)
Systemic	235 (3.7%)

ADVERSE EVENT TREATMENT	N (%)
Treated Treatment	259 (4%)
Antihistamines	258 (4%)
Epinephrine	0 (0%)
Albuterol	2 (0.03%)
Steroids	1 (0.02%)
ED Visit	0 (0%)

### LIMITATIONS

- Self-/family report of AEs
- Ongoing antihistamine use was not routinely documented
- Sensitization to environmental aeroallergens was not ascertained

### FOODS COMMONLY CROSS-REACTIVE WITH GRASS



### CONCLUSIONS:

- Peanut SLIT is associated with frequent AEs, though nearly all are graded mild and most symptoms are limited to the oropharynx.
- Systemic reactions are rare, but do occur and are undertreated.
- The increased rate of AEs in the summer months suggests cross-reactive pollen sensitization as one mechanism for AEs in peanut SLIT.