42 Ventricular Assist Devices

Sebastian C. Tume, Hari P. Tunuguntla, Jack F. Price, Barbara A. Elias, Robin Rae Schlosser, Iki Adachi

Treatment of children with end-stage heart failure has been revolutionized by the development of progressively smaller-in-size durable ventricular assist devices (VAD). The Texas Medical Center has played a crucial role in VAD development. In 1966, the first successful human VAD was implanted by Dr. DeBakey, and in 1969, Dr. Cooley attempted the first clinical application of the total artificial heart (TAH). Such historical background had a profound impact on the development of the VAD program at TCH, which is recognized as the largest program of its kind worldwide. VAD support has become the standard therapy for end-stage heart failure in adults, resulting in an exponential increase in the number of implants worldwide over the last decade. Likewise, VAD therapy is becoming a common practice in the pediatric field, although there still remains a substantial "lag" when compared with the adult field.

Patient Selection

A decision to offer VAD support involves careful clinical assessment and excellent interdisciplinary communication in an often limited timeframe. VAD therapy should be offered if its benefits are deemed to outweigh the expected risks. The risk-benefit profiles, however, vary across different age groups, cardiac diagnoses, and institutions. The timing of initiating VAD support is critical to ensure successful outcomes in all aspects of postoperative care. The decision for mechanical circulatory support in the setting of refractory cardiogenic shock should never be delayed. This assessment must be accompanied at times by rapid deployment of short-term VAD followed by careful assessment for durable VAD candidacy once shock is reversed and end-organ recovery emerges.

The common indications for durable VAD support in children include: bridge to recovery, bridge to transplantation, and at times, destination therapy. Undetermined transplant candidacy is not necessarily a contraindication for VAD support.

All inotropic-dependent patients with suboptimal circulation should be evaluated for VAD support. Patient's size (<5 kg) and anatomy may limit their long-term mechanical support options. It is important to identify those patients in need of long-term invasive support (invasive mechanical ventilation or circulatory support) before they develop significant secondary organ failure. End-organ dysfunction is the single most important predictor of patient mortality at the time of VAD implantation; careful monitoring of end-organ function cannot be overstated.

The commonly described conditions that preclude durable VAD therapy include extreme prematurity, low body weight (<2.5 kg), irreversible multiorgan failure, active systemic infection, coagulopathy not amenable to anticoagulation, intracranial hemorrhage or irreversible severe neurologic insult, major chromosomal aberrations, and irreversible pulmonary hypertension. Additionally, there are other complicating factors to be considered when providing VAD support in children. Anatomic variations pose technical challenges, and previous surgical procedures such as systemic-to-PA

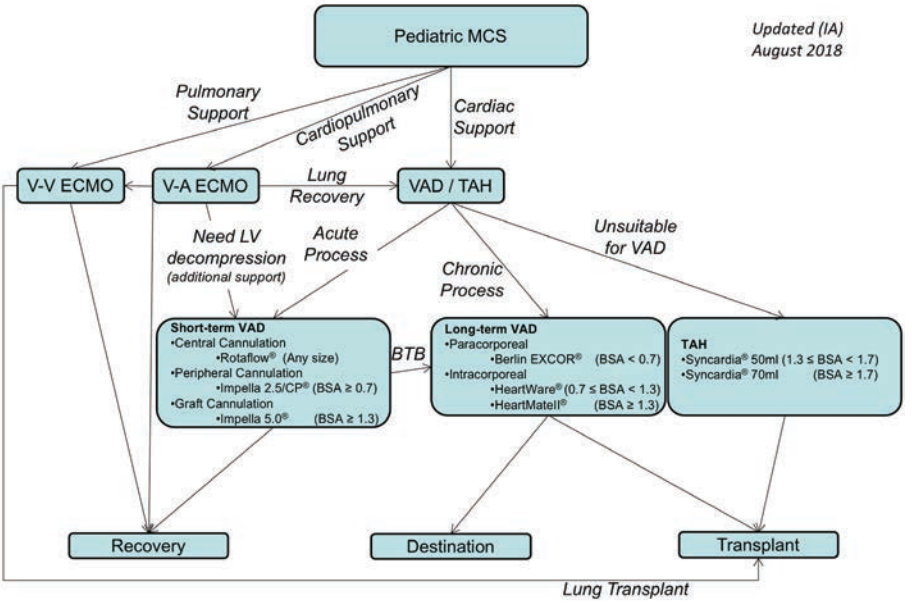

Figure 42-1. TCH mechanical circulatory support selection algorithm. BSA: body surface area, BTB: "bridge-to-bridge", ECMO: extracorporeal membrane oxygenation, LV: left ventricle, MCS: mechanical circulatory support, V-A: venoarterial, VAD: ventricular assist device, V-V: venovenous, TAH: total artificial heart.

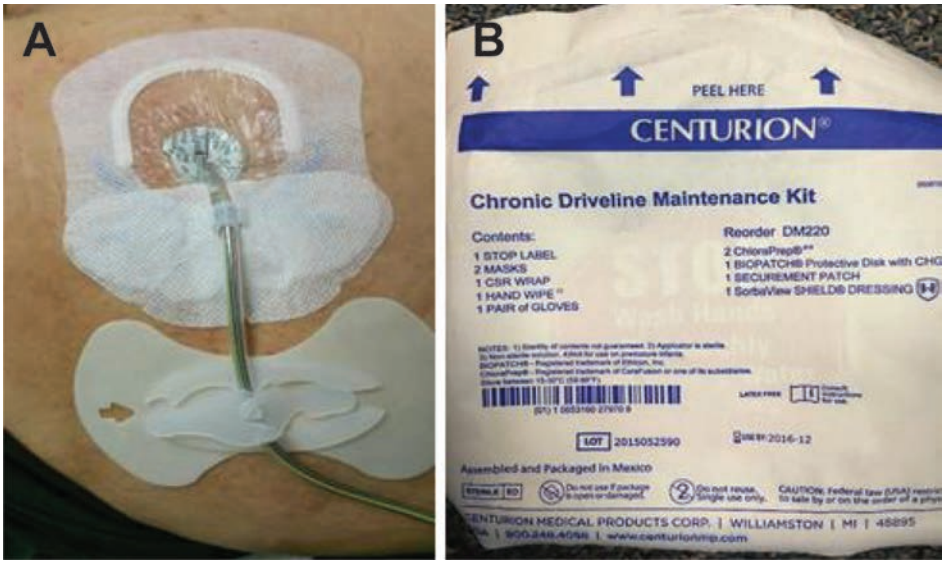

Figure 42-2. Appropriate driveline dressing and securing techniques. A) Dressing and anchoring device in place. B) Kit used for driveline maintenance and dressing.

Table 42-1. INTERMACS profiles. From Stevenson LW, Pagani FD, Young JB, et al. INTERMACS Profiles of Advanced Heart Failure: The Current Picture. J Heart Lung Transplant 2009;28:535-541.

INTERMACS profile	Profile description
1	Critical cardiogenic shock
2	Progressive decline
3	Stable but inotrope dependent
4	Resting symptoms
5	Exertion intolerant
6	Exertion limited
7	Advanced NYHA class III

shunts or disconnected caval veins after Glenn or Fontan operations may jeopardize the application of VAD therapy.

Timing of VAD implantation is crucial and to a large degree determines the trajectory of the patient's postoperative course and recovery. There continues to be a lack of accurate clinical pre-implantation assessment tools to aid with risk stratification. INTERMACS profiles (Table 42-1) are frequently used to recognize the severity of illness and make decisions. Databases such as PediMACS show that patients with low INTERMACS profiles are high-risk VAD candidates. At TCH, we have shifted away from offering durable VAD support to children with INTERMACS profiles 1 and 2, electing to first stabilize their circulation with short-term devices. The INTERMACS criteria also lacks assessment of end-organ function and fails to incorporate other comorbidities that are crucial for VAD candidacy and choice of optimal support technology. Figure 42-1 shows the TCH algorithm for selection of mechanical support.

Device Selection

Optimal device selection and avoidance of patient-to-device mismatch are critical to optimal outcome. VAD functions as a mechanical pump that augments the intrinsic function of the LV and RV to maintain cardiac output. In addition to generating cardiac output, the device must maintain function at appropriate preload and afterload pressures with minimal power consumption, have minimal activation of the inflammatory, hematologic, and immunologic systems, enable patient mobility and rehabilitation, and have a long-term endurance. Despite the variety of devices available for adults, the options for children remain limited.

The device armamentarium available at TCH is depicted in Table 42-2. Short-term devices include RotaFlow® (surgically implantable) and Impella® (percutaneous). Care must be taken when considering Impella® as it might have limited flow capability in patients with long-standing heart failure since they typically require substantially higher flows to facilitate end-organ recovery. The Berlin EXCOR® is a pulsatile-flow VAD (PF-VAD) and is the primary device for infants and small children with BSA <0.7 m^2. The HeartWare™ HVAD™ continuous-flow VAD (CF-VAD) remains our first choice

Table 42-2. VAD selection available for circulatory support in children at TCH.

Device type	Device name	Characteristics	Patient selection	Considerations
Short-term	RotaFlow	Continuous centrifugal-flow LVAD or BiVAD	No size limitation	Used as bridge to decision
	Impella®	Continuous axial-flow Percutaneous RVAD: Impella® RP LVAD: Impella® 2.5, CP, 5.0* **Device flow, sheath size:** **RP**: 4 L/min, 11 Fr **2.5**: 2.5 L/min, 13 Fr **CP**: 4 L/min, 14 Fr **5.0***: 5 L/min, 21 Fr Flows might be limited with RV failure or abnormal position *Impella® 5.0 requires surgical implant	**Patient selection**: based on size of the ventricle and access vessel, and the etiology of heart failure **Anatomic requirements**: LV long diameter >7 cm Aortic annulus >1.5 cm Severe hemolysis might restrict full flow/ support	**Common uses:** High-risk cath procedures Acute circulatory support Examples: myocarditis, graft failure, refractory arrhythmias or as LA vent with VA-ECMO **Avoid with:** mechanical valves mod-severe AI/AS aortic disease LV thrombus intracardiac shunt
Long-term Pulsatile	Berlin EXCOR®	Paracorporeal LVAD or BiVAD	**Patient size:** >5 kg, BSA <0.7 m^2 **Available device sizes:** 10, 15, 25, 30, 50, and 60 mL pumps 5, 6, 9, 12 mm cannulas	**Use:** Bridge to transplant **Avoid:** severe AI severe MS CHD
	SynCardia (Total Artificial Heart)	Intracorporeal	**Patient size:** 50cc: BSA 1.2-1.7 m^2 70cc: T10 to sternum >10 cm, BSA >1.7 m^2	**Use:** Bridge to transplant Biventricular failure Examples: coronary vasculopathy **Avoid:** High PVR
Long-term Continuous Flow	HeartMate II	Intracorporeal Axial flow LVAD or BiVAD	**Patient size:** BSA ≥1.2 m^2 **Support parameters:** 6000-15000 RPM, up to 10 L/min	**Use:** Bridge to transplant or destination
	HeartWare	Intracorporeal Centrifugal flow LVAD or BiVAD	**Patient size:** BSA ≥0.7 m^2 **Support Parameters:** 1800-3200 RPM, up to 10 L/min	**Use:** Bridge to transplant or destination

BiVAD: biventricular assist device, LVAD: left ventricular assist device, RVAD: right ventricular assist device, VA: Venoarterial

Table 42-3. Structural and physiologic differences between pulsatile and continuous flow VADs

Pulsatile-flow devices	Continuous-flow devices
Positive displacement pumps undergoing filling and ejection period Pneumatic mechanism drives filling and ejection Flow (output) = HR x SV (chamber volume) Arterial pressure tracings reflect systole and diastole with palpable pulses	Continuous flow dependent on the rotational speed of the impeller and the pressure differential (aorta to ventricle) across the pump Sensitive to inflow (preload) and outflow (afterload) environments Presence of pulsatility is dependent on the intrinsic ejection of the native ventricle

HR: heart rate, SV: stroke volume

for children with BSA >0.7 m^2. Biventricular support can be achieved using any of the devices as biventricular support (BiVAD) or SynCardia TAH (where size permits).

Surgical Implantation

The key principle of surgical implantation of a VAD, irrespective of the type of device, is to complete the implant procedure while preserving end-organ function and RV function. If the end organs are severely compromised, the patient may not tolerate the invasive operation, even in the setting of optimal cardiac output. This is why timing of VAD implantation is so critical. In adults, there has been a dramatic change over the last decade shifting away from implant for impending death or progressive decline on inotropes (i.e., INTERMACS profiles 1 or 2) to elective surgery in more stable outpatients with chronic heart failure (i.e., INTERMACS profiles 3 or 4). As the pediatric field still lags behind the adult field, pediatric patients typically undergo surgery at a more advanced stage, requiring more careful management and end-organ preservation.

Intraoperative monitoring is crucial to determine appropriate device setting and optimize its function. LA lines and central venous catheters (CVC) are inserted in all patients, and pressures are monitored to assess the degree of ventricular unloading and evidence of right heart failure (RHF). The LAP is used to establish intraoperative degree of LV unloading at the time of device support titration. Intra- and postoperative TEE imaging allows assessment of the aortic valve for evidence of AI, position of the outflow cannula, and presence of ASDs. TEE is also used to measure the effects of VAD function such as degree of MR, ventricular septal position, and severity of RV dysfunction, which will help guide postoperative CICU management.

Postoperative Management

Familiarity with the basic function and structure of VADs is essential for optimal postoperative patient management and troubleshooting of VAD-related issues. Table 42-3 describes the major physiologic and structural differences between pulsatile- and continuous-flow VADs. In general, a VAD has 5 basic elements: the pump, the inflow and outflow cannulas, a controller/driver, and connection to the power source (battery or power adapter).

The postoperative course can be accompanied by numerous complications related to the preoperative clinical state of the patient, as well as physiologic/hemodynamic changes associated with VAD support. Table 42-4 lists some of the most common postoperative scenarios and their effect on VAD function. The use of hemodynamic monitoring is essential to provide optimal care and prevent some of the common complications. Each patient should have left- and right-heart pressure monitoring to provide accurate information in case of acute hemodynamic changes. Arterial BP should be monitored in all patients. In patients with CF-VADs that have minimal pulsatility, cuff pressure and pulse oximetry are unreliable, and BP should be measured manually using a Doppler and a cuff. We also encourage monitoring of oxygen delivery using NIRS technology.

Appropriate ventilator management and optimization of lung volume to reduce PVR cannot be overstated. PVR can be elevated due to atelectasis, pleural effusions, or pulmonary edema, which should be immediately treated. Typically, patients are extubated within 48 hours after surgery unless chronically ventilated prior to VAD placement.

Postoperative bleeding may be a problem after VAD placement. In addition to surgical bleeding, VAD therapy predisposes patients to additional bleeding risks through the use of anticoagulation for the device or coagulopathies such as acquired von Willebrand disease or liver dysfunction. Chest tube output should be monitored carefully, especially when titrating anticoagulation. Ongoing significant bleeding (>2 mL/kg/hr) must be urgently addressed as it can result in tamponade physiology, leading to suboptimal VAD preload and compromised flows.

RHF after VAD implantation is associated with significant morbidity and mortality. Commonly, right heart dysfunction may be observed in the OR, where initial therapies such as iNO and inotropic medications are instituted and the chest may be left open. In an attempt to prevent worsening of RHF, caution should be taken to control heart rate and rhythm, optimize RV afterload, avoid volume overload, and institute inotropic therapies when appropriate. CVP monitoring is very helpful. A rising CVP in the face of low LAP is suggestive of RHF and should be treated urgently. If elevated PVR is suspected, iNO and/or nebulized prostacyclin should be utilized. Some high-risk patients or those with significant RHF may require transition to sildenafil to enable early extubation and prevention of potential exacerbation of the disease. Right VAD support is rarely necessary but may be entertained in cases of severe refractory RHF.

Cerebrovascular events are a significant cause of morbidity and mortality in VAD patients. Neurologic injury is more common in PF-VAD compared with CF-VAD, and should be kept in mind as the patient transitions to full anticoagulation. Patients with poor device output and suction events are at a higher risk of thrombus formation due to stasis and turbulence. Close neurologic monitoring is essential and any behavioral or neurologic changes should be immediately addressed. Head CT is the primary imaging modality as current VAD technologies are not MRI compatible. CT may lack the diagnostic sensitivity to identify ischemic events, especially early in the course of the event, but should be able to identify hemorrhagic events.

Infections remain frequent in pediatric VAD patients. Nondevice infections are most common and can be easily treated with medical therapy. Device-related infections might require device replacement. Fever should be evaluated immediately with blood

Table 42-4. Common continuous-flow VAD scenarios

Pump flow change	Clinical condition	Hemodynamic changes				Pump parameters		
		CVP	LA/PCWP	MAP	SvO_2/ NIRS	Power	Pulsatility/ Filling	Flow
Decreased flow index	Right heart failure	↑	↓	<->	↓	<->	↓	↓
	Tamponade	↑	↑ or no change	↓	↓	↓	↓	↓
	Hypovolemia	↓	↓	↓	<->	<->	↓	↓
	Hypertension	<->	↑ or no change	↑	<->	<->	↑	↓
	Inlet obstruction or inlet clot	↑	↑	↓	↓	↓ less than expected	↓	<->
Increased flow index	Fluid overload	↑	↑	↑	↑	↑	↑	↑
	Vasodilation	↓	↓	↓	<->	<->	↓	↑
	Aortic insufficiency	<->	↑	↓	↓	↑	↓	↑
	Motor clot	↑	↑	↓	↓	↑	↓	↑ falsely high

CVP: Central venous pressure, LA: left atrial pressure, MAP: Mean arterial pressure, PCWP: Pulmonary capillary wedge pressure, SVO_2: Mixed venous saturation

cultures and appropriate antibiotic therapy. The driveline entry site requires frequent dressing changes as minimizing entry-site irritation helps facilitate wound healing.

Acute renal failure is commonly related to preoperative renal injury. CPB, use of diuretics, or elevated CVP due to RHF can further exacerbate renal injury. Optimizing systemic perfusion pressures and maintaining a low CVP helps optimize renal perfusion pressures and facilitate renal recovery. If present, hemolysis should be urgently addressed, as elevated levels of plasma-free hemoglobin can exaggerate renal injury.

Driveline Care and Transition to Home Environment

Driveline care is managed initially by the VAD coordinator and then by family members. Sterile driveline dressing changes occur daily until the wound sutures are removed and then transition to changes every Monday, Wednesday, and Friday, plus as needed after showering. Dressing kits that utilize BIOPATCH® and Tegaderm™ are the most convenient. Figure 42-2 shows appropriate driveline dressings and anchoring. Aquacel® Ag is used for those patients with signs of driveline infection or fat necrosis. Minimizing driveline mobility and irritation of the skin is crucial for optimal healing. We routinely document driveline sites and photo images in order to track healing.

Physical and occupational therapy are an integral part of the multidisciplinary team. Patients begin mobilizing as soon as medically tolerated, focusing on activities of daily living, strengthening, and mobility. The 6-minute walk test and functional mobility are monitored to track progress. Patient and family education is reinforced in all therapy sessions and local field trips are encouraged between hospital floors and play areas.

VAD education begins prior to implantation and escalates after. Education manuals including videos help reinforce new concepts and terminology. Advanced education should concentrate around driveline care, understanding controller and battery/power connection, common alarm simulations, and controller-exchange sessions with all caregivers taking part. The discharge binder contains emergency contacts, a letter to emergency medical services (EMS), a copy of the medication sheet, clinic appointments, device log, patient manual, EMS-controller exchange card, and a VAD luggage tag. In addition, patients are given an equipment bag to house batteries, charger, AC- and DC-power adaptors, and dressing supplies. Competency checklists are helpful to document progress and adherence to protocols, and to ensure a successful discharge and success in the community.

Full community involvement is encouraged. VAD teaching to the local fire department/EMS, place of worship, and schools is arranged by the VAD coordinator. A phone landline must be in place for secure emergency contact. Emergency phone contacts must be established and include a VAD-emergency line. Out-of-town patients are required to reside close to TCH for at least 3 months, with regular clinic visits. When cleared by the medical team, patients are allowed to return to their local home area with monthly clinic visits. The ultimate goal is to return the VAD-supported patient to a "new mode of normalcy and lifestyle" in which quality and safety are a priority.

Suggested Readings

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