Learning from Epinephrine Treatment Characteristics Among Patients with Severe Allergic Reactions including Anaphylaxis to Improve Professional and Patient Education: Analyses from a US Claims Database

Poster #: 022

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RATIONALE AND BACKGROUND

- Epinephrine is recognized as the only first-line, lifesaving therapy in the treatment of patients with severe allergic reactions (Type I) including anaphylaxis.[1]
- Epinephrine auto-injectors (EAIs) are commonly used in the community-setting for prompt delivery of epinephrine[2] and are associated with significant improvement in patient outcomes, especially among individuals experiencing anaphylaxis.[3,4]
- Despite potentially life-saving benefits of using EAIs, they are not commonly used to treat a majority of anaphylactic reactions for several reasons, including concerns related to safety, medication costs, or anxiety related to autoinjector use.[4,5]
- Multiple studies have highlighted a common theme that epinephrine is underused in the treatment of anaphylaxis demonstrating a need for improvement.[6] Delayed epinephrine administration leads to worse outcomes, including increased risk of hospitalizations and fatalities.[1,7,8]
- Improvement in patient outcomes related to delayed or underuse of epinephrine often begins by increasing awareness among healthcare providers and patients.[6] To ensure timely use of epinephrine and to improve professional and patient education, it is important to understand patient characteristics, physician and patient preferences related to use of EAIs and barriers related to EAI use.

AIMS

- To understand real-world prevalence and treatment characteristics among patients with serious allergic reactions (SAR) using US claims database.
- To gain insights into epinephrine use, particularly the impact that patient and physician preferences has on autoinjector non-utilization using self-reported data from physician/patient surveys.

METHODS

- The study used data from two sources:

1. US claims database

- A retrospective analysis using patient level real-world data from US claims was conducted over a 6-year period (07/2014-06/2019).
- The study sample comprised of patients with a documented SAR (>1 diagnosis of serious allergy) and >1 health care provider (HCP) visits in the office-based setting over a 36-month study observation period (07/2016-06/2019).
- A 2-year look back period was used to define prior SAR and product use. Patients were segmented into: 1) Anaphylactic and 2) Non-anaphylactic.

2. Self-Reported Physician/Patient Surveys

- To explore physician prescribing behavior and physician/patient preferences on EAI use, 45-60-minute surveys were conducted with:
  - Physicians (n=75) including allergists (n=25), pediatricians (n=25) and primary care providers (n=25); patients that filled an EAI prescription (n=100); parents that filled an EAI prescription for their child (n=100), non-EAI filling patients (n=100), including 50 patients that stopped filling and 50 that never filled an EAI
- Adaptive choice based conjoint (ACBC) modeling methodology was used to gauge top reasons for not having an EAI prescription on hand.
- Descriptive statistics were used to describe the study samples and treatment characteristics related to EAI use.

RESULTS

Findings from claims data analysis-Patient Characteristics

- In the 3-year study period, of the 11.6 million SAR patients with any HCP office-visits, 12% patients (N=1,448,884) were anaphylactic. More than half were females and 42% were less than 18 years of age (**Figures 1a, b and c**). An overall growth rate of 8% year-over-year (YoY) from 2017-2019 was observed for the number of patients with SAR in the US. Food sources accounted for 96% of anaphylactic reactions. It was observed that the most common food sources of anaphylaxis were peanuts (31%) followed by tree nuts/seeds (25%).

Figure 1a: SAR Patient Type Make Up n = 11,631,614

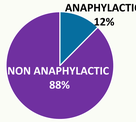


Figure 1b: SAR Patient Distribution by Age

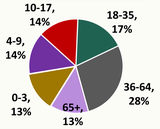
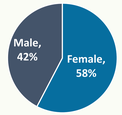
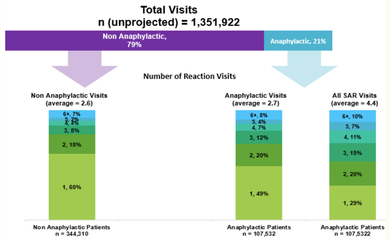


Figure 1c: SAR Patient Distribution by Gender



- Nearly half the patients with anaphylaxis (49%) only had a single anaphylactic reaction visit in a period of 3 years; but on an average, they had more reaction visits per patient as compared to non-anaphylactic patients (**Figure 2**).

Figure 2: Number of Anaphylactic and Non-Anaphylactic Reaction Visits in Three Years



Treatment Characteristics

- Of all patients with SAR, only 11% received any treatment over the study period (**Figure 3**). Most EAIs were prescribed to treat anaphylaxis. The most common type of specialist seen was allergist (32%), followed by primary care providers (22%) from July 2018-June 2019 (**Figure 4**).

Figure 3: SAR Patients (Jul 2016 to Jun 2019)

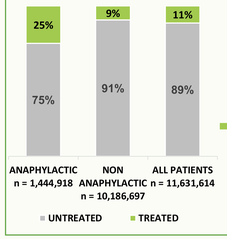
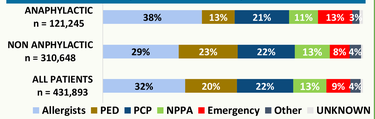


Figure 4: Total Epinephrine Prescribing: HCP Specialty (Jul 2018 to Jun 2019)

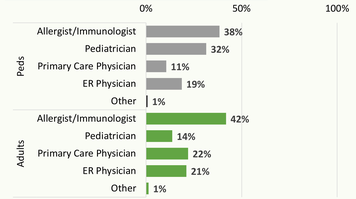


- About 77% of patients with SAR were treated with 0.3MG/0.3ML epinephrine; however, in-office epinephrine treatment was relatively higher among patients who experienced anaphylactic shocks, angioneurotic edema, and allergic urticaria.

Findings from Self-Reported Physician/Patient Surveys

- Overall, 100 physicians and 250 patients/parents participated in the study in 2019. Based on physician self-report, majority of initial diagnosis of patients with type 1 allergies was made by allergists (**Figure 5**); the majority of EAI prescriptions were written by allergists.

Figure 5: Physician View of who Made the Initial Patient Diagnosis



- Physicians indicated that 15-24% of at-risk patients do not get an EAI prescription. Out-of-pocket costs and fear of IM-administration were cited as the two most common reasons for not being able to prescribe an EAI (**Figures 6a and 6b**). Similar findings (attributes) were obtained from conjoint analysis.

Figure 6a: % of Patients that are Candidates for an EAI that aren't Prescribed

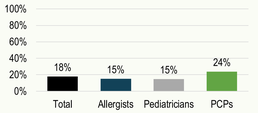
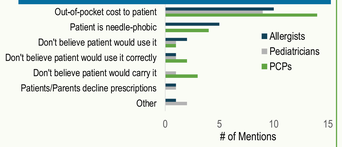


Figure 6b: Reasons Why Physicians Don't Prescribe an EAI



- Selected demographic characteristics of patients and parents who participated in the study are described in **Table 1.**

Table 1: Sample description of patients/parents who participated in the study

Respondents Interviewed	Those who filled an EAI prescription			Non-EAI filling patients	
	Adult Males (N=50)	Adult Females (N=50)	Parents (N=50)	Adult Males (N=41)	Adult Females (N=59)
Median Age Range	26-45 years old	26-45 years old	26-45 years old	26-45 years old	26-45 years old
Median Annual Household Income	$100,000 – $149,999	$50,000 – $99,999	$100,000 – $149,999	$100,000 – $149,999	$50,000 – $99,999
% That Have EAI Currently Filled	94%	92%	96%	N/A	N/A

- Patients indicated waiting up to 18 minutes before getting treatment with EAI.
- While physicians commonly prescribe and recommend carrying two devices, they believe that only slightly more than half of patients and 70% of parents actually follow their advice. As per patient self-reports, majority of patients carry less than 2 devices. Less than 80% patients claim to have an EAI either on their person (in bag/purse or pocket) or within few minutes from where they experience symptoms (**Figures 7a, b and c**).
- The survey also captured differences in readiness of using an EAI vs. over-the-counter (OTC) medications to manage SAR. Males appeared to reach more for an EAI, while females and parents relied more heavily on using OTC medications within the last six months. On an average, the study sample relied more on using an OTC medication as compared to EAIs in the past six months. Findings from non-EAI filling patients highlighted patient beliefs such as allergic reaction was not severe enough for an EAI use, lack of EAI prescription, and cost concerns as reasons for using an OTC medication instead of EAI.

Figure 7a: Number of Devices per EAI prescription

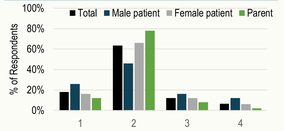


Figure 7a: Number of Devices per EAI prescription

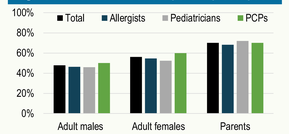


Figure 7c: Location of devices

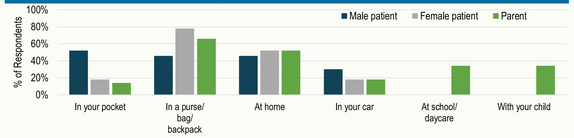
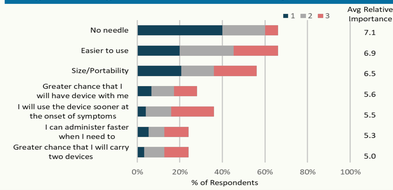


Figure 8: Average relative importance of patient/parent preferences for EAI use



- Regarding EAI use, most patient and parents, including non-EAI filling patients had preferences for no needle use, ease of use, and device size (**Figure 8**).

CONCLUSIONS

- Despite the severity of the conditions, timely and appropriate epinephrine treatment with EAIs among patients with SAR is often delayed or avoided. When prescribed, EAIs are generally used for treating more severe symptoms of anaphylaxis. Allergists appear to play a key role in patient's treatment journey, typically first to prescribe the initial epinephrine treatment most often compared with primary care physicians. Physicians suggest that more patients should utilize epinephrine promptly to immediately address allergic reactions and avoid progression to a life-threatening event. Physician as well as patient preferences can impact utilization as well as adherence to epinephrine treatment for SAR, which can eventually impact clinical outcomes. Patient education is also warranted to quickly recognize an allergic reaction and to treat with epinephrine immediately to avert progression to more serious symptoms or shock.
- LIMITATION: Patients with SAR included in the claims data analysis represent only those who present to an HCP office and may not be representative of patients seeking care in hospital or other healthcare settings. For example, our claims study estimated approximately 3.02 million patients in the institutional data sample; however, this number could not be projected.

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Presented at the AAAAI Annual meeting, Philadelphia, PA, USA, March 13–16, 2020

This research was supported by ARS Pharmaceuticals, Inc. Editorial Assistance was provided by IQVIA; funding for this assistance was provided by ARS Pharmaceuticals.