10 Databases for Assessing the Outcomes of the Treatment of Patients with Congenital and Pediatric Cardiac Disease: The Perspective of Anesthesia

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Abstract

The Joint Congenital Cardiac Anesthesia Society-Society of Thoracic Surgeons Congenital Cardiac Anesthesia Database is a multi-institutional registry that tracks variables related to the anesthetic management of patients with pediatric and congenital cardiac disease. This registry is an optional module of The Society of Thoracic Surgeons Congenital Heart Surgery Database and is part of the Congenital Cardiac Anesthesia Society's commitment to patient care and research on outcomes improvement. Patients in the registry include not only cardiac surgical patients but also those with pediatric and congenital cardiac disease undergoing procedures in locations other than the operating room, including in the cardiac catheterization laboratory, intensive care unit, general operating room, and radiology suite. Because of the relative infrequency of anesthesia-related events in this low-volume procedure, a multi-institutional database is the most reasonable approach to capture a sufficient number of patient encounters in a timely manner to support outcomes analysis, quality assessment, and quality improvement.

Children undergoing repair of congenital heart defects are among the sickest population treated by anesthesiologists. The incidence of complications such as cardiac arrest related to anesthesia is proportionally much higher, the difficulties associated with airway and vascular access are well known, and the time and money spent on their care is substantial. To date there have been no systematic reviews of their anesthetic care and the associated complications, particularly those that do not result in cardiac arrest. The Joint Congenital Cardiac Anesthesia Society-Society of

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P.R. Barach, J.P. Jacobs, S.E. Lipshultz, P.C. Laussen (eds.),
Pediatric and Congenital Cardiac Care: Volume 1: Outcomes Analysis,
DOI 10.1007/978-1-4471-6587-3_10, © Springer-Verlag London 2015

Thoracic Surgeons Congenital Cardiac Anesthesia Database marks the first real-time picture of the "state-of-the-art" of anesthetic care for patient with pediatric and congenital cardiac disease. This information will help guide future care as well as provide better information for the patients and their families.

Keywords

Anesthesia • Pediatric cardiac disease • Congenital cardiac disease • Joint Congenital Cardiac Anesthesia Society-Society of Thoracic Surgeons Congenital Cardiac Anesthesia Database

Background

Anesthesia for patients with congenital heart disease (CHD) is a frequent occurrence in children's hospitals as well as outpatient surgical centers and clinics worldwide. While many of the procedures are specifically related to the patient's heart defect, it is also common for these patients to undergo diagnostic and therapeutic interventions unrelated to their heart defect. Multiple investigations have now shown that this patient population is particularly vulnerable to anesthesia-related complications both in the cardiac operating rooms and in other locations as compared to the non-CHD patients [1–4]. There are ongoing discussions within the pediatric cardiac anesthesia community about both where and who should be caring for these patients and about stratifying patients into higher- and lower-risk populations. For example, a patient with an unrepaired ASD, restrictive VSD or other stable two-ventricle lesions probably represent a different risk group than those with pulmonary hypertension, single ventricle anatomy (functionally univentricular hearts), heart failure, severe aortic stenosis or shunt-dependent lesions. Until recently, data about improvements in outcomes in these patients has been limited due to the relative infrequency of cardiac arrest, the primary endpoint measurement of most outcome studies; meanwhile, almost nothing has been published about either associated morbidities or need-to-rescue interventions that were successful. Improved outcomes, or at least fewer cardiac arrests, are potentially possible by identifying the higher-risk patients and involving physicians familiar with congenital cardiac physiology in their care early on to prevent problems before they arise [5]. Unfortunately, without continuous surveillance monitoring by external observers, it is exceedingly difficult to document "prevented" adverse events or "near-misses."

Children's Hospital Boston and the Mayo Clinic have previously published their single-center results of anesthesia-related cardiac arrest in congenital heart disease patients [1, 3, 6]. Odegard et al. have reported on cardiac arrests, defined as cessation of circulation requiring chest compressions, at their institution in both the cardiac operating rooms and cardiac catheterization labs at Children's Hospital Boston. Their first publication reviewed 5,213 cardiac surgical patients cared for over a 6 year period between January 2000 and December 2005, during which they found 41 episodes of cardiac arrest probably related to anesthesia in 40 patients for an overall frequency of 0.79 % [3]. All of these children were cared for by a dedicated congenital cardiac anesthesia group. Their second publication examined the anesthesia records of 7,289 cardiac catheterizations from 2004 to 2009 and found 70 episodes of cardiac arrest (0.96 arrests per 100 procedures), of which only seven were felt to be likely related to anesthesia or nurse-managed sedation with no mortality [6]. Faculty at the Mayo Clinic in Rochester, Minnesota reviewed the incidence of perioperative cardiac arrest in 92,881 children undergoing all types of surgery

at their facility from November 1988 to June 2005. Four thousand two hundred forty-two of those patients were undergoing cardiac surgery during that 17 year period. They found that the incidence of cardiac arrest was 2.9 per 10,000 patients in the non-cardiac procedures compared to 127 per 10,000 in the cardiac surgical group. Anesthesia was found to be the primary cause of the arrest in only 7.5 % of all the 80 recorded cardiac arrests – the remainder due to factors other than anesthesia. Within the 80 patients who suffered cardiac arrests under anesthesia, 88 % occurred in patients with a history of congenital heart disease, regardless of the type of surgery being performed – a testament to the critical nature of these patients regardless of the procedure being performed. Anesthesia-related adverse events other than those leading to cardiac arrest are not discussed in any of these publications.

For pediatric anesthesia practitioners, the Peri-Operative Cardiac Arrest (POCA) Registry was one of the first multi-site studies examining the etiology and incidence of cardiac arrests in children. The registry, which was active from 1994 to 2005, was a voluntary reporting survey which compiled extensive data concerning cardiac arrests in patients less than 18 years of age. Participating institutions agreed to provide the POCA investigators with detailed information any time a cardiac arrest, defined for their purposes as the initiation of chest compressions or death, occurred. Independent examiners then determined whether the cardiac arrest was due to anesthesia-related factors versus non-anesthesia elements such as surgical manipulation. At various times the POCA registry had between 58 and 79 participants, ranging from free-standing pediatric hospitals to pediatric units located within larger adult institutions. Comparing the two Peri-Operative Cardiac Arrest (POCA) Registry results from the initial publication in 2000 to the update published in 2007 clearly illustrates the effect of the changes in anesthesia practice over long time periods – a major flaw in long-term longitudinal studies [4, 7, 8]. From the 1960s through the 1990s, the general anesthetic halothane was commonly used despite its widely known negative inotropic and chronotropic effects. This agent was the only one then available that was well-tolerated for inhalation induction of anesthesia. Beginning in the late 1990s, a newer agent, sevoflurane, was introduced into practice in the United States. Like halothane, it is readily tolerated for inhalation induction of anesthesia but is not associated with the negative cardiac effects at therapeutic levels that halothane is. In the 2000 report, containing data collected from 1994 to 1997, medication-related cardiac arrests accounted for 37 % of the reported arrests, while the results from 1998 to 2004 showed a medication-related incidence of 18 %, which the authors largely ascribed to the decline in halothane usage during this time period.

At its conclusion, the POCA registry had collected information on 373 anesthesia-related cardiac arrests. 127 of the 373 (34 %) patients determined to have an anesthesia-related event had congenital or acquired CHD. Ramamoorthy et al. examined the POCA data specifically to determine the effects of CHD on arrest etiology and outcomes [2]. They found that the 127 children with underlying CHD were both sicker than their non-CHD counterparts and more likely to arrest from cardiovascular-related events. Fifty-four percent of the arrests reported in the POCA registry in children with CHD occurred outside of the cardiac ORs, while 26 % were from cardiac ORs and 17 % in the cardiac catheterization labs. The lesion most associated with cardiac arrest was "single ventricle," while those most likely to have the highest mortality were aortic stenosis and cardiomyopathy – the former can be very difficult patients to resuscitate once the arrest has occurred, while the latter is associated with a significant incidence of sudden cardiac death [9, 10]. Because the POCA data did not have sufficient information about the total numbers of procedures performed on children less than 18 years of age at the reporting institutions, the investigators could not determine an accurate incidence of arrest. Analysis by Ramamoorthy et al. of the POCA data led to their recommendation that those involved in the care of these children understand the physiology of CHD, particularly those patients with unrepaired or

partially-palliated single ventricle as well as the pharmacodynamics of anesthetic agents in patients with impaired ventricular function [2].

Outside of pediatric anesthesia there are at least two major multi-site collection efforts ongoing utilizing Automated Anesthesia Information Systems (AIMS) data. The American Society of Anesthesiology's Anesthesia Quality Institute has developed a National Anesthesia Clinical Outcomes Registry (NACOR) while the Department of Anesthesia at the University of Michigan has developed the Multicenter Perioperative Outcomes Group. Both systems utilize a complete download of de-identified physiologic and anesthetic data from their participating centers. This data harvest can then be "mined" extensively to determine relationships between anesthetic management strategies and physiologic readings and subsequent outcomes [11–13]. The knowledge gained from these processes may eventually prove helpful in developing similar mechanisms of data-pooling for pediatric anesthesia.

Multi-Societal Collaboration

A considerable effort has been made over the last 15 years to develop a common language for international usage for patients with pediatric and congenital cardiac disease. As congenital heart programs evolved over the years, cardiac lesions and their treatments took on a wide variety of names, occasionally reflecting the embryological origin of the affected anatomy, the final appearance of the anatomy, and frequently an eponym for the name of the person most associated with first describing either the lesion itself or its surgical repair. Thus, a Central Shunt, a "Melbourne" Shunt and a "Mee" Shunt all describe variations on a surgical procedure providing systemic blood flow to the pulmonary arterial system directly off of the aorta. As described in the chapter in this book by Franklin and colleagues titled: "***Nomenclature for Congenital and Pediatric Cardiac Disease***: ***Historical Perspectives and the International Pediatric and Congenital Cardiac Code***", in 2000, an international group of physicians from multiple professional medical societies began to meet with the goals of developing a standardized global nomenclature for patients with pediatric and congenital cardiac disease, resulting in the creation of ***The International Pediatric and Congenital Cardiac Code*** (***IPCCC***) [www.ipccc.net], which has standardized the nomenclature for congenital cardiac malformations and the procedures associated with their repair [14]. The IPCCC is maintained by ***The International Society for Nomenclature of Paediatric and Congenital Heart Disease***. Without this dictionary of terminology, it would be impossible to develop and implement databases both nationally and internationally. The IPCCC is being incorporated into upcoming revision of the International Classification of Diseases (ICD), ICD-11, and is freely available to interested users at www.ipccc.net.

These efforts have been expanded now to an international group of specialists including cardiac surgeons, cardiologists, anesthesiologists, cardiac intensive care specialists, anatomists, nurses, and government representatives who meet annually as: ***The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease***. The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease meets annually to agree on definitions of database standards, strategies for linking databases across geographical, temporal, and subspecialty boundaries, and even the definition of complications associated with pediatric and congenital cardiac care [15–29].

The Joint Congenital Cardiac Anesthesia Society-Society of Thoracic Surgeons Congenital Cardiac Anesthesia Database

The Congenital Cardiac Anesthesia Society (CCAS), an affiliate of the Society of Pediatric Anesthesia, was formed in 2005. Its membership is open to anesthesiologists worldwide who either care for or have an interest in patients with congenital cardiac defects. Among its primary goals, the CCAS has committed to developing a

multi-site database covering anesthesia-related information in patients undergoing surgery or procedures in and out of the cardiac surgical suites, including non-cardiac surgery on patients with congenital heart disease (CHD). The CCAS chose to partner with the Society of Thoracic Surgeons' Congenital Heart Surgery Database (STS-CHSD) because of the enormous amount of shared data elements as well as the STS's long history of successful implementation of their databases. Because of our "shared" patient population, the collaboration between the two societies was a natural fit and strongly supported by the membership of both organizations. As part of the agreement, STS, for the first time, allowed the collection of data from non-cardiac surgical and cardiology procedures occurring in patients with a history of congenital heart defects – which, as discussed above, is one of the major areas where anesthesia-related morbidity occurs [30, 31].

The goal of the Joint CCAS-STS Congenital Cardiac Anesthesia Database is to provide a more "real-time" picture of the state of anesthetic care for these patients with pediatric and congenital cardiac disease, as well as information about outcomes related to the incidence of anesthetic complications beyond cardiac arrest. Single-site analysis of this patient population requires years of data collection because of the relatively small number of cases at any one institution. Multi-site data collection will allow investigators to collect and analyze data from a much larger patient population and report the results back to the CCAS membership and participating institutions in a timely manner [17, 32].

Joint CCAS-STS Congenital Cardiac Anesthesia Database: Mechanisms

The STS data is harvested semi-annually in the Spring and Fall. The Spring harvest, typically occurring in mid-March, captures and reports data on a calendar year basis, while the Fall harvest does so on an academic July–June calendar. Programs may choose to report their data at one or both of the harvests, and "back-filling" of data from previous years is allowable and encouraged. The requirements and forms for becoming a participant in the database are available online via the STS [33]. Because transmission of potential Private Health Information (PHI) is involved in the process, it is necessary for a business agreement to be in place prior to submission of data in order to be compliant with the Health Insurance Portability and Accountability Act of 1996 of the United States of America (HIPAA) Privacy and Security Rules [33].

Groups submitting data for the anesthesia portion of the STS-CHSD are responsible for paying a flat $3,300 per annum, regardless of the number of anesthesiologists participating or the quantity and type of cases submitted. This fee is in addition to the surgical participation fee. The CCAS negotiated a flat-fee with the STS because the traditional fee mechanism the STS had utilized, a charge for each surgeon and an additional charge per case submitted, would potentially discourage groups from participating because of the high annual costs. There are typically significantly more anesthesiologists providing care in a given program to patients with pediatric and congenital cardiac disease than there are surgeons, as many institutions utilize their cardiac anesthesiologists to cover "remote" locations such as cardiac catheterization labs, intensive care units, and diagnostic and interventional radiology suites, as well as care for patients with pediatric and congenital cardiac disease undergoing non-cardiac procedures. At other locations, the cardiac anesthesia care team is an integral part of the overall anesthesia staffing and many physicians may rotate only intermittently into the cardiac operating rooms. At Texas Children's Hospital in Houston, Texas, for example, there are currently 12 cardiac anesthesiologists and 5 congenital heart surgeons. In addition to the three cardiac ORs, the cardiac anesthesia group is responsible for three cardiac catheterization labs, Cardiac ICU coverage, and one radiology site, as well as acting as consultants for the non-cardiac operating rooms when patients with pediatric and congenital cardiac disease receive care for their for non-cardiac procedures. Additionally, there are several more anesthesiologists in the general anesthesia division with extensive cardiac experience who routinely provide care for cardiac patients having

non-cardiac procedures in the inpatient and outpatient operating rooms. Each of these physicians must sign the business agreement before their data can be submitted. It was felt that a fixed fee approach would encourage greater participation and enrollment of patients, especially among those being cared for outside of the cardiac operating rooms, by not financially penalizing institutions for reporting on this critical information.

It is necessary to have the appropriate software to collect and transmit the data to the Duke Clinical Research Institute (DCRI), the data warehouse and analytic center for the STS-CHSD. All STS-approved vendors for the STS-CHSD are required to include the anesthesia data elements as part of their software package, so there should be no additional fees associated with that element of the data management. Some programs have chosen to utilize locally developed software not commercially available in order to retain access to historical data collected prior to their participation in the STS-CHSD. These programs must follow the same guidelines as commercial products and undergo the same data validation and testing. Meanwhile, other programs who utilize commercially available software have transferred their historical data into their new commercially available vendor supplied software.

The most expensive component of any database is the manpower involved in accurately collecting and entering the data. Data entry may be completed by surgeons, anesthesiologists, cardiac perfusionists, nurses, research assistants or any combination of the above. In some institutions the data is entered directly into the software, some collect the data on paper records for later entry, while still other sites abstract the data from the records post-operatively [34].

Unlike the surgical data elements, the CCAS at this time has not committed to a mechanism of data audit to ensure both data completeness and accuracy. This is a conscious decision on the part of the CCAS Database Committee as various programs are working out the mechanics of their anesthesia data entry and the extent to which they will submit data. Ideally, all patients with pediatric and congenital cardiac disease are being entered at a given site, but for a combination of factors including manpower and training, some participating sites are currently only entering the cases performed in the cardiac operating room, while participating sites are including the procedures performed in the cardiac catheterization lab but not other hospital locations [20]. Regardless, in order to submit the anesthetic data, the cardiac surgical program at the submitting hospital must be a participant in the STS-CHSD. In other words, for a program to participate in the Joint CCAS-STS Congenital Cardiac Anesthesia Database, the program must also participate in the STS-CHSDB itself.

Joint CCAS-STS Congenital Cardiac Anesthesia Database: Data Reporting and Analysis

Anesthesia departments participating in the Joint CCAS-STS Congenital Cardiac Anesthesia Database receive their individual Feedback Reports approximately 2 months after the close of data submission in the Spring and Fall. The report consists of two sets of data:

- The site specific data and
- The aggregate national values.

Uses for the data include tracking personnel activity, the occurrence of complications, statistics about usage of medications, time to extubation, and other important variables. As is the case with the surgical data, participants do not receive information about other locations except in the context of the pooled aggregate national values, and occasionally deidentified hospital specific data. This precludes a site from directly comparing their outcomes against another specific individual site. The business agreement between the sites and the STS explicitly forbids this sort of site-to-site comparison. The anesthesia report is developed by members of the CCAS Database Committee and represents an abstract of the submitted data elements felt important to report, such as types of medications, monitoring modalities, airway management, and complications. Data is broken down into three sections:

- An overall anesthesia report,
- A section specific to cardiac operating room cases (both on-pump and off-pump), and

- A section on non-cardiac OR cases specifically from the cardiac catheterization laboratory.

All sites "own" their own data at all times and are free to conduct whatever research or publications on it that they desire (with appropriate IRB approval). Sites are also welcome to request from DCRI specific information from the national data. Any requests for data from the overall database are routed through the STS Access and Publications Task Force Congenital Subcommittee, which includes a representative from CCAS.

Joint CCAS-STS Congenital Cardiac Anesthesia Database: Dataset Management

The Joint CCAS-STS Congenital Cardiac Anesthesia Database went "live" on January 1, 2010 after several years of development and programming. The data set in use through December 31, 2013 is available through the STS website, as is the newer dataset which went into operation on January 1, 2014 [35]. The data specified for collection is reviewed on a triennial basis, with the latest version, operationalized on January 1, 2014, also available through the STS website. As users have gained experience with the database, changes have been made in this next iteration to "bundle" some drug categories and simplify data entry, while expanding other drug categories such as pulmonary vasodilators, antifibrinolytic agents, and procoagulant medications. The CCAS Database Committee has been in communication regularly to facilitate these changes and communicate them to the STS-CHSD Task Force. Efforts have also been made to eliminate the redundancy of data entry between the surgical side of the data set and the anesthesia portion. For example, blood component usage and near infrared spectroscopy data was previously collected in both areas, but is now concentrated in the anesthesia section in version 3.2, the most recent iteration which became effective in January 2014. Table 10.1 includes the listing and definition of the adverse events being collected in

Table 10.1 Adverse anesthesia event categories in joint CCAS-STS database (v3.2)

Event	Definition
None	No anesthesia-related adverse events noted in the perioperative period
Oral/nasal injury-bleeding	Bleeding noted in oropharynx or epistaxis, dental, lip or nasal injury
Respiratory arrest	Need to intervene in airway management in unplanned way (i.e. converting from cannula to ETT or LMA to ETT)
Laryngospasm requiring medication	Laryngospasm requiring medical intervention other than positive pressure
Difficult intubation/reintubation	Unplanned difficult intubation or reintubation
Bronchospasm	Wheezing requiring medical intervention other than suctioning
Hemoptysis/pulmonary hemorrhage	Bleeding either from endotracheal tube or post-op hemoptysis
Stridor/subglottic stenosis	New onset stridor noted after extubation requiring intervention
Extubation	Unplanned extubation (except if TEE-Related (see below)
Endotracheal tube migration	Endotracheal tube needing to be repositioned in ICU on arrival CXR
Airway injury	Barotrauma/pneumothorax secondary to positive pressure ventilation
Pulmonary hypertensive crisis	Probable or definite PH crisis requiring intervention
Unplanned need to remain intubated due to anesthesia	Need to remain intubated at conclusion of procedure due to anesthesia factors (oversedation, muscle relaxation)
Hypercyanotic episode (Tet spell)	Hypercyanotic episode (decrease in SpO2 >20 % from baseline) requiring intervention other than establishing airway ("Tet" Spell)
Arrhythmia – CVL placement	Arrhythmia therapy needed other than withdrawing wire or catheter
Myocardial injury – CVL placement	Myocardial perforation
Vascular compromise – CVL placement	Extremity ischemia or compromise with CVL placement
Pneumothorax – CVL placement	Pneumothorax during placement of CVL

(continued)

Table 10.1 (continued)

Event	Definition
Vascular access	Inability to obtain desired all desired vascular access within 1 h of induction anesthesia (PIV/Aline/CVL)
Hematoma requiring relocation of catheter	Significant Hematoma that requires changing site of desired access
Arterial puncture	Inadvertent arterial puncture during CVL placement
Intravenous/intraarterial air embolism	Air embolism causing hemodynamic change or ischemia
Arterial line placement – extremity ischemia	Extremity ischemia or compromise with arterial line placement
Intravenous infiltration	Peripheral or central IV infiltration
Bleeding – regional anesthestic site	Bleeding at site of regional anesthetia
Intrathecal puncture – regional	Inadvertent intrathecal puncture during caudal or epidural placement
Local anesthetic toxicity – regional	Systemic evidence of local anesthesia toxicity (ECG changes, CNS changes)
Neurologic injury – regional	Injury to peripheral nerve during regional nerve block
Anaphylaxis/anaphylactoid reaction	Suspected anaphylactic/anaphylactoid reaction requiring intervention for either hemodynamic support or respiratory intervention
Non-allergic drug reaction	Non-anaphylactic reaction such as “Red Man” syndrome or hypotension
Medication administration	Wrong medication administered
Medication dosage	Wrong dosage of correct medication
Intraoperative recall	Recall of intraoperative events
Malignant hyperthermia	Suspected or confirmed MH reaction requiring dantrolene
Protamine reaction	Significant reaction to protamine requiring intervention other than slowing administration
Cardiac arrest – anesthesia related	Cardiac arrest requiring CPR during anesthesia care NOT related to surgical or catheter manipulation
Cardiac arrest – not anesthesia related	Cardiac arrest requiring CPR during surgical or catheter manipulation
TEE-related esophageal bleeding/injury	TEE-related esophageal bleeding noted during or after TEE removal
Esophageal chemical burn	TEE-related injury to esophageal mucosa due to TEE cleaning chemicals
TEE-related airway compromise	TEE-related compromise of ventilation or oxygenation requiring removal of TEE
TEE-related extubation	TEE-related inadvertent extubation of patient
Complications during patient transfer	Any event occurring during movement of patient into/out of procedure, such as loss of IV or arterial line, airway compromise, disconnection of lines
Peripheral nerve injury due to positioning	Temporary or permanent nerve injury noted post-operatively due to positioning during procedure
Integument injury under anesthesia	Skin breakdown or dehiscence or alopecia noted post-operatively due to positioning during procedure
Ocular injury (corneal abrasion or injury)	Ocular injury noted post-operatively such as corneal abrasion
Post-operative nausea/vomiting	PONV requiring unplanned admission
Emergence delirium requiring medication	Emergence agitation or delirium requiring medication
Anesthesia equipment malfunction/failure	Any anesthesia equipment malfunction or failure during procedure
Other	Any event related to anesthesia care not otherwise listed

version 3.2. Updates have been made in this version to better clarify specific adverse events as well as include events not previously listed.

Joint CCAS-STS Congenital Cardiac Anesthesia Database: Results

The Fall 2013 Harvest of the Joint CCAS-STS Congenital Cardiac Anesthesia Database includes operations from January 1, 2010 to June 30, 2013, inclusive, and includes information from 37 programs. These programs were diverse in both geographic location and in case volume. A total of 41,008 discrete records had been submitted for the 42 months since the inception of the Joint CCAS-STS Congenital Cardiac Anesthesia Database on January 1, 2010, covering a wide spectrum of surgical types and ages. These data include:

- 26,953 cardiac surgery procedures,
- 7,532 interventional cardiology procedures, and
- 6,523 anesthetics for "Non-Cardiac, Non-Thoracic Procedure on a Cardiac Patient with Cardiac Anesthesia."

As mentioned, the latter cases will include everything from radiologic procedures to bronchoscopies to general surgeries such as a Ladd's Procedure on a patient with heterotaxy or a tracheostomy on a ventilator-dependent cardiac patient.

The overall anesthesia-related adverse event rate was 1.9 %, with unexpected difficulty with intubation or reintubation being the highest reported complication (0.4 %) followed by vascular access taking more than 1 h (0.3 %). Cardiac arrest not due to surgical manipulation occurred in 76 cases (0.2 %). The full range and incidence of complications reported to date is shown in Table 10.2. Because the reporting is voluntary and there is no audit process in place for the Joint CCAS-STS Congenital Cardiac Anesthesia Database at this time, there is no way to verify the completeness or accuracy of the data and there is a likely bias towards underreporting. With sufficient time and funding however, it is hoped that the Joint CCAS-STS Congenital Cardiac Anesthesia Database will become part of the STS audit process. Another mechanism for ensuring data completeness and accuracy would be the integration of AIMS information similar to the Multicenter Perioperative Outcomes Group or

Table 10.2 CCAS reported adverse events (January 2010–June 2013)

Event	N=	% of total
None/missing	40,218	98.1
Any event	790	1.9
Dental injury	8	0.0
Respiratory arrest	22	0.1
Difficult intubation/reintubation	145	0.4
Stridor/sub-glottic stenosis	56	0.1
Inadvertent extubation	26	0.1
Endotracheal tube malposition	23	0.1
Airway injury/barotrauma	10	0.0
CVP-arrhythmia	15	0.0
CVP-myocardial injury	0	0.0
CVP – vascular compromise	25	0.1
CVP – pneumothorax	1	0.0
Vascular access >1 h	141	0.3
Access related hematoma	21	0.1
Inadvertent arterial puncture	61	0.1
IV/IA air embolus	1	0.0
Regional anesthesia – bleeding	1	0.0
Regional anesthesia – intrathecal puncture	0	0.0
Regional anesthesia – local anesthesia toxicity	0	0.0
Regional anesthesia – neurologic injury	1	0.0
Anaphylaxis/anaphylactoid reaction	35	0.1
Non-allergic drug reaction	22	0.1
Medication error – wrong drug	13	0.0
Medication error – wrong dose	19	0.0
Intraoperative recall	2	0.0
Suspected malignant hyperthermia	1	0.0
Protamine reaction	32	0.1
Cardiac arrest – unrelated to surgery	76	0.2
TEE-related – esophageal bleeding/injury	13	0.0
TEE-related – chemical burn	0	0.0
TEE-related – airway compromise	48	0.1
TEE-related – extubation	16	0.0
Patient transfer event	8	0.0
Peripheral neurologic injury	17	0.0

the NACOR data [8, 9]. These data could be filtered appropriately and fed directly into STS-compliant software, eliminating much of the legwork required currently to enter data manually, and largely eliminating the inherent bias involved in selective reporting of cases or underreporting of adverse events.

Difficult Intubation

A recent large review of intubation in 11,219 pediatric patients from Germany showed that patients undergoing cardiac surgery were associated with a significantly higher rate of difficulty with laryngoscopy visualization (Grade III/IV laryngoscopy view with an age-appropriate Macintosh blade) [36]. The Spring 2012 Feedback Report of the Joint CCAS-STS Congenital Cardiac Anesthesia Database showed a self-reported incidence of "difficult intubation or re-intubation" of 62 cases out of 17,047 cardiac surgical records (0.4 %), which appears to be lower than that reported in previous case series [37]. For the purposes of our dataset, we attempted to focus our definition on "unexpected" difficult intubation rather than capture those patients who were known or suspected to have difficult to manage airways. This may account for the observed discrepancy.

Arterial and Venous Line Placement and Complications

Patients undergoing congenital heart surgery can be particularly difficult to obtain both peripheral and central venous access and arterial access due to their need for repeated access both in the hospital and the cardiac catheterization laboratory. Many of these patients have had thromboses in major vessels over the course of their treatments or repeated access causing scarring or collateral formation. As a result, line placement intraoperatively can take a significant amount of time after induction of anesthesia and may require surgical placement of lines such as radial or ulnar arterial catheters. Additionally, both central venous and arterial line attempts are associated with a significant number of complications which may impact both patient morbidity and mortality as well as adding to hospital length of stays, including vessel injury and thrombosis, myocardial injury, catheter-related blood stream infections, arrhythmia, chylothorax and others [38–42]. The Joint CCAS-STS Congenital Cardiac Anesthesia Database collects information on many of these events, particularly those occurring in the perioperative period such as venous or arterial occlusion, hematoma formation, arrhythmias, or other complications. Additionally, a "complication" category of difficulty with line access requiring more than 1 h after induction of anesthesia is included to try and document the incidence of this event occurring, even though it does not necessarily represent an adverse event. The new Version 3.2 of the Joint CCAS-STS Congenital Cardiac Anesthesia Database includes information about whether ultrasound guidance was utilized in the placement of arterial, venous, or both catheters. Based on practice patterns observed at Texas Children's and discussions with other providers, it appears that the need for surgical arterial cutdowns is decreasing as ultrasound utilization for this procedure is increasing. Additionally, many sites are now taking advantage of this technology to aid in peripheral intravenous line placement both preoperatively by specially trained IV teams and in the operating room and other sites by anesthesiologists [43].

Future Developments and the Unique Patient Identifier

Management and interpretation of data will be a critical component in providing members of CCAS with accurate information about the current state of anesthetic care and will provide direction for future research. It is hoped that the CCAS-STS collaboration will serve as a model for incorporating other specialties into the dataset with the goal of creating a "cradle-to-grave" model [44]. Because cardiac patients may see multiple providers at multiple locations over their lifetime,

members of the STS-CHSD Task Force are striving to collaborate with other subspecialties and professional organizations including The National Institutes of Health and The American College of Cardiology in order to develop a Unique Patient Identifier (Global Unique Identifier or GUID) based upon other variables in the medical record. This confidential alphanumeric identifier, which could potentially be calculated at any treating site, could then be used to track an individual patient across multiple care locations and time. Efforts are also ongoing to link records in the STS-CHSD to the Social Security Master Death File and National Death Index. Duke University's IRB, which covers the research activity at DCRI, has reviewed the ongoing submission of unique identifiers to the STS-CHSD and found this activity to be within the guidelines of the Health Insurance Portability and Accountability Act of 1996 of the United States of America (HIPAA), as has outside counsel retained by the STS to evaluate the process [45]. Nonetheless, not all programs are able yet to provide access to these unique identifiers because of local HIPAA-related concerns. Many Institutional Review Boards (IRBs), whose permission is required, have balked at this level of submission of data, despite the presence of a signed business contract. Commercial vendors supporting the STS-CHSD have included functionality in their software to "strip" the unique identifiers from patient records prior to transmission of data to DCRI for those programs unable to share these data with DCRI.

As described in the chapter in this book by Morales and colleagues titled: "***Use of National Death Registries to Empower Databases in Reporting Longitudinal Follow-up***", efforts are ongoing to transform the STS-CHSD into a platform for longitudinal follow-up. It is only through this process that the STS-CHSD will be able to determine accurately the long-term mortality and morbidity associated with the treatments of patients with pediatric and congenital cardiac disease. For example, a patient with hypoplastic left heart disease will typically undergo at least three major cardiovascular surgical procedures and numerous non-surgical procedures prior to age 4, sometimes at multiple institutions. If this patient happens to suffer a major morbidity or mortality after discharge from the hospital at any time, the institution(s) where the procedures were performed may have no way to record these data in their current STS-CHSD. Alternatively, if a patient undergoes a procedure at Hospital A and then is subsequently admitted to Hospital B due to complications or the need for revision, then the patient may be included in two separate data sets. The Unique Patient Identifier (Global Unique Identifier or GUID) is an attempt to control for these not uncommon scenarios and present a more accurate picture of the time course of various cardiac defects and their repairs. Including anesthetic data in this process will help augment the time-course of these patients and the various interventions involved in their care by adding more data elements beyond cardiac surgery.

Conclusion

Children undergoing repair of congenital heart defects are among the sickest population treated by anesthesiologists. The incidence of complications such as cardiac arrest related to anesthesia is proportionally much higher, the difficulties associated with airway and vascular access are well known, and the time and money spent on their care far outweighs their numbers. To date there have been no systematic reviews of their anesthetic care and the associated complications, particularly those that do not result in cardiac arrest. The Joint CCAS-STS Congenital Cardiac Anesthesia Database marks the first real-time picture of the "state-of-the-art" of anesthetic care for patient with pediatric and congenital cardiac disease [46]. This information will help guide future care as well as provide better information for the patients and their families.

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