

Clinical management of continuous-flow left ventricular assist devices in advanced heart failure

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Continuous-flow left ventricular assist devices (LVAD) have emerged as the standard of care for advanced heart failure patients requiring long-term mechanical circulatory support. Evidence-based clinical management of LVAD-supported patients is becoming increasingly important for optimizing outcomes. In this state-of-art review, we propose key elements in managing patients supported with the new continuous-flow LVADs. Although most of the presented information is largely based on investigator experience during the 1,300-patient HeartMate II clinical trial, many of the discussed principles can be applied to other emerging devices as well. Patient selection, pre-operative preparation, and the timing of LVAD implant are some of the most important elements critical to successful circulatory support and are principles universal to all devices. In addition, proper nutrition management and avoidance of infectious complications can significantly affect morbidity and mortality during LVAD support. Optimizing intraoperative and peri-operative care, and the monitoring and treatment of other organ system dysfunction as it relates to LVAD support, are discussed. A multidisciplinary heart failure team must be organized and charged with providing comprehensive care from initial referral until support is terminated. Preparing for hospital discharge requires detailed education for the patient and family or friends, with provisions for emergencies and routine care. Implantation techniques, troubleshooting device problems, and algorithms for outpatient management, including the diagnosis and treatment of related problems associated with the HeartMate II, are discussed as an example of a specific continuous-flow LVAD. Ongoing trials with other continuous-flow devices may produce additional information in the future for improving clinical management of patients with these devices. *J Heart Lung Transplant* 2010;29:S1–S39 © 2010 Published by Elsevier Inc.

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I. Introduction and overview of continuous-flow left ventricular assist systems

Key Points

Continuous-flow left ventricular assist systems are new-generation devices with a number of major advantages over previous pulsatile technology:

- Continuous-flow, rotary blood pumps eliminate the need for a blood pumping chamber and volume compensation.
- A lighter, smaller pump is better suited for patients with a smaller body size.
- Simple designs include only 1 internal moving part, the rotor, and no internal valves. This affords markedly enhanced device durability.
- They are silent in operation.
- The potential benefits of the smaller percutaneous lead include a reduced infection risk and greater patient comfort.

Mechanical circulatory support (MCS) for patients with advanced heart failure has evolved considerably during the past 30 years and is now standard therapy at many medical centers worldwide. Left ventricular assist systems (LVASs) that use continuous-flow rotary blood pumps have been developed during the past decade in response to the need for smaller and more durable devices.¹⁻⁹ Although the earlier pulsatile LVAS designs provided adequate cardiac output support, their large size and limited durability hindered long-term success. Continuous-flow left ventricular assist devices (LVADs) are small and durable, which offers a number of advantages that aid in minimizing complications associated with LVAD support.

Recent clinical studies of patients supported by continuous-flow LVADs indicate that there are fewer device-related complications and outcomes are improved.^{1,7,8} However, complications persist during LVAD support due to pre-existing effects of advanced heart failure, the requirement for extensive surgery to implant the device, and the

effects of the device in compromised patients. The continued improvement in survival rate and quality of life for this very ill population of patients requires consistent evidence-based clinical management throughout LVAD support.

This supplement is devoted to comprehensive information based on a large experience during the last decade with the clinical management of continuous-flow LVADs in advanced heart failure patients. Most of the information presented is based on the authors' experiences during the 1,300-patient clinical trial on the HeartMate II LVAS that led to Food and Drug Administration (FDA) approval for bridge to transplantation (BTT) and destination therapy (DT) approvals and on published data from this trial. However, because all continuous-flow LVASs are similar in basic features, some of the principles of clinical management are relevant to all devices. Specific differences between various LVAS designs are beyond the scope of this article.

Topics that are generic to most continuous-flow devices include patient selection, pre-operative assessment and optimization, intraoperative considerations related to medical issues such as valvular heart disease and hemostasis, and post-operative patient management, including right ventricular (RV) function, blood pressure monitoring, patient education, and outpatient management and medical therapy. Topics that are specific to the HeartMate II device include implantation techniques, anti-coagulation, post-operative device management, and troubleshooting. As additional experience is gained with the HeartMate II and other continuous-flow pumps, these recommendations may change.

We recommend that readers also refer to the directions for use, guidelines for care, and other published documents that are specific to each device or generic to all devices. For example, the 2-volume practice guidelines for destination therapy^{10,11} were written for the HeartMate XVE pulsatile-flow LVAD but contain applicable information for all long-term implantable LVADs, including candidate selection, team organization, nutrition management, infection control, intraoperative and peri-operative management, and discharge planning.

I.A. Continuous-flow LVASs

Continuous-flow LVASs use new-generation rotary blood pumps that are designed to provide extended circulatory support. They consist of an internal LVAD blood pump with a percutaneous lead that connects the pump to an external system controller and a power source (batteries or line power; [Figure 1](#)). Continuous-flow rotary designs significantly reduce LVAD size and weight compared with implantable pulsatile pumps. Continuous-flow LVADs are also silent during operation and create minimal motion and vibration. These features make continuous-flow devices more suitable for use in patients with smaller body size. Additional benefits over pulsatile LVAD technology include greater durability (no internal valves, and a single internal moving part, the pump rotor), greater patient comfort and enhanced quality of life, and a reduced infection risk. The enhanced durability and reliability of this new-gen-



Figure 1 The HeartMate II continuous-flow left ventricular assist device receives blood from the left ventricular apex and returns it to the ascending aorta. The pump is connected with a percutaneous lead to an external controller and batteries worn by the patient.

eration LVAD should lead to more patients being supported for extended durations.

All continuous-flow LVADs share important functional characteristics, the most important of which is the continuous unloading of the LV throughout the cardiac cycle. This type of support diminishes or eliminates the arterial pulse, making the routine assessment of blood pressure more challenging and much less reliable. Substantial clinical experience has confirmed that the human body can be adequately supported with a diminished or absent pulse with a continuous-flow LVAD. However, users of these systems should have a thorough understanding of the fundamental differences between pulsatile-flow and continuous-flow pumps. [Table 1](#) provides a general comparison of the 2 types of LVADs now in clinical use, and [Table 2](#) compares the pulsatile-flow and continuous-flow LVADs that are presently in clinical use.

Continuous-flow LVASs use centrifugal-flow or axial-flow blood pumps. The fundamental design characteristic of both types of pump is that they have a single moving component, the impeller. Conversely, pulsatile LVADs have multiple moving components that are all susceptible to wear and failure. The rotating impellers of the continuous-flow LVAD have 1 of 3 types of bearing: (1) blood immersed, (2) hydrodynamic, or (3) magnetic levitation. All 3 types have nominal or absent friction, heat generation, or wear, making these devices very durable during long-term support. There have been numerous reports of extended support with these devices and with promising clinical results.^{1,7,8,12-16}

Table 1 Comparison of Pulsatile and Continuous Flow Ventricular Assist Devices

Attribute	Pulsatile-flow VAD	Continuous-flow VAD
Size	Large; intracorporeal devices limited to large patients; extracorporeal devices especially suited for smaller patients or for biventricular support	Smaller; accommodates most patients, excluding infants
Blood flow capacity	Up to 10 liters/min	Up to 10 liters/min
Type of pump	Sac or diaphragm	Centrifugal or axial flow by rotating impeller
Implantation	Extracorporeal or intracorporeal types: sub-diaphragmatic intraperitoneal or preperitoneal	Extracorporeal, intracardiac, pericardial, sub-diaphragmatic
Main hemodynamic characteristic	Intermittent unloading of ventricle; pulsatile arterial pressure; asynchronous with heart	Continuous unloading of ventricle
Physiologic flow variables	Pre-load dependant	Pre-load and after-load dependant
Mechanical flow variables	Automatic or fixed rate and stroke volume capacity	Set speed of the impeller rotation

II. Patient selection and preoperative considerations

Key Points

- The highest risk of death after LVAD implant is before hospital discharge. Thus, patient selection and the timing of implant are two of the major determinants of success.
- Key selection criteria include assessment of the patient's severity of illness and ability to successfully undergo the implant procedure.
- The trend at many centers is toward earlier use of a LVAD to avoid progressive end-organ dysfunction.
- Pre-implant optimization of comorbid conditions is very important in minimizing the incidence and severity of post-operative adverse events and for enhancing survival. The most influential pre-implant measures are:
 - Improving nutritional status.
 - Lowering pulmonary vascular resistance to optimize right-heart function and to reduce right atrial pressure and secondary hepatic congestion.
 - Aggressively managing volume to minimize right ventricular workload and hepatic congestion.
 - Optimizing coagulation.
 - Optimizing renal, hepatic, pulmonary, and neurologic function.
 - Treating any infection or providing prophylactic anti-biotic therapy.
- The patient's support system, psychosocial status, compliance with care, and ability to operate and care for external system components all warrant considerations in the patient-selection process.

Patient selection and the timing of implant remain primary determinants of success for LVAD therapy. Patients are assessed for (1) appropriateness for LVAD support based on the degree of illness, (2) ability to successfully undergo the operative procedure, and (3) ability to be discharged to home with adequate family/caregiver support for long-term success.

During LVAD candidate assessment, risk factors for poor survival are identified and treated, when possible, to minimize their effect.

II.A. Patient selection for LVAD support: illness assessment for operative risk

Candidates for LVAD support will present with comorbidities that vary in severity, depending on the extent and duration of heart failure. The acceptance of candidates for LVAD support and the timing of device implant need to be determined by careful consideration of potential risks and benefits.

Many issues affecting successful outcomes after LVAD implant are related to patient illness and timing. For example, implanting the LVAD before irreversible end-organ failure has occurred, or delaying implant until comorbidities can be reversed or controlled, increases the likelihood of post-implant survival. The Heart Failure Survival Score¹⁷ and the Seattle Heart Failure Model¹⁸ can be used to estimate a heart failure patient's expected survival during the next 1 to 2 years on medical management and identify patients at high risk of death who might benefit from LVAD support. A recent study used the Seattle Heart Failure model to analyze patients in the Randomized Evaluation of Mechanical Assistance in Treatment of Chronic Heart Failure (REMATCH) trial and concluded that patients could be stratified into high, medium, and low risk for LVAD support.¹⁹

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry,²⁰⁻²² which follows all long-term mechanical circulatory support systems in the United States, has defined patient profiles that can help identify risks associated with the timing of implant (Table 3). The current 6-month survival data for patients receiving pulsatile LVADs indicates that patients in profile 1, cardiogenic shock, have the lowest survival, and those in profile 3, stable on inotropes, have the best survival.²⁰ These data indicate that patients with cardiogenic shock may be too sick for permanent LVAD support. Thus, for these patients, consideration should be given for immediate stabilization with biventricular support, using temporary percutaneous or surgically placed systems or other appropriate treatments, to optimize their condition, if possible, before

Table 2 Pulsatile-Flow and Continuous-Flow Long-term Left Ventricular Assist Devices in Clinical Use and Status of European and United States Food and Drug Administration Approvals and Ongoing Clinical Trials

	Manufacturer	Type of pumping mechanism	Type of support	EU approvals	FDA approvals
Pulsatile-flow devices					
HeartMate XVE	Thoratec Corp, Pleasanton, CA	Electric; pusher plate	LVAD	CE Mark	BTT DT
Thoratec PVAD	Thoratec Corp, Pleasanton, CA	Pneumatic sac-type pump	BiVAD or UniVAD	CE Mark	PC BTT
Thoratec IVAD	Thoratec Corp., Pleasanton, CA	Pneumatic sac-type pump	BiVAD or UniVAD	CE Mark	PC BTT
Excor	Berlin Heart, Berlin, Germany	Pneumatic sac-type pump	BiVAD or UniVAD	CE Mark	
MEDOS VAD	MEDOS Medizintechnik AG, Stolberg, Germany	Pneumatic sac-type pump	BiVAD or UniVAD	CE Mark	
CardioWest	TAH Syncardia Systems Inc., Tucson, AZ	Pneumatic sac-type pump	TAH	CE Mark	BTT
Continuous-flow devices					
Axial-flow pumps					
HeartMate II	Thoratec Corp, Pleasanton, CA	Axial-flow pump with blood-immersed bearings	LVAD	CE Mark	BTT DT
Jarvik 2000	Jarvik Heart Inc., New York, NY	Axial-flow pump with blood-immersed bearings	LVAD	CE Mark	IDE trial ongoing for BTT
Heart Assist 5	Micromed Cardiovascular Inc., Houston, TX	Axial-flow pump with blood-immersed bearings	LVAD	CE Mark	IDE trial ongoing for BTT
Incor	Berlin Heart, Berlin, Germany	Axial-flow pump with magnetic bearing	LVAD	CE Mark	
Synergy	CircuLite Inc, Saddle Brook, NJ	Axial-flow pump with blood-immersed bearings	LVAD	CE Mark trial ongoing	
Centrifugal pumps					
HVAD	HeartWare Inc, Miami Lakes, FL	Centrifugal pump with hydrodynamic bearing	LVAD	CE Mark	IDE trial ongoing for BTT
DuraHeart	Terumo Heart Inc, Grand Rapids, MI	Centrifugal pump with magnetic levitation	LVAD	CE Mark	IDE trial ongoing for BTT
Levacor VAD	World Heart Inc., Salt Lake City, UT	Centrifugal pump with magnetic levitation	LVAD		IDE trial ongoing for BTT
EVAHEART LVAS	EVAHEART USA, Pittsburgh, PA	Centrifugal pump	LVAD	Trial in Japan complete; PMDA pending	IDE trial for BTT

BiVAD, biventricular assist device; BTT, bridge to transplant; CE Mark, conformity mark in European Economic Area; DT, destination therapy; FDA, Food and Drug Administration; IDE, investigational device exemption; LVAD, left ventricular assist device; PC, post-cardiotomy; PMDA, Pharmaceutical and Medical Device Agency (Japan); TAH, total artificial heart; UniVAD, univentricular assist device.

permanent LVAD implant. These data also support the increasing practice of implanting a LVAD earlier in the progression of heart failure. Most patients who are stable on inotropes in INTERMACS category 3 would be appropriate candidates who would likely benefit from LVAD therapy. Outcomes from INTERMACS levels 4 and higher are under evaluation for appropriateness of support.

Many of the patients considered for long-term LVAD therapy have important comorbidities that may limit functionality and survival. Patients with multiple or severe non-cardiac con-

ditions that significantly limit quality or duration of life may not be suitable candidates for LVAD implantation.

II.B. Patient mortality risk for undergoing LVAD implantation

Once a patient's heart failure status indicates candidacy for LVAD support, his or her ability to survive the implant surgery should be assessed. Whenever possible, LVAD im-

Table 3 INTERMACS Patient Profiles and Timeframe for Initiating Mechanical Circulatory Support

Profile #	Description	Time to MCS
1	“Crashing and burning”—critical cardiogenic shock.	Within hours
2	“Progressive decline”—inotrope dependence with continuing deterioration.	Within a few days
3	“Stable but inotrope dependent”—describes clinical stability on mild-to-moderate doses of intravenous inotropes (patients stable on temporary circulatory support without inotropes are within this profile).	Within a few weeks
4	“Recurrent advanced heart failure”—“recurrent” rather than “refractory” decompensation.	Within weeks to months
5	“Exertion intolerant”—describes patients who are comfortable at rest but are exercise intolerant.	Variable
6	“Exertion limited”—describes a patient who is able to do some mild activity but fatigue results within a few minutes of any meaningful physical exertion.	Variable
7	“Advanced NYHA III”—describes patients who are clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent.	Not a candidate for MCS

INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; MCS, mechanical circulatory support; NYHA, New York Heart Association.

plant surgery should be elective and not emergent. This is especially true for the DT indication because most patients can be stabilized and their risks assessed and reduced before implant. Implantation of a long-term LVAD should *not* be considered for patients with irreversible major end-organ failure, uncertain neurologic status, severe hemodynamic instability, major coagulopathy, prolonged need for mechanical ventilation, sepsis, or right-heart failure. Other factors that may preclude implant include a “high-risk” classification, unresolved psychosocial issues, and non-compliance concerns.

II.B.1. Overall risk factors for operative mortality

A number of investigators have developed operative mortality outcome models based on a patient’s pre-operative status.^{23–26} Numerous factors influence outcome, but no single factor or specific combination of factors have been identified as definitive predictors of death. Most risk factors are additive. Thus, composite risk scores can be used to guide patient selection and treatment for pre-operative optimization. Risk assessment for medical and surgical issues for BTT and DT are nearly identical. Accurate assessment of right-heart function is crucial for DT candidates because transplantation is not an option, and those who require long-term inotropic therapy for RV support do poorly.

An analysis of the HeartMate XVE LVAD DT Registry by Lietz and Miller²⁷ demonstrated that death before hospital discharge in patients receiving an implant as DT was strongly influenced by worsening nutritional status, hematologic abnormalities, end-organ and right-heart dysfunction, and the lack of inotropic use, factors that are also relevant to BTT. These pre-operative clinical characteristics identified patients who were at high risk for not surviving surgery. Pre-operative risk factors associated with the highest risk of death were severe functional impairment, markers of global cardiac dysfunction, end-organ damage, and malnutrition.

Lietz and Miller²⁷ analyzed pre-operative clinical data from 222 patients who received the HeartMate XVE LVAD for DT. They established a risk scoring system to estimate

survival after implant. The multivariate analysis produced 9 risk factors for 90-day mortality, which were assigned a weighted score (Table 4). The cumulative scores for each patient were then used to determine the risk category: 0 to 8, low risk; 9 to 16, medium risk; 17 to 19, high risk; and >19 was very high risk. The survival to hospital discharge was 87.5%, 70.5%, 26%, and 13.7% for the low-, medium-, high-, and very high-risk groups, respectively. Examples of how a patient’s risk score is determined are provided in Table 5. This risk score stratified patients based on operative risk and identified the highest-risk patients (the “futile” group) with an extremely low likelihood for survival. Patients who initially present as high-risk or very high-risk are most likely to benefit from a period of optimization therapy to attempt to lower their risk score (eg, coagulation, nutrition, renal function, right atrial pressure) and then become more suitable candidates for LVAD support. Patients with a low risk should be considered for prompt elective LVAD implant before their condition worsens.

We must point out that a limitation of this risk model is that it was developed initially in only DT patients implanted with the pulsatile HeartMate XVE LVAD from 2002 to 2005. The risk model has not yet been validated with continuous-flow devices implanted for DT.

Table 4 Risk Factors for 90-Day Mortality and the Weighted Scores

Risk factor	Score
Platelet count <148 × 10 ³ /μl	7
Serum albumin <3.3 g/dl	5
International normalization ratio >1.1	4
Vasodilator therapy	4
Mean pulmonary artery pressures <25 mm Hg	3
Aspartate aminotransferase >45 U/ml	2
Hematocrit <34%	2
Blood urea nitrogen >51 mg/dl	2
No intravenous inotropes	2

Table 5 Examples of Destination Therapy Risk Scoring in Two Patients

Risk factor [score]	Patient 1		Patient 2	
	Value	Score	Value	Score
Platelet count $<148 \times 10^3/\mu\text{l}$ [7]	170	0	220	0
Serum albumin <3.3 g/dL [5]	3.1	5	4.2	0
INR >1.1 [4]	1.3	4	1.3	4
Vasodilator therapy [4]	Yes	4	Yes	4
Mean PAP <25 mm Hg [3]	28	3	24	0
AST >45 U/ml [2]	42	0	40	0
Hematocrit $<34\%$ [2]	32	2	36	0
Blood urea nitrogen >51 mg/dL [2]	55	2	53	2
No intravenous inotropes [2]	Inotropes used	0	No inotropes	2
Total score		20		12
Operative risk category		Very high		Medium

AST, aspartate aminotransferase; INR, international normalization ratio; PAP, pulmonary artery pressure.

II.B.2. Obesity paradox

Obesity is common in patients with heart failure. In the HeartMate II BTT and DT trials, a body mass index (BMI) >40 kg/m² was an exclusion criterion for study purposes. A recent report, however, showed that obesity had no deleterious effects on outcome in LVAD patients and that a low BMI was associated with higher risk.²⁸ Obesity is not a contraindication to using a continuous-flow LVAD, and these devices can provide sufficient cardiac output support to meet the metabolic demands of obese patients. Good outcomes in obese patients will likely depend on the capability of a LVAD to maintain adequate hemodynamics and the freedom from comorbidities, such as infection, that may occur more frequently in these patients.

Conversely, studies have shown that cachexia (a BMI <22 kg/m²) is associated with a high risk for peri-operative death, often due to infection.^{28,29} Hence, nutrition needs to be improved before LVAD implant (a pre-albumin level >15 mg/dl). It is equally important to maintain adequate nutrition after the implant surgery. Data from Lockard et al³⁰ has shown that patients with a pre-albumin level of <15 mg/dl at 2 weeks after LVAD implant had a significantly greater risk of dying in the hospital.

In some cases, LVADs have been used in obese patients as BTT eligibility, with the goal that during LVAD support, the obese patients will lose sufficient weight to become eligible for transplant. In general, however, few patients have achieved sufficient weight loss to qualify for transplantation. Providing hemodynamic support with a LVAD as a means for weight loss should be undertaken with a multidisciplinary team approach that includes physicians, nurses, dietitians, exercise physiologists, and potentially, bariatric surgeons.

II.B.3. Assessment of RV function

RV failure is a leading cause of morbidity and death after LVAD implant due to the inability of the RV to pump sufficient blood through the pulmonary circuit to adequately fill the left heart. It is a major contributing factor to other

serious adverse events such as bleeding, renal failure, and prolonged hospitalization. RV function is a major consideration for both volume-displacement and continuous-flow devices. LV unloading with a LVAD should decrease RV after-load by reducing pulmonary artery pressures (PAPs).³¹ However, mechanical support may increase systemic venous return to a myopathic right heart that is unable to accommodate the additional volume. Furthermore, reduction in LV pressure can cause the interventricular septum to shift leftward, potentially causing disadvantageous geometric changes in the RV that reduce septal contribution to RV stroke volume and exacerbate tricuspid regurgitation.³¹ Importantly, RV failure after implant can be anticipated pre-operatively and improved with various therapies that optimize RV function.

Historically, various studies have reported a wide range of use of RVADs or biventricular support. In the HeartMate XVE LVAS BTT study, 11% of 280 patients received an RVAD.³² In the paracorporeal Thoratec VAD BTT study, 48% of 213 patients received planned biventricular support, and 17% more were converted to biventricular support with the later addition of an RVAD.³³ In the HeartMate II BTT trial, right-heart failure was defined as the need for RVAD support, or inotropic support for at least 14 days after the implant, or inotropic support starting after 14 days. The incidence of right-heart failure in the BTT trial was 20%: 6% required RVAD support, 7% required extended inotropic support for more than 14 days, and 7% required use of inotropes after 14 days of support.³⁴ In the HeartMate II DT trial, there was a 4% use of RVADs.¹

RV failure patients had increased length of stay and reduced survival compared with patients without RV failure. Thus, the incidence of RV failure in patients with the continuous-flow HeartMate II is comparable to or better than previous pulsatile devices, but RV failure remains a significant factor for morbidity and mortality. Perhaps the ability to adjust pump speed in real time, as guided by surface echocardiography to define RV and LV size and function, has contributed significantly to the ability to man-

age patients on the new continuous-flow pumps and to thereby reduce RVAD use.

Two recent studies have reported predictive models for RV failure after LVAD implant.^{35,36} One model used a weighted scale that included the need for vasopressor support, bilirubin ≥ 2.0 mg/dl, aspartate aminotransferase ≥ 80 IU, and creatinine < 2.3 mg/dl to predict the probability of RV failure and the need for RVAD support.³⁶ In another study, a predictive algorithm for RVAD need used the cardiac index, RV stroke work index, severe pre-operative RV dysfunction, creatinine level, previous cardiac surgery, and systolic blood pressure.³⁵ Patients at risk for post-operative RV failure should not necessarily be eliminated from LVAD support. However, the implanting team should promptly treat RV failure using pharmacotherapeutics and mechanical RV support, as appropriate or needed.

Low pre-operative RV stroke work index (RVSWI) has been demonstrated to predict prolonged inotropic use after pulsatile LVAD implant, supporting the role of RVSWI as a predictor of RV dysfunction.³⁷ In 1 study, inotropic support > 14 days post-operatively was required in 38% of patients with a RVSWI ≤ 600 mm Hg \times ml/m² compared with 29% of patients with a RVSWI 600 to 900 mm Hg \times ml/m², and only 3% with a RVSWI > 900 mm Hg \times ml/m².³⁸ RVSWI provides a quantitative measure of the ability of the RV to generate pressure and flow and is calculated using this formula:

$$\begin{aligned} \text{RVSWI (mm Hg} \times \text{ml/m}^2) \\ = \{[\text{mean PAP (mm Hg)} - \text{mean CVP (mm Hg)}] \\ \times \text{SV (ml)}\} / \text{BSA (m}^2) \end{aligned}$$

With *BSA* as body surface area, *CVP*, as central venous pressure; *PAP* as pulmonary artery pressure, and *SV* as stroke volume.

An analysis of 484 patients in the HeartMate II BTT clinical trial demonstrated the following independent predictors of RV failure: pre-operative ventilatory support, CVP/pulmonary capillary wedge pressure ratio > 0.63 , and blood urea nitrogen > 39 mg/dl.³⁴ Univariate predictors also included a RVSWI < 300 mm Hg \times ml/m², CVP > 15 mm Hg, elevated BUN, and elevated white blood cell count. The HeartMate II trial found no difference in the incidence of RV failure in the heart failure patients with non-ischemic vs ischemic etiology.

Other signs of poor RV function can be found with pre-implant echocardiography. Close attention should be paid to RV size, with particular caution extended to patients who have a dilated, poorly contracting RV. Severe tricuspid regurgitation also can be associated with early post-operative RV failure. Some have advocated repair of the tricuspid regurgitation at the time of LVAD implant if its severity is judged to be more than moderate, either pre-operatively or intraoperatively by echocardiogram. Note that in patients with RV dysfunction, setting the pump speed to achieve appropriate flow may be more challenging with continuous-

flow devices than with volume displacement (ie, pulsatile) pumps.

Parameters to consider for evaluating right-heart function are listed in Table 6. Issues related to the presence of valvular heart disease are discussed in Section III. More information on the management of RV dysfunction is provided in Sections II.F., III.H., and IV.A.

II.C. Pre-operative assessment and optimization

Pre-operative optimization is targeted toward minimizing the frequency and severity of adverse events after implant. A complete system assessment should begin immediately upon referral for LVAD support. Table 7 outlines various tests and assessments that should be done in all patients before implant. Table 8 lists pre-operative goals in terms of relevant metabolic markers.

Nutrition. Holdy et al²⁹ report that “comprehensive pre-operative evaluation of the LVAD patient should include a nutrition assessment and formalized plan to initiate and advance nutrition support while addressing the metabolic imbalances associated with heart failure.” Careful attention must be paid to the nutritional status of any LVAD therapy candidate before implant. Poor nutritional status is often overlooked and is a potentially modifiable risk factor in LVAD candidates. Malnutrition is very common in patients with advanced heart failure. If not improved, it increases the risk of infection, decreases the body’s ability to recover after surgery, and is generally associated with poor outcomes.

Prospective LVAD patient assessment should be performed by a team consisting of a dietitian, a pharmacist, and a heart failure physician. Nutrition optimization should begin on initial presentation and continue throughout the entire peri-operative period. Patients with severe cachexia who are stable without worsening organ function should undergo nutrition optimization before implant, if possible, generally

Table 6 Evaluating Right-Heart Function

Parameter	Desirable value ^a
RVSWI	> 300 mm Hg \times ml/m ²
Central venous pressure	< 15 mm Hg
Tricuspid regurgitation	Minimal to moderate
Pulmonary vascular resistance	< 4 Woods units
Transpulmonary gradient	< 15 mm Hg
RV size	
RVEDV	< 200 ml
RVESV	< 177 ml
Need for pre-op ventilator support	None

PVR, pulmonary vascular resistance; RV, right ventricle; RVEDV, right ventricular end-diastolic volume; RVESV, right ventricular end-systolic volume; RVSWI, right ventricular stroke work index.

^aThese are conservative desired values indicating the least risk, and are not absolute cutoffs; pulmonary vascular resistance and transpulmonary gradient will typically be reduced during left ventricular assist device support.

Table 7 General Preoperative Assessment

Laboratory tests ^a	Studies	Other
CBC with differential and platelet count	Chest X-ray (AP and lateral)	Dental evaluation with panorex image
Complete chemistry panel	Carotid Doppler if history of CAD or >50 years old	
Uric acid		
Thyroid profile	Chest/abdominal CT if previous chest or abdominal surgery	
Lactate dehydrogenase	ABI if claudication history or diabetes	
PT/PTT, INR	Abdominal US for AAA screen if >60 years old or presence of PAD	
PRA (if potential transplant candidate)	EGD or colonoscopy within past 2 years	
Pregnancy test (HCG) for women		
Iron, transferrin, ferritin		
Glycosylated hemoglobin		
Heparin antibody only if clinically suspected, such as a platelet count <150,000 or recent decrease of <20%		
Serotonin release assay (if heparin antibody-positive)		
Albumin, pre-albumin		
Urinalysis, culture, and sensitivity		

AAA, abdominal aortic aneurysm; ABI, ankle-brachial index; AP, anteroposterior; CAD, coronary artery disease; CBC, complete blood count; CT, computed tomography; EGD, esophagogastroduodenoscopy; FFP, fresh frozen plasma; HCG, human chorionic gonadotropin; INR, international normalized ratio; PRA, plasma renin activity; PRBC, packed red blood cells; PT, prothrombin time; PTT, partial thromboplastin time; TSH, thyroid-stimulating hormone; US, ultrasonography.

^aIn addition to these tests, some centers check protein C, protein S, and anti-cardiolipin antibodies to identify coagulation abnormalities that may be used to guide postoperative management. Other non-routine tests that may be performed are rectal swab for vancomycin-resistant enterovirus, nasal swab for *Staphylococcus* infection, peripheral blood cultures, and plasma levels of free hemoglobin.

with an enteral feeding tube, even if surgery is delayed. During this time, however, these patients must be carefully monitored and the LVAD should be implanted promptly if their condition worsens, even if complete nutrition optimization has not been completed. A detailed pre-operative nutrition assessment form can be found in Appendix A.

General guidelines for nutrition management in LVAD-supported patients have been previously published.²⁹ Mark-

ers of severe malnutrition include a BMI <20 kg/m², albumin <3.2 mg/dl, pre-albumin <15 mg/dl, total cholesterol <130 mg/dl, lymphocyte count <100, and purified protein derivative skin test anergy. For patients with a pre-albumin <15 mg/dl, enteral feedings are often helpful pre-operatively and should be continued after implant until the patient is taking adequate nutrition. Several recent reports have also shown that patients with a pre-albumin <15 mg/dl at 2 weeks after implant are at high risk of dying before discharge.³⁰

Diets should be liberal and include oral supplements, food from home, and between-meal snacks. When possible, patients should take multivitamins, iron supplements, and erythropoietin. The pre-albumin level should be checked twice weekly and should exceed 15 mg/dl before implant, if possible. A nocturnal tube feeding may be useful in some patients to allow for more daytime activity, such as physical and occupational therapy. Heart failure patients often have a poor appetite due to poor perfusion, congestion, hepatomegaly, and inactivity and may benefit from appetite stimulants. Depression is also common in heart failure patients and may contribute to poor nutrition, but it can be effectively treated with antidepressants.

Hemodynamics. Pre-operative comorbidities are generally the result of acute or chronic low perfusion or congestion, or both. Optimizing hemodynamics, especially increasing cardiac output, if possible, with inotropic and intra-aortic balloon pump support can improve a patient's pre-operative condition.

A pulmonary artery catheter 24 hours before implant is useful in most patients to assess the cardiac index and

Table 8 Minimal Pre-implantation Goals

Parameter	Desired value
Renal	
Blood urea nitrogen	<40 mg/dl
Serum creatinine	<2.5 mg/dl
Estimated GFR	>50 ml/kg/min
Hematology	
INR	<1.2
Hemoglobin	>10 g/dl
Platelets	>150,000/mm
Nutritional	
Pre-albumin	>15 mg/dl
Albumin	>3 g/dl
Transferrin	>250 mg/dl
Hepatic	
Total bilirubin	<2.5 mg/dL
ALT, AST	<2 times normal
Hemodynamic	
Right atrial pressure	<15 mm Hg
PCWP	<24 mm Hg

ALT, alanine aminotransferase; AST, aspartate aminotransferase; GFR, glomerular filtration rate; INR, international normalized ratio; PCWP, pulmonary capillary wedge pressure.

volume status as well as to guide diuretic, vasodilator, and inotropic support. One of the main objectives is to reduce the CVP to 15 mm Hg or less. This will aid in reducing RV workload and minimizing hepatic congestion and the possible need for an RVAD. When the CVP exceeds 20 mm Hg, ultrafiltration and inotrope and vasodilator therapy should be used; also consider temporary RVAD support. Increasing the cardiac index with vasodilators, inotropes, and using an intra-aortic balloon pump will improve conditions for all organ systems. Because pre-operative use of vasopressor medications has been shown to be associated with poor outcomes, these agents should be avoided when possible.

Patients who present in cardiogenic shock may not be good candidates for an implantable LVAD. However, their condition can be optimized with temporary support with a short-term device as a bridge to decision.^{39–41} Paracorporeal biventricular support may be considered for BTT.⁴² Recent reports indicate that the planned use of biventricular support with LVAD and temporary RVAD or with bilateral paracorporeal VADs vs delayed RVAD after LVAD implant improves outcomes in selected patients with right-heart failure or pulmonary hypertension, or both.⁴³ Implementation of early mechanical support has been shown to improve the hemodynamic profile and end-organ function of patients in cardiogenic shock sufficiently to allow successful long-term LVAD support.

Medications that can lower pulmonary vascular resistance (PVR) and the improve cardiac index before surgery may be beneficial in reducing the incidence of RV failure after implant.^{44,45} Medications that have been shown to reduce PVR include angiotensin-converting enzyme (ACE) inhibitors, hydralazine, nitroglycerin, nitroprusside, nitric oxide, sildenafil, prostaglandins, and inotropes (milrinone and dobutamine). Patients with high pre-operative pulmonary pressures and normal right atrial pressure (and thus high RVSWI) are actually at lower risk of post-operative RV failure because findings demonstrate that the RV is capable of generating sufficient pressure. Conversely, low PAP (mean <25 mm Hg) often reflects significant RV failure and is associated with increased mortality.

Renal function. Renal dysfunction is another predictor of adverse outcomes in LVAD-supported patients.^{23,46–48} In general, indicators associated with poor outcomes are a creatinine level >2.5 mg/dl and BUN >40 mg/dl, or an estimated glomerular filtration rate (GFR) of <0.5 ml/kg/min (calculated using the new formula for estimated GFR),⁴⁹ because serum creatinine can seriously underestimate the severity of renal impairment, or chronic dialysis. Urine output as low as 20 to 30 ml/hour for 6 to 8 hours is also an identified risk factor for poor post-operative renal function and death.²⁵ Patients in the HeartMate II BTT trial were excluded if their creatinine level was >3.5 mg/dl or if they needed chronic dialysis; 11% of patients had some degree of renal dysfunction after implant.⁷

Optimizing renal function pre-operatively entails measures to increase renal perfusion and reduce CVP. Diuretic therapy may either improve or worsen renal function, depending on the patient's overall volume status and baseline renal function. However, normalization of volume status is a critical step in reducing secondary pulmonary hypertension and right-heart dysfunction.⁵⁰ Intravenous drips of loop diuretics may be more effective than an intravenous bolus administration in patients who demonstrate diuretic resistance. Intra-aortic balloon pump support can improve renal function by increasing cardiac output and renal perfusion pressure.

Renal dysfunction generally improves after LVAD implant if decreased GFR is due to low cardiac output before implant. In the HeartMate II BTT trial, patients with pre-operative BUN and creatinine values above normal had improvement after 6 months of support, from 37 mg/dl to 23 mg/dL for BUN, and from 1.8 mg/dl to 1.4 mg/dl for creatinine.⁵¹ Evidence of renal dysfunction is not an absolute contraindication to use of a continuous-flow LVAD. However, renal function may not improve in patients who have sustained acute or chronic renal injury from poor perfusion or, more commonly, in patients with underlying renal disease such as diabetes or chronic hypertension.

Gastrointestinal. Because the continuous-flow LVAD requires systemic anti-coagulation, its use in patients with a history of gastrointestinal (GI) bleeding should be carefully considered. Active GI blood loss should be assessed for 3 to 4 weeks before LVAD implant. Of 331 patients discharged from the hospital on HeartMate II support for BTT, 31 (9.4%) required blood transfusions due to GI bleeding.⁵²

Hepatic function. Hepatic dysfunction is associated with poor outcomes after LVAD implant.⁵³ Hepatic dysfunction that is secondary to right-heart failure may improve with mechanical support (LVAD or BiVAD), whereas cirrhosis is predictive of poor outcome. Liver dysfunction is associated with greater need for intraoperative and peri-operative blood transfusion, which can result in worsened right-heart function and the need for RVAD support. Many centers screen patients with clinical evidence of significant right-heart failure or serologic evidence of hepatic dysfunction using hepatic ultrasound imaging or liver biopsy to rule out cirrhosis.

As with renal function, there is evidence that hepatic function improves after implantation of a continuous-flow LVAD.^{54,55} In the HeartMate II BTT trial, alanine aminotransferase, aspartate aminotransferase, and total bilirubin values in patients with abnormal baseline parameters improved to normal over 6 months.⁵¹

Specific management strategies should be initiated to improve hepatic function before a LVAD is implanted in individuals with abnormal values for prothrombin time (PT), partial thromboplastin time (PTT), and international normalized ratio (INR). Right heart pressure and PVR should be decreased using combinations of drugs to reduce pre-load and after-load or ultrafiltration, or both. Consider-

ation of an intra-aortic balloon pump or a temporary percutaneous assist device to improve systemic blood flow is also warranted.

Supplemental vitamin K may be beneficial in repletion of vitamin K-dependent coagulation factors in chronically malnourished patients, those treated with warfarin, or in individuals with baseline hepatic insufficiency. Administering vitamin K to normalize INR levels and stopping all anti-coagulant and anti-platelet agents well in advance of surgery are critical to minimizing peri-operative bleeding.

Hematology. Thrombocytopenia and a low hematocrit are two hematology parameters associated with poor outcomes (Table 2). Patients should be thoroughly assessed for etiology and to correct any abnormalities before implant. In addition, type and cross-matches must be performed pre-operatively to prepare blood products for transfusion during and immediately after the operation.

Coagulation. Similar to the assessment of a patient undergoing any major surgical procedure, attempts should be made to correct or improve clotting abnormalities in prospective LVAD patients. At a minimum, the PT/PTT, INR, platelet count, and antibodies to heparin should be assessed.

Pre-operative abnormal coagulation is common in heart failure patients due to hepatic dysfunction and the use of anti-coagulant or anti-platelet medications. When possible, these medications should be stopped before implant. Vitamin K may be given to reverse the effects of warfarin. For patients who are at high risk of pre-operative thrombosis, a continuous infusion of heparin should be given as the effects of warfarin are reversed. Infusion of fresh frozen plasma may also be used to improve coagulation defects. A controversial issue at present relates to the use of clopidogrel during the peri-operative period in patients who have recently received a drug-eluting stent. Little data are available to guide this decision, thus the risks and benefits for each patient must be weighed.

Heparin-induced thrombocytopenia (HIT) is a clotting abnormality that warrants consideration for patients undergoing LVAD implant.⁵⁶ Although not monitored routinely in all patients, HIT should be assessed pre-operatively in patients with platelet counts <150,000 or in those who have had a recent drop of >20%. Clinical manifestations of HIT include a significant decrease in platelet count—even if the value is within the normal range—or any thrombotic event while receiving heparin. Laboratory evaluation should include a coagulation profile and heparin antibody assay. It may also include the thromboelastogram. Alternative anti-coagulants to heparin (eg, argatroban and bivalirudin) have been used anecdotally in LVAD-supported patients with HIT. Routine screening of all patients can be misleading, as can regular laboratory assays. The serotonin release assay is the most reliable test for establishing the diagnosis of HIT.^{57,58}

Peripheral vascular disease. Many LVAD clinical trials have excluded patients with significant peripheral vascular disease. Abdominal ultrasound imaging and determination of the ankle-brachial index may be warranted to evaluate the degree of disease in susceptible patients being considered for LVAD support.

Pulmonary function. Patients with severe obstructive or restrictive pulmonary disease are *not* eligible for LVAD therapy. There are no absolute pulmonary function criteria for LVAD exclusion, and severe cardiac dysfunction may preclude accurate assessment of pulmonary function.⁵⁰ When pulmonary function testing can be performed reliably, and the forced vital capacity, forced expiratory volume at 1 second, and carbon monoxide diffusing capacity are all less than 50% predicted, exclusion from LVAD implant should be considered. The screening scale for assessing post-implant survival devised by Oz et al²⁴ determined that pre-implant mechanical ventilation presented the highest risk for a poor outcome. Other studies have also determined that mechanical ventilation is a risk factor for RV failure.⁵⁹

Infection. Limiting device-related infections remains crucial to improving long-term morbidity and survival with implantable LVADs. “Adherence to evidence-based infection control and prevention guidelines, meticulous surgical technique, and optimal post-operative surgical site care form the foundation for LVAD-associated infection prevention.”⁶⁰

Patients with active systemic infection should not be considered for LVAD support because infection is one of the leading causes of morbidity and death. Implant should be delayed for patients with localized infections that can be effectively treated, if clinically feasible. Always exercise caution in patients who are at increased risk of infection, such as patients with established or suspected infections, prolonged intubation, cutaneous lesions at surgical sites, or other comorbidities, including multisystem organ dysfunction, immunosuppression, poorly controlled diabetes, renal failure, malnutrition, or debilitation. Correcting as many of these factors as possible before device implant can minimize the risk of infection and optimize long-term outcomes. Another consideration is checking an immune function assay and quantitative immunoglobulins to assess overall immunity and relative risk of opportunistic infections.

Strict adherence to the basic principles of infection control should be a primary goal of LVAD patient management. Table 9 outlines measures to minimize the risk that a peri-operative infection will develop.

Neurologic, psychosocial, and psychiatric considerations. Patients with neurologic or psychiatric disease that compromises their ability to use and care for external system components, or to ambulate and exercise, are poor candidates for LVAD support.⁶¹ All patients with an audible bruit or peripheral arterial disease, diabetes, or age >60 years,

Table 9 Preoperative Infection Control Guidelines

Area	Activity or technique
Patient Selection	<ul style="list-style-type: none"> Exercise caution with patients with conditions that increase infection risk, such as obesity (BMI >40 kg/m²), malnutrition (pre-albumin <15 mg/dl), WBC >10,000, or fever.
All indwelling catheters	<ul style="list-style-type: none"> Rotate the site every 72 to 96 hours. If patient is febrile, draw blood cultures. All catheters should be new or replaced with new access site <36 hours before LVAD surgery.
Remote infections	<ul style="list-style-type: none"> Assess dental hygiene. Exercise caution with patients who have remote infections, such as sinus, urinary tract, bowel, or skin.
Placement and maintenance of central venous catheters and monitoring catheters	<ul style="list-style-type: none"> Practice and promote good hand washing. Educate those who insert and maintain catheters. Use maximal sterile barrier. Use 2% chlorhexidine preparation for skin asepsis. Assure that dressings are occlusive and that moisture does not collect under the transparent dressings. Consider applying a chlorhexidine-impregnated sponge at the central venous catheter site to maintain anti-sepsis at the insertion site. Use anti-microbial- or anti-septic-impregnated central venous catheters to decrease the risk of catheter infections.
Administration of peri-op anti-biotic prophylaxis customized per institution's flora and susceptibility pattern	<ul style="list-style-type: none"> Vancomycin (15 mg/kg IV) 1 hr pre-op, then every 12 hrs × 48 hrs, or alternative agent effective against gram-positive bacteria. Rifampin (600 mg IV) 1 to 2 hrs pre-op, then every 24 hrs × 48 hrs. Fluconazole (400 mg IV) pre-op, then every 24 hrs × 48 hrs. Gram-negative coverage tailored to patient flora and/or institutional susceptibility. Adjust doses for renal and hepatic failure.
Patient preparation	<ul style="list-style-type: none"> Scrub patient with anti-septic soap such as chlorhexidine the night before surgery and again the morning of surgery. Clip the surgical area as close to the operative time as possible.
Prophylaxis against <i>Staphylococcus aureus</i>	<ul style="list-style-type: none"> Nasal culture for <i>S aureus</i> should be performed pre-op. If positive, administer mupirocin 2% nasal ointment the evening before surgery and then twice daily for 5 days.

BMI, body mass index; IV, intravenous; LVAD, left ventricular assist device; WBC, white blood cell.

should undergo a carotid ultrasound study to rule out significant stenosis or the presence of unstable plaque. Patients with previous stroke also warrant computed tomography (CT) scan or magnetic resonance imaging (MRI) to establish a pre-operative baseline study.

Psychiatric disorders, drug abuse, and other psychosocial issues must be investigated to assess the patient's ability to understand and comply with care instructions. Patients with known recent drug abuse and/or a history of non-compliance may not be suitable. Adequate family/caregiver support, housing, and community infrastructure are additional determining factors for potential LVAD candidates. Although not an absolute requirement, LVAD patients should have family or friends nearby to provide supportive care when necessary. Patients must have a reliable means of transportation for follow-up visits and a convenient, reliable telephone service to call for medical help in an emergency.

III. Intraoperative considerations

Key Points

- Moderate to severe aortic insufficiency and mitral stenosis must be corrected during LVAD implant.
- Inflow cannulas must be directed posteriorly toward the mitral valve. Obstruction may result if the cannula is directed or angled toward the septum or free wall or due to changes in position as the LV chamber size is reduced over time.
- Proper placement of the percutaneous lead is of utmost importance for long-term prevention of infection and damage to wires. Tunnel the percutaneous lead to maximize the amount of velour that is inside the body. It may be positioned in a gentle loop

Table 10 Valve Issues

Issue	Possible solution and comments
Aortic insufficiency	Aortic insufficiency that is greater than a moderate degree must be corrected. The aortic valve leaflets can be partially over-sewn or the valve can be replaced with a bioprosthetic valve. Note: The amount of expected post-operative aortic insufficiency may be underestimated pre-operatively in the presence of high left ventricular filling pressures. In the setting of substantially lower left ventricular filling pressures, reassessment of the degree of aortic insufficiency must be performed immediately after weaning of cardiopulmonary bypass with full pump support.
Mitral regurgitation	Generally does not require repair.
Mitral stenosis	Mitral stenosis to a moderate degree or greater must be corrected with mitral valve replacement with a bioprosthetic valve.
Tricuspid insufficiency	Moderate to severe tricuspid insufficiency should be considered for repair to optimize right ventricular function. This is especially important for patients with pulmonary hypertension. Tricuspid valve repair can be performed using annuloplasty repair (a ring or DeVega technique).
Mechanical prosthetic valves	A mechanical prosthesis in the aortic position must be replaced with a bioprosthetic valve or patch closure. The mitral valve generally does not require replacement; consider greater anti-coagulation.

or arc, leaving some internal slack for accidental tugs in the peri-operative period.

- Certain LVAD implant steps can be taken before initiation of cardiopulmonary bypass (CPB) to minimize CPB time: (1) tunnel the percutaneous lead, and (2) anastomosis of the outflow graft to the ascending aorta.
- Before the patient is taken off CPB, air removal should be conducted at low LVAD speeds. The patient should be weaned off CPB or at minimal CPB support (approximately ≤ 1 liter/min) before increasing rpm speeds to permit complete filling of the LV (>10 mm Hg) and to prevent aspiration of air around the inflow conduit.
- Initiate the pump at low speeds and make increases slowly.
- Use care to protect and preserve RV function, especially by not overstressing the RV. If RV dysfunction occurs, resulting in poor LVAD inflow, temporary right-heart bypass can be used to provide blood flow to the LVAD while transitioning from CPB. For more profound RV failure, a temporary RVAD should be considered and implemented expeditiously.
- Intraoperative echocardiography is essential for identifying valvular pathology, intracardiac thrombi, and an atrial septal defect or patent foramen ovale (PFO). A PFO should be closed at the time of implant. Intracardiac thrombus identified in the left atria or ventricle should be removed before LVAD implant. Echocardiography is critical for assessing LV chamber size, cannula position, septal shifting, and aortic valve opening—factors used to determine optimal pump position and speed setting.

This section addresses some general intraoperative considerations that are relevant to the implantation of any continuous-flow LVAD and a number of recommendations specific to the HeartMate II LVAS that are based on clinical experience after completion of the clinical trials.

III.A. Managing valvular heart disease

Table 10 lists valvular conditions that should be considered intraoperatively; and, where appropriate, potential solutions are presented. Outcomes in patients in the HeartMate II BTT trial with concurrent valvular procedures showed higher risk with aortic procedures vs no effect on survival with tricuspid or mitral procedures.⁶² Aortic, mitral, and tricuspid valve issues are described in detail the subsequent sections.

III.A.1. Aortic valve pathology

In the HeartMate II BTT trial, 12 of 281 patients underwent concurrent aortic valve procedures, consisting of 8 aortic valve replacements and 4 with an over-sewn aortic valve or aortic patch.⁶²

Aortic stenosis. Existing stenosis of the aortic valve usually does not require correction before implanting the LVAD. The LVAD will decompress the LV and provide most of the cardiac output. Therefore, aortic stenosis is generally insignificant with regard to pump performance.

Aortic insufficiency. With continuous-flow devices, the patient usually has minimal or no pulse pressure. The native LV, although contracting, may not generate enough pressure to open the aortic valve. Aortic insufficiency (AI) may be present in both diastole and systole, resulting in rapid ventricular filling and high pump flows. Thus, AI tends to have a significant effect on pump performance and the estimated flow rates.

The clinical effect of AI is related to the duration of anticipated LVAD support. For very long-term LVAD support, for example, AI may represent a significant lesion because AI is likely to progress over time. Commissural fusion of the aortic valve leaflets has been reported with an increasing prevalence of AI during HeartMate II support.⁶³ Function of the aortic valve should be monitored throughout support, especially in patients being considered for myocardial recovery and device explant. On the other hand, for

patients being supported for BTT with an expected short duration, AI may be a less significant problem. Most surgeons do not recommend treating mild AI.

AI may appear minimal before implant but become more severe as the LVAD unloads the LV and ejects blood into the ascending aorta, increasing the pressure differential across the valve. Studies have demonstrated that AI can become more significant over the duration of LVAD support, but is usually only mild to moderate.^{63,64} When AI is severe, the amount of regurgitant flow may be reduced by lowering the pump speed to reduce the transvalvular pressure gradient,⁶⁵ although this may not improve systemic perfusion.

Moderate to severe AI warrants surgical repair or replacement. There are two approaches. The first is partial stitching of the aortic valve leaflets, in which some surgeons sew the leading edges of the cusps together (the “Park stitch”) to eliminate most of the AI.⁶⁶

The second is complete over-sewing of the outflow tract, which can be done with a couple of approaches.^{67,68} One approach is to leave the leaflets intact and place a patch: size the opening with an aortic valve sizer, and put in a Hemashield (Boston Scientific, Natick, MA) circular patch using standard aortic valve suturing techniques. Care should be taken to make sure that the edges of the patch are below the coronary ostia. If a mechanical valve is in place, it is also quick and easy to sew a patch to the sewing cuff of the mechanical valve, thereby covering it and excluding it from the blood flow. Another approach, which is an inexpensive option, is to use the excess end of the HeartMate II outflow graft and trim it to appropriate size using a valve sizer. **Note:** *A patient with an over-sewn aortic valve is completely dependent on the LVAD, and even short-term disruption of device function could be fatal.*

If aortic valve replacement is necessary, use of a mechanical valve is *not* recommended because of the increased potential for thromboembolic complications. Thrombus may form sub-valvularly due to infrequent opening, inadequate strut washing, and stasis. Tissue valves are therefore preferred. Pump speed may need to be reduced to allow intermittent opening of the valve as long as adequate support can be provided. There have been reports of LVAD-supported patients with a bioprosthetic aortic valve in whom fibrosis or endothelialization of the bioprosthetic valve developed and resulted in its functional closure.^{68–70}

Pre-existing aortic mechanical valves. Although patients were excluded from the HeartMate II BTT trial if they were not converted to a bioprosthetic valve, a pre-existing aortic mechanical valve is not considered an absolute contraindication to LVAD support. There is ongoing debate whether to leave the mechanical valve in place or replace it with a tissue valve. The individual patient’s indications for LVAD support may dictate the course of action.

If a patient requires long-term LVAD support, then a mechanical valve should be replaced with a tissue valve or the outflow tract over-sewn as previously described because there may be a greater chance for thromboembolic events over an extended period.

III.A.2. Mitral valve pathology

Mitral valve stenosis. Mitral stenosis needs to be corrected at time of LVAD implant to maximize ventricular filling.⁶² Unlike aortic valve stenosis, mitral stenosis will limit pump flow while maintaining a high left atrial pressure (LAP). Elevated LAP could cause persistent pulmonary hypertension and RV dysfunction. Currently, valve replacement with a tissue valve would be most appropriate. However, there may be specific situations where a mitral valvuloplasty may be indicated.

Mitral insufficiency. There is general consensus that mitral insufficiency, in most cases, does not require repair in continuous-flow LVAD patients. In the HeartMate II BTT trial, only 5 of 281 patients had concurrent mitral valve repair procedures (plus 4 in conjunction with other cardiac procedures).⁶² Most mitral insufficiency in end-stage heart failure is from annular enlargement secondary to LV dilation. Once the LV is decompressed with the LVAD, the mitral regurgitation (MR) will likely improve. Although some have suggested that mitral valve repair can improve post-operative LVAD and LV function, no surgical procedure usually is required for MR in patients being supported by a LVAD. Also, MR can be reduced by increasing the speed of the pump when appropriate, which may improve unloading of the ventricle. In cases where the pump is removed after myocardial recovery, significant residual mitral insufficiency should be repaired.

Existing prosthetic valves. Functioning bioprosthetic or mechanical mitral prostheses generally do not require removal or replacement, although greater anti-coagulation should be considered to avoid thromboembolic risk. If anti-coagulation is discontinued or reduced due to bleeding events, patients are at an increased risk of valve thrombosis and thromboembolism.

III.A.3. Tricuspid valve pathology

Tricuspid insufficiency. Because of the importance of improving early right-heart function, there is consensus that severe tricuspid insufficiency should be repaired or treated with valvular replacement, which would have an early beneficial effect. Mild to moderate tricuspid regurgitation and a functional valve would probably improve with a reduction in RV afterload that typically occurs during LVAD support.

III.B. Pre-clotting considerations

Some device conduits require pre-clotting. To avoid unnecessary bleeding from the LVAD conduits, the porous graft on the inflow and the outflow conduits must be thoroughly covered with an adherent material. Users of the HeartMate II should meticulously follow the pre-clotting instructions in the instructions for use. The inflow cannula assembly and the outflow graft both need to be pre-clotted correctly and meticulously (Figure 2). Care must be taken to ensure that pre-clotting material is inserted along the graft down into

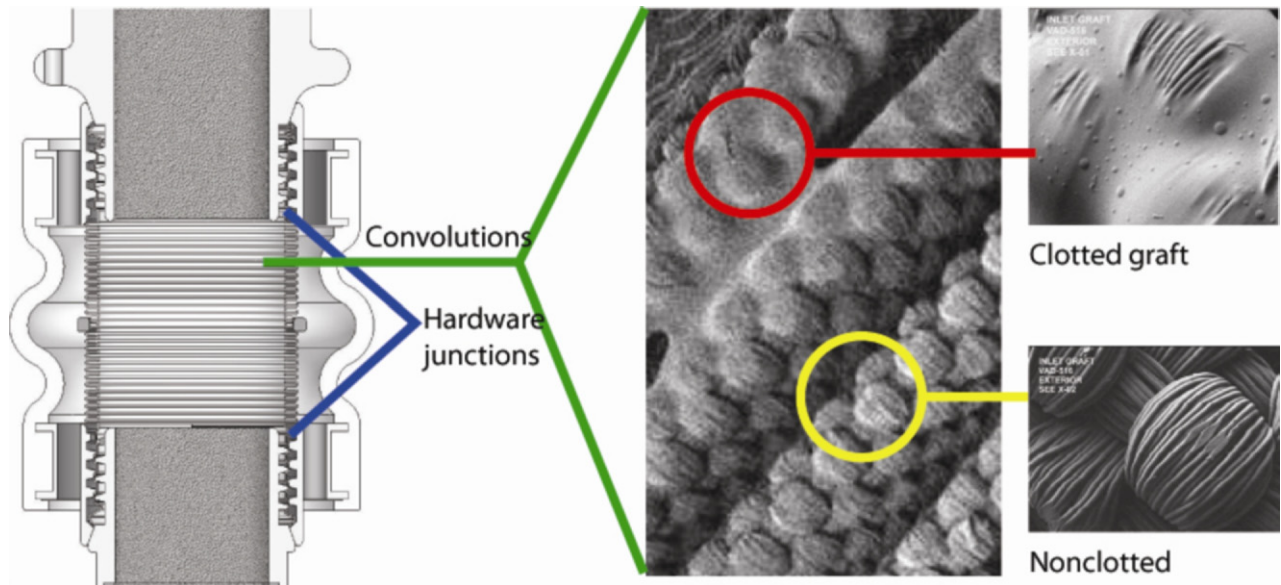


Figure 2 (Left) Inflow cannula pre-clotting must ensure coating between the convolutions and at the junction of the hardware and the graft. (Right) Scanning electron microscopy after explantation shows that the pre-clotting material has not completely covered the graft.

the space between the graft and the metal junction of the connector to the LVAD. Inserting material into this space may be accomplished more easily if the material remains fluid for a time after application; for example, albumin solution, followed by autoclaving, or cryoprecipitate, followed by thrombin. If a react-in-place sealant is used, special care must be taken to deliver the sealant into these spaces before the reaction is complete. The instructions for use for these materials should be closely followed to ensure that the material adheres well to the porous materials.

Note: Hemostatic matrix materials such as Surgiflo (Ethicon, Somerville, NJ) or FLOSEAL (Baxter International, Inc., Deerfield, IL) should not be used because these materials do not produce a layer with sufficient strength to ensure that the graft is sealed.

III.C. Pump placement

Devices should be placed in the intended anatomic location as designed. As an example, we describe placement of the HeartMate II, but similar recommendations also apply to other devices. The HeartMate II LVAD pump was designed for preperitoneal placement; that is, below the left rectus muscle, above the posterior rectus sheath (Figure 3). Keys to proper placement include:

- The inflow cannula must point posteriorly toward the mitral valve. It should not be pointing or angled toward the septum or free wall because this may cause partial occlusion of the inflow cannula, which may lead to poor flow into the LVAD and possible hemolysis or thromboembolic complications.
- The placement of the inflow cannula should accommodate anticipated reductions in LV chamber size that can occur over time.
- The position of the inflow cannula should be assessed before and after chest closure.

- The outflow graft should be pulled tight when estimating length for attachment to the ascending aorta in an end-to-side fashion.

During placement of the silastic cuff on the LV apex, proper attention must be given to the heavy green ligature that is used to secure the inflow cannula. The green ligature should be loosened and hanging freely before the cuff is attached. The cuff should be rotated so that the open portion of the ligature is facing upward and is easily accessible after the inflow conduit is in position. A hemostat or Rommel should be placed on the green ligature to isolate it from the other suture that is used for securing the cuff to the epicardium. Once the inflow cannula is in place, the green ligature is tied tightly around the cuff and inflow cannula to secure its position. Do not cross the ligature such that the ligature will cut the silastic cuff when it is tightened. It may also be necessary to place an additional ligature between the green ligature and the felt portion of the apical sewing ring to reduce bleeding from the holes through which the green ligature passes.

The sequence of surgical steps for positioning the pump includes:

1. Create a sternotomy with a 4- to 6-cm extension in the upper midline.
2. Incise the left anterior rectus fascia.
3. Elevate the left rectus muscle.
4. With the heart beating, select the location on the dome of the diaphragm for the inflow cannula.
5. Set the pump below the left rectus muscle, anterior to the posterior rectus sheath. No opening is made in the diaphragm.

A detailed description for the entire surgical implant procedure has been published by Thoratec.⁷¹

Preperitoneal placement of the HeartMate II requires the dissection of a pump pocket that is significantly smaller than with the HeartMate XVE. In most patients in

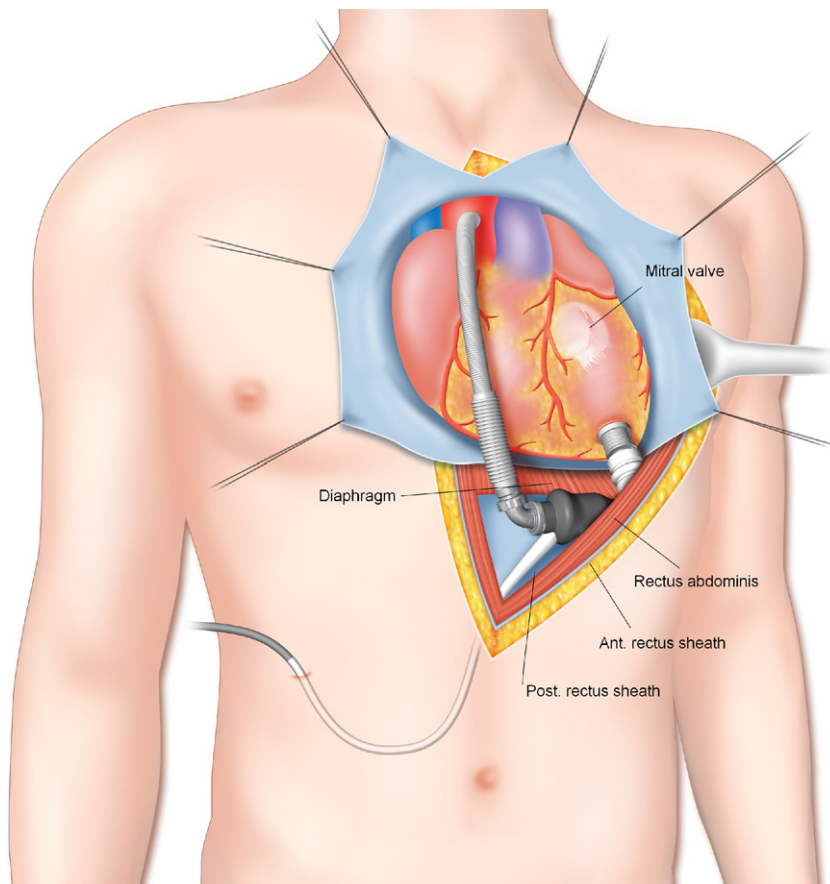


Figure 3 Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).

the BTT trial, the pump was placed in the preperitoneal position, although there are anecdotal reports of intra-abdominal placement.

III.D. Percutaneous lead placement

Proper placement and externalization of the percutaneous lead is of utmost importance to minimize infection and damage to the percutaneous lead. Planning for the percutaneous lead exit site location should begin well before the operation. When possible, the site should be selected with the patient standing; this will help expose anatomic factors and limitations. Site selection might also involve patient input, with a discussion of patient habits and preferences such as waistband or clothing considerations. In general, the distance between the pump pocket and exit site is maximized to allow the greatest portion of the velour covering to be within the subcutaneous tissue. The percutaneous lead should exit the pump housing with a gentle curve. Sharp bends or kinks may result in damage to the electrical wires or data cables within the lead (Figure 4).

There are two main techniques for tunneling the percutaneous lead:

1. The percutaneous lead is tunneled in a U-shape, which increases the amount of velour covering within the subcutaneous tissue (Figure 5A). The tunneling instrument bent into a U-shape allows the lead to be brought downward toward the naval, and then back upward to the exit site at the midclavicular line below the right subcostal margin.

2. The percutaneous lead is positioned in a gentle loop near the midline leaving some internal slack for accidental tugs and to avoid tight bends (Figure 5B). A Vicryl (Ethicon, Somerville, NJ) suture is placed around the percutaneous lead and through the peritoneum to secure the loop into position. This method maximizes the length of velour covering within the subcutaneous tunnel and is a preferred method by some of the most experienced surgeons.

The exit site can be prepared with the circular skin knife. If a circular skin knife is not used, then the size of the exit site created by a punch or incision should be as small as possible. A small exit site minimizes exposure of the subcutaneous tissue and reduces tension on the skin. There should be approximately 1 to 2 cm of the velour-covered lead outside of the skin exit. The lead must be stabilized with one of several external stabilizing methods.

As is emphasized in the post-operative management in Section IV, immobilizing the percutaneous lead is imperative. Immobilization reduces exit site trauma, which promotes wound healing and tissue ingrowth, and this minimizes the risk of infection.

III.E. Cardiopulmonary bypass

Issues surrounding CPB during LVAD implantation have been covered in detail previously and should be reviewed.¹⁰ In addition, information related to the transition from CPB

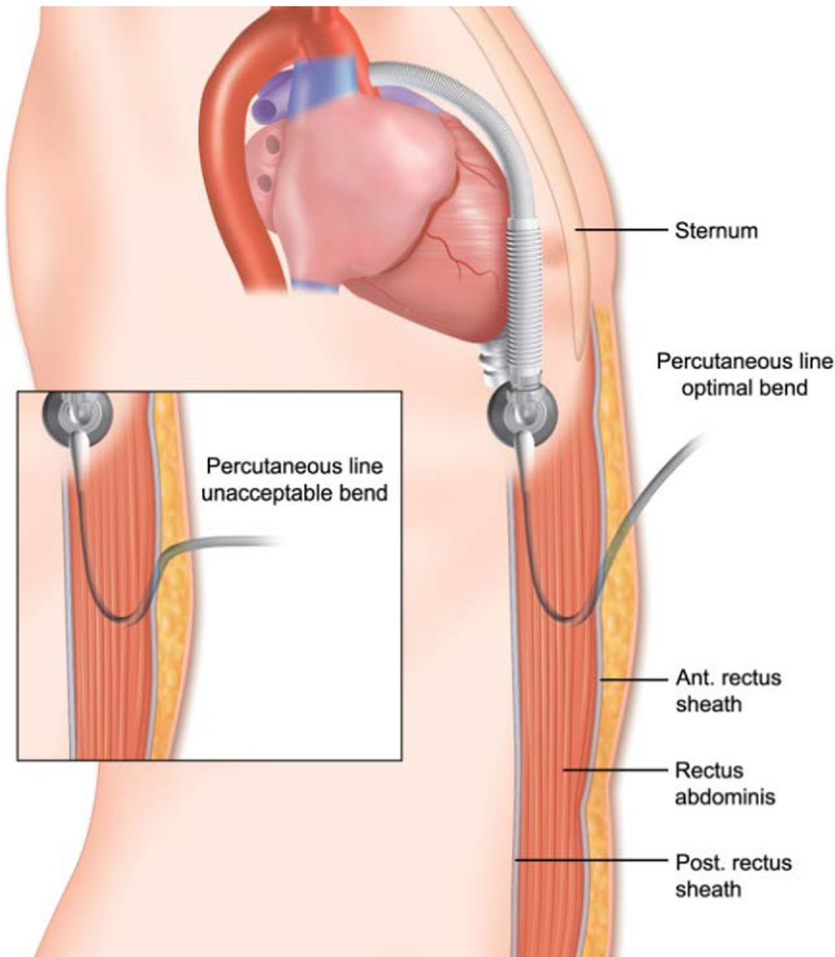


Figure 4 The percutaneous lead must be tunneled without sharp bends. The large illustration shows an acceptable bend radius of the lead. The insert shows a bend radius that is too sharp, which should be avoided.

to the HeartMate II implantation is contained in Section III.F, which follows. In general, adjusting inotropic and afterload-reducing drugs before CPB can maximize RV function and reduce PVR while optimizing systemic perfusion pressure. Prolonged CPB can have deleterious effects, particularly coagulopathy and inflammatory responses contributing to systemic hypotension, pulmonary hypertension, and resultant right-sided circulatory failure.⁷²

Certain LVAD implantation steps can be taken before CPB is initiated to minimize bypass times. These include tunneling the percutaneous lead, completing the outflow graft anastomosis, and positioning the pump, if the patient is stable. Generally, CPB is used during apical coring and placement of the inflow cannula within the ventricle.

Although a few experienced surgeons have implanted LVADs using off-pump techniques, the safety of these approaches have not been validated for widespread use.^{73–75}

III.F. De-airing and transitioning from CPB

Before the LVAD is activated, all air should be removed and the left heart should be readily filling with blood. Transesophageal echocardiography should be used through-

out the de-airing and LVAD startup procedures to identify the presence of air in the LV or aorta. For the HeartMate II, air is removed from the LV and pump through the Luer lock connection on the outflow cap. Air is expelled from the outflow graft by partially releasing the cross-clamp and allowing backflow from the aorta. Once all air is removed from the LV pump and the outflow graft, the graft is attached to the pump. Before attachment, however, the threads of the graft and pump should be examined and any thrombus should be removed. When necessary, the heart rhythm is cardioverted and blood volume is shifted from the CPB circuit to the patient's circulation.

De-airing is continued during startup of the LVAD with a cross-clamp on the outflow graft, and a needle is placed into the highest portion of the outflow graft. Elevating the LV apex can aid in the removal of air from the heart; however, this should not be done after the LVAD is activated because there is a risk of air entrainment. With the HeartMate II set at the lowest speed setting (6,000 rpm), initiate pumping while continuing de-airing through the needle. CPB flow is decreased, followed by removal of the cross-clamp from the graft. With an adequate volume of blood moving through the LV and LVAD, there should be continuous blood flow through the needle vent.

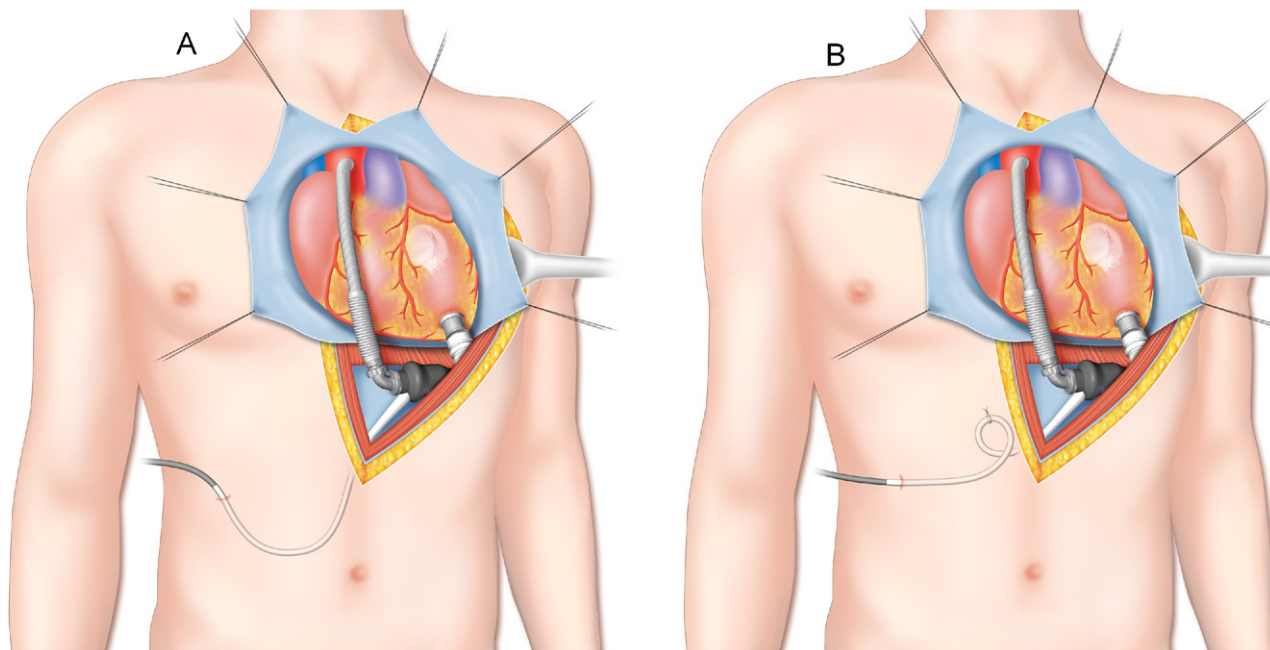


Figure 5 (A) The percutaneous lead is tunneled with a U-shape to increase the amount of velour covering exposed to the subcutaneous tissue. (B) A gentle loop, with care to avoid tight bends, is created in the percutaneous lead before it is tunneled, which maximizes the amount of velour covering exposure to the subcutaneous tissue.

A temporary ultrasonic flow probe may be used to determine LVAD flow at the lower speed (flow <3 liters/min is not estimated). Most surgeons do not use a LV vent and will vent through the outflow graft.

Initiate the pump at low speeds; increase speeds slowly. The use of higher speeds (eg, about 8,000 rpm) before completely filling the LV and coming off CPB is not recommended because it can lead to entrainment of air. CPB support should be stopped and the LV should be full (LAP >10 mm Hg) before a higher pump speed is used. Flooding the chest with carbon dioxide, blood, or saline during de-airing reduces air entrainment. Transesophageal echocardiography should be used to assess for air in the LV or aorta, and for LV size and septal position to determine initial pump speeds. Where cardiac function is adequate, CPB can be completely discontinued to allow thorough de-airing before the device is activated.

Some centers have found that direct measurements of LAP are useful in setting pump speeds and assuring that there is adequate RV output. Only centers with routine experience in placing and using direct LA monitoring catheters should attempt this. If an LA catheter is placed, use extreme caution to avoid sucking air into the LA through the insertion site and to avoid flushing air into the LA directly through the LA catheter. There is also a risk that tamponade will develop after the catheter is removed.

A straightforward method for de-airing is:

- Before connecting the outflow graft to the pump, allow blood to fill the pump from the LV, temporarily release the cross-clamp on the outflow graft to fill the graft with blood from the aorta, and then attach the screw ring connector on the graft to the outflow of the pump.
- Insert a needle in the outflow graft at the highest point.

- Look for air on the echocardiogram.
- If no air is observed, remove the clamp from the outflow graft (de-air through outflow graft).

Note: Assure that the porous areas of inflow conduits that have not been pre-clotted are completely covered with the pre-clotting material and the pump is sealed properly to avoid entraining air into the pump through the inflow conduit. See Section III.A.3 for pre-clotting considerations.

III.G. Coagulopathy and bleeding

Post-operative bleeding is one of the most frequent adverse events after LVAD implant. It can contribute to right-heart failure, infection, and a number of adverse effects related to blood transfusion. Owing to the comorbid conditions and treatments related to heart failure, patients undergoing LVAD implant are highly susceptible to developing serious coagulopathy. It is important to withhold any anti-platelet or anti-coagulant medication for 4 to 7 days before the LVAD is implanted and attempt to normalize INR before surgery to minimize the risk of bleeding requiring reoperation. There are a number of intraoperative measures that can minimize bleeding:

- Minimize CPB time to reduce the coagulopathic effect of extracorporeal circulation.
- Minimize dissection and practice meticulous surgical technique for hemostasis.
- Normothermia should be maintained by keeping the room temperature as high as tolerable, and CPB temperature should be adjusted to normal body temperature.

- When the apical cuff is attached in an area of friable myocardium, felt reinforcement is recommended.
- Dissection of the pump pocket should be minimal, with careful cauterization of potential bleeding sites.
- Use autologous blood transfusion and ensure that adequate blood products for transfusion are readily available during the implant procedure.
- Platelets should be transfused in patients with thrombocytopenia; some centers preemptively transfuse platelets.
- Whole blood and plasma may be used to prime the CPB system in patients who are anemic or who have persistent elevation of liver enzymes or an elevated INR.
- Aminocaproic acid may be given after CPB is complete.
- Some centers use a thromboelastogram for intraoperative management of coagulation factors.

III.H. Intraoperative management of RV dysfunction

Management of RV dysfunction should focus on prevention rather than treatment. The tricuspid valve should be evaluated and repaired, if necessary. If RV dysfunction is due to ischemia, consider revascularization. Avoid RV volume overload and maintain CVP <16 to 18 mm Hg. If CVP is ≤ 10 mm Hg, some volume may be given to improve flow. The use of carbon dioxide in the operative field may reduce air embolism, which is believed to contribute to intraoperative RV dysfunction. Normal ventilation and oxygenation should be maintained to avoid pulmonary vasoconstriction caused by acidosis or hypoxia. Milrinone, epinephrine, isoproterenol, or vasopressin can be used with moderate RV dysfunction. The need for or use of vasopressor agents may increase the risk of significant RV failure and need for an RVAD. Inhaled nitric oxide can reduce PVR, and some centers have found that inhaled Flolan (GlaxoSmithKline, Middlesex, UK) is effective and less expensive than nitric oxide.^{76–79} Pacing can be used if the heart rate is not optimal. High pump speeds that cause leftward septal shift should be avoided. Leaving the sternum open for 24 hours has been reported to help reduce CVP in patients with CVP >16 mm Hg but there is an increased risk of infection.

If RV failure results in poor flow to the LVAD, short-term intraoperative right-heart bypass can be established to reduce the load on the RV and deliver oxygenated blood to the LVAD.⁸⁰ This can be done by returning part of the blood from the CPB circuit through a cannula inserted in the pulmonary artery or LA through the right superior pulmonary vein. This technique allows adequate filling of the LVAD without requiring excessive right-heart work.

If in spite of these interventions if the cardiac index is <2.0 liters/min/m² and the CVP >20 mm Hg, a temporary RVAD should be considered before leaving the OR. A CentriMag (Levitronix, Waltham, MA) or a paracorporeal Thoratec VAD (Thoratec Corp., Pleasanton, CA), are two of the most commonly used devices for temporary RV support. In assessing the need of an RVAD, the proper function of the LVAD must be confirmed. Use the echocardiogram to determine if the LV is being unloaded or not and to help

guide positioning of the inflow cannula, which should be directed toward the mitral valve and not toward the septum or lateral wall. The HeartMate II pump speed should be set in a range that provides a sufficient level of cardiac output support (i.e., usually 8,600 to 9,800 rpm). High pump speed that causes leftward septal shift or collapse of the LV and LA should be avoided. Finally, the outflow graft should be inspected to ensure that there is no obstruction or kinking.

III.I. Intraoperative echocardiography

Intraoperative echocardiography is a standard procedure during LVAD implant for assessing LV, RV, and valvular function, for detecting the presence of a PFO,^{81–84} and for locating intracardiac thrombi. Detecting and removing intraventricular thrombi before pump insertion is critical to avoiding thrombi entry into the pump when it is started. Because detection of intraventricular thrombi with echocardiography is not completely reliable, visual inspection should be performed. Intraoperative echocardiography also plays a critical role in determining optimal pump speed. How to use echocardiography as a guide for setting pump speed is described in Section V.A.3.

Some centers visually inspect the atrial septum to rule out PFO because of a significant incidence of false-negative results in pre-bypass examinations (including bubble studies). If direct inspection is not done, it may be necessary to repeat the bubble study after implant and weaning from CPB. With the left heart decompressed and the right heart working and loaded, a previously undetected PFO may be unmasked and significant shunting may be seen by color-flow Doppler and bubble study (Figure 6). It is important to repair a PFO to prevent right-to-left shunting and, potentially, hypoxemia after implant.



Figure 6 This transesophageal echocardiogram shows significant flow by color Doppler across a patent foramen ovale (PFO) after the left ventricle was decompressed by left ventricular assist system support. The PFO was not apparent in the pre-bypass period due to the previously high left atrial pressure.

III.J. Replacing a HeartMate XVE LVAD with a continuous-flow LVAD

The pulsatile-flow HeartMate XVE LVAD can be replaced at the end of its pump life with a continuous-flow LVAD. Detailed information on exchange techniques has been published.^{85–88} In this section, we describe a procedure for replacing the device with a HeartMate II LVAD, although similar techniques could be used for any continuous-flow LVAD:

- A redo sternotomy approach is recommended.
- The patient is placed on CPB. Alternative cannulation strategies may be used, such as femoral or axillary cannulation.
- The apical sewing cuff from the HeartMate XVE is usually retained.
- The inflow cannula of the HeartMate XVE is removed.
- The inflow cannula from the HeartMate II LVAD is placed through the old silastic cuff.
- The HeartMate II outflow graft is beveled and anastomosed back to the aorta, or alternatively, end-to-end to a remnant of the HeartMate XVE outflow graft (see below).
- The new HeartMate II percutaneous lead is externalized through a new sub-cutaneous tunnel and exit site, which can be to the left upper quadrant to avoid possible contamination from the old site.
- Pump pocket drains may be required for the residual space left by the HeartMate XVE. This pocket should eventually close. Sometimes removing part or the entire old fibrous capsule from the HeartMate XVE will diminish the potential space difference.

The outflow graft on the HeartMate II device is smaller (16 mm) than the HeartMate XVE aortic graft (20 mm), but they can be sewn together end-to-end. The HeartMate II grafts should be beveled to accommodate the larger HeartMate XVE graft. This technique will also work if removing the HeartMate XVE graft and attaching the HeartMate II back to the aorta. Alternatively, a linear down-size of the aortotomy can be used. De-airing issues are similar to those described in Section III.F.

III.K. Exchanging a HeartMate II LVAD with a HeartMate II LVAD

The HeartMate II LVAD may require exchange due to infection of the percutaneous lead or pump, irreparable damage to the percutaneous lead, or pump thrombosis.⁸⁷ The connections from the inflow and outflow conduits to the pump have been designed to allow exchange of the pump and percutaneous lead only. The exchange can be accomplished without entry into the chest cavity, and the inflow and outflow conduits are left in place unless there is evidence that these components should also be exchanged, such as obstruction due to thrombosis. For this procedure:

1. Establish femoral-femoral or axillary-femoral cannulation for CPB.
2. Make a left subcostal “chevron” incision over the area of the pump.

3. Expose and dissect free the connections of the inflow and outflow conduits and a portion of the outflow graft. A sufficient area of the graft is exposed for cross-clamping when the device is removed. The screw ring connectors on either side of the pump must be accessible to facilitate detachment and removal.
4. Place the patient into the Trendelenburg position and initiate CPB.
5. Cross-clamp the outflow graft and detach the screw ring connectors.
6. Divide the percutaneous lead and remove the pump.
7. Place the new pump in the same position and attached with the screw ring connectors.
8. Externalize the new percutaneous lead in a new sub-cutaneous track.
9. De-air the pump with a needle in the outflow graft.
10. Turn on the pump on at a low speed setting (about 8,000 rpm or less) while the de-airing needle and cross-clamp are in place.
11. After all air has been removed and confirmed with echocardiography, remove the needle from the graft and remove the cross-clamp.
12. Slowly wean off CPB while gradually increasing the pump speed to about 9,000 rpm, depending on patient conditions.
13. Irrigate the entire surgical area with an antibiotic solution and close all incisions in standard fashion.

HeartMate II exchange can be easily accomplished with rapid recovery from the exchange surgery.⁸⁷ Routine post-operative care is provided.

IV. Post-operative patient management

Key Points

- A patient’s RV function can be affected by pump speed. Avoid setting the pump speed too high or too low.
- To avoid severe post-operative bleeding, anti-coagulation should be completely reversed after CPB. Routine use of heparin is not indicated immediately after the LVAD is implanted. Patients are usually anti-coagulated with warfarin and anti-platelet agents (aspirin) when they are able to take oral medications.
- Mean arterial blood pressure should be maintained between 70 and 80 mm Hg and should not exceed 90 mm Hg. In the early post-operative period, an arterial catheter is used to monitor blood pressure. After the catheter is discontinued, the most accurate non-invasive method is with Doppler and a sphygmomanometer.
- A proper balance of LV pressure and pump speed is desirable. This is typically accomplished with a pulse pressure of 10 to 20 mm Hg and the aortic valve opening approximately once every 3 beats. Echocardiography may be used to confirm ideal pulse pressure and aortic valve opening frequency.

The presence of a dicrotic notch in the arterial line also signifies aortic valve opening.

- Self-care should stress rigorous adherence to aseptic technique for exit site care and immobilization of the percutaneous lead.

The post-operative management of continuous-flow LVAD patients in most instances is quite similar to the management of all patients after major cardiac surgery. Continuous-flow LVAD patients have special considerations related to RV function and volumes, anti-coagulation and bleeding, blood pressure monitoring and management, and patient education, which are described the subsequent sections.

IV.A. RV function

General considerations for evaluating and managing RV function and setting the pump speed in the post-operative setting include the following:

- Avoid setting the pump speed so high that it causes a significant leftward septal shift and abnormal RV geometry, which can adversely affect RV function. High pump speeds also can collapse the LV and obstruct flow through the LVAD inlet cannula draining the LV. See Section V.A.3 regarding proper pump speed settings.
- Because of the potential for large volume shifts in the early post-operative period, echocardiography should be performed routinely because these volume changes alone may cause changes in RV and LV function.
- How often the aortic valve needs to open is debated. A common practice aims to adjust pump speed so that the aortic valve opens every second or third beat. This frequency reduces the risk of aortic valve thrombosis and at the same time ensures that the LV is reasonably loaded and not near collapse. In some patients, however, the aortic valve will not open even at low pump speed due to poor LV function. There are insufficient data to make firm conclusions about the long-term effects of this phenomenon. Although long-term mechanical circulatory support with the aortic valve remaining closed without apparent negative clinical effect has been reported, there are also reports of aortic valve fusion^{63,89,90} and anecdotal reports of aortic valve thrombus developing on the non-coronary cusp.

- If a patient is clinically decompensating (signs of poor forward flow or right-heart failure), consider a repeat echocardiogram and reevaluate pump speed and also for possible tamponade.
- When the pump speed is set, the RV should be assessed to see if it becomes dilated and hypocontractile at high or low speeds. Use extreme care when increasing pump speed to assess RV dysfunction, because once the RV begins to show signs of failure it can be very difficult to reverse.
- A sign of poor LV unloading in some patients is the amount of MR. If the patient has severe MR, consider increasing the pump speed and evaluating inflow and outflow position.

IV.B. Anti-coagulation

Anti-coagulation therapy is required during support with continuous-flow LVADs to avoid thrombotic complications. However, results from the HeartMate II BTT trial indicate that anti-coagulation requirements for this therapy are less than was initially believed. Early in the BTT trial experience, anti-coagulation therapy was aggressive and included the optional post-operative use of intravenous dextran, followed by intravenous heparin as a transition to oral warfarin and anti-platelet therapy. The target INR range was 2.5 to 3.5.^{91,92} However, results from the clinical trial revealed that the incidence of thrombotic events is very low—much lower than bleeding—which remains one of the most frequent adverse events.^{1,7,8} Other studies have confirmed this observation, which has resulted in reduced anti-coagulation therapy at the most experienced centers.^{52,93–95} The 2009 revised proposals for anti-thrombotic therapy during HeartMate II support are presented in Table 11.

IV.B.1. Titrating anti-coagulation

Starting anti-coagulation too early is a common mistake. Adequate hemostasis should be achieved before anti-coagulation is initiated. Modification of the anti-coagulation regimen may be required in the face of changing clinical situations. If LVAD flow remains low (<3.0 liters/min), consider increasing anti-coagulation. If there is a risk of bleeding, consider decreasing the warfarin dose and increasing or maintaining anti-platelet medications. Anti-platelet effect may be confirmed with laboratory studies.

In most cases, the use of intravenous heparin as a transition to long-term warfarin therapy in the early post-oper-

Table 11 Postoperative Anti-coagulation Guidelines for the HeartMate II Based on Results From the Clinical Trial

Timing	Action
Before leaving OR	Completely reverse the anti-coagulation.
Immediate post-op period	Generally, no action. Patients with other indications for anti-coagulation therapy, such as atrial fibrillation, history of LVA or LA thrombus, or low LVAD flow should be treated with anti-coagulants.
Day 2 to 5	Once there is no evidence of bleeding and the chest tubes have been removed, begin warfarin therapy with a target range for the INR of 1.5 to 2.5. Also begin aspirin at a dose of 81 to 325 mg daily.
Duration of support	Maintain on aspirin and warfarin,

INR, international normalized ratio; IV, intravenous; LA, left atrium; LVA, left ventricular aneurysm; LVAD, left ventricular assist device; OR, operating room.

ative period is not necessary. In a recent study by Slaughter et al⁹⁶ of 418 patients, 300 (72%) who had sub-therapeutic or no heparin therapy before warfarin was begun did not have an increased risk of thromboembolic events; therefore, heparin may not be needed in most cases. However, there are some clinical conditions of higher thrombotic risk where post-operative heparin may be indicated in the transition to warfarin therapy, such as small patients who have low LVAD flow rates, a small ventricle, previous stroke or transient ischemic attack, chronic atrial fibrillation, or documented LA or LV thrombus.

In a recent study by Boyle et al⁵² of long term anti-coagulation therapy in 331 outpatients supported by the HeartMate II, the risk for thromboembolism was also shown to be much lower than that of bleeding. This study concluded, "the risk of thrombotic events increases with an INR < 1.5 while the risk of hemorrhagic events is present at all INR ranges and is particularly increased with INRs > 2.5." Therefore, current recommendations are to adjust the warfarin dose to achieve a target INR of 1.5 to 2.5. In addition to warfarin, patients should also be given anti-platelet therapy, such as aspirin (81 to 325 mg daily). The use of dipyridamole was optional in the trial and varied among centers; thus, it is no longer part of the standard anti-coagulation and anti-platelet algorithm.

Anti-coagulation and anti-platelet therapy may need to be adjusted for some clinical conditions. Some types of infection, especially bacteremia, are associated with a higher incidence of stroke due to increased endothelial activation and platelet aggregation.⁹⁷ Therefore, increased anti-platelet therapy may be warranted during systemic bacterial infections.

GI bleeding is a complication of continuous-flow pump support that may be severe and require that anti-coagulation therapy be reduced or discontinued.⁹⁸⁻¹⁰¹ Two hypotheses of the cause of GI bleeding during LVAD support that are being studied are acquired von Willebrand syndrome caused by increased shear stress,¹⁰²⁻¹⁰⁴ and reduced pulsatility of the continuous-flow device.¹⁰¹ There are anecdotal reports from some centers that have decreased the speed of continuous-flow LVADs with the hypothesis this would create a greater pulse pressure and reduce shear stress through the pump and might potentially reduce the risk of GI bleeding. These practices have not been studied in a series of patients. There are also anecdotal cases where patients have been without warfarin and/or aspirin for extended durations after episodes of persistent GI bleeding. The risks and benefits of removing warfarin or antiplatelet therapy should be thoroughly assessed and discussed with the patient.

IV.B.2. Thromboelastography

Some experienced centers are using thromboelastography to manage and adjust anti-coagulation therapy, but its use in continuous-flow LVAD patients is insufficient to make recommendations. Teams should be well trained to ensure consistent results. The thromboelastogram is initially performed daily to assess anti-platelet needs until stable and satisfactory levels are achieved.

IV.C. Blood pressure monitoring and management

The major hemodynamic effects of a continuous-flow LVAD are increases in diastolic pressure and flow.¹⁰⁵ Because these devices pump continuously throughout the entire cardiac cycle, aortic flow is also present during diastole when normal pulsatile flow is absent. When the pump speed of a continuous-flow LVAD is increased, the diastolic pressure rises, the systolic pressure remains fairly constant, and the pulse pressure (systolic – diastolic) is greatly reduced. The pulse pressure is influenced by LV contractility, intravascular volume, pre-load and after-load pressure, and by pump speed. Therefore, assessment of the arterial blood pressure values and waveform gives valuable information about the physiologic interaction between the LVAS and the cardiovascular system.

Owing to the reduced pulse pressure during continuous-flow LVAD support, it is often difficult to palpate a pulse and measure blood pressure accurately by the usual auscultatory or automated methods. When listening with a manual blood pressure cuff, the start of the Korotkoff sound is a pressure value that is estimated to be in the range of the systolic and diastolic pressures. In the early post-operative period, an arterial catheter is necessary to monitor blood pressure properly. After the arterial catheter is removed, the arterial blood pressure is most reliably assessed using Doppler and a sphygmomanometer. Pressure values obtained using the Doppler method may be measured at any point during the cardiac cycle and should not necessarily be considered the actual systolic, diastolic, or mean pressure values.

Arterial blood pressure should be controlled with vasoactive and inotropic medications and intravascular fluid volume management. The pump speed should *not* be adjusted to achieve a desired arterial blood pressure. The goal is to maintain the mean arterial blood pressure in the range of 70 to 80 mm Hg. It should not exceed 90 mm Hg. Unlike a pulsatile LVAD, the amount of cardiac output support by a continuous-flow pump is affected by the after-load, or systemic vascular resistance. Maintaining the mean arterial pressure in the desired range will optimize cardiac support. It may also reduce stroke due to hypertension.

It is desirable to have some arterial pulsatility and aortic valve opening during support.¹⁰⁶ A flat arterial blood pressure waveform with a low pulse pressure indicates that LV function is extremely poor or that the set pump speed is close to exceeding the available pre-load (LV volume). When pulsatility is absent, ventricular suction and collapse are more likely to occur. See Section V.A.3 on proper pump speed setting.

Pulse oximetry, if obtainable, may be unreliable due to diminished pulse pressure. Instead, some centers use cerebral oximetry for assessing hemodynamic conditions when more invasive monitoring is not available.

IV.D. Patient education

Effective education requires a collaborative, multidisciplinary team approach that extends to the LVAD patient, family member(s), and companion(s) in care. Training on proper self-care

and system operation, with an emphasis on meticulous care of the percutaneous lead and exit site, should begin pre-operatively. Training continues throughout hospitalization. Eventually, the patient's demonstration of understanding and competency may be a requirement for discharge. The fundamental features of an effective patient education program have been described previously.^{10,11,107,108} Also, refer to Section VII.

IV.D.1. System operation

A thorough understanding of LVAS operation and system component features for any specific device type is necessary to ensure patient safety, particularly in the outpatient setting. The LVAS patient and his or her family member(s) or companion(s) must be able to competently perform routine activities of self-care as well as LVAS care and operation. They must also be prepared to respond appropriately to alarm symbols and audible tones. Of particular importance, the device must have adequate power at all times. In the case of the HeartMate II LVAS, a power base unit/power module or batteries serve as a routine power supply. Loss of power will cause the pump to stop. Pump cessation may have serious consequences, especially in those patients who are device-dependent or in whom the outflow tract has been over-sewn. Owing to this critical dependence on a continuous power supply, patient training should focus on the proper procedures for switching between power sources and for estimating available charge levels during battery-powered operation. Troubleshooting pump stoppage is covered in Section VIII.B.

IV.D.2. Self-care infection prophylaxis and percutaneous lead immobilization

The best measure for infection prophylaxis is to protect the percutaneous lead from movement at the exit site.⁶⁰ Movement of the percutaneous lead will disrupt the sub-cutaneous tissue ingrowth in the velour lining of the lead, resulting in infection. This tissue ingrowth is delicate and is easily damaged with minor trauma. The lead should be immobilized in the operating room with a stabilization belt or restraint device that should be worn continuously. Patients and their caregivers should always take precautions to avoid any unnecessary exit site movement, especially sudden pulling on the lead. A patient's ability to accomplish this goal in day-to-day life can greatly depend on the effectiveness of the education to which he or she has access. Thus, education should routinely emphasize to the patient that proper exit site care is critical to long-term survival. The importance of meticulous aseptic techniques for exit site care must also be stressed and periodically demonstrated. See Section VII.C.1 for more information on outpatient device management and percutaneous lead and exit site care.

IV.D.3. Maintaining volume status and hydration

It is common for LVAD patients to become dehydrated because they continue to limit their oral intake and maintain a salt-restricted diet. To help monitor volume status after discharge, patient self-care routines should include daily charting of weight and paying attention to symptoms such as orthostatic hypotension. Patients should be prompted to

call if their weight fluctuates more than 1.3 kg (3 lb) during a 24-hour period. Consider repeating echocardiogram studies during outpatient visits to determine if the patient's pump is set at the proper speed.

V. Post-operative device management

Key Points

- Continuous-flow LVADs do not contain valves. If the pump stops, there may be back flow that can have severe consequences (similar to aortic insufficiency). Avoid power interruption or inadvertent power lead disconnection that would lead to loss of support.
- Continuous-flow pumps can generate large negative pressures at the pump inlet, which may result in septal shift or ventricular collapse. Consequently, pump-speed optimization and device monitoring present unique challenges compared with pulsatile devices.
- Avoid setting the pump speed too high, which can result in ventricular collapse or inlet obstruction and initiate arrhythmias.
- The system-provided parameters of speed, power, pulsatility index, and estimated flow in conjunction with echocardiography serve as the primary indicators of proper device function. The patient's clinical status should always be assessed when device function is evaluated.
- The range of safe operating speed is determined by means of a ramped speed study with echocardiography. Changes in ventricular shape and function and the patient's physiologic response to changing pump speeds will determine the appropriate speed setting.
- The flow rate displayed on most systems is an estimate that should be used for trending and not as a precise measurement of cardiac output.

Continuous-flow LVADs present unique challenges in monitoring and optimizing support compared with pulsatile devices. Because each device has specific system characteristics, it is not possible to cover all possible scenarios for device management for all devices. We will focus on the HeartMate II, although some properties are generic to other devices as well. This section first describes how the system-provided parameters of speed, power, pulsatility index (PI), and estimated flow are used to assess the adequacy of support; it concludes with troubleshooting tips. **Note:** The term *pulsatility index* is shortened to "Pulse Index" for display on the HeartMate II system monitor screen.

V.A. Monitoring device function

Continuous-flow LVADs do not contain valves. As a result, flow can become retrograde if the pump is turned off or in the presence of high afterload pressure and low pump speed.

Another distinctive feature of continuous-flow LVADs is their ability to generate large negative pressures at the pump inlet, which may result in septal shift or ventricular collapse. Consequently, speed optimization and device monitoring with continuous-flow LVADs present some unique challenges compared with pulsatile devices.

The system-provided parameters of speed, power, PI, and estimated flow for the HeartMate II, in conjunction with echocardiography, serve as the primary indicators of proper LVAS function. It is important to view each of these device parameters in the larger context of the patient's overall condition. Once baseline values representing a satisfactory level of patient support are established, the degree of change in a parameter usually has more clinical significance than its absolute value.

V.A.1. Flow and power

Flow estimate and power at a given speed are closely related. Power is directly measured by the HeartMate II system controller, and the reported flow is an estimated value determined from power and pump speed. An increase in power is converted into an increase in flow through the pump and will be displayed as such on the system monitor or display module.

An increase in power not related to increased flow, such as thrombus on the rotor, will cause an erroneously high estimated flow reading. Power values under normal conditions of operation will run within an expected range for each set speed (Figure 7). If the power values are outside of the expected range, the display of estimated flow will be replaced with “+++” or “---” when the calculated flow is above or below the expected physiologic limits at the current set speed, respectively.

The minimum value for the flow estimator is 3.0 liters/min. Gradual increases in power, without a change in the set speed, an increase in volume status, or a decrease in afterload, may indicate the formation of thrombus on the bearing or rotor. Conversely, an occlusion of the flow path will decrease flow and cause a corresponding decrease in power. In either situation, an independent assessment of pump output should be performed.

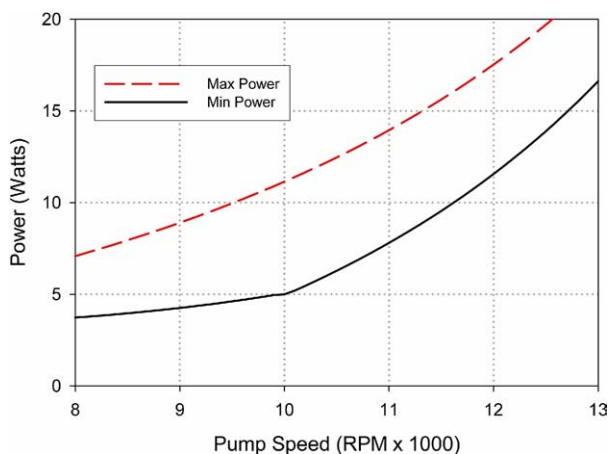


Figure 7 The minimum and maximum expected power values over the range of speed settings for the HeartMate II.

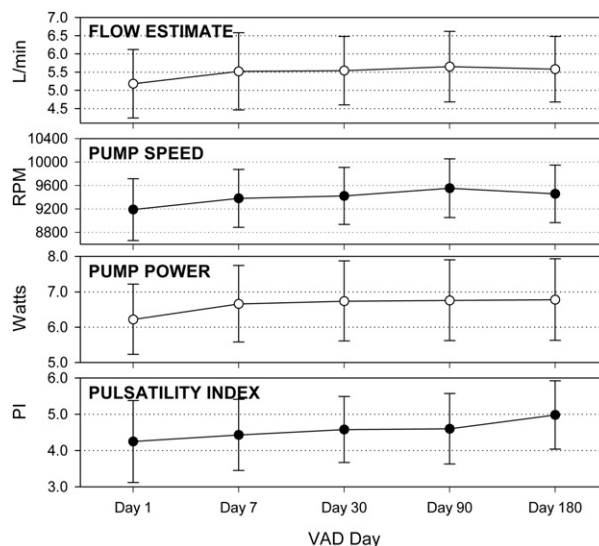


Figure 8 Flow, speed, power, and pulsatility index (PI) during the HeartMate II bridge-to-transplant trial are shown. Data presented are the mean values with the standard deviation (range bars).

The average values of power, flow, and pulsatility index in the HeartMate II BTT trial are shown in Figure 8. At 6 months of support, the average estimated flow was 5.6 ± 0.9 liters/min, pump power was 6.8 ± 1.2 W, the PI was 5.0 ± 0.9 , and the pump speed was $9,450 \pm 490$ rpm.

V.A.2. Pulsatility index

When the LV contracts, the increase in ventricular pressure causes an increase in pump flow. The magnitude of these flow pulses is measured and averaged for a 15-second interval to produce the displayed PI value (appears as *Pulse Index* on monitor). In general, the magnitude of the PI value is inversely related to the amount of assistance provided by the pump. As the level of pump support increases, there is less ventricular filling, less pressure development, and a corresponding decrease in the measured PI. A significant drop in the PI without an increase in pump speed may indicate a decrease in circulating blood volume. Conversely, an increase in left ventricular contractility, as may occur with an increase in volume status, myocardial recovery, and inotropic medications, or during exercise, will cause the PI to increase.

V.A.3. Selecting optimum pump speed

Optimal pump speed is achieved when the cardiac index and LV size are within normal range and there is no rightward or leftward shift of the septum. In addition, it is desirable to have some pulsatility with intermittent aortic valve opening.^{7,93} A ramped speed study using echocardiography and hemodynamic assessment provides the most direct method to ascertain what speed provides the desired level of cardiac support for each patient.¹⁰⁹ Throughout the procedure, LV size, position of the septum, blood pressure, and aortic valve opening should be monitored to determine the appropriate combination of factors that define the optimum operating point.

Ideally, a ramped speed study with echocardiography is performed in the operating room after the patient is stable

and before the transesophageal echocardiography probe is removed. A transthoracic echocardiogram may be performed in the intensive care unit when the patient is stable and before invasive monitoring catheters are removed, and again before hospital discharge. Additional studies should be performed when there are symptoms of inadequate support. Some experienced centers prefer to set the pump speed in the operating room using hemodynamic and echocardiography parameters and to leave the speed setting constant most of the time throughout support unless there are indications of inadequate support, at which point the setting will be reassessed.

Note: The range of speed that is used for the remainder of support is optimally determined when the patient's hemodynamic condition is stable (ie, volume is normal and vasoactive and inotropic agents are not supporting the patient).

The proper speed setting of the HeartMate II is in a range that is well above the minimum setting and well below the maximum setting. The usual speed range is 8,600 to 9,800 rpm; only rarely is the setting outside of this range.

To set the pump speed in patients who are stable and euvolemic, the following protocol can be used:

1. **Determine the low-end of the speed range.** Starting from the current fixed speed, lower the speed gradually until the aortic valve opens with each heart beat and there are no signs of heart failure. **Note:** Some patients with very poor LV function may not have aortic valve opening. If the aortic valve is not opening and a PA catheter is in place, the lowest speed setting can be determined when the cardiac index is about 2.5 liters/min/m² and/or the pulmonary wedge pressure begins to increase. Without a PA catheter, the low speed setting can be established when the LV size increases and there is rightward shift of the septum. If an arterial pressure catheter is present, observe and record the pressure values and calculate the pulse pressure. Record the LV dimensions. Allow the patient to stabilize at each speed setting and do *not* allow the fixed speed to decrease below 8,000 rpm. It is possible that even at 8,000 rpm the aortic valve will not open.
2. **Determine the high-end of the speed range.** Starting from the low-end fixed speed as determined above, increase the pump speed gradually until the parasternal short-axis or apical 4-chamber views show flattening of the septum (Figure 9). The LV diastolic dimension should decrease near the low-end of the normal range. In patients whose aortic valve was opening at the low-end speed, the aortic valve will most likely remain closed, and the pulse pressure should be in the range of 10 to 15 mm Hg. The cardiac index should increase and the pulmonary wedge pressure will decrease. The high-end speed is usually below 9,600 rpm.
3. **An appropriate fixed speed setting usually will fall midway between the low-end and high-end speed range.** The selected speed may be adjusted from the midpoint based on clinical judgment, taking into consideration the desire for periodic aortic valve opening and a palpable pulse. To accommodate normal shifts in volume and hemodynamic status, the fixed speed should gener-

ally be set at least 400 rpm below the maximum speed as determined above. If premature ventricular contractions or ventricular tachycardia occurs with increased pump speed, the speed is too high and should be reduced.

VI. Diagnosing and managing post-operative complications

Key Points

- Perform physical examinations and laboratory testing regularly throughout LVAD support.
- Teach patients and family member(s)/caregiver(s) how to identify and respond to signs and symptoms of the most common problems.
- Echocardiography is very useful in diagnosing problems with the patient-pump interface. Echocardiography can assess:
 - Adequacy of pump speed and support by determining ventricular size.
 - Valvular function.
 - Inflow and outflow abnormalities.
- Left and right-heart catheterization may be necessary in some clinical circumstances such as suspected pump thrombosis or kinked conduit.
- Computed tomography may be useful in confirming problems with the pump.
- Bleeding complications:
 - Consider lowering anti-coagulation and anti-platelet medication.
- TIA/stroke:
 - To avoid hemorrhagic stroke, do not aggressively anti-coagulate.
 - Maintain pump flow >3.0 liters/min.
- Infection:
 - Educate patients and family member(s)/caregiver(s) on percutaneous lead and exit site care, emphasizing rigid adherence to aseptic techniques for dressing changes and lead immobilization.
- Arrhythmias:
 - Strong consideration on placing an implantable cardioverter defibrillator for those that meet the requirements.
 - To avoid suction-induced arrhythmias, do not set pump speeds too high.

Physical examination and laboratory testing should be performed regularly throughout LVAD support. Patients should be educated on identifying signs and symptoms of the most common problems and know how to respond to each. Subtle symptoms, such as low energy and fever, can be signs of impending serious problems and should be assessed promptly. In addition to routine examinations,

Parasternal Long Axis

Apical 4 Chamber

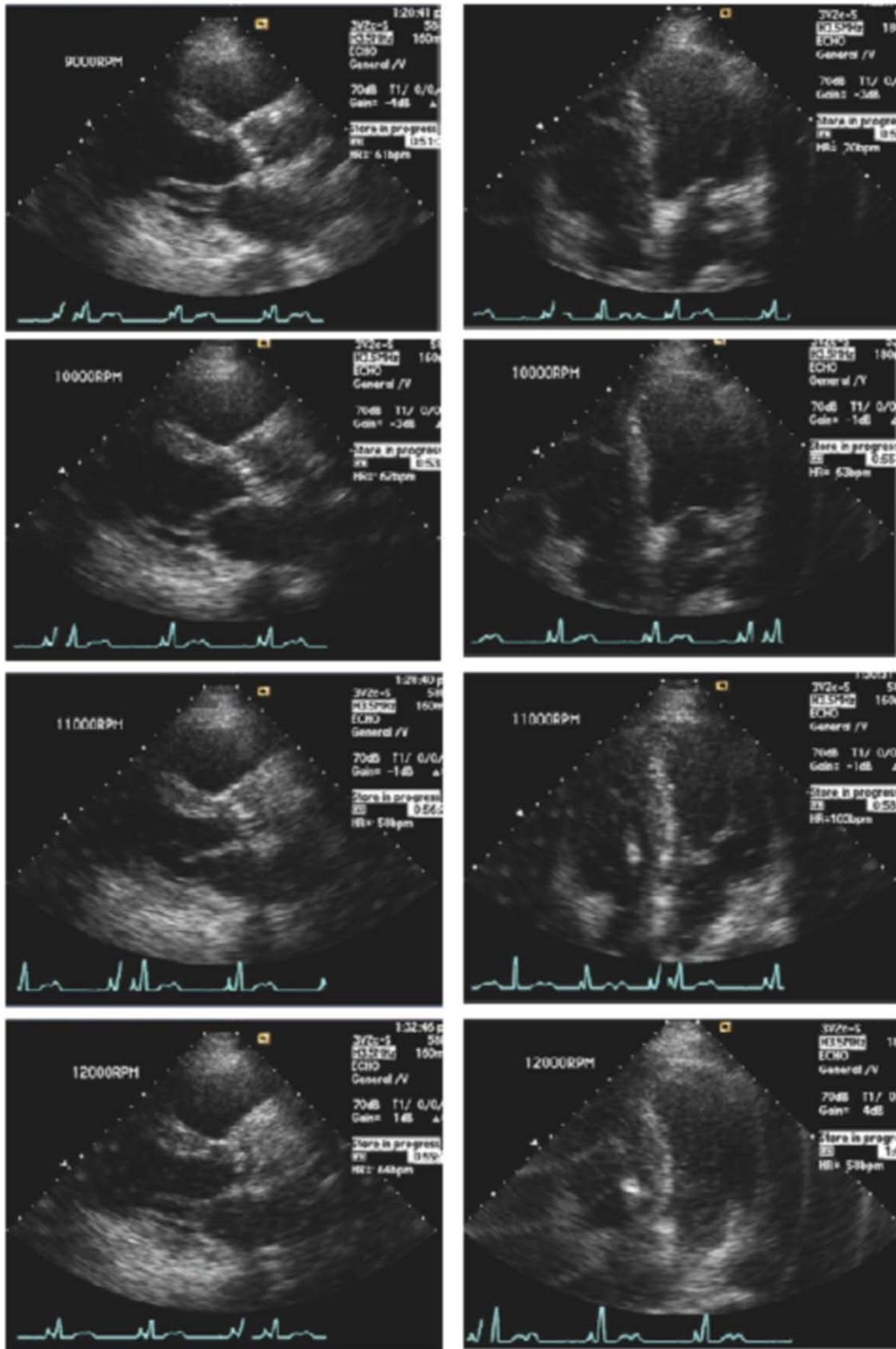


Figure 9 Echocardiography is shown for (left) parasternal long-axis and (right) apical four-chamber views at HeartMate II pump speed of (top to bottom) 9,000, 10,000, 11,000, and 12,000 rpm.

some specialized tests are particularly useful in diagnosing problems associated with LVAD support, such as:

- **Echocardiography.** Echocardiography is very useful for assessing post-operative complications because it allows visualization of the cardiac chambers and blood flow at the LVAD inlet and outlet. Echocardiography is essential for evaluating cardiac valve function. Transthoracic echocardiography is often adequate for assessing inlet and outlet velocities. If transthoracic echocardiography is insufficient to provide adequate assessment, consider transesophageal echocardiography. Occasionally, cardiac catheterization or CT may be helpful for diagnosing both inflow and outflow obstruction.
- **Left-Heart Catheterization.** Some patients on LVAD support may have progression of coronary artery disease, with either acute or sub-acute coronary syndromes. It is appropriate to treat these patients the same as non-LVAD patients, and it is safe to perform coronary arteriograms. Because the outflow graft is attached to the ascending aorta, guiding wires and catheters could potentially enter the graft. A pigtail catheter can be placed in the LV in the same manner as for a left ventriculogram, but passing the catheter into the pump *must be avoided*. Panning over the inflow and outflow cannula permits visual assessment for graft kinking and flow obstruction.
- **Right-Heart Catheterization.** Because the flow shown on the HeartMate II system monitor is an estimate of flow through the LVAD and does not necessarily reflect the total cardiac output, a right-heart catheterization can be performed for a more precise estimate of right-heart and left-heart function. Thermodilution or Fick methods for obtaining cardiac outputs should be accurate in most cases.
- **Computed Tomography.** CT can be used to assess the outflow and inflow graft for kinking, twisting, or thrombus (Figure 10). It does not allow visualization of the titanium portions of the pump or inlet cannula.

Note: Magnetic resonance imaging (MRI) should never be performed on a patient with an implanted LVAD due to the strong magnetic fields.

Table 12 lists potential complications and suggested management approaches related to support with the HeartMate II LVAS.

VII. Outpatient management

Key Points

- Successful long-term LVAD support depends on comprehensive care from a multidisciplinary team, including the patient and his or her family member(s)/caregiver(s).

- Effective patient education and support are key components of successful outpatient support.
- The target INR for patients receiving the HeartMate II is 1.5 to 2.5 with warfarin therapy, and aspirin at 81 to 325 mg daily for anti-platelet therapy.
- Stabilize the INR before discharge from the hospital.
- Over-anti-coagulation should be avoided.
- Hypertension must be controlled to avoid decreased LVAD support and cardiac output as well as to avoid cerebrovascular events.
- Before discharge, thoroughly assess the patient's medical readiness.
- Immobilizing the percutaneous lead to prevent exit site trauma reduces infection risk. Care of the percutaneous lead and exit site must be a priority for successful outpatient care.

The outcomes of patients discharged from the hospital while supported by the continuous-flow LVADs have been excellent.¹ Successful long-term LVAD support depends on comprehensive care from a multidisciplinary team, including the patient and his or her family/caregiver(s), or friends.^{110–113} Parents often become the primary caregiver for younger patients. Responsibility for patient care shifts from the heart failure team to the patient and his or her family/caregiver(s) when the patient is discharged from the hospital. Educating the patient and his or her family and companion(s) or caregiver(s) begins when the decision is made to implant the device. After implant, patients should be taught some aspect of outpatient care during each hospital day; consequently, there is a high level of confidence at discharge that the patient will not experience avoidable complications.

Managing LVAD outpatients with different types of systems is similar in many ways. However, users must be aware of the key points specific to each device to minimize complications and to optimize survival. Users are encouraged to take advantage of the manuals, documents, and clinical support pieces developed by the manufacturers to support outpatient success. A 2-volume document developed from experience with pulsatile devices as DT are still useful as a reference for continuous-flow devices.^{10,11} Also, readers should refer to material by MacIver et al¹¹¹ for management of LVAD patients in the community. These documents provide a number of checklists, forms, and protocols to aid in discharge planning and proper outpatient management.

VII.A. Preparing for hospital discharge

Preparing patients for hospital discharge begins during patient selection, when a prospective patient's support system and outpatient living environment are assessed. Before implant, the patient and his or her family members(s)/caregiver(s) must be informed of the requirements for successful outpatient support. In addition to the patient's spouse, life partner, or companion, his or her children, neighbors, and

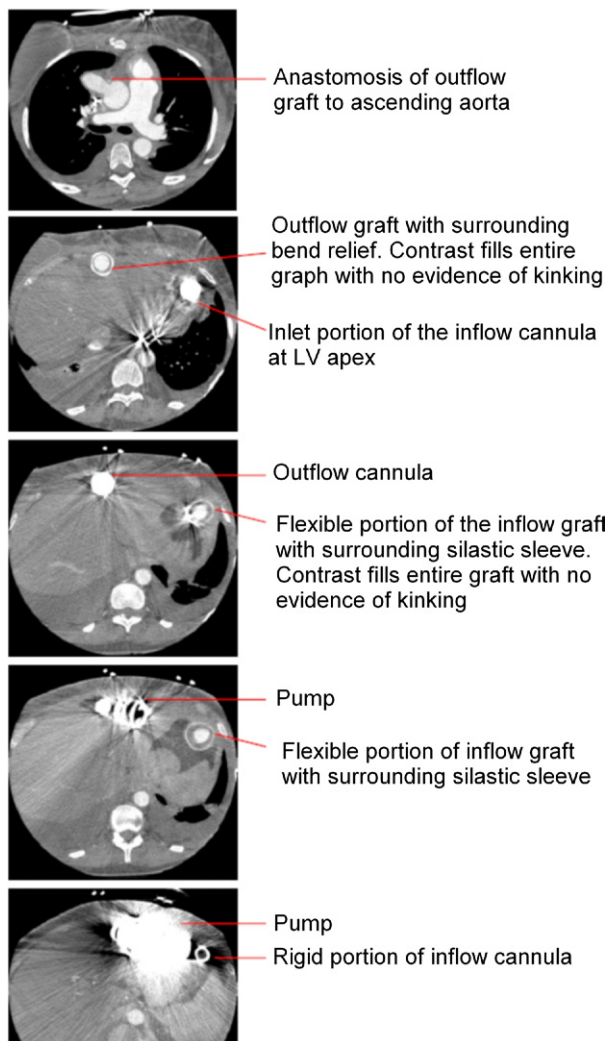


Figure 10 Computed tomography scan with contrast is used to assess inflow and outflow grafts. LV, left ventricle.

friends should be enlisted to participate in care and monitoring efforts.¹¹¹ Creating a broad network of involved individuals maximizes support for the patient and can minimize the burden of the primary caregiver during long-term LVAD support such as for DT patients. Before the LVAD is implanted, it may be worthwhile to have the patient and his or her family member(s)/caregiver(s) execute a “behavioral contract” that lists caregiver tasks and specifically identifies the responsible party(ies) for each expectation or need.

Heart failure teams. Although a VAD coordinator is usually the person charged with training patients and their family members/caregivers, and for assuring follow-up throughout LVAD support, all heart failure team members have valuable contributions to make when preparing the patient for discharge.¹¹⁴ When appropriate, the patient’s primary care physician should be involved, and communication among all team members should be coordinated. For example, the heart failure team must communicate the same information to the patient and the patient’s support group to avoid any

contradictions regarding care and emergency measures. For inexperienced users, discharge planning meetings with the entire team can facilitate a smooth transition for the patient.

Patient education. Effective education for the patient and those who will be caregiver(s) is the key to outpatient success. Accordingly, all team members must learn the essentials of LVAD patient care, as well as system operation, maintenance, troubleshooting, and emergency response. Competency evaluation must be performed and documented before discharge, and the need for retraining should be assessed periodically.

Discharge readiness. Before discharge, the patient’s medical readiness must be thoroughly assessed. One of the most important tasks before discharge is stabilizing the INR and the dose of anti-coagulants. Fluid balance may be a key outpatient concern for many patients and should be normalized before discharge. Physical, occupational, and respiratory therapy rehabilitation should be complete, and the patient must be physically capable of managing much of his or her own care.

Community services. Community preparation varies greatly among users and should be individualized accordingly.¹¹⁵ Training of emergency medical services personnel on proper LVAS emergency measures should be considered. Specific written instructions or an emergency identification card with contact numbers to the VAD center for emergency notification should be with the patient at all times.

VII.B. Outpatient medical therapy

Anti-coagulation. Proposals for post-operative anti-coagulation therapy are discussed in Section IV.B. and carry into the outpatient phase of support. Adjusted warfarin doses are used to achieve a target INR in most cases of 1.5 to 2.5 for HeartMate II recipients. Aspirin (81 to 325 mg daily) is typically used for anti-platelet therapy. This therapy is individually adjusted to minimize the risk of ischemic stroke and major bleeding.⁵² Of 331 patients discharged with HeartMate II support, the total thrombotic event rate was 3.3%, compared with a much higher rate of hemorrhagic events of 22%, suggesting that some patients have been over anti-coagulated.⁵² Results from the clinical trial show that the current recommended anti-coagulation therapy is considerably less than it was when the trial was started. Of the outpatients who had non-surgical bleeding events, the GI system was identified as the most frequent site of bleeding. Regular testing of the coagulation and hematology profiles are recommended. Because hemolysis may potentially occur, the lactate dehydrogenase and plasma free hemoglobin values should be determined when occult bleeding is present.

Hypertension. Cardiovascular medical therapy is prescribed with consideration to avoid hypertension while maintaining

Table 12 Potential Complications Specific to Continuous-Flow Left Ventricular Assist Device Patients

Potential problem	Assessment	Management
Bleeding	<ul style="list-style-type: none"> Hct, PT/PTT, INR, TEG, PFA-100 	<ul style="list-style-type: none"> Reduce or eliminate anti-coagulation therapy, depending on the severity and location of bleeding. Consider surgical assessment, especially in the face of post-op bleeding. Consider the pump (leaky connection), or polyester grafts on the conduits (inadequate preclotting) as potential sources of bleeding. See anti-coagulation, Section IV.B.
Hematoma with falls	<ul style="list-style-type: none"> Hct, PT/PTT, INR, TEG, PFA-100 	<ul style="list-style-type: none"> Reduce anti-coagulation.
Epistaxis GI bleed	<ul style="list-style-type: none"> Hct, PT/PTT, INR, TEG, PFA-100 Hct, PT/PTT, INR, TEG, PFA-100 	<ul style="list-style-type: none"> Reduce anti-coagulation and antiplatelet therapy. Reduce anti-coagulation and anti-platelet therapy. Consider a more complete work-up by a gastroenterologist. Consider reducing pump speed to achieve greater pulsatility or to reduce shear stress. Non-surgical bleeding due to acquired von Willebrand syndrome caused by shear stress through the pump has been proposed.^{102,104}
TIA/stroke	<ul style="list-style-type: none"> CT, Hct, PT/PTT, INR, TEG, PFA-100 	<ul style="list-style-type: none"> Do not aggressively anti-coagulate a patient who experiences a TIA or potentially reversible ischemic stroke to avoid the more serious complications of hemorrhagic stroke.
Cardiac		
Volume overload	<ul style="list-style-type: none"> Physical exam (JVP, edema) Echocardiography Right heart catheterization Increased PI, flow, power 	<ul style="list-style-type: none"> Consider diuretics and fluid restriction. Increase pump speed under echocardiography.
Dehydration	<ul style="list-style-type: none"> Physical exam (JVP, edema), echocardiography Right heart catheterization Suction events and arrhythmias Decrease in PI 	<ul style="list-style-type: none"> Monitor hydration/volume status (adjust diuretics). Decrease pump speed.
Arrhythmias	<ul style="list-style-type: none"> ECG (telemetry, Holter monitor, event monitors), heart failure symptoms Potential suction events Decrease in flow, power, PI 	<ul style="list-style-type: none"> Decrease pump speed if arrhythmias occur with suction events. Consider anti-arrhythmic medications. Evaluate pump speed under echocardiography for excessive unloading or for contact between the inflow cannula and LV wall. Carefully assess RV function. Consider cardioversion. Consider ICD.
RV failure	<ul style="list-style-type: none"> Physical exam, symptoms, echocardiography (RV size, TR) Suction events Displayed pump speed drops below fixed speed setting Decreased pump flow 	<ul style="list-style-type: none"> Consider inotropes. Consider pulmonary vasodilators: <ul style="list-style-type: none"> Sildenafil Nitric oxide Isoproterenol Prostaglandins ACE inhibitors Milrinone. Change pump speed under echocardiography. Consider RVAD support.

Table 12 Continued

Potential problem	Assessment	Management
Tamponade	<ul style="list-style-type: none"> ● Physical exam, symptoms, echocardiography, chest X-ray, CT scan ● Suction events ● Sudden and unexpected decrease in chest tube output ● Decreased pump flow 	<ul style="list-style-type: none"> ● Return to OR for re-exploration. ● Consider pericardiocentesis.
Hypotension	<ul style="list-style-type: none"> ● Symptoms, BP monitoring ● Increase in pump flow and power ● Decrease in PI 	<ul style="list-style-type: none"> ● Adjust vasoactive medications. ● Consider volume expansion.
Hypertension	<ul style="list-style-type: none"> ● BP monitoring, assess volume status ● Decrease in pump flow and power ● Increase in PI 	<ul style="list-style-type: none"> ● Decrease afterload with medications. ● Consider diuretics for volume overload.
Recurrence of heart failure symptoms	<ul style="list-style-type: none"> ● Physical exam, symptoms; other testing as appropriate ● Decrease in pump flow and PI ● Pulmonary dysfunction, edema and hypoxemia 	<ul style="list-style-type: none"> ● Evaluate pump speed settings. ● Evaluate RV function. ● Treat pulmonary symptoms.
Aortic insufficiency	<ul style="list-style-type: none"> ● Physical exam, symptoms ● Echo ● Fluoroscopy ● Decreased perfusion ● Dilated LV with high pump flow 	<ul style="list-style-type: none"> ● Repair/replace as needed (see Section III.A).
Infection		
Percutaneous lead	<ul style="list-style-type: none"> ● Exam ● Culture and sensitivity 	<ul style="list-style-type: none"> ● Administer anti-biotics. ● Improve percutaneous lead exit site care and immobilization. ● Consider wound VAC for significant wound healing issues. ● See details in Outpatient Management Section.
Pocket	<ul style="list-style-type: none"> ● Exam ● X-ray ● Ultrasound ● CT scan ● Tap pocket 	<ul style="list-style-type: none"> ● Administer anti-biotics. ● Explore pump pocket and drain abscess fluid. ● Place PMMA beads (typically containing vancomycin and/or tobramycin) into pump pocket. ● Irrigate and débride pump pocket. ● Consider pocket revision, though a new access may be required. ● Cultures
Other		
Percutaneous lead site tearing	<ul style="list-style-type: none"> ● Exam 	<ul style="list-style-type: none"> ● Patient education: Warn patient to avoid tugging or twisting percutaneous lead or allowing the controller to fall or drop. ● Use a stabilization belt or abdominal binder to secure the system controller (driver) and immobilize percutaneous lead.
Percutaneous lead insulation tearing	<ul style="list-style-type: none"> ● Visual exam 	<ul style="list-style-type: none"> ● Patient education: Warn patient to avoid tugging or twisting percutaneous lead or allowing the controller to fall or drop. ● Contact Thoratec.

Table 12 Continued

Potential problem	Assessment	Management
Hemolysis	<ul style="list-style-type: none"> ● LDH test ● Plasma-free hemoglobin ● Consider decreasing speed 	<ul style="list-style-type: none"> ● Evaluate potential sources: inflow/outflow occlusions, pump issues, etc (see Section V). ● Consider temporarily reducing pump speed (most cases are transient).

ACE, angiotensin-converting enzyme; AV, arteriovenous; BP, blood pressure; CT, computed tomography; ECG, electrocardiogram; GI, gastrointestinal; Hct, hematocrit; INR, international normalized ratio; JVP, jugular venous pressure; LDH, lactate dehydrogenase test; LV, left ventricle; OR, operating room; PI, pulsatility index; PFA-100, Platelet Function Analyzer (PFA)-100 (Dade Behring Inc, Deerfield, IL); PMMA, polymethylmethacrylate; PT, prothrombin time; PTT, partial thromboplastin time; RV, right ventricle; RVAD, right ventricular assist device; TEG, thromboelastogram; TIA, transient ischemic attack; TR, tricuspid regurgitation; VAC, vacuum assisted closure.

fluid balance and glycemic control. Hypertension is normally controlled with β -blockers, with careful monitoring of RV function; or with ACE inhibitors, with careful monitoring of renal function. Because hypertension may decrease LVAD support and total cardiac output and cause cerebral events, frequent assessment of blood pressure is imperative.

Other therapy. When indicated, antibiotics, statins, and thyroid medications should be prescribed. A prescribed diet should be followed and adjusted as necessary.

VII.C. Outpatient device management

Each continuous-flow LVAD system has specific peripherals and components for outpatient use. As an example, a HeartMate II patient receives a complete primary set and a backup set of external system components before discharge (Table 13). The patient may also receive a stabilization belt and the accessories listed in Table 13.

Table 13 Required HeartMate II Equipment for Hospital Discharge

Component	Required	Backup	Optional
System controller	✓	✓	...
Batteries (2 sets)	✓	✓	...
Battery clips	✓	...	Backup optional
Emergency power pack	✓
Display module	✓
Power base unit or power module with cable	✓
Universal battery charger	✓
System controller battery module	...	✓	...
Stabilization belt	✓	...	Backup optional
Modular belt	✓	...	Backup optional
Shower bag	✓	...	Backup optional
Holster vest	✓	...	Backup optional
Consolidated bag	✓	...	Backup optional
Patient handbook	✓

Before discharge, the backup system controller must be programmed with the same parameters as the primary controller. Patients must keep the backup controller, charged spare batteries, battery clips with cables, and emergency ID card with them *at all times*. Before discharge and during follow-up training, the critical nature of the backup equipment and the proper use and safe maintenance of all equipment should be emphasized.

Patients and their caregivers must be able to recognize system alerts and alarms and know the appropriate measures to be taken for each. This is a significant part of patient/caregiver education. Patients and family members/caregivers are trained to handle alarms and taught when to contact the physician or VAD coordinator. Patients are taught how to record all alarm conditions and any related circumstances that may aid in troubleshooting.

VII.C.1. Percutaneous lead care and exit site wound management

Percutaneous lead infection and damage to the wires within the lead are potentially serious adverse events that are leading reasons for hospital re-admission. The incidence of percutaneous lead infections in the HeartMate II DT trial was 0.48 events/patient-year, and lead damage was the most frequent cause of pump replacement.¹ Many of these events are preventable through meticulous protection and care of the percutaneous lead. Updates in the design of the percutaneous lead are expected to improve its durability in the future.

Outpatient prevention of percutaneous lead infection begins in the early post-operative period when the patients and caregivers become involved in self-care. Established protocols for inpatient and outpatient percutaneous lead care have proven to be effective for pulsatile devices and should be followed.^{10,60,107,108} Infection prevention has been addressed throughout this document because it is a serious and preventable adverse event that requires meticulous attention from the time of LVAD implant and for the remainder of support.⁶⁰ Some key points for outpatient support that deserves emphasis are:

- Immobilization of the percutaneous lead at the exit site is vital to prevent disruption of subcutaneous tissue ingrowth.

- All caregivers must perform exit site care with meticulous sterile technique (some centers use clean technique when the patient is at home and the site is well healed).
- The observation of erythema or increased drainage should be immediately reported and prompt an investigation for cause.
- Cleansing of the exit site must be gentle and non-traumatic.
- Various immobilization methods may need to be evaluated by the patient for optimal comfort and effectiveness.

Various methods of immobilization are used by different centers. Stabilization belts have been very effective in protecting the exit site and percutaneous lead. Alternative techniques for percutaneous lead stabilization have been devised to accommodate patient preferences or for patients with poor compliance.

When signs of infection develop, the method of percutaneous lead stabilization should be re-evaluated and revised, if necessary. If there is serous or purulent drainage, the frequency of dressing changes should be increased until the infection is resolved. For worsening infections, consider hospitalization for more intensive therapy. Surgical revision, wound vacuum-assisted closure therapy, antimicrobial beads, and pump exchange may be necessary. Prolonged anti-biotic use in the absence of infection should be avoided to decrease the chance of developing infection from resistant organisms. However, some patients need chronic antibiotic suppression therapy if their infection cannot be eliminated. **Note:** Refer to Chinn et al⁶⁰ for detailed clinical outlines on handling percutaneous lead infection.

VII.D. Handling emergencies

Patients and their caregivers must be able to recognize and respond to emergency conditions and should refer to training documents on how to handle emergencies.¹⁰⁷ For example, HeartMate II patients must be able to respond to “red heart,” or low-flow alarms immediately, followed by appropriate notification of the VAD coordinator. A list of emergency contacts must remain with the patient at all times. The patient should be encouraged to contact his or her physician or VAD coordinator for all conditions that may be considered serious. Because emergencies are rare, frequent retraining is advisable.

VII.E. Outpatient follow-up

Ongoing follow-up is a key part of effective care for outpatients supported by continuous-flow LVADs. A comprehensive, multidisciplinary team approach to outpatient care may have an important effect on long-term survival. A proactive approach to outpatient care can help to identify problems earlier with more effective treatment. The following aspects of outpatient follow-up warrant consideration:

- The frequency of follow-up clinic visits varies among patients, depending on medical issues, concerns for self-care, and the distance a patient is from the implant center.
- Patients usually return to the clinic weekly until the heart failure team determines that less frequent visits are prudent. As a patient’s condition improves and there are no medical concerns, outpatient visits can be decreased further.
- Follow-up by telephone calls may be useful in maintaining a constant communication with patients, especially those who do not live near the implant center.
- Anti-coagulation therapy must be carefully monitored to avoid large variations in the INR.
- Outpatients should be assessed whenever significant changes in pump flow, PI, or power are observed and after any alarm condition. Teaching patients to record this information every day on a chart may assist them in knowing what their “normals” are.
- Changes in exercise tolerance, weight, appearance of the percutaneous lead exit site, or other symptoms should be considered as potentially serious adverse events, and a thorough evaluation should be promptly performed.
- Outpatients must have access to the heart failure team at all times. The patient should have contact information for emergencies or for questions and technical support.
- Serial echocardiograms with a ramped speed study during routine clinic visits may be useful to reassess the pump speed setting and to evaluate the potential of myocardial recovery.

VIII. Troubleshooting

As has been described, each LVAS provides a number of parameters that can be used to monitor patient and pump conditions specific to each device. The authors’ experience in the clinical trial with the HeartMate II LVAS has been used to write this chapter specifically for patients with that device. These parameters and their significance in troubleshooting are listed in [Table 14](#).

Pump operating parameters are not surrogates for monitoring the patient’s clinical status. The changes in all parameters should be considered when assessing a situation. Owing to variability between patients, trends observed in the system parameters are usually more valuable than the absolute values presented. Abrupt changes in the parameters not associated with normal physiologic changes can be used to identify conditions that warrant further evaluation.

The use of these parameters in troubleshooting several selected complications is presented subsequently and in [Table 15](#). Typical methods for assessing situations are given, along with the corresponding device behavior. It is important to monitor pump readings and interpret changes as they may relate to patient complications.

VIII.A. Pump thrombus

Clinically relevant pump thrombus was rare during the HeartMate II clinical trial, occurring in 5 of 133 DT patients (4%)¹ and in 4 of 281 BTT patients (1.4%), 2 of whom required pump replacement and 2 died.⁸ The source of the

Table 14 Significance of Displayed HeartMate II Pump Parameters

Parameter	How parameter is generated	Significance of changes
Pump rotor speed	Direct measurement through motor	<ul style="list-style-type: none"> ● System operates at a fixed speed that matches displayed setting of about 100 rpm under normal conditions. ● Large speed changes in fixed speed mode indicate an abnormal condition: <ul style="list-style-type: none"> ● Suction event will precipitate decrease in speed to lower speed limit (default: 9,000 rpm). ● At the end of a suction event, speed gradually increases to the fixed speed setting. ● Failure of the system to maintain the fixed speed setting without a suction event indicates other pump or controller issues.
Power	Direct measure of current and voltage applied to motor	<ul style="list-style-type: none"> ● Varies directly with pump speed and flow under normal conditions: <ul style="list-style-type: none"> ● Increased flow results in increased power. ● An increase or decrease in pump speed will result in an increase or decrease in pump power, respectively. ● Changes in physiologic demand can affect power. ● Flow obstruction without contact with the LVAD rotor results in reduced power. ● Flow obstruction in the form of a thrombus with contact with the rotor can result in increased power. ● Abrupt changes in power should be evaluated for potential ingested thrombus into the pump: <ul style="list-style-type: none"> ● Note that abrupt power changes up to 2 W have been reported in the clinical trial with no adverse events. ● Contact Thoratec technical support. ● Gradual power increase (over hours or days) may signal deposition or thrombus on the bearings or rotor (see Sections V.A.1 and VIII.A.).
Pulsatility index	Calculated from pump power normalized by mean power	<ul style="list-style-type: none"> ● PI corresponds to magnitude of flow pulse through the pump: <ul style="list-style-type: none"> ● PI fluctuates with changes in volume status and the natural heart's contractility. ● Under normal conditions, PI increases with increased pressure developed by the natural heart, which can result from increased LV pre-load or contractility. ● PI decreases: <ul style="list-style-type: none"> ● Decrease in volume status. ● Inflow/outflow obstruction, which reduces relative magnitude of the flow pulse and consequently the power pulse. ● Abnormal power elevation (eg, from deposition or thrombus on the rotor or bearings).
Flow	Estimation based on pump speed and power	<ul style="list-style-type: none"> ● Under normal conditions, reflects actual pump flow changes due to patient conditions or device operation. ● Estimation assumes normal pump operation. ● Imprecise at flow rates less than about 3 liters/min. ● Flow estimation should be used for trending changes in conditions rather than as an absolute measurement of flow.⁷⁷ ● Increases with decreased pressure differential across the pump and with increased pump speed. ● Abnormal power elevation (eg, from deposition or thrombus on rotor or bearings) can result in overestimation of flow: <ul style="list-style-type: none"> ● May introduce a false-negative when using flow estimate to rule out low-flow conditions. ● Even in abnormal situations, flow estimate is unlikely to under-predict actual flow.

LV, left ventricle; LVAD, left ventricular assist device; PI, pulsatility index; RV, right ventricle.

thrombus may have grown from smaller deposits within the pump or could have been ingested from the left atrium or left ventricle.

Thrombus within the pump can affect all 4 parameters of the HeartMate II LVAS: speed, power, flow, and PI. A

sufficiently large thrombus can obstruct the flow through the pump. A large thrombus in contact with the rotor or bearings can increase the drag on the rotor and increase the power requirement. Such increases in power have been gradual, taking hours or days as opposed to abrupt changes,

Table 15 Potential Device Complications

Problem	LVAS response	Assessment	Management
Inflow obstruction without contact with LVAD rotor	<ul style="list-style-type: none"> ● Decreased pump power ● Decreased PI ● Decreased flow ● Suction events 	<ul style="list-style-type: none"> ● HF symptoms ● Hemolysis ● Inflow position ● Chest X-ray, echocardiography ● Angiography ● CT angiography ● Evaluate right heart function ● Tamponade ● Ramped speed study for LV size change with speed change ● Diastolic arterial blood pressure change with speed change 	<ul style="list-style-type: none"> ● Ensure patient is hydrated. ● Consider reducing pump speed in presence of inlet obstruction against myocardium or septum. ● Provide supportive therapy to optimize right heart function. ● Consider re-exploring chest to relieve tamponade or adjust pump position and anchor pump.
Outflow obstruction without contact with LVAD rotor	<ul style="list-style-type: none"> ● Decreased pump power ● Decreased PI ● Decreased flow ● Suction events 	<ul style="list-style-type: none"> ● HF symptoms ● Hemolysis ● Outflow position ● Echocardiography, chest X-ray, and angiography to determine flow through the outflow graft; assess for graft kink ● Ramped speed study ● LV size change with speed change ● Diastolic arterial blood pressure change with speed change 	<ul style="list-style-type: none"> ● Consider re-exploring chest.
LV suck down or suction event	<ul style="list-style-type: none"> ● Pump speed automatically decreases below set speed to low speed limit and ramps back up to set speed ● Decreased pump flow 	<ul style="list-style-type: none"> ● Echocardiography and chest X-ray (inflow position, LV size) ● Evaluate RV function ● Arrhythmias 	<ul style="list-style-type: none"> ● Ensure patient is hydrated. ● Decrease pump speed.
Percutaneous lead or motor failure	<ul style="list-style-type: none"> ● Pump runs rough/vibrates ● not maintaining set pump speed; damaged controllers ● PI >10 	<ul style="list-style-type: none"> ● HF symptoms ● Arterial blood pressure decreases with increased pulse pressure 	<ul style="list-style-type: none"> ● Contact Thoratec to determine if lead repair is feasible; if not, replace pump. ● If controllers are damaged, operate the LVAS on batteries rather than PBU/PM power.
Thrombus in pump in contact with rotor	<ul style="list-style-type: none"> ● High power and estimated flow, or flow blanking ● Decreased PI ● Sound of pump (w/stethoscope) changes 	<ul style="list-style-type: none"> ● HF symptoms ● Hemolysis ● Arterial blood pressure decreases with increased pulse pressure ● Angiography and echocardiography to confirm lack of pump inflow 	<ul style="list-style-type: none"> ● Consider pump replacement. ● Consider thrombolytic therapy with caution. Continuous IV heparin may prevent progression of thrombus.

HF, heart failure; IV, intravenous; LV, left ventricle; LVAD, left ventricular assist device; LVAS, left ventricular assist system; PI, pulsatility index; PBU, power base unit; PM, power module; RV, right ventricle.

which may indicate an ingested thrombus. With the increased power, PI is reduced because the pulsatile component of power becomes relatively small compared with the steady component of power required to overcome the drag.

If the flow obstruction is substantial, the pressure difference across the pump will be increased by the obstruction, so the relative influence of the pressure pulse and consequently the PI is diminished. In such situations, the pump flow is also limited. The normal unloading of the LV with increasing pump speed, therefore, is not observed. Thus, the combination of decreased PI and increased arterial pulse pressure from the increased preload can be an indication of a pump blockage.

Thrombus should also be suspected with the presence of hemolysis, for example, if the lactate dehydrogenase level increases to $>1,500$ or 3 times the previous level, or if there is any hemoglobinuria or significantly elevated plasma free hemoglobin.

In an extreme case, although rare, the drag on the rotor can become high enough that the motor can no longer maintain the pump speed and the speed will fall below the fixed speed setting. In cases where thrombus increases pump power, the flow display may be replaced with “+++” if it is outside the expected operating range. However, it also may be overestimated and displayed flow could appear in the normal range even though the pump flow is very low.

VIII.B. Pump stops

Because not all pump stops may be associated with a hardware malfunction, it is important to understand why stoppage occurs. A pump stop condition can be created if the pump stop command is entered on the system monitor. Loss of power to the pump (eg, disconnecting both power leads simultaneously) will cause the pump to stop and so will disconnecting the percutaneous lead from the controller. Two of the 281 patients in the HeartMate II BTT trial and 5 of 133 (4%) in the initial DT study died after loss of external power due to incorrect replacement of batteries.^{1,8} It is imperative that only 1 battery be replaced at a time, as explained in the instructions for use.

Unlike a positive-displacement LVAD that contains valves, if a continuous-flow LVAD stops, there will be regurgitant flow from the aorta to the LV. Under normal physiologic pressures, this regurgitant flow will be approximately 1 to 2 liters/min for the HeartMate II. Just as the pump in the stopped condition will limit the backflow, the pump provides substantial resistance to forward flow. As a result, if the pump is stopped and the LV outflow tract is occluded, the ability of the device to support the patient will be very limited.

If the pump stops, an audible alarm will sound. If the stop is a result of complete loss of power, there will be a continuous audible alarm and no indicator lights will illuminate on the system controller. If the controller is still receiving power, a pump stop will be accompanied by an audible

alarm and a “red heart” alarm will illuminate on the controller. The pump stop condition will also be indicated on the system monitor or display module screen if they are connected to the power base unit or power module; however, the pump speed and flow will not be displayed and the power will be zero.

If the pump is stopped and all connections to the controller are intact, pressing the *Test Select* button or *Alarm Reset* switch will restart the pump. At a fixed speed setting of 8,000 rpm or higher, if the power to the pump is interrupted and the pump stops, when power is restored the system controller will automatically restart the pump at the previously set speed. However, if the fixed speed setting is slower than 8,000 rpm, the user must press and hold the *Silence Alarm* or *Test Select* button for 2 seconds to restart the pump. Pressing the *Test Select* and *Alarm Reset* buttons simultaneously will start the controller in the backup mode.

When the system monitor is connected to the HeartMate II LVAS, pump operation can be verified by the display of pump speed and power information on the system monitor screen. If the monitor is not connected, it is possible to confirm pump operation through the system controller. When the pump is running properly, the green power symbol on the controller will be illuminated and there will be no visual or audible alarms. If the pump is not running, the red heart symbol will be illuminated and a continuous audible alarm will sound. If all power to the controller has been disconnected, no lights will be illuminated and a continuous audible alarm will sound. An alternative approach for confirming that the pump is running is to listen for pump sounds with a stethoscope over the pump location.

VIII.C. Suction events

The system parameters can also be used to troubleshoot suction events. Suction events occur when the pump speed is set higher than appropriate in relation to the available volume in the LV. Such events are typically precipitated by the patient becoming hypovolemic, but can also be caused by anything that reduces the return of blood to the LV, such as RV failure, cardiac tamponade, or pulmonary hypertension. Poor cannula positioning can also increase the propensity for a suction event because the LV wall or septum may obstruct the inflow cannula.

When the system detects a suction event, the pump speed is automatically reduced below the fixed speed setting to the low speed limit setting in the controller (user adjustable, between 8,000 and 10,000 rpm and is usually set 400 to 800 rpm below the fixed speed setting). When suction is no longer present, the speed gradually increases (at a rate of 100 rpm per second) back to the original speed setting. This drop in speed is also associated with a reduction in pump flow and is reflected in the displayed flow estimate.

VIII.D. Obstruction

Flow path obstruction can occur if the inflow or outflow cannula is blocked or kinked. A kink in the grafts or a

blockage of the inflow cannula results in a higher pressure difference across the pump and, consequently, lower pump flow. Because such flow restrictions do not influence the action of the pump rotor, the flow estimator will reflect the reduction in flow. If the HeartMate II estimated flow is below about 3 liters/min the flow display will be “— — —.”

With decrease in flow, there is also a decrease in pump power. A flow obstruction will limit pump flow, so the normal unloading of the LV associated with increasing pump speed will be diminished or absent.

The location of a flow obstruction cannot be determined from the pump parameters because the pump only responds to the differential pressure across the pump, and changes upstream or downstream of the pump have identical effects. CT, angiography, or echocardiography may be useful in assessing the location of a flow obstruction.

IX. Results from completed clinical trials

The first continuous-flow LVAD to complete FDA clinical trials for BTT and for DT is the HeartMate II. Other devices are in ongoing trials and results will be published after those trials are completed. The BTT clinical trial for the HeartMate II resulted in FDA market approval in April 2008. Of the 489 patients in the BTT trial, the results in the initial 133 patients were published,⁷ and an 18 month follow-up analysis has been completed in 281 patients.⁸ The Kaplan-Meier survival at 12 months was 68% in the initial cohort⁷ and 73% after inclusion of additional patients.⁸ The DT trial, with a randomized comparison between the HeartMate II and the HeartMate XVE, was also completed, and details on the first cohort of patients who received a LVAD from March 2005 to May 2007 were published in the *New England Journal of Medicine*.¹ The HeartMate II had a highly significantly increased percentage of patients compared with the XVE who reached the primary end point of survival at 2 years free of disabling stroke and reoperation for pump replacement. The actuarial survival of 68% and 58% at 1 and 2 years was significantly improved compared with the 55% and 24% for the HeartMate XVE. Results of additional cohorts of DT patients who received LVADs later in the trial will be published as they reach 2-year end-points. Since FDA approval for BTT, HeartMate II patients have been tracked by INTERMACS and initial results in over 500 patients show a six month survival of 88%.²⁰

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Appendix. Supplementary data

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