Original Article

Venoarterial Extra Corporeal Membrane Oxygenation and Blood Component Usage in Pediatric Patients Undergoing Cardiac Surgery: Single Centre Experience

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Background: Extra Corporeal Membrane Oxygenation (ECMO) is a well-known tool for providing life-saving support in patients developing post cardiotomy cardiogenic shock in post cardiac surgeries. The current study was designed to evaluate blood transfusion requirements and its relation to mortality in neonate and pediatric cardiac patients requiring venoarterial cardiac ECMO during post-operative period following cardiac surgery.

Materials and Methods: Overall 24 pediatric patients (including neonates) who underwent VA ECMO in post cardiac surgery at our institute from January 2016 to October 2017 were included in the study. The details of demographics, blood transfusion, ECMO, and morbidity and mortality were collected for all the patients.

Objective of the Study: The primary objective of our study was to assess the outcome of patients on ECMO in post pediatric cardiac surgery. The secondary objective of the study was to assess the effect of blood transfusion on the outcome of the patients.

Results: Overall mortality rate was 50% ($n = 12$). The overall transfusion rate of packed red blood cells was higher in patients who did not survive even after institution of VA ECMO. The transfusion of other blood products like platelets, cryoprecipitate, and fresh frozen plasma were also higher in this group of patients though it was statistically non-significant except for packed red cell transfusion. Though statistically non-significant, the patients who didn't survive even after institution of VA ECMO post-surgery had relatively higher mean age (703.88 ± 998.94 days) as compared to their counterparts (510.63 ± 384.36 days).

Conclusion: The use of ECMO is associated with considerable morbidity and mortality. Packed red cell transfusion is definitely higher in expired patients, indicative of deteriorated status of the patient. However, considering non-significant association of other blood components, except packed red cell it is recommended that patients' overall clinical condition should be taken into consideration for transfusion of blood products and not only targeting the transfusion triggers.

Keywords: Blood transfusion, extra corporeal membrane oxygenation, pediatric cardiac surgeries

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INTRODUCTION

The use of Extra Corporeal Membrane Oxygenation (ECMO) has been dated since 1973 as a tool for salvaging life of both—adult and pediatric patients developing post cardiotomy cardiogenic shock following cardiac surgeries. These patients develop either severe ventricular dysfunction post cardiac surgery or have gradually increase in lactate levels despite optimum ionotropic supports. It has been estimated that about 3.2 to 8.4% of children undergoing

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cardiac surgeries may require ECMO in post-operative period either to rest the heart after operative insult, to allow recovery of function or as a bridge to recovery. The overall survival rates post ECMO are as high as 75% and 54% in neonatal and pediatric patients, respectively.

However, the use of ECMO is associated with significant adverse effects and complications such as circuit related inflammation, coagulopathy, hemolysis, and mechanical events.[1] The reported incidences of hemorrhagic complications in pediatric patients requiring VA ECMO in post cardiac surgery were 60% in contrast to 29% and 49% respectively in case of neonates and pediatric patients requiring VV ECMO for respiratory causes.[2] These complications lead to the need for transfusion of multiple blood products which in turn resulted in increased morbidity and mortality, increased hospital cost and stay. Generally, patients receiving venovenous ECMO for respiratory failure tend to need smaller transfusions compared to patients receiving venoarterial ECMO for cardiac failure. Observation studies have reported that a higher transfusion volumes were associated with increased mortality.[3] Till date very few studies have been conducted in pediatric patients to assess the effect of blood products usage on in hospital outcome of patients on ECMO.

Herewith we aimed to report a retrospective analysis of blood transfusion requirements and its relation to mortality in neonate and pediatric cardiac patients requiring venoarterial cardiac ECMO in post-operative period following cardiac surgery.

METHODOLOGY

Following approval by the Ethics committee of our Institute, we retrieved the hospital records of 24 pediatric patients (including neonates) who underwent VA ECMO in post cardiac surgery at our institute from January 2016 to October 2017. Along with demographic details, the record of ECMO start day and stop day, shifting of patients from critical care unit to step down unit, and the number and volume of platelets, fresh frozen plasma, cryoprecipitate and packed red cells utilized while the patients were on ECMO were collected for the study population. We also recorded the number of failed extubations and the hours spent on ventilator after each intubation.

ECMO therapy

The clinical conditions leading to ECMO requirement were found as—failure to wean off from cardiopulmonary bypass following cardiac surgery, for circulatory support in patients developing ventricular dysfunction post cardiac surgery and increase in lactates despite optimum ionotropic supports. Informed consent was taken from the patient's relative. All patients underwent central cannulation (veno arterial ECMO). It included two cannulas. The venous cannula was either 16 or 18 FR metal tip DLP cannula (sized according to the weight of the patient) and was directly inserted in right atrium. The arterial cannula was either 8 or 10 FR straight Medtronic DLP which was cannulated in ascending aorta. In some patients, LA vent of size 11 or 12 FR straight DLP was also used. The ECMO equipment consisted of a roller pump, a silicon oxygenation membrane (Maquate oxygenator), circuit, heater, flow meter and bubble detector. Filter was connected according to the requirement only. Transmembrane gradient was kept between 10 mm Hg to a maximum of 50 mm HG. The cannula pressures did not have any effect on transfusion requirement of the patients, and this was assessed by ruling out hemolysis by sending urine (routine and micro) and serum LDH levels. The pump flow was kept at 80–100 ml/kg per min. Ventilatory parameters were set to rest settings of FIO2 = 0.21 to 0.3, tidal volume of 4–6 ml/kg, frequency of 12–18/min, and PIP/PEEP of 20/8.

The ECMO therapy was instituted to restore end organ perfusion and provide myocardial rest. ECMO helps to drain the blood from patient circulation into the ECMO circuit which helps to unload the left ventricle and decrease the left ventricular end diastolic pressure which in turn promotes coronary blood flow to myocardium and helps in recovery.

Laboratory monitoring and transfusion criteria

At our Institute, transfusion requirements are monitored according to Extracorporeal Life Support Organization (ELSO) guidelines. Arterial and venous blood gases analysis were done at every 2 hours on 1st day of ECMO and thereafter at every 4 hours from day 2. Blood samples were sent for assessment after every 12 hours. The trigger for red blood cell transfusion was 10–12 gm% for acyanotic and cyanotic patients, respectively. Hemoglobin was maintained at 12–14 gm% according to the ELSO guidelines. Activated clotting time was repeated hourly on first day to monitor heparin anticoagulation and maintained at 160–180 for bleeding patients and 180–200 for patients at low risk of bleeding with continuous infusion of heparin according to our institutional protocol. Platelet count was kept above 100×10^9/l. Prothrombin time was measured, and INR was kept below 1.5 and FFP was transfused to maintain this level. Cryoprecipitate was given to keep fibrinogen level above 150 mg/dl.

Statistical analysis

All the analysis was performed using SPSS v20. The categorical data is expressed as frequency and continuous data was presented as mean and standard deviation. Chi-square test was used to assess difference between various parameters in survived versus expired patients. The level of significance was accepted at $P < 0.05$.

RESULTS

Relevant clinical and demographic data of the patients were collected [Table 1]. Overall 24 patients were identified and enrolled in the study which included both neonates and pediatric patients. The patients underwent surgery for various congenital heart diseases [Table 2]. Out of 24 patients, 19 patients were cyanotic who were operated for Arterial Switch Operation, Arterial Switch Operation + Ventricular Septal Defect, Intracardiac Repair, Bidirectional Glenn Operation, Nikaidoh, ICR + CONDUIT. Rest were acyanotic patients. The mortality was observed in 12 (50%) patients.

Age on ECMO versus survival

The patients who did not survive even after institution of VA ECMO had relatively higher mean age (703.88 ± 998.94 days) as compared to their counterparts (510.63 ± 384.36 days). So, the older children had a higher mortality rate on ECMO. However, this did not reach a statistical significance ($P = 0.908$)

Timing of ECMO and survival

The survival rate was higher in patients who were kept either electively or earlier on ECMO as compared to patients who were subjected to delayed ECMO. ECMO was instituted on the day of surgery in 12 patients with mean of 1.083 ± 0.288 days, either in operation theatre or few hours after surgery. The mean time was 2.083 ± 2.109 days in other half of the patients who had mortality. However, this also did not yield a statistical significant ($P = 0.113$) result.

Duration of ECMO and survival

The relationship between ECMO duration and survival was correlated. It was observed that shorter the ECMO duration, better was the survival rate. In patients who survived, duration of ECMO was shorter (4.917 ± 2.021 days) as compared to expired patients (5.889 ± 2.804 days). When analyzed, this also did not reach to a statistically significance ($P = 0.366$) level.

Table 1: Overall details of the population

Variables	Mean	Std. Deviation
Age In Days	607.250	746.757
ECMO Start Day	1.583	1.5581
ECMO Stop Day	6.667	2.6141
PC	16.3	16.8
CRYO	6.0	4.2
FFP	4.3	2.7
PCV	8.8	3.9

PC: Platelet Count, FFP: Fresh Frozen Plasma, PCV: Packed Cell Volume

Shifting of survived patients to step down unit

Twelve patients survived to ECMO decannulation. Following weaning of ECMO and complete recovery in critical care unit, these patients were shifted to step down unit of our hospital at mean time of 21.75 ± 5.594 days indicating a stay of 2 weeks post ECMO decannulation in critical care unit.

Transfusion requirements and survival rate

A summary of transfusion requirements in all the patients requiring ECMO during the study period is shown in Table 3. Requirements are expressed as number of units of each blood product transfused to the patients when they were on ECMO. A higher mortality rate was found in patients who received higher number of packed red cell transfusion and it was statistically significant ($P = 0.048$). This could be related to more bleeding post-surgery, cyanotic heart disease or bleeding diathesis during ECMO. The overall transfusion rate for other blood products like platelets, cryoprecipitate and fresh frozen plasma was also higher in patients who did not survive even after institution of ECMO, though no statistical significance was found between mortality and transfusion of other blood products ($P = 0.281, 0.071, 0.134$, respectively). It was also observed that the transfusion requirement of all blood products increased post 7th day on ECMO corresponding to less likelihood of survival.

Ventilation hours and correlation with survival

It was seen that the patients who survived post ECMO had a mean of 101.273 ± 98.52 hours of ventilation time and the patients who expired on ECMO had 244 ± 146.917 hours of ventilation time. This suggested that prolonged ECMO support had a direct correlation with mortality (heading is about correlation between ventilation hours and survival, but inference is being taken that prolonged ECMO has direct relationship with mortality which has already been mentioned in another paragraph above). However, no statistical significance was found between mortality and ventilation hours. ($P = 0.079$).

DISCUSSION

Extracorporeal membrane oxygenation (ECMO) is now increasingly being used around the world.[4]

Table 2: Types of Surgery

TYPES OF SURGERY	MEDIAN AGE (DAYS)	MEAN AGE (DAYS)	OPERATED	SURVIVED	EXPIRED
ASO	548	759	11	08	03
ICR	365	888	02	00	02
ROSS	240	240	01	00	01
VSD	1205	1205	01	01	00
BDG	3650	3650	01	00	01
HYPOPLASTIC ARCH + VSD + PDA	15	15	01	01	00
HYPOPLASTIC ARCH + AP WINDOW + VSD	10	10	01	01	00
ASO + VSD	39	34	02	01	01
NIKAIDOH	475	475	01	00	01
ICR + CONDUIT	859	438	02	00	02
MV + TV REPAIR	730	730	01	00	01

ASO: Arterial switch operation, ICR: Intracardiac Repair, VSD: Ventricular Septal Defect, BDG: Bidirectional Glenn, PDA: Patent ductusarteriosus, MV: Mitral valve, TV: Tricuspid valve

Table 3: Comparison between survived and expired patients

Variables	Mortality	Mean	Std. deviation	Significance
Age In Days	Survived	510.63	384.36	0.908
	Expired	703.88	998.94	
ECMO Start Day	Survived	1.083	0.2887	0.113
	Expired	2.083	2.1088	
ECMO Stop Day	Survived	6.000	2.0889	0.087
	Expired	7.556	3.0867	
PC	Survived	11.091	5.7525	0.281
	Expired	21.167	21.9289	
CRYO	Survived	4.364	3.4430	0.071
	Expired	7.500	4.4415	
FFP	Survived	3.364	1.7477	0.134
	Expired	5.250	3.2228	
PCV	Survived	7.000	2.3664	0.048
	Expired	10.417	4.3580	

PC: Platelet Count, FFP: Fresh Frozen Plasma, PCV: Packed Cell Volume

Based on the international registry of Extracorporeal Life Support Organization (ELSO), the number of pediatric and neonatal patients on ECMO have increased to 46% in recent decade.[5] However, the management of hemoglobin levels and transfusion of blood products in patients receiving ECMO is still a subject of debate. Although the ELSO recommends maintaining hemoglobin levels within the normal range (12–14 g/dL) during ECMO.[4] these guidelines are not evidence-based. In addition, modern ECMO systems are more biocompatible, and associated with less hemolysis and fewer bleeding complications, compared to those in the early ECMO era, further reducing the need for transfusion.

Blood transfusions are well known to be associated with adverse effects, such as infections and immune-mediated reactions [Table 1].[6,7] As advocated by various randomized controlled trials,[8,9] current guidelines on red blood cell (RBC) transfusion recommend a restrictive strategy in critically ill patients. Accordingly, patients on ECMO may also benefit from the restrictive strategy that does not require maintaining hemoglobin levels within the normal range. Moreover, while the primary aim of RBC transfusion is to increase oxygen delivery (DO_2), where an increase in DO_2 is not always followed by an increase in oxygen uptake (VO_2).[6,10] Therefore, unless patients experience severe bleeding, the beneficial effect of transfusions on oxygenation may be small. Regarding platelet transfusions, like other blood components, they can cause various transfusion reactions and be associated with increased risk of multiple donor exposures.[11]

It is important to remember that an early 40% to 50% decrease in platelet (PLT) count is frequently observed on ECMO patients[12] and that a variable degree of coagulopathy is described during ECMO due to activation of platelets and of the coagulation system by the circuit surfaces.[13] Finally, centrifugal and/or roller pumps in ECMO circuits may cause significant hemolysis, leading to anemia.[14,15] In addition to these factors, a significant subset of patients may present coagulation factor deficiencies and abnormal activation of the coagulation system even prior to initiation of ECMO.[16]

In our study, we studied a total of 24 neonatal and pediatric patients who required ECMO post congenital pediatric cardiac surgery either electively or in emergency. The main objectives were to quantify the usage of blood and blood components during ECMO and their correlation with patient survival rate.

In our study, the packed cells transfusion was 7 ± 2.36 units over the period of 6 days' for patients who survived post ECMO with a better survival rate than patients who received higher amount of packed cells of 10.4 ± 4.35 units over 7.5 days' period and did not survive even after institution of ECMO. It was also concluded that the number of platelets, fresh frozen plasma and cryoprecipitate transfused were less in the survival group as compared to the expired group.

In a study by Henríquez-Henríquez *et al*.[17] the authors noted that pediatric patients undergoing ECMO due to cardiac disease or congenital diaphragmatic hernia received more transfusions than those undergoing ECMO due to respiratory disease.

Smith *et al*.[18] reported that among 484 infants or children (cardiac ECMO 40%, non-cardiac ECMO 42%, and extracorporeal cardiopulmonary resuscitation [ECPR], (18%), transfusion volume was the largest among patients undergoing cardiac ECMO, followed by those on ECPR; non-survivors received more transfusions than survivors. Also, in a study by Omar *et al*.[19] the transfusion volume (RBCs and platelets) was higher in non-survivors compared to survivors.

One of the important study conducted by the Canadian Critical Care Trial Group[8] showed that a restrictive strategy, using a hemoglobin level of 7.0–9.0 g/dL to trigger RBC transfusion, was as effective as or superior to a liberal transfusion strategy (using hemoglobin level 10.0–12.0 g/dL). In case of patients with septic shock, European investigators compared lower and higher hemoglobin thresholds [Transfusion Requirements in Septic Shock (TRISS) trial] and reported that patients who were transfused at a hemoglobin threshold of 7 g/dL, as compared to those transfused at a hemoglobin threshold of 9 g/dL, received fewer transfusions and had similar rates of 90-day mortality and ischemic events.[6]

In contrast to some authors showing results against restrictive transfusion,[20] a meta-analysis by Holst *et al*.[21] showed that restrictive transfusion strategies were associated with a reduction in the number of RBCs transfused and percent of patients transfused, without increasing mortality or ischemic events. Hence, upon comprehensive analysis, restrictive transfusion strategies are more likely to be beneficial than liberal strategies in critically ill patients, and at present, a low hemoglobin target (i.e. 7 g/dL) is recommended to be used for transfusion threshold. These are all adult trials and no such trial has been conducted in neonates and pediatric age group.

We also identified that the mortality rate was as high as 40% for patients who were on ECMO for a period of more than a week. The average time period spent on ECMO in non-survival group was 7.5 ± 3 days whereas the survival group was on ECMO for a time span of 6 ± 2 days. Khorsandi M, *et al*. also reported that a longer duration of ECMO of >10 days has a direct correlation with mortality.[22]

Gupta *et al*.[23] performed the largest study in the literature on this subject to date. In a multicenter study of 998 children from 37 centers in the USA, they reported 48.1% survival rate to hospital discharge. They identified that prolonged VA ECMO duration beyond 7 days increased the odds of mortality by 12% for every extra day on VA ECMO.[23] In an intermediate-sized study of 100 consecutive patients with refractory cardio respiratory failure requiring VA ECMO, Alsoufi *et al*.[24] reported 37% rate to hospital discharge. They identified factors such as performing a postoperative angiogram, prolonged VA ECMO support, renal failure, non-normalization of serum lactate, and elevated liver enzymes to increase the risk of mortality in such patients[24] Shah *et al*.[25] in another intermediate-sized study of 84 patients reported 36.9% survival to hospital discharge. They identified high arterial serum lactate at the onset of ECMO (14.4 ± 7.5 mmol/L) and prolonged ECMO duration to be associated with mortality.[25]

The duration of ECMO was associated with volume of transfusion and a tendency towards decreased platelet count. Hence, it is recommended to attempt to shorten the duration of ECMO.[26,27] Furthermore, minimizing daily samplings could be regarded as a strategy for fewer blood transfusions, and some authors have emphasized the importance of standardized transfusion protocol and education of medical personnel.[27,28] Although feasible in clinical practice, they need to be further investigated in the future.

CONCLUSIONS

ECMO has a definite role in improving the outcome of patients post cardiac surgery. However, factors leading to institution of ECMO should be anticipated at an early stage so as to decrease the time required for cardio respiratory recovery on ECMO. Prolonged ECMO support has a direct correlation with mortality. Also, the need to transfuse blood and blood products increases with increased duration of time. Restrictive transfusion strategies should be taken into consideration. Patient's overall clinical condition should be taken into consideration for transfusion of blood products and not only the targeting transfusion triggers.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the Patients' parents have given their consent for images and other clinical information to be reported in the journal. They understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest
There are no conflicts of interest.

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