Interstage evaluation of homograft-valved right ventricle to pulmonary artery conduits for palliation of hypoplastic left heart syndrome

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ABSTRACT

Objective: Palliation of hypoplastic left heart syndrome with a standard non-valved right ventricle to pulmonary artery conduit results in an inefficient circulation in part due to diastolic regurgitation. A composite right ventricle pulmonary artery conduit with a homograft valve has a hypothetical advantage of reducing regurgitation, but may differ in the propensity for stenosis because of valve remodeling.

Methods: This retrospective cohort study included 130 patients with hypoplastic left heart syndrome who underwent a modified stage 1 procedure with a right ventricle to pulmonary artery conduit from 2002 to 2015. A composite valved conduit (cryopreserved homograft valve anastomosed to a polytetrafluoroethylene tube) was placed in 100 patients (47 aortic, 32 pulmonary, 13 femoral/saphenous vein, 8 unknown), and a nonvalved conduit was used in 30 patients. Echocardiographic functional parameters were evaluated before and after stage 1 palliation and before the bidirectional Glenn procedure, and interstage interventions were assessed.

Results: On competing risk analysis, survival over time was better in the valved conduit group ($P = .040$), but this difference was no longer significant after adjustment for surgical era. There was no significant difference between groups in the cumulative incidence of bidirectional Glenn completion ($P = .15$). Patients with a valved conduit underwent more interventions for conduit obstruction in the interstage period, but this difference did not reach significance ($P = .16$). There were no differences between groups in echocardiographic parameters of right ventricle function at baseline or pre-Glenn.

Conclusions: In this cohort of patients with hypoplastic left heart syndrome, inclusion of a valved right ventricle to pulmonary artery conduit was not associated with any difference in survival on adjusted analysis and did not confer an identifiable benefit on right ventricle function. (J Thorac Cardiovasc Surg 2018;155:1747-55)

Two-dimensional and color Doppler images of homograft valved RV-PA conduits in 2 patients.

Central Message

Using a valved RV to PA conduit to palliate HLHS neither improved survival to BDG nor altered RV function.

Perspective

Placement of a valve in the RV to PA conduit in patients undergoing stage 1 palliation of HLHS did not provide a clear benefit in survival to BDG and was not associated with any difference in RV function in the interstage period compared with use a non-VC.

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Hypoplastic left heart syndrome (HLHS) is the most common form of functionally single ventricle heart disease, with an estimated incidence of 2.3 cases per 10,000 live

births.¹ Despite surgical advances to palliate HLHS, systemic right ventricular (RV) failure remains a significant cause of morbidity, with an estimated prevalence of 11% at 3 months after stage 1 palliation.² Initial palliative surgery for HLHS uses a conduit from the systemic RV to the pulmonary artery (PA) or a modified Blalock-Taussig

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Abbreviations and Acronyms

BDG	= bidirectional Glenn
ECMO	= extracorporeal membrane oxygenation
FAC	= fractional area change
HLHS	= hypoplastic left heart syndrome
HR	= hazard ratio
mBTS	= modified Blalock–Taussig shunt
NVC	= nonvalved conduit
PA	= pulmonary artery
PTFE	= polytetrafluoroethylene
RV	= right ventricle
TAPSE	= tricuspid valve annular plane systolic excursion
TR	= tricuspid regurgitation
TV	= tricuspid valve
VC	= valved conduit

shunt (mBTS) to establish pulmonary blood flow. The Single Ventricle Reconstruction Trial demonstrated improved transplant-free survival at 12 months with an RV-PA conduit compared with the mBTS, although with a higher rate of unintended interventions or adverse events.³ Although there have been no direct comparisons, the RV-PA conduit has a theoretical advantage of improving coronary perfusion and the overall systemic-pulmonary flow balance by eliminating diastolic runoff, thereby increasing diastolic pressure.^{4,5} With both procedures, the systemic RV is volume loaded, but in the setting of a nonvalved RV-PA conduit, diastolic conduit regurgitation can further increase volume load and consequently compromise ventricular efficiency, which may be detrimental and predispose to progressive tricuspid regurgitation (TR) and RV failure.

Inclusion of a valve in the RV-PA conduit has a hypothetical advantage of reducing regurgitation during the interstage period, which could favorably affect remodeling of the RV as it adapts to pump blood to the pulmonary and systemic vascular beds in parallel. However, the valved portion of the conduit itself may remodel and undergo stenotic changes requiring conduit interventions, which are already relatively common in patients who undergo a stage 1 procedure with an RV-PA conduit.⁶⁻¹⁰

At our institution, most patients with HLHS are palliated with an RV-PA conduit rather than an mBTS. We previously reported our experience using composite RV-PA conduits that include a homograft valve and demonstrated 89% survival to discharge and preserved RV function.¹¹ In the present study, our primary aim was to evaluate potentially significant clinical differences in cardiac functional parameters and conduit-related interventions in the interstage period depending on the

use of a valved conduit (VC) or nonvalved conduit (NVC) RV-PA conduit.

MATERIALS AND METHODS**Study Population and Design**

We performed a retrospective analysis of all patients with HLHS and HLHS variants who underwent a stage 1 procedure with an RV-PA conduit (Sano modification) at Lucile Packard Children's Hospital Stanford from January 2002 to August 2015. All patients received follow-up care at our institution and were followed until one of the following end points occurred: completion of a bidirectional Glenn (BDG) procedure (survival through 30 days post-BDG and hospital discharge), death, or transplant. All data were obtained from medical records or clinical databases. The study was approved by the Stanford University Research Compliance Office/Institutional Review Board.

Operative Technique

Details regarding operative technique and conduit size selection were described previously.¹¹ In brief, a composite conduit was created by sewing the distal end of a polytetrafluoroethylene (PTFE) tube (usually 5 mm, with or without ring reinforcement) to an aortic or pulmonary homograft valve (usually 1-2 mm larger than the PTFE tube) and then inserting the valved conduit (VC) between an RV infundibulotomy and the PA bifurcation to the left side of the neo-aorta. In a minority of cases, a valved saphenous or femoral vein homograft was used instead and implanted in similar fashion. Regardless of conduit or valve type, patients were maintained on aspirin but no additional anticoagulation.

Echocardiography

Clinical echocardiograms just before the stage 1 palliation and stage 2 BDG palliation were reviewed independently by the study authors (NS, RP, and SNS) for the following functional parameters: RV 2-dimensional fractional area change (FAC) and tricuspid valve (TV) annular plane systolic excursion (TAPSE), and the presence of moderate or greater TR. TV annulus measurements were converted into *z* scores and used as a 2-dimensional surrogate measure of RV size.¹² RV FAC, TAPSE, and TV annulus diameters were all obtained from the apical-4 chamber view. TR was evaluated in multiple imaging planes and graded as none, trace, mild, moderate, or severe by qualitative assessment of jet width. In patients who did not complete a BDG procedure but had an echocardiogram available for review at an age beyond the earliest BDG in the cohort, that echocardiogram was included in the analysis.

To assess homograft valve competence in the VC group, the first echocardiogram performed after the stage 1 procedure and the last echocardiogram performed before the BDG procedure were reviewed for the presence of a vena contracta jet of regurgitation in proximity to the valve within the RV-PA conduit (Figure 1). Vena contracta width was normalized to the valve diameter (at implant) and used as a surrogate measure of conduit valve competence; vena contracta widths were expressed both in absolute terms (millimeters) and as a percentage of the implanted valve diameter.

Invasive Hemodynamics and Interventions

Interstage hemodynamic data from cardiac catheterization before BDG were recorded. If the systemic oxygen saturation was not reported or recorded on the day of pre-BDG catheterization, it was obtained from the medical record within a few days of the procedure. For this study, we ascertained interventions on the pulmonary circulation after the stage 1 procedure and before BDG. We defined intervention as a percutaneous or surgical procedure performed after the initial stage 1 procedure to augment, reduce, or improve the distribution of pulmonary blood flow (excluding

FIGURE 1. Two-dimensional and color Doppler images of homograft valved RV-PA conduits in 2 patients demonstrating the valve itself (*arrowheads*) as well as the vena contracta of the insufficiency jet. The vena contracta width was measured to assess valve competency.

closure of aortopulmonary or venous collaterals). Interventions were categorized as early if they were performed within 30 days of the stage 1 procedure and late if beyond 30 days.

Statistical Analysis

Continuous variables were compared between groups using independent samples *t* test or Mann–Whitney *U* test. Categorical data were compared between groups using the chi-square or Fisher exact test. The primary outcome was survival through BDG or to 1 year of age, whichever was earlier. Because of variability in timing of the BDG, midterm freedom from death or transplant was evaluated through 30 days after BDG completion or 1 year of age if BDG had not yet been performed. Specifically, patients were censored event-free 30 days after a successful BDG or at 1 year of age if a BDG had not been performed by that time. To account for competing outcomes (ie, death and BDG), we performed competing risk analysis to compare VC and NVC groups, using Gray's test of cumulative incidence. To adjust for potential confounding by other factors, stratified analysis was performed, incorporating variables that were also associated with the cumulative incidence outcome. Freedom from surgical or percutaneous intervention related to pulmonary blood flow, and freedom from intervention for conduit obstruction was analyzed using Kaplan–Meier

curves and Cox regression analysis, with multivariable analysis if appropriate. Hazard ratios (HRs) were presented with 95% confidence intervals. Early outcomes (the longer of 30 days or hospital discharge) after the stage 1 procedure were also compared between groups using logistic regression, with adjustment for surgical era, surgeon, intact/restrictive atrial septum, prematurity, and mitral stenosis/aortic atresia subtype. Comparison of echocardiographic data between groups at prestage 1 and pre-BDG, and comparison of changes in these variables from prestage 1 to pre-BDG, was performed using the *t* test or Fisher exact test. Comparison of echocardiographic variables from prestage 1 to pre-BDG, both overall and within conduit groups, was performed with paired *t* test. Data were analyzed at a significance level of .05 and presented as mean $\pm$ standard deviation or median (minimum–maximum). Data were analyzed using R version 3.3.1 and SPSS version 23 (IBM, Armonk, NY).

RESULTS

Patient Demographics

A total of 142 patients were identified with HLHS and HLHS variants who received an RV-PA conduit during the stage 1 procedure and received follow-up care at our

institution. Eleven patients were excluded because the stage 1 procedure was performed at an outside institution or reliable operative data specifying the type of conduit used were not available. One patient was excluded because an mBTS was placed in addition to the RV-PA conduit at the stage 1 procedure. Thus, 130 patients were included in the analysis: A total of 100 patients received a VC and 30 patients received an NVC (Table 1). There was decreasing use of the VC during the latter half of this experience ($P < .001$), and there were differences in the distribution of shunt type among the 3 surgeons who performed these procedures.¹³ Other high-risk characteristics, such as prematurity, the presence of an intact atrial septum, HLHS subtype, and moderate or severe TR, were similarly represented in both groups. Age and weight at stage 1 were similar in the VC and NVC groups, and RV-PA conduit size did not differ.

Bidirectional Glenn Completion

Successful BDG was achieved in 77 patients with a VC at a median age of 120 days (77-376) and 17 patients with an

NVC at a median age of 123 days (96-218), with no difference in the cumulative incidence of BDG completion ($P = .15$) (Figure 2, A). In the VC group, 76 patients completed a BDG by the age of 276 days (4 of these were aged 6-12 months) and 1 patient at 376 days. In the NVC group, 17 patients had completed a BDG by age 218 days, including only 1 who underwent BDG between 6 and 12 months. The median age at BDG procedure was similar between groups.

Mortality

Early mortality after the stage 1 procedure (within 30 days or during the same hospitalization) was 18% overall and did not differ between the VC ($n = 15$, 15%) and NVC ($n = 8$, 27%) groups ($P = .14$) on unadjusted analysis or after adjustment for other risk factors. Cardiopulmonary resuscitation with extracorporeal membrane oxygenation (ECMO) in the early poststage 1 period was performed in 10 NVC cases and 8 VC cases ($P = .0014$); 5 NVC cases and 4 VC cases who required ECMO died within 30 days. There were 4 interstage deaths (after hospital discharge, 1 at 585 days without having undergone a BDG or Fontan procedure) in the VC group, 1 interstage death and 1 transplant in the NVC group, and 1 early post-BDG death in each group. Survival over time was significantly worse in NVC cases by Gray's test of cumulative incidence ($P = .040$) (Figure 2, A), but this difference was no longer significant after stratification on surgical era (first half or second half) ($P = .23$).

Echocardiography

Echocardiographic measures of RV size and function could be evaluated completely and reliably in 78 VC cases (78%) and in 20 NVC cases (66%) before both stage 1 and BDG procedures (Table 2). In 6 VC cases and 2 NVC cases, a BDG was not performed, but echocardiographic data were available at an age greater than 73 days (ie, age of the youngest patient who underwent successful BDG in this study) and were included in the echocardiographic analysis. The median ages were similar in the 2 groups at both echocardiographic time points. There was no difference between groups at either time point in quantitative measures of RV function or TV annulus diameter z score. In both groups, the RV FAC and TV annulus diameter and z score increased, whereas the TAPSE z score decreased (all $P < .001$), but there were no differences in prestage 1 to pre-BDG change between groups in any of these variables. Although there was an increase in the prevalence of moderate or greater TR in both groups from prestage 1 to pre-BDG, there was no difference between conduit types.

Adequate color Doppler imaging at the level of the valve within the conduit was available in 64 patients after the stage 1 procedure (median 11 days post-Norwood; range, 1-55) and in 64 patients pre-BDG. Paired comparisons of

TABLE 1. Demographic, diagnostic, procedural, and outcome data

	VC (n = 100)	NVC (n = 30)	P value
Era 1 (first half of experience)	61 (61%)	4 (13%)	<.001
Gestational age at birth (wk)	39 (31.4-41.6)	39 (36-40.7)	.91
Gestational age <37 wk	13 (13%)	2 (7%)	.34
Age at stage 1 (d)	5 (1-37)	5 (1-11)	.57
Weight at stage 1 (kg)	3.2 ± 0.5	3.2 ± 0.5	1.0
Weight <2.5 kg	11 (11%)	2 (7%)	.41
Male sex	62 (62%)	15 (50%)	.29
Intact atrial septum	8 (8%)	0 (0%)	.20
Mitral stenosis/aortic atresia subtype	22 (22%)	7 (23%)	1.0
RV-PA conduit diameter*			.92
4 mm	5 (5%)	1 (3%)	
5 mm	77 (79%)	24 (80%)	
6 mm	16 (16%)	5 (17%)	
RV-PA conduit valve type*			—
Aortic homograft	47 (51%)	—	
Pulmonary homograft	32 (35%)	—	
Femoral/saphenous vein homograft	13 (14%)	—	
RV-PA conduit valve diameter†			—
5 mm	1 (1%)	—	
6 mm	39 (40%)	—	
7 mm	52 (53%)	—	
8 mm	5 (5%)	—	

Data presented as median (minimum-maximum), mean ± standard deviation, or number (%) where indicated. P values are for t test, Mann-Whitney, or chi-square/Fisher exact test. VC, Valved conduit; NVC, nonvalved conduit; RV-PA, right ventricle-pulmonary artery. *Data available for 92 VC patients. †Data available for 97 VC cases.

FIGURE 2. A, These competing outcomes curves demonstrate the probability of 3 mutually exclusive outcomes over time in VC (dashed lines) and NVC (solid lines) cohorts out to 1 year: death (red lines), completion of a BDG procedure with early survival (blue lines), and survival without a BDG (black lines). There was a significant difference in the probability of death over time ($P = .04$), but this was no longer significant after stratification for surgical era. There was no difference in the probability of BDG completion with early survival ($P = .15$). B, These Kaplan–Meier curves depict freedom from reintervention for conduit obstruction in the VC and NVC groups. Despite the divergence of curves over time, there was no significant difference ($P = .16$). The number of patients at risk is summarized along the x-axis and 95% confidence intervals are depicted with bars at 60, 120, 180, and 240 days. VC, Valved conduit; BDG, bidirectional Glenn; NVC, nonvalved conduit.

both time points were available for 51 patients. Among 23 patients who had no identifiable conduit regurgitation after stage 1, 9 subsequently developed regurgitation. Among the remaining 28 patients who had conduit regurgitation at baseline, the vena contracta width of the homograft valve regurgitation jet decreased in 5, increased in 10, remained unchanged in 3, and resolved completely in 10. Altogether, 24 patients had no identifiable conduit regurgitation pre-BDG (Figure E1). Among the 18 patients who had a measurable vena contracta at both time points, the width was 2.5 ± 1.1 mm early after stage 1 and 3.0 ± 1.1 mm before BDG ($P = .13$); the width-to-valve diameter ratio increased slightly in the interstage period but did not reach statistical significance (poststage 1: 0.37 ± 0.16 , pre-BDG: 0.45 ± 0.16 , $P = .12$).

Invasive Hemodynamics and Interventions

Pre-BDG catheterization was performed at a similar age in both groups (median 99 days VC and 102 days NVC, $P = .39$) and demonstrated no difference in systemic oxygen saturation ($72\% \pm 8\%$ VC vs $73\% \pm 7\%$ NVC, $P = .52$) or the pulmonary-to-systemic blood flow ratio (Qp:Qs, 0.9 ± 0.4 VC vs 0.9 ± 0.2 NVC, $P = .50$). Percutaneous or surgical interventions to augment or reduce pulmonary blood flow were performed in 23 VC cases (29%) and 4 NVC cases (15%), as detailed in Table 3 (Video 1).

There was no significant difference in freedom from intervention between VC and NVC groups ($P = .31$). Interventions for conduit obstruction were performed in 17 VC cases and 2 NVC cases, with no difference between groups ($P = .16$) (Figures 2-4). This did not change with adjustment for conduit size, surgeon, patient age/weight, or era. In the VC group, smaller valve size was associated with shorter freedom from intervention for conduit obstruction (HR, 0.36 per mm [95% confidence interval, 0.16-0.79], $P = .010$).

DISCUSSION

In patients undergoing stage 1 palliation for HLHS, the RV-PA conduit was originally adopted to reduce or eliminate problems encountered with an mBTS in achieving a stable balance between systemic and pulmonary blood flow, including (1) runoff during diastole that compromises coronary, cerebral, renal, and intestinal perfusion; and (2) a relatively high Qp:Qs contributing to a systemic ventricular volume load and the deleterious effects thereof, especially with larger shunts. Both higher diastolic pressure and a lower Qp:Qs have been confirmed in patients who receive a nonvalved RV-PA conduit compared with those with an mBTS.⁵ Further, these hemodynamic benefits have been associated with improved perioperative, interstage, and 12-month survival.^{3,5} However, there is concern for the

TABLE 2. Echocardiographic data before stage 1 and bidirectional Glenn

	Prestage 1			Pre-BDG		
	VC (n = 78)	NVC (n = 20)	P value	VC (n = 78)	NVC (n = 20)	P value
Age (d)	1 (0-24)	1 (0-10)	.60	107 (34-275)	115 (89-210)	.35
2-dimensional RV FAC (%)	36.9 ± 9.3	36.2 ± 7.8	.72	38.7 ± 8.3	39.1 ± 11.7	.89
TV annulus diameter (cm)	1.2 ± 0.2	1.2 ± 0.3	.81	1.6 ± 0.2	1.6 ± 0.2	.79
TV annulus z score	0.8 ± 1.0	0.7 ± 1.5	.90	2.2 ± 1.4	1.8 ± 1.2	.24
2-dimensional TAPSE z score	-2.8 ± 1.2	-2.5 ± 1.6	.43	-4.8 ± 1.1	-4.7 ± 1.3	.89
Moderate or greater TR	2 (3%)	0 (0%)	1.00	10 (13%)	3 (15%)	.73

Data presented as median (minimum-maximum), mean ± standard deviation, or number (%). Unpaired *t* test and Fisher exact test were used for continuous and categorical data, respectively. By paired *t* test overall, there was no significant change in FAC (*P* = .72) but significant increases (TV annulus diameter and z score) or decreases (TAPSE z score) from prestage 1 to pre-BDG (all *P* < .001). There were no differences between groups in the prestage 1 to pre-BDG change in any of the values. *BDG*, Bidirectional Glenn; *VC*, valved conduit; *NVC*, nonvalved conduit; *RV*, right ventricle; *FAC*, fractional area change; *TV*, tricuspid valve; *TAPSE*, tricuspid annular place systolic excursion; *TR*, tricuspid regurgitation.

negative effects of a ventriculotomy and free conduit regurgitation, as deterioration in RV ejection fraction has been observed in those with stage 2 and 3 in RV-PA conduit but not in those with an mBTS.^{14,15} Although the ventriculotomy cannot be eliminated, a reduction in diastolic conduit regurgitation could improve long-term RV function and outcomes more broadly in patients who undergo palliation with an RV-PA conduit.

Although we were not the first to use a composite valved RV-PA conduit, this is the largest and most comprehensive

study to evaluate the hemodynamic consequences of a VC. Shortly after describing the first known palliative surgery for HLHS using a systemic-to-PA shunt,¹⁶ Norwood and colleagues¹⁷ and Sano and colleagues¹⁸ described the RV-PA conduit as an alternative to establish pulmonary blood flow and reported their experience using both VC and NVC. The conduits used in that formative experience were large (12 mm), and excess pulmonary blood flow contributed to mortality. Drawing from Norwood's experience with VCs as well as that of Kishimoto and colleagues,¹⁹ Sano and colleagues¹⁸ first published their experience in 19 patients using smaller diameter (5-6 mm) nonvalved PTFE conduits to limit pulmonary blood flow and improve perioperative survival. Since

TABLE 3. Interventions during the interstage period

	VC n = 23	NVC n = 4
Method of intervention		
Percutaneous intervention	19*	2
Surgical intervention	6*	2
Timing of first intervention		
Early (within 30 d of stage 1)	6	2
Late (30 d or more after stage 1)	17	2
Indication and type of intervention		
Intervention to increase pulmonary blood flow	22	3
Conduit stent	15	2
Proximal conduit only	2*	1
Distal conduit only	7	1
Both proximal and distal conduit	6	0
Conduit balloon angioplasty without stent	1	0
Branch PA balloon angioplasty	3	0
RV myectomy at origin of conduit	1	0
Added mBTS	2	0
Conduit replaced with larger NVC	1	0
Conduit replaced with central shunt	0	1
Intervention to reduce pulmonary blood flow	3	1
Surgical conduit clip	2*	1
Covered stent with waist	1	0

VC, Valved conduit; NVC, nonvalved conduit; PA, pulmonary artery; RV, right ventricle; mBTS, Modified Blalock-Taussig shunt. *These numbers included 2 patients who underwent early surgical clipping of the conduit followed later conduit stenting.

VIDEO 1. This angiogram in the lateral projection shows the RV-PA conduit in a patient with palliated HLHS. The tip of the catheter is just beyond well-functioning valve leaflets, but there is a stenosis distal to the valve leaflets. Video available at: [http://www.jtcvsonline.org/article/S0022-5223\(17\)32427-3/fulltext](http://www.jtcvsonline.org/article/S0022-5223(17)32427-3/fulltext).

FIGURE 3. Pre-stent (A) and post-stent (B) angiograms from a lateral projection in a patient who had distal obstruction of the RV-PA conduit that involved the homograft valve (*arrow*). This patient had a VC composed of a 7-mm aortic homograft valve on a 4-mm PTFE (Gore-Tex; WL Gore & Associates Inc, Flagstaff, Ariz) tube.

then, various groups have incorporated valves into the RV-PA conduit, including valved saphenous vein homografts, valved porcine xenografts, bovine pericardial conduits with porcine valves, and composite grafts using PTFE and Hemashield material.²⁰⁻²⁴ Most of these experiences were described as case reports or case series, the largest of which comprised 34 patients (21) and 8 patients (20), 5 and 4 of whom had a VC, respectively.

Currently, the significance of the diastolic conduit regurgitation on RV size and function in this population is not well understood. The most robust data to date were derived

FIGURE 4. Pre-stent (A) and post-stent (B) angiograms from a lateral projection in a patient who had obstruction of the RV-PA conduit (*dashed arrow*) that was distal to the homograft valve (*solid arrow*). This patient had a VC composed of a 6-mm aortic homograft valve on a 5-mm PTFE (Gore-Tex) tube.

from studies in which nonvalved RV-PA conduits were compared with mBTS. Mathematic modeling studies have suggested that diastolic regurgitation is minimal (<7%) after palliation of HLHS with an RV-PA conduit but increases with increasing pulmonary vascular resistance (or potentially branch PA stenosis).²⁵ Simulated pressure-volume analyses showed that, although RV mechanical efficiency with an RV-PA conduit is better than with a mBTS, there appears to be no additional value in adding a valve to the conduit.^{25,26} Our echocardiographic data are consistent with these predictions, showing no differences in RV dilation (represented by the TV annulus *z* score) or RV function (by FAC) between groups at the prestage 1 or

pre-BDG time points. The VC also did not have an appreciable effect on reducing the incidence of TR during the interstage period. However, the differences in early support with ECMO and survival over time, which favored the VC group on unadjusted analysis, may be an indication that the presence of a valve in the conduit promoted a more stable postoperative recovery. Along these lines, further analysis will be necessary to determine whether a VC imparts a protective effect immediately after the stage 1 procedure. For logistical reasons, we were unable to assess detailed data related to inotropic or other support in the intensive care unit, which might have provided some insight into this hypothesis.

Our data also highlight the challenges of using 2-dimensional echocardiography to quantify RV function in this setting. Although FAC increased from stage 1 to BDG, the TAPSE *z* score paradoxically decreased. This discrepancy may suggest a complex adaptation and remodeling of the force generating contractile mechanisms of a volume- and pressure-loaded RV over time. Despite this limitation, our FAC data were similar to those from the Pediatric Heart Network Single Ventricle Reconstruction trial at both time points.²⁷ Using both 2- and 3-dimensional echocardiography, those investigators showed no differences in RV function or the prevalence of significant TR between those undergoing mBTS and RV-PA conduit during the interstage period and up to age 14 months.^{27,28} Considering the lack of a measurable difference between patients with those vastly different shunt physiologies, it is not surprising that we did not observe a difference between the VC and NVC groups.

Although a higher Qp:Qs and systemic oxygen saturation might be expected in patients with a VC, as was predicted in mathematic models, our data from the pre-BDG catheterization showed no difference.²⁶ However, models may fail to account for other phenomena, such as patient growth and a biological system's natural tendency to restore equilibrium,²⁵ and it is possible that VC cases transiently had higher pulmonary blood flow and systemic saturations than were captured in our study. Similar to our findings related to RV function, however, it is more likely that the inclusion of a valve in the RV-PA conduit does not significantly alter net pulmonary blood flow or that the benefit of a valve in the pulmonary circulation was neutralized by the development of conduit obstruction in some patients.

There was no statistical difference in freedom from intervention between VC and NVC groups, but there was a suggestive divergence of the Kaplan–Meier curves. Given our unequal sample size and nonrandomized retrospective design, however, it is difficult to discern whether inclusion of a homograft valve in a composite RV-PA conduit increases the risk of intervention. Multiple reports show that the standard nonvalved RV-PA conduit itself has a rate of intervention as high as 36%, which increases to 41%

when branch PA interventions are included.³ Freedom from reintervention (overall and for conduit obstruction) in both VC and NVC groups was within the range of what has been reported. Further, we previously reported a higher rate of interventions with aortic valve homografts compared with pulmonary valves,¹¹ but there was no relationship between conduit type and frequency of interventions in the current analysis.

Study Limitations

In addition to the factors discussed, there were potentially important limitations to this study. Although an RV-PA conduit was used in essentially all patients undergoing stage 1 palliation of HLHS during the study period, the decision to implant a VC or NVC was at the discretion of the surgeon, and patient-related factors may have shaped this decision in a manner that resulted in uncontrolled confounding. Accordingly, the observed difference in survival according to conduit type may be related to other factors that were not accounted for, such as cardiopulmonary interactions in the early postoperative period,²⁹ and as such cannot be attributed only to the use of a VC. Moreover, the focus of this analysis was on hemodynamic/functional parameters and conduit reinterventions that may have been related to the type of conduit used to connect the RV to the PAs.

Prior studies have shown that branch PA growth after stage 1 palliation differs according to the method of providing pulmonary blood flow, with better growth in patients who receive an RV-PA conduit.^{30–32} In theory, reduction of conduit regurgitation with a VC could augment this benefit, but we did not evaluate PA size in this study for logistical reason. However, given the lack of other hemodynamic and volumetric differences, we suspect that any such benefit would likely be modest at best.

CONCLUSIONS

This retrospective study showed that VC was associated with improved survival and stability after stage 1 palliation for HLHS on unadjusted analysis, but may also increase the risk of interventions to augment or reduce pulmonary blood flow during the interstage period. There was no detectable cardiac functional benefit from reducing RV-PA conduit regurgitation using a homograft valved composite conduit during stage 1 palliation, although benefits that were modest or limited to the interstage period cannot be ruled out.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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Key Words: bidirectional Glenn, hypoplastic left heart syndrome, right ventricular function, tricuspid regurgitation

FIGURE E1. This flow diagram depicts the distribution of conduit regurgitation early after stage 1 and on the pre-BDG echocardiogram in the patients in the VC group for whom it was characterized in the early poststage 1 period. BDG, Bidirectional Glenn.