Laparoscopy Is Safe in Infants and Neonates with Congenital Heart Disease: A National Study of 3684 Patients

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Abstract

Purpose: Concerns have been raised about the use of laparoscopic surgery (LS) in infants with congenital heart disease (CHD) due to their unique physiology. Prior studies on the safety and effectiveness of laparoscopy in children with CHD are limited in scope and cohort size.

Materials and Methods: We identified children <1 year of age with CHD who underwent abdominal surgery in the 2012–2013 American College of Surgeons National Surgical Quality Improvement Project Pediatric database. Patients were stratified by surgical approach: open surgery (OS) versus LS. We then compared postoperative complications, postoperative length of stay, and 30-day mortality by using multivariable regression methods.

Results: In total, 3684 patients met study criteria: 2502 underwent OS while 1182 underwent LS. Infants who underwent LS were older (98 days versus 36 days), larger by weight (4.2 kg versus 3.2 kg), and more likely to require nutritional support preoperatively (74.7% versus 60.5%) (all $P < .001$). After multivariable adjustment, LS was associated with lower overall complication rate (odds ratio [OR] 0.42, 95% confidence interval [CI] 0.34–0.52, $P < .001$) and shorter postoperative length of stay (effect size –1.8 days, 95% CI –1.8–1.2, $P < .001$). LS and OS demonstrated similar 30-day mortality (OR 0.71, 95% CI 0.38–1.32, $P = .28$).

Conclusions: Laparoscopy can be performed safely in infants with CHD who need abdominal surgery. Although further studies may be useful in determining which infants with congenital cardiac disease benefit the most from use of laparoscopy, minimally invasive techniques can be applied to routine and complex abdominal procedures.

Keywords: laparoscopy, infant, heart diseases, clinical study

Introduction

LAPAROSCOPIC SURGERY (LS) has been increasingly adopted in children, as it has been shown to reduce complication rates and shorten length of hospital stay, compared to the traditional open approach.^{1,2} However, there is ongoing concern regarding use of laparoscopy in children with congenital heart disease (CHD) due to the potential hemodynamic risks posed by insufflation. In normal children, CO₂ insufflation has been shown to reduce lung compliance and stroke volume, while increasing peak airway pressure and systemic vascular resistance.^{3,4} Although these hemodynamic changes generally are not associated with clinical adverse events in normal children, they may result in worse

outcomes for children with CHD who have less cardiopulmonary reserve.^{5,6}

Despite these concerns, children with CHD often need abdominal surgery to provide enteral access or treat gastroesophageal reflux disease, and surgeons have guardedly explored laparoscopic techniques in children with CHD. Understanding the impact of the laparoscopic approach on clinical outcomes would be important for optimizing perioperative care for these children. Although several institutions have published their experience with laparoscopy in CHD children, there is a paucity of population-level evidence on the safety and effectiveness of LS in this specialized cohort.^{5,7} Therefore, we used a national surgical dataset to survey practice patterns and clinical outcomes associated with laparoscopy use in a large cohort of children with CHD.

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Materials and Methods

Data source

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) Pediatric dataset is a collaboration between the American College of Surgeons and the American Pediatric Surgical Association. NSQIP Pediatric collects ~94 data points from patients <18 years of age undergoing major surgical procedures. It currently collects 1400 cases per year and continues to grow as it enrolls an increasing number of pediatric hospitals across the United States.⁸

Study design

This study was considered exempt from review by the Duke University Institutional Review Board. We identified children <1 year of age with congenital cardiac disease who underwent abdominal surgery in the 2012–2013 ACS NSQIP Pediatric database. CHD was defined as the presence of cardiac risk, which was further stratified into minor, major, or severe risk groups (Table 1). Abdominal surgery was identified by Current Procedural Terminology (CPT) codes 38100–38999, 39000–39599, and 40490–49999.

Preoperative comorbidities were defined by aggregates of variables reported by the NSQIP Pediatric. Neurologic comorbidity was defined as the presence of developmental delay or impaired cognitive status, cerebral palsy, seizures, tumor involving the central nervous system, stroke, brain injury, or coma. Pulmonary comorbidity was defined as the preoperative presence of mechanical ventilation, asthma, pneumonia, cystic fibrosis, supplemental oxygen use, tracheostomy, structural pulmonary disease, or chronic lung disease. Gastrointestinal comorbidity was defined as the need for nutritional support (either total parenteral nutrition or enteral feeding support) or preoperative weight loss. Hematologic comorbidity was defined as the presence of a bleeding or hematologic disorder, bone marrow or organ transplantation, immunosuppressant use, or steroid use.

The primary outcome was overall complications, defined as any cardiac, pulmonary, neurologic, infectious, renal, wound-related, thrombotic, or bleeding complication within 30 days

after surgery. Secondary outcomes were bleeding complications requiring transfusion, wound complications, pulmonary complications, postoperative length of hospital stay, 30-day mortality, and 30-day readmission. Wound complications included superficial, deep, and organ space surgical site infections. Pulmonary complications included pneumonia, inability to wean from ventilator, and unplanned reintubation after surgery.

Statistical analysis

Patients were stratified by surgical approach: open surgery (OS) versus LS. Baseline characteristics were compared using the Kruskal–Wallis test for continuous variables and χ^2 test for categorical variables. We compared perioperative outcomes between the two groups by using multivariable logistic regression models, while adjusting for age, sex, race, American Society of Anesthesiologists classification, cardiac risk severity, anatomic location of surgery, case urgency, preoperative pulmonary comorbidity, and preoperative gastrointestinal comorbidity. A *P*-value of less than .05 was considered statistically significant. Statistical analysis was performed using R version 3.1.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

In total, 3684 patients met study criteria: 2502 underwent OS while 1182 underwent LS (Table 2). Preoperatively, infants who underwent LS were older (98 days versus 36 days, *P* < .001) and larger by weight (4.2 kg versus 3.2 kg, *P* < .001). Cardiac risk severity was similar between LS and OS (minor: 48.7% versus 51.0%, major: 51.3% versus 49.0%, respectively, *P* = .199). Children who received LS were more likely to have undergone previous cardiac surgery (34.7% versus 21.5%, *P* < .001).

Children who underwent LS experienced improved or equivalent postoperative outcomes, compared to OS. The LS group had shorter postoperative hospital stay (7 days versus 15 days, *P* < .001) and a lower overall complication rate (15.7% versus 36.4%, *P* < .001). Specifically, LS resulted in fewer wound complications (3.2% versus 5.4%, *P* = .004), pulmonary complications (5.5% versus 10.4%, *P* < .001), and bleeding complications (7.0% versus 25.3%, *P* < .001). LS

TABLE 1. CARDIAC RISK SEVERITY STRATIFICATION, AS DESCRIBED BY THE NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM PEDIATRIC

Cardiac risk severity	Description
Minor	<ol style="list-style-type: none"> 1. Cardiac condition with or without medication and maintenance (e.g., atrial septal defect, small-to-moderate ventricular septal defect with no symptoms, or symptoms of well-controlled congestive heart failure, patent ductus arteriosus) 2. Status after repair of congenital heart defect with normal cardiovascular function and no meds (e.g., atrial septal defect/patent foramen ovale, ventricular septal defect, patent ductus arteriosus, coarctation of the aorta).
Major	Status after repair of congenital heart defect with residual hemodynamic abnormality with or without medications (e.g., tetralogy of Fallot with wide open pulmonary insufficiency, aortic valve disease with aortic stenosis, or aortic insufficiency based on presence of echocardiographic gradient, all single-ventricle patients)
Severe	<ol style="list-style-type: none"> 1. Uncorrected cyanotic heart disease 2. Patients with any documented pulmonary hypertension 3. Patients with ventricular dysfunction requiring medications, who may or may not be on heart transplant list (e.g., hypertrophic cardiomyopathy)

TABLE 2. BASELINE CHARACTERISTICS OF CHILDREN WITH CONGENITAL HEART DISEASE WHO UNDERWENT OPEN OR LAPAROSCOPIC SURGERY IN THE NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM PEDIATRIC

	<i>Open</i> (N=2502)	<i>Laparoscopic</i> (N=1182)	P
Preoperative variables			
Age (days)	36 (4, 114)	98 (47, 174)	<.001
Sex			.341
Male	56.2% (1405)	54.5% (644)	
Female	43.8% (1097)	45.5% (538)	
Race			.070
White	64.1% (1605)	65.1% (769)	
Black	15.7% (394)	17.7% (209)	
Weight at surgery (kg)	3.2 (2.4, 4.7)	4.2 (3.3, 5.5)	<.001
ASA classification			.027
<3	14.0% (349)	11.4% (134)	
≥3	86.0% (2143)	88.6% (1046)	
Cardiac risk severity			.199
Minor	51.0% (1276)	48.7% (576)	
Major or severe	49.0% (1226)	51.3% (606)	
Previous cardiac surgery	21.5% (538)	34.7% (410)	<.001
Preoperative comorbidities			
Central nervous system	16.2% (405)	26.7% (316)	<.001
Pulmonary	57.8% (1445)	59.7% (706)	.256
Gastrointestinal	60.5% (1513)	74.7% (883)	<.001
Hematologic	26.4% (660)	23.9% (282)	.102
Intraoperative variables			
Anatomic location of surgery			<.001
Foregut	30.3% (759)	86.9% (1027)	
Midgut	42.8% (1070)	5.6% (66)	
Hindgut	9.1% (228)	2.7% (32)	
Case urgency			<.001
Elective	60.4% (1512)	84.3% (996)	
Urgent	18.5% (463)	11.2% (132)	
Emergent	21.1% (527)	4.6% (54)	
Postoperative variables			
Postoperative complications			
Overall	36.4% (910)	15.7% (186)	<.001
Cardiac arrest	1.8% (45)	1.1% (13)	.112
Pulmonary	10.4% (259)	5.5% (65)	<.001
Bleeding	25.3% (633)	7.0% (83)	<.001
Sepsis	3.7% (92)	2.0% (24)	.008
Wound	5.4% (134)	3.2% (38)	.004
Postoperative length of stay (days)	15 (5, 33)	7 (3, 16)	<.001
30-Day readmission	5.6% (141)	12.4% (146)	<.001
30-Day mortality	4.8% (120)	1.4% (16)	<.001

and OS had similar rates of postoperative cardiac arrest (1.1% versus 1.8%, $P < .112$).

After multivariable adjustment, LS was independently associated with a lower overall complication rate (odds ratio [OR] 0.34, 95% confidence interval [CI] 0.34–0.52, $P < .001$) (Table 3). LS also was associated with a shorter postoperative hospital stay (effect size –1.8 days, 95% CI –1.8 to –1.2, $P < .001$), but higher 30-day readmission rate (OR 1.62, 95% CI 1.21–2.17, $P < .001$). LS and OS demonstrated similar 30-day mortality (OR 0.71, 95% CI 0.38–1.32, $P = .28$).

Discussion

To date, our study describes the largest cohort of infants with CHD undergoing LS. We found that LS in infants with CHD is associated with reduced postoperative complications, shorter

postoperative hospital stay, and equivalent mortality, compared to OS. These findings provide continued support for use of laparoscopy in appropriately selected children with CHD.

In the general pediatric population, LS has been shown to provide short-term postoperative benefit in both institutional- and national-level studies.^{1,9,10} An institutional study of 55 infants who underwent open or laparoscopic fundoplication showed the laparoscopic approach to be associated with shorter time to feed initiation (1.3 days versus 3 days, $P < .05$) and reduced risk of recurrent reflux (2.6% versus 14.3%, $P < .05$).⁹ More recently, in a study using the Pediatric Health Information System database that included children <19 years of age, laparoscopic fundoplication was associated with a significant reduction in both overall infection (OR 0.76, 95% CI 0.66–0.88, $P < .05$) and postoperative complications (OR 0.49, 95% CI 0.42–0.58, $P < .05$).¹

TABLE 3. MULTIVARIABLE ADJUSTED OUTCOMES OF LAPAROSCOPIC VERSUS OPEN ABDOMINAL SURGERY IN CHILDREN WITH CONGENITAL CARDIAC DISEASE

Variables	OR/effect size	Lower 95% CI	Upper 95% CI	P
Complications				
Overall	0.42	0.34	0.52	<.001
Pulmonary	0.56	0.4	0.78	<.001
Bleeding	0.35	0.26	0.46	<.001
Wound	0.6	0.39	0.93	.02
Postoperative length of stay (days)	-1.8	-1.8	-1.2	<.001
30-Day readmission	1.62	1.21	2.17	<.001
30-Day mortality	0.71	0.38	1.32	.28

Adjusted variables include age, sex, race, ASA class, cardiac risk severity, anatomic location of surgery, case urgency, preoperative pulmonary comorbidity, and preoperative gastrointestinal comorbidity. CI, confidence interval; OR, odds ratio.

Specifically in children with CHD, previous studies have reported findings similar to our work, but only in very small, single institutional cohorts.^{5,7} In 2007, Slater et al. conducted a retrospective review of 12 patients with hypoplastic left heart syndrome (HLHS) who underwent LS.⁷ Six patients experienced postoperative complications, none of which were cardiopulmonary in etiology. Based on this study, the authors deemed laparoscopy to be safe and provide acceptable outcomes for children with HLHS. Subsequently, Gillory et al. examined 111 children with CHD who underwent 121 laparoscopic procedures over a decade at their institution.⁵ Gastrostomy tube placement and fundoplication were the most common laparoscopic procedures performed in their cohort. Compared to a group of CHD children who underwent OS, the LS group had no difference in patient demographics, procedure type, operative time, complication rate, or 30-day mortality. In comparison, we found no difference in 30-day mortality, but did find reduced complication rates associated with LS, which may be attributable to the larger cohort size allowing adequate statistical power.

Beyond short-term outcomes, research also has shown LS to provide long-term benefit for children with CHD. In an institutional retrospective of 112 children with CHD who received fundoplication, 93% were performed laparoscopically.¹¹ Postoperatively, 28% experienced complications: the most common complication was recurrent gastroesophageal reflux, followed by prolonged mechanical ventilator dependence. Over the next 5 years, the study cohort achieved significant weight gain, with median weight percentile rising from 1.5% to 20%.

We recognize that our study has limitations applicable to any retrospective study that uses national, secondary datasets, such as coding errors and lack of data granularity. There is also inherent selection bias, as surgeons are more apt to use laparoscopy in elective, technically simpler cases. To address this bias, we adjusted for several patient- and surgery-specific variables. For example, to address differences in the types of procedures being performed laparoscopically versus open, we accounted for anatomic location of surgery in the multivariable model, as it was impractical to adjust for all surgery types reported in the database. Also, based on the cardiac severity stratification scheme, we could not accurately identify and examine outcomes for the specific subgroup of patients with

single-ventricle physiology, who present additional anesthetic challenges during laparoscopy and may experience worse outcomes than other CHD children.^{6,11–13}

Despite these limitations, this study describes the largest cohort of infants with CHD undergoing LS, to date. We find that LS is not only safe for infants with CHD but is also associated with reduced complication rates and postoperative length of stay compared to open abdominal surgery. These results support continued, judicious expansion of LS in children with CHD.

Disclosure Statement

No competing financial interests exist.

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