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Mortality and Morbidity after Laparoscopic Surgery in Children with and without Congenital Heart Disease

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Objectives To determine the risk of morbidity and mortality after laparoscopic surgery among children with congenital heart disease (CHD).

Study design Cohort study using the 2013-2014 National Surgical Quality Improvement Program-Pediatrics, which prospectively collected data at 56 and 64 hospitals in 2013 and 2014, respectively. Primary exposure was CHD. Primary outcome was overall in-hospital postoperative mortality. Secondary outcomes included 30-day mortality and 30-day morbidity (any nondeath adverse event). Among 34 543 children who underwent laparoscopic surgery, 1349, 1106, and 266 had minor, major, and severe CHD, respectively. After propensity score matching within each stratum of CHD severity, morbidity and mortality were compared between children with and without CHD.

Results Children with severe CHD had higher overall mortality and 30-day morbidity (OR 12.31, 95% CI 1.59-95.01; OR 2.51, 95% CI 1.57-4.01, respectively), compared with matched controls. Overall mortality and 30-day morbidity were also higher among children with major CHD compared with children without CHD (OR 3.46, 95% CI 1.49-8.06; OR 2.07, 95% CI 1.65-2.61, respectively). Children with minor CHD had similar mortality outcomes, but had higher 30-day morbidity compared with children without CHD (OR 1.71, 95% CI 1.37-2.13).

Conclusions Children with major or severe CHD have higher morbidity and mortality after laparoscopic surgery. Clinicians should consider the increased risks of laparoscopic surgery for these children during medical decision making. *(J Pediatr 2017;185:88-93).*

The prevalence of congenital heart disease (CHD) in the US is ~10 per 1000 live births,[1] but the prevalence continues to grow because of increased survival in children with CHD from advances in diagnosis, treatment, and technology.[2] Nearly one-half of children with CHD may require additional noncardiac surgeries over their lifetime.[3] Children with CHD have a higher risk of postoperative mortality and morbidity following noncardiac surgery when compared with children without CHD.[4] However, outcomes of children with CHD who undergo laparoscopic surgery, which is a minimally invasive approach, have not been well characterized.

Laparoscopic surgery, which uses 3-12 mm incisions rather than larger incisions used in open surgery, has increased in clinical practice and is now a common surgical approach.[5,6] Numerous disciplines including pediatric general surgery[5,6] and pediatric urology[7] use laparoscopic approaches in both minor and major operations, which decreases postoperative pain and hospital stays in otherwise healthy children.[8] Laparoscopy requires insufflation of the surgical field with carbon dioxide to allow for visualization of the operative site. The insufflation pressure required (10-20 mm Hg) can reduce cardiac output, increase peripheral vascular resistance, increase peak airway pressures required for proper ventilation, and decrease end-tidal lung volumes for given pressures needed for ventilation in healthy subjects.[9-13] These adverse physiologic effects of insufflation may, thus, potentially counteract any advantages conferred by the less-invasive approach in children with CHD, although the balance remains unclear.

We conducted a cohort study to compare postoperative mortality and morbidity following laparoscopic surgery among children with and without CHD. We hypothesized that children with more severe CHD will have greater adverse outcomes than children without CHD, but no difference will be seen with mild CHD.

ASA	American Society of Anesthesiologists
CHD	Congenital heart disease
NSQIP-P	National Surgical Quality Improvement Program-Pediatrics

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Methods

This is a cohort study using prospectively collected data in National Surgical Quality Improvement Program-Pediatrics (NSQIP-P) from 2013 to 2014. Because the dataset is completely deidentified, this study was determined to be nonhuman subjects research and deemed exempt from review by our institutional review board.

The NSQIP-P dataset contains information on children <18 years of age undergoing general, urologic, and other subspecialty surgeries except cardiac surgery at participating hospitals throughout the US. Participating hospitals increased from 56 in 2013 to 64 in 2014, and include freestanding general acute care children's hospitals, children's hospitals within a larger hospital, specialty children's hospitals, or general acute care hospitals with a pediatric wing. NSQIP-P contains detailed information on baseline characteristics such as age and race, perioperative characteristics such as case urgency and surgical complexity, postoperative complications, and mortality. Data were collected up to 30-days after surgery, although discharge and death date were available if patients were still hospitalized past the 30-day window. Each participating hospital has a full-time trained and certified surgical clinical reviewer who abstracts and audits the data to ensure high accuracy, completeness, and precision, with an overall inter-rater reliability of 98%. A systematic sampling strategy is employed by every surgical clinical reviewer to reduce selection bias within and between hospitals. Hospitals which had an inter-rater reliability disagreement rate >5% and/or 30-day follow-up rate <80% were excluded per NSQIP criteria.

Children ages 0 to 17 years old of all races who underwent any laparoscopic surgery in 2013 and 2014 were included. These surgeries included any procedures that required insufflation of a body cavity (such as the mediastinum or peritoneum) with carbon dioxide gas to create a working space. For example, laparoscopic appendectomy or laparoscopic pyeloplasty were common procedures within pediatric general surgery and pediatric urology, respectively. Laparoscopic surgery was ascertained within NSQIP-P using an indicator variable that NSQIP-P began recording in 2013. Laparoscopic cases that were converted to open were included. Children who underwent open-only surgery or who were missing an indicator for laparoscopic surgery were excluded.

The primary exposure was diagnosis of CHD, which was ascertained using an indicator variable defined by NSQIP-P. CHD was classified as minor, major, and severe. These definitions defined by NSQIP-P prospectively classify CHD severity based on repair status and residual hemodynamic abnormality and have been validated in other studies of postoperative outcomes in children with CHD.[4,14] As an example, NSQIP-P defines a minor CHD as an atrial septal defect that does not have symptoms of congestive heart failure or a patient who had a repair of a CHD with normal cardiovascular function. This is in contrast to the definition of a severe CHD, which could be an uncorrected cyanotic heart disease, a patient with pulmonary hypertension, or ventricular dysfunction.

The primary outcome was overall mortality. Overall mortality was defined as any in-hospital death occurring during the same hospitalization after surgery, regardless of whether it occurred within the 30-day postoperative window.

Secondary outcomes were 30-day postoperative mortality and 30-day morbidity, which are standardly measured in surgical research and clinical care. Thirty-day morbidity was a composite measure comprising of any 30-day postoperative complication, excluding mortality, measured by NSQIP-P. These included surgical site infection, pneumonia, urinary tract infection, central line-associated blood stream infection, reintubation, readmission, renal insufficiency, venous thrombotic events, neurologic sequelae (coma, seizure, stroke, nerve injuries), graft failure, cardiac arrest, sepsis, transfusion, unplanned readmission, or unplanned reoperation. This composite measure of morbidity was chosen because of the expected overall low incidence of individual adverse events and it has been used in previous analyses of NSQIP-P outcomes.[15] Morbidity outcome events were based on the number of patients experiencing any complication, rather than number of complications per patient.

Propensity scores were used to balance characteristics associated with CHD between the cohorts (with and without CHD). Clinical characteristics chosen a priori to be incorporated in the propensity scores included age at surgery (<6 months, 6-12 months, 1-6 years, 6-12 years, >12 years), sex, race (non-Hispanic white, non-Hispanic black, and other), year of operation, case urgency (elective vs nonelective), American Society of Anesthesiologists (ASA) class (1-2, >2), and procedural complexity. Procedural complexity was defined as a continuous variable using work relative value units based on the Centers for Medicare and Medicaid Services Resource Based Relative Value Scale.[16] Including surgical complexity, which has been associated with postoperative mortality, mitigates potential confounding by indication.[17] Race was included because it has been previously shown to be associated with postoperative complications.[15] As part of the hospital agreements with NSQIP-P, no data that could potentially identify individual hospital were included in the released databases; therefore, no hospital-level information or characteristics were available for analysis. Variables that may mediate the effect of CHD on postoperative mortality, such as length of surgery, were not included as covariates because inclusion of mediators may adjust away any true associations between the exposures and outcomes of interest.[18]

Statistical Analyses

Power calculations for the primary outcome, overall mortality, were performed for matched pairs with power = 80% and alpha = 0.017 (Bonferroni correction = 0.05/3 for 3 outcome models). Assuming an overall mortality rate of 1% in the unexposed children without CHD following surgery,[4] the sample sizes available within NSQIP-P would allow detection of ORs of 6.60, 2.88, and 2.65, in the severe, major, and minor CHD groups, respectively.