The Effect of Institutional Volume on Complications and Their Impact on Mortality After Pediatric Heart Transplantation

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Background. **This study evaluated the potential association of institutional volume with survival and mortality subsequent to major complications in a modern cohort of pediatric patients after orthotopic heart transplantation (OHT).**

Methods. **The United Network of Organ Sharing database was queried for pediatric patients (aged ≤18 years) undergoing OHT between 2000 and 2010. Institutional volume was defined as the average number of transplants completed annually during each institution's active period and was evaluated as categoric and as a continuous variable. Logistic regression models were used to determine the effect of institutional volumes on postoperative outcomes, which included renal failure, stroke, rejection, reoperation, infection, and a composite complication outcome. Cox modeling was used to analyze the risk-adjusted effect of institutional volume on 30-day, 1-year, and 5-year mortality. Kaplan-Meier estimates were used to compare differences in unconditional survival.**

Results. **A total of 3,562 patients (111 institutions) were included and stratified into low-volume (<6.5 transplants/year, 91 institutions), intermediate-volume (6.5 to 12.5 transplants/year, 12 institutions), and high-volume (>12.5 transplants/year, 8 institutions) tertiles. Unadjusted survival was significantly different at 30 days ($p = 0.0087$) in the low-volume tertile (94.2%; 95% confidence interval, 92.7% to 95.4%) compared with the high-volume tertile (96.8%; 95% confidence interval, 95.7% to 97.7%). No difference was observed at 1 or 5 years. Risk-adjusted Cox modeling demonstrated that low-volume institutions had an increased rate of mortality at 30 days (hazard ratio, 1.91; 95% confidence interval, 1.02 to 3.59; $p = 0.044$), but not at 1 or 5 years. High-volume institutions had lower incidences of postoperative complications than low-volume institutions (30.3% vs 38.4%, $p < 0.001$). Despite this difference in the rate of complications, survival in patients with a postoperative complication was similar across the volume tertiles.**

Conclusions. **No association was observed between institutional volume and adjusted or unadjusted long-term survival. High-volume institutions have a significantly lower rate of postoperative complications after pediatric OHT. This association does not correlate with increased subsequent mortality in low-volume institutions. Given these findings, strategies integral to the allocation of allografts in adult transplantation, such as regionalization of care, may not be as relevant to pediatric OHT.**

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The association between institutional volume and improved outcomes has been established for many surgical procedures, including complex pediatric heart operations [1–8]. Studies specifically examining the effect of institutional volume on pediatric orthotopic heart transplantation (OHT) are more limited. Previous studies that demonstrated improved long-term (>15 years) survival in high-volume institutions might no longer be relevant given the advancements in perioperative care and immunosuppression during the past decade [9]. Furthermore, although the volume-related survival benefit in adult OHT populations has been attributed to a decreased incidence in postoperative complications, similar interactions have not been explored in the pediatric literature. Accordingly, we sought to examine the effect of institutional volume on the development of postoperative complications and to determine their subsequent effect on survival in the modern era of pediatric OHT.

Patients and Methods

Study Population

The United Network of Organ Sharing (UNOS) database was queried for pediatric patients (aged ≤18 years)

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Abbreviations and Acronyms

CAD = coronary artery disease
CI = confidence interval
CM = cardiomyopathy
ECMO = extra-corporeal membrane oxygenation
HR = hazard ratio
ICU = intensive care unit
LVAD = left ventricular assist device
OHT = orthotopic heart transplantation
OR = odds ratio
UNOS = United Network for Organ Sharing

undergoing OHT between the years 2000 and 2010. Patients undergoing simultaneous lung or solid abdominal organ transplantation were excluded. This study was exempt from Institutional Review Board approval due to the deidentified nature of the data set. The United Network for Organ Sharing (UNOS) permitted the use of this information for its intended purpose.

Defining Institutional Volume and Operative Outcomes

Unique transplant institutions were identified using an encrypted identifier assigned in the UNOS data set. The active time period was defined as the interval between the earliest and the most recent recorded transplants during the study period for each institution. Average heart transplant volume was calculated by dividing the total number of transplants performed at each institution by its number of active years during the study period. This method of defining institutional volume was decided in an a priori fashion to reflect the true average for each institution rather than the average over the study period. Relatively equally sized volume cohorts were then generated from the tertile stratification of the transplants in the study population.

Postoperative outcomes examined included death (30 days, 1 year, and 5 years), in-hospital complications (including renal failure requiring hemodialysis, stroke, reoperation, and any infection), rejection within 1 year of OHT, a composite complication outcome (any one or more postoperative complications), and an aggregate complication outcome (the total number of complications experienced by each patient). Mortality subsequent to any one or more of the postoperative complications was examined.

Some of the outcomes were not uniformly collected due to limitations of the UNOS data set. Data for reoperation and infection were collected from 2000 to 2006, with data missing in 3.2% and 3.3% of the patients, respectively. Data for renal failure, stroke, and rejection were available for the entire study period, with data missing in 3.8%, 2.5%, and 10.0% of the patients, respectively. The rates of complications analyzed in this study represent data from these specific time intervals.

Statistical Analysis

Institutional volume was assessed as both a continuous and categoric variable in all of the models constructed. Baseline recipient-specific, donor-specific, and transplantation-specific characteristics were compared among the volume tertiles. Individual and composite complication rates were compared for each of the tertiles. Logistic regression modeling was used to determine whether institutional volume independently predicted the rate of postoperative complications after risk adjustment. Cox proportional hazard regression models were constructed to examine the effect of institutional volume on mortality in patients with and without the composite complication outcome. Differences in unconditional survival were estimated with the Kaplan-Meier method. Continuous parametric data were analyzed with analysis of variance and are reported as mean ± standard deviation. Categoric variables were compared with the χ^2 test and are reported as number (%). Significance was established at a p value of less than 0.05. Stata 12.1 software (StataCorp LP, College Station, TX) was used for statistical analysis.

Results

Baseline Characteristics

A total of 3,562 patients met criteria for inclusion in this study. Average institutional volume was 9.6 ± 5.2 transplants per year. The study population was stratified into low-volume (0 to 6.5 transplants per year, 91 institutions), intermediate-volume (6.5 to 12.5 transplants per year, 12 institutions), and high-volume (>12.5 transplants per year, 8 institutions) tertiles. The number of active institutions remained relatively stable during the study period and ranged between 49 and 60 (Fig 1). A number of differences in recipient-specific, donor-specific, and transplant-specific characteristics were noted. Patients in the low-volume tertile were older and had a heavier body weight compared with the high-volume tertile. In addition, they were more likely to be managed in the intensive care unit before transplantation, receive an allograft from an older, race-matched donor, and to undergo traditional

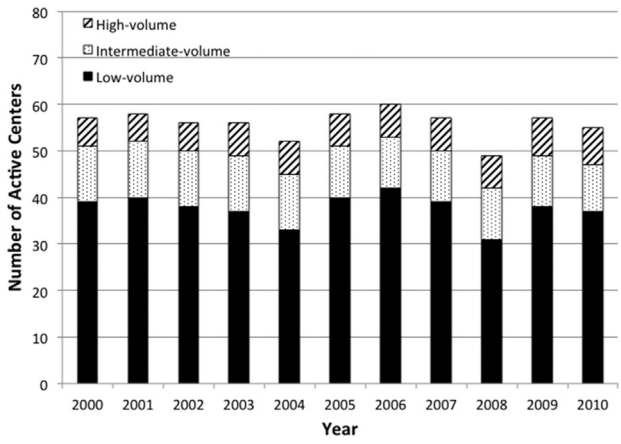

Fig 1. Number of active institutions stratified by high (diagonal bar), medium (dotted bar), and low (black bar) institutional volume.

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