

ORIGINAL ARTICLE

A randomized maternal evaluation of epinephrine autoinjection devices

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Abstract

Background: Intramuscular epinephrine (adrenaline) is the first-line therapy for anaphylaxis and prompt administration improves outcome. In 2011, two epinephrine autoinjectors existed in the United Kingdom, differing in their users' administration method: EpiPen[®] and Anapen[®]. We routinely train all families who receive these devices.

Aim: To evaluate:

- (i) Maternal competence in using epinephrine autoinjectors following our standard anaphylaxis training package.
- (ii) Which device mothers found easier to use.

Methods: Mothers with no previous epinephrine autoinjector experience were approached to participate. One clinician provided a standardized demonstration on using a randomly assigned autoinjector device. She immediately evaluated the mothers' performance using ten predetermined criteria. Four criteria were device specific and six were common criteria to both devices.

Results: One hundred mothers participated: 50 EpiPen[®] and 50 Anapen[®]. A substantial proportion of mothers (15% overall) were not able to successfully 'fire' these training devices: Anapen[®] 4% and EpiPen[®] 26% (OR 8.43, $p = 0.005$). Only 22% of mothers overall were able to perform all ten procedures completely successfully: Anapen[®] 32% and EpiPen[®] 12%. Chi-squared analysis showed a significantly higher proportion of mothers correctly performing all Anapen[®] specific procedures than EpiPen[®] (OR 14.24, $p < 0.0001$).

Conclusion: It is concerning that 15% of mothers overall could not 'fire' these devices correctly despite a one-to-one demonstration, identifying a need for more user friendly devices and training. Mothers found the Anapen[®] device significantly easier to use, which may have implications for future prescribing. Evaluation of the next generation of autoinjectors and their training packages needs to be performed as important practical differences may be found.

In Europe, 87 million people suffer from allergic disease, and one in four children will be allergic (1). In the United Kingdom, allergic diseases affect up to one third of the population during their lifetime (2). Although severe allergic reactions are uncommon, the UK incidence of anaphylactic reactions is increasing, with the highest number of cases being seen in children and adolescents (3, 4). Anaphylaxis is a severe hypersensitivity reaction that is rapid in onset and occasionally fatal (4–6). Current data suggests that the incidence of anaphylaxis lies between 30 and 950 cases per 100,000 persons per year, with a mortality prevalence estimate in the United Kingdom of 0.33 deaths per million persons per year for all causes (3, 4, 7).

Intramuscular epinephrine (adrenaline) is the first-line therapy for anaphylaxis and prompt administration improves outcome (4–6, 8, 9). Epinephrine autoinjectors exist for self

administration in the community. A delay in epinephrine administration is a consistent risk factor in fatal anaphylaxis. Despite this, many patients do not carry their autoinjectors all of the time (4, 5, 10). Parents and children who have been prescribed an epinephrine autoinjector should be given instructions and training on when and how to use it (11). However, many patients are often unable to demonstrate correct administration of the devices when assessed (12–15). This may reflect several issues including training effectiveness, user stress during administration or inherent differences consequent of the design of the individual autoinjector.

Two widely prescribed autoinjection devices existed in the United Kingdom contemporaneously at the time of this device evaluation (May 2010), EpiPen[®] and Anapen[®], differing in their users' administration method. EpiPen[®] has a spring-

loaded needle that delivers a fixed dose of epinephrine when the pen is swung and jabbed firmly into the outer thigh. Anapen[®] has a mechanism whereby on pressing a firing trigger button with the pen already in position on the thigh, a spring activated plunger pushes the needle in. No comparison data for successful device usage by parents for these autoinjection devices exists. We routinely train all families in the use of adrenaline autoinjectors if they have been prescribed for children attending our clinic, with a standard anaphylaxis package.

Aims

- (i) To evaluate potential maternal competence in using existing adrenaline autoinjectors following our standard anaphylaxis training package.
- (ii) To evaluate which device mothers found easier to use.

Methods

Mothers were approached in general paediatric outpatient departments and inpatient children's wards within one tertiary hospital to participate. They were included if they had no previous epinephrine autoinjector knowledge or experience. One clinician (JB) provided a standardized 30 min individual demonstration on anaphylaxis treatment using an epinephrine autoinjector and immediately evaluated the mother's performance using the device-specific trainer pens. Our normal practice is also to give written information sheets and school care plans during such training. Evaluation of mothers' performance was by 10 predetermined criteria. Four criteria were taken from the company datasheets on the individual autoinjection devices' correct administration (e.g. EpiPen[®] (Meridian Medical Technologies, Columbia, MD, USA) – swing and jab device firmly into outer thigh and Anapen[®] (Lincoln Medical Limited, Salisbury, UK) – press device on thigh). This was combined with six common criteria for the two devices from our routine anaphylaxis training (e.g. hold pen in place for 10 seconds after

administration). A maximum score of 10 points was possible (Table 1). The two main outcome standards assessed were that parents would be able to do all their device-specific and common criteria correctly. Whether the mothers fired the device successfully – whatever their technique – was also recorded. Results were compared by chi-squared analysis to assess the proportion of mothers completing all tasks correctly. A *p* value of <0.05 was taken as significant. A computer-generated random numbers sequence allocated mothers to be trained and evaluated in just one specific device (EpiPen[®] or Anapen[®]).

Ethical and funding considerations

This service evaluation of our existing routinely prescribed autoinjector devices and training package was approved as a clinical governance project by the Cardiff and Vale NHS Trust. No funding was received for this project.

Results

A total of 100 mothers participated: 50 EpiPen[®] and 50 Anapen[®]. No mothers refused to participate. The results are summarized in Table 2.

A substantial proportion of mothers (15% overall) were not able to successfully 'fire' these training devices; Anapen[®] 2/50 (4%), EpiPen[®] 13/50 (26%), (OR 8.43, *p* = 0.005). Only 22% of mothers overall were able to perform all ten procedures completely successfully following one individual training session; 12% EpiPen[®], 32% Anapen[®]. Chi-squared analysis showed a significantly higher proportion of mothers correctly performing all Anapen[®] specific procedures than EpiPen[®] (OR 14.24, *p* < 0.0001).

Discussion

This study compares the impact of training on the ability of autoinjector naive mothers to use one

Table 1 The 10 predetermined criteria used to assess mother's performance in using a randomly assigned epinephrine autoinjector device following a standardized teaching session by one clinician. Six criteria were common to both devices and four criteria were device specific

Common criteria to both autoinjector devices (6)	Device-specific criteria – 'EpiPen [®] ' (4)	Device-specific criteria – 'Anapen [®] ' (4)
1. Reassures and explains procedure to child.	7. Holds EpiPen [®] correctly when removing grey safety cap.	7. Removes black needle cap.
2. Removes child's clothes/checks pockets etc at injection site.	8. Removes grey safety cap.	8. Removes black trigger safety cap from firing button.
3. Holds EpiPen [®] /Anapen [®] in place for 10 seconds after administration.	9. Holds EpiPen [®] approximately 10 cm away from child's outer thigh, with black tip pointing toward the thigh, and outlines position on leg to inject.	9. Outlines position on leg to inject and holds Anapen [®] in correct position ready to administer.
4. Massages site for 10 seconds after removal of pen.	10. Swings and jabs EpiPen [®] correctly resulting in its administration.	10. Presses red firing button and administers Anapen [®] .
5. Places EpiPen [®] /Anapen [®] in a safe place after administration.		
6. Phones 999.		

Table 2 Number of mothers performing the predetermined identical and device-specific procedures correctly when assessed on their use of a randomly assigned autoinjector device following standardized teaching by one clinician. Six procedures were common to both devices and four were device specific

Identical procedures EpiPen® (6)	EpiPen® – number and (%) of mothers performing procedure correctly (n = 50)	Identical Procedures Anapen® (6)	Anapen® – number and (%) of mothers performing procedure correctly (n = 50)	Chi-squared analysis
1. Reassures and explains procedure to child.	44 (88%)	1. Reassures and explains procedure to child.	47 (94%)	p = ns
2. Removes child's clothes/checks pockets etc at injection site.	43 (86%)	2. Removes child's clothes/checks pockets etc at injection site.	37 (74%)	p = ns
3. Holds EpiPen® in place for 10 seconds after administration.	32 (64%)	3. Holds Anapen® in place for 10 seconds after administration.	40 (80%)	p = ns
4. Massages site for 10 seconds after removal of pen.	37 (74%)	4. Massages site for 10 seconds after removal of pen.	45 (90%)	p = ns
5. Places EpiPen® in a safe place after administration.	37 (74%)	5. Places Anapen® in a safe place after administration.	34 (68%)	p = ns
6. Phones 999.	38 (76%)	6. Phones 999.	40 (80%)	p = ns
Identical Procedures Mean Score out of 6 and (SD)	4.62 (1.19)		4.86 (1.05)	
Device specific procedures EpiPen® (4)	EpiPen® – number and (%) of mothers performing procedure correctly (n = 50)	Device specific procedures Anapen® (4)	Anapen® – number and (%) of mothers performing procedure correctly (n = 50)	Chi squared analysis
7. Holds EpiPen® correctly when removing grey safety cap.	22 (44%)	7. Removes black needle cap.	49 (98%)	
8. Removes grey safety cap.	48 (96%)	8. Removes black trigger safety cap from firing button.	48 (96%)	
9. Holds EpiPen® approx. 10 cm away from child's outer thigh, with black tip pointing toward the thigh, and outlines position on leg to inject.	31 (62%)	9. Outlines position on leg to inject and holds Anapen® in correct position ready to administer.	47 (94%)	
10. Swings and jabs EpiPen correctly resulting in its administration.	37 (74%)	10. Presses red firing button and administers Anapen.	48 (96%)	
Device-specific procedures Mean Score out of 4 and (SD)	2.76 (1.08)		3.84 (0.51)	
Combined Mean Score out of 10 and (SD)	7.38 (1.64)		8.70 (1.28)	
Identical procedures – Mothers Scoring 6/6 and (%)	14 (28%)		17 (34%)	p = ns
Device-specific procedures – Mothers Scoring 4/4 and (%)	17 (34%)		44 (88%)	p < 0.0001
Mothers Scoring 10/10 – all procedures performed completely successfully and (%)	6 (12%)		16 (32%)	
Autoinjector device successfully fired (out of 50) and (%)	37 (74%)		48 (96%)	p = 0.005

randomly assigned epinephrine autoinjector device following a standardized training package. There were two key findings.

First, a substantial proportion of mothers (15% overall) were not able to successfully 'fire' these training devices; Anapen 4% and EpiPen 26% (p = 0.005). Only 22% of

mothers in total were able to perform all procedures completely successfully when assessed.

Second, there were no significant differences in mothers' performance of the techniques common to both devices. Mothers scoring 6/6 in the identical procedures; EpiPen® 14 compared with Anapen® 17 ($p = \text{ns}$). However, mothers were more likely to demonstrate correct and successful usage of Anapen® than EpiPen® when appraised. Mothers scoring 4/4 in the device-specific procedures; EpiPen® 17 compared with Anapen® 44 ($p < 0.0001$). This may have implications for future practice and prescribing as results indicate mothers found the Anapen® device significantly easier to use.

These findings are clinically important. Children and adolescents are reliant on their parents to take responsibility for their allergy, to recognize the signs and symptoms of anaphylaxis, and to remember the management plan (16–17). It is concerning that 15% of mothers overall were not able to successfully 'fire' these training devices and only 22% of mothers overall were able to use these devices completely correctly despite a 30 minute one-to-one demonstration. Considering in the real world parents are likely to receive less one-to-one tuition, these results identify a need to improve the delivery of training and a requirement for closer monitoring and assessment of technique of mothers using these devices.

This is supported by previous literature which has also recognized a need for improved education for allergic individuals and their caregivers, using support material such as on-line videos, DVD instruction and printed information, via a multidisciplinary approach, and for more active implementation of anaphylaxis guidelines amongst paediatricians. Additionally it is recommended that patients see their doctor on an annual basis to renew autoinjector prescriptions, update action plans and refresh their knowledge in the use of these devices (18–23). It is also acknowledged that families who attend a specialist multidisciplinary paediatric allergy clinic on at least one occasion have a significant improvement in their knowl-

edge of when and how to use an EpiPen® (24). Ours is a multidisciplinary clinic.

Variability in mother's performance in their use of epinephrine autoinjection devices will not only depend on which device is being used and the quality of the education given, but also whether currently advised methods are appropriate. There were two key steps in our study where mothers using the EpiPen® scored poorly. Only 44% of mothers held the EpiPen® in the correct position when removing the grey safety cap. Only 62% of mothers held the EpiPen® 10 cm away from the thigh in the correct position ready to 'swing and jab'. The recommended 'swing and jab' administration method for EpiPen® is not always advised by some authorities (25). Some recommendations suggest holding the EpiPen® against the outer thigh and pushing it into the thigh firmly until a click is heard and the needle is injected. The data produced in our study suggest that the 'swing and jab' method may not be the best means of administration as this is the area where mothers scored poorly. It would be beneficial to confirm these findings in a future study by evaluating this alternative method of administration.

To our knowledge, this is the first published evaluation comparing parental ability to use these two autoinjection devices.

The study could not be conducted with 'live' autoinjectors, which may fire more readily than the trainer pens. Issues regarding the dose ranges available and needle length were outside of the scope of our training package and device evaluation, but have important clinical relevance. Evaluation of the new generation of autoinjectors just released in the United Kingdom, and their training packages, needs to be performed to evaluate how 'user friendly' each of them is; important practical differences may be found in user ability.

One hundred mothers were evaluated in our study: 50 EpiPen® and 50 Anapen®. Although a number of our findings were statistically significant, it is possible that this number of mothers does not fully represent the population and therefore evaluation of a larger sample size would be justified.

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