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Current Approaches to Device Implantation in Pediatric and Congenital Heart Disease Patients

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Summary

The pediatric ventricular assist device (VAD) has recently shown substantial improvements in survival as a bridge to heart transplant for patients with end-stage heart failure. Since that time, its use has become much more frequent. With increasing utilization, additional questions have arisen including patient selection, timing of VAD implantation and device selection. These challenges are amplified by the uniqueness of each patient, the recent abundance of literature surrounding VAD use, as well as the technological advancements in the devices themselves. Ideal strategies for device placement must be sought, for not only improved patient care, but for optimal resource utilization. Here, we review the most relevant literature to highlight some of the challenges facing the heart failure specialist, and any physician, who will care for a child with a VAD.

Keywords

Pediatric; Ventricular Assist Device; dilated cardiomyopathy; myocarditis; heart failure; mechanical circulatory support; HeartWare; HeartMate; Berlin Heart

Background

The treatment options for pediatric heart failure are rapidly evolving. Patients who develop end-stage heart failure who are unlikely to recover are optimally treated with a heart transplant (HT). The number of pediatric heart transplants has been relatively consistent at 350–400 per year [101], therefore, a HT is often not possible prior to the development of significant complications. Until recently, patients who developed medically refractory cardiogenic shock were treated with extracorporeal membrane oxygenation (ECMO) until a donor heart became available. This management strategy, however, is wrought with complications that render it feasible for only a finite period of time. Ventricular assist devices (VAD) have subsequently emerged with improved survival as a bridge to transplant (BTT). Compared to ECMO, it allows for an increased survival and longer duration of

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support [1–5]. The Berlin Heart EXCOR (Berlin HeartGmbH, Berlin, Germany), originally used as early as 1992 in Germany [2], came into main stream use in North America in 2004, and its use has rapidly increased. Currently, 20% of pediatric patients who undergo HT are successfully bridged with either a VAD or total artificial heart [6].

Though it is clear that VAD support is superior to ECMO, many issues remain unresolved. Currently, patient selection and the timing of VAD implantation represent two of the more difficult decisions facing the heart failure specialist. The timing is challenging due to the desire to avoid the complications of a low-flow state seen with later VAD placement, but to also avoid the morbidity of VAD placement unnecessarily. Additionally, the different etiologies of heart failure should not necessarily be treated the same. Another continued controversy is when to place a right VAD (RVAD) for biventricular assist device (BiVAD) support. Further complicating these decisions is that the device designs are rapidly changing and the currently available data is often based on previous devices, and therefore may not be accurate. Lastly, the timing of when the patient will receive a transplant is always uncertain, and now may represent even more of a moving target. The increases in survival associated with a VAD, many experts believe, will further increase time spent on the transplant waiting list [7].

In this article we review the most relevant literature used to guide decision making. We will focus on pediatric patients with end-stage heart failure caused by dilated cardiomyopathy (DCM), myocarditis and congenital heart disease (CHD) with some mention of other etiologies.

Devices

Initially, pediatric VADs suffered from a lack of device development when compared to that for adults. The number of pediatric patients who necessitate VAD support is much lower than for adults, reducing the financial incentive for device development. Additionally, the pediatric VAD presents additional challenges, such as necessitating a flow low enough for a very small patient without forming thrombus. The overall range of flows necessary to support patients with a range of BSAs may require an eventual pump change or a device which can function at a wide range. With the less well understood pediatric coagulation system, these challenges are further exaggerated.

Berlin Heart EXCOR

The Berlin Heart EXCOR (Figure 1) was the first widely utilized VAD for pediatric patients in the US. It is a pneumatically driven pulsatile device with a flexible diaphragm separating the air and blood chambers. Due to the pulsatile design, it requires inflow and outflow valves as well as a reservoir. As it was originally designed for pediatric patients, it is available in 10, 25, 30, 50 and 60 ml pump sizes, as well as the only recently available 15 ml. It functions well as a left VAD (LVAD) and is the most common device used for BiVAD support, often with a slightly smaller pump used as the RVAD.

HeartWare HVAD and HeartMate II

The HeartWare HVAD (HeartWare Inc., MA, USA) (Figure 2) is a continuous-flow device with a centrifugal flow design and the inflow cannula connected to the housing [8]. It is placed intrapericardial, so it does not require the creation of a pocket. The HeartMate II (Thoratec Corp., CA, USA) (Figure 3) is a continuous-flow device, with an axial design, that has a separate inflow and outflow cannula and is placed in a surgically created subcutaneous pocket [9]. Due to the pump speed necessary to avoid thrombosis, both require a patient of sufficient size. Use of both has been described, and is gaining popularity, in the larger pediatric population [10–12].

Total Artificial Heart

The Total Artificial Heart (TAH) (SynCardia systems Inc., AZ, USA) is a pulsatile device used to provide biventricular support. While uncommon, its use has been described in larger pediatric patients [13]. The majority of pediatric patients, however, are typically too small and have too small an anterior-posterior diameter to allow for implantation of the current device [14].

Short-Term Devices

A different category of VADs exist, and though they will not be discussed at length, do deserve mention. They are typically utilized for short-term support. The CentriMag (Thoratec Inc., CA, USA) is an extracorporeal pump, similar to ECMO, that provides cardiac support alone. The PediMag (Thoratec Inc., CA, USA), a smaller version of the CentriMag, is the comparable device for pediatric patients [15]. The Impella (Abiomed Inc., MA, USA) is an adult device placed via the femoral artery and positioned across the aortic valve to provide partial support. Its use has been described in larger pediatric patients for temporary support [16, 17]. The TandemHeart (CardiacAssist Inc., PA, USA) utilizes an inflow cannula placed in either the right atrium or, via septal puncture, into the left atrium via a femoral vein. It is a centrifugal device with the outflow cannula placed into the arterial system. Its use has also been described in pediatric patients [18].

Device and Implantation Characteristics

Pulsatile or Continuous-Flow Device

Though the adoption of the Berlin Heart EXCOR in the US is relatively recent, a substantial experience does exist. The 15 year (1990–2005) original institution experience highlights their 62% survival to transplant or successful wean from device with a median duration of support of 35 days, a duration not previously feasible with ECMO [2]. While this pneumatic pulsatile device was the original device approved for large scale pediatric implementation, recently the smaller adult continuous-flow devices have been utilized in larger pediatric patients. The continuous-flow devices have the advantage of a much smaller size, due to a blood reservoir being unnecessary. Further, valves are unnecessary with a continuous flow design. These devices also allow for patient discharge. For these reasons, the continuous-flow VADs have become the preference of many pediatric cardiac surgeons when they are feasible. Use of the HeartMate II has been described in pediatric patients with a BSA >1.2 m², with similar outcomes to use in young adults [11]. Use of the HeartWare HVAD has

also been described, with some surgeons favoring it for its smaller size and intrapericardial placement, with reports of placement in patients with a BSA as low as 0.7 m² [10, 12, 19].

LVAD or BiVAD

The pathology leading to left ventricular heart failure in the pediatric population is also more likely to lead to right ventricular failure than the typical adult ischemic cardiomyopathy [20]. For that reason BiVAD support is more often necessary in pediatric patients with reports of BiVAD utilization occurring in 25–45% [7, 21, 22]. Patients who receive BiVAD support clearly have a reduced survival demonstrated in multiple studies [3, 22–24]. Though it seems intuitive to assume that multiple devices will lead to an increased risk of adverse events, and therefore increased mortality, some experts have questioned if the worse outcomes for BiVAD patients are in fact solely due to the worse pathology necessitating BiVAD support. Indeed, some experts advocate for judicious BiVAD placement, mainly to avoid the poor outcomes associated with delayed RVAD placement [25]. The majority of specialists, however, recommend LVAD support alone when feasible.

Outcomes

When evaluating all comers from many series, survival to transplant with a pediatric VAD is approximately 75%, [3, 4, 7, 10, 21, 23, 26–28]. The anticipated survival for any individual patient who requires VAD support can be dramatically better or worse. The survival is influenced by many different factors, both patient and physician specific.

Unfortunately, many of the patient specific factors are unable to be altered. One of the more important factors influencing survival is the indication for VAD support. Studies have shown differing survival based on pathology from 85% with cardiomyopathy to 67% with myocarditis and 65% with CHD [29]. The patients overall degree of heart failure can also play a significant role, with a known decrease in survival with a lower GFR or higher bilirubin [3]. Additionally, there seems to be a decrease in survival associated with lower BSA, though CHD could be a confounding factor, as this has been shown to be a driver of poor outcomes [7].

Many of the physician specific factors are, at least somewhat, controversial. One of the main factors influencing survival is patient selection. This decision often centers around timing while the patient is on the transplant waiting list. As a patient continues to develop worsening heart failure, a decision has to be made when to place a VAD. Ideally, a heart will become available prior to any end-organ dysfunction; however, this cannot be anticipated. Therefore, the timing of VAD support can be a subject of debate. Another difficult issue can be the presence of a variable degree of biventricular failure. BiVAD use has traditionally been associated with a worse outcome, though again, it is unclear if this is an association with worse pathology rather than a harmful impact of BiVAD support. Other physician-influenced factors include experience, as it has been shown that higher volume institutions have improved survival [29].

Post-Transplant Survival

When evaluating post-HT survival, patients who required a VAD prior to HT were compared to patients who did not require mechanical circulatory support (MCS) and were found to have a similar survival, which is significant because these patients clearly had more severe heart failure [30]. Their survival was significantly increased when compared to patients who required ECMO. These patients likely represent a different cohort, with ECMO patients requiring either emergent cannulation or pulmonary support. This further strengthens stance that VAD and ECMO support are different therapies with different indications.

Indications for VAD placement

As stated above, the initial cause of heart failure has a dramatic impact on the anticipated survival. The indications for VAD in some of the larger studies were DCM in 40–60%, myocarditis in 10–15% and CHD in 10–20% [7, 29]. Other indications include patients who are not eligible for transplant and adults with CHD. An additional special circumstance is the failing single ventricle.

Dilated Cardiomyopathy

DCM is the most common indication for VAD placement, and it has proven to be a very effective treatment option. When looking at a large population of patients with DCM listed for HT, VAD support was not a risk factor for death, though ECMO and mechanical ventilation were found to confer additional risk [31]. The authors hypothesize that this is due to the longer duration of support possible with a VAD. This increased duration can be utilized to manage some unique situations. For a patient with chemotherapy induced DCM, the proven durability of VADs allows for device placement and the achievement of a 2-year cancer free interval prior to heart transplant.

Myocarditis

For pediatric patients with acute failure due to myocarditis, the VAD has been used successfully as a bridge to recovery (BTR). Though most reports of successful BTR for myocarditis consist of small subgroups of larger studies [21] or case reports [32, 33], one study of 13 patients had a successful BTR for 62% of patients with acute onset of heart failure, many of which were likely caused by myocarditis [34]. Patients were more likely to be successfully weaned to device explant if the VAD was placed soon after the heart failure diagnosis. It is unclear if this is a marker for more acute pathology which resolves more completely or an actual indication that early VAD placement off loads the ventricle and lessens progression of the disease. Though myocarditis represents an indication with the potential to wean a VAD to explant, the point should be made, that the majority of patients who undergo VAD implantation for acute myocarditis eventually undergo HT.

Congenital Heart Disease

Pediatric patients with CHD pose a unique challenge, particularly with regards to VAD placement. These patients have often had prior operations, making the surgical implantation more technically complicated. Further, each congenital anomaly is somewhat unique,

meaning the literature surrounding, and any surgeon's experience with, VAD placement in the setting of any specific lesion will be limited. Intra- and extracardiac shunts, either congenital or surgically created may have to be ligated. CHD patients might also have complications with overall failing physiology leading to cirrhosis or pulmonary hypertension and therefore, a much worse anticipated outcome, specifically for some patients with a failing single ventricle (SV) (see below). Though most consider CHD patients who require VAD support to have a lower survival than other VAD indications, VADs have been utilized successfully for these patients. A study focusing solely on outcomes of patients with CHD who required MCS as a BTT had an overall survival of 72% to recovery or transplant and 59% to discharge [35]. While many case reports and small studies exist highlighting successful VAD utilization in these patients, it should be noted that it is likely that significantly more have a worse outcome and are under-reported. Indeed, a recent study from Conway et al. highlights the inferior survival in the smallest patients, specifically in those with CHD [36].

Heart failure in the non-transplantable

A unique indication, one which includes only a small number of pediatric patients, is the development of heart failure in patients who are not eligible for transplant, placement for destination therapy. This indication is by far the exception, having been described only rarely in children with Duchenne muscular dystrophy. Recently, with improved therapies, some children are surviving to develop DCM, which may become their life-limiting factor. In two patients, a VAD implantation was described; both were alive greater than 10 months after VAD placement [37].

Adults with Congenital Heart Disease

Adults with CHD, a group with increasing numbers as the survival for pediatric CHD operations continues to improve, will likely represent a small, but increasing, indication for VAD placement in adults. Specifically patients with CHD leading to a right sided systemic ventricle, congenitally corrected transposition of the great arteries (CC-TGA), D-TGA after atrial switch or any morphological right SV, are at an increased risk for the development of heart failure. These patients are likely to benefit from VAD support as their pathology is failing systemic ventricular function. This has been described in many small reports, each a unique case [38–43]. One larger report evaluated 6 patients with a systemic right ventricle, 2 of which had a SV. They showed good results are possible with 5 successfully receiving VAD support for an extended period of time [44]. Another report shows good results with a long duration of support in 3 patients, they note the difficulty of inflow cannula placement due to the risk of obstruction by the moderator band [45]. Again, though there are many case reports with positive outcomes, there is likely a larger unpublished patient population with a worse outcome for this, oftentimes, difficult problem.

Long-term device utilization has been described in some adults with CHD, with some encouraging results. There have been reports of long-term VAD support in a patient with CC-TGA who developed pulmonary hypertension and was initially assumed to need a heart-lung block. However, after VAD support there was a sufficient reduction in the pulmonary vascular resistance to allow for HT alone [46]. The placement of an RVAD alone has also

been described for an adult with a SV with pulmonary hypertension, but preserved ventricular function. This was performed by the formation of a capacitance chamber which was separated from the PAs. This patient survived 13 months to HT [47].

Failing Single Ventricle

Patients with a failing single ventricle pose a difficult challenge to physicians. When analyzing these patients they are often considered in two different categories, those with impaired ventricular function (IVF) and those with preserved ventricular function (PVF) but failing Fontan physiology [48]. Though both can be anticipated to have a difficult operation due to the altered anatomy and multiple prior operations, recent literature has questioned if they have similar outcomes after HT. Intuitively, and as has been shown in recent studies, patients with IVF are most likely to benefit from a HT, as this replaces the failing organ. For patients with PVF, a HT is beneficial, though with a reduced survival compared to IVF [49]. It seems reasonable to extrapolate this data to VAD support, though this has not yet been evaluated as the number of Fontan patients who have undergone VAD support is limited.

Multiple case reports have described the use of a VAD in a patient with a failing SV [50–56]. A recent study focused specifically on pediatric patients with a failing SV found that they were able to be successfully bridged to transplant 42% of the time, though this was significantly worse than biventricular patients [57]. The VAD was utilized predominately to support the SV, however, in 2 patients it was utilized in BiVAD configuration with the pulmonary arteries reconstructed and a capacitance chamber formed for the inflow cannula. Another study evaluated MCS use in CHD, both ECMO and VAD, and found a survival to transplant of 73% in BV and 71% in SV, a nonsignificant decrease [35]. Though it seems likely that SV patients will have a reduced survival to transplant with VAD use, more data needs to be accumulated for this relatively rare indication. A large multi-institutional database has been formed to evaluate the outcomes of SV patients who require MCS [58].

VAD Adverse Events

Cerebrovascular Accident

The risk of cerebrovascular accident (CVA) is approximately 30% when evaluating the Berlin EXCOR [3]. A CVA can be ischemic or hemorrhagic, with ischemic being more common but hemorrhagic often being more devastating. However, it has been shown that with increased experience, and appointing a single physician to manage a patient's anticoagulation therapy, the risk of a CVA can be decreased [59]. Also, future devices have the potential for a reduction in the degree of anticoagulation in addition to a reduced risk of CVA, which could dramatically increase survival by reducing CVAs as well as hemorrhagic complications.

Infection

Infection is a relatively common complication occurring in 50–69% [1, 60]. Infections occur commonly due to prolonged hospitalizations and exposure to invasive therapies and. There is also the potential for VAD specific (driveline, hardware or pump pocket) or related (mediastinitis, endocarditis or blood stream) infections [61]. Aggressive antibiotic or

antifungal therapy, in addition to source control, is crucial as every effort must be made to clear the infection prior to HT with the required antirejection medications. Additionally, the presence of infection or inflammation is known to induce a procoagulant response via the tissue factor pathway [62, 63]. This further complicates the anticoagulation regimen necessary with a VAD.

Hemorrhage

A hemorrhagic complication can pose a substantial problem due to the required anticoagulation, occurring in approximately 40–60% of patients [1, 23]. Multiple transfusions present a concern due to the potential development of antibodies in a patient who will eventually undergo HT. More commonly, the hemorrhage can lead to the immediate threat of tamponade, and therefore require an urgent reoperation. This, often urgent, complication occurs more commonly early in the post-operative course [64].

Increased Panel Reactive Antibody

Another potential, though certainly less clear, association with the pediatric VAD is an increase in panel reactive antibodies (PRA), with some studies noting an increased risk as high as 35% [65]. The causes are thought to be due to immune activating properties of the circuit material in addition to the increased blood product utilization, though blood product use has been controlled for in some studies which still showed an increased PRA [65]. While VAD use itself has the potential to increase times on the waiting list by improving survival, it may also do so by increasing PRA. Potentially, by increasing the size of the recipient pool, it may also allow for improved matches. The impact of the VAD on rejection will be interesting to analyze going forward. In a recent study, there was a decrease in survival approximately 5 years after transplant for patients who received VAD support [66]. These authors postulated that this could be due to increased risk of graft failure, secondary to increased allosensitization in VAD patients.

Gastrointestinal Bleeding

Currently only described in the adult population, the association of gastrointestinal (GI) bleeds with continuous-flow devices has been established [67]. It occurs due to a combination of factors including: the required anticoagulation, an acquired von Willebrand Factor (vWF) deficiency and decreased pulsatility leading to the formation of arteriovenous malformations [68]. Though this has not been described in the pediatric population, an acquired vWF deficiency has been described and is thought to form due to the destruction of the large vWF multimers by the rotor [10]. The risk of a GI bleed may become an issue in pediatric VAD patients as more receive continuous-flow devices and for longer durations.

Patient Selection

Patient selection is one of the more challenging aspects of VAD implantation. The ability to place a VAD early in the disease course to prevent complications could potentially improve overall survival. Conversely, avoidance of VAD implantation in patients who are unlikely to benefit would be important from a patient treatment point of view as well as for the management of limited resources. For many it becomes an element of timing, the continued

decline in cardiac function is balanced with the question of when a donor heart will be available. Experience of the heart failure team is crucial as the patient's clinical status, any end organ dysfunction as well as their PRA and BSA have to be considered when determining the utility of VAD placement. In the adult population, there has been a noticeable "downshifting" of risk, VADs are being placed earlier in the disease course as outcomes continue to improve [69, 70]. This has been advocated in pediatric patients by some [66], and it seems inevitable as survival to transplant with a VAD continues to improve with no indication of an increase in available donors. If waiting list times increase due to a larger recipient pool as well as increased PRAs, VAD use will no doubt increase and be placed earlier to prevent the development of complications due to a longer waiting list duration. This may have the impact of improving VAD associated survival due to the prevention of organ dysfunction as well as artificially improving survival by placing VADs in a healthier cohort of patients. This further highlights the importance of minimizing the adverse event rate. If the duration of VAD support increases, so too will the overall number of adverse events.

Quality of Life and Cost-Effectiveness

Quality of Life

In the adult population, the improvements in survival have been accompanied by improvements in quality of life (QoL) [71, 72]. In the pediatric patient, QoL while supported with a VAD has not been investigated. It has been shown that patients who require MCS prior to HT, assuming they survive to HT, have an equivalent post-HT QoL to those who do not require MCS [73]. This was confirmed by another study which evaluated VADs specifically and again showed no detriment to the QoL for patients who require VAD support compared to those who do not require MCS [74].

Cost

The pediatric VAD has undergone only preliminary cost evaluation. Total cost of pediatric VAD implantation is approximately \$174,753, and was found to be lower at high volume institutions [29]. Another study showed the incremental cost effectiveness ratio, estimated cost per quality adjusted life year (QALY), to be \$119,937 using the estimated increase in QALY calculated by increased survival over ECMO [75]. Though this is above the commonly accepted cost-effectiveness threshold, it is not out of line with other emerging therapies or pediatric lifesaving treatments [76]. With improving survival, decreased complication rates, ability to discharge a patient while supported by a device and improving device design, a decrease in the cost/QALY, by both decreasing the associated costs and improving the QoL, to socially acceptable levels can be anticipated.

Future Devices

The PumpKIN trial was designed to test a new VAD, the Jarvik 2000 (Jarvik Heart Inc., NY, USA) (Figure 4), which is a pediatric specific design, with an axial flow, meant to be suitable for the smallest of patients [77]. Also, some devices on the horizon aimed at partial flow in adults could potentially be modified for children, such as the Synergy (CircuLite/HeartWare Inc., MA, USA) (Figure 5) [78]. As adult device development improves, many

adult devices will continue to be placed in smaller and smaller children. Ideally, they will be able to function at lower flows and be small enough to be comfortably supported by the smaller patient frame. Some devices have the potential of decreasing the anticoagulation need while reducing the risk of CVA. Other adult devices are also employing algorithms to simulate pulsatile flow [79].

The HeartWare MVAD (HeartWare Inc., MA, USA) (Figure 6) is an intrapericardial placed axial flow device. HeartWare is also testing a trans-apically placed MVAD with the outflow positioned across the aortic valve (Figure 7) in some configurations [80]. Thoratec (Thoratec Corp., CA, USA) has currently begun initial human implantation of the HeartMate III (Figure 8), a centrifugal device positioned intrapericardial in adults. It will feature coated surfaces to promote pseudoneointimal growth to help reduce the risk of thrombus formation [79]. Thoratec is also in the early stages of testing the HeartMate X (Figure 9), an axial flow device that is also positioned intrapericardial.

For patients with a failing Fontan, a future device, currently in the early stages of design, has some potential to temporize a patient until a donor becomes available. A cavopulmonary assist device has been proposed which is placed intravascular at the junction of the superior vena cava, inferior vena cava and the pulmonary arteries. It would act to augment pulmonary blood flow against the elevated pulmonary resistance and increase preload to the failing ventricle [81, 82].

Expert Commentary

The field of pediatric heart failure is rapidly evolving to equip heart failure specialists with tools that were not previously available. The pediatric VAD has undergone extensive comparison to ECMO, and shown dramatic improvements in survival. Since that time, VAD therapy has continued to improve and specialists have begun to consider VAD and ECMO support as different therapies with unique indications. With the known survival advantages of a VAD, there are situations that ECMO use is inappropriate. The choice of a particular device can be difficult, especially with the rate of technological advancement. Currently, the field is evolving to incorporate adult devices in the larger pediatric patients, which we feel offers many advantages. Our practice is to favor continuous-flow devices in any patient large enough to tolerate their flow rate, and even more so if the child is likely to require prolonged support.

Five Year View

One of the major limitations at this time is supporting the smallest of patients. Smaller continuous-flow devices which are currently under evaluation may offer significantly better options to the heart failure specialist. Additional new devices appropriate for larger pediatric patients will continue to progress through the development process. It seems likely that physicians will increasingly favor the smaller continuous-flow devices which will allow for hospital discharge of some patients. The practice of discharging patients with a VAD will likely progress to include patients with a paracorporeal device as well.

Attempting to predict the next 5 years of pediatric VAD support is very difficult because the field of pediatric heart failure is rapidly evolving and many issues that arise are unforeseen. What can be anticipated, however, is that specialists will continue to gain experience with VAD implantation and postoperative care. This will eventually lead to improved patient selection and survival as well as the ability to prevent and minimize the impact of adverse events. An additional issue, which will impact the decision of VAD placement, is the long-term risk of rejection, a factor which is currently unclear. As VAD support is a relatively new intervention, data will continuously be published that will aid in answering these questions.

Conclusion

The pediatric VAD has proven effective for treating pediatric patients with end-stage heart failure. Though this field has advanced substantially over the previous decade, many challenges remain. As we continue to gain experience and develop improved devices, survival will improve, as will resource utilization. Due to the uniqueness of each patient, it is imperative that pediatric heart failure specialists work to develop optimal strategies for device placement and the avoidance of adverse events and publish these data to advance the overall knowledge of pediatric heart failure.

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Key Issues

- Children with end-stage heart failure are optimally treated with a heart transplant. When they are unable to receive a donor heart prior to the death, they can be bridged with a VAD. Pediatric VADs have shown potential to bridge pediatric patients successfully to transplant for long periods of time.
- The current outcomes with a pediatric VAD are encouraging with survival to transplant approximately 75%, and are likely to improve.
- Though survival with a VAD is improving, many difficult and only partially understood issues remain.
 - When to place an RVAD for BiVAD support rather than LVAD alone.
 - Which device to use, and in how small of a patient can an adult continuous-flow device be safely utilized.
 - Patient selection and the timing of implantation remain one of the most vital and difficult decisions.
 - This is the most important factor determining survival and can allow for early VAD implantation to prevent the development of complications and conversely to avoid VAD placement, and its associated morbidity, in patients who are unlikely to benefit.
- A VAD can be implanted for different etiologies of heart failure, some of which have unique implications.
- The VAD is associated with significant adverse events including CVA, hemorrhage and infection.
 - This includes patients with congenital heart disease and those with a single ventricle.
- New devices have the potential to further improve survival and reduce the adverse event rate.

Figure 1. Berlin Heart EXCOR. Reprinted with permission from Berlin Heart. The different sizes of the Berlin Heart EXCOR.

Figure 2.
HeartWare HVAD. Reprinted with permission from HeartWare Inc. HeartWare HVAD

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Figure 4.
Jarvik 2000. Reprinted with permission. Adult, child and infant Jarvik 2000

Figure 5.
Synergy. Reprinted with permission from HeartWare Inc. Synergy

CAUTION: Investigational device. Limited by United States law to investigational use.

Figure 6.
HeartWare MVAD. Reprinted with permission from HeartWare Inc. HeartWare MVAD

Figure 7.
Transapical MVAD. Reprinted with permission from HeartWare Inc. Intraventricular
MVAD across aortic valve configuration.

Figure 8.
HeartMate III. Reprinted with permission from Thoratec Corporation. HeartMate III

Figure 9.
HeartMate X. Reprinted with permission from Thoratec Corporation. HeartMate X