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Clinical paper

Implementation of a regional extracorporeal membrane oxygenation program for refractory ventricular fibrillation out-of-hospital cardiac arrest

Nichole Bosson[a,b,c,*], *Clayton Kazan*[d], *Stephen Sanko*[e,f,l], *Tiffany Abramson*[e,f], *Marc Eckstein*[e,f], *David Eisner*[g], *Joel Geiderman*[h,i], *Walid Ghurabi*[c,j], *Vadim Gudzenko*[c,k], *Anil Mehra*[e,f], *Sam Torbati*[h], *Atilla Uner*[c,k], *Marianne Gausche-Hill*[a,b,c], *David Shavelle*[m]

Abstract

Background: eCPR, the modality of extracorporeal membrane oxygenation (ECMO) applied in the setting of cardiac arrest, has emerged as a novel therapy which may improve outcomes in select patients with out-of-hospital cardiac arrest (OHCA). To date, implementation has been mainly limited to single academic centres. Our objective is to describe the feasibility and challenges with implementation of a regional protocol for eCPR.

Methods: The Los Angeles County Emergency Medical Services (EMS) Agency implemented a regional eCPR protocol in July 2020, which included coordination across multiple EMS provider agencies and hospitals to route patients with refractory ventricular fibrillation (rVF) OHCA to eCPR-capable centres (ECCs). Data were entered on consecutive patients with rVF with suspected cardiac aetiology into a centralized database including time intervals, field and in-hospital care, survival and neurologic outcome.

Results: From July 27, 2020 through July 31, 2022, 35 patients (median age 57 years, 6 (17%) female) were routed to ECCs, of whom 11 (31%) received eCPR and 3 (27%) treated with eCPR survived, all of whom had a full neurologic recovery. Challenges encountered during implementation included cost to EMS provider agencies for training, implementation, and purchase of automatic chest compression devices, maintenance of system awareness, hospital administrative support for staffing and equipment for the ECMO program, and interdepartmental coordination at ECCs.

Conclusion: We describe the successful implementation of a regional eCPR program with ongoing patient enrolment and data collection. These preliminary findings can serve as a model for other EMS systems who seek to implement regional eCPR programs.

Keywords: Out-of-hospital cardiac arrest, extracorporeal membrane oxygenation, emergency medical services

Introduction

Despite resuscitation attempts by Emergency Medical Services (EMS), approximately 70% of patients with out-of-hospital cardiac arrest (OHCA) never achieve return of spontaneous circulation (ROSC) and overall survival remains a dismal ten percent.[1,2] For those who survive, OHCA is a leading cause of disability-adjusted life years.[4] Use of extracorporeal membrane oxygenation (ECMO), termed eCPR, has emerged as a novel therapy, to support cardiac and pulmonary function while efforts are undertaken to treat the primary cause of the patient's arrest.[5]

Several high-performing regional systems of care have demonstrated improved survival with good neurologic outcome with eCPR compared to conventional therapy.[6–9] Integration of these regional programs with the existing EMS system was critical for success of the ECMO program.[9] However, overall success with eCPR varies significantly by system.[10] Despite its increasing use, a 2017 report

* Corresponding author at: LA County EMS Agency, 10100 Pioneer Blvd, Santa Fe Springs, CA 90670, USA.
E-mail address: nbosson@dhs.lacounty.gov (N. Bosson).

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from the international Extracorporeal Life Support Organization (ELSO) database failed to demonstrate an improvement in risk-adjusted survival.[11]

Implementation has been mainly limited to single academic centers,[9] due to the needs for extensive resources, specialized training, and interdisciplinary coordination.[12,12] Regional programs have been met with significant challenges, including the ability to move rapidly from the scene to the eCPR-capable centre, and they have not demonstrated the same improvement in patient outcomes.[14,14] Access to eCPR may remain limited to highly-resourced communities with ready access to tertiary care centres unless regional systems create equitable access to this time-sensitive therapy through uniform EMS protocols and patient routing. A recent consensus paper provides operational guidance on the implementation of eCPR for OHCA.[17] However, there is a lack of guidance to inform integration of this novel therapy into existing OHCA systems of care.

We describe the Los Angeles County EMS Agency (LAC-EMS) regional eCPR program's implementation, including the challenges faced and the strategies used to overcome them, in order to inform other regional systems. We present the initial patient outcome data as a demonstration of the challenges and feasibility of a regional eCPR system of care with further study underway.

Methods

This is a preliminary report of an ongoing observational cohort study. Local Institutional Review Board approval was obtained for data collection at all participating hospitals.

Population and setting

LAC-EMS coordinates EMS care throughout the County of Los Angeles, which includes 88 cities spanning 4084 square miles with a diverse population of 10 million. 9–1-1 response is provided by 29 public EMS agencies operating under uniform treatment protocols. The LAC-EMS regional system of cardiac care has been previously described.[18] Beginning in 2019, all patients transported after OHCA were routed to one of 36 designated cardiac arrest receiving centres, which were already designated ST-elevation myocardial infarction (STEMI) Receiving Centres. The system responds to approximately 7800 OHCA resuscitations annually, including 1100 OHCA with initial shockable rhythm. OHCA treatment protocols promoted on-scene resuscitation with transport after ROSC. Following publications demonstrating benefit with eCPR in select patients with refractory cardiac arrest,[6,6] three cardiac arrest receiving centres with ECMO capabilities began initiating eCPR per the treating physicians' discretion in patients routed based on LAC-EMS protocols. This included one of the three county 9–1-1 receiving hospitals serving the region.

Regional eCPR program

In July 2020, LAC-EMS implemented an eCPR protocol for Advanced Life Support (ALS) units in the regions surrounding the three eCPR capable centers (ECCs) serving approximately 40% of LA County as a pilot program for eventual consideration of systemwide implementation. (Supplemental Fig. 1) The protocol was developed through collaborative effort including EMS and hospital partners, with regular meetings and consensus development of standardized protocols and data collection tools. Participants included the EMS Provider Agency Medical Directors, EMS Provider Agency Nurse Educators, emergency department physicians, Prehospital Care Coordinators, cardiologists, Cardiac Program Coordinators (Registered Nurses working in the Cath Lab), neurologists, intensivists, cardiovascular surgeons and other specialists performing ECMO cannulation, and EMS Agency Medical Directors and Administrators.

Patients were included if they had an initial shockable rhythm refractory to at least 3 defibrillations, age $\geq$ 15 to $\leq$ 75 years (with an a priori plan to analyse patients aged 15–65 as a subgroup), and there was a participating ECC within a 30-minute transport time by ground ambulance. Patients were excluded if the suspected aetiology was non-cardiac, if there was a Do-Not-Resuscitate order, evidence of terminal illness, pregnancy, chronic nursing home resident, chronic cognitive impairment, or contraindication to use of the mechanical compression device (MCD) were present, or if no ECC was available within a 30-minute ground ambulance transport time. Patients with rVF despite field resuscitation were managed per the eCPR protocol, which deviated from usual field management, based upon the need to rapidly transport from the scene. (Fig. 1) If the patient did not meet criteria, care was continued per usual LAC-EMS treatment protocols.[19]

Participating ECCs were required to demonstrate: 1) STEMI treatment time intervals in accordance with system performance metrics and national guidelines, 2) an established ECMO program (for any indication) with at least one case per month on average for the past 12 months, 3) a protocol that included collaboration between the emergency department, interventional cardiology, ECMO team, and neurology, 4) an MCD for use on patient arrival, 5) willingness to adhere to the inclusion/exclusion criteria, and 6) ability to enter data for all patients who met inclusion criteria. The approach to ECMO initiation varied by ECC. At one ECC the patient was cannulated by interventional cardiology in the cardiac catheterization laboratory (CCL) after a brief emergency department (ED) assessment. At the other ECCs, the ECMO team, based with the Department of Cardiovascular surgery, cannulated the patient in the ED and then the patient was transported to the CCL. Initiation of eCPR was at the discretion of the ECMO team, but decision-making was based on having no more than one of the following pre-defined prognostic indicators ($EtCO_2$ < 10 mmHg, PaO_2 < 50-mmHg or O_2 saturation < 85%, lactate > 18 mmol/L, >60 minutes since first medical contact). (Supplemental Fig. 2) The EMS provider agencies were required to: 1) rapidly deploy an MCD prior to transport; 2) adhere to pilot inclusion/exclusion criteria; and 3) collect data on all patients who met inclusion criteria.

Three ECCs (Cedar-Sinai, Ronald Reagan-UCLA, and LAC-USC Medical Centres) and four EMS provider agencies (Beverly Hills, Culver City, Los Angeles City Fire (LAFD), and Los Angeles County Fire Departments (LACoFD)) were involved in the planning phase. The program launched on July 27, 2020 with the three ECCs and three EMS provider agencies (Beverly Hills, Culver City, and LACoFD). LACoFD operated the program on select units within the proximity of the ECCs. When additional MCDs became available, additional units were included. On May 3, 2021, LAFD implemented the program and, on June 21, 2021, Santa Monica Fire Department joined the program.

Each provider agency and ECC was responsible for conducting training. Provider agencies conducted hands-on scenario-based training for all paramedics participating in the program. All of the fire departments provided at least quarterly refresher training on the eCPR protocols. ECCs conducted interdisciplinary exercises to prac-

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Los Angeles County Refractory Ventricular Fibrillation/Ventricular Tachycardia ECMO Program Field Protocol

INITIATE TREATMENT OF NON-TRAUMATIC CARDIAC ARREST PER TP 1210

Potential ECMO Candidate?

- VF or VT cardiac arrest
- Age ≥15 and ≤75
- Within 30 minutes of ECMO Center
- **NO** obvious contraindication to study (Noncardiac etiology, DNR, terminal illness, chronic nursing home resident/dependent due to cognitive impairment, pregnancy, cannot apply MCD)

NO → Proceed with usual treatment per TP 1210*

Yes to ALL

DEFIBRILLATION #1

- Continuous chest compressions (limit interruptions ≤5 sec)
- Apply MCD as soon as available
- Establish IV/IO access

Persistent VF/VT at 2 minutes?

NO → Proceed with usual treatment per TP 1210*

Yes

DEFIBRILLATION #2

- Maintain continuous chest compressions (manual or MCD as soon as available)
- Administer epinephrine 1mg IV/IO q 5 minutes (3 doses total)
- **Begin packaging and preparing patient for transport**
- Contact ECMO center Base Station to notify of potential patient
- Insert advanced airway and apply ITD (if not done with BMV)

Persistent VF/VT at additional 2 minutes?

NO → Proceed with usual treatment per TP 1210*

Yes

DEFIBRILLATION #3

- Confirm destination with ECMO Base - meets ALL indications? Route on judgment?
- Immediately load patient and initiate transport with ongoing resuscitation (ensure ACCD applied prior to transport) **GOAL scene time 10-15 minutes maximum**
- Administer Amiodarone 300mg IV/IO

*ITD/LUCAS should be also used by participating units whenever available for all OHCA patients.

Fig. 1 – Los Angeles County eCPR Program Field Protocol.

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tice the coordination and choreography of the activation process and patient care.

Monthly meetings were established to discuss implementation challenges and protocols were updated in an iterative fashion. One hundred percent of cases were reviewed at the individual provider agency and hospital level. Provider agency quality improvement included review of the cardiac monitor/automated external defibrillator (AED) data facilitated with dedicated software platforms. Each case was also reviewed with participants at the monthly meetings. Challenges were identified and collaborative solutions implemented. The discussions informed additional material development, including the Base Hospital Checklist for online medical control, as well as minor additions to the data collection tool. (Supplemental Fig. 3).

Data collection, measurements, and outcomes

A centralized REDCap database (Research Electronic Data Capture, Vanderbilt University, Nashville, TN) was established. Each participating entity could enter and view data on patients for whom they were involved in the care. Initiation of the record by the EMS provider agency triggered an alert to the ECC to enter follow-up data. The workgroup developed a list of data elements to collect and agreed upon standardized definitions. Data entry personnel received training from the primary investigator. The provider agencies and ECCs developed processes to review all OHCA cases and identify patients meeting program inclusion. When an ECC identified a potential patient that was not identified by the provider agency, this triggered a patient care record review to determine whether the patient met criteria and should be entered into the database.

Data were collected from the provider agencies on patient demographics (age, gender), location, witness, bystander cardiopulmonary resuscitation (CPR), initial rhythm, end-tidal CO_2 ($EtCO_2$) readings, number of defibrillations, epinephrine and amiodarone dosing, airway management, use of MCD, compression fraction, field ROSC, and key time metrics. Data were collected from the hospitals on race and ethnicity), emergency department (ED) care, ECMO cannulation, catheterization lab management, percutaneous coronary intervention (PCI), targeted temperature management (TTM), use of an intra-aortic balloon pump, select laboratory values (initial PaO_2, lactate, and $EtCO_2$; peak creatinine and troponin), comorbidities, neuro-imaging, ejection fraction, survival to admission and discharge, cerebral performance category (CPC) at discharge, and modified Rankin scale at discharge and 30- and 90-days post-discharge. For patients on ECMO, electroencephalogram results and neurologic assessments on day 0, 3, and 7 were also obtained. The complete list of data elements is provided in Supplementary Table 1.

The outcomes were assessed to determine feasibility of the regional eCPR program, which included 1) time intervals (response time, scene time, transport time, time from ED arrival to eCPR and total time from cardiac arrest to eCPR), 2) survival to hospital discharge and 3) good neurologic outcome of survivors based on cerebral performance category (CPC) 1 and 2.

Analysis

We performed interim analysis of data from July 27, 2020 through July 31, 2022 including descriptive statistics on patient demographics, care time intervals, and primary outcome of survival and survival with neurologic outcome for the overall cohort and groups stratified by application of eCPR.

Results

At the time of this analysis, there were 46 patients in the REDCap database, of whom 11 had one or more exclusion criteria (2 had a MCD contraindication, 4 had no MCD available, and 6 had no ECC available within 30 minutes). Of the remaining 35 patients, 11 (31%) were placed on ECMO. Three patients had sustained ROSC without ECMO, the remaining patients were not cannulated due to one or more poor prognostic indicators. Median age was 57 years (interquartile range [IQR] 46–64) and was similar amongst those who received and did not receive ECMO. Six of the patients (17%) were female, one of whom received ECMO. Patients were 11% Non-Hispanic White, 17% Non-Hispanic Black, 23% Asian, 34% Hispanic and 14% Other.

Overall, 5 (14%) patients survived to hospital discharge, of whom 4 (80%) survived with good neurologic outcome (CPC of 1). Of the 11 patients treated with eCPR, 3 (27%) survived to hospital discharge and all survivors had a CPC of 1. The additional survivor who did not receive ECMO after sustained ROSC in the field had a CPC of 3. The average hospital length of stay overall was 3.5 ± 7.6 days, 5.3 ± 8.5 days for patients who received ECMO, and 2.7 ± 7.2 days for patients without ECMO. (Table 1).

Table 2 shows the average time intervals for field care and ECMO cannulation. Scene times were significantly shorter among patients who were cannulated, median difference 8 minutes (95% CI 2–13), p = 0.02. Four patients (11%) did not receive cannulation due to documentation of downtime exceeding 60 minutes.

Table 1 – Preliminary Patient Outcomes.

	All (N = 35)		eCPR (N = 11)		No eCPR (N = 24)	
	N	%	*N*	%	*N*	%
Survival to Cath Lab	23	65.7	11	100	12	50.0
Survival to ICU Admission	16	45.7	9	81.8	7	29.2
Survival to Discharge	5	14.3	3	27.3	2	8.3
CPC 1 at Discharge*	4	80.0	3	100	1	50.0
Time on ECMO (days), mean/std	–	–	2.4	2.2	–	–
Hospital length of stay (days), mean/std	3.5	7.6	5.3	8.5	2.7	7.2

CPC = Cerebral Performance Category; mRS = Modified Rankin Scale; ICU = Intensive Care Unit; ECMO = Extracorporeal Membrane Oxygenation.

* Percent of survivors.

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Table 2 – Time Intervals for Care.

	All		eCPR		No eCPR	
	median	*IQR*	*median*	*IQR*	*median*	*IQR*
EMS response time (min)	6	5–8	8	6–10	6	5–8
EMS scene time (min)	25	18–33	19	16–25	29	24–34
Transport time (min)	16	12–19	16	12–18	16	12–22
Time from ED arrival to ECMO (min)	–	–	31	16–54	–	–
Time from cardiac arrest to ECMO (min)	–	–	76	53–94	–	–

EMS = Emergency Medical Services; ED = Emergency Department; ECMO = Extracorporeal Membrane Oxygenation.

Discussion

We describe the successful implementation of a regional eCPR program within an established cardiac system of care. These preliminary results demonstrate that nearly-one third of patients routed received ECMO of whom 27% survived. All survivors after ECMO were neurologically intact at discharge. This compares favourably to the survival rate of patients with rVF arrest receiving conventional therapy.

To implement this multi-centre, multi-agency program, there were many challenges to overcome. Initial rollout was hindered by cost. MCD's are expensive. However, because of their logistical advantages, particularly in maintaining consistency of cardiac compressions during transport, all EMS provider agencies were required to utilize MCDs. Additional related equipment including batteries and suction cups, which have limited shelf life, further contributed to the cost for EMS provider agencies. Costs also included training time, which came at the expense of other educational needs. Due to these barriers, LAFD was unable to purchase the required MCDs for all rescues and opted for a rendezvous implementation plan using regional EMS supervisors dispatched to all cardiac arrest calls. In this way, for patients meeting criteria for eCPR, the MCD could be placed prior to transport. While this worked the majority of the time, four patients were excluded because the MCD was not available. All other participating agencies deployed the MCDs on the ALS units, which was optimal but came at a much higher cost. Many sought grant funding or devices loaned from the vendor to support the program.

Maintaining system awareness of the program was an additional challenge, given the rarity of patients meeting inclusion. Frequent messaging was needed to encourage rapid identification of patients and coordination of care to minimize scene time. One EMS provider agency used stickers on the cardiac monitor as an additional reminder to the paramedics.(Fig. 2). Not surprisingly, on scene time was significantly shorter amongst patients who received ECMO. Reducing scene time was a major focus of the group's effort to increase chances for successful eCPR and favourable outcome. The field protocol was updated to include a 15-minute target for on-scene time. This protocol was circulated to both field paramedics and personnel who provide online medical control, in order to encourage efficiency in field care. While the median scene time is not yet at the target (median 25 minutes in these initial patients), the majority of patients were cannulated within the recommended 90-minute overall target.[6] Individual EMS provider agencies were tasked with implementing reminders and retraining to their personnel as needed. A feedback loop to the treating paramedics was essential to provide communication on process improvement and patient outcome.

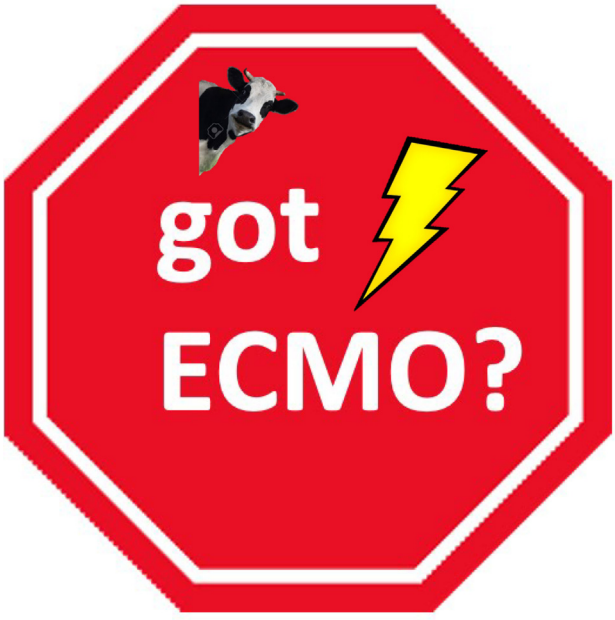

Fig. 2 – Los Angeles County Fire Department 'Got ECMO' Sticker, placed on the cardiac monitors to serve as a reminder regarding the eCPR program.

Hospital administrative buy-in was key to implementation. eCPR requires considerable resources, including physicians trained in cannulation and management of patients supported with ECMO, perfusionists or nurses to manage the circuit, nurses for direct patient care, and potentially additional nurses for interventions such as haemodialysis. Given the current nursing shortages, ensuring availability of these resources must come at the highest level. There is often a misperception that patients receiving eCPR remain on ECMO in intensive care units for extended periods of time. Prior eCPR studies have demonstrated that time on ECMO is short (median of 4 days), and the average length of ICU stay for non-survivors was only 3.5 days.[9] Our results support this, with a median time on ECMO of 2.4 days. Resource challenges may be exacerbated at community hospitals and smaller facilities, especially in rural areas, that lack additional support from physicians in training and are less academically driven to adopt newer and/or more resource intensive technologies.

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A multidisciplinary approach to in-hospital care was essential. Advanced notification from the field through online medical control to the ECMO team allowed for efficient transition of care and rapid assessment and cannulation upon arrival if the patient met criteria for ECMO initiation. Efforts were made to streamline the report process between paramedics and online medical control to reduce time on that task. Hospitals developed batch page options to notify all necessary personnel of the incoming patient. While some facilities cannulated in the ED and others in the cardiac catheterization laboratory suite, the coordination process was key to optimize the process. At the ECCs, each case was reviewed to evaluate inefficiencies, and to improve ED throughput time for those cannulating in the CCL. The wide variation in time from arrival to cannulation likely reflects the multiple factors that could affect cannulation time, including transient ROSC, decision-making by the team, and the small number of patients. All patients received immediate coronary angiography. Following the initial care, intensive care and neurology were also essential to ensure ongoing stabilization of the patient with avoidance of early prognostication, which otherwise might have resulted in premature withdrawal of interventions. Coordination also allowed for the successful data capture that ensured transparency and ongoing quality improvement.

Comprehensive, centralized data collection was invaluable to allow for ongoing assessment of the program and iterative changes, training, and system messaging of recommendations. The lead investigator also regularly reviewed submitted data, and missing data and other data validity questions were resolved expeditiously. A particular focus was on shortening scene times, which required streamlining field processes and communications with online medical control. Additionally, clarifying and standardizing as much as possible hospital-based decision-making regarding ECMO implementation was an ongoing process early in the program. Data elements were added to capture the decision-making, and rationale when ECMO was withheld.

LAC-EMS was tasked with ensuring system awareness and integration of the program within the existing system of care. Further, the goal was to reduce disparities and expand, as much as possible during the early phase, access to this novel therapy. For this reason, with the approval of the EMS Agency's Medical Director, bypass routing was implemented to transport patients meeting criteria for eCPR past the closest designated cardiac arrest receiving centre to the ECC if it was within a 30-minute transport time via ground ambulance. This change was discussed at systemwide meetings emphasizing the rarity of the patients meeting eCPR criteria, the potential benefit of the eCPR for those patients, and the goal to pilot eCPR for future system expansion, in order to gain buy-in from stakeholders who were impacted by the destination policy changes. The location of one ECC in downtown Los Angeles, which serves a very diverse population, allowed for a more representative population of patients in LA County during the pilot phase, which may otherwise have been limited to the less diverse areas of LA County.

Despite the challenges, these initial data are encouraging. Given the initial successful implementation of the program, we are in the process of expanding to an additional receiving centre and EMS provider agency, which have met the criteria for participation as outlined. Participating provider agencies, particularly the larger agencies where participation has been limited to select units and/or deployment of MCDs via EMS field supervisors, continue to seek avenues for additional funding to expand availability of MCDs in order to include more ALS units.

Limitations

These results are limited to a single urban-suburban EMS system with an established cardiac system of care for more than a decade and readily available cardiac specialty resources. While the sample size in this demonstration project was small; the data presented represent early feasibility data and will be included in a full analysis once the pilot phase of the program is complete. In this initial evaluation of program implementation, we are not able to evaluate the cost effectiveness. The COVID-19 pandemic posed specific challenges, which required the ECMO teams to develop specific protocols and pause the program during periods of surge, when hospitals were severely encumbered with COVID patients and ECMO became a scarce resource as did intensive care beds.

Conclusion

Our data demonstrate that a multi-centre, multi-agency eCPR program is feasible and can potentially result in good patient outcomes. This can serve as a model for other EMS systems who seek to implement regional eCPR programs.

Conflict of interest statement

David Shavelle, MD receives research support from v-wave medical, Avicena and Neurescue and serves as a consultation to ShifaMed, Inc.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.resuscitation.2023.109711.

Author details

[a]*Los Angeles County EMS Agency, 10100 Pioneer Blvd, Santa Fe Springs, CA 90670, USA*[b]*Harbor-UCLA Medical Center Department of Emergency Medicine and the Lundquist Institute for Research, 1000 W Carson Street, Torrance, CA 90502, USA* [c]*David Geffen School of Medicine at UCLA, 10833 Le Conte Ave, Los Angeles, CA 90095, USA*[d]*Los Angeles County Fire Department, 1320 N. Eastern Avenue, Los Angeles, CA 90063, USA* [e]*Los Angeles County-USC Medical Center, Department of Emergency Medicine, 2051 Marengo Street, Los Angeles, CA 90033, USA* [f]*University of Southern California, Keck School of Medicine, 1975 Zonal Ave, Los Angeles,*

CA 90033, USA [g]Culver City Fire Department, 9770 Culver Blvd, Culver City, CA 90232, USA [h]Cedars-Sinai Medical Center, 8700 Beverly Blvd, Los Angeles, CA 90048, USA [i]Beverly Hills Fire Department, 445 N Rexford Dr., Beverly Hills, CA 90210, USA[j]Santa Monica Fire Department, 333 Olympic Blvd, Santa Monica, CA 90401, USA [k]Ronald Reagan UCLA Medical Center, Department of Emergency Medicine, 757 Westwood Plaza, Los Angeles, CA 90095, USA [l]Los Angeles Fire Department, 200 N Main Street, Los Angeles, CA 90012, USA [m]MemorialCare Heart and Vascular Institute (MHVI), Long Beach Medical Center, 2801 Atlantic Ave, Long Beach, CA 90807, USA

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