

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

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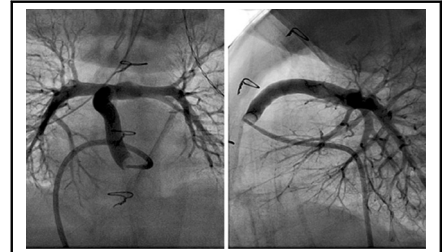
ABSTRACT

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: $([\pi\{(RPA\ diameter/2)^2\}] + [\pi\{(LPA\ diameter/2)^2\}]/BSA)$, 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 excavation 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 categoric 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,

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