Association of Center Volume With Mortality and Complications in Pediatric Heart Surgery

WHAT'S KNOWN ON THIS SUBJECT: Previous analyses have suggested that center volume is associated with outcome in children undergoing heart surgery. There are limited data regarding factors that may mediate this volume–outcome relationship.

WHAT THIS STUDY ADDS: A multicenter analysis of 35 776 children revealed that the higher mortality observed at lower volume centers may be related to a higher rate of mortality in those with postoperative complications, rather than a higher rate of complications alone.

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KEY WORDS

congenital heart disease, heart surgery, outcomes research

ABBREVIATIONS

STS—Society of Thoracic Surgeons

EACTS—European Association for Cardiothoracic Surgery

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abstract

OBJECTIVE: Previous analyses have suggested center volume is associated with outcome in children undergoing heart surgery. However, data are limited regarding potential mediating factors, including the relationship of center volume with postoperative complications and mortality in those who suffer a complication. We examined this association in a large multicenter cohort.

METHODS: Children 0 to 18 years undergoing heart surgery at centers participating in the Society of Thoracic Surgeons Congenital Heart Surgery Database (2006–2009) were included. In multivariable analysis, we evaluated outcomes associated with annual center volume, adjusting for patient factors and surgical risk category.

RESULTS: A total of 35 776 patients (68 centers) were included. Overall, 40.6% of patients had ≥ 1 complication, and the in-hospital mortality rate was 3.9%. The mortality rate in those patients with a complication was 9.0%. In multivariable analysis, lower center volume was significantly associated with higher in-hospital mortality. There was no association of center volume with the rate of postoperative complications, but lower center volume was significantly associated with higher mortality in those with a complication ($P = .03$ when volume examined as a continuous variable; odds ratio in centers with <150 vs >350 cases per year = 1.59 [95% confidence interval: 1.16–2.18]). This association was most prominent in the higher surgical risk categories.

CONCLUSIONS: These data suggest that the higher mortality observed at lower volume centers in children undergoing heart surgery may be related to a higher rate of mortality in those with postoperative complications, rather than a higher rate of complications alone. *Pediatrics* 2012;129:e370–e376

Several previous studies have documented a relationship between center volume and outcome in children undergoing a variety of surgical procedures including liver transplant, appendectomy, pyloromyotomy, and heart surgery.^{1–10} In children undergoing heart surgery, it has been shown that higher surgical volume is associated with improved survival, particularly for high risk surgeries.¹ However, there are limited data regarding factors that may mediate this volume–outcome relationship, and may thus be targeted for quality improvement.

The Centers for Medicare and Medicaid Services has recently focused on reducing postoperative complications in surgical patients and began withholding payment for certain complications.¹¹ However, in adults undergoing cardiac operations as well as a variety of other surgical procedures, it has been shown that higher performing centers do not necessarily have a lower rate of complications themselves, but a lower rate of mortality in those who suffer a complication.^{12,13} It has been hypothesized that complications may be more related to patient factors and may be unavoidable in many cases, whereas the ability to recognize and treat complications once they occur may vary and be more related to quality of care.^{12,14} The case–fatality rate in patients with a complication has been termed “failure to rescue.”^{14,15} This measure has been used to compare quality of care across hospitals in adults and was endorsed as a performance measure in 2008 by the National Quality Forum.^{12–17} It is unknown whether a similar relationship between complications and mortality is present in the pediatric population or specifically in children undergoing heart surgery. A more clear understanding of this relationship may have health policy implications regarding strategies for improving outcomes.

Our purpose for this study was to evaluate the association of center volume with complications, mortality, and mortality in those with a complication in children undergoing heart surgery utilizing a large multicenter registry.

METHODS

Data Source

The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database is the largest pediatric heart surgery registry in the world, containing information on >180 000 children undergoing surgery since 1998. The database currently represents >75% of US centers performing congenital heart surgery.¹⁸ Data collected include perioperative, operative, and outcomes data on all children undergoing heart surgery at participating centers. Data quality and reliability are evaluated through intrinsic verification of data (for example, identification and correction of missing and out of range values and inconsistencies in values across fields), along with a formal process of in-person site visits and data audits conducted by a panel of independent data quality personnel and pediatric cardiac surgeons at 5 randomly chosen institutions each year.¹⁹ Although data are collected primarily for quality improvement purposes, the STS National Databases (Congenital, Adult Cardiac, and Thoracic) are also used extensively in outcomes research.²⁰ The Duke Clinical Research Institute serves as the data warehouse and analysis center for the STS National Databases. This study was reviewed and approved by the Duke University Institutional Review Board with waiver of consent. The study was also reviewed and approved by the STS Access and Publications Committee.

Study Population

This analysis focused on the most recent 4 years of data available in the STS

Congenital Heart Surgery Database. Seventy-nine North American centers that submitted data from 2006 to 2009 were eligible for inclusion. As described previously, centers ($n = 11$) with >15% missing data for key study variables were excluded.²¹ Although the STS Database contains nearly complete data for the standard core data fields required to calculate in-hospital mortality, not all centers submit complete data for the other variables in the STS Database such as patient preoperative factors and complications. Therefore, it is standard practice to exclude centers with >15% missing data for key study variables to maximize data integrity and minimize missing data. The distribution of center congenital heart surgery volume was similar in the excluded centers versus those included. The 68 remaining centers in the final study population were also similar to the overall cohort submitting any data to the STS Database during this time period in regard to outcome (in-hospital mortality rate was 3.9% and median postoperative length of stay was 6 days in both groups).

Patients 0 to 18 years of age from included centers undergoing any surgery classified in the STS-European Association for Cardiothoracic Surgery (STS-EACTS) risk stratification system were included (category 1 = lowest mortality risk, category 5 = highest mortality risk).²² This system was recently developed based on empirical data from nearly 80 000 patients, and it includes a greater number of operations compared with other risk stratification systems.²² Only the first cardiovascular operation of the admission was analyzed.

Data Collection

Data collected included patient age, weight, presence of any noncardiac abnormality/genetic syndrome or other preoperative risk factors (including cardiovascular, respiratory, neurologic,

renal, hematologic, and infectious factors) as defined in the STS Congenital Heart Surgery Database, preoperative length of stay, and number of previous cardiothoracic surgeries.²³ The primary operation performed was classified by STS-EACTS risk category.²² Center characteristics were also collected, including region of the country and average annual center surgical volume of STS-EACTS classified cases during the study period.

Outcomes

Center-level outcomes included in-hospital mortality rate, proportion of patients with any postoperative complication, and of those with a postoperative complication, the proportion who died (mortality in those with a complication). The complications evaluated included any postoperative complication collected in the STS Database: cardiovascular complications (cardiac arrest, mechanical circulatory support, arrhythmia, heart block requiring temporary or permanent pacemaker, low cardiac output, acidosis, pericardial effusion requiring drainage, pulmonary hypertension), pulmonary (pneumothorax, pleural effusion requiring drainage, pneumonia, chylothorax, tracheostomy, phrenic or recurrent laryngeal nerve injury, respiratory insufficiency requiring mechanical ventilation >7 days postoperatively or reintubation), neurologic (transient or permanent neurologic deficit, new onset seizures), infectious (wound/sternal dehiscence or infection, sepsis, mediastinitis, endocarditis), renal (acute renal failure requiring temporary or permanent dialysis), surgical (unplanned reoperation during the admission, systemic vein obstruction, pulmonary vein obstruction, bleeding requiring reoperation, sternum left open), and “other” postoperative complications.²³

“Major” postoperative complications were also evaluated; these included the following: unplanned reoperation

during the admission, acute renal failure requiring temporary or permanent dialysis, permanent neurologic deficit persisting at discharge, new onset seizures, mediastinitis, tracheostomy, cardiac arrest, mechanical circulatory support, and heart block requiring permanent pacemaker.

Analysis

Patient and center characteristics were described by using standard summary statistics. Center volume was examined both as a continuous and categorical variable. When evaluated as a categorical variable, volume was analyzed as <150, 150 to 250, 250 to 350, and >350 cases per year, consistent with previous analyses.¹ Patient and center characteristics were described overall and within each volume group. Unadjusted outcomes were compared between center volume groups using the Wilcoxon rank sum test. Marginal logistic regression models were then used to evaluate the association of center volume with each outcome (mortality, complications, and mortality in those with a complication as described above) adjusting for the following patient characteristics: age (modeled as a linear function with changes in slope at 30 days and 1 year), weight-for-age z score, any noncardiac/genetic abnormality, any other preoperative risk factor (as defined above), preoperative length of stay, number of previous cardiothoracic surgeries, and STS-EACTS surgical risk score. Empirical (sandwich) standard error estimators were used to account for correlation between outcomes of patients at the same center. For all models, center volume was first entered as a continuous variable to evaluate the overall association with each outcome and then as a categorical variable (as described above). The association of center volume with mortality after a major postoperative complication (as defined above) was also evaluated to assess

whether the volume–outcome relationship was consistent for these more definitive endpoints. Finally, stratified analysis was performed to evaluate whether the impact of center volume on outcome differed across varying levels of surgical risk. For this analysis, patients were stratified by STS-EACTS risk categories 1 to 3 (low risk) and 4 to 5 (high risk), and the models rerun in these subgroups. Odds ratios and 95% confidence intervals are reported for all models. Missing data were rare (<0.5% for all variables). Patients with missing data for a study endpoint were excluded from analysis involving that endpoint. All analyses were performed by using SAS version 9.2 (SAS Institute, Inc, Cary, NC). A *P* value <.05 was considered statistically significant.

RESULTS

Patient and Center Characteristics

A total of 35 776 patients from 68 centers (45% South, 21% West, 18% Midwest, 15% Northeast, 1% Canada) were included. There were 33 centers (49%) with <150 cases per year, 21 centers (31%) with 150 to 250 cases per year, 9 centers (13%) with 250 to 350 cases per year, and 5 centers (7%) with >350 cases per year. Patient characteristics, overall and stratified by volume category, are displayed in Table 1. Patient characteristics were similar between groups, with the exception that lower volume centers tended to have a greater proportion of patients with preoperative risk factors but operated on a lower proportion of patients in the higher STS-EACTS categories.

Outcomes

The overall in-hospital mortality rate was 3.9%, and 40.6% of patients had 1 or more postoperative complications. Overall, the median number of complications was 0 (interquartile range, 0–1). Of those with at least 1 complication, the median number of complications

TABLE 1 Patient Characteristics

Variable	Overall (<i>n</i> = 35 776)	Center Volume (cases per year)			
		<150 (<i>n</i> = 8433)	150–250 (<i>n</i> = 12 297)	250–350 (<i>n</i> = 7230)	>350 (<i>n</i> = 7816)
Age, mo	6.4 (1.0–48.4)	7.4 (1.6–55.2)	5.9 (0.7–44.3)	6.0 (0.9–49.1)	6.8 (0.9–47.5)
Male	16 196 (45.3)	3861 (45.8)	5635 (45.8)	3192 (44.2)	3508 (44.9)
Weight, kg	6.4 (3.6–15.4)	6.9 (3.8–16.8)	6.1 (3.5–14.9)	6.2 (3.6–15.4)	6.5 (3.7–15.0)
Weight-for-age z score	−1.1 (−2.1 to −0.09)	−1.1 (−2.1 to −0.06)	−1.1 (−2.1 to −0.1)	−1.1 (−2.0 to −0.09)	−1.0 (−2.0 to −0.1)
Any noncardiac/genetic abnormality	10 546 (29.5)	2568 (30.5)	3640 (29.6)	2227 (30.8)	2111 (27.0)
Any preoperative risk factor	10 090 (28.2)	2742 (32.5)	3316 (27.0)	2167 (30.0)	1865 (23.9)
Preoperative LOS ≥2 d	12 264 (34.3)	2647 (31.4)	4380 (35.6)	2588 (35.8)	2649 (33.9)
≥1 previous cardiothoracic surgery	7303 (18.8)	1715 (20.3)	2480 (20.2)	1483 (20.5)	1623 (20.8)
STS-EACTS surgical risk category					
1	12 760 (35.7)	3292 (39.0)	4207 (34.2)	2624 (36.3)	2637 (33.7)
2	9825 (27.5)	2376 (28.2)	3399 (27.6)	2004 (27.7)	2046 (26.2)
3	4226 (11.7)	928 (11.0)	1442 (11.8)	867 (12.0)	989 (12.7)
4	7193 (20.1)	1530 (18.2)	2617 (21.3)	1358 (18.8)	1688 (21.6)
5	1772 (5.0)	307 (3.6)	632 (5.1)	377 (5.2)	456 (5.8)
Median (interquartile range)	2 (1–4)	2 (1–3)	2 (1–4)	2 (1–3)	2 (1–4)

Data are displayed as median (interquartile range) for continuous variables, and frequency and percent for dichotomous variables. LOS, length of stay.

was 3 (interquartile range, 2–4). The mortality rate in those with a complication was 9.0%. Mortality in those without any of the complications captured in the database was rare (*n* = 75, 0.4%). In unadjusted analysis (Table 2), lower center volume was associated with higher mortality, complications, and mortality in those with a complication. In multivariable analysis adjusted for patient characteristics and surgical case complexity (Table 3), lower center volume was significantly associated with higher in-hospital mortality. There was no significant association of center volume with the rate of complications; however, lower center volume was significantly associated with higher mortality in those with a complication.

We subsequently restricted the analysis to only major postoperative complica-

tions to evaluate whether the volume–outcome relationship was consistent for these more definitive endpoints (as defined above). Results were similar in that there was a significant association between center volume and mortality in those with a major complication (*P* = .004 for overall trend when volume examined as a continuous variable; odds ratio in centers with <150 vs >350 cases per year = 1.31 [95% confidence interval: 1.00–1.75]).

We further evaluated the association of volume and outcome stratified by surgical risk group. In the lower risk patients (STS-EACTS categories 1–3), there was not a significant relationship between center volume and any of the outcomes examined: mortality (*P* = .67 for volume as a continuous variable), complications (*P* = .38 for volume as

a continuous variable), or mortality in those with a complication (*P* = .95 for volume as a continuous variable). In contrast, in the higher risk patients (STS-EACTS categories 4–5), there was a significant relationship between center volume and mortality (*P* = .0001 when volume examined as a continuous variable; odds ratio in centers with <150 vs >350 cases per year = 1.89 [95% confidence interval: 1.39–2.56]) and mortality in those with a complication (*P* = .003 when volume examined as a continuous variable; odds ratio in centers with <150 vs >350 cases per year = 1.89 [95% confidence interval: 1.29–2.77]) but no association of center volume with complications alone (*P* = .76 for volume as a continuous variable).

DISCUSSION

In this large multicenter analysis, we found that lower center volume was significantly associated with higher mortality in those with a postoperative complication, but not with a higher rate of postoperative complications alone, in children undergoing heart surgery. This association was most prominent in those in the higher surgical risk categories. These data suggest that the higher mortality observed at

TABLE 2 Unadjusted In-Hospital Outcomes

Variable	Overall (<i>n</i> = 35 776)	Center Volume (cases per year)				<i>P</i>
		<150 (<i>n</i> = 8433)	150–250 (<i>n</i> = 12 297)	250–350 (<i>n</i> = 7230)	>350 (<i>n</i> = 7816)	
Mortality, <i>n</i> (%)	1383 (3.9)	380 (4.5)	474 (3.9)	280 (3.9)	249 (3.2)	.0003
Any postoperative complication, <i>n</i> (%)	14 512 (40.6)	3447 (40.9)	5319 (43.3)	2665 (36.9)	3081 (39.4)	<.0001
Mortality in those with a complication, <i>n</i> (%)	1308 (9.0)	362 (10.5)	451 (8.5)	260 (9.8)	235 (7.6)	.0002

Outcomes include in-hospital mortality rate, proportion of patients with any postoperative complication, and of those with a postoperative complication, the proportion who died (mortality in those with a complication).

TABLE 3 Adjusted In-Hospital Outcomes

Outcome	OR (95% CI)	P
Mortality		
Center volume (cases per year)		
Volume as continuous variable	1.10 (1.04–1.17)	.002
Volume as categorical variable		
<150	1.60 (1.23–2.08)	.0004
150–250	1.18 (0.92–1.52)	.19
250–350	1.25 (0.94–1.64)	.12
>350	Reference	
Any postoperative complication		
Center volume (cases per year)		
Volume as continuous variable	1.07 (0.90–1.25)	.45
Volume as categorical variable		
<150	1.15 (0.57–2.33)	.69
150–250	1.18 (0.57–2.43)	.66
250–350	0.87 (0.40–1.88)	.73
>350	Reference	
Mortality in those with a complication		
Center volume (cases per year)		
Volume as continuous variable	1.10 (1.01–1.20)	.03
Volume as categorical variable		
<150	1.59 (1.16–2.18)	.004
150–250	1.22 (0.87–1.71)	.24
250–350	1.33 (0.96–1.83)	.09
>350	References	

Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) are displayed both for center volume as a continuous variable and categorical variable. The data displayed for center volume as a continuous variable represent the OR and 95% CI associated with a decrease in center volume of 100 cases per year. Outcomes include in-hospital mortality rate, proportion of patients with any postoperative complication, and of those with a postoperative complication, the proportion who died (mortality in those with a complication).

lower volume centers may in part be due to a higher rate of mortality after a complication and not necessarily a higher rate of complications.

Multiple previous studies have shown that center volume is associated with outcome in children undergoing a variety of surgical procedures, including heart surgery.^{1–10} Hirsch et al² evaluated 547 patients undergoing the arterial switch operation and 624 patients undergoing the Norwood operation in the 2003 Kids' Inpatient Database (a national administrative dataset) and found a significant inverse association between institutional volume and hospital mortality for both procedures. Checchia et al³ found similar results analyzing 801 patients undergoing the Norwood operation from 1998 to 2001 in the Pediatric Health Information Systems Database, a large administrative database of US children's hospitals. Similar findings have been reported from analyses of state databases in

New York, California, and Massachusetts.^{5–7} Finally, using the same clinical registry used in our study, Welke et al¹ evaluated >30 000 children undergoing heart surgery from 2002 to 2006 and found an inverse association between pediatric cardiac surgical case volume and mortality that became increasingly important as case complexity increased. Similarly, in the present analysis of a more recent cohort we found that there was a significant association between center volume and mortality in the higher risk patients (STS-EACTS categories 4–5) but not in the lower risk patients (STS-EACTS categories 1–3).

However, studies to date have not evaluated potential factors associated with the volume–outcome relationship, and the clinical mechanisms underlying this variation have not been elucidated. In the adult literature, numerous studies have revealed that high performing centers do not necessarily have lower

rates of complications but a lower rate of mortality in those who suffer a complication.^{12,13,15} Ghaferi et al¹⁵ studied Medicare beneficiaries undergoing 6 major operations from 2005 to 2006 (pancreatectomy, esophagectomy, abdominal aortic aneurysm repair, coronary artery bypass grafting, aortic valve replacement, and mitral valve replacement), stratified hospitals by mortality rate, and found similar complication rates at worst and best performing hospitals but a higher rate of mortality in those with a complication at the worst performing hospitals (16.7% vs 6.8%). The authors concluded that reducing variation in mortality will require strategies to improve the ability of hospitals with high mortality to manage postoperative complications.¹⁵ The case-fatality rate in patients with a complication, or failure to rescue, has been used to compare quality of care across hospitals in the adult literature and was endorsed as a performance measure by the National Quality Forum.^{12–17}

Differences across centers in the rate of complications or mortality in those with a postoperative complication have not been previously evaluated in the pediatric population. Similar to previous analyses utilizing administrative data, we found that complications in general are common in the pediatric heart surgery population.²⁴ In the present analysis, we did not find a significant difference in the rate of postoperative complications across centers. Although there were differences seen in unadjusted analyses across volume categories, these were no longer significant in adjusted analyses once patient factors were taken into account. Thus, it has been speculated that complications may be more related to patient factors rather than differences between centers in quality of care.^{12,14} In addition, similar to previous adult surgical studies, we found that there were significant

differences between centers in mortality among those who had suffered a complication, with higher rates seen in lower volume centers.^{12,13,15}

Thus, these data suggest that in addition to focusing on reducing complications themselves, quality improvement in the pediatric cardiac surgery population may also require attention to initiatives aimed at recognition and management of complications once they occur. Further study is needed to develop and refine a failure to rescue measure in the pediatric cardiac surgery population, to analyze which postoperative complications should be included in such a measure, and to evaluate potential factors that may influence this measure, including differences in training and availability of personnel, and hospital structure, processes, and management practices.^{25,26}

LIMITATIONS

This study has several limitations. First, the STS Congenital Heart Surgery Database does not capture all possible postoperative complications. In addition, there may be variability in how complications are coded within and across centers. STS data quality and reliability are evaluated through intrinsic verification of data as well as a formal process of site visits and data audits.¹⁹ However, there may still be

variability in coding of complications and this may have influenced our evaluation of complications across centers. For example, results similar to those in our study could occur if there was systemic overcoding of complications in larger volume hospitals or systematic undercoding in lower volume hospitals. This does not seem to be the case in our analysis as higher volume hospitals reported fewer complications compared with lower volume hospitals. Not all STS centers were included in this analysis and not all US centers submit data to the STS Database. However, the generalizability of our results is supported by the similarity of outcomes in our study cohort to the overall cohort of STS centers. In addition, although we attempted to adjust for important patient confounders, it is possible that there could be other unmeasured confounders present impacting our analysis. We focused on analyzing the relationship of outcome measures with center volume in the current study; ongoing analyses are also focusing on surgeon volume. In this study, we were not able to evaluate the impact of variables such as hospital structure and process measures, training or availability of personnel, or nursing factors on outcome because the STS Database currently does not contain detailed information regarding these variables. Finally,

this analysis represents a first step in evaluating the overall relationship between mortality and complications in this population; further analyses will also need to evaluate specific complications in more detail.

CONCLUSIONS

Data from this large multicenter analysis suggest that the higher mortality observed at lower volume centers in children undergoing heart surgery may in part be related to a higher rate of mortality in those with postoperative complications and not necessarily a higher rate of complications alone. This relationship was most prominent in higher risk patients. Thus, initiatives aimed at improving outcomes may need to focus on not only reducing complications themselves but also improving recognition and management of complications once they occur. Further research is needed to develop and refine a failure to rescue measure in the pediatric heart surgery population and to evaluate factors that may influence this outcome measure.

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