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Complications after the Norwood Operation: An Analysis of the STS Congenital Heart Surgery Database

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Abstract

Background—Limited multi-center data exist regarding the prevalence of post-operative complications following the Norwood operation and associated mortality risk.

Methods—We evaluated infants in the Society of Thoracic Surgeons Congenital Heart Surgery Database undergoing the Norwood operation from 2000–2009. Prevalence of post-operative complications following the Norwood operation and associated in-hospital mortality were described. Patient factors associated with complications were evaluated in multivariable analysis.

Results—A total of 2557 patients from 53 centers were included. Median age at surgery was 6 days (interquartile range 4–9 days) and 90% had a right dominant ventricle. Overall mortality was 22%, and 75% had ≥ 1 complication. Mortality increased with increasing number of complications: one complication (17%), two complications (21%), three complications (26%), four complications (33%) and ≥ 5 complications (45%). Renal and cardiovascular complications carried the greatest mortality risk. Patient factors associated with ≥ 1 complication included: weight < 2.5 kg (OR 1.6, 95% CI 1.2–2.1), single right vs left ventricle (OR 1.4, 95% CI 1.01–2.0), pre-operative shock (OR 1.5, 95% CI 1.1–2.1), non-cardiac/genetic abnormality (OR 1.5, 95% CI 1.2–1.9), and pre-operative mechanical ventilatory (OR 1.3, 95% CI 1.03–1.6) or circulatory support (OR 4.0, 95% CI 1.6–10.2).

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Disclosures

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Conclusions—Complications following the Norwood operation are common, carry significant mortality risk, and are associated with several pre-operative patient characteristics. These data may aid in providing prognostic information to families, and in guiding quality improvement initiatives.

Keywords

CHD; Norwood operation; Surgery; complications; Postoperative care

Introduction

Over the past 3 decades, survival following the Norwood operation for patients with single ventricle defects has improved with refinement of surgical technique and advances in peri-operative care [1,2]. Despite these improvements, post-operative morbidity and mortality remain significant [2,3]. Several previous studies have examined various factors associated with poor outcome following the Norwood operation [4–10]. The majority of these studies have focused on evaluating patient pre-operative risk factors, different surgical techniques, and cardiopulmonary bypass strategies [4–7]. There are few studies to date which have evaluated post-operative complications and associated mortality [7–10]. These consist primarily single center reports limited by small sample size [7–10].

The purpose of this study was to describe the prevalence of post-operative complications following the Norwood operation and associated mortality risk using multi-center data from the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database. In addition, we evaluated patient pre-operative factors associated with postoperative complications.

Patients and Methods

Data Source

The STS Congenital Heart Surgery Database contains operative, peri-operative, and outcomes data on >180,000 children undergoing heart surgery since 1998, and currently represents nearly three quarters of all US centers performing congenital heart surgery [11]. Data on all children undergoing heart surgery at participating centers are entered into the database. Data quality and reliability are evaluated through intrinsic verification of data and a formal process of site visits and data audits [12]. The Duke Clinical Research Institute serves as the data warehouse for the STS Databases. This study was approved by the Duke Institutional Review Board with waiver of consent. This study was also reviewed and approved by the STS Access and Publications Committee.

Patient Population

Analysis was restricted to 53 STS centers who performed >5 Norwood operations from 2000–2009, and who had >85% complete data for all study variables. While the STS Database contains nearly complete data for the standard core data fields required to calculate discharge mortality, not all centers submit complete data for the other variables in the STS Database. Therefore it is standard practice to exclude centers with >15% missing data for key study variables, in order to maximize data integrity and minimize missing data. From the included centers, patients with missing data on complications, mortality, or pre-operative factors (n=32 patients) were excluded.

Data collection

Data collected included patient age, weight, sex, and cardiac diagnosis. All patients undergoing the Norwood operation were included in the study regardless of underlying

anatomy, and characterized by type of single ventricle: right dominant, left dominant, and undifferentiated [13]. The Norwood operation in the STS Database is defined according to the International Pediatric and Congenital Cardiac Code (IPCCC): “The Norwood operation is synonymous with the term ‘Norwood (Stage 1)’ and is defined as an aortopulmonary connection and neo-aortic arch construction resulting in univentricular physiology and pulmonary blood flow controlled with a calibrated systemic-to-pulmonary artery shunt, or a right ventricle to pulmonary artery conduit” [14]. The presence of other secondary lesions such as total anomalous pulmonary venous return was also collected, along with the presence of any non-cardiac/genetic abnormality, pre-operative length of stay, and other pre-operative factors including mechanical ventilatory or circulatory support, shock, arrhythmia, and neurologic deficit as defined in the STS Database [15]. Operative characteristics included cardiopulmonary bypass time, use of delayed sternal closure, and year of surgery.

Post-operative complications as defined in the STS Database were collected, including: surgical (unplanned re-operation during the admission, systemic or pulmonary venous obstruction, bleeding requiring reoperation), renal (acute renal failure requiring temporary or permanent dialysis), neurologic (transient or permanent deficit neurologic deficit, or seizures), infectious (wound or sternal dehiscence, wound infection, mediastinitis, septicemia, endocarditis), pulmonary (pneumothorax, pleural effusion requiring drainage, pneumonia, chylothorax, tracheostomy, phrenic or recurrent laryngeal nerve injury, respiratory insufficiency requiring mechanical ventilation >7 days, and respiratory insufficiency requiring reintubation), cardiovascular (cardiac arrest, mechanical circulatory support, arrhythmia, atrioventricular block requiring temporary or permanent pacemaker, low cardiac output, acidosis, pericardial effusion requiring drainage, and pulmonary hypertension), and other post-operative complications [15]. Finally, data on in-hospital mortality was collected.

Statistical Analysis

Study variables were described using standard summary statistics. The proportion of patients with each post-operative complication was calculated, along with the mortality risk associated with each complication. Mortality associated with multiple complications was also described. Complications found to be associated with a significant mortality risk were then evaluated further. Patient pre-operative characteristics associated with one or more of these complications were examined in multivariable logistic regression. The method of generalized estimating equations (GEE) was utilized to account for correlation between outcomes of patients at the same center. Variables entered into the models included those with a p-value <0.1 in univariate analysis as well as those found to be associated with outcome in previous studies [7]. Models were also adjusted for year of surgery. Unadjusted and adjusted results from the logistic regression model are displayed as odds ratios and 95% confidence intervals. All analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, NC). A p-value <0.05 was considered statistically significant.

Results

Patient characteristics

A total of 2557 infants from 53 centers (64% with 0–10 Norwood cases/year, 25% with 11–20 Norwood cases/year, and 11% with >20 Norwood cases/year) were included. Patient characteristics are displayed in Table 1. As expected, the median age of surgery was within the first week of life. Lesions with right ventricular dominance were the most prevalent (90%). Patients weighing <2.5kg, those with a non-cardiac/genetic abnormality, or other pre-operative factors such as mechanical ventilatory support and shock were more likely to have a post-operative complication (Table 1).

Complications and associated mortality

Post-operative complications are displayed in Table 2. Of the 2557 patients, 1906 (75%) suffered at least one complication: 584 (23%) had one complication, 388 (15%) had two complications, 310 (12%) had three complications, 212 (9%) had four complications, and 412 (16%) had ≥ 5 complications. The most common post-operative complications were mechanical ventilation >7 days, arrhythmia, and low cardiac output.

Overall, in-hospital mortality in the cohort was 22%. Mortality for patients with any complication was 27%, while mortality for patients who did not suffer a complication was 7% ($p < 0.0001$). Of those with a complication, mortality increased with increasing number of complications: one complication (17%), two complications (21%), three complications (26%), four complications (33%) and ≥ 5 complications (45%). Mortality risk associated with specific complications is displayed in Table 2. Acute renal failure requiring temporary or permanent dialysis and cardiac arrest were associated with the highest mortality risk.

Pre-operative factors associated with complications

The results from multivariable analysis are displayed in Table 3. Weight <2.5 kg, right versus left dominant ventricle, pre-operative shock, any non-cardiac/genetic abnormality, and pre-operative mechanical circulatory or ventilatory support were significantly associated with ≥ 1 post-operative complication.

Comment

In this multi-center evaluation of post-operative complications after the Norwood operation, we found that complications are common and associated with significant mortality, with renal and cardiovascular complications carrying the greatest risk. The majority of studies to date of factors impacting outcome in patients undergoing the Norwood operation have focused on evaluating pre-operative characteristics and intra-operative variables [4–6, 16]. While there are several studies of the impact of postoperative complications on outcome in the overall population undergoing pediatric heart surgery, there are limited data regarding post-operative complications in the Norwood population.

In the present study, we identified several complications associated with increased mortality after the Norwood operation. Complications associated with the highest mortality included renal failure requiring dialysis. Previous studies of children undergoing heart surgery have demonstrated a significant mortality risk associated with renal complications. In a study of 120 children undergoing cardiopulmonary bypass, acute kidney injury of any severity was associated with significantly increased mortality and longer length of stay compared with those who have normal renal function after surgery [17]. We also found that post-operative cardiac arrest and the need for mechanical circulatory support were each associated with particularly high mortality. Similar results have been reported in a single center study of 158 infants undergoing the Norwood operation, where post-operative mechanical circulatory support was associated with significant mortality [7]. Respiratory complications such as pneumonia and the need for tracheostomy also carried a high mortality risk in our study. A previous analysis of 100 pediatric cardiac patients has also shown that mortality and length of stay were significantly higher in those with post-operative ventilator associated pneumonia [18]. In contrast, in a study of 132 infants undergoing the Norwood operation, airway anomalies, including need for tracheostomy were not found to be associated with increased interstage mortality [9]. However, this was a single center report and may have been underpowered. Post-operative neurologic complications were also associated with high mortality in our study. A previous study of 122 infants from a single center found that peri-operative stroke was not associated with outcome following heart surgery [19]. All but one

of the 12 total strokes identified on prospective brain imaging in that study were not associated with any clinical symptoms. However, another study of 217 infants undergoing heart surgery involving circulatory arrest revealed a higher proportion of post-operative neurologic events in non-survivors vs. survivors (41% vs. 19%) [20]. Re-operation during the admission whether related to bleeding or other causes also carried a high mortality risk in our study. In a previous single center report of 99 infants undergoing the Norwood operation, the need for re-operation was associated with prolonged length of stay; however association with mortality was not evaluated [8]. Finally, we found that mortality increased with the number of post-operative complications. This has also been demonstrated in a study utilizing a large administrative database. In 10,032 patients undergoing congenital heart surgery, increasing number of complications was associated with increasing mortality [21].

Thus, it may be possible that improvement in outcome following the Norwood operation could be achieved through reducing post-operative complications. It has previously been reported that the use of standardized management protocols may decrease post-operative complications and morbidity in the congenital heart surgery population. In a study of 175 patients with acyanotic congenital heart disease, a standardized post-operative management protocol was reported to reduce length of stay, cost, and post-operative infections [22]. In another study of 64 patients after atrio-ventricular canal defect repair, standardized management of post-operative pulmonary hypertension with inhaled nitric oxide versus conventional therapy resulted in significantly decreased mortality [23]. In patients undergoing the Norwood operation, one center reported their experience with a standardized post-operative monitoring protocol involving venous oximetry, near-infrared spectroscopy and heightened interstage surveillance [24]. With these efforts, high risk infants including premature and low birth weight infants and those with extracardiac anomalies had operative mortality rates similar to the standard risk group.

In contrast, it has been shown that a reduction in complications does not always translate into improved survival. In a study of patients in a general pediatric intensive care unit, implementation of a protocol based on Centers for Disease Control guidelines significantly reduced rates of ventilator associated pneumonia, but did not affect length of stay or mortality [25]. In addition, as previously postulated in the adult surgical population, it may be that some complications are unavoidable and related to patient pre-operative factors or to the severity of the underlying disease [26]. Several studies in the adult surgical literature have reported that high performing centers do not necessarily have a lower rate of complications, but rather a lower rate of death following complications [26,27]. Thus, it has been hypothesized that early recognition and treatment of complications once they occur is important. Studies in the adult literature have suggested that certain hospital characteristics such as teaching hospital status, size and bed occupancy, and nurse-to-patient ratio may be important factors associated with a lower rate of mortality following complications [28,29].

We identified several patient pre-operative factors associated with post-operative complications in multivariable analysis. These included several factors shown by others to impact outcome in the single ventricle population such as the presence of non-cardiac/genetic abnormalities, and weight <2.5 kg at surgery [13,30]. We also found that those with a right dominant single ventricle were more likely to have complications compared to those with a dominant left ventricle. Some previous studies have also found that ventricular morphology may impact post-operative outcomes in single ventricle patients undergoing the Norwood operation, while others have not [13,31]. Finally, we found that the presence of pre-operative shock and pre-operative mechanical circulatory or ventilatory support were associated with post-operative complications. It is possible that these factors may in part be related to the presence of a restrictive or intact atrial septum which has been shown to be a risk factor for poor outcome in previous studies [9].

Limitations

The limitations of this study are primarily related to the nature of the STS Database. While the Database contains information from the majority of US programs performing congenital heart surgery, not all centers submit complete complications data. Therefore, while this represents the largest analysis of complications following the Norwood operation to date, these data may not be generalizable to all Norwood patients. We included all patients undergoing the Norwood operation regardless of underlying anatomy; thus our results may differ from studies restricted to patients with hypoplastic left heart syndrome, or from studies evaluating patients undergoing hybrid procedures rather than the Norwood operation. In addition, although there is a formal process of data audits and assessment of data quality, we cannot rule out the possibility of undercoding, overcoding, or miscoding of complications. For example, it is difficult to rationalize how some of the patients with no complications coded died.

The Database also does not currently collect information regarding certain pre-operative characteristics such as anatomic subtype of hypoplastic left heart syndrome (ie. mitral stenosis/atresia or aortic stenosis/atresia) or presence of a restrictive atrial septum, though pre-operative shock and mechanical ventilation are captured in the database (and accounted for in our analysis) and may be related to the latter. Longer pre-operative length of stay may also be a surrogate measure for a more complicated pre-operative course, and was accounted for in our analysis. In addition, not all complications that may occur following the Norwood operation are currently captured in the STS Database. For example, during the study period post-operative cardiac catheterizations or interventional procedures were not captured, although these were added in 2010. Information regarding post-operative feeding difficulties or necrotizing enterocolitis is also not captured. In addition, we were not able to differentiate between planned vs. unexpected use of post-operative mechanical circulatory support. During the study period, the source of pulmonary blood flow (modified Blalock-Tausig shunt vs. right ventricle-to-pulmonary artery conduit) was also not specified in the database (this variable was subsequently added in 2010). Therefore we were unable to account for this variable in our analysis. However, we were able to adjust for year of surgery in our models, with use of the right ventricle-to-pulmonary artery conduit becoming more prevalent in recent years. In addition, despite our large sample size, certain complications, such as need for post-operative tracheostomy, permanent pacing, or dialysis still had a very low prevalence, making interpretation of their significance challenging. We were also not able to evaluate change in variables such as creatinine levels from the pre- to the post-operative period as these data are not currently collected. Finally, in this descriptive study, without any knowledge of interventions undertaken at the time of the complication, we cannot offer insight into which clinical settings or interventions offer the best chance of survival despite the occurrence of postoperative complications.

Conclusions

Complications following the Norwood operation are common and associated with significant mortality. These data may aid in counseling families and offer multiple potential targets for therapeutic interventions and quality improvement. Further investigation into characteristics of hospital care and personnel associated with a lower rate of complications, or mortality following complications, may lead to specific strategies to improve outcome in this population.

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Table 1

Patient and operative characteristics

	Post-operative complication		
	Overall (n=2557)	Yes (n=1906)	No (n=651)
Patient characteristics			
Age at surgery, days	6 (4–9)	6 (4–9)	6 (4–9)
Weight, kg	3.18 (2.80–3.50)	3.14 (2.80–3.50)	3.20 (2.89–3.50)
Weight <2.5kg	247(10%)	198 (10%)	49 (8%)
Sex, female	1069(42%)	799 (42%)	279 (41%)
Diagnosis			
Right dominant single ventricle	2293(90%)	1715 (90%)	578 (89%)
Left dominant single ventricle	203(8%)	142(7%)	61 (9%)
Undifferentiated	61(2%)	49 (3%)	12 (2%)
TAPVR	33(1%)	28 (1%)	5 (1%)
Any non-cardiac/genetic abnormality	508(20%)	417 (22%)	91 (14%)
Other pre-operative factors			
Mechanical ventilatory support	1021(40%)	823 (43%)	198 (30%)
LOS >7 days	532(21%)	409 (21%)	123 (19%)
Shock	170 (7%)	145 (8%)	25 (4%)
Arrhythmia	66 (3%)	56 (3%)	10 (2%)
Neurological deficit	33 (1%)	27 (1%)	6 (1%)
Mechanical circulatory support	20 (1%)	18 (1%)	2 (0.3%)
Operative characteristics			
Cardiopulmonary bypass time, min	151(116–187)	151 (113–190)	150 (121–181)
Delayed sternal closure	1472(56%)	1136 (60%)	336 (52%)

Data are presented as frequencies and percentages or medians and interquartile range.

LOS=length of stay, TAPVR=total anomalous pulmonary venous return.

Table 2

Post-operative complications and associated mortality

Post-operative complications	Prevalence (n, %) n=2557	Mortality (%)		p-value
		With complication	Without complication	
Acute Renal Failure Requiring Permanent Dialysis	12 (0.5%)	91.7	21.3	<0.0001
Cardiac Arrest	311 (12.2%)	67.5	15.9	<0.0001
Acute Renal Failure Requiring Temporary Dialysis	141 (5.5%)	66.7	19.5	<0.0001
Mechanical Circulatory Support	365(14.3%)	57.3	16.3	<0.0001
Systemic Vein Obstruction	13 (0.5%)	53.9	22.0	<0.01
Pulmonary Vein Obstruction	2 (0.1%)	50.0	22.1	0.34
Transient Neurological Deficit	4 (0.3%)	50.0	20.8	0.15
Persistent Neurologic Deficit	83 (3.3%)	48.2	21.3	<0.0001
Low Cardiac Output	415 (16.2%)	47.7	17.2	<0.0001
Tracheostomy	19 (0.7%)	47.4	22.0	<0.01
Pneumonia	55 (2.2%)	47.3	21.6	<0.0001
Acidosis	280 (11.0%)	45.4	19.3	<0.0001
Bleeding Requiring Reoperation	205 (8.0%)	44.4	20.2	<0.0001
Pulmonary Hypertension	84 (3.3%)	39.3	21.6	<0.001
Unplanned Reoperation	303 (11.9%)	38.9	19.9	<0.0001
Mediastinitis	35 (1.4%)	34.3	22.0	0.08
Complete AV Block Requiring Temporary Pacemaker	71 (2.8%)	33.8	21.8	0.01
Sepsis	287 (11.2%)	33.7	20.7	<0.0001
Seizure	110 (4.3%)	31.8	21.7	0.01
Pleural Effusion Requiring Drainage	150 (5.9%)	31.3	21.6	<0.01
Respiratory Insufficiency Requiring Intubation > 7d	551 (21.6%)	30.0	20.0	<0.0001
Arrhythmia	492 (19.2%)	27.5	20.8	0.001
Pericardial Effusion Requiring Drainage	50 (2.0%)	26.0	22.1	0.50
Chylothorax	159 (6.2%)	23.3	22.1	0.72
Respiratory Insufficiency Requiring Reintubation	334 (13.1%)	19.5	22.6	0.21
Pneumothorax	88 (3.4%)	19.3	22.3	0.52
Endocarditis	17 (0.7%)	17.7	22.2	0.66
Wound Infection	115 (4.5%)	14.8	22.5	0.05
Wound Dehiscence	48 (1.9%)	14.6	22.3	0.20
Phrenic Nerve Injury/Paralyzed Diaphragm	81 (3.2%)	8.6	22.6	0.003
Recurrent Laryngeal Nerve Injury/Paralyzed Vocal Cord	128 (5%)	3.9	23.1	<0.0001
Sternal Dehiscence	1 (0.1%)	0	20.8	0.61

Prevalence of complications following the Norwood operation and associated mortality risk, displayed in order of mortality risk. Mortality rates refer to mortality in any patient with the specified complication. Note, a patient with a specified complication may have additional complications.

AV = atrioventricular

Table 3Patient pre-operative factors associated with ≥ 1 post-operative complication

Pre-operative factors	Unadjusted Odds Ratio (95% CI)	p-value	Adjusted Odds Ratio (95% CI)	p-value
Prolonged pre-op LOS*	0.98 (0.78–1.22)	0.82	0.84 (0.65–1.1)	0.2
Weight < 2.5 kg	1.72 (1.30–2.27)	<0.001	1.59 (1.22–2.08)	<0.001
Female gender	1.08 (0.96–1.21)	0.18	1.02 (0.91–1.15)	0.71
Right dominant ventricle (vs left)	1.48 (1.13–1.93)	0.004	1.36 (1.01–1.82)	0.04
TAPVR	2.21 (1.08–4.55)	0.03	1.61 (0.84–3.08)	0.15
Non-cardiac/genetic abnormality	1.61 (1.28–2.04)	<.0001	1.5 (1.19–1.91)	<0.001
Shock	1.66 (1.17–2.35)	0.004	1.52 (1.08–2.15)	0.02
Arrhythmia	1.31 (0.91–1.87)	0.15	1.24 (0.84–1.82)	0.29
Mechanical circulatory support	4.51 (1.52–13.39)	0.007	4.0 (1.57–10.18)	0.003
Mechanical ventilatory support	1.37 (1.1–1.7)	0.004	1.28 (1.03–1.6)	0.03
Neurological deficit	1.81 (0.78–4.20)	0.17	1.33 (0.55–3.17)	0.53

* > 75th percentile for pre-operative length of stay

LOS = length of stay, TAPVR=total anomalous pulmonary venous return