Association of Center Volume With Outcomes: Analysis of Verified Data of European Association for Cardio-Thoracic Surgery Congenital Database

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Background. The relation between surgical volumes and outcome in congenital heart surgery (CHS) was investigated with no clear conclusions. We sought to quantify the relationship between surgical volume and surgical performance defined as the relation between outcome and Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery Congenital Heart Surgery (STAT) Mortality Score and The Society of Thoracic Surgeons (STS) Morbidity Score.

Methods. We have used only the verified data of the European Association for Cardio-Thoracic Surgery Congenital Database. The verified dataset consists of 17,861 procedures performed in 23 congenital heart surgery centers between 2003 and 2011. The centers were divided into 4 volume-related groups with annual caseload of below 150, 150 to 250, 250 to 350, and over 350. Stepwise logistic regression was used to calculate the ratio between volume and mortality, as well as between volume and onset of complications. The relations between volume and STAT Mortality Score, and STS Morbidity Score were evaluated using the analysis of variance test. The performance was calculated as the following: 100 – observed mortality/STAT Mortality Score; and 100 – observed complications/STS Morbidity Score.

Results. The study showed no relation between volume and raw mortality ($p = 0.94$) and between volume and complications ($p = 0.6$). The STAT Mortality Score and STS Morbidity Score were higher in larger volume centers ($p < 0.001$). Surgical performances measured as related to mortality and morbidity were higher at high-volume centers ($R^2 = 0.95$ and $R^2 = 0.92$).

Conclusions. Our analysis suggests that after adjustment for case mix higher programmatic volume is associated with lower rates of mortality and morbidity. The small- and medium-volume centers have higher rates of major complications. When complications occurred the chance of rescue is higher in large-volume centers.

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Several previous studies have documented a relationship between center volume and outcome in children undergoing cardiac surgery. Earlier investigations, where authors analyzed the case mix of all kinds of congenital heart surgeries, demonstrated an inverse relationship between volume and in-hospital mortality [1–3]. More recent studies concentrated on specific subsets of procedures as Norwood operation and arterial switch procedure confirmed that higher volume of these operations is associated with better early outcome [4, 5]. The largest and most recent studies demonstrated an inverse association between volume and mortality after adjusting for patient risk factors and surgical case mix [6, 7]. The large Society of Thoracic Surgeons (STS) multicenter analysis showed that the higher mortality observed at lower volume centers was rather related to a higher rate of mortality in patients with postoperative complications and not necessarily a higher rate of complications alone. That relationship was most prominent in higher risk patients. This conclusion suggested that future initiatives should concentrate on reducing the rate of complications and improving their management [8].

It has been suggested that in order to evaluate the quality of care of patients in small and larger units one should evaluate other outcomes than mortality alone, especially the postoperative rate of complications and other morbidity measures. Recent development of the STS Morbidity Score by Jacobs and colleagues [9] created a tool for analyzing the relationship between volume and performance where morbidity was defined as the occurrence of major complications. The aim of this retrospective study was to quantify the relationship between surgical volume and outcomes including the surgical performance defined as relation between outcome and STAT Mortality Score and STS Morbidity Score.

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Abbreviations and Acronyms

AoX = aortic cross-clamp
CHS = congenital heart surgery
CPB = cardiopulmonary bypass
EACTS = European Association for Cardio-Thoracic Surgery
ECHSA = European Congenital Heart Surgeons Association
IPPV = intermittent positive-pressure ventilation
PLOS = postoperative length of stay
STAT = Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery Congenital Heart Surgery
STS = The Society of Thoracic Surgeons

Material and Methods

The study was carried out according to the European Association for Cardio-Thoracic Surgery (EACTS) Congenital Database policy (www.eactscongenitaldb.org, paragraph 2). Because the individual patients were not identified, the need for parental consent was waived by the EACTS Congenital Database Committee. The study was accepted by the EACTS Database Director according to the policy (paragraph 6).

Database

This study was designed as a retrospective cohort analysis. We obtained data from the EACTS Congenital Database [10]. The EACTS Congenital Database collects procedure-related data on patients undergoing surgery for Congenital Heart Defects. The EACTS Congenital Database, established by the European Congenital Heart Surgeons Association (ECHSA) and EACTS in 1999 and sponsored by the EACTS and ECHSA since, is the result of transformation of the European Congenital Heart Defects Database created by the ECHSA in 1992. Data collected in the database include basic demographic information, anatomic diagnoses, associated noncardiac abnormalities, preoperative risk factors, intraoperative data, type of surgical procedure, and postoperative complications, as well as hospital and 30-day mortality. The database is entirely anonymous regarding patient, hospital, and surgeons' identifiable information.

Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery Congenital Heart Surgery; (STAT) Mortality Score

The STAT Mortality Score, the mortality risk stratification tool published in 2009, is based on empirically obtained data from nearly 80,000 operations, derived from the combined STS Congenital Heart Surgery Database [11] and EACTS Congenital Database [10]. In the STS-EACTS Mortality Score (STAT Score) each procedure was assigned a numeric categoric score by shifting and rescaling the estimated procedure-specific mortality rates to lie in the interval from 0.1 to 5.0 and then rounding to 1 decimal place, and has 29 unique values [12].

STS Morbidity Score

The STS Morbidity Score is the morbidity risk stratification tool based on empirically obtained data from nearly 63,000 operations driven from the STS Congenital Heart Surgery Database. Morbidity was quantified for each procedure on the basis of the proportion of patients experiencing major complications and by the average postoperative length of stay. Major complication was defined as the occurrence of any 1 or more of the following 6 postoperative complications: acute renal failure requiring temporary or permanent dialysis; neurologic deficit persisting at discharge; atrioventricular block requiring a permanent pacemaker, mechanical circulatory support (intraaortic balloon pump, ventricular assist device, extracorporeal membrane oxygenation, or cardiopulmonary support); phrenic nerve injury or paralyzed diaphragm; and unplanned reoperation. The categoric STS Morbidity Score was obtained by rescaling this overall morbidity measure to lie in the interval 0.1 to 5.0. Thus, by design it ranged from 0.1 to 5.0 [9].

Study Population

The study population consisted of patients who underwent a cardiovascular operation at an EACTS Congenital Database-participating program, which was verified according to the EACTS Database verification protocol between January 1, 2003 and December 31, 2011. The data have been submitted by 23 congenital cardiac surgical centers. All data were internally validated by an integrated software module that rejects all records that do not meet given criteria and sends these data back for correction. The dataset was additionally verified using on-site back-to-back data verification protocol. We limited the study to the cohort of the dataset that was verified. That is, the database staff visited the sites and verified the accuracy of 100% of the records for the following fields: hospital mortality; postoperative length of stay; intermittent positive-pressure ventilation time; date of birth; date of admission; date of surgery; date of discharge or mortality; body weight; case category; cardiopulmonary bypass time; aortic cross-clamp time; and circulatory arrest time. Patients were included if they underwent 1 of the cardiovascular procedures scored by STAT Mortality Score [12]. In cases in which patients had multiple operations during the same admission, only the first operation was analyzed. For all operations involving combinations of procedures the operation was classified according to the highest STAT Mortality Score procedure.

Data Collection

Data collected included patients' age, weight, presence of any noncardiac abnormality or genetic syndrome or other preoperative risk factors, as defined in the EACTS Congenital Database. To each primary operation STAT Mortality Score and STS Morbidity Score were assigned. Center characteristics included annual center surgical volume of STS-EACTS classified cases during the study