

# Management of 239 Patients with Hypoplastic Left Heart Syndrome and Related Malformations from 1993 to 2007

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**Background.** We reviewed our entire programmatic operative experience with children with hypoplastic left heart syndrome (HLHS) and related malformations.

**Methods.** As of October 1, 2007, 239 patients with HLHS and related malformations underwent surgical treatment at the Congenital Heart Institute of Florida. This manuscript focuses on the 199 initially treated with Norwood stage 1.

**Results.** One hundred and ninety-nine patients were initially treated with Norwood stage 1. Univariate analysis demonstrated the following significant predictors of mortality: right ventricular dominance ( $p = 0.0023$ ), mechanical circulatory support before stage 1 ( $p = 0.0192$ ), and significant noncardiac abnormality or syndrome, including Down syndrome, Turner syndrome, heterotaxy, asplenia, polysplenia, biliary atresia, or other chromosomal abnormality ( $p < 0.0001$ ). Multivariable logistic regression analysis revealed the presence of a significant noncardiac abnormality or syndrome or prematurity less than 35 weeks or mechanical circulatory support before stage 1 to be a sig-

nificant predictor of mortality ( $p < 0.0001$ ). Over the 14 years of this patient series, survival for the 157 "low-risk" patients managed with Norwood staged palliation (those patients without significant noncardiac abnormality or syndrome or prematurity less than 35 weeks or mechanical circulatory support prior to Stage 1) was 86%, 80%, and 69% at 30 days after Stage 1, hospital discharge after Stage 1, and 1 year of after Stage 1, respectively.

**Conclusions.** Several treatment options are available for HLHS and related malformations. The appropriate treatment strategy must be matched to the individual patient, taking into consideration anatomic variables as well as other patient-specific characteristics. The majority of patients with HLHS and related malformations can undergo successful staged palliation with risk that varies according to several documented anatomic and patient-specific variables.

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The evolution of surgical management of hypoplastic left heart syndrome (HLHS) and related malformations represents one of the great successes of the last quarter century [1, 2]. In the past, the initial surgical approach, be it staged palliation or transplantation, has been a hotly debated issue [3-6]. The extent of the differences within these approaches attests to the very significant challenges that remain in optimizing care of these patients. Today, there seems to be an emerging complimentary role for both options, favoring a staged reconstructive approach in the majority of circumstances. Many centers today achieve dramatically improved outcomes with staged palliation [7-10].

Despite the generally improved outcomes for these patients, significant variations in management strategies continue to exist [11]. In order to understand our outcomes and

identify trends in our management strategies for these complex patients, we reviewed our entire programmatic operative experience with children with HLHS and related malformations, including tricuspid atresia with transposition, double-inlet left ventricle (DILV) with transposition, and severely unbalanced atrioventricular septal defect (AVSD). Our cardiac transplant operative and management strategies, and immunosuppression protocols, have been previously published for both standard transplant patients as well as for those who have failed staged palliation and those with high panel reactive antibody (PRA) who are immunosensitized [12, 13]. Our approach to biventricular repair in the management of HLHS and related malformations has also been previously published [14, 15]. The purpose of this manuscript is to review our management strategy and the outcomes for our first 199 patients treated initially with the Norwood stage 1 operation in order to identify potential risk factors and opportunities for improvement.

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Dr Jacobs discloses that he has a financial relationship with CardioAccess.

**Material and Methods**

*Definitions*

In this manuscript, we use the consensus definitions for the terms “functionally univentricular heart,” “HLHS,” “hypoplastic left heart complex (HLHC),” and “Norwood stage 1 operation” published by the Nomenclature Working Group of the International Society for Nomenclature of Paediatric and Congenital Heart Disease [16, 17].

*Patients and Selection of Management Strategy*

The Congenital Heart Institute of Florida (CHIF) is a university-affiliated private practice that performs complex cardiac surgery at two hospitals: All Children’s Hospital (ACH) and Children’s Hospital of Tampa (TCH). Institutional Review Board (IRB) approval for this study and waiver of the need for parental consent have been obtained from both hospitals (ACH IRB protocol number 03-0513 and TCH IRB protocol numbers JJ2739).

The first Norwood stage 1 was performed at CHIF on July 19, 1993, and the first transplant for HLHS was performed at CHIF on June 19, 1995. Before 2001, ACH employed primary transplantation for HLHS whereas TCH employed staged palliation. Beginning in 2001, protocols were standardized at the two hospitals, and the majority of our patients are now treated primarily through staged palliation. We now

*Table 1. Diagnoses for All 169 Patients Initially Treated with Norwood (Stage 1) whose Dominant Ventricle is a Morphologic Right Ventricle*

Number of Patients	Diagnoses
169	<i>Patients initially treated with Norwood stage 1 where the dominant ventricle is a morphologic right ventricle (RV)</i>
145	Hypoplastic left heart syndrome (HLHS)
24	HLHS-related malformation with dominant morphologic RV
145	<i>HLHS</i>
9	HLHS, not otherwise specified
51	HLHS, aortic atresia + mitral atresia
30	HLHS, aortic atresia + mitral stenosis
12	HLHS, aortic stenosis + mitral atresia
42	HLHS, aortic stenosis + mitral stenosis
1	HLHS, without intrinsic valvar stenosis, hypoplastic aortic valve + mitral valve + LV = hypoplastic left heart complex (HLHC)
24	<i>HLHS-related malformation with dominant morphologic RV</i>
13	HLHS-related malformation, severely unbalanced atrioventricular septal defect (AVSD) = severely unbalanced atrioventricular canal (AVC)
7	HLHS-related malformation, double-outlet RV with LV hypoplasia
4	HLHS-related malformation, aortic atresia + VSD

AVC = atrioventricular canal; AVSD = atrioventricular septal defect; HLCH = hypoplastic left heart complex; HLHS = hypoplastic left heart syndrome; LV = left ventricle; RV = right ventricle; VSD = ventricular septal defect.

*Table 2. Diagnoses for All 27 Patients Initially Treated with Norwood (Stage 1) whose Dominant Ventricle is a Morphologic Left Ventricle*

Number of Patients	Diagnoses
27	<i>Patients initially treated with Norwood stage 1 where the dominant ventricle is a morphologic left ventricle (LV)</i>
12	Hypoplastic left heart syndrome (HLHS)-related malformation, double-inlet left ventricle (DILV) with transposition
10	HLHS-related malformation, tricuspid atresia with transposition
3	Single ventricle, mostly LV
2	Transposition of the great arteries (TGA) (Complex) with small right ventricle (RV)

DILV = double-inlet left ventricle; HLHS = hypoplastic left heart syndrome; LV = left ventricle; TGA = transposition of the great arteries; RV = right ventricle.

selectively offer transplantation in the setting of significant ventricular dysfunction, severe atrioventricular or ventriculoarterial valvar regurgitation, severe ventricle to coronary artery fistulas with ventricular dependent coronary circulation, strong family preference, and for patients suffering failure at any point in the process of staged palliation.

As of October 1, 2007, a total of 239 patients underwent cardiac surgery at CHIF as treatment for HLHS or HLHS-related malformations. Patients belong to five different treatment arms: 199 patients initially treated with Norwood stage 1, 25 patients initially treated with primary transplantation, 10 patients initially treated with biventricular approach, 1 patient initially treated with hybrid approach, and 4 patients initially treated with staged palliation at other programs with subsequent transplantation at CHIF (1 after Norwood [stage 1], 1 after stage 2 Glenn, and 2 after stage 3 Fontan). Between 1993 and 2000, 17 of 92 surgically treated patients with HLHS and related malformations (18.5%) underwent primary transplantation. Between 2001 and 2007, 8 of 147 surgically treated patients with HLHS and related malformations (5.4%) underwent primary transplantation.

Five of the 199 patients initially treated with Norwood stage 1 eventually were managed with strategies other than staged palliation. One patient who underwent Norwood stage 1 was successfully converted to a biventricular circulation on day 500 of life after undergoing a right ventricle to pulmonary artery conduit insertion combined with intra-ventricular tunnel of the left ventricle to the neo-aorta. Four patients underwent Norwood stage 1 at our program with subsequent transplantation (2 after Norwood stage 1, 1 after stage 2 Glenn, and 1 after stage 3 Fontan).

This manuscript will focus in the management strategies and outcomes of the 199 patients who were initially treated with Norwood stage 1. Of these 199 patients treated initially with Norwood stage 1, the dominant ventricular morphology was right in 169, left in 27, and uncertain in 3. Additional diagnostic data for these patients are shown in Tables 1 and 2.

Table 3. Mortality Timing for Patients Who Underwent Norwood (Stage 1)

Time Period	Mortality	Percentage
Mortality reported as a percentage of patients at risk in the time period under analysis		
Mortality within 30 days of stage 1	37/199	18.6
Mortality more than 30 days after stage 1, but before hospital discharge from stage 1	20/162	12.3
Mortality before hospital discharge for patients undergoing stage 1 and stage 2 in the same hospitalization (these 4 patients are also included in the 20 who are reported as mortality in the row above)	4/4	100
Mortality interstage between stage 1 and stage 2	15/142	10.6
Mortality before discharge to home from stage 2 not done in the same hospitalization as stage 1	4/105	3.8
Mortality interstage between stage 2 and stage 3	6/101	5.96
Mortality before discharge to home from stage 3	2/64	3.1
Total mortality	84/199	42.2
Mortality reported as a percentage of all 199 patients undergoing Norwood stage 1		
Mortality within 30 days of stage 1	37/199	18.6
Mortality more than 30 days after stage 1, but before hospital discharge from stage 1	20/199	10.1
Mortality interstage between stage 1 and stage 2	15/199	7.5
Mortality before discharge to home from stage 2	4/199	2.0
Mortality interstage between stage 2 and stage 3	6/199	3.0
Mortality before discharge to home from stage 3	2/199	1.0
Total mortality	84/199	42.2

*Operative Strategy*

The operative strategy varied somewhat among our six surgeons who have performed Norwood stage 1 operations. The technique for aortic arch reconstruction varied at the surgeon's discretion and was either a patch of the entire arch undersurface or a posterior arch direct anastomosis with an anterior arch patch. Atrial septectomy was routinely performed whenever evidence of obstruction to blood flow existed at the level of the atrial septum. The aortic isthmus was either excised or patch augmented at the surgeon's discretion. The native ascending aorta was routinely incised down to near level of native transected proximal pulmonary artery. The decision to use circulatory arrest versus the selective utilization of intermittent or continuous antegrade cerebral perfusion was made by the surgeon.

The source of pulmonary blood flow for our Norwood stage 1 has been either a systemic artery to pulmonary artery shunt (usually a right modified Blalock-Taussig [MBTS]), or a "Sano" modification with a right ventricle (RV) to pulmonary artery valveless conduit. The first Sano performed at CHIF was on September 30, 2002; before this date, all patients underwent a MBTS. In all, 172 patients have undergone MBTS and 27 have undergone Sano. Our first 12 Sanos (done in 2002 and 2003) had the shunt directed left of the neo-aorta. The most recent 15 Sanos (done on or after September 7, 2005) have the Sano directed right of the neo-aorta. Patients with a dominant left ventricle (LV) always undergo MBTS. For patients without a dominant LV, the source of pulmonary blood flow is at the discretion of the surgeon, except for 22 patients who were in the National Institutes of Health randomized trial.

*Database and Statistics*

A registry and database (a component of the CardioAccess International Clinical Outcomes Database: Comprehensive Cardiovascular and Thoracic Module, CardioAccess Inc, St.

Petersburg, FL, and Fort Lauderdale, FL: <http://www.cardioaccess.com>) has been prospectively maintained on all patients and has been utilized for data collection and analysis. Informed consent was obtained in all cases.

The statistical analysis was performed utilizing software produced by SAS Institute (Cary, North Carolina). The frequency of in-hospital mortality and 30-day mortality was compared across patient subgroups using Fisher's exact test (for comparing two groups) or the Freeman-Halton test (for comparing two or more groups). Survival curves were estimated using the Kaplan-Meier method. The log-rank test was used to compare survival curves across patient subgroups. A *p* value of less than 0.05 is considered to be significant.

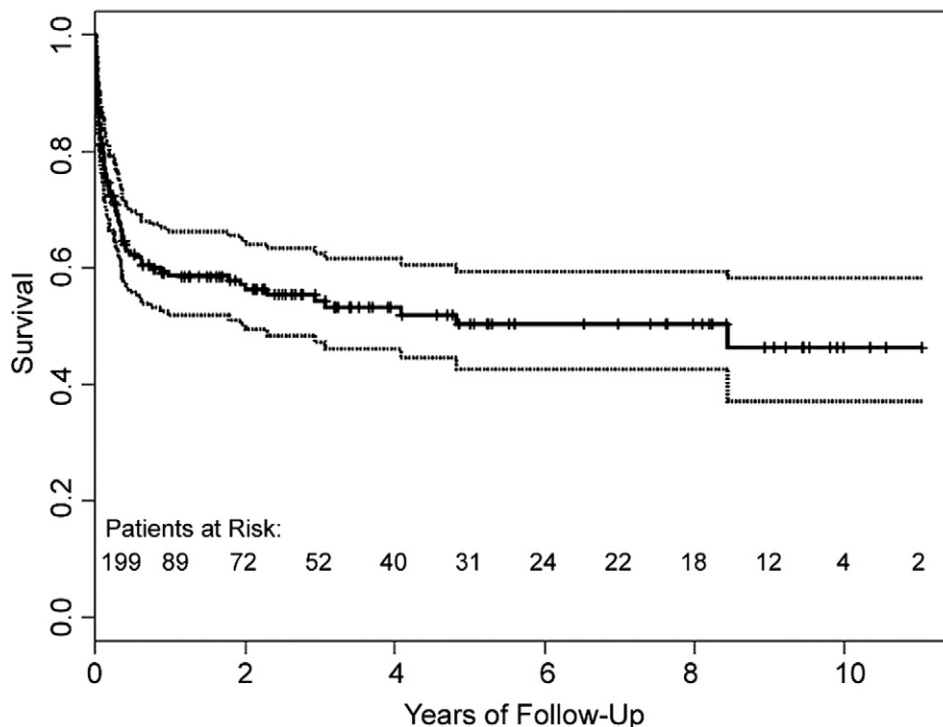
**Results**

Table 3 presents the timing of mortality for patients who underwent Norwood stage 1.

Table 4. Multivariable Logistic Regression Analysis Examining Association Between Preoperative Risk Factors and Discharge Mortality After Norwood (Stage 1)

Variables	<i>p</i> Value
Era, comparing before 2001 to 2001 and later	0.4789
Weight, comparing less than 2,500 g to 2,500 g or more	0.6485
Age (days) at Norwood stage 1, comparing less than 30 days to 30 days or more	0.4429
Operative technique for source of pulmonary blood flow, comparing modified Blalock-Taussig shunt and Sano	0.1782
Dominant ventricle	0.0524
Presence of a significant noncardiac abnormality or syndrome or prematurity less than 35 weeks or mechanical circulatory support before stage 1	< 0.0001

Fig 1. Survival for all patients undergoing Norwood stage 1, shown with 95% confidence intervals.



Univariable analysis was performed examining risk factors versus discharge mortality after (Norwood stage 1). The following variables were not significant predictors of discharge mortality: age at stage 1, less than 30 versus 30 days or more; cardiopulmonary bypass time; diagnostic subgroup; hospital; prematurity less than 35 weeks; operative technique of aortic arch reconstruction; operative technique, MBTS versus Sano; surgeon; and weight, less than 2,500 g versus 2,500 g or more.

The following variables were significant predictors of discharge mortality: dominant ventricle, right ( $p = 0.0023$ ); mechanical circulatory support before stage 1 ( $p = 0.0192$ ); significant noncardiac abnormality or syndrome (including Down, Turner, heterotaxy, asplenia, polysplenia, biliary atresia, or other chromosomal abnormality;  $p < 0.0001$ ).

Multivariable analysis logistic regression analysis revealed the presence of a significant noncardiac abnormality or syndrome or prematurity less than 35 weeks or mechanical circulatory support before stage 1 to be a significant predictor of mortality ( $p < 0.0001$ ; Table 4).

Figure 1 demonstrates the survival curve for all 199 patients undergoing Norwood stage 1. During the follow-up, 6 patients have died remotely after discharge home from successful stage 3 Fontan. One of these 6 died during the hospitalization for a Fontan revision being performed to treat protein losing enteropathy. Thus, 6 of 199 of the total Norwood group (3%) has died after successfully completing all three stages of palliation. Figure 2 documents the survival curves by ventricular dominance among Norwood patients, excluding 3 patients with uncertain ventricular dominance. Figure 3 documents the survival curves for Norwood patients with and without high-risk risk factors (the presence or absence of a significant noncardiac abnormality or syndrome or prematurity less than 35 weeks or

mechanical circulatory support before stage 1). Over the 14 years of this patient series, survival for the 157 "low-risk" patients managed with Norwood staged palliation (those patients without significant noncardiac abnormality or syndrome or prematurity less than 35 weeks or mechanical circulatory support prior to Stage 1) was 86% (135/157), 80% (126/157), and 69% (101/147) at 30 days after Stage 1, hospital discharge after Stage 1, and 1 year of after Stage 1, respectively.

### Comment

Outcomes continue to improve for patients with HLHS and related malformations [7-10]. Nevertheless, significant variations in practice patterns and management strategies continue to exist [11]. Furthermore, data from The Society of Thoracic Surgeons database reveals that discharge mortality for Norwood stage 1 has ranged from 18.0% to 30.4% from 1998 to 2006 [18].

The purpose of this manuscript is to review the entire programmatic operative experience with children with HLHS and related malformations in a university-affiliated private practice and to focus specifically on those treated initially with the Norwood stage 1 operation. The total series of 239 patients in this manuscript include all patients in our program who were either initially treated with Norwood stage 1 or were legitimate candidates for Norwood stage 1 but were initially managed with transplantation, biventricular repair, or hybrid procedure. In this manuscript, we specifically focus on the 199 patients initially treated with Norwood stage 1 operation. An argument could be made to limit this analysis either to only patients with a dominant RV or only to patients with HLHS. However, we chose to examine our overall institutional manage-

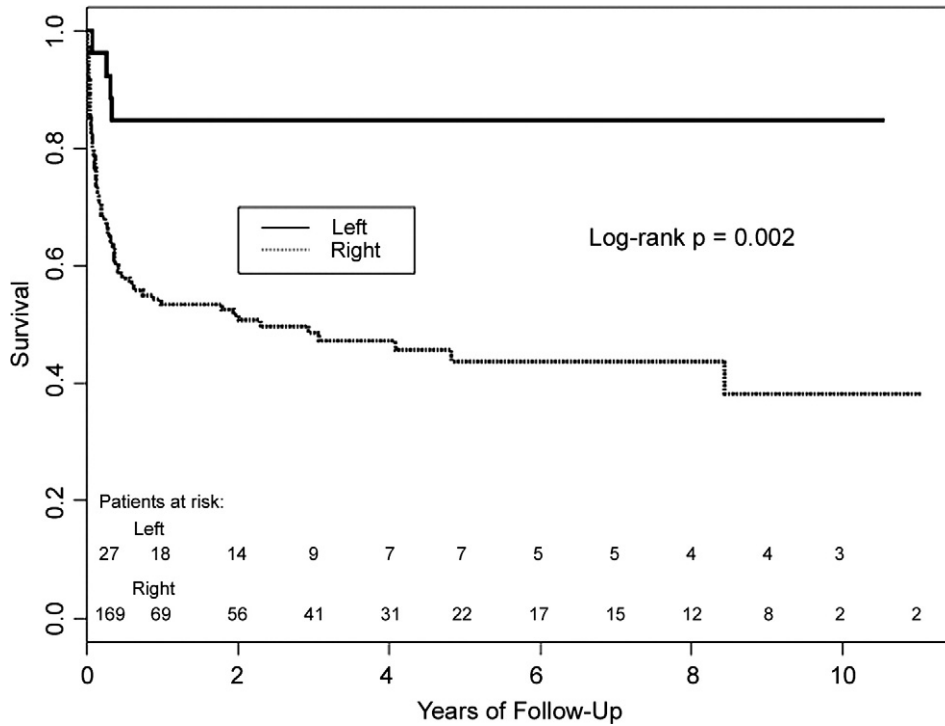


Fig 2. Survival by dominant ventricle among Norwood patients (excludes 3 patients with dominant ventricle = uncertain.) (Solid line = left; broken line = right.)

ment strategy of all patients with HLHS and related malformations, in other words, a group of patients with potentially univentricular hearts and partial or fully ductal dependent systemic blood flow. Others have used a similar strategy to report outcomes of the procedural cohort of patients undergoing Norwood stage 1 including those with both right and left ventricular dominance [7, 8, 10].

Our program currently uses surgical staged palliation as

our primary treatment modality for these patients, with the selective use of transplantation, biventricular repair, and the hybrid approach. This manuscript documents our outcomes with this strategy. For patients undergoing staged palliation in our series, univariable analysis revealed RV dominance ( $p = 0.0023$ ), preoperative mechanical circulatory support ( $p = 0.0192$ ), and significant noncardiac abnormality or syndrome ( $p < 0.0001$ ) to be related to hospital

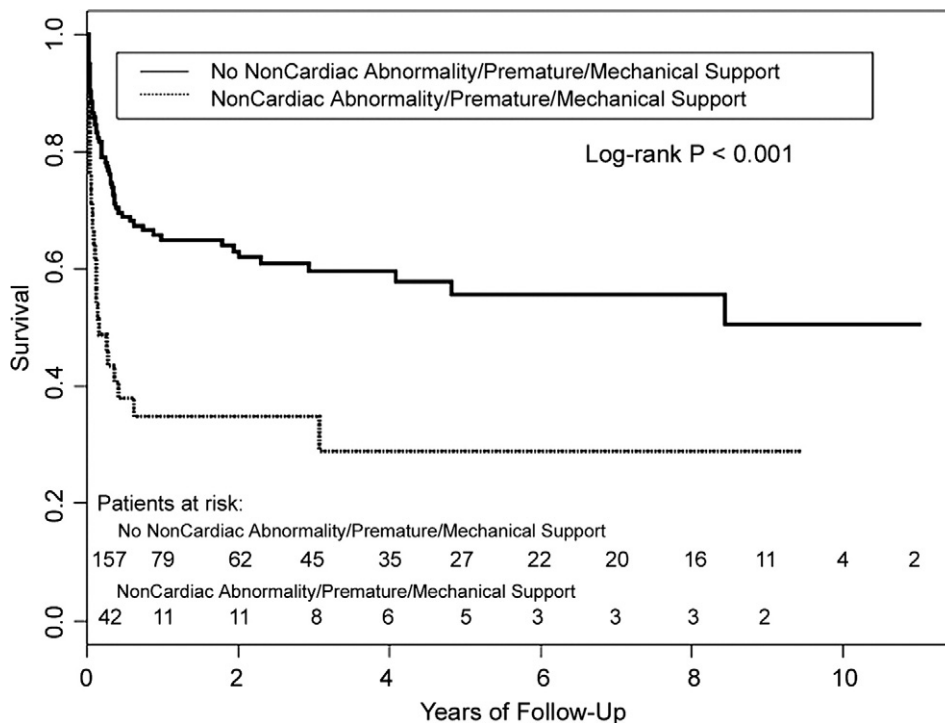


Fig 3. Survival for Norwood patients with and without high-risk factors: presence (broken line) or absence (solid line) of a significant noncardiac abnormality or syndrome or prematurity less than 35 weeks or mechanical circulatory support before stage 1.

death. On multivariable analysis, only the presence of a significant noncardiac abnormality or syndrome or prematurity less than 35 weeks or mechanical circulatory support before stage 1 was a significant predictor for hospital death ( $p < 0.0001$ ).

Others have examined risk factors for hospital death after Norwood stage 1. In a series of 111 patients undergoing Norwood procedure for a single-ventricle malformation, Bove and colleagues [7] reported that univariable analysis revealed noncardiac abnormalities (genetic or significant extracardiac diagnosis,  $p = 0.0018$ ), gestational age ( $p = 0.03$ ), diagnosis of unbalanced atrioventricular septal defect ( $p = 0.017$ ), and weight less than 2.5 kg ( $p = 0.0072$ ) to be related to hospital death. On multivariable analysis, only weight less than 2.5 kg and noncardiac abnormalities were independent risk factors [7].

The risk associated with dominant RV anatomy is not clear from the literature. Spray and colleagues [8] reported that survival was no different when comparing patients undergoing Norwood stage 1 as treatment for HLHS versus other lesions. Jonas and colleagues [10] reported that the survival of patients with malformations other than HLHS after the Norwood procedure is greater than for those with HLHS. In our series, dominant RV morphology was a risk factor by univariable analysis ( $p = 0.0023$ ) and showed a strong trend in multivariable analysis ( $p = 0.0524$ ).

Important mortality occurs after hospital discharge after Norwood stage 1. Strategies to improve outcome of these patients must focus not only on the hospital course related to stage 1, but also on the interstage time intervals and subsequent stages.

Future studies should analyze the surviving patients in this cohort to examine further late mortality, morbidity, and long-term quality of life. This study demonstrates that several treatment options are available for HLHS and related malformations, and the appropriate treatment strategy must be matched to the individual patient taking into consideration anatomic variables as well as other patient-specific characteristics. The majority of patients with HLHS and related malformations can undergo successful staged palliation with risk that varies according to several documented anatomic and patient-specific variables.

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## DISCUSSION

**DR EDWARD L. BOVE** (Ann Arbor, MI): Thank you very much. I appreciate the opportunity to have reviewed the data and the manuscript ahead of time, which Dr Jacobs kindly supplied me.

This was an exhaustive and comprehensive statistical analysis of a fairly large group of patients operated on by one surgical team over a nearly 15-year period, during which 239 patients with hypoplastic left heart syndrome were analyzed. The authors also included in their analysis conditions which they refer to as "related complex." From the number of statistical evaluations down to the number of authors, there are a lot of data and a lot of information presented.

In reading the manuscript, I have one comment and two questions. The first is a comment. The authors themselves state that an argument can be made to limit the analysis to just those patients with dominant right ventricles or perhaps just those undergoing stage 1 palliation, and I would have to make that same argument. It's difficult to understand why they didn't follow that concept through. In the manuscript, one of the groups includes only 1 patient and another group, only 3, which makes it difficult to sift through all the statistical analyses. Perhaps confining the study to a smaller group of patients with consistent anatomy and surgery would have made the data more meaningful.

Jeff, you asked, what can we learn from all this? Much of the data that you showed have been reported by other centers, including the major risk factors. The hospital mortality for the Norwood operation was 30%, yet in that group there were 27 patients who had a dominant left ventricle. By your own data, if they were excluded, the mortality for HLHS alone would be higher. So, can you really justify your conclusion that excellent results can be achieved by having an individual treatment approach that you are proposing in this paper? Other centers, including the CHSS data, have concluded that a center dedicated to one particular treatment with standard protocols gets better outcomes. It was apparent from reading the manuscript that there was a great deal of variability among individual surgeons and patients. I would make the argument that your outcomes might be different if your group adopted a uniform strategy of management.

Secondly, you suggested in the manuscript, and you alluded to it in your presentation this morning, that the use of NIRS and regional cerebral perfusion have been routinely adopted and that these modalities have improved your outcomes. What data do you have to support that conclusion? Thank you very much.

**DR JACOBS:** Thank you, Dr Bove. I think that clearly anyone studying hypoplastic left heart syndrome is well aware of the important contributions that you and your team have made to the treatment of this disease process.

I think I will start by addressing your two questions in reverse order, and then I will discuss your comment preceding these two questions. First, over the course of the transition from era 1, between 1993 and 2000, and era 2, between 2001 and 2007, we did initiate several changes including the utilization of NIRS and the intermittent use of selective cerebral perfusion, as well as other changes in management strategies. When we looked at the comparative outcomes between era 1 and era 2, we found the 30-day mortality after Norwood stage 1, for example, decreased from 22% to 16%, which is not significantly different by a *p* value of 0.05, but does potentially show somewhat of a trend. With all the different changes that were initiated during this time period, it was really not possible to say that any one of the definitive variables that we studied had an effect on outcome, because so much changed at the same time. Despite looking at this question with a variety of statistical techniques and using some statistical consultants, I think that the best we could say is that we changed a lot of different things all at the same time, and although we had a trend of improved outcomes, we clearly didn't have a statistically significant improvement in mortality.

Second, we do know that we were able to shift our management strategy so that in era 1, 18.5% of the patients in this analysis were transplanted, and in era 2 only 5.4% of these patients underwent

transplantation. I think that we consciously made this shift in management strategy based on the fact that not enough hearts are available to transplant all these children; therefore, we now choose to only transplant those who we think are extremely high risk for staged palliation.

Regarding your initial comments about the inclusionary criteria for this analysis: Well, it was a challenge, and we went back and looked at the literature and saw how these patients have been studied previously. Some published manuscripts just talk about hypoplastic left heart syndrome. Other papers talk just about patients who underwent Norwood stage 1 palliation regardless of their disease process and whether they had a dominant right ventricle or a dominant left ventricle. After reviewing all these published manuscripts, we felt that we should pool our entire experience of patients who we felt could have been treated with Norwood stage 1 palliation, and then we should study that group and see what happened to that group. So, basically, we took all the patients in the history of our program, who underwent surgery by our group, who surgically could have been treated with a Norwood stage 1 legitimately. Now, I know that people have argued that one can do a Norwood on a normal heart, and that is true, you could do a Norwood on a normal heart. But this patient cohort includes all of our patients, who when discussed in our Joint Cardiology and Cardiac Surgery Conference, one possible legitimate management strategy was a stage 1 palliation.

**DR THOMAS L. SPRAY** (Philadelphia, PA): I was interested to see that your sort of biventricular repair group, if you will, had such a high mortality, which would suggest that either you picked the wrong strategy or there is something intrinsic about those patients, and were there any insights that you came to looking back at the mortality in that group? I mean, can you tell us, were these patients inappropriately selected for this particular strategy?

**DR JACOBS:** Yes, patients in this cohort who are managed with biventricular repair do represent a challenging group of patients, and I think that probably a few of the patients, who died, retrospectively, would have been better served by just having a Norwood. I think what we learned from that group is, first of all, those patients who do have biventricular repair, when they are discharged from the hospital as a survivor, they continue to survive without any interstage mortality. Second, a biventricular approach does not mean fewer operations. It is just that instead of having a Norwood and then a Glenn and a Fontan, the patient undergoes a biventricular repair, and then later, surgery for either conduit changes or to address left ventricular outflow tract obstruction. And third, patient selection is a challenging problem, and there are times when we tried to do biventricular repair in this subset of patients when clearly, retrospectively, the patient probably would have been better off palliated with a Norwood procedure.

**DR KIRK R. KANTER** (Atlanta, GA): We all agree nowadays that the Norwood operation is a team sport and the surgeon alone can't make it work. I was struck that one of the major changes you made between era 1 and era 2 was to have a dedicated group of anesthesiologists and a dedicated group of caregivers in the intensive care unit. Yet, there is no difference statistically in the survival between the two eras. Can one contrarily therefore conclude from your results that it doesn't make a difference who takes care of these patients?

**DR JACOBS:** I don't think so, because I think that in order to really assess the impact of having dedicated anesthesiologists and dedicated intensivists who know about Norwood physiology caring for these patients, many more endpoints need to be examined besides just mortality. Our mortality did drop from 22% to 16%, which is not statistically significant, but potentially is important. And to really figure out the value of those changes, many other morbidity and long-term variables must be studied.