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Original Article / Özgün Makale

Extracorporeal membrane oxygenation support after pediatric cardiac surgery: our single-center experience

Pediyatrik kalp cerrahisi sonrası ekstrakorporeal membran oksijenasyon desteği: Tek merkez deneyimimiz

Ahmet Yüksel,[1] Mustafa Güneş,[2] Atıf Yolgösteren,[1] İrem İris Kan,[1] Fahrettin Uysal,[3] Mehmet Hadi Çağlayan,[1] Işık Şenkaya Sığnak[1]

Institution where the research was done:
Medical Faculty of Uludağ University, Bursa, Turkey

Author Affiliations:
Departments of [1]Cardiovascular Surgery, [3]Pediatric Cardiology, Medical Faculty of Uludağ University, Bursa, Turkey
[2]Department of Cardiovascular Surgery, Mehmet Akif Ersoy Thoracic Cardiovascular Surgery Training and Research Hospital, İstanbul, Turkey

ABSTRACT

Background: In this study, we present our five-year extracorporeal membrane oxygenation experiences in patients requiring mechanical support after pediatric open heart surgery.

Methods: We retrospectively reviewed the medical records of 29 children (16 males, 13 females; mean age 21.6 months; range 5 days to 162 months) who underwent open heart surgery and required extracorporeal membrane oxygenation support due to postcardiotomy circulatory failure between February 2010 and March 2015.

Results: The most common diagnosis was tetralogy of Fallot in eight patients (27.5%). The most common extracorporeal membrane oxygenation indication was failure to wean from cardiopulmonary bypass in 12 (41%) patients. The mean duration of extracorporeal membrane oxygenation support was 6.9 days (range 14 hours to 32 days). The most common complication related to extracorporeal membrane oxygenation support was renal insufficiency in 14 patients (48.3%). Fourteen patients (48%) were able to be successfully weaned from extracorporeal membrane oxygenation support, while six patients (20.7%) were discharged without any neurological sequelae. No significant predictor of mortality was found. Failure to wean from cardiopulmonary bypass resulted improved outcomes than other extracorporeal membrane oxygenation indications.

Conclusion: Extracorporeal membrane oxygenation provides an effective cardiopulmonary support for cardiopulmonary failure after pediatric open heart surgery. Careful patient selection, and correct timing and appropriate management of extracorporeal membrane oxygenation are crucial for optimal outcomes.

Keywords: Extracorporeal membrane oxygenation; mechanical support; pediatric cardiac surgery; postcardiotomy circulatory failure; venoarterial.

ÖZ

Amaç: Bu çalışmada, pediyatrik açık kalp cerrahisi sonrası mekanik destek gereken hastalarda beş yıllık ekstrakorporeal membran oksijenasyonu deneyimimiz sunuldu.

Çalışma planı: Şubat 2010 - Mart 2015 tarihleri arasında açık kalp cerrahisi yapılan ve postkardiyotomi dolaşım yetmezliği nedeniyle ekstrakorporeal membran oksijenasyonu desteği gereken 29 çocuğun (16 erkek, 13 kız; ort. yaş 21.6 ay; dağılım 5 gün-162 ay) tıbbi kayıtları retrospektif olarak incelendi.

Bulgular: En sık tanı, sekiz hastada (%27.5) Fallot tetralojisi idi. En sık ekstrakorporeal membran oksijenasyonu endikasyonu, 12 hastada (%41) kardiyopulmoner baypastan ayrılmada yetersizlik idi. Ortalama ekstrakorporeal membran oksijenasyonu destek süresi 6.9 gündü (dağılım 14 saat-32 gün). En sık görülen ekstrakorporeal membran oksijenasyonu ile ilişkili komplikasyon, 14 hastada (%48.3) böbrek yetmezliği idi. On dört hasta (%48.3) başarıyla ekstrakorporeal membran oksijenasyonu desteğinden ayrılırken, altı hasta (%20.7) herhangi bir nörolojik sekel olmaksızın hastaneden taburcu edildi. Hiç bir anlamlı bir mortalite öngördürücüsü bulunmadı. Kardiyopulmoner baypastan ayrılmada yetersizlik, diğer ekstrakorporeal membran oksijenasyonu endikasyonlarına kıyasla, daha iyi sonuçlar ile neticelendi.

Sonuç: Ekstrakorporeal membran oksijenasyonu, pediyatrik açık kalp cerrahisi sonrasında etkili bir kardiyopulmoner desteği sağlar. Dikkatli hasta seçimi ve ekstrakorporeal membran oksijenasyonu için doğru zamanlama ve uygun tedavi optimum sonuçlar için çok önemlidir.

Anahtar sözcükler: Ekstrakorporeal membran oksijenasyonu; mekanik destek; pediyatrik kalp cerrahisi; postkardiyotomi dolaşım yetmezliği; venoarteriyel.

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Correspondence: Ahmet Yüksel, MD. Uludağ Üniversitesi Tıp Fakültesi, Kalp ve Damar Cerrahisi Anabilim Dalı, 16059 Görükle, Bursa, Turkey.
Tel: +90 224 - 295 23 41 e-mail: ahmetyuksel1982@mynet.com

Extracorporeal membrane oxygenation (ECMO) is frequently used for mechanical support in pediatric cardiac surgery patients with postcardiotomy circulatory failure who are refractory to the conventional medical treatments.[1,2] It is particularly suitable for these patients, as ECMO deployment is rarely limited by extremes of the patient size, anatomy or circulatory physiology, and as it can be initiated by cannulation of peripheral vasculature (e.g. femoral artery and vein or internal jugular vein, and carotid artery. According to the most recent Extracorporeal Life Support Organization (ELSO) Registry database published in July 2012, the survival to discharge rates of neonatal and pediatric patients receiving cardiac ECMO support are 40% and 49%, respectively.[3]

Although left ventricular failure is a common cause for ECMO support in adult patients, right ventricular failure, respiratory failure and pulmonary hypertension often contribute substantially, when mechanical circulatory support is required in pediatric cases. Many published reports of ECMO outcomes from several institutions have demonstrated considerable variability in survival rates, due to the differences in anatomic diagnosis, surgical procedures, ECMO indications, and management of ECMO.[1,4,5] Therefore, an appropriate ECMO support and management can be chosen individually for each case, based on their anatomy and surgical procedure.[6]

In the present study, we present our five-year ECMO experiences in patients requiring mechanical support after pediatric open heart surgery.

PATIENTS AND METHODS

Between February 2010 and March 2015, a total of 1,273 patients underwent pediatric open heart surgery in our institution. Of these, 29 patients received ECMO support due to postcardiotomy circulatory failure. We retrospectively reviewed the medical records including hospital admission records, operative reports, perfusion data, and intensive care unit records to collect demographic data and survival outcomes of a total of 29 patients (16 males, 13 females; mean age 21.6 months; range 5 days to 162 months). The study protocol was approved by Uludag University Medical Research Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Venoarterial ECMO was used in all patients. Extracorporeal membrane oxygenation circuit consisted of a centrifugal pump, membrane oxygenator, heat exchanger, inlet and outlet cannulas, and circuit tubing. The cannulation sites were the ascending aorta for arterial inflow and right atrium for venous outflow. The ECMO circuit was established with the same cannulas (DLP, Medtronic, Inc., Minneapolis, MN, USA) used for cardiopulmonary bypass (CPB) in patients with intraoperative failure to wean from CPB. The MEDOS Deltastream II (MEDOS, Medizintechnik AG, Stolberg, Germany) ECMO system was used in all patients. In infants up to 15 kg of body weight, the Terumo Capiox FX05 (Terumo Cardiovascular Systems Corporation, Ann Arbor, MI, USA) oxygenator was used, while in children over 15 kg, the Terumo Capiox FX15 (Terumo Cardiovascular Systems Corporation, Ann Arbor, MI, USA) oxygenator was utilized. The ECMO circuit was primed with human albumin 20%, fresh frozen plasma, and sodium bicarbonate before its connection to the cannulas. After ECMO system was set, the flow rate was slowly increased up to 100 to 200 mL/min/kg according to age and body surface area of each patient, and additionally depending on hemodynamic stability, blood gas samples, serum lactate levels, urine output, and mixed venous oxygen saturation reflecting the effectivity of tissue perfusion. None of the patients were cooled during the ECMO support. The main goal was to provide a mean systemic oxygenated arterial blood flow of 2.4 L/min/m^2 as a complete circulatory support.[7]

Anticoagulation was administered by heparin infusion, maintaining activated clotting time (ACT) ranging between 180 and 200 sec. Activated clotting time and arterial blood gas parameters were checked hourly. Mechanical ventilation was set to 'ECMO resting settings', which includes a respiratory rate of 8 to 12/min, tidal volume of 6 to 8 mL/kg with a positive end-expiratory pressure of 5 to 10 cmH_2O, and 40% fraction of inspired oxygen (FiO_2). All patients were paralyzed with neuromuscular blocking agents, and deeply sedated with benzodiazepine and narcotic analgesics. Inotropic drugs were continued in most patients to support cardiac functions and to prevent left ventricle distension. Blood product administration during ECMO was based on our institutional standard protocol for the management of ECMO patients including packed red blood cells to maintain hematocrit above 30% and platelets to maintain their count above 75,000/μL.

Echocardiography was performed once daily in all patients to evaluate cardiac functions and to determine if any potentially correctable cardiac defect was present. In case of hemodynamic stability, as evidenced by recovered ventricular function on echocardiography, normal blood pressure, lactate levels (≤2 mmol/L), and mixed venous saturation (≥65), weaning was attempted. Before weaning, ventilator support, fluid

status, and inotropic support, and vasodilator treatment were optimized.

Weaning from ECMO was achieved by optimizing inotropic and ventilator support and gradually decreasing ECMO flow rates within 12 hours to minimum (approximately 100 mL/min). When flow rates decreased to approximately 25% of the maximal support, the bridge between the arterial and venous systems was opened, turning the stopcocks and allowing blood flow through the bridge from the arterial to venous side. The arterial and venous lines above the bridge were clamped to isolate the patient from ECMO, and the circuit was allowed to re-circulate. Once the patient was off complete support, hemodynamic stability was monitored, and tissue perfusion was assessed by arterial blood gases with serum lactate and base deficit values. Echocardiography was often used to evaluate myocardial function during the weaning process. After at least one hour of hemodynamic stability, cannulas were removed, and all purse-string sutures were left in place and re-snared. The chest was left open, and skin edges were sutured primarily.

Statistical analysis

Statistical analysis was performed using the PASW version 18.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed in mean ± standard deviation and median (min-max), while categorical variables were presented in frequency and percentage. The normality test of all the variables was performed. Continuous variables were compared by survival status using the Student t-test, while categorical variables were compared by survival status using the chi-square or Fisher's exact tests. Two-tailed p values of <0.05 were considered statistically significant.

RESULTS

Demographic data, diagnosis, surgical procedures, and indications for ECMO support are summarized in Table 1. The mean weight was 10.9 kg (range 3.2 to 65 kg). The most common diagnosis was tetralogy of Fallot in eight patients (27.5%). None of the patients required preoperative ECMO support. The most common ECMO indication was failure to wean from CPB in 12 patients (41%). Other ECMO indications were low cardiac output syndrome (LCOS), cardiac arrest in the intensive care unit, and cardiorespiratory failure.

The patients were also classified according to the risk adjustment for congenital heart disease based on the Risk Adjustment in Congenital Heart Surgery (RACHS-1) scores (Table 2).[8] The mean

Table 1. Demographic data, diagnosis, surgical procedures, and extracorporeal membrane oxygenation indications

	n	Mean	Range
Age (month)		21.6	0-162
Gender			
Male	16		
Female	13		
Weight (kg)		10.9	3.2-65
Height (cm)		74.9	50-152
Diagnosis and procedures			
Total correction for tetralogy of Fallot	8		
Total correction for atrioventricular septal defect	4		
Ventricular septal defect closure	3		
Total correction for double outlet right ventricle	3		
Total correction for total anomalous pulmonary venous return	2		
Arterial switch operation for transposition of great arteries	2		
Norwood operation for hypoplastic left heart syndrome	2		
Aortic or mitral valve replacement/repair	2		
Total correction for truncus arteriosus	2		
Direct left coronary artery implantation for ALCAPA	1		
Indications			
Failure to wean from cardiopulmonary bypass in operation room	12		
Low cardiac output syndrome in intensive care unit	9		
Extracorporeal cardiopulmonary resuscitation in intensive care unit	5		
Cardiorespiratory failure in intensive care unit	3		

ALCAPA: Anomalous left coronary artery origin from pulmonary artery.

Table 2. Weaning and survival rates according to the RACHS-1 classification

RACHS-1	Patients	Weaning	Survival
	n	%	%
Risk category 1	0	NA	NA
Risk category 2	11	64	18
Risk category 3	11	45	27
Risk category 4	5	40	20
Risk category 5	0	NA	NA
Risk category 6	2	0	0

RACHS: Risk Adjustment in Congenital Heart Surgery; NA: Not available.

aortic cross-clamp time and CPB time during surgery were 74.1±21.6 min and 127.6±51.9 min, respectively. The mean duration of ECMO support was 6.9 days (range 14 hours to 32 days). Complications during ECMO included renal insufficiency requiring additional hemofiltration or dialysis in 14 (48%), bleeding from surgical and cannulation sites in nine (31%), liver insufficiency in six (21%), pulmonary edema in six (21%), tubing or pump head occlusion in three (10%), intracranial hemorrhage in two (7%), and gastrointestinal bleeding in one patient (3%). Fourteen patients (48.3%) were able to be successfully weaned from ECMO support. Six patients (20.7%) were discharged. None of the remaining survivors had any neurological sequelae at the time of discharge.

Possible risk factors affecting mortality is shown in Table 3. Mortality was not associated with demographic characteristics of the patients. Interestingly, longer aortic cross-clamp time and CPB time during surgery did not result in a statistically poorer outcome. In addition, longer duration of ECMO support was not found to be associated with mortality. The laboratory tests at ECMO initiation such as arterial pH and lactate were not found to be associated with mortality, either. However, failure to wean from CPB resulted improved outcomes than other ECMO indications.

DISCUSSION

Since the first application of ECMO as a cardiac support after palliative repair of congenital heart disease in a pediatric patient was performed by Baffes et al.[9] in 1970, the use of ECMO for postcardiotomy mechanical support has gradually increased and achieved a great importance in the treatment of congenital heart diseases in children. It has become an invaluable tool in the postoperative management in many pediatric cardiac surgery centers over the past two decades. The main goal of cardiac ECMO is to profoundly unload the heart and reduce its workload, allowing a limited time interval for the myocardial recovery from damage or an alternative means of support to be found (i.e., donor heart, implantable assist device).[2,10] Extracorporeal membrane oxygenation support is rarely required after pediatric cardiac surgery. The incidence of cardiac ECMO after congenital heart surgery ranges between 2% and 5%.[1,2,10-12] Similarly, the incidence of ECMO after surgery was 2.3% in our study.

Currently, indications for use of ECMO in pediatric population have been expanded, including circulatory

Table 3. Variables of survivors and non-survivors

Variable	Survivors (n=6)		Non-survivors (n=23)		
	n	Mean±SD	n	Mean±SD	*p*
Age (month)		18.9±26.5		22.4±42.0	0.979
Gender					0.228
Male	2		14		
Female	4		9		
Weight (kg)		8.1±6.0		11.7±14.5	0.581
Height (cm)		72.8±23.5		75.5±25.3	0.694
RACHS-1		2.8±0.8		3.0±1.2	0.937
Cardiopulmonary bypass time (min)		139.5±31.2		124.5±56.2	0.127
Aortic cross-clamp time (min)		70.7±14.1		74.9±23.3	0.896
Duration of ECMO support (days)		5.7±4.3		7.2±7.3	0.773
Blood urea nitrogen level at ECMO initiation (mg/dL)		28.8±12.3		35.8±17.2	0.511
Arterial pH at ECMO initiation		7.33±0.1		7.3±0.1	0.114
Arterial lactate level at ECMO initiation (mmol/L)		8.5±5.8		13.4±6.0	0.071
Failure to wean from cardiopulmonary bypass	5		7		0.030
Extracorporeal cardiopulmonary resuscitation	0		5		0.283

SD: Standard deviation; RACHS: Risk Adjustment in Congenital Heart Surgery; ECMO: Extracorporeal membrane oxygenation.

support before congenital cardiac surgery,[13] severe myocardial dysfunction and myocarditis as a bridge to recovery,[14,15] or as bridge to transplantation,[14-16] treatment of pulmonary hypertension,[17] circulatory support after congenital cardiac surgery,[1,2,10-12] and after transplantation.[18] Extracorporeal membrane oxygenation indications for postcardiotomy circulatory support in pediatric cardiac surgery cases are affected by many factors such as ventricular function, response to conventional inotropic support, and pulmonary artery pressure. Unfortunately, no universally accepted standardized indication criteria or management guidelines have been established for ECMO in congenital heart disease, due to its complex nature and specificity of use.[19] Therefore, many centers have constituted their own indication criteria and management protocols based on their experiences. In a recent study, the establishment of an ECMO program, creating a trained and experienced ECMO team, and multidisciplinary approach have been suggested to be critical to obtain good results.[20]

Many factors including baseline ECMO clinical status, diagnosis, cardiac surgical procedures, timing of initiation of ECMO and ECMO-related factors may affect outcomes for postcardiotomy patients supported with ECMO. The risk factors associated with mortality in children who were supported with ECMO after cardiac surgery were described by Morris et al.[21] These risk factors were age below one month, male gender, longer duration of mechanical ventilation before support, and development of renal or hepatic dysfunction while on support. However, functional cardiac physiology (univentricular or biventricular), ECMO indications, and duration of ECMO were not found to be associated with an increased risk of mortality. On the other hand, in a recent study, Gupta et al.[22] reported that prolonged ECMO support was associated with low survival rates. Consistent with the aforementioned study, although there was no significant difference in duration of ECMO, those who survived had a shorter period of ECMO support in our study.

Extracorporeal membrane oxygenation support for failure to wean from CPB was also reported to be a risk factor for mortality in pediatric patients requiring postcardiotomy ECMO in several studies.[23,24] However, other reports showed that outcomes for patients receiving ECMO support for failure to wean from CPB might be similar to those patients in whom ECMO support was initiated after successful weaning for CPB.[2,10,11,25] In our study, interestingly, failure to wean from CPB in the operating room was found to be associated with a better prognosis than other indications.

Furthermore, the timing of initiation of ECMO before circulatory collapse is crucial to prevent end-organ injuries, particularly neurological and renal injuries. However, the optimal timing of initiation of ECMO support is not well-defined, and it is often institution-specific.[26] In a study conducted by Itoh et al.,[19] the authors defined an aggressive ECMO approach as the commencement of ECMO as early as possible before end-organ dysfunction or complete circulatory collapse and without hesitation for the introduction of ECMO. They reported that aggressive ECMO approach might result in better ECMO outcomes than the delayed approach in patients with congenital heart disease. Based on our experiences, we also believe that early institution of ECMO in patients with borderline hemodynamics may result in improved outcomes.

In several studies, survival rates of over 50% have been reported after surgery.[1,10,13] In our series, the weaning rate from ECMO was 48%, and the survival to discharge rate without any neurological sequelae was 20%, which is relatively lower than previous reports in the literature. This can be partly explained by the relatively radical patient selection. In our institution, ECMO use has been increasing for pediatric cardiac surgery cases with postcardiotomy circulatory failure; however, familiarity with this technique is relatively new. In addition, considering the results of the past two years, it seems that our survival rate has increased from 20 to 30%, indicating that we still need to have a learning curve period to obtain satisfactory results. Of note, it should be kept in mind that the ECMO protocol and ECMO team have been recently created in our institution.

Complications related to ECMO decrease the survival rates in all patients, and the incidence of ECMO complications increases with prolonged ECMO support. There are several complications which are directly and indirectly related to ECMO circuit. The common complications which are directly related to the ECMO circuit include oxygenator degradation, deterioration of the pump, and other circuit and cannula-related problems. Indirect ones are bleeding from the surgical site, cannulation-site, intracranial, gastrointestinal areas, neurological events, renal insufficiency, hemolysis, arrhythmia, pneumothorax, and culture-confirmed infections at any site.[15,27]

To the best of our knowledge, our study is the first including the largest case series of ECMO for

pediatric cardiac surgery cases in Turkey. Nonetheless, it has several limitations. First, as ECMO therapy is relatively new in our institution, we have relatively a small sample size. Second, the retrospective design of the study is the inherent limitation of the potentially inconsistent nature of data in the medical records. Third, there was a significant difference in the number of survivor and non-survivors, precluding statistically significant analyses of the risk factors associated with mortality.

In conclusion, extracorporeal membrane oxygenation provides an effective cardiopulmonary support for cardiopulmonary failure after open heart surgery in pediatric cases. Careful patient selection, and correct timing and appropriate management of extracorporeal membrane oxygenation are of utmost importance to achieve optimal outcomes. However, further experiences, technological improvements, and establishment of an ECMO program with experienced ECMO team are required to obtain improved outcomes.

Declaration of conflicting interests

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