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CARDIAC ARREST: NEW SIMULATION MODALITIES AS TOOLS FOR IMPROVING MEDICAL EDUCATION AND PATIENT CARE

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ABSTRACT

Introduction. The challenge of Emergency Medicine is to guarantee optimal care in very complex and environmentally dependent situations. Within all acute events, cardiac arrest is the most dramatic event that could occur.

Having tools for training, research and the validation of protocols and procedures is necessary. Simulation encompasses all of these aspects and could meet the challenge of increasingly good patient care.

Aim. My main project was to develop new simulation modalities to improve training and research in cardiac arrest.

Methods. 1) Holo-BLSD is an Augmented Reality self-instruction training system, in which a standard CPR manikin is "augmented" within an interactive virtual environment that reproduces realistic scenarios. During the experience, users were trained to use the device while being guided through an emergency simulation and, at the end, were asked to complete a survey to assess the usability of the Holo-BLSD.

Subsequently we enrolled 58 volunteer first-year nursing students randomly split in two groups: 29 participants underwent a self- training with the Holo-BLSD tool, and 29 students (control group) were trained in a traditional instructor-led course. We analyzed the appropriateness of action learning.

2) This study is a multi-center randomized controlled three-arm trial based on simulation. The intervention arm tested the PediAppRREST app; the two control arms, instead, were allocated to the PALS pocket card and to no cognitive aid, respectively. All participants are residents in Pediatrics, Anesthesia and Intensive Care or Emergency Medicine. The primary outcome of the study is a score calculated according to the c-DEV15plus checklist, which represents the number of deviations from PALS guidelines performed by each team during the management of the simulated cardiac arrest scenario.

Results. 1) Holo-BLSD was rated easy to use (mean 4.00, SD 0.94), and the trainees stated that most people would learn to use it very quickly (mean 4.00, SD 0.89). Voice (mean 4.48, SD 0.87), gaze (mean 4.12, SD 0.97), and gesture interaction (mean 3.84, SD 1.14) were judged positively, although some hand gesture recognition errors reduced the feeling of having the right level of control over the system (mean 3.40, SD 1.04).

The average overall examiner scores of the two groups are rather close (39.48 for the traditional training group, 37.07 for the Augmented Reality training group, on a maximum score of 44) and their difference is not statistically significant.

2) This is an interim analysis of the trial, including a sample size equal to approximately 78% of the final sample; so far, 82 teams. The c-DEV15plus score, expressed as median (IQR), was 3.0 (2.0-4.0) in the intervention arm and 6.0 (4.0-7.0) and 6.0 (5.0-7.0) in the CtrlPALS+ and CtrlPALS- control arms, respectively ($p<0.0001$). The CPT score, a validated indicator of the resuscitation performance, showed an improvement trend in the intervention group, which is statistically significant ($p=0.0059$). The team leaders' workload resulted similar in the three groups. With regards the time of the first compression and ~~to~~ first adrenaline administration, no statistically significant differences were shown between the study groups. RCP quality was suboptimal, with no significant statistical differences between the three groups. The usability of the app was good according to the System Usability Scale (median of 77.5).

Conclusions. We found the Holo-BLSD system to be a feasible and acceptable tool for BLS training. The main experimental results indicate that Holo-BLSD can provide both a learning experience similar to instructor-led training and a reliable automatic assessment of the learner's performance.

As regards PediAppRREST the analysis shows a statistically significant reduction in the number of deviations from the guidelines (c-DEV15plus score) in the PediAppRREST arm and also highlighted an improvement in the overall performance of the teams that used the app.

The different simulation modalities (AR and High fidelity) were used in both the training and research and showed good results. These can be considered as some evidence of how simulation is useful improving the management of emergency events in real life, to increase survival and improve the outcome for patients.

INTRODUCTION

Emergency Medicine

The management of acute events in Emergency Medicine (EM) is a significant problem in clinical practice a mainly because they are rare, stressful, and unpredictable. Many unpredictable factors may occur during an acute event and contribute to an often difficult to manage situation. Settings may vary and include not only the Emergency Room (ER), but also the prehospital setting, the Observation Medicine Units, the EM's handling of community emergency medical response, medical control, and disaster preparedness. The environment is anything but relaxed, usually overcrowded, and stressful, there are many unrequested stops, the staff has complex work algorithms, and patients are increasingly complex. Furthermore, the Emergency physician must deal with time-depending pathologies, and usually treat and diagnose at the same time. In such a context, the chances of medical error are very high, and the EM's challenge to guarantee optimal care in very complex time and depending on the environment. Among all acute events, Cardiac Arrest (CA) is the most dramatic event that could occur.

Cardiac arrest

The CA is defined as the loss of circulation that requires cardiopulmonary resuscitation [1] and can be divided in out-of-hospital cardiac arrest (OHCA) and in-hospital cardiac arrest (IHCA).The first step in both is to recognize the CA.

If we have a patient that is found to be unresponsive and with no breathing (or only gasping), it is necessary to shout for nearby help and activate the emergency response system and send for a defibrillator. After that, it is necessary to check for a pulse and start cardiopulmonary resuscitation (CPR) if there is no pulse. Proceeding in a high-quality CPR is essential for a patient's survival [2].

The high-quality CPR is characterized by:

- chest compressions (CC) of adequate rate and depth
- allowing for complete chest recoil after each compression
- to minimize interruptions in compressions
- avoid excessive ventilation

Finally, the care provider has to attach the Electrocardiogram (ECG) monitor or the automated external defibrillator (AED) pads as soon as possible to check central rhythm to distinguish:

- shockable rhythm: ventricular fibrillation (VF) or pulseless Ventricular tachycardia (pVT)
- non shockable rhythm: asystole/ Pulseless electrical activity (PEA)

We used cardiopulmonary resuscitation management for both adults and children in agreement with the American Heart Association (AHA) guidelines[3] (Figure 1 and Figure 2).

Figure 1: Adult Cardiac Arrest Algorithm

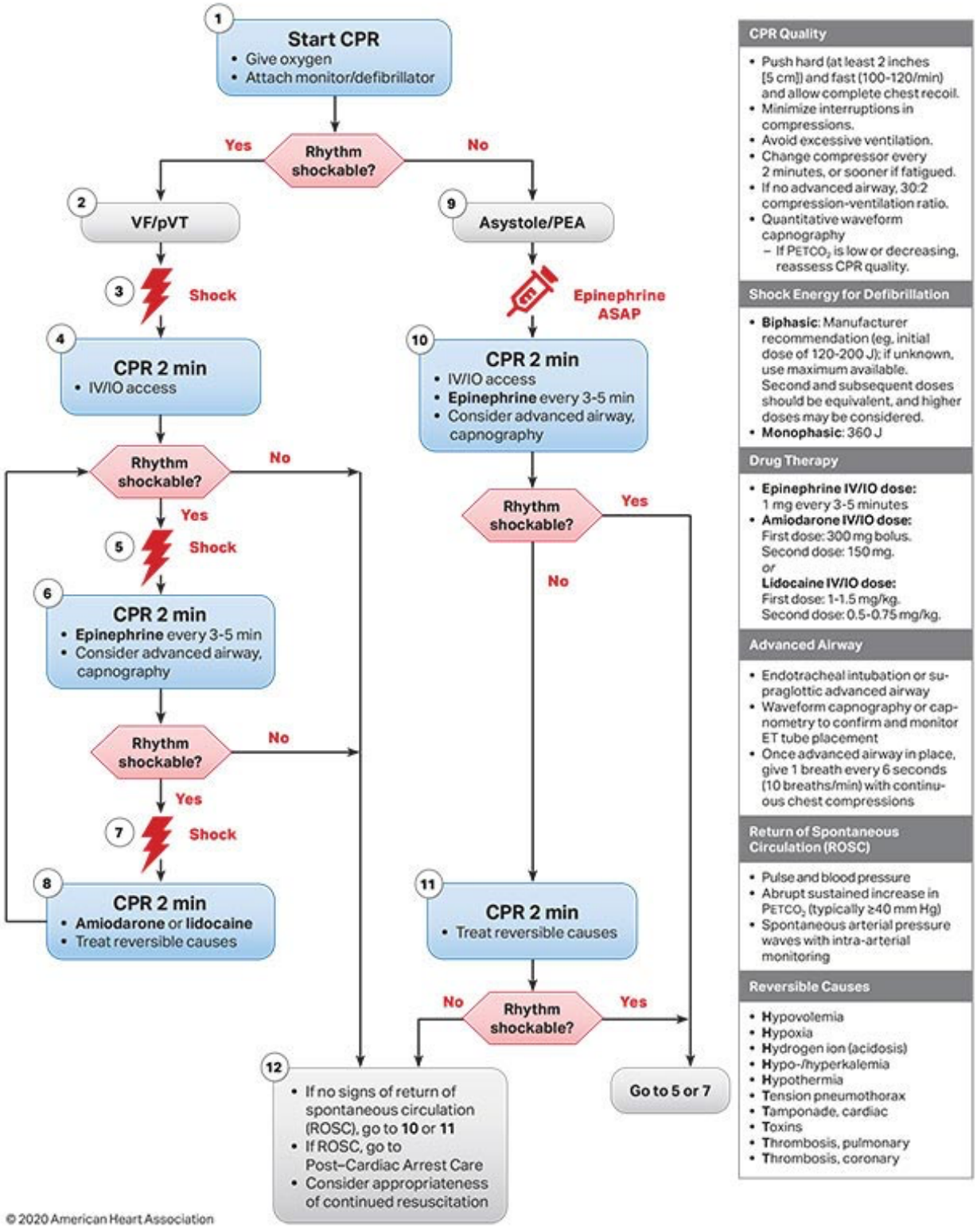
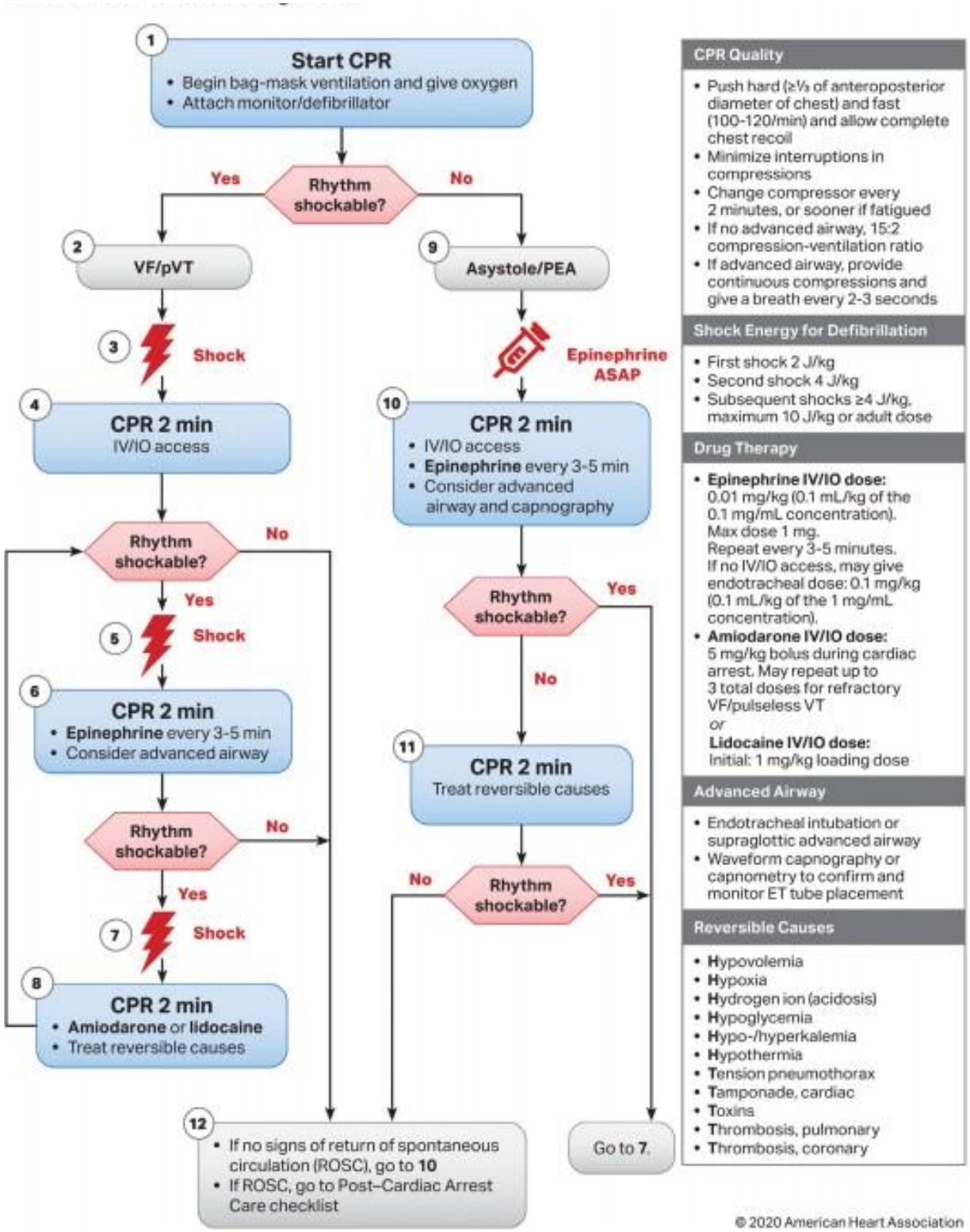


Figure 2: Pediatric cardiac arrest algorithm



Shockable rhythm

At this point, in the presence of VF or pVT, one shock must be delivered (360 j with manual monophasic and 120 to 200 J with biphasic defibrillator) and then 2 more minutes of CPR with CC must be performed. Early defibrillation and high-quality CC are associated with a higher survival rate in patients with a shockable rhythm[4]. Moreover, the healthcare provider must administer epinephrine 1 mg intravenous (IV) every 3 to 5 minutes.

After a second shock the use of other antiarrhythmic drugs may be considered (Amiodarone 300 mg IV/intraosseous (IO) bolus, then consider 1 additional 150 mg IV/IO, or Lidocaine 1 to 1.5 mg/kg IV/IO first dose, then 0.5 to 0.75 mg/kg IV/IO at 5- to 10-minute intervals, to a maximum dose of 3 mg/kg) even if, there is still no evidence of their association with better survival.

Non-shockable rhythm

In the case of asystole or PEA (electrical activity detectable on the monitor, in the absence of a pulse) the rhythm is not shockable, and the electric shock should not be delivered.

Epinephrine IV must be administered as soon as possible[5] and repeated every 3-5 minutes, because its early use is associated with return of spontaneous circulation (ROSC). Check the rhythm every 2 minutes and minimize interruptions in chest compressions (not exceed 10 seconds).

Underlying Causes

Furthermore, it is also necessary to determine the underlying causes because they will provide the best chance for a successful resuscitation.

AHA divides the potential causes of CA into H and T to memorized better. All these causes can be discovered by analyzing the ECG, blood gas analysis, using bedside ultrasound and a focused medical history:

H's

- Hypovolemia
- Hypoxia
- Hydrogen ion (acidosis)
- Hypo / hyperkalemia

- Hypothermia

T's

- Pneumothoracic tension
- Tamponade (cardiac)
- Toxins (intoxication)
- Thrombosis (pulmonary)
- Thrombosis (coronary)

Once a cause has been identified, it is necessary to proceed with specific treatment to increase the chances of recovery of circulation.

If ROSC is finally achieved, it is important to continue with close monitoring.

Pediatric cardiac arrest

AHA guidelines (Figure 2) have also developed guidelines for pediatric cardiac arrest. There are some differences between the algorithms:

- energy of the electric shock is 2 J / kg, increased to 4 J / kg at the second discharge, and progressively higher up to a maximum of 10 J / kg
- an initial dose of epinephrine within the first 5 minutes from the start of CC has to be administered (epinephrine dose: bolus of 0.01 mg / kg (0.1 ml / kg if diluted with saline at a ratio of 1: 10,000) followed by a flush of 10 ml of physiological solution that favors its entry into the circulation
- dose of amiodarone: bolus of 5mg / kg, for a maximum of 200mg.
- lidocaine dose: initial bolus of 1mg / kg, followed by a continuous infusion at 20-50 mcg / kg / min.
- ventilation after the positioning of an advanced airway: always carried out asynchronously, but at a frequency of no more than 10 / min but of 20-30 / min (1 ventilation every 2-3 seconds instead of every 6).
- indications for the use of cuffed endotracheal tubes to reduce air loss
- no recommendations for the use of routine cricoid pressure in the intubation of children

- new recommendations for the evaluation and support of patients who survived cardiac arrest, for any rehabilitation services, with constant neurological evaluation, for at least one year after the event

The "Heart Disease and Stroke Statistics—2019 Update[6] reports that OHCA incidence in adults is 140.7 individuals per 100000 population (95% CI, 138.3–143.1), or 347322 adults (95% CI, 341397–353246) out of the total population of the United States (ROC Investigators, unpublished data, July 7, 2016) and incidence of adult IHCA events was a mean of 8.27 (SD, 10.01) per 1000 hospital admissions and 1.56 (SD, 1.36) per 1000 inpatient days in the 2017 GWTG data (GWTG–Resuscitation, unpublished data, 2017).

The study of Abella BS et al. [7] shows that CPR quality was failing and did not satisfy guideline recommendations.

Some factors such as an early recognized CA, high quality CPR and rapid defibrillation improve survival. But the AHA guidelines include also:

- Training healthcare providers to become more knowledgeable about what improves survival rates
- Proactive planning and simulation of cardiac arrest to provide the opportunity for a healthcare provider to practice and improve in responding to cardiac arrest

Therefore, having a training tool, research and validation of protocols and procedures are needed in EM. The simulation encompasses all these aspects and could win the challenge of increasing good patient care by acting on all these characteristics.

How can Simulation meet this challenge?

Definition and modalities of simulation

The acclaimed simulation expert David Gaba in his famous article "The Future Vision of Simulation in Healthcare" defined Simulation as "a technique–not a technology–to replace or amplify real experiences with guided experiences that evoke or replicate substantial aspects of the real world in a fully interactive manner" [8].

Chiniara[9] selects features that describe simulation, such as modalities, simulator types, instructional method, fidelity, of team composition, feedback, identifying four different modalities of simulation and a hybrid simulation related to specific educational goals:

- Computer-based simulation: the student interacts through a screen-based interface
- Procedural simulation: the user trains a specific psychomotor skill and procedure
- Simulated clinical immersion: the experience includes a real or simulated environment and actors, patient or patient simulators are present in simulation
- Simulated patient: a real patient is interpreted by an actor, a patient, or a patient simulator
- Hybrid simulation: two or more modalities are present in a simulation scenario

The types of simulators can be categorized in:

- Actor: an individual that plays a role in a simulation scenario
- Computer of web application: a real system reproduced by a computer-based program
- Organic: an organic substance that is used in a simulation session
- Part-task trainer: part of patient or a system replicated by a plastic simulator
- Patient: a real patient that plays out their own actual role
- Patient simulator: a synthetic simulator that replicates a life-size patient
- Virtual patient, reality, world: a computer-based program that allows the user to interact with a digital patient or to immerse in a digital environment through a screen-based interface

AIM

My main project was to develop new simulation modalities to improve training and research in cardiac arrest.

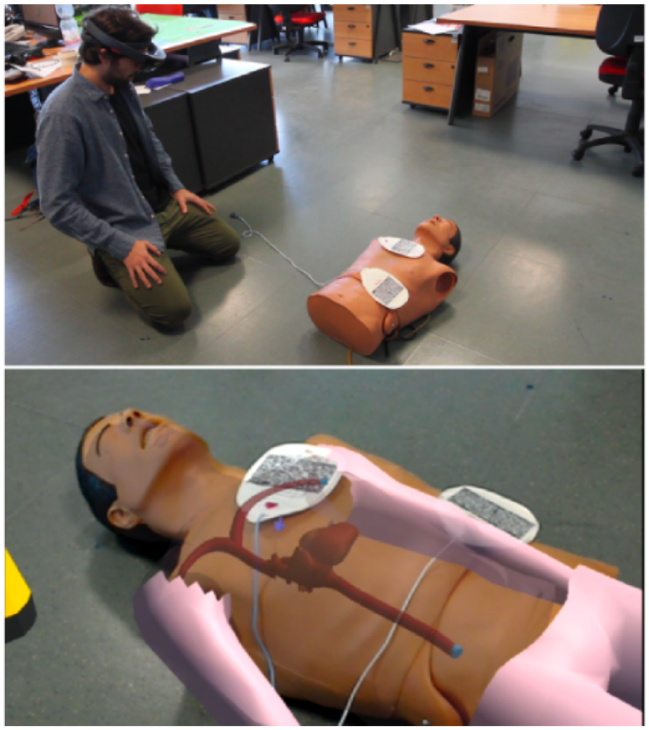
To this purpose, we studied the efficacy of new simulation methods for both residents and students (medical and nurses) in EM settings. Finally, we extended our experience to residents of Pediatric training programs.

METHODS

A) Augmented reality

Holo-BLSD is augmented reality (AR) prototype tool of CPR training, developed jointly by the SIMNOVA simulation center (Novara, Italy) and the Department of Computer Engineering of Politecnico di Torino, in collaboration with Logosnet's e-REAL Immersive Simulation Labs in Lugano, Switzerland.

Figure 3: a trainee using the Hololens device (above) and AR displayed in the trainee's field of view (below)



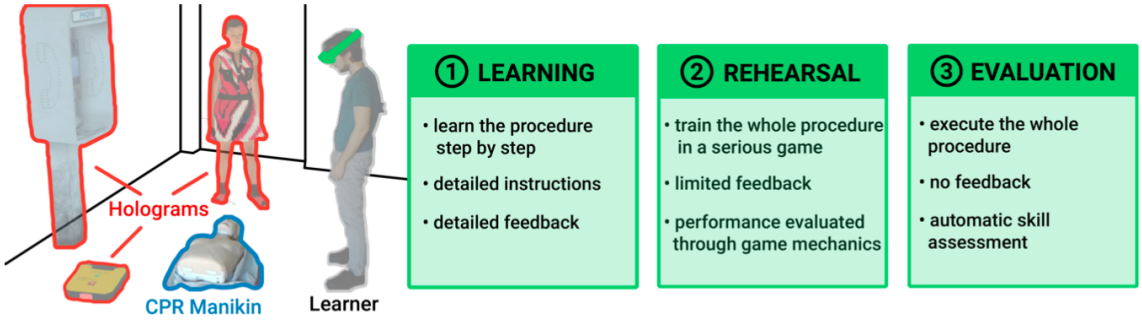
Holo-BLSD is an application for the Microsoft HoloLens headset that combines a standard low-cost CPR manikin with holographic interactive contents reproducing a realistic emergency scenario (Figure 3). Within the application, learners can use natural gestures, body movements and spoken commands to perform their tasks.

The learning path of Holo-BLSD is divided into three different modes (Figure 4):

1. a learning mode, where users are guided step-by-step through the correct sequence of actions, they have to perform to complete the procedures of interest.

2. a rehearsal mode, envisioned as a serious game where users can train the intervention procedures, they have learned in the previous phase.
3. an evaluation mode, where trainees' Basic life Support and Defibrillation (BLSD) skills are automatically assessed by the system.

Figure 4: Holo-BLSD: AR enviroment (left) and outline of the proosed learning path, including three modes (right).



Users are free to repeat learning and rehearsal until they feel confident with the procedures and ready to be evaluated.

Its AR environment and the sequence of managed actions can be tailored and easily configured to simulate a variety of emergency scenarios (e.g., indoor, outdoor, with different hazards and victims' state of consciousness).

It provides feedback on performed actions and features an automatic self-assessment tool of the skills learned that reproduces traditional evaluation by limiting the impact of subjective and/or visual measurements.

It includes a debriefing companion application that allows learners to review and critically analyze what they have done.

Thus, Holo-BLSD has been designed to be flexible enough to support the different configurations, scenarios and action sequences mentioned above, as well as to facilitate the introduction of new elements, thus enabling future extensions (e.g., to support emergency team training). The technical aspects, design of the simulator, and introduction of new elements into the AR environment and the User Interface are included in a study by

Strada F et al. “Holo-BLSD - A Holographic Tool for Self-training and Self-evaluation of Emergency Response Skills” [10].

Holo-BLSD provides a specific training session to help users get acquainted with the system.

After interactive training, users can embark on the BLS training. Holo-BLSD guides users step-by-step through the resuscitation procedure of an adult experiencing cardiac arrest. All generated data are logged, and a feedback sheet can be generated, thus supporting debriefing sessions and enabling the creation of a library of training events.

The progressive experimentation process of this new tool for the training of health workers has been divided into two stages.

Involved subjects

1) During a national simulation competition for medical residents[11], we trained 26 participants to use the device (Table 1: characteristics of the participants) and who filled out a survey[12] at the end to assess the usability of the Holo-BLSD.
2) Subsequently we enrolled 58 volunteers first year nurse students randomly split in two groups: 29 participants underwent a self- training with Holo-BLSD tool, and 29 students (control group) were trained in a traditional instructor-led course. We analyzed appropriateness of actions learning (Table 3). The examiner (through visual inspection) and the AR-based tool (in an automatic way) used the same BLSD procedure score to evaluate the actions.

Table 1: characteristics participants survey HoloBLSD

characteristics	participants
gender	
male	16 (62)
female	10 (38)
age group (years)	
20-29	15 (58)
30-39	9 (35)
40-49	0 (0)
50-59	2 (8)
practice type	
resident	19 (73)
physician	3 (12)
nurse	1 (4)
other	
space system engineer	1 (4)
designer	1 (4)
secretary	1 (4)
speciality	
emergency medicine	7 (32)
anesthesiology	6 (27)
general surgery	2 (9)
internal medicine	1 (5)
pediatrics	1 (5)
cardiology	1 (5)
not specified	4 (18)

Table 2: actions learning HoloBLSD

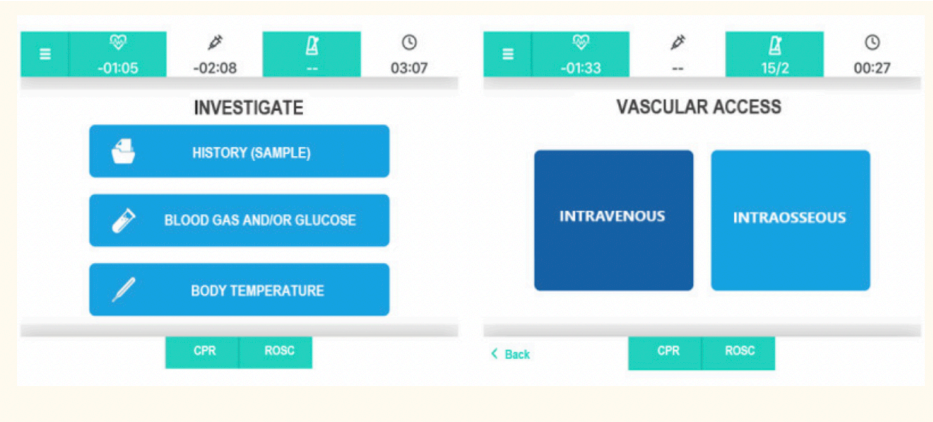
	action	evaluation criteria
1	scene safety	In the scene there are always 3 objects to remove. If no object is removed by the learner, 0 points; 1–2 removed, 1 point; 3 objects removed (action completed), 2 points
2	LOC evaluation	Learner is requested to assess level of consciousness by shaking the victim and ask if he or she is all r loud voice. Action is completed only if both the operations have been accomplished: for instance, cal victim without shaking him or her (or vice versa) means that action is not completed (1 point)
3	vital signs evaluation	Learner has to observe the victim at least for five seconds to see whether he or she is breathing or not otherwise the action is considered as not started (0 points).
4	emergency call	Action is assigned 2 points is the call is completed. If the learner makes errors in informing the medic about victim's LOC and vital signs, score is reduced to 0.
5	Get AED	If the learner asks bystanders for the defibrillator, 2 points, otherwise 0 points (the lack of the defibril make it impossible for the learner to start and complete steps 12–15 and 20–21)
6	Clear chest	If the learner clears victim's chest from the obstructing arm (which blocks CPR), 2 points, otherwise
7	1st CPR – Start	If compression is initiated within 30 second after having asked for the defibrillator, 2 points, otherwis
8	1st CPR – Rate	Score is assigned based on average compression rate (BPM): 95 <BPM <125, 2 points; 80 <BPM <9 <BPM <140, 1 point, BPM <80 or BPM >140, 0 points.
9	1st CPR – Depth†	If the compressions are 5 cm deep, 2 points, otherwise 0 points. Not assessed by the AR tool.
10	1st CPR – Expansion†	If the chest returns in a neutral position after each compression, 2 points, otherwise 0 points. Not asse AR tool.
11	AED turned on	If the defibrillator is turned on, 2 points, otherwise 0 points.
12	Paddles placed	If the defibrillator's paddles are placed correctly on the victim's chest, 2 points, otherwise 0 points.
13	Paddles plugged in	If the paddles' connector is plugged in to the defibrillator, 2 points, otherwise 0 points.
14	1st security protocol	Defibrillation security protocol requests to move away from the victim, use loud voice to ask bystand same, look around to make sure that nobody approaches the victim. The AR tool only assesses the las operations: if both of them are performed, 2 points; if just one of them is performed, 1 point; otherwis
15	1st defibrillation	If the defibrillator is discharged after having been invited to do that by the device (ready signal), 2 po defibrillator is never discharged, 0 points.
16	2nd CPR – Start	If compression is initiated within 30 second after having discharged the defibrillator, 2 points, otherw
17	2nd CPR – Rate	Same as for action 8.
18	2nd CPR – Depth†	Same as for action 9.
19	2nd CPR – Expansion†	Same as for action 10.
20	2nd security protocol	Same as for action 14.
21	2nd defibrillation	Same as for action 15.

B) A new app

The researcher team at the Pediatric Emergency Department and Pediatric Intensive Care Unit of the University Hospital of Padova (Italy), human–machine interface designers, human factor experts, and app/software developers of RE:Lab S.r.l. (Interaction Engineering company Reggio Emilia, Italy) have developed a simple app PediAppRREST[13] based on the Pediatric Advance Life Support (Pals) algorithms[14] that can guide the healthcare provider in the resuscitation in cardiac arrest of children.

The screens are simple (Figure 5) and every two minutes the app acoustically and visually reminds the user to check the rhythm and deliver a shock if necessary. The app prompts to search / treat reversible causes of CA and correctly manage the airway.

Figure 5: Screens PediappRREST



To evaluate the efficacy of the app in reducing deviations from guideline recommendations in the management of Pediatric Cardiac Arrest (PCA), we conducted a simulation-based multicenter randomized controlled study[15].

We recruited 82 teams (246 residents) (Table 3) from the medical residency programs in Pediatrics, Emergency Medicine and Anesthesiology, at the University of Padova, Meyer University Hospital, University of Firenze, Maggiore della Carità University Hospital, University of Piemonte Orientale (Novara) and Agostino Gemelli University Hospital, Catholic University of Sacro Cuore (Rome).

Table 3: participants

Residency program	Padova	Firenze	Roma	Total
Pediatrics	30	19	11	60
Anesthesiology	7	0	4	11
Emergency Medicine	7	0	4	11
Total	44	19	19	82

All trainees were certified holders of BLS or Pediatric-BLS (P-BLS) or PALS or Advance Life Support (ALS) or Advanced Cardiovascular Life Support (ACLS), with the team leader having to be PALS certified under AHA or European Resuscitation Council (ERC) guidelines (Table 4).

Table 4: charateristics of participants

demographic characteristics	PediAppRREST	CtrlPocketPALS +	CtrlPocketPALS-	P value
Age, mdn (IQR)	28.0 (27.0-30-0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	0.1253
year of residency, mdn (IQR)	2.0 (2.0-3.0)	2.0 (2.0-4.0)	2.0 (2.0-4.0)	0.4506
Residencyn (%)				0.9054
Pediatrics	57 (76.0%)	60 (74.1%)	57 (73.1%)	
Anesthesiology	9 (12.0%)	12 (14.8%)	9 (11.5%)	
Emergency Medicine	9 (12.0%)	9 (11.1%)	9 (15.6%)	
Residency, n (%)				0.9289
padova	39 (52.0%)	42 (51.9%)	45 (57.7%)	
Firenze	18(24.0%)	21 (25.9%)	18 (23.1%)	
Roma	18(24.0%)	18 (22.2%)	15 (19.2%)	
months from last PALS certification, mdn (IQR)	12.0 (2.0-30.0)	7.5 (2.0-17.0)	10.5 (2.0-18.0)	0.3202
training in pediatric simulation,n(%)	45 (60.0%)	41 (51.9%)	38 (48.7%)	0.3202
training in CPR simulation, n (%)	46 (61.3%)	51 (63.0%)	53 (67.9%)	0.6713
months from last RCP simulation, mdn (IQR)	9.5 (2.0-18.0)	10.0 (3.0-17.0)	8.0 (2.0-15.0)	0.6596
RCP in reality, mdn (IQR)	2.0 (1.0-10.0)	2.0 (1.0-5.0)	3.0 (1.0-8.0)	0.7057
months from last RCP in reality, mdn (IQR)	6.0 (3.0-24.0)	10.0 (3.0-24.0)	6.0 (2.0-21.0)	0.7497

The study includes an intervention arm (PediAppRREST arm) that use the new app, one control arm CtrlPocketPALS + that use the PALS Pocket Reference Card and a second control arm CtrlPocketPALS- that no use cognitive aids.

As primary outcome we studied the number of deviations from the PALS guidelines during the non-shockable PCA. The deviations from PALS guideline recommendations are defined as delays and errors according to a novel check- list named c-DEV15plus (Table 5).

Table 5: c-DEV15plus

	c-DEV15 plus_total, mdn (IQR)
1	CPR started within 30 seconds from recognition of pulseless state: *1, n (%)
2	CPR board/rigid surface positioned underneath the manikin within 60 s from recognition of pulseless state : *2, n (%)
3	Compression/ventilation ratio 15:2: *3, n (%)
4	hospital emergency response system activated within 60 s from recognition of pulseless state: *4, n (%)
5	Compressors swiched more than once during CPR: *5, n (%)
6	ECG-monitoring started within 60 s from recognition of pulseless state : *6, n (%)
7	IV/IO access called within 60 s from recognition of pulseless state: *7, n (%)
8	First epinephrine called within 30 s from recognition of pulseless state: *8, n (%)
9	First epinephrine administered at the correct dose and dilution and by the cireect route (V/IO) followed by a normal saline flush while compression are being performed, within 3000 s from recognition of pulseless state : *9, n (%)
1o	Second epinephrine called between 3 and 5 minutes from the first administration of epinephrine: *10, n (%)
11	epinephrine administered at the correct dose and dilution and by the cireect route (V/IO) followed by a normal saline flush while compression are being performed, within 5 minutes from the first administration of epinephrine: *11, n (%)
12	Blood gas called during CA: *12, n (%)
13	Reversible causes treated: *13, n (%)
14	Shock not administered: *14, n (%)
15	Medication other than epinephrine: *15, n (%)

Furthermore, we have collected the secondary outcomes:

- CPR quality (CC depth and rate, the percentage of time during CA with chest compressions) measured by the Skill Reporter (Laerdal), the internal software of the manikin[16].
- time to accomplish critical resuscitation interventions[14 17]
- team resuscitation performance as evaluated with the Clinical Performance Tool (CPT) [1819]
- team leaders' workload measured by the validated, multidimensional NASA-Task Load Index (NASA-TLX)[2021].
- usability of the app tested by validated questionnaire, the System Usability Scale (SUS)[2223] and a questionnaire with open- ended questions.

RESULTS

A) Augmented reality

1) Usability of the Holo-BLSD tool

The cognitive load required to operate the HoloLens was minimal (mean 1.77, Standard Deviation (SD) 0.86) with no high physical effort required (mean 1.19, SD 0.40). The users felt confident using the software (mean 3.62, SD 1.06) and voice (mean 4.48, SD 0.87), gaze (mean 4.12, SD 0.97), and gesture interaction (mean 3.84, SD 1.14) were evaluated positively as words and symbols (mean 4.70, SD 0.56) with audio instructions (mean 4.43, SD 0.79) easy to understand. The sensorial information provided by the AR gave participants the impression of being physically on the scene (mean 3.52, SD 0.95). The partecipants reported that the experience was pleasant (mean 4.13, SD 0.81) and enjoyable (mean 4.65, SD 0.57) and that the virtual contents were realistic (mean 3.74, SD 1.05). Moreover they judged the system as capable of providing real benefitS as a training tool (mean 4.22, SD 0.67). They were mostly critical just about the quality of the display (mean 2.45, SD 1.47), although they rated it as appropriate for the function involved (mean 3.62, SD 1.17).

2)Objective measurements

Objective results collected during the experiments are summarized in Table 6. The first column reports the actions of the BLSD procedure. The second and third columns tabulate scores assigned by the examiners in, respectively, the traditional (TE) and AR (AE) training groups (mean values and standard deviations reported). The fourth column provides calculated p-values. The fifth column (AT†) reports the automatic scores assigned by the tool in the AR course (actions that cannot be assessed so far are marked with † in the first column). The sixth column reports p-values calculated on the comparison between examiner's scores for the traditional training course (TE†) and automatic scores for the AR training group (AT†). Finally, the last column provides inter-rater agreement between the examiner (AE†) and the tool (AT†) when scoring the AR training group.

The average overall examiner scores of the two groups (second and third columns) are rather close (39.48 for the traditional training group, 37.07 for the AR training group, on a maximum score of 44) and that their difference is not statistically significant. This finding suggests that the learning outcomes achieved by the instructor- led and the AR-based courses are overall comparable.

Table 6: Objective measurements HoloBLSD

	Trad.–Ex. (TE)	AR–Ex. (AE)	p (TE–AE)	AR–Tool (AT†)	p (TE†-AT†)	k (AE†-AT†)
1. Scene safety	1.97 (0.19)	2.00 (0.00)	0.322	1.97 (0.19)	1.000	0.926
2. LOC evaluation	2.00 (0.00)	1.86 (0.35)	0.039*	1.93 (0.26)	0.161	–0.101
3. Vital signs evaluation	1.97 (0.19)	1.72 (0.45)	0.011*	1.93 (0.26)	0.562	–0.124
4. Emergency call	2.00 (0.00)	2.00 (0.00)	-	2.00 (0.00)	-	1.000
5. Get AED	1.86 (0.35)	1.90 (0.41)	0.732	1.90 (0.41)	0.732	1.000
6. Clear chest	1.93 (0.26)	1.97 (0.19)	0.561	1.90 (0.31)	0.647	0.055
1st CPR – Start	2.00 (0.00)	1.90 (0.31)	0.078	1.93 (0.37)	0.326	0.374
1st CPR – Rate	1.90 (0.31)	1.79 (0.41)	0.285	1.69 (0.66)	0.135	0.329
1st CPR – Depth†	1.83 (0.38)	1.76 (0.51)	0.564	-	-	-
1st CPR – Expansion†	2.00 (0.00)	1.90 (0.41)	1.179	-	-	-
AED turned on	1.97 (0.19)	1.86 (0.44)	0.249	1.83 (0.47)	0.149	0.877
Paddles placed	1.97 (0.19)	1.83 (0.47)	0.146	1.79 (0.62)	0.161	0.699
Paddles plugged in	1.86 (0.44)	1.86 (0.44)	1.000	1.93 (0.37)	0.977	0.651
1st security protocol	1.86 (0.35)	1.79 (0.56)	0.576	1.72 (0.65)	0.320	0.836
1st defibrillation	2.00 (0.00)	1.66 (0.77)	0.019	1.72 (0.70)	0.043	0.869
2nd CPR – Start	2.00 (0.00)	1.66 (0.77)	0.013	1.66(0.72)	0.023	0.879
2nd CPR – Rate	1.76 (0.51)	1.48 (0.78)	0.118	1.45 (0.74)	0.021	0.620
2nd CPR – Depth†	1.62 (0.56)	1.59 (0.73)	0.841	-	-	-
2nd CPR – Expansion†	1.93 (0.37)	1.66 (0.72)	0.072	-	-	-
2nd security protocol	1.45 (0.74)	1.38 (0.90)	0.751	1.48 (0.87)	0.299	0.873
2nd defibrillation	1.62 (0.78)	1.52 (0.87)	0.635	1.52 (0.87)	0.055	1.00
All actions	39.48 (2.50)	37.07 (7.07)	0.088	-	-	-
All actions except †	32.11 (2.28)	30.34 (5.60)	-	30.17 (5.41)	0.109	0.794

B) A new app

Primary outcome (c-DEV15plus score)

The values of c-DEV15plus were 3.0 (2.0-4.0) in PediAppRREST arm and respectively 6.0 (4.0-7.0) in CtrlPocketPALS + and 6.0 (5.0 -7.0) in CtrlPocketPALS - (Table 7).

Table 7: c-DEV15 plus

	PediAppRREST	CtrlPocketPALS +	CtrlPocketPALS-	P value
c-DEV15 plus_total, mdn (IQR)	3.0 (2.0-4.0)	6.0 (4.0-7.0)	6.0 (5.0-7.0)	<0.0001
CPR started within 30 seconds from recognition of pulseless state: *1, n (%)	22 (88.0%)	23 (85.2%)	23 (88.5%)	1.0000
CPR board/rigid surface positioned underneath the manikin within 60 s from recognition of pulseless state: *2, n (%)	18 (72.0%)	4 (14.8%)	3 (11.5%)	<0.0001
Compression/ventilation ratio 15:2: *3, n (%)	24 (96.0%)	27 (100.0%)	21 (80.8%)	0.0201
hospital emergency response system activated within 60 s from recognition of pulseless state: *4, n (%)	18 (72.0%)	1 (3.7%)	1 (3.8%)	<0.0001
Compressors swiched more than once during CPR: *5, n (%)	18 (72.0%)	12 (44.4%)	15 (57.7%)	0.1328
ECG-monitoring started within 60 s from recognition of pulseless state : *6, n (%)	24 (96.0%)	23 (85.2%)	24 (92.3%)	0.4898
IV/IO access called within 60 s from recognition of pulseless state: *7, n (%)	14 (56.0%)	19 (70.4%)	16 (61.5%)	0.5557
First epinephrine called within 30 s from recognition of pulseless state: *8, n (%)	0 (0.0%)	5 (18.5%)	2 (7.7%)	0.0635
First epinephrine administered at the correct dose and dilution and by the cireect route (V/IO) followed by a normal saline flush while compression are being performed, within 3000 s from recognition of pulseless state : *9, n (%)	22 (88.0%)	10 (37.0%)	7 (26.9%)	<0.0001
Second epinephrine called between 3 and 5 minutes from the first administration of epinephrine: *10, n (%)	21 (84.0%)	17 (63.0%)	16 (61.5%)	0.1511
epinephrine administered at the correct dose and dilution and by the cireect route (V/IO) followed by a normal saline flush while compression are being performed, within 5 minutes from the first administration of epinephrine: *11, n (%)	22 (88.0%)	11 (40.7%)	8 (30.8%)	<0.0001
Blood gas called during CA: *12, n (%)	24 (96.0%)	21 (77.8%)	21 (80.8%)	0.1561
Reversible causes treated: *13, n (%)	23 (92.0%)	25 (92.6%)	26 (100.0%)	0.4586
Shock not administered: *14, n (%)	24 (96.0%)	26 (96.3%)	26 (100.0%)	0.7662
Medication other than epinephrine: *15, n (%)	24 (96.0%)	27 (100.0%)	25 (96.2%)	0.5415

There was a statistically significant reduction of deviations in:

- the CPR board/rigid surface positioned underneath the manikin (c-DEVplus item 2)
- compressions/ventilations ratio 15: 2 (c-DEVplus item 3)
- hospital emergency response system activated (c-DEVplus item 4)
- first epinephrine administered at the correct dose, dilution and by the correct route (c-DEVplus item 9)
- second epinephrine administration (c-DEVplus c-DEVplus item 11).

Secondary outcome

- CPR quality: there were no statistically significant differences between the arms (Table 8)
- The time of start of CC (chest compression) and the first epinephrine administration: there were no statistically significant differences between the arms (Table 9)
- Team resuscitation performance (CPT): there was a statistically significant difference about median CPT score: 9.0 (IQR 6.0-12.0) in PediAppRREST arm, 8.0 (IQR 4.0-10.0) for the CtrlPALS + and 8.0 (6.0-12.0) CtrlPALS- groups, ($p = 0.0059$)
- Workload: No statistically differences in PediAppRREST arm were found, although a decrease in this arm was noted (Table 10)
- Usability*:* usability in SUS score is good (between 68 and 80)[23] (Median 77.5 with IQR 65.0-85.0).

Table 8: CPR quality

	PediAppRREST (n=23)	CtrlPocketPALS + (n=24)	CtrlPocketPALS- (n=23)	P value
chest compressions depth (mm), mean	47.4 (6.3)	45.3 (7.0)	48.0 (6.2)	0.3495
compression with chest recoil, mean	84.0 (42.0-94.0)	93.0 (83.0-97.5)	76.0 (53.0-94.0)	0.0975
number of chest compressions with 50-60 mm (%) depth, mdn (IQR)	50.0 (24.0-74.0)	24.5 (4.5-62.5)	46.0 (17.0-72.0)	0.3712
adeguate rate (bpm), mdn (IQR)	110.0 (106.0-115.0)	110.0 (105.0-121.0)	110.0 (100.0-120.0)	0.8027
chest compressione fraction (%), mdn (IQR)	65.0 (59.0-70.0)	63.5 (59.5-76.5)	74.0 (63.0-80.0)	0.3827

Table 9: time of start of CC and the first epinephrine administration

	PediAppRREST (n=25)	CtrlPocketPALS + (n=27)	CtrlPocketPALS- (n=26)	P value
start of compressions (s), mdn (IQR)	8.0 (1.0-75.0)	6.0 (0.0-55.0)	4.5 (-3-43.0)	0.3638
First epinephrine administered (s), mdn (IQR)	173.0 (76.0-396.0)	159.0 (80.0-307.0)	163.0 (46.0-398.0)	0.8018

Table 10: Workload

	PediAppRREST (n=25)	CtrlPocketPALS + (n=27)	CtrlPocketPALS- (n=26)	P value
Raw-TLX score, m (SD)	58.8 (14.4)	60.2 (13.1)	61.5 (11.6)	0.7614
cognitive load (1-100), mdn (IQR)	75.0 (50.0-85.0)	82.5 (70.0-90.0)	80.0 (80.0-95.0)	0.1057

DISCUSSION

A) Augmented reality

Despite ongoing advances in resuscitation science, cardiac arrest survival rates remain suboptimal, and the educational efficiency of caregivers still critical, as highlighted in 2003[24] and 2018[25]. Education facilitated through technology has been identified as a strategy to improve the effectiveness of BLS training.

We present evidence that validated the Holo-BLSD app as a BLS training tool.

In the survey, the users reported that the mental effort required to operate the device was minimal. This is an important goal because an excessive cognitive load may impair participants' perceptions and performance, decreasing attention and problem-solving skills[26], and fatigue may reduce user enjoyment of the experience. The users rated the system as easy to use and judged the learning experience as pleasant and enjoyable.

Users judged the lack of peripheral view, which is known to increase cognitive load[27], as a major limitation even if users indicated that the head-mounted display was comfortable.

Some users noted that ambient light affected the quality of the holograms and made visual instructions difficult to interpret.

The virtual assembled environment was considered complex enough to be of use, allowing users to focus on the tasks without leaving them disoriented and trainees found the virtual contents realistic, stating that the system could provide real benefit as a training tool and help practitioners be more effective.

In the comparison experiment of the Holo-BLSD self-training course and the traditional one the main results indicate that Holo-BLSD can provide a learning experience similar to instructor-led training.

However, it is also worth observing that standard deviation is much higher for AR learners. This difference could be due to difficulties that some of the learners may have experienced in interacting with the AR tool, e.g., due to missed recognition of gesture and voice inputs. Some difficulties have also emerged with other head-mounted displays, such as the Google Glass used in Chaballout's study[26].

Another explanation could be the higher complexity for examiners to judge learners' performance. In fact, the execution of many actions required learners to interact with virtual elements and, even though examiners were allowed to see the point of view of the learners, delays due to data transmission made it difficult in some cases to fully appreciate their actual behavior. The cases in which differences are significant are only four, namely LOC and vital signs evaluation, start of first defibrillation and of second CPR (rows marked with * in the

fourth column). In some cases, differences can be explained again with the difficulty for examiners to judge learners' operation. For instance, in the LOC evaluation, learners were expected to shake the victim and call him or her loud; in some cases, examiners judged the force applied or the voice level used as not appropriate. However, examiners could not rely on any quantitative information in the assessment. Furthermore, differently than in the traditional training group, users of the AR tool did not have a ground truth, since they had not seen the instructor execute those actions. In the evaluation of the victim's vital signs, learners' have to observe the victim for five seconds; even using measurement instruments, examiners tended to approximate actual time.

Few actions of both courses received low scores. This outcome is particularly relevant, since it suggests those parts of the learning path that should be improved, no matter how the course is aimed to be delivered.

Other interesting insights can be obtained about the effectiveness of Holo-BLSD as a self-evaluation tool. Comparing the overall scores assigned in the AR training group by the examiner (AE†) and the tool (AT†), it can be observed that mean values are comparable (30.17 vs. 30.34, with no significant difference), as in standard deviations. This finding is confirmed by a Cohens k value equal to 0.794 (last column), which suggests a quite high inter-rater agreement. Since scores automatically computed by the tool were found to be largely consistent with those assigned by the (human) examiners to the same learners, it can be concluded that the proposed system can also be regarded as a reliable instrument for self-assessment.

The study has some limitations. As for the CPR quality assessment, methods capable of analyzing compression depth and chest recoil will be investigated, possibly without resorting to external sensors or devices. The use of conversational agents will also be explored, in order to mimic the presence of a human instructor and provide a more functional dialog-based interaction while executing the procedure. Finally, there are plans to make the application consider both co-located and remote emergency team training. Future work will include the development of several features to improve the tool.

B) A new app

The results showed a statistically significant reduction in the number of deviations from the guidelines (c-DEV15plus score) in PediAppRREST arm.

A recent retrospective study [17] based on real events, demonstrated a correlation between the reduction of deviations from the guidelines and an increase in probability of obtaining ROSC following an PCA event.

Therefore, to use a cognitive tool induces a reduction in deviations from guidelines and consequentially could have a significant impact on the clinical outcomes of PCA victims.

Real events clinical studies that evaluate the effectiveness of cognitive tools in improving the management of CA are not available in the literature, as showed in International Liaison Committee on Resuscitation (ILCOR) systematic review[28]. Instead, in a systematic review and meta-analysis[29], 14 simulation-based studies were found.

The meta-analysis results showed an improvement in performance of the intervention groups compared to the control ones, similar to what was observed in our analysis.

Regarding adult CA, 12 simulation-based studies were identified. Similarly, the use of digital and/or Pocket Reference Card tools was associated with a better performance than the absence of cognitive supports. In addition, the use of digital media is better than the use of Pocket Reference Card[2830-41] according to our analysis. As far as time spent for execution and decision making is concerned, there was no delay in PediAppRREST arm.

The use of the app does not interfere with the initial resuscitation procedures during the management of PCA. Its application is not associated with an increase in workload perceived by the team leaders, and the cognitive load was lower in the team leaders who used the app. These results highlight that using a digital support could reduce the cognitive load of team leaders and help reducing the likelihood of errors and delays in managing a PCA event. CPR quality was not significantly different between the three groups. This is not concerning as PediAppRREST app does not provide real-time feedback on the quality of the CPR. CPR performance of all the participants was suboptimal in according with the literature. The data showed that healthcare providers do not frequently reach the standards of CPR[42,43,44]. The real-time feedback tools have been included in the latest resuscitation guidelines, as a reasonable intervention to optimize the quality of CPR[45]. Furthermore assigning a role of "CPR coach" to a member of the resuscitation team, associated with a real-time feedback device, helps optimize the quality of CPR[16]. In an ideal scenario, PediAppRREST, CPR coaches and feedback devices, should be used together to improve adherence to guidelines and quality of chest compressions. Finally, the app was evaluated by the participants in a positive way from the point of view of usability and their observations and suggestions will be considered to optimize the app and its use.

There are some limitations in PediAppRREST study. One is the exclusive recruitment of residents. This population was chosen because it was possible to insert the simulations in the residency training. A further limitation of the study is represented by the too short familiarization time with the app (never used before). An increase of the familiarization time can improve the performance of the team. Furthermore, it is very important to underline that the results of a simulation-based study cannot be directly reported in clinical practice. Further studies based on real scenarios of PCA case management are needed to verify the impact of these cognitive tools on clinical outcomes. However, in emergency settings and for rare events such as PCA, clinical trials are often difficult to carry out. In these scenarios, simulation acquires an essential role as a research tool.

CONCLUSION

Holo-BLSD, an AR based self- learning and self-evaluation tool, helps to maximize learning results while reducing associated costs.

The main experimental results indicate that Holo-BLSD can provide both a learning experience similar to instructor-led training and a reliable automatic assessment of the learner's performance. Results also demonstrated the usability of the devised tool and the capability to stimulate learners' attention to levels like those achieved with traditional training. The above findings suggest that Holo- BLSD could be used as a cost-effective learning tool for supplementing traditional training and for possibly replacing it when appropriate.

As regards PediAppRREST the analysis shows a statistically significant reduction in the number of deviations from the guidelines (c-DEV15plus score) in the PediAppRREST arm and also highlighted an improvement in the overall performance of the teams that used the app. The use of the app was not related to an increase in workload or a worsening in quality of the CPR.

More studies are needed to improve HoloBLSD and PediAppRREST and expand populations to definitively validate these tools.

The different simulation modalities (AR and High fidelity) were used in both training and research and showed good results. These can be considered as some evidence of how simulation is useful improving the management of emergency events in real life, to increase survival and improve the outcome for patients.

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