Evaluation for a Ventricular Assist Device: Selecting the Appropriate Candidate

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Selecting the Appropriate Candidate

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Case presentation: A 57-year-old woman with ischemic and valvular heart disease presents with progressive heart failure while awaiting cardiac transplantation. Several years ago, after a large anterior myocardial infarction, she underwent 4-vessel CABG. Her subsequent course was complicated by atrial fibrillation and then recurrent heart failure. She also developed progressive aortic stenosis and mitral and tricuspid regurgitation and underwent aortic valve replacement with a 17-mm St. Jude valve, as well as mitral and tricuspid valvuloplasty. Two years later, she developed worsening symptoms of heart failure. She continued to fail despite escalating medical therapy and was listed for cardiac transplantation 6 months before this hospitalization. She is now admitted with severe heart failure and has been stabilized on intravenous positive inotropic therapy. She is 5 feet 2 inches tall, weighs 104 pounds, and has a body surface area of 1.4 m^2. What are the best options to manage her as she awaits transplantation: Continued parenteral inotropic support, a ventricular assist device (VAD), or both as a bridge to transplantation?

Heart failure is the final pathway of a progressive disease that can originate from a variety of cardiovascular processes. Improved acute medical care and prevention of sudden cardiac death have led to an increased prevalence of advanced heart failure. The prognosis of heart failure is dismal, with 50% of patients dead within 4 years, a percentage that matches that of many common malignancies.[1] Of those hospitalized with an acute exacerbation, the mortality rate within 1 year has been reported to be between 30% and 50%.[2,3] Numerous factors in clinical studies consistently have been identified to be associated with poor prognosis: Advanced age, decreased blood pressure, reduced ejection fraction, chronic kidney disease, diabetes mellitus, anemia, hyponatremia, and persistently high levels of natriuretic peptides. Yet, no single clinical variable or risk score is adequate to predict outcomes in the individual patient.[4,5] It is estimated that more than 100 000 patients have severe, refractory (American Heart Association/American College of Cardiology stage D) heart failure.[3]

Medical therapy has a major impact on the prognosis and symptoms of early heart failure, yet there are few options for care of end-stage heart disease, which primarily includes cardiac transplantation or mechanical support. The potential for cardiac transplantation remains limited, for donor supply has not changed substantially in the past decade.[6] On the other hand, the technologies for VADs have expanded rapidly, and these devices may now be considered in patients with terminal heart failure. This review will discuss the unique clinical dilemmas encountered in selecting candidates for therapy with currently available VAD technology.

Selection of a VAD Patient

Although there are no consensus guidelines for VAD implantation, criteria have been developed to help optimize patient selection and outcomes.[7–9] Patients who may benefit from a mechanical assist device include those who cannot be weaned from inotropic therapy, develop intolerance to ACE inhibitors because of progressive cardiorenal dysfunction, have a peak oxygen consumption ≤ 12 mL $\cdot$ kg^{-1} $\cdot$ min^{-1}, or cannot be restored to New York Heart Association class III symptoms despite optimization of medical therapy (Table 1). Various composite risk scores have been devised that incorporate hemodynamic

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Table 1. Patient Selection for VAD Implantation

Indications
NYHA functional class IV symptoms
Life expectancy <2 years*
Not a candidate for heart transplantation*
Failure to respond to optimal medical management for at least 60 of the last 90 days*
Left ventricular ejection fraction ≤25%*
Refractory cardiogenic shock or cardiac failure†
Peak oxygen consumption ≤12 mL · kg^{-1} · min^{-1} with cardiac limitation
Continued need for intravenous inotropic therapy limited by symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion*
Recurrent symptomatic sustained ventricular tachycardia or ventricular fibrillation in the presence of an untreatable arrhythmogenic substrate
Body surface area >1.5 m^2*‡
Relative contraindications
Age >65 years, unless minimal or no other clinical risk factors
Chronic kidney disease with serum creatinine level >3.0 mg/dL
Severe chronic malnutrition (BMI <21 kg/m^2 in males and <19 kg/m^2 in females)
Morbid obesity (BMI >40 kg/m^2)
Mechanical ventilation
Severe mitral stenosis or moderate to severe aortic insufficiency, or uncorrectable mitral regurgitation
Contraindications
Potentially reversible cause of heart failure
High surgical risk for successful implantation
Recent or evolving stroke
Neurological deficits impairing the ability to manage device
Coexisting terminal condition (eg, metastatic cancer, cirrhosis)
Abdominal aortic aneurysm ≥5 cm
Biventricular failure in patients older than 65 years
Active systemic infection or major chronic risk for infection
Fixed pulmonary or portal hypertension
Severe pulmonary dysfunction (eg, FEV_1 <1 L)
Impending renal or hepatic failure
Multisystem organ failure
Inability to tolerate anticoagulation
Heparin-induced thrombocytopenia
Significant underlying psychiatric illness or lack of social support that may impair ability to maintain and operate VAD

NYHA indicates New York Heart Association; BMI, body mass index; COPD, chronic obstructive pulmonary disease; and FEV_1, forced expiratory volume in 1 second.

*Requirements necessary for destination therapy implantation as stated by Centers for Medicare & Medicaid Services.

†Cardiogenic shock or failure may be seen after a spectrum of conditions including an acute myocardial infarction or cardiac surgery. Implantation should only be considered in patients without potential for recovery.

‡Smaller individuals may be fitted with available paracorporeal, small-sized pulsatile, or newer axial-flow devices.

parameters and measures of end-organ function to help identify predictors of survival and guide patient selection (Table 2).[10–12] Although useful in clinical decision making, none of the algorithms have been prospectively validated, and they are derived from small selected populations and are limited to specific mechanical devices.

The Interagency Registry for Mechanical Assisted Circulatory Support (INTERMACS) was initiated in 2005 to track, refine and ultimately optimize outcomes for patients who receive VADs in the United States. Sponsored by the National Institutes of Health, Center for Medicare & Medicaid Services, and the Food and Drug Administration, this nationwide registry will provide additional insights and guidelines. To help improve the assessment of implant risk, INTERMACS recently analyzed all patients who were entered during the first 18 months.[13,14] A proposed series of 7 clinical profiles for patient selection was developed that better

Table 2. Risk Scores for Mortality After VAD Implantation

Variable*	OR/Risk Score	Variable†‡	Relative Risk/Risk Score	Variable§	OR/Risk Score
Platelet count $\leq 148\times10^3/\mu L$	7.7/7	Urine output <30 mL/h	3.9/3	Respiratory failure and sepsis‖	11.2/1
Serum albumin ≤3.3 g/dL	5.7/5	CVP >16 mm Hg	3.1/2	Preexisting right heart failure	3.2/1
INR >1.1	5.4/4	Mechanical ventilation	3.0/2	Age at implant >65 years	3.0/1
Vasodilator therapy	5.2/4	PT >16 seconds	2.4/2	Acute postcardiotomy	1.8/1
Mean PAP ≤25 mm Hg	4.1/3	Reoperation	1.8/1	Acute infarction	1.7/1
AST >45 U/mL	2.6/2	WBC >15 000/mm^3	1.1/0		
Hematocrit ≤34%	3.0/2	Temperature >101.5°F	0/0		
BUN >51 U/dL	2.9/2				
No intravenous inotropes	2.9/2				
Destination therapy risk score:					
Low risk: 0 to 8		Bridge to transplantation risk score:		Bridge to transplantation risk score:	
Medium to high risk: 9 to 19		Low risk: <5		Low risk: 0	
Very high risk: >19		High risk: ≥5		High risk: ≥1	

CVP indicates central venous pressure; INR, international normalized ratio; PT, prothrombin time; PAP, pulmonary artery pressure; AST, aspartate aminotransferase; WBC, white blood cell count; and BUN, blood urea nitrogen.

*Adapted from Lietz et al.[11]

†Adapted from Oz et al.[10]

‡All patients met hemodynamic criteria consisting of cardiac index <2.0 L · min^{-1} · m^{-2} with left atrial or pulmonary capillary wedge pressure >20 mm Hg.

§Adapted from Deng et al.[12]

‖Includes patients with preimplantation septicemia (fever >38.5°C) and positive blood cultures who required mechanical ventilation.

recognizes the acuity and severity of illness and may simplify the assessment of implant risk (Table 3).[13,15]

Before consideration for VAD implantation, candidates are typically evaluated at a transplant center, where they receive aggressive medical management for advanced heart disease. If patients remain refractory to standard therapy, they will be assessed and, if appropriate, listed for cardiac transplantation. The criteria for recipient selection have not changed substantially in the last 15 years.[16] Three general categories of VAD patients have emerged. These include (1) individuals who require temporary circulatory support who are expected to recover after a cardiac insult and will not need cardiac transplantation (bridge to recovery); (2) patients awaiting a cardiac transplantation but who would not survive until an organ is available owing to low cardiac output and/or noncardiac comorbidities (bridge to transplantation); or (3) individuals who need long-term support but who have a relative or absolute contraindication to cardiac transplantation (destination therapy).

The distinction between *bridge to transplant* and *destination therapy* may oversimplify the potential risks of VAD, as well as the potential benefits, and may be too arbitrary in 2009. There are bridge to transplant patients who meet conventional transplant recipient criteria at the time of VAD implantation but who develop postoperative complications (eg, stroke or sepsis) that prevent further transplant consideration. There are destination

Table 3. INTERMACS Patient Profiles and Timing of Mechanical Circulatory Support*

Patient Profile†	Patient Characteristics	Time Frame Until Intervention
1	Critical cardiogenic shock despite escalating support	Within a few hours
2	Progressive decline with inotrope dependence	Within a few days
3	Clinically stable with mild to moderate inotrope dependence	Elective implantation over the next few weeks
4	Recurrent, not refractory, advanced heart failure that can be stabilized with intervention	Elective implantation over weeks to months
5	Exertion intolerant but is comfortable at rest and able to perform activities of daily living with slight difficulty	Variable; depends on nutrition, organ function, and activity
6	Exertion limited; is able to perform mild activity, but fatigue results within a few minutes of any meaningful physical exertion	Variable, depends on nutrition, organ function, and activity
7	Advanced NYHA functional class III	At this time, mechanical circulatory support is not indicated

NYHA indicates New York Heart Association.

*Adapted from Stevenson et al.[15]

†Arrhythmia modifier (A), recurrent ventricular tachyarrhythmias (may be added to any INTERMACS level except 7).

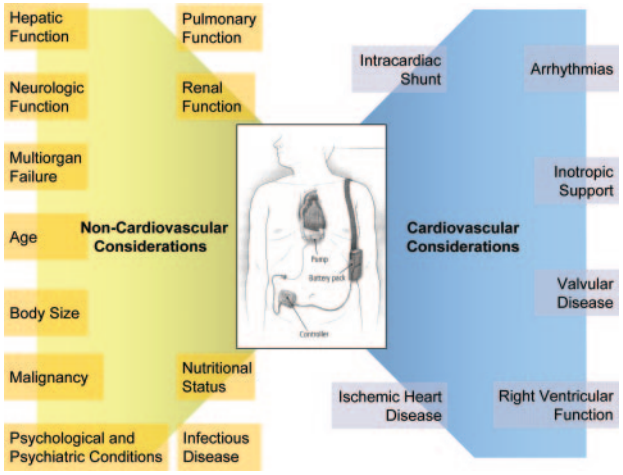

Figure. Factors involved in determining appropriateness of VAD implantation.

therapy patients who are stabilized with VAD insertion and become suitable cardiac transplant candidates; this includes patients with secondary renal or hepatic dysfunction or reversible pulmonary hypertension. In a recent report, 17% of destination-therapy recipients underwent heart transplantation after a mean mechanical support time of 10 months.[11] In addition, a small proportion (≈5%) of patients with an acutely reversible process, such as fulminant myocarditis or peripartum cardiomyopathy, may be bridged to myocardial recovery and undergo successful VAD explantation.[17] Hence, a more suitable designation for all potential VAD patients is "bridge to decision," for it neither raises false hopes for patients and their families nor ignores the substantial improvements in comorbidities that can be achieved with mechanical circulatory support. If a patient receives a VAD, Medicare and Medicaid, along with most insurance carriers, will cover the cost of surgery, hospitalization, and follow-up care as long as the device is approved by the Food and Drug Administration, is placed by an approved program, and is being used according to labeled instructions.

Unique Cardiovascular and Noncardiovascular Considerations for VAD Implantation

In addition to screening for cardiac transplantation eligibility, there are unique clinical cardiovascular and noncardiovascular considerations in the selection of a patient for mechanical circulatory support (Figure; Table 1).[8,18–20]

Cardiovascular Considerations

Aortic Valve Competency

The competency of the aortic valve must be assessed by echocardiography. A left VAD cannot be placed if there is aortic regurgitation, for this will simply distend the left ventricle, generating hemodynamically compromising volume overload of the VAD and inadequate forward flow. In fact, a criterion for VAD effectiveness is lack of aortic valve opening, which signals that the native ventricle has been unloaded adequately and that the VAD is providing all cardiac output. Because the aortic valve does not open, individuals with mechanical aortic valves will develop thrombus on the aortic side of the prosthesis, which can have dire embolic consequences. In rare instances of intrinsic aortic valve pathology or a bioprosthesis, the aortic valve leaflets may be oversewn to allow adequate VAD function. Pathology of the ascending aorta (eg, mobile atheromata, aneurysm, or anastomoses of patent coronary bypass grafts) may also be a contraindication to outflow cannula placement. Inspection of the aorta should be undertaken by echocardiography to assess for the presence of atheromata at the outflow cannula insertion site.

Mitral Valve Function

Under optimal VAD function, the left ventricle is a passive conduit to the VAD pumping chamber and must have unimpaired filling. Mitral stenosis should be corrected at the time of implantation, but mitral regurgitation can usually be addressed when the VAD fully decompresses the left ventricle and there is significant improvement in functional mitral regurgitation.

Right Ventricular Function

Right ventricular function is a major determinant of early postimplantation outcomes (Table 4).[21–23] Because there is no current biventricular support mechanism approved for destination therapy, adequate assessment of right ventricular function is a critical preoperative variable. Indications of right-sided heart failure that may require right ventricular mechanical support include right ventricular dilation with increased end-diastolic and end-systolic volumes, marked elevation in right atrial pressure (eg, ≥ 20 mm Hg) or right atrial pressure greater than left atrial pressure, reduced right ventricular stroke work index, and severe tricuspid regurgitation.[24–27] Signs of right ventricular dysfunction are further evidence that VAD placement is a "bridge to decision." At times, native right ventricular function can be supported with positive inotropic therapy, pulmonary vasodilators such as inhaled nitric oxide, and/or temporary placement of a right VAD. A risk score for predicting right-sided heart failure and need for right VAD support has been proposed recently and requires further validation.[21] Isolated right ventricular failure is usually not an indication for VAD; patients with primary pulmonary hypertension are not candidates for this technology or for heart transplantation and must be considered for heart-lung or lung transplantation.

Intracardiac Shunts

An intracardiac shunt from a patent foramen ovale or an atrial septal defect must be identified and closed before mechanical support is instituted. After VAD implantation, the left ventricle

Table 4. Consideration of Right Ventricular Function in VAD Candidates

Predictors of RV failure after LVAD implantation
Clinical variables
Female gender
Small body surface area
Nonischemic cardiomyopathy or myocarditis
Preoperative mechanical ventilation
Preoperative circulatory support (eg, ECMO, percutaneous VAD)
Vasopressor requirement*
Laboratory variables
Elevated BUN and creatinine*
Elevated AST, ALT, and total bilirubin*
Decreased platelet count
Echocardiographic parameters
Dilated RV with increased end-diastolic and end-systolic volumes
Severe RV systolic dysfunction (eg, fractional area change <20%)
Severe tricuspid regurgitation
Moderate to severe pulmonic insufficiency
Low estimated pulmonary artery systolic pressure
Hemodynamic parameters
Elevated right atrial pressure (or greater than left atrial pressure)
Elevated transpulmonary gradient
Low mean and diastolic pulmonary artery pressures
Low right ventricular stroke work index
Pathophysiology of RV failure
RV myocardial dysfunction
RV ischemia
Ventricular interdependence
Increased RV preload and/or afterload
Strategies to optimize perioperative RV function
Avoid bleeding: preoperative vitamin K, intraoperative FFP
Avoid excess RV preload when transitioning off CPB
Decrease RV afterload: milrinone, inhaled nitric oxide
Consider RCA bypass and/or tricuspid valvuloplasty

RV indicates right ventricular/right ventricle; LVAD, left VAD; ECMO, extracorporeal membrane oxygenation; BUN, blood urea nitrogen; AST, aspartate aminotransferase; ALT, alanine aminotransferase; FFP, fresh frozen plasma; CPB, cardiopulmonary bypass; and RCA, right coronary artery.

*Components of right ventricular failure risk score, from Matthews et al.[21]

and atrium should have normal filling pressures, and in the setting of right-sided heart failure, there can be reversal of flow, with a right-to-left shunt to the VAD provoking systemic hypoxemia.

Ischemic Heart Disease

After insertion, VAD patients may continue to experience ischemia resulting from coronary artery disease, but preservation or maximization of right ventricular function now becomes paramount. Antiischemic therapy should be optimized preoperatively and continued during mechanical circulatory support to minimize device failure or development of right-sided heart failure as a result of ischemia. Some surgeons will perform CABG to the right coronary artery if a significant stenosis exists.

Arrhythmias

Patients in atrial flutter or fibrillation may receive mechanical support, but maintenance of a sinus mechanism is preferred. Use of VADs to support refractory tachyarrhythmias has been reported. Ventricular arrhythmias that occur after implantation are generally tolerated and have not been associated with worsening hemodynamics or clinical deterioration. The defibrillator function of an implantable cardioverter defibrillator is often turned off to prevent "inappropriate" discharge. In other patients, cessation of arrhythmogenic activity may occur with adequate mechanical support and normalized hemodynamics.[28,29]

Noncardiovascular Considerations

Body Size

Body habitus is a critical determinant in the choice of a VAD. A body surface area of less than 1.5 m^2 is probably too small to accommodate abdominal implantation of the conventional pulsatile devices. Intra-abdominal crowding may occur in smaller patients, leading to chronic abdominal discomfort, poor appetite, and nutritional impairment. In these small patients, paracorporeal devices or devices that utilize axial flow technology, such as the HeartMate II (Thoratec Corp, Pleasanton, Calif), must be considered, because they are lower-profile devices. Prior abdominal surgery must be taken into account, because adhesions or extensive procedures may preclude proper VAD placement and increase the risk of bleeding, infection, or recurrent abdominal complications. In addition, the presence of an intra-abdominal VAD limits the use of traditional noninvasive imaging techniques such as ultrasound or CT to evaluate abdominal structures.

Hepatic Function

Underlying cirrhosis and portal hypertension are associated with a poor prognosis after VAD, and any clinical evidence of liver disease should be resolved with a biopsy before implantation. Patients should be considered cautiously for an assist device if they have an alanine aminotransferase (serum glutamic pyruvic transaminase) or aspartate aminotransferase (serum glutamic-oxaloacetic transaminase) >3 times the upper limit of normal or an international normalized ratio >1.5. An elevated total bilirubin >5 mg/dL has been shown to be the strongest marker of hepatic impairment associated with mortality. After VAD insertion, reduction of pulmonary artery pressure and right ventricular afterload may improve cardiac-induced hepatic dysfunction. Despite adequate circulatory support, some individuals continue to have deterioration of hepatic function due to increased activation of proinflammatory cytokines.[30] Hepatic congestion may also be a marker of impaired right ventricular function and has been related to an increased need for biventricular support.[31]

Renal Function

Although renal dysfunction resulting from reduced cardiac output is often reversible, it is strongly associated with poor outcomes after VAD implantation.[32] An assessment should be made to determine whether renal insufficiency is secondary to poor perfusion or whether it is irreversible. A short trial of positive inotropic therapy

may be indicated. Long-term dialysis patients and individuals with a creatinine level >3.0 mg/dL are at highest risk and should not be considered for support.

Pulmonary Function

Another important predictor of postimplantation morbidity and mortality is the duration of mechanical ventilation, especially in those with cardiogenic shock.[33,34] All acute respiratory processes from pneumonia to a pulmonary embolus should be resolved before VAD surgery to increase the success of implantation and patient recovery. Candidates with chronic lung disease, including chronic obstructive pulmonary disease or pulmonary arterial hypertension, with a forced expiratory volume in 1 second of <1 L or pulmonary vascular resistance >3 to 4 Wood units are not eligible for a VAD.

Nutrition

Although end-stage heart failure is associated with metabolic imbalances, satisfactory preimplantation nutritional status is essential to the perioperative management of VAD patients. Cachexia, defined as a body mass index <21 kg/m^2 in males and <19 kg/m^2 in females, is a strong independent predictor of mortality, along with other markers of poor nutritional status, including low serum levels of albumin, prealbumin, and total protein; reduced absolute lymphocyte count; and elevated C-reactive protein.[35,36] Adequate nutritional support reduces the risk of postoperative infection and improves functional recovery.[37]

Neoplastic Disease

A solid tumor diagnosed within the last 5 years is a relative contraindication to transplantation, but VAD therapy may allow time for definitive treatment of certain curable cancers, such as prostate or breast cancer. In many instances, patients with recent cancers may be best advised not to take immunosuppressant agents, which theoretically enhance their predisposition to recurrent neoplasm. A past history of malignancy may make destination therapy a better option, especially as the new axial flow technology evolves. However, post-VAD complications, such as stroke related to a hypercoagulable state or subclinical metastases, may be more common in patients with a history of malignancy and require further study.

Impaired Self-Care

A history of stroke, neuropathy, or musculoskeletal disease, along with other limiting diseases such as chronic obstructive pulmonary disease and obesity, needs to be evaluated carefully. Such impairments may have a greater impact on VAD candidacy than on heart transplantation. A neurological deficit with loss of hand mobility or dexterity that precludes proper operation of the VAD must be acknowledged. Irreversible cognitive impairment due to prior stroke may also preclude proper device care or management (eg, alarm recognition or hand pumping).

Social Services and Psychiatric Conditions

Psychosocial issues need to be explored before VAD surgery is recommended. As with neurological status, these issues are more important for the VAD patient than the heart transplant recipient, because the VAD patient needs a sophisticated backup system at home and in the community. These patients can never be assumed to be solely capable for their care, because issues with device malfunction need to be addressed promptly by support personnel. Before VAD implantation, patients must be screened for emotional and psychological readiness, family and social support, and home safety.[10,12,38] Family members or friends should be aware that the demands on them will be great; although the long-term demands of care providers decrease with time after heart transplantation, this is not the case with VADs.

VAD patients face a unique set of challenges from the loss of independence, concern with burdening caregivers, fear of complexity of managing the device or related equipment, change in family dynamics, strain on finances, and fear of dying. This engenders a higher level of stress with family and friends, which must be taken into account in patients being considered for this technology. Patients with a recent history of tobacco, alcohol, or substance abuse should have documented abstinence for 3 to 6 months and may require home inotropic support while waiting for a transplant or a decision regarding VAD therapy.[39]

Perhaps more so than for any other form of therapy, consideration of VAD implantation must engender a clear understanding among the patient, family, and healthcare providers as to end-of-life issues. This technology has the ability to maintain stable hemodynamics despite difficult and unanticipated complications that the patient, family, and healthcare providers do not wish to suffer. To avoid confusion and in addition to a conventional living will, the patient's and family's end-of-life desires should be documented prospectively. Such documentation should include the circumstances under which the VAD will be turned off, which would result in almost certain death.

Clinical Follow-Up

Our patient was a 57-year-old woman with end-stage ischemic/valvular cardiomyopathy who presented with refractory heart failure requiring positive inotropic support. She was listed for cardiac transplantation, had a strong family support system, and had multiple indications for mechanical circulatory support as a bridge to transplantation (Table 1). However, she also had several contraindications to VAD implantation, including small body size, mechanical aortic valve, and high surgical risk because of prior sternotomies. Given these considerations, we opted to continue medical therapy and were able to optimize hemodynamics using a pulmonary artery catheter to adjust vasoactive and diuretic therapy. She was discharged home on a continuous infusion of milrinone but was readmitted 1 day later when a suitable donor heart was identified. She under-

went successful cardiac transplantation and was discharged home on postoperative day 13.

Summary

Much progress has been made over the last 2 decades in the field of mechanical circulatory support. VADs are now seen as a credible lifesaving option to support the failing heart for short- and long-term therapy. Improved understanding of cardiac and noncardiac risk factors through prospective and retrospective analyses has optimized care for patients with end-stage heart failure. The ground work has been set for a promising future for VADs through the establishment of the INTERMACS registry, and there is continued widespread interest in improving the characterization and selection of VAD patients, as well as the timing of surgery.

Disclosures

None.

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