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ORIGINAL ARTICLE

Arrhythmias Requiring ECMO in Infants Without Structural Congenital Heart Disease

Andrew Well[1,2] · Arnold Fenrich[1,3] · Daniel Shmorhun[1,3] · Daniel Stromberg[1,3] · Preston Lavinghousez[1,3] · Ziv Beckerman[1,2] · Charles D. Fraser Jr.[1,2] · Carlos M. Mery[1,2]

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Abstract

Arrhythmias account for 55 per 100,000 patient evaluations in pediatric emergency departments. Most arrhythmias in children are amenable to medical management or cardioversion. Rarely, arrhythmias lead to significant hemodynamic instability requiring extracorporeal membrane oxygenation (ECMO) support. This study seeks to evaluate children under 1 year of age with a structurally normal heart requiring ECMO for an arrhythmia. This is a retrospective review of the Extracorporeal Life Support Organization Registry. All patients less than 1 year of age between 2009 and 2019 with a diagnosis of arrhythmia and without a diagnosis of structural heart malformation were included. Demographics, clinical characteristics, and outcomes were assessed with descriptive statistics and univariate and multivariable analyses. A total of 140 eligible patients were identified from the dataset. The most common arrhythmia was supraventricular tachycardia (SVT) in 70 (50%) patients. ECMO complications occurred in 106 (76.3%) patients and survival to discharge was achieved in 120 (85.7%) patients. In-hospital mortality was associated with neuromuscular blockade prior to ECMO [aOR 10.0 (95% CI 2.95–41.56), $p < 0.001$], neurologic ECMO complication [aOR 28.1 (95% CI 6.6–155.1), $p < 0.001$], and race with white race being protective [aOR 0.13, (95% CI 0.02–0.21), $p = 0.002$]. Similar survival and complication rates were found in subgroup analysis of SVT arrhythmias alone. Arrhythmias necessitating ECMO support in infants without structural congenital heart disease is a rare occurrence. However, survival to hospital discharge is favorable at greater than 85%. Given the favorable survival, earlier and more aggressive utilization of ECMO may result in improved outcomes.

Keywords Extracorporeal membrane oxygenation · Arrhythmias · Outcomes · Extracorporeal Life Support Organization Registry

Introduction

Pediatric arrhythmias account for 55 per 100,000 patients evaluated in pediatric emergency departments [1]. Supraventricular Tachycardia (SVT) accounts for 13% of these emergency department admissions [1]. Arrhythmias in children with structurally normal hearts are frequently amenable to medical management and/or cardioversion [2–5]. In rare cases, these arrhythmias are refractory to these interventions and require Extracorporeal Membrane Oxygenation (ECMO) support. One small study of 6 infants under the age of 1 year requiring ECMO for arrhythmias revealed a 100% survival to discharge [6]. Recently, Ghaleb et al. presented data for patients under 21 years of age requiring ECMO support for supraventricular arrhythmias and found a 65% survival to discharge, with decreased survival in patients with concomitant structural congenital heart disease, those requiring extracorporeal cardiopulmonary resuscitation (ECPR), and those that developed ECMO complications [7].

Limited data exist on the outcomes of infants with arrhythmias requiring ECMO support. This study analyzes the multidisciplinary and multinational Extracorporeal Life Support Organization (ELSO) Registry to specifically

✉ Andrew Well
Andrew.Well@Austin.UTexas.edu

1 Texas Center for Pediatric and Congenital Heart Disease, UT Health Austin and Dell Children's Medical Center, Austin, TX, USA

2 Department of Surgery and Perioperative Care at the University of Texas at Austin Dell Medical School, Austin, TX, USA

3 Department of Pediatrics at the University of Texas at Austin Dell Medical School, Austin, TX, USA

evaluate outcomes of infants under 1 year of age with no known structural congenital heart disease who require ECMO support for intractable arrhythmias. We further seek to identify patient and ECMO characteristics associated with survival.

Methods

Study Population

This study is a retrospective review of the ELSO Registry, a multicenter, multinational registry that collects clinical information on both pediatric and adult patients requiring ECMO support [8]. Data were extracted from the ELSO Registry from 2009 through 2019. Patients less than 1 year of age who had a diagnosis of arrhythmia without a diagnosis of structural congenital heart disease or cardiac surgical intervention were included in the analysis. The study was approved as exempt by the Institutional Review Board at the University of Texas at Austin Dell Medical School and no informed consent was required given the deidentified nature of the registry.

International Classification of Diseases (ICD) 9th and 10th edition codes were used to identify those patients in the registry with a diagnosis of an arrhythmia and to identify and exclude those with structural congenital heart disease. (Table 1).

Patient Characteristics

Patient demographics including race, gender, and age were extracted from the dataset. Age was defined at the initiation of ECMO and was used as a continuous variable as well as categorized into neonatal (≤ 30 days of age) and infants (> 30 days of age). Weight was determined at the time of ECMO initiation and used as a continuous variable.

ECMO Characteristics

Characteristics of patients' ECMO support were extracted from the ELSO Registry. These included patient laboratory data at ECMO initiation and at 24 hours, pre-ECMO medication administration, and cannulation sites. ECMO complications during ECMO support and ECMO duration were also included in the analysis.

ECMO Complications and Outcomes

ECMO complications are categorized into cardiovascular, mechanical, metabolic, hemorrhagic, neurologic, pulmonary, infectious, and renal in the ELSO Registry. Reason for ECMO discontinuation (died/poor prognosis, expected recovery, complications, heart transplant, ventricular assist device, and unknown) and successful separation from ECMO were assessed as well as survival to hospital discharge.

Statistical Analysis

Variables are expressed as means with standard deviations for normally distributed variables and medians with interquartile ranges (IQR) for non-normally distributed variables. Frequencies were calculated for categorical variables. Chi-Square Tests and Fisher's Exact Tests (when observed frequency was < 5) were utilized to compare categorical variables. Independent sample *T* Tests, ANOVAs, and Kruskal–Wallis tests (for non-normal continuous variables) were used to compare categorical and continuous variables. Logistic regression models were utilized for multivariable analysis assessing outcomes adjusting for patient characteristics identified through univariable analysis. All statistical analysis were performed using R and RStudio [9]. All statistical tests were 2-tailed and a p-value < 0.05 was considered significant.

Table 1 International Classification of Diseases 9th and 10th edition codes for arrhythmias and structural heart disease

Arrhythmias
ICD-9
427.0, 427.1, 427.2, 427.3, 427.31, 427.32, 427.4, 427.41, 427.42, 427.89, 427.9
ICD-10
I47.1, I47.2, I47.9, I48.91, I48.92, I49.01, I49.02, I49.8, I49.9
Structural heart disease
ICD-9
745.0, 745.10, 745.11, 745.12, 745.19, 745.2, 745.3, 745.4, 745.5, 745.60, 745.61, 745.69, 745.7, 745.8, 745.9, 746.00, 746.01, 746.02, 746.09, 746.1, 746.5, 746.6, 746.7, 746.81, 746.82, 746.83, 746.84, 746.85, 746.89, 746.9, 746.2, 746.3, 746.4
ICD-10
Q20.0, Q20.1, Q20.2, Q20.3, Q20.4, Q20.5, Q20.6, Q20.8, Q20.9, Q21.0, Q21.1, Q21.2, Q21.3, Q21.4, Q21.8, Q21.9, Q22.0, Q22.1, Q22.2, Q22.3, Q22.4, Q22.5, Q22.6, Q22.8, Q22.9, Q23.0, Q23.1, Q23.2, Q23.3, Q23.4, Q23.8, Q23.9, Q24.2, Q24.3, Q24.4, Q24.5, Q24.8, Q24.9

Results

Participants

Over the study period, 24,218 cases of all forms of ECMO in children less than 1 year of age were identified in the ELSO Registry. Of this group, 20,158 (83.2%) were VA-ECMO. A total of 140 eligible patients were identified from the ELSO Registry representing 0.58% of all cases less than 1 year of age and 0.69% of all cases of VA-ECMO less than 1 year of age. Of the cohort, 87 (62.1%) were white and 56 (40%) were female. Median age was 28 [13.75–100.5] days and mean weight at ECMO initiation was 4.7 ± 1.78 kg. Seventy (50%) patients had a diagnosis of Supraventricular Tachycardia followed by 33 (23.6%) with an unspecified arrhythmia. Location of ECMO cannulation was known in 132 (94.3%) of patients with 17 (12.9%) centrally cannulated. (Table 2).

Pre-ECMO Characteristics

Primary indication for ECMO was coded as arrhythmia in 94 (67.1%) patients, followed by cardiac arrest in 24 (17.1%). Ninety-six (69.1%) patients experienced an arrest prior to ECMO initiation and 51 (36.4%) were initiated on ECMO during ECPR. Pre-ECMO medications were known in 139 (99.3%) and are presented in Table 3. Laboratory values at initiation of ECMO and at 24 hours of ECMO support are presented in Table 4.

ECMO Complications and Outcomes

Complications while on ECMO were known for 139 (99.3%) patients, with 106 (76.3%) patients having at least 1 complication. The median number of total complications was 2 [1–4] with patients having complications in a median of 2 [1–3] categories. The breakdown of complications is presented in Table 5.

No patient characteristics were associated with incidence of ECMO complications in this analysis. Only use of unspecified pressor/inotropic medication prior to ECMO (12.1% vs. 37.7%, $p = 0.005$) and narcotics prior to ECMO (30.3% vs. 57.5%, $p = 0.006$) were associated with incidence of any ECMO complication.

Survival to discharge was achieved in 120 (85.7%) patients. Of the 20 (14.3%) mortalities, 13(65%) occurred while being supported on ECMO. The remaining 7 (35%) were successfully separated from ECMO support but did not survive to discharge. One (0.7%) patient was transitioned from ECMO to a ventricular assist device (VAD). Median time on ECMO support was 94 [69–158.5] hours in the entire cohort, with no difference between survivors 98 [70–158] hours and non-survivors 85.5 [56.75–158.75] hours ($p = 0.432$). A competing risk model between

Table 2 Patient demographics and characteristics

	All Patients ($n = 140$)	Survivors ($n = 120$)	Non-survivors ($n = 20$)	Sig
Weight (kg), Mean ± SD	4.70 ± 1.78	4.68 ± 1.71	4.82 ± 1.71	$p = 0.787$
Age at ECMO (days), Median [IQR]	28 [13.75–100.5]	28.5 [14–100]	21.5 [7–117.5]	$p = 0.696$
Neonates, *n*(%)	76 (54.3)	64 (53.3)	12 (60)	$p = 0.580$
Female, *n*(%)	56 (40)	47 (39.2)	9 (45)	$p = 0.535$
Race, *n*(%)				
White	87 (62.1)	79 (65.8)	8 (40)	$p = 0.103$
Black	0 (0)	0 (0)	0 (0)	
Hispanic	18 (12.9)	13 (10.8)	5 (25)	
Asian	21 (15)	17 (14.2)	4 (20)	
Other	14 (10)	11 (9.2)	3 (15)	
Non-white, *n*(%)	53 (37.9)	41 (34.2)	12 (60)	**$p = 0.027$**
Arrhythmia, *n*(%)				
Supraventricular Tachycardia	70 (50)	62 (51.7)	8 (40)	$p = 0.594$
Unspecified	33 (23.6)	27 (22.5)	6 (30)	
Ventricular Tachycardia	20 (14.3)	15 (12.5)	5 (25)	
Multiple	6 (4.3)	6 (5)	0 (0)	
Ventricular Fibrillation	4 (2.9)	4 (3.3)	0 (0)	
Atrial Fibrillation/Flutter	3 (2.1)	2 (1.7)	1 (5)	
Neonatal Tachycardia	2 (1.4)	2 (1.7)	0 (0)	
Supraventricular Premature Beats	1 (0.7)	1 (0.8)	0 (0)	

Bold indicate p-value < 0.05

Table 3 Medications administered prior to ECMO initiation

Medication	Overall *n*(%) (*n* = 139)	Survivors *n*(%) (*n* = 119)	Non-Survivors *n*(%) (*n* = 20)	Sig
Epinephrine	77 (55.4)	65 (54.6)	12 (60.0)	$p = 0.654$
Narcotics	71 (51.1)	56 (47.1)	15 (75.0)	$\mathbf{p = 0.021}$
Neuromuscular Blockade	48 (34.5)	35 (29.4)	13 (65.0)	$\mathbf{p = 0.002}$
Unspecified Pressors/Inotropic Medication	44 (31.7)	39 (32.8)	5 (25.0)	$p = 0.489$
Bicarbonate	39 (28.1)	32 (26.9)	7 (35.0)	$p = 0.455$
Milrinone	29 (20.9)	23 (19.3)	6 (30.0)	$p = 0.370$
Dopamine	23 (16.5)	19 (16.0)	4 (20.0)	$p = 0.745$
Nitric Oxide	12 (8.6)	8 (6.7)	4 (20.0)	$p = 0.072$
Unspecified Vasodilator	10 (7.2)	8 (6.7)	2 (10.0)	$p = 0.637$
Norepinephrine	9 (6.5)	5 (4.2)	4 (20.0)	$\mathbf{p = 0.025}$
Systemic Steroids	7 (5.0)	5 (4.2)	2 (10.0)	$p = 0.265$
Inamrinone	4 (2.9)	3 (2.5)	1 (5.0)	$p = 0.467$
Esmolol	3 (2.2)	3 (2.5)	0	$p = 1$
Dobutamine	3 (2.2)	2 (1.7)	1 (5.0)	$p = 0.375$
THAM	2 (1.4)	1 (0.8)	1 (5.0)	$p = 0.268$
Inhaled Anesthetic	2 (1.4)	1 (0.8)	1 (5.0)	$p = 0.268$
Vasopressin	2 (1.4)	1 (0.8)	1 (5.0)	$p = 0.268$
Alprostadil	2 (1.4)	2 (1.7)	0	$p = 1$
Surfactant	2 (1.4)	1 (0.8)	1 (5.0)	$p = 0.268$
Nitroglycerine	1 (0.7)	1 (0.8)	0	$p = 1$
Levosimendan	1 (0.7)	1 (0.8)	0	$p = 1$
Sildenafil	1 (0.7)	0	1 (5.0)	$p = 0.144$
Metaraminol	1 (0.7)	1 (0.8)	0	$p = 1$
Nitroprusside	1 (0.7)	1 (0.8)	0	$p = 1$

Bold indicates p-value < 0.05

Table 4 Laboratory findings at ECMO initiation and after 24 h of ECMO support

Laboratory	ECMO initiation (*n* = 111)	24 h of ECMO support (*n* = 115)
pH, mean ± SD	7.138 ± 0.238	7.385 ± 0.078
pCO_2, mean ± SD	50.8 ± 22.6	43.2 ± 24.2
pO_2, median[IQR]	62 [40–117.5] (*n* = 104)	149 [105–195]
Bicarbonate, mean ± SD	17.5 ± 8.0 (*n* = 109)	24.8 ± 4.4 (*n* = 113)
SaO2, mean ± SD	78.1 ± 25.7 (*n* = 89)	97.1 ± 6.6 (*n* = 109)

successful separation from ECMO and death while on ECMO between neonates and infants is presented in Fig. 1.

Non-survivors were more likely to be of non-white race ($p = 0.027$) (Table 2). No differences were seen in weight and age between non-survivors and survivors. Further, non-survivors were more likely to have received narcotics, neuromuscular blockade, and norepinephrine prior to ECMO initiation (Table 3). ECMO was initiated via central cannulation in 7 (36.8%) non-survivors compared to 10 (8.8%) survivors ($p < 0.001$) (Table 6).

In multivariable analysis of the entire cohort, in-hospital mortality was associated with neuromuscular blockade prior to ECMO [OR 10 (95% CI 3–42)] and any neurologic complication while on ECMO [OR 28 (95% CI 7–155)], while in-hospital mortality decreased with white race [OR 0.13 (95% CI 0.02–0.21)] (Table 7).

Supraventricular Tachycardia

Subgroup analysis of the 70 patients with a diagnosis of supraventricular tachycardia showed that 62 (88.6%) patients survived to discharge. Non-survivors had an increased incidence of neurologic ECMO complications (50% vs. 6.5%, $p = 0.004$), pre-ECMO placement of a pacemaker (25% vs. 1.6%, $p = 0.033$), bicarbonate administration prior to ECMO (62.5% vs.24.2%, $p = 0.038$), and neuromuscular blockade prior to ECMO (75% vs. 27.4% $p = 0.013$). Non-survivors were also more likely to have central cannulation for ECMO (50% vs. 9.7%, $p = 0.015$) (Table 8). A total of 50 (71.4%)

Table 5 Number of ECMO complications by category and survival

Complication category ($n=139$)	Total number of complications	Overall – number(%) of patients with complications	Survivors – number(%) of patients with complication $n=119$	Non-survivors – number(%) of patients with complication $n=20$	Sig
Mechanical	58	41 (29.5)	35 (29.4)	6 (30.0)	$p=0.957$
Cardiac	126	80 (57.6)	69 (58.0)	11 (55.0)	$p=0.803$
Metabolic	37	29 (20.9)	23 (19.3)	6 (30.0)	$p=0.370$
Pulmonary	10	10 (7.2)	8 (6.7)	2 (10.0)	$p=0.637$
Neurologic	26	19 (13.7)	10 (8.4)	9 (45.0)	**$p<0.001$**
Infectious	6	6 (4.3)	1 (0.8)	5 (25.0)	**$p<0.001$**
Renal	42	36 (25.9)	30 (25.2)	6 (30.0)	$p=0.651$
Bleeding	36	33 (23.7)	25 (21.0)	8 (40.0)	$p=0.087$

Bold indicates p-value < 0.05

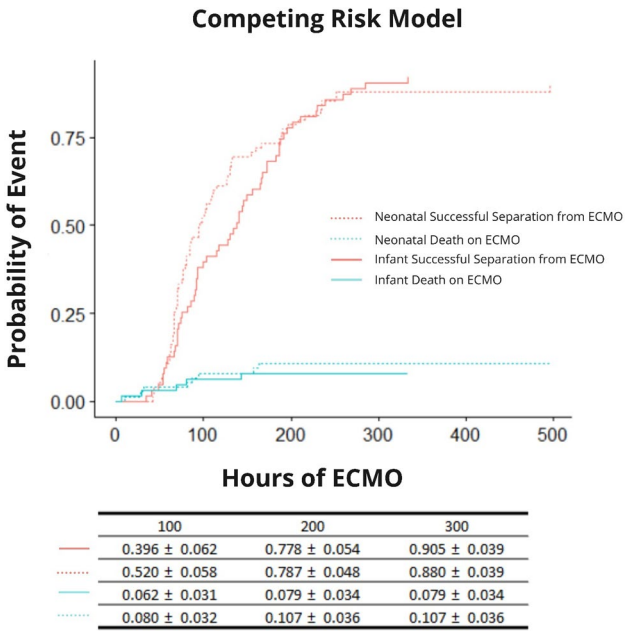

Fig. 1 Competing risk of death on ECMO and successful separation from ECMO

patients had at least 1 ECMO complication. No patient factors, medication prior to ECMO, or laboratory values were associated with ECMO complications in this subgroup.

In multivariable analysis of the isolated SVT cohort, in-hospital mortality was associated with central ECMO cannulation (OR 51 (95% CI 3–1,652) and any neurologic complication while on ECMO [OR 21 (95% CI 3–216)] (Table 7).

Comment

Arrhythmias in children less than 1 year of age without known structural heart disease are not infrequent. However, it is rare for these arrhythmias to be refractory to medication and cardioversion. In these rare cases, ECMO support may be required in the hemodynamically unstable patient. A recent report evaluated outcomes of all pediatric patients requiring ECMO for SVT. This review revealed a 65% survival to discharge for the overall cohort as well as the isolated SVT cohort [7]. Aside from case reports and series, there has been no evaluation of the outcomes specifically in infants with isolated SVT requiring ECMO. This analysis revealed a survival to discharge of 85.7%. This compares favorably to other reports of ECMO survival in other populations, ranging from 40 to 75% [10–12]. The favorable survival to other ECMO cohorts likely is influenced by the reversibility of the underlying arrhythmias and the potential for temporary and/or permanent pacing to restore hemodynamic stability with or without ablation if the underlying arrythmia is unable to be controlled.

An elevated incidence of arrest prior to ECMO and ECPR were noted in this cohort. While challenging to gain a comprehensive view of all events surrounding initiation of ECMO from registry data, this cohort comprises patients

Table 6 Univariate associations with in-hospital survival

	All patients ($n=140$)	Survivors ($n=120$)	Non-survivors ($n=20$)	Sig
Number of ECMO complications, Median[IQR]	2 [1–4]	2 [0–3]	4 [2–6]	**$p=0.013$**
Number of ECMO complication categories, Median[IQR]	2 [1–3]	2 [0–3]	2.5 [1.75–3]	**$p=0.024$**
Central cannulation, n(%) $n=132$	17 (12.9)	10 (8.8)	7 (36.8)	**$p<0.001$**

Bold indicates p-value < 0.05

Table 7 Multivariable analysis of associations with in-hospital mortality

	OR	95% CI	Sig
In-hospital mortality			
White	0.13	0.02–0.21	***p* = 0.002**
Neuromuscular blockade prior to ECMO	10.01	2.95–41.56	***p* < 0.001**
Any neurologic ECMO complication	28.12	6.58–155.12	***p* < 0.001**
In-hospital mortality—SVT only			
Pacemaker Placement pre-ECMO	6.33	0.79–60.23	$p = 0.083$
Central ECMO Cannulation	50.5	2.96–1,651.93	***p* = 0.009**
Any Neurologic ECMO Complication	20.82	2.75–215.52	***p* = 0.005**

Bold indicates p-value < 0.05

Table 8 Univariate associations with in-hospital survival in SVT patients

Variable, *n*(%)	All SVT patients	Survivors $n = 62$	Non-survivors $n = 8$	Sig
Neurologic ECMO complication	8 (11.4)	4 (6.5)	4 (50)	***p* = 0.004**
Pacemaker Pre-ECMO	3 (4.3)	1 (1.6)	2 (25)	***p* = 0.033**
Bicarb Pre	20 (28.6)	15 (24.2)	5 (62.5)	***p* = 0.038**
Neuromuscular blockade	23 (32.9)	17 (27.4)	6 (75)	***p* = 0.013**
Central ECMO cannulation	10 (14.3)	6 (9.7)	4 (50)	***p* = 0.015**

Bold indicates p-value < 0.05

with arrythmias who required ECMO support, thus representing a population with marginal hemodynamics to begin with. This may also represent a reluctance of providers to initiate ECMO in this population prior to an arrest event. The percentage of patients recorded as centrally cannulated (12.9%) was higher than expected. Given the nature of the registry data, it is unclear the etiology of this increased percentage. A portion may represent patients who were unable to be peripherally cannulated due to size or anatomic constraints, required higher flows for support then able to achieve peripherally or needed left ventricle decompression. It is also possible a portion are miscategorized and either are truly peripheral cannulations labeled as central or are patients who indeed had previously undergone cardiac surgery without record of it in the ELSO Registry.

ECMO-related complications were frequent in this study with more than three quarters of patients experiencing at least one complication. Importantly, total number of complications and number of types of complications were associated with worse survival to discharge and specifically presence of any neurologic complication remained associated with worse survival in multivariable analysis. This likely represents the morbidity of ECMO itself and is not a product of the indication for support. However, this highlights the need for continued work to reduce the rates of complications experienced during ECMO support. In this analysis, median duration of ECMO support was 90 hours, this is a significantly shorter duration than reported across other neonatal and pediatric ECMO indications which report averages ranging from 144 to 288 hours [12]. This shorter duration, which is not different when excluding non-survivors, may indicate that arrhythmias are frequently controlled quickly allowing for a rapid return of hemodynamic stability and the ability to wean from ECMO support.

Interestingly, white race was found to be associated with improved survival, even in multivariable analysis. The influence of race on survival may act as a proxy for unmeasured social determinants of health. However, between center differences in racial makeup and outcomes cannot be determined. This represents an opportunity for further inquiry into the underlying influence of race on outcomes in this population. It will be important to evaluate other indicators of socioeconomic status such as insurance type to determine if those characteristics have similar impacts as race.

It should be noted that type of arrhythmia was not associated with complications or mortality and that the SVT group had a similar survival to discharge as the overall arrhythmia cohort. Other pre-ECMO factors including laboratory findings and need for ECPR were not associated with survival. In the multivariable analysis, neuromuscular blockade was the only pre-ECMO medication which was associated with worse survival. The presence of pre-ECMO neuromuscular blockade likely represents sicker, more unstable patients prior to initiation of ECMO. This may also represent patients who had a longer period of instability prior to the initiation of ECMO compared to those patients who either presented in extremis or had

rapid decompensation limiting the ability for other medical interventions prior to ECMO initiation. Unfortunately, the registry does not capture amiodarone administration in the pre-ECMO period. This is a potentially important medication, as not infrequently it's use can precipitate cardiac arrest, particularly in young children [13].

Further prospective multicenter studies are needed to allow for the collection of more detailed data on arrhythmias as well as greater detail in the events leading up to initiation of ECMO.

Limitations

This is a retrospective review of registry data which includes inherent limitations. These include the potential for misclassification of diagnoses and outcomes. This limitation is likely mitigated by the rigor to which ELSO holds its member sites to data collection quality. Further, the use of diagnosis codes reduces detail needed to fully evaluate the types of arrhythmias and the patient's underlying comorbidities. This registry also does not allow for assessment of duration of arrhythmia or potential inciting causes of the arrhythmia prior to ECMO. It is also possible that a patient had an unrecognized structural heart abnormality which was not known or identified at the time of ECMO cannulation and thus never coded as a diagnosis, resulting in misclassification and inclusion into this analysis. The risk of this misclassification is likely low as in most cases, children on ECMO will undergo multiple echocardiographic assessments that would likely identify structural abnormalities. There is further, a potential for the presence of unaccounted for confounders. Lastly, the retrospective nature of the study does not allow for the determination of causation only association.

Conclusion

Arrhythmias necessitating ECMO in infants less than 1 year of age with structurally normal hearts is a rare occurrence with 140 cases identified over a 10-year period. However, in these instances, survival to hospital discharge is greater than 85% which compares favorably to other populations requiring ECMO support. ECMO-related complications, which are most likely related to the morbidity of ECMO itself, were most strongly associated with in-hospital mortality. Given the favorable outcomes after ECMO initiation in this population, earlier and more aggressive utilization of ECMO may result in improved outcomes. Further prospective multicenter research is needed to further detail arrhythmia characteristics and in particular administration of amiodarone and the need for ECMO as well as association with outcomes.

Funding Not applicable.

Data Availability With Extracorporeal Life Support Organization (ELSO) Registry approval.

Code Availability At request.

Declarations

Conflict of interest All the authors declared that they have no conflict of interest.

Ethical Approval Approval as an Exempt study with waiver of informed consent by the University of Texas at Austin IRB (IRB# 2020-03-0077).

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