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RESEARCH

The adherence of parents regarding epinephrine auto-injector use in anaphylaxis management: a real-life study

Anafilaksi tedavisinde epinefrin oto-enjektör kullanımı konusunda ebeveynlerin uyumu: gerçek yaşamdan bir çalışma

Mahir Serbes[1], Ayse Şenay Şasihüseyinoglu[1], Dilek Özcan[1], Rabia Miray Kışla Ekinci[2], Sibel Balcı[2], Derya Ufuk Altıntaş[1]

[1]Cukurova University Faculty of Medicine, Department of Pediatric Allergy and Immunology, [2]Department of Pediatric Rheumatology, Adana, Turkey

Abstract

Purpose: The purpose of this study was to identify unmet needs in the management of anaphylaxis by assessing the practical skills of the parent(s) regarding the use of epinephrine auto-injectors (EAIs) and determining the factors influencing them.

Materials and Methods: The study included 114 primary caregivers of children prescribed an EAI with an anaphylaxis risk. A structured mini-interview with a practice test using a trainer device was performed.

Results: Epinephrine was described as a life-saving and first-line treatment for anaphylaxis by 93 parents (81.6%). However, only 53 parents (46.5%) stated that they carry an EIA device with them regularly in their daily lives. 38 children (33.3%) had relapsing episodes, but among those experiencing anaphylaxis, only 6 parents (20%) used EAI despite carrying. According to respondents, the main factor avoiding AEI's regular carriage was a lack of belief in necessity (18, 29.5%). Among participants, only 13 (11.4%) of the parents were able to administer EAI correctly in all 5 steps. An inverse relationship between the ability to use the device and the time elapsed since the last visit s was found.

Conclusion: Low adherence levels among parents highlighted the urgent need to improve this situation. Interventions including regular EAI training and psychological support should be provided among parents, but may not guarantee to maintain acquired adherence to EAIs in real life.

Keywords:. Anaphylaxis, children, parents, epinephrine auto-injectors, adherence

Öz

Amaç: Bu çalışmanın amacı, ebeveyn(ler)in epinefrin oto-enjektörlerinin (EAI) kullanımına ilişkin pratik becerilerini değerlendirerek ve bunları etkileyen faktörleri belirleyerek anafilaksi yönetimindeki eksikleri belirlemektir.

Gereç ve Yöntem: Çalışma, anafilaktik riski olan ve EAI reçete edilen 114 çocuk hastanın birincil bakıcısını yani ebeveynleri içeriyordu. Ebeveynlerle hem yüz yüze görüşme hem de bir EAI demo cihazı kullanılarak pratik beceri testi uygulanmıştır.

Bulgular: Epinefrin, 93 ebeveyn (%81.6) tarafından anafilaksi için hayat kurtarıcı ve birinci basamak tedavi olarak tanımlandı. Ancak sadece 53 ebeveyn (%46.5) günlük yaşamlarında EAI cihazını düzenli olarak taşıdıklarını belirtti. 38 çocukta (%33.3) tekrarlayan ataklar olduğu saptandı. Bu hastalarda EAI cihazını taşımasına rağmen sadece 6 ebeveynin (%20) EAI cihazını uyguladığı saptandı. Katılımcılara göre AEI'nin düzenli taşınmasını engelleyen ana faktör, gerekliliğe olan inanç eksikliğiydi (18, %29.5). Katılımcılar arasında, ebeveynlerin sadece 13'ü (%11.4) EAI'yi tüm basamaklarda doğru şekilde uygulayabildi. Cihazı kullanma becerisi ile son ziyaretten bu yana geçen süre arasında ters bir ilişki bulundu.

Sonuç: Ebeveynler arasındaki EAI kullanımı konusunda bulunan düşük uyum seviyeleri, bu durumu iyileştirmeye yönelik acil ihtiyacın altını çizmiştir. Ebeveynlere yönelik düzenli EAI doğru kullanım eğitimlerinin yanı sıra psikolojik destek de dahil olmak üzere daha kapsamlı müdahaleler sağlanmalıdır, ancak bu müdahaleler bile gerçek hayatta EAI'lere kazanılmış uyumu sürdürmeyi garanti etmeyebilir.

Anahtar kelimeler: anafilaksi, çocuklar, ebeveynler, epinefrin oto-enjektörleri, uyum

Address for Correspondence: Mahir Serbes, Çukurova University, Faculty of Medicine, Department of Pediatric Allergy and Immunology, Adana, Turkey E-mail: mahirpediatrics@hotmail.com, mserbes@cu.edu.tr
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INTRODUCTION

Anaphylaxis is an acute, life-threatening, systemic hypersensitivity reaction that requires urgent and proper management and is associated with a risk of unpredictable future episodes. Epinephrine is the first-line emergency treatment, and patients at risk of anaphylaxis should be prescribed and carry epinephrine at all times, preferably in the form of an epinephrine auto-injector (EAI)[1,2]. An immediate and accurate diagnosis of anaphylaxis with prompt and appropriate use of EAI is critical for recovery[2]. For EAIs, the term "adherence" means the degree, to which the patient collects the prescription, carries the device, and uses it correctly[3].

The majority of anaphylaxis episodes occur outside of hospitals, in non-hospital settings such as homes and public places, and are common in preschool age, particularly during the first year of life[4]. Therefore, the adherence of parents, who are the main caregivers of children, regarding EAI use, plays a crucial role in delivering their own children's care and managing anaphylaxis[5,6]. Despite the published guidelines' recommendations, recent studies show that adherence levels are still very low among patients and families caring for their children[5-6]. Due to the increasing prevalence of anaphylaxis in children, there is a growing body of work in Turkey on the recognition and treatment of anaphylaxis using EAI among physicians, teachers, and families[7-10]. However, the studies regarding the adherence of EAI among families in real life were very limited and not performed with the Penepin device, which is the only auto-injector device currently available in Turkey[11,12]. Therefore, our study, performed among parents who were the main caregivers of the children, is the first study aiming to assess their attitudes and adherence regarding EAI usage in anaphylaxis management. Our findings may be useful to identify the measures needed to improve compliance and effective use of EAI devices among families and caregivers after prescription, while highlighting the gaps in EAI device adherence. We were primarily interested in determining how much a standard training program provided by allergists in an allergy outpatient clinic could aid the parents (primary caregivers) in maintaining their adherence and competence for EAI devices, as well as what associated factors may be affecting their learned skills for adherence and competence.

MATERIALS AND METHODS

Sample

This was a single center, cross-sectional descriptive study involving 114 parents of children who had previously been prescribed an epinephrine auto-injector (EAI) in the Allergy Unit of Cukurova University Faculty of Medicine over a period of 5 years (from 2014 to 2019).

Procedure

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and the 1964 Declaration of Helsinki. The Ethics Committee of Cukurova University of Medicine in Adana, Turkey, approved this research study (approval date: 8.3.2019-86). Informed consent was obtained from all participants.

Parents who were the main caregivers of the child, including the mother and father, grandparents, uncles and aunts, and any other individual who lives in the same household, were called and invited to the hospital for a face-to-face interview. Each parent was asked whether they carried EAI on a regular basis and why they did not. Each family was also asked if any anaphylactic reaction requiring EAI administration occurred after the prescription of EAI, and, in this case, whether they used EAI or not, and why they didn't or misused it. During the interview, the medical history of the children, including triggers, age during the study, previous anaphylaxis history, severity of anaphylactic reactions, the time lapse since the last visit, and demographic data of the parents were recorded. In the second part of the study, the parents were asked to demonstrate EAI usage in one-to-one practice, and their practical ability for EAI administration technique was assessed by a physician using a trainer device (Penepin® trainer) with a five-step examination (Table 1).

The steps where EAI administration errors occurred were recorded on forms prepared for this study. Those who demonstrated the six steps of EAI administration in the right order and correctly were regarded as competent with the adrenaline auto-injector. The correct use of the device was compared according to children and parents' associated risk factors, including demographic data, medical history of previous anaphylaxis episodes, and time elapsed

since the last visit. The children were grouped according to their age at the initial diagnosis that AEI provided: 0–1 year: infant; 2–6 years: preschooler; 7–11 years: school-aged; 12–18 years: adolescent; and according to triggers: [food, bee venom, drugs and medications, idiopathic and others (mastocytosis, exercise, etc)]. The time intervals for a policlinic visit were divided into 3 groups according to the time elapsed since the last visit: 3-6 months (1), 6–9 months (2), and 9–12 months (3). The parents were also asked how they felt about the device's usability and for their suggestions for an ideal device that would improve their competency. Anaphylactic reactions were graded according to the Ring and Messmer anaphylaxis severity score and categorized as mild, moderate, or severe[13].

Table 1. The examination steps of EAI trainer device (Penepin® Vem Pharmaceuticals, Ankara, Turkey) administration in practice test.

No	Steps of EAI device use
1	Remove the orange cap located bottom of the device by pulling down
2	Open the safety lock located top of the device by turning the trigger to arrow direction
3	Select upper outer thigh and place the appropriate injection tip into selected place
4	Press the trigger down to activate (so it clicks)
5	Hold for >10 seconds and massage the injection area for 10 seconds

Eligibility criteria

The parents of children who had at least one visit to an allergy clinic in the last year and who received standardized education and training on anaphylaxis were enrolled in the study. The parents and caregivers reporting no training and education were not involved in the study. The parents of children who were health workers were also not involved in the study.

Statistical analysis

Data analysis was performed using the SPSS package software program, version 22.0 (SPSS, Inc., Chicago, IL, USA). The demographic data and clinical features of the population were described using frequencies and proportions (percentage) for categorical varabilen. Fisher's exact or Pearson's Chi-Square tests were used to assess the association between demographic data, factors, and the rate of correct use of the EAI device. All significance tests were two-sided, and a p value < 0.05 was considered statistically significant.

RESULTS

29 (25.4%) of the children were infants, 33 (28.9%) aged 1-5 years, 31 (27.2%) aged 6-11 years, and 21 (18.4%) adolescants aged 12-18 years. The median age of the 114 children was 11 years old (range, 9 months to 18 years), and 62 (54.4%) were boys. The most common indication for EAI prescription was food allergy (n = 50, 43.6%), followed by drug allergy (n = 31, 27.2%), venom allergy (n = 15, 13.2%), idiopathic anaphylaxis (n = 4, 3.5%), and others (n = 14, 12.3%). Most of the patients were taken care of by their mother (89.9%), and the percentage of parents with a university or higher level of education was (n = 55, 48.2%) (Table 2).

Of these 114 parents, 93 (81.6%) cited that EAI is the first and life-saving treatment of anaphylaxis. However, 61 parents (53.5%) stated that they did not carry EAI regularly. The most common self-reported reason for not carrying EAI regularly among these 61 parents was no longer feeling it was necessary as they could avoid allergen exposure to their child (n = 18, 29.5%), followed by forgetting to carry (n = 12, 19.7%), and considering the physical features of the device not appropriate (n = 10, 16.4%). In addition, 21 parents (34.4%) stated no reason for not carrying EAI regularly (Table 3).

One-third of EAI-prescribed children (n = 38) had experienced at least one case of anaphylaxis episode, of which foods were the most frequently reported etiology. Among the 38 parents of these children, 30 parents (78.9%) carried EAI at the time of the reaction. Furthermore, only 6 parents (20.0%) had used their EAI to treat this reaction despite carrying (Table 3). In addition, the most common reasons for not using the EAI during the previous episode among 32 parents were feeling unconfident and afraid to hurt their child by using the EAI (n = 15, 46.9%), having no EAI on hand (not carrying EAI) (n = 8, 25.0%) during the reaction, preferring to wait until the attack resolves spontaneously (n = 6, 18.7%), and

attending the nearest hospital (n = 3, 9.4%) (Table 3). When asked why they were afraid to hurt their child, parents stated that they were unconfident for a correct diagnosis and their child chucked his leg so violently that they became afraid of hurting their child. 40 parents (35.1%) were unaware of the expiration date of the EAI device (Table 3).

Table 2. Demographic and Clinical Features of Children who prescribed Epinephrine auto-injector

Variable	n (%)
Patients number, n (%)	114 (100)
Age at admission, year, median, range	11 (0.75-18)
Male, n (%)	62 (54.4)
Age, year, n (%)	
0-1 year	29 (25.4)
1-5 years	33 (28.9)
6-11 years	31 (27.2)
>12 years	21 (18.4)
Triggers type	
Food	50 (43.6)
Drug	31 (27.2)
Venom	15 (13.2)
Idiopathic	4 (3.5)
Others (mastocytosis, etc)	14 (12.3)
History of anaphylaxis after prescription	38 (33.3)
Parents' education level	
Lower than university	59 (51.8)
University or High school	55 (48.2)

Table 3. The attitudes of 114 parents toward the regular carrying and proper use of an Epinephrine auto-injector.

Attitude	n (%)
Not carrying EAI regularly	61 (53.5%)
Main reasons reported by 61 parents for not carrying EAI regularly	
• Feeling no need as they could avoid allergen exposure	18 (29.5%)
• Forgeting to put it in their bag	12 (19.7%)
• Considering the physical features of the device not appropriate	10 (16.4%)
• No reason was stated	21 (34.4%)
Having an anaphylaxis episode after prescription	38 (33.3%)
EAI carriage among the 38 families who experienced a previous episode	30 (78.9%)
EAI use among the 30 families who carried EAI during the episode	6 (20.0%)
Reasons reported by 32 parents for not using EAI during the episode:	
• Hesitating to act as they are afraid /worried to harm their child	15 (46.9%)
"unconfident for correct diagnosis"	10 (31.2%)
"The child jerked his leg so violently"	5 (15.6%)
• Having no EAI on hand during the reaction	8 (25.0%)
• Prefer to wait until the attack resolves spontaneously	6 (18.7%)
• Prefer to attend nearest hospital	3 (9.4%)
Unaware of the expiry date of the EAI	40 (35.1%)

All the parents of children who had prescribed an EAI received standardized education and training on anaphylaxis in our allergy out patient clinic. The use of the EAI device had been regulary shown to all 114 parents (at least one parent from each family) by the physician with a trainer and written instructions at each visit. During the time of the study, 84 (73.6%) of the parents removed the orange cap located bottom of the device correctly (step 1) and 75 (65.8%) of the parents knew the administration route by selecting the outer thigh (step 3), but only 13 parents (11.4%) demonstrated all the steps of EAI device use correctly (Figure 1). Four parents (30.8%) who demonstrated all steps correctly were not

carrying the device. The EAI usage steps with the most errors were Step 5: "Hold for >10 seconds and massage the injection area for 10 seconds"; Step 2: "Open the safety lock located at the top of the device by turning the trigger in an arrow direction"; and Step 4: "Press the trigger down to activate (so it clicks)," respectively (57.1%, 53.5%, and 51.8%, respectively) (Figure 1).

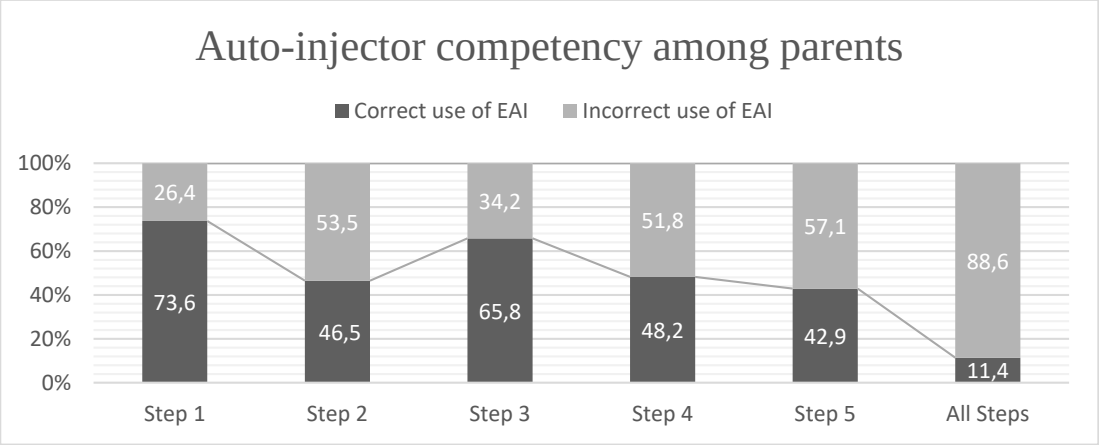

Figure 1. The percentage of correct use of EAI device (competency) by parents with examination of five steps in administration technique.

Table 4. Factors associated with epinephrine auto-injector competency for parents.

Factors	Correct EAI use in all steps	Incorrect EAI use	p
Patients number, n (%100)	13	101	
Age at diagnosis, n (%)			
0-1 year	4 (30.8)	25 (24.8)	0.639
1-5 years	2 (15.4)	31 (30.7)	0.252
6-11 years	6 (46.2)	25 (24.8)	0.103
>12 years	1 (7.7)	20 (19.8)	0.287
Triggers type, n (%)			
Food	3 (23.1)	47 (46.5)	0.109
Venom	3 (23.1)	12 (11.9)	0.261
Drugs	6 (46.2)	25 (24.8)	0.103
Idiopathic	1 (7.7)	3 (3.0)	0.384
Others	0 (0.0)	14 (13.9)	<0.001
History of previous anaphylaxis, n (%)	6 (46.2)	32 (31.7)	0.298
History of severe anaphylaxis, n (%)	2 (15.4)	10 (9.9)	0.544
Parents' education level (University Degree), n (%)	7 (53.8)	48 (47.5)	0.548
Time elapsed since the last visit, n (%)			
< 6 months	11 (84.6)	56 (55.4)	0.044
6-9 months	1 (7.7)	18 (17.8)	0.356
>9 months	1 (7.7)	27 (26.7)	0.133

The correct use of EAI in all steps was also found to be unrelated to any of the parents' (socioeconomic status, education level) or children's (sex, age), trigger type of anaphylaxis, previous history of anaphylaxis, or severity of a previous reaction. The highest percentage of competancy among participants were detected in the group of the participants (n = 11, 84.6%) who had the shortest time interval since last visit (< 6 months) when compared to other time intervals. (p = 0.044) (Table 4). However, logistic

regression analysis showed that the time from the last visit (EAI training) was not an independent factor associated with the highest percentage of participants who completed all steps correctly.

When asked about their concerns and ideal EAI device ideas, 49 (42.9%) of parents stated the five steps of penepin administration were difficult and impractical to perform in an emergency situation. Furthermore, 44 parents (38.6%) stated that the device's shape and size are unsuitable for carrying and holding, and 40 parents (35%) felt that the prescribing physician's EAI device training was insufficient. 31 parents (27.2%) expressed concern about the lack of reliable information available on social media (Figure 2).

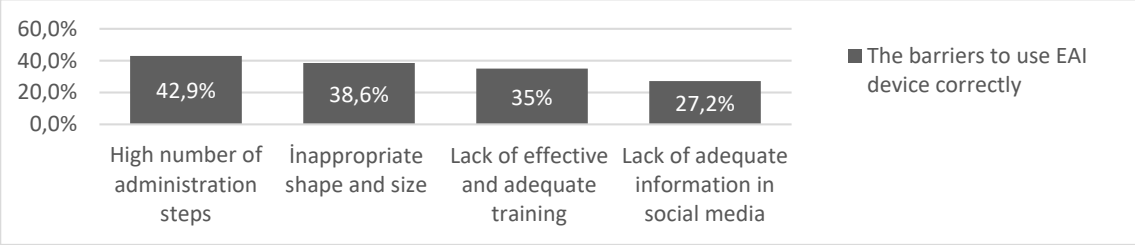

Figure 2. Parents' perceived barriers for epinephrine auto-injector device competency.

DISCUSSION

Anaphylaxis is a severe, potentially fatal, systemic hypersensitivity reaction that needs to be treated immediately and it carries a risk of unpredictable recurrence[1,2]. There is a significant increase in the frequency of anaphylaxis, particularly in children, and food is the most known cause in children[3]. Early diagnosis and prompt treatment of anaphylaxis with correct use of epinephrine is a priority for better outcomes, and majority of the anaphylactic reactions developed outside the hospital[3-4]. However, patients and/or parents frequently lacked the necessary skills to regularly carry and utilize EAIs, which are created and manufactured to facilitate quick treatment in public settings (home, park, schools etc)[2,5]. Studies from other countries, including our own, have shown gaps and unmet needs in parents' and caregivers' adherence to EAI[2,5].

In our study population, food allergy was the most common reason for pediatric EAI prescriptions, and most of the children who received these prescriptions were under 6 years old, notably infants. Previous studies from Turkey[4-6], Japan[7], and the United States[8] found that the most common reason for prescribing EAI was food allergy, which is consistent with our findings. The European Anaphylaxis Registry reports that 44% of anaphylaxis patients were preschoolers, and more recent studies have shown an increasing prevalence of infant anaphylaxis[3,4,9]. These findings highlighted not only young children's potential vulnerability, but also the critical importance of improving the management skills of these children's primary caregivers in order to reduce anaphylaxis-related mortality and morbidity.

The prompt administration of epinephrine to patients experiencing anaphylactic reactions is part of the standard treatment for anaphylaxis. However, many studies have found that among patients with a history of anaphylaxis, the prevalence of carrying and using EAIs—devised and produced to enable quick treatment in public settings (home, park, schools, etc.) before visiting the emergency department—is quite low [10,11]. The rate of carrying EAI was 84.7%-86.0% (always 57%-67%) and proper use of AAIs was 25%-58% according to previous studies[10-12]. In our study, the rate of EAI carrying was 78.9% at the time of reaction (always 46.5%), and only 6 out of 30 parents (20.0%) administered epinephrine injections despite carrying. This result might be explained by the fact that parents in our study had lower sociocultural and educational levels than the study populations in question. It was also noteworthy that in all studies that were comparable to our study, the frequency of EAI use by parents was low (25%-58%) despite carrying[10-12]. In comparison to the most recent recommendations and guidelines, our findings still have very low frequencies[1-3].

The two most common explanations given by parents for not having an EAI on them were that they had forgotten and didn't think it was necessary. This suggested that the parents were unaware of the risk of anaphylaxis or the necessity of always having an autoinjector on hand. Additionally, the most frequently cited explanations for parents' low perceptions of risk in our study were similar to those in earlier studies: they believed they could avoid allergen exposure and that any future reactions wouldn't be severe enough to necessitate adrenaline treatment[13-15]. Therefore, the management plan's focus areas should also include the patient's or the parent's psychological perceptions of the severity of his or her child's allergic disease, as well as the drawbacks and possible consequences of an unanticipated future anaphylaxis episode, which must be addressed in a clear and concise manner. Additionally, many parents expressed their displeasure with the EAI's size, believing it to be too large and cumbersome to carry. By highlighting its potential advantages despite the inconvenience, patients and parents should be encouraged to carry an auto-injector as well[16].

The parents in our study frequently hesitated to use EAI because they were worried about hurting their child because of EAI's detrimental emotional and psychological effects on their child, which is in line with findings reported in several studies[16,17]. Many parents reported that their child jerked their leg violently when they see the device, and they were often unsure if the reaction was severe enough to necessitate the administration of EAI. They would rather wait for the attack to end or go to a nearby hospital than act, which is consistent with previous studies[17,18]. The majority of studies found that parents are dealing with emotional experiences such as panic, anxiety, fear, stress, regret, helplessness, and guilt while dealing with their child's anaphylaxis[19,20]. In our study, the psychological burden, which includes anxiety and a sense of helplessness in this urgent and life-threatening situation, is once more the main contributor to the underutilization of EAIs, addressing the significance of enhancing parental psychological comfort and preparedness in the management plan. Patients' and parents' worries and concerns should be taken into account at every opportunity and during every clinical visit, and the required psychological support should be given to help patients and parents cope with the detrimental effects of these feelings[19-20]. Additionally, the child jerking his legs as described in our study may have unintended consequences like lacerations and ineffective dosing necessitating a second dose, which are traumatic for both the child and parent[27]. Therefore, we advise updating the directions and labeling of EAI (Penepin) to recommend holding the child's leg during administration, especially for young children (under 6 years old), and reducing the holding time of 10 seconds to a time that is ideal for reducing laceration injuries. Furthermore, considering that one-third of parents were unaware of the device's expiration date, we suggest emphasizing it by writing it in large, black letters in a visible location.

In earlier studies, Topal et al. (EAI device was Epipen) and Köse et al. (EAI device was Penepin) examined the proper use of the adrenaline autoinjector by the child's primary caregivers[6,21]. The rate of competancy of the EAI device was found to be 39.4% and 69.5%, respectively, by Topal et al[6]. and Köse et al[21]. Our results were lower than those of these two studies, despite the fact that our participants were also trained by allergists, as in these studies. Our study's primary difference from the research conducted by Topal et al. was that our participants used a different EAI kit (Penepin), whereas Topal et al. used Epipen. While the rate of university graduation was 48.2% in our study, it was 53.5% in Köse et al.'s study, indicating a higher level of education among caregivers. Similar to recent studies' findings, the two EAI usage steps with the highest frequency of errors in all participant groups were "Hold for >10 seconds" and "Open the safety lock located at the top of the device by turning the trigger in an arrow direction" [6,21]. Studies using Penepin® and other commercial EAIs revealed that regardless of the identity of the applicant, the steps in which errors were made for each EAI could be the same[6,21,24]. This reinforces the idea that EAI application errors may be related to EAI design. It was demonstrated that in recent years, reducing the number of steps in EAI usage, and adding audio instructions were effective in increasing rates of correct usage and reducing problems associated with erroneous applications[25]. It may be possible to improve correct usage rates for Penepin® by making modifications that no longer require the application step of "Open the safety lock located at the top of the device by turning the trigger in an arrow direction"[22].

The level of education of the user, the interval since the last training, the user's age, a history of severe anaphylactic reaction, and the regular clinical follow-up of patients were all factors that were connected in

previous studies to the accurate application of EAIs[6,20-26]. The ability of the participants to correctly use EAI was not significantly impacted by any factor in our study, though. Our findings indicate that barriers to achieving ideal adherence to EAI use are numerous and complex, and are unlikely to be removed by using straightforward educational interventions.

A growing number of recent studies emphasize the significance of device design, usability, and accessibility, which encourages the pharmaceutical industry to create the ideal life-saving device[25,26]. Our findings revealed that the high number of administration steps, the inappropriate shape and design, and the lack of effective and adequate training were the three most frequently mentioned concerns by parents regarding adherence[27].

In conclusion, our study showed that a more comprehensive approach is needed in real life to overcome parents' multiple and challenging barriers for EAI adherence with addressing the psychosocial dimensions of anaphylactic emergencies as well as treatment. Regular training of the patients/ caregivers and psychological support in coping with negative feelings while dealing with their child anaphylaxis may not gurantee to maintain acquired adherence on epinephrine auto-injectors in real life. Besides, parents/caregivers are also interested to search more helpful information sources in internet and desire for an ideal device which is simple, convenient, practically designed and safe to use.

Yazar Katkıları: Çalışma konsepti/Tasarımı: MS, ASS, DÖ, RMKE, SB, DUA; Veri toplama: MS, ASS, DÖ, RMKE, SB, DUA; Veri analizi ve yorumlama: MS, ASS, DÖ, RMKE, SB, DUA; Yazı taslağı: MS; İçeriğin eleştirel incelenmesi: MS, ASS, DÖ, RMKE, SB, DUA; Son onay ve sorumluluk: MS, ASS, DÖ, RMKE, SB, DUA; Teknik ve malzeme desteği: MS, ASS, DÖ, RMKE, SB; Süpervizyon: MS, DUA; Fon sağlama (mevcut ise): yok.
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