Challenges in Oral Immunotherapy

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Target Audience: Physicians and researchers within the field of allergic disease.

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1. Discuss treatment options for food allergy with shared decision making.
2. Address potential adverse reactions during treatment.

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Whereas avoidance remains a standard of food allergy management, US Food and Drug Administration approvals of a peanut oral immunotherapy product and the injected anti-IgE biologic omalizumab for food allergy give patients more treatment options than ever before. Here, we review a case that highlights the nuances in shared decision-making for finding the best treatment option for food allergy therapy and demonstrates the difficulty of approaching treatment side effects.

CASE

A 16-year-old girl with food allergies to peanut, tree nuts, and shellfish; mild intermittent asthma; and allergy to dogs presented to discuss long-term allergy management options in preparation for college. She previously experienced anaphylaxis to peanut requiring epinephrine use and multiple additional food-allergic reactions of milder severity. There was no history to suggest eosinophilic esophagitis (EoE) or reflux.

Diagnostic evaluation confirmed the patient's history of multiple food allergies. Skin prick testing (millimeter wheal size) was positive to peanut (10 mm), cashew (8 mm), and walnut (5 mm). Serologic testing revealed elevated levels of peanut Ara h 2 (>100 kUA/L), cashew ana o 3 (37.1 kUA/L), and walnut jug r 1 (13.1 kUA/L). Total IgE levels were elevated at 905 IU/mL.

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The patient disclosed experiencing anxiety related to meals and decreased quality of life after having multiple reactions despite avoidance measures. The patient had goals of becoming bite-safe, limiting food anxiety in social settings and decreasing her chances of anaphylaxis. She also preferred a non-pharmaceutical approach with minimal exposure to injections. We discussed the potential for omalizumab to address multiple food allergies and asthma as well. In consideration of the patient's goals, we decided to pursue peanut OIT.[1,2] In consideration of the time available to dedicate to treatment, the patient had ample time to complete a peanut OIT protocol as well as OIT to additional tree nuts before starting college. The peanut OIT protocol selected aimed for a maintenance dose of 300 mg of peanut protein, likely to be reached over the course of nine visits over approximately 6 months.

Throat itching and pain with swallowing were noted during the initial in-clinic peanut OIT escalation visit. Each subsequent up-dosing visit resulted in similar episodes that were described as "tasting like velvet" in the mouth or "feeling like a paper cut" in the throat. The symptoms lasted 5 to 15 minutes before self-resolving. She was instructed, as a first line of treatment for this type of immediate reaction, to mix the dose with more food and eat it with a meal. At home, symptoms resolved with this approach.

The patient also experienced three episodes of nausea and reflux over the treatment course (visits 5, 6, and 8) but denied abdominal pain, dysphagia, or vomiting. Because of the symptoms, there was initial concern for OIT-induced EoE; however, with lengthened up-dosing intervals, symptom diary tracking, and proper mixing of the OIT product with food, the symptoms resolved. The patient successfully completed the peanut OIT protocol to a maintenance dose of 300 mg and subsequently completed tree nut OIT to cashew and walnut. Mild mouth itching was noted for final up-dosing to 300 mg for tree nut OIT but was otherwise well tolerated.

DISCUSSION

This case emphasizes the importance of shared decision-making both in deciding how to pursue food allergy treatment and how to approach challenges during the treatment course. With currently available options including avoidance alone, OIT or omalizumab (Table I), many factors should be considered when choosing the best option for an individual patient. For the current patient, relying solely on avoidance proved unfavorable because the patient experienced multiple allergic reactions despite efforts to avoid exposure. This led to anxiety in food-related situations outside the home. The patient had a fear of needles, complicating the use of injectable treatments such as omalizumab. The family and patient additionally shared interest in a natural approach without medication use. Because the patient was preparing to attend college in 20 months, she had time to dedicate to the OIT process. Ultimately with preferences to pursue a therapy to be bite-safe, the choice of OIT was favored based on her comfort with recognizing and treating allergic reactions, preferring a therapy without injections, having time available to dedicate to the treatment course, and the lack of potential contraindications based on the medical history (ie, no history of EoE).[2]

During the OIT course, this patient experienced some adverse effects concerning for EoE (nausea and reflux), some of which may have been related to minor IgE-mediated local reactions (brief pain, throat itch, or both). Oral symptoms with OIT dosing, such as oral pruritus, are one of the most common adverse reactions. The approach to immediate allergic reactions differs from the approach to chronic symptoms because the latter may represent gastrointestinal inflammation triggered by OIT (see Supplemental Material in this article's Online Repository at www.jaci-inpractice.org).

TABLE I. Food allergy treatment options

US Food and Drug Administration–approved treatment options	Non-US Food and Drug Administration–approved treatment options
Trigger avoidance	OIT: off-label with food products
OIT: commercially available peanut OIT product	Sublingual immunotherapy
Omalizumab	

OIT, oral immunotherapy.

In this case, we suspected IgE-mediated reactions to be the primary problem based on the timing and atypical symptom descriptions such as "tasting like velvet." With first-line interventions such as lengthened up-dosing intervals and proper mixing of the OIT product with food, the symptoms resolved. Other recommended interventions include the use of antihistamines for symptom management. The resolution of the patient's adverse effects with minor adjustments was also reassuring against the development of eosinophilic gastrointestinal disease that would require assessment by a gastroenterology specialist and endoscopy.[3]

Continuation of OIT after the development of EoE remains a point for shared decision-making. There are reports of cases in which OIT was successfully continued with medical treatment of EoE, demonstrating that OIT can still be pursued with careful consideration and proper monitoring.[3] Shared decision-making is crucial to determine a treatment plan with which both the patient and provider feel comfortable moving forward, contributing to compliance with the protocol despite challenges, and ultimately a successful treatment outcome. This case demonstrates how a systematic, symptom-specific approach may be used to guide the management of individualized food allergy treatment.

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Challenges in Oral Immunotherapy

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Disclosures

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Learning Objectives

- Discuss treatment options for food allergy with shared decision making
- Address potential adverse reactions during treatment

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Initial Presentation for treatment of food allergy

- 16-year-old with multiple food allergies (peanut, tree nut, shrimp)
  - clinical history of anaphylaxis to peanut and shrimp treated with epinephrine
  - abdominal pain, nausea and vomiting with cashew and walnut ingestion
  - tolerates almonds and hazelnuts
- Other relevant history:
  - mild intermittent asthma
  - dog allergy
  - no personal or family history of eosinophilic esophagitis (EOE) or reflux
- Presents with her mother to clinic to discuss her food allergy treatment options in preparation for college

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Additional Details

- Patient is pursuing college, possibly across the country in about 20 months
- Patient and family have found peanut avoidance particularly problematic:
  - several reactions despite care
  - significant restrictions on eating outside of the home, for travel, and being with friends
  - anxiety in food situations
- Patient reports always carrying epinephrine but has strong reluctance to self-inject- "needle averse"
- Family and patient are reluctant to using medications on a daily basis and prefer natural treatments when possible

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Diagnostic Evaluation

Skin Prick Test	Wheal/Flare (mm)
Peanut	10/40
Cashew	8/15
Pistachio	8/42
Walnut	5/12
Pecan	4/15
Shrimp	10/30
Saline	0/0
Histamine	7/37

ImmunoCAP	k UA/L
Peanut Ara h 1	60.6
Peanut Ara h 2	>100
Peanut Ara h 3	13.3
Peanut Ara h 6	62.2
Peanut Ara h 8	<0.10
Peanut Ara h 9	<0.10
Cashew ana o 3	37.1
Pistachio	56.9
Walnut jug r 1	13.1
Walnut jug r 3	0.82
Pecan	13.3
Crab	35.4
Shrimp	61.9
Total IgE	905 [IU]/mL


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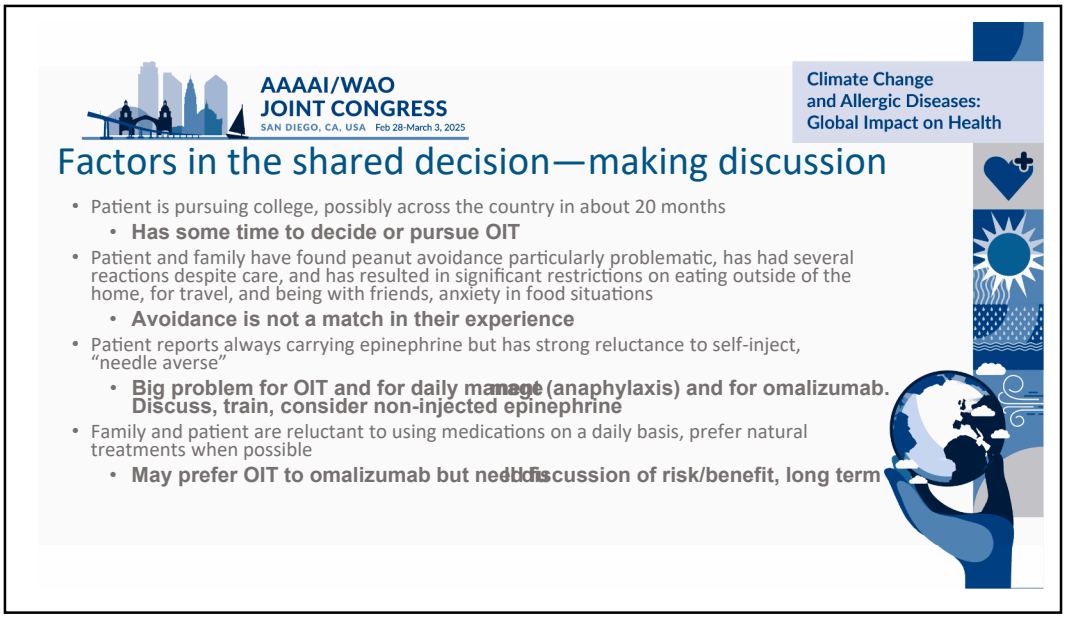
Treatment Options
FDA Approved Options:
• Avoidance of Triggers
• Oral Immunotherapy using commercially available peanut OIT product
• Omalizumab
Non-FDA Approved Options:
• Oral Immunotherapy using food products
• Sublingual Immunotherapy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Factors in the shared decision—making discussion
• Patient is pursuing college, possibly across the country in about 20 months
• Has some time to decide or pursue OIT
• Patient and family have found peanut avoidance particularly problematic, has had several reactions despite care, and has resulted in significant restrictions on eating outside of the home, for travel, and being with friends, anxiety in food situations
• Avoidance is not a match in their experience
• Patient reports always carrying epinephrine but has strong reluctance to self-inject, "needle averse"
• Big problem for OIT and for daily manage (anaphylaxis) and for omalizumab. Discuss, train, consider non-injected epinephrine
• Family and patient are reluctant to using medications on a daily basis, prefer natural treatments when possible
• May prefer OIT to omalizumab but need discussion of risk/benefit, long term

Omalizumab Implementation in Practice: Lessons Learned From the OUtMATCH Study

JACI Pract 2024;12:2947-54

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TABLE II. Example scenarios that may indicate more or less favorable candidates for omalizumab therapy (assuming age and dosing criteria met)

Examples of patient scenarios possibly not favoring treatment	Examples of patient scenarios possibly favoring treatment
Infant, toddler with an allergy likely to be transient	Multiple and/or persistent food allergies
Infant, toddler with allergy amenable to alternative approaches	Single or few food allergies with impactful avoidance behaviors
Patient who has been undertaking avoidance successfully and without significant lifestyle impact, or a mild allergy or allergy treatable by control of cofactors (pollen–food allergy syndrome, food-associated exercise-induced anaphylaxis)	Single or few food allergies with allergic comorbidities that may benefit from treatment (eg, asthma, chronic urticaria, chronic rhinosinusitis with nasal polyps)
Patients with higher reaction threshold(s) that place them at reduced risk of accidental ingestion reaction/significant reaction by accidental ingestion	Past severe reactions or increased risk of severe reactions (severe asthma, reactions to trace exposures, hereditary α tryptasemia)
Allergy to a food that has been easy for the patient to avoid	Avoidance of foods like milk, egg, wheat, and sesame may be far more difficult—and limiting to day-to-day life—than foods like peanut or tree nuts Multiple reactions despite careful avoidance even if single food Life circumstances increasing risk (eg, frequent international travel, traveling to location where avoidance would be difficult because of language barriers and/or absence of labeling laws or access to emergency medical care may be compromised) Allergy(ies) to foods not covered by labeling laws
Patient already on successful OIT	Chronic gastrointestinal symptoms with allergen ingestion during OIT and/or development of eosinophilic esophagitis preventing adherence to OIT regimen
Patient with anxiety that results in avoidance behaviors or anxiety-related symptoms not related to allergic reactions or sufficient risk (consider mental health support and counseling)	Significant anxiety or QoL burden deemed rectifiable through therapy

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The use and implementation of omalizumab as food allergy treatment: Consensus-based guidance and Work Group Report of the Adverse Reactions to Foods Committee of the American Academy of Allergy, Asthma & Immunology

JACI 2024; doi: 10.1016/j.jaci.2024.09.031

Delphi panel for 8 statements

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Statement	Notes
Option for 1 or more food allergies	Should discuss alternatives
Meet treatment criteria and likely allergic (tests and or history)	Need more research for outside nomogram or weight based
OFC not required	Can be considered
Determination of threshold not required	Can be considered
Consider determining treatment success	Perhaps pick 1 food, treat at least 16-20 weeks
Approved with avoidance; off label use should document discussion	More study needed
OK to vaccinate	
Discuss comfort about home dosing	

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Preparing Patients for Oral Immunotherapy (PPOINT): International Delphi consensus for procedural preparation and consent

Mack et al JACI 2024;153:1621-33

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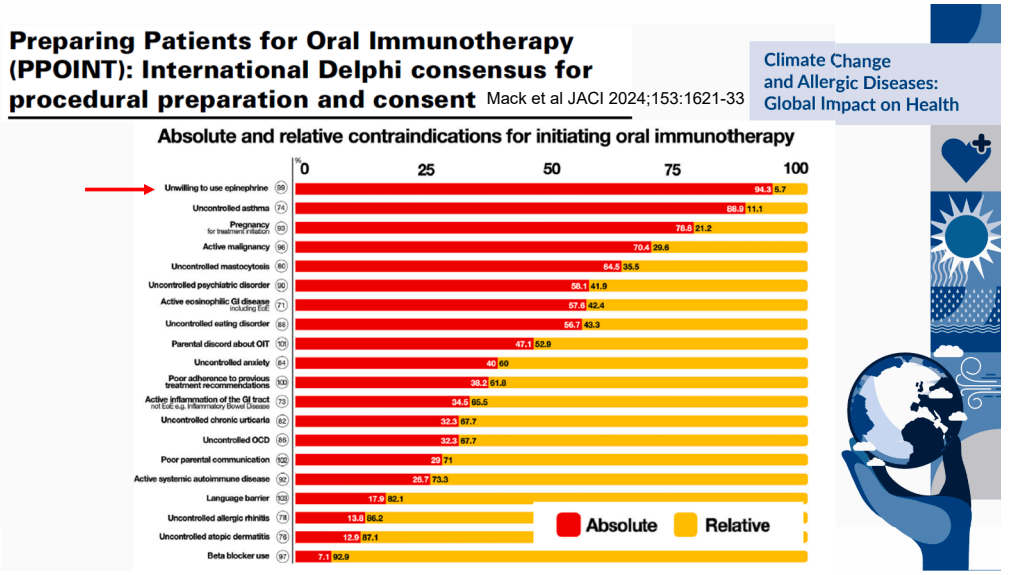

Development and acceptability of a decision-aid for food allergy oral immunotherapy in children

Allergy 2025;80:205-214

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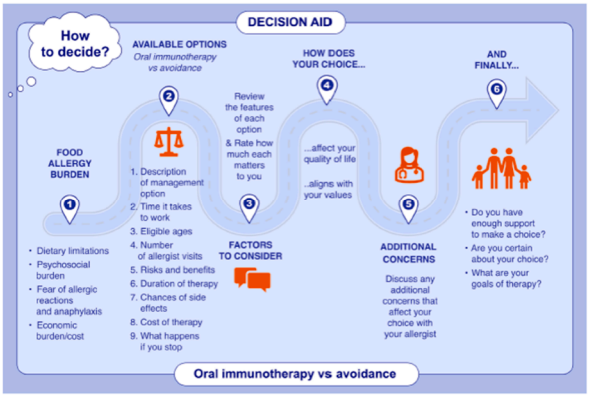

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Treatment Decision

- Decision made to initiate peanut OIT
  - Endorsed goal of at least becoming "bite safe" with hopes of being less anxious and protected for social events, travel, restaurants
  - Endorsed comfort with recognition and treatment of allergic reactions
  - Family and patient are "rule followers"
  - Schedule and timing was amenable to OIT (more than a year until college, after school activities are flexible)
  - Matched strong preference for a treatment that does not involve "medicine" and was more natural

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New Developments

In clinic:

- During initial dose escalation, patient noted throat itching and difficulty swallowing that self-resolved
- With subsequent updosing, developed mouth itching and throat pain
  - "Tastes like velvet" in the mouth
  - "Feels like a paper cut" in the throat
- Symptoms occurred with each updosing and lasted 5-15 minutes before self-resolving, no other symptoms

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New Developments (cont.)

At home:

- Mouth itching and throat pain occurred with OIT product only, not other foods
- Improved when OIT product is mixed thoroughly with other foods
- Symptoms self resolve by the end of a two-week timeframe then recur with each updose visit
- Rare episodes of nausea and reflux (3 episodes total in 2 months)
- Denies abdominal pain, vomiting, dysphagia
- Normal CBC, no eosinophilia at month two of treatment

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Are we worried about a chronic GI issue?

- Gastrointestinal symptoms during OIT are common and could be OIT-related or not:
  - Infection, constipation, functional, reflux, Celiac's Disease
  - Immediate IgE reaction
  - Non-immediate: EoE, ELORS (eosinophilic esophagitis-like oral immunotherapy-related syndrome), OITIGER (OIT induced GI symptoms and eosinophilic response), eosinophilic gastrointestinal disease

*This patient had acute onset of symptoms with dosing, no clear chronic GI issues, no vomit, no reflux, no dysphagia, no chronic pain, no eosinophilia.

How We Manage Gastrointestinal Symptoms During Oral Immunotherapy Through a Shared Decision-Making Process—A Practical Guide for the Community Practitioner

JACI Pract 2023;11:1049-55

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Different pathways for different symptoms and timing and context

IgE symptoms timed to dose

Chronic symptoms and their type and duration

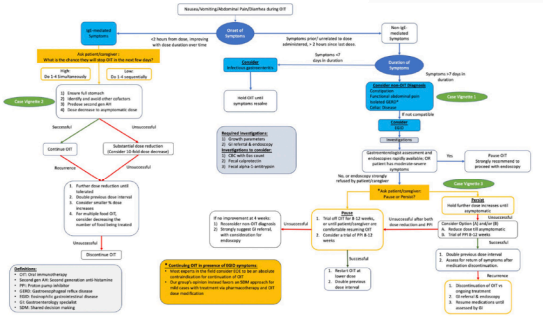

FIGURE 1. Flow diagram of diagnosis of gastrointestinal symptoms during oral immunotherapy. *CBC*, Complete blood count; *EoE*, eosinophilic esophagitis; *EoS*, eosinophilic colitis.

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If we were worried about chronic GI…

- EoE incidence and prevalence for OIT is about 1-3.2% and 2.7-6.9%, respectively
  - GI evaluation if suspected
- Continuing OIT with EoE is controversial and needs personalized shared decision-making
- Can consider management via:
  - discontinuation
  - dose modifications
  - medications
- Management should be made after shared decision making discussion with patients and their families

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Final disposition

- Given self-resolving nature of symptoms, and timing to dosing, it was decided to complete OIT protocol to a maintenance dose of 300 mg OIT
  - Updosing intervals were lengthened
  - Patient kept a symptom diary at home
  - Dose mixed with food and taken during a meal
  - Patient decided to avoid antihistamine
    - Use of cetirizine had been suggested
- Symptoms abated during last several updoses to 300 mg maintenance dose
- Patient continues on peanut OIT and subsequently completed tree nut OIT to cashew and walnut
  - Mild mouth itching on final updosing visit to 300 mg for tree nut OIT but otherwise well tolerated

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Thank you!