

Oral Food Challenges in Children with a Diagnosis of Food Allergy

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Objective To assess the outcome of oral food challenges in patients placed on elimination diets based primarily on positive serum immunoglobulin E (IgE) immunoassay results.

Study design This is a retrospective chart review of 125 children aged 1–19 years (median age, 4 years) evaluated between January 2007 and August 2008 for IgE-mediated food allergy at National Jewish Health and who underwent an oral food challenge. Clinical history, prick skin test results, and serum allergen-specific IgE test results were obtained.

Results The data were summarized for food avoidance and oral food challenge results. Depending on the reason for avoidance, 84%–93% of the foods being avoided were returned to the diet after an oral food challenge, indicating that the vast majority of foods that had been restricted could be tolerated at discharge.

Conclusions In the absence of anaphylaxis, the primary reliance on serum food-specific IgE testing to determine the need for a food elimination diet is not sufficient, especially in children with atopic dermatitis. In those circumstances, oral food challenges may be indicated to confirm food allergy status. (*J Pediatr* 2010; ■:■–■).

In 2007, the Centers for Disease Control and Prevention reported an 18% increase in the prevalence of food allergy in children over the previous decade, with approximately 4% of US children having some form of food allergy.¹ Given the wide commercial availability of serum food-specific immunoglobulin E (IgE) antibody testing (immunoassay), health care providers have been using these test results to prescribe elimination diets for children with possible food allergy, especially those with moderate to severe atopic dermatitis (AD). Many of these patients are on elimination diets because of concerns that the foods are exclusively contributing to their AD. Of greater concern, a growing number of patients referred to our practices are being placed on strict, unproven food elimination diets that have led to poor weight gain and malnutrition. In addition, there is a common misunderstanding that removing the foods of concern from the diet will lead to the resolution of AD, resulting in neglect of basic skin care. Skin prick testing and determination of food-specific serum antibody levels are known to be valid in predicting the probability of a positive challenge for only a few foods (cow's milk, hen's egg, fish, peanut, and tree nuts).^{2–10} For other foods, no level accurately predicts whether a given individual will react to the suspected food when challenged. Further complicating the matter is that both prick skin testing and serum-specific-IgE testing to foods often detect sensitization that is not associated with symptoms on ingestion. This reportedly occurs in approximately 50% when the results are compared with those of the gold standard test the double-blind, placebo-controlled food challenge (DBPCFC),¹¹ especially in highly atopic patients. Thus, the most reliable test for true food allergy is whether the food can be ingested without triggering an immediate clinical reaction.

The present study was a retrospective chart review of a group of individuals referred to National Jewish Health (NJH) for evaluation of AD and food allergy and the results of their medically supervised oral food challenges (OFCs). The aim is to raise awareness about the overreliance on serum immunoassay test results as the primary indicator for food elimination in the diets of children, many of whom have AD.

Methods

This study, which was approved by the National Jewish Health Institutional Review Board, included 125 out of the 127 patients evaluated between January 2007 and August 2008 in the NJH Pediatric Food Allergy and Eczema Program who underwent at least one OFC to determine IgE-mediated reactivity to a suspected food. Two identified charts were rejected because the OFCs were performed to evaluate the resolution of food protein-induced enterocolitis syndrome. As part of each

AD	Atopic dermatitis
DBPCFC	Double-blind, placebo-controlled food challenge
IgE	Immunoglobulin E
NJH	National Jewish Health
OFC	Oral food challenge
PST	Prick skin test

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child's evaluation, a complete history and physical examination were performed, previous laboratory data were reviewed, and, in children with AD, an intensive skin care and AD education program was initiated.¹² The severity of AD was determined by the percentage of body surface area involvement present on admission: severe, >50%; moderate, 25%-50%; or mild, <25%.

Specific IgE tests performed before referral to NJH varied according to the referring clinician's practice and included traditional prick skin tests (PSTs), fresh food PSTs, food-specific immunoassays, and total serum IgE level. We could not control for the various techniques and methods of interpretation used for laboratory tests (PSTs and immunoassay) obtained before admission to NJH. These were reported as positive/negative, by wheal size, by class, and by food-specific IgE levels.

All immunoassay tests at NJH were performed using the Phadia ImmunoCAP system (Phadia, Uppsala, Sweden). Results are reported in kilounits of antibody/liter (kU_A/L). All skin tests at NJH were performed with the Duotip Test Device (Lincoln Diagnostics, Decatur, Illinois). Most standard PSTs were performed using commercial extracts from Greer Laboratories (Lenoir, North Carolina); if extracts were not available from Greer, then extracts from Hollister-Stier (Spokane, Washington) or ALK-Abello (Round Rock, Texas) were used. A fresh food PST was commonly used for fruits and vegetables and other foods, especially if testing with the commercial extract was negative and the patient had a concerning history of a reaction to a negative commercial extract. At NJH, fresh food PSTs are performed by extracting the juice from the fruit or vegetable, applying the extract to the skin, and pricking through this extract. The performance of ImmunoCAP and PSTs before an OFC varied based on history, reliability of previous tests, how long before admission the tests were performed, recent use of short-acting or long-acting antihistamines, and length of stay. OFCs were performed based on the patient's history of ever ingesting the food, type of reaction, patient age, size of the PST performed at NJH, and/or results of the food-specific ImmunoCAP (for those foods with positive predictive values). OFCs were not performed in any patient with a history of a life-threatening reaction or a convincing history of a reaction occurring within the previous 6-12 months. Note that a few challenges were performed in some patients even if NJH immunoassay value exceeded the published 95% cutoff levels.⁵⁻⁷ Some of the subjects had previously ingested foods associated with high immunoassay levels without developing symptoms; thus, challenges to these foods were performed. OFCs were performed after appropriate treatment for AD. None of the patients was receiving an oral corticosteroid or a short-acting or long-acting antihistamine at the time of an OFC.

All OFCs were medically supervised in the NJH Pediatric Food Allergy and Eczema Programs with baseline vital signs, including lung function, obtained when applicable. Baseline symptoms and skin condition were noted. OFCs were performed in a nonblinded or open fashion, unless patient or pa-

rental anxiety mandated the use of a single- or double-blind method. Patients were given between 6 and 10 doses of a food at 15- to 30-minute intervals. If there was a question of a possible reaction, doses could be repeated or the time interval could be increased to up to 60 minutes before escalating doses. Cumulatively, patients consumed more than the usual age-appropriate amount of the food. A negative challenge was defined as no reaction occurring for at least 2 hours after completion of the graded challenge. By definition, a negative OFC also meant that patients with AD did not experience worsening of their AD beyond the 2-hour observation period when IgE-mediated symptoms are expected to occur. Patients also were examined on the following day, before the next OFC, or were instructed to return to NJH on the weekend if the AD flared the next day for an examination if the last OFC was done at the end of the week. An OFC was deemed positive when a patient developed any type of allergic reaction consistent with IgE-mediated symptoms (eg, urticaria, angioedema, rhinitis, throat itching or tightness, wheezing, vomiting, diarrhea) within the 2-hour observation period.

Results

Of the 125 children (median age of 4 years) identified in the chart review (Table I), 96% had active AD at the time of evaluation. The severity of AD was classified as mild in 30%, moderate in 24%, and severe in 42%.

A total of 364 OFCs were performed on foods avoided at admission, of which 325 were negative (89%). The results of these OFCs are summarized by the reason the food was being avoided. Note that all reactions to foods during the OFCs occurred within the 2-hour observation period; there were no documented cases of AD flares on the day after an OFC was performed.

Table II illustrates the results of food challenges in subjects avoiding foods due to previous immunoassay and PST results. A total of 111 foods were challenged in 44 children. Except for wheat, 80% or more of the OFCs were negative to the foods being avoided due to the results of these tests. Note that the foods to which there were positive OFCs

Table I. Patient demographic data

Age at time of OFC, years, median (range)	4 (1-19)
Male sex	57%
Race/ethnicity	Caucasian: 70% Hispanic: 8% Asian: 6% African American: 4% Other: 12%
Referral: Geographic distribution	In-state (Colorado): 41% Out-of-state: 55% Other country: 4%
Total IgE, IU/L, median (range) (n = 95)	1241 (14-66 520)
AD, n (%)	120 (96%)
Sensitization to environmental allergens	Positive: 87% Negative: 9% Not done: 4%
Asthma, n (%)	65 (52%)

Table II. OFC results on foods avoided due to immunoassay or PST

Food group	Avoiding on admission	OFC positive result	OFC negative result	Avoiding on discharge	% Negative
Egg	10	1	9	1	90%
Fruits	10	2*	8	2	80%
Meats	13	0	13	0	100%
Milk	9	0	9	0	100%
Oats	4	0	4	0	100%
Peanut	7	1	6	1	86%
Shellfish	2	0	2	0	100%
Soy	19	1	18	1	95%
Vegetables	6	0	6	0	100%
Wheat	13	3	10	3	77%
Other	18	0	18	0	100%
Totals	111	8	103	8	93%

*Two positive tests to banana.

were egg, banana (both fruit reactions), peanut, soy, and wheat.

Table III presents the results of OFCs to foods being avoided due to a reaction before admission to NJH. Previous reactions included anaphylaxis (5%), gastrointestinal (17%), lower respiratory (8%), upper respiratory (10%), and skin (76%). Multiple reactions were sometimes cited, and thus the total exceeds 100%. A total of 122 foods were challenged in 67 children. Except for peanut and oat (for which the numbers are small), >75% of OFCs were negative, and the foods were returned to the child's diet. Positive OFCs were obtained to egg, chicken, milk, oat, peanut, soy, pea, wheat, beans, and pork and beans.

Table IV summarizes all foods avoided due to previous immunoassay, including those for which an OFC was not done. In many cases, immunoassay was repeated at NJH. **Table IV** shows the mean values for these immunoassays. The challenges to egg, milk, and peanut are divided into two groups based on established levels to commonly cited decision points: (1) challenges performed with immunoassay levels above these decision points versus (2) challenges done because of levels <5 kU_A/L. When levels were in the very high serum food-specific IgE range, egg and peanut OFCs were not done, but it is noteworthy that 2 of 5 subjects with high milk-specific IgE levels were OFC-negative. For foods other

than egg, milk, and peanut, there was a wide range of immunoassay levels, and the vast majority of the OFCs for these foods (all but banana [$n = 2$] and wheat [$n = 3$]) were negative (66 of 71 [93%]), resulting in return of these foods to the child's diet.

Numerous foods were being avoided for various other reasons, including the following: child never ate the food before, another family member had an allergy to that food, parent was afraid to have the child try the food, child refused to eat the food, parent was uncertain whether AD worsened with the food, atopic child too young for the food based on allergist's recommendation, and uncertain reasons. Most of these reasons are not related to a history linking the avoided food to observed symptoms. A total of 131 foods were challenged in 48 children; the results are given in **Table V** (available at www.jpeds.com). Of these 131 OFCs, only 11 were positive, and >90% of the foods were returned to the child's diet at the time of discharge.

Discussion

Many of the children in our study were on an overly restrictive diet that excluded foods that they had never eaten or foods that they had once tolerated without a known reaction

Table III. OFC results on foods avoided due to previous reaction

Food group	Avoiding on admission	OFC positive result	OFC negative result	Avoiding on discharge	% Negative
Egg	23	5	18	5	78%
Fruits	11	0	11	0	100%
Meats	7	1*	6	1	86%
Milk	14	3	11	4†	79%
Oat	3	1	2	1	67%
Peanut	10	3	7	3	70%
Shellfish	1	0	1	0	100%
Soy	13	3	10	3	77%
Tree nuts	6	0	6	0	100%
Vegetables	7	1*	6	1	86%
Wheat	5	1	4	1	80%
Other	22	2*	20	2	91%
Totals	122	20	102	21	84%

*Positive results to chicken ($n = 1$), beans ($n = 1$), peas ($n = 1$), and pork and beans ($n = 1$).

†One patient was subsequently diagnosed with lactose intolerance and avoided cow's milk.

Table IV. Avoiding foods due to previous immunoassay, OFC versus no OFC

Cutoff applied	Food group	Avoiding on admission	NJH/IA done	NJH/IA mean	OFC performed		OFC result	
					No	Yes	Positive	Negative
Above cutoff	Egg	11	9	68.9 ± 38.9	11	0	0	0
	Milk	5	5	44.7 ± 22.7	3	2	0	2
	Peanut	15	14	77.3 ± 27.6	15	0	0	0
	Subtotals	31	28		29	2	0	2
Below cutoff	Egg	6	5	1.9 ± 1.3	1	5	0	5
	Milk	5	4	2.2 ± 2.8	0	5	0	5
	Peanut	9	7	2.9 ± 3.5	5	4	0	4
	Subtotals	20	16		6	14	0	14
Not applied	Fruits	8	2	1.3 ± 1.2	1	7	2	5
	Meats	13	5	6.4 ± 9.9	6	7	0	7
	Oats	3	2	9 ± 5.3	0	3	0	3
	Shellfish	14	4	31.5 ± 46.8	12	2	0	2
	Soy	16	11	22 ± 29.4	4	12	0	12
	Tree nuts	18	6	11.3 ± 8.6	18	0	0	0
	Vegetables	4	0	-	2	2	0	2
	Wheat	15	9	32.3 ± 23.8	7	8	3	5
	Other	35	14	29.8 ± 30.9	21	14	0	14
	Subtotals	126	53		71	55	5	50
	Totals	177	97		106	71	5	66

Egg: age <2 years, 2 kU_A/L and age > 2 years, 7 kU_A/L; milk: age <2 years, 5 kU_A/L and age >2 years, 15 kU_A/L; peanut: 14 kU_A/L. IA, Immunoassay.

based primarily on in vitro immunoassay results. OFCs demonstrated that the majority of foods were being unnecessarily eliminated from the diet, thus further complicating management of these complex cases. Rather than serum food-specific IgE immunoassays or PST results, OFCs, particularly DBPCFCs, remain the gold standard for distinguishing mere sensitization from true food allergy. However, it is important to note that in this setting, which excluded challenges to foods to which the child had a history of anaphylaxis, OFCs were helpful because most (89%) were negative. In patients with AD, initial optimal clearing of the skin through appropriate skin care is essential if the effects of food elimination and reintroduction are to be accurately assessed, given the difficulty of evaluating exacerbations of skin disease in a patient with active severe AD. Clearly, there continues to be a significant overreliance on the results of food-specific immunoassay results and PSTs in making a diagnosis of food allergy in patients, especially in those with AD. The conclusions reached by these tests, if not supported by the results of an OFC, can easily result in unnecessary food restrictions that further complicate the care of these patients. Thus, misinterpretation of the results of food-specific immunoassays, for which there is no correlation between the immunoassay level and the probability of reacting to a food, is leading to unnecessary dietary restrictions that could result in nutritional deficiencies.

The overdiagnosis of food allergy due to misinterpretation of test results is not unique to the AD population; the positive predictive accuracies of PSTs are <50% compared with DBPCFCs, and serum immunoassays are generally considered less sensitive than PSTs.¹¹ Thus, although patients with AD may be more likely to have false-positive PSTs or immunoassays because they potentially have higher total IgE levels, false-positive tests commonly occur in patients without AD as well.

The decision to perform OFCs in this study was based on a combination of factors including: (1) history of ever ingesting the food; (2) type of reaction; (3) patient age; (4) size of the PST performed at NJH; and (5) food-specific immunoassay results. OFCs were not performed on patients with a history of a life-threatening reaction; a convincing history of a reaction within the previous 6-12 months; an ImmunoCAP level that exceeded the 95% predictive value for milk, egg, peanut, or fish; or an associated large PST. For the two patients who had milk-specific IgE levels above the 95% predictive value, their recent clinical history of ingestion of small amounts of milk-containing products without reaction and minimal PSTs to milk led us to deem graded OFCs safe to perform. In the other patients with high milk-specific IgE levels, clinical history and associated large PSTs did not warrant OFCs. In patients with low food-specific IgE levels, a history of a life-threatening reaction, recent allergic reaction, or large PSTs at NJH precluded us from performing OFCs. All of the patients with tree nut allergy also had peanut allergy; thus, regardless of their tree nut-specific IgE levels, they were instructed to avoid all tree nuts in accordance with current recommendations, due to the possibility of cross-contamination with peanut food products.

Our findings are consistent with those of previous studies.^{11,13-17} The persistent overuse of food elimination diets despite the availability of previously published warnings about this practice is of concern. The ready availability of immunoassay panels to identify possible food allergies continues to add to the ongoing potential for misinterpretation of results. We believe that this is due in part to increasing advertisements for in vitro immunoassay testing for food allergies, in concert with a lack of distinction between IgE sensitization and symptomatic hypersensitivity or clinical food allergy. In addition, managed care organizations are

discouraging referrals to specialists who can help interpret these results. Compounding the problem is the insufficient numbers of allergy practices and centers that perform OFCs, possibly due to cost or safety issues.

Unfortunately, we occasionally see children with failure to thrive due to severe dietary restriction based solely on in vitro immunoassay testing.¹⁸ Other concerns include: (1) parental perception of unclear messages about which foods are essential to avoid; (2) attempts to treat AD with food elimination in lieu of an appropriate therapeutic AD regimen; (3) pressure from parents to obtain blood tests to identify food allergens; (4) incomplete understanding of the immunoassay class designations; and (5) application of the few well-established serum food-specific IgE clinical confidence levels to other foods for which they have not been validated or for other immunoassay tests for which they have not been confirmed. Although larger PST wheal sizes may indicate an increased likelihood of reaction,^{2,19} as do higher food-specific IgE levels,^{9,20} the predictability is not clear. It also should be noted that larger PST wheal sizes and higher food-specific IgE levels are not correlated with or predictive of the severity of the reaction. Furthermore, in vitro cross-reactivity between foods does not necessarily correlate with the need to avoid all foods in a given botanical family.^{21,22}

The recommended evaluation for food allergy, including a detailed history and physical examination, followed by selected in vivo and in vitro tests based on the history, food elimination determined by the results, and OFCs when uncertain, has not changed over the years.^{11,20,23-25} Because children with moderate AD have at least a 33% risk of having a food trigger their eczema,^{13,26} appropriate control of their skin disease before evaluating the role of food allergy is paramount in these children. Once the AD is appropriately controlled, then PSTs can be properly evaluated and OFCs reliably performed by properly trained staff when medically indicated.

Although our findings confirm that many foods were unnecessarily avoided, they also confirm several important points with respect to food allergy. First, based on OFC outcomes, the most common food allergens in the United States account for the vast majority of true food allergies in our patient population: milk, egg, peanut, soy, wheat, tree nuts, and shellfish. Although some of our children proved to be truly allergic to meats, fruits, vegetables, or other grains, the vast majority had negative OFCs. Second, even though 95% predictive decision points are available for only a few foods, they did prove to be helpful for milk, egg, and peanut. Those patients with food-specific IgE levels below these decision points all had negative OFCs, but two patients with milk-specific IgE levels above the 95% predictive value also had a negative OFC, demonstrating that these thresholds are not infallible and require clinical correlation and interpretation to be most useful.

The present study has some limitations. The retrospective design did not allow for OFCs on all suspected foods. Some subjects could have outgrown their food allergy between the

time the food was removed and the time of the study challenge. Other circumstances, such as parental preferences and inadequate time at NJH, precluded some OFCs. It was not possible to rank every suspected food by skin test size, food-specific serum IgE level, and OFC results. The vast majority of the OFCs in the study were open OFCs, not DBPCFCs. Although the DBPCFC has been the gold standard for diagnosing food-related disorders since its introduction in 1976, open OFCs are more practical in busy clinical settings and are more often used in clinical practice. A prospective study in a population of children with AD and elevated food-specific serum IgE levels would be the best way to address the question of the predictive value of cutoff levels.

The results of this retrospective study demonstrate that a primary reliance on serum food-specific IgE testing to determine the need for food elimination diets in children, especially those with AD, is not sufficient. A detailed clinical history is the key first step in the diagnosis of potential food allergy, followed by skin testing and immunoassay testing when indicated by the history. Ultimately, however, OFCs (in the case of nonanaphylactic reactions) may be needed to make an accurate diagnosis of food allergy. ■

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Table V. OFC results for foods avoided due to other reasons*

Food group	Avoiding on admission	OFC positive result	OFC negative result	Avoiding on discharge	% Negative
Egg	7	3	4	3	57.1%
Fruits	16	1 [†]	15	1	93.8%
Meats	11	2 [†]	9	2	81.8%
Milk	4	1	3	1	75.0%
Oats	7	0	7	0	100.0%
Peanut	8	0	8	0	100.0%
Shellfish	8	1 [†]	7	1	87.5%
Soy	6	1	5	1	83.3%
Tree nuts	10	0	10	0	100.0%
Vegetables	19	0	19	0	100.0%
Wheat	5	0	5	0	100.0%
Other	30	2 [†]	28	2	93.3%
Totals	131	11	120	11	91.6%

*Other reasons include: never eaten, family member with allergy to that food, parent afraid to try foods, patient refuses to eat the food, parent uncertain if atopic dermatitis worsens with the food so avoids it, atopic child too young for the food based on allergist recommendation, uncertain.

†Positive results to strawberry (n = 1), beef (n = 1), chicken (n = 1), shrimp (n = 1), Alimentum (1), and barley (n = 1).