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# Seminal Postoperative Complications and Mode of Death After Pediatric Cardiac Surgery

Michael Gaies, MD<sup>1</sup>, Sara K. Pasquali, MD<sup>1</sup>, Janet E. Donohue, MPH<sup>2</sup>, Justin B. Dimick, MD<sup>3</sup>, Sarah Limbach, RN<sup>4</sup>, Nancy Burnham, CRNP<sup>4</sup>, Chitra Ravishankar, MD<sup>5</sup>, Richard G. Ohye, MD<sup>6</sup>, J. William Gaynor, MD<sup>4</sup>, and Christopher E. Mascio, MD<sup>4</sup>

<sup>1</sup>Department of Pediatrics and Communicable Diseases, University of Michigan Medical School, Ann Arbor, MI

<sup>2</sup>Michigan Congenital Heart Outcomes Research and Discovery Unit, Ann Arbor, MI

<sup>3</sup>Department of Surgery, University of Michigan Medical School, Ann Arbor, MI

<sup>4</sup>Division of Cardiac Surgery, The Children's Hospital of Philadelphia, Philadelphia, PA

<sup>5</sup>Department of Pediatrics, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

<sup>6</sup>Department of Cardiac Surgery, University of Michigan Medical School, Ann Arbor, MI

# Abstract

**Background**—Understanding the seminal complications leading to death after pediatric cardiac surgery may provide opportunities to reduce mortality. We analyzed all mortalities at two pediatric cardiac surgical programs and developed a method to identify the seminal complications and modes of death.

**Methods**—Trained nurses abstracted all cases of in-hospital mortality meeting inclusion criteria from each site over 5 years (2008–2012). Complication definitions were consistent with those of a multi-center clinical registry. An adjudication committee assigned a seminal complication in each case (the complication initiating the cascade of events leading to death). Seminal complications were grouped into categories to designate "mode of death". The epidemiology of seminal complications and mode of death was described.

**Results**—In 191 subjects, low cardiac output syndrome (LCOS, 71% of all subjects), cardiac arrest (52%), and arrhythmia (48%) were the most common complications. The committee assigned LCOS (30%), failure to separate from bypass (16%), and cardiac arrest (12%) most frequently as seminal complications. Seminal complications occurred a median 2 hours (interquartile range, [IQR] 0–35 hours) post-operatively. Patients experienced a median 7 (IQR, 3–12) additional complications prior to death at median 15 days (IQR, 4–46). Systemic circulatory

Corresponding author: Michael Gaies, C.S. Mott Children's Hospital, 1540 E. Hospital Drive, Ann Arbor, MI 48109-4204, Fax: 734-936-9470, mgaies@med.umich.edu.

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failure was the most common mode of death (51%), followed by inadequate pulmonary blood flow (13%) and cardiac arrest (12%).

**Conclusions**—Seminal complications occurred early post-operatively and systemic circulatory failure was the most common mode of death. Our classification system is likely scalable for subsequent multi-center analysis to understand cause-specific mortality variation across hospitals and drive quality improvement.

#### Keywords

Congenital Heart Disease; Cardiac Surgery; Complications; Postoperative Care; Outcomes

Despite advances in operative technique and perioperative care, surgical mortality for children undergoing complex congenital cardiac surgery remains high, with rates approaching 25% for more complex procedures like the Norwood operation [1, 2]. Furthermore, significant variation in postoperative mortality exists across centers, suggesting opportunities for continued improvement [3, 4].

For adults undergoing cardiac surgery, postoperative mortality has declined significantly [5], and this improvement resulted in part from research elucidating high-leverage postoperative complications and the drivers of differences in mortality between low- and high-performing surgeons [6, 7]. Methods to identify the seminal complication or "mode of death" – the first complication that begins a cascade of downstream events ultimately leading to death (Figure 1) – served as the foundation for successful quality improvement initiatives to improve mortality rates. In contrast, the epidemiology of seminal complications leading to death after pediatric cardiac surgery is not well established. Further, the existing literature [8] has not been translated into actionable quality improvement. Determining the modes of death, cause-specific mortality rates, and variation in these rates across centers could inform efforts to reduce preventable deaths for children undergoing cardiac surgery.

In this context, we performed a detailed analysis to characterize post-operative complications leading to mortality at two high-volume pediatric cardiac surgical centers. We aimed to identify the seminal complication that ultimately led to mortality using standardized definitions from a multi-institutional clinical registry - the Pediatric Cardiac Critical Care Consortium (PC<sup>4</sup>) [9] - in order to facilitate future research efforts intended to characterize causes of perioperative mortality, describe variation between centers, and highlight targets for quality improvement.

# **Material and Methods**

#### Setting

This analysis was performed at The Children's Hospital of Philadelphia and the University of Michigan C.S. Mott Children's Hospital. Both centers participate in the Pediatric Cardiac Critical Care Consortium (PC<sup>4</sup>), a quality improvement collaborative for children with critical cardiovascular disease maintaining a clinical registry on all surgical patients admitted to the cardiac intensive care unit (CICU) pre- and post-operatively. We undertook this study

to inform a subsequent prospective investigation of variation in mode of death across  $PC^4$  centers.

#### **Case selection**

We used surgical registry data collected for the Society of Thoracic Surgeon's (STS) Congenital Heart Surgery Database to identify every in-hospital mortality after cardiothoracic surgery between 1/1/2008 and 12/31/2012 at both hospitals. We excluded cases from analysis according to the following criteria: 1) patient died in the operating room, 2) postoperative care not provided in the CICU, 3) procedure other than cardiovascular surgery or thoracic surgery with cardiopulmonary bypass, 4) primary procedure was PDA ligation in neonate <2.5kg, or 5) the patient's only surgical procedure was placement of temporary pacemaker wires for congenital heart block and fetal hydrops. Both Institutional Review Boards provided approval for the study without the need for written informed consent prior to data collection.

#### **Data collection**

Our methodology largely mirrors the seminal work of O'Connor [6], and methods explored by Ma [8] in a congenital cardiac population. In each of these analyses patient charts were abstracted and from these data expert clinicians assigned a mode of death. Mode of death was the complication or condition that represented the primary reason for the patient's death.

Chart abstraction forms were created and included pre-operative characteristics, comorbidities, anatomy, all major invasive procedures, and intraoperative variables from the index cardiothoracic operation. We defined prematurity in neonates as gestational age at birth <39 weeks [10]. We classified surgical complexity using the Society of Thoracic Surgeons- European Association for Cardiothoracic Surgery (STAT) mortality categories [11]. Complications were defined according to the PC<sup>4</sup> data dictionary, which will be the data source for follow-up investigation. The definition of almost every shared field matches that of the STS database. The investigators defined low cardiac output syndrome and complications not currently collected by either registry in the study manual of operations.

Trained cardiac surgical research nurses with clinical experience in caring for postoperative pediatric cardiac surgical patients reviewed each chart including physician notes, laboratory data, flowsheets, and imaging reports. The abstractors recorded every defined postoperative complication and the date and time the complication occurred. Complications could be recorded multiple times. Investigators held regular meetings with the teams to review definitions, discuss coding difficulties, and ensure consistency between sites.

# Identifying the seminal complication

After determining the sequence of complications the abstractor was asked to code the seminal complication as described by O'Connor et al [6]. The seminal complication is that which starts the cascade of clinical events that ultimately lead to a patient's demise, and frequently is not the terminal condition immediately preceding death. For example, a patient undergoing arterial switch operation may fail to separate from cardiopulmonary bypass

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necessitating mechanical circulatory support. While that patient may eventually be weaned, if he/she subsequently develops sepsis and multiorgan failure, the initial complication of failure to separate from bypass would be considered the seminal complication. The conceptual framework for this approach suggests that downstream complications are likely the result of those occurring earlier. In the previous example, the patient who requires extracorporeal membrane oxygenation (ECMO) assumes greater risk for infection given the dependence on invasive devices, tissue damage, inflammation, delay in feeding, and multiple interventions. Sepsis and multiorgan failure likely would not have occurred if the patient separated easily from bypass and did not require ECMO.

In most cases, the seminal complication was one of the first to occur after the initial index cardiothoracic surgery. For patients undergoing a second planned operation after the index procedure during the same hospitalization (e.g. superior cavopulmonary anastomosis after stage 1 palliation for functional single ventricle), we only considered complications occurring after the second procedure as possible seminal complications. We believed patients who survived a first operation to undergo an elective planned operation with an intervening period of clinical stability were most likely to die as the result of an event occurring after the most recent surgery. For patients having unplanned surgical reintervention we assessed complications after the index surgery.

In the unique situation where a patient was cannulated to ECMO in the operating room, this was always selected as the seminal complication and was termed "failure to separate from bypass." We did not attempt to determine the specific etiology for failure to separate. All other events leading to mechanical circulatory support were preceded by another complication, and that complication was selected as the seminal complication.

After assignment of the seminal complication by the abstractors, the investigators convened an adjudication meeting to confirm or change the seminal complication designation. Three pediatric cardiac surgeons, two cardiologists, and one cardiac intensivist met in-person to review the data abstraction forms and perform a limited secondary review of the medical record. The adjudication committee rendered its decision on the seminal complication independently, and agreed unanimously on all cases.

#### Classifying mode of death

Following the methodology of O'Connor [6], seminal complications were grouped into categories based on consensus among the clinician investigators (see AppendixTable 1): systemic circulatory failure, inadequate pulmonary blood flow, cardiac arrest, postoperative hemorrhage, respiratory failure, arrhythmia, and other. These categories represent the mode of death.

#### Analysis

Standard descriptive statistics were used to characterize the overall cohort and frequencies of complications. Differences in seminal complication designation between the nurse abstractors and clinical adjudication committee are presented, and an overall percentage agreement calculated. Since systemic circulatory failure was the most common mode of death seen in just over half the patients, we performed univariate comparisons of patient and

operative variables between those with systemic circulatory failure and those with other modes; Chi-square and fisher's exact tests for categorical variables, and Wilcoxon rank-sum test for continuous variables. All analyses were performed using SAS Version 9.4 (SAS Institute Inc, Cary, NC), with statistical significance at a p-value less than 0.05.

# Results

Across both institutions there were 205 in-hospital mortalities during the study period. Of these, 14 were excluded based on the defined criteria: 4 patients died in the operating room, 5 patients did not receive care in the CICU post-operatively, 3 patients had only placement of temporary pacing wires for congenital heart block and hydrops fetalis, and two patients did not have a qualifying surgery.

Characteristics of the 191 patients included for analysis are shown in Table 1. Neonates and infants made up 87% of the total cohort. Pre-operative shock, mechanical circulatory support, and cardiac arrest occurred infrequently. Most patients (n=136, 71%) were classified in STAT categories 4 or 5, or had unassignable primary procedures.

#### Epidemiology of all postoperative complications

Table 2 shows the percentage of patients who experienced each complication at least once postoperatively. Low cardiac output syndrome (LCOS), cardiac arrest, arrhythmia, need for mechanical circulatory support, and chronic respiratory failure were the most common complications. Also shown in Table 2 is the epidemiology of the initial complication for each patient. LCOS was the most common initial complication, followed by failure to separate from bypass and arrhythmia.

#### Epidemiology of seminal complications

Table 3 illustrates the frequency of seminal complications designated by the clinical adjudication committee and compared to the nurse abstractors. The seminal complication (assigned by the committee) was most commonly LCOS, failure to separate from bypass, or cardiac arrest. These were also the three most common chosen by the nurse abstractors, but there were differences on individual cases. The clinical adjudication committee and the nurse abstractors agreed in 66% of cases; agreement includes both complication type and timing (i.e. if a patient had multiple episodes of LCOS, both the committee and abstractor chose the same episode).

The seminal complication was the initial postoperative complication in only 66% of cases. Seminal complications occurred at median 2 hours (interquartile range [IQR], 0–35 hours) after admission to the CICU. In 36% of cases the seminal complication was present at CICU arrival, and in 73% the seminal complication occurred within the first 24 hours. The median time from seminal complication to death was 15 days (IQR, 4 – 46 days), and patients experienced a median of 7 (IQR, 3–12) additional complications prior to death.

#### Mode of death

Individual complications were grouped into categories defining mode of death as described above. As shown in Figure 2, systemic circulatory failure was the most common mode of death, followed by inadequate pulmonary blood flow and cardiac arrest. Table 4 shows the comparison of patients with systemic circulatory failure to those in all other mode of death categories. Patients with systemic circulatory failure had longer median total bypass time (130 vs. 91 minutes, p<0.0001) and were less likely to have undergone a pre-operative non-surgical intervention (14% vs. 26%, p=0.046) than patients in other mode of death categories. Age, preoperative risk factors, non-cardiac anomalies, and surgical complexity were similar between the groups.

# Comment

We performed a detailed analysis characterizing the epidemiology of postoperative complications from all in-hospital mortalities at two large pediatric cardiac surgical centers over five years. In this analysis, the seminal complication usually occurred within 24 hours after postoperative admission to the CICU, and patients experienced several downstream complications thereafter prior to death. Systemic circulatory failure was the most common mode of death, occurring in approximately half of the overall cohort. Important case mix factors such as age, comorbidities, and surgical complexity were similarly distributed among those with systemic circulatory failure and all other modes of death.

The experience of the Northern New England Cardiovascular Disease Study Group suggests that understanding the epidemiology of postoperative complications and analyzing variation in mode of death across hospitals can be a cornerstone for effective initiatives to reduce operative mortality [7]. Their analysis of mode of death after coronary artey bypass grafting demonstrated that variation in low output heart failure accounted for 80% of the difference in surgeon mortality rates within the collaborative [6]. Armed with this information, clinicians and researchers were able to focus on the key drivers of death from low output heart failure, and discovered the practices of high performing surgeons and hospitals that positively impacted prevention, identification, and treatment of this seminal complication. After disseminating these practices throughout the region the group achieved significant and longlasting reductions in operative mortality [7, 12].

Based on this roadmap for successful quality improvement in cardiac surgical care, we sought to develop a methodology for analyzing the seminal complication and mode of death after pediatric cardiac surgery in a way that can be scaled up for analysis in a multi-institutional quality collaborative. We believe that understanding variation in mode of death across hospitals may provide actionable data to help elucidate the hospital structures and processes that underlie high quality pediatric cardiac surgical care.

Several important insights were gleaned from this study to inform future research efforts. Our findings suggest that we cannot simply assign the first complication chronologically as the seminal complication; one-third of the seminal complications adjudicated by the clinicians were not the initial complication. Secondly, this study illustrates the necessity of the adjudication committee review; the committee changed the seminal complication in 33%

of cases based on a different interpretation of the clinical events. Similarly, in O'Connor's study [6] the coming a complication could be excited according to acding rules in only 400

study [6] the seminal complication could be assigned according to coding rules in only 40% of cases, while the clinical endpoints committees assigned mode of death in the remainder. Clinical adjudication is a logistical challenge for a multi-center study, but our analysis and previous work suggest that simpler methods may not lead to accurate classification of cases.

Our study represents a necessary initial step in a larger effort to characterize the epidemiology of postoperative mortality after pediatric cardiac surgery and plan interventions to reduce preventable deaths. However, our analysis remains limited in important ways, in part due to the heterogeneity of the patient population with regard to age and disease. We have characterized the mode of death using observable variables in the medical record captured in a clinical registry, but there are additional factors that might provide a deeper view into the etiology of perioperative mortality, and may be lesion and/or procedure specific. For example, systemic circulatory failure could be due to severe preoperative myocardial dysfunction, poor myocardial preservation during bypass, residual cardiac lesions, or ineffective recognition or treatment of postoperative circulatory failure. Further study must identify the high-leverage modes of death driving the difference between low-and high-mortality hospitals. Ultimately, this will inform further study of specific etiologies of complications, and the clinical practices and hospital factors that lead to high quality care.

Our study is also limited similar to previous mode of death analyses by not including survivors. Determining the frequency of complications in all patients is necessary to understand whether low-mortality hospitals achieve these results through prevention or treatment of key complications. Recent literature suggests that a hospital's response to complications may be of equal or greater importance than prevention. Failure-to-rescue (mortality rate among patients with a complication) explains much of the variation in overall perioperative mortality between hospitals across multiple surgical specialties, including pediatric cardiac surgery [4, 13]. Future analyses that demonstrate how high-performing hospitals achieve better rescue rates are necessary to create actionable data that can be disseminated to drive quality improvement. Since all events and therapies are time-stamped in the PC<sup>4</sup> database, it will be possible in subsequent studies to delineate the frequency and sequence of all postoperative complications. This will facilitate calculation of cause-specific mortality and failure-to-rescue rates since the frequency of complications will be known in survivors and non-survivors. Analysis of cause-specific failure-to-rescue in a multiinstitutional dataset would be unique and could provide valuable insight that accelerates improvements in perioperative care for pediatric cardiac surgical patients.

Finally, aspects of clinical decision-making - not captured in this study or any clinical registry – may profoundly impact patient outcome: was the correct surgery selected among the different options? Was the timing of the procedure optimal given the patient's physiology and comorbidities? These questions and many others must be addressed through empirical analyses and collaborative learning approaches. These future iterations can be accomplished more effectively if the approach we present here is repeated across a multi-institutional dataset providing guidance for more refined investigation.

In conclusion, it remains unknown how mode of death after pediatric cardiac surgery varies across hospitals, and determining this variation could provide targets to improve clinical outcomes. We present a method for classifying the seminal complication and mode of death for children undergoing cardiac surgery that will be applied prospectively within a multi-institutional quality collaborative. Similar research efforts have proved invaluable in adult cardiac surgery quality improvement, and if replicated will perhaps lead to important advances in the pediatric realm as well.

# Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

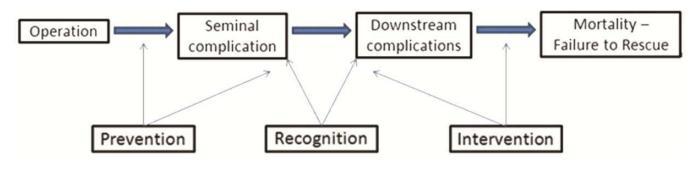
# Acknowledgments

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# Figure 1.

Conceptual model of postoperative complications leading to mortality

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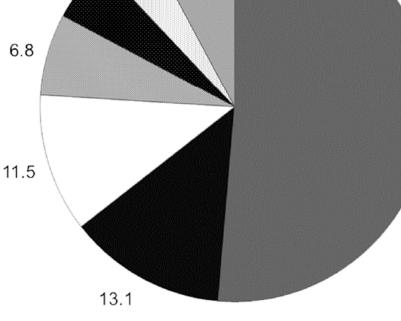
- Systemic Circulatory Failure
- Inadequate Pulmonary Blood Flow

Cardiac Arrest

- Respiratory Failure
- Postoperative Bleeding
- 🗉 Arrhythmia

Other

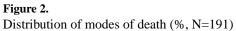
51.3



7.8

4.2

5.2



# Overall cohort characteristics

Characteristic	N(%), Med (IQR)
Patient/Pre-operative	
Age, days	13 (5–129)
Neonate (0-30 days)	110 (57%)
Infant (1 mo – 1 year)	57 (30%)
Child (1 – 18 years)	24 (13%)
Weight for age z-score	
<-2	81 (42%)
-2 to +2	108 (57%)
>2	2 (1%)
Hospital	
Philadelphia	95 (50%)
Michigan	96 (50%)
Non-cardiac abnormalities	
Genetic abnormality	18 (9%)
Extracardiac anomaly	35 (18%)
Syndrome	39 (20%)
Prematurity (<39 weeks gestational age) if neonate	71/110 (65%)
37–39 weeks	40 (36%)
<37 weeks	31 (28%)
Pre-operative risk factors	
Cardiac arrest	4 (2%)
Pre-op MCS	2 (1%)
Shock at surgery	1 (1%)
Shock, resolved	10 (5%)
Mechanical ventilation	51 (27%)
Previous cardiothoracic surgery	38 (20%)
Pre-operative non-surgical intervention during hospitalization	38 (20%)
Operative	
STAT category (or score)	
1	4 (2%)
2	23 (12%)
3	28 (15%)
4	83 (43%)
5	45 (24%)
Unassignable	8 (4%)
Primary procedure (groups)	
Hypoplastic left heart and related	44 (23%)
Palliative procedures	27 (14%)
Right heart lesions	20 (10%)

Characteristic	N(%), Med (IQR)
Thoracic arteries/veins	17 (9%)
Pulmonary venous anomalies	14 (7%)
Septal defects	14 (7%)
Transposition of the great arteries	12 (6%)
Other single ventricle	11 (6%)
Left heart lesions	9 (5%)
Ventricular assist device	9 (5%)
Truncus arteriosus	4 (2%)
Double outlet right ventricle	3 (2%)
Conduit operations	2 (1%)
Electrophysiological	2 (1%)
Pericardial disease	1 (1%)
Thoracic and mediastinal disease	1 (1%)
Miscellaneous procedures	1 (1%)
Primary procedure	
Single ventricle, with arch involvement	43 (23%)
Single ventricle, no arch involvement	34 (18%)
Two ventricle, with arch involvement	14 (7%)
Two ventricle, no arch involvement	100 (52%)
Cardiopulmonary bypass time, minutes	106 (73–158)

MCS, mechanical circulatory support; STAT, Society of Thoracic Surgeons-European Association for Cardiothoracic Surgery

# Frequency of complications

Complication	Ever among all patients, N (%)	As initial complication, N (%)
Cardiac and operative		
Low cardiac output syndrome	135 (71%)	73 (38%)
Need for MCS	88 (46%)	30 (16%)
Cardiac arrest	99 (52%)	12 (6%)
Unplanned cardiac re-intervention	62 (32%)	2 (1%)
Pulmonary hypertension	18 (9%)	9 (5%)
Hypoxemia	53 (28%)	11 (6%)
Pericardial effusion	9 (5%)	0
Arrhythmia	92 (48%)	25 (13%)
CHB requiring PPM	3 (2%)	0
Hemorrhagic/Thrombotic		
Bleeding requiring transfusion	40 (21%)	7 (4%)
Bleeding requiring operation	27 (14%)	4 (2%)
Thrombosis	28 (15%)	0
Shunt thrombosis	5 (3%)	0
Respiratory		
Acute respiratory failure	41 (21%)	3 (2%)
Chronic respiratory failure	83 (43%)	1 (1%)
Chylothorax	28 (15%)	1 (1%)
Pleural effusion requiring drainage	47 (25%)	1 (1%)
Prolonged pleural drainage	18 (9%)	0
Vocal cord paralysis	4 (2%)	0
Diaphragm paralysis	1 (1%)	0
Neurologic		
Seizure	42 (22%)	0
Stroke	16 (8%)	0
Hypoxic-ischemic encephalopathy	37 (19%)	0
Renal		
Acute kidney injury	51 (27%)	2 (1%)
Acute renal failure requiring dialysis	43 (23%)	0
Other		
Necrotizing enterocolitis	17 (9%)	1 (1%)
Hospital acquired infection	74 (39%)	0
Hepatic failure	28 (9%)	0
Other	122 (64%)	9 (5%)

CHB, Complete heart block; MCS, mechanical circulatory support; PPM, permanent pacemaker

# Seminal complications

Complication	N (%) seminal complication by adjudication commmittee	N (%) seminal complication by abstractor
Cardiac and operative		
Low cardiac output syndrome	57 (30%)	78 (41%)
Failure to separate from bypass	31 (16%)	30 (16%)
Cardiac arrest	22 (12%)	18 (9%)
Unplanned cardiac re-intervention	7 (4%)	4 (2%)
Pulmonary hypertension	12 (6%)	7 (4%)
Hypoxemia	13 (7%)	14 (7%)
Arrhythmia	8 (4%)	18 (9%)
Hemorrhagic/Thrombotic		
Bleeding requiring transfusion	4 (2%)	4 (2%)
Bleeding requiring operation	6 (3%)	1 (1%)
Thrombosis	1 (1%)	3 (2%)
Shunt thrombosis	1 (1%)	0
Respiratory		
Acute respiratory failure	3 (2%)	5 (3%)
Chronic respiratory failure	9 (5%)	1 (1%)
Chylothorax	3 (2%)	2 (1%)
Diaphragm paralysis	1 (1%)	0
Neurologic		
Stroke	1 (1%)	0
Hypoxic-ischemic encephalopathy	0	1 (1%)
Renal		
Acute kidney injury	1 (1%)	1 (1%)
Other		
Necrotizing enterocolitis	1 (1%)	1 (1%)
Hospital acquired infection	1 (1%)	1 (1%)
Hepatic failure	0	1 (1%)
Other	9 (5%)	1 (1%)

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Characteristics of patients with circulatory failure vs. others

Characteristic	Patients with circulatory failure (N=98)	Patients with other mode of death (N=93)	p <sup>‡</sup>
Patient/Pre-operative			
Age			0.41
Neonate (0–30 days)	60 (61%)	50 (54%)	
Infant (1 month – 1 year)	25 (26%)	32 (34%)	
Child (1 – 18 years)	13 (1413%)	11 (12%)	
Weight for age z-score			0.07
<-2	36 (37%)	56 (60%)	
-2 to +2	60 (61%)	47 (51%)	
>2	2 (2%)	0	
Hospital			0.03
Philadelphia	41 (42%)	54 (58%)	
Michigan	57 (58%)	39 (42%)	
Non-cardiac abnormalities			
Genetic abnormality	8 (8%)	10 (11%)	0.54
Extracardiac anomaly	15 (15%)	20 (22%)	0.27
Syndrome	18 (18%)	21 (23%)	0.45
Prematurity (<39 wks) if neonate	37/60 (62%)	34/50 (68%)	0.40
Pre-operative risk factors			
Cardiac arrest	1 (1%)	3 (3%)	0.36
Pre-operative MCS	0	2 (2%)	0.24
Shock at surgery	0	1 (1%)	0.49
Shock, resolved	5 (5%)	5 (5%)	1.00
Mechanical ventilation	25(25%)	26 (28%)	0.70
Previous cardiothoracic surgery	18 (18%)	20 (22%)	0.56
Pre-operative non-surgical intervention during hospitalization	14 (14%)	24 (26%)	0.046
Operative			
STAT category			0.70
1–3	27 (28%)	28 (30%)	
4–5 and unassigned	71 (72%)	65 (70%)	
Primary procedure (groups)			0.35
Single ventricle, arch	26 (27%)	17 (18%)	
Single ventricle, no arch	14 (14%)	20 (21%)	
Two ventricle, arch	6 (6%)	8 (9%)	
Two ventricle, no arch	52 (53%)	48 (52%)	
Cardiopulmonary bypass time, minutes	130 (91–196)	91 (71–119)	< 0.0001

 $^{\ddagger}$ Chi-square/fisher's exact for categorical; Wilcoxon rank-sum for continuous

MCS, mechanical circulatory support; STAT, Society of Thoracic Surgeons-European Association for Cardiothoracic Surgery