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ORIGINAL ARTICLE

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The effect of right ventricular function on survival and morbidity following stage 2 palliation: An analysis of the single ventricle reconstruction trial public data set

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Abstract

Objective: Limited information is known on how right ventricular function affects outcomes after stage 2 palliation. We evaluated the impact of different right ventricular indices prior to stage 2 palliation on morbidity and mortality.

Design: Retrospective study design.

Setting: Pediatric Heart Network Single Ventricle Reconstruction Trial Public Data Set.

Patient: Any variant of stage 1 palliation and all anatomic hypoplastic left heart syndrome variants in the trial were evaluated. Echocardiograms prior to stage 2 palliation were analyzed and compared between those who failed and those who survived.

Intervention: None.

Outcome measures: Mortality was defined as death, listed for transplant, or transplanted after stage 2 palliation. Morbidity was evaluated as hospital length of stay and duration of intubation.

Results: A total of 283 patients met criteria for analysis. Of those, only 18 patients failed stage 2. Right ventricular fractional area change was less in those who failed (30% vs 34%, $P = .039$) and right ventricular indexed end-diastolic volume and end-systolic volume were larger in those who failed (142.74 mL/ $BSA^{1.3}$ vs 111.29 mL/ $BSA^{1.3}$, $P = .023$, 88.45 mL/ $BSA^{1.3}$ vs 62.75 mL/ $BSA^{1.3}$, $P = .025$, respectively). Larger right ventricular indexed end-diastolic and systolic volumes were associated with failure (OR 1.17 [1.01-1.35] $P = .021$, OR 1.25 [1.03-1.52] $P = .021$, respectively). Every 10% increase in RV ejection fraction had a 63% decrease in length of stay and a 68% decrease in duration of intubation ($P = .014$, and $P = .039$, respectively).

Conclusion: Patients with decreased right ventricular fractional area change and larger right ventricular indexed end-diastolic and systolic volumes were more likely to fail stage 2 palliation. Those with preserved right ventricular function had a shorter hospital length of stay and duration of intubation. Echocardiographic measurements of right ventricular indices during the interstage period can be utilized to determine the prognosis following stage 2 palliation.

KEYWORDS
echocardiography, hypoplastic left heart syndrome, right ventricular function, stage 2 palliation, SVR

1 | INTRODUCTION

Hypoplastic left heart syndrome consists of an anatomically small left ventricle in conjunction with either aortic or mitral stenosis or atresia. Due to the inability of the hypoplastic ventricle to support systemic circulation, this defect necessitates a three-staged palliation for survival. Stage 1 involves the establishment of pulmonary blood flow through a shunt that directs blood from either the systemic vasculature or the right ventricle to the pulmonary arteries—depending on the underlying anatomy and institution preference. In addition, the right ventricle is converted into the systemic ventricle and a neoaorta and augmented aortic arch is formed. Stage 2 then establishes a passive source of blood flow from the superior vena cava to the pulmonary arteries. Stage 3 completes the palliation by redirecting deoxygenated blood from the lower part of the body to the pulmonary circulation with an anastomosis of the inferior vena cava to the pulmonary artery.

It is well known that there is significant mortality associated with these procedures, with the highest risk being between stage 1 and stage 2 palliation.[1-5] It is for this reason that previous work has attempted to determine what are the predictors of success in transitioning from stage 1 to stage 2 palliation.

Multiple different risk factors have been shown to be associated with poor stage 2 outcomes. Historical risk factors include low weight at the time of stage 2 palliation, history of a genetic syndrome, and requirement of extracorporeal support or renal dialysis during stage 2 palliation hospitalization.[6-9] Nonetheless, previous work has suggested tricuspid regurgitation is the single, largest, echocardiographic predictor of stage 2 failure.[10,11] Yet, echocardiographic measurement of right ventricular function as an independent variable to predict the success of stage 2 palliation in terms of both morbidity and mortality, is yet to be fully elucidated.

2 | METHODS

A retrospective study was performed. The NIH/NHLBI Pediatric Heart Network Single Ventricle Reconstruction Trial data set was used in preparation of this work. Data were downloaded from https://www.pediatricheartnetwork.com/pud_login.asp?study_id=SVR on October 17, 2016. The trial's design and results have been previously published and was completed to evaluate outcomes following the Norwood operation with patients randomized to receive either a modified Blalock-Taussig shunt (MBTS) or a right ventricle to pulmonary artery conduit (RV-PA) as part of the initial procedure.[5,12] Data were collected from 15 centers initially between 2005 and 2009 and included echocardiographic measurements that were made at birth, at stage 1 palliation, prior to stage 2 palliation, and at 14 months of age. A core echocardiography lab was utilized to standardize all reported echo measurements and calculations on the patients in the data set.[5,12]

All patients with anatomical variants requiring staged palliation were eligible for inclusion if they met the trial's original inclusion and exclusion criteria. Hypoplastic left heart syndrome, critical aortic stenosis with or without left ventricular hypoplasia, single right ventricle with systemic outflow tract obstruction, right dominant atrioventricular canal with systemic outflow obstruction, and straddling mitral valve with left ventricular hypoplasia and outflow obstructions were among the variants manifested by the patients. Subjects were initially excluded if they did not make it to stage 2 palliation. Further criteria were then applied excluding those who underwent a surgical procedure out of the scope of a routine stage 2 palliation at the time of stage 2 such as aortic arch repair, atrioventricular valve replacement, repair of atrioventricular valve regurgitation, MBTS placement, pacemaker insertion, repair of RV-PA conduit complication or placement, and semilunar valve replacement. The rationale for excluding these cases was to minimize confounding that could occur with the risk associated with additional procedures. Those who had a pacemaker prior to stage 2 palliation were excluded as well for the concern that the shape and kinesis of a paced right ventricle may be skewed and, as a result, function and size would have been challenging to accurately measure.

We evaluated morbidity in terms of length of intubation and duration of hospital stay. Length of stay in the intensive care unit was not evaluated since each institution has different postoperative bed and unit management approaches and was not standardized or completely defined as part of the trial's initial data dictionary. Those who died, were transplanted, or were listed for transplant following stage 2 and before 14 months of age were considered stage 2 palliation failures. Echocardiographic measurements of right ventricular (RV) size and function were performed on each patient prior to stage 2 palliation. Measurements surrounding the right ventricle that were analyzed for each patient included RV end-diastolic area, RV end-systolic area, RV fractional area change, RV ejection time, RV indexed end-diastolic volume/BSA$^{1.3}$, RV indexed end-systolic volume/ BSA$^{1.3}$, RV ejection fraction, and RV cardiac index to BSA by volume. These echocardiographic measurements were then compared among stage 2 palliation survivors and stage 2 palliation failures.

Categorical data were presented as a percentage. Continuous data were presented as means with standard deviation. Descriptive data comparing means was compared by use of *t* tests where appropriate. Further analysis entailed the use of regression models to assess the association of each of the individual echocardiographic parameters to stage 2 palliation failure, with adjustment for baseline tricuspid valve

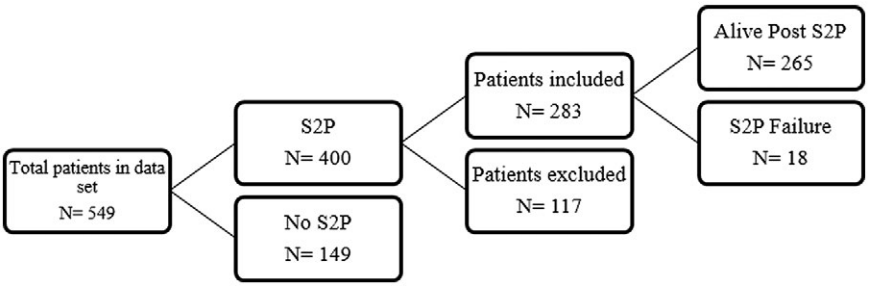

FIGURE 1 Study population. Demonstrates the resultant study population after inclusion and exclusion criteria was applied. Abbreviation: S2P, stage 2 palliation.

regurgitation (TVR) severity. For the length of stay and duration of intubation outcomes, negative binomial regression models were used to assess the simultaneous effect of the echo parameters, with and without adjustment for possible confounding variables. Historical confounders that we controlled for included low birth weight, prematurity, presence of a genetic syndrome, history of tracheostomy, duration of cardiac bypass, use of high-frequency ventilation or renal dialysis surrounding the operation, and any need for post-op cardiopulmonary resuscitation. The echocardiographic confounder we controlled for was significant systemic atrioventricular valve regurgitation, which was defined as moderate or severe regurgitation with a vena contracta width greater than 2.5 mm per the Pediatric Heart Network Reconstruction Trial Core Echocardiography Lab.[13] This study met the requirement for exempt status by the local IRB.

3 | RESULTS

Study flow sheet is presented in Figure 1. There were a total of 549 patients in the data set who underwent stage 1 palliation. Of those, 400 proceeded to the stage 2 palliation and were the focus of this study. There were 149 patients who did not proceed to stage 2 palliation with the majority being secondary to death in the perioperative or interstage period—approximately 20% of the population. Of the 400 patients who continued on to stage 2 palliation, a total of 117 patients were excluded for undergoing the additional surgeries that were previously discussed. There were a total of 73 pacemaker placements, 51 aortic arch repairs, and 26 atrioventricular valve repairs. After the exclusions, there were 283 patients who underwent standard stage 2 palliation and were eligible for analysis.

Baseline patient demographics are listed in Table 1. The patient population was predominantly male and Caucasian. The percentage of patients with MBTS to RV-PA conduits was essentially equal (46% vs 53%) secondary to the trial's randomization. Mean age at the time of stage 2 palliation was 5.4 months. In regard to atrioventricular valve regurgitation, 59% of the patients had mild regurgitation at the time of stage 2 palliation, while 18% has moderate-to-severe atrioventricular valve regurgitation.

Comparison of echocardiographic measurements of right ventricular size and function between those who survived stage 2 palliation and those who failed is depicted in Table 2. The right ventricular fractional area change was less in those who failed (30% vs 34%, $P = .039$). In addition, right ventricular indexed end-diastolic volume (RVEDVI) and end-systolic volume (RVESVI) were larger in those who failed (142.74 mL/BSA$^{1.3}$ vs 111.29 mL/BSA$^{1.3}$, $P = .023$, and 88.45 mL/BSA$^{1.3}$ vs 62.75 mL/BSA$^{1.3}$, $P = .025$, respectively). Results of logistic regression analysis of right ventricular echocardiographic indices are depicted in Table 3, controlling for degree of tricuspid valve regurgitation. Those patients with larger RVEDVI were 1.17 more

TABLE 1 Patient demographics

Demographics	*N*	%
Male	181	63.96
White	232	82.56
Black or African American	40	14.23
Asian	4	1.42
Native Hawaiian or Pacific Islander	0	
More than 1 race	5	1.78
Hispanic	54	19.35
Birth weight < 2500 g	30	10.6
Gestational age < 37 weeks	58	20.49
HLHS	251	88.7
Critical AS with or without LV hypoplasia	3	1.1
Single RV with systemic outflow tract obstruction	9	3.2
Right dominant AV canal	12	4.2
Straddling mitral valve with LV hypoplasia	1	0.4
Other functional single RV with critical LV hypoplasia	7	2.5
MTBTS	132	46.64
RV-PA	151	53.36
AVVR severity at S2P		
0	66	23.57
1	164	58.57
2	46	16.43
3	4	1.43

Values are presented in total number of patients and percentage for demographic characteristics.
Abbreviations: HLHS, hypoplastic left heart syndrome; AS, aortic stenosis; LV, left ventricle; RV, right ventricle; AV, atrioventricular; MBTS, modified Blalock-Taussig shunt; RV, right ventricle; RV-PA, RV-PA conduit; AVVR, atrioventricular valvar regurgitation; S2P, stage 2 palliation.

TABLE 2 RV echo measurements and mortality

Echo measurements	Survivor (*n* = 265) Mean (SD)	Failure (*n* = 18) Mean (SD)	*P* value
RV end-diastolic area (cm^2)	10.42 (2.40)	9.97 (3.13)	.434
RV end-systolic area (cm^2)	6.90 (1.92)	7.01 (2.63)	.88
RV fractional area change (%)	34.0 (7.0)	30.0 (7.0)	.039
RV ejection time (ms)	222.51 (28.48)	217.33 (35.79)	.478
RV indexed end-diastolic volume/$BSA^{1.3}$	111.29 (32.82)	142.74 (46.34)	.023
RV indexed end-systolic volume/$BSA^{1.3}$	62.75 (23.19)	88.45 (42.32)	.025
RV ejection fraction (%)	44.34 (7.62)	38.84 (8.02)	.068
RV cardiac index to BSA by volume	25.86 (5.54)	27.45 (7.75)	.452

Values of right ventricular echocardiogram measurements are presented in means and standard deviations between those who survived stage 2 palliation (left) to those who failed (right) based off of multivariable negative binomial regression. RV ejection fraction was calculated as: End-diastolic volume – End-systolic volume)/End diastolic volume. The RV percent area change calculated as: End-diastolic area – End-systolic area/End-diastolic area.

times likely to fail, and those with larger RVESVI measurements were 1.25 times more likely to fail (OR 1.17 [1.01-1.35] *P* = .035, OR 1.25 [1.03-1.52] *P* = .021, respectively).

Table 4 demonstrates the evaluation of morbidity in terms of hospital length of stay and duration of intubation. Negative binomial regression was utilized and adjusted for both historical and echocardiographic confounders. Right ventricular ejection fraction (RVEF) showed that for every 10% increase, there was a 63% decrease in length of stay (*P* = .014). With every 10 mL/$BSA^{1.3}$ increase in RVEDVI, hospitalization was prolonged 1.6 times.

Similar results can be seen with duration of intubation. With every 10% increase in RVEF, there was a 68% decrease in duration of intubation. For every 10 mL/$BSA^{1.3}$ increase in RVEDVI, intubation duration was prolonged 1.76 times. With every 10 mL/$BSA^{1.3}$ increase in RVESVI, the duration of intubation was reduced by a factor of 0.42 times.

TABLE 3 RV echo measurements on stage 2 failure

Echo measurements	Odds ratio (per 10 units)	95% CI	*P* value
RV end-diastolic area (cm^2)	0.39	(0.05, 3.27)	.383
RV end-systolic area (cm^2)	1.32	(0.13,13.63)	.813
RV fractional area change (%)	0.43	(0.21, 0.89)	.022
RV ejection time (ms)	0.93	(0.78, 1.11)	.442
RV indexed end-diastolic volume/$BSA^{1.3}$	1.17	(1.01, 1.35)	.035
RV indexed end-systolic volume/$BSA^{1.3}$	1.25	(1.03, 1.52)	.021
RV ejection fraction (%)	0.41	(0.18, 0.92)	.03
RV cardiac index to BSA by volume	1.42	(0.63, 3.20)	.398

Values demonstrate the results of logistic regression for predicting failure of stage 2 palliation using right ventricular echocardiographic parameters.

4 | DISCUSSION

Right ventricular function as an independent variable has not been evaluated in isolation until this study. These results demonstrated that poor cardiac function prior to stage 2 palliation, even in the absence of significant tricuspid valve regurgitation, can predict failure of a successful surgical outcome. Specifically, those patients who had dilated hearts with presumed diastolic dysfunction and low RVEF independent of confounders were more likely to fail stage 2 palliation. Thus, noninvasive echocardiographic measurements of right ventricular function and volumes during the interstage could contribute significantly to making critical decisions in regard to what is the best next step for palliation.

The decision to list for transplant following stage 1 palliation, or to continue to stage 2 palliation prior to listing for transplant is often a difficult one for the borderline struggling patient. Yet, a quantitative measurement of function through right ventricular echocardiographic indices can help guide that decision. Those with more adequate function would most likely benefit from proceeding to a more stable circulation, even if their clinical course previously was guarded. In addition, the use of these echocardiographic indices can also help to predict the postoperative course in regard to hospital length of stay and duration of intubation.

The type of shunt selected at the time of stage 1 palliation, whether it is an RV-PA conduit versus a MBTS was previously thought to cause changes in right ventricular size, function, and echocardiographic measurements that could be seen later on in life. Frommelt et al performed a study in 2012 utilizing the Pediatric Heart Network Single Ventricle Reconstruction Trial and compared echocardiographic indices of cardiac size and function strictly between the two shunt types. It was found that the initial shunt type did not impact

TABLE 4 RV echo measurements and morbidity

	Hospital length of stay			Duration of intubation		
	Fold change	95% CI	*P* value	Fold change	95% CI	*P* value
Echo measurements						
Neoaortic valve regurgitation	0.75	(0.60, 0.94)	.014	0.63	(0.45, 0.88)	.007
RV end-diastolic area (cm^2)	0.83	(0.41, 1.68)	.604	1.11	(0.47, 2.61)	.807
RV end-systolic area (cm^2)	1.2	(0.43, 3.38)	.727	0.83	(0.24, 2.89)	.767
RV fractional area change (%)	1.2	(0.39, 3.67)	.751	0.73	(0.19, 2.77)	.64
RV ejection time (ms)	0.91	(0.88, 0.95)	<.001	0.89	(0.85, 0.94)	<.001
RV indexed end-diastolic volume/BSA$^{1.3}$	1.6	(1.10, 2.33)	.013	1.76	(1.04, 2.98)	.034
RV indexed end-systolic volume/BSA $^{1.3}$	0.52	(0.28, 0.97)	.04	0.42	(0.18, 0.99)	.048
RV ejection fraction (%)	0.37	(0.16, 0.82)	.014	0.32	(0.11, 0.94)	.039
RV cardiac index to BSA by volume	0.73	(0.34, 1.57)	.42	0.68	(0.23, 1.99)	.48

Values represent echocardiographic measurements in regard to morbidity following the results of negative binomial regression adjusting for potential confounders.

echocardiographic indices measured at 14 months of age, including right ventricular systolic, diastolic, and global function.[13] A follow-up study in 2014 looked at the same patients six months pre–stage 3, instead finding that those with a MBTS, in fact, had a higher RVEF and smaller right ventricular end-systolic volume than those with an RV-PA conduit.[14] These findings, however, have not been consistently demonstrated among other data sets that have found no effect on shunt type on degree of right ventricular dysfunction.[15] It was for this reason that we chose to assess later right ventricular function irrespective of shunt-type chosen at the time of stage 1 palliation.

The assessment and measurement of the right ventricular function through echocardiography has always proven to be a difficult task because of its unique morphologic features such as trabeculations and shape. Echocardiographic measurements of RV function analyzed in this study used indexed end-diastolic and systolic volumes, and end-diastolic and systolic areas to calculate ejection fraction, fractional area change, and the cardiac index. The Pediatric Heart Network Reconstruction Trial Core Echocardiography Lab measured these volumes and areas in the transverse apical 4-chamber view.[13] A limitation of these measurements could include possible foreshortening of the RV in the transverse apical 4-chamber view and therefore an underestimation of the volumes and areas. The only consistent echocardiographic variable that has been shown to correlate with stage 2 outcome has been the degree of atrioventricular valvar regurgitation.[10] This study took this into account and controlled for atrioventricular valvar regurgitation, unlike other studies, instead analyzing outcomes solely based on right ventricular function. In doing this, we were able to demonstrate that those with worse right ventricular function independent of atrioventricular regurgitation were more likely to die, require transplant, or have prolonged hospitalization. Another study also attempted to look at right ventricular function in those patients who underwent stage 1 palliation with an RV-PA conduit solely. They had an interstage mortality rate of 12%, and found that 80% of those occurred because of right ventricular dysfunction. Interestingly though, they did not control for moderate or severe tricuspid valve regurgitation in making conclusions about the right ventricular function. Despite the previous finding, their pre–stage 2 palliation echo revealed no association between right ventricular dysfunction and interstage mortality.[11] It is important to keep in mind that although atrioventricular valvar regurgitation was controlled for, function and atrioventricular valvar regurgitation are never truly independent. Significant atrioventricular valvar regurgitation may result in falsely reassuring ejection fraction and conversely reduced function may cause further dilation and worsening tricuspid valve function.

Overall, these results support this study suggesting that in those with normal right ventricular function prior to stage 2 palliation, the correct clinical course would be continuing on the path of palliation. It would further suggest that RVEF measured by echocardiography is a useful indicator of prognosis and should be given weight in conjunction with clinical variables, serial imaging, and hemodynamics when considering indications for transplantation.

There are a few limitations in this study. The largest was our ability to only study those patients who were deemed by their institution as being potential candidates for stage 2 palliation—a degree of selection bias. There clearly exists a group of patients in the interstage period that were not offered stage 2 palliation because of poor right ventricular indices that could have had an effect on the outcome of interest. In addition, our definition of failure was death or transplant after stage 2 palliation prior to 14 months of age, but stage 3 palliation is usually performed at 3-5 years of age and it is possible that a subset of patients with failure after stage 2 palliation that occurred beyond the 14 months of age was not captured. Furthermore, structured echocardiographic measurements of right ventricular indices may be clinically challenging as standardizing those measurements have issues with reliability secondary to the right ventricle's unique morphology. While that does not affect the results of this study, as a core echocardiographic lab was used and multiple observer variability was kept to a minimum, other indices including subjective

assessment of the right ventricle may be more appropriate and much more clinically reproducible. Though the models controlled for these variables to study just the effect of RV function, they clearly cannot be ignored when making a clinical decision.

5 | CONCLUSION

Patients with decreased right ventricular fractional area change and larger RVEDVI and RVESVI were more likely to have failed stage 2 palliation, regardless of their degree of atrioventricular valvar regurgitation. Preserved right ventricular function was associated with a shorter hospital length of stay and duration of intubation. Echocardiographic measurement of right ventricular function and volumes during the interstage period can be utilized to determine the prognosis of patients following stage 2 palliation.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest with the contents of this article.

DISCLOSURES

The author, Jeffrey Vergales has two disclosures. He serves as the medical director Locus Health Home Monitoring Program which is a nonpaid position. In addition, he has research grant support from Merck for a different study.

AUTHOR CONTRIBUTIONS

Research design, acquisition, interpretation of data, drafting of manuscript, approval of article: Vanessa Marie Hormaza.
Statistical analysis, analysis or interpretation of data, revising it critically, approval of article: Mark Conaway.
Data acquisition, interpretation of data, revising it critically, approval of article: Daniel Scott Schneider.
Research design, acquisition, interpretation of data, drafting of manuscript, revising it critically, approval of article: Jeffrey Eric Vergales.

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