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The impact of cardiac risk factors on short-term outcomes for children undergoing a Ladd procedure☆

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ABSTRACT

Background/Purpose: The purpose of this study was to describe the outcomes of children with and without congenital heart disease who undergo a Ladd procedure.
Methods: The 2012–2014 National Surgical Quality Improvement Program Pediatric (NSQIP-P) data were queried for patients undergoing a Ladd procedure. Utilizing NSQIP-P definitions, patients were categorized into four cardiac risk groups (none, minor, major, severe) based on severity of cardiac anomalies, previous cardiac procedure(s), and ongoing cardiac dysfunction. Ladd procedures were elective/non-elective. Outcomes included length of stay, adverse events, and mortality.
Results: 878 patients underwent Ladd procedures. 633 (72%) patients had no cardiac risk factors and 84 (10%), 109 (12%), and 52 (6%) had minor, major, and severe cardiac risk factors, respectively. Children with congenital heart disease experienced increased morbidity and mortality and longer hospital stays (all $p < 0.05$). Elective Ladd procedures were associated with similar morbidity but shorter length of stay and lower mortality than non-elective procedures. Older age at time of operation was associated with fewer adverse events.
Conclusions: Although overall mortality remains low, children with higher risk cardiac disease experience increased morbidity and mortality when undergoing a Ladd procedure. Older age at the time of the Ladd procedure was associated with improved outcomes in children.

Intestinal malrotation is concomitantly diagnosed in 40–90% of pediatric patients with a wide spectrum of congenital heart disease [1]. Despite this close association, outcomes for patients with CHD undergoing a Ladd procedure for intestinal malrotation are not widely reported. Both conditions are relatively rare, making it difficult for any one institution to develop a cohort sizeable enough to study them in a meaningful way.

In order to examine a large cohort of patients with both CHD and intestinal malrotation, we analyzed data from the American College of Surgeons National Surgical Quality Improvement Program – Pediatric (NSQIP-P). This multi-institutional registry collects data from more than 50 children's hospitals around the country and reports national outcomes for pediatric surgical patients. NSQIP-P utilizes a robust method for categorizing patients with CHD into four cardiac risk tiers based on the severity of the cardiac condition, the degree of cardiovascular impairment, and need for pharmacologic cardiac support [2]. CHD encompasses a wide spectrum of conditions ranging from benign atrial septal defects to life-threatening, single ventricle anatomy. Therefore, risk-adjustment among patients with CHD is essential in order to adequately classify patients into appropriate risk tiers for comparative purposes.

The purpose of this study was to describe the outcomes of children with various degrees of cardiac risk factors who undergo a Ladd procedure. Secondary goals were to determine whether factors such as elective status, age at repair, or surgical approach impact the outcomes for this cohort of patients.

1. Methods

1.1. Data source

The NSQIP-P Participant Use Files for 2012–2014 were reviewed. The dataset comprises data of patients less than 18 years undergoing major procedures at any of the 50+ participating institutions in the United States. For each patient, up to 147 variables including

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preoperative risk factors, operative characteristics, and 30-day postoperative outcomes were recorded. Data collection was performed by a trained and certified surgical clinical reviewer (SCR) at each institution using a standardized sampling technique [3]. Institutional review board approval was not required for observational studies using de-identified data from NSQIP-P.

1.2. Patient selection & case status

Patients undergoing a Ladd procedure were identified in the NSQIP-P dataset using the *Current Procedural Terminology* code 44,055 for the primary procedure. Patients with concomitant secondary procedures such as central line catheter placement were included. Patients were excluded from analysis if incomplete data were present.

All NSQIP-P cases were classified as elective, urgent, or emergent based on timing of surgery after surgical consultation. Cases were categorized as elective if scheduled and performed on an elective basis with no time constraints. Urgent cases were those scheduled and performed within 24 h of surgical evaluation or when the anesthesiologist or surgeon noted the case was urgent. Similarly, cases scheduled and performed within 12 h of surgical consultation were classified as emergent. We have simplified the categories to elective and non-elective (urgent or emergent) status in our analyses.

To better understand how age at repair may affect outcomes in elective cases, patients were stratified by age into three groups (<60 days, 60–120 days, >120 days). These age groups were determined by plotting the distribution of morbidity over patient age and identifying inflection points in the morbidity rates.

1.3. Cardiac risk groups

Based on standardized NSQIP-P definitions, cardiac risk group categories were assigned to patients based on the severity of the cardiac condition, the degree of cardiovascular impairment before or after repair, and whether or not ongoing pharmacologic cardiac support was required [2]. There were four cardiac risk categories: no risk factors, minor, major, and severe (Table 1). Every patient in the NSQIP-P database who underwent a Ladd procedure was classified into one of these four categories.

1.4. Outcome measures

The outcomes of interest were postoperative adverse events and mortality within 30-days after the Ladd procedure. Adverse events encompassed: readmission, reoperation, reintubation, surgical site infection (incisional and organ/space), wound dehiscence, central line associated blood stream infection, sepsis, pneumonia, acute renal failure, urinary tract infection, stroke, seizure, and cardiac arrest. Given the relative infrequency of any single adverse event, all adverse events were aggregated into one adverse event variable, as has been done in other NSQIP-P studies [4]. Mortality and hospital length of stay were recorded separately.

1.5. Statistical analysis

Count data were described using frequencies and assessed with χ^2 or Fisher's exact tests. Normally distributed continuous data were reported as means ± standard deviation and assessed with Student's t-test or one way analysis of variance. Non-parametric continuous data were reported as medians (interquartile range) and assessed with Mann–Whitney U or Kruskal-Wallis tests. P-values ≤0.05 were considered statistically significant. All statistical analyses were performed using Stata 13.1 (College Station, Texas).

2. Results

2.1. Patient and operative characteristics

A total of 878 patients were identified as having undergone a Ladd procedure from 2012 to 2014. CHD was documented in 245 (28%) of these patients. Minor, major, and severe cardiac risk factors were present in 84 (10%), 109 (12%), and 52 (6%) patients, respectively.

The median (interquartile range) age of patients who underwent a Ladd procedure was 110 (11–1760) days. Patients in each cardiac risk group differed significantly with regard to age, prematurity, previous cardiac surgery, and the requirement for supplemental oxygen at the time of surgery (Table 2).

The mean case duration for all patients was 93 ± 55 min and total anesthesia time was 155 ± 77 min. Both case duration and anesthesia time were significantly longer in patients with cardiac risk factors, and patients with cardiac risk factors were more likely to undergo an elective Ladd procedure than patients without cardiac risk factors (Table 2).

2.2. Overall outcomes

Overall, the median hospital length of stay was 8 (4–17) days. Patients with cardiac risk factors experienced significantly longer hospital lengths of stay than patients without cardiac risk factors ($p < 0.001$). Adverse events occurred in 193 (22%) of patients, ranging from 18% in patients with no cardiac risk factors to 37% in patients with severe cardiac risk factors ($p < 0.001$, Table 3). The most common adverse events were readmissions (10%), reoperations (6%), and surgical site infections (4%), which did not vary significantly between cardiac risk groups. Mortality rate was low at 1% overall, ranging from 0.6% to 3.9% based on cardiac risk factors (Table 3).

2.3. Impact of case status, age at operation, and operative approach on outcomes

A similar percentage of elective and non-elective Ladd procedures were performed during the study period (45% vs 55%). Overall, patients undergoing elective procedures experienced shorter hospital length of stay (6, 3–15 days vs 9, 5–17 days, $p < 0.001$), similar adverse event rates (21% vs 22%, $p = 0.722$), and decreased mortality (0.3% vs 2.1%, $p < 0.001$) than patients undergoing non-elective procedures.

Table 1
NSQIP-P cardiac risk factor categories, criteria, and examples.

Category	Criteria	Examples[a]
None:	1. No pre-existing cardiac condition 2. No compromise of cardiac function requiring medication	NA
Minor:	1. Cardiac condition with or without medications and maintenance 2. S/P repair of congenital heart defect with normal cardiovascular function and no medications	Atrial septal defect; small to moderate ventricular septal defect with no symptoms Repaired atrial septal defect, ventricular septal defect, or patent ductus arteriosus
Major:	1. S/P repair of congenital heart defect with residual hemodynamic abnormality with or without medications	Tetralogy of Fallot; aortic valve disease with aortic stenosis or insufficiency based on echocardiographic gradient, all single ventricle patients (including stage 1 repair)
Severe:	1. Uncorrected cyanotic heart disease 2. Any pulmonary hypertension 3. Ventricular dysfunction requiring medications	Hypoplastic left heart syndrome; hypoplastic right ventricle; mitral atresia; single ventricle without repair; truncus arteriosus

[a] As described in Chapter 4: Variables and Definitions, NSQIP-P Operations Manual.