

Current outcomes and risk factors for the Norwood procedure

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Objective: Tremendous strides have been made in the outcomes for hypoplastic left heart syndrome and other functional single-ventricle malformations over the past 25 years. This progress relates primarily to improvements in survival for patients undergoing the Norwood procedure. Previous reports on risk factors have been on smaller groups of patients or collected over relatively long periods of time, during which management has evolved. We analyzed our current results for the Norwood procedure with attention to risk factors for poor outcome.

Methods: A single-institution review of all patients undergoing a Norwood procedure for a single-ventricle malformation from May 1, 2001, through April 30, 2003, was performed. Patient demographics, anatomy, clinical condition, associated anomalies, operative details, and outcomes were recorded.

Results: Of the 111 patients, there were 23 (21%) hospital deaths. Univariate analysis revealed noncardiac abnormalities (genetic or significant extracardiac diagnosis, $P = .0018$), gestational age ($P = .03$), diagnosis of unbalanced atrioventricular septal defect ($P = .017$), and weight of less than 2.5 kg ($P = .0072$) to be related to hospital death. On multivariate analysis, only weight of less than 2.5 kg and noncardiac abnormalities were found to be independent risk factors. Patients with either of these characteristics had a hospital survival of 52% (12/23), whereas those at standard risk had a survival of 86% (76/88).

Conclusions: Although improvements in management might have lessened the effect of some of the traditionally reported risk factors related to variations in the cardiovascular anatomy, noncardiac abnormalities and low birth weight remain as a future challenge for the physician caring for the patient with single-ventricle physiology.

Until only a quarter century ago, hypoplastic left heart syndrome (HLHS) was a uniformly fatal condition. Without early intervention, 95% of affected infants died within the first month of life.¹ The outlook has improved dramatically since Norwood and colleagues² reported the first successful staged palliative reconstructive operations for infants with HLHS in 1983 and Bailey and associates³ introduced cardiac transplantation for the disease in 1986. However, despite improvements in survival, HLHS continues to be the most common anomaly resulting in death within the first year of life in the United States.⁴ Most of the mortality associated with staged repair occurs during the first stage, the Norwood

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Abbreviations and Acronyms

CPB	= cardiopulmonary bypass
DHCA	= deep hypothermic circulatory arrest
FSV	= functional single ventricle
HLHS	= hypoplastic left heart syndrome
RCP	= regional cerebral perfusion

procedure. Therefore the elucidation of preoperative risk factors associated with higher mortality could lead to better identification of those infants more likely to benefit from transplantation rather than staged repair.

Many authors have previously reported risk factors for the Norwood procedure. Despite these numerous reports, there exists no consensus on which risk factors are significant. Forbess and coworkers⁵ found lower preoperative pH to be a significant risk factor for stage I mortality, whereas in a previous report⁶ our group found no increased risk. Initial operations after 14 or 30 days have both been reported as a risk factor,⁶⁻⁸ whereas others have found no increased risk for those infants operated on after 14 days of life.⁹ The data are similarly ambiguous for fetal diagnosis,¹⁰⁻¹³ anatomic subtype of HLHS,^{5,6,8,10,14,15} lower operative weight,^{5,6,8,10,16-18} smaller ascending aortic diameter,^{5,6,16,17,19-21} longer circulatory arrest^{6,11,17,20} or cardiopulmonary bypass (CPB) time,^{11,17,21} noncardiac congenital anomalies,^{7,16,22,23} and the presence of moderate-to-severe tricuspid regurgitation before the operation.^{5,17,19,24} In addition to these risk factors, 3 authors have reported a higher risk of mortality associated with obstructed pulmonary venous return.^{7,8,22,25}

Many of these previously reported risk factors were derived from small cohorts of patients or collected over relatively long periods of time, during which management patterns have evolved. These factors might account for the level of disparity among risk factors described in the literature. This report describes our recent experience with the Norwood procedure for palliation of HLHS and other functional single ventricle (FSV) malformations, with a focus on identifying relevant risk factors in the current era.

Patients and Methods**Study Design**

A single-center retrospective review of the medical records of children undergoing a Norwood procedure for the correction of HLHS or other FSV malformations at the C.S. Mott Children's Hospital of the University of Michigan Health Systems from May 1, 2001, through April 30, 2003, was performed. Approval was obtained from the institutional review board before initiation of the study.

The study hypothesis was that because of improvements in operative technique and perioperative management, many of the traditional risk factors previously reported for the Norwood procedure have been overcome.

Patient Population

Between May 1, 2001, and April 30, 2003, 111 infants underwent a Norwood procedure for HLHS or other FSV malformations. The demographic data that were collected included gestational age at birth, age at initial operation, weight at operation, sex, race, cardiac anatomy, noncardiac diagnoses, and fetal diagnosis. Surrogates for condition at presentation included history of cardiac arrest or seizures, the lowest pH, and the peak creatinine levels. Preoperative pH and creatinine levels estimated adequacy of resuscitation and immediate preoperative condition. Also noted were the need for balloon atrial septostomy and the presence of pulmonary venous obstruction, as defined by significant hypoxemia in conjunction with radiographic evidence of pulmonary edema and an intact or nearly intact atrial septum confirmed by means of Doppler echocardiography and direct surgical or pathologic inspection. Echocardiographic parameters, including cardiac valve sizes and functions, aortic size and the presence of antegrade flow, and ventricular function, were all collected. Operative parameters included time in the operating room, deep hypothermic circulatory arrest (DHCA) or regional cerebral perfusion (RCP) time, CPB time, and shunt type and size. Postoperative parameters included time to chest closure and extubation, days in the intensive care unit, and days in the hospital. Time of follow-up and continuation to hemi-Fontan or Fontan procedures were also recorded. A detailed list of the potentially significant factors that were recorded is included in Appendix 1. Hospital survival was the primary outcome.

Surgical Technique

The technique used for the first stage of reconstruction was a classic Norwood procedure, as initially described by Pigott and associates.²⁶ Important modifications, including the manner of the proximal aortic anastomosis, technique and extent of the arch reconstruction, and the use of smaller shunts, have been previously detailed in a publication from our group.²² One hundred five of the patients received a systemic-to-pulmonary artery shunt, of which 66% (69/105) were 3.5 mm, 31% (33/105) were 4.0 mm, and 3% (3/105) were 3.0 mm. Six patients (median weight, 2.2 kg; range, 1.7-3.2 kg) received a right ventricle-to-pulmonary artery shunt ranging in size from 4.0 to 5.0 mm.

Statistical Analysis

Normally distributed data are expressed as means \pm standard deviation. Nonnormal data are expressed as medians and ranges. Dichotomous variables were analyzed with the Fisher exact test, and continuous variables were subjected to the Student *t* test. Wilcoxon rank sum testing was used for nonnormally distributed data.

Results**Patient Population**

Of the 111 patients, there were 71 (64.0%) male and 40 (36.0%) female patients. Mean age at the time of the operation was 9 ± 5 days. Twelve (10.8%) patients were more than 14 days old at the time of their initial operation, and 2 (1.8%) of these patients were more than 30 days old. Median weight at the time of the operation was 3.2 kg (range,

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