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Clinical Research

Hypoalbuminemia and Albumin Replacement during Extracorporeal Membrane Oxygenation in Patients with Cardiogenic Shock

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Background: Extracorporeal membrane oxygenation (ECMO) has been widely used in patients with cardiorespiratory failure. The serum albumin level is an important prognostic marker in critically ill patients. We evaluated the efficacy of using pre-ECMO serum albumin levels to predict 30-day mortality in patients with cardiogenic shock (CS) who underwent venoarterial (VA) ECMO.

Methods: We reviewed the medical records of 114 adult patients who underwent VA-ECMO between March 2021 and September 2022. The patients were divided into survivors and non-survivors. Clinical data before and during ECMO were compared.

Results: Patients' mean age was 67.8±13.6 years, and 36 (31.6%) were female. The proportion of survival to discharge was 48.6% (n=56). Cox regression analysis showed that the pre-ECMO albumin level independently predicted 30-day mortality (hazard ratio, 0.25; 95% confidence interval [CI], 0.11–0.59; p=0.002). The area under the receiver operating characteristic curve of albumin levels (pre-ECMO) was 0.73 (standard error [SE], 0.05; 95% CI, 0.63–0.81; p<0.001; cut-off value=3.4 g/dL). Kaplan-Meier survival analysis showed that the cumulative 30-day mortality was significantly higher in patients with a pre-ECMO albumin level ≤3.4 g/dL than in those with a level >3.4 g/dL (68.9% vs. 23.8%, p<0.001). As the adjusted amount of albumin infused increased, the possibility of 30-day mortality also increased (coefficient=0.140; SE, 0.037; p<0.001).

Conclusion: Hypoalbuminemia during ECMO was associated with higher mortality, even with higher amounts of albumin replacement, in patients with CS who underwent VA-ECMO. Further studies are needed to predict the timing of albumin replacement during ECMO.

Keywords: Albumin, Extracorporeal membrane oxygenation, Cardiogenic shock

Introduction

Extracorporeal membrane oxygenation (ECMO) is a mechanical circulation support system for patients with cardiopulmonary failure [1-3]. The number of patients who undergo ECMO is increasing annually, and approximately 17,000 patients received ECMO therapy in 2021. The mechanism of the device can be classified as venoarterial (VA) ECMO or venous-venous (VV) ECMO. In general, VA-ECMO is indicated for patients with cardiogenic shock (CS) related to cardiac problems [1], and VV-ECMO is indicated for patients with acute pulmonary failure that does not adequately respond to mechanical ventilation support [1]. In adult patients, the mortality rate for VA-ECMO is 55% and 42% for VV-ECMO. To decrease mortality, various guidelines have been presented, with some papers reporting serum laboratory data related to survival [4]. However, there are still debates over the guidelines for ECMO patients.

Most patients undergoing ECMO therapy are critically ill and hemodynamically unstable; thus, fluid resuscitation

and various drugs are essential to maintain a stable hemodynamic status. In general, the fluids used for resuscitation of critically ill patients are crystalloid or colloidal agents [5,6]. Crystalloid solutions are selected initially for patients who need fluid therapy. However, the effect of crystalloid agents on intravascular volume expansion is relatively low. Colloidal solutions can be considered for those who show acute hypovolemia [6]. There are various colloidal agents, including albumin, gelatin, dextran, and hydroxyethyl starch. Because colloidal agents have high osmolarity, they prevent capillary leakage with their high oncotic effect. Albumin is a typical colloidal agent, consisting of 50% human protein, and is formed naturally in the human body. The main effect of albumin is maintenance of normal oncotic pressure and the transport of various substances within the circulatory system. Therefore, albumin is an ideal colloidal agent for acutely ill patients needing volume resuscitation. In various contexts, albumin is also an important prognostic factor [7]. In critically ill patients, serum albumin concentrations can decrease because of capillary leakage, and patients with hypoalbuminemia have worse outcomes than patients with normal albumin levels [8]. Therefore, in critically ill patients, adequate infusion of a crystalloid solution is needed, but an adequate infusion of albumin to maintain serum albumin levels may also be essential for the patients' prognosis.

In patients receiving ECMO, selection of the appropriate fluid solution is a matter of debate, but the appropriate fluid choice is just as important as in typical critically ill patients [9]. Recent research has shown that adequate volume resuscitation is necessary initially, but excessive infusion can increase the risk of mortality [10]. Therefore, colloidal solutions, including albumin, can be considered for preserving adequate intravascular volume in patients with less volume than required with a crystalloid infusion.

This study evaluated the efficacy of using pre-ECMO serum albumin levels to predict the 30-day mortality of patients undergoing VA ECMO for CS. We also assessed whether albumin-based fluid resuscitation could effectively resolve hypoalbuminemia in this type of patient. We aimed to determine if serum albumin could be used as a critical prognostic factor for patients undergoing ECMO.

Methods

Patient selection

Patients who underwent VA-ECMO for CS from March 2021 to September 2022 at Chonnam National University Hospital were retrospectively studied. VA-ECMO was indicated in patients with CS who showed tissue hypoperfusion, high demand for inotropic agents and vasopressors, and reduced left ventricular ejection fraction. During the study period, 114 patients underwent VA-ECMO. We excluded patients with post-cardiotomy shock, septic shock, or undifferentiated shock, and those <18 years old. Patients were divided into survivor and non-survivor groups based on 30-day mortality, and we compared the clinical data of both groups.

ECMO protocol

All ECMO-related procedures were performed in settings sterilized with chlorhexidine. Peripheral cannulation was applied through the femoral artery and vein in all patients. The size of the cannula was determined by the surgeon, considering the patient's body weight, height, and the size of the vessel. A polymethyl pentene fiber oxygenator (Maquet Inc., Hirrlingen, Germany) was used for gas exchange in extracorporeal circulation machines. During the ECMO treatment, unfractionated heparin was infused for anticoagulation. A multidisciplinary ECMO team determined the initiation of ECMO support based on the patient's characteristics, disease progression, and organ failure. In general, we followed the management protocol of the Extracorporeal Life Support Organization guidelines [11].

Fluid management strategy

Plasmalyte was routinely selected as the primary crystalloid solution for all patients, with the infusion rate based on the patient's body weight and the fluid intake and output balance. We infused albumin in patients with severe shock who showed unstable hemodynamics, and if capillary leak syndrome was expected in patients who had undergone cardiopulmonary resuscitation, immediate ECMO support, or had a serum albumin level <2.6 g/dL. We infused 250 mL of 5% albumin solution if the patient needed volume resuscitation. We also infused 100 mL of 20% albumin solution if the patient had a low serum albumin level and had maintained a positive intake and output balance.

Data collection

The clinical variables of all patients were retrospectively collected, including clinical and laboratory data before and during the ECMO period. Pre-ECMO laboratory data were collected within 12 hours of ECMO onset. Serum albumin

levels were measured using the Beckman Coulter albumin analyzer (Beckman Coulter Inc., Brea, CA, USA).

Statistical analyses

The results are expressed as mean values±standard deviation for continuous variables and as frequency and percentage (%) for categorical variables. We used the independent t-test or chi-square test to compare continuous variables or categorical variables, respectively, according to 30-day mortality. Cox proportional hazards models were used to evaluate the univariable and multivariable hazard ratios (HRs) for 30-day mortality with a combination of pre-ECMO covariates that were confirmed to be statistically significant by the independent t-test or the chi-square test. A candidate variable with a univariate p-value ≤0.05 was retained in the multivariable model. Receiver operating characteristic (ROC) curve analysis was done to identify the cut-off value of albumin-related parameters (pre-ECMO serum albumin level, calculated mean albumin value within the initial 48 hours after initiation of ECMO, calculated mean albumin value during the whole period of ECMO support, the amount of albumin infused [adjusted with ECMO duration], and the mean albumin value during intra-ECMO) using the DeLong test. Kaplan-Meier curves and the log-rank test were used to assess time-to-death, from the date of ECMO initiation to 30-day survival, for groups stratified according to the cut-off value of the pre-ECMO albumin level. We used MedCalc software ver. 17.9.7 (MedCalc Software; BVBA., Ostend, Belgium) for the statistical analysis. To evaluate the Cox proportional regression between the pre-ECMO risk factors and 30-day mortality, we used RStudio ver. 2022.07.1+554 (RStudio Inc., Boston, MA, USA). In all analyses, p-values <0.05 were considered to indicate statistical significance.

Ethics statement

The Institutional Review Board of Chonnam National University Hospital validated the research. All data from this study were obtained without patients' consent due to the retrospective nature of this work (CNUH-2022-376).

Results

Patient demographics and outcomes of ECMO support

We evaluated 114 patients with CS who were treated with VA-ECMO. The mean patient age at the time of ECMO support was 67.8±13.6 years, and 36 patients (31.6%) were female. First, we found significant differences in pre-ECMO albumin levels between the 2 groups based on 30-day mortality. The albumin levels of patients in the survival group were significantly higher than those in the non-survival group (p=0.002). There were also significant differences in age; pre-ECMO hemoglobin, potassium, and bicarbonate (HCO_3-) levels; and Survival After Venoarterial Extracorporeal Membrane Oxygenation (SAVE) scores between the 2 groups. The results of analyzing all characteristics in the 2 groups before ECMO support are summarized in Table 1.

We also evaluated the calculated mean values of laboratory data (albumin, bilirubin, lactate, and platelets) throughout the entire ECMO support period. The albumin levels of patients in the non-survival group were significantly lower than patients in the survival group (p=0.004), and more albumin was infused in the non-survival group than in the survival group. In addition to the albumin data, there were significant differences in platelet, lactate, and bilirubin levels, as well as ECMO duration (days), and blood product transfusion amounts between the 2 mortality groups. The clinical data within the intra-ECMO period are summarized in Table 2.

Cox proportional hazard regression for pre-ECMO 30-day mortality risk factors

Using Cox proportional hazards regression, we estimated the hazard for 30-day mortality according to the pre-ECMO covariates that had been confirmed to be statistically significant: age; pre-ECMO albumin, potassium, hemoglobin, and HCO_3- levels; and SAVE scores. Using the Cox model, the pre-ECMO albumin level and age were shown to be significantly associated with 30-day mortality, and the pre-ECMO albumin level was shown to be an independent predictor of 30-day mortality (HR, 0.25; 95% confidence interval [CI], 0.11–0.59; p=0.002 and HR, 1.05; 95% CI, 1.01–1.09; p=0.006, respectively) (Fig. 1).

Comparison of ROC curves among albumin-related parameters for the prediction of 30-day mortality

The albumin-related parameters included the pre-ECMO serum albumin level, the calculated mean albumin value within the initial 48 hours after initiation of ECMO, the calculated mean albumin value throughout the entire period of ECMO support, and the adjusted amount of albumin infused. The adjusted amount of albumin infused was cal-

Table 1. Patient characteristics before ECMO support and a comparison between survivors and non-survivors

Characteristic	Total patients (N=114)	Survivor (N=56)	Non-survivor (N=58)	p-value
Age (yr)	67.8±13.6	63.7±14.2	71.6±11.7	0.002
Female	36 (31.6)	17 (30.4)	19 (32.8)	0.783
Body weight (kg)	65.6±13.0	65.8±11.3	65.3±14.4	0.851
Underlying disease				
Hypertension	63 (56.2)	30 (53.6)	33 (58.9)	0.569
Diabetes mellitus	47 (42.0)	20 (35.7)	27 (48.2)	0.182
Dyslipidemia	18 (16.2)	9 (16.1)	9 (16.4)	0.966
Acute coronary syndrome	73 (64.0)	34 (60.7)	39 (67.2)	0.469
Cerebrovascular accident	15 (14.6)	4 (8.2)	11 (20.4)	0.080
Smoking	38 (34.2)	18 (32.7)	20 (35.7)	0.860
Laboratory data				
White blood cells (10^3 mm^3)	13.0±5.5	12.7±5.7	13.4±5.4	0.521
Hemoglobin (g/dL)	11.7±3.2	12.5±3.2	11.0±3.0	0.018
Platelets (10^3 mm^3)	95.2±113.1	78.1±99.7	109.4±122.2	0.179
Lactate (mmol/L)	7.3±4.7	6.8±4.5	7.8±4.8	0.368
Sodium (mEq/L)	136.3±8.9	136.4±11.4	136.1±6.3	0.883
Potassium (mEq/L)	4.4±1.0	4.1±0.9	4.7±1.0	0.010
Calcium (mg/dL)	1.0±0.1	1.0±0.1	1.0±0.1	0.318
Bilirubin (mg/dL)	1.2±1.4	0.9±1.1	1.4±1.6	0.129
Albumin (g/dL)	3.4±0.6	3.6±0.5	3.2±0.6	0.002
AST (U/L)	414.9±963.4	253.3±352.2	570.1±1,291.7	0.101
HCO_3^- (mmol/L)	14.6±5.9	16.0±6.0	13.4±5.5	0.042
Creatinine (mg/dL)	1.9±2.3	1.6±2.0	2.1±2.5	0.259
Prothrombin time (INR)	2.5±9.4	1.4±0.7	3.5±13.2	0.289
Other risk factors before ECMO				
SAVE score	-7.1±4.4	-5.9±4.3	-8.2±4.3	0.021
SOFA score	8.3±3.7	7.7±3.1	8.9±4.2	0.095
GCS	11.7±4.7	12.5±3.9	10.9±5.1	0.083
Previous CPR	52 (46.8)	27 (50.0)	25 (43.9)	0.519
MV before ECMO	56 (49.1)	24 (42.9)	32 (55.2)	0.191

Values are presented as mean±standard deviation or number (%).
ECMO, extracorporeal membrane oxygenation; AST, aspartate aminotransferase; HCO_3-, bicarbonate; INR, international normalized ratio; SAVE, survival after veno-arterial extracorporeal membrane oxygenation; SOFA, Sequential Organ Failure Assessment; GCS, Glasgow Coma Scale; CPR, cardiopulmonary resuscitation; MV, mechanical ventilation.

culated as the total amount of albumin infused divided by ECMO duration (days) and intra-ECMO albumin. We then created a ROC curve to compare the albumin-related parameters (Fig. 2).

The area under the ROC curve of albumin (pre-ECMO) levels was 0.73 (standard error [SE], 0.05; 95% CI, 0.63–0.81; p<0.001; cut-off value=3.4 g/dL). The area under the ROC curve of albumin (mean value within initial 48 hours of ECMO) levels was 0.62 (SE, 0.05; 95% CI, 0.53–0.71; p=0.02; cut-off value=3.1). The area under the ROC curve of albumin levels (mean value during intra-ECMO) was 0.62 (SE, 0.05; 95% CI, 0.53–0.71; p=0.021; cut-off value=3.2). The area under the ROC curve of the amount of albumin infused (adjusted) was 0.74 (SE, 0.05; 95% CI, 0.65–0.81; p<0.001; cut-off value=4.8). The pre-ECMO albumin level and the adjusted amount of albumin infused were the strongest parameters for predicting 30-day mortality.

Cumulative incidence of 30-day mortality from the time of ECMO initiation

The impact of the pre-ECMO albumin level on 30-day mortality was estimated using Kaplan-Meier survival analysis. Patients with pre-ECMO albumin levels <3.4 g/dL had a lower survival probability (p<0.001) than patients with pre-ECMO albumin levels >3.4 g/dL (Fig. 3).

Probability regression between albumin infusion and 30-day mortality

We found a correspondence between the adjusted amount of albumin infused and the possibility of 30-day

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Table 2. Patient characteristics during ECMO support and a comparison between survivors and non-survivors

Variable	Total patients (N=114)	Survivors (N=56)	Non-survivors (N=58)	p-value
Laboratory data				
Platelets, intra-ECMO (10^3 mm^3)[a]	111.2±50.5	131.6±49.3	91.4±47.2	0.048
Lactate, intra-ECMO (mmol/L)[a]	4.7±5.2	2.9±5.2	5.7±3.1	0.017
Bilirubin, intra-ECMO (mg/dL)[a]	2.9±3.7	1.2±1.7	4.2±5.3	0.002
Albumin related parameters				
Albumin, initial 48 hours (g/dL)[a]	3.1±0.5	3.2±0.5	3.0±0.5	0.012
Albumin, intra-ECMO (g/dL)[a]	3.1±0.4	3.1±0.3	2.9±0.4	0.004
Albumin infusion, adjusted (g)[b]	7.9±13.5	3.5±2.6	12.6±18.1	<0.001
Transfusion data with ECMO				
PRC infusion (unit)	5.9±4.9	4.2±3.3	7.5±5.6	0.001
FFP infusion (unit)	2.0±2.9	0.9±1.9	2.8±3.2	0.005
PC infusion (unit)	26.9±40.5	6.6±13.2	40.7±46.6	<0.001
CRYO infusion (unit)	6.1±15.1	2.4±9.1	9.3±18.4	0.084
ECMO outcome				
Left heart unloading	60 (52.6)	27 (48.2)	33 (56.9)	0.355
ECMO duration (day)	8.2±8.3	6.5±5.3	9.7±10.1	0.038
Infection	36 (34.3)	14 (28.0)	22 (40.0)	0.198
Infection in pneumonia	6 (5.7)	3 (6.0)	3 (5.5)	0.905

Values are presented as mean±standard deviation or number (%).
ECMO, extracorporeal membrane oxygenation; PRC, packed red blood cells; FFP, fresh frozen plasma; PC, platelet concentrate; CRYO, cryoprecipitate.
[a]The calculated mean value during ECMO support. [b]Adjusted albumin infusion was calculated by the equation: total amount of albumin infused divided by ECMO duration (days) and albumin intra-ECMO.

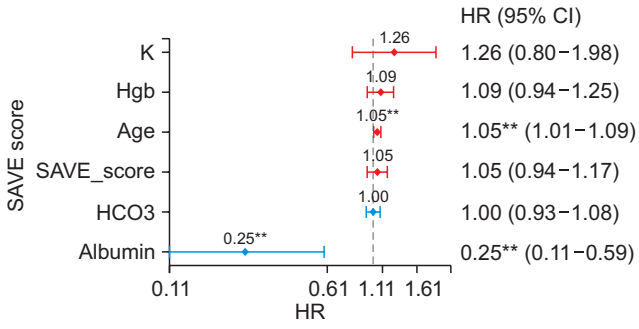

Fig. 1. Cox proportional hazard regression for pre-extracorporeal membrane oxygenation (ECMO) risk factors associated with 30-day mortality in patients with cardiogenic shock during ECMO support. SAVE, Survival After Venoarterial Extracorporeal Membrane Oxygenation; HCO_3-, bicarbonate; Hgb, hemoglobin; K, potassium; HR, hazard ratio; CI, confidence interval. **p<0.01.

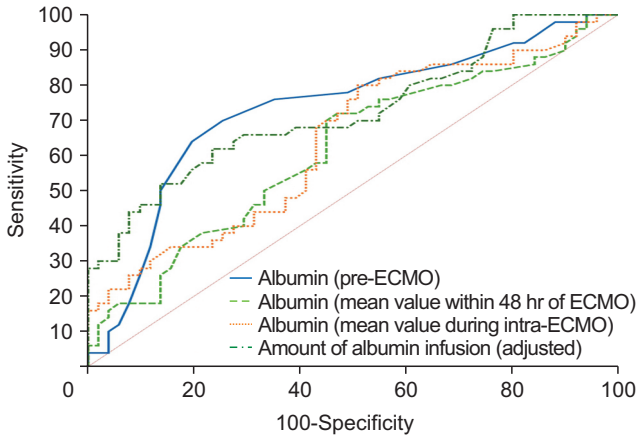

Fig. 2. Comparison of receiver operating characteristic (ROC) curves among albumin-related parameters for the prediction of 30-day mortality. The area under the ROC curve of albumin (pre-extracorporeal membrane oxygenation [ECMO]) levels was 0.73 (standard error [SE], 0.05; 95% confidence interval [CI], 0.63–0.81; p<0.001; cut-off value=3.4 g/dL). The area under the ROC curve of albumin (mean value within initial 48 hours of ECMO) levels was 0.62 (SE, 0.05; 95% CI, 0.53–0.71; p=0.02; cut-off value=3.1). The area under the ROC curve of albumin levels (mean value during intra-ECMO) was 0.62 (SE, 0.05; 95% CI, 0.53–0.71; p=0.021; cut-off value=3.2). The area under the ROC curve of the amount of albumin infused (adjusted levels) was 0.74 (SE, 0.05; 95% CI, 0.65–0.81; p<0.001; cut-off value=4.8).

mortality. As the adjusted amount of albumin infused increased, the possibility of 30-day mortality also increased (coefficient=0.140; SE, 0.037, p<0.001) (Fig. 4).

Discussion

Hypoalbuminemia is defined as a serum albumin level <3.0 g/dL and is common in critically ill patients, including ECMO-implanted patients. The most common causes

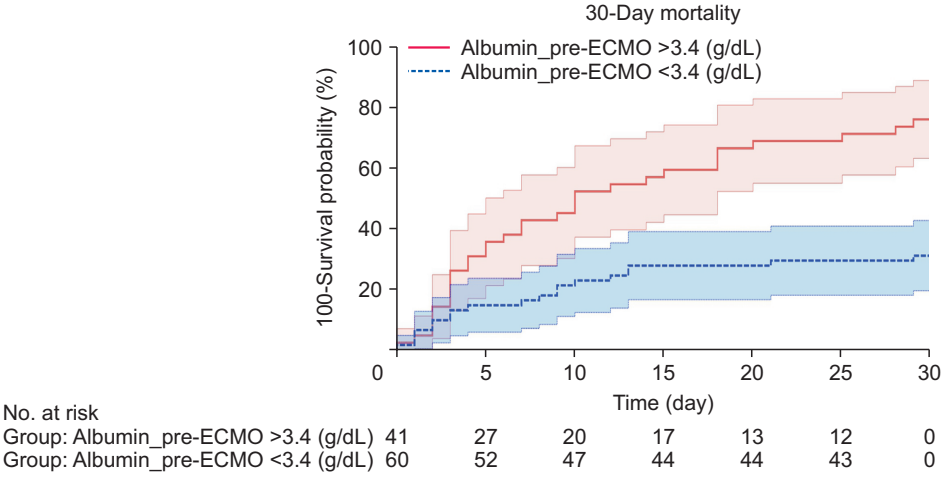

Fig. 3. Cumulative incidence of 30-day mortality from the time of extracorporeal membrane oxygenation (ECMO) initiation. Survival analysis with cumulative 30-day mortality incidence from the time of ECMO initiation. Patients with pre-ECMO albumin levels of less than 3.4 g/dL had a lower survival probability ($p<0.001$) than patients with pre-ECMO albumin levels of more than 3.4 g/dL.

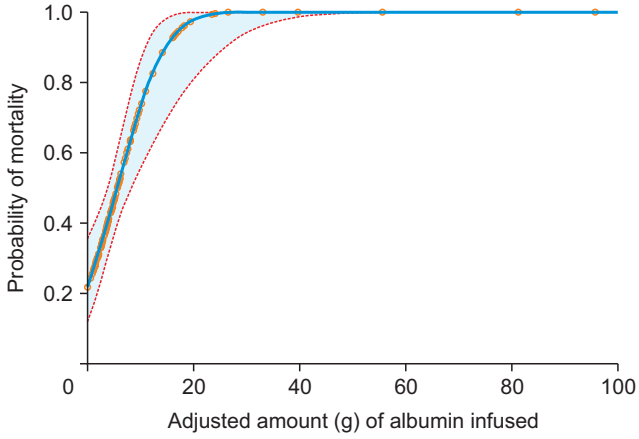

Fig. 4. Probability regression between albumin infusion and 30-day mortality. This figure showed a correspondence between the adjusted amount of albumin infused and the possibility of 30-day mortality. As the adjusted amount of albumin infused increased, the possibility of 30-day mortality also increased (coefficient=0.140; standard error, 0.037; $p<0.001$).

of albumin loss in critically ill patients are decreased production and loss by bleeding or leaking of albumin into the interstitial space because of increased capillary permeability [12].

We first tried to determine the relationship between the initial serum albumin level and mortality. Several studies have found that a low serum albumin level is related to in-hospital mortality and is a good prognostic factor in critically ill patients. Jellinge et al. [13] investigated the relationship between hypoalbuminemia and 30-day all-cause mortality in acutely ill patients. They found that mortality was higher in patients with low albumin levels, which was also related to the length of hospital stay [13], proving that albumin levels can be used as a prognostic tool in patients. In 2020, a study by Huang et al. [14] investigated the prognostic factors for patients receiving ECMO and found that the pre-ECMO albumin level was related to the prognosis of patients. We also found that the mean serum albumin level in the non-survival group was lower than in the survival group (Table 1). Thus, hypoalbuminemia has a significant relationship to the prognosis of critically ill patients who need ECMO support.

Because it is widely accepted that the prognosis of patients with hypoalbuminemia is poor, correcting low serum albumin levels with intravenous infusion of albumin should be considered. However, there is still debate about whether supplemental albumin is effective in critically ill patients. In 2011, Delaney et al. [15] conducted a meta-analysis to determine the efficacy of using supplemental albumin in sepsis patients, and concluded that albumin infusion did decrease mortality for those patients. Patients with CS and cardiac arrest present with a sepsis-like syndrome caused by a similar production of endotoxins and cytokines [12,16]. Therefore, we hypothesize that intravenous infusion of albumin will improve the prognosis of patients with CS, and by extension, patients receiving ECMO. In contrast, a 2014 study by Caironi et al. [17] found that using albumin or saline in intensive care unit (ICU) patients showed similar outcomes. Therefore, it remains to be determined whether albumin infusion is related to a better prognosis in acutely ill patients, especially for patients in the ICU or with sepsis. If we limit the patient groups to those receiving ECMO, the efficacy of albumin infusion is not clear. Further expanded studies are needed to determine if albumin infusion is significantly related to the prognosis of patients receiving ECMO.

There is also some debate about whether intravenous supplementation with human albumin in patients with hypoalbuminemia helps correct low serum albumin levels. In

1991, Guthrie and Hines [18] reported that human albumin administration was not related to albumin synthesis in humans; thus, albumin levels were not significantly increased. They reasoned that this was because serum albumin concentrations are decreased in critically ill patients due to vascular leakage into extravascular spaces within 3 to 7 days. The half-life of albumin is approximately 20 days; therefore, hypoalbuminemia is related to the extravascular loss, not to its synthesis [18]. In non-critically ill patients, there is approximately 10% albumin loss through extravascular spaces during albumin supplementation. However, because of the increased capillary leakage in critically ill patients, albumin loss is also increased, and albumin supplementation is ineffective [18].

This study had some limitations. First, this was a single-center study with a relatively small number of patients. Second, as a retrospective cohort study, a few patients were lost to follow-up, resulting in selection bias. Finally, we followed the general design of a clinical study conducting survival analysis. However, categorizing the study group into survivors and non-survivors was an intentional division, and this method may have created selection bias.

In conclusion, we found that lower serum albumin levels in the pre-ECMO period were related to the prognosis of patients with CS who underwent VA-ECMO. As the patients in this study were critically ill, mean serum albumin levels tended to be low, and higher volumes of albumin solution were likely to be infused. Because there was not a strong correlation between the amount of albumin infused and serum albumin levels in this study, we suggest that the amount of infused albumin may not be associated with the serum albumin level, especially in critically ill patients. Therefore, in addition to albumin supplementation, future studies should analyze other methods for correcting hypoalbuminemia in patients who need ECMO support to improve their likelihood of survival.

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Conflict of interest

No potential conflict of interest relevant to this article was reported.

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