Effect of center catheterization volume on risk of () crossMark catastrophic adverse event after cardiac catheterization in children

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Background Procedural volume has been shown to be associated with outcome in cardiac catheterization and intervention in adults. The impact of center-level factors (such as volume) and their interaction with subject- and procedure-level factors on outcome after cardiac catheterization in children is not well described. We hypothesized that higher center catheterization volume would be associated with lower risk of catastrophic adverse events.

Methods We studied children and young adults 0 to 21 years of age undergoing one or more cardiac catheterizations at centers participating in the Pediatric Health Information Systems database between 2007 and 2012. Using mixed-effects multivariable regression, we assessed the association between center catheterization volumes and the risk of a composite outcome of death and/or initiation of mechanical circulatory support within 1 day of cardiac catheterization adjusting for patient- and procedure-level factors.

Results A total of 63,994 procedures performed on 40,612 individuals from 38 of 43 centers contributing data to the Pediatric Health Information Systems database were included. The adjusted risk of the composite outcome was 0.1%. Increasing annual catheterization laboratory volume was independently associated with reduced risk of the composite outcome (odds ratio per a 100-procedure/y increment 0.78 [95% CI 0.65-0.93], P < .006). Younger age at catheterization, previous cardiac operation in the same admission as the catheterization, preprocedural vasoactive medications, and hemodialysis were also independently associated with an increased risk of adverse outcomes.

Conclusions Higher cardiac catheterization laboratory volume was associated with reduced risk of catastrophic adverse outcome in the immediate postcatheterization period in children. The observed benefit of catheterization at a larger volume center may be attributable to transmissible best practices or inextricable benefits of larger systems. (Am Heart J 2015;169:823-832.e5.)

Cardiac catheterization is critical for the diagnosis of and treatment for patients with a variety of cardiac conditions. The caseload of a pediatric cardiac catheterization laboratory comprises a wide range of diagnoses and procedures in a broad range of patient ages and sizes, which makes defining the risk associated with cardiac catheterization challenging. Single-center case series have reported outcomes over several decades.^{1–7} More recently, data from multicenter registries has been used to develop post hoc risk adjustment models, which include hemodynamics, patient age, and specific trans-catheter procedure.^{8–11} However, low event rates and the small number of centers included have made comparison of outcomes between centers challenging.

Procedural volume has been associated with improved outcomes across many medical and surgical procedures. In studies of coronary angioplasty, both patient-level characteristics and center procedural volume are associated with risk of adverse outcome.¹²⁻¹⁷ In congenital cardiology, center surgical volumes have been associated with improved outcomes,¹⁸⁻²⁵ but to date, we are not

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aware of other studies that have assessed the association of center volume and catastrophic adverse events after cardiac catheterization in children.

Administrative databases provide access to data from multiple centers, allowing for analysis of outcomes while adjusting for covariates. We performed a retrospective multicenter cohort study using data from the Pediatric Health Information Systems (PHIS) database. We hypothesized that increased cardiac catheterization procedural volume would be associated with reduced risk of adverse outcome after adjusting for possible confounders.

Methods

Data source

The PHIS database is an administrative database that contains data from inpatient, emergency department, ambulatory surgery, and observation encounters from 43 not-for-profit, tertiary care pediatric hospitals in the United States (online Technical Appendix B).²⁶ A data-use agreement was signed with Children's Hospital Association (CHA). The institutional review board of The Children's Hospital of Philadelphia reviewed the proposed project and determined that it did not represent human subjects research in accordance with the Common Rule (45 CFR 46.102(f)).

Study population

We included children and adults aged 0 to 21 years who were undergoing cardiac catheterization, as identified by the International Classification of Disease, Ninth Revision (ICD-9; code: 37.21-37.29), at any of the 43 PHIS centers between January 1, 2007, and December 31, 2012. Encounters in PHIS include inpatient and observation admissions but exclude outpatient procedures (those without overnight observation). It does include subjects who die or undergo extracorporeal membrane oxygenation (ECMO) on the date of catheterization after an outpatient procedure. We excluded subjects undergoing electrophysiology studies (ICD-9 codes: 37.2, 37.26, and 37.27) because it was felt that the procedure and risk were qualitatively different from diagnostic and interventional cardiac catheterization procedures. We excluded subjects who were already receiving ECMO prior to the date of catheterization, which is identified in the database. We also excluded subjects from centers (1) reporting fewer than 25 cardiac catheterization procedures per year over the study period or (2) not reporting cardiac catheterization procedures in at least 4 of 6 years during the study period. This was intended to restrict analysis to centers with stable reporting practices and procedural volumes.

Study measures

Data were extracted from the PHIS database by direct query using *ICD-9* codes for diagnoses and procedures as

well as Clinical Transaction Codes for pharmaceutical products (online Appendix Supplementary Table 1). The primary exposure was defined as mean annual number of catheterizations performed at the center over the study period. This was chosen over individual annual catheterization volume because it was felt that the experience of an individual center was durable and unlikely to be prone to year-to-year variation. The primary outcome was a composite of death or initiation of mechanical circulatory support (ECMO, percutaneous ventricular assist device, or balloon pump) on the date of service of catheterization or the following day. Patient-level data included subject age, sex, race, insurance payer (private, public, other), genetic syndrome,²⁷ noncardiac congenital anomalies, history of prematurity (defined as gestational age < 34weeks in patients <1 year of age), cardiac diagnoses (congenital heart disease in isolation, congenital heart disease with pulmonary hypertension, pulmonary hypertension without congenital heart disease, myocarditis, cardiomyopathy, and orthotopic heart transplantation [OHT]), location of patient prior to the procedure (outpatient, neonatal intensive care unit, intensive care unit (ICU), coronary intensive care unit, and step-down unit/cardiac unit), receipt of mechanical ventilation prior to catheterization, receipt of inotropic agents, systemic vasodilators, and pulmonary vasodilators. Procedural data included whether a transcatheter intervention was performed during the case. Center-level data included center average annual catheterization and cardiac operative volume over the study period.²⁸ Outcome data collected included in-hospital death, initiation of ECMO, and length of stay.

Statistical analysis

Descriptive statistics were expressed as mean \pm SD, median (range and interquartile range [IQR]), and percentages and counts as appropriate. Centers were divided into quintiles based on mean annual center catheterization volume over the study period. Comparisons of quintile characteristics were made using Kruskal-Wallis and χ^2 tests. Multiple catheterizations were performed on individual subjects over the study period. All eligible procedures were included, and all statistics are reported per procedure not per individual subject, except where noted. As noted below, attempts were made to account for the bias introduced by multiple catheterizations, first through adjustment and later through restriction in a sensitivity analysis.

The association between center volume and composite outcome was assessed using logistic mixed-effects modeling. Adjusted risks of outcomes were estimated using conditional standardization (the risk estimated if variables are set at either the mean values for continuous variables or the referent group for categorical variables) to provide a clinically relevant estimate. No interaction terms were included in the initial model. Post hoc Download English Version:

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