Outcomes Associated With Preoperative Use of Extracorporeal Membrane Oxygenation in Children Undergoing Heart Operation for Congenital Heart Disease: A Multi-institutional Analysis

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ABSTRACT

Background: There are very sparse data on patient outcomes related to the use of extracorporeal membrane oxygenation (ECMO) prior to heart operation in children with congenital heart disease. This study was designed to evaluate this association using the Pediatric Health Information System (PHIS) database.

Hypothesis: We hypothesize that patients receiving ECMO prior to heart operation will have worse outcomes, including mortality, compared with patients receiving ECMO after heart operation.

Methods: Patients age ≤ 18 years receiving ECMO before or after pediatric heart operation (with or without cardiopulmonary bypass) at a PHIS-participating hospital from 2004 to 2013 were included. Multivariable logistic regression or Cox proportional-hazards models were fitted to study the effect of timing of ECMO initiation in relation to cardiac surgery on study outcomes.

Results: A total of 3498 patients from 42 hospitals qualified for inclusion. Of these, 494 (14%) received ECMO prior to heart operation (presurgery ECMO) and 3004 (86%) received ECMO after heart operation (postsurgery ECMO). Unadjusted mortality was significantly lower in the presurgery ECMO group compared with the postsurgery ECMO group (30% vs 45%; $P < 0.0001$). After adjusting for patient and center characteristics, odds of mortality were significantly lower in the presurgery ECMO group (odds ratio: 0.46, 95% confidence interval: 0.36-0.59, $P < 0.0001$). There were no significant differences in ECMO duration, length of hospital stay, and hospital charges between the 2 groups in adjusted models.

Conclusions: This study suggests that ECMO can be used with satisfactory outcomes prior to heart operation in children with congenital heart disease.

Introduction

Extracorporeal membrane oxygenation (ECMO), first introduced clinically in 1972, has been applied as a means of cardiopulmonary support for both neonatal and non-neonatal patients with potentially reversible cardiac and/or respiratory failure in whom conventional medical strategies have been exhausted.¹⁻⁵ The common indications for ECMO use in children undergoing heart operation include low cardiac output syndrome, inability to wean from cardiopulmonary bypass (CPB), refractory arrhythmias, pulmonary hypertension, inotrope-refractory cardiogenic shock, bridge to heart transplant, and extracorporeal cardiopulmonary resuscitation.¹⁻⁸

Up to 2% to 5% of all children undergoing corrective or palliative cardiac surgery require mechanical cardiac support with ECMO in their postoperative period.¹⁻⁸ However, literature on the use of ECMO prior to heart operation in children with congenital heart disease is very limited.⁹ Cardiopulmonary support in children with unrepaired heart defects remains challenging, and hence is worth investigating. To address these knowledge gaps, we undertook this study to evaluate the outcomes among patients receiving ECMO prior to heart operation using the Pediatric Health Information System (PHIS) database. Outcomes evaluated included mortality, duration of ECMO, duration of hospital stay, and hospital charges.

Methods

Data Source

Data were obtained from PHIS, a multicenter, administrative, national dataset. The PHIS database is powered by 43

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children's hospitals across the United States with the aim of improving quality, enhancing performance, and providing safe, effective, and efficient care.¹⁰ Institutions are affiliated with the Child Health Corporation of America (CHCA; Shawnee Mission, KS), a business alliance of children's hospitals, and account for 20% of all tertiary-care children's hospitals. Institutions are labeled within the database but cannot be identified in public reporting. For the purposes of external benchmarking, participating hospitals provide discharge data including demographic information as well as diagnoses and procedures coded with *International Classification of Diseases, Ninth Revision* (ICD-9) codes.¹¹ Billing data are also available detailing medications, imaging studies, laboratory tests, and supplies charged to each patient, and these are coded under the Clinical Transaction Classification (CTC) System (Truven Health Analytics, Ann Arbor, MI).^{10,11} Individual patient medical-record numbers, billing numbers, and zip codes are encrypted. Data are de-identified at the time of submission and are subjected to a number of reliability and validity checks before being processed into data quality reports.

Study Population

Patients in the age group from 1 day through 18.0 years receiving ECMO before or after pediatric heart operation (with or without CPB) at a PHIS-participating hospital from January 2004 through December 2013 were included. Only patients receiving 1 ECMO run during their hospital stay were included. The University of Arkansas for Medical Sciences Institutional Review Board for the Protection of Human Subjects reviewed the study protocol and determined that querying de-identified patient data does not fall under the jurisdiction of the institutional review board review process.

Data Collection

Data collection included demographic information, baseline characteristics, pre-ECMO risk factors, operation details, patient diagnoses, and center data. Study variables were identified using codes from *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) and/or the CTC system defined in the PHIS database.^{10,11} The patients were identified for inclusion in the study population using cardiac surgery procedure code (ICD-9 codes 35.xx, 36.xx, 37.3x, 39.0, 39.21, 39.23) and ECMO procedure code (ICD-9 39.65 and/or CTC code 521181). Demographics information collected included age, sex, weight, presence of genetic abnormality or syndrome (ICD-9 758.xx, 279.11, 756.xx, 759.89), and gestational age. Risk factors evaluated prior to ECMO initiation included need for inotropes (epinephrine, dopamine, norepinephrine, milrinone, vasopressin), need for nitric oxide (ICD-9 00.12 and/or CTC 521173), need for antiarrhythmic drugs (amiodarone, lidocaine, flecainide, quinidine, propranolol, digoxin), need for anticonvulsant drugs (fosphenytoin, phenytoin, phenobarbital, lamictal, levetiracetam), and need for dialysis (ICD-9 39.95, 54.98). All drugs were identified using the first 6-digit root code in the 13-digit CTC code defined in PHIS database.¹⁰ The specific

diagnoses collected in our study included pneumonia (ICD-9 480.xx–486.xx, 770.xx), sepsis (ICD-9 995.91, 995.92, 771.81, 038.9, 785.52, 790.7, 771.83, 038.xx, 998.59, 38.xx), renal insufficiency (ICD-9 584.70, 584.90, 586.00, 584.50, 593.90), cardiopulmonary arrest (ICD-9 427.5, 779.85, 770.87), cerebral hemorrhage or ischemia (ICD-9 43.3x, 43.4x, 43.5x, 43.0, 43.1x, 43.6x, 43.7x), and seizures (ICD-9 345.xx, 780.31–780.39, 779.0). Center-specific data collected included average annual patient admissions per center, average annual mechanical ventilators per center, average annual CPB cases per center, and average annual ECMO cases per center.

Statistical Analysis

Continuous variables were summarized as median and interquartile range (Q1–Q3), where Q1 is the 25th percentile and Q3 is the 75th percentile. Categorical variables were presented as numbers and percentages. For univariate comparisons, the study population was divided into 2 groups based on the timing of ECMO initiation in relation to heart operation. The presurgery ECMO group included patients receiving ECMO prior to heart operation, and the postsurgery ECMO group included patients receiving ECMO after heart operation. Categorical variables were compared between the presurgery ECMO and postsurgery ECMO groups using a χ^2 test of association, whereas continuous variables were compared using a Wilcoxon rank-sum test. Mortality, duration of ECMO, length of hospital stay, and hospital charges were the outcomes of interest. The effect of the timing of ECMO initiation (presurgery vs postsurgery) on the odds of mortality was analyzed using multivariable logistic regression after adjusting for other patient and center-level confounding variables. Cox proportional-hazard regression models were used to quantify the effect of timing of ECMO initiation on time to event outcomes, such as time to be weaned off ECMO and time to hospital discharge. Patients who died before being weaned off ECMO or before being discharged from the hospital were considered to be censored in the above models. To account for censoring of hospital charges due to death of the individual, hospital charges were also analyzed using Cox proportional-hazard regression models. The clustering effect of patients from different centers was taken into account by introducing a random effect for the center in each of the above models. Variables significant at the 10% level in univariate comparisons were entered into the multiple regression models. Variables with $\geq 10\%$ missing values were not considered for inclusion into the multivariate models. The following patient-level variables were selected for multivariable models: age at surgery, sex, any genetic abnormality, Risk Adjustment for Congenital Heart Surgery (RACHS-1) score for classified congenital cardiothoracic procedures, pediatric charge weight, total complex chronic conditions, >1 heart operation, orthotopic heart transplant, use of a ventricular assist device, congenital diaphragmatic hernia, use of inotropes (pre-ECMO), use of nitric oxide, use of antiarrhythmic drugs, use of antiepileptic drugs, necrotizing enterocolitis, sepsis, renal insufficiency, bloodstream infections, urinary tract infections, seizures,

Figure 1. Natural log of the number of patients requiring ECMO support by the number of days from surgery to ECMO initiation. Abbreviations: ECMO, extracorporeal membrane oxygenation.

cardiopulmonary arrest, use of dialysis, brain ischemia, and brain hemorrhage. Center-level variables selected for multivariable models include average annual admissions per center, average annual mechanical ventilators per center, average annual CPB cases per year, and average total ECMO cases per year.

Finally, stratified analysis was performed to evaluate the relationship of presurgery vs postsurgery ECMO with various outcomes across varying level of surgical risk. For this analysis, patients were grouped on the basis of RACHS-1 categories (categories 1, 2, and 3 representing low risk and categories 4, 5, and 6 representing high risk). The model results were expressed in terms of adjusted odds ratio for in-hospital mortality and hazard ratios for the time to event and hospital charge outcomes, corresponding 95% confidence intervals, and *P* values. Several additional multiple logistic regression models were performed to explore variables left out of the model and to achieve a parsimonious model. The model's goodness-of-fit was evaluated using the Hosmer-Lemeshow test, and the discrimination of the model was assessed using the area under the receiver operating characteristic curve. All statistical analyses were generated using SAS/STAT software, version 9.4 of the SAS System for Windows 7 (SAS Institute, Inc., Cary, NC). Plots were generated using the ggplot2 package in R (R Core Team, Vienna, Austria). All tests were 2-sided assuming a significance level of 5%.

Results

In total, 3498 patients from 42 hospitals qualified for inclusion. Of these, 494 (14%) received ECMO prior to

heart operation, and 3004 (86%) received ECMO after heart operation. More than half the patients were male (1971, 56%), and the median age at surgery was 4 days (IQR, 1–183 days). Among the study centers, the average number of annual CPB cases per center was 298 (IQR, 234–380) and the average number of annual ECMO cases per center was 41 (IQR, 25–53). Figure 1 depicts the number of patients requiring ECMO support by the number of days from surgery to ECMO initiation. Figure 2 depicts the patient mortality in both the presurgery ECMO group and postsurgery ECMO group as a function of duration of ECMO.

Of the 494 patients requiring ECMO prior to heart operation, 213 (43%) were decannulated prior to their heart operation, 111 (22%) required ECMO until their heart operation, and 170 (34%) required ECMO after heart operation. In the presurgery ECMO group, the median timing of ECMO initiation was 6 days (IQR, 2–14 days) prior to heart operation. In contrast, the median timing of ECMO initiation in the postsurgery ECMO group was 0 days (IQR, 0–1 days) after heart operation. The median duration of ECMO was 5 days (IQR, 2–9 days) in the presurgery ECMO group and 4 days (IQR, 1–7 days) in the postsurgery ECMO group.

Table 1 depicts the patient characteristics for the study patients. Prior to ECMO initiation, inotropic support was required in 2051 (59%) patients. Nitric oxide was used in 2035 (58%) patients, anti-arrhythmic drugs in 2841 (81%) patients, and antiepileptics in 955 (27%) patients. Common complications among the study patients were necrotizing enterocolitis (61 patients, 2%), sepsis (1158 patients, 33%),

Figure 2. Patient mortality in the presurgery ECMO group and the postsurgery ECMO group as a function of duration of ECMO. Abbreviations: ECMO, extracorporeal membrane oxygenation.

bloodstream infections (135 patients, 4%), urinary tract infections (272 patients, 8%), renal insufficiency (1271 patients, 36%), brain hemorrhage or ischemia (383 patients, 11%), seizures (276 patients, 8%), cardiopulmonary arrest (1200 patients, 14%), and dialysis (483 patients, 14%). Using the RACHS-1 score to classify congenital cardiothoracic procedures, 2152 (61%) patients had associated heart operation in the low-risk category (RACHS score 1–3), whereas 1346 (39%) patients had associated heart operation in the high-risk category (RACHS score 4–6). One hundred sixty-one (4%) patients required orthotopic heart transplantation, and 152 (4%) patients required support from a ventricular assist device after their heart operation.

Unadjusted and adjusted in-hospital outcomes are depicted in Tables 2 and 3, respectively. In unadjusted analysis, mortality was significantly lower in the presurgery ECMO group compared with the postsurgery ECMO group (30% vs 45%; $P < 0.0001$). However, in unadjusted analysis, length of ECMO, length of mechanical ventilation, length of hospital stay, and hospital charges were longer/higher in the presurgery ECMO group. After adjusting for patient and center characteristics, odds of mortality were significantly lower in the presurgery ECMO group (odds ratio: 0.46, 95% confidence interval: 0.36–0.59, $P < 0.0001$). These trends continued for low-risk (RACHS 1–3) and high-risk (RACHS 4–6) operations. In adjusted models, there were no significant differences in ECMO duration, length of hospital stay, or hospital charges in the 2 groups (see Supporting Tables 1–12 in the online version of this article).

Discussion

In this large retrospective multicenter database, we found that the proportion of children requiring ECMO prior to their heart operation is small (14%). Our study demonstrated that patients requiring ECMO prior to their heart operation have significantly lower mortality compared with patients requiring ECMO after their heart operation. However, there was no significant difference in ECMO duration, length of hospital stay, or hospital charges in the 2 groups, after adjusting for patient and center factors.

To our knowledge, this is the largest study to date reporting outcomes related to use of ECMO prior to heart surgery in children undergoing surgery for congenital heart disease. The literature on the use of preoperative ECMO in children with congenital heart disease is limited.⁹ In a single-center study, Bautista-Hernandez et al reported 26 patients with congenital heart disease who were bridged to surgical palliation or anatomic repair with ECMO. Of these, 62% survived to hospital discharge. Our study reports similar results, with a survival of ~70% in patients requiring ECMO prior to heart operation.

One of the postulated mechanisms for cardiovascular collapse necessitating ECMO prior to heart operation could be the presence of congestive heart failure due to a myriad of factors. The most common pathophysiological factors associated with heart failure in children with congenital heart disease prior to heart operation include unobstructed pulmonary blood flow, obstruction to systemic flow, obstruction to pulmonary venous return, insufficiency of the

Table 1. Patient and Center Characteristics

	Postsurgery ECMO (n = 3004)	Presurgery ECMO (n = 494)	P Value
Demographics			
Male sex	1679 (55.9)	292 (59.1)	0.18
Birth weight, g	3000 (2636–3401)	3090 (2600–3480)	0.23
Gestational age, wk	38 (37–39)	38 (36–39)	0.57
Age at surgery, d	4 (1–168)	52.5 (1–368)	<0.0001
Genetic abnormality	484 (16.1)	54 (10.9)	0.003
Congenital diaphragmatic hernia	34 (1.1)	21 (4.3)	<0.0001
Operation and severity of illness			
RACHS score			<0.0001
1–3	1801 (59.9)	351 (71.1)	
4–6	1203 (40.1)	143 (28.9)	
>1 Cardiothoracic surgery	1864 (62.1)	200 (40.5)	<0.0001
Orthotopic heart transplant	96 (3.2)	65 (13.2)	<0.0001
VAD	84 (2.8)	68 (13.8)	<0.0001
Pediatric charge weight	56.08 (45.44–56.08)	49.96 (45.44–56.08)	0.0002
Total complex chronic conditions	1 (1–2)	1 (1–2)	0.06
Pharmacologic interventions			
Inotropes (pre-ECMO)	1853 (61.7)	198 (40.1)	<0.0001
Nitric oxide	1706 (56.8)	329 (66.6)	<0.0001
Antiarrhythmic drugs	2412 (80.3)	429 (86.8)	0.0006
Antiepileptic drugs	817 (27.2)	138 (27.9)	0.73
Complications			
Necrotizing enterocolitis	55 (1.8)	6 (1.2)	0.33
Sepsis	958 (31.9)	200 (40.5)	0.0002
Renal insufficiency	1074 (35.8)	197 (39.9)	0.08
Bloodstream infections	101 (3.4)	34 (6.9)	0.0002
Urinary tract infections	208 (6.9)	64 (13.0)	<0.0001
Pneumonia	1369 (45.6)	217 (43.9)	0.26
Seizures	227 (7.6)	49 (9.9)	0.07
Cardiopulmonary arrest	1033 (34.4)	167 (33.8)	0.80
Need for dialysis	406 (13.5)	77 (15.6)	0.22
Brain ischemia	182 (6.1)	63 (12.8)	<0.0001
Brain hemorrhage	110 (3.7)	28 (5.7)	0.03
Center data			
Annual patients per center	9928 (8074–11 941)	10 122 (8590–12 019)	0.004
Annual mechanical ventilators per center	1237 (993–1515)	1298 (993–1660)	0.001

Table 1. Continued

	Postsurgery ECMO (n =3004)	Presurgery ECMO (n =494)	P Value
Annual CPB cases per center	298 (234–380)	298 (236–478)	0.16
Annual ECMO cases per center	41 (25–53)	38 (25–53)	0.18
Abbreviations: CPB, cardiopulmonary bypass; ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit; RACHS, Risk Adjustment for Congenital Heart Surgery; VAD, ventricular assist device. Continuous variables are summarized by the triplet of quartiles 50th (25th–75th). Categorical variables are given as n (%).			

Table 2. Unadjusted In-Hospital Outcomes

	Overall (N =3498)	Postsurgery ECMO (n =3004)	Presurgery ECMO (n =494)	P Value
Mortality	1492 (42.7)	1346 (44.8)	146 (29.6)	<0.0001
Length of ECMO, d	4 (1–7)	4 (1–7)	5 (2–9)	<0.0001
Length of ventilation, d	17 (8–34)	16 (8–33)	20 (10–41)	<0.0001
Length of hospital stay, d	35 (17–68)	34 (16–64)	49 (24–93)	<0.0001
Hospital charges (in thousands)	680 (372–1235)	655 (357–1170)	864 (471–1677)	<0.0001
Abbreviations: ECMO, extracorporeal membrane oxygenation. Continuous variables are summarized by the triplet of quartiles 50th (25th–75th). Categorical variables are given as n (%).				

Table 3. Adjusted In-Hospital Outcomes (Presurgery vs Postsurgery)

	Unadjusted ^a		Adjusted ^a	
	OR or HR (95% CI)	P Value	OR or HR (95% CI)	P Value
Mortality				
All patients	0.52 (0.42–0.64)	<0.0001	0.46 (0.36–0.59)	<0.0001
RACHS score 1–3	0.52 (0.40–0.68)	<0.0001	0.43 (0.32–0.58)	<0.0001
RACHS score 4–6	0.58 (0.40–0.82)	0.002	0.55 (0.35–0.86)	0.009
Length of ECMO				
All patients	0.92 (0.83–1.01)	0.09	0.97 (0.87–1.09)	0.61
RACHS score 1–3	0.90 (0.80–1.02)	0.11	0.95 (0.83–1.09)	0.49
RACHS score 4–6	0.90 (0.75–1.09)	0.28	1.02 (0.82–1.26)	0.88
Length of hospital stay				
All patients	0.90 (0.80–1.01)	0.08	0.89 (0.78–1.01)	0.07
RACHS score 1–3	0.85 (0.74–0.98)	0.02	0.86 (0.74–1.00)	0.06
RACHS score 4–6	0.92 (0.74–1.15)	0.47	0.92 (0.70–1.22)	0.56
Hospital charges				
All patients	0.91 (0.81–1.02)	0.10	0.98 (0.86–1.11)	0.70
RACHS score 1–3	0.88 (0.76–1.00)	0.06	0.96 (0.83–1.11)	0.57
RACHS score 4–6	0.92 (0.74–1.15)	0.47	0.94 (0.71–1.24)	0.64
Abbreviations: CI, confidence interval; ECMO, extracorporeal membrane oxygenation; HR, hazard ratio; OR, odds ratio; RACHS, Risk Adjustment for Congenital Heart Surgery. ^a The postsurgery ECMO group is the reference group.				

atrioventricular valve(s), myocardial abnormalities or dysfunction, and coronary hypoperfusion.^{12,13} Congestive heart failure in these children could result from volume overload, pressure overload, cyanosis, primary myocardial disease of either or both ventricles, metabolic abnormalities, and genetic mutations.^{12,13} Given the limitation of the dataset, it was difficult to determine the exact pathophysiological reason for the need for ECMO in our study patients.

Study Limitations

This study is subject to the limitations of all observational analyses, including selection bias, residual confounding, and measurement by error. Although we attempted to adjust for important patient and center-level confounders, it is possible that there could be other unmeasured confounders present impacting our analysis. Another limitation of this study could be the use of an administrative database for case ascertainment. It has been shown that differences in coding of procedures between administrative and clinical datasets have led to differences in reported outcomes associated with these procedures.^{14,15}

In addition, our study lacked data related to the decision-making process prior to initiation of ECMO. Although the missing data for the variables used in our study were negligible (<1%), coding errors can occur in administrative databases. Although we used severity-of-illness scores available in the dataset, we were unable to finely adjust for severity of illness with respect to progressive organ failure not captured by diagnosis coding. Finally, this data source lacks information on important ECMO-related variables such as mode of support, type of cannulation, and ECMO-related complications, and, as mentioned, a center-specific breakdown of cardiac ECMO cases.

Conclusion

Data from this large multicenter database suggest that the proportion of patients requiring ECMO prior to heart surgery is relatively small (~14%) and the mortality rate among those requiring ECMO prior to heart surgery is low (~30%). Furthermore, use of ECMO prior to heart operation was not associated with increasing ECMO duration or increasing hospital length of stay. We therefore conclude that ECMO in children with unrepaired heart defects is a useful modality and could be employed with satisfactory results. Further study is warranted to determine the exact

pathophysiological reasons for the need for ECMO in the preoperative period.

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