

Legume and sesame oral food challenge outcomes

Jacob J. Pozin, B.S.,¹ Ashley L. Devonshire, M.D.,^{1,2,4} Kevin Tom, B.S.,¹ Melanie Makhija, M.D.,^{1,2} and Anne Marie Singh, M.D.^{1,3}

ABSTRACT

Background: Legume and sesame are emerging food allergens. The utility of specific immunoglobulin E (sIgE) testing to predict clinical reactivity to these allergens is not well described.

Objective: To describe clinical outcomes and sIgE in sesame and legume oral food challenges (OFC).

Methods: We performed a retrospective review of 74 legume and sesame OFCs between 2007 and 2017 at the Ann and Robert H. Lurie Children's Hospital of Chicago. Clinical data, OFC outcome, and sIgE to legume and sesame were collected. Receiver operating characteristic curves and logistic regression models that predicted OFC outcome were generated.

Results: Twenty-eight patients (median age, 6.15 years) passed legume OFC (84.9%), and 25 patients (median age, 5.91 years) passed sesame OFC (61.0%). The median sIgE to legume was 1.41 kU/L and, to sesame, was 2.34 kU/L. In patients with failed legume OFC, 60.0% had cutaneous symptoms, 20.0% had gastrointestinal symptoms, and 20.0% had anaphylaxis. Of these reactions, 80.0% were controlled with antihistamine alone and 20.0% required epinephrine. In patients for whom sesame OFC failed, 50.0% had cutaneous symptoms, 12.5% had gastrointestinal symptoms, and 37.50% had anaphylaxis. Of these reactions, 6.3% required epinephrine, 31.3% were controlled with diphenhydramine alone, and 63.50% required additional epinephrine or prednisone.

Conclusion: Most OFCs to legumes were passed and reactions to failed legume OFCs were more likely to be nonsevere. Sesame OFC that failed was almost twice as likely compared with legume OFC that failed, and reactions to sesame OFC that failed were often more severe. Sesame sIgE did not correlate with OFC outcome.

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Food allergy (FA) is the result of a specific immune response that reproducibly occurs on exposure to a given food.¹ Over the past 2 decades, the prevalence of FA in children has increased, with reports of new emerging allergens.^{2–5} In the United States, between 1992 and 2006, outpatient FA presentations in children have increased more than threefold, whereas, between 2000 and 2009, food anaphylaxis hospital admissions have more than doubled.⁶ These allergies can cause significant distress, including physical symptoms if the

trigger allergen is ingested, and may increase anxiety.⁷ The latter can cause children to remove various foods from their diet as a precaution. Prolonged avoidance of food allergens has been correlated with increased rates of FAs.⁸

The criterion standard for FA diagnosis is oral food challenge (OFC), which can elicit adverse reactions in response to ingestion of foods.^{9–11} OFC exposes the patient to significant risks, including anaphylaxis, and deciding when and in whom to perform OFC is an important clinical question. Previous work has associated OFC outcomes to specific immunoglobulin E (sIgE) levels for the most common food allergens.^{12,13} Although there are studies that describe OFC outcomes to common allergens, similar studies on less common antigens with increasing recognition, such as sesame and legumes, are lacking.

Studies with regard to sesame allergy have been small and have mixed responses with regard to predicting clinical reactivity.^{5,14,15} It has been suggested that the Ses-i-1 sIgE level better predicts the probability of a sesame induced reaction compared with sesame sIgE, but there was overlap in values between those with passed and those with failed OFC, and sesame skin-prick testing (SPT) may best predict sesame allergy.¹⁶ Similar to that of sesame, FAs to legumes are increasingly reported, and studies with regard to legume allergy are limited. The most recent published studies that investigated legume OFC outcomes focused on the

From the ¹Department of Medicine, Northwestern Feinberg School of Medicine, Chicago, IL, ²Department of Pediatrics, Ann and Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, ³Department of Pediatrics, University of Wisconsin-Madison, Madison, WI, and ⁴Department of Pediatrics, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

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Address correspondence to Anne Marie Singh, M.D., Food Allergy Research and Education Center of Excellence, Department of Pediatrics, University of Wisconsin-Madison, 600 Highland Ave., Clinical Sciences Center 9988, Madison, WI 53792

E-mail address: amsingh@wisc.edu

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diagnostic use of SPT.^{17–19} The purpose of our study was to describe a single tertiary-care center's experience with sesame and legume OFCs. We sought to characterize OFC pass rates to these foods, the severity of allergic responses in failed challenges, and investigate clinical determinants of OFC outcomes.

METHODS

Study Design

We performed a retrospective chart review of 74 patients who underwent open legume and/or sesame OFCs performed between 2007 and 2017 at the Ann and Robert H. Lurie Children's Hospital of Chicago. OFCs were offered to patients by their primary allergy provider to either confirm the diagnosis of FA or to assess for natural tolerance development. Patients challenged to legume consumed beans, peas, or lentils. Data were collected with regard to initial FA presentation (clinical history, SPT, sIgE testing), follow-up sIgE testing, and OFC details, including sIgE level at the time of OFC, food quantity consumed, symptoms, and/or treatment required. The study was approved by the institutional review board. Informed consent was exempted because this was a retrospective chart review. J.J. Pozin drafted the manuscript and performed data collection and analysis. K. Tom and M. Makhija contributed to the manuscript and data analysis, and edited and revised the manuscript. AD helped complete the statistical analysis, and edited and revised the manuscript. A.M. Singh oversaw all aspects of the work, including the design of the study, data collection, analysis, and drafting of the manuscript.

Laboratory Studies

Routine clinical evaluation laboratory studies were reviewed. The ImmunoCAP system (Phadia, Uppsala, Sweden) in Lurie Children's diagnostic immunology laboratory measured food sIgE levels before OFC.²⁰ Serum IgE was measured at the most recent allergy clinic visit, typically within weeks to months of OFC. Per clinic policy, we perform OFC if the most recent ImmunoCAP test had been obtained within 1 year.

Open OFCs

Open OFCs were conducted in patients at their primary allergist's discretion by using a clinical protocol in which patients receive incrementally increasing doses of the goal quantity of the challenge food. Doses were administered every 15 minutes as tolerated. Goal quantities amounted to one full serving size (30 g sesame, 60 g legume), which is ~5.4 g of protein. Patients were monitored for 2 hours after final dose ingestion. Challenges were stopped at the discretion of the supervising provider, typically when objective reaction symptoms occurred or after the full serving was

tolerated. Challenge results with subjective symptoms only were considered inconclusive and were excluded from the analysis. Criteria for when to stop the OFC were consistent with a recent American Academy of Allergy, Asthma and Immunology Work group Report.²¹ Patients were treated based on the provider's assessment. In general, reactions that consisted of cutaneous symptoms only were first treated with antihistamines. If the child did not respond to the antihistamine (*i.e.*, the reaction progressed or continued), then the child was treated with additional medications, including epinephrine. Any child with multiple organ system involvement (*e.g.*, hives and vomiting) were treated with epinephrine. In addition, a child may be treated with epinephrine for a single organ system reaction if it was thought to be potentially life threatening (*e.g.*, wheezing).

Statistics

Parametric and nonparametric statistical tests were used as appropriate. Statistical analysis, *t*-tests, and figures were completed by using Graphpad Prism v7.03 (San Diego, CA). Stata v14 (StataCorp, College Station, TX) generated logistic regression models to predict OFC outcome. The following variables (all of which had complete data) were included in the logistic regression analysis: age at the date of OFC, history of atopic dermatitis, history of asthma, history of rhinitis, IgE level on the date of OFC, and allergic reaction history.

RESULTS

Total Population

Seventy-four OFCs, 33 legume and 41 sesame challenges, were reviewed. The patients often had a history of atopic disease, primarily including eczema and FAs. Demographic data are detailed in Supplemental Table 1. OFC pass rates, median age, and food sIgE level at the time of OFC are presented in Table 1. The overall OFC pass rate was 71.62%. Twenty-eight patients (84.85%) passed and five patients (15.15%) failed legume OFC, whereas 25 (60.98%) passed and 16 (39.02%) failed sesame OFC. The median time from the patient's first reaction to the date of the most recent sesame OFC was 4.42 years (range, 0.50–16 years) and 5.27 years (range, 0.60–10.84 years) for legume OFC. The subsequent median time from the patient's most recent reaction to the date of the most recent sesame OFC was 4.42 years (range, 0.50–11.25 years) and 4.80 years (range, 0.60–10.84 years) for legume.

Clinical predictors of OFC outcome were examined by logistic regression analyses. A model that included personal reaction histories to the food, atopic dermatitis, asthma, allergic rhinitis, age, and sIgE value at the time of OFC did not significantly predict OFC outcome. Twenty-four patients (58.54%) were avoiding

Table 1 Descriptive statistics of the overall population, patients who had legume OFC, and patients who had sesame OFC

OFC	No. Patients	Median Age, y	Pass Rate, %	Median IgE Level, kUA/L			<i>p</i> *
				All Patients	Patients with Failed OFC	Patients with Passed OFC	
All challenges	74	6.83	71.62	2	2.71	1.66	0.09
Legume	33	6.12	84.85	1.44	3.04	1.41	0.15
Sesame	41	5.9	60.98	2.34	2.7	2.28	0.48

IgE = Immunoglobulin E; OFC = oral food challenge.

**The *p* values represent statistical significance when comparing median IgE levels between the patients who passed and patients who failed OFC.*

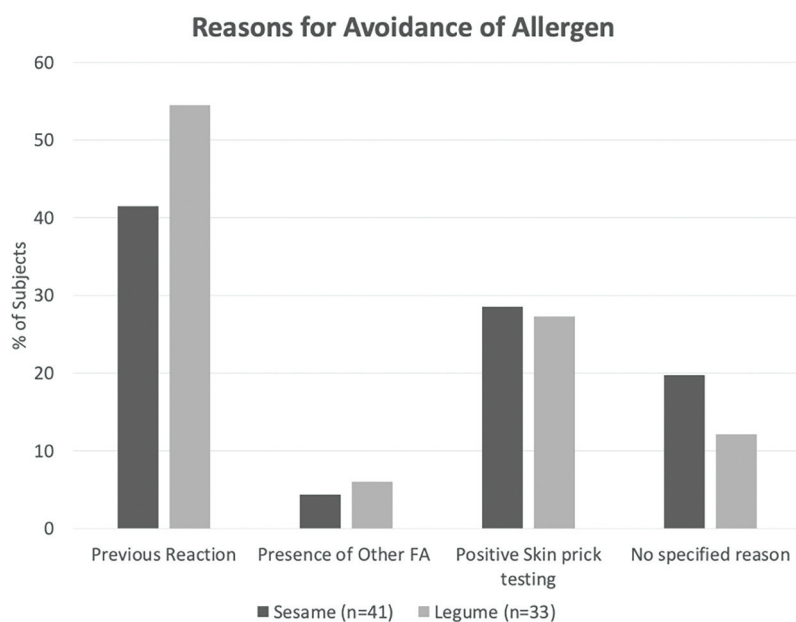


Figure 1. Reasons for preventative avoidance. Bar chart that describes the reasons that patients preventatively removed food allergens tested from their diet.

sesame as a precaution due to positive testing results and another FA (e.g., peanut), and 15 patients (45.45%) were avoiding legumes as a precaution without an ingestion history due to another FA (i.e., peanut) or evidence of sesame sensitization on testing performed before to oral exposure (Fig. 1).

Sesame OFCs

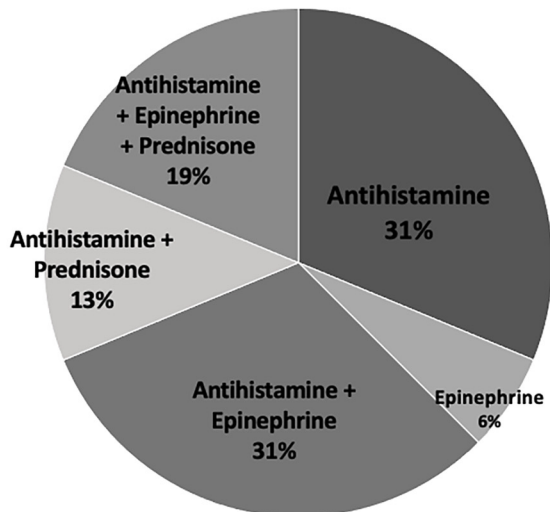
Forty-one sesame OFCs were reviewed. Demographic data were similar to the overall population (Supplemental Table 1). Among the 16 patients with failed sesame OFC, 50.00% had reactions characterized by cutaneous symptoms only, 12.50% had gastrointestinal symptoms only, and 37.50% experienced anaphylaxis; 9 of the 16 (56%) required epinephrine. Symptoms and treatments are presented in Fig. 2 The median sIgE value for the patients challenged to sesame is presented in Table 2. The sesame sIgE values did not significantly differ between the patients who passed and those who failed sesame OFC (Table 1, Fig. 3) (*p* = 0.48). Sesame IgE levels

were then categorized into quartiles (Table 2). The highest OFC pass rate (87.5%) was identified for sIgE levels between 3.91 and 6.66 kUA/L, whereas the lowest pass rate (37.5%) was for sIgE levels between 6.66 and 59.1 kUA/L.

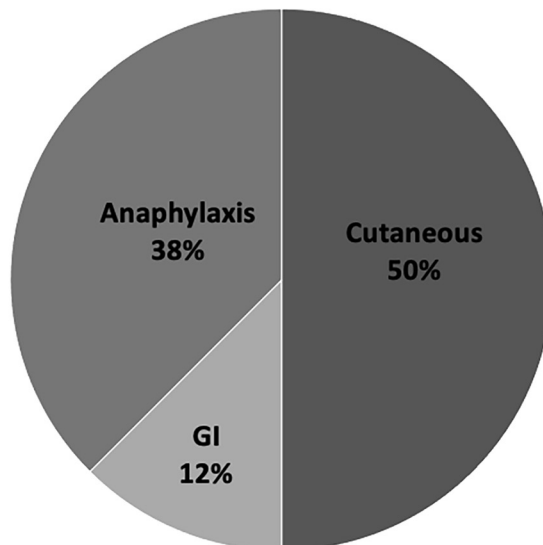
Twenty-two of 25 patients (88.0%) who passed sesame OFC had a history of atopic dermatitis, whereas only 8 of 16 (50.0%) of those who failed had a history of atopic dermatitis (*p* = 0.01). Per logistic regression analysis, the odds ratio of failed sesame OFC among the patients without a history of atopic dermatitis was 7.14 times that of the patients with a history of atopic dermatitis (*p* = 0.02). A personal history of asthma, allergic rhinitis, and age at OFC did not significantly differ between the patients who passed and those who failed sesame OFCs.

Seventeen patients described an allergic reaction history to sesame during an exposure that occurred before the patient's initial evaluation. Eight (47.1%) passed sesame OFC. Twenty-four patients (58.5%)

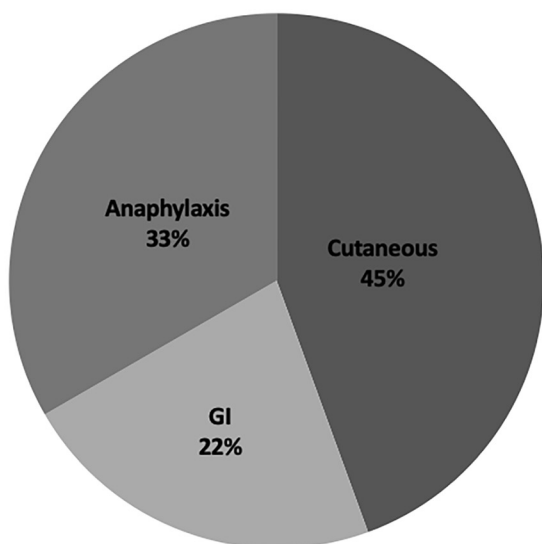
A Medications Administered During OFC Reactions to Sesame



B Symptoms involved in OFC Reactions to Sesame



C Symptoms involved in OFC Reactions to Sesame with Prior Reaction History



Symptoms involved in OFC Reactions to Sesame with No Prior Reaction History

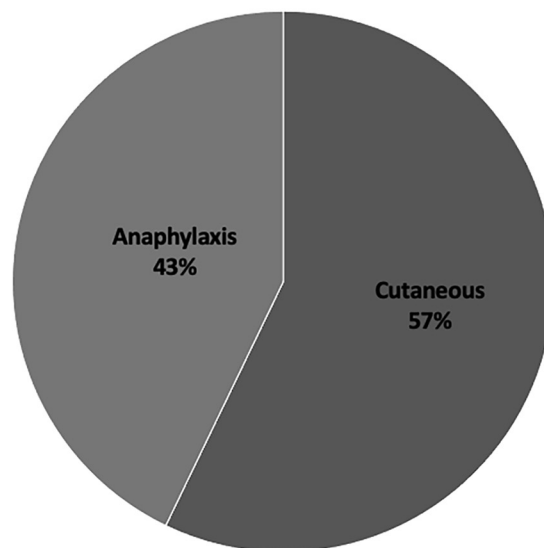


Figure 2. Sesame oral food challenge (OFC) outcomes. (A) Medications administered for reactions to sesame during OFC. (B) Symptoms of reactions during OFC to sesame. (C) Symptoms of reactions during OFC to sesame divided by reaction history. Symptoms in positive OFCs results were characterized as cutaneous if they included rash, hives, or localized edema, whereas gastrointestinal (GI) reactions included nausea, abdominal cramps, or emesis. Anaphylaxis was characterized as allergic reactions, including a combination of multiple organ systems.

challenged to sesame had no reaction history to sesame. Of these 24 patients, 70.8% passed sesame OFC. There was no significant difference between the patients who passed and those who failed sesame OFC based on their reaction history ($p=0.12$). Of those who failed OFC, the patients who were avoiding sesame without a history of reaction to sesame demonstrated similar rates of anaphylaxis versus those with reaction histories (33.0% vs 43.0%;

$p=0.28$). Many of these anaphylactic reactions began with cutaneous symptoms only; however, the patients did not respond to antihistamine administration alone, which required an escalation in therapy, including epinephrine or prednisone.

Legume OFCs

Thirty-three legume OFCs were reviewed. Demographic data were similar to the overall cohort (Supplemental

Table 2 Sesame OFC pass rate within sIgE quartile ranges

	Total No.	Patients Who Passed OFC, <i>n</i>	Patients Who Failed OFC, <i>n</i>	Patients Who Passed OFC, %
Total	41	25	16	60.98
Sesame sIgE value				
<0.35 kUA/L	7	5	2	71.43
0.35–1.47 kUA/L	9	4	5	44.44
1.47–3.91 kUA/L	9	6	3	66.67
3.91–6.66 kUA/L	8	7	1	87.50
6.66–59.1 kUA/L	8	3	5	37.50%

OFC = Oral food challenge; sIgE = specific immunoglobulin E.

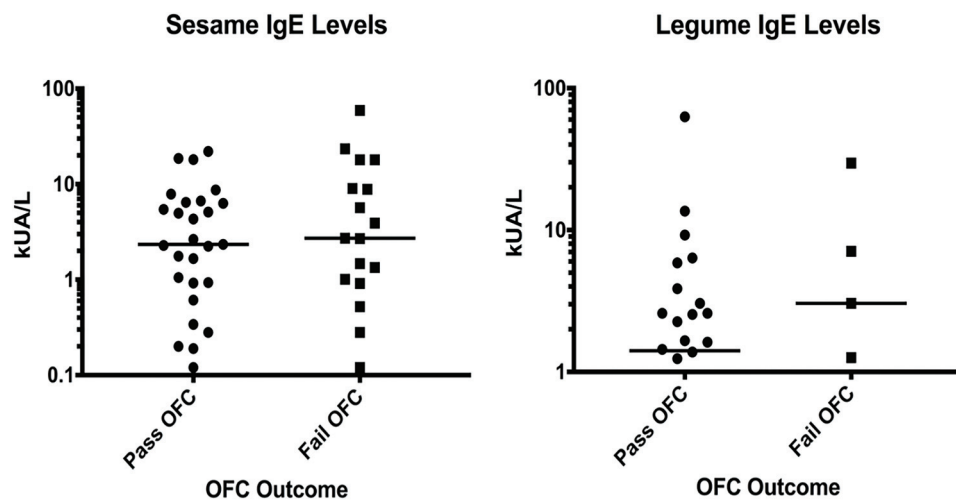


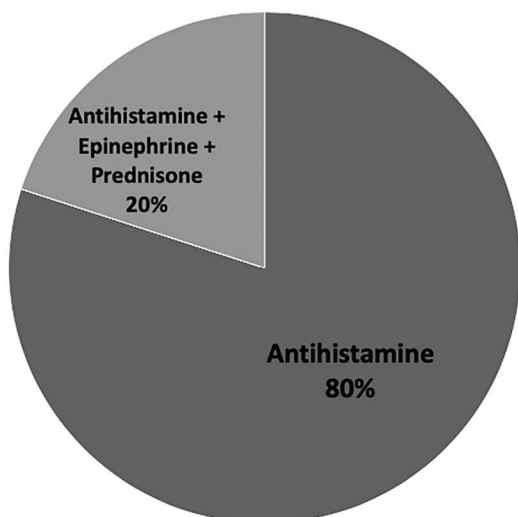
Figure 3. Sesame and legume sIgE levels at the time of OFC. A dot plot illustrates sesame and legume sIgE levels at the time of challenge by OFC outcome. The horizontal bar represents the median. There is no statistically significant difference between sesame sIgE levels when comparing the patients who passed or those who failed OFC. However, patients in the highest quartile of sesame sIgE had the lowest pass rate (see Table 2). There is also no statistically significant difference in legume sIgE levels between the patients who passed or those who failed OFC. However, there is a high rate of passing OFC to legumes overall. sIgE = Specific immunoglobulin E; OFC= oral food challenge.

Table 1). Differences in age at OFC and personal history of atopy were not predictive of legume OFC outcome. Twenty-eight of 33 patients (85.0%) passed legume OFC. Of the five patients who failed legume OFC, three (60.0%) had reactions that consisted of cutaneous symptoms only, one (20.0%) had gastrointestinal symptoms only, and one (20.0%) experienced anaphylaxis (Fig. 4A). The patient with anaphylaxis was challenged because the patient had demonstrated a significant decline in the sIgE level over a 7-year period from the date of diagnosis (88.80 kUA/L) to the date of OFC (29.60 kUA/L). The patient reacted after consuming 10.0% of the goal dose, and anaphylaxis was characterized by oral pruritis, lip swelling, and a sensation of chest tightness. Symptoms resolved with a combination of diphenhydramine, epinephrine, and prednisone. There was no significant difference in the reaction history to legume

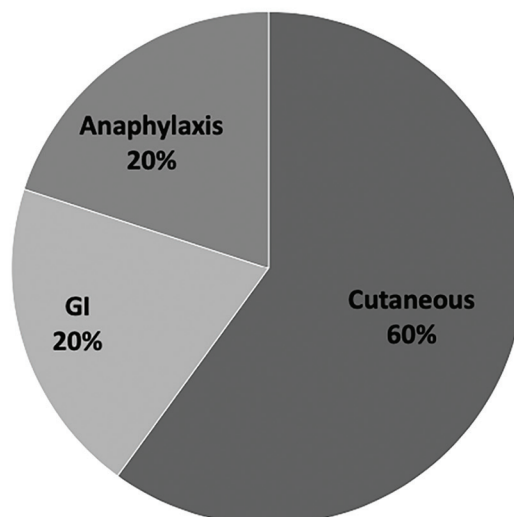
between the patients who passed and those who failed OFC ($p = 0.35$).

Of the 18 patients (54.5%) with a previous reaction to legume, 14 (77.8%) passed legume OFC. Of the 15 patients who were avoiding a legume without a prior history of reacting to that legume, 14 passed OFC. The one patient (6.7%) who failed OFC was characterized by having cutaneous symptoms alone, which were treated with diphenhydramine. Symptoms and treatments are presented in Fig. 4 The median sIgE value for the patients challenged to legume is presented in Table 1 ($p = 0.15$) (Table 1, Fig. 3). The legume sIgE values were divided into negatives and quartiles, and OFC pass rates were examined (Table 3). Negatives and one quartile (<0.35 kUA/L, and 1.26–2.54 kUA/L) had 100% passed legume OFCs. The lowest percentage of OFCs passed (66.7%) was the upper quartile (5.86–62.8 kUA/L). There was at least a 60.0% pass rate, regardless of sIgE quartile.

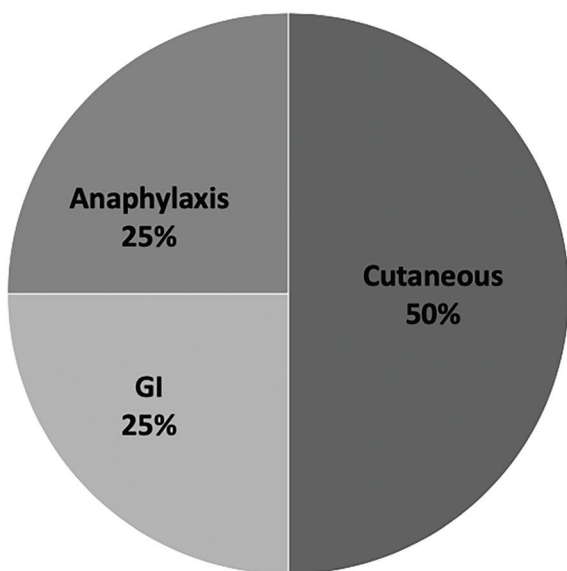
A Medications Administered During OFC Reactions to Legume



B Symptoms involved in OFC Reactions to Legume



C Symptoms involved in OFC Reactions to Legume with a Prior Reaction History



Organ Systems involved in OFC Reactions to Legume with No Prior Reaction History

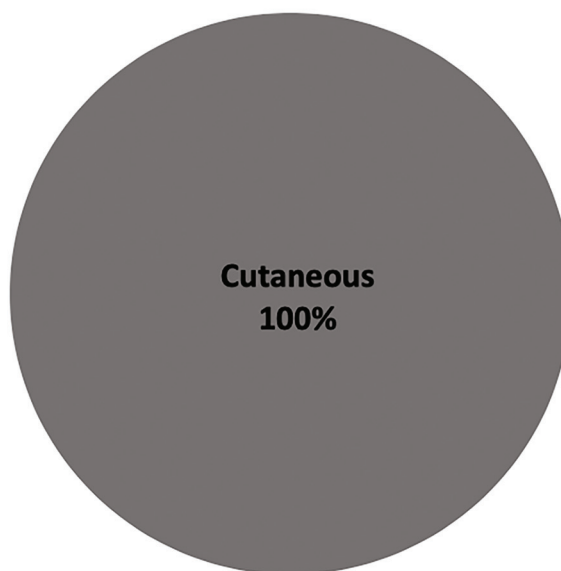


Figure 4. Legume oral food challenge (OFC) outcomes. (A) Medications administered for reactions to legume during OFC. (B) Symptoms of reactions during OFC to legume. (C) Symptoms involved in OFC reactions did not differ based on reaction history ($p > 0.05$). Symptoms in positive OFC results were characterized as cutaneous if they included rash, hives, or localized edema, whereas gastrointestinal (GI) reactions included nausea, abdominal cramps, or emesis. Anaphylaxis was characterized as an allergic reaction, including a combination of multiple organ systems.

DISCUSSION

This study's purpose was to identify factors, including food-allergen serum sIgE levels associated with OFC outcomes to antigens that are gaining increased awareness. Understanding these associations may help

clinicians better identify OFC candidates. This study identified a high pass rate to legume OFC throughout a range of sIgE levels, and allergic reactions during challenges were often mild. Although 84.50% of the patients passed legume OFCs, there was no significant

Table 3 Legume OFC pass rates within sIgE quartile ranges

	Total No.	Patients Who Passed OFC, <i>n</i>	Patients Who Failed OFC, <i>n</i>	Patients Who Passed OFC, %
Total	33	28	5	84.85
Legume sIgE value				
<0.35 kUA/L	9	9	0	100.00
0.35–1.26 kUA/L	6	4	2	66.67
1.26–2.54 kUA/L	6	6	0	100.00
2.54–5.86 kUA/L	6	5	1	83.33
5.86–62.8 kUA/L	6	4	2	66.67

OFc = Oral food challenge; sIgE = specific immunoglobulin E.

difference between legume sIgE levels in patients who passed versus patients who failed legume OFC. The study found that patients challenged to legumes often tolerated the food and that avoiding legumes without a reaction history was unnecessary. However, sesame OFC pass rates were variable, particularly as sesame sIgE levels increased, and there are few clinical and laboratory predictors that differentiate children who will pass or fail sesame OFC. Importantly, reactions to sesame were more severe, which often required escalated therapeutic intervention. Improved diagnostic tests are required to better predict sesame OFC outcomes.

The sesame sIgE level does not predict OFC outcome. Although previous studies showed a cutoff of <0.35 kUA/L is useful for excluding a sesame allergy diagnosis,^{7,14} our findings demonstrated that two patients with a sesame sIgE value of <0.35 kUA/L failed sesame OFC (which accounted for 12.5% of failed sesame OFCs), which resulted in a sesame FA diagnosis. One patient previously reacted to sesame and ultimately failed OFC. The sesame sIgE level had decreased from diagnosis to <0.35 kUA/L at time of challenge, which resulted in the decision to pursue OFC.

Our findings also demonstrated variable pass rates (35.00–90.00%) for individuals with positive sesame sIgE values (>0.35 kUA/L), which indicated that the sesame sIgE level did not predict clinical reactivity to sesame, consistent with the current literature.^{14–16} This is of importance because sesame allergy is becoming more common and is now considered one of the “top 9” allergens. In addition, this study demonstrated that allergic reactions to sesame may be severe, with > 33.00% of failed challenges, which resulted in anaphylaxis and 69.00% who required more than diphenhydramine to treat symptoms. Importantly, our study did not identify a difference in OFC outcome and reaction severity based on reaction history and avoidance of sesame. A history of eczema was the sole statistically significant predictor of passing OFC ($p=0.02$). This

suggested that children with eczema may be more likely to exhibit sensitization and not true FA. This has been shown for other foods in which > 50.00% of children considered sensitized to a food allergen based on positive screening tests may not clinically react during OFC.²¹

To our knowledge, this was the first study to describe a pediatric experience with legume OFCs, including exploration of legume sIgE values and OFC outcomes. Importantly, we noted that the patients were equally likely to pass legume OFC, despite the legume sIgE level. Overall, 84.85% of the patients passed legume OFC. Throughout the entire range of legume sIgE values studied, legume OFC pass rates were high, with only mild reactions. Among children with a legume reaction history, we found that anaphylaxis and gastrointestinal symptoms were equally as common but less common than cutaneous symptoms during legume OFC. The presentation of cutaneous symptoms as the most predominant allergic reaction to legumes, along with an infrequency of anaphylaxis, suggests that clinicians may consider challenging to legumes at higher sIgE levels. This underscores the importance of a clinical history when deciding whether to offer OFC to legumes. Furthermore, analysis of the data suggested that preventative avoidance of legumes was unnecessary.

Limitations of this retrospective study included describing challenges that were deemed clinically indicated and appropriate by the practitioners at a single center. Every patient who presented with a concern for a sesame or legume allergy did not have OFC. Also, providers used their clinical judgment to select who would undergo OFC; therefore, it is likely that pass rates presented were actually higher than if all the patients underwent OFC. However, these data are critical to report because our study was representative of clinical decisions made in the care of children with concern for allergy to these increasingly prevalent allergens. Furthermore, our study did not include SPT when describing legume and sesame OFC outcomes.

SPT was only done routinely when standardized extract was available. Extracts are not available on all legumes and seeds. Because there was a large portion of the study population who did not have SPT completed, we did not use that data in our analysis. Increased development of standardized extracts could be used in future studies to further identify other determinants of OFC outcomes.

CONCLUSION

The FA landscape is ever changing, with newer emerging allergens becoming more common. Here, we described our center's clinical experience with OFCs to sesame and legume. Current serum testing does not predict sesame OFC outcomes, and reactions can be severe. In patients sensitized to legumes and without a history of reaction, almost all the patients in our study tolerated these foods, and reactions that did occur were mild, which suggested that preventive avoidance of legumes is unnecessary. These findings highlighted the continued need for clinically indicated OFCs to confirm or refute the diagnosis of sesame and legume allergy.

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