Initial Experience With Hybrid Palliation for Neonates With Single-Ventricle Physiology

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Background. **Hybrid palliation consisting of bilateral pulmonary artery banding and ductal stenting (PAB/DS) is an emerging method to palliate neonates with functional single ventricles.**

Methods. **Outcomes were reviewed for a newly established hybrid program. PAB/DS was performed in 18 patients for three indications: Norwood alternative (n = 11), pretransplant palliation (n = 5), and salvage (n = 2). Comparison is made with a concurrent group of 25 patients treated with a Norwood procedure.**

Results. **Among Norwood-alternative patients, there were two deaths, followed by nine stage II procedures, with one death. One salvage patient died. All pretransplant palliation patients underwent subsequent transplantation, with one death 49 days after the transplantation. Three deaths were due to clearly defined technical errors, and one death (salvage patient) was due to an error in patient selection. Kaplan-Meier survival at 1 year was 68% for the hybrid patients. By indication, survival at 1 year was 80.0% for Norwood-alternative, 69.7% for pretransplant palliation, and 50.0% for salvage ($p = 0.31$). Overall Norwood survival at 1 year was 71.4% ($p = 0.56$ vs overall hybrid). Among Norwood-alternative survivors, combined (stage I and stage II) intubation times and lengths of stay in the intensive care unit and in the hospital tended to be shorter than Norwood survivors but did not reach statistical significance (9.6 ± 6.9, 15 ± 8, and 35.7 ± 15.3 days versus 15.4 ± 4.9, 23.5 ± 16.7, and 50.5 ± 43.6 days, respectively, p = NS).**

Conclusions. **Despite comparison with a well-established Norwood program, a newly established hybrid program provides initial results that are comparable with those obtained with the Norwood procedure, suggesting that the learning curve in the current era is relatively short. As refinements in patient selection and technical issues evolve, survival can be expected to rapidly improve.**

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The hybrid strategy consisting of bilateral pulmonary artery banding (PAB) and ductal stenting (DS) has emerged as a new and promising strategy for palliation of neonates with single-ventricle physiology [1–3]. By combining surgical and interventional cardiology paradigms, the hybrid strategy is designed to achieve the objectives of the Norwood procedure (control of pulmonary blood flow, unobstructed systemic cardiac output, unobstructed coronary blood flow, and an unrestricted atrial septum) while avoiding cardiopulmonary bypass, cardioplegic arrest, and circulatory arrest in the neonatal period. The benefit of the hybrid strategy rests on the unproven assumptions that avoiding neonatal cardiopulmonary bypass and deferring aortic arch reconstruction until later in infancy will result in superior survival and enhanced neurologic and cardiac functional outcomes.

At the Hospital for Sick Children in Toronto, we embarked on the development of a hybrid strategy to augment well-established Norwood and transplant programs. In this article, we report our early outcomes and clarify the role of hybrid palliation in the context of Norwood and transplantation management pathways.

Patients and Methods

From May 2004 to January 2006, 43 neonates underwent palliation for single-ventricle physiology at the Hospital for Sick Children in Toronto. A program-wide decision was made during this period to begin hybrid procedures as a "Surgical Innovation" under an ethical review process specifically designed to provide oversight for the development of new surgical approaches at the Hospital for Sick Children. Decisions to proceed with PAB/DS palliation were made by the referring

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Table 1. Demographic Data[a]

Variable	Hybrid (n)	Norwood (n)
Total patients	18	25
Diagnosis		
HLHS	13	21
Unbalanced AVSD	3	—
TGA	2	2
Univentricular heart	—	2
Weight (kg)	3.4 ± 0.5	3.5 ± 0.5
Age, days		
At first stage	17 ± 16	11 ± 18
At second stage	174 ± 69	176 ± 46
Gender (male)	9	16

[a] P = not significant for all comparisons.

AVSD = atrioventricular septal defect; HLHS = hypoplastic left heart syndrome; TGA = transposition of the great arteries.

cardiologist, surgeon, parents, and the cardiovascular program through interdisciplinary conferences on a case-by-case basis. No specific protocol was in place to guide these decisions. Ethical Review Board approval was obtained, and a separate consent was obtained for patients undergoing placement of pulmonary artery–to–innominate artery shunts (reverse Blalock-Taussig shunts). Finally, Ethical Review Board approval was obtained for the retrospective review of prospectively accumulated data that follows.

During this period, 18 patients underwent PAB/DS procedures as their initial palliative procedure for one of three indications:

1. Staged surgical palliation (Norwood alternative) was undertaken in 11 patients where a Norwood procedure was considered feasible but a hybrid procedure was chosen as an alternative because of the potential benefits of avoiding cardiopulmonary bypass and aortic arch reconstruction in the neonatal period.
2. Pretransplant stabilization of neonates listed for heart transplantation was undertaken in 5 patients in whom a decision to undergo transplantation was made according to parental preference and in whom instability had developed while on the transplant waiting list.
3. Salvage procedures for 2 critically unstable neonates unsuitable for staged surgical palliation and not expected to survive on the waiting list for a heart transplant were undertaken in an attempt to stabilize these critically ill neonates in whom death appeared imminent.

During the same period, 25 patients underwent a Norwood procedure as the primary palliation for single-ventricle physiology in accordance with the standard management strategy of the cardiovascular program.

The first patient in whom a hybrid procedure was performed was a critically ill neonate awaiting heart transplantation in whom the hybrid procedure resulted in rapid stabilization and ultimate transplantation. This favorable early experience resulted in the development of the hybrid program. A subsequent delay in entering patients was due to the process of organizing site visits to other programs to educate the surgical, cardiologic, and anesthetic teams, and the obtainment of ethical approval through the Surgical Innovation process described above.

Surgical Techniques

Patients undergo hybrid palliation in the catheterization laboratory using previously described techniques [2].

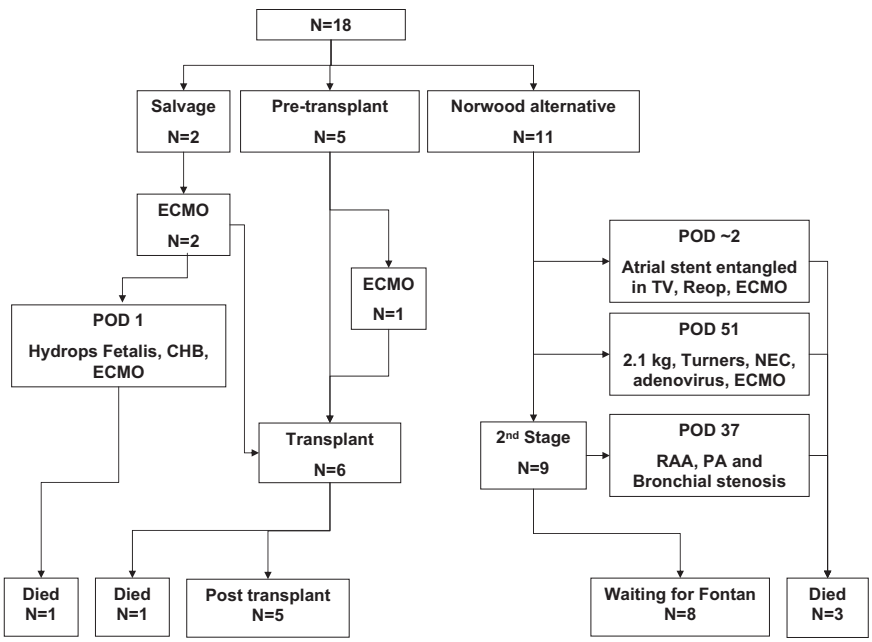

Fig 1. Schematic depicts patient outcomes for neonates undergoing the hybrid procedure for each of three primary indications. (CHB = complete heart block; ECMO = extracorporeal membrane oxygenation; NEC = necrotizing enterocolitis; PA = pulmonary artery; RAA = right aortic arch; POD = postoperative day; TV = tricuspid valve.)

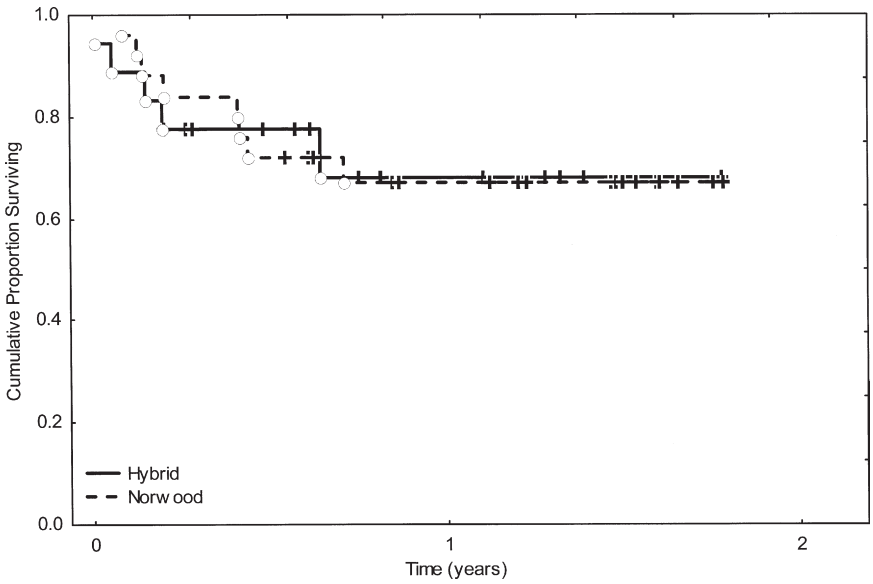

Fig 2. Patient survival stratified by hybrid (solid line) or Norwood procedure (dashed line) group (p = 0.91). Each circle or hashmark represents a single patient after an uncensored or censored interval, respectively.

Through a median sternotomy, bilateral PABs are placed using 3.5-mm polytetrafluoroethylene conduits divided longitudinally and wrapped around the branch pulmonary arteries for a distance of about 3 mm. The DS is then performed through a purse string in the main pulmonary artery under fluoroscopic guidance. Confirmation of the PAB is then made using fluoroscopy.

In patients with aortic atresia, we and others [4] have been concerned that malplacement of the ductal stent could restrict retrograde flow to cerebral and coronary circulation across the aortic isthmus. To protect against this potential problem, we used a reversed Blalock-Taussig shunt from the main pulmonary artery to the innominate artery in 6 patients, as previously described [5].

Treatment of the atrial septum evolved during the timeframe of the study. In the earlier portion of our experience, we aggressively pursued decompression of the atrial septum with balloon septostomy or stenting at the time of the PAB/DS procedure. As it became apparent that this practice could be safely deferred in patients with mild-to-moderately restrictive atrial septal defects, we delayed procedures designed to decompress the left atrium until a few days after the PAB/DS procedure. At this later setting, the patients were more stable and appeared to better tolerate the instrumentation required. Thin atrial septae were decompressed with balloon septostomy, and stents were placed when the atrial septum was thick or septostomy decompression was inadequate. Close monitoring (eg, weekly echocardiograms for the first month and biweekly echocardiograms thereafter) was used, with repeat septostomy or atrial septal stenting at subsequent procedures as needed.

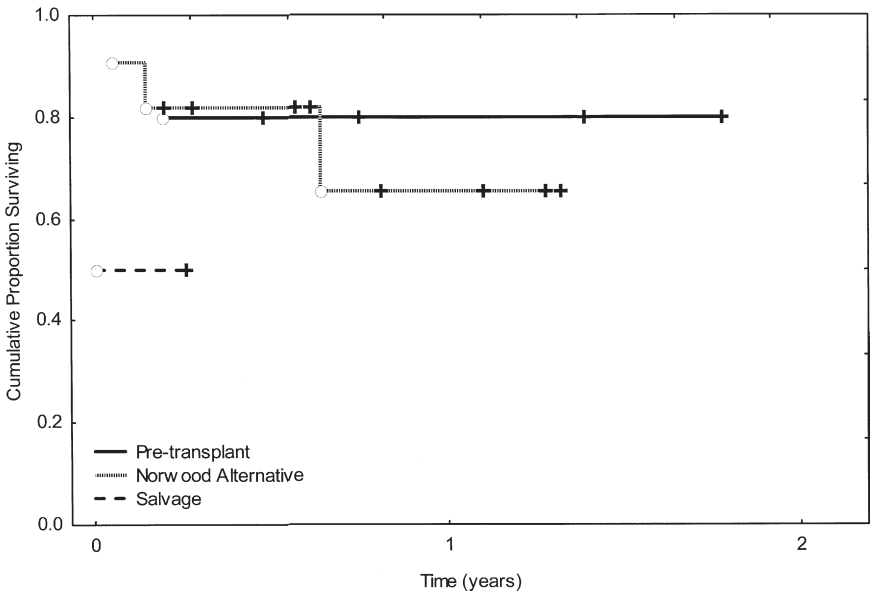

Fig 3. Patient survival stratified by indication of pretransplant (solid line), Norwood alternative (patterned line,) or salvage (dashed line; p = 0.46). Each circle or hashmark represent a single patient after an uncensored or censored interval, respectively.

Norwood procedures were performed using standard surgical techniques, regional cerebral perfusion, and modified Blalock-Taussig shunts. Postoperative management was according to standardized protocols, including continuous monitoring of superior vena cava saturations and liberal use of systemic vasodilation with phenoxybenzamine and milrinone [6].

Statistical Analysis

All data analyses were performed using Statistica 6 software (Statsoft, Inc, Tulsa, OK). Data are presented as frequency, median with range, or mean ± standard deviation, as appropriate, with the number of nonmissing values indicated. Unrelated two-group comparisons were performed with unpaired, two-tailed t tests for means of normally distributed variables, or the Mann-Whitney test for nonnormal data. Paired data were examined using paired two-tailed t tests. Time-related freedom from death was analyzed by the Kaplan-Meier method.

Results

Patient Characteristics

General patient characteristics are summarized in Table 1 and were similar between Norwood and hybrid groups.

The indications for hybrid procedures and subsequent outcomes are depicted in Figure 1. Eighteen hybrid procedures were performed for one of three indications: Norwood alternative (n = 11), pretransplant palliation (n = 5), and salvage procedures (n = 2). Overall patient survival for the entire hybrid group was about 68% at 2 years and was similar to the concurrent Norwood group (p = 0.91, Fig 2). Patient survival stratified by each indication for the hybrid procedure is shown in Figure 3.

The Hybrid Procedure As a Norwood Alternative

Eleven patients underwent hybrid procedures as an alternative to Norwood-based first-stage palliation.

Two patients died after the first-stage hybrid procedure. One patient was a 2.1-kg neonate with Mosaic Turner syndrome. After hybrid palliation, the patient failed multiple extubation attempts, and necrotizing enterocolitis developed. Severe adenoviral pneumonitis developed after a prolonged intensive care unit (ICU) stay, and the patient eventually required extracorporeal membrane oxygenation (ECMO) for pulmonary support. The patient died on postoperative day 53.

A second patient, with aortic atresia/mitral stenosis, had an uneventful hybrid procedure and was returned to the catheterization laboratory for atrial stenting. The atrial stent had an open-cell design that became entangled in the tricuspid valve and resulted in progressive tricuspid insufficiency. The patient was returned to the operating room for tricuspid valve repair, atrial septectomy, and retrieval of the stent. In the postoperative period, there was severe myocardial dysfunction believed due to intramyocardial air embolism derived from air captured in the diminutive left ventricle through left ventricle–to–coronary artery sinusoidal connections. ECMO support was initiated, but ventricular function failed to recover and the patient died on postoperative day 18.

One patient who had hybrid repair died after second-stage palliation. This patient had an unbalanced atrioventricular septal defect and a right aortic arch. The first-stage hybrid palliation was uneventful. The right aortic arch reconstruction at the time of second-stage palliation caused compression of the pulmonary arteries, which required pulmonary artery stenting, takedown of her cavopulmonary shunt, and eventually stenting of the right mainstem bronchus. A respiratory arrest occurred on postoperative day 37, from which she was not resuscitated.

The duration of intubation, ICU time, and hospital length of stay was recorded for all survivors undergoing Norwood procedures or Norwood alternative hybrid procedures and is presented as the sum total for first-stage and second-stage procedures (Table 2). Nonsurvivors and a patient who remained hospitalized from the time of Norwood procedure to the time of the stage II procedure were excluded. The combined total of both admissions is reported because the first-stage hybrid procedure may require less hospital time than a Norwood; however, the second-stage procedure may require more hospital time than a simple cavopulmonary shunt. When combined times for first-stage and second-stage procedures among survivors were compared, the hybrid procedures were associated with trends towards shorter intubation times, ICU times, and hospital lengths of stay than Norwood procedures.

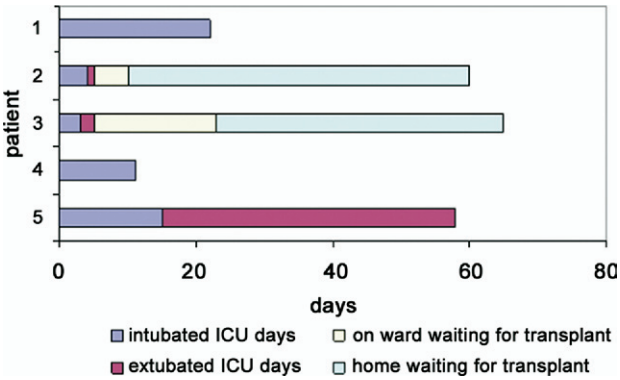

Fig 4. Bar chart illustrates the clinical course of patients undergoing hybrid procedures for pretransplant palliation. Time zero represents hybrid palliation and each bar terminates at the time of transplantation. Patients 2 and 3 were discharged home before transplantation.

Table 2. Combined Times for Stage I and Stage II Procedures

Time (days)[a]	Hybrid	Norwood	p Value
Intubation	7 (3–24)	13 (5–61)	0.197
Length of stay			
Intensive care unit	11 (9–31)	18 (9–74)	0.101
Hospital	30 (20–66)	32 (20–184)	0.223

[a] Data are presented as median (range).

The Hybrid As Pretransplant Palliation

Five patients underwent pretransplant palliation with the hybrid procedure. Figure 4 illustrates the time course of postpalliation events. The patients who were chronically ill in the ICU (eg, more than 1 week of intubation before hybrid procedures) were slower to extubate and required longer posthybrid ICU stays. Patients who were palliated for more elective indications (eg, tachypnea, failure to thrive) were extubated within 2 days of the hybrid procedure and were discharged home before transplantation (patients 2 and 3 in Fig 4).

All patients subsequently underwent transplantation. The interval between hybrid palliation and subsequent transplantation was 10, 11, 58, 60, and 65 days.

One patient required ECMO support after hybrid palliation and was supported until undergoing ABO-incompatible transplantation after 22 days. Diffuse myocardial calcification developed, and the patient died 49 days after transplantation.

The objective of hybrid palliation was to preserve the patient's respiratory and cardiovascular stability while awaiting a donor organ. One patient remained intubated until undergoing transplantation 11 days after the hybrid procedure. The remaining 3 patients were extubated before transplantation. One was extubated after 15 days and remained in the ICU for 43 more days until undergoing transplantation. Two patients were discharged home, and after intervals of 42 and 50 days, returned to the hospital for uneventful transplantation.

The Hybrid for Salvage Procedures

Two patients underwent hybrid procedures after hemodynamic stability was not obtainable in the ICU with standard supportive measures. One patient was diagnosed with fetal hydrops and congenital complete heart block in utero and had an unbalanced atrioventricular septal defect. After delivery, the patient was severely edematous and had hemodynamic derangements consistent with inadequate cardiac output in association with excessive pulmonary blood flow. After placement of temporary pacemaker wires, the patient was brought to the catheterization laboratory for placement of bilateral PABs. During the procedure, the patient was extremely unstable and was placed on ECMO. After weaning from ECMO, the patient destabilized and sustained another cardiac arrest refractory to resuscitative measures.

The second salvage patient had hypoplastic left heart syndrome with aortic atresia and had evidence of repetitive episodes of myocardial ischemia before intervention. These episodes were believed due to coronary steal through ventricular-coronary fistulae. Consequently, the patient was not considered to be a satisfactory Norwood candidate and was recommended for hybrid palliation. The patient was unstable during the hybrid procedure and required ECMO support until undergoing transplantation on postoperative day 10. The patient's posttransplant course has been unremarkable. Of interest, the explanted heart was noted to have diffuse myocardial necrosis.

Comment

Hybrid palliation with bilateral PAB and stenting of the ductus arteriosus offers a method to achieve control of pulmonary blood flow and unobstructed systemic cardiac output in neonates with single-ventricle physiology. The strategy is useful for multiple indications, including an alternative to Norwood-type palliation, stabilization of patients before transplantation, and as a method of salvaging patients in whom stability cannot be obtained with standard ICU techniques.

As an alternative to the Norwood procedure, survival after the hybrid procedure was comparable with our well-established Norwood program. This comparison is made while acknowledging that the hybrid strategy is on the early portion of the learning curve, whereas the Norwood program is relatively mature, with decades of experience [6]. Survival after the Norwood procedure has been reported to have a significant era effect, with more favorable results in the more recent era [7]. Because the hybrid strategy is relatively new, only limited data are available, suggesting that the hybrid procedure will enjoy a similar era effect. Galantowicz and colleagues [1] have reported a rapid improvement in survival over a 3-year period after initiation of a hybrid program.

Refinement of the indications for a hybrid procedure as an alternative to the Norwood procedure is currently evolving. Some centers have considered relative contraindications to the hybrid procedure according to the geometry of the aortic arch and isthmus area in patients with aortic atresia due to the potential for obstruction to retrograde flow in the aortic isthmus [1, 4]. We have used a shunt from the pulmonary artery to the innominate artery to provide an alternative source of blood flow to the aortic arch and have not considered aortic atresia to be a relative contraindication to a hybrid procedure. In contrast, Galantowicz and colleagues [8] have defined specific anatomic characteristics of the aortic isthmus that are thought to be at risk for obstruction and have considered these characteristics to be a relative contraindication to DS.

Refinement of indications for the hybrid procedure is also required to determine its suitability in patients with preoperative tricuspid insufficiency and ventricular dysfunction. Because cardioplegic arrest may result in diminished ventricular function and exacerbation of tricuspid insufficiency, it is tempting to speculate that avoidance of cardioplegic arrest and cardiopulmonary bypass with the hybrid procedure will result in myocardial preservation that is superior to the Norwood procedure.

Refinement of the indications for the hybrid procedure in small neonates (<2.5 kg) is also evolving. We have found that extremely small changes in the circumference in the PABs can have marked effects on the amount of pulmonary blood flow demonstrated on angiography at the time of the hybrid procedure. Consequently, avoiding complete occlusion of the pulmonary artery while creating the desired amount of obstruction can be difficult, and this sensitivity to small changes in circumfer-

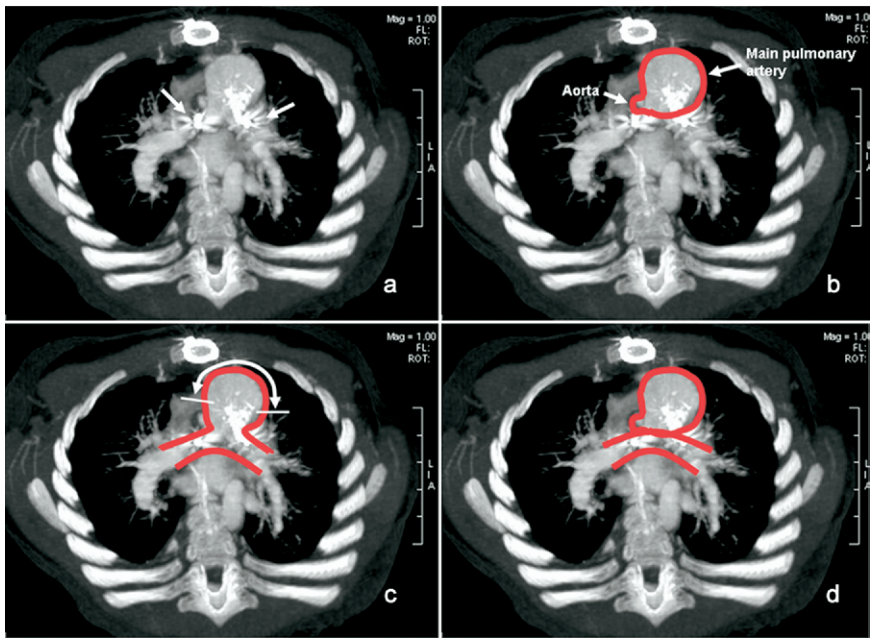

Fig 5. Representative computed tomography scan of a patient after the hybrid procedure immediately before stage II palliation. The bilateral pulmonary artery bands are seen in (a). The aorta and main pulmonary artery are outlined in (b). Panel c outlines the pulmonary artery confluence, which must remain posterior to the reconstructed aortic arch (composed of the ascending aorta and homograft of approximately the same diameter as the main pulmonary artery). The central confluence typically is bulky and excessive and can cause pulmonary artery compression through twisting and kinking when left intact behind the reconstructed aortic arch. Generous resection at the points marked by the curved arrow results in a slender, nonobstructive pulmonary artery confluence (d).

ence is maximized in the smallest patients. Pulmonary overcirculation after hybrid procedures is a common event, and small neonates may be at particular risk [9]. Prospective comparison of the hybrid and Norwood procedure will be required to establish the relative efficacy of these management strategies in the face of small size as well as other modifiers of case complexity noted above (eg, ventricular dysfunction, tricuspid insufficiency).

In the current series, we are optimistic that we have gained valuable experience that will result in future improvements. Many of the deaths incurred were related to easily identifiable technical errors, and this recognition is incorporated into our institutional knowledge, with improvements in future management. For example, the use of an open-cell design for the stenting of the atrial septum in the present series led to entrapment of the tricuspid valve chordae and initiated a train of events leading to the patient's death. This is an example of an unforeseen technical issue that can be easily prevented in the future by avoidance of an open-cell stent design.

A second important lesson learned was the use of the hybrid procedure as an attempt to salvage a critically ill neonate with fetal hydrops, congenital complete heart block, and severe hemodynamic instability. The hybrid procedure is not a magic bullet that immediately stabilizes the patient, and consideration of this point is warranted in counseling parents before embarking on a procedure in an extremely unstable patient.

This consideration has led us to earlier referral for patients requiring pretransplant palliation. Pretransplant palliation with the hybrid procedure allowed extubation in most of our pretransplant palliation patients and discharge home to await a donor organ in 2 of 5 patients. As our experience has evolved, it has become apparent that earlier institution of hybrid palliation, before hemodynamic instability, has been associated with more favorable recovery from the procedure and a greater likelihood of early extubation and discharge to home.

It remains, however, exceedingly difficult to determine the ideal timing of the hybrid procedure in mildly symptomatic patients because the arrival of a donor organ cannot be predicted [10]. Waiting until a patient has begun to deteriorate on the ventilator or has severe hemodynamic instability may result in a more difficult hybrid palliation procedure as well as the accumulation of risk factors for subsequent transplantation (eg, necrotizing enterocolitis, ventilator-associated pneumonia).

Conversely, a threshold for recommending hybrid palliation that is too low will result in some patients incurring complications associated with the hybrid procedure that could be avoided if they were left unpalliated to await the arrival of a donor organ. Recognizing the difficulty of this clinical dilemma, we currently use the following as criteria for hybrid pretransplant palliation: respiratory compromise (eg, persistent tachypnea), failure to thrive due to pulmonary overcirculation, or any complication associated with systemic hypoperfusion.

Another technical difficulty encountered at the time of stage II reconstruction was the large amount of redundant main pulmonary artery, which is proportionally greater than that encountered during a Norwood procedure. After creating a neoaortic arch, composed of ascending aorta and homograft of roughly the same diameter of the main pulmonary artery, we found it difficult to accommodate the redundant pulmonary artery tissue behind the reconstructed aortic arch (Fig 5a, b). The bulk of this excess tissue was noted to cause pulmonary artery obstruction due to kinking and twisting. Paradoxically, generous resection of the pulmonary artery confluence prevents obstruction from this mechanism (Fig 5c, d).

One of the appealing advantages of the use of the hybrid strategy is that the clinician does not burn any

bridges and a patient can cross over into a different management pathway with more facility than can be obtained after Norwood palliation. For example, a patient managed with a hybrid strategy for pretransplant palliation is well suited to undergo transplantation because a bypass run with associated transfusions and the potential for homograft-related sensitization, which can limit the pool of acceptable donor organs, [11, 12] has been avoided. If a donor organ does not become available, the patient can undergo stage II palliation and crossover into the Fontan track without any additional risk beyond that associated with an initial choice of a Fontan track management strategy. Thus, the patient has not incurred additional risk by crossing over.

Hybrid palliation has theoretic advantages that may offer superior benefits to the Norwood procedure for neonates with single-ventricle physiology. At the onset, our experience with this procedure has been favorable, with outcomes that are equivalent to our Norwood experience and the additional benefit that the strategy can be extended to pretransplant palliation and salvage procedures. We speculate that we will be able to refine our techniques and obtain more favorable outcomes in the future.

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