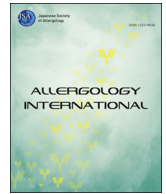




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Original article

## Surveillance of the use of adrenaline auto-injectors in Japanese children

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#### Abbreviations:

AAI	adrenaline auto-injector
ELT	emergency life-saving technicians
JSPACI	The Japanese Society of Pediatric Allergy and Clinical Immunology
FDEIA	food-dependent exercise-induced anaphylaxis
ED	emergency department

### ABSTRACT

**Background:** The appropriate usage of an adrenaline auto-injector (AAI, EpiPen<sup>®</sup>) is a key aspect of patient and social education in the management of anaphylaxis. However, although AAIs are being prescribed increasingly frequently, there are few reports on their actual use.

**Methods:** The Anaphylaxis Working Group of the Japanese Society of Pediatric Allergy and Clinical Immunology requested that society members register cases in which AAIs were used. Two hundred and sixty-six cases were collected from March 2014 to March 2016.

**Results:** The cases included 240 events of immediate-type food allergies caused by cow's milk (n = 100), hen's egg (n = 42), wheat (n = 40), and peanuts (n = 11). Exercise-related events were reported in 19 cases; however, the diagnosis of food-dependent exercise-induced anaphylaxis with a specific causative food was only made in 4 cases (wheat, n = 2; fish, n = 1; squid, n = 1). The frequent reasons for the causative intake included programmed intake (n = 48), failure to check the food labeling (n = 43), and consuming an inappropriate food (n = 26). AAIs were used at schools or nurseries in 67 cases, with school or nursery staff members administering the AAI in 39 cases (58%). On arriving at the hospital, the symptom grade was improved in 71% of the cases, while grade 4 symptoms remained in 20% of the cases. No lethal cases or sequelae were reported.

**Conclusions:** AAIs were used effectively, even by school teachers. The need to visit a hospital after the use of an AAI should be emphasized because additional treatment might be required.

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### Introduction

Anaphylaxis is defined as “a serious, life-threatening generalized or systemic hypersensitivity reaction”, and “a serious allergic reaction that is rapid in onset and might cause death”.<sup>1</sup> The intramuscular injection of adrenaline is the first-line treatment for anaphylaxis.<sup>2</sup> Adrenaline auto-injectors (AAIs; EpiPen<sup>®</sup>; Pfizer Japan Inc. Tokyo) are prescribed to patients who are at risk of anaphylaxis.

In Japan, the 0.3-mg AAI was first approved for bee venom-induced anaphylaxis in 2003. The indication was expanded to food- and drug-induced anaphylaxis in 2005; at the same time, the

0.15-mg AAI was approved for children 15–30 kg in body weight. The number of AAI prescriptions dramatically increased after 2011, when AAIs received national health insurance coverage. Since 2009, emergency life-saving technicians (ELTs) have been allowed to administer a prescribed AAI under medical control.

Many efforts had been made to manage children who are at risk of developing anaphylaxis in schools and nurseries.<sup>3</sup> These efforts have included identifying students who are at risk of anaphylaxis, providing school lunches safely and—importantly—establishing a social consensus that school teachers are allowed to use AAIs in case of emergencies involving students. However, despite these nationwide efforts, a fatal accident occurred in December 2012 when a student suffered from anaphylaxis after ingesting a milk product that was served in a school lunch.

This event led to the publication of the anaphylaxis guidelines by the Japanese Society of Allergology.<sup>4</sup> The Japanese Society of Pediatric Allergy and Clinical Immunology (JSPACI) also proposed a

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list of symptoms that are indicators for the use of AAI by individuals other than medical professionals (Table 1).<sup>3</sup>

According to a nationwide surveillance of the prescription and usage of AAI in Japan from 2003 to 2009, 51,447 AAI were prescribed, while AAI were actually used in 449 cases (0.87%).<sup>5</sup> This low prevalence of AAI usage suggests that many physicians who prescribe AAI have little chance of encountering an event in which an AAI is needed. Information about situations in which an AAI was actually used may help improve the understanding of patients and attendees of social education programs.

The JSPACI organized the Anaphylaxis Working Group in 2013. This group immediately issued a statement regarding the indications for AAI usage (Table 1). The present project was then initiated to collect information on cases involving the use of AAI from members of the society.

## Methods

The present survey was conducted from March 2014 to March 2016. The Aichi Pediatric Clinical Study Group (Director: Professor Seiji Kojima, Nagoya University Graduate School of Medicine) also supported this study in the Aichi area. The members of each committee are listed in Supplementary Table 1. The project was announced to the members of the JSPACI (n = 3880 in November 2014) through the society's official journal and website.

The data collection sheet was provided via the website, and JSPACI members—mostly pediatricians working in hospitals or clinics—were asked to register cases. The data collection sheet consisted of 5 pages: 3 pages were a questionnaire asking patients or their caregivers to describe the details of the event; the attending doctors were then asked to confirm the information and complete a 2-page survey. Of note, the attending doctors were asked to judge the major symptoms that led the caregiver using the AAI (Table 1) and to judge the grade of anaphylaxis<sup>3</sup> before the use of the AAI and at the time of arrival at the hospital.

The target patients were <20 years of age when the AAI was used. The following events were reported: 1) cases involving the use of the AAI that had been prescribed by the participating doctor; 2) cases in which the physician followed the patient as a family doctor; and 3) cases involving direct consultation for treatment at the time of the event.

The report was sent to the study office (Aichi Children's Health and Medical Center) by posted mail, fax or e-mail. Duplicated reports were recognized and integrated in the study office.

The sheet did not contain any personal information about the patients. The completion of the survey form was considered to

indicate the patient's consent to participate in the study. All of the procedures of this study were approved by the ethics committee of Aichi Children's Health and Medical Center (No. 201331).

## Results

### Data collection

A total of 266 events (male, n = 174; female, n = 92) were collected from 52 hospitals in 23 of the 47 prefectures in Japan. Most reports came from urban prefectures (Aichi, Osaka, Tokyo, Shiga, Kanagawa). This reflected the population of children and the number of cooperative doctors in the prefectures.

The median age of the patients was 7.6 years (range 1–19 years; Fig. 1). Their grades of education were as follows: senior high school or higher ( $\geq 15$  years old, n = 15), junior high school (12–15 years old, n = 28), primary school (6–12 years old, n = 113) and kindergarten or nursery ( $\leq 6$  years old, n = 96). A 0.15-mg AAI was used in 196 (74%) cases, while a 0.3-mg AAI was used in 70 (26%) cases. At the time of usage, 186 (70%) of the patients were using an AAI for the first time, while 55 (21%), 13 (5%), 6 (2%), and 6 (2%) were using an AAI for the second, third, fourth and fifth time or more, respectively.

### Triggers of anaphylaxis

The clinical background that led to the prescription and AAI usage was immediate food allergy in 240 cases (90%). The most frequent causative food was cow's milk (n = 100, 42%), followed by hen's egg (n = 42, 18%), wheat (n = 40, 17%), peanut (n = 11), tree nuts (n = 3), fruits (n = 2) and other foods (n = 16). The offending food was not specified in the remaining 26 cases.

Exercise after the intake of food was associated with the onset of anaphylaxis in 19 cases (7%). Among these, 6 cases were diagnosed as food-dependent exercise-induced anaphylaxis (FDEIA) to wheat (n = 3), shrimp, fish and fruit (apple and peach). However, the offending food at the event was only specified in two cases involving wheat allergy, one case of fish allergy and one case of 'shrimp allergy' in which the patient used an AAI after consuming squid. Nine cases had a clinical history of immediate food allergy to wheat (n = 6), cow's milk (n = 2) and hen's egg (n = 1), and the

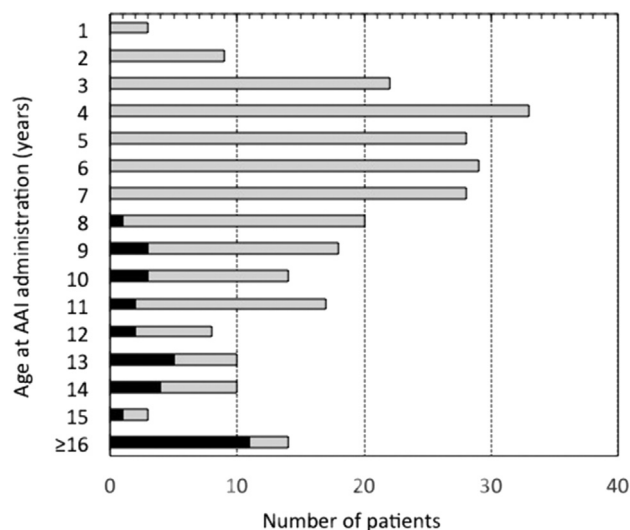


Fig. 1. Patients ages at the time of AAI usage. The distribution of the patients' ages at the time of adrenaline auto-injector (AAI) usage is shown in the bars (n = 266). Black bars indicate the number of patients who used an AAI by themselves (n = 32).

Table 1

Indications for the use of adrenaline auto-injectors by general persons (Japanese Society of Pediatric Allergy and Clinical Immunology).<sup>3</sup>

The EpiPen <sup>®</sup> should be administered to patients with suspected anaphylactic shock and for whom an EpiPen <sup>®</sup> is prescribed when the patient presents at least one of the following symptoms:	
Digestive symptoms	Repeated vomiting Persistent severe (intolerable) abdominal pain
Respiratory symptoms	Tightening in the throat or chest Husky voice Barking cough Persistent severe cough Wheezing
Systemic symptoms	Breathing difficulty Pale lips or nails Hardly palpable pulse Confusion Fatigue Incontinence

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