Effect of Instruction on the Ability to Use a Self-Administered Epinephrine Injector

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ABSTRACT: **Background:** Patients with allergy as well as their parents frequently fail to use the self-administered epinephrine injection (EpiPen®) properly in cases of allergic emergencies.
Objectives: To determine the benefit of an instruction session with follow-up instruction.
Methods: We evaluated 141 patients aged 1.9–23.4 years (median 5.8 years, 83% with food allergy) or their parents (for those aged < 12 years) who were trained in the use of the EpiPen during the first diagnostic visit to the allergy clinic during 2006–2009. At the next follow-up visit, the patients or their parents were asked to list the indications for epinephrine administration and to demonstrate the five steps involved in using the EpiPen. Each step was scored on a scale of 0–2.
Results: Fourteen participants (9.9%) had used self-injectable epinephrine in the past. Only 65 (46%) brought the device with them to the follow-up visit. The mean total score for the whole sample was 4.03 ± 3. Fifty-three participants (38%) failed to remove the cap before trying to apply the device. Only 8 (5.6%) had a maximum score. The patients and their parents were reinstructed in the use of the device: 41 participants were reexamined at a subsequent follow-up visit after 1.02 ± 0.56 years; their mean score improved from 4.71 ± 3.04 to 6.73 ± 3.18 ($P < 0.001$).
Conclusions: Patients with severe allergic reactions, as well as their parents, are not sufficiently skilled in the use of the EpiPen after only one instruction session with a specialist. Repeated instruction may improve the results and we therefore recommend that the instructions be repeated at every follow-up visit.

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The occurrence of anaphylaxis in developed countries is increasing, especially in the first and second decades of life [1]. Food allergy is the leading cause of anaphylaxis in children and adolescents, and allergy to drugs, hymenoptera sting, and latex are the leading causes in adults [2]. In Israel, a study of 92 patients under the age of 18 years admitted to a single pediatric medical center for anaphylactic reaction during 1993–2004 found that food allergy was the cause in 43%, drug allergy in 22%, and hymenoptera sting allergy in 14% [3].

The treatment of choice for anaphylactic reaction is epinephrine injection [4]. However, several studies have shown that patients and parents often receive inadequate instruction in the application of the epinephrine auto-injector, the EpiPen® (NAPA, CA, USA), and their skills in its use were poor [5-9]. Correct use of the device improved after a single visit to a multidisciplinary allergy clinic [10].

In Israel, the prescription rate for the EpiPen increased by 76% from 1997 to 2004 [11], while the population increased by 16% [12]. At the Schneider Children's Medical Center of Israel, where the present study was performed, all patients with anaphylactic reactions are referred to allergists, and they or their parents are routinely given guidance in EpiPen use at the first visit to the allergy clinic [13]. Each patient/parent also receives an individualized written emergency plan for possible additional severe allergic reaction (translated into Hebrew from the site: www.foodallergy.org) [13]. The aim of the present study was to evaluate the ability and knowledge of both patients with allergy and their parents to properly use the injector after the first clinic visit and to assess the benefit of reinstruction in the use of the EpiPen at a follow-up visit.

PATIENTS AND METHODS

The study population was recruited from children and adolescents who attended the allergy clinic of the Schneider Children's Medical Center of Israel, a tertiary university-affiliated hospital, from June 2006 to June 2009. The patients had been referred for evaluation by the hospital ward or by their primary care physician. The diagnosis of anaphylactic reaction was confirmed at the first clinic visit according to the criteria proposed by an international task force [14]. Prick-skin tests (ALK-Abello, Port Washington, NY, USA) and/or blood tests (Immulite 2000, Siemens Medical Solutions Diagnostics, Tarrytown, NY, USA) were performed to detect specific immunoglobulin E antibodies. According to our departmental protocol, all patients and parents received an individualized written emergency plan and instructions for the use of the EpiPen injector. They were also trained in its use in the clinic by one of three physicians (Y.L., N.S., B.-Z.G.).

At the next follow-up visit, the patients (age > 12 years, n=12) and parents (n=129) were asked to complete a questionnaire on the indications for the epinephrine injection and on availability of an emergency kit at school. They were also asked if they had used the EpiPen, and if they had brought the device with them to the present clinic visit. The expiration date was checked for each available EpiPen device. Thereafter, using a trainer injector, patients or parents were asked to demonstrate how to use it. Each step of the procedure was scored on a scale of 0–2 (maximum score 10) by the same physician who served as the trainer, as follows: 1) removing the cap, 2) holding the device, 3) placing the injector tip against the upper outer thigh and pressing the top until a "click" is heard, 4) holding the needle in place for about 10 seconds, 5) pulling the needle out and massaging the injection site. A score of 0 meant the participant did not know what to do; a score of 1 meant that the participant hesitated for a few minutes before performing the step and/or did not perform it correctly (i.e., held the injector upside down, used it in the wrong anatomic site or immediately removed it from the injection site); a score of 2 meant the step was performed correctly and without hesitation. Some of the patients were asked to repeat the demonstration at the second follow-up visit.

STATISTICAL ANALYSIS

Data were analyzed using BMDP statistical software [15]. Continuous variables were compared across groups with one-way analysis of variance (ANOVA). Variables with a non-Gaussian distribution were compared with the Mann-Whitney non-parametric U test. Discrete variables were compared using Pearson's chi-square test or Fisher's exact test, as appropriate. A P value ≤ 0.05 was considered significant.

RESULTS

The study group consisted of 141 children with anaphylactic reactions who had been prescribed the EpiPen and trained in its use in our allergy clinic. Ninety-three children (66%) were male; median age was 5.8 years (range 22 months to 23.4 years). The clinical characteristics of the patients and the cause of the anaphylactic reactions are shown in Table 1. Food allergy was the main cause (n=118, 83%), followed by hymenoptera sting allergy (n=15, 11%). The interval from the diagnostic visit to the first follow-up visit was 0.04–6.54 years (mean 1.28 years).

KNOWLEDGE ABOUT ANAPHYLACTIC REACTION

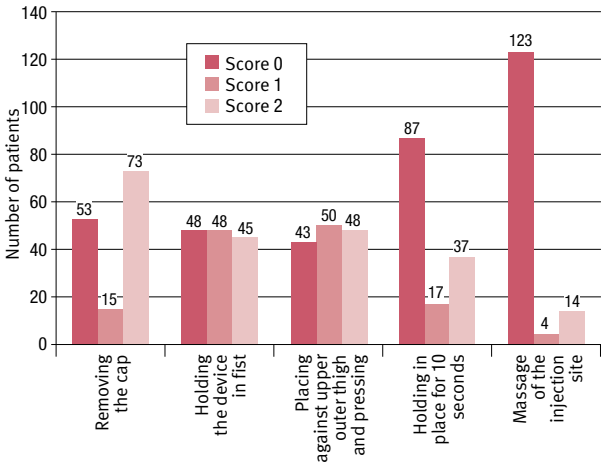
When the patients or parents were asked to describe the indications for epinephrine injection, 109 (77%) were able to cite at least two symptoms of systemic allergic reaction: rash, angioedema, dyspnea, or wheezing. In addition, 106 (75%) knew what needed to be done in emergencies according to their individualized emergency plan. Although all reported that they had the device with them at all times, only 66 (47%) had brought it to the clinic, and in 14 of these cases (21%) the device had passed its expiry date. Thus, only 52 participants (37%) had a valid device at hand at the time of the survey.

Table 1. Data of patients with anaphylaxis

	Causes of anaphylaxis			
	Food	**Insect bite**	**Other**	**Total**
No. of children, n (%)	118 (83)	15 (11)	8 (6)	141
Male/female	79/39	10/5	4/4	93/48
Allergenic trigger, n*	Milk 75 Peanut 34 Nut 19 Sesame 17 Egg 13 Fish 6 Soy 1 Almond 1 Peach 1	Honey bee 7 Yellow jacket 5 Wasp 3	Drugs (penicillin) 1 Pollens 2 Cold 1 Idiopathic 4	
Age at presentation (yrs, mean ± SD)	1.13 ± 1.82	10.07 ± 4.17	9.33 ± 6.05	2.55 ± 4.09
Age at study (yrs, mean ± SD)	2.67 ± 3.19	12.99 ± 4.98	12.01 ± 5.06	7.2 ± 4.39
Medical history, n (%)*				
Asthma	52 (44)		3 (37.5)	55 (39)
Atopic dermatitis	33 (28)			34 (24)
Allergic rhinitis	7 (4.2)	1 (6.6)	2 (25)	9 (6)

*Some children had several allergies

Figure 1. Distribution of performance scores for use of the EpiPen for each of the five steps



ABILITY TO USE THE EPIPEN

Fourteen participants (10%) had used the EpiPen in the past. The demonstration performance scores for the use of the EpiPen by steps of the procedure are shown in Figure 1. Fifty-three participants (37.5%) failed to remove the cap (step 1), which is essential for effective application of the injector. Most of the patients (62%–87%) incorrectly performed the final two steps. The distribution

Table 2. EpiPen use scores in 141 patients at the first follow-up visit

Score	No. (%)
0	27 (19)
1–4	55 (39)
5–7	39 (28)
8–10	20 (14)

Table 3. EpiPen use scores of 41 patients at the first and second follow-up visits*

	First follow-up visit	Second follow-up visit
Score	No. (%)	No. (%)
0	7 (17)	4 (10)
1–4	11 (27)	4 (10)
5–7	15 (36)	11 (27)
8–10	8 (19)	22 (53)

*The mean score per patient improved from 4.71 ± 3.04 to 6.73 ± 3.18 ($P < 0.001$)

of total scores is presented in Table 2. Twenty-seven participants (19%) received a score of 0, and only 8 (5.6%) received a maximum score of 10. The mean score per patient was 4.03 ± 3.

REEVALUATION

Forty-one participants (29%) were reevaluated at the second follow-up visit after 1.02 ± 0.56 years (range 0.08–2.6 years). Six (15%) did not remove the cap. The mean score of this subgroup improved from 4.71 ± 3.04 to 6.7 ± 3.18 ($P < 0.001$). The distribution of the total scores at the second follow-up visit is presented in Table 3.

There were no statistically significant differences in the score between the 12 older patients (age > 12 years), who demonstrated the use of the EpiPen themselves, and the parents who demonstrated the use of the device on the younger children. In addition, there were no differences in total score between participants who had or had not used the EpiPen previously. The time elapsed from the initial diagnostic visit to the first follow-up and between the first and second follow-up visits had no effect on the total score (data not shown).

EMERGENCY KIT AT SCHOOL

According to the survey responses, 83 of the 138 children attending school or kindergarten at the time of the survey had access to the EpiPen at school: 52 (63%) kept the device in their schoolbag, 22 (27%) kept it in the classroom in an easy-to-reach place (teacher's drawer/closet or on a shelf), and 9 (11%) kept it outside the classroom (in the principal's, secretary's, or nurse's room). Five children (6%) had two devices at school: one in their bag and the other with a staff member. Fifty-four participants (39%) stated that the school staff knew the indications for administering the drug and had been trained in the use of the injector.

DISCUSSION

The present study focused mainly on the degree of patient/parental knowledge and ability in the use of the EpiPen on follow-up after a single training session in a specialized allergy clinic. The majority of patients and their parents (75–77%) correctly identified the symptoms and signs of anaphylaxis and knew what needed to be done in emergencies. This finding is in accordance with previous studies in which 48–75% of patients cared for by allergists successfully identified skin and respiratory symptoms indicating the need for epinephrine [16-19]. However, our patients were not skilled in the practical aspects: only 5.6% performed all five steps of the procedure correctly. This rate is lower than the rates reported in earlier studies – namely 38% [6], 24% [7] and 14–35% [9], although the difference can be attributed to differences in the scoring systems used. We assigned a maximal score of 2 points when the step was performed quickly and without hesitation, whereas other investigators did not quantify the performance. In addition, our scoring method might explain the considerably lower proportion of our patients who were completely unable to use the device (19%, score 0) compared to an earlier study (43%) [8]. The rate of failure to perform the last two steps of the procedure correctly (holding the injector in place for 10 seconds and massaging the site) was higher than the failure rate for the first three steps, which are more crucial to proper administration of the drug. At the first follow-up visit, 37.5% of our patients did not remove the cap of the injector (score 0), a rate similar to the 32% found in the study of Blyth and Sundrum [7], but lower than the 55% in the study of Sicherer et al. [6]. One exception is the study by Huang [5], which observed that 89.8% of the patients knew that the cap had to be removed.

In an earlier study on the effectiveness of patient/parent education in an allergy clinic, 52.2% of the 23 participants identified all the critical steps of EpiPen administration at the initial visit before instruction, and 95% did so at a follow-up visit 3 months later [10]. The patients in our study were also trained in an allergy clinic, but more time had elapsed between the diagnostic visit and the first follow-up visit, a factor that might have influenced the score. It is noteworthy that on further analysis of the impact of repeated training (n=41), the results were significantly improved. The mean score per patient rose from 4.71 to 6.7, and the percentage of patients who did not remove the cap decreased from 37% to 15%. Thus, it seems that repeated training in the use of the EpiPen at the allergy clinic resulted in a considerable improvement in patient/parent skills in its usage. Also important is the finding that there was no difference in scores between the small group

of children older than 12 years (n=12) who demonstrated the use of the injector on themselves and the parents of the younger patients (n=129). We therefore conclude that it is worthwhile to educate and instruct this age group of allergic children in the use of the EpiPen.

Most of the patients in the present study (83%) had food allergy, in accordance with earlier studies [6-8,11]. Food allergy is responsible for the majority of anaphylactic reactions in children [2]. In our sample, milk was the allergenic food in 63.5% of the food-allergic patients. This finding was not unexpected given that milk is the most prevalent allergenic food in Israel (in contrast to peanuts in the United States and Europe) [20]. Our patients with food allergy also had a high rate of asthma (44%). In a previous study in our institute, the rate of asthma in patients with persistent milk allergy was 60% [13]. Since asthma is a risk factor for fatal anaphylaxis [21], this high value further emphasizes the need for proper training in the use of the EpiPen for patients with food allergy in order to prevent fatalities in case of accidental exposure.

Only half of our patients had the EpiPen with them at the first clinic follow-up visit, and in more than 21% the expiry date had passed. Allen et al. [22] also reported that 30% of 120 patients with anaphylaxis who were in the care of an allergist did not always carry an EpiPen. These findings highlight the need for more involvement of primary physicians in the community in the care and follow-up of patients with anaphylactic reactions.

Although 60% of the participants reported that an emergency kit was accessible at school, for only 39% was the school personnel instructed in its use. Gold and Sainsbury [17] found a 97% rate of reportage of child allergies to the school and a 40% rate of EpiPen availability at the school, with staff trained in its use. Pouessel at al. [19] reported that up to 72% of their patients had an EpiPen at school. Considering that 20% of children with food allergy experience a reaction at school according to survey studies [23], it is very important that medical facilities communicate with school authorities on this topic. The Ministry of Education in Israel recently published recommendations for the management at school of children with food allergy [24].

In conclusion, training and instruction of patients and parents in EpiPen use should be repeated in subsequent follow-up visits at the allergy clinic to improve performance. Primary care pediatricians and the school health care system should be actively involved in the management of patients at risk of anaphylactic reactions, with guidance from attending allergists.

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