Current Status of the European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons Congenital Heart Surgery Database

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Background. **After utilizing separate congenital databases in the early 1990s, the Society of Thoracic Surgeons (STS) and the European Association for Cardio-Thoracic Surgery (EACTS) collaborated on several joint database initiatives.**

Methods. **In 1998, the joint EACTS-STS International Congenital Heart Surgery Nomenclature and Database Project Committee was created and a common nomenclature and common core minimum database dataset were adopted and published by the STS and the EACTS. In 1999, the joint EACTS-STS Aristotle Committee was created and the Aristotle Score was adopted and published as a method to provide complexity adjustment for congenital heart surgery. Collaborative efforts involving the EACTS and STS are underway to develop mechanisms to verify data completeness and accuracy.**

Results. **Since 1998, this nomenclature, database, and methodology of complexity adjustment have been used by both the STS and EACTS to analyze outcomes of over 40,000 patients. A huge amount of data have been generated which allow comparison of practice patterns and outcomes analysis between Europe and North America. The aggregate data from the first 5 years of data collection not only make for interesting comparison but also allow examination of regional difference in practice patterns. For example, in the EACTS, out of 4,273 neonates, 885 (20.7%) underwent arterial switch procedures and 297 (6.95%) underwent Norwood stage 1 procedures. In the STS, out of 3,988 neonates, 472 (11.8%) underwent arterial switch procedures and 575 (14.4%) underwent Norwood stage 1 procedures.**

Conclusions. **This analysis of the EACTS-STS multi-institutional outcomes database confirms that in both Europe and North America, case complexity and mortality is highest among neonates, then infants, and then children. Regional differences in practice patterns are demonstrated, with the overall goal being the continued upgrade in the quality of surgery for congenital heart disease worldwide.**

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During the 1990s, both the Society of Thoracic Surgeons (STS) and the European Association for Cardio-thoracic Surgery (EACTS) created congenital heart surgery outcomes databases [1–4]. These early multi-institutional congenital cardiac registries demonstrated four primary requirements to allow this type of database system to facilitate meaningful multi-institutional outcomes analysis [3–6]:

1. Common language = nomenclature.
2. Mechanism of data collection (database or registry) with an established uniform core dataset.
3. Mechanism of evaluating case complexity.
4. Mechanism to assure and verify data completeness and accuracy

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The EACTS and STS now both utilize the same nomenclature [3], dataset [3], and methodology of complexity-adjustment to facilitate congenital heart surgery outcomes analysis [7–10]. Collaborative efforts involving the EACTS and STS are underway to develop mechanisms to verify data completeness and accuracy. This manuscript presents the first joint report of the EACTS and STS Congenital Heart Databases. The purpose of this manuscript is multifactorial, including the goal of demonstrating the potential of a multi-institutional transcontinental congenital heart surgery outcomes database with the hope of increasing the level of global participation; however, without formal verification of the completeness and accuracy of the data (which is currently being performed), it would not be appropriate to make extensive formal statistical comparisons of the EACTS and STS data (with p values).

Material and Methods

The STS Congenital Heart Surgery Database has now undergone four data harvests [1, 2, 10–14]. The STS data utilized in this manuscript were generated from the most recent three STS data harvests [11, 13, 14], all conducted by the STS Congenital Heart Surgery Database Taskforce and Duke Clinical Research Institute (DCRI). These data come from 24 centers submitting data and represent surgical procedures performed between 1998 and 2003 inclusive. Mortality is reported according to "discharge status." Data from other mortality fields (including "30 day status", "operative mortality", and "mortality assigned to this operation") are not sufficiently complete to allow meaningful analysis. If a patient had more than one operation during a hospitalization, assignment of mortality is made to the first operation of the given hospitalization. Records with a missing value for discharge mortality and sites for which the level of missing mortality status at discharge exceeded 10% were removed from mortality analyses. These records were included in all other areas of the report. Discharge mortality was 100% complete in the data from 9 of 24 centers, greater than or equal to 99.7% complete for 16 of 24 centers, and greater than or equal to 94% complete for 21 of 24 centers. For three of the 24 sites, mortality data were missing for more than 10% of the cases. Concerns about site-level comparisons led to blinding of participant identifications. Sites are categorized as low volume if they perform up to 100 cases per year on average, medium volume if they perform between 101 and 250 cases per year on average, and high volume if they perform more than 250 cases per year on average. Each single operation is considered a case. Any single operation may have multiple component procedures. Only operation types "CPB" and "No CPB cardiovascular" are included in site volume categorizations and in all the analyses in this report. The STS portion of the overall analysis included 25,402 operations of the 30,408 submitted operations; the 25,402 operations were all of the operation types "CPB" and "No CPB cardiovascular" and involved 23,454 patients.

The European Congenital Heart Surgeons Association (until 2003 named the European Congenital Heart Surgeons Foundation [ECHSF]) was established in 1992 and created the European Congenital Heart Defects Database (ECHDD), the precursor of today's EACTS Congenital Database [15]. The ECHDD initially was headquartered at the Great Ormond Street Hospital for Children and in 1998 moved to Warsaw's Children's Memorial Health Institute. In 1999, the ECHDD became part of the EACTS Database Project and the EACTS and ECHSF adopted the nomenclature and database of the The International Congenital Heart Surgery Nomenclature and Database Project [3, 4]. Access to the ECHDD (including software, continued support, and reports) is free of charge and available through the Internet for all cardiothoracic units. No personal data contained in the EACTS Congenital Database are accessible. Only surgeons and centers know their own identities and those of their patients. Patient's personal data are not transmitted at all and patient identification is replaced with a number before transmission to the Database [15]. As of October 2004, the ECHDD involved 137 centers from 49 countries including 99 European centers from 29 European countries. Of these, 54 centers are actively submitting data. The overall data pool includes 23,735 operations including 7,938 infants and 4,518 neonates.

Both the EACTS and STS databases utilize the Aristotle Basic Complexity (ABC) Score to characterize case mix and facilitate complexity adjustment [7, 8, 9, 10]. The ABC scoring is based on the primary procedure of a given operation as defined by the short list of procedures of the EACTS-STS International Nomenclature [3]. The ABC score defines complexity through three factors: potential for mortality, potential for morbidity, and technical difficulty. Each procedure in the short list of procedures of the EACTS-STS International Nomenclature is assigned an ABC score of 1.5 through 15 with 1.5 representing the lowest complexity and 15 representing the highest complexity. A detailed discussion of the methodology of developing this score has been previously published [7–10].

Results

This combined STS and EACTS analysis includes all harvested cases in either database reported with the nomenclature and minimum dataset of the EACTS-STS International Nomenclature and Database [3]. These cases represent all harvested data in either database from 1998 until the time of submission of this abstract to the 2005 STS meeting. Patients are only eligible for analysis if their discharge status (alive or dead) is known. This report includes 18,928 eligible patients from the STS (3,988 neonates, 6,152 infants, 8,788 older patients) and 21,916 eligible patients from the EACTS (4,273 neonates, 7,316 infants, 10,327 older patients).

This analysis of the combined 40,844 patients produced a huge amount of data, some of which have been published on the Internet (http://www.sts.org/, accessed Jan 12, 2005, and http://www.echsa.org/, accessed Jan 12, 2005) and in print [10–15]. A small portion of these data

Table 1. EACTS and STS Data Aggregate Data

STS	All	0 to 28 Days	29 Days to 1 Year	Other
Eligible patients	18,928	3,988	6,152	8,788
Discharge mortality	825	487	202	136
Discharge mortality %	4.4%	12.2%	3.3%	1.5%
Basic complexity score	7.1	8.6	7.0	6.5
EACTS				
Eligible patients	21,916	4,273	7,316	10,327
Discharge mortality	1,097	514	377	206
Discharge mortality %	5.4%	13.3%	5.56%	2.1%
Basic complexity score	6.5	7.6	6.6	5.9

EACTS = European Association for Cardio-Thoracic Surgery; STS = The Society of Thoracic Surgeons.

will be summarized in this report in order to illustrate the type of data collected and provide a basis for the subsequent discussion.

Table 1 shows aggregate data for all patients, documenting the number of eligible patients, discharge mortality, and ABC score. These data are then presented by patient age group. As one would expect, neonates have the highest mortality and complexity, followed by infants, and then older patients.

When one evaluates the spectrum of procedures done in the neonatal age group, this evaluation reveals differences in practice profiles between North American and European centers. Table 2 examines this breakdown comparing the prevalence of neonatal arterial switch procedures and Norwood (stage 1) procedures in each database. In the EACTS, out of 4,273 neonates, 885 (20.7%) underwent arterial switch procedures and 297 (6.95%) underwent Norwood stage 1 procedures. In the STS, out of 3,988 neonates, 472 (11.8%) underwent arterial switch procedures and 575 (14.4%) underwent Norwood stage 1 procedures.

To derive a contemporary picture of regional practice differences, further analysis was performed on the data from 2002 and 2003, the most recent 2 years of available data (Table 3). Twenty-eight EACTS centers and 19 STS centers submitted data in both 2002 and 2003. Three broad areas of volume and outcomes data from this time window were biopsied in this part of the analysis: neonatal cardiac surgery, staged palliation in older children, and biventricular repair in older children.

Table 2. EACTS and STS Neonatal Arterial Switch and Norwood (Stage 1) Data

	EACTS	STS
Neonates	4,273	3,988
Arterial switch procedures	885	472
Arterial switch procedures %	20.71%	11.84%
Norwood (stage 1) procedures	297	575
Norwood (stage 1) procedures %	6.95%	14.42%

EACTS = European Association for Cardio-Thoracic Surgery; STS = The Society of Thoracic Surgeons.

First, neonatal cardiac surgery was examined more closely (Table 3). A higher proportion of STS centers performed more that 10 Norwood (stage 1) procedures per year compared to EACTS centers. The discharge mortality for Norwood (stage 1) procedures was higher in the EACTS centers than the STS centers. At the same time, the arterial switch procedure, which accounted for a larger proportion of neonatal operations in the EACTS database than in the STS database (Table 2), was associ-

Table 3. EACTS and STS Data: 2002 and 2003

	EACTS	STS
No. of centers with data in both 2002 and 2003	28	19
Centers with zero Norwood procedures	5	0
Centers with 1–10 Norwood procedures per year	18	12
Centers with >10 Norwood procedures per yer	5	7
Discharge mortality for neonatal Norwood procedures	35.5%	26.0%
Discharge mortality for neonatal ASO procedures	5.2%	7.4%
Mean age for Glenn procedures (years)	2.4	0.9
Median age for Glenn procedures (years)	0.9	0.5
Mean age for Fontan procedures (years)	6.3	5.2
Median age for Fontan procedures (years)	4.17	3
Percentage of infant TOF undergoing palliation	70.0%	61.6%
Percentage of infant TOF undergoing complete repair	30.0%	38.4%
Mean age for TOF complete repair procedures (years)	2.2	1.1
Median age for TOF complete repair procedures (years)	0.9	0.4
Mean age for CAVSD repair procedures (years)	0.9	0.6
Median age for CAVSD repair procedures (years)	0.4	0.4

ASO = arterial switch operation; EACTS = European association for Cardio-Thoracic Surgery; STS = The Society of Thoracic Surgeons; TOF = tetralogy of fallot.

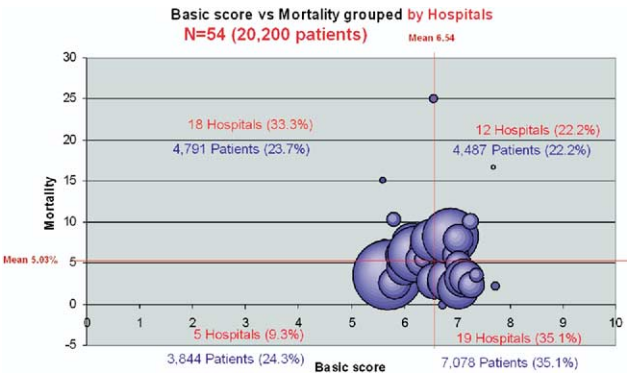

Fig 1. This graph shows program specific overall discharge mortality plotted against program specific mean basic complexity score plotted by annual volume of cases for the 54 participating EACTS sites. Center annual volume is depicted as the size of the bubble.

ated with a lower mortality in EACTS centers compared with STS centers (Table 3).

Analysis of data concerning staged palliation of functionally univentricular hearts revealed that superior cavopulmonary anastomosis procedures (Glenn procedures) and Fontan procedures were both performed at older ages in the EACTS centers compared with the STS centers (Table 3). Similar analysis of lesions amenable to corrective operations revealed the following patterns (Table 3): A higher proportion of infants with tetralogy of Fallot (TOF) undergo palliative procedures prior to corrective surgery in the EACTS centers compared with the STS centers (70% of EACTS infants with TOF were palliated while 61.6% of STS infants were palliated). Ultimately, correction of TOF was completed at an older age in the EACTS centers compared with the STS centers. The same fact is true with regard to age of complete atrioventricular septal defect repair.

The mean ABC score for the two databases were similar (EACTS = 6.5, STS = 7.1). Figure 1 shows EACTS program specific overall discharge mortality plotted against program specific mean ABC score. The size of the bubble corresponds to annual program volume of cases. Figure 2 shows STS program specific overall discharge mortality plotted against program specific mean ABC score. Again, the size of the bubble corresponds to annual program volume of cases.

Comment

This analysis of the EACTS-STS multi-institutional outcomes database confirms that in both Europe and North America, both case complexity and mortality are highest among neonates, then infants, and then children. Regional differences in practice patterns are demonstrated and the complex nature of the relationship between annual program volume and outcome is demonstrated. Inferences can be made about the benefits of transcontinental collaboration and cross-fertilization of knowledge.

This manuscript represents a transition for our global database initiative. During the first four years of the new millennium, our publications have, on a large part, described the process of developing and standardizing our database. We are hopeful that we can now focus more on the data and less on the process as we move forward. A broad overview of the data reveals that, as one would expect, neonates have the highest mortality and complexity, followed by infants, and then older patients. This finding is consistent across the Atlantic Ocean.

Interestingly, in North America, the prevalence of Norwood (stage 1) procedures is greater than that of arterial switch procedures. In Europe, the converse is true. This fact is consistent with the previously reported fact [16] that for patients with hypoplastic left heart syndrome (HLHS), "Europe overall clearly refers less patients to surgery and has a selective approach to management." The lower prevalence and higher mortality of Norwood (stage 1) procedures in the EACTS centers probably reflect a later acceptance of staged palliation for HLHS in Europe than in North America. The February 1988 publication of the J. Maxwell Chamberlain Memorial Paper at the annual STS meeting reported institutional results of 104 consecutive, nonselected neonates who underwent Norwood (stage 1) palliation of HLHS with an early mortality of 28.8% [17]. Over a decade transpired before a sizeable series of Norwood (stage 1) operations with encouraging results was published from a center in the United Kingdom [18]. On the other hand, several centers in both Europe and North America began to evaluate systematically the neonatal arterial switch operation as primary therapy for transposition of the great arteries in the early 1980s [19–22]. Clearly, we have learned that, in our field of medicine, multiple similarities exist between Europe and America. Nevertheless, important cultural and practical differences also exist, in our field of medicine, between Europe and America. In a manuscript comparing American and European approaches to the management of hypoplastic left heart syndrome, Martin Elliott acknowledged the American political commentator Robert Kagan who described Americans as being from Mars and Europeans as being from Venus [16]. Kagan stated that "they agree on little and understand one another less and less" [16]. Still, the world is becoming a smaller

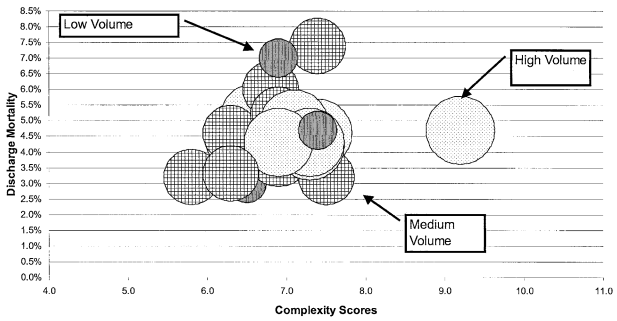

Fig 2. This graph shows program specific overall discharge mortality plotted against program specific mean basic complexity score plotted by annual volume of cases for the 21 participating Society of Thoracic Surgeons sites with greater than or equal to 94% complete discharge mortality data. Center annual volume is depicted as the size of the circle.

place. The Internet makes it possible for large documents to circumnavigate the globe faster than the time it takes to drink a cup of coffee [23].

Both Europe and North America have struggled with evaluation of the potential relationship between program volume and outcome [6, 24]. Analysis of the data generated thus far from our multi-institutional databases do not provide any clear answer to this question. In this regard, as well as with respect to practice patterns, it must be conceded that the data from centers currently submitting data may not be representative of all centers in either Europe or North America. For example, it is entirely possible that the relatively high incidence of palliative treatment of infants with TOF may be more reflective of a bias on the part of participating centers than truly representative of global practice patterns.

Data quality and accuracy are now central issues as we move forward. Collaborative efforts involving the EACTS and STS are underway to develop mechanisms to verify data completeness and accuracy. Verification of the completeness of the data is crucial because it has been previously shown that patients not included in medical audit have a worse outcome than those included [25]. The importance of the verification of the accuracy of the data is demonstrated in a recent report from the United Kingdom Central Cardiac Audit Database (UK CCAD). The UK CCAD analyzed 3,666 surgical procedures and 1,828 therapeutic catheterizations from 2000 and 2001 performed at all 13 UK tertiary centers performing cardiac surgery or therapeutic cardiac catheterization in children with congenital heart disease. Thirty-day mortality was identified both by volunteered life status from the hospital databases and by independently validated life status through the Office for National Statistics, using the patient's unique National Health Service number, or the general register offices of Scotland and Northern Ireland. Central tracking of mortality identified 469 deaths, 194 occurring within 30 days and 275 later. Forty-two of the 194 deaths within 30 days (21.6% of the 30-day mortality) were detected by central tracking but not by volunteered data. In other words, hospital-based databases under reported 30-day mortality by 21.6% even though the hospitals were aware that the data would be independently verified [26].

In the field of congenital heart surgery, multiple collaborative efforts are now ongoing between America and Europe with the common goal of improving our ability to care for our patients [27, 28]. The global benefits of international collaboration are achievable with the abilities for electronic meetings and video conferencing. Our ability to rapidly manipulate, transport, and store huge amounts of data will continuously improve our ability to practice evidence-based medicine in an environment of international collaboration [4]. Congenital heart surgeons, through their commitment to developing evidence-based practice decisions and their willingness to share data, have the opportunity to "lead the parade" toward international collaboration. This transcontinental cooperation is facilitated by increasing our interactions with one another and our understanding of one another. Thus, one of the primary objectives of this project is to improve transcontinental understanding, cooperation, and collaboration in our specialty. The EACTS-STS multi-institutional outcomes databases can be used for collaborative research and process improvement. These databases are truly sister databases that function as a tool for patient care, teaching, research, practice management, and quality improvement. Efforts are ongoing to increase the involvement from Africa, Asia, Australia, and South America, in order to create a truly global congenital heart surgery database. The overall goal of this project is to improve congenital heart surgery outcome analysis with the long-term objective of continued upgrade in the quality of surgery for congenital heart disease worldwide.

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DISCUSSION

DR BRADLEY S. ALLEN (Houston, TX): If I correctly read the data chart in the abstract book, the Aristotle basic complexity score for the European data in newborns is 7.6, and this correlated with an overall mortality of 13%. In contrast, in the STS data, you have a basic complexity score for the older children of 7, which is not much different than 7.6, and yet a mortality of only 3%. Now we're trying to use the complexity score to predict mortality and risk, so that, as you said, all centers feel like they're getting a fair shake.

Nevertheless, it seems from this chart that the complexity score is not really indicative of mortality. I'm just wondering if I'm reading this wrong or if you can explain the problem.

DR JACOBS: No, you are reading the data absolutely correctly. I can answer your question by pointing out two facts. First, the Aristotle Complexity Score is a work in evolution. I think it is currently the best tool available to adjust for case complexity or, in other words, case-mix. Certainly, we feel that no better system currently exists. However, it is not perfect and it is in the process of being validated. As we speak, we are in the process of both validating the tool for complexity adjustment and also verifying the data that we're using to validate the tool.

The second part of my answer is quite important. Mortality potential only represents one-third of what makes up the Aristotle score. The Aristotle Basic Complexity Score actually has three components: the potential for mortality, the potential for morbidity, and the technical difficulty of the operation. Therefore, the score cannot be correlated just directly with mortality because the other components also come into play.

DR ALLEN: I would have thought with the thousands of patients already entered into the database, you'd be able to validate the scoring system using the data you've already collected.

DR JACOBS: Efforts involving both the DCRI and the EACTS data center in Warsaw currently are underway to do exactly what you are suggesting. This project is really a two-step process. First, we must verify that the data is complete and accurate and then we must validate the score. This project represents an area of active ongoing research.

DR FRANÇOIS G. LACOUR-GAYET (Denver, CO): I want to raise two points. It's clear that the Aristotle basic score is already providing some information and that it is a good case mix. But it's totally insufficient and we know that from the beginning. Actually this basic score was ready in 2000. We never published it because we thought it was not enough, and we took 4 years to build what we call a comprehensive score explaining that all the Norwood are not the same, all the switch are not the same, and so forth.

We have clearly a problem of validation because we are dealing with subjective probability. There are only a few medical statisticians dealing with subjective probability. Hopefully, we have now discovered that subjective probability can be handled by another type of statistics as it is the case in many other disciplines.

The second point I would like to make is that so far we have Europe and North America associated in this evaluation of quality of care in the field of congenital heart surgery. Our goal is, of course, in the future to associate the colleagues from Asia, Australia, South America, Middle East, and Africa. And ultimately, our ambition and our pride would be that, for the first time, pediatric cardiac surgery could be fairly evaluated on a global level.

DR JACOBS: Thank you, François. You are clearly known as an international leader in this field and I agree completely with your comments. I would just like to briefly make two additional comments.

First, I agree with François completely that it's important that we expand this effort outside of Europe and North America and involve Africa, Asia, Australia, and South America. Efforts are ongoing to make this happen.

Second, I think it is extremely important that within Europe and within North America, we increase the percentage of programs that submit data and participate in our multi-institutional outcomes registries. I know that over 50 congenital heart surgery programs in the United States have software that allows them to track their outcomes and allows them to submit their data to the STS database. Unfortunately, I also know that less than half of these programs actually submit their data. I would encourage everybody in our profession to understand that this database is an important project. Everybody in this room should be submitting data and participating. My home state, Florida, is the fourth largest state in the United States. In the state of the Florida, all 8 congenital heart surgery programs have agreed that starting in 2005, all programs in Florida will be submitting their data to the STS database (with data from the year 2004 moving forward). I challenge everybody in this room by stating that if you're not submitting data, you should be.