

Review Article



Pediatric Ventricular Assist Device

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ABSTRACT

There have been great advances in ventricular assist device (VAD) treatment for pediatric patients with advanced heart failure. VAD support provides more time for the patient in the heart transplant waiting list. Augmented cardiac output improves heart failure symptoms, end-organ function, and general condition, and consequently provides beneficial effects on post-transplant outcomes. Miniaturized continuous flow devices are more widely adopted for pediatric patient with promising results. For infants and small children, still paracorporeal pulsatile device is the only option for long-term support. Younger age, congenital heart disease, biventricular support, patient's status and end-organ dysfunction at the time of implantation are risks for poor outcomes. Patient selection, timing of implantation, and selection of device for each patient are critical for optimal clinical outcomes.

Keywords: Heart failure; Pediatric; Ventricular assist device; Extracorporeal membranous oxygenation; Cardiac transplantation

INTRODUCTION

Advances in mechanical circulatory support have changed the management strategy of the advanced heart failure. Heart transplantation had been the only solution for end-stage heart failure refractory to medical management. With the technological development, more durable and smaller ventricular assist devices (VADs) with less complication became available and accumulation of clinical experience made improvement in care of patients on mechanical circulatory support. Durable implantable VAD has become a standard mode of care for advanced heart failure. In the current era, 30–50% of patients listed for heart transplant utilize a bridge to transplant strategy. VAD is also adopted as a mode of long-term destination therapy (DT) for end-stage heart failure.

Like adults, number of pediatric patients with advanced heart failure is increasing.¹⁾ The evolution of surgical repair and medical management in congenital heart disease and the availability of cardiac transplantation as a treatment option in end-stage heart disease have increased the need for mechanical cardiopulmonary support in pediatric patients. In many countries, children and infants listed for heart translation tend to have longer waiting time

than adults, and significant portion of the patients die due to progression of the heart failure while awaiting a suitable donor heart. Mechanical circulatory support can improve survival to transplant by allowing critically ill patients to be bridged to transplantation. Despite widely available advanced implantable VADs in adults, devices for small patients are still very limited. In the absence of appropriate sized VADs for pediatric patients, extracorporeal membrane oxygenation (ECMO) has been most widely used mechanical circulatory support for pediatric patients. Although ECMO has advantages such as easy availability, quick initiation of support, low cost and providing oxygenation, it has limitations including limited durability, incomplete decompression of the failing ventricle and relatively high-risk of complications. In a prospective clinical trial of a pediatric VAD in the United States, compared to the propensity-score-matched historical control groups who were undergoing ECMO, survival rates were significantly higher with the VAD support group.²⁾ Definitely ECMO has its role in selected patients, but selection of appropriate mechanical circulatory support are critical for optimize patient's outcomes.

PATIENT SELECTION

The etiology of advanced heart failure in pediatric patient include diverse disease such as acute myocarditis, cardiomyopathy, and various forms of congenial heart disease.³⁾ Patient selection and timing of VAD implantation is important to successful outcome. End-organ dysfunctions such as acute and chronic kidney, liver, pulmonary disease are common complications of end-stage heart failure. Early intervention became the rule in adult heart failure to prevent irreversible end-organ damage and optimize patient outcome.⁴⁾ Experience of VAD in pediatric patients is are still limited compared to those of adult counterparts. However, the Berlin EXCOR[®] USA trial clearly demonstrated that degree of hepatic or renal dysfunction as well as Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile at the time of VAD implantation are major risk factors for mortality.⁵⁾ Clinical review of German Heart Institute's 23-year experience also demonstrated earlier implantation yielded better results.⁶⁾ However, it should be considered that still mechanical circulatory support is not risk-free treatment. To identify the optimal timing, there should be balance between the device related complication risks (thrombosis, anticoagulation related problems, infection, etc.) and the risks of progression of end-organ dysfunction.

Evaluation of need for mechanical circulatory support should begin in any patients requiring inotropes and/or showing signs of worsening heart failure with early evidence of end-organ dysfunction despite medical treatment. An increase in serum blood urea nitrogen, creatinine, hepatic enzymes, worsening pulmonary edema, rising serum lactate, and decrease in mixed venous oxygen saturation are indicators of worsening cardiac output.⁷⁾ Presence or progression of end-organ dysfunction (e.g., neurologic: altered mental status; respiratory: intubated; gastrointestinal: inability to tolerate enteral feeds; serum markers for renal and hepatic function; musculoskeletal: inability to ambulate) should be thoroughly evaluated and monitored.

Hetzer et al.⁶⁾ reported that criteria for VAD implantation have been modified and changed towards earlier implantation. Their current indications are 1) low cardiac output associated with metabolic acidosis; 2) rapid deterioration of the circulation with cardiac index <2.0 L/min/m² with inotrope dependence, especially on epinephrine; 3) mixed venous saturation <40%; 4) oliguria (<1 mL/kg/min); 5) critical peripheral perfusion; and 6)

echocardiographically confirmed massive impairment of cardiac function despite maximal pharmacological treatment, signs of early renal hepatic and respiratory failure and high or progressive increase in B-type natriuretic peptide (BNP) or N-terminal proBNP level.

The contraindications to mechanical circulatory support in pediatric patients are similar to those in adults. When the indication for a VAD is as a bridge to transplantation, any contraindication to transplant constitutes a contraindication to use of mechanical support. Generally, active systemic infection, extreme prematurity, very body weight (<2.0 kg), severe significant neurologic damage, a constellation of congenital anomalies with poor prognosis, and chromosomal aberrations are considered contraindications for mechanical circulatory support.⁸⁾⁹⁾ Multisystem organ failure is a relative contraindication, however special consideration needs to be given as hemodynamic improvement may reverse end-organ dysfunction in some cases. Both hepatic and renal dysfunction have been shown to improve with VAD related improved hemodynamics.¹⁰⁾ Likewise, among the described contraindications, several of these are relative contraindications and need to be evaluated on an individual patient basis.

Pulmonary hypertension and elevated pulmonary vascular resistance are commonly encountered complication of chronic heart failure. VAD support may improve pulmonary hypertension by unloading the left ventricle (LV) and decreasing the left atrial pressures.¹¹⁻¹³⁾ The presence of irreversible pulmonary hypertension is considered a contraindication for VAD support, but still patients should be evaluated for candidate for biventricular support rather than left ventricular support alone before preclude from the mechanical circulatory support.

Neuromuscular disease has generally been considered a contraindication to mechanical circulatory support. However, there has been change in some specific diseases. Duchenne muscular dystrophy (DMD) is an X-linked recessive disorder, characterized by progressive skeletal muscle weakness, loss of ambulation, and death secondary to cardiac or respiratory failure. Improvements in general management and respiratory support, heart failure is a frequent finding in this patient population, and major cause morbidity and mortality, but they are rarely candidates for cardiac transplantation. The use of VADs as a DT in DMD patients has been described.¹⁴⁾¹⁵⁾ The benefit of VAD treatment for this patient group is still unclear and must be studied.

SPECIAL CONSIDERATIONS

Special consideration should be given to small infants and patients with congenital heart disease (CHD) because of limited device options and a higher morbidity profile for these patients. In the congenital heart disease population, several anatomic issues and complex physiologic features make it difficult to implant an assist device. In the presence of intra-cardiac shunt, regulation of pump flow and balancing the patient's systemic and pulmonary circulation under VAD support is very difficult. In short-term support, such patients can be treated with ECMO. For long-term support with VADs, Intracardiac shunt or extracardiac systemic-to-pulmonary shunt including a patent ductus arteriosus, aortopulmonary window or surgically created shunt needs to be ligated or closed prior to implantation of device.

Circulatory support using VAD is more challenging for patients with univentricular physiology. There was successful use of Berlin Heart EXCOR[®] for 7 weeks until heart transplantation

in a 15-month-old patient with single ventricle and systemic to pulmonary artery shunt physiology.¹⁶⁾ Another case report described a successful bridge to transplant a 14-month-old patient.¹⁷⁾ Despite these cases, overall the support option for failing shunted single ventricle patients are limited and the outcomes are poor. For patients with Glenn physiology, there have been reported cases of successful use VAD for ventricular dysfunction.¹⁸⁾¹⁹⁾ Although the evidence is limited and success has been inconsistent, systemic VAD support with a continuous flow device appears to be feasible and may provide an effective support.²⁰⁾

Surgical outcome and long-term survival after Fontan operation had dramatic improvement, however a significant portion of patients will experience Fontan circulatory failure. In patients with failing Fontan circulation, there have been several reports describing successful application of for systemic VAD using pulsatile device²¹⁾²²⁾ and implantable continuous flow VADs.²³⁻²⁵⁾ For this group of patients, continuous-flow (CF)-VAD is regarded superior to the pulsatile VADs.²⁴⁾ In Fontan physiology, there is no subpulmonary ventricle and pulmonary circulation depends on passive flow via cavopulmonary connections. Pulsatile device decompresses the systemic ventricle only during the diastolic phase of the pump. The pulmonary circulation might be more efficient with continuous decompression with CF-VADs than intermittent decompression with pulsatile VADs. There are multiple reasons for Fontan circulatory failure such as systemic ventricular systolic and/or diastolic dysfunction, elevated pulmonary vascular resistance, associated lymphatic abnormalities (chylothorax, protein losing enteropathy, and plastic bronchitis).²⁶⁾ Systemic VAD support will be effective for those who has features of ventricular failure. A case of successful long-term isolated RVAD was also has been reported. A patient with severe right side circulatory failure with preserved ventricular function after Fontan conversion could be successfully bridged with right side VAD support with a Berlin Heart EXCOR[®].²⁷⁾ If Fontan failure is due to other hemodynamic reasons rather than systemic ventricular dysfunction, biventricular support or implantation of total artificial heart (TAH) can be options,²⁸⁾²⁹⁾ although experience is still limited. Indication, timing, mode of support and device selection should be further refined.

Prior to VAD implantation, all patients should be evaluated for valvar insufficiency. Competence of the native aortic valve is important in left ventricular assist device (LVAD) setting. Aortic valvar regurgitant flow can make the device ineffective for hemodynamic support. Aortic valve regurgitation should be addressed prior to implantation of the device. In patients with severe aortic regurgitation with structural abnormality, aortic valve needs to be replaced or closed. For mild to moderate aortic regurgitation simple coaptation stitch at the central portion of the aortic cusps can effectively eliminate the regurgitation.³⁰⁾ In patients with mitral insufficiency, the severity of mitral insufficiency often improves after device implantation. However, in others, the valve may need to be repaired at the time of device implantation, especially for pulsatile VADs.

Another issue that requires special considerations is the small or severely hypertrophic systemic ventricle cavity. In patients with restrictive or hypertrophic cardiomyopathy, the systemic ventricle cavity is small and the standard left ventricular apical cannulation has a significant risk of inflow cannula occlusion. Inflow cannula can be placed in the left atrium for pulsatile VADs. Initial use of Berlin Heart EXCOR[®] was with the left atrial cannula, but LV apical cannula is superior in clinical outcome.³¹⁾ If atrial cannulation is not feasible or for continuous flow devices, aggressive left ventricular myectomy³²⁾ and more aggressively resection of papillary muscle of the mitral valve with mitral valve replacement technique³³⁾ can be used to avoid inflow obstruction.

DEVICE SELECTION

The etiology of advanced heart failure in pediatric patient include diverse disease such as acute myocarditis, cardiomyopathy, and various forms of congenial heart disease.³⁾ The etiologies of heart failure are important to choose the optimal mechanical support devices and mode support.⁸⁾³⁴⁾ Diverse patient's physique is another critical feature of pediatric patients. Patients can present at any time from infancy to adolescent, and these size differences have important implications for support options.

Once a patient is determined to be a candidate for mechanical circulatory support, options of device include ECMO, temporary VAD, or durable VADs.⁸⁾³⁵⁾ In acute settings (cardiac arrest or acute refractory cardiac failure), ECMO is often the first choice because of its rapid availability. It may be delivered by percutaneous venous and arterial cannulation through the neck or femoral vessels. ECMO may be beneficial when there is hypotension despite inotropes, respiratory failure, severe coagulopathy or hepatic dysfunction. However, ECMO support should remain limited to patient with cardiorespiratory failure. The presence of the oxygenator in the ECMO circuit increase the inflammatory response and thereby increase the need for higher anticoagulation level compared to temporary VAD circuit. After a few days of ECMO support, if the patient's pulmonary function is adequate, switch over the ECMO to VAD should be considered to avoid ECMO related complications such as coagulation disorders or infection. Based on the etiology of the disease, short-term or long-term devices are chosen.

Once decision is made to proceed with VAD placement, the next step is to determine if only LVAD is required or if the right heart also need right VAD support. And the device should be chosen based on the anticipated duration of support, the destination of MCS and the availability of devices.

For acute and potentially reversible diseases patients can be supported with temporary VAD. Potential advantages over ECMO are owing to the avoidance of an oxygenator and better unloading of a failing ventricle. Short-term devices are usually used for acute process such as myocarditis, postcardiotomy ventricular dysfunction, or acute cardiac graft rejection with a hope to cardiac recovery and subsequent VAD explant.³⁵⁾ The purpose is to support a patient with acute decompensated heart failure until the patient recovers sufficient cardiac function or until further long-term therapy is indicated based on recovery of end-organ function. Generally, length of support is limited to 2 weeks. Centrifugal flow pumps are most commonly used for temporary ventricular assist. Commonly used pumps include Rotaflow[®] (MAQUET Cardiovascular, Wayne, NJ, USA) and CentriMag[®] (Thoratec Corp., Pleasanton, CA, USA). These pumps require central cannulation and can be used in children of all sizes from neonates to adolescents.

Percutaneous temporary VAD devices are developed and used. These devices can be placed without sternotomy. Tandem Heart (Cardiac Assist Inc., Pittsburgh, PA, USA) is an extracorporeal centrifugal pump with percutaneously placed inflow cannula in the left atrium across the inter-atrial septum and an outflow cannula in the femoral artery. Impella[®] (Abiomed, Danvers, MA, USA) is another type of recently used percutaneous device. It is inserted through the femoral artery and placed in the LV across the aortic valve, it enables continuous blood flow up to 5.0 L/min. These percutaneous devices offer the ability to augment the cardiac output and left heart decompression with a less invasive approach. This can be a valuable operation in the setting of redo-sternotomy or complex anatomy for central

cannulation. However, it cannot be applied for small children and experience in pediatric patients are still very limited.

Short-term devices are also used for bridge to decision purpose. When a patient present with refractory heart failure and the etiology or candidacy for transplantation due to end-organ dysfunction is not clear. For a period of support with short-term devices, these patients may be considered to a long-term VAD if they are indeed candidate for recovery or heart transplant.

In the chronic disease process, implantation of durable VADs provides numerous benefits. The patients can be extubated, fed normally and start exercise or walking to regain physical strength. Presently, more than 95% of the VAD implanted in adults are intracorporeal continuous flow devices.³⁶⁾ The blood pumping mechanism of VAD has changed from pulsatile pumps to continuous flow pump using axial flow or centrifugal flow technology. Much smaller size and less energy consuming feature made it possible to be intracorporeally implanted. Magnetically or hydrodynamically levitating technology pump structure further decrease the risk of thrombosis. continuous flow LVAD is superior to pulsatile devices in stroke and device failure.³⁴⁾ Progressively miniaturization of devices has allowed for implantation of this device for children. The earliest reports of durable VAD use in children were rare and largely limited to the off label use of adult sized pulsatile VADs or short-term smaller, pulsatile pumps.

The HeartMate II (St. Jude Medical, St. Paul, MN, USA) is a Food and Drug Administration (FDA) approved 2nd generation implantable device with axial-flow technology. HeartMate II is approved for bridge to transplant and DT by FDA in the USA, and is the most widely used device in adults with over 20,000 implants worldwide.³⁷⁾ It can be used in adolescent patients probably down to a body surface area (BSA) 1.2 m². The HVAD (HeartWare Inc., Framingham, MA, USA), is a 3rd generation continuous flow VAD with a centrifugal pump. It is even smaller than HeartMate II and is implanted in pericardial space. Owing to Its compact size, the HVAD has been widely adopted in the pediatric patients. It can be used in small patients down to BSA 0.7 m².³⁸⁾³⁹⁾ Analyzing the outcome of 205 pediatric patients demonstrated satisfactory results; a 1-year mortality rate was 10% and the other patients received heart transplantation, explanted for recovery or remained on device support.⁴⁰⁾ Thoratec Company also released a 3rd generation centrifugal pump (HeartMate 3) which is designed to be placed in the pericardial space. Like HVAD, this device may be a good option for pediatric use due to its relatively compact design.

Miniaturized continuous flow devices for infants and children has been developed and some of them got FDA approval for clinical trial. Until now, only device suitable for infants or small children are pulsatile pumps. The Berlin Heart EXCOR[®] (Berlin Heart GmbH, Berlin, Germany) is a pulsatile pneumatically driven paracorporeal VAD. It is the most commonly used pediatric VAD throughout the world and only long-term FDA approved VAD available for neonates and infants in the United States. The variety of pump sizes (10, 15, 25, 30, 50, 60, and 80 mL stroke volume) made it possible to support children ranging from neonates to adulthood. In patients for whom the stroke volume of the pump is insufficient, the pump is easily replaced either in the operation theater or at the bedside.⁶⁾ Multiple studies have demonstrated the benefit of VAD support on mortality and overall condition at transplant.²⁾⁵⁾

For patients with multiple valvar disease, multiple residual abnormalities that requires surgical correction prior to VAD implantation, or complex anatomy for implantation of VADs, TAH is an option.²⁸⁾ Currently, SynCardia TAH (SynCardia Systems Inc., Tucson, AZ, USA) is

the only approved available TAH. It is an implantable biventricular device that anatomically replace both ventricles. Patient can be discharged from the hospital with a portable driving unit (Freedom® Portable Driver). Successful bridge to transplantation rate is up to 79%.⁴¹⁾ Children with rejection post heart transplant also can benefit from TAH implant, as immunosuppression can be discontinued. Large size of the device limits this device to be used only for patients with big body physique. Now the company manufactures a smaller 50 cc pump to fit patients of smaller stature, allowing more women and adolescents to access this device, although still cannot be used for small children.

PATHOPHYSIOLOGIC AND CLINICAL CHANGES AFTER VENTRICULAR ASSIST DEVICE SUPPORT

Initiation of LVAD support results in significant physiologic and hemodynamic changes. LVAD support unloads the left ventricle throughout the cardiac cycle and this LV unloading reduces LV end-diastolic volume and pressure (**Figure 1**). And reduction of the left atrial pressure and pulmonary arterial pressure follows.⁴²⁾ Reduction of LV end-diastolic pressure also improves the coronary perfusion pressure and improves coronary circulation. In case of CF devices, the forward flow during the diastole improves coronary perfusion.

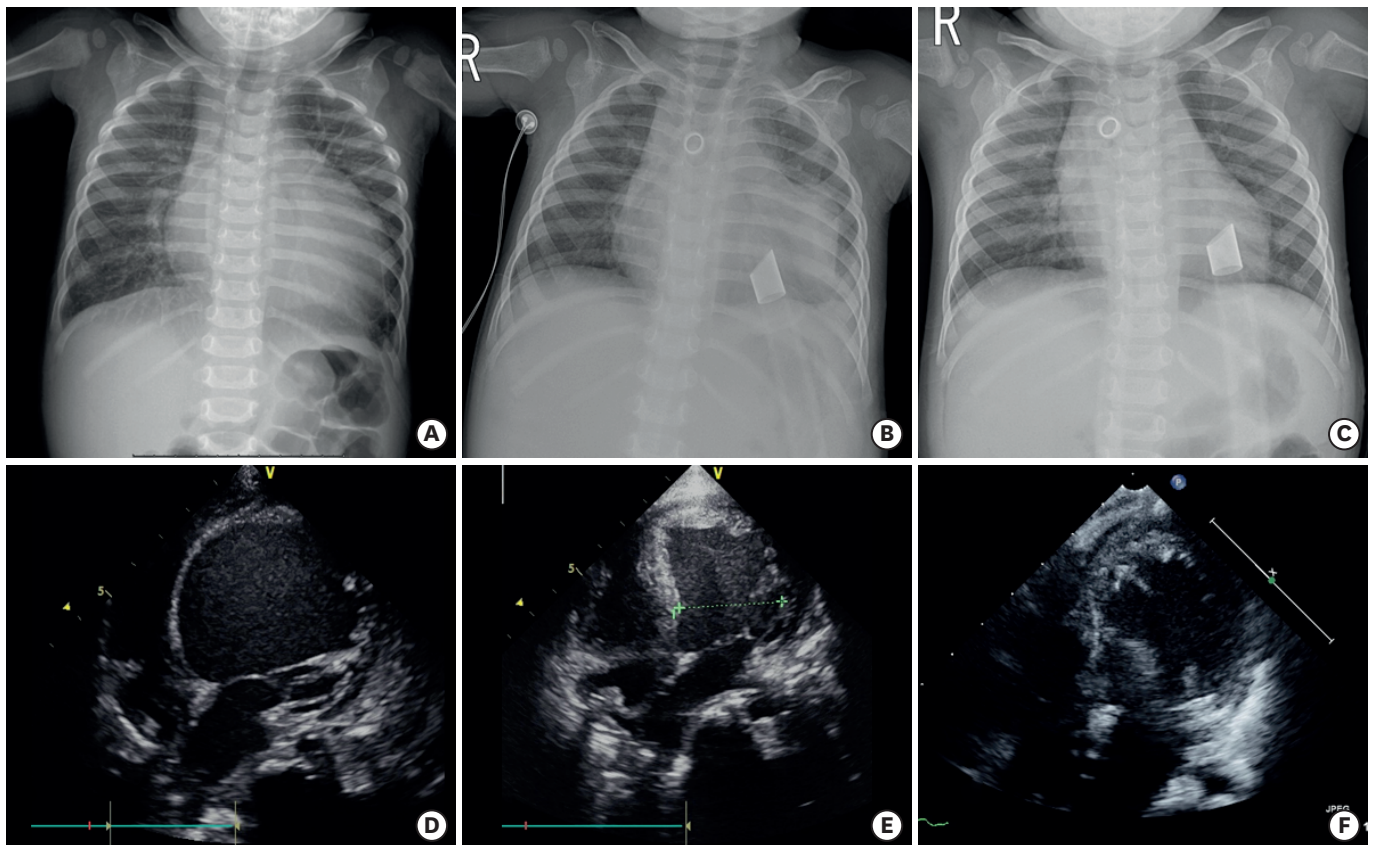


Figure 1. Chest X-ray (A-C) and echocardiographic finding (D-F) before and after LVAD support. (A, D) pre-LVAD support, (B, E) post-LVAD support 2 weeks, (C, F) post-implantation 5 months. Serial chest-ray demonstrates the progressive decreased heart size and pulmonary congestion. On pre-LVAD support echocardiography, left ventricle was dilated and interventricular septum was deviated to the right. After LVAD support, left ventricle is unloaded and interventricular septum is in neutral position. LVAD = left ventricular assist device.

The unloading of the LV reduces the wall stress and as a consequence decreases the metabolic demand of the left ventricular myocardium. Changes in right ventricular (RV) afterload also reduces the workload and metabolic demand of the right ventricle. Over a period of time, these changes result in positive remodeling of the left and right ventricle that allows the recovery of the myocardium in some cases. Some of the mechanisms related to the post-LVAD support recovery of ventricular myocardium are related to the molecular changes, reduction in cardiomyocyte hypertrophy, interruption or changes to the apoptotic pathway, changes in calcium handling, improved excitation-contraction coupling and changes to the extracellular matrix.⁴³⁾ These mechanisms need to be further investigated to reveal the process of myocardial recovery and to provide a more chance of recovery for the patients.

Augmented cardiac output by LVAD support improves end-organ function. The most immediate response occurs in the respiratory system; improvement in the respiratory compliance leads to improved symptoms. Stabilization of RV function also allows rapid weaning off respiratory support and oxygen. Enhanced cardiac output and systemic organ perfusion leads to renal and hepatic functional improvements. A majority of patients have pre-implantation cardiorenal syndrome and this improves significantly after initiation of LVAD support.⁴⁴⁻⁴⁶⁾ Similarly, patients with pre-implantation hepatic dysfunction experience hepatic recovery. Preoperative total bilirubin, postoperative bilirubin and central venous pressure (CVP) were predictors of recovery or non-recovery of liver dysfunction.⁴⁷⁾ Most pediatric patients with chronic heart failure suffer from poor nutritional status. Restoration of cardiac output and mesenteric perfusion allows for enteral feeding and nutritional rehabilitation.

Preservation and restoration of end-organ function under VAD support allows to wean from ventilator and extubate, mobilize, feed and rehabilitate the patient. Improved patient's condition waiting for heart transplantation improves the post-transplantation survival.⁴⁸⁾⁴⁹⁾ Compared to bridging to heart transplant with ECMO, post-transplantation course bridged with VAD was notably better.⁵⁰⁾ VAD is effective in improving patient's clinical condition, survival and post-transplantation course.

RV failure

Usually, LVAD support gives beneficial effects on RV function. This is mainly related to the reduction of the RV afterload. Decreased LV end-diastolic pressure, left atrial pressure, and pulmonary capillary wedge pressure lowers the pulmonary arterial pressure. However, acute change in ventricular geometry may cause deleterious effect on RV systolic function. The synchronous movement of the interventricular septum during systole contributes 40% to the overall output from the RV. LV unloading with the LVAD support results in displacement of the interventricular septum towards the LV. This results in loss of septal contribution to the RV systolic function and RV output. This effect is aggravated when LV is too aggressively unloaded. Also augmented cardiac output by LVAD support significantly increase the RV preload.

In addition to cardiac geometric and RV preload changes, underlying pathology, such as cardiomyopathy or pulmonary hypertension, may contribute to RV failure. Although PA pressure is expected to decrease after LVAD support, chronically elevated PA pressure and elevated pulmonary vascular resistance may not decrease immediately. Cardiac surgery and cardiopulmonary bypass related lung injury can also elevate the pulmonary vascular resistance postoperatively. RV failure after LVAD implantation is noted in 40–60% of pediatric patients and in 20–25% of adults.⁵¹⁾⁵²⁾ The RV failure is a significant independent risk factor for morbidity and mortality and should be thoroughly assessed and managed.

For patients with post-LVAD RV failure, optimization of VAD setting may help to restore RV function. By reducing the LV drainage to restore the adequate LV volume, the interventricular septum can achieve a midline position. This should be balanced with adequate systemic cardiac output and perfusion. Reduction in the systemic cardiac output is usually well compensated by improvement in the RV output and increase in the left heart preload. Over displacement of interventricular septum towards the left ventricle can also contribute the tricuspid valve regurgitation. Optimizing LVAD setting and interventricular septal configuration can improve the tricuspid regurgitation.

Management of volume status is also important in the setting of RV dysfunction and dilatation after LVAD implantation. Echocardiography is helpful to assess RV systolic function and its relationship with the interventricular septal configuration. Hemodynamic monitoring such as CVP and pulmonary capillary wedge pressure provide more detailed information to understand the patient's post-LVAD implantation hemodynamic changes. A high CVP has been associated with hepatic dysfunction, delayed recovery, requirement for biventricular support and mortality. Contrarily, very low CVP reduce the left heart preload and left heart cardiac output. Therefore, maintenance of adequate intravascular volume status is crucial in the immediate postoperative period.⁵³⁾

After implantation of LVAD, treatment of elevated pulmonary vascular resistance must be initiated early to prevent RV failure. Management should target to get optimal ventilation and oxygenation and management of volume overload. Inhalation of nitric oxide has been proven to decrease pulmonary vascular resistance. In a randomized trial of patients with LVAD and pulmonary hypertension, inhaled nitric oxide of 20 ppm was associated with significant reduction in mean pulmonary artery pressure and significant increase in LVAD outputs compared to nitrogen.⁵⁴⁾ This beneficial effect has also been shown in other series and reports.⁵⁵⁾⁵⁶⁾ Sildenafil can be used to for patients requiring longer-term therapy for pulmonary hypertension.⁵⁷⁾ For patients with signs of refractory RV dysfunction such as elevated CVP and persistent low cardiac output, short-term or long-term right side mechanical support should be considered.

OUTCOMES

With the increased use of VAD in pediatric age group, many reports of single-center experience⁸⁾⁵⁸⁾ and device specific results⁵⁾³⁹⁾ has been published. These reports described improvement in outcomes of mechanical circulatory support for children in bridge to transplant or recovery purpose. In 2012, Registry for Pediatric Mechanical Assisted Circulatory Support (PedMACS) was launched to serve as a comprehensive registry of temporary and durable VADs in children and adolescents. Until the end of 2017, data on more than 750 devices in more than 600 patients were collected. In the latest report published in 2019, because of data incompleteness, data of 423 patients with 508 devices at 30 hospitals in the United States were analyzed.⁵⁹⁾ The diagnosis was cardiomyopathy (62%), congenital heart disease (20%), myocarditis (11%) and others in 7% with 52 patients (12% of total patients and 60% of patients with CHD) in single-ventricle physiology. Forty-seven percent of the patients had implantable continuous flow pumps and 29% of patients had paracorporeal pulsatile devices and the remaining 19% were supported with paracorporeal continuous devices. Positive outcome (alive on device or bridge to transplantation/recovery) was achieved in 80% of the patient. The patient cohort for implantable continuous flow was significantly

different from the paracorporeal pulsatile cohort. Understandably, paracorporeal pulsatile cohort was younger than implantable continuous flow pump cohort (age at implant, 3.9 ± 5.2 vs. 13.4 ± 3.8 years). Moreover, they are in more advanced heart failure (41% vs. 19% in INTERMACS profile 1 and 77% vs. 12% intubated at implant). And CHD was more common in paracorporeal pulsatile pump cohort (21% vs. 12%). Consistent with their cohort composition, device type positive outcomes at 6 months were 77% in paracorporeal pulsatile pumps and 92% in implantable continuous flow pumps. INTERMACS profile 1, biventricular assist device, paracorporeal devices, small-volume institutions, low age, low weight, intubation and liver dysfunction at time of implant were hazards for early death.

Major adverse events were not uncommon and include infection, bleeding, neurologic events and device malfunction. In paracorporeal pulsatile pump, incidence of device malfunction and neurologic dysfunction were 33% for each, bleeding 26% and infection 26%. Implantable continuous flow pumps have almost same risk of bleeding and infection (28% and 30%). Incidence of device malfunction (19%) and neurologic dysfunction (18%) was relatively low, but still not negligible. Although positive outcomes can be obtained in majority of the patients, still patients are exposed to major complications.

CONCLUSION

There have been great advances in VAD treatment in pediatric heart failure patients. With the improvement in patient care, patient selection and timing of VAD implantation, as well as technologically advanced devices, in selected group of pediatric patients, majority of them can be successfully bridged to transplant or supported for recovery. However, it is still challenging to support infants and small children and patients with congenital heart disease. Further clinical and technical improvement will lead to more pediatric lives saved by VAD support.

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