A reinforced right-ventricle-to-pulmonary-artery conduit for the stage-1 Norwood procedure improves pulmonary artery growth

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ABSTRACT

Objective: To compare early postoperative outcomes, angiographic, and intervention findings and 1-year survival between 2 groups of infant patients: those receiving a standard right-ventricle-to-pulmonary-artery (RV-PA) conduit versus a ring-reinforced RV-PA conduit, in undergoing Norwood stage-1 surgery for hypoplastic left heart syndrome (HLHS). The technique of using such a ring-reinforced graft, placed through a limited ventriculotomy, has theoretic advantages in preserving right ventricular function, compared with the standard technique of RV-PA conduit creation.

Methods: This retrospective cohort study was performed between July 2006 and July 2013. A total of 87 patients with HLHS underwent Norwood stage-1 surgery during this period; 48 received a standard nonreinforced RV-PA conduit; 39 received a ring-reinforced conduit. Primary and secondary outcomes were survival and need for cardiac reintervention up to age 12 months.

Results: No difference was found in transplant-free survival by age 12 months (87% ring-reinforced vs 73% nonreinforced, $P = .12$). The group with the nonreinforced, versus ring-reinforced, grafts had more interventions in the first year (69% vs 35%, respectively; $P < .01$). Before stage 2, the pulmonary artery pulse pressure was greater in the group with ring-reinforced grafts (9.1 ± 4.1 vs 4.8 ± 3.1 mm Hg, $P < .001$), with no difference in mean pressure (15.2 ± 3.32 vs 14.3 ± 3.48 mm Hg, $P = .27$). The corrected pulmonary artery index (Nakata) was greater in the group with ring-reinforced grafts (213 ± 76 vs 134 ± 68 mm²/m², $P < .0001$).

Conclusions: A ring-reinforced conduit is associated with reduced intervention, as well as higher pulse pressures and improved pulmonary artery growth, in infants undergoing stage-1 palliation for HLHS. (J Thorac Cardiovasc Surg 2015;149:1502-8)

Angiograms of a ring-reinforced conduit demonstrate preserved uniformity of conduit caliber.

Central Message

Debate remains on shunt strategy for Norwood surgery. A ring-reinforced right-ventricle-to-pulmonary-artery conduit is associated with reduced intervention, higher pulse pressures, and improved pulmonary artery growth.

Perspective

A reinforced, versus nonreinforced, conduit requires a more limited ventriculotomy and preserves conduit size and blood flow over the conduit's life. Whether these advantages create tangible and hemodynamically important long-term differences, without detrimental right ventricular effects, remains to be determined.

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Supplemental material is available online.

Hypoplastic left heart syndrome (HLHS) accounts for 2% to 3% of all congenital heart defects and is a severe cardiac abnormality in which the left ventricle and associated structures fail to develop sufficiently to support the systemic

circulation.¹ Infants with the condition undergo a series of reconstructive procedures, to allow the right ventricle to support both the pulmonary and systemic circulation.² The first stage of that surgery continues to be associated with substantial mortality and appreciable morbidity, such that identifying factors to improve short- and longer-term outcomes is of considerable interest.^{3,4}

The Pediatric Heart Network Single Ventricle Reconstruction trial was established in light of emerging evidence that coronary perfusion pressure might be better supported by a right-ventricle-to-pulmonary-artery (RV-PA) conduit rather than a Blalock-Taussig (BT) shunt, as part of stage-1 Norwood surgery.^{5,6} The trial demonstrates a difference in transplant free-survival between the 2 approaches at 12 months (74% vs 64%, $P < .01$). However, a ventriculotomy is required for RV-PA conduit formation, and concerns remain about its long-term effects on ventricular function. Furthermore, high reintervention rates occurred in

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Abbreviations and Acronyms

BT	= Blalock-Taussig
HLHS	= hypoplastic left heart syndrome
NR Sano	= nonreinforced RV-PA Sano graft with no valve
RR Sano	= ring-reinforced RV-PA Sano graft with no valve
RV-PA	= right ventricle to pulmonary artery

the group who underwent surgery to establish an RV-PA conduit (41% vs 26%).^{5,7-9}

In light of these findings, the technique of RV-PA conduit creation has undergone further modification.¹⁰ Our present technique of a ring-reinforced graft, positioned into the right ventricle through a limited ventriculotomy, has theoretic advantages, compared with the standard technique of using a more extended ventriculotomy and myectomy. The current study was designed to determine whether demonstrable differences occur in surgical outcomes between these 2 groups of patients: infants undergoing stage-1 treatment for HLHS, with either a standard RV-PA conduit or a ring-reinforced RV-PA conduit.

METHODS

Study Population and Design

This single-center, retrospective, cohort study was performed by chart review of all patients diagnosed with HLHS between July 2006 and July 2013 who were admitted to Boston Children's Hospital having undergone no prior interventions or surgery. Infants who underwent a BT-shunt procedure as part of their stage-1 Norwood surgery were excluded. Groups were assigned based on whether the infant underwent surgery (by 1 of 5 surgeons) to receive a ring-reinforced RV-PA conduit with no valve (RR Sano) or a nonreinforced conduit with no valve (NR Sano). The primary outcomes were survival to 12 months, transplant free-survival, and survival without need for extracorporeal membrane oxygenation. Secondary outcomes included hospital morbidity after Norwood surgery and stage-2 surgery; the incidence of unintended interventions, to 12 months, on the Sano conduit, the pulmonary arteries, and the neo-aortic arch; the degree of tricuspid valve regurgitation after the Norwood surgery, at stage 2, and at 12 months; as well as hemodynamic, angiographic, and magnetic resonance imaging findings at the pre-stage-2 evaluation.

Patient Details

Baseline demographic and echocardiographic variables before Norwood surgery were analyzed, to ensure similarity of the 2 cohorts. Surgical procedural details, hospital morbidity, and echocardiographic details after stage-1 surgery and stage-2 bidirectional Glenn surgery were collected on all patients. Catheterization data from before stage-2 surgery were captured, if available. Hemodynamic variables were collected at a baseline state, during a period of stability, and when the patient had a fraction of inspired oxygen of 0.21. All infants were intubated and ventilated for these studies. Some infants required inotropic support to achieve a stable state for assessment.

Angiographic assessment of pulmonary artery dimensions was performed only if a reliable calibration factor was present; such

measurements were made using digital calipers (Merge Cardio software, Merge Healthcare, Chicago, Ill). The right and left pulmonary artery measurements were obtained between the shunt anastomosis and proximal to the upper lobe branch pulmonary artery. Given the relative frequency of stenotic lesions, the narrowest diameter was not necessarily recorded, but rather the length of pulmonary artery most representative of the overall vessel diameter was recorded (from multiple measurements in 2 views) along with the means. Pulmonary artery diameter was corrected for body surface area at the time of the procedure and also by using the Nakata index¹¹: $([\pi\{(RPA \text{ diameter}/2)^2\}] + [\pi\{(LPA \text{ diameter}/2)^2\}]/BSA)$, with right and left pulmonary artery (RPA and LPA) diameter given in mm², and body surface area (BSA) given in m².

Magnetic resonance imaging data, when available, were analyzed for right ventricular ejection fraction, right ventricular end diastolic volume (corrected for body surface area), and pulmonary artery dimension. The pulmonary artery measurements were again taken before the removal of the upper lobe branch. From short-axis cine images, manual segmentation of the ventricles was completed, giving ventricular volume and ejection fraction.¹²

Surgical Details

Ring-reinforced Sano right-ventricle-to-pulmonary-artery

shunt. Attention is turned to creating the RV-PA shunt, after completion of arch reconstruction with pulmonary homograft patch placement, ascending-aorta-to-pulmonary-artery anastomosis, and atrial septectomy. The proximal end of a 5-mm or 6-mm polytetrafluoroethylene (Gore-Tex, registered trademark of W.L. Gore & Associates, Inc, Flagstaff, Ariz) ring-reinforced conduit, without valves, was inserted transmurally into a limited-incision right ventriculotomy, without removing myocardium, and with limited fixing sutures (or purse string sutures) and surgical glue to the right ventricular free wall.

The shunt size was chosen at the discretion of the surgeon, based on the patient's weight, considering a 6-mm shunt to be for patients weighing >3.5 kg. The ringed conduit was placed through the ventriculotomy at a sufficient distance to be sure that no underlying myocardial bridge would create obstruction, and without substantially protruding into the right ventricular cavity. The pulmonary artery end was sewn to the distal main/right pulmonary artery with a running suture. The conduit was brought to the right of the aorta.

Nonreinforced Sano right-ventricle-to-pulmonary-artery

shunt. A right ventriculotomy was performed in the infundibulum, with excision of myocardium sufficient to anastomose a nonreinforced, beveled, 5-mm polytetrafluoroethylene conduit (Gore-Tex, registered trademark of W.L. Gore & Associates, Inc, Flagstaff, Ariz), by direct suture to the epicardium. The pulmonary artery end was sewn to the main pulmonary artery with a running suture. The conduit was brought to the right of the aorta.

Statistical Analysis

Shunt comparisons were performed using the Student *t* test or the Wilcoxon rank sum test for continuous measures. The Fisher exact test was used for categorical measures. Means with either SDs or interquartile ranges are given. The presented *P* values were not adjusted for multiple comparisons. The study was reviewed and approved by the institutional review board.

RESULTS

Baseline Demographics and Primary Outcome Measures

Of 345 infants who underwent stage-1 surgery between July 2006 and July 2013, only 154 had HLHS. Of these,

FIGURE 1. Study group subject selection flow chart, with inclusion and exclusion criteria. *HLHS*, Hypoplastic left heart syndrome; *BT shunt*, modified Blalock-Taussig shunt; *Sano*, right ventricle to pulmonary artery conduit; *d/c*, discharge; *MA*, mitral atresia; *AA*, aortic atresia; *MS*, mitral stenosis; *AS*, aortic stenosis.

65 underwent a BT shunt procedure and were excluded. A total of 87 met the eligibility criteria, although 2 were later excluded from the analysis. The 2 cases were excluded at the beginning of the surgical experience involving use of a reinforced conduit; they were converted to a BT shunt in the first postoperative week. Both of these cases had a standard right ventriculotomy with myomectomy, for conduit placement with the proximal rings of the conduit removed. Overall, 39 underwent stage-1 palliation with a ring-reinforced RV-PA conduit (a 6-mm conduit in 18 patients, at a median weight of 3290 g; a 5-mm conduit in 21 patients, at a median weight of 2868 g; $P < .0001$); 48 received a nonreinforced 5-mm conduit (Figure 1). Baseline characteristics were similar in the 2 groups (Table 1).

Survival to discharge after stage-1 Norwood surgery was 98% (1 death) in the RR Sano group, and 83% (8 deaths) in the NR Sano group ($P = .038$). After this, 1 death occurred during the first interstage period (before stage 2), and 1 additional death occurred after stage-2 surgery and before 12 months, in the RR Sano group. By comparison, in the NR Sano group, 1 death occurred in the first interstage period, and 3 occurred in the second interstage period (and before 12 months). Overall, a significant difference was found in survival at 12 months in the RR Sano versus the NR Sano groups (36 of 39 [92%] vs 36 of 48 [75%], respectively; $P = .047$). Two transplants were needed in the RR Sano group, and 1 in the NR Sano group, by 12 months, giving a cumulative death- and transplant-free survival of 87% in the RR Sano group, and 73% in the

FIGURE 2. Right-ventricle-to-pulmonary-artery conduit wedge occlusion angiograms. Both studies were performed before patients underwent bidirectional Glenn, stage-2 surgery. A, Posteroanterior and (B) lateral angiograms performed in a subject with a nonreinforced polytetrafluoroethylene (Gore-Tex, registered trademark of W.L. Gore & Associates, Inc, Flagstaff, Ariz) RV-PA Sano shunt. Note that there is no stenosis of the branch pulmonary arteries, which are uniform along their length, but the lateral projection demonstrates significant variation in the caliber of the conduit, particularly at its proximal origin from the right ventricle and its distal anastomosis with the pulmonary artery. C, Posteroanterior and (D) lateral angiograms performed in a subject with a ring-reinforced polytetrafluoroethylene (Gore-Tex, registered trademark of W.L. Gore & Associates, Inc, Flagstaff, Ariz) RV-PA Sano shunt. Here, the conduit caliber is relatively uniform along its length, with no narrowing. The branch pulmonary arteries, in cases such as these, are easily measured at a point before the origin of the upper lobe branch, which is easily seen.

TABLE 1. Patient demographics before stage-1 Norwood surgery

Pre-Norwood surgery variable	Ringed Sano group (n = 39)	Nonringed Sano group (n = 48)	P value
Native ascending aorta (mm)	3.7 ± 2.1	3.5 ± 1.99	.75
Aortic valve patency	12 (36)	11 (25)	.47
Mitral valve patency	18 (46)	24 (50)	.83
Moderate or severe tricuspid insufficiency	3 (8)	4 (8)	1
Mean atrial septal pressure gradient >5 mm Hg	10 (26)	22 (46)	.08
Birth weight (kg)	3.08 ± 0.47	3.08 ± 0.56	.95
Gestational age (y)	38.8 ± 1.6	38.7 ± 1.53	.99
Male gender	24 (62)	33 (69)	.5
Fetal diagnosis	37 (95)	41 (856)	.17
Fetal intervention	3 (8)	6 (13)	.73
Age at surgery (y)	4.4 ± 1.8	5.4 ± 3.5	.1

Values are mean ± SD, median, or n (%), unless otherwise indicated. *P* values were obtained using Fisher exact test or Student *t* test of nonpaired samples (2-tailed). The native ascending aortic dimension, aortic and mitral valve patency, and severity of tricuspid insufficiency were determined at the presurgical echocardiographic study. Sano, Right-ventricle-to-pulmonary-artery conduit.

NR Sano group (*P* = .12). Overall freedom from death, transplant, or need for extracorporeal membrane oxygenator support in the first year was similar in the 2 groups (RR Sano: 72%; NR Sano: 67%).

Hospital and Procedural Morbidity

During stage 1, the crossclamp time was significantly longer in the RR Sano group (122.8 ± 24.1 vs 74.9 ± 25.3 minutes, *P* < .001), with no difference in the circulation arrest time (24 ± 12.8 vs 27 ± 22 minutes) or the bypass time (167.6 ± 34.3 vs 162 ± 51 minutes). The RR Sano group had significantly fewer cases returning to the intensive care unit with the sternum open (RR Sano group: 54%; NR Sano group: 85%, *P* < .01). No difference was found in measures of postoperative recovery, including days ventilated, duration of cardiac intensive care unit stay, or duration of hospital stay either post stage 1 (Table 2) or post stage 2 (Table E1). Echocardiographic measures of right ventricular function were limited to severity of tricuspid regurgitation; they showed a nonsignificant indication of an increase in the number of cases with moderate-to-severe tricuspid regurgitation in the NR Sano group, versus the RR Sano group, before stage 2, (2 of 35 [6%] vs 8 of 38 [21%], respectively; *P* = .09).

Pre-Stage-2 Investigation Variables

At the pre-stage-2 catheter evaluation, evidence indicated an increased pulsatility in the pulmonary artery pressure waveforms, with a significantly increased pulse pressure (RR Sano: 9.1 ± 4.1 mm Hg vs NR Sano: 4.8 ± 3.1 mm Hg; *P* < .001) and systolic pressure (RR Sano: 20.1 ± 4.8 mm Hg vs NR Sano: 17 ± 3.7 mm Hg; *P* < .01) in the RR Sano group, but without an appreciable

TABLE 2. Hospital morbidity and surgical details after stage-1 Norwood surgery

Post-Norwood surgery variable	n	RR Sano	n	NR Sano	P value
Bypass time (min)	39	167.6 ± 34.3	45	162 ± 51	.56
Crossclamp time (min)	39	122.8 ± 24.1	46	74.9 ± 25.3	.0001
Circulation arrest time (min)	38	24 ± 12.8	24	27 ± 22	.55
Days ventilated	36	8.2 ± 8.5	40	7.6 ± 6.1	.74
Days in CICU	36	14.6 ± 13.5	40	19.1 ± 44	.55
Days in hospital	36	34.3 ± 30.3	40	31.7 ± 45	.77
Open sternum	39	21 (54)	48	41 (85)	.002
ECMO	39	5 (13)	48	8 (17)	.77
CPR	39	4 (10)	48	4 (8)	.73
Moderate or severe TR at discharge	38	2 (5)	39	3 (8)	1
Moderate or severe TR at pre stage 2	34	1 (3)	38	7 (18)	.07
RVEDV (ml/m ²)	11	126 ± 26	9	121 ± 39.6	.71
RVEF (%)	11	52.7 ± 9.4	9	55.6 ± 8.2	.71
RV mass/volume	11	0.4 ± 0.14	9	0.4 ± 0.12	.38
RPA (mm A-P)	11	6 ± 2.3	9	4.8 ± 1.9	.83
LPA (mm A-P)	11	5.2 ± 1.8	9	4.2 ± 0.7	.24

Values are mean ± SD, median, or n (%), unless otherwise indicated. *P* values were obtained using Fisher exact test or Student *t* test of nonpaired samples (2-tailed). RR Sano, Ring-reinforced RV-PA Sano graft with no valve; NR Sano, nonreinforced RV-PA Sano graft with no valve; CICU, cardiac intensive care unit; ECMO, extracorporeal membrane oxygenation; CPR, cardiopulmonary resuscitation; TR, tricuspid regurgitation; RVEDV, right ventricular end diastolic volume; RVEF, right ventricular ejection fraction; RV, right ventricular; RPA, right pulmonary artery; A-P, anterior-posterior; LPA, left pulmonary artery.

effect on the mean pressure (RR Sano: 15.2 ± 3.32 mm Hg vs NR Sano: 14.3 ± 3.48 mm Hg; *P* = .27; Table 3) or pulmonary-to-systemic flow ratio.

The absolute branch pulmonary artery dimensions, as well as the corrected pulmonary artery index (Nakata), were greater in the RR Sano versus the NR Sano group (213 ± 76 mm²/m² vs 134 ± 68 mm²/m²; *P* < .0001). Subgroup analysis of the RR Sano group demonstrated no additional difference in the hemodynamic profile or the pulmonary artery dimensions between the 2 shunt sizes used (5 and 6 mm; data not shown). A reduction was found in the number of interventions performed in the first 12 months in the RR Sano group (13 of 35 [40%] vs 24 of 35 [69%] in the NR Sano group; *P* = .015), with the largest proportion of this difference being attributable to interventions on the Sano shunt (5 of 34 [15%] vs 13 of 38 [34%], *P* = .054) (Figure 2).

Subgroup analysis of the 12 cases in the RR Sano group and the 9 cases in the NR Sano group who underwent pre-stage-2 magnetic resonance imaging failed to demonstrate a difference in: right ventricular mass/volume ratio (RR Sano: 0.4 ± 0.14 vs NR Sano: 0.4 ± 1.12, *P* = .38); right ventricular ejection fraction (RR Sano: 52.7% ± 9.4% vs NR Sano: 55.6% ± 8.2%); or the right ventricular end diastolic volume (RR Sano: 126 ± 26 ml/m² vs NR Sano: 121 ± 39.6 ml/m², *P* = .71; Table 3).

TABLE 3. Pre-stage-2 surgery cardiac investigation with cardiac catheterization and magnetic resonance imaging

Pre-BDG catheter and MRI variables	n	RR Sano group	n	NR Sano group	P value
Interventions on Sano	36	5 (14)	36	13 (36)	.055
Interventions on Sano or PAs pre stage 2	36	8 (22)	36	14 (39)	.2
Interventions on aortic arch pre stage 2	36	1 (3)	36	5 (14)	.2
PA systolic pressure (mm Hg)	26	20.1 ± 4.8	23	17 ± 3.7	.01
PA diastolic pressure (mm Hg)	26	11 ± 2.46	23	12.1 ± 2.7	.14
PA pulse pressure (mm Hg)	26	9.1 ± 4.1	23	4.8 ± 3.1	.001
PA mean pressure (mm Hg)	31	15.2 ± 3.32	35	14.3 ± 3.48	.27
QpQs	31	1.2 ± .47	35	1.0 ± .47	.18
Hgb (g/dl)	31	14.6 ± 1.75	35	14.2 ± 2	.42
LA pressure (mm Hg)	31	8.6 ± 2.68	35	8.8 ± 2.32	.66
Transpulmonary gradient (mm Hg)	31	6.7 ± 3.5	35	5.4 ± 2.8	.11
Mid main LPA (mm)	29	5.8 ± 1.3	34	4.8 ± 1.5	.0050
Mid main LPA indexed (mm/m ²)	29	20.9 ± 5	34	16.7 ± 5.3	.0020
Mid main RPA (mm)	29	6.2 ± 1.5	34	4.8 ± 1.2	<.0001
Mid main RPA indexed (mm/m ²)	29	22.4 ± 5	34	16.7 ± 3.7	<.0001
Nakata index	29	213 ± 76	34	134 ± 68	<.0001
MRI RVEDV (ml/m ²)	11	126 ± 26	9	121 ± 39.6	.71
MRI RVEF (%)	11	52.7 ± 9.4	9	55.6 ± 8.2	.71
MRI RV mass/volume	11	0.4 ± 0.14	9	0.4 ± 0.12	.38
MRI RPA (mm A-P)	11	6 ± 2.3	9	4.8 ± 1.9	.83
MRI LPA (mm A-P)	11	5.2 ± 1.8	9	4.2 ± 0.7	.24

Values are mean ± SD, median, or n (%), unless otherwise indicated. *P* values were obtained using Fisher exact test or Student *t* test of nonpaired samples (2-tailed). Eleven patients in the RR Sano group, and 9 patients in the NR Sano group, underwent MRI as part of their pre-bidirectional Glenn evaluation. The transpulmonary gradient = mean pulmonary artery pressure – mean left atrial pressure. *BDG*, Bidirectional Glenn; *MRI*, magnetic resonance imaging; *RR Sano*, ring-reinforced RV-PA conduit; *RV-PA*, right-ventricle-to-pulmonary-artery; *NR Sano*, nonreinforced RV-PA conduit; *PA*, pulmonary artery; *QpQs*, pulmonary to systemic blood flow ratio determined by Fick principle oximetry; *Hgb*, hemoglobin concentration; *LA*, left atrium; *LPA*, left pulmonary artery; *RPA*, right pulmonary artery; *RVEDV*, right ventricular end diastolic volume; *RVEF*, right ventricular ejection fraction; *RV*, right ventricle; *A-P*, anterior-posterior.

DISCUSSION

This study analyzes outcomes of use of 2 Sano shunt types as part of stage-1 Norwood surgery for HLHS. Demonstration of increased branch pulmonary artery dimensions and a reduction in the number of interventions on the Sano shunt or the pulmonary arteries, during the 12 months studied, strongly suggests that the reinforced shunt is associated with improved pulmonary artery growth.¹³⁻¹⁵ Consistent with this finding is the fact that the ring-reinforced shunt was associated with higher pulmonary artery systolic and pulse pressure at pre-stage-2 catheter evaluation; in addition, it supports the hypothesis that improved pulmonary artery growth relates to volume and pulsatility of blood flow.

Branch pulmonary artery stenosis and pulmonary artery hypoplasia can have substantial deleterious effects in a circulation that will ultimately be dependent on almost passive systemic venous return to the heart as part of a Fontan circulation (Figure 3). The opportunity to realize improved pulmonary artery growth along with a reduction in higher-risk catheter interventions on the Sano shunt or pulmonary arteries, in infants, is of obvious interest. Equally important is that this outcome is achieved without an adverse effect on transplant-free survival or hospital morbidity. This approach does, however, raise the important question of whether it has detrimental

effects on right ventricular volume or function. This study fails to address these issues. Sano shunts as part of stage-1 Norwood surgery have always been subject to these concerns.^{7,8}

Demonstration of improved transplant-free survival at 12 months with a Sano RV-PA shunt, compared with a BT shunt,⁵ is somewhat tempered by the more recent report of near equivalence when patients reach age 3 years, with a lower right ventricular ejection fraction on echocardiography.¹⁶ Theoretically, a limited right ventriculotomy of a reinforced shunt that is “dunked” into the right ventricular free wall might be associated with improved ventricular function, although the greater volume load from shunt regurgitation might have an opposing and more important effect. Analysis of the subgroups that underwent pre-stage-2 magnetic resonance imaging is partly supportive of this hypothesis, with a higher right ventricular end diastolic volume in the RR Sano group (126 ± 26 vs 121 ± 39.6 ml/m²), but with a reduction in the right ventricular ejection fraction (52.5% ± 9.4% vs 55.6% ± 8.2%). Longer-term follow up is critical to understanding this concern, as well as exploring other types of conduits with valves, in terms of design, size, and potentially, site of origin from the ventricle.

The significantly longer crossclamp time in the RR Sano group during stage-1 surgery likely relates to 2 factors.

FIGURE 3. Pulmonary artery angiograms performed in a subject in the nonreinforced right-ventricle-to-pulmonary-artery conduit group who required multiple conduit and pulmonary artery procedures during infancy. Right-ventricle-to-pulmonary-artery conduit angiograms in (A) caudal and (B) lateral projections performed before stage-2 bidirectional Glenn surgery. A, Both branch pulmonary arteries are narrowed at their proximal origin and immediately after the insertion of the conduit onto the main pulmonary artery. B, There is severe proximal stenosis where the conduit has been anastomosed to the right ventricle that is stented (B'). C, Pulmonary artery angiogram performed through the superior vena cava to pulmonary artery anastomosis. After bidirectional Glenn stage-2 surgery and left pulmonary arterioplasty, severe left pulmonary artery stenosis remains that requires further intervention and is stented (C'). This artery subsequently became disconnected secondary to thrombosis.

First, surgical practice has changed, to a more extensive coarctectomy, compared with patching the aortic arch through to the coarctation segment. The second factor is placement of the ring-reinforced conduit's proximal and distal anastomosis while still under crossclamp. No evidence indicates that the crossclamp time results in increased postoperative morbidity, and it creates no increase in need for ventilation, intensive care stay, or hospital stay in the RR Sano group.

Study Limitations

This single-center, cohort study is retrospective. Although the use of a single center significantly limits generalization of these results to other institutions, and the study design introduces inherent biases, 1 major advantage of analyzing a single-center experience is the very similar patterns of care used throughout the study period. The study was performed over a 7-year time span, with 5 surgeons operating (3 throughout the study period) and with the NR Sano, control cohort being the older one. These concerns would be more significant if more favorable differences had been found in hospital morbidity and transplant-free survival.

The similarity of the 2 groups on measures of hospital morbidity demonstrates, to some extent, that practice did not vary significantly over the time period of the study. Nevertheless, this limitation is significant. In light of this limitation, the study does not seek to overinterpret the survival advantage demonstrated for the RR Sano cohort. Given that this advantage is lost when all outcome measures

are included (transplant and need for extracorporeal oxygenator support), some of the advantage is likely attributable to improvements in these aspects of care.

An incomplete pre-stage-2 evaluation, which would have had catheter and magnetic resonance imaging in all cases, significantly limits the possible analysis of the potential impact of an RR Sano on ventricular function and ventricular volumes, and of whether the improved potential for pulmonary artery growth demonstrated is at the expense of higher right ventricular diastolic volume secondary to increased shunt regurgitation. In 3 cases early in the period of using an RR Sano, the conduit was placed with a more conventional extended ventriculotomy. Two of these cases were excluded from this analysis, as they were converted early to a BT shunt; 1 case was included in the NR Sano group, owing to the nature of conduit placement. Analysis on the basis of intention to treat did not alter our conclusions; these data are available on request.

CONCLUSIONS

An RR Sano shunt is associated with a reduction in the need for reintervention, as well as with higher pulse pressures and improved pulmonary artery growth in infants undergoing stage-1 palliation for HLHS. The remaining question is whether this reduction equates to tangible and hemodynamically important differences after bidirectional Glenn or Fontan surgery, and whether any such benefit is achieved without detrimental effects on right ventricular function.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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Key Words: Congenital heart disease, hypoplastic left heart syndrome, right ventricle to pulmonary artery conduit, Norwood surgery

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Jose Pedro da Silva. Pulmonary root translocation for anatomical repair of congenitally corrected transposition of the Great Arteries. *Oper Tech Thorac Cardiovasc Surg*. 2014;19(3):304-323.

TABLE E1. Hospital morbidity and surgical details after stage-2 bidirectional Glenn surgery

Post stage-2 variable	n	Ringed Sano	n	Nonringed Sano	P value
Days ventilated	35	3.9 ± 6.7	37	2.9 ± 6.5	.53
Days on CICU	35	7 ± 10	37	5.6 ± 12.3	.61
Days in hospital	35	14 ± 14.1	37	13.5 ± 17.5	.9
Open sternum	35	1 (3)	37	1 (2.7)	1
ECMO	35	0 (0)	37	0 (0)	1
CPR	35	4 (11)	37	1 (2.7)	.19
Interventions on Sano or PAs to 12 mon	36	9 (25)	36	18 (50)	.05
Moderate or severe TR at discharge	35	1 (3)	37	2 (5)	1
Moderate or severe TR at 12 mon	29	2 (6.7)	37	2 (5)	1
Mortality to 12 mon	39	3 (8)	48	12 (25)	.047
Heart transplant to 12 mon	39	2 (5)	48	1 (2)	.56

Values are mean ± SD, median, or n (%), unless otherwise indicated. *P* values were obtained using Fisher exact test or Student *t* test of nonpaired samples (2-tailed). *CICU*, Cardiac intensive care unit; *ECMO*, extracorporeal membrane oxygenation; *CPR*, cardiopulmonary resuscitation; *Sano*, right-ventricle-to-pulmonary-artery conduit; *PA*, pulmonary artery; *TR*, tricuspid regurgitation.