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Long-Term Outcome of Palliation with Internal Pulmonary Artery Bands After Primary Heart Transplantation for Hypoplastic Left Heart Syndrome

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Abstract

The purpose of this study was to describe the long-term outcome of infants with hypoplastic left heart syndrome (HLHS) who underwent placement of internal pulmonary artery bands as part of a transcatheter palliation procedure followed by primary heart transplantation. Transcatheter palliation included stenting of the ductus arteriosus, decompression of the left atrium by atrial septostomy, and internal pulmonary artery band placement. Cardiac hemodynamics, pulmonary artery architecture, and pulmonary artery growth since transplantation are described. Nine infants with HLHS had internal pulmonary artery bands placed and underwent successful heart transplant. No infant required reconstruction of the pulmonary arteries at the time of transplant. At 1 year after transplant, all of the recipients had normal mean pulmonary artery pressure, pulmonary vascular resistance, and transpulmonary gradient. Pulmonary angiography performed at 1 year

after transplant demonstrated no distortion of pulmonary artery anatomy with significant interval growth of the branch pulmonary arteries. There was 100% survival to hospital discharge after transplant in this cohort of infants. Transcatheter placement of internal pulmonary artery bands for HLHS offers protection of the pulmonary vascular bed while preserving pulmonary artery architecture and growth with good long-term outcome.

Keywords

Congenital heart disease; Heart catheterization; Heart transplant; Infant

Introduction

Hypoplastic left heart syndrome (HLHS) is a constellation of lethal congenital heart defects that can be managed by staged surgical palliation or by heart transplantation. The outcome for HLHS has improved during the last couple of decades; however, it remains a major cause of morbidity and mortality in the congenital heart disease population. Stage 1 Norwood survival ranged from 70% to 90% in recent series, with improved outcomes toward the more contemporary era [2–4, 13–15, 19, 21]. Infant (<1 year) heart transplantation has proven to be successful with excellent long-term outcomes to date, but it is limited by donor supply. Overall 5-year survival for infants with HLHS who are managed by primary transplantation is 72%; 1- and 5-year survival rates are 92% and 85%, respectively, in those who survive 1 month after transplant [7]. One of the biggest challenges in managing patients listed for heart transplantation is to overcome the problem of scarce donor supply, which results in potentially long waiting times and subsequent risk of wait-list mortality [7].

For infants undergoing staged surgical palliation, mortality is greatest surrounding stage 1 of the Norwood procedure, although interstage mortality is also problematic for these patients [3, 8]. A hybrid approach consisting of transcatheter stenting of the ductus arteriosus, atrial septostomy, and surgical pulmonary artery band placement is being performed as an alternative management approach for HLHS [1, 9–11, 16]. A hybrid approach can serve as a bridge to transplantation or to staged surgical reconstruction [9, 10, 17].

The hybrid approach requires an open chest procedure for surgical placement of external pulmonary artery bands. The degree of “banding” can be variable, and surgical reconstruction of the band site may be required at the next stage of repair. We employed a similar approach using surgically placed pulmonary artery bands for infants with HLHS awaiting transplant [17]. We also previously described the technical aspects, complications, and feasibility of using a catheter-based interventional palliative approach for infants with HLHS who had a prolonged wait time to transplantation [5, 6].

The interventional palliation procedure is performed in its entirety in the cardiac catheterization laboratory and involves percutaneous placement of internal pulmonary artery band devices (manufactured by AGA Medical Corporation, Plymouth, MN, USA), stenting of the ductus arteriosus, and atrial septostomy. In this article, we describe the long-term outcome and impact of internal pulmonary artery band placement in infants with HLHS undergoing primary cardiac transplantation.

Materials and Methods

Patient Selection

The entire pediatric heart transplantation database maintained at our institution since November 1995 was reviewed, and all neonates with HLHS that were listed for primary transplantation were identified. From November 1995 to the present, we have used a standard protocol for the management of infants with HLHS before and after transplantation [17]. Inclusion criteria for this long-term outcome study were as follows: (1) diagnosis of HLHS without previous surgical intervention, (2) completion of a comprehensive interventional palliation procedure consisting of stenting of the ductus arteriosus, decompression of the left atrium, and placement of *internal* bilateral pulmonary artery band devices, and (3) survival to time of transplant.

Transcatheter Palliation

Informed consent was obtained for all infants undergoing the interventional palliation procedure, and the experimental pulmonary artery bands were placed under an investigational protocol for compassionate use approved by the Colorado Multiple Institutional Review Board (IRB). Per the IRB protocol, because of the experimental nature of the pulmonary artery band devices, placement of the internal pulmonary artery bands could *not* be the primary indication for performing the catheterization procedure. Therefore, either restriction of an atrial septal defect (ASD) or placement of a stent in the ductus arteriosus was the primary indication to perform the catheterization procedure, and the internal pulmonary artery bands were placed as part of that procedure (Fig. 1). The indication for atrial septostomy was a critically restrictive ASD, which was defined as a peak flow velocity across the ASD >2.5 m/s by echocardiogram and/or systemic desaturation caused by left atrial hypertension (pulse oximetry $\leq 60\%$ despite supplemental oxygen). Stenting of the ductus arteriosus was performed so that prostaglandin infusion could be discontinued and was indicated when the infant had stable hemodynamics in room air and was otherwise ready to be discharged home. The procedures for stenting of the ductus arteriosus as well as decompression of the left atrium in patients with HLHS were performed for these infants as previously described [6, 12]. The details of the internal pulmonary artery band placement and complications have been described elsewhere, but the procedure will be reviewed here [5, 6].

Internal Pulmonary Artery Band Placement—Balloon-occlusion selective angiograms were obtained of the branch pulmonary arteries. The diameter of the proximal pulmonary artery was measured, and a pulmonary artery band device that was 120% to 130% of these measured diameters was chosen. Pulmonary artery band devices were available in 1-mm increments from 6 to 12 mm in diameter and 7 to 8 mm in length. The pulmonary bands are self-expanding nitinol-based flow restrictors with polyester inserts. Each device has two lumens that are 2 mm in diameter located on either side of a central locking pin [6]. The devices were delivered through a 6F AGA delivery sheath using a ductus arteriosus stent delivery wire. Abciximab, 0.25 mg/kg, was administered by intravenous bolus, and 25 mg/kg cefazolin were given before band placement. An additional dose of cefazolin was given 6 hours later. Immediately after deployment of the devices, the patient was started on an abciximab infusion at 0.125 μ g/kg/min and was given 1 mg/kg intravenous dipyridamole for additional antiplatelet effect. A main pulmonary artery angiogram was performed subsequent to device deployment to evaluate positioning and to ensure patency of the devices. A transthoracic echocardiogram was also obtained in the catheterization laboratory immediately after band placement for confirmation of placement and to assess the Doppler-derived pressure drop across the devices.

After completion of the palliation procedures, echocardiograms, electrocardiograms, and chest radiographs were performed at 1 day, 1 week, and 1 month after the procedure and then as clinically indicated to evaluate patency of the stent in the ductus arteriosus, to monitor the Doppler pressure gradient across the pulmonary artery bands, and to assess the adequacy of the communication between the left and right atrium.

Heart Transplantation

Transplant methodology at our institution has been previously described [17]. The stent within the ductus arteriosus was removed along with the entire ductus arteriosus itself and then aortic arch reconstruction using donor tissue was subsequently performed. The internal pulmonary artery bands in all patients were simply extracted with the use of forceps under direct visualization on dividing the main pulmonary trunk. No dissection or incision of the branch pulmonary arteries was required during this removal process.

Outcome Variables

Clinical Course After Internal Pulmonary Artery Band Placement—The clinical course after placement of the internal pulmonary artery bands is described.

Pulmonary Artery Development—We routinely perform cardiac catheterization in infant recipients at 1 year after transplant. Pulmonary angiography was performed at 1-year catheterization in these patients specifically to assess interval arterial growth and to evaluate for evidence of stenosis or anatomic distortion given the experimental nature of the pulmonary artery band devices.

Statistics

Variables are expressed as the calculated mean and SD unless otherwise stated. Where indicated, z-scores were calculated for comparison with population-based mean measurements based on body surface area.

Results

Interventional Palliation Procedure

Review of our database of successfully transplanted infants with HLHS identified nine infants who met the inclusion criteria for this study as described in Materials and Methods [20]. Table 1 lists all of the interventional procedures performed on each patient and the patient's age when the procedures were performed. Ultimately, through experience it was determined that it was technically easier to complete the entire palliation during a single procedure. Difficulty in manipulating the pulmonary artery band delivery sheath beyond the ductal stent and into the branch pulmonary arteries was noted to result in prolonged procedure time and increased potential for hemodynamic instability [6]. Therefore, for the final 3 patients in our experience, palliation was performed as a single procedure with the pulmonary artery bands being placed first, followed by stenting of the ductus, and, finally, atrial septostomy.

The infants had a mean age of 79 ± 34 days and a mean weight of 4.2 ± 0.5 kg at the time of band placement. Five of the nine patients were electively admitted from home for pulmonary artery band placement, and all were able to be discharged home after the procedure. Mean length of hospital stay was 1.6 days (range 1–2). None of the patients required readmission to the hospital for complications related to the banding procedure, and no patient had any infections related to the banding procedure. Doppler velocities of the branch pulmonary arteries just before transplantation were obtained in all patients. Mean

velocity in the left pulmonary artery was 2.9 ± 0.4 m/s and in the right pulmonary artery was 3.1 ± 0.3 m/s (Table 2).

Heart Transplantation

Eight of the nine internal pulmonary artery banded patients were outpatients at the time of transplant. The hospitalized infant was on inotropic support (milrinone), but not intubated, and was hemodynamically stable at the time of transplant. Mean age at the time of transplant was 138 ± 52 days, and mean weight was 5 ± 0.6 kg. Mean time that the internal pulmonary artery bands were in place was 59.1 days (range 6–199; Table 2).

Extraction of the ductus arteriosus stent was an uncomplicated procedure in all infants. Removal of the internal pulmonary artery bands was performed as described in Materials and Methods and was without complication. Importantly, none of these patients required any repair or reconstruction of their branch pulmonary arteries because the devices were removed by forceps through the divided main pulmonary trunk without the need for any dissection. Overall survival to hospital discharge after transplantation was 100%.

Long-Term Outcome

Posttransplant Doppler Assessment—All patients had normal branch pulmonary artery Doppler velocities after transplant. Mean right pulmonary artery velocity was 1.2 m/s (SD 0.4), whereas mean left pulmonary artery velocity was 1.4 m/s (SD 0.4). Mean right pulmonary artery and left pulmonary artery diameter as measured by two-dimensional echocardiography were equal at 0.6 cm (SD 0.1).

Posttransplant Cardiac Catheterization—One-year survival for this group of infants was 100%, and mean pulmonary artery pressure at 1 year after transplant was 17.1 mm Hg (SD 4.1) and an indexed pulmonary vascular resistance of 3.0 Woods units/m² (SD 1.7). Mean left ventricular end-diastolic pressure was 7.3 mm Hg (SD 2.6; range 5–12). Mean transpulmonary gradient was 9.8 mm Hg (SD 2.6).

Eight of the nine patients had pulmonary artery angiography performed at 1 year after the transplant catheterization procedure. One patient required catheterization at 5 months after transplant secondary to superior vena cava obstruction. Pulmonary artery angiogram performed at that time did not demonstrate any evidence of significant pulmonary artery distortion; therefore, repeat angiogram was not performed on this patient at 1-year catheterization. This patient was not included in the angiographic evaluation of pulmonary artery size; however, by ultrasound assessment, this patient had normal branch pulmonary artery diameter without stenosis at 1 year after transplant.

There was no evidence of distortion or stenosis of the pulmonary arteries in any patient (Fig. 2). There was significant interval growth of the pulmonary arteries when comparing angiographically measured diameters at placement time of the internal pulmonary artery bands compared with the diameters at 1 year after transplant (Fig. 3). The Nakata Index (right pulmonary artery area [in mm²] + left pulmonary artery area (in mm²)/body surface area (in m²)) was used to quantitatively assess the cross-sectional area of the branch pulmonary arteries by angiography. A normal Nakata Index is 330 mm²/m² (SD 30) [18]. The mean Nakata Index for the internal pulmonary artery band patients was normal at 305 mm²/m² (SD 69), which resulted in a z-score of -0.8 . No patient required transcatheter angioplasty of the branch pulmonary arteries at any point after transplant.

Discussion

Despite advances in staged reconstruction surgical techniques and infant transplant management, HLHS remains a complex and difficult congenital problem that presents a lifetime of challenges for patients, families, and cardiologists. The Norwood procedure continues to evolve; however, long-term outcomes are largely dependent on the unpredictable nature of the single systemic right ventricle. Cardiac transplantation for infants with HLHS results in a biventricular and physiologic outcome for the recipient, including excellent long-term survival; however, it requires lifelong immunosuppressive therapy [17] (see <http://www.ishlt.org/registries/>). The complex physiologic state of the infant with HLHS and the unpredictable and limited nature of donor supply are responsible for increased wait-list mortality and post-transplant morbidity. The recent addition of the hybrid procedure as another management option for infants with HLHS is valuable and can serve as a bridge toward surgical single-ventricle palliation or transplantation.

This observational study involved a small number of patients, and its results demonstrated that long-term outcome for infants with HLHS undergoing internal pulmonary artery banding as a bridge to transplantation is good. All of the patients admitted from home for pulmonary artery band placement were sent home within 48 hours after the procedure. The internal bands were easily removed at the time of transplant without the need for pulmonary artery repair in any patient.

The internal pulmonary artery bands did not adversely affect the growth or development of the branch pulmonary arteries in these infants. The long-term implications of having foreign bodies in place for an extended period of time and the subsequent impact of removal at the time of transplant was one of the primary areas of concern in this investigation. However, despite the fact that one of the infants had the internal pulmonary artery bands in place for 199 days, there were no complications in device removal and no late stenosis. No patient required reconstruction or subsequent intervention on the branch pulmonary arteries after pulmonary artery band device removal despite the significant length of time that they were in place. All patients demonstrated normal pulmonary artery growth and architecture after device removal. The internal bands do not seem to interfere with pulmonary vascular development, and their easy removal is a major advantage of the device design.

Given the recent resurgence in the use of external pulmonary artery bands as part of the hybrid approach to HLHS, consideration of expanding the use of the internal pulmonary artery bands into this realm is enticing. The technical aspects of placement of internal pulmonary artery bands at an earlier point in time are feasible because the size range of our patients included normal birth weight. In an ideal setting, the entire palliation procedure could be performed in the first 2 weeks of life, thereby providing the infant with both the option of primary transplantation or surgical palliation as definitive management.

In conclusion, this article described the long-term outcome of infants at our institution who underwent internal pulmonary artery band placement before primary transplantation for HLHS. This palliation procedure allows infants a greater wait-list safety margin; however, it also makes it more likely for the transplant to be successful in patients who are several months old at the time of transplant [17]. The intrinsic advantage of being able to accomplish effective palliation by interventional techniques is important. In addition, internal pulmonary artery bands could be placed as part of a hybrid palliation and retain the advantage of a predictable obstruction while not causing distortion or stenosis of the pulmonary arteries after removal, thus allowing normal pulmonary artery growth.

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Fig. 1.

Angiograms of ductus arteriosus stents and internal pulmonary artery bands. **a**

Anteroposterior and **b** lateral projections of the ductus arteriosus stents and bilateral internal pulmonary artery band devices. The catheter is visualized within the main pulmonary artery segment. **c** Anteroposterior and **d** lateral projections after main pulmonary artery angiogram with the palliative devices in place

Fig. 2.

Pulmonary artery angiograms during pulmonary artery band placement and at 1 year after removal. **a** Fifteen-degree cranial and 15° right anterior oblique angulation and **b** 30° cranial and 70° left anterior oblique angulation views represent test injections performed during placement of the right and left internal pulmonary artery bands, respectively. **c** Fifteen-degree cranial and 15° right anterior oblique angulation and **d** 30° cranial and 70° left anterior oblique angulation views demonstrate a pulmonary artery angiogram obtained 1 year after transplantation as well as removal of the internal pulmonary artery bands

Fig. 3.

Pulmonary artery growth at cardiac catheterization performed approximately 1 year after transplant in the palliated group of patients. Angiography demonstrates significant interval growth of the branch pulmonary arteries, which were 6.4 mm (SD 0.6) for the left artery and 7.3 mm (SD 1.1) for the right artery at the time of placement of the internal pulmonary artery bands, compared with diameters at 1 year after transplant of 8.9 mm (SD 1.4) for the left artery ($P<0.01$) and 9.5 mm (SD) 1.4 for the right artery ($P<0.001$)

Table 1
Timing of all interventional procedures performed on the patients before heart transplantation

Patient no.	Procedure no. 1	Age (d)	Procedure no. 2	Age (d)
1	PDA stent	25	PAB + septostomy	78
2	PDA stent	20	PAB + septostomy	52
3	Septostomy	45	PAB + PDA stent + septostomy	131
4	PDA stent	6	PAB + septostomy	114
5	PDA stent + septostomy	44	PAB + septostomy	118
6	PAB + septostomy	47	PDA stent + septostomy	77
7	PAB + PDA stent + septostomy	47		
8	PAB + PDA stent + septostomy	52		
9	PAB + PDA stent + septostomy	69		

PAB Placement of internal pulmonary artery bands, *PDA* stent Placement of a stent in the ductus arteriosus, *septostomy* Atrial septostomy performed for left atrial decompression

Table 2

Demographics and pretransplant Doppler velocities of the internal pulmonary artery bands

Patients (no.) with internal pulmonary artery band	Age (d) at time of pulmonary artery band placement	Age (d) at transplant (days bands were in place)	Weight (kg) at transplant	Doppler velocity (m/s) at time of transplant	
				Left artery	Right artery
1	78	114 (36)	4.7	2.5	2.9
2	52	121 (69)	5.68	2.9	3.1
3	131	173 (42)	4.34	2.8	3.3
4	114	120 (6)	5.7	2.1	2.5
5	118	127 (9)	4.375	3	3.0
6	47	246 (199)	5.4	2.8	3.5
7	47	74 (27)	4.685	3.3	3.0
8	52	92 (40)	5.245	3.1	3.0
9	69	173 (104)	4.48	3.6	3.6
Mean (SD)	79 (34)	138 (52)	5 (0.6)	2.9 (0.4)	3.1 (0.3)