Use of Over-the-Counter Products to Treat Severe Allergic Reactions Before an Epinephrine Auto-Injection (EAI) Device: Results of a Patient/Caregiver Survey

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RATIONALE

International guidelines agree that rapid administration of epinephrine is the first-line treatment for severe allergic reactions including anaphylaxis[1,2]; however, a recent meta-analysis of 88 studies representing 36,557 anaphylaxis events revealed that epinephrine was only administered in 50.4% of these reactions.[3]

The reluctance and hesitation to administer epinephrine with a needle injector during a severe allergic reaction is well-documented[4,5,6,7] and increases the risk of serious outcomes.[8,9,10]

Over-the-counter (OTC) medications, such as antihistamines, do not effectively treat the hypotension or bronchospasms associated with severe allergic reactions[1] and are not recommended by any recognized guideline as appropriate treatment accordingly; however, patients and caregivers often use them in lieu of epinephrine, increasing risk of hospitalization and/or fatal outcomes.

Understanding the contributing factors for the failure of or incorrect use of needle injector devices, including patient preparedness (failure to have epinephrine on hand due to not filling prescription, carrying 2 devices), is crucial to effective delivery of epinephrine for the best chance of intended epinephrine-mediated clinical outcomes when treating severe allergic reactions including anaphylaxis.

neffy is an intranasal (IN) epinephrine spray and needle-free delivery device being developed as an alternative to EAIs for the emergency treatment of (Type I) allergic reactions, including anaphylaxis. ***neffy*** is expected to have significant clinical benefit by increasing the likelihood that epinephrine will be administered without delay at the first signs of a severe allergic reaction.

METHODS

- Data from a third-party database was used to identify potential patient and caregiver respondents within the United States, who were then directed to an online screener where they were asked about their experience with allergies. Patients who have been diagnosed by a physician with a severe or potentially life-threatening allergy (defined for patients as "an allergy where you may go into anaphylaxis") and caregivers whose children have been diagnosed by a physician with a severe or potentially life-threatening allergy (defined for caregivers as "an allergy where your child may go into anaphylaxis") were enrolled from a pool of qualified respondents.
- All participants must have used an EAI for an allergic reaction, for themselves or their child, within the past 12 months.
- A 20-minute double-blind web-based survey was then administered to the qualifying 200 participants (100 patients and 100 caregivers).
- Participants were questioned regarding their usage of epinephrine and OTC allergy medications for severe allergic reactions, including questions about their or their child's allergy, current treatment, the last allergic reaction, what medication(s) were taken for the reaction, and how a needle-free epinephrine device may change their behavior.

RESPONDENT BACKGROUND

ALLERGY HISTORY

Allergic triggers included peanuts (29%), followed by insect venom (22%), shellfish (14%), tree nuts (13%), dairy (7%), and medicine (4%). The majority of participants (82%) had been aware of their/their children's allergy(ies) for at least three years, and more than one-quarter of subjects had been aware for at least 10 years.

EXPERIENCE WITH EAIs

The majority of participants had used an EAI within the prior 6 months.

	Caregivers	Male Patients	Female Patients
Percent of subjects who had used an EAI less than 3 months ago	50%	60%	38%
Percent of subjects who had used an EAI 4 to 6 months ago	28%	18%	24%
Percent of subjects who had used an EAI 6 to 12 months ago	22%	22%	38%

RESULTS

- Participants were categorized as those who treated symptoms with OTC treatments "only" at least 50% of the time and those who treated symptoms with OTC treatments "first" at least 50% of the time. Ninety percent of participants said they would use a needle-free epinephrine device instead of an OTC treatment in more than 80% of severe allergic reactions. (Table 1)
- Despite the risks associated with serious allergic reactions and anaphylaxis, as well as the documented ineffectiveness of OTC products, 91% of respondents reported using an OTC product as a sole or initial treatment. (Figure 2)
- The average time from onset of symptoms to use of an EAI was 8.3 minutes for caregivers and 9.3 minutes for patients/self-administrators. The reasons for not using an EAI immediately following symptom onset are presented in Figure 1.
- The most common reason given for a failure to use EAIs was a dislike of the needle. (Figure 1)
- The majority of participants would be more likely to administer epinephrine if delivered via a needle-free device. (Table 1)

Ninety-one percent of participants used an OTC product to treat a serious allergic reaction, either before or in lieu of an epinephrine injection.

The majority of participants would be more likely to administer epinephrine if it was delivered via a needle-free device.

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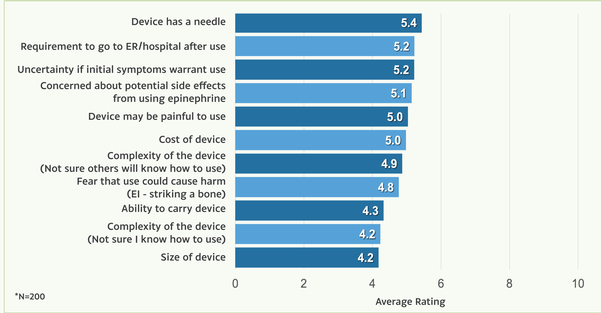
Figure 1: Reasons for Delayed Use of an EAI



*N=200

Figure 2: Usage of OTC Product For SAR (Alone or Prior to Using an EAI)

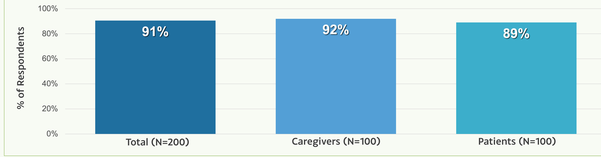


Table 1: Overview of OTC Use and Willingness to Use a Needle Free Epinephrine Device Instead of an OTC

Participant Cohort	N (%)	Only Used OTC (Average % of Time)	First Used OTC (Average % of Time)	Would Use a Needle-Free Device Instead of OTC (Average % of Time)
Only Used OTC at the Onset of Symptoms	102 (51%)	67%	n/a	74%
First Used OTC at the Onset of Symptom	107 (54%)	n/a	73%	76%
Total Participants	200	42%	46%	72%

REFERENCES

1. Shaker MS, Wallace DV, Golden DBK, Oppenheimer J, Bernstein JA, et. al. Anaphylaxis-a 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis. J Allergy Clin Immunol. 2020 Apr;145(4):1082-1123.
2. Murano A, Worm M, Alviani C, Cardona V, DunnGalvin A, Garvey LH, Riggioni C, et al. European Academy of Allergy and Clinical Immunology, Food Allergy, Anaphylaxis Guidelines Group. EAACI guidelines: Anaphylaxis (2021 update). Allergy. 2022 Feb;77(2):357-371.
3. Patel N, Chong KW, Yip AYG, Ierodiakonou D, Bartra J, Boyle RJ, Turner PJ. Use of multiple epinephrine doses in anaphylaxis: A systematic review and meta-analysis. J Allergy Clin Immunol. 2021 Nov;148(5):1307-1315.
4. Asthma and Allergy Foundation of America. My Life with Food Allergy Parent Survey Report. Asthma and Allergy Foundation of America. 2019.
5. Brooks C, Coffman A, Erwin E, Mikhail I. Diagnosis and treatment of food allergic reactions in pediatric emergency settings. Ann Allergy Asthma Immunol. 2017 Nov;119(5):467-468.
6. Flemming JT, Clark S, Camargo CA Jr, Rudders SA. Early treatment of food-induced anaphylaxis with epinephrine is associated with a lower risk of hospitalization. J Allergy Clin Immunol Pract. 2015 Jan-Feb;3(1):57-62.
7. Neimark L, Wales J, Du Toit G, Pastacaldi C, Haddad D, Gardner J, Hyer W, Vance G, Townshend C, Alfaham M, Arkwright PD, Rao R, Kapoor S, Summerfield A, Warner JO, Roberts G. The use of adrenaline autoinjectors by children and teenagers. Clin Exp Allergy. 2012 Feb;42(2):284-92.
8. Sampson HA, Mendelson L, Rosen JP. Fatal and near-fatal anaphylactic reactions to food in children and adolescents. N Engl J Med. 1992 Aug 6;327(6):380-4.
9. Sennbo E, Bourad T, Harbow S. Severe anaphylactic reactions outside hospital: etiology, symptoms, and treatment. Acta Anaesthesiol Scand. 1998 May;23(4):339-42.
10. Pumphrey RS. Lessons for management of anaphylaxis from a study of fatal reactions. Clin Exp Allergy. 2000 Aug;30(8):1144-50.

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