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ORIGINAL RESEARCH

Hospital outcomes after emergent peripheral veno-arterial extracorporeal membrane oxygenation in adult patients presenting with cardiogenic shock

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Abstract

Background: Emergent peripheral veno-arterial extracorporeal membrane oxygenation (VA-ECMO) has been used frequently to support patients with refractory cardiogenic shock with variable rates of complications. We retrospectively analyzed adult patients who received peripheral VA-ECMO support between 2015 and 2019 at our tertiary care hospital.

Results: Sixty five patients with a mean age of 37.9 $\pm$ 14.9 years, mostly males (70.8%), were supported with femoral VA-ECMO with a median duration of 8 (IQR: 3–40) days. Hospital mortality occurred in 29 (44.6%) patients. Complications included acute kidney injury (AKI) in 39 (60%), acute cerebral strokes in 13 (20%), gastrointestinal bleeding in 14 (21.5%) and acute limb ischemia in 21 (32.3%) patients. Non-survivors had significantly higher mean Sequential Organ Failure Assessment (SOFA) scores and significantly increased rates of acute kidney injury, renal replacement therapy, ischemic cerebral strokes, cannulation site exploration for bleeding, atrial fibrillation and anticoagulation discontinuation. Multivariable regression analysis revealed significant Odds Ratios (OR), 95% Confidence Intervals (CI) of hospital mortality with: increasing SOFA scores after 48 hours (2.15, 1.441–3.214, $p < 0.001$), atrial fibrillation (11.351, 1.354–83.222, $p = 0.025$) and hyperlactatemia (2.74, 1.448–6.719, $p = 0.016$).

Conclusion: High mortality and frequent morbidities due to emergent peripheral VA-ECMO should be considered before initiation for cardiogenic shock. According to our results, increasing trend of SOFA scores, atrial fibrillation and progressive hyperlactatemia are independent predictors of hospital mortality of peripheral VA-ECMO.

Keywords

Extracorporeal membrane oxygenation; Extracorporeal life support; VA-ECMO; Cardiogenic shock; SOFA score; Lactate; Atrial fibrillation

1. Background

Emergent peripheral veno-arterial extracorporeal membrane oxygenation (VA-ECMO) support has been considered as a rescue procedure in patients with cardiogenic shock refractory to standard therapies to achieve cardiopulmonary support until recovery or a plan for long-term management is made [1]. It is usually applied according to clinical judgment for a patient with deteriorating hemodynmics despite inotropes and ventilatory support with a risk of imminent death. Currently, VA-ECMO has been widely used with variable rates of complications and mortality [2–6]. We conducted this retrospective study to report our experience with emergent femoral VA-ECMO at our tertiary care hospital.

2. Methods

2.1 Study design

This work was a retrospective study including all consecutive patients $\geq$18 years of age who received peripheral VA-ECMO support according to our management protocol between 2015 and 2019. The ethics committee board of our institution approved the study without requiring patients' consents as the study was a retrospective work and involved no confidential patient data. The primary endpoint was hospital mortality with secondary endpoints of acute cerebrovascular stroke, acute kidney injury (AKI), use of hemodialysis and acute limb ischemia. The studied patients were divided according into survivor and non-survivor groups. We used Sequential Organ Failure Assessment (SOFA) score to assess the enrolled patients. We calculated SOFA upon ICU admission and then at 48 and 96 hours since admission. The Δ1 SOFA was the difference between SOFA scores at third and first days. The

Δ2 SOFA was the difference between SOFA scores at the fifth and first days.

2.2 Veno-arterial ECMO management protocol

The studied patients were supported with Maquet Cardiohelp and Rotaflow ECMO machines (Getinge group, Germany). The Maquet Heart-Lung Support (HLS) module advanced and cannulae are biocompatible with bioline coating. Cannulation was done via femoral vessels and was performed percutaneously at the bedside (in most of the studied patients) by the Seldinger technique unless there was a difficulty where cutdown was done for direct visualization of femoral vessels. The size of cannulae used was chosen according to the required blood flow and body surface area (BSA). A concomitant femoral distal perfusion catheter (DPC) was routinely inserted to avoid limb ischemia unless there was technical difficulty.

Adjustment of blood flow after ECMO support was done according to clearance of lactate, mixed venous oxygen saturation and clinical stabilization. Oxygen and sweep flows titration were gradually performed to achieve acceptable oxygenation and ventilation. Intravenous unfractionated heparin infusion was used for therapeutic anticoagulation and was adjusted based on heparin assay (target 0.3–0.7 units/mL), Antithrombin III level (goal 80–120%) and clinical tolerance. Intravenous morphine and midazolam infusions were routinely used to achieve sedation and analgesia with daily sedation withdrawal for neurological assessment. Near-infrared spectroscopy (NIRS) was used to for continuous brain oxygenation monitoring (rSO2%) via frontal probes. If any neurological manifestations or significant rSO2% changes developed, a brain computed tomography imaging was rapidly done to exclude acute stroke.

2.3 Statistical analysis

Data was coded and entered using the Statistical Package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY, USA). Quantitative data were summarized using mean (±standard deviation) or median (interquartile range (IQR)); categorical data were described using frequencies. Comparisons between quantitative variables were done using the non-parametric Kruskal-Wallis Mann-Whitney test. For comparing categorical data, Chi square (χ^2) test was performed. Multivariable logistic regression was done to detect independent predictors of mortality. p-values less than 0.05 were considered statistically significant.

3. Results

3.1 Demographic and clinical variables of the studied patients

Sixty-five patients with a mean age of 37.9 ± 14.9 years, mostly males 70.8%, were supported on femoral VA-ECMO with a 44.6% hospital mortality. The studied patients had a mean BMI of 26.1 ± 6.7 kg/m^2 and a mean BSA of 1.77 ± 0.27 m^2. The non-survivors had statistically more frequent CKD, chronic AF and receipt of oral anticoagulants while the survivors had significantly frequent DPC insertion (Table 1).

3.2 Laboratory criteria at VA-ECMO initiation

Non-survivors had a significantly greater lactic acidosis before VA-ECMO initiation compared to the survivors ($p < 0.001$). The mean peak blood lactate and median level after 24 hours were significantly higher in the non-survivors compared to the survivors. There were statistically insignificant differences between both groups regarding pre-ECMO hemoglobin, platelet count and coagulation profile (Table 2).

3.3 Outcomes of peripheral VA-ECMO supported patients

The non-survivors had significantly frequent AKI ($p = 0.001$), use of renal replacement therapy ($p < 0.001$), ischemic strokes ($p = 0.001$), cannulation site exploration for bleeding ($p = 0.02$) and new onset atrial fibrillation ($p < 0.001$) compared to the survivors. Rates of bleeding complications were not significantly different in both groups including ICH, GI bleeding, hemoptysis and cannulation site bleeding, however the discontinuation of heparin infusion was significantly more frequent in the non-survivors ($p = 0.001$). The mean SOFA scores were (11.3 ± 3.01 vs 14.6 ± 3.5, $p < 0.001$) on the first day, (9.3 ± 2.6 vs 18.5 ± 2.9, $p < 0.001$) on the third day and (8 ± 2.1 vs 19.1 ± 3.1, $p < 0.001$) on the fifth day in the survivor and non-survivor groups, respectively. The median Δ 1 SOFA and Δ 2 SOFA were significantly higher in the non-survivors. There were no statistically significant differences between the groups regarding ICU, ECMO or ventilator days, tracheostomies, acute limb ischemia nor angioplasty. However, fasciotomies were statistically more frequent in the non-survivors compared to the survivors (Table 3 and Fig. 1).

3.4 Mortality predictors with peripheral VA-ECMO support

Multivariate regression analysis was done to examine predictors of hospital mortality after emergent VA-ECMO support. Increasing trend of SOFA score after 48 hours (OR = 2.15, 95% CI: 1.441–3.214, $p < 0.001$), atrial fibrillation (OR = 11.351, 95% CI: 1.354–83.222, $p = 0.025$) and increasing blood lactate (OR = 2.74, 95% CI: 1.448–6.719, $p = 0.016$) were significantly associated with hospital mortality. Although occurrence of acute cerebral strokes and use of renal replacement therapy were significantly more frequent in the non-survivors, these were not significant in the multivariate analysis (Table 4).

4. Discussion

Hospital mortality was 44.6% in our retrospective analysis of patients receiving emergent peripheral VA-ECMO support in adult patients with cardiogenic shock; additionally, frequent morbidities, especially acute kidney injury, occurred. Multivariate regression analysis identified an increasing trend of SOFA score after 48 hours, atrial fibrillation and increasing blood lactate as independent predictors of hospital mortality. Previously published mortality reports after VA-ECMO are

TABLE 1. Baseline and clinical criteria of the studied patients.

Characteristics	All patients	Survivors	Non-survivors	*p* value
	(n = 65)	(n = 36, 55.4%)	(n = 29, 44.6%)	
Age (years)	37.9 ± 14.9	37.4 ± 11.7	38.5 ± 18.3	0.56
Sex				
Females	19 (29.2)	12 (33.3)	7 (24.1)	0.41
Males	46 (70.8)	24 (66.7)	22 (75.9)	
BSA (m^2)	1.77 ± 0.27	1.8 ± 0.26	1.74 ± 0.29	0.37
BMI (kg/m^2)	26.1 ± 6.7	26.4 ± 6.1	25.7 ± 7.6	0.64
CKD	10 (15.4)	1 (2.8)	9 (31)	0.004
Diabetes mellitus	13 (20)	7 (19.4)	6 (20.7)	0.9
Pre-ECMO AF	17 (26.2)	5 (13.9)	12 (41.4)	0.012
Underlying heart disease				
Dilated cardiomyopathy	26 (40)	14 (38.8)	12 (41.4)	0.13
Valvular heart disease	12 (18.5)	5 (13.9)	7 (24.1)	
Ischemic cardiomyopathy	19 (29.2)	9 (25)	10 (34.5)	
Viral myocarditis	3 (4.6)	2 (5.6)	1 (3.5)	
ACHD	3 (4.6)	1 (2.7)	2 (6.9)	
Left ventricle EF %	26.8 ± 13.4	26.1 ± 12.9	27.6 ± 14.2	0.63
Previous CVS	2 (3.1)	1 (2.8)	1 (3.4)	0.9
Anticoagulant receipt	18 (27.7)	5 (13.9)	13 (44.8)	0.006
IABP	13 (20)	9 (25)	4 (13.8)	0.26
Arterial cannula (Fr)	17.9 ± 1.4	18.1 ± 1.3	17.6 ± 1.5	0.32
Distal perfusion cannula	52 (80)	32 (88.9)	20 (69)	0.04
Venous cannula (Fr)	21.7 ± 1.3	21.8 ± 0.9	21.6 ± 1.7	0.86
Cardiothoracic surgeries	17 (26.2)	10 (27.8)	7 (24.1)	0.74
Type of surgery				
CABG	2 (3.1)	2 (5.6)	0	0.23
Valve surgery	6 (9.2)	3 (8.3)	3 (10.3)	
CABG plus valve surgery	7 (10.8)	3 (8.3)	4 (13.8)	
Heart transplantation	1 (1.5)	1 (2.8)	0	
Pulmonary endarterectomy	1 (1.5)	1 (2.8)	0	
Cardio-Pulmonary Bypass (minutes)	217.2 ± 78.9	190.3 ± 80.3	241.4 ± 73.2	0.15
Aortic cross clamping (minutes)	128.7 ± 42.3	128.6 ± 43.3	128.7 ± 44.4	0.6

Data are presented as mean ± SD or N (%).

highly variable worldwide, with survival to discharge ranging from 30–45%; this may be related to heterogeneity of the studied patients demographic criteria and indications of VA-ECMO support [3–10].

Our better survival rate may be related to the younger age of patients in our study (37.9 ± 14.9 years). Schmidt *et al.* [7] studied VA-ECMO supported patients with a median age of 54 years and reported 42% survival to discharge. Chung *et al.* [2] reported hospital mortality of 57.5% among VA-ECMO supported patients with a mean age of 51.8 ± 20.5 years. Chen *et al.* [10] reported 64.9% mortality rate of the studied patients with a median age of 51.7 years. Lorusso *et al.* [8] reported that older patients had a higher in-hospital mortality and higher rates of multi-organ dysfunctions compared to the younger patients and that age was an independent predictor of mortality. Our studied patients were younger overall, but without significant age differences between survivors and non-survivors.

Our analysis revealed that pre-ECMO CKD or AKI and dialysis were significantly more frequent in the non-survivor group. Also, the use of renal replacement therapy was significantly associated with hospital mortality in the multivariate regression analysis. Our results were comparable to other studies that reported the association between AKI and use of renal replacement therapy with about 50% reduction in survival [5, 7, 11, 12]. Schmidt *et al.* [7] reported renal

TABLE 2. Laboratory variables at VA-ECMO initiation.

Characteristics	All patients	Survivors	Non-survivors	*p* value
Hemoglobin (g/L)	112.9 ± 17.9	114.3 ± 19.5	111.3 ± 16.1	0.8
Platelet count (10^9/L)	181 (38–447)	189 (66–404)	148 (38–447)	0.74
INR	1.77 ± 0.62	1.79 ± 0.69	1.74 ± 0.53	0.84
Fibrinogen (g/L)	3.39 ± 1.4	3.58 ± 1.54	3.15 ± 1.17	0.53
Antithrombin III	59.78 ± 13.1	62.3 ± 12.13	56.68 ± 13.82	0.12
aPTT (seconds)	47.68 ± 18.9	45.57 ± 13.13	50.31 ± 24.35	0.63
Base excess (mmol/L)	–9 ± 3.7	–7.83 ± 3.8	–10.57 ± 3.11	0.002
Pre-ECMO blood lactate (mmol/L)	5.48 ± 2.01	4.37 ± 0.96	6.95 ± 2.11	<0.001
Serum creatinine (umol/L)	91 (9.5–320)	83 (42–198)	105 (9.5–320)	0.33
Serum bilirubin (umol/L)	28.6 (5.8–389)	28.6 (7.5–100.9)	37.4 (5.8–389)	0.27
Peak blood lactate level	13.27 ± 3.9	10.88 ± 2.3	16.23 ± 3.39	<0.001
Blood lactate at 24 hours	3.1 (1.1–20)	2.1 (1.1–6.1)	4.7 (1.3–20)	<0.001

Data are presented mean ± SD, median (IQR) or N (%).

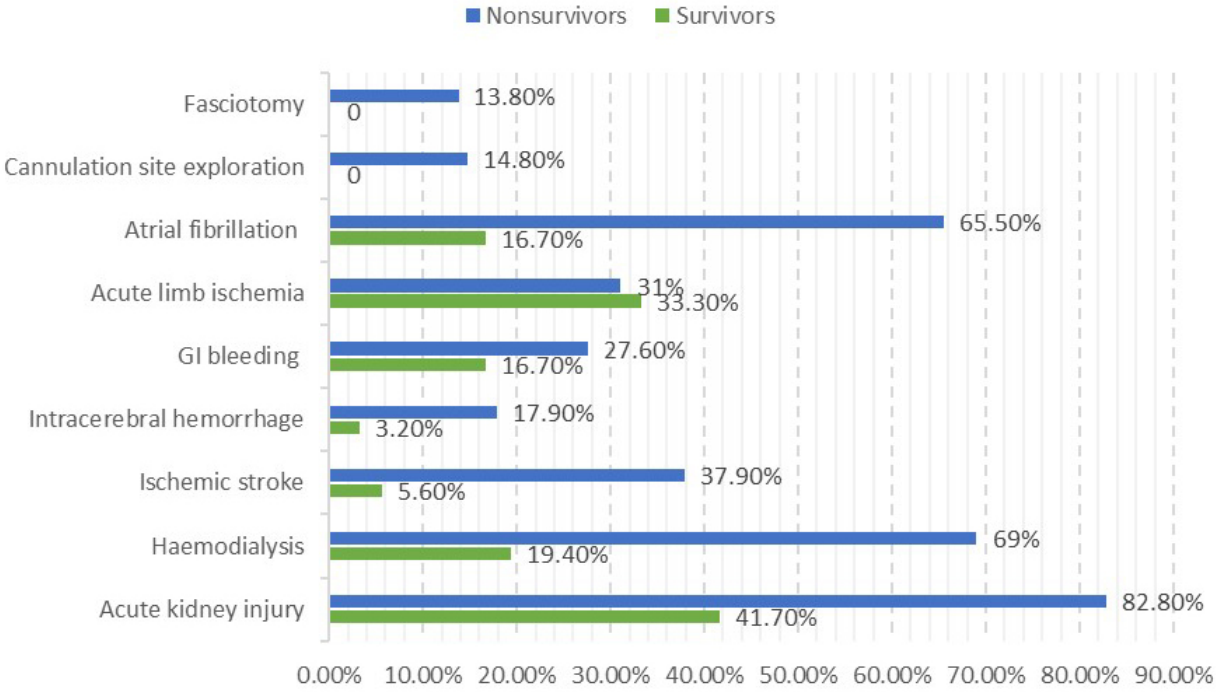

FIGURE 1. Hospital outcomes of femoral VA-ECMO treated patients.

impairment as a significant variable linked to mortality and used it in the SAVE score to assess survival after ECMO support.

Our results showed that the non-survivors had a significantly greater pre-ECMO lactic acidosis with a higher mean peak lactate level and delayed clearance after 24 hours compared to the survivors. Lactate level was an independent predictor of mortality in the multivariate analysis. Blood lactate was linked to protracted cardiogenic shock with multi-organ system failure and hospital mortality of VA-ECMO supported patients in many studies [5, 10–13]. Chen *et al.* [10] reported a significantly greater lactic acidosis in the non-survivors supported with VA-ECMO and used lactate levels to initiate the modified SAVE score.

Our results detected a significantly more frequent rate of atrial fibrillation before ECMO initiation and occurrence of new onset AF during ECMO support in the non- survivors group compared to the survivors group. Moreover, the AF was associated with increased mortality in the multivariate analysis. Wang *et al.* [12] described the higher frequency of AF in the non-survivors of VA-ECMO treated patients. The VA-ECMO support increases the left ventricle end diastolic, left atrial and pulmonary artery pressures and may affect aortic valve opening resulting in left ventricle and aortic root stasis. Furthermore, VA-ECMO increase LV afterload and coronary perfusion gradient which can result in further myocardial ischemia and LV loading with failed cardiac recovery and ECMO weaning [14, 15]. Theoretically, concomitant Intra-aortic Balloon Pump (IABP) use will revert these drawbacks of VA-ECMO but there were different reports about IABP with

TABLE 3. ICU course of the studied VA-ECMO supported patients.

Studied criteria	All patients	The survivors	The non-survivors	*p* value
Acute kidney injury	39 (60)	15 (41.7)	24 (82.8)	0.001
Renal replacement therapy (CRRT)	27 (41.5)	7 (19.4)	20 (69)	<0.001
Cerebrovascular stroke	13 (20)	2 (5.6)	11 (37.9)	0.001
Intracerebral hemorrhage	6 (10.2)	1 (3.2)	5 (17.9)	0.09
Cerebral ischemic stroke	7 (11.9)	1 (3.2)	6 (21.4)	0.04
ICU days	19 (3–191)	19 (11–93)	19 (3–191)	0.15
Post ICU days	17 (8–32)	17 (8–32)	——	——
ECMO days	8 (3–40)	8 (3–28)	8 (3–40)	0.63
Ventilator days	10 (2–191)	9 (2–81)	14 (3–191)	0.21
Tracheostomy	13 (20.6)	6 (16.7)	7 (25.9)	0.36
SOFA score day 1	12.8 ± 3.4	11.3 ± 3.01	14.6 ± 3.5	<0.001
SOFA score day 3	13.4 ± 5.4	9.3 ± 2.6	18.5 ± 2.9	<0.001
Δ1 SOFA	–1 (–5 to 6)	–2 (–5 to 5)	4 (–3 to 6)	<0.001
SOFA score day 5	12.5 ± 6.1	8 ± 2.1	19.1 ± 3.1	<0.001
Δ2 SOFA	–2 (–7 to 9)	–4 (–6 to 3)	5 (–7 to 9)	<0.001
Gastrointestinal bleeding	14 (21.5)	6 (16.7)	8 (27.6)	0.29
Gastrointestinal endoscopy	11 (16.9)	6 (16.7)	5 (17.2)	0.82
Gastric ulceration	11 (16.9)	6 (16.7)	5 (17.2)	0.82
Hemoptysis	3 (4.8)	1 (2.8)	2 (7.4)	0.28
Cannulation site bleeding	16 (24.6)	7 (19.4)	9 (31)	0.28
Cannulation site exploration	4 (6.3)	0	4 (14.8)	0.02
Discontinued anticoagulation	16 (24.6)	2 (5.6)	14 (48.3)	0.001
Atrial fibrillation (new onset)	25 (38.5)	6 (16.7)	19 (65.5)	<0.001
ECMO circuits thrombi	4 (6.2)	1 (2.8)	3 (10.3)	0.32
Intracardiac thrombi	4 (6.2)	1 (2.8)	3 (10.3)	0.32
Acute limb ischemia	21 (32.3)	12 (33.3)	9 (31)	0.8
Femoral angioplasty	20 (31.3)	12 (33.3)	8 (28.6)	0.68
Leg compartmental syndrome & fasciotomy	4 (6.2)	0	4 (13.8)	0.035
Toe amputation	1 (1.5)	1 (2.8)	0	0.91
Changing to central VA-ECMO	3 (4.6)	0	3 (10.3)	0.06
Changing to LVAD	11 (16.9)	8 (22.2)	3 (10.3)	0.06

Data are presented mean ± SD, median (IQR) or N (%).

TABLE 4. Multivariable regression analysis of the peripheral VA-ECMO supported patients.

Variables	*p* value	OR	95% CI for OR
Cerebrovascular strokes	0.372	3.105	0.268–33.965
Increasing SOFA score	<0.001	2.15	1.441–3.214
Atrial fibrillation	0.025	11.351	1.354–83.222
Renal replacement therapy	0.06	9.212	0.905–93.808
Lactate peak	0.016	2.74	1.448–6.719

ECMO. In our study, we did not find a survival benefit with IABP use. Our finding was consistent with studies by Schmidt *et al.* [7] and Wang *et al.* [16] which found no survival benefit with IABP either before or concomitant with ECMO initiation. However, Wang *et al.* [12] reported a survival benefit with IABP concomitant with VA-ECMO for post cardiotomy shock after valvular surgery in univariate and multivariate analysis.

In our cohort, acute cerebrovascular strokes in 20% of the patients with a significantly higher frequency in the non-survivors in the univariate analysis. It is unclear if the neurological manifestations were directly related to ECMO support itself or a part of the multi-organ dysfunction with the shock state or cardiac surgery complications. Cardiac surgeries were done in 26% of our studied patients and there were not significant differences between the survivors and non-survivors regarding frequency of surgeries nor cardiopulmonary and aortic cross clamping times. There are variable reported rates of neurological complications

with ECMO due to heterogeneity of the studied patients, definitions of neurological manifestations and type and duration of ECMO support [7, 12, 17, 18].

Our study reported acute limb ischemia in 32% of the patients without significant differences between the survivors and non-survivors but the DPC insertion was significantly more frequent with fewer fasciotomies done in the survivors. There are different reported rates of vascular complications with peripheral VA-ECMO due to different patients with different cannulation approaches and DPC insertion [19–22].

Emergent VA-ECMO provides rapid cardiovascular and ventilatory support for adult patients with refractory cardiogenic shock but it is associated with multiple morbidities and high hospital mortality in addition to its high costs. Therefore, appropriate patient selection and early decision making should be considered. There are multiple scoring models including SOFA, SAVE and modified SAVE scores that can help predict mortality [5, 7, 10]. We used the SOFA score due to its simplicity and its ability to be repeated every 48 hours allowing follow up of the patients' condition and assessment of dysfunction of different systems. The trend of SOFA score over days, especially after the first 48 hours of ECMO support, significantly correlated with mortality in both the univariate and multivariate analyses. Schmidt *et al*. [7] scored VA-ECMO treated patients with SOFA, APACHE II and APACHE III at ECMO initiation only and reported that the non-survivors had higher mean scores and the AUROC were 0.79, 058, and 0.59 for SOFA, APACHE II, and APACHE III, respectively in predicting mortality. Schmidt *et al*. [7] did not repeat the SOFA scoring to detect the trend over days after support. SOFA score was used to assess the cardiac patients without ECMO and increased score was associated with increased mortality [23]. Also, SOFA scoring was used to evaluate the VA-ECMO treated patients and increased trend was linked to increased hospital mortality [5].

Our study included adult patients before the COVID-19 pandemic. The use of veno-venous ECMO (VV-ECMO) has been demonstrated to decrease mortality in patients with refractory respiratory failure due to COVID-19 [24, 25]. However, VA-ECMO has been reported in only 4% of all patients with COVID-19 requiring ECMO due to its doubtful benefit. Patients with COVID-19 who develop cardiovascular collapse usually have multi-organ failure and right ventricular dysfunction not amendable to VA-ECMO [26, 27]. COVID-19 is associated with cytokine storm syndrome characterized by elevation of cytokine levels resulting in cardiovascular and pulmonary disturbances with severe vasoplegia [28, 29]. Similarly during ECMO support, the extracorporeal circuit exposure of blood components results in activation of inflammation and coagulation cascades which may result in systemic inflammatory response and disseminated intravascular coagulation [30, 31].

Finally, the frequent complications and high hospital mortality with VA-ECMO support cannot be attributed to the ECMO itself and may be related to refractory cardiogenic shock with multi-organ system dysfunction. However, it should be considered before ECMO initiation.

5. Conclusions

High mortality and frequent morbidities due to emergent peripheral VA-ECMO should be considered before initiation for cardiogenic shock. According to our results, increasing trend of SOFA score, progressive hyperlactatemia and atrial fibrillation are independent predictors of hospital mortality of peripheral VA-ECMO.

6. Limitations

Our work was a single center retrospective study with a relatively limited number of patients.

ABBREVIATIONS

ACHD, Adult congenital heart disease; AF, Atrial Fibrillation; AKI, Acute Kidney Injury; APACHE, Acute physiology, age and chronic health evaluation; aPTT, activated Partial Thromboplastin Time; AUROC, Area under Receiver operating characteristic; BMI, Body Mass Index; BSA, Body Surface Area; CABG, Coronary Artery Bypass Graft; CI, Confidence interval; CKD, Chronic Kidney Disease; CRRT, Continuous Renal Replacement Therapy; CVS, Cerebrovascular Stroke; DM, Diabetes Mellitus; DP, Distal Perfusion Cannula; GI bleeding, Gastrointestinal bleeding; IABP, Intra-Aortic Balloon Pump; ICH, Intracerebral Hemorrhage; INR, International Normalized Ratio; LVAD, Left Ventriclular Assist Device; LV EF, Left Ventricle Ejection Fraction; OR, Odds Ratio; SOFA, Sequential Organ Failure Assessment; VA-ECMO, Veno-Arterial Extracorporeal Membrane Oxygenation; VV-ECMO, Veno-Venous Extracorporeal Membrane Oxygenation.

AUTHOR CONTRIBUTIONS

ML has taken part in design of the study, collection, analysis and interpretation of the data and drafting of the manuscript. MA has taken part in the design of the study, analysis, collection and interpretation of the data. RQ has taken part in the design of the study, analysis, collection and interpretation of the data. All authors contributed to the research and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Ethical Committee of King Faisal Specialist Hospital and was given a reference number 2191186.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AVAILABILITY OF DATA AND MATERIALS

The data used in this study are available from the corresponding author upon a reasonable request.

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