

Hybrid stage 1 palliation with simultaneous off-pump ventricular assist device placement in neonates with high-risk single ventricle anatomy: Initial experience



Constantine D. Mavroudis, MD, MSc, MTR, Matthew J. O'Connor, MD, Carol Wittlieb-Weber, MD, Jonathan B. Edelson, MD, Jonathan J. Edwards, MD, Justin H. Berger, MD, PhD, Kimberly Y. Lin, MD, Joseph Rossano, MD, and Katsuhide Maeda, MD, PhD

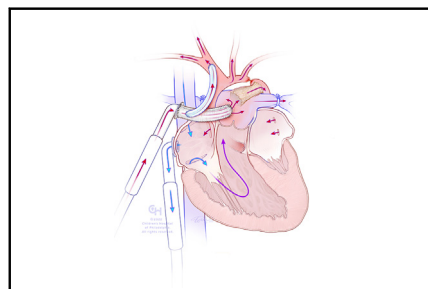
ABSTRACT

Background: Infants with single ventricle heart disease and severe atrioventricular valve regurgitation have poor outcomes following conventional staged palliation. As such, ventricular assist device (VAD) placement along with hybrid stage 1 palliation has been proposed as a bridge to heart transplant. We present a novel surgical technique for VAD implantation concurrent with hybrid stage 1 that avoids cardiopulmonary bypass.

Methods: We performed a retrospective review of our institutional experience with this novel surgical technique.

Results: Three patients (weight, 2.7-3.5 kg; age, 3 to 5 days) underwent hybrid stage 1 with VAD placement, consisting of bilateral 3.5-mm expandable polytetrafluoroethylene (PTFE) pulmonary artery bands, a ductal stent, a 6-mm Berlin Heart outflow cannula onto the main pulmonary trunk with a 10-mm graft, a 6-mm Berlin Heart outflow cannula onto the right atrium, and a 10-mL Berlin Heart pump. In patients with severe aortic arch hypoplasia or coarctation, a 4-mm PTFE graft was sewn from the VAD outflow graft to the innominate artery to protect coronary and cerebral perfusion. Procedures were performed off bypass with minimal blood product use. Patients were extubated on postoperative days 2, 2, and 5. There were no procedural complications. All patients were transferred out of the intensive care unit and demonstrated appropriate weight gain. Anticoagulation strategy was bivalirudin and antiplatelet therapy. The patients underwent transplantation after 149 days, 157 days, and 288 days of support.

Conclusions: Off-pump single ventricle VAD placement is technically feasible and can be done at the time of hybrid stage 1 palliation with minimal operative morbidity as a bridge to transplant. (JTCVS Techniques 2024;24:164-8)



Single ventricle VAD placement during hybrid stage 1, performed off-pump.

CENTRAL MESSAGE

Off-pump single ventricle ventricular assist device placement is technically feasible and is possible at the time of hybrid stage 1 palliation with minimal operative morbidity as a bridge to transplant.

PERSPECTIVE

A single ventricle ventricular assist device can be placed at the time of hybrid stage 1 palliation without the use of cardiopulmonary bypass. This technique may allow for quicker recovery, less blood product exposure, and less morbidity while providing a stable platform for bridge to transplant in patients who are not candidates for conventional staged palliation.

See Discussion on page 169.

From the Divisions of Cardiothoracic Surgery and Cardiology, Children's Hospital of Philadelphia, Philadelphia, Pa.

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Address for reprints: Constantine D. Mavroudis, MD, MSc, MTR, Division of Cardiothoracic Surgery, Children's Hospital of Philadelphia, 3401 Civic Center Blvd, Suite M875, Philadelphia, PA 19104 (E-mail: mavroudisc@chop.edu). 2666-2507

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Abbreviations and Acronyms

AVVR	=	atrioventricular valve regurgitation
BNP	=	b-type natriuretic peptide
CPB	=	cardiopulmonary bypass
ICU	=	intensive care unit
PRA	=	panel reactive antibody
PTFE	=	polytetrafluoroethylene
VAD	=	ventricular assist device

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Despite consistent advances in surgical palliation and medical management of single ventricle congenital heart disease, patients with certain anatomic and physiologic substrates continue to have unacceptably poor outcomes. Controversy exists concerning the optimal treatment strategy for these neonates, including those with poor systemic ventricular function and moderate or severe atrioventricular valve regurgitation (AVVR). The poor outcomes following stage I Norwood in these patients have prompted renewed interest in alternative treatment strategies. Although primary cardiac transplantation has been offered as a strategy in these cases, current limitations of the donor pool and resulting extended wait times require mechanical circulatory support strategies that can maintain circulation and minimize end-organ injury while awaiting transplant.

Recently, several groups have described innovative strategies for performing concomitant hybrid stage I palliation with ventricular assist device (VAD) placement to avoid morbidity and mortality associated with salvage VAD placement following attempted conventional stage I Norwood or hybrid palliation.¹⁻⁴ This approach has allowed for successful bridging to transplantation in these high-risk neonates, but the optimal surgical strategies remain elusive. Here we review our institutional experience with a novel cannulation strategy for hybrid VAD placement that avoids the use of cardiopulmonary bypass (CPB), minimizes blood use, and protects against reverse coarctation in high-risk neonates who are poor candidates for conventional staged palliation.

METHODS

We conducted a retrospective review of our experience with simultaneous off-pump hybrid VAD placement between June 2021 (our first case) and March 2023. According to institutional standard operating protocol, any retrospective study of fewer than 5 patients is exempt from Institutional Review Board review. Therefore, this study was exempt from Institutional Review Board review. Demographic, procedural, and outcome data were collected from the electronic medical record. Informed consent

was not obtained from subjects because the study data were completely de-identified, contained no images that could be linked to patient identifiers, and did not fall under what our institution considers research that requires patient-level consent to present or publish. Because of the descriptive nature of this study, no statistical tests of significance were performed.

Surgical Methods and Cannulation

All patients underwent bilateral pulmonary artery banding using a 3.5-mm graft (ExGraft; PECA Labs). The use of such an expandable graft as a banding material permits the theoretical possibility of catheter-based pulmonary artery band adjustment to compensate for somatic growth during long waiting times. In each case, a side-biting clamp was applied to the main pulmonary artery, a pulmonary arteriotomy was performed, and a 10-mm Gelweave graft (Terumo Cardiovascular Systems) was sewn to the main pulmonary trunk. This graft was then backbled and used as the access for ductal stenting. Following ductal stenting, this graft also served as VAD outflow by securing it to a 6-mm outflow cannula (Berlin Heart North America) (Figure 1).

In those patients who had coarctation of the aorta or in whom the development of coarctation of the aorta was deemed likely, a 4-mm polytetrafluoroethylene (PTFE) graft (WL Gore) was sewn from the Gelweave graft to the innominate artery to protect the cerebral and coronary circulations (Figure 2) without the use of an isthmal stent. VAD inflow in all cases was performed via direct right atrial cannulation using a 6-mm Berlin Heart outflow cannula (Figure 1). A pursestring suture was placed along the lateral aspect of the right atrium, and 4 pledgeted sutures were placed in the 4 quadrants of the sewing ring and through the 4 quadrants of the proposed atriotomy. A right atriotomy was performed, and the cannula was parachuted down via the pledgeted sutures and advanced into the atrium. The pledgeted sutures were tied down and were run circumferentially for hemostasis. In our first case using this technique, we administered intravenous adenosine (0.3 mg/kg) to arrest the heart, optimize cannula positioning, and avoid air entrainment. We then modified our technique and inserted the atrial cannula directly without arresting the heart. We did not experience any issues with inflow cannula malposition or obstruction. The cannulas were then tunneled, deaired, and connected to a 10-mL Berlin Heart pump to target a VAD index of ≥ 5 L/min/m². All operations were done without the use of CPB and with minimal blood product administration. Pump changes were made as needed to treat thrombosis and/or to up-size in the event of somatic growth.

Patient 1

This 5-day-old, 2.7-kg male was born at term with a prenatal diagnosis of hypoplastic left heart syndrome (mitral atresia, aortic stenosis), muscular ventricular septal defect, and severe tricuspid regurgitation. He underwent successful hybrid VAD placement using a brief period of adenosine-induced (0.3 mg/kg) cardiac arrest during atrial cannulation. The arch and atrial septal communication were deemed adequate at this point and were not addressed. The patient was extubated on postoperative day 5. The intensive care unit (ICU) course was complicated by an increasing gradient across the interatrial septum that prompted balloon atrial septostomy on postoperative day 17, with subsequent improvement. An increasing retrograde coarctation gradient prompted cardiac catheterization and stenting of the aortic isthmus on postoperative day 65, with resulting improvement.

The patient was discharged from the ICU on postoperative day 71 and remained in the step-down unit until transplantation was performed, following 157 days of support. He required one Berlin Heart pump exchange on postoperative day 58. He experienced a brief elevation of b-type natriuretic peptide (BNP) level to 1000 pg/mL during the diagnosis and treatment of coarctation, but otherwise these values and serum creatinine were within normal limits throughout the duration of support. He was able to grow and feed throughout his time on VAD. Prior to transplant, his

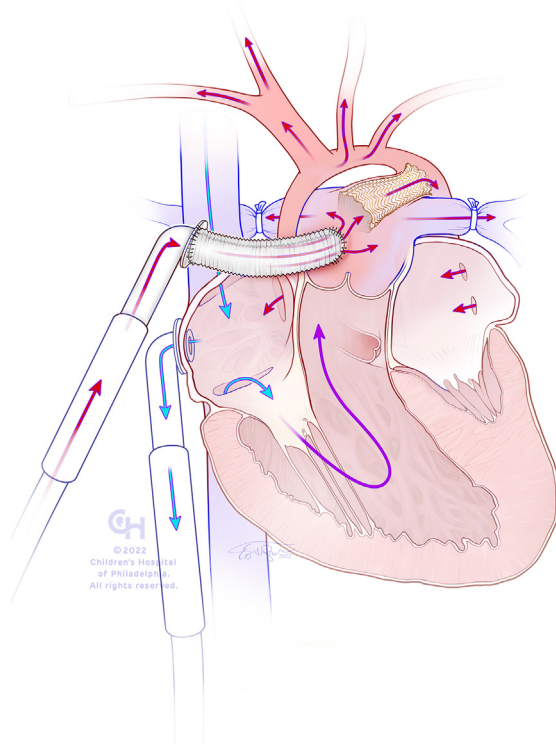


FIGURE 1. Illustration of the cannulation strategy for hybrid ventricular assist device placement, with common atrial inflow cannula and outflow cannula sewn to a chimney graft sewn to the main pulmonary trunk. Note the presence of pulmonary artery bands and a ductal stent.

class I panel reactive antibody (PRA) was 8%, and his class II PRA was 0%. His weight at the time of transplant was 5.75 kg (1.5th percentile). His intraoperative course was notable for poor aortic tissue quality following removal of the isthmal stent, which complicated aortic arch reconstruction. Although this did not result in any technical complications or increased graft ischemic time, this experience led us to abandon isthmal stenting in these patients.

Post-transplantation, the patient developed graft failure necessitating bi-ventricular assist device placement. His condition progressed to multiorgan failure, and care was withdrawn at 19 days post-transplant.

Patient 2

This 3-day-old, 2.8-kg male was born at term with a prenatal diagnosis of heterotaxy (asplenia), unbalanced atrioventricular canal to the right with left ventricular hypoplasia, double-outlet right ventricle, severe AVVR, and ipsilateral pulmonary veins. He underwent successful hybrid VAD placement. The aortic arch and interatrial septum were deemed adequate and were not addressed. He was then extubated on postoperative day 2 and had a prolonged but uncomplicated ICU stay of 41 days. He required one Berlin Heart pump exchange on postoperative day 97. Following 149 days of support, he underwent successful cardiac transplantation. His BNP remained low, and his serum creatinine remained within normal limits. He was able to feed and grow throughout his time on support.

Before transplant, his class I and II PRA were 0%. His weight at the time of transplant was 6.8 kg (11.8th percentile). Post-transplant, he experienced graft failure necessitating extracorporeal membrane oxygenation support. His condition progressed to multiorgan failure and refractory hypotension, and care was withdrawn at 27 days post-transplantation.

Patient 3

This 3-day-old, 3.5-kg male was born at term with a prenatal diagnosis of a severely unbalanced atrioventricular canal to the left with right ventricular hypoplasia, d-transposition of the great vessels, severe left-sided AVVR, large anterior malalignment ventricular septal defect, mild ascending arch hypoplasia, and discrete coarctation of the aorta. He underwent successful hybrid VAD placement. To address the aortic coarctation, a 4-mm PTFE (WL Gore) side graft was sewn from the VAD outflow graft to the innominate artery prior to initiation of VAD support.

The patient was extubated on postoperative day 2 and had an uncomplicated ICU course, leading to discharge from the ICU on postoperative day 14. He underwent Berlin Heart pump exchanges on postoperative days 24, 54, 104, and 170. He suffered a hemorrhagic stroke on postoperative day 205 but demonstrated good recovery, with no obvious residual defects. His BNP remained low, and his serum creatinine remained within normal limits.

Following 288 days of support, he underwent successful cardiac transplant. He was able to feed and grow throughout his time on support, achieving a weight of 8.5 kg (29.9th percentile) at the time of transplant, and his class I and class II PRA were 0%. His post-transplantation course was unremarkable. He underwent delayed sternal closure and extubation on postoperative day 2, was discharged from the ICU on postoperative day 6, and was discharged from the hospital on postoperative day 13.

DISCUSSION

These 3 cases demonstrate our initial experience with our newly implemented strategy of concomitant off-pump VAD placement and hybrid stage 1 palliation in neonates deemed at unacceptably high risk for conventional staged palliation. The advantages of this technique include the avoidance of CPB with minimal blood product use and its associated morbidities; ductal stenting through a side graft instead of directly cannulating the main pulmonary artery; the ability to bypass aortic coarctation and equalize flow to systemic, cerebral, and coronary circulations; and avoidance of the tenuous physiology of conventional staged palliation with high-risk features, such as severe AVVR. Additional benefits include the ease with which the VAD outflow graft can be cannulated or the entire VAD system can be converted for CPB at the time of transplant. Furthermore, the use of a bypass graft avoids aortic isthmal stent placement, which can complicate arch reconstruction at the time of transplant.

Our technique differs from the reported operative strategies primarily in the avoidance of CPB. Previous reports have used CPB with either cardioplegic or fibrillatory arrest.¹⁻⁵ Putative advantages of avoiding CPB in these patients include decreased coagulopathy and resulting blood transfusions, decreased pulmonary and renal morbidity, and potentially decreased ICU-related and postoperative morbidities. Because our experience with hybrid palliation and VAD is relatively new, we are not able to make any comparisons between patients who underwent a single stage, off-pump hybrid VAD procedure and patients who had either sequential hybrid and later VAD placement or patients who underwent hybrid VAD procedures while on CPB. As we have gained experience with this technique and in managing these patients, our ICU length of stay has

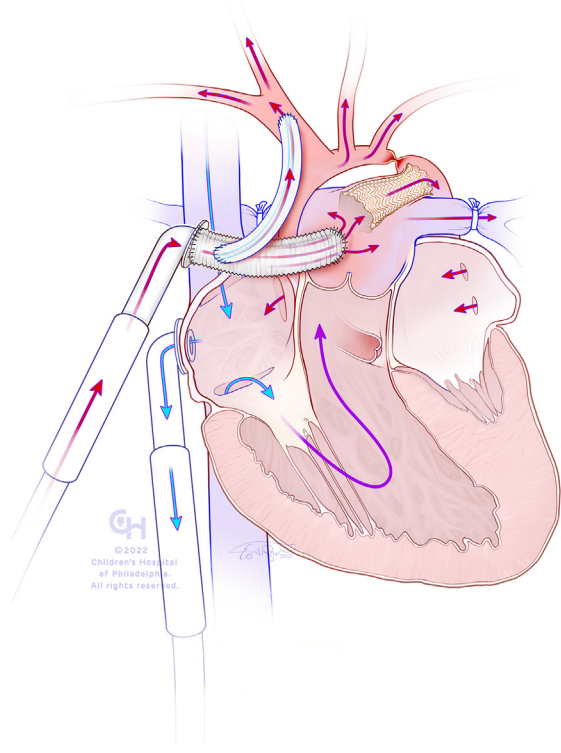


FIGURE 2. Illustration of the cannulation strategy for hybrid ventricular assist device placement in patients with a hypoplastic aortic arch or aortic coarctation, with common atrial inflow cannula and outflow cannula sewn to a chimney graft sewn to the main pulmonary trunk, with an additional graft sewn from the outflow graft to the innominate artery. Note the presence of pulmonary artery bands, a ductal stent, and aortic coarctation.

decreased, suggesting that there may be a learning curve associated with introducing this surgical strategy.

Interestingly, Merritt and colleagues,² in a report of their univentricular VAD strategies, stated that they initially attempted off-pump VAD placement in these patients but abandoned this technique after experiencing issues with VAD inflow. We have not encountered any issues with VAD inflow in our current cannulation strategy. Further studies will be needed to determine whether the theoretical advantages of avoiding CPB translate into improved outcomes. Our mean duration of ventilation of 3 days is shorter than previous reports (7 ± 3 days¹), and ICU length of stay, while heterogeneous, is also considerably shorter than what has been reported previously,⁵ suggesting that there may be some benefit from avoiding CPB in these patients.

Despite these differences, many aspects of our intraoperative and postoperative care are similar to what have been reported previously. The use of Berlin Heart outflow cannulas minimizes the interface between the cannula and the atrium, while the interposition graft connected to the outflow cannula allows for unobstructed flow and optimal cannula positioning away from the midline. Furthermore,

as has been described previously,¹ our institutional preference is to use bivalirudin for anticoagulation. As other groups have reported, early initiation of mechanical support and avoiding accrual of morbidity and organ dysfunction are key to stabilizing these patients and optimizing their candidacy for transplant.¹⁻⁵ The VAD support times reflect the unfortunate reality of prolonged waitlist times for neonates, and are similar to what has been reported previously.¹ Avoiding small cannulas and small interposition grafts can help decrease the risk of hemolysis and its associated comorbidities. Notably, none of our patients demonstrated significant hemolysis or renal insufficiency during their support time.

The preliminary nature of this study and small patient population challenges interpretation of the post-transplant outcomes. Although only 1 patient survived to discharge, all patients were nutritionally replete, hemodynamically stable, and mostly unsensitized at the time of transplant. The profound graft dysfunction that occurred in 2 patients is difficult to explain and reflects both the unique challenges that these children face and an incomplete understanding of how best to prevent and manage graft dysfunction in these fragile children. All hybrid VAD patients have risk factors for graft dysfunction, including a VAD at the time of transplantation and congenital heart disease. Of note, graft ischemic times for our 3 patients were 286, 200, and 228 minutes. Other groups have published more auspicious transplant outcomes,¹ and we anticipate that our incidence of graft dysfunction in these patients will regress to a previously reported level.⁶

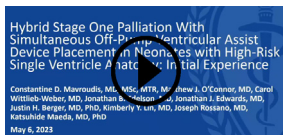
Improvements in surgical methods have prompted renewed interest in early initiation of ventricular assist as a bridge to transplant in high-risk single ventricle neonates. Although such improvements have shown considerable promise as a stable platform on which to bridge these high-risk neonates to cardiac transplant, the optimal surgical and treatment methods remain to be established. Challenges to VAD placement in these patients include higher flows to accommodate single ventricle physiology, somatic growth while awaiting transplantation, the potential for prolonged ICU stay and inability to be discharged home, bleeding that can lead to blood product administration and subsequent immunologic sensitization, and anatomic challenges such as reverse coarctation and the need for durable pulmonary blood flow. Our strategy of avoiding CPB in hybrid stage 1 palliation with VAD placement attempts to overcome many of these challenges while avoiding the operative complexity and morbidity associated with CPB. Although the hybrid VAD physiology imparts long-term ductal stenting and pulmonary artery banding that may complicate later cardiac transplant, we have found that aortic arch and pulmonary artery reconstruction is technically feasible at the time of transplant. Furthermore, by avoiding the long-term sequelae of valve regurgitation

and/or heart failure, patients can arrive at cardiac transplant without as much end-organ injury.

This strategy might not be feasible for all patients, as some patients may need surgical septectomy or other concomitant procedures that require CPB. However, in selected patients, this strategy can be performed with acceptable short-term results. Further studies are needed to establish optimal surgical techniques and improve outcomes in this very high-risk group of patients.

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: <https://www.aats.org/resources/hybrid-stage-1-palliation-with-simultaneous-off-pump-ventricular-assist-device-placement-in-neonates-with-high-risk-single-ventricle-anatomy-initial-experience>.



Conflict of Interest Statement

Dr Rossano has served as a consultant for Bayer, Merck, Bristol Myers Squibb, and AskBio. Dr Maeda reported serving as a surgical consultant for Berlin Heart, Abbott Laboratories, and PECA Labs. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: congenital heart disease, single ventricle heart disease, heart failure, staged palliation, ventricular assist device, hybrid procedure, bridge to transplant