Stage 1 hybrid palliation for hypoplastic left heart syndrome—assessment of contemporary patterns of use: An analysis of The Society of Thoracic Surgeons Congenital Heart Surgery Database

Tara Karamlou, MD,[a] David Overman, MD,[b] Kevin D. Hill, MD,[c] Amelia Wallace, MS,[d] Sara K. Pasquali, MD, MPH,[e] Jeffrey P. Jacobs, MD,[f] Marshall L. Jacobs, MD,[g] and Christopher A. Caldarone, MD[h]

Objective: Hybrid palliation is an alternative to Norwood stage 1 for the initial management of hypoplastic left heart syndrome. Contemporary multicenter hybrid use and institutional/patient factors associated with hybrid use relative to the Norwood have not been evaluated. We describe hybrid use in relation to institutional volume, patient factors, and short-term outcomes.

Methods: Infants aged 60 days or less listed in The Society of Thoracic Surgeons Congenital Heart Surgery Database (2010-2012) undergoing initial palliation of hypoplastic left heart syndrome were included. Annual institutional hybrid use rates were calculated: [hybrid procedures/(Norwood + hybrid + transplant procedures)]. In-hospital outcomes for primary hybrid and primary Norwood were compared and stratified by high (defined as $\geq$50%) versus low (defined as $\leq$10%) institutional hybrid use.

Results: Of 1728 patients (100 centers), most (n = 1496, 87%) underwent an index Norwood; 232 patients (13%) underwent an index hybrid procedure. Preoperative patient risk factors were more prevalent in patients undergoing the hybrid procedure. Only 13 of 100 institutions were high hybrid users, and these tended to have lower annual hypoplastic left heart syndrome index case volume. Unadjusted in-hospital mortality was higher for the hybrid compared with the Norwood procedure (30% vs 16%; $P < .001$). In-hospital mortality for the hybrid procedure was not associated with hybrid use (26% among institutions with low use vs 28% among institutions with high use). However, centers with high hybrid use had higher mortality after the Norwood (43%) compared with centers with low hybrid use (16%).

Conclusions: Few centers currently select the hybrid procedure for most infants with hypoplastic left heart syndrome. Although unadjusted in-hospital hybrid mortality is higher than Norwood mortality, potential risk factors are more prevalent among hybrid cases. Institutions with higher hybrid use have lower hypoplastic left heart syndrome case volume and higher Norwood mortality. (J Thorac Cardiovasc Surg 2015;149:195-202)

CHD

From the Division of Pediatric Cardiac Surgery,[a] Benioff Children's Hospital, University of California San Francisco, San Francisco, Calif; Division of Cardiovascular Surgery,[b] The Children's Heart Clinic, Children's Hospitals and Clinics of Minnesota, Minneapolis, Minn; Division of Pediatric Cardiology,[c] Duke University Medical Center, Durham, NC; Outcomes Research and Assessment Group,[d] Duke Clinical Research Institute, Durham, NC; Department of Pediatrics,[e] University of Michigan C. S. Mott Children's Hospital, Ann Arbor, Mich; Division of Cardiac Surgery,[f] Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, Md; Department of Surgery,[g] Johns Hopkins School of Medicine, Baltimore, Md; and Division of Pediatric Cardiac Surgery,[h] Hospital for Sick Children, Toronto, Canada.

Disclosures: Dr Pasquali receives support from the National Heart, Lung, and Blood Institute (K08HL103631, Principal Investigator: Dr Pasquali). All other authors have nothing to disclose with regard to commercial support.

Read at the 94th Annual Meeting of The American Association for Thoracic Surgery, Toronto, Ontario, Canada, April 26-30, 2014.

Received for publication April 9, 2014; revisions received Aug 5, 2014; accepted for publication Aug 11, 2014; available ahead of print Sept 26, 2014.

Address for reprints: Tara Karamlou, MD, Benioff Children's Hospital, University of California, San Francisco, 513 Parnassus Ave, Suite S-549, San Francisco, CA 94143 (E-mail: tara.karamlou@ucsfmedctr.org).

0022-5223/$36.00

Copyright © 2015 by The American Association for Thoracic Surgery

http://dx.doi.org/10.1016/j.jtcvs.2014.08.020

See related commentary on pages 203-4.

Supplemental material is available online.

In cardiovascular surgery, the term "hybrid procedure" refers broadly to procedures that combine open surgical approaches with endovascular or other catheter-directed approaches. With respect to surgical palliation of hypoplastic left heart syndrome (HLHS) and related anomalies, the term "hybrid" is widely used to refer to a palliative strategy that includes placement of bilateral pulmonary artery (PA) bands, usually, although not always in combination with deployment of an intravascular stent to ensure patency of the arterial duct. The hybrid procedure for neonatal stage 1 palliation of

Abbreviations and Acronyms

HLHS = hypoplastic left heart syndrome
IQR = interquartile range
PA = pulmonary artery
STSCHSD = Society of Thoracic Surgeons Congenital Heart Surgery Database

HLHS was developed as a surgical alternative to the Norwood procedure, especially for high-risk candidates.[1-11] The evolution and prevalence of use of the hybrid procedure (since its introduction in 2002), relative to other surgical strategies for single ventricle palliation, have not been studied. We sought to describe contemporary use of the hybrid procedure in relation to the Norwood procedure across a large multicenter cohort and identify institutional and patient factors associated with increased hybrid use.

MATERIAL AND METHODS

Data Source

The Society of Thoracic Surgeons Congenital Heart Surgery Database (STSCHSD) was used for this study. As of January 2014, the database contains de-identified data on more than 292,000 surgeries conducted since 2000 at 120 centers in North America, representing approximately 93% of all US centers performing congenital heart surgery and greater than 96% of all operations.[12-15] Preoperative, operative, and outcomes data are collected on all patients undergoing pediatric and congenital heart surgery at participating centers. Coding for this database is accomplished by clinicians and ancillary support staff using the International Pediatric and Congenital Cardiac Code,[12,13] and data are entered into the contemporary version of the STS-CHS data-collection form (version 3.0).[14] The Duke Clinical Research Institute serves as the data warehouse and analysis center for all of the STS National Databases. Evaluation of data quality includes the intrinsic verification of data, along with a formal process of in-person site visits and data audits conducted by a panel of independent data quality personnel and pediatric cardiac surgeons at approximately 10% of participating institutions each year.[1,5,6] This study was approved by the STSCHSD Access and Publications Committee and the Duke University institutional review board and was not considered human subjects research by the Duke University Institutional Review Boards in accordance with the Common Rule (45 CFR 46.102(f)).

Patient population

Infants (aged ≤60 days) with a primary diagnosis of HLHS with initial palliation procedures between 2010 and 2012 entered in the STSCHSD were included. Assignment to the hybrid or Norwood group was based on the index operation (first cardiovascular operation of the hospital admission). Hybrid procedures were defined using any 1 of 3 STSCHSD procedural codes: Hybrid Approach "Stage 1," Application of RPA & LPA bands (2160), Hybrid Approach "Stage 1," Stent placement in arterial duct (2170) or Hybrid Approach "Stage 1," or Stent placement in arterial duct + application of RPA and LPA bands (2180). We excluded patients (N = 90) with code 1640, indicating main PA banding, because after further inspection, these patients represented a heterogeneous population who would have confounded the present analysis. Ambiguity regarding coding of PA banding in populations intended to represent patients with HLHS has been a weakness of other studies,[16] and we sought to avoid any influence that such vagaries would contribute to our results and inferences. The resultant population included 1728 patients undergoing the hybrid or Norwood procedure from 100 centers.

Data collection

Data collection included demographic information, baseline characteristics, preoperative factors as defined in the STSCHSD, operative variables, and outcomes data. Center characteristics were collected, including average annualized center Norwood volume and total case volume. Center case volumes were calculated using only index cardiopulmonary bypass or non-cardiopulmonary bypass cardiovascular operations classifiable by the STS-European Association for Cardio-Thoracic Surgery mortality categories.[12-15] Annual institutional rates of hybrid use were calculated as follows: [hybrid procedures/(Norwood + hybrid + transplant procedures)]. The patients receiving a transplant, because of their exceedingly small numbers, were not included in the analysis in any other respect other than for use in the denominator to calculate hybrid use rate.

Outcomes

The primary outcome measure was use of the hybrid strategy, expressed both as frequency and as percentage of all index palliative procedures for HLHS (sum of hybrid and Norwood). Additional outcome measures include in-hospital mortality (during the same hospital admission) after initial palliation and hospital length of stay after initial palliation.

Analysis

Patient characteristics and outcomes were summarized overall and stratified by initial surgical approach (hybrid vs Norwood stage I). Outcomes were compared for institutions with high hybrid use (defined as ≥50% use) versus institutions with low hybrid use (defined as ≤10%). Although there were 50 centers that did not use the hybrid procedure, these centers were still included in the analysis because they used the Norwood procedure. The 50 centers that performed zero hybrid procedures were grouped into the "low hybrid use" group. These cut points were chosen to represent sites with the clearest patterns of adoption of the hybrid strategy, recognizing that at the remaining centers the choice of approach, on a case-by-case basis, may be influenced by any number of unique circumstances. Neither multivariable modeling nor risk-adjusted comparison of both groups was performed for 2 reasons: (1) The study was meant as a descriptive report of hybrid use among adopting centers; and (2) many of the potential morphologic and intraoperative risk factors were not captured in the version of the STSCHSD used. Data analyses used frequencies and proportions for categoric variables and medians and interquartile ranges (IQRs) for continuous variables. The Wilcoxon rank-sum test was used to compare continuous variables, and the chi-square test was applied to binary outcomes. All analyses were performed using SAS version 9.3 (SAS Institute, Inc, Cary, NC) and R version 2.15.2 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Patient and Center Characteristics Associated With Hybrid Use

A total of 1728 infants underwent initial palliation for HLHS at 100 centers. The majority (N = 1496, 87%) underwent the Norwood operation as the index procedure, with 232 (13%) undergoing the hybrid as an index procedure and 7 (0.4%) undergoing primary transplantation. Compared with the Norwood group, the hybrid group had a higher prevalence of prematurity (23% vs 9%; $P < .001$) and chromosomal anomalies/syndromes (13% vs 9%, $P = .04$). Overall, preoperative factors defined in the STSCHSD were more frequent in the hybrid group (52% vs 37%; $P < .001$), including a

Download English Version:

https://daneshyari.com/en/article/2980064

Download Persian Version:

https://daneshyari.com/article/2980064

Daneshyari.com