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Outcomes of oral food challenge in children with IgE-mediated food allergy

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Abstract
Background: Oral food challenges (OFCs) are the gold standard for diagnosing IgE-mediated food allergies in children, although they carry an inherent risk of inducing allergic reactions, including anaphylaxis. This study examined clinical outcomes and predictors of positive OFC results in a pediatric cohort from a region with high exposure to sesame and tree nuts.
Methods: We retrospectively analyzed 310 OFCs in 211 children (median age: 21 months [IQR: 14–37.3]) at a tertiary pediatric allergy center from January 1 to December 31, 2023. Reaction patterns and predictors of OFC positivity, including age, sex, initial reaction type, skin prick test (SPT) wheal size, and serum-specific IgE (sIgE) levels, were evaluated.
Results: OFC positivity occurred in 12.3% (38/310) of the challenges, and was most commonly triggered by milk or dairy products (44.7%), tree nuts (23.6%), and eggs (18.4%). Cutaneous symptoms predominated (94.7%), followed by gastrointestinal (10.6%) and respiratory (7.9%) manifestations. Anaphylaxis occurred in 13.2% (5/38) of the positive OFCs. Positive OFC patients were older (P = 0.009), had longer follow-up (P = 0.046), and were more likely to have presented with urticaria (P < 0.001) or anaphylaxis (P < 0.001). Multivariate logistic regression identified milk or dairy products (OR: 3.326, 95% CI: 1.437–7.702, P = 0.005), sesame (OR: 7.022, 95% CI: 1.194–41.311, P = 0.031), and hazelnut (OR: 11.286, 95% CI: 3.858–33.017, P < 0.001) as independent predictors of OFC positivity.
Conclusion: OFC positivity was 12.3%, and was predominantly triggered by milk, tree nuts, and eggs. Severe reactions, including anaphylaxis, occurred despite low sIgE and SPT values, confirming the limited utility of sensitization markers in predicting clinical reactivity. Older age, longer follow-up, history of urticaria or anaphylaxis, and challenges with milk, sesame, or hazelnut were independently associated with positive OFCs. These results underscore the

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critical role of risk-stratified, closely monitored OFCs in ensuring diagnostic accuracy and guiding safe, personalized management in pediatric IgE-mediated food allergy.

Introduction

Food allergy, a growing public health concern, affects 6–8% of children and 3–4% of adults worldwide, with increasing prevalence in developed countries.[1,2]

It involves immune-mediated reactions to food proteins, eliciting symptoms ranging from mild cutaneous manifestations to life-threatening anaphylaxis, thereby requiring precise diagnostic and management.[3]

Oral food challenges (OFCs), the gold standard for diagnosing IgE-mediated food allergies, confirm clinical reactivity to allergens such as cow's milk, egg, peanuts, tree nuts, and sesame, which are common in young children.[4,5] OFCs distinguish true allergies from sensitization, assess tolerance, and guide dietary management but require careful monitoring due to the risk of inducing allergic reactions, including anaphylaxis.[6,7]

The European Academy of Allergy and Clinical Immunology (EAACI) guidelines recommend conducting OFCs in specialized facilities experienced in managing food challenges, guided by the patient's history and food-specific IgE (sIgE) cut-off levels, which vary with allergen.[8] Recent updates emphasize that high-risk patients, particularly those with a history of anaphylaxis, should undergo OFCs in centers equipped to handle severe reactions.[9] However, these recommendations are largely based on expert consensus, with limited studies evaluating their clinical utility.

Clinical reactions during OFCs may include cutaneous (e.g., urticaria, eczema), respiratory (e.g., wheezing), gastrointestinal (e.g., vomiting), cardiovascular (e.g., hypotension), or neurological (e.g., syncope) symptoms, with severity and onset varying widely.[9,10] Factors such as food type, patient age, and atopic disease history influence OFC positivity and reaction severity.[11]

Despite the pivotal role of OFCs in confirming IgE-mediated food allergy, data on clinical outcomes and risk factors remain limited in pediatric populations.[4,8] This study investigates reaction profiles, severity, multisystem involvement, and demographic, clinical, and laboratory predictors of OFC positivity to optimize safety and diagnostic precision in children with IgE-mediated food allergies.

Materıals and Methods

Study design

We conducted a retrospective cohort study at a tertiary pediatric allergy center (from January 1 to December 31, 2023. Medical records of children with suspected or confirmed IgE-mediated food allergy who underwent OFC were reviewed, and the clinical outcomes, laboratory results, demographic data, comorbidities, reaction details, and administered treatments were evaluated.

Ethical statement

Written informed consent for OFC procedures and data publication was obtained from parents or guardians. The study was approved by the Institutional Ethics Committee (Approval No: GOA-122) and conducted in accordance with the Declaration of Helsinki.

Participants

Children aged ≥6 months undergoing OFC for diagnostic confirmation or tolerance assessment were included. Patients with incomplete documentation of pre- or post-OFC clinical, laboratory, or demographic data, or absence records of reactions and treatments, were excluded (n = 7). Patient selection and study procedures are illustrated in Figure 1.

Skin prick testing and specific IgE

Skin prick tests (SPTs) and prick-to-prick tests were performed with fresh foods (milk, egg, wheat, fish, walnut, sesame, hazelnut, peanut, pistachio, cashew, and lentils). A wheal diameter ≥3 mm and larger than the negative control was considered a positive SPT or prick-to-prick test. Specific IgE levels ≥0.35 kUA/L were considered positive (IMMULITE 2000, Siemens Healthcare Diagnostics, Tarrytown, NY, USA).[4]

Oral Food Challenge Protocol

Oral food challenges were performed in accordance with the PRACTALL consensus and national guidelines.[4] Antihistamines and interfering medications (e.g., tricyclic antidepressants) were discontinued ≥7 days prior; asthma controller therapies (inhaled corticosteroids, leukotriene receptor antagonists) were allowed to continue.[8]

Increasing doses of dietary protein (3, 10, 30, 100, 300, 1000, and 3000 mg) were administered at 15- to 30-min intervals.

Challenges were terminated upon the onset of objective symptoms (e.g., urticaria, angioedema, vomiting, respiratory distress) or persistent subjective symptoms (e.g., throat tightness, abdominal pain).[4]

Allergic reactions were managed per symptom severity: cutaneous symptoms with age-appropriate antihistamines,[9] and anaphylaxis with immediate epinephrine, with emergency resuscitation equipment available.[12]

Data collection

Variables included age, sex, age at diagnosis, initial symptoms, allergenic foods, concomitant atopic diseases, family

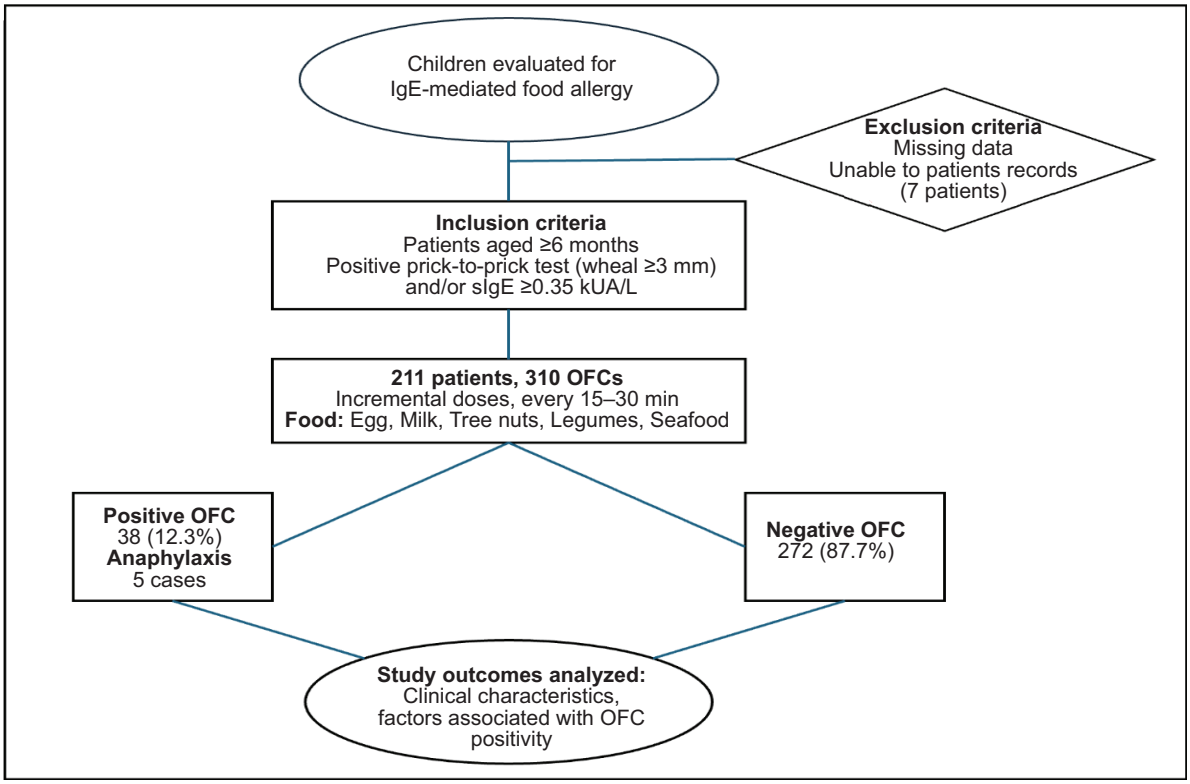

Figure 1 Flowchart of patient selection and study procedures.

history of atopy, OFC purpose (diagnostic versus Tolerance assessment), reaction type and severity, and treatments administered.

Statistical analysis

Analyses were performed using IBM SPSS Statistics v22.0 (IBM Corp., Armonk, NY, USA). Continuous variables were reported as median (IQR) for non-normal distributions (Shapiro–Wilk test) or mean ± SD for normal distributions. Categorical variables were expressed as frequencies (%). Between-group comparisons used χ^2 or Fisher's exact test (categorical) and Mann–Whitney U or Kruskal–Wallis test (continuous). Univariate and multivariate logistic regression identified predictors of OFC positivity. Variables with $P < 0.10$ in univariate analysis were entered into the multivariate model. Results were reported as odds ratios (OR) with 95% confidence intervals (CI), and $P < 0.05$ was considered statistically significant.

Results

Patient characteristics

A total of 310 OFCs were performed in 211 children with suspected or confirmed IgE-mediated food allergy (63.0% males; median age at OFC: 21 months [IQR: 14–37.3]). Multifood allergy was present in 30.8%. Median age at initial presentation was 9 months (IQR: 5–14.7), with a median follow-up of 11 months (IQR: 1.2–21.8). Initial symptoms included eczema (71.6%), urticaria (20.4%), and anaphylaxis (8.1%). Concomitant atopic conditions comprised asthma (16.6%) and allergic rhinitis (2.4%); family history of atopy was reported in 35.5% (Table 1).

Of the OFCs, 82 (26.5%) were diagnostic (suspected sensitization based on history and positive SPT/sIgE), and 228 (73.5%) were for tolerance assessment in previously diagnosed patients. The most frequently challenged foods were eggs (47.5%), milk or dairy (36.5%), tree nuts (7.5%), legumes (6.7%), and seafood (2.3%) (Table 1).

Oral food challenge outcomes

The positivity rate of OFCs was 12.3% (38/310). Diagnostic OFCs had a higher positivity rate (18.3% [15/82]) than tolerance-assessment OFCs (10.1%, $P = 0.048$). The most common elicitors were milk or dairy (44.7%), tree nuts (23.6%), and eggs (18.4%), followed by legumes (5.3%), sesame (5.3%), and fish (2.6%) (Figure 2).

Reactions occurred at a median cumulative protein dose of 43 mg (IQR: 13–43) and median step 3 (IQR: 2–4). Lower thresholds were observed for peanut or sesame (8 mg, Step 2) and fish (3 mg, Step 1). Symptom onset was within 1 h in 60.5% and 1–6 h in 39.5%. Cutaneous symptoms predominated (94.7%), followed by gastrointestinal (10.6%), respiratory (7.9%), cardiovascular (7.9%), and neurological (5.3%) manifestations (Table 2).

Table 1 Demographic and clinical characteristics of patients and OFC results.

	Value
Gender, n (%)	
Female	78 (37.0)
Male	133 (63.0)
Age at first visit (months), median (IQR)	9 (5–14.7)
Age at OFC (months), median (IQR)	21 (14–37.3)
Follow-up duration (months), median (IQR)	11 (1.2–21.8)
Symptoms at first visit, n (%)	
Eczema	151 (71.6)
Urticaria	43 (20.4)
Anaphylaxis	17 (8.1)
Concomitant atopic disease, n (%)	
Asthma	35 (16.6)
Allergic rhinitis	5 (2.4)
Family history of atopy, n (%)	75 (35.5)
Food allergy, n (%)	
Single food allergy	146 (69.2)
Multiple food allergies	65 (30.8)
Eosinophil count (cells/μL), median (IQR)	270 (190–470)
Eosinophil percentage (%), median (IQR)	3.1 (2.1–5.0)
Total IgE (kU/L), median (IQR)	60.6 (17.6–156.5)
Food-specific IgE at first visit (kU/L), median (IQR)	
Milk	4.07 (1.2–9.7)
Casein	0.71 (0.35–4.1)
Egg white	3.08 (0.98–9.03)
Egg yolk	1.72 (0.77–4.6)
Wheat	4.59 (0.49–6.9)
Tree nuts (walnut, hazelnut, pistachio, cashew)	1.07 (0.58–4.35)
Foods tested in OFC, n (%)	
Egg	147 (47.5)
Milk or dairy products	113 (36.5)
Tree nuts (walnut, hazelnut, pistachio, cashew)	23 (7.5)
Legumes	21 (6.7)
Seafood	7 (2.3)
Aim of the OFC, n (%)	
Diagnosis of food allergy	82 (26.5)
Tolerance development	228 (73.5)
OFC results, n (%)	
Positive	38 (12.3)
Negative	272 (87.7)

IQR: Interquartile Range; OFC: Oral Food Challenge; IgE: Immunoglobulin E. Values are presented as n (%) for categorical variables and median (IQR) for continuous variables.

Serious reactions

Anaphylaxis occurred in 13.2% (5/38) of positive OFCs, triggered by milk or dairy (n = 4) and walnut (n = 1). Notably, 60% (3/5) had comorbid eczema, and all had sIgE <15 kUA/L and SPT wheal ≤9 mm, which highlighted the limited predictive value of sensitization markers for severe reactivity.

Predictors of OFC positivity

Oral food challenge–positive patients were older (median: 25.5 vs 20 months; P = 0.009) and had longer follow-up durations (median: 12 vs 11 months; P = 0.046). Initial presentation with urticaria (55.3% vs 8.1%; P < 0.001) or anaphylaxis (13.2% vs 4.4%; P < 0.001) was associated with OFC positivity, whereas eczema was more common in OFC-negative cases (31.6% vs 87.5%; P = 0.043). No significant differences were observed in sex, concomitant atopic diseases, total IgE levels, or eosinophil counts (all P > 0.05) (Table 4). Multivariate logistic regression identified milk or dairy (OR: 3.326, 95% CI: 1.437–7.702, P = 0.005), sesame (OR: 7.022, 95% CI: 1.194–41.311, P = 0.031), and hazelnut (OR: 11.286, 95% CI: 3.858–33.017, P < 0.001) as independent predictors of OFC positivity.

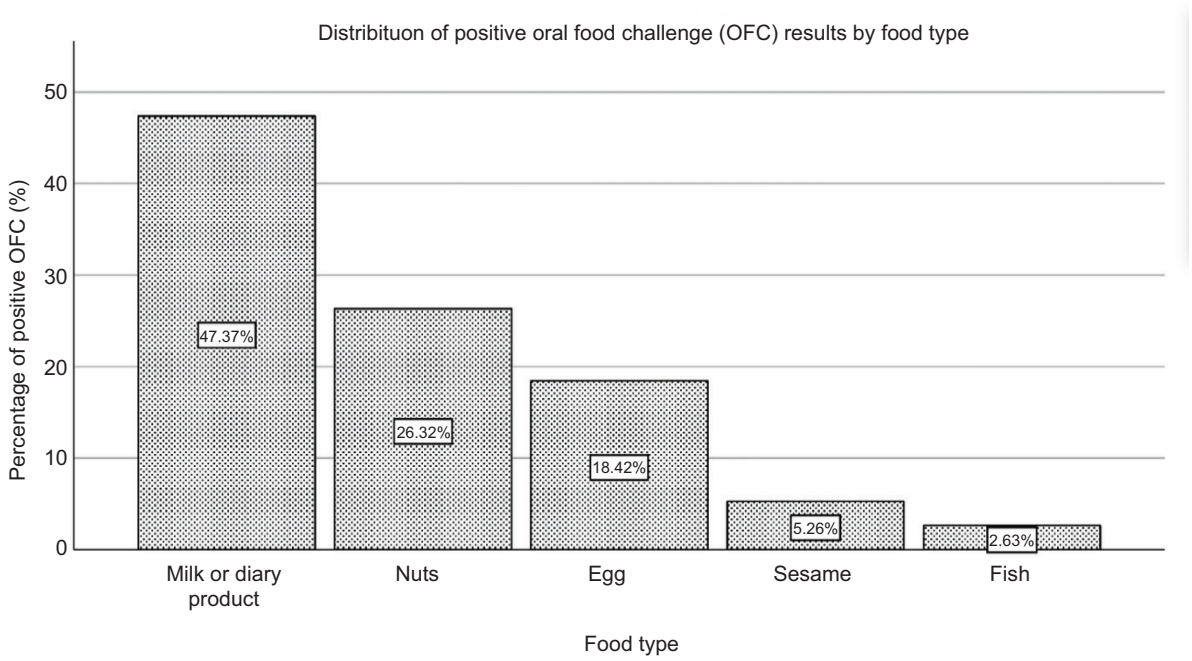

Figure 2 Distribution of foods associated with positive oral food challenge results.

Discussion

This analysis of 310 OFCs in 211 children yielded valuable insights into pediatric IgE-mediated food allergy outcomes. The positivity rate of 12.3% is lower than the 33% reported by Abrams et al.,[13] which likely stems from the inclusion of baked or fermented milk and eggs (often tolerated due to protein denaturation[14]) and the exclusion of patients with recent severe reactions. The most frequently challenged foods, egg (47.5%), milk or dairy (36.5%), and tree nuts (7.5%), align with prevalent pediatric allergens.[6]

Oral food challenge–positive children were older (P = 0.009) and had longer follow-up (P = 0.046), consistent with delayed resolution of milk and egg allergies. Initial urticaria (P < 0.001) or anaphylaxis (P < 0.001) strongly predicted positivity, corroborating links between prior severe reactions and persistent clinical reactivity.[11] Conversely, eczema was associated with OFC negativity (P = 0.043), likely reflecting the predominance of baked milk or egg challenges in this subgroup, where sensitization rarely translates to clinical allergy.[15] This contrasts with Jacob et al.,[16] who reported increased reactivity risk with eczema (OR 1.99, particularly to peanut [OR 3.2]), underscoring allergen- and context-specific effects that warrant further study.

Anaphylaxis occurred in 13.2% (5/38) of positive OFCs (milk/dairy: n = 4; walnut: n = 1), despite sIgE <15 kUA/Land SPT wheal ≤9 mm in all cases, reinforcing the poor predictive value of sensitization markers for severe reactions.[4,10] Notably, 60% (3/5) had comorbid eczema, aligning with Perry et al.'s 11% anaphylaxis rate in low-sIgE patients.[17] These observations highlight the indispensable role of OFCs in unmasking latent risks and the imperative for immediate epinephrine access and trained personnel.[7,18]

Multivariate logistic regression identified milk/dairy (OR 3.326, 95% CI 1.437–7.702, P = 0.005), sesame (OR 7.022, 95% CI 1.194–41.311, P = 0.031), and hazelnut (OR 11.286, 95% CI 3.858–33.017, P < 0.001) as independent predictors of OFC positivity. The pronounced associations with sesame and hazelnut reflect regional dietary exposure in the Eastern Mediterranean, where early and frequent consumption sustains reactivity.[19] These findings parallel Brough et al.'s multicenter data on elevated risks for sesame and tree nuts[20] and underscore hazelnut's persistence as a high-risk allergen.[19-21]

The clinical implications of our findings are significant for allergy management. OFCs not only confirm diagnoses but also prevent unnecessary dietary restrictions, improving the quality of life for children and families.[1] By identifying the determinants of OFC positivity, clinicians can customize protocols, prioritize closer monitoring of children with a history of severe reactions, and consider testing at earlier stages to confirm tolerance in those with eczema.

These insights are particularly valuable in regions such as the Middle East, where food allergy management is evolving, and standardized protocols are needed to address the rising prevalence.[10]

Limitations include the retrospective, single-center design, which potentially introduces selection bias, mitigated by standardized protocols and limiting generalizability beyond Mediterranean diets. Reliance on prick-to-prick testing may reduce reproducibility, though it mirrors real-world practice. The small anaphylaxis cohort (n = 5) precludes robust severe reaction modeling. Multicenter prospective studies are essential in validating these predictors and refining OFC strategies.

Table 2 Characteristics of patients with positive OFC results.

	Value
Time to OFC positivity (minutes), median (IQR)	42.5 (15–70)
Step of OFC positivity, median (IQR)	3 (2-5)
Foods associated with positive OFC, n (%),Cumulative protein (mg) median (IQR), Positive Stage, median (IQR)	
Milk or dairy products	17 (44.7)
Tree nuts (walnut, hazelnut, pistachio, cashew)	9 (23.6)
Egg	7 (18.4)
Legumes	2 (5.3)
Sesame	2 (5.3)
Fish	1 (2.6)
Foods Cumulative protein (mg) median (IQR)/ Step of OFC median (IQR)	
Milk or dairy products	43 mg (13–143)/3 (2–4)
Walnut	43 mg (13–143)/3 (2–4)
Hazelnut	43 mg (3–43)/3 (1–3)
Egg	43 mg (13–43)/3 (2–3)
Legumes	8 mg (3–13)/2 (1–2)
Sesame	8 mg (3–13)/2 (1–2)
Fish	3 mg (3–3)/1 (1–1)
Anaphylaxis, n (%)	5 (13.2)
Symptoms during positive OFC, n (%)	
Cutaneous	36 (94.7)
Pruritus	29 (76.3)
Urticaria	16 (44.4)
Angioedema	3 (8.3)
Respiratory	3 (7.9)
Cough	3 (50.0)
Tachypnea	3 (50.0)
Gastrointestinal	4 (10.6)
Nausea/vomiting	3 (75.0)
Abdominal pain	1 (25.0)
Neurological	2 (5.3)
Syncope (with normal blood pressure)	2 (100.0)
Cardiovascular	3 (7.9)
Tachycardia	1 (33.3)
Bradycardia	1 (33.3)
Hypotension	1 (33.3)

IQR: Interquartile Range; OFC: Oral Food Challenge. Values are presented as n (%) for categorical variables and median (IQR) for continuous variables. Time to OFC positivity is measured in minutes.

Conclusion

Oral food challenges remain the gold standard for diagnosing and managing pediatric IgE-mediated food allergies. This study demonstrates that severe reactions, including anaphylaxis, can occur despite low sensitization markers. Milk, sesame, and hazelnut are identified as the robust predictors of reactivity, particularly in regions with high exposure. Cutaneous symptoms predominated, yet multisystem involvement underscored reaction unpredictability. These findings reinforce the need for risk-stratified, vigilantly monitored OFCs to ensure safety, facilitate tolerance confirmation, and personalize management, ultimately improving outcomes for children and families.

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Mandatory Disclosure on Use of Artificial Intelligence

The authors declare that no AI-assisted tools were used in the preparation of this manuscript. All references have been manually verified for accuracy and relevance.

Table 3 Clinical features of patients with anaphylaxis during OFC.

	Case 1	Case 2	Case 3	Case 4	Case 5
Age at OFC (months)	38	24	9	18	44
Symptom at first visit	Eczema	Urticaria	Eczema	Eczema	Urticaria
Follow-up duration (months)	30	18	5	14	33
Age at first visit (months)	8	6	4	4	11
Aim of the OFC	Tolerance development	Tolerance development	Diagnosis	Tolerance development	Tolerance development
Single/Multiple food allergy	Multiple	Multiple	Single	Multiple	Multiple
Food allergens tested	Cow's milk, Egg	Cow's milk, Egg, Sesame	Cow's milk	Cow's milk, Egg, Legumes	Cow's milk, Egg, Legumes, Tree nuts
OFC food tested	Cow's milk	Cow's milk	Yoghurt	Yoghurt	Walnut
sIgE (kIU/L)	Cow's milk: 4.4, Casein: 0.8	Cow's milk: 1.8, Casein: 1.2	Cow's milk: 4.8, Casein: 0.3	Cow's milk: 11.8, Casein: 1.9	Walnut: 1.6
SPT (mm)	Cow's milk: 4	Cow's milk: 6	Cow's milk: 9	Cow's milk: 6	Walnut: 4
Step of OFC	2	1	3	3	1
Cumulative dose protein (mg)	13	3	43	43	3
Symptoms	Urticaria, Cough, Tachypnea, Vomiting	Urticaria, Cough, Tachypnea, Tachycardia	Urticaria, Vomiting, Syncope	Urticaria, Bradycardia, Hypotension, Syncope	Urticaria, Cough, Tachypnea
Grade of anaphylaxis	Grade 2	Grade 2	Grade 3	Grade 3	Grade 2
Medications administered	Adrenaline, Salbutamol, Antihistamine, IV hydration, Ondansetron	Adrenaline, Salbutamol, Antihistamine	Adrenaline, IV hydration	Adrenaline, IV hydration	Adrenaline, Salbutamol, Antihistamin

OFC: Oral Food Challenge; sIgE: Specific Immunoglobulin E; SPT: Skin Prick Test; IV: Intravenous. Values are presented as n (%) for categorical variables. Anaphylaxis grades are based on Sampson's clinical severity criteria. Anaphylaxis diagnosis was based on EAACI guidelines.[9]

Table 4 Comparison of patients with positive and negative OFC results.

Characteristic	OFC-Positive Patients (n=38)	OFC-Negative Patients (n=272)	p-value
Male, n (%)	23 (60.5)	170 (62.5)	0.814
Age at OFC (months), median (IQR)	25.5 (19–47.5)	20 (14–34)	0.009*
Age at first visit (months), median (IQR)	12 (6–20)	9 (5–14)	0.213
Follow-up duration (months), median (IQR)	12 (8–29)	11 (1–19)	0.046*
Food allergy, n (%)			
Single food allergy	22 (57.9)	174 (64.0)	0.467
Multiple food allergies	16 (42.1)	98 (36.0)	
Symptoms at first visit, n (%)			
Eczema	12 (31.6)	238 (87.5)	0.043*
Urticaria	21 (55.3)	22 (8.1)	<0.001*
Anaphylaxis	5 (13.2)	12 (4.4)	<0.001*
Asthma, n (%)	5 (13.2)	43 (15.8)	0.666
Allergic rhinitis, n (%)	1 (2.6)	7 (2.6)	1.000
Family history of atopy, n (%)	17 (44.7)	89 (32.7)	0.144
Total IgE (kU/L), median (IQR)	70 (34–158.3)	58 (14.9–157.5)	0.189
Eosinophil count (cells/μL), median (IQR)	270 (195–445)	270 (187.5–490)	0.835
Eosinophil percentage (%), median (IQR)	3.7 (2.5–5.7)	3 (2–4.9)	0.244

*IQR: Interquartile Range; OFC: Oral Food Challenge; IgE: Immunoglobulin E. Values are presented as n (%) for categorical variables and median (IQR) for continuous variables. p<0.05 indicates statistical significance.

Author Contributions

All authors contributed equally to this article.

Conflicts of Interest

The authors declare no conflicts of interest.

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