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Review

Outcomes of extracorporeal life support for the treatment of acute massive pulmonary embolism: A systematic review

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Abstract

Background: Massive pulmonary embolism (PE) can cause hemodynamic instability leading to high mortality. Extracorporeal life support (ECLS) has been increasingly used as a bridge to definitive therapy. This systematic review investigates the outcomes of ECLS for the treatment of massive PE.

Methods: Electronic search was performed to identify all relevant studies published on ECLS use in patients with PE. 50 case series or reports were selected comprising 128 patients with acute massive PE who required ECLS. Patient-level data were extracted for statistical analysis.

Results: Median patient age was 50 [36, 63] years and 41.3% (50/121) were male. 67.2% (86/128) of patients presented with cardiac arrest. Median heart rate was 126 [118, 135] and median systolic pulmonary artery pressure (sPAP) was 55 [48, 69] mmHg. The majority of ECLS included veno-arterial ECLS [97.1% (99/102)]. Median ECLS time was 3 [2, 6] days. 43.0% (55/128) patients received systemic thrombolysis, 22.7% (29/128), received catheter-guided thrombolysis, and 37.5% (48/128) underwent surgical embolectomy. 85.1% (97/114) were weaned off ECLS. Post-ECLS complications included bleeding in 23.4% (30/128), acute renal failure in 8.6% (11/128), dialysis in 6.3% (8/128), heparin-induced thrombocytopenia in 3.1 (4/128), and extremity hypoperfusion in 2.3% (3/128). The most common cause of death was shock at 30.3% (10/33). The median length of hospital stay was 22 [11, 39] days including 8 [5, 13] intensive care unit (ICU) days. The 30-day mortality rate was 22% (20/91).

Conclusions: ECLS is safe and effective therapy in unstable patients with acute massive pulmonary embolism and offers acceptable outcomes.

Introduction

Massive pulmonary embolism (PE) can often cause hemodynamic instability and is associated with high mortality.[1] Extracorporeal life support (ECLS) has been used since the late 1980's for this purpose and its use continues to the present day acting as a bridge to definitive therapy via surgical embolectomy, systemic thrombolysis, and more recently catheter-directed thrombolysis in hemodynamically unstable PE patients.[2,3] To date, small case-series have identified a select few

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patients who have undergone ECLS treatment who previously sustained acute massive pulmonary embolism, but there have been no large case-series or cohort analyses on this topic.[4,5] Acute PE remains a persistent problem with recent epidemiological data estimating its incidence to be 60–70 per 100,000, and deep vein thrombosis's (DVT) incidence being 124 per 100,000 in a European population.[6] Given pervasive risk factors including post-operative states following major surgery, malignancy, hospitalization, obesity, and history of previous venous embolism, 85% of all PE's can develop following DVTs of the iliac veins, renal veins, and inferior vena cava.[1] Once diagnosed, treatment of PE is then focused on preventing recurrence or propagation of the embolus via anticoagulation treatment. Further still, if the PE is of significant size to cause hemodynamic instability or severe symptoms, treatment is aimed at reducing the clot burden and restoring physiologic normalcy.

Returning patients to physiologic normalcy is of paramount importance as recent population-based studies demonstrate 40.7% of hemodynamically unstable PE patients die within the first day of hospital admission. Interventions must be aimed at addressing the physiologic cardiac output derangement and acute right-heart failure caused by PE.[7] ECLS fulfills a unique void in treatment of this disease process as it can bridge these patients to definitive therapy and prevent these early mortalities by alleviating the hemodynamic instability associated with significant clot burden. We sought to review whether implementation of ECLS during this critical period could be an effective method of reducing these mortalities. Specifically, our study aimed to investigate the treatment of patients placed on ECLS to evaluate their periprocedural outcomes and long-term survival following acute massive PE.

Methods

Electronic search was performed in April of 2019 using MEDLINE, Scopus, Cochrane Controlled Trials Register, and Cumulative Index of Nursing and Allied Health Literature to identify all relevant studies published on the use of ECLS in patients with PE. The search was performed using the following terms: "pulmonary embolism," "pulmonary emboli," "pulmonary thromboembolectomy," "extracorporeal membrane oxygenation," "extracorporeal circulation," "ECMO," "extracorporeal life support," "ECLS," "circulatory assist," and "assisted circulation." Articles that did not mention specific use of ECLS in the treatment of acute PE were excluded. Further, articles reporting patient cohorts were excluded since individual patient-level data could not be obtained from these reports, and there were not studies to perform an adequate meta-analysis. Patients less than 17 years of age were excluded to maintain an adult series of patients. Reports not published in the English language, abstracts, conference presentations, editorials, reviews and expert opinions were also excluded. Initially, 61 case series or reports were selected comprising 149 patients who underwent ECLS treatment for acute massive PE. Fig. 1 shows the distribution of these cases over time. This was narrowed to 50 case series or reports comprising 128 patients following further exclusion of studies published before 2005 to have a more contemporary patient cohort. Patient-level data were extracted for statistical analysis. Decision to perform patient-level data analysis was made after a thorough search did not identify enough reports with study-level data for adequate pooling into a meta-analysis. Articles selected for the present systematic review included case reports or case-series from 2005 to present that focused on the use of ECLS for the treatment of pulmonary embolism to ensure more contemporary cohort.

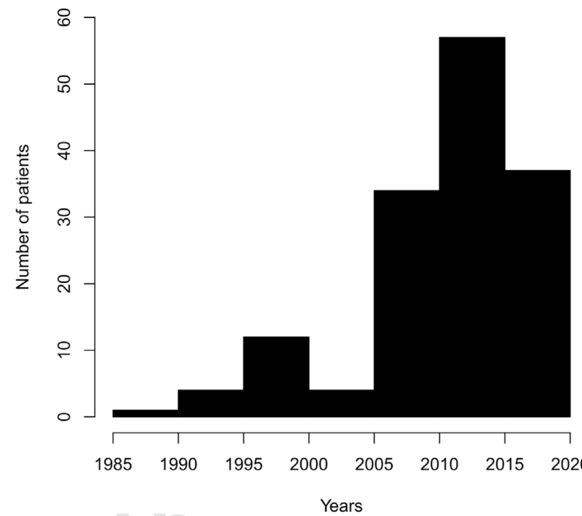

Fig. 1 – Histogram demonstrating distribution of patients who underwent ECLS for PE over time. Abbreviations: ECLS, extracorporeal life support; PE, pulmonary embolism.

Statistical analysis

Patient level data were extracted from article texts, tables, and figures (JC, ND, MM). Discrepancies between the reviewers were resolved by discussion and consensus. When data were not available, attempts were made to contact the corresponding authors to obtain the relevant data for the current study. Baseline characteristics and demographics were reported using descriptive statistics, including medians and interquartile ranges (IQR), for continuous data and percentages for categorical variables. Individual patient survival and follow up data from each case report and series were combined for a Kaplan–Meier survival analysis. P values <0.05 were considered statistically significant. All analyses were performed with R software, version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Overall, 6284 articles were identified in the literature search. Following application of the selection criteria and elimination of duplicate articles, a total of 50 case reports/series, consisting of 128 patients total were included in the analysis. A manual search of references was performed and did not reveal any additional studies. A Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram depicting the overall search strategy is provided in Fig. 2. Median patient age was 50 [36, 63] years, median body mass index (BMI) was 27 [22, 32], and 41.3% (50/121) were male. The remaining seven patients did not have a designated sex in their respective case reports. The majority of patients, 67.2% (86/128), presented with cardiac arrest. The median heart rate was 126 [118, 135], median systolic pulmonary artery pressure (sPAP) 55 [48, 69] mmHg. Details on baseline characteristics are outlined in Table 1.

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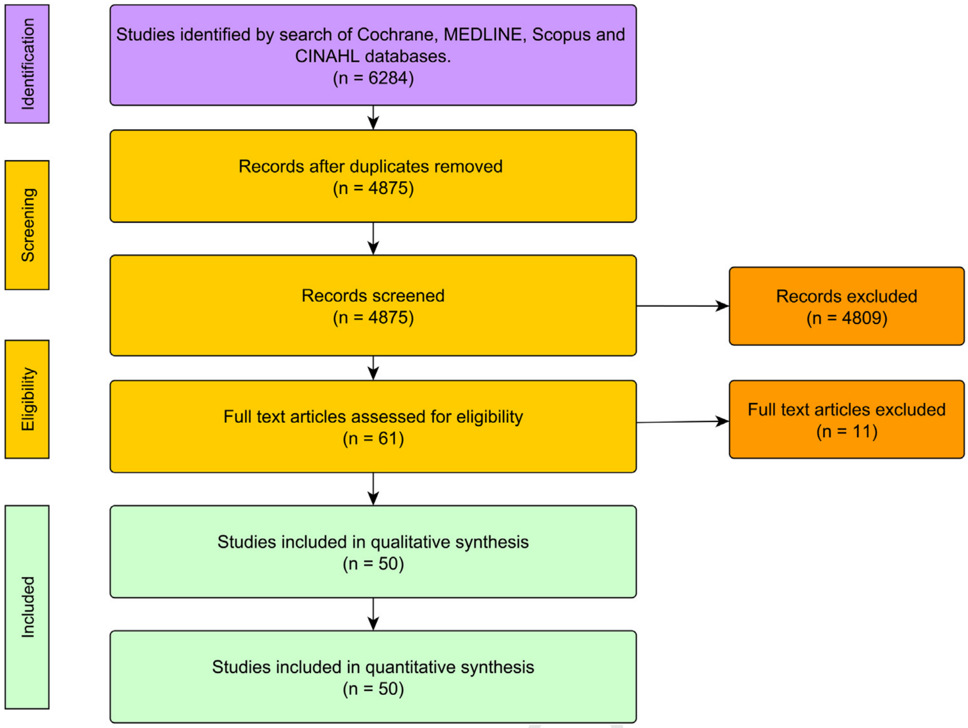

Fig. 2 – PRISMA schematic diagram of the search strategy. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis.

Operative variables, outcomes, and complications

The vast majority of ECLS included veno-arterial ECLS, 97.1% [99/102] of which 98.0% (97/99) had peripheral arterial and 99.0% (101/102) had peripheral venous cannulation. The median ECLS time was 3 [2, 6] days, with median flow rate of 3.5 [3.5, 4.0] L/min. Overall, 43.0% (55/128) patients received systemic thrombolysis, 22.7% (29/128) received catheter-guided thrombolysis, and 37.5% (48/128) underwent surgical embolectomy. IVC filter was placed in 89.3% (50/56). Eventually, 85.1% (97/114) of patients were weaned off ECLS. Details on operative variables are outlined in Table 2. Post-ECLS complications included bleeding in 23.4% (30/128), acute renal failure in 8.6% (11/128), dialysis in 6.3% (8/128), heparin-induced thrombocytopenia in 3.1% (4/128), and extremity hypoperfusion in 2.3% (3/128). The average length of hospital stay was 22 days [11, 39] including 8 ICU days [5, 13]. The 30-day and in-hospital mortality rate was 22% (20/91). Overall mortality was 25.8% (33/128) with the most common cause of death being due to shock, 30.3% (10/33). 12.1% (4/33) of the patients that died experienced cerebral hemorrhage while 12.1% (4/33) died from hemorrhagic shock. While 30 patients experienced bleeding complications, 26.7% (8/30) of those patients died from bleeding-related complications. Details on the complications and outcomes are outlined in Table 3 and the Kaplan–Meier survival analysis is shown in Fig. 3. Fig. 4 demonstrates major outcomes following ECLS implementation.

Table 1 – Baseline characteristics.

Variable	Total (n = 128)
Age (years), median [IQR]	50 [36, 63]
Male, % (n/N)	41.3 (50/121)
BMI, median [IQR]	27 [22, 32]
Cardiac arrest, % (n/N)	67.2% (86/128)
Heart rate (bpm), median [IQR]	126 [118, 135]
Respiratory rate (bpm), median [IQR]	30 [30, 32]
Systolic PAP (mmHg), median [IQR]	55 [48, 69]

Abbreviations: BMI, body mass index; bpm, beats per minute; IQR, interquartile range; PAP, pulmonary artery pressure.

Discussion

Despite diagnostic and treatment advances in pulmonary embolism, mortality rates have not changed significantly over a thirty year period. Hemodynamic impact remains the strongest marker of short-term prognosis. Unloading the right ventricle, early restoration of this pulmonary blood flow, and preventing recurrence are of paramount importance. Mortality from this disease process usually occurs within the first few hours of presentation and early diagnosis can lead to intervention, thus mitigating the right ventricular failure and improving outcomes.[1]

Given the improvement in both technique and devices, ECLS has been documented to be safe and effectively instituted.[8] Takahashi et al. reported a survival rate of 87.5% ± 6.8% in their cohort of 16 patients with acute PE with median follow up of 5.6 years and Maggio et al. reported a survival rate of 62% in their cohort of 21 patients to discharge.[4,5] Compared to the overall ECLS survival rate to discharge of 41%, when ECLS is instituted for cardiac support, this number gives hope to those who present in circulatory collapse from acute massive PE.[9] Studies have demonstrated presentation in cardiac arrest results in survival rates of 20–30% of patients who undergo ECLS administration for this reason.[10]

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Table 2 – Operative variables.

Variable	Total (n = 128)
Veno-arterial ECLS, % (n/N)	97.1 (99/102)
Site of arterial catheterization	
Central	2.0 (2/99)
Aorta	1.0 (1/99)
Left atrium	1.0 (1/99)
Peripheral, % (n/N)	98.0 (97/99)
Femoral, % (n/N)	70.7 (70/99)
Axillary	5.1 (5/99)
Subclavian	2.0 (2/99)
Site of venous catheterization	
Central	1.0 (1/102)
Right atrium	1.0 (1/102)
Peripheral, % (n/N)	99.0 (101/102)
Femoral, % (n/N)	94.1 (96/102)
Jugular	4.9 (5/102)
Subclavian	1.0 (1/102)
Veno-venous ECLS, % (n/N)	2.9 (3/102)
Site of catheterization	
Peripheral, % (n/N)	100 (3/3)
ECLS time (days), median [IQR]	3 [2, 6]
ECLS flow rate (L/min), median [IQR]	3.5 [3.5, 4.0]
Weaned, % (n/N)	85.1 (97/114)
Systemic thrombolysis, % (n/N)	43.0 (55/128)
Catheter thrombolysis, % (n/N)	22.7 (29/128)
Embolectomy, % (n/N)	37.5 (48/128)
Venal caval filter, % (n/N)	89.3 (50/56)

Abbreviations: ECLS, extracorporeal life support; IQR, interquartile range.

Table 3 – Outcomes and complications.

Variable	Total (n = 128)
Follow up (days), median [IQR]	54 [15, 365]
ICU stay (days), median [IQR]	8 [5,13]
Hospital stay (days), median [IQR]	22 [11, 39]
30-day mortality, % (n/N)	22.0 (20/91)
Complications	
Bleeding	23.4 (30/128)
Acute renal failure	8.6 (11/128)
Dialysis	6.3 (8/128)
Pneumonia	3.1 (4/128)
Heparin-induced thrombocytopenia	3.1 (4/128)
Hematoma	2.3 (3/128)
Hypoperfusion	2.3 (3/128)
Cause of death	
Shock	30.3 (10/33)
Hemorrhagic	40.0 (4/10)
Unspecified	27.3 (9/33)
Anoxic encephalopathy/brain death	15.2 (5/33)
Cerebral hemorrhage	12.1 (4/33)
Multi-organ failure	9.1 (3/33)
Cardiac arrest	3.0 (1/33)
Aortic dissection	3.0 (1/33)

Abbreviations: ICU, intensive care unit; IQR, interquartile range.

These data suggest ECLS can be used safely and effectively to treat the physiologic derangement of pulmonary embolism and provide patients with an opportunity to reach definitive treatment. Future directions could best study ECLS use in a prospective manner and used in conjunction with available interventions whether they be systemic thrombolysis, catheter-directed thrombolysis or surgical embolectomy. Larger cohorts of patients that fit this population with more thorough complication reporting from centers would also better elucidate the morbidity of such treatment.

We found that interventions aimed at treating acute massive PE were varied. Of the 128 patients, 43.0% (55/128) received systemic thrombolysis, 22.7% (29/128) received catheter-guided thrombolysis, and 37.5% (48/128) underwent surgical embolectomy. The data are incomplete to suggest that these interventions occurred independently in all patients or in conjunction with each other. Of the patients initially placed on ECLS, 85.1% were weaned off ECLS while the remaining patients died. Given this data, it is possible that ECLS provided the physiologic offload to prevent cardiac collapse while allowing time to definitive treatment or for the body to resorb the embolism. While data are lacking and the nature of this study could have interventions go undocumented in articles, in certain cases, it is possible that ECLS alone could be used as an intervention for acute massive PE without necessarily requiring definitive treatment with thrombolysis or surgical embolectomy. This, however, would require further study.

The 78% survival rate of our systematic review stands in contrast to the few existing cohort studies who report markedly higher mortality rates. A recent retrospective cohort study by George et al. notes a 53.1% survival to discharge rate for ECLS use in acute PE.[11] A second retrospective cohort study by Meneveau et al. notes a 30 day mortality of 61.5% in patients with acute PE who were treated with ECLS.[12] Given these studies were presented as cohort-level data, they could not be combined with our analysis. However, these cohort studies could be used as external data for qualitative comparisons. Given this patient-level data, it is likely that much of this lower mortality rate is secondary to publication bias as noted in our limitations. Further, Meneveau et al. note that their mortality rate is higher than expected.[12] The authors reason this may be due to ECLS institution as a method of treatment of last resort and was implemented in most cases after systemic fibrinolysis had failed. 76.5% of their ECLS cohort had undergone systemic thrombolysis while only 43.0% of our series had. Perhaps this difference may explain some of the difference in mortality, though it is likely due to multiple factors.

Aside from evaluation of mortality rate at thirty days, our study demonstrated ECLS for acute massive PE is reasonably well tolerated with regard to complication rates. The most frequent complication was bleeding and occurred in 23.4% of patients, yet unfortunately the case reports that noted this complication often presented them as ECMO- or ECLS-related bleeding complications without further detail. Given this, we are unable to make inferences as to whether these bleeding events were catastrophic or not, nor could we assess whether these events occurred at the site of the cannula, internally or externally. However, 12.1% (4/33) of patients died due to cerebral hemorrhage and another 12.1% (4/33) died due to hemorrhagic shock demonstrating ECLS is not without bleeding risk. These bleeding complications are likely secondary to multiple factors including heparinization for both ECLS and prevention of clot progression as well as use of thrombolytics that can promote bleeding. This appears to be in line with systematic reviews of ECLS bleeding episodes as Sklar et al. reported a bleeding rate of 16% though this was for veno-venous ECLS (VV-ECLS) only while Cheng et al. reported major or significant bleeds in 40.8% of patients.[13,14] Other complications such as acute renal failure, dialysis, and others were present at lower rates and likely reflect overall illness of the patient population. Given these

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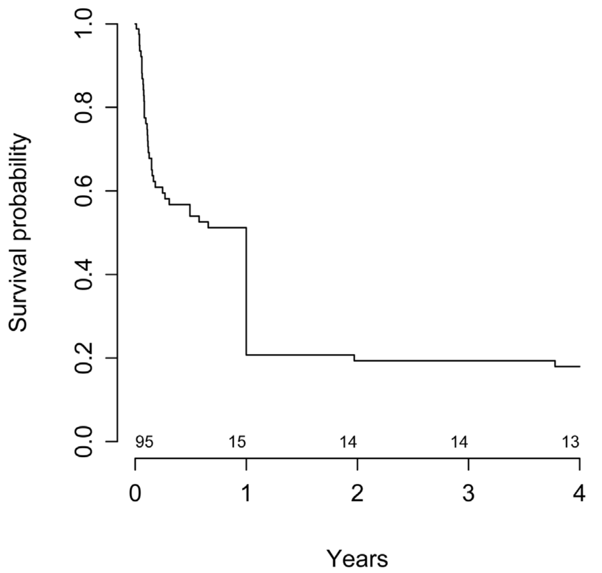

Fig. 3 – Kaplan–Meier curve indicating probability of survival following ECLS use in acute PE. Abbreviations: ECLS, extracorporeal life support; PE, pulmonary embolism.

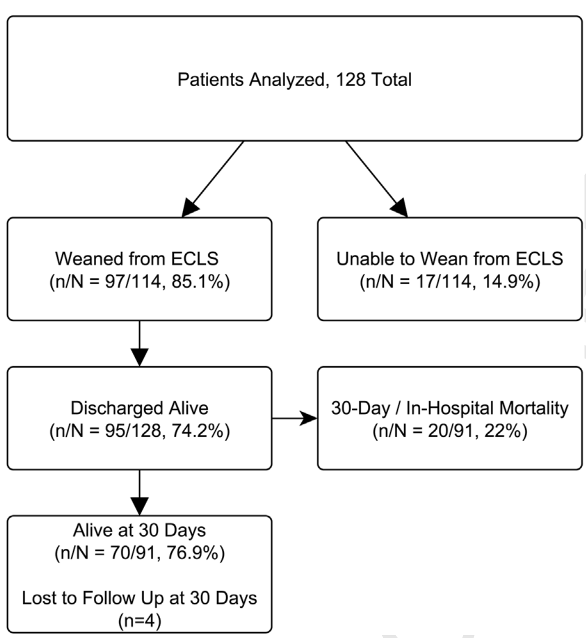

Fig. 4 – Flow chart demonstrating major outcomes following ECLS implementation.

reported complication rates, ECLS seems to be well tolerated with minimal post-procedural morbidity though this may be limited by reporting bias as discussed in our limitations.

Given the nature of these patient-level data, many data points were not consistent across cohorts and series. Due to this, assumptions had to be made in the data analysis. Given these assumptions, our data likely underestimates complication rates since it was assumed if an article did not mention a complication, the patient did not suffer one. Additionally, many articles did not mention follow up points and therefore our Kaplan–Meier analysis may not be fully representative of survival following ECLS for acute massive PE. Further, this study is limited by reporting bias in literature. Centers with poor ECLS outcomes are less likely to report their survival rates and therefore their actual survival rates may be lower than found in this systematic review. Due to the nature of this systematic review, some of the patient cohort is not listed as having undergone definitive PE treatment with systemic thrombolysis, catheter-directed thrombolysis or surgical thromboembolectomy as there are some patients who underwent multiple interventions. Therefore, it is unclear if some patients only had ECLS as an intervention versus one of the other interventions, anticoagulation, vena cava filter or another unlisted procedure.

Despite these limitations, this systematic review demonstrates there is virtue to treatment of acute PE with ECLS. While the mortality rate of those patients requiring ECLS is likely between the rate found by our study and those found by other cohort studies, these rates still demonstrate a significant number of patients who could benefit from ECLS implementation. While there are costs associated with an ECLS program, ECLS is an important tool in the clinician armamentarium to combat PE causing hemodynamic instability and worthy of consideration in all patients who present with acute massive PE.

Conclusion

ECLS is safe and effective bridge to therapy in unstable patients with acute massive pulmonary embolism and offers acceptable outcomes in this high risk patient population. Survival rates following ECLS instituted for acute massive PE are better compared to all patients undergoing ECLS and therefore suggest ECLS is an appropriate intervention to prevent significant mortality and morbidity from acute massive PE.

Conflicts of interest

None.

Disclosures

TJO, JHC, EJM, CTW, NDD, MM, FMW, TG, CFG, GDM, BKA, GJM, and VT have no conflicts of interest.

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Acknowledgments and authors' contributions

VT had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis, including and especially any adverse effects. TJO, JHC, EJM, CTW, NDD, MM, FMW, TG, CFG, GDM, BKA, GJM, and VT contributed substantially to the study design, data analysis and interpretation, and the writing of the manuscript.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.resuscitation.2019.11.018.

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