Review Article on Left Ventricular Assist Devices

Pediatric ventricular assist devices

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Abstract: The domain of pediatric ventricular assist device (VAD) has recently gained considerable attention. Despite the fact that, historically, the practice of pediatric mechanical circulatory support (MCS) has lagged behind that of adult patients, this gap between the two groups is narrowing. Currently, the Berlin EXCOR VAD is the only pediatric-specific durable VAD approved by the U.S Food and Drug Administration (FDA). The prospective Berlin Heart trial demonstrated a successful outcome, either bridge to transplantation (BTT), or in rare instances, bridge to recovery, in approximately 90% of children. Also noted during the trial was, however, a high incidence of adverse events such as embolic stroke, bleeding and infection. This has incentivized some pediatric centers to utilize adult implantable continuous-flow devices, for instance the HeartMate II and HeartWare HVAD, in children. As a result of this paradigm shift, the outlook of pediatric VAD support has dramatically changed: Treatment options previously unavailable to children, including outpatient management and even destination therapy, have now been becoming a reality. The sustained demand for continued device miniaturization and technological refinements is anticipated to extend the range of options available to children—HeartMate 3 and HeartWare MVAD are two examples of next generation VADs with potential pediatric application, both of which are presently undergoing clinical trials. A pediatric-specific continuous-flow device is also on the horizon: the redesigned Infant Jarvik VAD (Jarvik 2015) is undergoing pre-clinical testing, with a randomized clinical trial anticipated to follow thereafter. The era of pediatric VADs has begun. In this article, we discuss several important aspects of contemporary VAD therapy, with a particular focus on challenges unique to the pediatric population.

Keywords: Pediatric; children; ventricular assist device (VAD); mechanical circulatory support (MCS)

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Introduction

Recently, there has been increasing awareness about the emerging field of pediatric ventricular assist device (VAD) support. Although VAD support has begun to change the clinical outlook of children with severe heart failure, producing consistent outcomes across all ages, sizes, and underlying cardiac diagnoses is certainly challenging. This is in stark contrast to VAD therapy in the adult population where it has become the standard of care for intractable heart failure over the last decade with proven benefit. In this article, we discuss several important aspects of pediatric VAD therapy, with a particular focus on challenges unique to the pediatric population.

Indications for pediatric VAD support

Patient selection

In general, VAD therapy should be offered if its potential benefits are deemed to outweigh the expected risks. The risk-benefit profiles, however, vary across different age groups and cardiac diagnoses. Institutional experience in pediatric VAD therapy also has an impact on the risk-benefit profiles. Therefore, although there are no uniform criteria for instituting pediatric VAD support, there are some widely held basic tenets. It is essential for each program to develop individualized guidelines based on a solid foundation comprised of available data, prior institutional experience and expert guidance. A strategy of implanting a VAD in all patients who present with compromised cardiac function is ill-advised, having the potential to cause inadvertent harm to the recipient, their family as well as the burgeoning VAD program. As well demonstrated in the large adult experience (1), the timing of initiating VAD support is critical to ensuring successful outcomes in all aspects of postoperative care, including the reduction of hemorrhagic complications or subsequent need for right ventricular assist device (RVAD). Our institutional guidelines have continually evolved over the years as greater experience is accrued. Presently, all inotropic-dependent patients with suboptimal circulation will be evaluated for VAD support. While we do not want to wait until severe end-organ dysfunction is established, instituting VAD therapy too early is counterproductive due to inherent risk profiles associated with pediatric VAD therapy. In our experience, decision-making on the appropriate timing is relatively straightforward in small infants. Typically, infants with severe congestive heart failure who require mechanical ventilation as part of heart failure management are placed on a Berlin Heart EXCOR VAD (Berlin Heart, The Woodland, TX). In older children with chronic heart failure, the development of respiratory failure requiring mechanical ventilation is encountered much less frequently. Typically, the latter group shows signs of end-organ dysfunction, such as renal/hepatic failure or feeding intolerance, before the need for mechanical ventilation. The aforementioned study in pediatric VAD patients has clearly demonstrated that the single most important predictor of patient mortality is the degree of end-organ dysfunction, specifically renal and hepatic dysfunction, at the time of VAD implantation (2). Careful monitoring of serial changes in end-organ function, as well as nutritional status, is thus essential, and, if seen, VAD therapy should be considered. Larger children with a body surface area (BSA) >0.7 m^2 who may be eligible for an implantable continuous-flow VAD (e.g., HeartMate II and HeartWare HVAD) at a center with significant experience are often considered for a VAD if they are inotrope-dependent and awaiting transplantation. The severity of the patient's physical deconditioning while on inotropic support is often underappreciated, until rapid improvement is witnessed by family and providers after transition to VAD therapy. Additionally, there are other complicating factors that must be considered in providing VAD support in children. Children with congenital heart disease often have anatomic variations that pose technical challenges (e.g., abnormal size and location of the aorta or unusual orientation of ventricular chambers). Previous surgical procedures may jeopardize the application of VAD therapy secondary to derangement of anatomy and physiology. These include systemic-pulmonary artery shunts or disconnected venae cavae after Glenn or Fontan operations. A thorough understanding of the unique pathologic and anatomic features of pediatric heart failure is an absolute prerequisite to successful outcomes with VAD support.

In considering contraindications, extreme prematurity, low body weight (<2.5 kg), significant neurologic impairment, barriers to adequate anticoagulation, a constellation of congenital anomalies with poor prognoses, and major chromosomal aberrations generally preclude VAD therapy. Historically, long-term VAD support has been offered most frequently as a bridge to transplantation (BTT). In recent years, however, VAD support to determine candidacy for heart transplantation (i.e., bridge to candidacy) is becoming more common. Therefore, undetermined transplant candidacy is not necessarily a contraindication for VAD support; with implantable continuous-flow devices, VAD therapy no longer needs to be a "bridge" in children, but simply a mode of treating medically resistant heart failure (chronic VAD therapy). It should be noted that contraindications may change over time as the global VAD experience grows. Defining circumstances which influence the incidence of adverse events in a certain subpopulation is challenging when implant rates are low. A knowledge of contemporaneous trends in complications, supported by an adequate sample size, provides evidence based on which inferences regarding contraindications can be made. Over the past decade, data from the extensive adult VAD experience (>15,000 patients from 158 centers) have been pooled into Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry. This practice has been conducive to tracking trends surrounding

Figure 1 CentriMag (Thoratec Corp.; Pleasanton, CA).

mortality and morbidity in adults implanted with VADs. In September 2012, a pediatric component, PediMACS, was founded to collect data on children (<19 years) implanted with VADs. Per the 7th INTERMACS report, enrollment has been steadily increasing, with 36 centers reporting on 216 patients through April 2015 (3). It is hoped that this registry will provide important insight into implant strategies and adverse events specific to children.

Device selection

Temporary devices

Device selection is another important aspect of pediatric VAD therapy which is influenced by several factors: patient size, type of support [left ventricular assist device (LVAD) or biventricular assist device (BiVAD)], anticipated duration of support, the ultimate goal of support, and device availability. In patients with heart failure of acute etiology, it is generally advisable that a temporary mechanical support device be selected. Patients with relatively short-lived etiologies, such as viral myocarditis and acute rejection of cardiac grafts, may experience a recovery of cardiac function when the inflammatory/immune storm subsides; thus VAD therapy simply supports the circulation as the underlying process runs its course. In such circumstances, temporary devices are a preferred mode of support (4,5). Temporary VAD support is also helpful when presented with a patient who needs support but whose etiology of heart failure, neurological status, or candidacy for transplantation is unknown. Strategies available to such a patient may include bridge to recovery, to long-term device, or to a rational decision in which the family has had time to consider other options such as hospice or withdrawal of care. Historically, and even now in many pediatric heart centers worldwide, extracorporeal membrane oxygenation (ECMO) has been used for this particular purpose (6-8). One of the major advantages of ECMO over short-term VAD support is the option of peripheral cannulation, thereby avoiding the need for sternotomy. That being said, in a critically ill child, avoidance of a sternotomy should not be the primary determinant of treatment strategy. Permanent damage or loss of cervical vessels is also not without consequence. Conversely, the failing left ventricle is decompressed to a lesser degree with peripheral ECMO than VAD. Instituting short term VAD support via median sternotomy allows direct drainage of the struggling left ventricle through larger cannulae. This is a superior option, particularly when there is increased cardiac return (e.g., systemic-pulmonary collaterals) which is often encountered in the pediatric population. We hold the opinion that adequate decompression of the left ventricle increases the likelihood of cardiac recovery; the paucity of supporting clinical data notwithstanding, primarily because not many pediatric centers worldwide utilize short-term VAD support in this particular setting. Owing to the rapid expansion of pediatric VAD use, nonetheless, more institutions are now using short-term VAD in children. It may be worth considering multi-institutional randomized trial to provide greater insight into this matter.

A circuit configuration of short-term VAD support is very similar to that of ECMO. The major difference between the two systems is whether an oxygenator is incorporated, which is a significant source of inflammatory and coagulation issues with ECMO. The absence of an oxygenator may result in lower morbidity with temporary VADs. A rotary or centrifugal pump, such as CentriMag/PediMag (Thoratec Corp.; Pleasanton, CA) (*Figure 1*) and Jostra Rotaflow (MAQUET Cardiovascular; Wayne, NJ) (*Figure 2*), can be used for short-term VAD support. This type of extracorporeal VAD system is a device of choice in patients with critical cardiogenic shock. Depending on the patient's condition, additional organ support system such as hemodialysis and plasma exchange system, can easily be added to the VAD circuit. In other words, the extracorporeal VAD system serves as a platform for multi-organ support in critically ill patients.

There also has been growing interest in the use of

Figure 2 Rotaflow (MAQUET Cardiovascular; Wayne, NJ).

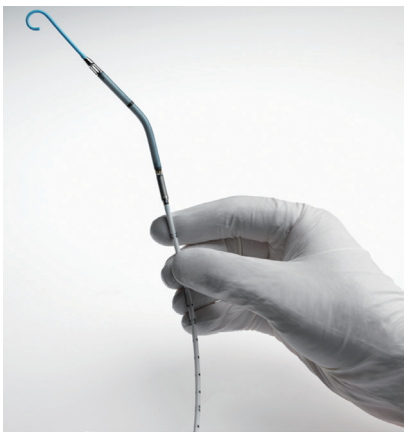

Figure 3 Impella 2.5 (Abiomed Inc., Danvers, MA).

Figure 4 Berlin Heart EXCOR (Berlin Heart, Inc.; The Woodlands, TX).

percutaneous VADs in children. The Impella axial VAD catheter is an example. The Impella family has several different sizes, with the smallest (Impella 2.5, Abiomed Inc. MA) (*Figure 3*) being 12 Fr size in size at its pump motor (max flow of 2.5 L/min). The smallest patient in our experience who received an Impella 2.5 was a 6-year-old female (weight 22 kg and BSA 0.85 m^2) with acute cardiac graft dysfunction. Greater experience is warranted to identify the lower margin of size limitations with this device. Despite there being limited experience in the pediatric population (9,10), these percutaneous VAD technologies may play an important role in management of pediatric heart failure in select situations (e.g., unstable hemodynamics during or after catheter procedures).

Durable devices

When the etiology of heart failure is chronic in nature, hence less prone to recovery, the patient will most likely need durable support in the form of a long-term VAD. The EXCOR (Berlin Heart, Inc.; The Woodlands, TX) (*Figure 4*) is the only pediatric-specific device that enjoys global acceptance. This system contains several different pump sizes (10, 15, 25, 30, 50, and 60 mL) and cannula sizes (5, 6, 9, and 12 mm). Choosing an appropriately sized pump and cannula is of utmost importance to avoid patient-device size mismatch, which is known to be a significant risk factor for poor outcome in long-term VAD therapy in children (11). Despite the known risk of patient-device size mismatch, adult continuous-flow devices are being increasingly used in children. This shift in paradigm is driven by significantly better complication profiles of continuous-flow devices compared to pediatric pulsatile pumps, and the option of discharge to home. Therefore, there has been ongoing discussion regarding how small of a patient is too small for

Figure 5 HeartMate II (Thoratec Corp.; Pleasanton, CA).

Figure 6 HVAD (HeartWare Inc.; Framingham, MA).

continuous-flow devices, as well as strategies to minimize, or even altogether avoid, the risk of patient-device size mismatch.

The HeartMate II (Thoratec Corp.; Pleasanton, CA) (*Figure 5*) is an excellent option for adolescents with BSA approximately 1.3 m^2 or larger. This device is currently the most widely used intracorporeal device for several reasons, most notably for its very low incidence of thromboembolic events compared to previous VADs. With appropriate patient selection and implantation techniques, the outcome of HeartMate II LVAD support in the pediatric population is very favorable (>90% bridge to transplant) (12). The use of the HeartMate II has essentially eliminated the need of Berlin EXCOR 50 ml and 60 mL pumps in the pediatric population. Also, it allows for pediatric patients with medically resistant heart failure whose ultimate treatment goal is uncertain (i.e., presently not a transplant candidate, cancer patient) to be treated and discharged home with ongoing VAD support.

The HVAD pump (HeartWare Inc.; Framingham, Massachusetts) (*Figure 6*) is also a widely used continuous-flow device. The HVAD has a centrifugal pump that is directly attached to the inflow cannula. Owing to its unique design, the HVAD pump is much smaller than the HeartMate II, therefore, has substantial potential for pediatric application. The smallest patient we experienced was a 4-year-old child weighing 13 kg, with a BSA of 0.65 m^2 at the time of implantation. The standard implantation technique for the HVAD involves directly implanting the pump adjacent to the heart with its pump housing placed within the pericardial space. A key concern exists, however, with this standard technique among experienced adult surgeons (13). The inflow cannula often sits more or less perpendicularly to the interventricular septum. From extensive experience with the HeartMate II, it is known that the perpendicular relationship of the inflow cannula to the septum may predispose to pump thrombosis (14). Ideally, the inflow should be in parallel to the septum rather than aligned perpendicularly. In order to achieve such a favorable orientation, OH Frazier's group at Texas Heart Institute has developed a technique that involves insertion of the pump into the diaphragmatic surface of the left ventricle, instead of cardiac apex (13). While their approach is an attractive option in adults, inserting the pump through the diaphragmatic surface of the left ventricle is technically more challenging in children. The posterior descending coronary artery runs in close proximity to the proposed implantation site, and may easily be distorted or jeopardized by anchoring a sewing ring in small hearts. Our preference is to use the cardiac apex as an insertion point, as is the case with the standard approach. Subsequently, we place the pump housing in a small pocket created above the left hemidiaphragm (15). With this maneuver, the cardiac apex is relocated more medially and caudally. This technique is reproducible and provides a favorable orientation of the inflow cannula. A caveat remains, though, in that the smaller the left ventricular cavity, the lower the tolerance for technical imperfections (16). We believe an optimal inflow configuration is extremely important in pediatric patients in whom a patient-device mismatch is inevitable.

The use of implantable continuous-flow VADs such

Figure 7 Total Artificial Heart 70 cc (Syncardia Inc.; Tucson, AZ).

as HeartMate II and HVAD has opened the era of outpatient management of children with ongoing VAD support. This is a dramatic paradigm change not only for healthcare professionals but also for the society at large. For instance, these children often return to school and do many normal daily activities. In order to achieve such 'return to normalcy', societal support is necessary. Examples would include education of school teachers and nurses, as well as local medical personnel regarding handling routine maintenance (i.e., changing batteries) as well as VAD emergencies. In our program, a VAD coordinator plays an important role in education.

Special situations where ordinal VAD support may not be suitable

There are certain situations where VAD support is not an ideal solution to managing heart failure. Patients with chronic graft dysfunction (e.g., transplant coronary vasculopathy) comprise a challenging population in terms of VAD support owing to their immunocompromised status. The necessity of continued immunosuppression for the cardiac graft poses a significant risk for infectious complications (17). In this scenario, the total artificial heart (TAH) (Syncardia Inc., Tucson, AZ) (*Figure 7*) may make postoperative care simpler since it eliminates the need for immunosuppressive therapy. The TAH should also be considered if multiple or complex concomitant cardiac repairs are needed before VAD support can be effectively commenced (e.g., repair or replacement of aortic and/or atrioventricular valves, replacement of conduits, closing of ventricular septal defects). We experienced a case of a 17-year-old male with a history of congenitally corrected transposition of the great arteries who developed profound biventricular dysfunction, severe aortic insufficiency and obstruction of the previously-placed left ventricle to pulmonary arterial conduit (18). While awaiting cardiac transplantation, he suffered acute cardiopulmonary collapse resulting in multisystem organ failure. The presence of severe aortic insufficiency precluded any type of temporary support via peripheral cannulation. Supporting global cardiac systolic function would have required BiVAD implantation in addition to aortic valve replacement (or closure) and conduit exchange in the setting of abnormally located ventricles and great arteries (*L*-looped ventricles and *L*-malposed vessels). Given the complexity of the proposed operation, the TAH was chosen as a preferable device to address all anatomical issues in a single step. Despite a tenuous preoperative state, the patient was extubated at 48 hours and was successfully bridged to heart transplantation at 6 months of support. This experience, and in similar patients presenting with biventricular failure, unremitting arrhythmias, large ventricular clot burden, and/or those with restrictive disease have convinced us that there are certain situations where VAD support is not the best solution, and the TAH needs to be included in the armamentarium of any complete pediatric heart failure program. The TAH also has the advantage that children can be discharged home with the use of the Freedom Driver to await transplantation. The TAH 50 cc pediatric Food and Drug Administration (FDA) trial has now started and will allow for the application of this technology in patients down to BSA 0.9 m^2, or in a patient in which virtual fit has determined that size is appropriate (19). This marks the first time the FDA has allowed for virtual fit to be a criteria for the use of mechanical circulatory support (MCS).

Complex congenital heart disease with single ventricle physiology also poses difficulty in VAD support. Weinstein and colleagues reviewed the outcome of the Berlin Heart EXCOR support in this patient population during the Berlin Heart IDE trial (20). Not surprisingly, the outcome in patients with single ventricle physiology is significantly worse (42% survival) compared to that in the biventricular group (73% survival). There are, however, clear differences in success rates based on the stage of single ventricle palliation; whereas patients after stage I (e.g., Norwood operation) experience dismal outcomes (11% survival), those with stage II or stage III do significantly better (58%

and 60% survival, respectively). Given the poor outcome of ECMO support in this population [stage II: 41% survival (21) and stage III: 35% survival (22)], it would be reasonable to consider that VAD support is a preferred mode of mechanical support over ECMO in stage II and III patients. In larger patients, the use of implantable continuous-flow VADs is also an option. Both the HeartMate II (23) and HeartWare HVAD (24) have successfully been used to support children with a failing Fontan physiology. When considering VAD support for this specific indication, it is crucial that the primary mode of circulatory failure is systolic ventricular dysfunction, since Fontan failure may occur at multiple levels. If the end-diastolic pressure of the systemic ventricle is not elevated (>10 mmHg), then VAD support of the failing Fontan circulation will probably not be successful. Patients with long-standing Fontan failure typically have multiple comorbidities such as protein-losing enteropathy. By enhancing the patient's overall physical condition, it stands to reason that long-term VAD support or in the most ill patients (liver and/or renal insufficiency and protein-losing enteropathy), VAD support will not only decreases the risk of wait-list mortality, but may also improve post-transplant outcomes by resuscitating these patients physically, nutritionally and psychologically. This remains to be determined in future studies.

New devices on the horizon

The HeartMate 3 (Thoratec Corp.; Pleasanton, CA) is a miniaturized intrapericardial continuous-flow device with a full magnetically levitated rotor. At full range of operation, it is able to provide between 2.5 and 10 L/min, as well as an artificial pulse presumably to reduce thrombus formation in the device. In October 2015, the device received the Conformité Européenne (CE) Mark approval (25). The trial enrolled 50 patients in 10 hospitals in six countries outside the US. Six-month survival was 92%. The trial reported no pump thrombosis events, and adverse event rates were lower than or consistent with expectations for severely ill and complex patients requiring LVAD support. The MOMENTUM 3 IDE trial is ongoing in the US. Although the device is slightly larger than the HeartWare HVAD, there is potential for pediatric application.

Another device on the horizon for children is the MVAD (HeartWare Inc.; MA). Though the inflow cannula size is identical with that of HVAD, its pump housing is comparatively smaller. This device's compactness will lend itself to use in smaller children with end stage heart failure. Additionally, unique features such as an adjustable inflow angle relative to the sewing ring (±10 degrees) and an adjustable inflow cannula depth permit customizable configuration to ensure a good fit. The CE Mark trial commenced in July 2015 with first implants performed in the UK and Austria.

The wave of implantable continuous-flow VADs may finally reach small children. The Jarvik Infant VAD has recently undergone significant design overhaul. In the latest iteration, the Jarvik Infant 2015, the size of inflow cannula has increased from 11 mm to 15 mm. This long awaited device is currently undergoing pre-clinical testing as collaboration between Texas Children's Hospital and the Texas Heart Institute; early results are greatly encouraging. Once successfully completed, this device will be evaluated in the Pumps for Kids, Infants and Neonates (PumpKIN) trial funded by the National Institute of Health. This trial is intended to be a two-arm prospective randomized trial where patients will be randomly allocated to receive either the Berlin EXCOR or the Jarvik Infant 2015 device, with each group consisting of 44 patients. This trial may open the era of the use of implantable continuous-flow VADs in small children.

Conclusions

Timing of VAD implantation is one of the most important aspects of VAD therapy and will determine the trajectory of the patient's intraoperative and post-operative course as well as the overall outcome. Device selection and avoidance of patient-device size mismatch is also critical since it directly impacts outcome. Adult continuous-flow devices have changed the field of pediatric VAD therapy in allowing for earlier implantation, the ability to be discharged home, and the potential for chronic therapy. As technology improves and the field matures, VAD therapy will play an increasingly important role in the successful management of children with heart failure.

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None.

Footnote

Conflicts of Interest: I Adachi—New England Research Institute (NERI): Consultant; HeartWare, Inc.: Consultant;

Sony-Olympus: Consultant. DL Morales—Berlin Heart: Participated in the Berlin Heart PAS clinical events committee and has been a moderator/presenter in Berlin Heart, Inc academic activities. He is a consultant for Berlin Heart EXCOR and his program (Cincinnati Children's Medical center) is a training center for Berlin Heart Inc.; HeartWare, Inc.: Consultant; Syncardia: Serves as a Procter and consultant for Syncardia TAH training as well as the National PI for the 50 cc TAH FDA Trial. S Burki and F Zafar have no conflicts of interest to declare.

References

1. Kirklin JK, Naftel DC, Pagani FD, et al. Sixth INTERMACS annual report: a 10,000-patient database. J Heart Lung Transplant 2014;33:555-64.
2. Almond CS, Morales DL, Blackstone EH, et al. Berlin Heart EXCOR pediatric ventricular assist device for bridge to heart transplantation in US children. Circulation 2013;127:1702-11.
3. Kirklin JK, Naftel DC, Pagani FD, et al. Seventh INTERMACS annual report: 15,000 patients and counting. J Heart Lung Transplant 2015;34:1495-504.
4. Thuys CA, Mullaly RJ, Horton SB, et al. Centrifugal ventricular assist in children under 6 kg. Eur J Cardiothorac Surg 1998;13:130-4.
5. del Nido PJ, Duncan BW, Mayer JE Jr, et al. Left ventricular assist device improves survival in children with left ventricular dysfunction after repair of anomalous origin of the left coronary artery from the pulmonary artery. Ann Thorac Surg 1999;67:169-72.
6. Duncan BW, Bohn DJ, Atz AM, et al. Mechanical circulatory support for the treatment of children with acute fulminant myocarditis. J Thorac Cardiovasc Surg 2001;122:440-8.
7. Haines NM, Rycus PT, Zwischenberger JB, et al. Extracorporeal Life Support Registry Report 2008: neonatal and pediatric cardiac cases. ASAIO J 2009;55:111-6.
8. Teele SA, Allan CK, Laussen PC, et al. Management and outcomes in pediatric patients presenting with acute fulminant myocarditis. J Pediatr 2011;158:638-643.e1.
9. Andrade JG, Al-Saloos H, Jeewa A, et al. Facilitated cardiac recovery in fulminant myocarditis: pediatric use of the Impella LP 5.0 pump. J Heart Lung Transplant 2010;29:96-7.
10. Ricci M, Gaughan CB, Rossi M, et al. Initial experience with the TandemHeart circulatory support system in children. ASAIO J 2008;54:542-5.
11. Blume ED, Naftel DC, Bastardi HJ, et al. Outcomes of children bridged to heart transplantation with ventricular assist devices: a multi-institutional study. Circulation 2006;113:2313-9.
12. Cabrera AG, Sundareswaran KS, Samayoa AX, et al. Outcomes of pediatric patients supported by the HeartMate II left ventricular assist device in the United States. J Heart Lung Transplant 2013;32:1107-13.
13. Gregoric ID, Cohn WE, Frazier OH. Diaphragmatic implantation of the HeartWare ventricular assist device. J Heart Lung Transplant 2011;30:467-70.
14. Taghavi S, Ward C, Jayarajan SN, et al. Surgical technique influences HeartMate II left ventricular assist device thrombosis. Ann Thorac Surg 2013;96:1259-65.
15. Adachi I, Guzmán-Pruneda FA, Jeewa A, et al. A modified implantation technique of the HeartWare ventricular assist device for pediatric patients. J Heart Lung Transplant 2015;34:134-6.
16. Kirklin JK, Naftel DC, Kormos RL, et al. Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) analysis of pump thrombosis in the HeartMate II left ventricular assist device. J Heart Lung Transplant 2014;33:12-22.
17. Adachi I, Guzmán-Pruneda FA, Khan MS, et al. Ventricular Assist Device in Children with Cardiac Graft Failure. ASAIO J 2015;61:729-30.
18. Morales DL, Khan MS, Gottlieb EA, et al. Implantation of total artificial heart in congenital heart disease. Semin Thorac Cardiovasc Surg 2012;24:142-3.
19. Moore RA, Madueme PC, Lorts A, et al. Virtual implantation evaluation of the total artificial heart and compatibility: Beyond standard fit criteria. J Heart Lung Transplant 2014;33:1180-3.
20. Weinstein S, Bello R, Pizarro C, et al. The use of the Berlin Heart EXCOR in patients with functional single ventricle. J Thorac Cardiovasc Surg 2014;147:697-704; discussion 704-5.
21. Jolley M, Thiagarajan RR, Barrett CS, et al. Extracorporeal membrane oxygenation in patients undergoing superior cavopulmonary anastomosis. J Thorac Cardiovasc Surg 2014;148:1512-8.
22. Rood KL, Teele SA, Barrett CS, et al. Extracorporeal membrane oxygenation support after the Fontan operation. J Thorac Cardiovasc Surg 2011;142:504-10.
23. Morales DL, Adachi I, Heinle JS, et al. A new era: use

of an intracorporeal systemic ventricular assist device to support a patient with a failing Fontan circulation. J Thorac Cardiovasc Surg 2011;142:e138-40.
24. Niebler RA, Ghanayem NS, Shah TK, et al. Use of a HeartWare ventricular assist device in a patient with failed Fontan circulation. Ann Thorac Surg 2014;97:e115-6.
25. St. Jude Medical Announces CE Mark Approval for the HeartMate 3 Left Ventricular Assist System. Available online: https://www.thoratec.com/medical-professionals/vad-product-information/heartmate3/HeartMate3-CE-Mark-Press-Release.pdf

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