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In situ simulation in the management of anaphylaxis in a pediatric emergency department

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Abstract

Anaphylaxis is a potentially life-threatening, rapid-onset hypersensitive reaction, usually treated in the emergency department (ED). Failure to recognize anaphylaxis leads to under-treatment with epinephrine and even when correctly diagnosed, epinephrine is not always administered. In addition, often patients who are treated in the ED are not referred for allergy work-up. Simulation is a tool that increases exposure to events in a safe environment, allowing trainers to develop skills without harming patients. The main purpose of our study was to determine whether in situ simulation training increases the frequency of epinephrine use. The secondary aim was to observe whether simulation modifies the number of children investigated over the years before and after the setting up of the simulation training. All patients with anaphylaxis referred to the Pediatric Emergency Department (PED) of the Anna Meyer Children's Hospital from 2004 to 2010 [pre-simulation (PRE-s) period], and from 2011 to 2016 [post-simulation (POST-s) period], were retrospectively included in this observational study. Simulation was carried out using a high-fidelity patient simulator mannequin (SimBaby, Laerdal Medical, Inc, Stavanger, NY). The diagnosis of anaphylaxis was based on the EAACI guidelines. The use of epinephrine significantly increased ($p < 0.05$) between the PRE-s and POST-s time periods: 2.4% versus 10% patients, respectively. During the two time periods, we also observed a significant increase ($p = 0.011$) in the number of patients who underwent a complete allergy work-up: 36% versus 51% patients, respectively. According to our results, the in situ simulation program improved the correct management of anaphylaxis in terms of prompt use of epinephrine, and it also led to a higher number of patients being referred to the allergy unit for evaluation.

Keywords Anaphylaxis · Children · Epinephrine · In situ simulation · Pediatric emergency department

Introduction

Anaphylaxis is a potentially life-threatening, rapid-onset hypersensitive reaction, usually treated in the emergency department (ED) [1].

The number of cases of anaphylaxis referred to pediatric emergency departments (PEDs) has risen significantly over the past 10 years (five–sevenfold) [2]. Moreover, in the USA, the rates of ED visits for anaphylaxis have increased in all age groups. However, the greatest increase has been reported in children aged 5–17 years (196% increase), with a marked rise (by 124%) in the rate of food-related anaphylaxis [3].

Based on three European population studies, the prevalence of anaphylaxis is estimated to be 0.3%. Nevertheless, the fatality rate of anaphylaxis has not increased and is still low, below 0.001% [4]. It is unclear whether the incidence of anaphylaxis is really increasing, or whether the apparently increasing rates are instead due to improved awareness, recognition and diagnosis of this event [3].

Both the US and World Health Organization guidelines identify epinephrine as an essential medicine for anaphylaxis treatment [5, 6].

In an ED setting, with the broad and often atypical presentation of anaphylaxis, failure to recognize anaphylaxis is a real possibility that leads to under-treatment with epinephrine. Studies have shown that a large percentage of patients

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(57%) referred to the ED with anaphylaxis may be misdiagnosed [7, 8].

Moreover, even when correctly diagnosed, epinephrine often is not administered (up to 80% of the time) [9–11].

Delayed administration of epinephrine is an important risk factor for fatal anaphylaxis [12].

In addition, patients who are treated in the ED for anaphylaxis, are not usually referred for allergy work-up [11, 13].

Simulation is a tool that increases exposure to events in a safe and supportive environment, allowing trainees to develop skills without harm to patients and without penalties for the trainees themselves [14].

Recently, the reforms in medical education have placed increased emphasis on patient-centered care, focusing on patient safety and the quality of care, including simulation in innovative educational programs [15]. Simulation scenarios can be tailored as needed, allowing for customized trainee education. So far, most studies that use simulation report on pre- and post-intervention data, using data to verify acquired skills, however, very few studies provide information on education and skill retention over time [16, 17].

To our knowledge, no studies have been published to date on the in situ effects of simulation over the years in the same PED.

Although the case fatality rate of anaphylaxis is low, the emergency physician must be trained through in situ simulation to recognize and treat anaphylaxis. In situ simulation is more useful than others (e.g. laboratory simulation) due to being more realistic, especially with regard to drug administration and organization of space that are the same as those where the nurse and ED physician work and manage emergencies every day.

The main aim of our study is to determine whether in situ simulation training improves recognition and treatment of anaphylaxis in a clinical setting. In particular, the primary skill evaluated is the frequency of epinephrine use. The secondary aim of our study is to observe whether simulation modifies the time latency between the anaphylactic event and the allergological evaluation, and the number of children investigated over the years before and after simulation training at the Anna Meyer Children's Hospital.

Methods

Patients

All patients with anaphylaxis referred to the PED of the Anna Meyer Children's Hospital from 2004 to 2010 [presimulation (PRE-s) period] and from 2011 to 2016 [post-simulation (POST-s) period] were included in this observational, descriptive study. On arrival in the PED, the patients were triaged according to the Emergency Severity Index (ESI) 5-level triage system adapted to color code (red, yellow, green, white and blue) by our PED [18]. Treatment priority is decided on the basis of disease severity and the expected resources required. Unstable patients with life-threatening conditions are assigned to the ESI triage level 1, corresponding to the red code; patients with potentially life-threatening symptoms are assigned to triage level 2, corresponding to the yellow code [18].

We searched the records of the outpatient clinic for all occurrences of the specific codes of the International Classification of Disease, Ninth Revision (ICD-9) for anaphylaxis (995.0, anaphylactic shock; 995.6, anaphylactic shock caused by adverse food reactions; 999.4) and non-specific codes for anaphylaxis (708.0, allergic urticaria; 708.9, unspecified urticaria; 995.1, angioneurotic edema; 995.3, unspecified allergy; 695.1, erythema multiforme; 989.5, toxic effect of venom). The diagnosis of anaphylaxis was based on the European Academy of Allergy and Clinical Immunology (EAACI) guidelines [19]. Only the patients' charts with red and yellow admission codes to PED were reviewed.

The clinical characteristics, pharmacological treatment, suspected triggers and results of the allergy work-up (clinical history, skin prick test with culprit allergen, intradermal test and oral provocation test with culprit allergen when indicated) during the two time periods (PRE-s and POST-s) were recorded and compared.

The pharmacological treatments were divided into Pre-PED and In-PED, meaning before and after admittance to the PED, respectively. In particular, this meant that drugs in the Pre-PED setting could be administered by patients themselves, parents, care givers or physicians in the ambulance, whereas treatment in the In-PED setting was only administered by the emergency department physician.

Educational intervention—in situ simulations

Five sessions of high-fidelity simulation were examined in a pediatric patient admitted to the PED. The simulation session consisted in three scenarios: one with cardiac arrest (ventricular fibrillation), one with peri-arrest (hypovolemic shock with bradycardia), and one with anaphylactic shock. Four hourly simulations were scheduled over 3 months for each team. Each team only participated in a simulation session once.

Participants

Doctors and nurses from the PED of the Meyer Children's Hospital (15 doctors and 15 nurses) participated in the simulation program.

The staff was divided into five teams (six members per team) reproducing the same characteristics of the team currently managing the red codes in our PED.

All course scenarios were realized in situ [20] using the same equipment and supplies (code cart, medications, defibrillators, etc.) as those used for real patients.

Simulations were carried out using a high-fidelity patient simulator mannequin (SimBaby, Laerdal Medical, Inc, Stavanger, NY), set up in the resuscitation room.

The progression of the clinical scenario was controlled by facilitators in real time to correspond with interventions carried out by the teams.

All the simulation scenarios were videotaped, and then immediately followed by structured video-based debriefings performed by trained facilitators (physicians and nurses) using widely established methodologies [21].

At the end of each debriefing, an analysis of the issues raised was conducted via use of Incident Reporting cards proposed by the Clinical Risk Group (GRC) of the Tuscany Region. The reports led to the creation of Clinical Audits with identification of improvement actions for each group. The establishment of each improvement action gave rise to an assistance diagnostic pathway (ADP) in collaboration with the Allergy Unit of the Anna Meyer hospital in line with the international guidelines [19].

Statistical analysis

The patient characteristics (age, gender, clinical manifestation, anaphylaxis treatment, and triggers) were described using appropriate medians and percentages. We calculated annual rates of anaphylaxis using the number of PED admissions for anaphylaxis as the numerator and the total enrollees as the denominator. Rates were expressed as the number of PED visits for anaphylaxis per 100,000 enrollees. All significance tests were two-sided and a p value of less than 0.05 was considered statistically significant. The entire statistical analysis was performed using STATA Statistics 16.0 for Windows.

Results

Eight-hundred and seventy-three patients out of 257,462 (0.33%) and 481 out of 256,117 (0.18%) were admitted to the PED of the Anna Meyer Children's Hospital for suspected allergic reactions in the PRE and POST-s period, respectively.

During the two time periods, 82 out of 873 patients (9.4%) and 136 out of 481 patients (28.2%) were assigned red or yellow codes, respectively.

In the PRE-s period, 41 out of 82 patients (50%) had had a previous anaphylactic reaction, versus 59 out of 139 patients (43.4%) in the POST-s period.

The demographic characteristics and clinical presentation of children referred to the PED with anaphylaxis are shown in Table 1.

During the PRE and POST-s period, the medications used to treat the anaphylactic reactions before (Pre-PED) and after (In-PED) admission to the PED are illustrated in Table 2.

Epinephrine use increased significantly ($p < 0.05$) between the two time periods: 1 out of 41 (2.4%) patients and 6 out of 59 (10%) patients, respectively.

The average incidence of anaphylaxis-related PED visits increased by 37.5% over the two time periods, from 16 per 100,000 cases/year (PRE-s period) to 22 per 100,000 cases/year ($p = 0.33$) (POST-s period).

Moreover, during the two time periods (PRE-s and POST-s) we also observed a significant increase in the number of patients who underwent a complete allergy work-up, 49 out of 82 (60%) and 120 out of 136 (88.2%) patients with red and yellow codes, and in particular 15 out of 41 (36%) and 30 out of 59 (51%) patients with anaphylaxis, respectively.

Conversely, in neither time period did we observe any significant reduction in the mean time latency between the anaphylactic event and the allergological evaluation [31.15 days (± 43.3 SD versus 27.6 days (SD ± 34.9)].

Table 1 Demographic characteristics and clinical presentation of children presenting to the PED with anaphylaxis in PRE and POST-s period

	PRE-s	POST-s
No. of total ED visits	257,462	256,117
No. of total ED visit for suspected allergic reactions	873	481
No. of anaphylaxis	41	59
Age (years) [mean ± SD]	7,3±5,6	8,2±6,5
Male; females	28;13	30;29
Symptoms presented in patients with anaphylaxis		
Cutaneous [*n*;(%)]	33; (81,7)	52; (89)
Respiratory [*n*;(%)]	21; (51,2)	25; (42)
Gastrointestinal [*n*;(%)]	8; (20,7)	12; (20)
Circulatory [*n*;(%)]	4,5; (10,8)	2; (3)
Not described [*n*;(%)]	2; (4,8)	–
Place where the anaphylaxis occurred		
Home [*n*;(%)]	31; 76	43; 72
School [*n*;(%)]	3; 7	4; 7
Outdoors [*n*;(%)]	5; 12	10; 17
Hospital [*n*;(%)]	2; 5	2; 4

ED emergency department, *No* number, *PED* pediatric emergency department, *PRE-s* pre-simulation period, *POST-s* post-simulation period, *SD* standard deviation, *y* years, % percentage

Table 2 Treatment of anaphylactic reactions in PRE-s and POST-s period

Medications		2004–2010 (*n*;%)	2011–2016 (*n*;%)	*p*
Antihistamines	Pre-PED	14; 34.1	15; 24.4	NS
	In-PED	21; 51.2	35; 59.3	NS
Corticosteroids	Pre-PED	22; 53.7	27; 45.7	NS
	In-PED	19; 46.3	35; 59.3	<0.05
Bronchodilators	Pre-PED	7; 17	6; 10.2	NS
	In-PED	10; 23.4	11; 18.6	NS
IM Epinephrine	Pre-PED	4; 9.8	6; 10.2	NS
	In-PED	1;2,4	6; 10	<0.05
No treatment	Pre-PED	12; 29.3	18; 30.5	NS
	In-PED	11;27.4	8; 13.5	<0.05
Oxygen	Pre-PED	np	np	–
	In-PED	np	3; 5.1	NS
IV fluid	Pre-PED	np	2; 3.4	NS
	In-PED	np	17; 28.8	<0.05
Epinephrine aerosol	Pre-PED	np	2; 3.4	NS
	In-PED	np	np	NS

IM intramuscular, *in-PED* after admission to PED, *IV* intravenous, *np* not performed, *NS* not significant, *PED* pediatric emergency department, *Pre-PED* before admission to PED, *PRE-s* pre-simulation, *POST-s* post-simulation

Discussion

Anaphylaxis is an acute, potentially life-threatening systemic allergic reaction [1] and the cases of anaphylaxis referred to the PED have risen significantly in the past 10 years [2]. Our results show that over the 11 years of the study period, the average incidence of anaphylaxis-related PED visits increased by 37.5%, rising from 16 per 100,000 (0.16%) [2004–2010] to 22 per 100,000 (0.22%) [2011–2016] cases/year. The frequency observed in this study is comparable to that reported by Alvarez-Perea et al. in Spain (0.12%), Huang et al. in the United States (0.18%), and Ben-Shoshan et al. in Canada (0.21%) [13, 22, 23].

The main purpose of our study is to determine whether in situ simulation training improves the frequency of epinephrine use in a clinical setting. We observed a statistically significant increase in epinephrine use between the PRE and POST-s periods (from 2.4 to 10%; $p<0.05$). Despite this increase, the study shows that epinephrine, considered the first-line treatment of anaphylaxis by both the EAACI and the World Allergy Organization [4, 19, 24], is under-utilized in our PED. In fact, only from 2.4 to 10% patients with anaphylaxis received this medication. Our results are in line with the current literature, and similar studies conducted in Europe and in the USA, which have shown that epinephrine is under-utilized in the management of anaphylaxis. In particular, Grabenherich et al. find that only 12% of all patients with anaphylaxis are treated with epinephrine in a German study [2]. Worm et al. report that epinephrine is given for grade three and four anaphylaxis to 14.5 and 43.9% of patients in the Austrian-Swiss and German anaphylaxis registry [25]. In the USA, Russell et al. report the use of epinephrine in 42% of patients with anaphylaxis [26].

Furthermore, in our study, corticosteroids and antihistamines were the most commonly administered pharmacological treatment In-PED even though there is little evidence supporting the use of these medications as first and second line treatments in cases of anaphylaxis [20, 22, 27–30]. Our results are in line with other studies [13, 22, 31] in which the use of corticosteroids and antihistamines is greater than epinephrine for treating anaphylaxis.

As regards the secondary aim, no statistically significant decrease observed is between the PRE- and POST-s periods in the mean time latency from the anaphylactic event to the allergological evaluation [31.15 (DS ± 43.3) days versus 27.6 ± (DS ± 34.9) days]. However, we did observe a significant increase in the number of patients with red and yellow codes who underwent a complete allergy work-up [49 out of 82 (60%) and 120 out of 136 (88.2%) patients ($p=0.011$), respectively], especially those with a confirmed diagnosis of anaphylaxis [15 out of 41 (36%) and 30 out of 59 (51%) patients ($p=0.035$), respectively]. This last result allowed for identifying a greater number of anaphylaxis triggers, thus breaking down the percentage of unidentified cases [from 25 to 20% ($p>0.05$) and from 28 to 17% ($p<0.05$) in the PRE- and POST–s periods, respectively]. This is in line with another pediatric study [22] in which the percentage (33%) of patients discharged from the PED without a diagnosis of anaphylaxis dropped to 8% after the allergy work-up. Nevertheless, it differs significantly from a study conducted in adults [32] in which only half the anaphylactic patients are referred to the Allergy Department, and it is even lower in the study conducted by Campbell et al. [33] in Minnesota that reports a rate of 38%. These differences between adults and children can be explained by the fact that adults are prone to invest more time and effort on their children's health than on their own [32].

Simulation has been used to develop the skills required to manage patients who are critically ill. Within medical training programs, simulation has been used to train for rare cases and unforeseen events. In situ simulation provides an opportunity to practice in the same healthcare units where doctors and nurses perform their work every day without putting patients at risk [17]. This is a formative way of identifying latent safety threats for patients, and addressing possible corrections before mistakes occur in real life or on the actual patient [34]. The inclusion of a structured phase of clinical risk analysis during and after the training debriefing allowed us to share the changes in management with the PED staff. In situ simulation, therefore, serves not only as a training event, but also for correcting improper management [35].

The effectiveness of simulation in improving individual performance is already well known [16, 17]. In addition, the retention of long-term skills is better than frontal lessons, however, these aspects have never been studied with in situ simulation.

To our knowledge, this is the first study that shows the real-life effect of in situ simulation between the PRE-s and POST-s period over the years in the same PED. We observe a statistically significant increase in epinephrine use between the two time periods (from 2.4 to 10%; $p < 0.05$) as well as a significant rise in the number of patients with anaphylaxis who underwent a complete allergy work-up (from 36 to 51%; $p < 0.05$).

This study has a series of limitations. First, it is a retrospective study so one limit is our reliance on medical records for information about the characteristics of the anaphylactic episode, with the risk of the chart documentation not being complete. Second, data were collected in the PED of a tertiary hospital and the incidence may vary in smaller centers. Patients with milder or more severe cases of anaphylaxis were probably cared for in a primary care center closer to home or in other emergency departments.

In the end, some patients who had anaphylaxis did not come to our Allergy Unit for the allergy work-up due to referring to hospitals nearer to them.

Lastly, despite that fact that the in situ simulation was the only educational intervention target for anaphylaxis from 2010 to 2016, it cannot be assumed that it was the only intervention able to modify the use of adrenaline in a PED. In fact, in such a wide timeframe, other external factors may have interfered, such as individuals continuing medical education, new incoming physicians, and the updating of the anaphylaxis guidelines in 2014 [19], but we were not able to evaluate these factors.

This study also has several strengths. First of all, the overall time of the retrospective study is very long: 11, 6 years before and 5 years after the beginning of the in situ simulation; secondly, we utilized both specific and non-specific anaphylaxis codes to search the records of patients with anaphylaxis, avoiding the risk of losing patients in the case of only using the specific anaphylaxis codes. Finally, this is the first study that shows the real-life in situ effect of simulation over the years in the same PED.

In conclusion, according to our results, in situ simulation improved the management of anaphylaxis both during the acute phase and in the follow-up management of allergic patients.

Compliance with ethical standards

Conflict of interest The authors do not have conflicts of interest to declare.

Statement of human and animal rights This study has been approved by the local ethic committee.

Informed consent Informed consent was obtained from all participants included in the study.

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