Perioperative Risk Factors and Outcomes in Children with Congenital Heart Diseases in Armenia

Master of Public Health Integrating Experience Project

Professional Publication Framework

By

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LIST OF ABBREVIATIONS

EACTS	European Association for Cardio-Thoracic Surgery
CHD	Congenital Heart Disease
NMMC	Nork Marash Medical Center
RACHS	Risk Adjustment in Congenital Heart Surgery
STS	Society of Thoracic Surgeons

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ABSTRACT

Objective: The study describes the perioperative risk factors and outcomes of congenital heart disease surgery at Nork Marash Medical Center (NMMC) in Yerevan, Armenia to benchmark NMMC's performance against international peers and guide quality improvement efforts.

Background: Congenital heart disease (CHD) is one of the three leading types of birth defects causing perinatal mortality in Armenia. CHD surgery outcomes depend on institution, hospital and surgeon volume, case complexity and patient characteristics such as age, weight, sex, presence of prematurity and a number of concomitant clinical conditions. The only hospital in Armenia specializing in pediatric cardiac surgery is the Nork Marash Medical Center (NMMC). This project analyzed NMMC's existing CHD pediatric surgery performance data.

Methods: This cross-sectional quantitative study analyzed perioperative risk factors and cardiac surgery outcome indicators (early postoperative complications and mortality rates) among the pediatric population diagnosed with congenital heart disease (CHD) who underwent surgery at NMMC from the year 2005 to 2010. To adjust for the different risks associated with various procedure types, the study used the Risk Adjustment in Congenital Heart Surgery-1 method (RACHS-1). This method classifies CHD surgery cases into one of six risk categories, from 1(the lowest risk) to 6 (the highest risk), based on the specific procedure codes. Independent predictors of surgical outcomes were identified using survival analysis and logistic regression modeling.

Results: A total of 400 consecutive cases (medical records) were reviewed. Nearly half of the study population was under the age of 12 months. Early postoperative complications were observed in 12.4% of studied cases; the crude early mortality rate was 9%. Mortality rates of specific RACHS-1 categories were 2.1% in the 1^{st}, 2.3% in 2^{nd}, 18.9% in 3^{rd}, 41.2% in 4^{th} and 66.7% in 6^{th} category. Kaplan-Meier survival analysis identified a significant inverse trend across RACH-1 groups ($p< 0.001$, log rank test). In the final logistic regression models, lower weight and higher RACHS-1 score were associated with increased operative death and complication rates.

Conclusion: Risk Adjustment for Congenital Heart Surgery-1 method can be used to predict CHD surgical mortality at NMMC. Higher RACHS-1 score and lower weight in this study clinically and statistically predicted significantly poorer outcome. The crude operative mortality at NMMC was comparable to the results other international studies.

INTRODUCTION

Congenital heart disease (CHD) is responsible for a significant percentage of neonatal and infant morbidity as well as mortality throughout the world and particularly in Armenia.(1-5) CHD occurs in 0.5-0.8% of live births and, despite the advances in palliative and corrective surgery, remains the leading cause of death in children with congenital malformations.(6)

This study describes the outcomes of congenital heart surgery among pediatric population at Nork Marash Medical Center (NMMC), Yerevan, Armenia, in terms of early mortality and early complications rates. Furthermore, based on existing methodologies and previous research findings, this study evaluated the predictors for the CHD surgery outcomes at NMMC. This information benchmark's NMMC's performance against international peers and guide NMMC's quality improvement efforts.

The retrospective analysis of outcome data, with hypothesis testing to identify differences in outcomes of statistical significance, is the traditional approach in surgical quality assessment.(7) Mortality and complication rates are among the most frequently cited patient care outcome measurements, generally, and, particularly, in the assessment of CHD surgery performance (8-10). In developed countries, mortality from CHD surgery varies between 1-10%.(11-13) The rate of complications of congenital heart surgery in the US is estimated at 30 % among all admissions.(10)

To accurately assess the differences in mortality rates among institutions performing pediatric cardiac surgery, a methodology that accounts for risks associated with different types of surgeries is needed.(14) Currently, two major methods to measure the complexity of pediatric cardiac operations exist: the Risk Adjustment in Congenital Heart Surgery-1 (RACHS-1) method and the Aristotle Complexity Score (ACS). Both systems correlate well with outcomes, such as

in-hospital mortality and length of stay. (13;15) Among other significant variables, that affect CHD surgery outcomes are patient age, weight, and hospital and surgeon volume.(12;13;16)

Leading American and European centers dealing with CHD surgery established a “minimum dataset” in 2000. The standards include four short lists of data points that are mandatory for data sharing and basic interpretation of trends in CHD surgery performance.(13;17;18) These short lists served as a basis for data collection during the proposed study.(13;17;18) Short lists particularly are defined for: 1) noncardiac abnormalities/general preoperative risk factors; 2) diagnoses; 3) procedures; and 4) complications, from which an appropriate entry can be chosen (Appendices I–IV).

1. LITRETURE REVIEW

Mitchell et al define congenital heart disease as *“a gross structural abnormality of the heart or intra-thoracic great vessels that is actually or potentially of functional significance.*”(19) In symptomatic patients with CHD, surgical or trans-catheter intervention usually is considered.(20) Obtaining and analyzing data on such outcome measures as mortality and complications is one of the important steps in continuous quality assurance cycle for CHD surgery. (21;22)

1.1. *Congenital heart disease*

C. Bacino defines **“***Malformations [as] defects of organs or body parts due to an intrinsically abnormal developmental process. In this process, a structure is not formed, is partially formed, or is formed in an abnormal fashion*”.(23) Malformations are classified as major and minor. Major malformations have medical and/or social implications and often require surgical repair. Congenital heart disease includes several cardiovascular malformations and malformations of great vessels, which are often divided into two groups: a) Cyanotic: teratology of Fallot, pulmonary atresia with an intact septum, tricuspid atresia, total anomalous pulmonary venous return with obstruction, transposition of the great vessels, single ventricle, truncus

arteriosus, total anomalous pulmonary venous return without obstruction and b) Non-cyanotic: atrial septal defect(ASD), ventricular septal defect (VSD), AV septal defects (AV canal), Patent ductus arteriosus (PDA), pulmonic or aortic valve stenosis, narrowing of one of the great vessels (coarctation of the aorta). (6;23) Clinical manifestations of CHD range from asymptomatic to symptomatic and include cardiac failure or pulmonary vascular disease.(13) The causes of most congenital heart defects are unknown. Most cases of congenital heart disease are explained as having multifactorial origin comprised of a combination of genetic predisposition and environmental factors. A small percentage of congenital heart lesions are related to chromosomal abnormalities.(6)

1.2. *Types of interventions in CHD*

CHD treatment can be provided through a medical management, surgical or transcathether intervention. Medical management of symptomatic structural congenital heart disease usually only improves symptoms and stabilizes the patient. In symptomatic newborn babies and in the majority of symptomatic older infants, it is appropriate to consider surgical or transcathether intervention. Generally, the surgical correction is provided early in the infancy whenever possible, but in many cases this is not possible. Heart surgery can be either closed or open. Corrective surgical procedures except for the coarctation repair and clipping of the ductus arteriosus are open. Some conditions may be treated either surgically or by catheter intervention (e.g., neonatal critical aortic stenosis), for some catheter intervention is generally first choice (e.g., pulmonary stenosis) and for some surgery is appropriate (e.g., repair of transposition, truncus arteriosus, total anomalous pulmonary venous drainage (TAPVD), atrioventricular septal defect (AVSD) and ventricular septal defect (VSD)). The decision on the specific type of the management in these cases is determined by the local practice.(20)

1.3. *Quality and quality indicators in CHD surgery*

Safety and quality have become an important aspect generally in surgical care.(24) Avedis Donabedian defines the term Continuous Quality Improvement (CQI) as "*the management that is expected to achieve the best balance of health benefits and risks*". Three different components to assess the quality of health care are structure, process and outcome.(25) One of the steps in the cycle of CQI is obtaining data on process measures and outcomes. (26) Different groups of stakeholders in pediatric health care, such as parents, practitioners, program directors and policy makers often demand information on outcomes of treatment for serious diseases in children (5).

The most frequently used indicators of pediatric health care quality are biological outcomes: survival, disease, and growth.(27) Among other outcome measures are functional status, length of stay and reoperation rates(22). Mortality is the most frequently used outcome indicator in CHD surgery performance measurement.(5;9;10;12;28-30). In developed countries, mortality from CHD surgery varies between 1-10%.(11-13).

In 2006, the Society of Thoracic Surgeons (STS) Congenital Database Taskforce and the Joint EACTS-STS Congenital Database Committee purposed specific definitions and recommendations for measuring the operative mortality in CHD surgery, which where summarized under the heading "*Rules to Define Operative Mortality*" and are provided in the Appendix V. (30;31) These "Rules", particularly, provide specific definition of operative mortality, provide solution on how to deal with multiple surgeries during a given hospitalization, as well as give guiding information on case selection procedures. Here Operative Mortality is defined as any death, regardless of cause occurring (1) within 30 days after surgery in or out of the hospital, and (2) after 30 days during the same hospitalization subsequent to the operation.(31)

The rate of operative complications is another outcome indicator of CHD surgeries. (18;22;32) The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

defines “complication” as: ‘‘A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breech in the standard of care that constitutes medical negligence or medical malpractice. An operative or procedural complication is any complication, regardless of cause, occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention.” (31;32) The rate of complications of congenital heart surgery in US is estimated as 30 % among all admissions.(10)

1.4. *Known risk factors for CHD surgery outcomes*

Biological characteristics and the type of procedure can affect the results of the CHD surgery and increase the risk of poor outcome in some children; thus it is important to account for these differences during an outcome analysis.(5)

1.4.1. *Case complexity*

The most important risk factor of CHD surgery outcome is the type of performed surgical procedure.(5;29) Currently two major methods exist for accounting for differences in risks associated with different types of CHD surgeries: the Risk Adjustment in Congenital Heart Surgery-1(RACHS-1) method and the Aristotle Complexity Score. These methods are widely used throughout the world and correlate well with the outcome of in-hospital mortality. (13;33) RACHS-1 method allows simplifying the procedural and anatomic diversity of CHD surgery case mix into six risk groups (see Appendix VI). The major independent variable of the RACHS-1 method is the type of the procedure performed.

1.4.2. *Other risk factors*

Variables describing age at procedure, prematurity, presence of a major noncardiac anomaly and multiple procedures performed simultaneously also are included in the RACHS-1 method.(5;22) Among other significant variables, that affect CHD surgery outcomes are weight at operation, hospital and surgeon volume. (12;13;34) The clinical factor that provided the most additional predictive information, after RACHS-1 score, in the study described in the article by Jenkins et al was age at operation, followed by prematurity.(5)

1.5. *Research objectives*

This study accomplished the following research objectives:

- Described the postoperative outcomes of congenital heart surgery, defined as early postoperative death and early complication rates, among pediatric population at NMMC.
- Explored potential risk factors for the CHD surgery outcomes at NMMC
- Compared the NMMC's CHD surgery outcomes with those from international studies

2. METHODS

2.1. *Study design*

This cross-sectional quantitative study utilized a retrospective review of the hospital pediatric database and medical records, including CHD surgeries from year 2005 to 2010. Information on following variables was derived: patient age, weight, height, presence of prematurity, diagnosis, type of the provided procedure and any preoperative risk factors as mentioned in the "minimum dataset short list", complications – any complication diagnosis within 30 days after surgery in or out of the hospital, or after 30 days during the same hospitalization subsequent to the operation, listed in the "minimum dataset short list" and appeared in the patient data, and mortality – operative death within 30 days after surgery in or

out of the hospital, or after 30 days during the same hospitalization subsequent to the operation.(31) The follow up services provided by NMMC facilitate tracking postoperative events, even if the patients are discharged from the hospital before the 30 days.

2.2. *Risk Adjustment in Congenital Heart Surgery-1 method*

To adjust for the different risks associated with various procedure types the study used the Risk Adjustment in Congenital Heart Surgery-1 method (RACHS-1). This method classifies CHD surgery cases into one of six risk categories, from 1(the lowest risk) to 6 (the highest risk) , based on the specific diagnoses and procedure codes (see Appendix VI).(5) In cases where the procedure type mentioned in the patient data differed from the "minimum dataset short list" nomenclature or in cases where discrepancies were revealed between the database and the medical record, NMMC physicians were consulted to determine the appropriate assignment.

2.3. *Study population*

Inclusion criteria: Children under 18 years of age, who underwent inpatient cardiac surgery at NMMC with the diagnoses of CHD from 2005 to 2010, were included in the research. Exclusion criteria: Neonates 30 days of age or younger with patent ductus arteriosus as an isolated cardiac defect were excluded, because it was considered that mortality in these patients is generally explained by other comorbidities. Also patients, who underwent only transcathether intervention and no surgery, were excluded. This method of congenital heart surgical case selection has been previously described.(5;10;35)

Sample size was calculated on the basis of results summarized in two articles exploring similar outcomes (5;10). Study used these studies' estimate of the outcomes (complications, mortality) and exposures (high risk categories of RACHS-1 method as exposed vs. RACHS-1 low risk categories as non-exposed) to calculate the required sample size in this study. The STAT-CALC procedure in EPI-INFO for a cross-sectional study with alpha = 0.05 and power =

80% yielded a minimum sample of 321 based on the first study's data and 366 from the second's. (36) To allow for a margin of safety, the proposed sample size for this study was increased by approximately 10% over the higher estimate to 400.

The pediatric follow up database of NMMC served as a sampling frame for this study, allowing identifying medial record number of cases mentioned in the inclusion criteria, excluding those mentioned under exclusion criteria. All consecutive records of patients who underwent CHD open heart surgery from year 2005 to 2010 meeting inclusion criteria were included. Study started review of records from year 2010 and went retrospectively up to the year 2005, until a total of 400 cases was reached. The quality of medical records across this time period was comparable.

2.4. *Measurements*

Table 1 summarizes the dependent and independent variables addressed in this study. The study addresses two main outcomes: early postoperative complications and early postoperative death.

2.4.1. *Dependent (outcome) variables*

Post operative complication and early postoperative death were created as dichotomous variables based on established standards.(31) Postoperative complication was noted in any case meeting the criteria of EACTS and The STS Congenital Databases based on the medical record (and/or medical judgment). Early postoperative mortality was noted for any death occurring within 30 days after surgery in or out of the hospital, or after 30 days during the same hospitalization subsequent to the operation.(31)

2.4.2. *Independent variables*

Independent variables explored in this study are case complexity score (RASHS-1), age at operation, sex, weight at operation, presence of prematurity, and presence of "major noncardiac abnormality/preoperative risk factors" as mentioned in the short list of Congenital Heart Surgery Nomenclature and Database Project (such as Down syndrome, Marfan syndrome, preoperative arrhythmia, preoperative pulmonary hypertension crises, preoperative renal failure, preoperative endocarditis, other preoperative noncardiac abnormalities, and other preoperative risk factors). (17;18)

Table 1. Overview of the study variables

	Measurement	**Type of data**	**Source of data**
Dependent (outcome) variables	1) Early (< 30 days) Postoperative Complication	Dichotomous (Y/N)	Med. Records , Database
	2) Early (< 30 days) Postoperative Death	Dichotomous (Y/N)	
Independent variable s	1) Sex	1) M/F	Med. Records , Database
	2) Age	2) Continuous (months)	
	3) Weight	3) Continuous (kilos)	
	4) Presence of prematurity	4) Yes/No	
	5) Presence of major noncardiac abnormality	5) Yes/No	
	6) Case complexity (RACHS-1) score	6) Categorical (1 to 6)	

2.5. *Data collection*

Two data collection forms (see Appendices VII, VIII) were used for data collection purposes; one of the forms contained patient information without patient identifiers, and the second one, which contained patient identifying information, which was used for backup

purposes. Using these forms, medical histories were abstracted from cases identified via the pediatric follow up database. The specific types of "noncardiac abnormalities/preoperative risk factors", diagnoses, procedures and complications as defined in the "minimum dataset" short lists, as well as surgery, discharge and mortality dates were collected from medical records (see Appendixes I to IV). In cases of an uncertain diagnosis or procedure or discrepancies in the data between the registry and medical record needed to determine the RACHS category of the certain case, NMMC physicians were consulted to resolve the matter. For each patient, only a single (most recent) surgery was included into the study. Data were abstracted, cleaned, and then de-identified into an SPSS 11 compatible file format for subsequent analysis.

2.6. *Ethical considerations*

The NMMC Administration consented to provide access to the pediatric database and related medical records for research purposes. The research protocol was reviewed and approved by the Institutional Review Board (IRB) within the College of Health Science at AUA (American University of Armenia).

2.7. *Data analysis*

Univariate analysis explored the distributions and frequencies of the dependent and independent variables. Survival analysis was done using Kaplan- Meier product-limit method. The multivariable analysis were conducted using logistic regression models for each outcome of interest through backward elimination method starting from variables with p-values <0.15 in univariate analyses. Wald and Log Rank tests were used to obtain p-values during the Logistic regression and Kaplan-Meier survival analysis. The models were checked for potential confounders and effect modifiers. The Hosmer-Lemeshow goodness-of- fit test was used to determine the fit of the final logistic regression models.

3. RESULTS

3.1. *General patient characteristics*

In total, 402 patient medical records were reviewed and included in the final sample. Table 2 summarizes the baseline characteristics of the study population. Males predominated in the sample (n = 241, 60%). Approximately half of the study population was under 12 months of age, ranging from newborn to 17 years old. Mean weight was 11.2±10.9 kg, ranging from 1.9 to 69 kg. Prematurity was registered in 1.7% of the cases, which precluded a subgroup analysis. Major noncardiac abnormalities were observed in 14.7% of the cases. Nearly half of the study patients were classified in RACHS-1 category 2 (43.8%), with the first three (lowest) RACHS-1 categories accounting for 95% of all cases. There were no patients classified into RACHS-1 category 5. Operative complications occurred in 12.4% of the cases. Crude operative mortality was 9% (n =36).

Table 2. Characteristics of study population

Patient characteristics	**N = 402***
Male	241 (60.0)
Age	
< 1 year	206 (51.2)
1 to 5 years	126 (31.3)
> 5 years	70 (17.4)
Weight (kg), mean ± sd	11.2 ± 10.9
Prematurity	7 (1.7)
Major noncardiac abnormality	59 (14.7)
RACHS-1 category	
1	95 (23.6)
2	176 (43.8)
3	111 (27.6)
4	17 (4.2)
5	-
6	3 (0.7)
Complication	50 (12.4)
Operative mortality	36 (9.0)

**Results are presented as numbers and percentages, unless specified otherwise.*

3.2. *Bivariate analysis*

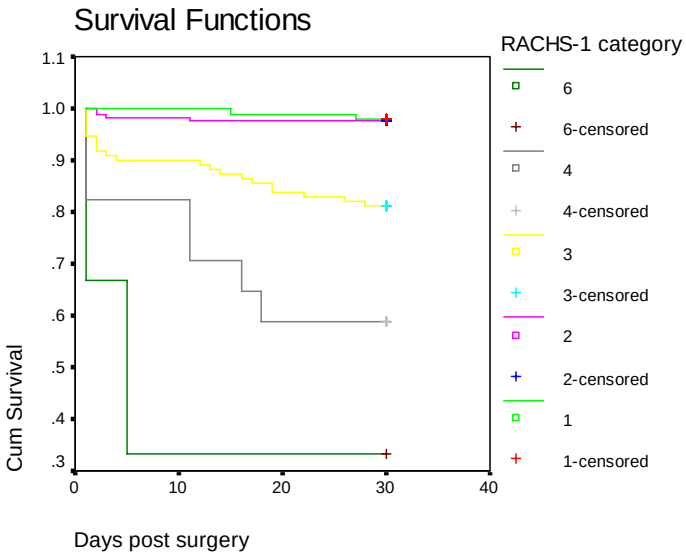
3.2.1. *Early operative mortality*

A total of 36 cases of early mortality were registered (9.0%). Table 3 presents the counts and percentages of mortality within each RACHS-1 category, showing that first two RACHS-1 categories have only 2.1 to 2.3% operative mortality rates vs. higher RACHS-1 categories, in which the death rate increases up to 66.7%.

Table 3. Early mortality by RACHS-1 category

RACHS-1 category	**1**	**2**	**3**	**4**	**6**	**Total**
Surgeries (n)	95	176	111	17	3	402
Deaths (n)	2	4	21	7	2	36
Death rate (%)	**2.1%**	**2.3%**	**18.9%**	**41.2%**	**66.7%**	**9.0%**

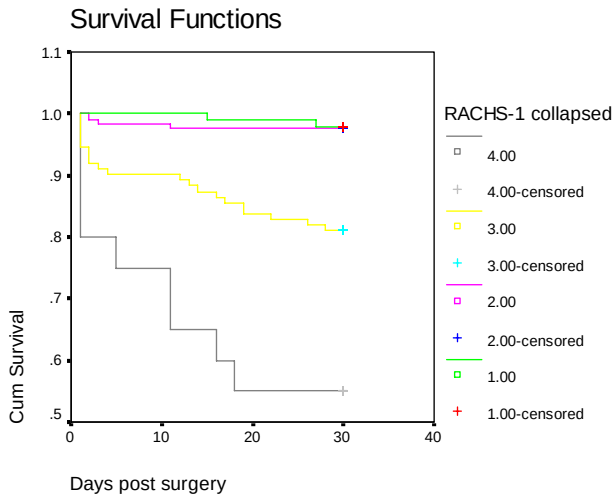
The Kaplan-Meier survival curve (Figure 1) depicts significantly different survival trends across RACH-1 groups (p< 0.001, log rank test).



Log Rank p-value < .0001

Figure 1. Survival through 30 days post surgery by RACHS-1 category

Based on similar survival trends, the absence of the fifth category and a small number of patients in the last category, the fourth through sixth RACHS-1 categories were collapsed for further analysis (Figure 2).



Log Rank p-value < .0001

Figure 2. Survival through 30 days post surgery by collapsed RACHS-1 categories

The RACHS-1 categories were entered into a logistic regression with potential other predictors including age, sex, weight, prematurity, noncardiac abnormality (Table 4), and crude (unadjusted) odds ratios were calculated. Increasing age and weight and lower RACHS-1 scores were associated with significantly reduced odds of operative mortality. Variables such as sex, prematurity, and noncardiac abnormalities were not significantly associated with the operative mortality ($p > 0.05$).

Table 4. Simple logistic regression analyses of possible risk factors for operative mortality

	Odds Ratio	P-value	95% Confidence Intervals	
Female sex	1.825	.120	.855	3.896
Age (years)	.976	.014	.957	.995
Weight (kg)	.855	.002	.775	.944
Prematurity (Yes)	.583	.622	.068	4.984
Noncardiac abnormalities (Yes)	1.414	.528	.481	4.157

RACHS category				
RACHS(1)	.026	.000	.005	.138
RACHS(2)	.028	.000	.008	.107
RACHS(3)	.285	.014	.105	.776
RACHS (4-6)	1.00	-	-	-

3.2.2. *Complications*

The same risk factors were separately explored for the outcome of complications (Table 5) and crude (unadjusted) odds ratios calculated. The same pattern of effect size and significance as noted for early mortality was observed: increasing age and weight and lower RACHS-1 scores were associated with significantly reduced odds of complications. Sex, prematurity, and noncardiac abnormalities were not significantly associated with complications ($p>0.05$).

Table 5. Simple logistic regression analysis of possible risk factors for early complication

	Odds Ratio	**P-value**	**95% Confidence Intervals**	
Female sex	1.216	.533	.657	2.251
Age (years)	.964	.001	.943	.985
Weight (kg)	.807	.000	.730	.892
Prematurity (Yes)	.850	.881	.100	7.208
Noncardiac abnormalities (Yes)	.754	.479	.345	1.647
RACHS category				
RACHS(1)	.044	.000	.012	.166
RACHS(2)	.067	.000	.023	.194
RACHS(3)	.291	.014	.109	.777
RACHS (4-6)	1.00	-	-	-

3.3. *Multivariable analysis*

3.3.1. *Early operative mortality*

All of the potential predictor variables for early postoperative mortality were then entered into a multivariable logistic regression model, and adjusted odds ratios were calculated (Table 6). In the full model, RACHS-1 score and weight were statistically significantly associated with operative mortality. Age was reduced to marginal significance and reversed direction. Sex,

prematurity and noncardiac abnormality were not statistically significantly associated with the operative mortality.

Table 6. First step of multivariate logistic regression analysis for early mortality

	Odds Ratio	P-value	95% Confidence Intervals	
Female sex	1.872	.145	.806	4.349
Age (years)	1.043	.059	.998	1.090
Weight (kg)	.760	.014	.610	.946
Prematurity (Yes)	1.033	.978	.098	10.854
Noncardiac abnormalities (Yes)	1.956	.262	.606	6.309
RACHS category				
RACHS(1)	.042	.001	.007	.259
RACHS(2)	.040	.000	.010	.156
RACHS(3)	.331	.038	.117	.939
RACHS (4-6)	1.00	-	-	-

Hosmer and Lemeshow Goodness of fit test p-value =.373

Variables with a p-value more than 0.15 were removed. Age was also removed from the model, because of its high correlation with weight (Variance Inflation Factor of 1.000) and a final fitted logistical regression model run (Table 7). The odds of CHD surgical mortality decrease with lower RACHS-1 scores and increasing weight. Sex remained insignificant despite its appreciable effect size.

Table 7. Final model of multivariate logistic regression analysis for early mortality

	Odds Ratio	P-value	95% Confidence Intervals	
Weight (kg)	.918	.050	.843	1.000
RACHS				
RACHS(1)	.053	.001	.009	.295
RACHS(2)	.036	.000	.009	.138
RACHS(3)	.310	.026	.111	.867
RACHS (4-6)	1.00	-	-	-

Hosmer and Lemeshow Goodness of fit Test p-value =.259
Results are adjusted for Sex

3.3.2. *Complications*

Multivariate logistic regression analysis was performed for the outcome of complications. All predicting variables explored in the previous bivariate analysis were included in the model (Table 8). In the full model, RACHS-1 score and weight were statistically significantly associated with complications. Age, again like in the analysis of operative mortality, reversed direction, and moved towards statistical significance. Prematurity was not statistically significant, which could be caused by its very low incident rate. Sex and noncardiac abnormality were not statistically significantly associated with operative complications.

Table 8. First step of multivariate logistic regression analysis for early complication

	Odds Ratio	**P-value**	**95% Confidence Intervals**	
Female sex	1.176	.641	.595	2.327
Age (years)	1.037	.074	.997	1.080
Weight (kg)	.732	.003	.597	.898
Prematurity (Yes)	2.163	.505	.224	20.842
Noncardiac abnormalities (Yes)	.985	.972	.417	2.326
RACHS category				
RACHS(1)	.105	.002	.025	.443
RACHS(2)	.105	.000	.034	.325
RACHS(3)	.363	.058	.128	1.033
RACHS (4-6)	1.00			

Hosmer and Lemeshow Goodness of fit test p-value =.175

Sex, prematurity and “noncardiac abnormality” variables were removed from the adjusted model because their p-value exceeded the 0.15 inclusion threshold (Table9). Age was removed from the model, because of its high correlation with weight (Variance Inflation Factor of 1.000). The odds of early complications significantly increased directly with RACHS-1 score and inversely with weight at operation.

Table 9.Final model of multivariate logistic regression analysis for early complication, adjusted for sex

	Odds Ratio	P-value	95% Confidence Intervals	
Weight	.859	.001	.783	.943
RACHS category				
RACHS(1)	.110	.002	.027	.455
RACHS(2)	.094	.000	.030	.290
RACHS(3)	.335	.038	.119	.943
RACHS (4-6)	1.00	-	-	-

Hosmer and Lemeshow Goodness of fit test p-value =.042

4. DISCUSSION

Consistent with the results of previous studies(5;37-39), this study found that RACHS-1 method of risk assignment for congenital heart surgery appropriately reflected the risk of operative death and complications in CHD surgery and can be used to predict outcomes for the Armenian population. The odds of operative mortality and complications varied directly with RACHS-1 score and inversely with weight. Sex remained insignificant despite a persistent, appreciable effect size.

4.1. *Main findings*

Crude operative mortality was estimated as 9%, which is comparable to results of other studies showing a range of 2.5% to 11.4% (38;40). In the two lowest RACHS-1 categories (low risk), which account for nearly 70.0% of the study population, operative mortality was 2.1 to 2.3%, and increased monotonically in higher RACHS categories.

Complications were seen in 12.4% of studied cases. This number is significantly lower than the 32% rate of complications reported by Benavidez et al(10) in a study of over ten thousand surgical admissions throughout the US in 2000. The case selection method was similar in the current study. The methodology and short list for identification of the complications used in this study were comparable, however slightly different than the approach used by Benavidez et

al(10;18). The distributions of different patient characteristics found in this study, like age, sex, number of patients in specific RACHS-1 categories were very similar to those reported by Benavidez et al. The differences in methodology and also differences in reporting could be possible explanations for differences in complication rates between these studies.

RACHS-1 score and weight were identified as the statistically significant predictors of early death and early complications. Similar findings were reported by Larsen et al. for the Danish population.(37) As the RACHS-1 method was developed to assess CHD mortality and its predictive validity demonstrated in different populations and at different institutions (37;40;41), this association was expected and confirmed by this study.

The effect of patient weight on CHD surgical outcomes is less examined. No clear consensus emerges from the scant published literature on the relationship between weight CHD surgery outcome.(42-44) Current study's findings support the inverse relationship between weight at operation and poor outcome found in previous research, however, further research is needed to examine this trend in specific age groups of children undergoing CHD surgery.

4.2. *Limitations*

The study's modest sample of 400 cases, might have limited the detection of important predictor variables such as sex and presence of prematurity. The NMMC representative charged with assigning RACHS-1 score was aware of the patient's 30 day mortality status, which could potentially have biased the assignment. However, this threat was minimized by the clear methodology for assigning RACHS-1 score and limited latitude for judgment when assigning the score.

Unlike the majority of studies which have analyzed CHD surgical outcomes , this study used one surgery per patient and was based on the number of patient admission to follow up service,

rather than on the number of surgical admissions(5;35;37). This deviation from standard approach does not affect the study's internal validity; however it results in a smaller denominator during the calculation of outcome rates which introduces a conservative bias.

5. RECOMMENDATIONS

The study's results, in combination with the literature suggest two actions:

1) replicate this analysis on NMMC complete pediatric follow up dataset;
2) establish an electronic registry for pediatric cardiac surgical admissions at NMMC, where the data of patients admitted for a CHD surgery will be collected.

Replicating the study will increase the numbers of patients in some RACHS categories, increase the study's power to reveal clinically and statistically significant associations, especially those that had marginally significant impact on outcomes in this study (e.g., sex) or yielded large odds ratio (e.g., like prematurity). . The establishment of a registry and the use of internationally developed standards for data collection (17;18) will be an essential contribution for further continuous quality assurance and research at NMMC.

6. CONCLUSION

NMMC's overall operative mortality was comparable to that reported at similar institutions.

The same significant associations were observed between the predictors of weight and case complexity (RACHS-1) and the study outcomes of death and complications: higher weight and lower RACHS score were associated with decreased odds of operative death and complication.

This study demonstrated that the Risk Adjustment for Congenital Heart Surgery-1 method can be used to predict operative mortality at NMMC, Yerevan, Armenia. The estimated mortality

rates within each RACHS-1 category can be used to compare NMMC's performance against international peers and to guide NMMC in future quality assurance efforts.

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Appendix I: Noncardiac Abnormalities/General Preoperative Risk Factors Short List

(Each of the listed factors is a binary variable; yes/no)

None
Asplenia
Polysplenia
Down syndrome
Turner syndrome
DiGeorge
Williams Beuren syndrome
Alagille syndrome (intrahepatic biliary duct agenesis)
22q11 deletion
Other chromosomal/syndromic abnormality
Rubella
Marfan syndrome
Preoperative mechanical circulatory support (IABP, VAD, ECMO, or CPS)
Preoperative complete AV block
Preoperative arrhythmia
Preoperative shock
Preoperative acidosis
Preoperative pulmonary hypertension crises (PA pressure > systemic pressure)
Preoperative mechanical ventilatory support
Preoperative tracheostomy
Preoperative renal failure (creatinine >2)
Preoperative renal failure requiring dialysis
Preoperative bleeding disorder
Preoperative endocarditis
Preoperative septicemia
Preoperative neurological deficit
Preoperative seizures
Other preoperative noncardiac abnormality
Other preoperative risk factor

Appendix II: Diagnosis Short List

Septal defects	
ASD	**PFO** **ASD, Secundum** **ASD, Sinus venosus** **ASD, Coronary sinus** **ASD, Common atrium (single atrium)** **ASD, NOS**
VSD	**VSD, Single** **VSD, Multiple** **VSD, NOS**
AV canal	**AVC (AVSD), Complete (CAVSD)** **AVC (AVSD), Intermediate (transitional)** **AVC (AVSD), Partial (incomplete) (PAVSD) (ASD, Primum)** **AVC (AVSD), NOS**
AP window	**AP window (aortopulmonary window)** **Pulmonary artery origin from ascending aorta (hemitruncus)**
Truncus arteriosus	**Truncus arteriosus** **Truncal valve insufficiency**
Pulmonary venous anomalies	
Partial anomalous pulmonary venous	**Partial anomalous pulmonary venous connection (PAPVC)** **Partial anomalous pulmonary venous connection (PAPVC), Scimitar**
Total anomalous pulmonary venous	**Total anomalous pulmonary venous connection (TAPVC), Type 1 (supracardiac)** **Total anomalous pulmonary venous connection (TAPVC), Type 2 (cardiac)** **Total anomalous pulmonary venous connection (TAPVC), Type 3 (infracardiac)** **Total anomalous pulmonary venous connection (TAPVC), Type 4 (mixed)** **Total anomalous pulmonary venous connection (TAPVC), NOS**
Cor triatriatum	**Cor triatriatum**
Pulmonary venous stenosis	**Pulmonary venous stenosis**
Systemic venous anomalies	
Anomalous systemic venous connection	**Systemic venous anomaly** **Systemic venous obstruction**
Right heart lesions	
Tetralogy	**TOF** **TOF, AVC (AVSD)** **TOF, Absent pulmonary valve**
Pulmonary atresia	**Pulmonary atresia** **Pulmonary atresia, IVS** **Pulmonary atresia, VSD (including TOF, PA)** **Pulmonary atresia, VSD-MAPCA (pseudotruncus)** **MAPCA(s) (major aortopulmonary collateral[s]) (without PA-VSD)**
Tricuspid valve disease and Ebstein's	**Ebstein's anomaly** **Tricuspid regurgitation, Non-Ebstein's related** **Tricuspid stenosis** **Tricuspid regurgitation and tricuspid stenosis** **Tricuspid valve, Other**
RVOT obstruction, IVS **Pulmonary stenosis**	**Pulmonary stenosis, Valvar** **Pulmonary artery stenosis (Hypoplasia), Main (Trunk)** **Pulmonary artery stenosis, Branch, Central (Within the hilar**

	bifurcation) **Pulmonary artery stenosis, Branch, Peripheral (At or beyond the hilar bifurcation)** *Pulmonary artery stenosis, NOS* *Pulmonary artery, Discontinuous* **Pulmonary stenosis, NOS** *Pulmonary stenosis, Subvalvar* **DCRV** **Pulmonary valve, Other**
Conduit stenosis/insufficiency	**Conduit failure**
Pulmonary valve disease	**Pulmonary insufficiency** **Pulmonary insufficiency and pulmonary stenosis**

Left heart lesions	
Aortic valve disease	**Aortic stenosis, Subvalvar** **Aortic stenosis, Valvar** **Aortic stenosis, Supravalvar** **Aortic stenosis, NOS** **Aortic valve atresia** **Aortic insufficiency** **Aortic insufficiency and aortic stenosis** **Aortic valve, Other**
Sinus of Valsalva fistula/aneurysm	**Sinus of Valsalva aneurysm**
LV to aorta tunnel	**LV to aorta tunnel**
Mitral valve disease	**Mitral stenosis, Supravalvar mitral ring** **Mitral stenosis, Valvar** **Mitral stenosis, Subvalvar** **Mitral stenosis, Subvalvar, Parachute** **Mitral stenosis, NOS** **Mitral regurgitation and mitral stenosis** **Mitral regurgitation** **Mitral valve, Other**
Hypoplastic left heart	**Hypoplastic left heart syndrome (HLHS)**
Cardiomyopathy	**Cardiomyopathy** **Cardiomyopathy, End stage congenital heart disease**
Pericardial disease	**Pericardial effusion** **Pericarditis** **Pericardial disease, Other**
Single ventricle	
Single ventricle	**Single ventricle, DILV** **Single ventricle, DIRV** **Single ventricle, Mitral atresia** **Single ventricle, Tricuspid atresia** **Single ventricle, Unbalance AV canal** **Single ventricle, Heterotaxia syndrome** **Single ventricle, Other** **Single ventricle, NOS**
Transposition of the great arteries	
Congenitally corrected TGA	**Congenitally corrected TGA**
Transposition of the great arteries	**TGA, IVS** **TGA, IVS-LVOTO** **TGA, VSD** **TGA, VSD-LVOTO** **TGA, NOS**
DORV	
DORV	**DORV, VSD type** **DORV, TOF type**

	DORV, TGA type **DORV, Remote VSD (uncommitted VSD)** **DORV, NOS**
DOLV	
DOLV	**DOLV**
Thoracic arteries and veins	
Coarctation of aorta (All types)	**Coarctation of aorta** **Aortic arch hypoplasia**
Coronary artery anomaly	**Coronary artery anomaly, Anomalous aortic origin** **Coronary artery anomaly, Anomalous pulmonary origin (includes ALCAPA)** **Coronary artery anomaly, Fistula** **Coronary artery anomaly, Aneurysm** *Coronary artery anomaly, Other* **Coronary artery anomaly, NOS**
Interrupted arch	**Interrupted aortic arch**
Patent ductus arteriosus	**Patent ductus arteriosus**
Vascular rings and slings	**Vascular ring** **Pulmonary artery sling**
Aortic aneurysm	**Aortic aneurysm (including pseudoaneurysm)** **Aortic dissection**
Lung disease	
Lung disease	**Lung disease, Benign** **Lung disease, Malignant**
Pectus excavatum, carinatum	**Pectus**
Tracheal stenosis	**Tracheal stenosis** **Tracheal disease, Other**
Electrophysiologic	
Electrophysiologic	**Arrhythmia** **Arrhythmia, Heart block, Acquired** **Arrhythmia, Heart block, Congenital** **Arrhythmia, Heart block, NOS** **Arrhythmia, Pacemaker, Indication for replacement**
Miscellaneous	
Miscellaneous	**Atrial isomerism, Left** **Atrial isomerism, Right** **Aneurysm, Ventricular, Right** **Aneurysm, Ventricular, Left** **Aneurysm, Pulmonary artery** **Aneurysm, Other** **Hypoplastic RV** **Hypoplastic LV** **Mediastinitis** **Endocarditis** **Prosthetic valve failure** **Myocardial infarction** **Cardiac tumor** **Pulmonary AV fistula** **Pulmonary embolism** **Pulmonary vascular obstructive disease, NOS** **Pulmonary vascular obstructive disease (Eisenmenger's)** **Primary pulmonary hypertension** **Persistent fetal circulation** **Meconium aspiration** **Pleural disease, Benign** **Pleural disease, Malignant**

	Pneumothorax
	Pleural effusion
	Chylothorax
	Empyema
	Esophageal disease, Benign
	Esophageal disease, Malignant
	Mediastinal disease, Benign
	Mediastinal disease, Malignant
	Diaphragm paralysis
	Diaphragm disease, Other
	Cardiac, Other
	Thoracic and/or mediastinal, Other
	Peripheral vascular, Other
	Miscellaneous, Other
	Normal heart

Appendix III: Procedure Short List

Septal defects	
ASD	**PFO, Primary closure** **ASD repair, Primary closure** **ASD repair, Patch** **ASD repair, Device** **ASD, Common atrium (single atrium), Septation** **ASD creation/enlargement** **ASD partial closure** **Atrial septal fenestration** **ASD repair, NOS**
VSD	**VSD repair, Primary closure** **VSD repair, Patch** **VSD repair, Device** **VSD multiple repair** **VSD creation/enlargement** **Ventricular septal fenestration** **VSD repair, NOS**
AV canal	**AVC (AVSD) repair, Complete (CAVSD)** **AVC (AVSD) repair, Intermediate (transitional)** **AVC (AVSD) repair, Partial (incomplete) (PAVSD)** **AVC (AVSD) repair, NOS**
AP window	**AP window repair** **Pulmonary artery origin from ascending aorta (hemitruncus) repair**
Truncus arteriosus	**Truncus arteriosus repair** **Valvuloplasty, Truncal valve** **Valve replacement, Truncal valve**
Pulmonary venous anomalies	
Partial anomalous pulmonary venous connection	**PAPVC repair** **PAPVC, Scimitar repair**
Total anomalous pulmonary venous connection	**TAPVC repair**
Cor triatriatum	**Cor triatriatum repair**
Pulmonary venous stenosis	**Pulmonary venous stenosis repair**
Systemic venous anomalies	
Anomalous systemic venous connection	**Atrial baffle procedure (non-Mustard, non-Senning)** **Anomalous systemic venous connection repair** **Systemic venous stenosis repair**
Right heart lesions	
Tetralogy	**TOF repair, No ventriculotomy** **TOF repair, Ventriculotomy, Nontransanular patch** **TOF repair, Ventriculotomy, Transanular patch** **TOF repair, RV-PA conduit** **TOF, AVC (AVSD) repair** **TOF, Absent pulmonary valve repair** **TOF repair, NOS**
Pulmonary atresia	**Pulmonary atresia-VSD (including TOF, PA) repair** **Pulmonary atresia-VSD-MAPCA (pseudotruncus) repair** **Unifocalization MAPCA(s)** **Occlusion MAPCA(s)**
Tricuspid valve disease and Ebstein's anomaly	**Valvuloplasty, Tricuspid** **Valve replacement, Tricuspid (TVR)** **Valve closure, Tricuspid (exclusion, univentricular approach)** **Valve excision, Tricuspid (without replacement)** **Valve surgery, Other, Tricuspid**

RVOT obstruction, IVS **Pulmonary stenosis**	**RVOT procedure** **1 ½ ventricular repair** **PA, reconstruction (plasty), Main (Trunk)** **PA, reconstruction (plasty), Branch, Central (Within the hilar bifurcation)** **PA, reconstruction (plasty), Branch, Peripheral (At or beyond the hilar bifurcation)** **PA, reconstruction (plasty), NOS** **DCRV repair**
Conduit stenosis/insufficiency	**Conduit reoperation** **Conduit placement, NOS**
Pulmonary valve disease	**Valvuloplasty, Pulmonic** **Valve replacement, Pulmonic (PVR)** **Conduit placement, RV to PA** **Conduit placement, LV to PA** **Valve excision, Pulmonary (without replacement)** **Valve closure, Semilunar** **Valve surgery, Other, Pulmonic**
Left heart lesions	
Aortic valve disease	**Valvuloplasty, Aortic** **Valve replacement, Aortic (AVR)** **Valve replacement, Aortic (AVR), Mechanical** **Valve replacement, Aortic (AVR), Bioprosthetic** **Valve replacement, Aortic (AVR), Homograft** **Aortic root replacement** **Aortic root replacement, Mechanical** **Aortic root replacement, Homograft** **Ross procedure** **Konno procedure** **Ross-Konno procedure** **Other annular enlargement procedure** **Aortic stenosis, Subvalvar, Repair** **Aortic stenosis, Supravalvar, Repair** *Valve closure, Semilunar* **Valve surgery, Other, Aortic**
Sinus of Valsalva fistula/aneurysm	**Sinus of Valsalva, Aneurysm repair**
LV to aorta tunnel	**LV to aorta tunnel repair**
Mitral valve disease	**Valvuloplasty, Mitral** **Mitral stenosis, Supravalvar mitral ring repair** **Valve replacement, Mitral (MVR)** **Valve surgery, Other, Mitral**
Hypoplastic left heart	**Norwood procedure** **HLHS biventricular repair** **Transplant, Heart**
Cardiomyopathy	**Transplant, Heart** **Transplant, Heart and lung** **Partial left ventriculectomy (LV volume reduction surgery) (Batista)**
Constrictive pericarditis	**Pericardial drainage procedure** **Pericardiectomy** **Pericardial procedure, Other**
Single ventricle	
Single ventricle	**Fontan, Atrio-pulmonary connection** **Fontan, Atrio-ventricular connection** **Fontan, TCPC, Lateral tunnel, Fenestrated** **Fontan, TCPC, Lateral tunnel, Nonfenestrated** **Fontan, TCPC, Lateral tunnel, NOS** **Fontan, TCPC, External conduit, Fenestrated**

	Fontan, TCPC, External conduit, Nonfenestrated **Fontan, TCPC, External conduit, NOS** **Fontan, Other** **Fontan, NOS** **(Additional procedures are listed under the "Palliative Procedures" section so as to avoid repetitive listings. However, these procedures are discussed in the "Single Ventricle" paper.)**
Transposition of the great arteries	
Congenitally corrected TGA	**Congenitally corrected TGA repair, Atrial switch and ASO (double switch)** **Congenitally corrected TGA repair, Atrial switch and Rastelli** **Congenitally corrected TGA repair, VSD closure** **Congenitally corrected TGA repair, VSD closure and LV to PA conduit** **Congenitally corrected TGA repair, Other** **Congenitally corrected TGA repair, NOS**

Transposition of the great arteries	**Arterial switch operation (ASO)** **Arterial switch operation (ASO) and VSD repair** **Senning** **Mustard** **Rastelli** **REV** **TGA, Other procedures (Norwood, Kawashima, LV-PA conduit, other)**
DORV	
DORV	**DORV, Intraventricular tunnel repair** **DORV repair, NOS**
DOLV	
DOLV	**DOLV repair**
Thoracic arteries and veins	
Coarctation of aorta (all types)	**Coarctation repair, End to end** **Coarctation repair, End to end, extended** **Coarctation repair, Subclavian flap** **Coarctation repair, Patch aortoplasty** **Coarctation repair, Interposition graft** **Coarctation repair, Other** **Coarctation repair, NOS** **Aortic arch repair**
Coronary artery anomaly	**Anomalous origin of coronary artery from pulmonary artery repair** **Coronary artery fistula ligation** **Coronary artery bypass** **Coronary artery procedure, Other**
Interrupted arch	**Interrupted aortic arch repair**
Patent ductus arteriosus	**PDA closure, Surgical** **PDA closure, Device** **PDA closure, NOS**
Vascular rings and slings	**Vascular ring repair** **Pulmonary artery sling repair**
Aortic aneurysm	**Aortic aneurysm repair** **Aortic dissection repair**
Lung disease	
Lung disease	**Lung biopsy** **Transplant, Lung(s)** **Lung procedure, Other**
Pectus excavatum, carinatum	**Pectus repair**

Tracheal stenosis	Tracheal procedure
Electrophysiologic	
Electrophysiologic	**Pacemaker implantation, Permanent** **Pacemaker procedure** **ICD (AICD) Implantation** **ICD (AICD) ([Automatic] Implantable Cardioverter Defibrillator) procedure** **Arrhythmia surgery-atrial, Surgical ablation** **Arrhythmia surgery-ventricular, Surgical ablation** **Arrhythmia surgery, NOS**
Interventional cardiology procedures	
Interventional cardiology procedures	**ASD creation, Balloon septostomy (BAS) (Rashkind)** **ASD creation, Blade septostomy** **Balloon dilation** **Stent placement** **Device closure** **RF ablation** **Coil embolization**

Palliative procedures	
Palliative procedures	**Shunt, Systemic to pulmonary, Modified Blalock-Taussig shunt (MBTS)** **Shunt, Systemic to pulmonary, Central (from aorta or to main pulmonary artery)** **Shunt, Systemic to pulmonary, Other** **Shunt, Systemic to pulmonary, NOS** **Shunt, Ligation and takedown** **PA banding (PAB)** **PA debanding** **Damus-Kaye-Stansel procedure (DKS) (creation of AP anastomosis without arch reconstruction)** **Bidirectional cavopulmonary anastomosis (BDCPA) (bidirectional Glenn)** **Glenn (unidirectional cavopulmonary anastomosis) (unidirectional Glenn)** **Bilateral bidirectional cavopulmonary anastomosis (BBDCPA) (bilateral bidirectional Glenn)** **Hemifontan** **Palliation, Other**
Miscellaneous	

Miscellaneous	**Aneurysm, Ventricular, Right, Repair**
	Aneurysm, Ventricular, Left, Repair
	Aneurysm, Pulmonary artery, Repair
	Atrial baffle procedure, NOS
	Cardiac tumor resection
	Conduit placement, NOS
	Pulmonary AV fistula repair/occlusion
	Ligation, Pulmonary artery
	Pulmonary embolectomy
	Pleural drainage procedure
	Pleural procedure, Other
	Ligation, Thoracic duct
	Decortication
	Esophageal procedure
	Mediastinal procedure
	Bronchoscopy
	Diaphragm plication
	Diaphragm procedure, Other
	Intraaortic balloon pump (IABP) insertion
	ECMO procedure
	Right/left heart assist device procedure
	VATS (video-assisted thoracoscopic surgery)
	Minimally invasive procedure
	Bypass for noncardiac lesion
	Delayed sternal closure
	Mediastinal exploration
	Sternotomy wound drainage
	Organ procurement
	Thoracotomy, Other
	Cardiotomy, Other
	Cardiac procedure, Other
	Thoracic and/or mediastinal procedure, Other
	Peripheral vascular procedure, Other
	Miscellaneous procedure, Other
	Other

Appendix IV. Complications Short List

None
Reoperation during this admission (unplanned reoperation)
Postoperative cardiac arrest
Postoperative mechanical circulatory support (IABP, VAD, ECMO, or CPS)
Postoperative complete AV block requiring temporary pacemaker
Postoperative complete AV block requiring permanent pacemaker
Postoperative arrhythmia
Postoperative low cardiac output
Postoperative acidosis
Sternum left open
Pericardial effusion requiring drainage
Systemic vein obstruction
Pulmonary vein obstruction
Postoperative pulmonary hypertension crises (PA pressure > systemic pressure)
Postoperative respiratory insufficiency requiring mechanical ventilatory support > 7 days
Postoperative respiratory insufficiency requiring reintubation
Postoperative tracheostomy
Pneumonia
Pneumothorax
Pleural effusion requiring drainage
Chylothorax
Acute renal failure requiring temporary dialysis
Acute renal failure requiring permanent dialysis
Bleeding requiring reoperation
Wound dehiscence
Wound infection
Mediastinitis
Postoperative endocarditis
Postoperative septicemia
Phrenic nerve injury/paralyzed diaphragm
Recurrent laryngeal nerve injury/paralyzed vocal cord
Postoperative neurological deficit persisting at discharge
Postoperative new onset seizures
Other postoperative complication

Appendix V: Rules to Define Operative Mortality

1. In the EACTS and The STS Congenital Database, Operative Mortality is defined as any death, regardless of cause occurring (1) within 30 days after surgery in or out of the hospital, and (2) after 30 days during the same hospitalization subsequent to the operation.
2. If a patient had more than one operation during a hospitalization, assignment of mortality is made to the first operation of the given hospitalization that meets the criteria of an operation type that will be included in the overall programmatic mortality analysis as described in Rule number 10. This operation that would be assigned the mortality can be called the ‘‘index operation.’’ (Previously, no useful data was obtained when we allowed the individual surgeon or other data entry personnel to choose the operation to which a given mortality is assigned. We now believe that better data will be obtained by assigning mortality to the first operation of an admission. In the future, algorithmically driven assignment of mortality to the most complex case of the admission might further minimize assignment errors.)
3. The EACTS and STS Congenital Database Reports will employ patient admission-based operative mortality calculation. The numerator is the number of patients who have died as measured by the criteria of Operative Mortality. The denominator is the number of surgical patient admissions. Any patient admission that includes one or more cardiac operations of operation types ‘‘CPB’’ or ‘‘No CPB Cardiovascular’’ will be considered a ‘‘cardiovascular surgical admission’’ and add to the denominator. (Rule number 10 below clarifies which interventions will actually be counted as operations in the EACTS-STS Congenital Database mortality calculations.) It should be noted that the patient who dies after admission but before any surgery will not count as an operative mortality and therefore will not count when calculating patient admission-based operative mortality, unless the patient had prior surgery within 30 days (of the mortality) and is readmitted to the hospital in which case the patient would count as an operative mortality of the prior index operation as described in Rules number 1 and 2 above.
4. Any mortality that occurs for a patient with multiple cardiovascular surgical admissions is assigned to the latest cardiovascular surgical admission. Each cardiovascular surgical admission will be treated as an independent observation. For example, a given patient will contribute only 1 encounter to the total denominator for the single hospitalization for the Norwood (Stage 1) operation even if that particular hospitalization involves multiple operations. If this same patient is discharged home and is later re-admitted and undergoes a superior cavo-pulmonary connection operation more than 30 days after the Norwood (Stage 1), this patient will now contribute 2 encounters (observations) to the denominator. However, if a patient is readmitted to the hospital and undergoes surgery within 30 days of a prior index operation, mortality is assigned to the earlier index operation.
5. In order for a record to be complete and eligible for mortality analysis, the following database fields must be complete:
A. Date of Admission
B. Date of Surgery
C. Operation Type (‘‘CPB,’’ ‘‘No CPB Cardiovascular,’’ ‘‘ECMO,’’ ‘‘Thoracic,’’ ‘‘Interventional Cardiology,’’ or ‘‘Other’’ in the minimum
dataset. [CPB is cardiopulmonary bypass and ECMO is extracorporeal membrane oxygenation]. Software vendors may supply other
operation types [eg, ‘‘CPB Standby,’’ ‘‘CPS,’’ ‘‘Minor Procedure,’’ ‘‘Bronchoscopy,’’ ‘‘Other Endoscopy,’’ where CPS is Cardiopulmonary
support]; these are converted by the vendor during data harvest export to the appropriate operation type from the official list of
choices. For example, operations coded as ‘‘Minor Procedure’’ are converted by the vendor during data harvest export to Operation
Type ‘‘Other.’’)
D. Primary Diagnosis
E. Primary Procedure
F. Discharge Status (Alive or Dead)
G. 30-day Status (Alive or Dead).
A record cannot be included in the mortality analysis until both Discharge Status and 30-day Status fields are completed.
6. Patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure will not be included in the mortality calculation in the EACTS and The STS Congenital Database reports. (We acknowledge that mortality after surgical PDA closure in low-birth weight premature infants can be related to surgical judgment or technique; however, the vast majority of deaths in this patient population are multifactorial and largely unrelated to the surgical procedure in time and by cause. Therefore, because mortality in this patient group could potentially

impact significantly on the expression of overall programmatic mortality, we have decided to exclude from mortality analysis patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure.)
7. If a patient was admitted from their home, they must be either dead or discharged to home prior to completing the field discharge status. If a patient was admitted from their home, the field discharge status can not be completed if the patient is transferred to another acute care facility or chronic care facility until they are either dead or discharged to home. However, if this patient survives in a chronic care facility for 6 postoperative months (ie, 183 postoperative days), the patient can then be considered ''alive'' in the discharge status field. (Some institutions may not have a setup that allows transfer to a chronic care facility and instead utilizes their own institution as the chronic care facility. If an institution does not utilize a chronic care facility and instead keeps these chronic patients in-house, this institution can apply to this Rule [number 7] whenever one of their patients survives for 6 postoperative months (ie, 183 postoperative days) on ''chronic care status'' within their institution.)
8. If a patient was admitted from (ie, transferred from) a chronic care facility where they chronically reside, they must be either dead or discharged either to home or to a chronic care facility prior to completing the field discharge status.
9. If a patient was admitted from (ie, transferred from) another acute care facility, Rule number 7 as previously stated applies if they lived at home prior to their admission to the transferring acute care facility. If a patient was transferred from another acute care facility, Rule number 8 as previously stated applies if they lived in a chronic care facility prior to their admission to the transferring acute care facility.
10. Only Operation types ''CPB'' and ''No CPB Cardiovascular'' will be included in the overall programmatic mortality analysis. (All cases classified as operation ''CPB'' and ''No CPB Cardiovascular'' will be included in the mortality analysis except for patients weighing less than or equal to 2,500 g undergoing PDA (patent ductus arteriosus) ligation as their primary procedure, as discussed in Rule number 6 above, and organ procurement cases, as discussed in Rule number 11 below).
11. Operations coded as operation type ''CPB Standby'' will be converted to operation type ''No CPB Cardiovascular'' by the software vendor prior to analysis, with two exceptions: (1) Pectus repair procedure coded as ''CPB Standby'' should be converted to operation type ''Thoracic'' and (2) purely bronchoscopic procedures coded as ''CPB Standby'' should be converted by the vendor to operation type ''Bronchoscopy'' if it is an available option, or by the vendor to operation type ''Thoracic.'' (Centers and surgeons may use cardiopulmonary bypass standby or ECMO standby when performing the Nuss pectus repair or complex bronchoscopic interventions. While other ''CPB Standby'' operations are converted appropriately to operation type ''No CPB Cardiovascular'' by the software vendor prior to analysis, these two examples are best not analyzed as ''No CPB Cardiovascular'' cases in the mortality analysis.) Lung transplantation employing CPB will be coded as such, whilst lung transplantation without CPB will be coded as ''No CPB Cardiovascular.'' Organ procurement is coded as operation type ''No CPB Cardiovascular,'' but will be excluded from both the numerator and the denominator in all mortality analysis.
12. Operation types ''ECMO,'' ''Thoracic,'' ''Interventional Cardiology,'' and ''Other'' will not be included in the overall programmatic mortality analysis. Minor procedures, such as central line placement procedures or arterial line placement procedures and similar vascular access procedures, will count as operation type ''Other'' and will not be included in the overall programmatic mortality analysis.
13. When measuring both programmatic volume and programmatic mortality, only Operation types ''CPB'' and ''No CPB Cardiovascular'' will be included. When measuring both programmatic volume and programmatic mortality, Operation types ''ECMO,'' and ''Thoracic,'' ''Interventional Cardiology'' and ''Other'' will not be included. Therefore, minor procedures such as central line placement procedures will not be included in programmatic volume or mortality measurements. Although organ procurement and patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure will be excluded from the mortality analysis, they will be included in programmatic volume measurement. Thus, only Operation types ''CPB'' and ''No CPB Cardiovascular'' will be included in the mortality analysis; and as stated above, organ procurement and patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure will be excluded from the numerator and the denominator of the mortality analysis.

Reference: Jacobs JP, Mavroudis C Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ. What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report of the STS Congenital Database Taskforce and the Joint EACTS-STS Congenital Database Committee. Ann Thorac Surg 2006; 81: 1937–1941.

Appendix VI: RACHS-1 score; Individual procedures by risk category

Risk category 1
Atrial septal defect surgery (including atrial septal defect secundum, sinus venosus atrial septal defect, patent foramen ovale closure)
Aortopexy
Patent ductus arteriosus surgery at age >30 d
Coarctation repair at age >30 d
Partially anomalous pulmonary venous connection surgery
Risk category 2
Aortic valvotomy or valvuloplasty at age >30 d
Subaortic stenosis resection
Pulmonary valvotomy or valvuloplasty
Pulmonary valve replacement
Right ventricular infundibulectomy
Pulmonary outflow tract augmentation
Repair of coronary artery fistula
Atrial septal defect and ventricular septal defect repair
Atrial septal defect primum repair
Ventricular septal defect repair
Ventricular septal defect closure and pulmonary valvotomy or infundibular resection
Ventricular septal defect closure and pulmonary artery band removal
Repair of unspecified septal defect
Total repair of tetralogy of Fallot
Repair of total anomalous pulmonary veins at age >30 d
Glenn shunt
Vascular ring surgery
Repair of aorta-pulmonary window
Coarctation repair at age ≤30 d
Repair of pulmonary artery stenosis
Transection of pulmonary artery
Common atrium closure
Left ventricular to right atrial shunt repair
Risk category 3
Aortic valve replacement
Ross procedure
Left ventricular outflow tract patch
Ventriculomyotomy
Aortoplasty
Mitral valvotomy or valvuloplasty
Mitral valve replacement
Valvectomy of tricuspid valve
Tricuspid valvotomy or valvuloplasty
Tricuspid valve replacement
Tricuspid valve repositioning for Ebstein anomaly at age >30 d
Repair of anomalous coronary artery without intrapulmonary tunnel
Repair of anomalous coronary artery with intrapulmonary tunnel (Takeuchi)
Closure of semilunar valve, aortic or pulmonary
Right ventricular to pulmonary artery conduit
Left ventricular to pulmonary artery conduit

Repair of double-outlet right ventricle with or without repair of right ventricular obstruction
Fontan procedure
Repair of transitional or complete atrioventricular canal with or without valve replacement
Pulmonary artery banding
Repair of tetralogy of Fallot with pulmonary atresia
Repair of cor triatriatum
Systemic to pulmonary artery shunt
Atrial switch operation
Arterial switch operation
Reimplantation of anomalous pulmonary artery
Annuloplasty
Repair of coarctation and ventricular septal defect closure
Excision of intracardiac tumor

Risk category 4

Aortic valvotomy or valvuloplasty at age ≤30 d
Konno procedure
Repair of complex anomaly (single ventricle) by ventricular septal defect enlargement
Repair of total anomalous pulmonary veins at age ≤30 d
Atrial septectomy
Repair of transposition, ventricular septal defect, and subpulmonary stenosis (Rastelli)
Atrial switch operation with ventricular septal defect closure
Atrial switch operation with repair of subpulmonary stenosis
Arterial switch operation with pulmonary artery band removal
Arterial switch operation with ventricular septal defect closure
Arterial switch operation with repair of subpulmonary stenosis
Repair of truncus arteriosus
Repair of hypoplastic or interrupted arch without ventricular septal defect closure
Repair of hypoplastic or interrupted aortic arch with ventricular septal defect closure
Transverse arch graft
Unifocalization for tetralogy of Fallot and pulmonary atresia
Double switch

Risk category 5

Tricuspid valve repositioning for neonatal Ebstein anomaly at age ≤30 d
Repair of truncus arteriosus and interrupted arch

Risk category 6

Stage 1 repair of hypoplastic left heart syndrome (Norwood operation)
Stage 1 repair of nonhypoplastic left heart syndrome conditions
Damus-Kaye-Stansel procedure

Appendix VII: Data collection form 2

1. Study ID number (non-identifying record identifier: max. 3 digit number) _ _ _
2. Date of birth (mm/dd /yyyy) _ _ / _ _ / _ _ _ _
3. Gender 0. □ Male 1. □Female
4. Date of admission (mm/dd/yyyy) _ _ / _ _ / _ _ _ _
5. Presence of prematurity 0. □No 1. □Yes
   If Yes, specify _____
6. Noncardiac abnormalities/general preoperative risk factors (from Noncardiac Abnormalities/General Preoperative Risk Factors Short List) Check all that applies (appendix I) ----------
7. Number of prior total cardiothoracic operations ___
8. Number of prior open cardiothoracic operations ___
9. Date of surgery(mm/dd/yyyy) _ _ / _ _ / _ _ _ _
10. Case category
    1. □ Cardiopulmonary bypass [CPB]
    2. □No CPB cardiovascular
    3. □Extracorporeal membrane oxygenation (ECMO)
    4. □Thoracic
    5. □Interventional cardiology
    6. □Other 6a. Specify other _____
11. Weight at operation (kg) ___
12. Height at operation(cm) ___
13. Primary diagnosis (from Diagnosis Short List) Check all that applies (appendix II)----------
13a Additional diagnoses(from Diagnosis Short List) Check all that applies (appendix II)----------
14. Operation (primary procedure from Procedures Short List) Check all that applies (appendix III)----------
14a Operation (**additional** procedures from Procedures Short List) Check all that applies (appendix III)----------
15. RACHS-1 category 1.□ 2.□ 3.□ 4.□ 5.□ 6.□
16. Complications (from Complications Short List) Check all that applies (appendix IV)----------
17. Reoperation after this operation in this admission? 0. □No 1. □Yes
28. Is this operation a reoperation during this admission? 0. □No 1. □Yes
    (no; yes—planned reoperation; yes—unplanned reoperation)
19. Date of discharge (mm/dd/yyyy) _ _ / _ _ / _ _ _ _
20. Operative mortality? 0. □No 1. □Yes
21. Mortality Discharge status 0. □Dead 1. □Alive
22. Mortality assigned to this operation? 0. □No 1. □Yes
23. Date of mortality
    Mandatory field only if Operative mortality = Yes(mm/dd/yyyy) _ _ / _ _ / _ _ _ _

Appendix VIII: Data collection form 1

1. Study ID (non-identifying record identifier: max. 3 digit number) _ _ _
2. Medical record number _ _ _ _ _
3. Family Name, Name _____ _____