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The clinical burden of food allergies: Insights from the Food Allergy Research & Education (FARE) Patient Registry

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ABSTRACT

Background: Food allergies are serious and potentially life-threatening, and often place a large burden on patients and their caregivers, including impacts on quality of life.

Objective: To assess the real-world patient burden of food allergies, using self-reported data available from the Food Allergy Research & Education (FARE) Patient Registry (NCT04653324).

Methods: The FARE Patient Registry is voluntary and captures real-world experiences of adults and pediatric patients in the United States, and their caregivers, through a series of surveys assessing patient health and experiences with food allergies. Self-reported data were descriptively analyzed.

Results: The FARE study cohort included 5587 patients with food allergies; 82% had multiple food allergies and 62% were aged <18 years. About half of the patients were first diagnosed by an allergist/immunologist (53%), most commonly with a skin prick test (71%) or a serum immunoglobulin E test (62%). This analysis found that food allergies (most commonly peanut [66%], tree nuts [61%], egg [43%], and milk [37%]) impart a large clinical burden on patients, many of whom experience food-related allergic reactions and comorbidities. Many patients experienced >1 food-related allergic reaction per year (42%), with 46% experiencing food-induced anaphylaxis. Half of all food-related allergic reactions occurred at home. Accidental exposures to food allergens were experienced by 77% of patients. The most common allergic comorbidities reported by patients with food allergies were atopic dermatitis (48%), asthma (46%), and allergic rhinitis (39%). The clinical burden of food allergies were found to be greater in patients with multiple food allergies, and different for adults versus pediatric patients.

Conclusion: This is the first study to assess patient experience and disease burden information from patients contributing to the FARE Patient Registry, thus providing a unique insight into the lives of patients in the United States with food allergies. These insights may assist clinicians and other public health stakeholders in the management of patients with food allergies.

Keywords: Food hypersensitivity, Food allergy, Allergic reaction, Clinical burden, Anaphylaxis

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INTRODUCTION

Food allergies are estimated to affect up to 11% of the population in the United States,[1-3] and allergic reactions can be caused by accidental exposure to 1 or more of over 160 food allergens recognized by the US Food and Drug Administration.[4] The most common food allergens leading to reactions include milk, egg, peanut, tree nuts, soybean, wheat, fish, shellfish, and sesame.[4] Food allergies can be life-threatening, and often place a large burden on patients and their caregivers,[5] including impacts on quality of life.[6-8]

To assess the patient burden of food allergies, we utilized self- and caregiver proxy-reported data available from the Food Allergy Research & Education (FARE) Patient Registry, the largest registry in the world of patients with food allergies. The FARE Patient Registry is voluntary and collects data from patients and their caregivers, assessing patient health and experiences with food allergies through a series of surveys.[9] The FARE Patient Registry has previously been used to evaluate allergic reaction frequency, biphasic reactions, characteristics of food allergy reactions in restaurants, food allergy characteristics associated with co-existing eosinophilic esophagitis, and food allergy symptoms in adults and children.[10-14] Thus, the FARE Patient Registry provides a unique opportunity to understand the burden of food allergies on patients, with a focus on diagnosis, food-related allergic reactions, and allergic comorbidities. Here, we extend previous studies reporting on the FARE Patient Registry to focus on diagnosis, reactions, and comorbidities, and to consider the implications of having multiple food allergies.

METHODS

The Food Allergy Research & Education (FARE) Patient Registry: A Registry for the Food Allergy Community (NCT04653324)[9] was the primary data source for this prospective, observational study, with a target follow-up duration of 5 years. Ethics approval was secured and informed consent was obtained from patients prior to the completion of the surveys.

For the current analysis, data were collected between May 2017 and March 2021 and there were an estimated >13 000 Registry participants at the time of data analysis. De-identified data from patients of all ages were included in this analysis. Patient inclusion criteria were voluntary completion of the online survey (N = 6166); United States residency; reporting $\geq$1 food allergy without discordant data for single food allergy; and reporting age at diagnosis. Patients with multiple food allergies were defined as having an allergy to >1 food allergen type. Tree nuts, defined as almond, Brazil nut, cashew, chestnut, coconut, hazelnut, macadamia nut, pecan, pine nut, pistachio, walnut, and other tree nuts, were grouped as 1 allergen type. Seeds, defined as fennel, flaxseed, mustard, poppy, pumpkin, sesame, sunflower, and other seeds, were grouped as 1 allergen type. Shellfish, defined as clam, crab, crayfish, lobster, octopus, oyster, scallop, squid, shrimp, and other shellfish, were grouped as 1 allergen type. For analysis of allergic comorbidities by food allergen, patients with a single food allergy to either peanuts, tree nuts, egg, milk, or shellfish were included in the analysis.

Data were obtained from the Food Allergy History and Food Allergy Reactions surveys in the FARE Patient Registry, which were administered once per registry participant. For each survey question, patients were given a list of selections to choose from or were asked to specify when the selection was not available (excerpts from the FARE surveys are provided as Supplementary Methods). "Self-reported" refers to data that were either self-reported by the patient or reported by the caregiver (usually reported by a parent or legal guardian for pediatric patients).

A descriptive analysis of outcomes was conducted; no formal statistical hypothesis testing was performed. For allergic comorbidities, rates were calculated using the total person-years of disease duration (defined as the age at survey completion minus age at diagnosis for each patient), the total person-years that the allergic comorbidity was experienced, and the total number of patients with food allergies. Rates were multiplied by 100 for ease of interpretation.

RESULTS

Patient characteristics

From the FARE Patient Registry, 5587 patients with food allergies were included in the study cohort (Table 1). Most patients in the study were White (78%), and over half were female (56%). The majority of patients were diagnosed with food allergies before 6 years of age (73%), and most patients reported multiple food allergies (82%) (Table 2). For patients with multiple food allergies, the mean (standard deviation [SD]) number of allergies was 4.26 (2.25) and the median number of allergens was 4 (range 2–14). The majority of patients in the FARE Patient Registry were pediatric (62%) and most needed a parent/caregiver to fill out their survey (Table 3). At the time of survey completion, most patients with food allergies had not outgrown or developed tolerance against food allergies (71%) (Tables 1–3), especially patients with a single food allergy (90%) (Table 2).

Diagnosis of food allergy

About half of all patients were first diagnosed by an allergist/immunologist (53%) (Fig. 1A). Of patients who had a diagnostic test (98.2%, 5577/5587), the initial tests were primarily a skin prick test (71%) or a serum test of allergen-specific immunoglobulin E antibody levels (62%); few patients had completed an oral food challenge (6.7%) (Fig. 1B). The most common food allergy diagnoses were peanut (66%), tree nuts (61%), egg (43%), milk (37%), soy (20%), seeds (20%), and shellfish (20%).

Food-related allergic reactions

Many patients with food allergies experienced more than 1 reaction per year (42%, 2343/5587) (Fig. 2A). Nearly half of all patients reported previously experiencing a reaction that involved anaphylaxis (46%), and 38% of patients experienced a severe or very severe reaction as their most recent reaction (Table 4). Allergic

Characteristic, n (%)[a]	Patients with food allergies (n = 5587)
Female	3139 (56)
White	4379 (78)
Age at diagnosis,[b] mean (SD)	8 (15)
0–1 y	3008 (54)
2–5 y	1074 (19)
6–10 y	219 (3.9)
11–17 y	185 (3.3)
18–26 y	327 (5.9)
27–64 y	751 (13)
≥65 y	23 (0.4)
Diagnosis at <6 years of age	4082 (73)
Duration of disease,[c] y, mean (SD)	11 (11)
Multiple food allergies	4594 (82)
Outgrew or developed tolerance[d]	1645 (29)
FARE survey respondent	
Self	1907 (34)
Parent	3442 (62)
Other caregiver	238 (4.3)

Table 1. Characteristics of patients with food allergies. *FARE, Food Allergy Research & Education; SD, standard deviation; y, years. [a]Unless stated. [b]Age at diagnosis is reported in response to the survey question,* "At what age was the participant diagnosed by a healthcare provider with a food allergy?" *[c]Duration of disease was calculated as the age at survey completion minus the age at diagnosis for each patient. [d]Reported in response to the survey question,* "Has the participant outgrown or developed tolerance (not allergic) to any food/food groups that previously produced an allergic reaction?"

Characteristic, n (%)[a]	Patients with single FA (n = 993)	Patients with multiple FA (n = 4594)
Female	604 (61)	2535 (55)
White	808 (81)	3571 (78)
Age at diagnosis,[b] mean (SD)	9 (15)	8 (14)
0–1 y	422 (42)	2586 (56)
2–5 y	253 (25)	821 (18)
6–10 y	67 (6.7)	152 (3.3)
11–17 y	36 (3.6)	149 (3.2)
18–26 y	62 (6.2)	265 (5.8)
27–64 y	142 (14)	609 (13)
≥65 y	11 (1.1)	12 (0.3)
Diagnosis at <6 years of age	675 (68)	3407 (74)
Duration of disease,[c] y, mean (SD)	9 (11)	11 (11)
≥1 reaction per year	404 (41)	2635 (57)
Experienced anaphylaxis	369 (37)	2187 (48)
Outgrew or developed tolerance	96 (9.7)	1549 (34)
Comorbidities		
Atopic dermatitis	326 (33)	2374 (52)
Asthma	320 (32)	2260 (49)
Allergic rhinitis	280 (28)	1921 (42)
FARE survey respondent		
Self	340 (34)	1567 (34)
Parent	600 (60)	2842 (62)
Other caregiver	53 (5.3)	185 (4.0)

Table 2. Characteristics of patients with single versus multiple food allergies. *FA, food allergies; FARE, Food Allergy Research & Education; SD, standard deviation; y, years.* [a]*Unless stated.* [b]*Age at diagnosis is reported in response to the survey question, "At what age was the participant diagnosed by a healthcare provider with a food allergy?"* [c]*Duration of disease was calculated as the age at survey completion minus the age at diagnosis for each patient.*

reactions and anaphylaxis were most frequent in patients with multiple food allergies, and in adult patients (Tables 2 and 3). The most common location where patients experienced their most recent allergic reaction was at home (50%) (Fig. 2B). Reactions outside the home mostly occurred at restaurants or while eating out (22%), at school (4.3%), or at work (3.5%) (Fig. 2B). Most patients were exposed through ingestion (86%), though some exposures also occurred through skin contact (7.5%) or inhalation (3.2%) (Table 4). Notably, unintentional (accidental) exposures were experienced by 77% of patients (2758/3586), including via cross-contact with the food allergen (29%), consuming a suspected new food allergen in food previously eaten without a reaction (17%), the food allergen not being listed on the label (15%), and after informing staff of food allergies but the reaction still occurring (15%) (Fig. 2C). Almost half of the patients were exposed via a manufactured or pre-packaged product (48%) (Table 4). Patients most frequently sought help from family and friends (27%) and emergency departments (18%) during a reaction (Fig. 2D). More than half of patients had previously visited an emergency department for food allergies (60%, 3252/5444), and 22% of patients have been hospitalized (1160/5300). Some patients did not seek help during a reaction (17%) (Fig. 2D). Most patients carried 2 epinephrine

Characteristic, n (%)[a]	Adult patients (n = 2098)	Pediatric patients (n = 3489)
Female	1791 (85)	1348 (39)
White	1720 (82)	2659 (76)
Age at diagnosis,[b] mean (SD)	20 (18)	1 (2)
0–1 y	392 (19)	2616 (75)
2–5 y	337 (16)	737 (21)
6–10 y	125 (6.0)	94 (2.7)
11–17 y	143 (6.8)	42 (1.2)
18–26 y	327 (16)	0
27–64 y	751 (36)	0
≥65 y	23 (1.1)	0
Duration of disease,[c] y, mean (SD)	18 (15)	6.1 (4.8)
Multiple food allergies	1719 (82)	2875 (82)
≥1 reaction per year	1345 (64)	1694 (49)
Experienced anaphylaxis	1112 (53)	1444 (41)
Outgrew or developed tolerance	452 (22)	1193 (34)
Comorbidities		
Atopic dermatitis	685 (33)	2015 (58)
Asthma	1179 (56)	1401 (40)
Allergic rhinitis	1126 (54)	1075 (31)
FARE survey respondent		
Self	1846 (88)	61 (1.7)
Parent	64 (3.1)	3378 (97)
Other caregiver	188 (9.0)	50 (1.4)

Table 3. Characteristics of adult versus pediatric patients with food allergies. *FARE, Food Allergy Research & Education; SD, standard deviation; y, years.* [a]*Unless stated.* [b]*Age at diagnosis is reported in response to the survey question,* "At what age was the participant diagnosed by a healthcare provider with a food allergy?" [c]*Duration of disease was calculated as the age at survey completion minus the age at diagnosis for each patient.*

auto-injectors (65%, 2325/3580), though almost all only required 1 dose of epinephrine (83%, 671/809) to treat the initial food allergy reaction.

Allergic comorbidities

The most common allergic comorbidities in patients with food allergies were atopic dermatitis (48%), asthma (46%), allergic rhinitis (39%), contact dermatitis (14%), and eosinophilic esophagitis (5%) (Fig. 3A, Table 5). These allergic comorbidities were more frequent in patients with multiple food allergies than patients with a single food allergy (Table 5). Atopic dermatitis was observed most commonly in patients with a single food allergy to peanut and in pediatric patients (Fig. 3B, Table 3). For asthma and allergic rhinitis, adult patients had a higher incidence than pediatric patients (Table 3), with asthma being most frequent in patients with a milk allergy (Fig. 3C), and allergic rhinitis being most frequent in patients with a shellfish allergy (Fig. 3D). Contact dermatitis was observed at similar levels across different food allergies (Fig. 3E). Although observed at low levels in the FARE cohort, eosinophilic esophagitis was most frequent in patients with a single food allergy to milk (Fig. 3F).

DISCUSSION

To our knowledge, this is the first study to assess the patient experience and clinical burden of food allergies (beyond reaction frequency and symptoms) from patients contributing to the FARE Patient Registry, which is the largest, most

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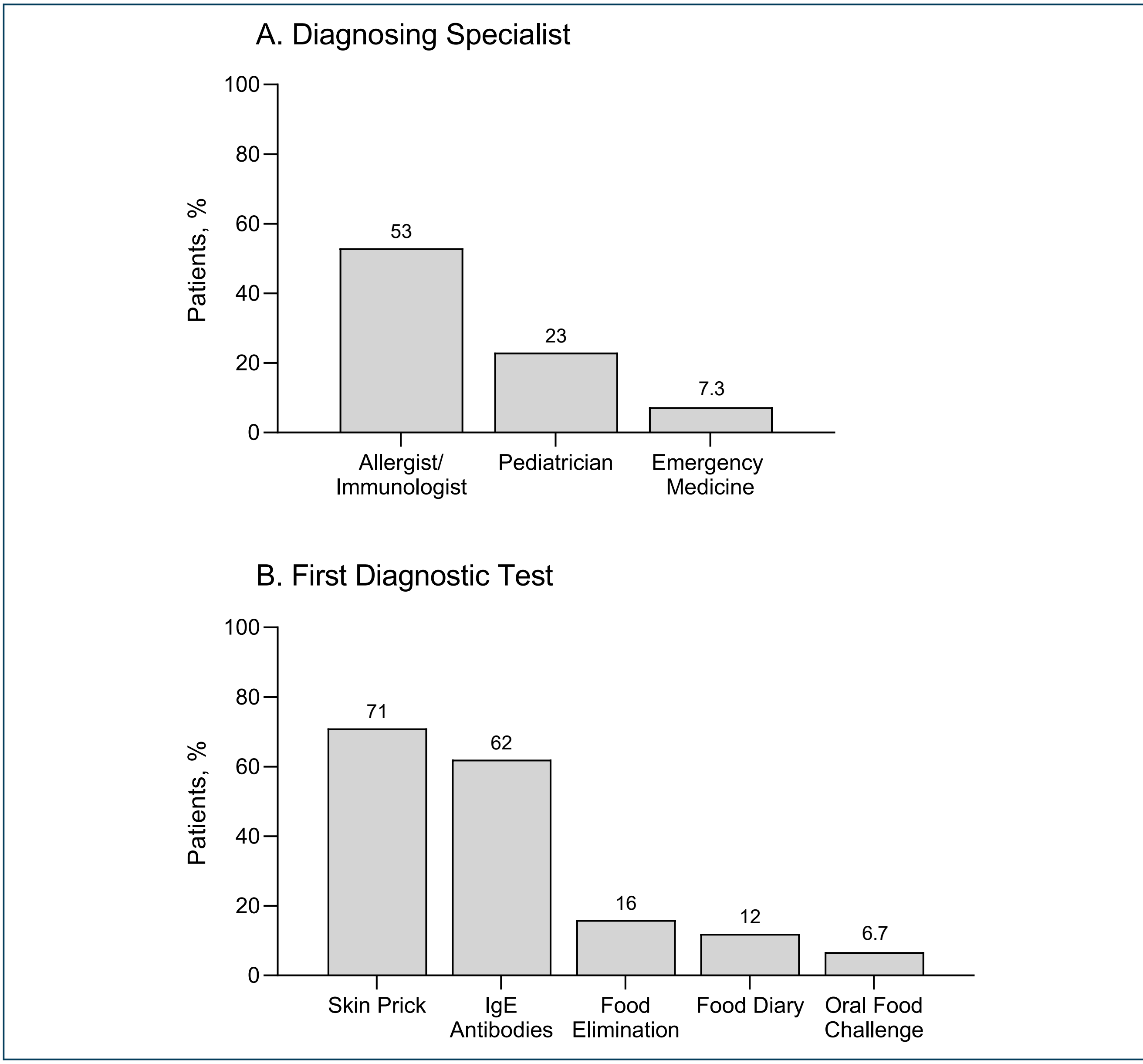

Fig. 1 Diagnosis of patients with food allergies (n = 5587). **A.** Response to the survey question, "*What type of doctor or healthcare provider first made the food allergy diagnosis?*" **B.** Response to the survey question, "*Which of the following diagnostic tests were performed to FIRST diagnose the food allergy or allergies? (Select all that apply)*". *Percent of patients with a diagnostic test

comprehensively phenotyped registry of patients with food allergies in the United States. We found that patients with food allergies experience a high frequency of clinical events and allergic comorbidities, and that the clinical burden may be greater in patients with multiple food allergies, and different for adults versus pediatric patients. Of note, this analysis uniquely highlights that patients with food allergies may experience different allergic comorbidities based on the type of food allergen, which may assist clinicians with diagnosis and management.

The real-world experiences of patients in the FARE Patient Registry are generally in alignment with previous studies on the burden of food allergies. For example, in the FARE cohort, peanuts and tree nuts were the most common food allergens, and studies have shown that these have been associated with more severe reactions and a significant burden on patients.[2,15–17] We also found that atopic dermatitis was the top allergic comorbidity in the FARE cohort; this is associated with increased risk for developing food allergy[18,19] and may also worsen upon exposure

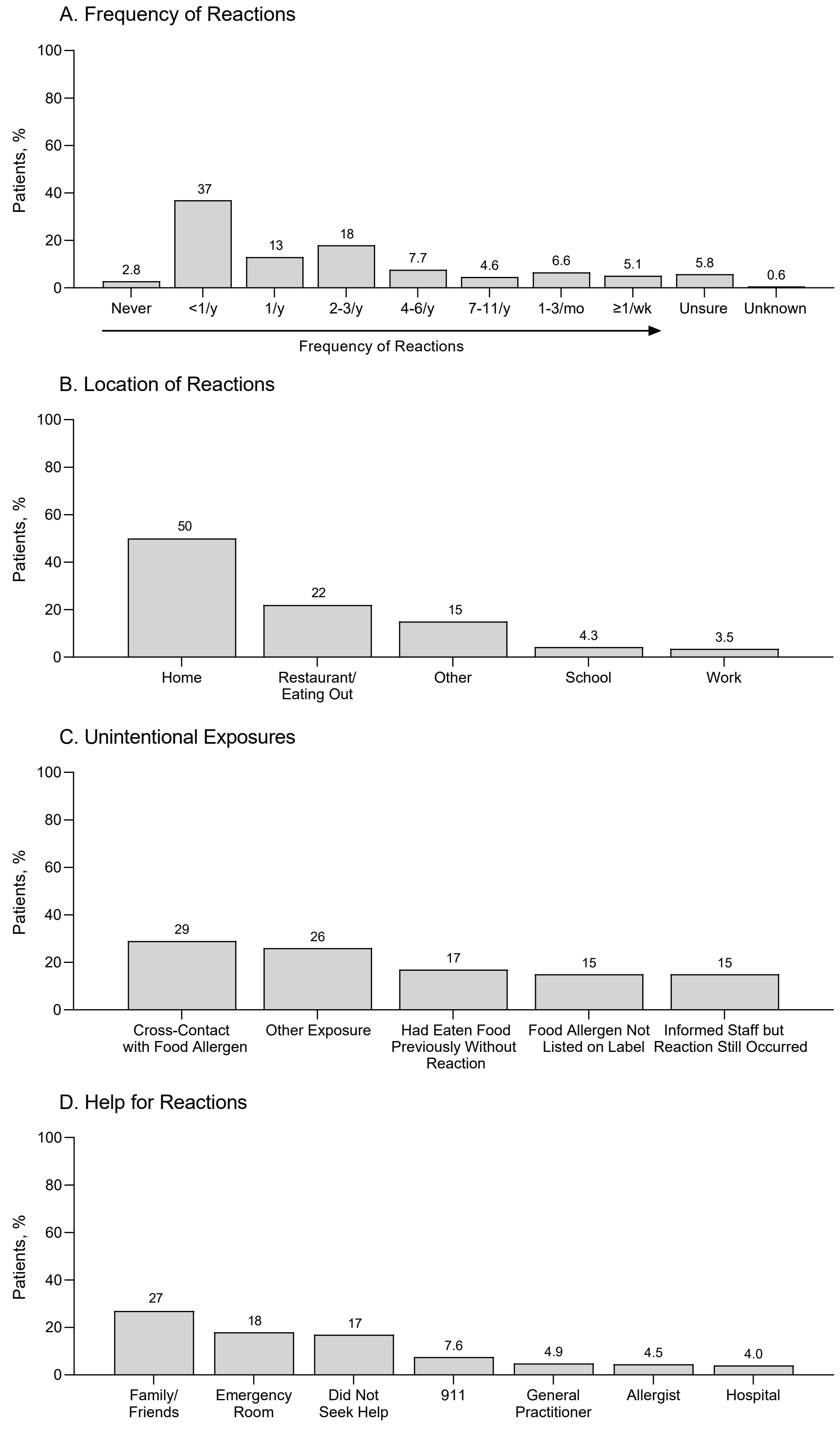

Fig. 2 Reactions in patients with food allergies. **A.** Response to the survey question, "*On average, how many food allergy reactions does the participant have per year?*" (n = 5587). Frequency of reactions in patients with food allergies were reported, including unsure and missing data. **B.** Response to the survey question, "*Where did the participant's most recent allergic reaction to foods occur?*" (n = 5587). **C.** Response to the survey question, "*Why do you think the participant experienced this unintentional (accidental) reaction? (Select all that apply)*" (n = 2758). **D.** Response to the survey question, "*Where or from whom did the participant receive help during the allergic reaction? (Select all that apply)*" (n = 5587). *y*, year; *wk*, week; *mo*, month

Characteristic, n (%)	Patients with food allergies (n = 5587[a])
Severity of most recent reaction[b]	
Mild	935 (26)
Moderate	1243 (35)
Severe	929 (26)
Very severe	440 (12)
Experienced anaphylaxis in any previous reaction	2556 (46)
Experienced a reaction within 5 min of exposure[c]	2334 (50)
Exposure route[d]	
Ingestion	3079 (86)
Inhalation	116 (3.2)
Skin contact	268 (7.5)
Unintentional (accidental) allergen exposure[e]	2758 (77)
Exposed via manufactured or pre-packaged product[e]	1724 (48)
No information to indicate potential exposure to the allergen	929 (17)

Table 4. Characteristics of food-related allergic reactions. [a]*Unless stated.* [b]*n = 3577, excluding unknown.* [c]*n = 4646, excluding unknown.* [d]*n = 3576, excluding unknown.* [e]*n = 3586, excluding unknown.*

to certain food allergens.[20,21] Analysis of the FARE Patient Registry also suggests that patients with a milk allergy could be particularly prone to comorbid asthma and eosinophilic esophagitis, which extends upon previous findings on the burden of milk allergy using insights from a larger registry population.[22]

Our study also highlights additional insights into the burden of food allergies, with half of all allergic reactions occurring outside the home, and the majority of reactions occurring after unintentional exposures, suggesting that further efforts to promote effective allergen avoidance may be helpful.[23] Of note, 82% of patients in the FARE Patient Registry reported multiple food allergies, which is substantially higher than that reported by previous studies (30–48%).[2,3,24,25] This may reflect patients who are more likely to engage with FARE; in addition, these patients may be more likely to consult with an allergist who may recommend avoidance of additional foods and/or complete further diagnostic testing, thus leading to higher reports of multiple food allergies. Our study also improves the understanding of food allergies in adult patients, a currently understudied area, and suggests that adult patients may need additional management strategies for comorbid asthma and allergic rhinitis.

There are several limitations to this study. The FARE Patient Registry is voluntary, meaning patients/caregivers with more severe food allergies were more likely to consult an allergist/immunologist, access the patient advocacy website, and receive information about the registry. The data are also self- and caregiver proxy-reported and could be subject to recall and other relevant biases, and food allergies did not need to be documented or confirmed by a physician so could have been IgE- or non-IgE-mediated. Furthermore, most respondents were White and may have been from a higher socioeconomic background; therefore, these findings may not be representative of all patients in the United States with food allergies.[2]

In conclusion, our assessment of FARE data found that a large burden of disease is placed on patients with food allergies, particularly allergic reactions and comorbidities. In addition, the findings suggest that patients with multiple food allergies may require elevated care, and that adults and pediatric patients may have differing clinical needs. Given most patients in FARE reported the onset of food allergy at a very young age and had not outgrown

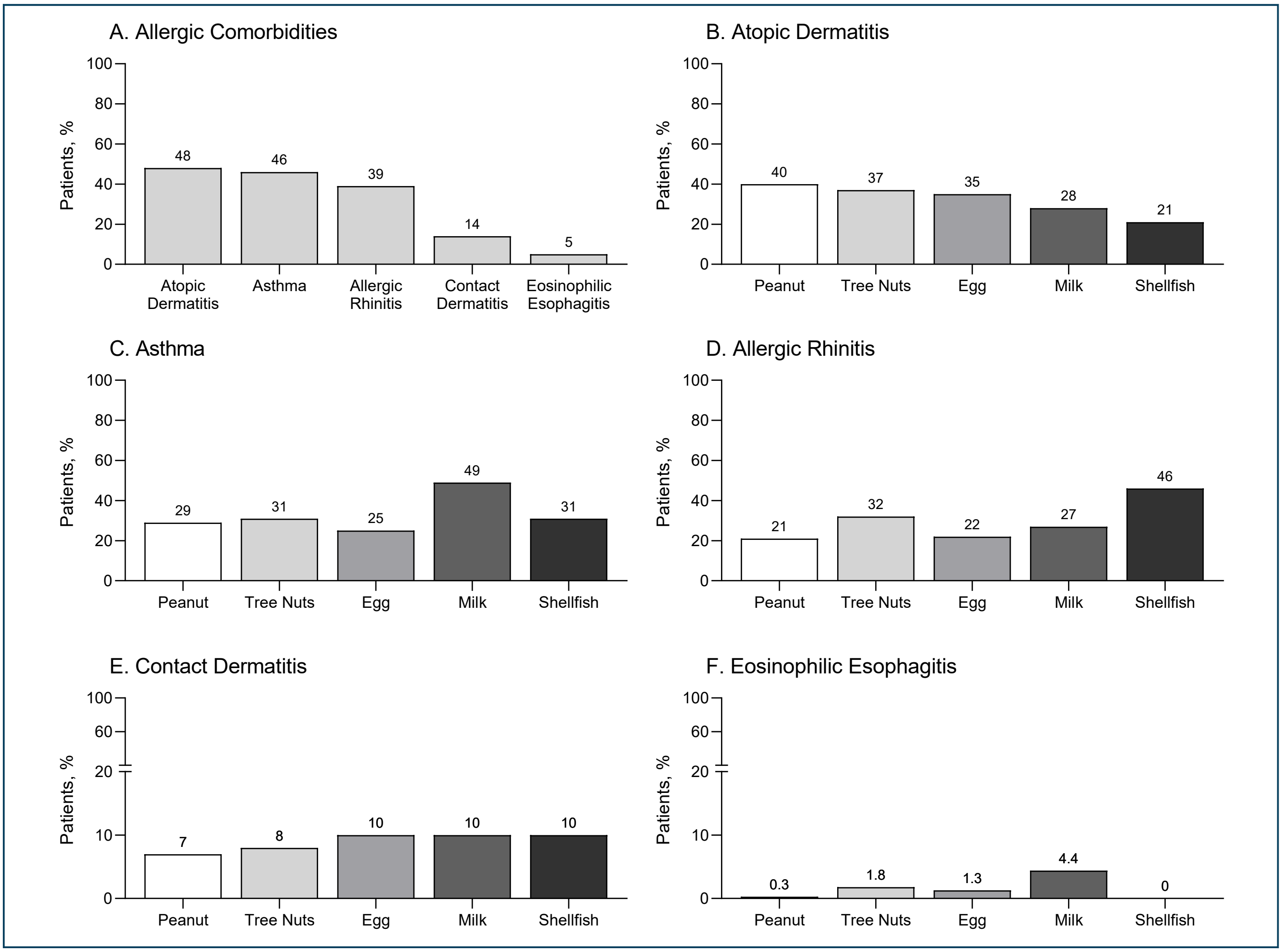

Fig. 3 Allergic comorbidities in patients with food allergies. **A-F.** Response to the survey question, "*Has the participant ever been diagnosed with any of the following conditions? (Select all that apply)*". **A.** Percent of patients with allergic comorbidities (n = 5587). **B-F:** atopic dermatitis (B), asthma (C), allergic rhinitis (D), contact dermatitis (E), and eosinophilic esophagitis (F) were reported. Patients with a single food allergy to peanut (n = 347), tree nuts (n = 217), egg (n = 77), milk (n = 138), and shellfish (n = 61) were included

Allergic comorbidity	All patients with FA (n = 5587)	Patients with single FA (n = 993)	Patients with multiple FA (n = 4594)
Atopic dermatitis	4.54	3.61	4.70
Asthma	4.34	3.55	4.48
Allergic rhinitis	3.70	3.10	3.80
Contact dermatitis	1.31	0.99	1.36
Eosinophilic esophagitis	0.45	0.16	0.50

Table 5. Rates of common allergic comorbidities in patients with food allergies. *FA, food allergies. Rates were calculated using the total person-years of disease duration (defined as the age at survey completion minus age at diagnosis for each patient), the total person-years that the allergic comorbidity was experienced, and the total number of patients with food allergies. Rates were multiplied by 100 for ease of interpretation. Rate = [(total N of patients with food allergies)/(total person-years that comorbidity was experienced)] × 100.*

their allergy, strategies aimed at prevention as well as treatment should be a priority. In addition, the clinical burden presented here is only a small part of the impact of food allergies – for example, burden may also extend to affect the mental health of both patients and their caregivers, and this has been considered by Casale et al.[26] In light of these findings, we support the development of holistic management strategies for patients with food allergies,[27] especially as this aligns with the recent DEFASE (Definition of Food Allergy Severity) initiative that considers signs/symptoms, therapy, eliciting dose, quality of life, and economic impact of food allergies.[28]

Abbreviations

DEFASE, Definition of Food Allergy Severity; FA, food allergies; FARE, Food Allergy Research & Education; mo, month; SD, standard deviation; US, United States; wk, week; y, years.

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Author contributions and consent for publication

CW, RG, AS, RS, RW, AI, SG, and TBC conceived the study, interpreted the results, and prepared the manuscript. AS, RS, and RW analyzed the data. All authors critically reviewed the manuscript, approved the final draft, and provided their consent for publication.

Ethics approval

Ethics approval was secured and informed consent was obtained from patients prior to the completion of the surveys.

Data availability

Data supporting this study are included within the article and/or supporting materials.

Role of the sponsor

Genentech, Inc. was involved in the study design, data analysis, and preparation of the manuscript.

Declaration of competing interest

Christopher Warren received institutional research funding from FARE, the National Institutes of Health, and the Sunshine Charitable Foundation. Ruchi Gupta received research grant support from Allergy & Asthma Network, FARE, Genentech, Inc., Melchiorre Family Foundation, National Confectioners Association, the National Institutes of Health, Stanford Sean N. Parker Center for Allergy Research, Sunshine Charitable Foundation, Thermo Fisher Scientific, UnitedHealth Group, and the Walder Foundation; acted as medical consultant/adviser for FARE, Genentech, Inc., and Novartis; and has ownership interest in YoBee Care, Inc. Arpamas Seetasith, Robert Schuldt, Rongrong Wang, Ahmar Iqbal, and Sachin Gupta are employees of Genentech, Inc. and stockholders in Roche. Thomas B. Casale is a consultant and speaker bureau member for Genentech, Inc.; consultant for Novartis Pharmaceuticals Corporation; and was chief medical adviser for FARE at the time of data acquisition.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.waojou.2024.100889.

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