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Procedure-Based Complications to Guide Informed Consent: Analysis of Society of Thoracic Surgeons-Congenital Heart Surgery Database

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Abstract

Background—Informed consent refers to the process by which physicians and patients engage in a dialogue to explain and comprehend the nature, alternatives, and risks of a procedure or course of therapy. The goal of this study is to better “inform the process of informed consent” by offering empirically derived procedural complication lists that provide objective contemporary data that surgeons may share with patients and families.

Methods—The Society of Thoracic Surgeons Congenital Heart Surgery Database was queried for complications for 12 congenital heart operations (2010 to 2011) performed across all Society of Thoracic Surgeons-European Association of Cardio-Thoracic Surgery Congenital Heart Surgery (STAT) risk categories.

Results—The 12 index procedures reviewed for rates of complications were repair of atrial septal defect (ASD), ventricular septal defect (VSD), atrioventricular septal defect (AVSD), tetralogy of Fallot (TOF), coarctation, and truncus arteriosus, as well as arterial switch operation (ASO), ASO-VSD, BiGlenn, Fontan, Norwood procedure, and systemic to pulmonary artery (S-P) shunt. Arrhythmia was the most frequent complication for VSD (5.8%), TOF (8.9%), and AVSD (14.7%) repairs. There was a high rate of sternum left open (planned, unplanned) for ASO (26%, 7%), ASO-VSD (29%, 10%), truncus repair (41%, 11%), and Norwood (63%, 7%). The most frequent complications for other procedures include ASD (unplanned readmission, 1.9%), BiGlenn (chylothorax, 7%), Fontan (pleural effusion, 16%), S-P shunt (reintubation, 10.6%), and coarctation (reintubation, 5.2%).

Conclusions—The informed consent process for congenital heart surgery may be served by accurate contemporary data on occurrence of complications. While a threshold rate of occurrence of individual complications may guide the physician, rare but important debilitating complications should also be discussed irrespective of frequency. We propose to better inform the process of informed consent by providing objective complications data.

Informed consent refers to a process by which physicians and patients engage in a dialogue to explain and comprehend the nature, alternatives, and risks of a procedure or course of therapy. In particular, most patients want to learn about the disease entity, its natural history, proposed operation, experience of the surgeon and team, reasonable alternatives, and the risks, including complications and mortality. The legal and moral tenets hold that the patient is responsible for her own autonomy and is free to “make medical decisions that reflect her beliefs and healthcare needs” [1]. It is assumed that this dialogue considers cultural diversity, language barriers, psychologic temperaments, socioeconomic conditions, and patient autonomy [2, 3].

Informed consent as a process was first introduced in the case of *Salgo v. Leland Stanford Jr. University Board of Trustees* [4]. In support of the litigants who claimed that physicians were not adequately performing their duty of responsible and adequate behaviors in their interactions with patients, the court ruled that “a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment” [4]. Subsequent court rulings have refined and clarified the legal concept of informed consent by broadening the scope from professional to patient-oriented standards [2] in order to further emphasize the tenets of autonomy, non-maleficence, beneficence, and justice.

The practice of informed consent is far from standardized [1]. The discussion between patients or parents and physicians largely depends on the informing physician’s knowledge of potential complications and interactive skills. These skills have been developed in the course of medical education and instantiated by role models who have taken the time to instill compassion, competence, and duty. In some instances, the informed consent process has been influenced by principles that apply to controlled, randomized, prospective clinical studies that demand certain identifiable consent processes, usually documented with comprehensive preprinted forms that have been vetted by Institutional Review Boards [2]. The actual physician-patient interaction has not been emphasized, allowing the process to continue under the amorphous scope of “the art of medicine.” Several authors [5, 6] have undertaken questionnaire studies that have chronicled physician opinion and offered suggestions, based in part on the occurrence of complications, which may guide the interaction between physician and patient. There remain significant uncertainties as to what complications should be mentioned in the informed consent process. Analysis of data in the Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSDB) [7] provides important information concerning occurrence rates of a group of 6 major complications that are generally but not always specifically discussed with patients and families. How and why physicians choose from the myriad of recognized complications in order to properly perform informed consent is unknown. The informed consent process affords an opportunity to establish a personal relationship with the patient and to review the

treatment plan, reveal reasonable expectations, instill confidence, project hope, and assure that complications, if they occur, will be treated in a compassionate and expeditious manner [8]. It is the “reasonable expectations” portion of this process that we address by collating objective data to inform the informed consent process for congenital heart operations.

The purpose of this study is to query the STS-CHSDB for the rates of occurrence of complications for 12 common operations, to review the literature, and to opine on the nature and process of informed consent as it applies to congenital heart surgeons.

Material and Methods

The STS-CHSDB was queried for complications (Table 1) for 12 congenital heart operations performed across all Society of Thoracic Surgeons-European Association of Cardio-Thoracic Surgery Congenital Heart Surgery (STAT) risk categories [9]. Table 2 lists these 12 operations and the STS-CHSDB procedures included in each group. All patients undergoing operations in one of the 12 procedural groups during 2010 and 2011 were eligible for inclusion in the analysis. Patients with missing data on hospital discharge status or complications were excluded from analysis, as were centers with greater than 15% missing data for complications. Standard STS-CHSDB definitions (STS-CHSDB Version 3.0) are used for the individual complications coded in the STS-CHSDB. In this study, analysis of the rates of the 6 major complications that contribute to the STS Morbidity Score [7] is likewise based on STS-CHSDB Version 3.0 codes. Summary statistics were expressed as counts and percentage frequency of occurrence for the indicated procedures.

Results

Tables 3 to 14 list complications that occurred in greater than 0.5% of patients undergoing these 12 types of operations. Arrhythmia was the most frequent complication for ventricular septal defects (VSD; 6%), tetralogy of Fallot (9%), and atrioventricular septal defect (15%) repairs. There was a high rate of sternum left open (planned, unplanned) for arterial switch operation (ASO; 26%, 7%), ASO-VSD (29%, 10%), truncus repair (41%, 11%), and Norwood (63%, 7%). The most frequent complications for other procedures include the following: atrial septal defect (unplanned readmission, 2%), BiGlenn (chylothorax, 7%), Fontan (pleural effusion, 16%), systemic to pulmonary artery/modified Blalock Taussig shunt (reintubation, 11%), and coarctation (reintubation, 5%). Figure 1 displays the frequency of the 6 major complications previously defined [7].

Comment

This inquiry was undertaken to provide congenital heart surgeons with empirically derived data, based on multi-institutional experience, which together with data from personal and institutional experience may help to guide discussions of procedural complications during the informed consent process.

The comprehensive list of complications, in its entirety, is cumbersome to review with patients or parents. We report complications (Tables 3 to 14) in each procedure category that had a rate of 0.5% or greater. As expected, patients undergoing neonatal surgery were more

likely to experience sternum left open (ASO, ASO-VSD, truncus arteriosus, Norwood), while those patients who required extensive superior vena cava or transverse arch dissection (BiGlenn, Fontan, coarctation) were more likely to have pleural effusions or chylothorax. For the most part, the rate of the 6 major complications [7] (Fig 1) demonstrates the increasing occurrence rates with increasing complexity across the procedure categories that were surveyed. The major complication, “Unplanned reoperation or cardiac catheterization reintervention” exhibited the highest rates (0% to 18%) among the procedure groups. Similar trends are noted for the other major complication categories, with the exception of “arrhythmia requiring permanent pacemaker,” which is more likely to occur in patients who had VSD closure as part of their repair.

An awareness of the rate of occurrence and gravity of these complications can help guide the surgeon’s interaction with the parents or patients. Some authors [5, 6] have performed survey studies and have concluded that minor and major complications that occur in over 5% and 0.1% of patients, respectively, are worthy of discussion. The comprehensive list is a supportive document for structured questions that demand more knowledge. Practical wisdom can guide the surgeon in certain specific conditions. For instance, one would discuss risk of paraplegia when discussing coarctation repair, but not in the context of most open heart procedures that do not involve arch reconstruction. The same can be said of other enduring complications such as heart block, nerve injury, and renal failure. Importantly, this discussion can also explore the concept of relative risk and long-term outcome, which places into opposition the untreated natural history of the disease process with the risks of the proposed reparative operation. Such a dialogue can form the rational basis for proceeding with what may be termed a “high risk” operation, when all options are considered. In a broader sense, the idea of learning how to perform informed consent has historical significance and dates back to antiquity [10]. The essential question was whether moral virtue can be taught. This issue would be taken up again by Aristotle, who described moral virtue as, “The habit of choosing the golden mean, between extremes, as it pertains to an emotion or an action” [11]. Informed consent therefore condenses into a virtuous way of presenting empirical data to the patient. This tension between scientific evidence and moral authority has been heretofore delegated to the “art of medicine,” a concept grounded in paternalism and practical wisdom. Some authors, based on physician surveys, have suggested certain thresholds to guide the informed consent process. The question arises, is it possible to look at a complication list and categorically state that anything over 5% occurrence rate is worth discussing and anything below is not? Obviously, this is not possible, at least not in the purist rational sense. What is possible is to invoke the “habit of choosing” [11], namely that we acquire a set of principles over a lifetime of study and learn from others who we feel match up with virtuous habits. We physicians then engage our acquired practical wisdom and knowledge of empirical data to do the right thing; namely to engage in a rational, sympathetic, and informative dialogue with our patients and venture to find the right balance of informed consent based on mutual trust, beneficence, and finding the “Golden Mean,” which may be something today and something else tomorrow based on the circumstances. The common threads are being aware of the empirical data and achieving moral virtue.

We should engage in the informed consent process more so for moral reasons based on Aristotelian [11] and Kantian [12] ethical tenets than for legal reasons established by the courts [4]. In a substantial way, being informed of potential complications solidifies the doctor-patient relationship by open discussion that recognizes the reality of human behavior, error, and disclosure. The process is meant to convey confidence, hope, and acceptance throughout the hospitalization and beyond.

The limitations of this study include all issues relating to a large registry database without long-term follow-up. In addition, reporting of frequencies of specific complications was constrained by the terms and definitions used in the STS-CHSDB. Consideration was given to grouping individual complications into categories (eg, arrhythmias). Because of the possibility of instances of dual entry and the uncertainty whether these represent unique events, we decided not to condense the data in this fashion. We therefore report the data as they are and leave to the reader to choose the golden mean as to what to tell the family in the informed consent process.

The informed consent process for congenital heart surgery may be enhanced by availability of accurate contemporary data on occurrence of complications associated with a given procedure. While complication rate thresholds may guide the clinician, rare but important debilitating complications, such as paraplegia after coarctation repair, should also be discussed irrespective of frequency. Our analysis should better inform the process of informed consent by providing the clinician with objective data about complications for each type of procedure.

Abbreviations and Acronyms

ASD	atrial septal defect
ASO	arterial switch operation
AVC	atrioventricular canal
AVSD	atrioventricular septal defect
BBD CPA	bilateral bidirectional cavopulmonary anastomosis or bilateral bidirectional Glenn
BDCPA	bidirectional cavopulmonary anastomosis or bidirectional Glenn
CAVSD	complete atrioventricular septal defect
CPS	cardiopulmonary support
ECMO	extracorporeal membrane oxygenation
IABP	intraaortic balloon pump
MBTS	modified Blalock Taussig shunt
MI	myocardial infarction
MODS	multi-organ dysfunction syndrome

MSOF	multi-system organ failure
PA	pulmonary artery
RV	right ventricle
S-P	systemic to pulmonary artery
STAT	Society of Thoracic Surgeons-European Association of Cardio-Thoracic Surgery Congenital Heart Surgery risk categories
STS-CHSDB	Society of Thoracic Surgeons Congenital Heart Surgery Database
TCPC	total cavopulmonary connection
TOF	tetralogy of Fallot
VAD	ventricular assist device
VSD	ventricular septal defect

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Fig 1.

Graphs display the frequency of 6 major complications categories [7]. The Society of Thoracic Surgeons Congenital Heart Surgery Database Version 3.0 complication codes for these 6 major complications are as follows: (A) Renal failure requiring temporary/permanent dialysis: 223, 224, 230; (B) Postoperative neurologic deficit persisting at discharge: 320; (C) Arrhythmia requiring permanent pacemaker: 74; (D) Postoperative mechanical circulatory support: 40; (E) Phrenic nerve injury/paralyzed diaphragm: 300; (F) Unplanned cardiac reoperation or catheterization intervention: 22, 24, 26, 240. (ASD = atrial septal defect; ASO = arterial switch operation; AVC = atrioventricular canal; MBTS = modified Blalock Taussig shunt; TOF = tetralogy of Fallot; VSD = ventricular septal defect.)

Table 1**Complications**

Code	Complication	Abbreviation
16	No complications during the intraoperative and postoperative time periods (no complications prior to discharge and no complications within 30 days of surgery)	None
350	Intraoperative death or intraoperative death	Intraoperative death
360	Unplanned readmission to the hospital within 30 days of surgery or intervention	Readmission
370	Multi-system organ failure (MSOF) = multi-organ dysfunction syndrome (MODS)	MSOF
30	Cardiac arrest, timing = cardiac arrest (myocardial infarction) during or following procedure (perioperative/periprocedural = intraoperative/intraoperative and/or postoperative/postprocedural)	Cardiac arrest
80	Cardiac dysfunction resulting in low cardiac output	Cardiac dysfunction+C22
384	Cardiac failure (severe cardiac dysfunction)	Cardiac failure
280	Endocarditis-postprocedural infective endocarditis	Endocarditis
110	Pericardial effusion, requiring drainage	Pericardial effusion
390	Pulmonary hypertension	Pulmonary hypertension
140	Pulmonary hypertensive crisis (pulmonary artery pressure > systemic pressure)	Pulmonary hypertensive crisis
130	Pulmonary vein obstruction	Pulmonary vein obstruction
120	Systemic vein obstruction	Systemic vein obstruction
240	Bleeding, requiring reoperation	Reoperation-bleeding
102	Sternum left open, planned	Sternum open-planned
104	Sternum left open, unplanned	Sternum open-unplanned
22	Unplanned cardiac reoperation during the postoperative or postprocedural time period, exclusive of reoperation for bleeding	Cardiac reoperation-not for bleeding
24	Unplanned interventional cardiovascular catheterization procedure during the postoperative or postprocedural time period	Unplanned interventional catheterization
26	Unplanned noncardiac reoperation during the postoperative or postprocedural time period	Noncardiac reoperation
40	Postoperative/postprocedural mechanical circulatory support (IABP, VAD, ECMO, or CPS)	Mechanical support
71	Arrhythmia	Arrhythmia
72	Arrhythmia requiring drug therapy	Arrhythmia-drug
73	Arrhythmia requiring electrical cardioversion or defibrillation	Arrhythmia-cardioversion/defibrillation
74	Arrhythmia necessitating pacemaker, permanent pacemaker	Arrhythmia-permanent pacemaker
75	Arrhythmia necessitating pacemaker, temporary pacemaker	Arrhythmia-temporary pacemaker
210	Chylothorax	Chylothorax
200	Pleural effusion, requiring drainage	Pleural effusion
180	Pneumonia	Pneumonia
190	Pneumothorax, requiring intervention	Pneumothorax
150	Postoperative/postprocedural respiratory insufficiency requiring mechanical ventilatory support > 7 days	Respiratory insufficiency-prolonged
160	Postoperative/postprocedural respiratory insufficiency requiring reintubation	Respiratory insufficiency-reintubation
170	Respiratory failure, requiring tracheostomy	Tracheostomy
230	Renal failure - acute renal failure, acute renal failure requiring dialysis at the time of hospital discharge	Renal failure-dialysis at discharge
223	Renal failure - acute renal failure, acute renal failure requiring temporary dialysis with the need for dialysis not present at hospital discharge	Renal failure-temporary dialysis

Code	Complication	Abbreviation
224	Renal failure - acute renal failure, acute renal failure requiring temporary hemofiltration with the need for dialysis not present at hospital discharge	Renal failure-hemofiltration
290	Sepsis	Sepsis
320	Neurologic deficit, neurologic deficit persisting at discharge	Neurologic deficit-at discharge
325	Neurologic deficit, transient neurologic deficit not present at discharge	Neurologic deficit-transient
300	Paralyzed diaphragm (possible phrenic nerve injury)	Paralyzed diaphragm
400	Peripheral nerve injury, neurologic deficit persisting at discharge	Peripheral nerve injury
331	Seizure	Seizure
410	Spinal cord injury, neurologic deficit persisting at discharge	Spinal cord injury
420	Stroke	Stroke
310	Vocal cord dysfunction (possible recurrent laryngeal nerve injury)	Vocal cord dysfunction
250	Wound dehiscence (sterile)	Wound dehiscence
255	Wound dehiscence (sterile), median sternotomy	Wound dehiscence-sternotomy
261	Wound infection	Wound infection
262	Wound infection-deep wound infection	Wound infection-deep
270	Wound infection-mediastinitis	Mediastinitis
263	Wound infection-superficial wound infection	Wound infection-superficial
900	Other complication	Other
901	Other operative/procedural complication	Other-operative

CPS = cardiopulmonary support; ECMO = extracorporeal membrane oxygenation; IABP = intraaortic balloon pump; VAD = ventricular assist device.

Table 2**Inclusion Criteria**

Benchmark Operations	STS Procedural Codes
Isolated coarctation	1210 = Coarctation repair, end to end 1220 = Coarctation repair, end to end, Extended 1230 = Coarctation repair, subclavian flap 1240 = Coarctation repair, patch aortoplasty 1250 = Coarctation repair, interposition graft
ASD (only collected for operations with primary diagnosis = 20 = ASD, Secundum)	20 = ASD repair, primary closure 30 = ASD repair, patch
VSD	100 = VSD repair, primary closure 110 = VSD repair, patch 120 = VSD repair, device
TOF	350 = TOF repair, no ventriculotomy 360 = TOF repair, ventriculotomy, nontransanular patch 370 = TOF repair, ventriculotomy, transanular patch 380 = TOF repair, RV-PA conduit
AVC	170 = AVC (AVSD) repair, complete (CAVSD)
Modified Blalock-Taussig Shunt	1590 = Shunt, systemic to pulmonary, Modified Blalock-Taussig Shunt (MBTS)
Superior cavopulmonary anastomosis(es)	1670 = Bidirectional cavopulmonary anastomosis (BDCPA) (bidirectional Glenn) 1690 = Bilateral bidirectional cavopulmonary anastomosis (BBDCPA) (bilateral bidirectional Glenn) 1700 = HemiFontan
Fontan	2130 = Superior cavopulmonary anastomosis(es) + PA reconstruction 950 = Fontan, atriopulmonary connection 960 = Fontan, atrioventricular connection 970 = Fontan, TCPC, lateral tunnel, fenestrated 980 = Fontan, TCPC, lateral tunnel, nonfenestrated 1000 = Fontan, TCPC, external conduit, fenestrated 1010 = Fontan, TCPC, external conduit, nonfenestrated 1030 = Fontan, other
Arterial switch	1110 = Arterial switch operation (ASO)
Arterial switch + VSD	1120 = Arterial switch operation (ASO) and VSD repair
Truncus	230 = Truncus arteriosus repair
Norwood	870 = Norwood procedure

ASD = atrial septal defect; AVSD = atrioventricular septal defect; CAVSD = complete AVSD; RV-PA = right ventricle-pulmonary artery; STS = Society of Thoracic Surgeons; TCPC = total cavopulmonary connection; TOF = tetralogy of Fallot; VSD = ventricular septal defect.

Table 3**Coarctation Repair (n = 1,861)**

Complications	Rate, n (%)
Respiratory insufficiency-reintubation	96 (5.16)
Chylothorax	66 (3.55)
Respiratory insufficiency-prolonged	63 (3.39)
Vocal cord dysfunction	59 (3.17)
Readmission	54 (2.90)
Non-cardiac reoperation	51 (2.74)
Cardiac reoperation-not for bleeding	42 (2.26)
Arrhythmia-drug	33 (1.77)
Pleural effusion	30 (1.61)
Wound dehiscence	28 (1.50)
Sepsis	28 (1.50)
Sternum open-planned	24 (1.29)
Unplanned interventional catheterization	23 (1.24)
Arrhythmia	21 (1.13)
Pneumothorax	18 (0.97)
Cardiac dysfunction	17 (0.91)
Pulmonary hypertension	17 (0.91)
Cardiac arrest	15 (0.81)
Seizure	14 (0.75)
Wound infection-superficial	13 (0.70)
Paralyzed diaphragm	10 (0.54)
Patients with no complications	1185 (63.68)
Patients with no major [7] complications	1,740 (93.50)

Table 4

Atrial Septal Defect Closure (n = 1,472)

Complications	Rate, n (%)
Readmission	28 (1.90)
Arrhythmia	19 (1.29)
Pneumothorax	14 (0.95)
Arrhythmia-temporary pacemaker	14 (0.95)
Arrhythmia-drug	12 (0.82)
Patients with no complications	1,201 (81.59)
Patients with no major [7] complications	1,459 (99.12)

Table 5

Ventricular Septal Defect Closure (n = 3,056)

Complications	Rate, n (%)
Arrhythmia-temporary pacemaker	178 (5.82)
Arrhythmia	125 (4.09)
Arrhythmia-drug	98 (3.21)
Respiratory insufficiency-reintubation	70 (2.29)
Cardiac dysfunction	60 (1.96)
Pleural effusion	60 (1.96)
Readmission	60 (1.96)
Respiratory insufficiency-prolonged	50 (1.64)
Chylothorax	40 (1.31)
Arrhythmia-permanent pacemaker	38 (1.24)
Pneumothorax	34 (1.11)
Cardiac reoperation-not for bleeding	32 (1.05)
Noncardiac reoperation	28 (0.92)
Pulmonary hypertension	30 (0.98)
Pericardial effusion	22 (0.72)
Pneumonia	22 (0.72)
Sepsis	22 (0.72)
Cardiac arrest	20 (0.65)
Reoperation-bleeding	20 (0.65)
Arrhythmia-cardioversion/defibrillation	17 (0.56)
Patients with no complications	2,026 (66.30)
Patients with no major [7] complications	2,941 (96.23)

Table 6

Tetralogy of Fallot Repair (n = 1,862)

Complications	Rate, n (%)
Arrhythmia-temporary pacemaker	166 (8.92)
Arrhythmia-drug	162 (8.70)
Pleural effusion	122 (6.55)
Arrhythmia	101 (5.42)
Respiratory insufficiency-reintubation	82 (4.40)
Respiratory insufficiency-prolonged	81 (4.35)
Chylothorax	81 (4.35)
Cardiac dysfunction	70 (3.76)
Cardiac reoperation-not for bleeding	44 (2.36)
Sternum open-planned	44 (2.36)
Noncardiac reoperation	43 (2.31)
Readmission	43 (2.31)
Sternum open-unplanned	38 (2.04)
Sepsis	32 (1.72)
Mechanical support	27 (1.45)
Paralyzed diaphragm	26 (1.40)
Cardiac arrest	25 (1.34)
Pneumothorax	25 (1.34)
Pneumonia	22 (1.18)
Seizure	22 (1.18)
Reoperation-bleeding	21 (1.13)
Arrhythmia-permanent pacemaker	20 (1.07)
Pericardial effusion	17 (0.91)
Pulmonary hypertension	17 (0.91)
Unplanned interventional catheterization	16 (0.86)
Wound infection-superficial	16 (0.86)
Cardiac failure	13 (0.70)
Vocal cord dysfunction	12 (0.64)
Neurologic deficit-at discharge	11 (0.59)
Arrhythmia-cardioversion/defibrillation	11 (0.59)
Wound infection	10 (0.54)
Patients with no complications	1,005 (53.97)
Patients with no major [7] complications	1,710 (91.84)

Table 7**Atrioventricular Canal Repair (n = 1,172)**

Complications	Rate, n (%)
Arrhythmia-temporary pacemaker	172 (14.68)
Respiratory insufficiency-reintubation	95 (8.11)
Chylothorax	94 (8.02)
Respiratory insufficiency-prolonged	89 (7.59)
Arrhythmia	80 (6.83)
Pulmonary hypertension	78 (6.66)
Pleural effusion	74 (6.31)
Arrhythmia-drug	63 (5.38)
Cardiac dysfunction	53 (4.52)
Cardiac reoperation-not for bleeding	51 (4.35)
Readmission	50 (4.27)
Sepsis	39 (3.33)
Sternum open-unplanned	34 (2.90)
Pneumonia	33 (2.82)
Cardiac arrest	31 (2.65)
Arrhythmia-permanent pacemaker	28 (2.39)
Noncardiac reoperation	26 (2.22)
Sternum open-planned	22 (1.88)
Mechanical support	21 (1.79)
Pneumothorax	18 (1.54)
Pericardial effusion	15 (1.28)
Seizure	14 (1.19)
Tracheostomy	12 (1.02)
Reoperation-bleeding	11 (0.94)
Wound infection-superficial	11 (0.94)
Vocal cord dysfunction	10 (0.85)
Cardiac failure	10 (0.85)
Neurologic deficit-at discharge	9 (0.77)
Multi-system organ failure	9 (0.77)
Unplanned interventional catheterization	9 (0.77)
Pulmonary hypertensive crisis	8 (0.68)
Wound infection	7 (0.60)
Patients with no complications	550 (46.93)
Patients with no major [7] complications	1,053 (89.85)

Table 8**Modified Blalock-Taussig Shunt (n = 857)**

Complications	Rate, n (%)
Respiratory insufficiency-reintubation	91 (10.62)
Cardiac reoperation-not for bleeding	89 (10.39)
Respiratory insufficiency-prolonged	86 (10.04)
Cardiac dysfunction	75 (8.75)
Cardiac arrest	71 (8.28)
Noncardiac reoperation	53 (6.18)
Sternum open-planned	44 (5.13)
Readmission	42 (4.90)
Arrhythmia-drug	40 (4.67)
Pleural effusion	29 (3.38)
Mechanical support	26 (3.03)
Arrhythmia	26 (3.03)
Wound infection-superficial	26 (3.03)
Chylothorax	25 (2.92)
Sepsis	24 (2.80)
Unplanned interventional catheterization	21 (2.45)
Sternum open-unplanned	19 (2.22)
Cardiac failure	18 (2.10)
Arrhythmia-temporary pacemaker	17 (1.98)
Pulmonary hypertension	16 (1.87)
Pericardial effusion	13 (1.52)
Reoperation-bleeding	13 (1.52)
Paralyzed diaphragm	12 (1.40)
Vocal cord dysfunction	12 (1.40)
Renal failure-temporary dialysis	12 (1.40)
Pneumothorax	10 (1.17)
Seizure	10 (1.17)
Wound dehiscence	9 (1.05)
Wound dehiscence-sternotomy	9 (1.05)
Multi-system organ failure	9 (1.05)
Tracheostomy	8 (0.93)
Mediastinitis	8 (0.93)
Pneumonia	7 (0.82)
Systemic vein obstruction	5 (0.58)
Neurologic deficit-at discharge	5 (0.58)
Wound infection	5 (0.58)
Patients with no complications	320 (37.34)
Patients with no major [7] complications	681 (79.46)

Table 9

Bidirectional Glenn (n = 1,694)

Complications	Rate, n (%)
Chylothorax	120 (7.08)
Respiratory insufficiency-reintubation	89 (5.25)
Pleural effusion	87 (5.14)
Unplanned interventional catheterization	70 (4.13)
Readmission	65 (3.84)
Respiratory insufficiency-prolonged	63 (3.72)
Noncardiac reoperation	54 (3.19)
Paralyzed diaphragm	53 (3.13)
Cardiac dysfunction	51 (3.01)
Pulmonary hypertension	51 (3.01)
Cardiac reoperation-not for bleeding	48 (2.83)
Arrhythmia-temporary pacemaker	46 (2.72)
Arrhythmia	43 (2.54)
Pneumothorax	36 (2.13)
Arrhythmia-drug	33 (1.95)
Sepsis	27 (1.59)
Reoperation-bleeding	23 (1.36)
Mediastinitis	22 (1.30)
Pneumonia	20 (1.18)
Mechanical support	18 (1.06)
Cardiac arrest	16 (0.94)
Sternum open-planned	16 (0.94)
Cardiac failure	14 (0.83)
Seizure	14 (0.83)
Wound infection-superficial	14 (0.83)
Sternum open-unplanned	11 (0.65)
Wound infection	11 (0.65)
Pericardial effusion	10 (0.59)
Systemic vein obstruction	10 (0.59)
Arrhythmia-permanent pacemaker	9 (0.53)
Stroke	9 (0.53)
Patients with no complications	933 (55.08)
Patients with no major [7] complications	1,483 (87.54)

Table 10

Fontan (n = 1,696)

Complications	Rate, n (%)
Pleural effusion	272 (16.04)
Arrhythmia-temporary pacemaker	171 (10.08)
Chylothorax	159 (9.38)
Readmission	102 (6.01)
Cardiac dysfunction	81 (4.78)
Arrhythmia	78 (4.60)
Arrhythmia-drug	58 (3.42)
Cardiac reoperation-not for bleeding	57 (3.36)
Reoperation-bleeding	45 (2.65)
Unplanned interventional catheterization	44 (2.59)
Respiratory insufficiency-reintubation	39 (2.30)
Noncardiac reoperation	38 (2.24)
Respiratory insufficiency-prolonged	37 (2.18)
Arrhythmia-permanent pacemaker	31 (1.83)
Pneumothorax	30 (1.77)
Pericardial effusion	26 (1.53)
Neurologic deficit-at discharge	24 (1.42)
Sepsis	23 (1.36)
Cardiac arrest	21 (1.24)
Mechanical support	20 (1.18)
Paralyzed diaphragm	19 (1.12)
Seizure	19 (1.12)
Stroke	18 (1.06)
Pulmonary hypertension	17 (1.00)
Sternum open-unplanned	15 (0.88)
Wound infection-superficial	13 (0.77)
Mediastinitis	12 (0.71)
Cardiac failure	12 (0.71)
Multi-system organ failure	11 (0.65)
Wound infection	11 (0.65)
Arrhythmia-cardioversion/defibrillation	10 (0.59)
Renal failure-temporary dialysis	10 (0.59)
Systemic vein obstruction	9 (0.53)
Pneumonia	9 (0.53)
Wound infection-deep	9 (0.53)
Patients with no complications	745 (43.93)
Patients with no major [7] complications	1,485 (87.56)

Table 11

Arterial Switch (n = 727)

Complications	Rate, n (%)
Sternum open-planned	189 (26.00)
Arrhythmia-drug	103 (14.17)
Cardiac dysfunction	67 (9.22)
Respiratory insufficiency-prolonged	65 (8.94)
Arrhythmia	59 (8.12)
Arrhythmia-temporary pacemaker	52 (7.15)
Chylothorax	51 (7.02)
Sternum open-unplanned	50 (6.88)
Reoperation-bleeding	42 (5.78)
Pleural effusion	41 (5.64)
Respiratory insufficiency-reintubation	33 (4.54)
Mechanical support	29 (3.99)
Paralyzed diaphragm	28 (3.85)
Cardiac reoperation-not for bleeding	27 (3.71)
Wound infection-superficial	23 (3.16)
Noncardiac reoperation	21 (2.89)
Pulmonary hypertension	19 (2.61)
Sepsis	17 (2.34)
Readmission	17 (2.34)
Cardiac failure	17 (2.34)
Unplanned interventional catheterization	16 (2.20)
Pneumothorax	14 (1.93)
Wound dehiscence	14 (1.93)
Wound infection	14 (1.93)
Cardiac arrest	13 (1.79)
Seizure	13 (1.79)
Systemic vein obstruction	12 (1.65)
Vocal cord dysfunction	12 (1.65)
Pericardial effusion	9 (1.24)
Neurologic deficit-at discharge	9 (1.24)
Arrhythmia-cardioversion/defibrillation	9 (1.24)
Multi-system organ failure	7 (0.96)
Wound dehiscence-sternotomy	6 (0.83)
Mediastinitis	5 (0.69)
Neurologic deficit-transient	5 (0.69)
Pneumonia	4 (0.55)
Renal failure-hemofiltration	4 (0.55)
Stroke	4 (0.55)
Patients with no complications	234 (32.19)

Complications	Rate, n (%)
Patients with no major [7] complications	607 (83.49)

Table 12

Arterial Switch and Ventricular Septal Defect (n = 346)

Complications	Rate, n (%)
Sternum open-planned	102 (29.48)
Arrhythmia-temporary pacemaker	50 (14.45)
Respiratory insufficiency-prolonged	44 (12.72)
Arrhythmia-drug	43 (12.43)
Arrhythmia	40 (11.56)
Sternum open-unplanned	36 (10.40)
Chylothorax	29 (8.38)
Cardiac dysfunction	28 (8.09)
Mechanical support	27 (7.80)
Pleural effusion	26 (7.51)
Cardiac reoperation-not for bleeding	24 (6.94)
Cardiac arrest	22 (6.36)
Respiratory insufficiency-reintubation	22 (6.36)
Reoperation-bleeding	18 (5.20)
Cardiac failure	16 (4.62)
Noncardiac reoperation	16 (4.62)
Pneumothorax	12 (3.47)
Pulmonary hypertension	11 (3.18)
Arrhythmia-permanent pacemaker	10 (2.89)
Vocal cord dysfunction	9 (2.60)
Renal failure-temporary dialysis	9 (2.60)
Wound dehiscence	7 (2.02)
Sepsis	7 (2.02)
Unplanned interventional catheterization	7 (2.02)
Arrhythmia-cardioversion/defibrillation	7 (2.02)
Wound infection-superficial	7 (2.02)
Pericardial effusion	6 (1.73)
Systemic vein obstruction	6 (1.73)
Mediastinitis	5 (1.45)
Paralyzed diaphragm	5 (1.45)
Neurologic deficit-at discharge	4 (1.16)
Readmission	4 (1.16)
Renal failure-hemofiltration	4 (1.16)
Wound infection-deep	4 (1.16)
Pneumonia	3 (0.87)
Multi-system organ failure	3 (0.87)
Seizure	3 (0.87)
Renal failure-dialysis at discharge	2 (0.58)
Wound infection	2 (0.58)

Complications	Rate, n (%)
Patients with no complications	82 (23.70)
Patients with no major [7] complications	267 (77.17)

Table 13

Truncus (n = 224)

Complications	Rate, n (%)
Sternum open-planned	92 (41.07)
Respiratory insufficiency-prolonged	40 (17.86)
Cardiac dysfunction	27 (12.05)
Sternum open-unplanned	24 (10.71)
Arrhythmia-drug	22 (9.82)
Respiratory insufficiency-reintubation	21 (9.38)
Cardiac reoperation-not for bleeding	19 (8.48)
Noncardiac reoperation	19 (8.48)
Cardiac arrest	18 (8.04)
Arrhythmia-temporary pacemaker	18 (8.04)
Reoperation-bleeding	17 (7.59)
Pulmonary hypertension	16 (7.14)
Arrhythmia	16 (7.14)
Mechanical support	13 (5.80)
Unplanned interventional catheterization	13 (5.80)
Paralyzed diaphragm	12 (5.36)
Pleural effusion	11 (4.91)
Chylothorax	11 (4.91)
Vocal cord dysfunction	9 (4.02)
Cardiac failure	7 (3.13)
Tracheostomy	6 (2.68)
Seizure	6 (2.68)
Readmission	5 (2.23)
Pneumonia	4 (1.79)
Pneumothorax	4 (1.79)
Wound dehiscence-sternotomy	4 (1.79)
Wound infection-superficial	4 (1.79)
Pericardial effusion	3 (1.34)
Systemic vein obstruction	3 (1.34)
Sepsis	3 (1.34)
Multi-system organ failure	3 (1.34)
Arrhythmia-cardioversion/defibrillation	3 (1.34)
Wound dehiscence	2 (0.89)
Mediastinitis	2 (0.89)
Neurologic deficit-at discharge	2 (0.89)
Renal failure-temporary dialysis	2 (0.89)
Patients with no complications	42 (18.75)
Patients with no major [7] complications	159 (70.98)

Table 14

Norwood (n = 1,151)

Complications	Rate, n (%)
Sternum open-planned	724 (62.90)
Respiratory insufficiency-prolonged	313 (27.19)
Respiratory insufficiency-reintubation	178 (15.46)
Mechanical support	175 (15.20)
Arrhythmia-drug	162 (14.07)
Cardiac dysfunction	160 (13.90)
Cardiac arrest	138 (11.99)
Cardiac reoperation-not for bleeding	136 (11.82)
Vocal cord dysfunction	118 (10.25)
Non-cardiac reoperation	114 (9.90)
Chylothorax	98 (8.51)
Reoperation-bleeding	94 (8.17)
Cardiac failure	87 (7.56)
Arrhythmia-temporary pacemaker	87 (7.56)
Pleural effusion	81 (7.04)
Sepsis	81 (7.04)
Sternum open-unplanned	77 (6.69)
Unplanned interventional catheterization	70 (6.08)
Arrhythmia	67 (5.82)
Seizure	57 (4.95)
Readmission	50 (4.34)
Pneumothorax	46 (4.00)
Renal failure-temporary dialysis	40 (3.48)
Paralyzed diaphragm	35 (3.04)
Pulmonary hypertension	34 (2.95)
Stroke	28 (2.43)
Multi-system organ failure	26 (2.26)
Wound infection-superficial	25 (2.17)
Neurologic deficit-at discharge	24 (2.09)
Systemic vein obstruction	23 (2.00)
Tracheostomy	21 (1.82)
Wound dehiscence	19 (1.65)
Arrhythmia-cardioversion/defibrillation	19 (1.65)
Wound dehiscence-sternotomy	17 (1.48)
Renal failure-hemofiltration	17 (1.48)
Renal failure-dialysis at discharge	16 (1.39)
Wound infection	16 (1.39)
Pericardial effusion	13 (1.13)
Pneumonia	12 (1.04)

Complications	Rate, n (%)
Arrhythmia-permanent pacemaker	12 (1.04)
Mediastinitis	11 (0.96)
Intraoperative death	8 (0.70)
Wound infection-deep	8 (0.70)
Postoperative endocarditis	7 (0.61)
Neurologic deficit-transient	6 (0.52)
Patients with no complications	117 (10.17)
Patients with no major [7] complications	713 (61.95)