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Authors
Pasquali, Sara K
Ohye, Richard G
Lu, Minmin
et al.

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Variation in Perioperative Care across Centers for Infants Undergoing the Norwood Procedure

Sara K. Pasquali, MD MHS[1], **Richard G. Ohye, MD**[2], **Minmin Lu, MS**[3], **Jonathan Kaltman, MD**[4], **Christopher A. Caldarone, MD**[5], **Christian Pizarro, MD**[6], **Carolyn Dunbar-Masterson, BSN, RN**[7], **J. William Gaynor, MD**[8], **Jeffrey P. Jacobs, MD**[9], **Aditya K. Kaza, MD**[10], **Jane Newburger, MD, MPH**[7], **John F. Rhodes, MD**[1], **Mark Scheurer, MD**[11], **Eric Silver, MD**[12], **Lynn A. Sleeper, ScD**[3], **Sarah Tabbutt, MD, PhD**[13], **James Tweddell, MD**[14], **Karen Uzark, PhD**[15], **Winfield Wells, MD**[16], **William T. Mahle, MD**[17], and **Gail D. Pearson, MD, ScD**[4]

[1]Duke University Medical Center, Durham, NC; Department of Pediatrics and Duke Clinical Research Institute

[2]University of Michigan, Ann Arbor, MI; Section of Pediatric Cardiovascular Surgery

[3]New England Research Institutes, Watertown, MA

[4]National Heart, Lung, and Blood Institute/NIH, Bethesda, MD, Division of Cardiovascular Sciences

[5]Toronto Hospital for Sick Children, Toronto, Ontario, Canada; Department of Surgery

[6]Nemours Cardiac Center, Alfred I. duPont Hospital for Children, Wilmington, DE

[7]Children's Hospital Boston, Boston, MA; Department of Cardiology

[8]Children's Hospital of Philadelphia, Philadelphia, PA; Division of Cardiothoracic Surgery

[9]Congenital Heart Institute of Florida, St. Petersburg, FL

[10]Primary Children's Medical Center, Salt Lake City, UT; Division of Pediatric Cardiothoracic Surgery

[11]Medical University of South Carolina, Charleston, SC; Division of Pediatric Cardiology

[12]Columbia University Medical Center, New York City, NY; Department of Pediatrics

[13]Children's Hospital of Philadelphia, Philadelphia, PA; Department of Pediatrics

[14]Children's Hospital of Wisconsin, Milwaukee, WI; Division of Cardiothoracic Surgery

[15]Cincinnati Children's Hospital Medical Center, Cincinnati, OH; Department of Pediatrics

[16]Children's Hospital of Los Angeles, Los Angeles, CA; Division of Cardiothoracic Surgery

[17]Children's Healthcare of Atlanta, Emory University School of Medicine, Atlanta, GA

Abstract

Corresponding Author: Sara K. Pasquali MD MHS Associate Professor of Pediatrics Division of Cardiology, Department of Pediatrics Duke University Medical Center Duke Clinical Research Institute PO Box 17969 Durham, NC 27715 Phone: 919-668-4686; Fax: 919-668-7058 sara.pasquali@duke.edu.

Objectives—In the Single Ventricle Reconstruction Trial, infants undergoing the Norwood procedure were randomized to a right ventricle-to-pulmonary-artery shunt or modified Blalock-Taussig shunt. Apart from shunt type, subjects received local standard of care. We evaluated variation in peri-operative care during the Norwood hospitalization across 14 trial sites.

Methods—Data on pre-operative, operative, and post-operative variables were collected prospectively on standardized case report forms, and variation across centers described for 546 enrolled subjects who underwent the Norwood procedure.

Results—Subjects' gestational age, birth weight, and proportion with hypoplastic left heart syndrome were similar across sites. In contrast, all recorded variables related to pre-operative care varied across centers, including fetal diagnosis (range 55–85%), preoperative intubation (range 29–91%), and enteral feeding. Perioperative/operative factors were also variable across sites including median total support time (range 74–189 minutes) and other perfusion variables, arch reconstruction technique, intraoperative medication use, and use of modified ultrafiltration (range 48–100%). Additional variation across centers was seen in variables related to postoperative care, including proportion with an open sternum (range 35–100%), median intensive care unit length of stay (range 9–44 days), type of feeding at discharge, and enrollment in a home monitoring program (range 1–100%; 5 sites did not have a program). Overall inhospital death/transplant occurred in 18% (range across sites 7–39%).

Conclusions—Perioperative care during the Norwood hospitalization varies across centers. Further analysis evaluating the underlying causes and relationship of this variation to outcome is needed to inform future studies and quality improvement efforts.

Introduction

The Norwood procedure for infants with hypoplastic left heart syndrome was first described in 1981 (1). Over the past 3 decades, outcomes following the Norwood procedure have improved due to refinements in surgical and perioperative care (2,3). However, morbidity and mortality remain significant, and evidence to guide optimal care is still evolving (4,5).

The Pediatric Heart Network (PHN), funded by the National Heart, Lung, and Blood Institute, recently conducted the Single Ventricle Reconstruction (SVR) trial in which 555 infants with hypoplastic left heart syndrome or related single right ventricle anomalies undergoing the Norwood procedure were randomized to the right ventricle-to-pulmonary artery shunt or modified Blalock-Taussig shunt as the source of pulmonary blood flow (5). The primary endpoint, transplant-free survival 12 months after randomization, was significantly higher in the right ventricle-to-pulmonary artery shunt group compared with the modified Blalock-Taussig shunt group (74% vs. 64%; p=0.01) (5). Follow-up of the trial cohort continues, to evaluate whether the survival benefit is maintained (5).

Apart from shunt type, subjects enrolled in the SVR trial received local standard of care, and detailed pre-operative, operative, and post-operative information was prospectively collected. Evaluation of these data provides a unique opportunity to describe the range of care across centers, and assess variation in a large well-characterized cohort. This is an important first step in identification of areas of potential future research focus and quality improvement. Previous studies have suggested variation in several aspects of care for patients undergoing the Norwood procedure, but have been limited in scope, and by the use of retrospective survey methodology (4,6,7). Thus, the purpose of this analysis was to describe the range of perioperative care during the Norwood hospitalization across sites participating in the SVR trial, and quantitate the degree of inter-institutional variation.

Patients and Methods

Patient population and trial design

Details of the SVR trial (ClinicalTrials.gov number, NCT00115934) design have been published previously (8). In brief, infants with a diagnosis of single, morphological right ventricle, undergoing the Norwood procedure were eligible for inclusion in the trial. Exclusion criteria included single, morphological left ventricle, preoperative anatomic features rendering either a modified Blalock-Taussig shunt or a right ventricle-to-pulmonary artery shunt technically impossible, and any major congenital or acquired extracardiac abnormality thought to independently affect survival or need for cardiac transplantation. Patients were randomized during 2005–2008 at 15 North American clinical centers with 39 surgeons participating. Dynamic allocation within surgeon was utilized to ensure that no single surgeon had a preponderance of one shunt type. All of the sites were medium or high-volume congenital heart surgery sites. For the purposes of this analysis, one site that enrolled only three patients during the trial was excluded. In the remaining 14 sites, the number of patients enrolled per site ranged from 10–101 (median = 34). The SVR trial was approved by the institutional review board at all participating institutions, and informed consent was obtained from a parent or guardian.

Data collection

Detailed information regarding preoperative, perioperative/operative, and postoperative care was prospectively recorded on standardized case report forms (8). Apart from the shunt type assigned in the trial, subjects received standard care at their institution. The postoperative period was defined as ending at the Norwood hospitalization discharge or the Stage II procedure if the patient was not discharged between the two operations. The goal of our study was to describe the range of care across sites in a large well-characterized cohort, rather than determine the specific underlying causes of any variation identified; thus, all data related to perioperative care were included. Some of the variables examined likely primarily reflect management practices, while others may be related more to patient characteristics or outcome. Several variables may represent a combination of these factors.

Preoperative variables collected included fetal diagnosis, fetal intervention, endotracheal intubation, use of inhaled gases, and enteral feeding. Perioperative/operative variables included age at surgery, total support time and perfusion techniques, type of aortic arch reconstruction (classic method using an allograft or xenograft patch to create the neoaorta vs. direct anastomosis of the pulmonary artery to the arch), use of standard or modified ultrafiltration, and the use of various medications in the operating room (aprotinin, corticosteroids, and alpha blockade with phenoxybenzamine or phentolamine). Perfusion type was defined as either deep hypothermic cardiac arrest (DHCA), regional cerebral perfusion (RCP) or a combination of the two techniques. Periods of up to 10 minutes of DHCA were included in the RCP group to allow for cannula repositioning. Lowest temperature on bypass was recorded from a core measurement site (nasopharynx, rectum, or bladder). The lowest hematocrit was recorded on bypass prior to initiating DHCA or RCP.

Postoperative variables included duration of ventilation and length of stay, whether the patient had an open sternum, postoperative interventions including interventional cardiac catheterization, cardiac surgery, or extracorporeal membrane oxygenation (ECMO; initiated either in the operating room or later in the postoperative period), in-hospital death/transplant, type and route of feeding at discharge, discharge medications, discharge on oxygen, and enrollment in a home monitoring program (including monitoring of weight gain, oxygen saturation, or both).

Analysis

Study variables were described using standard summary statistics. Aggregate rates for dichotomous variables, and mean ± standard deviation along with median and interquartile range for continuous variables, were calculated for the overall study population. Next, the total number of centers that utilized a particular practice or type of care was calculated. For these centers, center-level descriptive data were calculated. For continuous variables the median value at each site was calculated; for dichotomous variables the proportion of patients at each center in which the practice or type of care was utilized was calculated. Median, interquartile range, and range were then calculated from these center-level data. Due to the descriptive nature of the analysis, formal statistical comparisons were not made. All analyses were performed using SAS version 9.2 (SAS Institute, Inc., Cary, NC).

Results

Study population

Of 555 patients enrolled in the SVR trial, five patients consented but did not undergo the Norwood procedure, and one patient withdrew immediately after the Norwood procedure was performed such that no further follow-up information was collected. In addition, one site which enrolled only three patients was excluded. Thus, the 546 remaining patients from 14 trial sites are the basis for analysis. Median birth weight was 3.1 kg (interquartile range, 2.8–3.5 kg), median gestational age 38 weeks (interquartile range, 37–39 weeks), and 86% had a diagnosis of hypoplastic left heart syndrome (vs. other single right ventricle defects). Of note, there were no significant differences in any of these variables across sites.

Preoperative variables

Preoperative variables are displayed in Table 1. The majority of patients (76%) were diagnosed *in utero*, however this varied across centers ranging from 55–85%. Approximately half of patients were intubated preoperatively with a range of 29–91% of patients across centers. Five percent overall were specifically intubated for transport (range, 1–15% across 11 sites).

A minority of patients received all other preoperative therapies/interventions noted in Table 1, including fetal intervention, use of inhaled gases, and enteral feeding. However, although used in a minority of patients overall, these factors were also varied across sites, with the greatest variation seen in enteral feeding.

Perioperative/operative variables

Perioperative/operative variables are displayed in Table 2. The median age at surgery ranged from 4 –7 days across sites. Of those who were preterm (< 37 weeks gestation; n=64), median age at surgery ranged from 2–23 days across centers. Total support and cross clamp times varied more than two-fold. There was also variation in the use of DHCA and RCP across sites along with the lowest core temperature on bypass and lowest hematocrit (Table 2). Arch reconstruction was accomplished by the classic method in the majority of patients. Direct anastomosis of the pulmonary artery to the arch was used in a minority of patients at nine sites, and in the majority of patients at one site. Ultrafiltration of any type was used at all sites; at 13 sites it was used in the majority of patients. Modified ultrafiltration was used at 10 sites. Perioperative steroids were used at all sites; they were administered in 100% of patients at seven sites, and in the majority of patients at all but one site. Aprotinin was also used at all sites (while still available), and was used in the majority of patients at all but one site. There was more variability in the use of alpha-blockade, with six sites not using it at all, and the remaining sites using it in 2–100% of patients.

Postoperative variables

Postoperative variables are displayed in in Table 3. There was a four-fold difference in duration of ventilation across sites, and a nearly five-fold variation in intensive care unit length of stay. Twenty-two patients (4%) overall were kept in the hospital until their Stage II surgery with a range of 1–22% of patients across eight sites. More than three quarters of patients had an open sternum after the Norwood operation; this also varied across sites ranging from 35–100%. At seven sites, all patients had an open sternum. ECMO utilization ranged from 7–35% across sites. Interventional cardiac catheterizations and cardiac surgery in the postoperative period prior to discharge were infrequent but variable by site, ranging from 6–20% and 3–40%, respectively. Five centers did not perform any interventional catheterizations, and three centers did not perform any cardiac surgeries in the postoperative period following the Norwood procedure. Overall, 18% of patients died in-hospital or underwent transplant, with a range of 7–39% across sites (Table 3).

All surviving patients were discharged on at least one medication. The most frequent discharge medications included: aspirin (87%), furosemide (85%), ranitidine (50%), metoclopramide (38%), and digoxin (36%). The type and route of feeding was highly variable across sites. Only one-third of patients overall were feeding by mouth without any nasogastric or gastric feeds at discharge, and less than half were receiving breast milk (alone or in combination with formula). A minority of patients (11%) were discharged home with supplemental oxygen, but this varied by site from 2–57%. One-third of discharged patients were enrolled in a home monitoring program; 5 sites did not have a program.

Comment

This analysis describes the wide range of perioperative care across clinical centers for patients undergoing the Norwood procedure. Virtually every aspect of preoperative, operative, and postoperative care evaluated in this analysis varied across 14 sites participating in the SVR trial. Variation can foster scientific discovery and innovation, and allow for treatment plans individualized to the patient. Nevertheless, the degree of variability demonstrated in our analysis and others may also highlight the limited evidence to guide optimal care in this population, and lack of best practice guidelines (9). This in turn may play a role in the wide variability in outcomes following the Norwood operation. A recent analysis of >2,000 infants undergoing the Norwood operation across 69 centers showed that adjusted in-hospital mortality varied by 6-fold from 7% to 42% across centers (10). Data from the present study, although from a smaller subset of hospitals, are similar with the rate of in-hospital death/transplant varying from 7% to 39% across institutions. It has also been shown that variation in practice can account for a significant proportion of health care expenditures, which is of particular importance in this era of rising health care costs (11).

The present analysis builds on previous surveys of differences in practice across centers for patients undergoing the Norwood operation. In 2007, Wernovsky and colleagues surveyed 52 international centers performing the Norwood operation, and reported wide variation in ICU models of care, operative and perfusion techniques, medications, feeding, regimens, and postoperative monitoring (6). Other surveys evaluating not only Norwood patients but others undergoing congenital heart surgery have found wide variation in perfusion techniques, and postoperative care models including ICU structure and personnel (4,12). More recent studies have also analyzed specific practices in the Norwood population. Johnson et al. evaluated 1283 infants from 45 centers undergoing the Norwood procedure in the Society of Thoracic Surgeons Congenital Heart Surgery Database, and showed that use of delayed sternal closure varied widely across centers (7). Other studies have evaluated a wider range of practices in patients undergoing the Norwood operation, but have been

limited by analyzing only survivors to hospital discharge (13,14). The present study builds upon these previous analyses through using prospectively collected data related to perioperative care, as opposed to retrospective survey methodology, and evaluating a wide range of care encompassing the entire Norwood hospitalization in all patients enrolled in the SVR trial.

In the field of adult cardiac surgery, it has been shown that evaluation of variation in care across centers is a critical first step toward identifying areas of future research, development of quality improvement initiatives, and subsequent implementation of best practice guidelines. Prager et al. recently reported on The Michigan Society of Thoracic and Cardiovascular Surgeons quality collaborative (15). This group, composed of all adult cardiac surgery programs in Michigan, meets regularly to evaluate variation in practice and program outcomes. Through the adoption of practices utilized by high performing sites, variation in care is reduced, outcomes improved, and hospital costs lowered. For example, following sharing of protocols to facilitate timely extubation, variation in duration of ventilation across sites was reduced and the overall rate of prolonged ventilation decreased from 19% to 14% (15). The Northern New England Cardiovascular Disease Study Group pioneered work in this area in adult cardiac surgery in the 1980's, and their experience has also shown that a precise assessment of variation in practice and outcomes across institutions is a critical first step (16). In pediatric cardiology, the Joint Council on Congenital Heart Disease National Pediatric Cardiology Quality Improvement Collaborative has recently begun evaluating practice variation across sites in regard to feeding and home monitoring practices in the interstage period between the Norwood and Stage II procedures (17). These analyses are ongoing. Efforts are currently underway to develop a quality improvement collaborative in pediatric heart surgery.

Few previous studies have evaluated the impact of variation in management during the Norwood hospitalization on outcome. In their analysis of variation in use of delayed sternal closure after the Norwood procedure, Johnson et al. found that centers with greater use of delayed sternal closure had significantly higher rates of postoperative infection and prolonged length of stay, which persisted after accounting for a variety of patient and center factors (7). Variation in the use of perioperative corticosteroids and impact on outcome has also been previously evaluated. In a large study of >45,000 patients from 38 centers, perioperative corticosteroid use was found to vary widely by center, and in subgroup analysis, there was no significant benefit associated with corticosteroids in the high-risk group primarily composed of patients undergoing the Norwood procedure (18). Finally, investigators have also evaluated variation in center-related variables and impact on outcome. Analyses of both clinical and administrative datasets have found variation in intensive care unit (ICU) models of care (dedicated cardiac ICU vs. general pediatric ICU), but no significant impact of ICU type on outcome in patients undergoing the Norwood operation (19,20). Further evaluation of these and other variables examined in the present study will help to define which aspects of variation in care are reflective of local practices or underlying patient characteristics and are not independently associated with outcome, and which are associated with improved outcomes and should be evaluated as best practices. Rather than through a single study or trial, this may best be accomplished through a collaborative effort focused on sharing of information across sites and continuous quality improvement to identify best practices, reduce variation in care, and improve outcomes, similar to initiatives in adult cardiac surgery (15,16).

Limitations

There are several limitations to this analysis. This study focuses on a subset of medium and high volume centers performing the Norwood procedure, and only patients enrolled in the

SVR trial were included. Thus, we may actually underestimate the degree of variation in care across all patients and all sites performing this operation. In this initial analysis we have focused on describing the range of care across centers in a large cohort, and have not evaluated the potential role of variation in care within centers, random variation between centers, or change over time. These factors will require further study. We were inherently limited to evaluating aspects of perioperative care recorded in the SVR trial dataset. There may be other patient and center-level variables that are relevant. As noted above, the relationship of the variation identified in this study with outcome will also require further study. Finally, in this analysis we have not separated out variation in care specifically due to practice or management from the patient's severity of disease, although we did find that the baseline patient characteristics we examined did not differ across sites. It is likely that for several of the variables we evaluated, many factors may play a role and require further analysis.

Conclusions

We describe the wide range of perioperative care across clinical centers performing the Norwood procedure. Further analysis is necessary to evaluate the underlying causes of this variation and relationship of variation in management to patient outcomes including survival, neurodevelopmental outcomes, and cost. These analyses may aid in planning future clinical trials, allow us to begin to identify best practices, and facilitate the development of quality improvement initiatives to improve quality of care and outcomes across centers for patients undergoing the Norwood procedure.

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Table 1

Variation in Preoperative Variables

Variable	Aggregate Data	Center-level Data			
	Rate	Number of Centers	Median	Interquartile Range	Range
Fetal diagnosis	76%	14	73%	71–82%	55–85%
Fetal intervention *	3%	5	3%	2–4%	1–17%
Intubation	48%	14	50%	38–64%	29–91%
Inhaled gases					
CO_2	3%	5	16%	1–20%	1–40%
N_2	13%	9	15%	9–36%	1–55%
Enteral feeding	12%	13	11%	4–22%	1–100%

"Number of centers" represents the number of the 14 total centers that utilized a particular practice or type of care. Subsequent center-level descriptive data in the table refer to only these centers.

* Includes patients who underwent fetal intervention at their center, or who were referred to another institution to undergo fetal intervention.

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Table 2

Variation in Operative/Perioperative Variables

Variable	Aggregate Data			Center-level Data			
	Rate	Mean±SD	Median (IQR)	Number of Centers	Median	Interquartile Range	Range
Age at Norwood, days	--	5.8±4.1	5 (3,7)	14	5	4–6	4–7
Perfusion Data							
Total support time, min	--	144±54	139 (105,171)	14	149	124–166	74–189
Cross-clamp time, min	--	56±23	53 (40,67)	14	57	48–64	33–73
DHCA only	54%	--	--	9	97%	22–100%	3–100%
DHCA time, min	--	47±18	42 (36,54)	9	51	46–55	33–73
RCP only	24%	--	--	10	38%	19–82%	3–93%
RCP time, min	--	57±17	55 (46,66)	10	52	45–59	30–76
RCP flow, cc/kg/min	--	42±17	38 (30,50)	10	36	30–49	19–50
Both DHCA & RCP	22%	--	--	9	42%	18–60%	4–87%
DHCA time, min	--	25±16	21 (13–34)	9	24	15–34	12–71
RCP time, min	--	46±22	50 (26,61)	9	48	37–60	23–71
RCP flow, cc/kg/min	--	37±16	35 (25,49)	9	30	30–40	19–54
Lowest temperature (°C)	--	17±2	17 (16,18)	14	17	17–18	15–21
Lowest hematocrit, %	--	30±5	29 (27,32)	14	29	28–31	22–41
Arch Reconstruction							
Classic	88%	--	--	14	97%	82–100%	41–100%
Direct PA to arch	12%	--	--	9	15%	4–22%	3–59%
Ultrafiltration							
Any	84%	--	--	14	94%	88–100%	2–100%
Modified	66%	--	--	10	94%	88–100%	48–100%
Medications							
Aprotinin	78%	--	--	14	87%	60–93%	43–100%
Corticosteroids	91%	--	--	14	99%	96–100%	33–100%
Alpha-blockade	45%	--	--	8	90%	64–97%	2–100%

CPB - cardiopulmonary bypass, DHCA - deep hypothermic circulatory arrest, RCP - regional cerebral perfusion, PA - pulmonary artery, SD - standard deviation, IQR - interquartile range.

“Number of centers” represents the number of the 14 total centers that utilized a particular practice or type of care. Subsequent center-level descriptive data in the table refer to only these centers.

Table 3

Variation in Postoperative Variables

Variable	Aggregate Data			Center-level Data			
	Rate	Mean±SD	Median (IQR)	Number of Centers	Median	Interquartile Range	Range
Total ICU length of stay, days	--	24±31	14 (9,25)	14	13	12–18	9–44
Length of hospital stay, days	--	35±34	24 (17,40)	14	25	22–32	19–44
Ratio of ICU to total LOS	--	0.7±0.3	0.6 (0.5–1.0)	14	0.6	0.5–0.6	0.5–1.0
Ventilator time, days	--	12±25	7 (5,11)	14	7	6–9	4–16
% extubated within 72 hrs	18%	--	--	6	24%	6–32%	5–63%
Open Sternum	78%	--	--	14	99%	67–100%	35–100%
ECMO	16%	--	--	13	18%	13–20%	7–35%
Interventional cath	7%	--	--	9	8%	6–11%	6–20%
Cardiac surgery	8%	--	--	11	8%	4–13%	3–40%
Feeding at discharge							
Oral only	33%	--	--	12	29%	18–44%	3–81%
Any Oral	78%	--	--	14	79%	56–90%	33–100%
Any G/GJ Tube	18%	--	--	12	20%	13–27%	2–72%
Any NG/NJ Tube	49%	--	--	11	60%	53–78%	8–100%
Breast milk (via any route)	48%	--	--	14	47%	39–57%	17–67%
No. of discharge meds	--	5±2	5 (4,6)	14	5	4–6	3–6
Discharge on O_2	11%	--	--	11	11%	5–24%	2–57%
Home monitoring program	33%	--	--	9	69%	50–96%	1–100%
Death/transplant during Norwood hospitalization	18%	--	--	14	17%	15–30%	7–39%

ICU - intensive care unit, LOS - length of stay, ECMO - extracorporeal membrane oxygenation, SD - standard deviation, IQR - interquartile range, G - gastric, GJ - gastro-jejunal, NG - nasogastric, NJ - naso-jejunal.

“Number of centers” represents the number of the 14 total centers that utilized a particular practice or type of care. Subsequent center-level descriptive data in the table refer to only these centers.

Data on length of stay and duration of ventilation, along with discharge data excludes those who did not survive to hospital discharge or underwent cardiac transplant during the same admission (n=97)