

# Legume and Sesame Oral Food Challenge Outcomes

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## Research

**Keywords:** Food Allergy, Oral Food Challenge, IgE level, Sesame, Legume

**Posted Date:** November 25th, 2020

**DOI:** <https://doi.org/10.21203/rs.3.rs-113278/v1>

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# Abstract

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

**Objective:** To describe clinical outcomes and sIgE in sesame and legume OFCs.

**Methods:** We performed a retrospective review of 74 legume and sesame oral food challenges (OFC) performed between 2007-2017 at the Ann & Robert H. Lurie Children's Hospital of Chicago. Clinical data, OFC outcome, and sIgE to legume and sesame were collected. Receiver operating characteristic curves (ROC) and logistic regression models predicting OFC outcome were generated.

**Results:** Twenty-eight patients (median age 6.15 years) passed legume OFC (84.85%), and twenty-five patients (median age 5.91 years) passed sesame OFC (60.98%). The median sIgE to legume was 1.41 kU<sub>a</sub>/L, and 2.34 kU<sub>a</sub>/L, to sesame. For patients who failed legume OFC, 67% had cutaneous, 16.5% had gastrointestinal, and 16.5% had anaphylaxis. Of these reactions, 80% were controlled with Benadryl alone and 20% required epinephrine. For patients who failed sesame OFC, 53% had cutaneous, 12% had gastrointestinal, and 35% had anaphylaxis. Of these reactions, 6% required epinephrine, 31% were controlled with Benadryl alone, and 63% required additional epinephrine or steroids.

**Conclusion:** Most OFC to legumes were passed and reactions to failed legume OFCs were more likely to be non-severe. Failing an OFC to sesame was almost twice as likely compared to failing a legume OFC, and reactions to failed sesame OFC were often more severe. Sesame sIgE did not correlate with OFC outcome.

## Introduction:

Food allergy is the result of a specific immune response that occurs reproducibly on exposure to a given food<sup>1</sup>. Over the past two decades, the prevalence of food allergy in children has been increasing<sup>2,3,4</sup>. Tang *et al.* reported that between 1998 and 2012, hospital admissions due to food-related anaphylaxis in the United States had more than doubled. Additionally, there has been a threefold increase in food allergy presentations in an outpatient clinical setting<sup>5</sup>. For those affected, these allergies can be a cause of significant distress, including both physical symptoms if the trigger allergen is ingested, and an increase in anxiety<sup>6</sup>. In addition to the increase in prevalence of food allergy to well-known allergens, there are also reports of newer, emerging food allergens that are being more commonly seen in clinical practice<sup>7</sup>.

The gold standard for food allergy diagnosis is the oral food challenge (OFC)<sup>8,9,10</sup>. In a graded-dose OFC, patients ingest increasing amounts of the food being challenged until an adverse reaction occurs or the entire goal amount is consumed, which is typically an age-appropriate serving size. Thus, the OFC exposes the patient to significant risks, including anaphylaxis, and deciding when and on whom to perform an OFC is an important clinical question. To help weigh the risks and benefits of an OFC, previous work has associated OFC outcomes to specific IgE (sIgE) levels for the most common food

allergens<sup>11,12</sup>. These studies have aided physicians in determining when to offer an OFC. Although detailed studies have described OFC outcomes to the most common allergens, similar studies on newer, emerging antigens, such as sesame and legumes are lacking.

As the literature stands, studies regarding sesame allergy have been small and have not predicted clinical reactivity. Studies of sesame sIgE levels as predictors of clinical reactivity and reaction severity have been mixed<sup>13,14</sup>. Yanagida *et al.* identified that Ses i 1 sIgE better predicted the probability of a sesame induced reaction compared to sesame sIgE<sup>15</sup>. Recently, Saf *et al.* found that sesame skin-prick-testing has better accuracy at predicting an allergy to sesame compared to sesame sIgE. Sesame SPT is a more accurate predictor of sesame allergy compared with sesame sIgE<sup>22</sup>. Additionally, published studies investigating legume OFC outcomes have focused on the use of skin prick testing as a diagnostic test<sup>16,17,18</sup>. The purpose of this study was to describe a single tertiary care center's experience with oral food challenges to sesame and legumes. We sought to characterize the rates of passed OFC to these foods and investigate clinical determinants of OFC outcome.

## Methods:

**Study Design:** We performed a retrospective chart review of 74 patients who underwent open legume and/or sesame OFCs performed between 2007–2017 at the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Oral food challenges were offered to patients based on the discretion of their primary allergist to either confirm the diagnosis of food allergy or to assess for the development of natural tolerance (outgrowing the food allergy over time, without intervention). Patients challenged to legume consumed either beans, peas, or lentils. Data was collected regarding initial presentation of food allergy (clinical history, skin prick testing, and sIgE testing), follow-up sIgE testing, and oral food challenge details, including sIgE level at the time of OFC, amount of food consumed, any symptoms, and/or treatment required. The study was approved by the Institutional Review Board of Lurie Children's.

**Laboratory studies:** Laboratory studies included as part of a routine clinical evaluation were reviewed. As part of routine clinical evaluation, food sIgE levels were measured prior to OFC using the ImmunoCAP system (Phadia, Uppsala, Sweden) in the diagnostic immunology lab at the Ann and Robert H. Lurie Children's Hospital of Chicago<sup>19</sup>.

**Open Oral Food Challenges:** At the discretion of the primary allergist and based on a combination of clinical history and diagnostic testing results, patients were selected to complete an OFC. Open OFCs were conducted using a clinical protocol in which patients receive incrementally increasing doses of the goal quantity of the challenge food. The doses are administered every 15 minutes as tolerated. Goal quantities amounted to 1 full serving size (30 g sesame, and 60 g legume) which is approximately 5.4 g of protein. Patients were monitored for 2 hours after ingesting the final dose. Challenges were stopped at the discretion of the supervising provider, typically when objective symptoms of a reaction occurred or after the full serving had been tolerated. Patients were treated for reactions as indicated based on the assessment of the supervising provider.

**Statistics:** Parametric and non-parametric statistical tests were used as appropriate. Receiver operating characteristic curves (ROC), statistical analysis, including T-tests, and figures were completed using Graphpad Prism (v7.03, San Diego, CA). Logistic regression models predicting OFC outcome were generated using Stata (v14, College Station, TX).

## Results:

Total population:

**Table 1:** Demographics

Characteristic	% Overall (n=74)	% Sesame (n=41)	% Legume (n=33)
Male Sex, N (%)	35 (47.3)	20 (48.78)	15 (45.45)
<b>Race, N (%)</b>			
White	57 (77.03)	35 (85.37)	22 (66.67)
African American	2 (2.70)	1 (2.44)	1 (3.03)
Hispanic	2 (2.70)	1 (2.44)	1 (3.03)
Asian	2 (2.70)	0 (0.00)	2 (6.06)
Other	11 (14.86)	4 (9.76)	7 (21.21)
Median age (years) at time of challenge	6.12	5.91	6.15
<b>Personal Atopic History, N (%)</b>			
Eczema	53 (71.62)	32 (78.05)	22 (66.67)
Asthma	20 (27.03)	10 (24.39)	10 (30.30)
Allergic Rhinitis	38 (51.35)	23 (56.10)	15 (45.45)
History of other Food Allergy	60 (81.08)	38 (92.68)	22 (66.67)
Preventively avoiding, N (%)	40 (54.05)	24 (58.54)	16 (48.48)

Seventy-four OFCs were reviewed, comprised of thirty-three legume challenges and forty-one sesame challenges (Table 1). Of the total population, 47.3% participants were male, the median age at the OFC was 6.12 years (range 0.55 to 20.45 years). Patients often had history of atopic disease, with eczema and multiple food allergies being most common (Table 1).

The median age at the time of OFC, food sIgE level at the time of OFC, and OFC pass rates are presented in Table 2. The overall OFC pass rate was high at 71.62%. Twenty-eight subjects (84.85%) passed OFC to

legumes, while twenty-five (60.98%) passed OFC to sesame.

Of the failed challenges overall, 52.4% of the reactions consisted of cutaneous symptoms only, 14.3% were gastrointestinal symptoms alone, and 33.3% were anaphylaxis (defined as a reaction involving two or more organ systems (Additional Figure 1A). Medications required are shown in Additional Figure 1B. Overall, 48.6% of subjects who failed a sesame or legume OFC required epinephrine. These data underscore the risk of anaphylaxis to sesame and legumes.

Logistic regression analyses were performed to examine clinical predictors of OFC outcomes. A model including history of a reaction to the food, age at the time of OFC, personal history of atopic dermatitis, personal history of asthma, personal history of allergic rhinitis, and sIgE at the time of OFC did not significantly predict OFC outcome.

**Table 2:** Descriptive statistics of overall population, legume subjects, and sesame subjects referencing median age, pass rate, median IgE level, and level of significance. P values represent statistical significance comparing median IgE level between the cases that passed and failed an Oral Food Challenge.

	# of patients	Median Age	Pass Rate	Median IgE Level, all, (kU <sub>a</sub> /L)	Median IgE Level Fail, (kU <sub>a</sub> /L)	Median IgE Level, Pass, (kU <sub>a</sub> /L)	P value
All Challenges	74	6.83	71.62%	2	2.71	1.66	0.0886
Legume	33	6.12	84.85%	1.44	3.04	1.41	0.1512
Sesame	41	5.9	60.98%	2.34	2.7	2.28	0.4781

### Sesame Oral Food Challenges:

**Table 3:** Sesame OFC pass rate within sIgE quartile ranges

<u>Sesame IgE</u>	<u>Total</u>	<u>Passed</u>	<u>Failed</u>	<u>Percent Passed</u>
<b>Total</b>	41	25	16	60.98%
<b>Less than 0.35</b>	7	5	2	71.43%
<b>0.35 to 1.47</b>	9	4	5	44.44%
<b>1.47 to 3.91</b>	9	6	3	66.67%
<b>3.91 to 6.66</b>	8	7	1	87.50%
<b>6.66 to 59.1</b>	8	3	5	37.50%

Forty-one sesame OFCs were reviewed. Demographic data of patients undergoing sesame OFC were similar to the overall population (Table 1). Of patients challenged to sesame, 41.46% were avoiding sesame due to a history of clinical reactivity upon ingestion with evidence of sensitization on skin prick testing or serum sIgE testing. Twenty-four participants (58.54%) were preventatively avoiding sesame without a history of prior ingestion due to another food allergy (i.e. peanut) or evidence of sensitization to sesame on testing performed prior to oral exposure.

The majority (60.98%) of patients passed a sesame OFC. Among patients who failed a sesame OFC, 50% had a reaction characterized by cutaneous symptoms only, 12% with gastrointestinal symptoms only, and 38% experienced anaphylaxis. Of the sixteen subjects who failed a sesame OFC, 56% required at least one dose of epinephrine (Figure 1A, 1B). There was a significant difference in the number of individuals with a personal history of atopic dermatitis between subjects who passed and failed a sesame OFC. Among those who passed a sesame OFC, 88% had a personal history of atopic dermatitis, whereas only 50% of those who failed had a personal history of atopic dermatitis ( $p=0.012$ ). Logistic regression analysis found that a personal history of atopic dermatitis was the only significant predictor of a passed sesame OFC. The odds of a failed OFC to sesame among subjects with a personal history of atopic dermatitis was 0.14 times that of subjects without a personal history of atopic dermatitis ( $p=0.021$ ). A personal history of asthma, a personal history of allergic rhinitis, and age at OFC did not significantly differ between subjects who passed and failed sesame OFC.

We next compared patients with a prior reaction history compared to those that were preventatively avoiding sesame. Over half of the patients challenged to sesame had no previous history of a reaction to sesame (58.54%), and there was no significant difference between subjects who passed and failed sesame OFC based on previous reaction history ( $P=0.124$ ). Of the seventeen subjects who had a history of a reaction to sesame, 47% passed and 53% failed a sesame OFC. Among those who failed, symptoms experienced and treatment required are presented in Figure 1.

Of the remaining twenty-four subjects preventively avoiding sesame, 71% passed and 29% failed a sesame OFC. Of those who failed a sesame OFC, patients with previous reaction history demonstrated similar rates of anaphylaxis compared to those preventatively avoiding (43% vs 33%,  $p=0.28$ ). Interestingly, although many of these reactions began with cutaneous symptoms only, many of these patients did not respond to antihistamine administration alone and needed an escalation in therapy (Additional Figure 2A).

The median sIgE value for all subjects challenged to sesame was  $2.34 \text{ kU}_a/\text{L}$  (range  $0.12-59.1 \text{ kU}_a/\text{L}$ ). Patients who passed a sesame OFC had a median sIgE level of  $2.28 \text{ kU}_a/\text{L}$ , and subjects who failed had a median sIgE level of  $2.70 \text{ kU}_a/\text{L}$ . Sesame sIgE did not significantly differ between individuals that passed and failed an OFC to sesame (Table 2 and Figure 2,  $P=0.4781$ ).

Patients challenged to sesame were organized into two groups based on undetectable IgE values (<0.35) and those with positive IgE values (>0.35), and the pass rates of the subsequent challenges were recorded. The positive sesame sIgE levels were subsequently categorized into quartiles (25% -1.47 kU<sub>a</sub>/L, 50% - 3.91 kU<sub>a</sub>/L, 75% - 6.66 kU<sub>a</sub>/L), (Table 3). The highest percentage of passed OFCs was identified for sIgE levels between 3.91 and 6.66 kU<sub>a</sub>/L (87.5%), while the lowest percentage of passed OFCs (37.5%) came from subjects with the greatest range of IgE values, (6.66 to 59.1 kU<sub>a</sub>/L).

### **Legume Oral Food Challenges:**

**Table 4:** Legume OFC pass rates within sIgE quartile ranges

<u>Legume IgE</u>	<u>Total</u>	<u>Passed</u>	<u>Failed</u>	<u>Percent Passed</u>
<b>Total</b>	33	28	5	84.85%
<b>Less than 0.35</b>	9	9	0	100.00%
<b>0.35 to 1.26</b>	6	4	2	66.67%
<b>1.26 to 2.54</b>	6	6	0	100.00%
<b>2.54 to 5.86</b>	6	5	1	83.33%
<b>5.86 to 62.8</b>	6	4	2	66.67%

Thirty-three OFCs to legumes were reviewed. During the challenge patients consumed either beans, peas, or lentils at increasing doses. Demographic data is presented in Table 1 and is similar to the overall cohort. There were no significant differences in age at time of challenge or personal history of atopy between individuals who passed or failed legume OFC.

Twenty-eight of thirty-three subjects (84.9%) passed an OFC to legume. Of the five patients who failed a legume OFC (N=5), 60% had an allergic reaction consisting of cutaneous symptoms only, 20% presented with gastrointestinal symptoms only, and 20% of patients experienced anaphylaxis. Of the failed challenges, only one patient (20%) required epinephrine (Figure 3A).

Among patients challenged to legume, fifteen patients (45.46%) had no previous history of a reaction to peas, beans, or lentils (i.e. legumes). There was no significant difference in history of previous reaction to legume between subjects who passed or failed an OFC (P=0.346). Of the eighteen patients (54.54%) with a history of a reaction to legume, fourteen (77.78%) passed and four (22.22%) failed a legume OFC. Symptoms and treatments are presented in figure 3B and 3C.

Of the sixteen patients without a history of a reaction to legume, the one (6.67%) failed OFC was characterized by cutaneous symptoms alone and were treated with an antihistamine. The remaining fourteen subjects (93.33%) all passed their legume OFC.

Patients who passed a legume OFC had a median legume sIgE level of 1.41 kU<sub>a</sub>/L, and subjects who failed a legume OFC had a median legume sIgE level of 3.04 kU<sub>a</sub>/L (Table 2, P=0.1512 and Figure 4).

The legume sIgE values were divided into quartiles and the rates of passing a legume OFC, based on sIgE quartile, were examined (Table 4). There was a 100% legume OFC pass rate for individuals with a legume sIgE less than 0.35 kU<sub>a</sub>/L and for those with a level between 1.26 and 2.54 kU<sub>a</sub>/L. The lowest percentage of passed food challenges (66.67%), came from subjects within the upper quartile of legume sIgE values, between 5.86 and 62.8 kU<sub>a</sub>/L. Regardless of legume sIgE level, over 60% of legume OFCs were passed.

## Discussion:

The purpose of this study was to identify the factors associated with passed or failed OFCs to emerging antigens, including food-allergen serum sIgE levels. Understanding these associations may help clinicians better identify candidates for OFCs. This study identified a high success rate of passing an OFC to legumes throughout a range of sIgE levels, and allergic reactions to legumes during OFC were usually mild. While our study identified an 84.5% pass rate for legume OFCs, there was no significant difference between legume sIgE levels in patients who passed versus failed a legume OFC. The study found that patients challenged to legumes often tolerate the food, and avoiding legumes without a prior reaction history is unnecessary. However, the rate of passing an OFC to sesame is variable, particularly as sesame sIgE increases, and there are very few clinical and laboratory predictors that differentiate between children who will pass or fail an OFC to sesame. Importantly, reactions to sesame were more severe in nature and, as such, often required escalated therapeutic intervention. Improved diagnostic tests are required to better predict OFC outcome to sesame.

In this study, sesame serum sIgE was not a predictor of OFC outcome. While previous studies have shown that a cutoff of < 0.35 kU<sub>a</sub>/L may be useful for excluding a diagnosis of allergy to sesame<sup>7,14</sup>, our findings demonstrate that two patients with a sesame sIgE < 0.35 kU<sub>a</sub>/L failed a sesame OFC, resulting in a diagnosis of sesame allergy. One of these patients had a history of a prior reaction to sesame and subsequently failed the OFC. Their sesame sIgE level was monitored from time of diagnosis where it was 2.26 kU<sub>a</sub>/L and had decreased to level less than 0.35 kU<sub>a</sub>/L at the time of challenge, resulting in the decision to pursue an OFC. Our findings also demonstrate variable pass rates, between 35 to 90%, for individuals with sesame sIgE values between 0.35 and 62.8 kU<sub>a</sub>/L, supporting the notion that sesame sIgE level is a poor predictor of clinical reactivity to sesame, and that some patients will ultimately pass sesame OFCs. These findings are consistent with the current literature in that sesame sIgE does not strongly predict OFC outcome. Importantly, our study demonstrates that allergic reactions to sesame may be severe with over a third of challenges resulting in anaphylaxis and 69% requiring more than diphenhydramine alone to treat symptoms. The rate of anaphylaxis is more than double that described in Agne *et al.*, where only two of fourteen subjects (14.3%) experienced anaphylactic symptoms and the remainder experienced predominantly mild allergic reactions to sesame<sup>20</sup>. The results of our study are similar to the findings of Song *et al.*, who completed OFCs and graded food-induced allergic reactions

based on severity of clinical symptoms on a scale of 1 to 5 (ranging from least severe most severe). Their study found a median score of 3 for allergic reactions to sesame, indicating most clinical symptoms were mild<sup>13</sup>.

Importantly, we found a statistically significant association regarding history of atopic dermatitis and passing an oral food challenge. Among those who passed a sesame OFC, 88% had a personal history of eczema, whereas only 50% of those who failed had a personal history of eczema. We noted that for those with a history of eczema the odds of a failed OFC to sesame is 0.14 times as likely compared to subjects without a history of eczema ( $P = 0.021$ ). Similar relationships were not found for other atopic diagnoses. These data suggest that children with eczema may be more likely to exhibit sensitization and not true food allergy. This has been shown for other foods as well, per Spergel *et al.*, where over 50% of children who are considered sensitized to a food allergen based on a positive screening test may not clinically react during an OFC<sup>21</sup>.

To our knowledge, this study is the first to describe a pediatric experience with legume OFCs, including exploration of legume sIgE and OFC outcome. Importantly, we noted that patients were equally likely to pass a legume OFC, despite legume sIgE level. Overall, 84.85% of subjects passed a legume OFC, including those with higher sIgE levels. Throughout the entire range of legume sIgE values studied, pass rates of legume OFCs are high. When reactions did occur, they were primarily mild. In the absence of a clinical history of a reaction to legume, nearly all children passed an OFC, regardless of sIgE level, and the child who failed a legume OFC experienced cutaneous symptoms only. However, among children with a previous history of a reaction to legume, we found that anaphylaxis and gastrointestinal symptoms were equally as common as one another, but less common than cutaneous symptoms during a legume OFC. These data suggest that clinicians may consider challenging to legume at higher sIgE level and underscore the importance the clinical history in deciding whether to challenge a child to a legume.

There are several limitations of this study that should be addressed. This study is a retrospective study describing challenges that were deemed clinically indicated and appropriate by practitioners at a single center. Every patient who presented with concern for sesame or legume allergy did not have an OFC. Also, providers used their own clinical judgement to select who would undergo an OFC; therefore, it is likely that pass rates are actually lower than presented if all patients underwent an OFC. However, we feel this data is critical to report as our study is representative of clinical decisions made in the care of children with concern for allergy to these emerging allergens.

The food allergy landscape continues to change, with newer emerging allergens becoming more common triggers. Here, we describe our center's clinical experience with OFCs to sesame and legume. We found that sesame sIgE is a poor predictor of OFC outcome, and that among those who underwent legume OFC, patients can often tolerate the food. In patients sensitized to legumes without history of reaction, almost all patients in our study tolerated these foods and when reactions did occur, they were mild. This suggests that preventive avoidance of these foods is unnecessary. These findings highlight the continued need for OFC to confirm or refute the diagnosis of sesame and legume allergy when clinically indicated.

## **Abbreviations:**

OFC: Oral Food Challenge; IgE: Immunoglobulin E; sIgE: serum-specific Immunoglobulin E

## **Declarations:**

### **Ethics approval and consent to participate:**

The study was IRB approved. Informed consent was exempted as this was a retrospective chart review.

### **Consent for publication:**

Not applicable.

### **Availability of data and material:**

Not applicable.

### **Competing interests:**

None, not applicable.

### **Funding:**

NIAID K23 AI100995, Anonymous Family Foundation Grant to Northwestern Feinberg School of Medicine  
STU00200053, Bazely Foundation

### **Authors' contributions:**

JP drafted the manuscript, performed data collection and analysis. KT and MM contributed to the manuscript and data analysis, edited and revised the manuscript. DD helped complete the statistical analysis, edited, and revised the manuscript. AMS oversaw all aspects of the work, including design of the study, data collection, analysis and drafting of the manuscript.

### **Acknowledgements:**

Not applicable.

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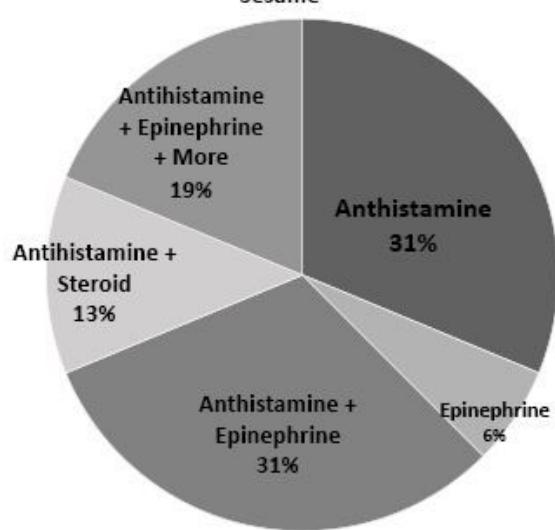
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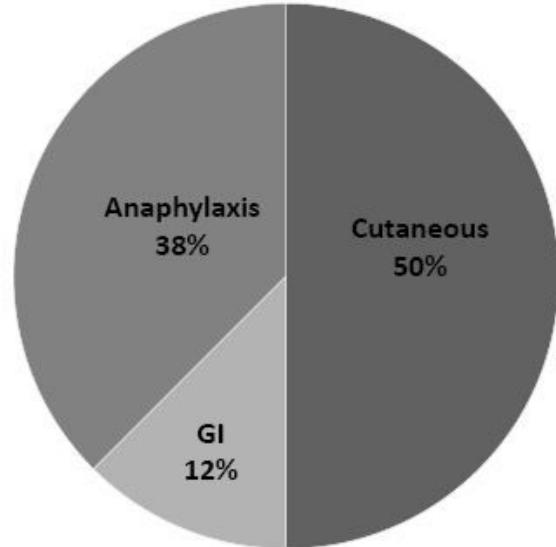
## Figures

Figure 1

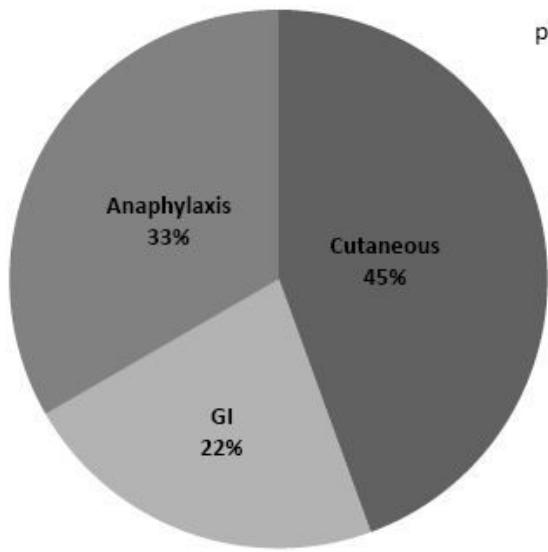
A. Medications Administered During OFC Reactions to Sesame



B. Symptoms involved in OFC Reactions to Sesame



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



$p > 0.05$

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

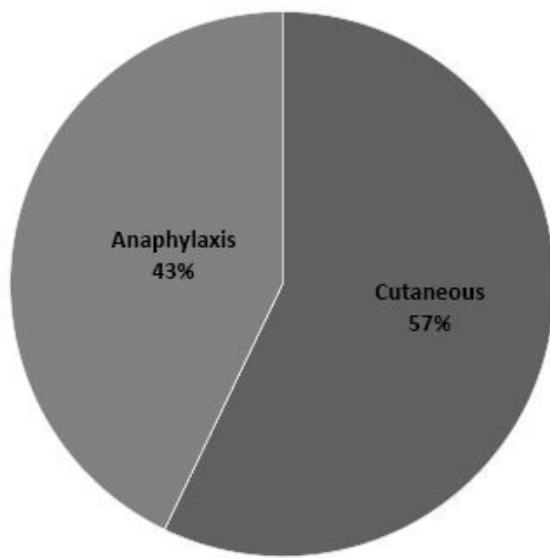


Figure 1

Sesame 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 previous reaction history. Abbreviations: OFC, oral food challenge.

Figure 2

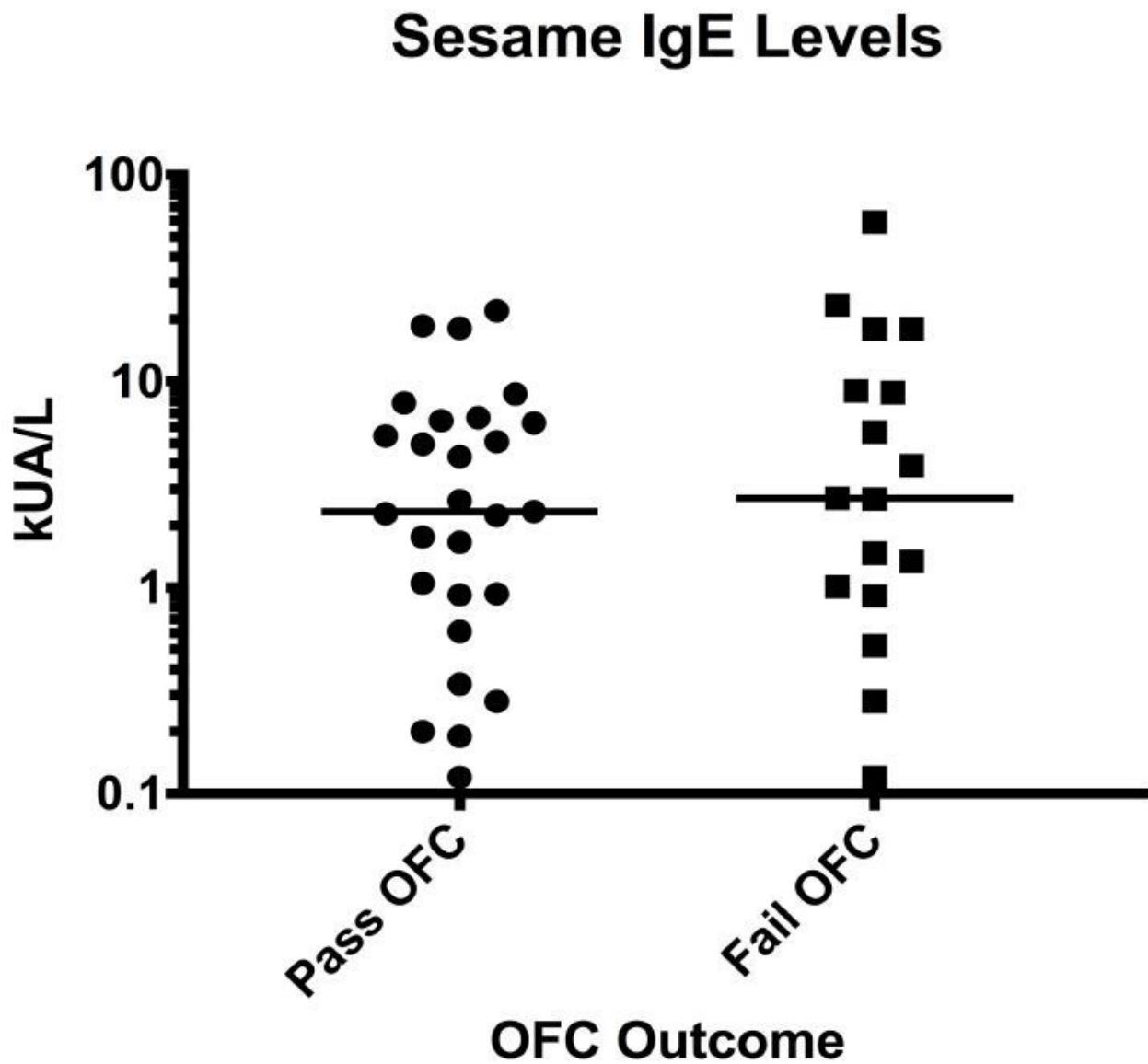
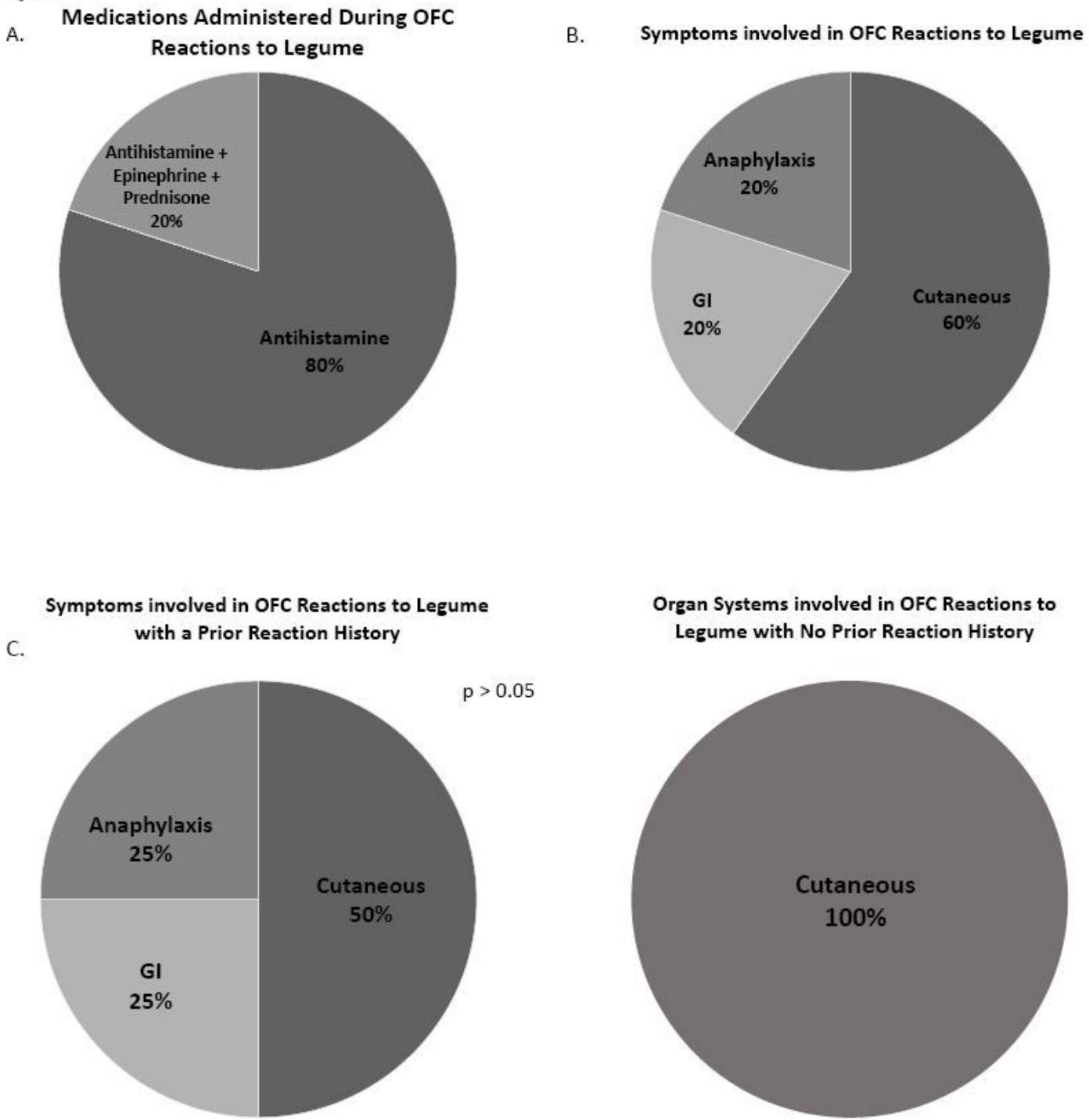


Figure 2

Sesame IgE Levels at Time of OFC. Dot plot illustrates sesame IgE levels at the time of challenge by OFC outcome. The horizontal bar represents the median. There is no statistically significant difference between sesame IgE levels when comparing individuals who passed or failed the OFC. However, patients in the highest quartile of sesame IgE had the lowest pass rate (see Table 4). Abbreviations: IgE, specific IgE; OFC, oral food challenge

Figure 3

**Figure 3**

Legume 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 to did not differ based on prior reaction history. ( $p>0.05$ ). Abbreviations: OFC, oral food challenge

Figure 4

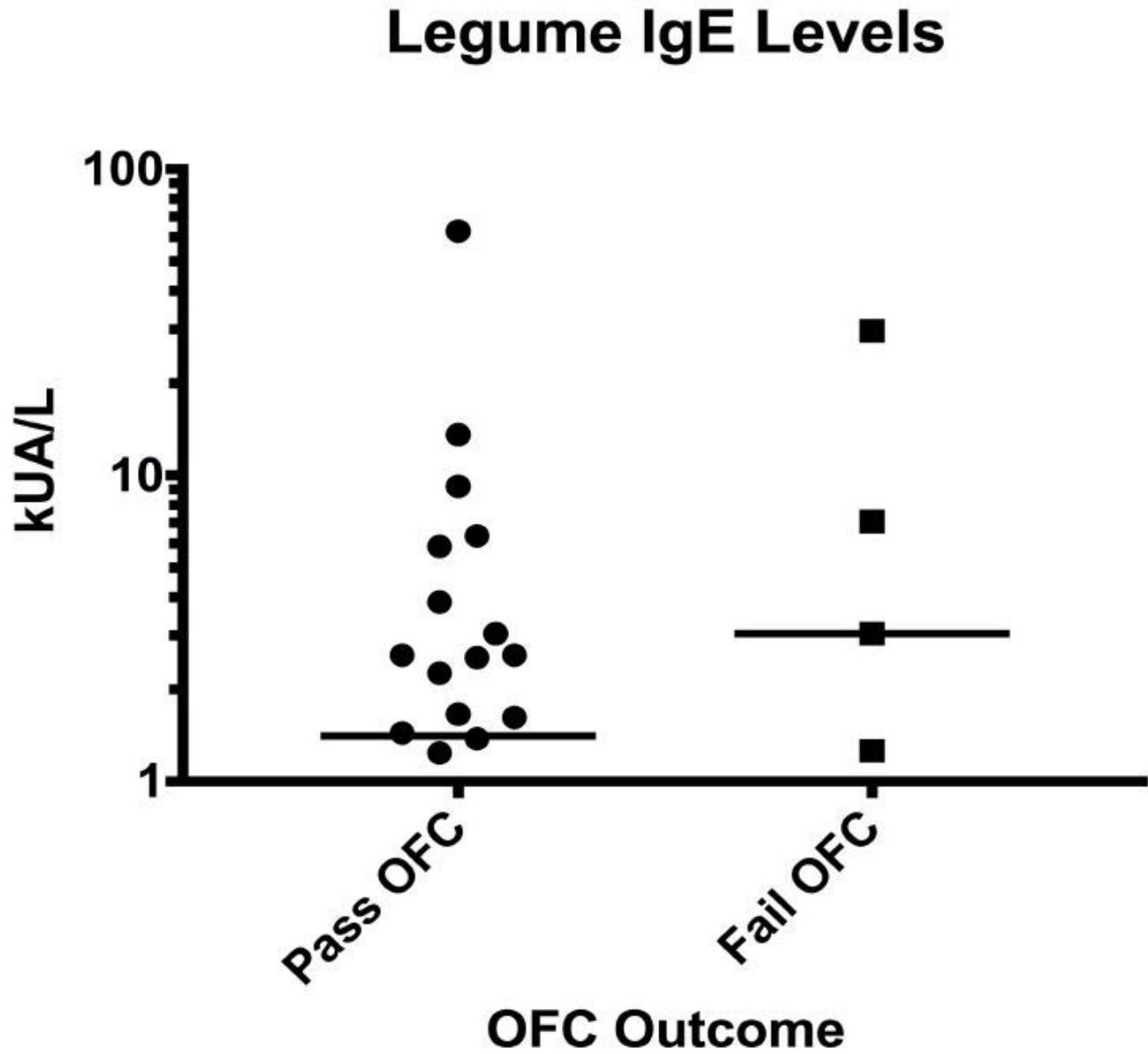


Figure 4

Legume sIgE Levels at the Time of OFC. Dot plot describing the range of legume sIgE levels by OFC outcome. The horizontal bar represents the median. There is no statistically significant difference in legume sIgE level between individuals who passed or failed the OFC. However, there is a high rate of passing an OFC to legumes overall. Abbreviations: sIgE, specific IgE; OFC, oral food challenge

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AdditionalFigures.pdf
- SupplementaryTable1.docx