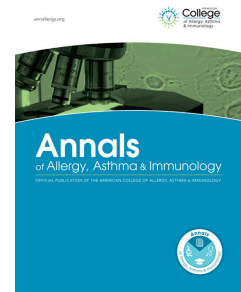


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Factors Contributing to Underuse of Epinephrine Autoinjectors in Pediatric Patients with Food Allergy

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Background: Epinephrine autoinjectors (EA) are the standard of care for severe food allergic reactions, although they are frequently underused or misused.

Objective: The goal of this work is to understand the factors associated with underuse of EA by caregivers of pediatric patients with food allergy.

Methods: A survey was administered to 200 caregivers of pediatric patients with food allergies to assess most severe lifetime allergic reaction, EA education, use and factors associated with incorrect use or underutilization.

Results: One hundred sixty-four surveys were completed; 118 (72%) of lifetime most severe reactions warranted EA use, but the EA was used in only 45 (38.1%). Reasons caregivers indicated for not administering the EA included: reactions did not seem severe enough, it was the patient's first allergic reaction, use of other medication, and fear of using EA.

Conclusion: Multiple factors contribute to underuse of EA for the treatment of severe allergic reactions. Results from this study highlight the need for continuous EA education in caregivers of and pediatric patients with food allergies, using a multipronged approach targeting clear symptom recognition and alleviation of fear of EA use.

Introduction

Anaphylaxis is a life threatening condition that is estimated to occur in 1.6% of the United States population¹. Food is the most common trigger for anaphylaxis in children, and up to 8% of children in the United States suffer from food allergy.¹⁻⁵ There are approximately 125,000 food-induced allergic reaction emergency room visits per year in the United States, 14,000 of which are due to anaphylaxis.⁶ Anaphylactic reactions are frequently undertreated.^{6,8}

Despite education about food avoidance, reactions due to accidental ingestion of food allergens still occur.^{5,6} The treatment of choice for anaphylaxis is intramuscular epinephrine, and guidelines support the prescription of auto-injectable epinephrine (EA) to patients with food allergy to ensure prompt access to life-saving medication if anaphylaxis occurs outside the medical setting.¹ Correct use of EA is surprisingly low, ranging from 16-32%, measured through both observational studies and via patient report.⁹⁻¹⁴ While patients or their caregivers are advised to carry an EA with them at all times, studies show that only about half of patients regularly carry an unexpired EA.¹⁵ A recent meta-analysis of EA use found that the most common reasons for pitfalls in the use of EA are lack of autoinjector availability, inadequate education of parents about how to administer the epinephrine, concern for systemic effects, failure to administer correctly, and accidental administration.¹⁶ This study aimed to identify parental factors that contribute to the underuse of EA during anaphylactic reactions in pediatric patients.

Methods

Study participants – Participants were recruited from the Jaffe Food Allergy Institute at the Mount Sinai Hospital in New York, NY. Surveys were offered to 200

caregivers of children with food allergy during office visits from June 1, 2017-October 1, 2018. Anonymous surveys were completed before allergy education was provided during the visit. Inclusion criteria required physician-diagnosed food allergy, and all patients must have previously been prescribed EA. The study was approved by the Icahn School of Medicine at Mount Sinai Hospital Institutional Review Board (IRB), and written informed consent was waived by the IRB.

Survey (eSupplement1) – A trained research assistant or clinical nurse distributed the survey to caregivers of children with food allergies. The anonymous survey was self-administered and collected at the end of the visit. Information collected included demographics, allergy and anaphylaxis history and past experience with EA use, education, and confidence. Participants were asked to rate their confidence in EA use based on past experience and training, with a score of 1 being “Very Confident” and 5 being “Not Confident At All.” The allergy history section of the survey focused on lifetime allergens, symptoms at time of most severe reaction, medication use (EA and other) at time of most severe reaction, and reasons for medication use or lack of use during most severe reaction.

Statistics – Data were analyzed using frequency analysis for demographic trends and descriptive statistics. Multiple regression analysis (SPSS, R) was conducted to examine the relationship between lack of EA use (when it should have been used) and (1) type of EA education received by caregiver, (2) patient food allergen, (3) symptoms experienced at time of most severe reaction, (4) caregiver level of confidence in using the EA, and (5) patient-reported cause for lack of EA use. Analyses were conducted via

Pearson correlation and Fisher Chi-Square tests. P-values less than .05 were considered statistically significant findings.

Results

Two hundred surveys were distributed to caregivers during the study timeframe. Fifteen caregivers declined participation; 14 agreed to participate but did not return the survey to the study investigators. Of the remaining 171 surveys, 7 did not meet inclusion criteria (3 patients had never received prescription for EA and 4 patients did not have a definitive diagnosis of food allergy). 164 completed surveys were included for analysis (Figure 1).

69.5% of the pediatric patients were male. The mean patient age was 7.5 years (+/- 5.2 years), and the average caregiver age was 40.6 years (+/- 10.2 years). Caregivers were 76.8% patient mothers, 22.6% fathers and 0.06% other. Further demographic information about the surveyed population can be found in Table I. The most common food allergens were tree nuts (n=139; 84.8%), peanuts (n=108; 65.9%), egg (n=58; 35.4%), sesame (n=48; 29.3%), and milk (n=47; 28.7%). Most patients had an associated atopic condition, including eczema (n=117; 71.3%), pollen allergy (n=89; 54.3%), and asthma (n=60; 36.6%).

All but one of the caregivers reported previously receiving education on how to use the prescribed EA (Table II). The most common mode of teaching was via verbal instruction (n=149; 90.9%), most frequently done by allergy specialist physicians (n=156, 95.1%). General pediatricians were the second most common teacher of how to use the EA (n=63; 38.4%). In addition to verbal instructions, caregivers were educated using printed materials (n=137; 83.5%) and live demonstrations (n=134;

81.7%). When asked how confident they were in their ability to use the EA in the case of a severe allergic reaction, 71 (43.3%) caregivers stated “very confident,” whereas 69 (42.1%) stated “fairly confident,” 21 (12.2%) stated “somewhat confident,” 3 (1.8%) stated “not too confident,” and one participant failed to respond. No caregivers stated that they were not at all confident in administering EA. There was no statistically significant correlation between the time since receiving EA education and the self-reported caregiver level of confidence in administering EA.

The survey inquired about the most severe allergic reaction the child had ever experienced. All participants reported at least one past food-related allergic reaction for their child. The most commonly reported symptom (Table III) was hives (n=139; 84.8%), followed by itching of skin (n=82; 50.0%), vomiting (n=68; 41.5%), swelling of lips (n=62; 37.8%), itching in throat (n=61; 37.2%), cough (n=55; 33.5%), swelling of eye (n=52; 31.7%), trouble breathing (n=51; 31.1%), wheezing (n=46; 28.0%), pain in stomach (n=31; 18.9%), change in behavior (n=27; 16.5%), swelling of tongue (n=16; 9.8%), chest tightening (n=13; 7.9%), and diarrhea (n=10; 6.1%). Severe reactions likely warranting EA use were defined as reactions in which symptoms included any one of the following: trouble breathing, wheezing, cough, swelling of tongue, dizziness, unintentional urination, chest tightness, loss of consciousness, low blood pressure; or a combination of at least one skin symptom, including pruritus or hives, and at least one gastrointestinal symptom, including itching in throat, swelling of lips, swelling of tongue, swelling of eye, vomiting, or diarrhea. 118 (72.0%) of the reported reactions were classified as severe. Of these severe reactions, the EA was used for a minority of reactions, n=45 (38.1%).

The caregivers who did not use EA when it was warranted were further questioned about the reason behind this choice (Table III). Average confidence in EA use was 1.7 +/- 0.7 in the cohort at large and 1.95 +/- 0.9 in this particular subset. This scales to between "Very Confident" and "Fairly Confident" on the distributed survey. The most common reason for lack of EA use in this cohort was that the symptoms did not seem severe enough (n=35; 47.9%). A significant correlation between lack of use of EA when warranted and belief that symptoms did not seem severe enough was noted, with a Pearson correlation of 0.18 (95% CI: 0.04-0.33, p=0.016), as seen in Table IV. The majority of caregivers used oral antihistamine (diphenhydramine) instead, n=56; 76.7%. A significant correlation between lack of use of EA when warranted and use of oral antihistamine was noted, with a Pearson correlation of 0.27 (95% CI: 0.12-0.40, p=0.0005). Twenty nine percent (n=21) reported they did not use EA because the caregiver was scared and/or nervous about the reaction; a significant correlation between lack of use of EA when warranted and fear of reaction was noted, with a Pearson correlation of 0.26 (95% CI: 0.11-0.40, p = 0.00077). Three caregivers reported specific fear of the needle as the cause for not using the EA. Another reason that contributed to lack of use of EA in this population was that the patient was evaluated by a nearby doctor (Pearson correlation p = 0.00025). No caregivers reported not knowing how to use the EA as a reason for not using it. No one cited financial constraints as a reason for not having the EA available. Sixteen (21.9%) caregivers reported not using the EA not because they were scared or nervous, but because they did not want to administer it.

There was no statistically significant relationship between patient or caregiver age or caregiver confidence and lack of EA use when the reaction was severe. This was true for both reactions defined as severe due to airway symptoms, and those defined as severe due to a combination of skin and gastrointestinal symptoms. There was no correlation between the type of education received by caregiver (including both method of teaching and person who taught) or time since receiving education and the reason caregivers chose not to use EA at the time of the reaction. Twenty-four (14.6%) of all participants stated that they would have used EA if they had received different education. Fifteen (20.5%) of the participants that did not use EA when it was likely warranted stated that they would have used EA if they had received different education. Symptoms of cough, trouble breathing and vomiting were significantly associated with use of EA to treat the allergic reaction (Pearson correlation p all <0.001).

Discussion

The results of this survey demonstrate that there are multiple barriers to EA use in severe reactions, and a multi-pronged approach will be needed to increase EA utilization for severe reactions in the community setting. The majority of caregivers did not give their allergic children epinephrine at the time of their most severe allergic reactions, when epinephrine injection should have been administered, despite declaring confidence in their ability to treat allergic reactions. While this is possibly due to caregivers answering regarding their comfort level at the time of survey administration rather than time of reaction, as well as desirability bias of the survey-taker, the underuse of EA is not a new phenomenon. Previous studies have sought to address its cause.^{7,8} An electronic survey of over one thousand food-allergic patients has been used to

address EA underuse. Researchers found that common causes of EA underuse include: lack of EA prescription, use of antihistamine medication at time of severe allergic reaction, mild severity of symptoms, and rapid disappearance of symptoms.⁷ While many of these themes were repeated in this present study, including the use of antihistamine medication and lack of recognition of symptom severity, this survey was different in that it focused solely on caregivers of food-allergic pediatric patients with EA prescriptions, rather than food-allergic patients of all ages without prescription restrictions. This was thus a unique opportunity to understand a population for whom patient education advances are particularly impactful and can have lifelong effects.

Caregivers recognized that presence of respiratory symptoms (trouble breathing, cough) were indications for administering epinephrine. However, many severe reactions were not recognized as needing epinephrine use because the combination of symptoms from multiple organ systems did not seem severe enough. This highlights a critical break in communication regarding what symptoms would be concerning and the benefits prompt administration of epinephrine as early as possible during the course of anaphylaxis. Hesitation to use EA when necessary may be particularly detrimental under circumstances of limited access to the emergency services, such as during the COVID-19 pandemic, when proactive at-home management of food-induced anaphylaxis is of critical relevance.¹⁸ Specifically, education must address the combination of less dramatic symptoms or gradual progression of symptoms from many organ systems as a possible presentation of anaphylaxis and the important indication for EA administration.

A third of children with severe reactions were treated with other medications instead. It is unclear whether this is due to more comfort with the other medications, uncertainty about indications for epinephrine, or other factors. This underscores the need for continued focus on educating patients and caregivers to recognize signs and symptoms of anaphylaxis and understanding the role of different allergy medications. A study of a new multidisciplinary educational tool for anaphylaxis management in the school-setting demonstrated efficacy in improving management by school personnel. This aligns with the need to adopt multifaceted educational techniques by patients and caregivers in the healthcare setting.¹¹

Another reason for not using the EA when warranted was fear and anxiety regarding the reaction itself on the part of the caregiver. Here we demonstrated that despite caregivers reporting confidence and recent education about EA use in clinic, at times of reaction, they feel nervous and/or anxious. This highlights a need to develop effective training strategies to prepare caregivers and increase their confidence to act during stressful situations. This finding complements that found in a recent survey of caregivers of pre-school age children with food allergies, which demonstrated that fears about epinephrine administration in young children (aged 3 to 15 months) limited use of EA at times of reactions.⁸ Our results suggest that these feelings are similarly experienced by parents of older children. Physicians have attempted to prepare families for episodes of anaphylaxis by creating individualized emergency action plans, which are delineated procedures to follow during potential anaphylactic reactions in pediatric patients.¹⁹ Data about the presence and use of emergency action plans during severe reactions was not collected in this survey, a noted limitation.

It is also remarkable that approximately one fifth of the caregivers reported choosing not to administer EA. This included those concerned about side effects, not liking giving drugs to children, child being nervous about the injection, and not wanting to activate emergency services or go to the emergency department. This observation points towards the need for targeted education to address these concerns. Future research focusing on the effective education strategies and active involvement of pediatric patients and their caregivers in decision making is of great importance.²⁰

This was an anonymous survey and as such, several limitations are acknowledged. Firstly, this study was conducted at one outpatient academic hospital-affiliated clinic in New York City, which limits generalizability of these results. The majority of participants reported both high education levels and high annual household incomes. Lower income is associated with greater difficulty managing food allergies, and has been associated with decreased health literacy, which can result in lack of knowledge of EA use and greater food allergy reaction rates.^{10,12, 21} Therefore, our findings of lack of recognition of anaphylaxis symptoms and misconceptions regarding medications in this privileged group of highly-educated caregivers with excellent access to health care resources are particularly alarming. A study of a broader population reflective of a wider sociodemographic would be needed to identify factors affecting EA use in the general population. Furthermore, selection bias could have skewed the results of this survey study, as caregivers who are more confident in their ability to treat anaphylaxis may have chosen to participate in the study, although only 7.5% declined participation. Additionally, this study was subject to recall bias as participants were

asked to describe their child's most severe lifetime allergic reaction, which could have occurred months to years before the survey was completed.

Despite these limitations, strengths of this study include the broad variety of food allergens and allergic symptoms of the surveyed population, the myriad of reasons for lack of EA use listed on the survey, as well as the opportunity for participants to share their own unique responses. This allowed for a significant amount of data accumulation and a thorough evaluation of the study aim, adding tenacity to the results. While previous studies have shed light on some causes of EA underuse, including lack of understanding anaphylaxis diagnostic criteria and use of alternative medications, this survey is the first to highlight fear and anxiety of the reaction itself as a specific, statistically significant, cause of epinephrine underuse in the pediatric food-allergy population.^{5,6} Characterizing these barriers helps to lay the groundwork for the educational efforts and novel interventions to improve food allergy management. In conclusion, it is important to account for the emotional education, as well as the continued emphasis on symptom recognition, that must take place when teaching families how to use the epinephrine autoinjector in children with food allergies. Future research should include analysis of novel educational interventions, which include thorough description of anaphylaxis diagnostic criteria as well as emphasis on assuaging fear surrounding EA use, for food allergic patients and caregivers. Identifying and addressing the range of barriers to treating severe allergic reactions will lead to improved care for food allergic children.

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Table I: Demographics

Child Age (mean, +/-SD)	7.5 +/- 5.2 years
Child Gender	
Male	69.5%
Female	29.9%
Caregiver Age	40.5 +/- 10.2 years
Caregiver Relationship to Child	
Mother	76.8%
Father	22.6%
Legal Guardian	0.6%
Marital Status	
Married	90.2%
Single, never married	3.4%
Divorced	3.4%
Decline to respond	2.4%
Living with partner	0.6
Self-Identified Race	
White/Caucasian	79.3%
Asian	13.4%
Black/African American	4.3%
Other	2.4%
Native Hawaiian or Pacific Islander	0.6%
Level of School Completed	
Graduate Degree	62.2%
4 Year College	34.1%
2 Year College	3.7%

# People in Household....	4.0 +/- 1.1 people
Annual household income	
Greater than \$150,000	75.6%
\$100,000-\$150,000	14.6%
\$75,000-\$100,000	3.7%
\$50,000-\$75,000	0.6%
Don't know	1.2%
Declined to respond	4.3%

Table II: Epinephrine Autoinjector Education

Caregivers were instructed to check off as many answers as apply for all questions, rather than just one response. Total numbers are reflective of this.

Provider Responsible for Caregiver Education	
Allergist	156 (95.1%)
Pediatrician (PCP)	63 (38.4%)
Nurse	23 (14.0%)
Other Doctor	18 (11.0%)
Online	6 (3.7%)
Nutritionist	4 (2.4%)
Pharmacist	1 (0.6%)
Other*	1 (0.6%)
Teaching Method	
Verbal	149 (90.9%)
Printed	137 (83.5%)
Demonstration	134 (81.7%)
Other**	1 (0.6%)
Time Since Last EA Education	
Today	11 (6.7%)
1-3 months ago	41 (25.0%)

4-6 months ago	21 (12.8%)
7-9 months ago	11 (6.7%)
10-12 months ago	19 (11.6%)
>12 months	58 (35.4%)
Other*	1 (0.6%)
Caregiver EA Use Confidence	
Very Confident	71 (43.3%)
Fairly Confident	69 (42.1%)
Somewhat Confident	20 (12.2%)
Not Too Confident	3 (1.8%)

*Not specified by caregiver; education might have been provided by more than 1 provider

**Video

Table III: Characteristics of Food-Allergies & Reaction

Caregivers were instructed to check off as many answers as apply for all questions, rather than just one response. Total numbers are reflective of this.

Lifetime Allergens	
Tree Nut	139 (84.8%)
Peanut	108 (65.9%)
Egg	58 (35.4%)
Sesame	48 (29.3%)
Milk	47 (28.7%)
Other*	46 (28.0%)
Soy	17 (10.4%)
Wheat	16 (9.8%)
Symptoms at time of most severe reaction	
Hives	139 (84.8%)
Pruritus	82 (50.0%)
Vomiting	68 (41.5%)
Swelling of Lips	62 (37.8%)
Itching in Throat	61 (37.2%)

Cough	55 (33.5%)
Swelling of Eye	52 (31.7%)
Trouble Breathing	51 (31.1%)
Wheezing	46 (28.0%)
Pain in Stomach	31 (18.9%)
Change in Behavior	27 (16.5%)
Swelling of Tongue	16 (9.8%)
Other**	14 (8.5%)
Chest Tightening	13 (7.9%)
Diarrhea	10 (6.1%)
Low Blood Pressure	4 (2.4%)
Loss of Consciousness	3 (1.8%)
Reason EA Not Used When Warranted (n=73)	
Symptoms did not seem severe enough	35 (47.9%)
First reaction	30 (41.1%)
Used other medication instead	26 (35.6%)
Caregiver scared/nervous about reaction	21 (28.8%)
Close to hospital or doctor	12 (16.4%)
Not nervous/scared, but didn't want to give	8 (11.0%)
Other (patient specific scenarios)	7 (9.6%)
On way to hospital or doctor	6 (8.2%)
Concerned about side effects	5 (6.8%)
Don't like to give child medication	5 (6.8%)
Child scared/nervous about needle	3 (4.1%)
Did not know when to use	2 (2.7%)
Did not want to go to Emergency Room	2 (2.7%)
Caregiver not with child	1 (1.4%)
Did not want to call 911	1 (1.4%)

*Fish/shellfish (n=20, 12.2%), legumes (n=12, 7.3%), mustard (n=8, 4.9%)

**Symptoms include: dizziness, unexpected urination, swelling of extremities, feeling of dread, confusion, sleepiness, change in color, runny nose, watery/glossy eyes, bad taste in mouth, itching of ears, swelling of face, sneezing, raspy voice/change in voice, runny nose, and bloody nose

Table IV: Factors Affecting EA Use with Significant Correlation to Lack of Use at Time of Severe Reaction

Reason EA Not Used When Warranted	Pearson Correlation, 95%CI, p-value
Symptoms did not seem severe enough	0.18, 0.04-0.33, p=0.016
Used oral antihistamine instead	0.27, 0.12-0.40, p=0.0005
Caregiver scared/nervous about reaction	0.26, 0.11-0.40, p=0.00077
Close to hospital or doctor	0.28, 0.13-0.42, p=0.00025

Figure 1: Flow of survey distribution in Mount Sinai Faculty Practice clinic office visits. A trained research assistant or nurse distributed all surveys. Patient caregivers completed the survey without help from the staff.

Figure 1: Survey Distribution

