

How New Support Devices Change Critical Care Delivery

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ABSTRACT: Mechanical support devices are used to support failing cardiac, respiratory, or both systems. Since Gibbon developed the cardiopulmonary bypass in 1953, collaborative efforts by medical centers, bioengineers, industry, and the National Institutes of Health have led to development of mechanical devices to support heart, lung, or both. These devices are used as a temporary or long-term measures for acute collapse of circulatory system and/or respiratory failure. Patients are managed on these support devices as a bridge to recovery, bridge to long term devices, or bridge to transplant. The progress in development of these devices has improved mortality and quality of life in select groups of patients. Care of these patients requires a multidisciplinary team approach, which includes cardiac surgeons, critical care physicians, cardiologists, pulmonologists, nursing staff, and perfusionists. Using a team approach improves outcomes in these patients.

INTRODUCTION

Mechanical circulatory support devices (MCS) are designed to support the left and/or right ventricles during heart failure, cardiogenic shock, or acute respiratory failure. In 1964, the National Heart Advisory Council established the Artificial Heart Program to develop devices that support severe heart failure.¹ The initial plan included development of emergency devices, temporary and short-term circulatory assist devices, and long-term ventricular assist devices. Short-term devices generally include extracorporeal pumps located outside the body, whereas long-term devices are implantable intracorporeal systems.

Cardiac disorders leading to acute circulatory shock include acute coronary syndrome, myocarditis, sustained arrhythmias, and end-stage cardiomyopathies from multiple etiologies. Circulatory shock is characterized by acute systemic hypoperfusion that results in tissue hypoxia and vital organ dysfunction. Under these circumstances, use of MCS appears to be a promising concept to improve hemodynamics while avoiding the cardiotoxicity of chemical support.² Similarly, acute respiratory failure in pneumonia, acute respiratory distress, and end-stage lung disease secondary to multiple etiologies can all be supported by extracorporeal membrane oxygenation as a bridge to recovery or bridge to transplant. The following is a review of established and novel mechanical support devices, suggestions for optimal use, and their role in the delivery of critical care.

SHORT-TERM MECHANICAL DEVICES

Cardiac and circulatory failure with organ hypoperfusion leads to a very high morbidity and mortality rate. Short-term MCS devices have been used successfully in patients with refractory

cardiogenic shock³ and during high-risk interventions such as revascularization or ablation.^{3,4} Short-term devices are used as bridge to recovery, bridge to long-term assist devices, and bridge to transplant.

Intra-Aortic Balloon Pump

The single most widely used circulatory assist device is the intra-aortic balloon pump (IABP) counterpulsation. A flexible catheter is inserted into the proximal descending aorta with a closed balloon that is inflated during diastole and deflated during systole. The device's counterpulsation effect increases total coronary blood flow.⁵⁻⁸

Indications. IABP is indicated in unstable patients with acute myocardial ischemia and can be used as a bridge therapy until the patient is able to undergo percutaneous coronary intervention or coronary artery bypass surgery. It may also be used as a bridge to surgery in cases of acute ventricular septal defect, acute mitral regurgitation, and critical aortic stenosis. Similarly, IABP is used as a bridge therapy for refractory heart failure until the patient can receive a long-term solution such as an implantable left ventricular assist device or a heart transplant.

The primary contraindication to IABP insertion is significant aortic insufficiency because the counterpulsation will increase the risk of aortic regurgitation, uncontrolled sepsis, uncontrolled bleeding, aortic dissection, and significant aortic aneurysm. IABP can be continued as long as the benefit outweighs the risk until definitive therapy can be performed. If prolonged support is anticipated, insertion via the axillary artery can be considered to facilitate ambulation and physical therapy.

Complications. The major risks associated with IABP insertion are vascular complications such as limb ischemia, lacerations,

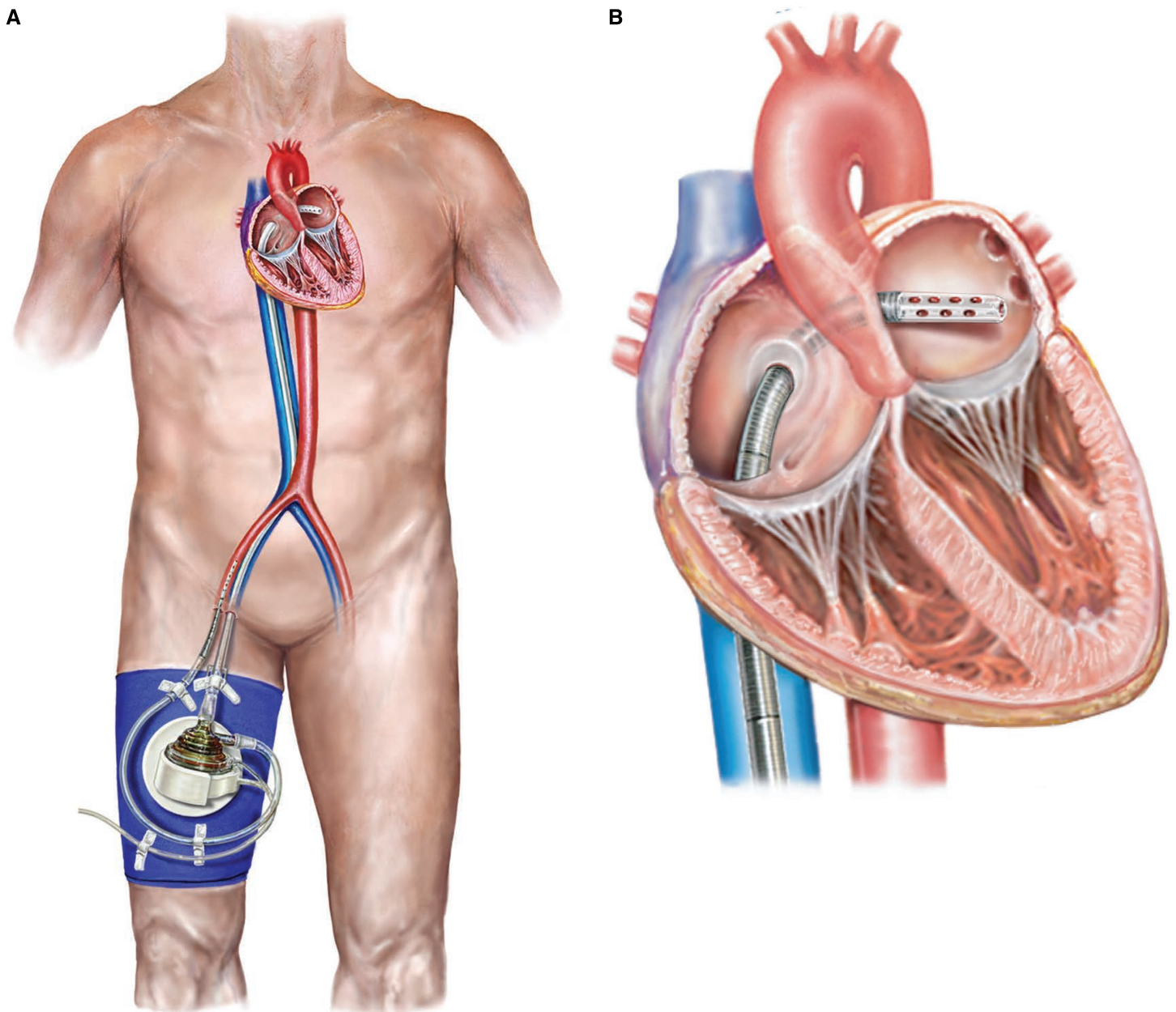


Figure 1.

TandemHeart (CardiacAssist, Inc.) percutaneous placed short-term left ventricular assist device. Reprinted with permission.

and hemorrhage.^{9,10} Other complications include arterio-arterial embolization, cerebrovascular accidents, sepsis, balloon rupture, and thrombocytopenia. Three randomized controlled trials have looked into the various roles of IABP use in high-risk PCI (BCIS-1),¹¹ acute myocardial infarction (CRISP-AMI),¹² and cardiogenic shock (IABP-SHOCK II).¹³ In a review article of these trials, along with others including use of TandemHeart in high-risk PCI, den Uil et al. concluded that Impella might be

superior to IABP in high-risk PCI, and routine use of IABP in acute myocardial infarction (MI) is not useful.¹⁴

TandemHeart

The TandemHeart (Cardiac Assist, Inc.) is a percutaneous ventricular assist device that requires placement of a venous catheter into the left atrium via a trans-septal puncture (Figure 1).

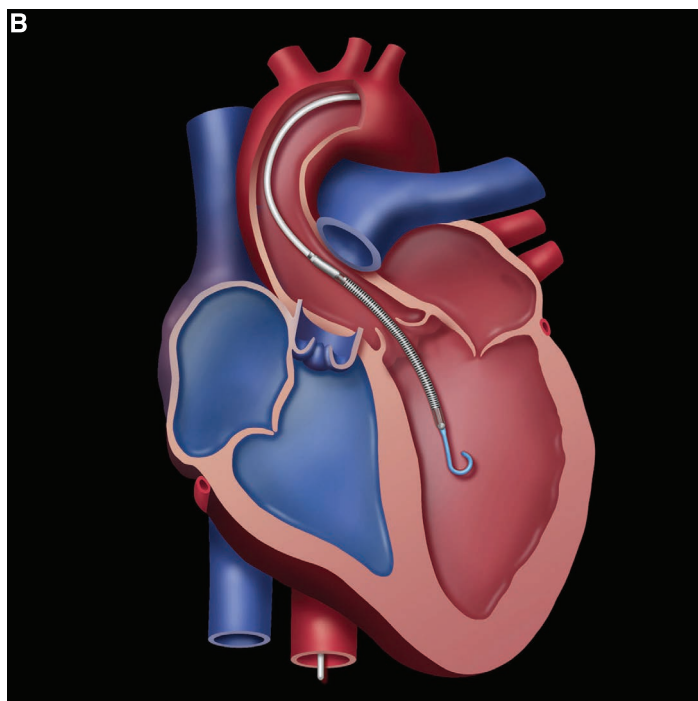
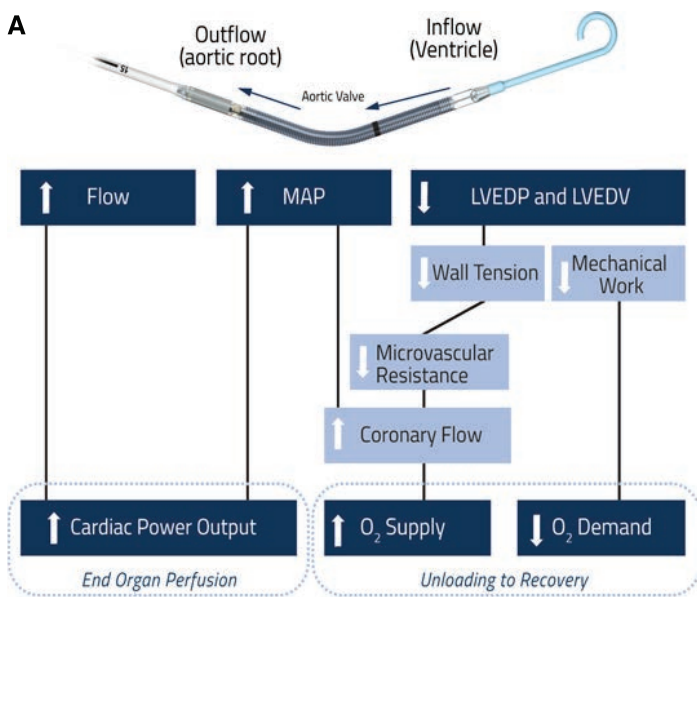


Figure 2.

(A) Effect of Impella® on cardiac output. (B) Position of Impella® inside the left ventricle. © 2018 Abiomed, Inc.

Cardiac output is augmented with a centrifugal pump, and blood returns to the body via a 21F trans-septal arterial cannula (64 cm or 72 cm length) inserted into the iliofemoral artery system. Adequate right ventricle function is required for optimal device performance. The TandemHeart is approved for 6 hours of support by the U.S. Food and Drug Administration (FDA) and for up to 30 days by the European Commission.

Indications. The TandemHeart is used in patients with severe decompensated heart failure, complications of MI including acute mechanical defects such as acute mitral regurgitation and ventricular septal rupture, and recurrent ventricular arrhythmias. Contraindications to TandemHeart placement are similar to those of IABP placement, such as significant aortic insufficiency, aortic aneurysm or dissection, uncontrolled bleeding, and uncontrolled sepsis.

Complications. Problems are often related to implant duration and include infection of the blood stream, local infections, bleeding, thromboembolic events, thrombocytopenia, hemolysis, and local vascular or neurologic injury from the large cannula sizes.

Impella System

The Impella devices (Figure 2 A, B) are nonpulsatile axial flow pumps inserted into the left ventricle (LV) from the aorta. They

work by unloading the LV and delivering blood to the ascending aorta, thereby increasing cardiac output and improving mean arterial pressure while reducing LV end-diastolic pressure, myocardial workload, and oxygen consumption. Augmentation of cardiac output is better seen with the Impella 5.0 than with the Impella 2.5 system.¹⁵ Impella 5.0 using right subclavian artery requires surgical cutdown and 8-mm vascular graft, or femoral arterial cutdown approach. The Impella CP provides intermediate cardiac support of 3.0 to 4.0 L/min. Positioning can readily be confirmed and readjusted by using bedside transthoracic echocardiography.

Indications. The Impella devices are used in patients with severe heart failure and/or cardiogenic shock and during high-risk percutaneous coronary interventions (PCI); they have also been used in severe coronary artery disease presenting with cardiac arrest.^{16,17} The PROTECT I trial demonstrated the safety of Impella 2.5 in high-risk PCI patients.¹⁸ In addition, the Impella can be used as a bridge to long-term assist devices by allowing the right ventricle to rest and recover its ability to pump blood.¹⁹ The Impella RP, for example, can provide circulatory assistance for up to 14 days in patients who develop acute right heart failure or decompensation following implantation of a left ventricular assist device (LVAD), myocardial infarction, heart transplant, or open-heart surgery. Contraindications to device placement include significant peripheral vascular disease,

moderate (< 1.5 cm²) aortic stenosis or insufficiency, ventricular septal defect, and LV thrombus.

Complications. Complications related to the Impella systems include bleeding secondary to heparinization, hemolysis, limb ischemia, aortic valve insufficiency, and malfunction due to device thrombosis and sometimes secondary to tip dislocation.

Extracorporeal Membrane Oxygenator

Indications. Extracorporeal membrane oxygenation (ECMO) can be used as bridge to recovery, bridge to long-term devices, or bridge to transplant in cases of circulatory collapse or severe respiratory failure. There are two types of ECMO systems: venoarterial or venovenous. In acute respiratory failure, two venous cannulas (V-V) can be inserted percutaneously at bedside, bypassing pulmonary circulation and acting as a bridge until recovery is achieved. Similarly, in hemodynamic collapse, arterial and venous cannulas are inserted on each side of the circulation until the patient recovers or receives further treatment. Dual lumen catheters, such as the Avalon Elite and Protek duo, are increasingly being used.²⁰ The Protek Duo inserted via the internal jugular vein with tips in the right atrium (inflow) and pulmonary artery (outflow) has shown added benefit for patients with right heart failure; it essentially functions as a right ventricular assist device.²¹

Complications. Problems related to ECMO include bleeding from the insertion site, pulmonary and cerebral hemorrhage, hemolysis, infection, and heparin-induced thrombocytopenia from concomitant use of heparin. Limb ischemia and cardiac thrombosis have also been reported.²²

Temporary Extracorporeal Flow Devices

Temporary extracorporeal flow devices include pulsatile flow devices, such as the ABIOMED AB5000, and continuous flow devices, such as the CentriMag (St. Jude Medical, Inc., formerly Thoratec).

Indications. Both types of devices can be used in acute cardiogenic shock, refractory myocarditis, or acute decompensation of heart failure. They may provide time for recovery of cardiac function or act as a bridge to decision making or to long-term device placement.

LONG-TERM MECHANICAL SUPPORT

According to the American Heart Association, there are 5.8 million people in the United States diagnosed with heart failure, and roughly 10% of them are considered to have advanced disease—classified as American College of Cardiology stage

D heart failure and New York Heart Association stages III and IV. Annualized mortality is > 50% in these patients, and there are limited therapeutic options.²³ Since heart transplantation is reserved for the most select patients, the only available alternative is implantable mechanical circulatory support.

The FDA has approved three indications for MCS that are reimbursed by the Centers for Medicare and Medicaid Services. The REMATCH trial demonstrated survival advantage of the LVAD over optimal medical management for three indications²⁴: bridge to recovery, bridge to transplantation, and destination therapy. These devices are implanted for long-term management, but initial pre- and postoperative care is provided in an intensive-care setting.

HeartMate II

HeartMate II (St. Jude Medical, Inc., formerly Thoratec) is the most-studied circulatory device. It is an axial flow pump with a flow rate between 4 and 6 L/min.

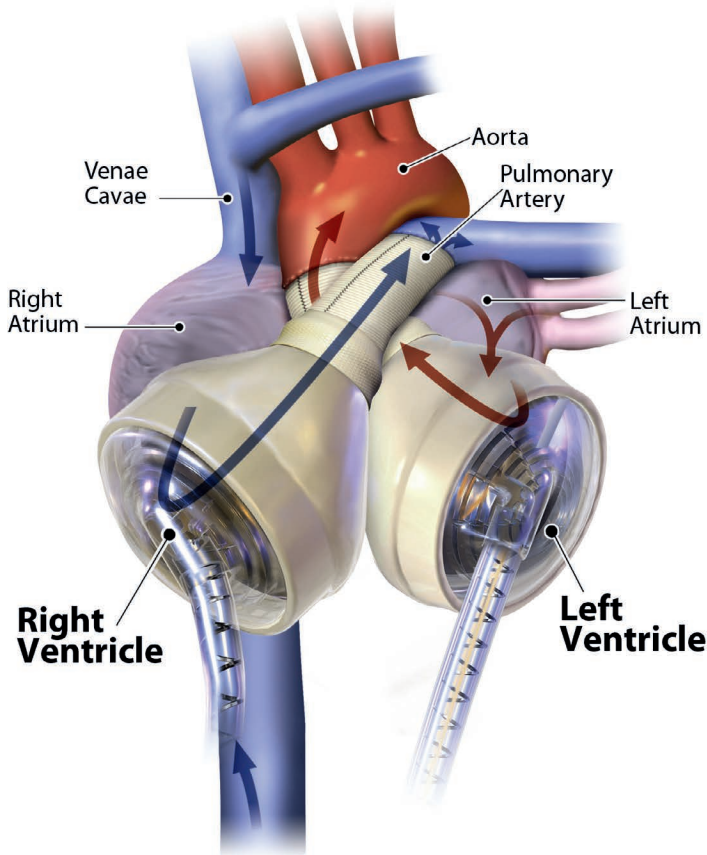
Complications. Immediate postoperative complications of LVAD placement include bleeding (often requiring blood product use),²⁵⁻²⁷ thromboembolic events leading to stroke, and other neurological events. These potential complications occur at a lower rate immediately after surgery but increase between 6 months to 1 year postoperatively.²⁸ The risk of developing bloodstream infection and sepsis is high in the perioperative period,²⁹ whereas driveline infection is a late complication. Patients may present with septic embolization to distant sites or a new incompetence of pump inflow or outflow valves. Right ventricular failure is quite common and can occur in 11% of patients after LVAD implantation.³⁰ Multisystem organ failure is sometimes seen as a result of acute right ventricular failure.

HeartMate III

A newer version of LVAD, the HeartMate III system is under trial. This will be further discussed in the investigational devices section.

HeartWare Ventricular Assist Device

The HeartWare HVAD System (HeartWare) is a centrifugal flow pump that is smaller in size and placed in the pericardium. This device was studied as a bridge to transplantation in a noninferiority trial and ultimately approved by the FDA for this indication.³⁰ Although most complications are similar in all continuous flow devices, one study found that bleeding and blood product requirements were less common with the HeartWare device.²⁶



Total Artificial Heart

Figure 3.

The SynCardia Total Artificial Heart is used in end-stage biventricular heart failure and is approved by the FDA as a bridge to heart transplantation. Courtesy of syncardia.com

Total Artificial Heart

The SynCardia temporary Total Artificial Heart (SynCardia Systems, LLC) is used in end-stage biventricular heart failure and is approved by the FDA as a bridge to heart transplantation.³¹ With the SynCardia Total Artificial Heart, the patient's ventricles and valves are explanted and replaced by a pulsatile, pneumatically powered device (Figure 3). Once homeostasis is achieved postoperatively, anticoagulation is started to prevent thromboembolism. Complications reported by Cook et al. included bleeding in about 24.7% of patients, especially mediastinal bleeding that required re-exploration, as well as a 7.9% incidence of stroke due to thromboembolism.³¹ In another study by Heatley et al.,

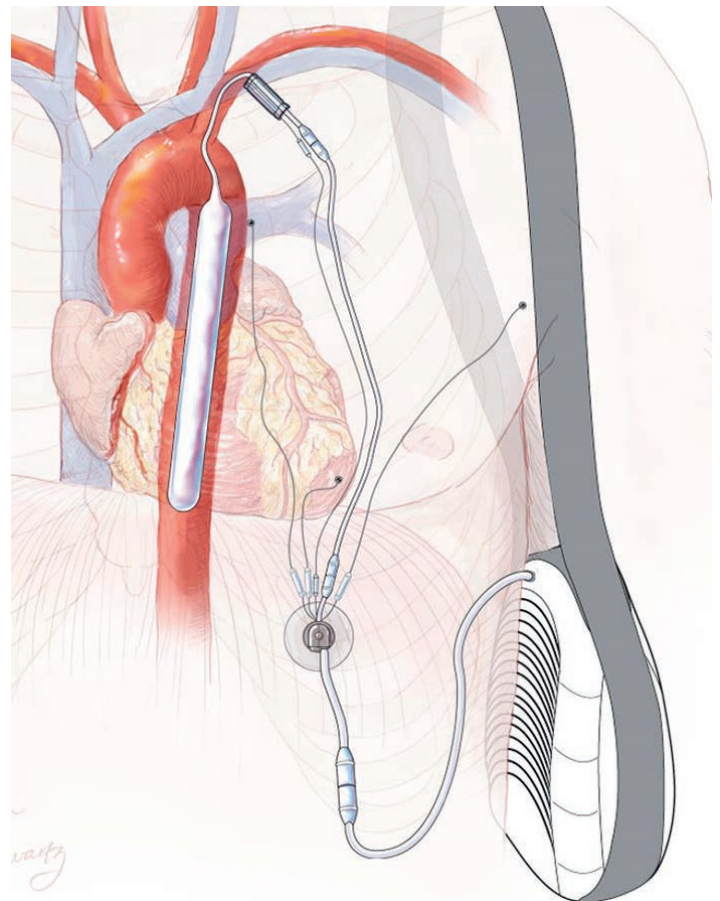


Figure 4.

The NuPulse cardiovascular intravascular assist system provides long-term hemodynamic support in advanced heart failure and is intended for use as a bridge to transplant or bridge to recovery. Reprinted with permission.

postoperative renal failure requiring dialysis was seen in about 12% of patients.^{32,33}

INVESTIGATIONAL DEVICES

The following investigational devices have been used at the Methodist DeBakey Heart & Vascular Center.

NuPulse CV iVAS

The NuPulse CV iVAS (cardiovascular intravascular assist system) (NuPulseCV, Inc.) provides long-term hemodynamic support in advanced heart failure (Figure 4) and is intended for use as a bridge to transplantation and bridge to recovery. The

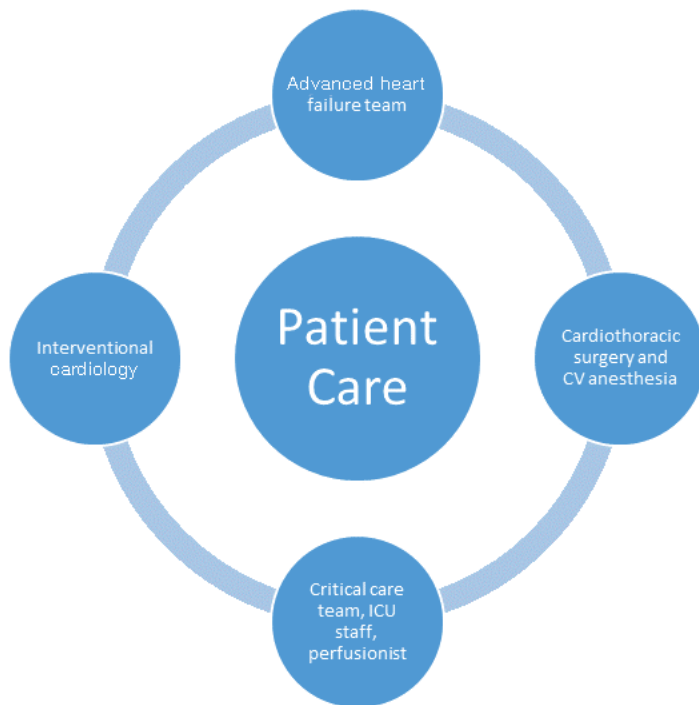


Figure 5.

Mechanical circulatory devices are best implanted by hospitals with multidisciplinary teams and specialized units experienced in caring for this exceedingly complex and critical patient population.

system is placed through the left subclavian vein and connected to an external battery. Patients can be discharged home with this device.

HeartMate 3 LVAD

The HeartMate 3 left ventricular assist system (St. Jude Medical, Inc., formerly Thoratec) is a centrifugal, magnetically levitated, continuous-flow pump that possesses intrinsic pulsatility and is intended to reduce sheer stress on blood cells. Its safety and efficacy is being evaluated in the MOMENTUM 3 trial, a noninferiority trial comparing it to the HeartMate II.³⁴

ROLE OF SPECIALIZED UNITS AND INTENSIVE CARE TEAM

The field of mechanical circulatory support is expanding along with the indications of these support strategies. However, these mechanical circulatory devices can be challenging to manage and are associated with complications. As a result, these devices are best implanted by hospitals with multidisciplinary teams and specialized units experienced in caring for this exceedingly complex and critical patient population.³⁵

Patients admitted to an intensive care unit who do not improve with conventional management of acute respiratory or circulatory failure may require emergent temporary MCS. The guidelines for contemporary management of cardiogenic shock are given by an American Heart Association scientific statement.³⁶ The option of bridging the patient to long-term devices or organ transplantation is a complex multidisciplinary decision that requires guidelines, algorithms, and/or protocols to minimize the risks and complications associated with these devices and to improve the risk-benefit ratio (Figure 5).³⁷ It is essential to not only keep a team of surgeons, cardiologists, critical care physicians, ICU staff, perfusionists, and respiratory therapists at the ready but also to ensure that their skills and knowledge base are maintained to provide optimal medical, psychological, and technical support.

ROLE OF PALLIATIVE CARE AND BIOETHICS

Patients on temporary MCS or respiratory devices are often compromised regarding their ability to participate in decision making. As a result, surrogate decision makers may be under extreme pressure to make complex decisions on the patient's behalf. In the case of long-term devices, very limited data is available regarding the psychosocial stress on patients and their families. Palliative care in these situations provides assistance with medical decision making and planning and provides psychological, emotional, and spiritual support to families.³⁸ In 2013, the U.S. Centers for Medicare and Medicaid Services issued a new regulation requiring all centers working with long-term MCS to include palliative care specialists on the team.³⁹

Advancing medical technology used to care for these highly complex patients with multiple organ dysfunction often leads to ethical dilemmas for both providers and families. Several ethical issues must be upheld, including the patient's right to decision making, beneficence of care provided, the physician's responsibility to do no harm, and fair use of resources.⁴⁰

The participation of a bioethics team in patient care and daily multidisciplinary rounds not only provides conflict resolution during end-of-life care but also facilitates communication with the family. In cases of mechanical circulatory support, a bioethics team can help with three stages of decision making: initiation, continued use, and deactivation (Figure 6).⁴¹

Conflict of Interest Disclosure:

The authors have completed and submitted the *Methodist DeBakey Cardiovascular Journal* Conflict of Interest Statement and none were reported.

Keywords:

mechanical circulatory support devices, role of multidisciplinary team, critical care management

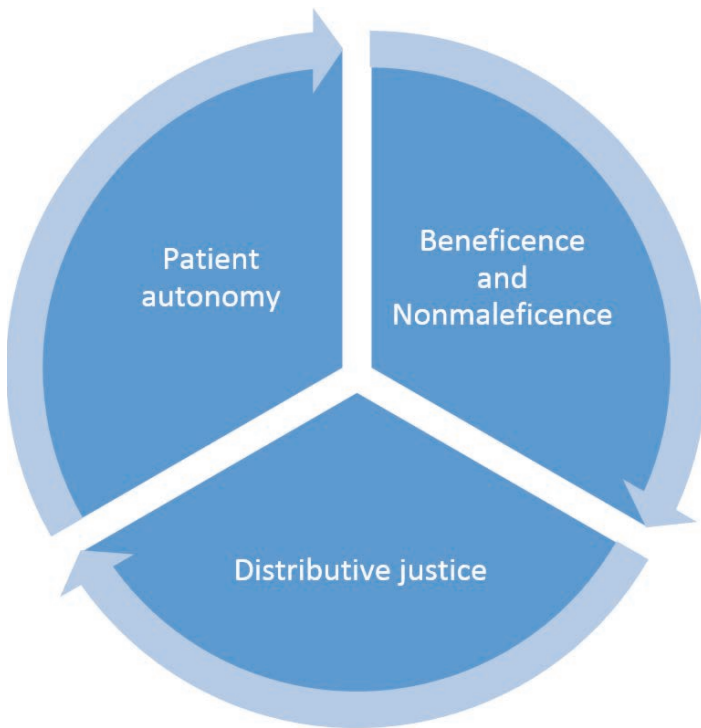


Figure 6.

Ethics teams must uphold and ensure the patient's right to decision making, beneficence of care provided, the physician's responsibility to do no harm, and fair use of resources.

KEY POINTS

- The field of mechanical circulatory support devices is expanding with promising new technology.
- Multidisciplinary teamwork is needed for decision making and management of these very critical patients.
- Skills and knowledge to manage immediate and late complications is needed for optimum care.
- The evolving roles of critical care physicians, allied health care, palliative care, and bioethics are a key feature for pre- and postop care as well as long-term management of complications.

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