



## Early versus delayed surgical correction of malrotation in children with critical congenital heart disease



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### ABSTRACT

**Purpose:** The purpose of this study was to compare outcomes between early and delayed surgical correction of malrotation in children with critical congenital heart disease (CHD).

**Methods:** Patients with CHD who underwent cardiac surgery by 1 year of age and had malrotation diagnosed during their initial admission at 34 hospitals contributing to the Pediatric Health Information System in 2004–2009 were included. Ladd's procedures performed during the first admission were considered early correction, and those at a subsequent admission were considered delayed. Interhospital variability in the proportion of patients undergoing delayed correction was assessed, and outcomes were compared between the groups.

**Results:** Of the 324 patients identified, 85.2% underwent early correction. Significant variability existed in the proportion of patients undergoing delayed correction across hospitals ( $p < 0.0001$ ). Baseline characteristics, including severity of CHD, were similar between the groups. In the delayed group, 27% of patients underwent a Ladd's procedure during an urgent or emergent admission, but none had volvulus or underwent intestinal resection. Rates of mortality and readmission within 1 year of malrotation diagnosis were similar in both groups. Chart validation confirmed 100% accuracy of diagnosis and treatment group assignment.

**Conclusions:** In patients with critical CHD, delayed operative intervention for malrotation without volvulus may be a reasonable alternative.

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Intestinal malrotation is an associated anomaly in patients with congenital heart disease (CHD). In this high risk group of children, current practice has traditionally included urgent abdominal exploration for any neonate with malrotation. However, some investigators have suggested that early exploration may not be necessary in all patients [1,2]. In particular, neonates with critical CHD may be at increased risk for perioperative complications that may outweigh the potential benefit of a Ladd's procedure to prevent intestinal volvulus during their index admission for cardiac repair [3–5].

Given the relative rarity of these coexisting conditions, studies in this population consist of only a handful of single-center series, and many of these focus on children with heterotaxy [6–8]. The objectives of this study are to: (1) create, validate, and describe a multiinstitutional cohort of patients with both congenital heart disease and malrotation who underwent repair of both anomalies, (2) determine if practice variability occurs in the timing of the correction of malrotation across

hospitals, and (3) identify any differences in outcomes in patients undergoing early versus delayed correction of malrotation.

### 1. Methods

#### 1.1. Data source and cohort development

The Pediatric Health Information System (PHIS) is an administrative database for 44 free-standing children's hospitals managed by the Children's Hospital Association. It contains demographic information, International Classification of Diseases, 9th Revision — Clinical Modification (ICD-9-CM) diagnosis codes, and date-stamped codes for procedures, radiology and laboratory tests, and medications.

A cohort of patients with critical CHD as defined by the Agency for Healthcare Research and Quality was developed using a combination of the diagnosis code for congenital heart disease and a procedure code for a cardiac surgical procedure by 1 year of age [9]. Patients were excluded if they underwent cardiac transplantation or if they underwent isolated patent ductus arteriosus ligation. Patients born between January 2004 and December 2009 who were treated at one of the 34 PHIS hospitals that contributed inpatient data to PHIS during the entire study period were included (Fig. 1). We then identified

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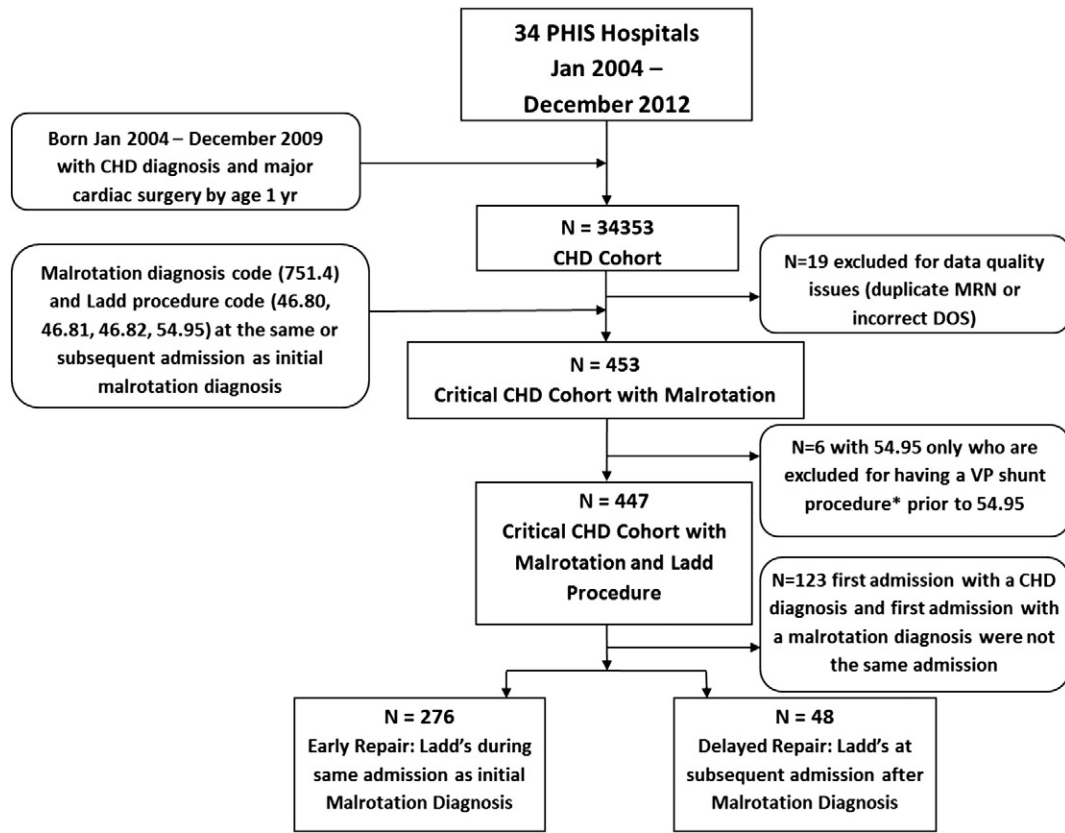


Fig. 1. Development of cohort and treatment groups from the PHIS database.

patients who had a malrotation diagnosis code (ICD-9-CM 751.4) at the admission at which they first had a CHD diagnosis, and who also had a procedure code for a Ladd's procedure (ICD-9-CM 46.80, 46.81, 46.82, 54.95) by the end of 2012. Because the code 54.95 is also a code for revision of a ventriculoperitoneal (VP) shunt, we excluded any patients who had a VP shunt placed before this code occurred. The index admission was defined as the first admission where the diagnosis of malrotation was made (i.e. the diagnosis code for intestinal malrotation was associated with the encounter). Patients with early correction of malrotation were defined as those who had the Ladd's procedure at the index admission. Patients with delayed correction were those who had the Ladd's procedure at a subsequent admission.

Medical record chart review validation of all patients treated at four of the 34 included PHIS hospitals (Nationwide Children's Hospital, Columbus, OH; Children's Hospital of Atlanta, Atlanta, GA; Children's Hospital Boston, Boston, MA; and Monroe Carell Jr Children's Hospital, Nashville, TN) was performed to estimate the rates of misclassification of variables in the PHIS. The validation cohort represents 12.7% of the entire cohort. The institutional review boards of each institution approved this study.

### 1.2. Outcomes and exposures

Outcomes were evaluated up to 1 year following the Ladd's procedure. The primary outcomes for comparison between early and delayed treatment groups were the rates of readmission, major abdominal operations, volvulus, and in-hospital mortality. In the delayed group, outcomes also included events that occurred after diagnosis of malrotation and discharge from the index admission, but prior to the Ladd's procedure, which was presumably not performed right away because the goal of treatment was either a delayed elective Ladd's procedure or watchful waiting. The pre-Ladd's outcomes, which were specific to the delayed group, included (1) an emergency admission

for their Ladd's procedure, defined as admission through the ED, urgent or emergent priority of admission, or a primary diagnosis of intestinal perforation or volvulus (ICD-9-CM 569.83, 560.2); (2) a diagnosis of volvulus (ICD-9-CM 560.2) at any admission after the malrotation diagnosis, including the admission at which Ladd's was performed; and (3) any intestinal resection up to and including the date of the Ladd's procedure. It should be noted that patients in the early group were unable to be classified as having an urgent or emergent admission by the first two criteria (ED admission and urgent/emergent priority of admission) and were considered as have undergone elective surgery.

Baseline characteristics included demographic and clinical characteristics at the index admission where congenital heart disease and malrotation were first diagnosed. Characteristics examined included age, gender, race, insurance status, birth weight, gestational age, prematurity, congenital anomalies, cardiac operations, and the maximum Risk Adjustment for Congenital Heart Surgery (RACHS-1) category at any admission up to age 3 years [10]. The total number of critical CHD patients treated at each hospital during the study period was also evaluated.

### 1.3. Statistical analysis

Baseline characteristics were compared between treatment groups using two sample t-tests or Wilcoxon rank sum tests for continuous variables and Pearson chi square or Fisher's exact tests for categorical variables. Outcomes were compared between groups using logistic or linear mixed effects models or, for rare binary outcomes, exact logistic regression models adjusting for exposures that differed between treatment groups at  $p < 0.05$  in bivariate analyses. Interhospital variability in the timing of the Ladd's procedure was assessed using a logistic mixed effects model that included random hospital intercepts, hospital volume of critical CHD patients, and any patient-level characteristics that differed between groups at  $p < 0.20$  in bivariate analyses. All analyses

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