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Five-year outcomes after regionalizing pediatric cardiac surgery centers

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ABSTRACT

Infant mortality after cardiac surgery is multifactorial, but can be related to center and surgeon case volume. One method to increase case volume is to consolidate or regionalize pediatric cardiac surgical care. We evaluated in-hospital and 5-year outcomes in three separate pediatric cardiac surgical programs before and after they formed one regional consortium. Infants (< 1 year of age) undergoing complete biventricular surgery were divided into two groups: pre-regionalization (when operations were performed at three separate hospitals between, 1991 and 1998) and post-regionalization (when all operations were performed at one regional program at two surgical centers between, 2001 and 2010). Cases during 1999 and 2000 were excluded as the consortium at that time included only two of the three programs. Primary outcomes were hospital mortality, 5-year survival, cardiac re-operation, and number of events (deaths plus re-operations) during the 5-year follow-up for each group. The 671 infants in the pre-regionalization group did not differ significantly from the 782 infants in the post-regionalization group in age at surgery, weight, or sex. Hospital mortality was significantly greater than the state average before regionalization (9.8% vs. 7.1%; 95% CI of difference: 0.008, 0.052, $P < 0.001$), but significantly lower than the state average after regionalization (1.9% vs. 4.5%; 95% CI of difference 0.013, 0.043, $P < 0.001$). Regionalization also significantly improved the 5-year survival (90.2% vs 95.2%; $P < 0.001$) and freedom from re-operation (83.4% vs. 91.1%; $P < 0.001$). Multivariate analysis showed that regionalization was independently associated with mortality lower event rate (hazard ratio, 0.35; 95% CI, 0.23 to 0.53; $P < 0.001$). In our experience, regionalizing and consolidating pediatric cardiac surgical care improved both in-hospital and 5-year survival outcomes. Application of this strategy in other regions of the US may be feasible and beneficial.

1. Introduction

Given the complexity of congenital cardiac surgery and the association between higher case volume and improved outcomes [1–6], some institutions have sought to consolidate or regionalize pediatric cardiac surgical services. Regionalization, as it relates to congenital heart disease, describes a process where patients from lower volume centers are redistributed to higher volume centers. There are several examples where regional programs in pediatric cardiac surgery exist, such as the United Kingdom, Sweden, and Norway. However, published data regarding the impact of regionalization are largely limited to a specific diagnosis of congenital heart disease such as the Norwood procedure or arterial switch [4–6] and/or evaluations of large administrative or health care databases [7,8]. In addition, most of these reviews report only 30 days of follow-up [1–3], and the impact of regionalization on intermediate-term outcomes is unknown.

Between 1991 and 1998, central and western New York State was served by three independent university-based, pediatric cardiac surgical programs in Syracuse, Rochester, and Buffalo. The programs were about equal in size and patient volume. In 1998 a report evaluating pediatric cardiac surgery programs in New York suggested that lower surgeon and hospital volume were independent predictors of increased hospital mortality [1]. Following this publication, the pediatric cardiac surgeon in Syracuse began discussions with all three pediatric cardiology groups about strategies to consolidate services, improve results, and sustain pediatric cardiac surgical care in the region. In late 1999, the Rochester and Syracuse pediatric cardiac surgical programs were combined, and by 2001, the care of pediatric cardiac surgical cases

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from all three programs was regionalized. We describe the impact of regionalizing pediatric cardiac surgical care on hospital and 5-year follow-up outcomes.

2. Methods

2.1. Regionalized Pediatric Cardiac Surgical Care

Since 2001, the central and western New York regionalized program has consisted of two pediatric cardiac surgical centers at Syracuse and Rochester (90 miles apart) that are supported by three pediatric cardiology groups in Syracuse, Rochester, and Buffalo. Infants with congenital heart disease are delivered and cared for by the individual cardiology groups and transferred to one of the two surgical centers when appropriate. (Further details within the Data Supplement) [9]. A geographical description of the centers can be found in Fig. S1A of the Data Supplement.

2.2. Data Collection

After obtaining institutional and New York State Review Board approval, we identified infants (< 1 year of age) who underwent cardiac surgery at either The State University of New York, Upstate Medical University in Syracuse, The University of Rochester Medical Center in Rochester, or Women's and Children's Hospital in Buffalo. Infants were identified from hospital records and from the New York State Cardiac Surgical database. (See Supplemental for information concerning the New York State Cardiac Surgery Database.) Data on peri-operative demographic and clinical characteristics, operations, risks, and complications were obtained from the Cardiac Surgery Database. Charts were reviewed to assess re-operation rates and survival status up to 5 years after surgery. Late mortality was defined as mortality at any time after hospital discharge.

2.3. Eligibility Criteria

Eligible infants were < 1 year old and had undergone complete biventricular surgery in western or central New York at any of the three centers between either 1991 and 1998 (before regionalization) or between 2001 and 2010 (after regionalization). Cases during 1999 and 2000 were excluded because Buffalo did not join the consortium until 2001.

Infants were excluded if they required isolated patent ductus arteriosus or vascular ring ligation or division, given the minimal surgical risk, excellent prognosis, and subsequent less-extended follow-up care [10,11]. Infants requiring single-ventricle palliation during the study period were also excluded. Outcomes after single ventricle palliations in infants both within New York State and nationwide particularly during the early and mid 1990s were exceedingly variable [12–16]. In addition, before regionalization, the majority of neonates and infants with single-ventricle physiology were transferred to higher-volume centers (Boston Children's, Columbia University, the Cleveland Clinic, etc.), limiting this group for analysis. Including only infants requiring biventricular surgery was intended to limit the differences in evolving surgical strategies for the care of congenital heart disease (e.g., shunting an infant with tetralogy of Fallot, which was often performed before 1998).

2.4. Hospital Mortality

To determine whether regionalization improved in-hospital mortality, we compared the region data to statewide data using the same eligibility criteria. In a separate query to the Cardiac Surgery Database, we identified the cumulative and annual hospital mortality rates for infants undergoing bi-ventricular surgery during the study period, excluding single ventricle palliations and patent ductus arteriosus and vascular ring divisions, at 13 individual pediatric cardiac surgery programs before regionalization and at 10 programs after regionalization (excluding the Buffalo, Rochester, and Syracuse programs).

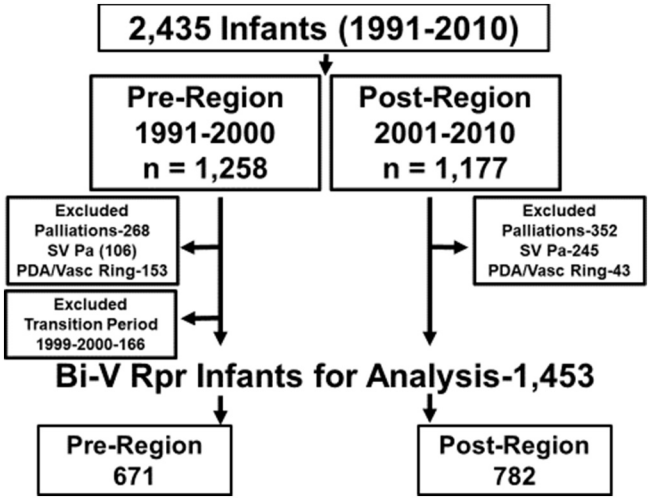

Fig. 1. Case selection process from three pediatric cardiac surgical programs between 1991 and 1998 and after regionalization of the three programs between 2001 and 2010. Abbreviations: SV Pa-Single Ventricle Palliations, PDA/Vasc Ring-Patent Ductus Arteriosus/Vascular Ring.

2.5. Infants Without Follow-up

For infants without 5 years of follow-up, we queried the New York State death index to determine survival status. The New York State death index is a state registry listing all deaths occurring in the State of New York. Infants without follow-up data were matched by both name and date of birth. Unfortunately, recording social security numbers is not mandatory, so deaths could not be verified by searching for social security numbers.

Re-operation was defined as an unplanned return to the operating room related to the primary operation, excluding issues related to the incision (i.e. scar revision, cutaneous sternal wire). This strict definition was intended to prevent bias toward a higher rate of re-operation during the pre-regionalization time period when in certain circumstances surgical repairs were often staged (Example: coarctation repair during early infancy, and ventricular septal defect repair several months later). The prevalence of intermediate-term events (death or re-operation) were compared with the results of a meta-analysis of the published literature specifically examining the outcomes for bi-ventricular surgery in infants. We focused primarily on death and re-operation after the repair of congenital heart disease, rather than other morbidities such as ventilator duration, arrhythmia, and cardiac arrest. Unlike the listed for mentioned peri-operative morbidity, reoperation rate and mortality are more commonly reported following the repair of congenital heart disease in the published literature. The cumulative number of adverse events per patient year was determined for each diagnosis, and we compared a weighted average to our regional data. (Details are in the Supplemental material).

The primary outcome was the 5-year adverse event rate, and secondary outcomes were the in-hospital mortality rates, and the 5-year rates of survival and freedom from re-operation.

2.6. Statistical Methods

The data are presented as means and standard deviations, frequencies and percentages, or medians and inter-quartile ranges, as appropriate. The distributions were evaluated for normality using the Shapiro-Wilks test and compared with either a two-tailed Student's *t*-