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Early Catheterization After Initiation of Extracorporeal Membrane Oxygenation Support in Children is Associated With Improved Survival

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Objectives: The study evaluated the institutional experience with cardiac catheterization on extracorporeal membrane oxygenation (ECMO) support. Background: There is scant literature on the outcomes of catheterization on ECMO. Methods: A retrospective review was performed of all children who underwent catheterization on ECMO from 2003 to 2013. Patients were categorized as cardiomyopathy (CM) or congenital heart disease (CHD). Results: During the study period, 215 children were placed on cardiac ECMO. Of these, 29.8% underwent 75 catheterization procedures while on ECMO support. The median age of the cohort was 1.5 months (range 0 days −16.7 years) and the median weight was 3.9 kg (2.2–63.1 kg). CM patients constituted 18.8% of the cohort and all of them underwent atrial septoplasty (an atrial septal stent in 7/12 and balloon atrial septoplasty or septostomy in 5). The survival to hospital discharge rate was 83% and the transplant-free survival rate was 58.3%. CHD patients constituted 81.2% of the cohort. In this group, transcatheter interventions were performed in 40.4% and subsequent surgical interventions in 40.4%. Survival to hospital discharge rate was 34.6% and transplant free survival rate was 32.7%. Overall, 76.7% underwent transcatheter or surgical interventions. The major catheterization complication rate was 6.7%. The mean ECMO-to-catheterization time was 1.6 days for survivors and 3.5 days for non-survivors ($P = 0.034$). Survival to discharge was better for the CM group compared to the CHD group ($P = 0.01$). Among CHD, survival was better with transcatheter interventions compared to no interventions or surgical interventions ($P < 0.001$). Conclusions: Cardiac catheterization and transcatheter interventions on ECMO can be performed with low rate of complications. Catheterization was associated with high rate of interventions. Better survival to hospital discharge was associated with transcatheter interventions, earlier performance of catheterization after ECMO and diagnosis of CM. © 2016 Wiley Periodicals, Inc.

Key words: pediatric; mechanical life support; transcatheter intervention

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INTRODUCTION

Extracorporeal membrane oxygenation (ECMO) is used to support pediatric patients in cardiorespiratory failure. ECMO is utilized in the postoperative period in children with congenital heart disease (CHD) in low cardiac output and/or severe ventricular dysfunction as well as in children with cardiomyopathy (CM) or acute myocarditis [1,2]. A recent report suggested that ECMO is used postoperatively in 5.5% of children undergoing cardiac surgery [3]. However, in small children undergoing complex cardiac surgery, including single ventricle palliation (e.g. following the Norwood operation), the utilization rate for ECMO is much higher [4,5] Cardiac catheterization may be useful in children who are supported on ECMO for diagnostic and therapeutic purposes. Previous studies have indicated the use of catheterization in children receiving ECMO support in approximately 30% of cases [1,6]. Recent advances in transcatheter therapeutics allow complex interventions to be undertaken in the setting of ECMO support. Although interventions in this critically ill population are necessarily high-risk, such interventions may be important therapies allowing for eventual recovery.

There is scant literature on outcomes of cardiac catheterization in the setting of ECMO support. Indeed, the most recent published systematic review of this cohort was in 2002 [6]. The purpose of our study was to assess our institutional experience with cardiac catheterization in infants and children receiving ECMO support, and to assess the safety of transcatheter interventions in this population.

METHODS

Study Design

This study is a retrospective single-center review. The data was collected from our hospital electronic medical records, our catheterization laboratory database, and the cardiac surgical database. All patients from March 2003 to August 2013 who were brought to the catheterization laboratory while already on ECMO support and who underwent cardiac catheterization were included in the study. Patients were excluded if ECMO support was initiated in the laboratory during an ongoing catheterization procedure. Patients who underwent only electrophysiologic interrogations while on ECMO were also excluded. Further, patients who were brought to the catheterization laboratory for fluoroscopy only, or for repositioning of ECMO cannulae were excluded. The primary endpoint of the study was survival to hospital discharge, with secondary endpoints including procedural complications, incidence of catheter-based interventions, and late post-discharge survival. Complications were categorized as major and minor. Major complications included death, stroke, cardiopulmonary resuscitation, and need for unexpected emergent surgery within 72 hours of the catheterization. Post-surgical status was assigned to CHD patients if they underwent cardiac catheterization following a cardiac surgical procedure occurring within 30 days of the catheterization, with no intervening discharge to home.

Data Collection

Demographic information including patient age and weight as well as underlying diagnosis, preceding surgical procedure, indication for ECMO initiation, time from surgery to ECMO, indication for cardiac catheterization, time from ECMO initiation to catheterization, vascular access during catheterization, hemodynamic and angiographic findings, transcatheter interventions, complications during catheterization, surgical procedures during or following catheterization, survival to discharge, and long term survival were collected. Single ventricle status was also noted, and determined by the palliative/operative strategy employed, not by underlying cardiac anatomy. We also collected data regarding late heart transplantation, death, and procedural complications. Attempts were made to determine if findings of the catheterization had a clinically relevant impact, such an impact was defined as either (a) a transcatheter intervention performed during the catheterization or (b) as a surgical intervention, which followed the catheterization, and which was directed by findings from the preceding catheterization.

Statistical Analysis

IBM SPSS 21 (IBM, Armonk NY) was used for data analysis. Data are expressed as median (range) or n=(%) where appropriate. Independent samples *t*-test and Mann-Whitney U were used to compare continuous variables, while $\chi[2]$ and Fishers exact tests were used for categorical comparisons. The cohort was divided into four groups for the purpose of Kaplan-Meier survival analysis: (a) Cardiomyopathy (CM) patients, (b) Congenital heart disease (CHD) patients who received transcatheter interventions, (c) CHD patients who received additional surgical procedures based on information obtained during catheterization, and (d) CHD patients with no additional interventions. Patients who underwent both transcatheter and surgical procedures based on information from catheterization were categorized into group (b) for the purpose of this analysis as transcatheter interventions necessarily preceded the surgical re-intervention. Log-rank *P*-values are

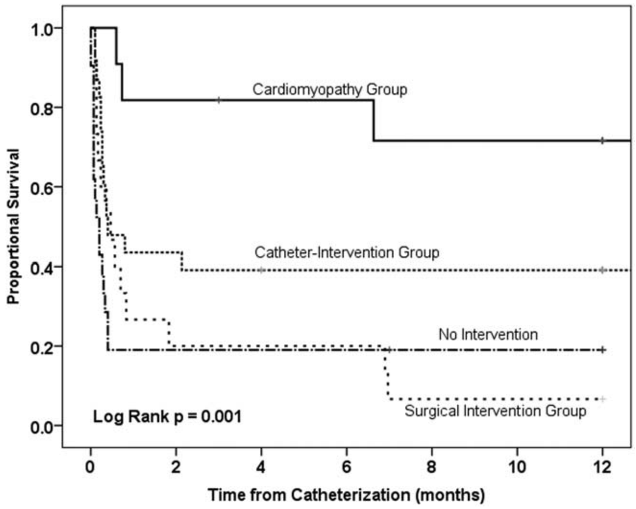

Fig. 1. Kaplan-Meier survival analysis shows the distinctly better survival curve for CM patients. The CHD group is further sub-categorized into catheter-intervention group, surgical-intervention group, and no intervention group. A vast majority of the attrition occurs shortly after the catheterization.

reported for comparisons of survival based upon Kaplan-Meier analysis. Cox regression multivariate analysis was employed for time-dependent endpoints including late survival. Multivariate analysis was performed for all candidate factors and variables, which had a $P < 0.10$ on univariate analysis. The institutional review board approved this study.

RESULTS

During the study period, a total of 215 children were supported on ECMO in our cardiac intensive care unit. E-CPR was instituted in 51.0% of these patients. Of all the cardiac ECMO patients, 64 children underwent 75 cardiac catheterizations while on ECMO support. At the time of cardiac catheterization, the median patient age was 1.5 months (0 days–16.7 years) and the median weight was 3.9 kg (2.2–63.1 kg). Neonates (n = 35) comprised 54.7% of the cohort who underwent catheterization. ECMO cannulation was performed through an open chest in 57.3% of patients, through neck access in 36%, and through the femoral vessels in 6.7% of patients. None of the patients underwent percutaneous cannulation. Cardiac catheterization was associated with percutaneous arterial access in 34.7% (26/75) of catheterizations. A 4 Fr arterial sheath was used in 46.2% (12/26), a 3 Fr arterial sheath was used during six (23%) catheterizations, a monitoring line during four (15%), while in three patients 5 Fr sheath, and in one patient a 6 Fr sheath was placed. Femoral arteries were the predominant arterial access except for three umbilical arterial accesses and one right carotid artery access. Femoral veins were the predominant venous access although the internal jugular veins were occasionally accessed. The venous sheath size ranged from 4 Fr to 14 Fr. When sheaths were removed during ECMO support, hemostasis was achieved by simple manual compression. In a 12-year-old patient, Perclose ProGlide 6F Suture-Mediated Closure (Abbott Vascular) System was used in a pre-close fashion to close the venotomy site to attain hemostasis after a 12F sheath had been used.

TABLE I. Underlying Cardiac Diagnosis

Diagnosis	N (%)
Dilated cardiomyopathy	12 (18.8)
Right heart obstruction (tetralogy of Fallot, truncus arteriosus, pulmonary atresia, Ebstein's anomaly)	9 (14.1)
Left heart obstruction (mitral stenosis, aortic stenosis, coarctation, interrupted aortic arch)	5 (7.8)
Single left ventricle (double inlet left ventricle, pulmonary and tricuspid atresia)	7 (10.9)
Single right ventricle (hypoplastic left heart syndrome and variants)	19 (29.7)
Transposition of great arteries	5 (7.8)
Others (total anomalous pulmonary venous return, mitral insufficiency, coronary anomaly, failed heart transplant)	7 (10.9)

Cardiomyopathy (CM) was the primary diagnosis in 12/64 patients (18.8%). The median age of the CM cohort was 1.3 years (18 days to 12.2 years) and the median weight was 10.3 kg (4–63.1 kg). In the CM group, all 12 patients underwent atrial septoplasty. In six of these patients, transseptal puncture was used to gain access across the atrial septum, while in the other half an existing communication was crossed to access the left atrium. In seven patients (58%) of the CM group, an atrial septal stent was placed (Supporting Information video 1 a,b), while in five, a static balloon septoplasty or balloon atrial septostomy was performed. One patient in this group underwent concomitant right ventricle endomyocardial biopsy. The rate of survival to hospital discharge was 83%, while the transplant free hospital survival was 58.3% (Fig. 1).

CHD was the primary diagnosis in 52/64 (81.2%) of the cohort, of whom 42/52 (80.8%) were postsurgical. For the CHD cohort, the median age at catheterization was 25.6 days (0 days −16.7 years) and the median weight was 3.7 kg (2.2–55 kg). The majority of patients in the CHD cohort were single ventricle patients (Table I), with the Norwood procedure being the most common preceding surgical procedure (n = 17, 40.5% of postsurgical patients) (Table II). Among the CHD cohort, 21 patients (40.4%) underwent 31 transcatheter interventions and additionally 21 patients (40.4%) underwent post-catheterization

TABLE II. Preceding Surgical Procedures

Surgical procedure	N (%)
Norwood procedure	17 (35.4)
RVOT reconstruction (transannular patch or conduit)±VSD patch	5 (10.4)
Repair of left heart obstruction (valve replacement, Ross/konno, coarctation repair)	5 (10.4)
Total anomalous pulmonary vein repair	5 (10.4)
Arterial switch operation	5 (10.4)
Blalock-Taussig Shunt placement	4 (8.3)
Orthotopic heart transplantation	3 (6.3)
Glenn procedure	2 (4.2)
Others (atrioventricular canal repair, Rastelli repair)	2 (4.2)

surgical interventions (five patients underwent both transcatheter and surgical re-intervention). The most common catheter-based intervention in the CHD cohort was stent placement across vascular stenoses or surgical conduits/shunts (Supporting Information videos 2 a,b,c,d; 3 a,b,c), while the most common surgical intervention was pulmonary artery patch plasty (Table III). Balloon angioplasty or stent placement across fresh suture lines (i.e. less than two weeks old) were performed in seven patients. In the CHD cohort, 34.6% survived to hospital discharge, while the transplant-free hospital survival rate was 32.7% (Fig. 1).

Atrial septal stents were placed during 13 catheterizations (seven in CMP and six in CHD). In all cases, Palmaz Genesis (Cordis, Fremont, CA) premounted stents ranging in diameter from 6 mm to 10 mm and in length from 15 mm to 29 mm were used. Levophase or direct left atrial angiography was used to define the atrial septum. Transesophageal echocardiography in older children and transthoracic echocardiography in infants were also used to guide precise stent placement. Atrial septal stent placement in the setting of CHD was predominantly in cases of hypoplastic left heart syndrome and mitral valve dysfunction.

Combining the CM and CHD groups, 76.7% (49/64) of the patients underwent transcatheter or surgical interventions while being supported on ECMO. The CM patients were significantly older ($P = 0.01$) and bigger ($P = 0.03$) compared to the CHD patients. Comparison of the demographics, interventions and outcomes between CM and CHD groups are given in Table IV. The overall complication rate for catheterization was 6.7% (5/75). These complications included: cardiac perforation requiring pericardial drain (n = 2), atrial septal stent embolization requiring surgical removal (n = 1), umbilical artery perforation treated by coil occlusion (n = 1; Supporting Information video 4 a,b,c,d), and entrapment of a catheter in the venous ECMO cannula requiring surgery (n = 1). No minor complications were

TABLE III. Transcatheter and Surgical Interventions

Procedure	N
Transcatheter interventions	
Atrial septoplasty	19
Collateral occlusion	5
Pulmonary artery stent placement	5
Stent placement (one each in right ventricular outflow tract, Sano shunt, left coronary artery, innominate artery, Blalock-Taussig shunt)	5
Balloon angioplasty (pulmonary vein, superior vena cava, pulmonary artery, aorta)	4
Blalock-Taussig shunt angioplasty	3
Right ventricular biopsy	3
Thrombectomy	1
Surgical Interventions	
Pulmonary artery patch plasty	7
Blalock-Taussig shunt revision	4
Atrial septal surgery	4
Mitral valve repair or replacement	3
RVOT revision	2
Coronary artery revision	2
Pulmonary vein re-repair	2
Take down of Glenn	2

reported. No complication related to transportation of patients to or from the catheterization laboratory were noted. Among the entire cohort, 28 patients (43.8%) survived to hospital discharge; transplant free survival to hospital discharge was 37.5% (24/64). During the same period, 49% (105/215) of all cardiac ECMO patients survived to hospital discharge (P =0.382).

The average interval from ECMO cannulation to catheterization was 1.6 days (IQR 0–2 days) in patients who survived to hospital discharge and 3.5 days (interquartile range [IQR] 1–4 days) in patients who did not ($P = 0.034$). Time to decannulation from catheterization was not significantly different between survivors and non-survivors (median 3 days, IQR 1–5 days for survivors compared with 5 days, IQR 2–8 days for non-survivors; $P = 0.08$). Average time on ECMO support for the patients who underwent catheterization, but no transcatheter or surgical interventions was 8.5 days (± 6.2) and for the group that underwent any intervention was 7.9 days (± 6.8), P value 0.677. As expected, survival to discharge (83% vs 34.6%, P = 0.01) and long-term survival (58.3% vs 32.7%, P = 0.02) were remarkably better for the CM group compared to the CHD group (Fig. 1, Table IV).

Importantly, survival was better for CHD patients who underwent transcatheter interventions compared to the CHD group who underwent no transcatheter or surgical interventions ($P < 0.001$).

DISCUSSION

Our study is the first comprehensive evaluation of pediatric cardiac catheterization on ECMO support in a

TABLE IV. Comparison of CMP and CM Groups

	Entire Cohort (n=64)	CM (n=12; 19%)	CHD (n=52; 81%)	*P* value
Age	1.5 months (0 days–16.7 year)	1.3 year (18 days–12.2 year)	25.6 days (0 days–16.7 year)	0.01
Weight (kg)	3.9 (2.2–63.1)	10.3 (4–63.1)	3.7 (2.2–55)	0.03
Prior Surgical Procedures (%)	70.5	0	86.5	
ECMO-to-Cath Interval, days	1 (0–25)	1 (0–7)	1 (0–25)	0.7
Rate of cath interventions (%)	51.6	100	40.4	0.04
Cath complications (%)	6.7	16.7	4.8	0.06
Survival to hospital discharge (%)	43.8	83	34.6	0.01
Transplant free survival to hospital discharge (%)	37.5	58.3	32.7	0.02
Long-term survival (%)	39	58.3	25	0.01

decade and the largest cohort to date. We have demonstrated in this study that cardiac catheterization in this high-risk, fragile population can be carried out with a relatively low risk of procedural complications. More than half of our cohorts were neonates and many patients were post-operative single-ventricle patients. Hence, this is a very high-risk cohort. Nevertheless, we were able to demonstrate that, cardiac catheterization may play an important role in the population of children on ECMO support. We found that the about three-quarters of catheterizations involved interventions and/or directed subsequent surgical interventions felt to be important to improve hemodynamics.

Utilization of Catheterization on Cardiac ECMO Patients

Our rate of cardiac ECMO (20.5 patients/year) and cardiac catheterizations while on ECMO (7.1 patients/year) are higher than reported in the previous large report (12.7 and 3.5 patients/year, respectively) [6]. Yet, these procedures accounted for only 0.7% of all catheterizations performed at our institution. Our experience is consistent with previous reports of about 30% utilization of catheterization on cardiac ECMO patients [3,6].

Atrial Septoplasty

Atrial septoplasty in the setting of CM was the most common intervention in our cohort; and the survival of this cohort is much better than that of CHD patients. In patients with CM, initiation of ECMO may increase left ventricular afterload and may in fact increase left atrial and left ventricular volume and pressure, wall stress, and may even result in myocardial ischemia [7]. In these patients, then, ECMO often results in severe left atrial hypertension and pulmonary edema. Adequate relief of left atrial hypertension is critical for recovery of cardiac and lung function [7–9]. Incidence of LA decompression in cardiac ECMO has been reported to be about 13%. In CM patients supported on ECMO, transcatheter decompression of left atrium can be reliably achieved with low rates of complication [7]. Blade and balloon atrial septostomy have been reported for atrial septoplasty previously [10–12]. Stents have been used to create and maintain atrial septal communication in a variety of situations, most commonly in congenital heart disease [11,13–17]. We report our successful use of atrial septal stents in the setting of dilated cardiomyopathy and ECMO support. The decision to perform static balloon atrial septoplasty Vs atrial septal stenting was based on subjective assessment of atrial septal thickness and presence or absence of existing septal opening. Stenting of a patent foramen ovale is associated with increased risk of stent embolization and so in those cases, static balloon dilation with or without blade septoplasty was the preferred approach. In cases where a new atrial communication was created by transseptal puncture, primary stenting was the approach used. Adequate characterization of the dilated left atrium and the displaced septal position using left atrial angiography and echocardiography is critical to ensure that the midpoint of the stent straddles the atrial septum. This reduces the risk of stent embolization. Care is also needed to ensure that the stent margins are not in contact with atrial walls to avoid risk of intractable arrhythmias.

Subsequent Interventions in CHD Patients

The rate of subsequent interventions, based upon catheterization data, is notably high in our study. In this cohort, 76.7% of the patients underwent transcatheter and/or surgical interventions while being supported on ECMO. This is consistent with the results of another recently published, smaller study, which found the rate of catheterization, surgical, or hybrid interventions to be 77% [18]. The high rate of interventions noted in our study in a sense justifies the undertaking of an invasive procedure, cardiac catheterization, on cardiac ECMO patients. It is remarkable that nearly half of the CHD patients undergoing cardiac catheterization had single ventricle cardiac physiology. In fact, hypoplastic left heart syndrome status post Norwood procedure constituted the single largest group of CHD patients. Children, particularly neonates, undergoing staged single ventricle palliation are at high risk for transcatheter interventions [19,20]. In a three-year follow up study of patients in the Single Ventricle Reconstruction trial, the incidence of catheter interventions was 43.1 per 100 patient years [19]. In another recent single center study, nearly 40% of patients undergoing staged single ventricle palliation underwent transcatheter interventions, most commonly following stage 1 palliation [20]. Our study suggests that cardiac catheterizations and transcatheter interventions can be performed safely among the highest risk single ventricle patients, e.g., those on ECMO support. This safety is important, as catheterization is a vital diagnostic and interventional tool for children with complex CHD on ECMO support. Cardiac catheterization is much more successful in identifying important residual cardiac defects in postoperative patients on ECMO, compared to non-invasive imaging such as echocardiography. In fact, cardiac catheterization detects residual lesions about four times more frequently than echo in cardiac ECMO patients [3,6,21–23].

Complications Associated With Cardiac Catheterization on ECMO

The rate of catheterization complications, while generally low, is higher compared to a previous report [6]. A total of five major complications resulted in unplanned catheterization (n = 3) or unplanned surgeries (n = 2). There was no mortality directly attributed to these complications. The complication rate in this cohort may be related to increased patient and procedure complexity. Recent studies have identified catheterization on ECMO as an important risk factor for life threatening complications, severity levels 4 and 5 [24–26]. The majority of the patients in our cohort belonged to risk category 3 or 4 according to the Catheterization for Congenital Heart Disease Adjustment for Risk Method (CHARM) scoring system [25]. A significant proportion of the patients being infants or neonates also contributed to the complexity of the cases. Previous reports from the Congenital Cardiac Catheterization Project on Outcomes (C3PO) registry noted a nearly 25% incidence of complications in patients weighing less than 5 kg [27].

As noted in our study, cardiac catheterization on ECMO is a rare occurrence, even in large volume centers. Further prospective evaluation of complications and outcomes of catheterization on ECMO through multicenter registries like C3PO registry and Improving Pediatric and Adult Congenital Treatment (IMPACT) registry are required for quality improvement [28]. What is also remarkable in our study is the absence of vascular access complications and intra-hospital transport related complications in our cohort.

Transport of critically ill patients supported on ECMO creates enormous logistical challenges and requires coordination of multiple services. Most of the transports on ECMO support are to the catheterization laboratory or to the radiologic suite and can be done safely in centers with experience [23]. Recent data from IMPACT registry reveals that 86% of all pediatric cardiac catheterizations are performed under general anesthesia [27]. In our experience, the performance of cardiac catheterization on children receiving ECMO support is best done with a dedicated cardiac team, preferably with a pediatric cardiac anesthesiologist and with appropriate cardiac surgical back-up. Such a comprehensive team approach is essential to conducting these high-risk procedures safely. Adequate preparation and expertise to deal with possible complications and appropriate pre-procedural family counselling prior to the procedure are also essential components in this high-risk procedure.

Survival Rates

Finally, analysis of the survival data reveals two distinct group of patients supported on ECMO who underwent catheterization. The first group is the CM cohort with a hospital survival rate of 83% and the second group being CHD patients with a hospital survival rate of 34.6%. These survival rates compare to a hospital discharge rate of 49.0% for all cardiac ECMO patients in our institution during the same period. Patients who undergo catheterization on ECMO are generally sicker than non-cath patients and that may explain in part the lower survival rate of cath-ECMO cohort. The published rates of survival to hospital discharge have varied widely. For cardiac ECMO-cardiopulmonary resuscitation (eCPR), survival has been reported at 46% [29]. For single ventricle patients, the overall survival rate has been reported at 37%, but for Glenn, Fontan, and total anomalous pulmonary venous connection patients, the survival rate is much lower yet [30]. Another large multicenter study indicated survival to discharge rate of 53% for all cardiac ECMO patients [31]. For a recent, albeit smaller cohort of catheterization on ECMO patients the survival to hospital discharge was 77.2%, similar to their control group of cardiac ECMO patients without any catheterization [18]. This higher survival rate may be attributable to their shorter ECMO to catheterization time (median of 8 hours) and lower patient complexity. In our study also, the ECMO to catheterization time was significantly shorter for survivors compared to non-survivors (1.6 days vs 3.5 days). This data may cause one to question the conventional wisdom of purposefully waiting to allow time for spontaneous cardiac recovery. Our results are consistent with a recent publication, which showed improved decannulation rates and hospital discharge if residual lesions are detected in the first 3 days after ECMO initiation [3]. Among the CHD patients on ECMO, the best survival was for patients who received percutaneous interventions. This also points to the utility of early cardiac catheterization on ECMO. The total time on ECMO support was not significantly different for patients who underwent transcatheter and or surgical interventions compared to the no-intervention group. This result is confounded by cases of withdrawal of care following irreversible complications on ECMO or perception of futility of continued care on ECMO following exclusion of reversible residual defects on catheterization. What is clear is that catheter-based interventions were performed, and performed safely, in this critically ill, vulnerable population.

Limitations

The authors felt that the indication for ECMO, catheterization, and the decision to undertake decannulation were based on clinical judgment and somewhat arbitrary and so they were not included in the analysis. We did not collect data on cardiac arrest to ECMO cannulation time as it was assumed to be immediate in most cases and not likely to be statistically significant.

CONCLUSIONS

Cardiac catheterization and transcatheter interventions can be performed with low rate of complications in patients supported by ECMO. Cardiac catheterization was associated with high rate of transcatheter and surgical interventions, which in turn conferred survival advantage in patients supported on ECMO. Earlier performance of catheterization after institution of ECMO was associated with better survival. CM group has a distinct survival advantage compared to the CHD group.

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