8 Surgical Volume and Outcome Relationship in Pediatric Cardiac Surgery

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Abstract

A significant inverse relationship between surgical institutional and surgeon volume and patient outcome has been demonstrated in many high-stakes surgical specialties. By in large, the same results were found in pediatric cardiac surgery, where a more thorough analysis has demonstrated that this relationship is mediated by case complexity and the type of surgical procedures. Lower-volume programs tend to underperform in comparison to larger programs as case complexity increases. High-volume pediatric cardiac surgeons have better results compared with low-volume surgeons, especially with complex procedures such as with the Norwood procedure. Nevertheless, this trend towards lower mortality at larger centers is not universal: all larger programs do not perform better than all smaller programs. Moreover, surgical volume seems to account for only a small proportion of the overall between-center variation in outcome. Thus the use of center-specific risk adjusted outcomes as a tool for quality assessment may be more reliable than relying upon surgical volume alone. Indeed, a patient's risk factors and their level of disease severity may play a more important

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P.R. Barach, J.P. Jacobs, S.E. Lipshultz, P.C. Laussen (eds.), *Pediatric and Congenital Cardiac Care: Volume 2: Quality Improvement and Patient Safety*, DOI 10.1007/978-1-4471-6566-8_8, © Springer-Verlag London 2015

role in determining their individual outcome than the impact of the surgeon or program's volume. Nevertheless, the relationship between surgical volume and outcome in pediatric cardiac surgery is strong enough that it ought to shape and influence public policy around the decision to centralise pediatric cardiac surgery and support strategies that support higher center and surgeon volumes and their impact on patients and providers.

Keywords

Case complexity • Norwood procedure • Outcome • Pediatric cardiac surgery • Quality assessment • Surgical volume

Introduction

Pediatric cardiac surgery is a high-risk field that depends on safe practices, continuous research into improvement of outcomes and measurement of quality [1]. However, the definition and measurement of quality in pediatric cardiac surgery is in its infancy [2]. One of the most simple and easily available tools for health quality measures in all surgical specialities is the surgical volume of a hospital. Birkmeyer et al. demonstrated that Medicare patients undergoing selected cardiovascular or cancer procedures can significantly reduce their risk of operative death by simply selecting a high-volume hospital for their procedure [3]. Two extensive reviews [4, 5] systematically assessed the methodology and results of studies dealing with this volume/outcome relationship in varied surgical and medical fields. Many of these studies were found to be compromised by the use of retrospective administrative data [6], inadequate risk adjustment and problematic statistical methodology [7]. In pediatric cardiac surgery, the specific relationship between institutional and surgeon volumes and outcome (mortality, complications) is currently the subject of numerous investigations and remains controversial. The conclusions drawn from these studies might have an outstanding impact internationally on the intra institution, inter institution and national organization of pediatric cardiac services.

This chapter aims at highlighting (1) current evidence of surgical volume on patient outcome relationships in pediatric cardiac surgery; (2) the specific volume/outcome relationship depending on case complexity, type of surgical procedures and surgeon volume; and, (3) the potential consequences in terms of quality improvement initiatives and regional/national public health policies.

Overall Relationship Between Institutional Surgical Volume and Outcome in Pediatric Cardiac Surgery

Studies Based on Administrative Data or Single-state Clinical Data

In 1995, Jenkins et al. reported preliminary observations of variation of in-hospital mortality in pediatric cardiac surgery depending on hospital caseload [8]. This study, based on retrospective assessment of administrative databases included children undergoing surgery for congenital heart disease in California or Massachusetts. These patients were identified by the presence of procedure codes indicating surgical repair of a congenital heart defect in computerized aggregated hospital discharge abstract databases in the two states. It was shown that centers performing less than 300 cases per year had higher risk-adjusted odds of in-hospital mortality when compared with thoses performing more than 300 cases (OR = 7.7, <10 cases; OR = 2.9, 10 to 100 cases; OR = 3, 101 to 300 cases). This study, limited by the absence of clinical detail in discharge abstract databases, concluded that, for children with a congenital heart defect who underwent surgery in

California in 1988 or Massachusetts in 1989, the risk of dying in-hospital was much lower if the surgery was performed at an institution performing more than 300 cases annually.

These preliminary findings were then confirmed by two investigations performed in New York State. In 1999, Sollano et al. examined the relationship between hospital volume and in-hospital mortality in 3 cardiovascular procedures: coronary artery bypass grafting, elective repair of abdominal aortic aneurysms, and repair of congenital cardiac defects [9]. Using a New-York State clinical database, this study demonstrated a significant inverse relationship between volume and death in pediatric cardiac surgery (OR, 0.944 for every 100 additional cases), which was most pronounced for neonates (OR, 0.636 for every 100 additional cases). It also demonstrated the absence of such a relationship in patients who benefited from coronary artery bypass grafting. The authors hypothesized that the NY State quality improvement program for bypass operations might explain the difference.

The other New-York State-based study was specifically designed to evaluate the effects of hospital and surgeon volume on in-hospital mortality after pediatric cardiac surgery [10]. This population-based retrospective cohort study used a single-state clinical database and demonstrated that both hospital volume and surgeon volume were significantly associated with risk-adjusted in-hospital mortality (8.26 % for center <100 cases versus 5.95 % for centers >100 cases). Moreover, these differences persisted for both high-complexity and low-complexity pediatric cardiac procedures.

The topic was addressed again in the early 2000s by two studies exploring two parallel hypotheses. In 2002, Chang et al. hypothesized that reducing the numbers of centers performing pediatric cardiac surgery in a given region would improve outcome [11]: based on abstracted state-wide hospital discharge data from California from 1995 to 1997, they showed that a theoretical regionalization of pediatric cardiac surgery in this State during this period was associated with a reduction in surgical mortality from 5.34 % to 4.08 % when all cases were referred to high-volume hospitals, or, mortality was decreased to 4.60 % when only high-risk cases were referred. They identified mean annual volume cut-off points of 70 and 170 cases per year. However, a group from Israel reported in 2003 that an increase in caseload in a department of pediatric cardiac surgery tended to decrease the complications-related mortality rate [12].

This evidence in favour of a significant inverse relationship between caseload and death in pediatric cardiac surgery has been consistent in five studies despite different methodologies including different databases, risk adjustments, and hospital volume cut-offs. This association was further reinforced in the late-2000s by two further studies. In 2007, Bazzani et al. reevaluated the volume-outcome relationship for pediatric cardiac surgery using a larger, more contemporary hospital discharge database (1998 –2003) from the state of California [13]. He and his team found a weaker and less consistent volume-mortality relationship than had been reported previously when he replicated the methodology of the previously mentioned studies [8–11]. A newly developed and updated model demonstrated a volume-mortality relationship but it was dependent on highly leveraged covariate patterns found in the largest-volume hospital. The attenuated relationship over time could be explained, according to the authors, by the avoidance of high-risk surgical procedures by low-volume hospitals on the one hand, and, by technological advances adopted at higher-volume centers sooner and more reliably than lower-volume centers [14]. Finally, the authors felt that the impact of quality improvement initiatives [15, 16] at larger hospitals were more pronounced and sustained.

Welke et al. demonstrated in 2008, the important need of risk-adjusted models to further understand the volume/outcome relationship in pediatric cardiac surgery [17]. They demonstrated using the national administrative data from the Nationwide Inpatient Sample (NIS), that, as a discriminator of mortality, volume alone performed significantly worse than a model with Risk Adjustment for Congenital Heart Surgery, version 1 (RACHS-1) category and age (ROC curve area, 0.60 vs 0.81). Indeed the unadjusted mortality rate at very small hospitals was not different than at large hospitals. Nevertheless, after adjustment for RACHS-1 category and age, large hospitals performed *significantly better* than all other volume groups, demonstrating that large-volume hospitals performed more complex operations and achieved superior results when compared to smaller ones.

These findings demonstrated the need for sophisticated risk-adjusted models. It also pointed to the limited reliability and predictive abilities of administrative data regarding the ability to adjust for patient-level risk factors and surgical case-mix designation. New studies exploring the volume/outcome relationship in pediatric cardiac surgery are now based on national or multicentric clinical databases.

Studies Based on Multi-state or National Clinical Data

Welke et al. first demonstrated in 2009, the inverse association between pediatric cardiac surgical volume and mortality in a national clinical database [18]. Using the Society of Thoracic Surgeons Congenital Heart Surgery Database, and after adjustment for patient-level risk factors and surgical case mix (Aristotle Basic Complexity ABC and RACHS-1 categories), they showed an inverse relationship between overall surgical volume as a continuous variable and mortality ($P = .002$), with an inflection point between 200 and 300 cases per year. This study also proved for the first time the modifying role played by case complexity in mediating the strength of the volume/outcome relationship. Indeed, surgical centers with less than 150 cases per year performed significantly worse those with more than 350 cases per year, especially for difficult operations (Aristotle technical difficulty component score more than 3.0), whereas all groups performed in similar manner for low-difficulty (Aristotle score less than 2.0) operations.

Pasquali et al. confirmed this volume/outcome relationship in 2012, in a national clinical database using a surgical risk category-adjusted multivariable risk analysis [19]. This study also explored the effect of the institutional volume on the occurrence of complications and the mortality rate in patients who suffered from complications. Interestingly, this study demonstrated that the higher mortality observed at centers with more than 150 cases per year compared to centers with more than 350 cases per year may be related to a higher rate of mortality in patients with postoperative complications ($OR = 1.59$), rather than a higher rate of complications alone. This association of volume with complication-related mortality was more marked in the higher surgical risk categories, which was consistent with data from Welke et al. [18].

Volume/Outcome Relationship According to the Case Complexity and the Type of Procedure

Volume/Outcome Relationship by Case Complexity

Welke et al. first explored the impact of case complexity in 2009, by showing the volume/outcome relationship in pediatric cardiac surgery [18]. They showed that this relationship was most apparent for difficult operations (Aristotle technical difficulty component score more than 3.0), for which mortality decreased from 14.8 % at programs less than 150 cases per year to 8.4 % at programs with more than 350 cases (OR, 2.41; $P < .0001$). The same was true for the subgroup of patients who underwent a Norwood procedure (36.5 % vs 16.9 %). To further investigate the volume–mortality relationship, they analyzed volume as a continuous variable and used logistic regression to adjust for patient-level risk factors and surgical case mix. The inverse relationship between surgical volume as a continuous variable and mortality was not significant for low-complexity cases ($P = 0.06$) but was consistent for high-complexity cases ($P = 0.007$) (Fig. 8.1). This suggests that lower-volume programs significantly underperformed in comparison to larger programs as case complexity increased, whereas volume was not associated with mortality for low-complexity cases in this study.

Pasquali et al. similarly confirmed a significant association between center volume and mortality in the higher risk patients (STS-EACTS or STAT categories 4–5) but not in the lower risk patients (STAT categories 1–3) [19].

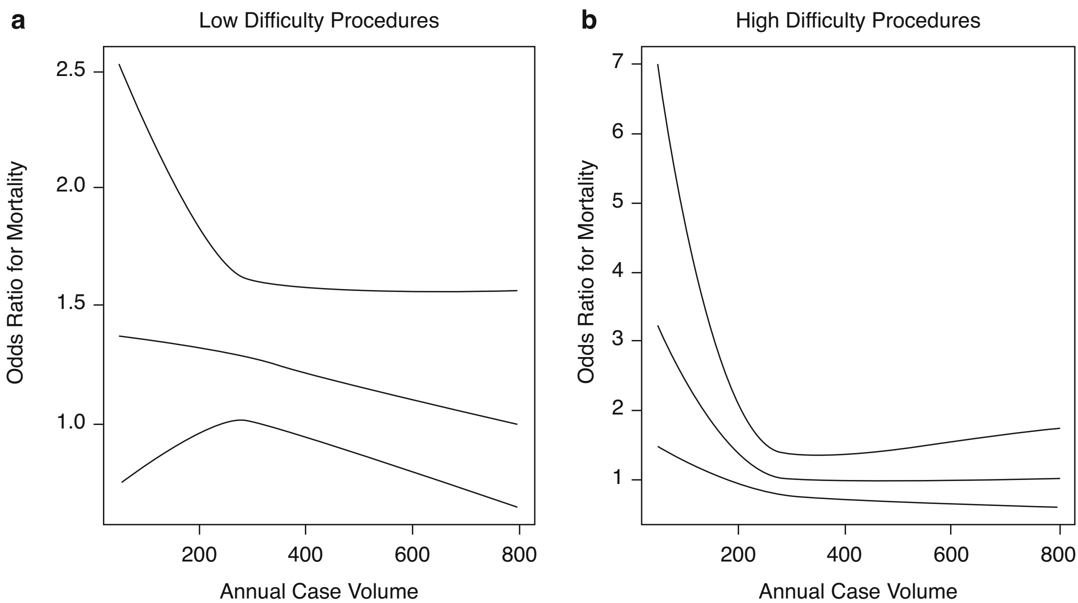

Fig. 8.1 Association between surgical volume and risk-adjusted mortality by Aristotle difficulty: (**a**) low difficulty, ≤3 (P = 0.059); (**b**) high difficulty,>3 (P = 0.007) (Reprinted from Welke et al. [18], copyright 2009 with permission from Elsevier)

Volume/Outcome Relationship by the Type of Procedure

Hirsch et al. used the administrative Kids' Inpatient Database (KID) in 2008 to explore the institutional volume/outcome relationship for the Norwood and arterial switch operations (ASO), that represent the most complex neonatal cardiac procedures [20]. They demonstrated that in-hospital mortality significantly decreased for both the ASO and the Norwood procedure as institutional volume increased. For ASO, mortality rates were 9.4 % for institutions performing two ASOs per year, 3.2 % for 10 ASOs/year, and 0.8 % for 20 ASOs oer year; for Norwood procedure, these rates were 34.8 % for two Norwood procedures per year, 25.7 % for 10 Norwood procedures/year, and only 16.7 % when 20 Norwood procedures were done per year.

Interestingly, Karamlou et al. showed in a Congenital Heart Surgeons Society (CHSS) study in 2010 the impact of institutional volume on the risk-adjusted mortality after ASO or repair of interrupted aortic arch, but not after a Norwood procedure or repair of a pulmonary atresia with intact ventricular septum [21]. The absence of a strong volume/outcome association in regards to the Norwood procedure in this study by Karamlou et al. was not confirmed in following studies that specifically investigated this topic. Finally, the same group investigated the volume/outcome relationship in 2013 after extracorporeal membrane oxygenation (ECMO) in patients younger than 20 years, using the Project Kids' Inpatient Database [22]. After adjustment to case complexity (RACHS-1 categories), the lower ECMO volume remained a significant determinant of in-hospital death (OR = 1.75; CI:1.03–2.94).

Volume/Outcome Relationship and the Norwood Procedure

Several recent studies have investigated the volume–mortality relationship specifically for the Norwood procedure because of the high level of system knowledge and coordination that this procedure requires. Welke et al. demonstrated that programs that do over 350 cases per year outperformed all other volume groups for the Norwood procedure [18] (Fig. 8.2).

Checchia et al. showed using the Pediatric Health Information System database including

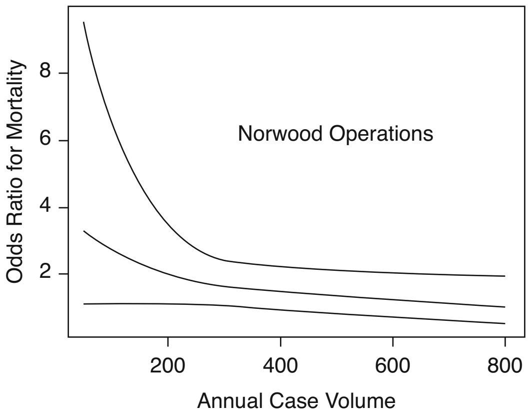

Fig. 8.2 Association between hospital volume and risk-adjusted mortality for Norwood operations (P<.001) (Reprinted from Welke et al. [18], copyright 2009 with permission from Elsevier)

801 Norwood procedures, that the survival after the Norwood procedure was associated with institutional Norwood procedure volume (p=0.02) [23]. Hirsch et al. evaluated 624 Norwood patients in the Kids' Inpatient Database and confirmed this significant inverse association between volume and mortality (35 % in low-volume centers versus 17 % in high-volume centers) [20].

A 2010 study by Karamlou et al. called the volume/outcome relationship into question [21]. The authors explained the absence of such a relationship in their study by three factors. First, the higher dependence of outcomes after Norwood procedure on preoperative and postoperative care, compared to the arterial switch operation; second, the higher anatomic heterogeneity of hypoplastic left ventricle compared to TGA; and third, the fact that this study missed the learning curve effect in the Norwood cohort compared to the arterial switch cohort. Moreover, the volume estimates in this CHSS study were based on the number of patients from each center enrolled in a cohort of patients with aortic atresia or stenosis selected for a Norwood operation, and not on the overall number of patients at each center undergoing the Norwood operation.

In 2012, Pasquali et al. demonstrated in a study using a large multicenter registry (The Society of Thoracic Surgeons Congenital Heart Surgery Database) that, after adjustment for patient

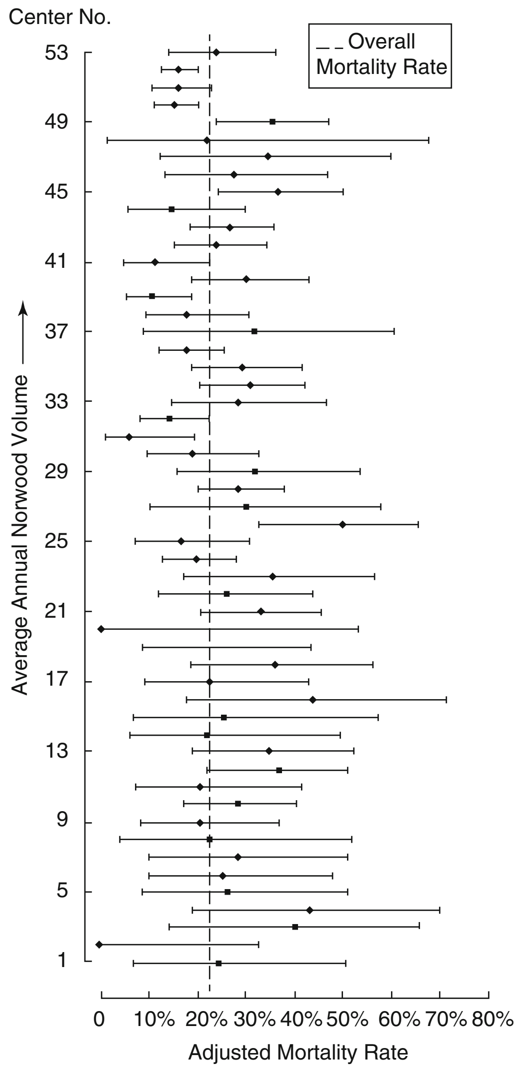

Fig. 8.3 Adjusted mortality rate displayed by increasing center volume (Reprinted from Pasquali et al. [24], copyright 2012 with permission from Elsevier)

characteristics, a lower Norwood center volume remained modestly but significantly associated with higher in-hospital mortality when evaluated as a continuous and categorical variable (OR=1.54 (1.02 to 2.32), p=0.04) [24]. Such a relationship did not vary significantly across preoperative risk tertiles but did not hold true across all centers (Fig. 8.3). Indeed, there are some middle volume centers with Norwood mortality rates comparable to those of higher volume centers, and some higher volume centers with mortality rates similar to those of lower volume groups. Finally, this study showed that the Norwood volume explained an estimated 14 % of the between-center variation in mortality observed after this procedure, and that the majority of between-center variation in mortality remained after adjusting for Norwood volume ($p<0.001$). Based on these results, the authors concluded that the use of *institutional volume alone* is not a good quality metric for the Norwood procedure, and, that we would be better off to rely on center-specific risk adjusted outcomes.

Institutional Volume, Surgeon Volume or Volume-Independent Center Effect?

Relative Impact of Surgeon and Center Volume in Pediatric Cardiac Surgery

Studies in adult cardiac surgery have concluded that the observed insitutional volume/ mortality association was largely mediated by individual surgeon volume [25]. It has even been suggested in adult vascular surgery that a means to improve one's chances of survival would be to select a surgeon who performs a specific operation frequently [26, 27]. In pediatric cardiac surgery, this issue was investigated by 4 groups. In 1998, Hannan et al. showed, using a New-York State clinical database, that surgeons with pediatric cardiac surgical cases volumes of less than 75 per year had significantly higher mortality rates (8.77 %) than surgeons with surgical volumes more than 75 cases per year (5.90 %) [10]. But this result was not confirmed by 2 subsequent studies that addressed this issue in the specific population of patients that required a Norwood procedure. Indeed, Checcia et al. found using a large administrative database that surgeon volume was not associated with patient outcomes after a Norwood procedure [23]. In 2010, the CHSS study by Karamlou et al. showed that neither center nor surgeon volume were associated alone with Norwood outcomes [21]. The results of these two studies might have been limited by the use of administrative data and the methodology used for calculating surgical volume.

More recently, Hornik et al. evaluated the relative impact of surgeon and center volume on mortality in a large Norwood cohort, using the Society of Thoracic Surgeons Congenital Heart Surgery Database [28]. They showed that, when analyzed individually, both lower center and surgeon volumes were associated with higher in-hospital mortality (odds ratio for surgeons with 0–5 cases versus surgeons with more than 10 cases per year = 1.60). This surgeon volume/mortality association after Norwood procedure was true in all center volume strata: lower volume surgeons had higher adjusted in-hospital mortality rates across low, medium, and high volume centers. A low-volume surgeon's outcomes were worse regardless of center volume, but the surgeons's results were mitigated by a large center volume. These results have been reproduced most potently in a recent analysis of the Single Ventricle Reconstruction trial, which also showed a significant survival advantage for high-volume surgeons [29]. This association can be easily understood as it has been shown that surgical technical performance improves outcomes irrespective of preoperative physiologic status or case complexity in the Stage 1 norwood procedure [30] and in other neonatal cardiac surgical procedures [31, 32]. These data could lead to the development of regional collaboration and centralization policies within and across centers through enhanced mentoring program by the highest-volume surgeons. Nevertheless, this impact of surgeon volume on Norwood mortality demonstrated by Hornik et al. was less strong when compared to the impact of surgeon volume in adult cardiac surgery [25]. This could be explained by the key role played by other providers, human factors and hospital-related factors impacting on the preoperative and postoperative management of complex single-ventricle physiology, thus decreasing the direct consequences of the impact of surgeon volume in pediatric vs adult cardiac surgery.[33]

A Volume-Independent Center Effect?

Recent studies have demonstrated that a volume-independent center-effect seems to contribute substantially to the between-center variability in outcomes. This center effect was has been demonstrated after orthotopic heart transplantation [34]: Kilic et al. demonstrated that institutional volume alone only accounted for 16.7 % of the variability in mortality between centers, and that a significant between-center variability persisted after adjusting for this factor ($P<0.001$). This finding was confirmed in pediatric cardiac surgery in 2013 by Vincour et al. [35]. Vinocur et al. aimed at characterizing the relative contribution of patient factors, center surgical volume, and a volume-independent center effect on early postoperative mortality in a retrospective cohort study of North American centers in the Pediatric Cardiac Care Consortium. Although the center volume was inversely associated with outcome in all age groups and risk categories (except the lowest one), a volume-independent center effect contributed substantially more to the risk model than did the volume.

Another group revealed the impact of prior hospital performance on the current outcomes after surgery for congenital heart disease [36]. They demonstrated using the Pediatric Health Information Systems database, that prior hospital postoperative mortality was significantly associated with mortality across all risk strata of congenital heart surgery, whereas, prior hospital surgical volume tended to be associated with improved mortality after only higher-risk operations. These intriguing recent results suggest that center-specific variation in outcomes after pediatric cardiac surgery is only partially explained by operative volume and that other factors have yet to be clearly identified.

Controversies and Perspectives

The Volume Alone as a Quality Metric?

The results of the most recent previously mentioned studies demonstrate that a relationship between case volume and mortality should be interpreted with caution. The trend for lower mortality at larger centers is not universal: all larger programs do not perform better than all smaller programs. Morevover, it has been shown that the volume accounted for only a small proportion of the overall between-center variation in outcome [24, 35, 36]. The lack of long-term follow-up (beyond 30 days) in most of these studies also limits the evaluation to the very early mortality. This serious challenge prevents the authors from addressing the long-term mortality, morbidity, functional status, and neurologic status which is quite significant in single vessel pathologies even after repair [18]. Thus, the center or surgeon volume alone may not be reliable enough to measure and compare center outcomes. The use of center-specific risk adjusted outcome as a proxy tool for quality assessment may be more reliable than relying upon volume alone [17, 37]. Such an adjustment should consider at the minimum both surgical case complexity and patient specific factors [24]. Indeed, a patient's risk factors and their level of disease severity may play a more important role in determining their individual outcome than the impact of the program's volume.

The Confounding Bias of the Volume Factor

The true mechanism of the volume/outcome association remains controversial. Higher volume centers probably have other organizational, logistical, technical and/or human characteristics that at least partially explain this relationship. These factors include the availability of highly equipped operating rooms and cath labs, better management of health resources, ergonimic design and deployment of new technologies, composition of the care team, advanced training programs, improved preoperative and intraoperative care, multidisciplinary discussions, the use of standardized management protocols, and better resilience and timely recognition and treatment of complication [18, 19, 28, 38–41]. That suggests that higher center volume may be a surrogate for other aspects of care that are more likely to be provided at larger centers. These process measures and structural characteristics of systems that lead to better outcomes are not currently captured in available databases. These aspects including the role of human factors, team training and debriefing and non technical team skills should be extensively studied to determine their respective roles in outcomes after pediatric cardiac surgery [33, 42, 43]. The increasing mobility of skillful and experienced surgical, anesthesia and ICU staff should also be taken into account when studying the volume/outcome relationship [44]. Finally, we could also wonder whether high case volumes may lead to the improvement of outcomes thanks to an increased practice or better results attract more referrals, thus leading to higher volumes [11]. The relation between high volume and better outcomes remains strong and persistent in the field of pediatric cardiac surgery. [24, 28, 29], What then should policy makers do? what should parents and healthcare mangers do? and in view of the results of the latest studies [45, 46].

What Do We Do with These Results?

The regionalization of care and the selective referral of patients to high performing centers have been proposed based on these results of the volume/outcome relationship in pediatric cardiac surgery. Chang et al., suggested that regionalization of services in California may result in decreased mortality in children undergoing cardiac surgery [11]. Such a regionalization of care has already been done in some European countries, most pronounced in Sweden, Norway, UK, the Netherlands and Poland. For example, in Sweden, care was centralized to two centers with the lowest mortality and early national mortality rates were reduced from 9.5 to 1.9 % [47]. In the US, Mainwaring et al. showed that a model based on affiliation of low volume programs with a larger academic program within the same region, including referral of high-complexity cases such as Norwood operations to the high volume program, was associated with lower overall mortality [48]. Whether regionalization of care for children undergoing heart surgery in the United States is politically and financially feasible or even desirable remains under debate. We suggest that regionalization should be conducted on a region-by-region basis, according to the characteristics of local geography, demographics, and healthcare markets [41].

Alternative strategies to regionalisation of care have been proposed to reduce the present unacceptable large variation between centers. Quality improvement initiatives, quality assurance initiatives, development of evidence-based best practice guidelines [24], (for instance standardizing the way we recognize and manage complications [19]) could lead to major improvement of outcomes in pediatric cardiac surgery. Recent quality improvement activities including widespread use of learning collaboratives in adult cardiac surgery involving the adult cardiac surgery programs in Michigan [49] or the Northern New England Cardiovascular Disease Study Group [50] proved the feasibility and impact of quality improvement initiatives and could be applied to the field of the pediatric cardiac surgery. The National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) is a potential model for applying system improvement and learning collaboratives.[51]

Conclusions

There is a significant inverse relationship between surgical institutional and surgeon volume and outcomes in pediatric cardiac surgery. This relationship depends on case complexity and the type of surgical procedures. Lower-volume programs tend to underperform larger programs as case complexity increases. High-volume pediatric cardiac surgeons also tend to have better results compared with low-volume surgeons, especially in the Norwood procedure. Nevertheless, this trend for lower mortality at larger centers is not universal: all larger programs do not perform better than all smaller programs. Morevover surgical volume seems to account for only a small proportion of the overall between-center variation in outcome. Thus the use of a center-specific risk adjusted outcome as a tool for quality assessment may be more reliable than relying upon surgical volume alone. However, the relationship between surgical volume and outcomes in pediatric cardiac surgery is strong enough that it ought to guide regional and national healthcare policies around centralization of complex pediatric cardiac surgery.

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