

A Real-Life Study on Acquired Skills from Using an Adrenaline Autoinjector

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Key Words

Adrenaline • Anaphylaxis • Autoinjector • Training

Abstract

Background: Training programs performed by allergists have increased the ability of patients' recognition and management of anaphylaxis. We aim to investigate the permanence of effect of an anaphylaxis training program and to determine the factors affecting it beyond training given by allergists. **Methods:** Children and/or their caregivers who had been prescribed an adrenaline autoinjector at least 1 year before were invited to take part in the study. The knowledge about anaphylaxis was assessed using a questionnaire and the skills were practically tested. **Results:** Sixty-four (50 caregivers/14 children >12 years of age) of 80 patients who accepted the invitation were included in the study. Fifty-nine patients obtained the autoinjector after initial prescription. Among them, 42 (71%) still had the device at the time of the study. The most common reason for not having the autoinjector was no longer feeling it was necessary (54.6%). Of the cases, 39.4% were competent in autoinjector use. There was a significant relation between adrenaline autoinjector competency and regular allergy visits ($p = 0.010$), believing that it is necessary ($p = 0.04$), having an adrenaline autoinjector

($p = 0.003$), and previous history of severe anaphylaxis ($p = 0.010$). Autoinjector competency score decreased as time elapsed from the last visit ($\rho = -0.382$; $p = 0.002$) and the first instruction ($\rho = -0.317$; $p = 0.01$). Regular visits ($p = 0.009$) and history of severe anaphylaxis ($p = 0.007$) were found as independent factors having an effect on adrenaline autoinjector competency. **Conclusions:** Training of patients/caregivers by allergists does not guarantee the permanence of acquired skills on anaphylaxis in the long run. Regular follow-up visits should be fostered.

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Introduction

Increasing awareness about early diagnosis and treatment of anaphylaxis is a priority to decrease anaphylaxis-related mortality and morbidity. It is estimated that about 29,000 anaphylaxis episodes due to food allergy occur each year and 150 of them result in death [1, 2]. Most cases of fatal anaphylaxis develop outside the hospital and only 10% of these cases have adrenaline available for use at the time of the reaction [3]. Similarly, only one third of the patients use an adrenaline autoinjector in subsequent anaphylaxis episodes, although two thirds of them

have ready access to a device [4]. Nevertheless, it was found that patients were not only insufficient in recognizing anaphylaxis symptoms, but also incompetent in the proper use of adrenaline autoinjectors [5–8]. Therefore, the factors leading to epinephrine autoinjector underuse are not simple, and personal factors as well as training issues seem to be the main offenders. In this respect, expertise of the trainer also seems to be an important determinant to proper training. When the trainer is an allergist, the ability of patients to use the adrenaline autoinjector increases 17-fold, compared to when the trainer is a general practitioner [8]. Supporting this data, training in a pediatric allergy clinic was reported to improve the knowledge and ability of families in handling allergic reactions and adrenaline autoinjector use by 85 and 80%, when checked 3 months later, respectively [5]. However, it is not easy to apply all recommendations to real life because it is not uncommon for patients to skip their scheduled visits. Therefore, we primarily wanted to investigate what happens in real life. To do so, we asked the questions: ‘Is training of patients and/or their caregivers in an allergy clinic on recognizing and managing anaphylaxis with an adrenaline autoinjector enough for maintaining the acquired skills?’ and ‘What are the other factors affecting its proper use?’

Methods

Participants

Patients and/or their caregivers, who had been diagnosed with anaphylaxis, prescribed an adrenaline autoinjector and followed in our clinic for at least 1 year were included in the study. Anaphylaxis was diagnosed in accordance with the second symposium on the definition and management of anaphylaxis [9]. The severity of reaction and indications of adrenaline autoinjector prescription were determined according to the position paper by the EAA-CI [10].

The research protocol was approved by the ethics committee of Gazi University Faculty of Medicine (No. 77, April 13, 2011), and all participants gave their informed consent.

Anaphylaxis and Autoinjector Education

In Turkey, adrenaline autoinjectors prescribed by allergists are provided and paid for by the Turkish Ministry of Health. In our clinic, since January 2005, a standardized education and training on anaphylaxis and its emergency management has been provided to all caregivers and children over 12 years of age diagnosed with anaphylaxis. This program includes a theoretical and a practical part. The theoretical part is printed on a sheet, taught by an allergy fellow, and given to all patients and their caregivers. The information on this action plan is written and shown by pictures. It covers symptoms and signs of anaphylaxis

and tells when and how to use the adrenaline autoinjector and how to avoid the responsible allergen. A practical session is done by the adrenaline autoinjector trainer (EpiPen Trainer; Meridian Medical Technologies Inc., Columbia, Md., USA) in all sessions. Both parents and other caregivers, if any, were trained by two pediatric allergy fellows (M.A., O.Y.), then caregivers and patients older than 12 years were asked to show how it is used. The training is repeated during the same visit until they become competent in its use. They are told to note the expiry date and to get a new one shortly before the date of expiration. Admission to the nearest health center is advised after autoinjector use. Caregivers are taught to use the adrenaline autoinjector in any condition of doubt. To encourage its use and decrease hesitation, they are told that it is life-saving and has no serious side effects. The patients are recommended to attend scheduled visits twice a year. Competence with the adrenaline autoinjector is checked at every follow-up visit and instructions for use are repeated for the patients and their caregivers whose competence with the autoinjector had decreased.

Assessment

The patients were invited to our clinic by phone. The caregivers and/or patients who were older than 12 were interviewed face-to-face by an allergy fellow (E.T.). Although children between 8 and 12 years of age can respond reliably to questionnaires, we chose to interview their parents because we also preferred the same age range for practical demonstration of the autoinjector. The survey consisted of 15 questions investigating demographic features, knowledge of patients/caregivers on anaphylaxis symptoms and the adrenaline autoinjector, and their decision on when to use it. The participant's decision on when to use the adrenaline autoinjector was questioned by five short case histories. Then the patients, if over 12 years, or their caregivers were asked to demonstrate autoinjector use. Written and visual instruction sheets were given to the ones who requested them. We used a trainer (EpiPen Trainer; Meridian Medical Technologies Inc.) exactly identical to the original adrenaline autoinjector, except for medication and needle, in all practical sessions.

Practical demonstration was scored in six steps (each step was 1 point) on a standard form composed by Sicherer et al. [6]. These steps consisted of recognizing the autoinjector (does not need to read the instruction before using the trainer), removing the gray safety cap, selecting the outer thigh, applying the black end to the thigh, pressing it down until it clicks, and holding it in place for at least 10 s. Patients/caregivers accomplishing all six steps correctly were regarded as competent with the adrenaline autoinjector. Additionally, participants playing with the injection tip after removing the safety cap were regarded as unsuccessful because it might cause unintentional firing and injection of the needle to fingers. The patients who were seen in the clinic at least once a year were assumed as ‘regularly controlled’ and the rest as ‘irregularly controlled’.

Statistical Analysis

Statistical analysis was performed by Statistical Package for Social Sciences (SPSS) 11.5 software (SPSS Inc., Chicago, Ill., USA). Categorical variables were compared using a χ^2 test. The variables with $p < 0.05$ were regarded as statistically significant. Spearman's correlation test was used to determine the correlation

between adrenaline autoinjector competency score and time since the last visit and the first instruction. A logistic regression model was constructed by including statistically significant and clinically important parameters to determine the factors affecting the proper use of the adrenaline autoinjector in study participants.

Results

There were 80 children in our database (beginning in January 2005) eligible for inclusion in the research. Seventy of them were reached by phone and 64 accepted the invitation. Fifty caregivers (40 mothers and 10 fathers) and 14 children older than 12 years were included in the study. The demographics of participants are given in table 1. The most common etiology of anaphylaxis was food.

Knowledge about Anaphylaxis Symptoms and Adrenaline Autoinjector

Ninety percent of participants expressed that they would have used the adrenaline autoinjector when urticaria and/or angioedema coexisted with wheezing or dyspnea; 87.5% in the case of fainting only, and 43.8% when urticaria coexisted with refractory vomiting.

Among the participants who obtained the adrenaline autoinjector after prescription ($n = 59$), 42 of them (71.1%) still had the device at the time of the study, but 4 had not realized that the expiry date had already passed. Twenty-two patients did not have the adrenaline autoinjector on hand at the time of study. The most common reason for this was the belief that the adrenaline autoinjector was no longer needed (table 2). Ten participants (15.6%) did not know how check the expiry date. Anaphylaxis recurred in 7 patients (10.9%) after training. Although 5 of these patients were carrying the device at the time of the reaction, only 1 patient had used it. The other cases did not use the autoinjector although they had recognized anaphylaxis.

Adrenaline Autoinjector Competency

There were 40 mothers, 10 fathers, and 14 children >12 years of age tested for adrenaline autoinjector competency. Seventy-six percent of the participants declared that they did not need to read the instructions before demonstration. Twenty-five participants (39.1%) showed all the steps of autoinjector use correctly. Seven patients (28%) who demonstrated all steps correctly were not carrying the device. The most frequent mistake in the practical

Table 1. Demographics of the patients ($n = 64$)

	n (%)
Male gender	41 (64.1)
Age, years	6.0 (7.0)
Time since the first instruction, months	17.5 (18.75)
Time since the last visit, months	6 (21)
Follow-up	
Regular	43 (67.2)
Irregular	21 (32.8)
Etiology	
Food	32 (50)
Cow's milk	14 (21.9)
Hen's egg	5 (7.9)
Fish	4 (6.3)
Other ¹	5 (7.9)
Venom	23 (35.9)
Vespid	20 (31.3)
Apis	3 (4.7)
Idiopathic	5 (7.8)
Mastocytosis	2 (3.1)
Other ²	2 (3.1)
Anaphylaxis episodes before prescription	
1	50 (80.6)
≥2	12 (19.4)
History of severe anaphylaxis episode	10 (15.6)

Continuous parameters are shown as medians (interquartile range).

¹ Lentil ($n = 2$), peach ($n = 1$), pomegranate ($n = 1$), beef ($n = 1$).

² Exercise induced ($n = 1$) and latex ($n = 1$).

Table 2. Reasons for not having an autoinjector ($n = 22$)

	n (%)
Did not buy it after prescription	5 (22.7)
Did not renew it because thought was no longer necessary	12 (54.6)
Could not buy it because did not renew device report	3 (13.7)
Bought adrenaline vial instead of autoinjector	1 (4.5)
Did not renew it for any definite reason	1 (4.5)

session was failing to hold the device in the thigh for 10 s (fig. 1). There was no meaningful difference between caregivers and children >12 years of age according to either adrenaline autoinjector competency (40 and 35.7%, respectively) or median score (interquartile range) [5 (2) and 5 (2), respectively; $p > 0.05$ for both]. Also, there was no difference between mothers and fathers according to either adrenaline autoinjector competency (39.5 and 55.6%, respectively) or median score [5 (2) and 6 (2), re-

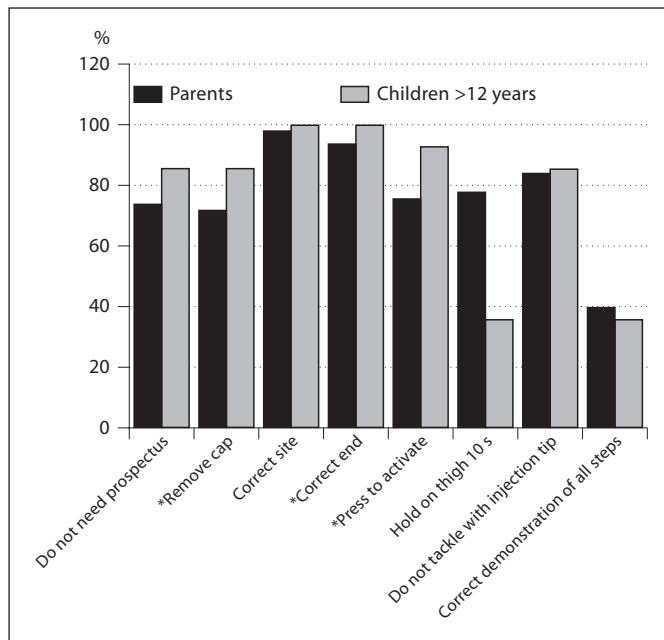


Fig. 1. Adrenaline autoinjector competency steps. * Critical steps.

spectively; $p > 0.05$ for both]. Results of adrenaline autoinjector competency for children >12 years of age and their caregivers are demonstrated separately in figure 1. Children >12 years of age and their caregivers did not differ significantly considering the steps to competency with the adrenaline autoinjector, except holding it for 10 s ($p = 0.007$).

Factors Associated with Adrenaline Autoinjector Competency

There was no statistically significant correlation between adrenaline autoinjector competency and socioeconomic status and education of the participant, having a written action plan, number of previous anaphylaxis episodes, recurrence of anaphylaxis after autoinjector prescription, coexistence of asthma or recognition of anaphylaxis symptoms, and making a decision when to use the autoinjector (disease comprehension; $p > 0.05$ for each). There was a statistically significant correlation between adrenaline autoinjector competency and the belief in the necessity ($p = 0.040$), having an autoinjector ($p = 0.003$), being on regular control ($p = 0.010$), and history of severe anaphylaxis episode ($p = 0.010$). Correlation analysis showed a moderately inverse relation between autoinjector competency score and time elapsed since the last visit ($\rho = 0.382$; $p = 0.002$) and since the first in-

struction ($\rho = 0.317$; $p = 0.01$). When statistically significant and clinically important (coexistent asthma) parameters were analyzed in a logistic regression model, being on regular control (OR: 17.1, 95% CI: 2.06–142.89, $p = 0.009$) and history of severe anaphylaxis (OR: 28.3, 95% CI: 2.50–321.38, $p = 0.007$) were found as the independent factors affecting the proper use of the adrenaline autoinjector.

Discussion

This is the first real-life study investigating the permanence of acquired skills on proper use of an adrenaline autoinjector. Our study did not aim to find the appropriate training intervals to attain the best autoinjector practice by patients or their caregivers. Therefore, we assessed autoinjector skills as the patients attend their routine follow-up visits rather than at regular intervals. This way, we wanted to evaluate what happens in real life at least 1 year after they were prescribed, trained, and attained competence in correct use of the adrenaline autoinjector by allergists. We found that correct use of the adrenaline autoinjector was less than 50% although they were trained in an allergy clinic at least 1 year ago. Regular follow-up and history of severe anaphylaxis were found as important factors influencing the proper use of the adrenaline autoinjector in patients/caregivers trained by allergists.

Kapoor et al. [5] showed that a multidisciplinary approach in an allergy clinic improved parental knowledge of allergen avoidance, management of allergic reactions, and adrenaline autoinjector usage on children with food allergies. In our study, although all participants had been prescribed, taught, and trained to use the adrenaline autoinjector by allergists as in the study of Kapoor et al. [5], less than 75% had their autoinjectors with them at the time of the study. Moreover, some of the participants did not notice that the expiry date had already passed. Previously, research results from Australia [4] and the USA [6] reported that 69 and 71% of patients with food allergy had their autoinjectors with them, respectively. These results were similar to ours and, once again, were good evidence that the patients either did not understand or ignored the risk of anaphylaxis and the importance of carrying the autoinjector with them in daily life.

The correct use of the adrenaline autoinjector by patients and their caregivers was previously studied by Sicherer et al. [6] and Kapoor et al. [5]. Sicherer et al. [6] found this rate to be 38%. In the study of Kapoor et al. [5],

the researches checked the ability of patients to use the adrenaline autoinjector 3 months after they trained them and found it to be 95.7%. Our results were similar to the results of Sicherer et al. [6] but lower than those of Kapoor et al. [5], although our participants were also trained by allergists as in the study of Kapoor et al. [5]. This may be due to several reasons: Kapoor et al. [5] evaluated their patients' ability only after 3 months, while we assessed it at least 1 year later. Although the study of Kapoor et al. [5] was the first to indicate the success of training given by allergists, telephone interviews were relied on for almost half of the participants. However, verbal expressions of patients may be different than what they actually do in practice. The best example to this is in the study of Sicherer et al. [6] where 71% of the patients had the adrenaline autoinjector with them at the time of the visit although all declared that they had it at all times. Therefore, we evaluated the ability of each participant to use the autoinjector by practical demonstration. Furthermore, one third of our patients were not on regular control, which might have decreased the rate of correct demonstration of autoinjector use. However, we think that our study population reflects real-life practices because one third of our patients did not attend their scheduled visits, although all were recommended to do so at least twice a year. Also, we know the level of proficiency in using the autoinjector at the initial prescription was not a factor effecting this result because we do not let any of our patients have one before we cross-check their ability to use it.

Factors determining the ability of parents to effectively administer an adrenaline autoinjector to allergic patients were studied only by Arkwright and Farragher [8]. They found that practical demonstration, prior consultation with an allergy specialist, independent search for additional information from the national self-help allergy organizations, and duration of the time with a device are the significant factors having an effect on this ability. In our study, since all the participants were trained by allergists, we wanted to investigate other factors determining the permanence of this ability. We found that attending regular-scheduled allergy visits and history of severe anaphylaxis episodes were significant independent factors determining this ability. Both of these factors seem to increase this ability manifold. However, the odds ratios are probably inflated because the confidence intervals are wide due to the number of the participants.

We think that patients with severe anaphylaxis, by experiencing the fear of death, comprehend the seriousness of anaphylaxis and the importance of the autoinjector

more than others. We relate the effect of regular follow-up on autoinjector skill to repeated training at each visit. However, the rate of participants competent with autoinjector use are less than the ones on regular control in our study, which certainly points to other personal and psychological factors such as injection phobia, ignorance, the level of anxiety, and propensity to risk-taking that may influence the ability to use the adrenaline autoinjector [7, 11]. Inability to inject the adrenaline autoinjector during reaction, although it is available, is probably related to these personal factors in patients who were competent in its use during the demonstration. The number of participants who experienced anaphylaxis after autoinjector training is few in our study, and only 1 of the 5 patients who were carrying the autoinjector was able to apply it during the real episode. The other 4 patients/caregivers did recognize the event, but did not dare to use it. Therefore, it does not seem to be related to inadequate knowledge about anaphylaxis symptoms or signs. This is also supported by questionnaire results which demonstrated that 90% of the patients declared that they would administer the adrenaline autoinjector when cutaneous and respiratory symptoms coexist. Still, when the gastrointestinal symptoms are concerned, the ability of parents to recognize the reaction decreases both in our study and the study by Gold and Sainsbury [4]. This is probably related to the low frequency of gastrointestinal symptoms in anaphylaxis which leads to less experience and thus poor learning by the patients/caregivers and/or less emphasis by the physicians. However, a very recent study demonstrated that inadequate knowledge may still be a problem for not using adrenaline in anaphylaxis among children and teenagers because the most common reasons were reported as 'thought adrenaline unnecessary' and 'unsure adrenaline necessary' [12].

In conclusion, the training of patients/caregivers in allergy clinics does not guarantee the permanence of acquired skills on the adrenaline autoinjector in real life over the long term. Although barriers to use are multiple and do not seem to be solved completely by training in an allergy center, we propose regular follow-up and repeated trainings of patients/caregivers, reminders when they miss a visit when possible, and checking the presence of and the ability to use the adrenaline autoinjector at all times. This approach would probably enable the physician to know his/her patient's or their caregivers' needs and fears better, and help with the preparation and development of a more comprehensive, desired individualized program.

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