

Office Based Oral Desensitization of Patients With Anaphylactic Sensitivity to Foods Is Safe and Effective

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- There are no additional disclosures.

Objective

To demonstrate that programs of oral food desensitization in patients with anaphylactic sensitivity can be conducted safely in an allergy/immunology office.

Psychological Impact of Food Allergy: Children with Food Allergy

- Anxiety about having a reaction
 - Peanut allergic children report more impairment of daily activities and social interactions than children with rheumatologic disease¹
 - Greater anxiety about eating and fear of a reaction than children with diabetes²
- Social stigmatization
 - “The peanut table”

1. Primeau, et al, Clin Exp Allergy. 2000 Aug;30(8):1135-43.
2. Avery, et al, Pediatr Allergy Immunol. 2003 Oct;14(5):378-82.

Anaphylactic Sensitivity

- Serum antigen specific IgE (kU/L) predicts >95% risk of anaphylaxis
 - Egg: 7
 - Milk: 15
 - Peanut: 14
- OR a recent (within one year) episode of a food reaction involving \geq two systems
- OR a positive food challenge involving \geq two systems

Sampson H. J Allergy Clin Immunol 2004;113:805-19

Garcia-Ara C, et al. J Allergy Clin Immunol 2001;107(1);185-90

Patient Eligibility

Age five years and older

History of systemic reaction to a food, usually involving two or more organ systems

Objective evidence of systemic reaction to food.

Patients must have either:

Positive food challenge

Serum specific IgE antibody to the food predicting a >95% risk of anaphylaxis on exposure

Antigen Specific IgE

DAI

- Egg
 - Range 5 to 49 kU/L
 - 5/5 > 7 kU/L
- Milk
 - Range 2 to 54 kU/L
 - 2/6 > 15 kU/L
- Peanut
 - Range 2 to >100 kU/L
 - 16/19 >14 kU/L

WSMR

- Milk
 - 43 kU/L
 - 1/1 >15kU/L
- Peanut
 - Range 6 to >100 kU/L
 - 7/11 >14 kU/L

The Process

- Parents of appropriate patients are offered the opportunity to have their child treated
- Parents are provided a custom consent form
- Approximately one to two weeks prior to the initiation of treatment, patients are evaluated for stability of asthma and allergy
- Immediately prior to initiating desensitization patients are reevaluated for stability of asthma and allergy

The Protocol

DAI

- Intake H&P
 - VS, WT, epinephrine and diphenhydramine doses are recorded on the flow sheet
 - First 5 peanut desensitization patients had an IV hep lock
 - Patient queried on how they feel, response is recorded
- Dosed at 15 minute intervals
- One hour observation after the last dose

WSMR

- Intake H&P
 - VS, WT, epinephrine and diphenhydramine doses are recorded on the flow sheet
 - VS, O₂ SAT and chest exam obtained prior to each dose
- **Doses at 15 minute intervals**
- **One hour observation after the last dose**

Food Allergens – Starting Dose

DAI

- Whole powdered egg
 - Starting dose 100 ug (protein)
- Whole organic milk
 - Starting dose 100 ug (protein)
- Peanut flour
 - Starting dose 2.5 ug (protein)

WSMR

- **Whole organic milk**
 - Starting dose 3.3 mg (protein)
- **Peanut flour**
 - Starting dose 100 ug (protein)

Protocol – Build up Phase

- Both DAI and WSMR follow the same protocol
 - Last tolerated dose twice a day for at least four days
 - Return to the office for the next dose
 - Brief H&P
 - Dose is administered
 - Patients are observed for one hour

Safety

- At each visit the child and parent are required to confirm the food for desensitization.
- EMR templates (DAI), flow sheets (WSMR) have been designed for each food with dosing guidelines.
- The previous dose and the next scheduled dose are entered automatically by the EMR (DAI) or recorded in visit chart for date along with VS and exam (WSMR). Patient given instruction sheet for next dose (WSMR).
- Every step is signed with a date/time stamp (DAI) or Dated and timed on paper chart (WSMR).
 - Doses are signed and/or co-signed

Protocol – Maintenance Phase

- Maintenance – first year
 - Egg – one egg per day
 - Milk – 240 ml per day or equivalent in Dairy products
 - Peanut – eight peanuts twice a day or equivalent in peanut flour (approx 6g) or peanut butter (8g) (El Paso)
- Additional food allowed
 - Most patients – unlimited
 - Selected patients – no intentional exposure
- Dose and frequency required to maintain tolerance
 - UNKNOWN!

Results as of December 31, 2009

DAI

- Patients completed/
withdrew
 - Egg – 5/0
 - Milk – 5/1
 - Peanut – 14/5
- Reactions
 - Milk – recurrent urticaria
 - Peanut
 - Anaphylaxis
 - Eosinophilic Esophagitis (2)
 - Oral itch
 - Vomiting

WSMR

- Patients completed/
withdrew
 - Peanut – 7/4
 - Milk – 1/0
- Reactions after day one*
 - Peanut
 - Asthma flare – lost to f/u
 - Child uncooperative
 - Family stress
 - Urticaria, lip swelling

* On Day 1 patients were given increasing doses until a reaction occurred.

Reactions After Day One - DAI

- Egg
 - Lowest triggering dose – 4ml 1mg/ml solution
 - Average triggering dose – approximately 1/2 egg
- Milk
 - Lowest triggering dose – 3ml 1mg/ml solution
 - Average triggering dose – 34 ml whole milk
- Peanut
 - Lowest triggering dose – 2ml 2.5 mg/ml solution
 - Average triggering dose – approximately 1.25 to 2 peanuts

Reactions on Maintenance (DAI)

- Egg
 - Anaphylaxis – no risk factors – Epi/ER
 - Oral itch and facial flush – ice cream with raw egg
- Milk
 - Cough and itch – no risk factors – Epi/ER
 - Recurrent urticaria
- Peanut
 - Anaphylaxis – exercised after dose – Epi/ER
 - Eosinophilic esophagitis – two patients

Summary

- A total of 42 children were treated for allergy to egg, milk or peanut at two independent allergy offices.
- 32/42 (76%) successfully completed the treatment.
- Anaphylaxis occurred in 7 patients during the initial or build-up phase of treatment.
- Anaphylaxis occurred in 3 patients on maintenance.
- No patient required hospitalization.
- Eosinophilic esophagitis occurred in two peanut allergic patients.

Conclusion

An allergy/immunology office can carefully design and execute programs of oral food desensitization that safely treat patients with anaphylactic sensitivity.

The benefits of the treatment are a tremendous improvement in the patient's and family's quality of life.

Outcome

“During the reaction he was unable to breathe and used hand signals to tell us he couldn't get air... I can't begin to explain how our lives have changed since we completed the program. ”

Tina Bennett, mother of Hudson.

“Thank you for making my life better”

Walter, the patient