



Extracorporeal mechanical circulatory assist

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Patient selection is the single most crucial factor in determining a successful outcome in patients who receive temporary mechanical circulatory support (MCS). The patient's history and overall clinical setting are considered in the decision process to initiate MCS [1]. Patients should not be considered for temporary MCS if they have significant contraindications to MCS or if they have significant contraindications to heart transplantation in situations where they are unlikely to wean from temporary MCS once it has been initiated. Absolute contraindications to MCS include the presence of irreversible renal, hepatic, or respiratory failure, as well as neurologic dysfunction with significant irreversible cognitive deficits.

Increasing degrees of chronic organ dysfunction also present relative but not absolute contraindications to initiating MCS. Chronic pulmonary disease associated with significantly impaired pulmonary reserve and systemic oxygenation can contribute to perioperative hypoxia and pulmonary vasoconstriction resulting in right-sided circulatory failure. Patients with severe chronic pulmonary disease may have a fixed (not responsive to pulmonary artery vasodilators) elevation of the pulmonary vascular resistance. A pulmonary vascular resistance > 4 Wood units that is not reversible represents a contraindication to heart transplantation, and thus temporary MCS in circumstances where weaning is unlikely.

Acute renal failure requiring dialysis is only a relative contraindication to initiating MCS. In

cardiogenic shock with acute renal failure, establishing normal hemodynamics with MCS may resolve the renal failure. Thus, the degree and duration of cardiogenic shock along with the patient's baseline renal function must be considered in estimating the probability of recovery of renal function. Underlying "nonreversible" causes of renal insufficiency or failure, including diabetic nephropathy or hypertensive renal disease, may significantly impact the degree of recovery. This is important in considering whether the patient will be a transplant candidate or not, in the event that native heart function does not recover while the patient is supported on MCS [2]. Similarly, improvement in hepatic congestion and recovery of synthetic functions of the liver can occur with institution of MCS. The presence of either portal hypertension or liver cirrhosis is an absolute contraindication to initiating MCS.

Age may represent an absolute contraindication to initiate temporary MCS if the patient is unlikely to wean and is too old to qualify for heart transplantation or has additional comorbidities that would preclude consideration for destination therapy. Data from the ASAIO-ISHLT Registry have demonstrated that patients > 70 years of age have a decreased survival on extracorporeal MCS. However, the probability of weaning from MCS is not affected by age [3,4].

Timing the initiation of temporary MCS is also crucial to patient outcome. In postcardiotomy shock, data from the Abiomed BVS 5000 Registry demonstrate that delay in initiating temporary MCS for > 6 hours after the initial weaning from cardiopulmonary bypass is associated with a significant decrease in survival: 44% versus 14% [4,5]. Early initiation of extracorporeal MCS, based on predictive models for device need using hemodynamic parameters and degree of intra-operative

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inotrope support, have demonstrated improved rates of weaning and survival to hospital discharge [6]. As the severity of illness and organ dysfunction increase as a result of delay in instituting MCS, the need for biventricular support, rather than univentricular support alone, increases [7,8]. Patients requiring biventricular support have a decreased survival [5,9]. An episode of cardiac arrest before the initiation of MCS significantly reduces survival: 47% versus 7% [4,5].

Selection of the appropriate MCS device is also critical to a successful outcome and is dependent on several factors: the cause of the circulatory failure, the duration of expected support, whether biventricular or univentricular support is required, whether combined cardiac and pulmonary failure is present, the size of the patient, the intended use for the device, and the current FDA restrictions and regulations for a particular device. Consideration of all these factors help define the end-point of therapy, which may include bridge to recovery, bridge to heart transplantation, or possibly bridge to destination.

Considerations in instituting temporary extracorporeal mechanical circulatory support

Valvular heart disease

Abnormalities of the cardiac valves have important adverse consequences in patients being considered for MCS and may require repair or replacement to initiate successful MCS or achieve weaning from support. Mild to moderate aortic stenosis in the absence of insufficiency is not a contraindication to placement of a ventricular assist device (VAD). However, severe aortic stenosis should be corrected before placement of a temporary VAD, preferably with a bioprosthetic valve, to facilitate future weaning or optimize native heart function in the event of device failure. The presence of even mild to moderate aortic insufficiency can have a significant impact on the effectiveness of VADs. In the cases where left ventricular assistance is initiated with left atrial to aortic cannulation, aortic insufficiency will result in left ventricular distention in the presence of significant left ventricular dysfunction. Left ventricular distention adversely affects subendocardial blood flow and can ultimately prevent weaning from MCS. In cases where left ventricular assistance is initiated with devices that require left ventricular apical to aortic cannulation, reductions in left ventricular pressure elicited by

mechanical assistance increase the pressure gradient across the aortic valve and increase the degree of aortic insufficiency. Thus, blood pumped into the aortic root by the device will flow backward across the incompetent aortic valve (aortic insufficiency), decreasing net forward flow and compromising end-organ perfusion. Even mild to moderate aortic insufficiency may become severe with initiation of MCS as a consequence of reducing left ventricular end-diastolic pressure by emptying of the left ventricular cavity by the device and elevation of the aortic root pressure due to an increase in device flow. The significance of the regurgitant volume of blood can be easily determined by measuring cardiac output with a thermodilution catheter and comparing it with device flow. In cases where device flow exceeds the cardiac output by > 1.5 to 2 L/min, the volume of regurgitation is considered significant. In addition, the presence of significant aortic insufficiency can be confirmed by echocardiography. Patients with a mechanical valve prosthesis in the aortic valve position should have the valve replaced with a bioprosthetic valve before institution of temporary left ventricular assistance. However, bioprosthetic valves in the aortic position are also prone to thrombosis as a result of complete unloading of the left ventricle with a VAD that obviates the need for prosthetic valve opening and closing during support. The management of aortic valve prosthesis for patients requiring long-term, bridge-to-heart transplant or destination support with implantable devices is controversial. Different strategies are necessary than for patients requiring only temporary support [10,11].

Patients with significant pre-existing mitral stenosis at the time of initiation of MCS may require correction of the valvular problem before initiation of MCS, depending on device selection and site of cannulation. In the setting of significant mitral stenosis, left ventricular filling is impaired. Device systems that use apical ventriculotomy for cannula placement for ventricular drainage may experience limitations in device filling due to the mitral stenosis. This problem can be circumvented by either choosing a device that can use left atrial drainage or by correcting the underlying valvular pathology (mitral valve repair or replacement with a bioprosthetic valve). In patients with prosthetic valves in the mitral position (either mechanical or bioprosthetic), left ventricular assist should be accomplished with left ventricular apical cannulation to ensure adequate blood flow across the mitral prosthesis to

prevent thromboembolism. Mitral regurgitation does not have an impact on the filling of a left VAD; however, elevations in pulmonary pressures may persist with severe regurgitation and remodeling of the left ventricle may be adversely effected [12]. In situations where weaning from MCS may be feasible, correction of the mitral pathology, either stenosis or regurgitation, is necessary to optimize ventricular function.

Adequate right heart function is extremely important to maintain LVAD flow in the early postoperative period in patients on univentricular support. Severe tricuspid regurgitation can significantly impair the forward flow of blood on the right side particularly in situations of high pulmonary vascular resistance. Further, severe tricuspid regurgitation contributes to elevated central venous pressure, hepatic congestion, and renal dysfunction. Severe tricuspid regurgitation may be present preoperatively in the setting of volume overload and biventricular failure or may develop after institution of LVAD support as a consequence of right ventricular dilation from leftward shift of the interventricular septum [13, 14]. If severe tricuspid regurgitation is present during the initiation of LVAD support, tricuspid valve repair should be performed to improve right-sided circulatory function.

Coronary artery disease

Patients that have significant obstructive coronary artery disease or patients with postcardiotomy shock after failed coronary bypass operations may continue to experience angina during MCS. The presence of obstructive coronary disease with ongoing ischemia may limit the degree of myocardial recovery, significantly impact the ability to wean from device support, or impact the ability to wean from cardiopulmonary bypass with left-sided support only in the presence of ischemia of the right ventricle. Perioperative ischemia of the right ventricle may be of hemodynamic significance during institution of MCS support. Right ventricular ischemia causing myocardial stunning or infarction that occurs during or soon after initiation of MCS can elicit right-sided circulatory failure, resulting in decreased flow to the LVAD. In patients who have had coronary bypass surgery and are candidates for MCS, patent bypass grafts, particularly to the right coronary artery or left anterior descending coronary artery, should be preserved to reduce the risk of perioperative right-sided circulatory failure

and arrhythmias. It may be necessary to perform a coronary artery bypass to the right coronary artery or left anterior descending coronary artery systems to optimize right heart function in the perioperative period if significant obstructive coronary lesions amenable to bypass are present in the distribution of these arteries.

Arrhythmias

Atrial and ventricular arrhythmias are common in patients with cardiogenic shock and underlying ischemic heart disease or idiopathic cardiomyopathies. These arrhythmias generally persist in the immediate postoperative period and subsequently resolve as the hemodynamic condition of the patient improves and inotrope therapy is weaned. In patients with ongoing ventricular arrhythmias, biventricular assistance is generally indicated to ensure adequate LVAD filling. When weaning from MCS is feasible or planned, elimination of the ventricular arrhythmias with antiarrhythmic therapy or electrophysiologic ablation is essential.

Atrial fibrillation and flutter may significantly alter right ventricular filling but is reasonably well tolerated in recipients of VADs. Early electrical or pharmacologic cardioversion is indicated to avoid thrombus formation and reduce risk of thromboembolic events. Anticoagulation is indicated in patients with persistent atrial or ventricular arrhythmias to prevent thrombus formation.

Intracardiac shunts

Potential intracardiac shunts such as a patent foramen ovale or atrial septal defect should be closed at the time of initiation of left ventricular assistance to prevent right to left shunting. These anomalies should be identified before surgery using transesophageal echocardiogram [15]. During the initiation of left ventricular assistance, left atrial pressure is reduced compared with right atrial pressure. This gradient causes shunting of deoxygenated blood from the right atrium into the left, resulting in significant systemic hypoxemia. In cases where a patent foramen ovale or atrial septal defect has been missed, treatment includes administering pulmonary vasodilators and inotrope agents to decrease the shunt by improving right heart function and lowering right atrial pressure. If significant hypoxia persists, reoperation or percutaneous interventions to close the anomaly is required.

Adverse events associated with mechanical circulatory support

The perioperative morbidity associated with seriously ill patients requiring temporary MCS is significant. Bleeding, right-sided circulatory failure, neurologic dysfunction, and progressive multisystem organ failure are the most frequent complications that occur in the early postoperative period after initiation of MCS.

Bleeding

Bleeding is a frequent, early complication in patients on MCS and generally requires reoperation in the early postoperative period. Risk factors for bleeding include preoperative hepatic congestion and failure, poor preoperative nutritional status, prolonged cardiopulmonary bypass times, extensive surgical dissection, reoperative surgery, multiple cannulation sites, decreased platelet function, and induction of fibrinolysis as a result of contact with biomaterial surfaces during cardiopulmonary bypass and MCS devices. The risk of major hemorrhage has decreased substantially with the use of the serine protease inhibitor, aprotinin, and supplemental administration of vitamin K before operation [16,17].

Right-sided circulatory failure

Right-sided circulatory failure occurs in ~10% to 20% of patients supported by left ventricular assistance. This incidence is significantly higher in patients presenting in multisystem organ failure. The cause of right-sided circulatory failure is multifactorial and includes primary pathologies within the pulmonary vascular bed or right ventricle. Frequently, the occurrence of right-sided circulatory failure is a consequence of both. Factors contributing to right-sided circulatory failure include impaired right ventricular function as a result of intraoperative air embolism, myocardial stunning as a result of poor intraoperative myocardial protection, ischemia and infarction from coronary artery disease, arrhythmias, volume loading, and alteration of right ventricular septal geometry induced by left ventricular unloading. Several studies have demonstrated that factors such as elevated central venous pressure, transpulmonary gradient greater than 16 mm Hg, acute decrease in pulmonary artery pressures \geq 10 mm Hg at the onset of LVAD support, low preoperative right ventricular stroke work index, degree of preoperative pulmonary edema, and increased need for perioperative transfusions, all increase

the need for right ventricular mechanical support after left ventricular assistance [8,18,19]. Acute unloading of the left ventricle by MCS may cause the septum to shift leftward, increasing right ventricular volume loading and reducing its function [13,20]. The negative consequences of this phenomenon may be offset by the reduction in pulmonary artery pressures and right ventricular afterload caused by device-mediated left ventricular decompression [13,20]. Limiting device flows in the early perioperative period may prevent septal shift and right ventricular overload, and thus prevent right-sided circulatory failure in some patients. More recently, the improved perioperative management of elevated pulmonary vascular resistance, including the use of inhaled nitric oxide, a specific, potent pulmonary vasodilator, in combination with milrinone, isoproterenol, or dobutamine, has significantly reduced the need for placement of a RVAD [21].

Thromboembolism and anticoagulation management

The occurrence of thromboembolic events after MCS is variable and depends on a number of factors including the type of device, duration of support, location and number of cannulation sites, and the presence of prosthetic valves within the heart. Overall, approximately 10% to 30% of patients receiving MCS will experience a thromboembolic event. Improvement in the rate of thromboembolic events has come from more aggressive antiplatelet therapy in conjunction with heparin and warfarin anticoagulation, improved device design, and more frequent use of left ventricular apical as compared with left atrial cannulation. In patients supported for short durations only, anticoagulation is usually achieved with heparin and antiplatelet therapy. Longer term support usually requires transition to warfarin and antiplatelet therapy for most temporary extracorporeal devices.

Infection

The incidence of early nosocomial infections (device related or not) in patients undergoing temporary MCS is ~30% to 40% in many series and is related to the acuity of illness in this population of patients [22,23]. Patients with persistent or recurrent sepsis and patients with device-related infections tend to have a higher mortality than patients without these complications.

Prolonged hospitalization, immobilization, endotracheal intubation, poor nutritional status, diabetes, obesity, indwelling catheters, intravascular lines, transcutaneous cannulas, and broad spectrum antibiotic therapy all contribute to the high incidence of nosocomial infections. Device-related infections can sometimes be successfully treated with antibiotic suppression and device exchange or removal.

Considerations in weaning patients from mechanical circulatory support

Several factors must be considered when weaning patients from MCS. First and foremost is the consideration of any pathologic abnormalities of the heart, such as valvular disease or severe coronary disease, that have not been addressed and corrected. If the underlying pathology that caused the patient to require MCS is not corrected, then the chances of weaning from MCS will be negligible. Cardiac tamponade must also be excluded. Bleeding is a major early complication of MCS, and reoperation for cardiac tamponade and bleeding is frequent. Transesophageal echocardiogram may not reliably identify cardiac tamponade in the early postoperative period. Thus, a high index of suspicion and low threshold for reoperation is critical to rule out tamponade. Volume status, preload and afterload, cardiac rhythm, and degree of inotropic support should be optimized for weaning. Noncardiac causes can contribute to failure to wean from MCS. Pulmonary edema, elevated pulmonary vascular resistance, acute respiratory distress syndrome, and pneumonia may hinder right ventricular function.

Once a patient's status has been optimized, weaning from MCS with the use of transesophageal echocardiogram is ideal. As device flows are reduced, transesophageal echocardiogram provides information on ventricular filling and performance and valve function. If patients can maintain satisfactory hemodynamics with reduction of pump flow, they can be considered for weaning. With biventricular support, it is important that device flows on the right side be reduced before turning down left-sided device flows to prevent pulmonary edema in the event of inadequate left-sided ventricular function. As device flows are reduced, native heart function will begin to support the circulation, and monitoring of the systemic arterial waveform will demonstrate native heart contractions in synchronization with the electrocardiogram.

If hemodynamics are unsatisfactory during the weaning trial, the patient will require continued support and subsequent weaning trials. In cases where weaning from temporary MCS is not possible, patients should be evaluated for heart transplantation or destination therapy and bridged to a mechanical device with long-term support capabilities when feasible and indicated.

Extracorporeal, nonpulsatile circulatory support devices

Extracorporeal membrane oxygenation

Extracorporeal membrane oxygenation (ECMO), also known as extracorporeal life support (ECLS), is a temporary form of MCS that uses a modified heart-lung machine to provide circulatory assistance as well as oxygenation and carbon dioxide removal from blood for days to weeks to permit recovery from severe cardiac or pulmonary failure (Fig. 1) [24,25]. The ECMO circuit is similar in concept to cardiopulmonary bypass routinely used in the operating room. However, certain modifications to the ECMO

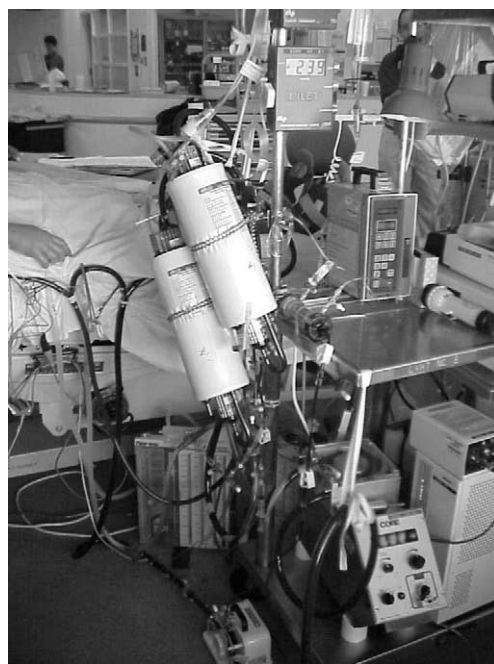


Fig. 1. Photograph of an ECMO circuit used at the University of Michigan. Note roller pump (*bottom center*) and membrane oxygenator (*center*). (Courtesy of Fresca Swaniker, MD, University of Michigan, Ann Arbor, MI.)

circuit, particularly the inclusion of membrane oxygenators, permit extended periods of support. The first successful use of prolonged ECMO was reported by Hill et al in 1972 [26]. Subsequently, ECMO has been used in an increasing number of indications including: neonatal, pediatric, and adult respiratory support; neonatal, pediatric, and adult postcardiotomy support; and as a bridge to an implantable LVAD (“bridge to bridge concept”) or heart and lung transplantation.

ECMO circuits are composed of a centrifugal pump with either a hollow fiber or a membrane oxygenator, oxygen blender, pump console, heat exchanger, and pump cart. A roller pump and membrane oxygenator are preferred by some centers [25]. Heparin-bonded circuits are also used. These circuits reduce, but do not eliminate, the need for systemic anticoagulation and may reduce the inflammatory response associated with ECMO. Cannulation for ECMO is extremely variable and depends on the clinical situation and whether a venoarterial or venovenous circuit is desired. Venovenous circuits are the preferred method for providing respiratory support, whereas venoarterial circuits can be used for either cardiac or respiratory support. In emergency situations where institution of MCS is needed within minutes (acute cardiac or respiratory arrest), percutaneous cannulation of the femoral vein and artery can be performed. In less urgent situations, cut-down on the internal jugular and carotid artery or respective femoral vessels can be performed. In cases of postcardiotomy failure in the operating room, venous access can be obtained by insertion of a cannula in the right atrium and arterial outflow obtained by cannulation of the ascending aorta.

ECMO provides MCS by draining blood from the venous circulation, oxygenating it, then returning it to the arterial circulation at physiologic perfusion pressures. ECMO support significantly unloads the right ventricle but does not satisfactorily unload the left ventricle, although left ventricular preload is reduced by decreasing pulmonary venous return. In patients with severe left ventricular dysfunction, left ventricular distention and subsequent development of significant pulmonary hypertension resulting in pulmonary hemorrhage may occur. The use of an intra-aortic balloon pump (IABP) may help to reduce left ventricular afterload during systole and improve myocardial contractility. The use of the IABP and inotropic therapy can maintain sufficient cardiac contractility to prevent ventricular distension and

thrombus formation. If application of an IABP does not effectively relieve ventricular distension and pulmonary hypertension, an atrial septostomy can be performed to vent pulmonary venous return [27,28]. Alternatively, a left-sided vent can be connected to the venous line of the ECMO circuit to relieve ventricular distention. It is important during ECMO support to maintain some degree of pulmonary blood flow to prevent thrombosis. Venovenous ECMO, unlike venoarterial ECMO, maintains flow through the heart. Additionally, it is important to continue ventilation of the lungs to keep the oxygen saturation of the blood ejected from the left ventricle > 90%. Poorly oxygenated blood ejected from the left ventricle will perfuse the coronary arteries and the cerebral circulation and may result in hypoxic injury to the heart and brain.

To promote recovery of respiratory function, it is important to manage the patient using low pressure and oxygen ventilator settings to avoid ventilator-induced injury, pressure-controlled ventilation, hemofiltration to dry weight, intermittent prone positioning, and nutritional support. Right atrial and left atrial pressures as well as pump flows are monitored, and mixed venous saturations are maintained > 75%, which is an accurate reflection of the adequacy of systemic flows. A sudden decrease in venous drainage is usually manifested by chugging of the venous lines with wide respiratory fluctuations and flow. Causes include hypovolemia, cannula kinking or malposition, pneumothorax, and pericardial tamponade.

Many large clinical series have reported successful use of ECMO for cardiac or respiratory support in adult, pediatric, and neonatal patients. In the largest series reported to date, Bartlett and colleagues at the University of Michigan tracked the outcomes of 1000 patients supported with ECMO from 1980 through 1998 [25]. Survival to hospital discharge was 88% for 586 cases of neonatal respiratory failure, 70% for 132 cases of respiratory failure in children, and 56% for 146 cases of respiratory failure in adult patients. Since 1988, venovenous ECMO has been the preferred method of respiratory support. For patients with cardiac failure, 33% of adult patients (31 cases) and 48% of pediatric patients (105 cases) survived to hospital discharge. Survival in adult patients was improved by using ECMO as a bridge to longer-term implantable devices in patients who did not demonstrate early recovery of myocardial function [27,28]. Conversely, the availability of

long-term implantable devices extended the use of ECMO in situations where recovery of myocardial function was unlikely [27,29]. Smedira and colleagues reported on the clinical experience of 202 adult patients receiving ECMO for cardiac failure at the Cleveland Clinic [30]. Survival at 24 hours, 30 days, and 1 year was 90%, 38%, and 29%, respectively. For patients alive at 30 days, survival at 5 years was 63%. Complications occurring during ECMO support were significant. Infectious complications occurred in 49% of patients; 40% of patients required dialysis; neurologic complications occurred in 33%; and limb complications occurred in 25%. Risk factors for death included older age, thoracic aortic operations, re-operations, decompensated heart failure, and nonuse of an IABP. The authors recommended concomitant IABP support for all patients requiring ECMO support to improve myocardial recovery and improve organ function with pulsatile flow. Magovern and colleagues reported on the outcome of 92 adult patients after institution of ECMO support [31]. Of the 55 patients, 20 (36%) survived to hospital discharge after ECMO support for postcardiotomy failure to wean. Twenty-three of 27 (85%) patients survived ECMO support after percutaneous interventions in the catheterization laboratory, whereas two of four (50%) survived ECMO for primary cardiac allograft failure. No patients [9] survived ECMO support for cardiac resuscitation.

Extracorporeal centrifugal pumps

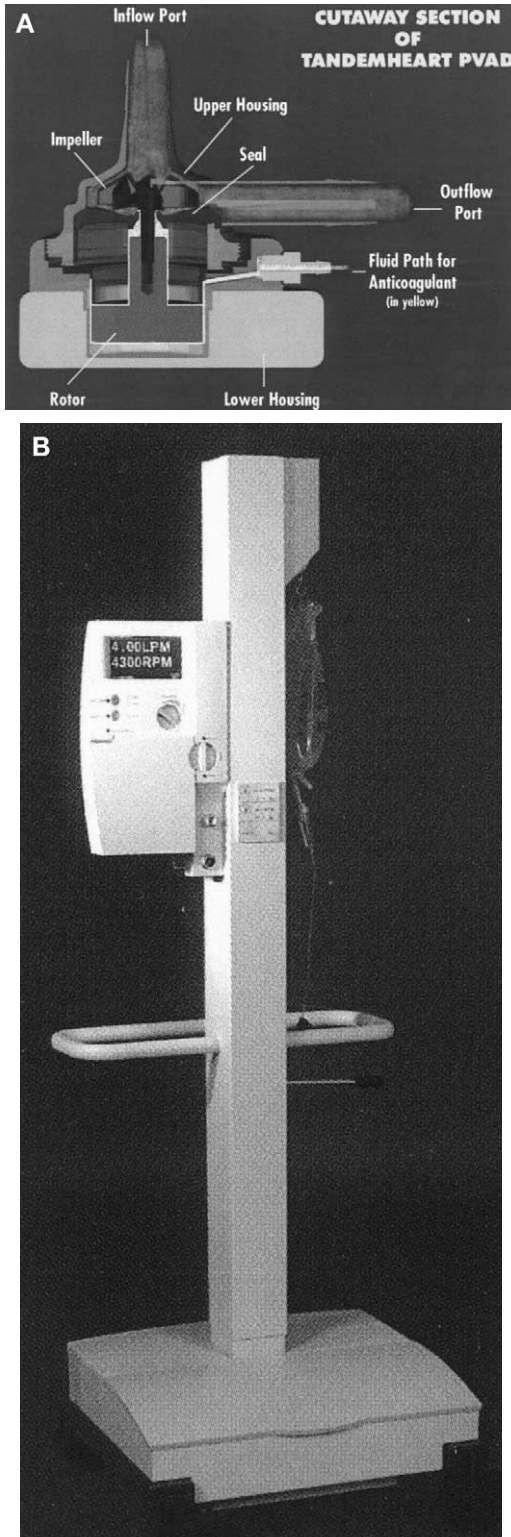
Centrifugal pumps are extracorporeal systems that provide short-term MCS [32,33]. The systems are easy to operate, widely available, disposable, and relatively inexpensive compared with most other forms of mechanical circulatory assist. These systems are most commonly used in cardiopulmonary bypass to support open heart operations. Thus, there is an extensive knowledge base on the use of these devices. Worldwide, numerous centrifugal pumps are available or are in development for clinical use. However, in the United States, until recently only three centrifugal pumps were commercially available. All are disposable, cost less than \$200 per unit, and are relatively simple to operate. The Sarns centrifugal pump (Terumo, Inc., Japan) uses a spinning impeller system to impart a rotary motion to incoming perfusate. The St. Jude Medical Lifestream centrifugal pump (St. Jude Medical, Inc. Cardiac Assist Division, Chelmsford, MA) has a curved vane design and

angled egress blood flow path that purports to minimize turbulence, decrease hemolysis, and reduce periods of flow stasis. The BioMedicus Bio-Pump centrifugal pump head manufactured and marketed by Medtronic BioMedicus, Inc. (Eden Prairie, MN) consists of valveless rotator cones that are made to impart a circular motion to incoming blood by viscous drag and constrained vortex principles generating pressure and flow. The Carmeda BioMedicus Biopump has heparin covalently bonded to the blood exposed surfaces. These four disposable pump heads can be magnetically coupled to an electric motor, which is controlled by a computerized console.

The most common use of the centrifugal pump, other than for conventional cardiopulmonary bypass operations for open heart procedures, is for patients who have had postcardiotomy failure and cardiogenic shock. Postcardiotomy cardiac failure occurs in 2% to 6% of patients who have cardiac procedures [32]. One percent will require MCS in addition to the IABP for counterpulsation. Results of a voluntary registry reporting the use of the centrifugal pump as right, left, or biventricular assist devices have shown that approximately 25% of patients were weaned from the device and eventually discharged [34]. Cannulation for left ventricular assistance is most commonly performed through the right superior pulmonary vein into the left atrium with return into the ascending aorta. Right ventricular assistance is provided by cannulation of the right atrium and pulmonary artery. The pulmonary artery catheter is either placed through the right ventricle and threaded through the pulmonary valve or inserted directly into the pulmonary artery. Cannulas are secured in place with two pursestring-pledgeted sutures and tourniquets.

Tandem Heart pVAD

The Tandem Heart pVAD (Cardiac Assist Technologies, Inc, Pittsburgh, PA) is a percutaneous, left atrial-to-femoral artery VAD (Figs. 2, 3). The pump is a low speed, continuous flow, centrifugal pump that has a very low potential for hemolysis and thromboembolism. It is a dual-chamber pump composed of an upper housing and a lower housing assembly. The upper housing provides a conduit for inflow and outflow of blood. The lower housing assembly provides communication with the controller, the means for rotating the impeller of the VAD, and an anticoagulation infusion line integral to the pump to



provide a hydrodynamic bearing, cooling of the bearing, and local anticoagulation. The controller is a microprocessor-based electromechanical drive and infusion system that is designed to be operated on either AC current or internal batteries.

Implantation of the device is performed percutaneously through the right femoral vein (Fig. 3). A standard Brockenbrough catheter is inserted into the superior vena cava and the interatrial septum is punctured in the fossa ovalis using a Ross needle. If the position is satisfactory, the Brockenbrough catheter is exchanged for a stiff guide wire with a distal soft wire loop identical to the device used for mitral valvuloplasty by the Inoue method. The transseptal puncture site is then dilated to 21F with a 2-stage dilator followed by insertion of a venous inflow cannula, which is sutured to the skin of the thigh. An arterial perfusion catheter of 14F to 19F is inserted percutaneously into the right femoral artery or two arterial perfusion catheters of 12F into both femoral arteries.

Thiele and colleagues reported on the use of the Tandem Heart pVAD in 18 patients presenting in cardiogenic shock [35]. Mean duration of support was 4 ± 3 days. After percutaneous placement of the device, mean cardiac index improved from 1.7 ± 0.3 L/min/M² to 2.4 ± 0.6 L/min/M². Mean device flow during support was 3.2 ± 0.6 L/min. Pulmonary wedge pressure decreased from 31 ± 8 mm Hg to 23 ± 6 mm Hg. Survival at 30 days was 56%. The Tandem Heart is currently undergoing a multicenter, Phase II, FDA trial to examine its effectiveness for patients presenting with acute cardiogenic shock.

Extracorporeal, pulsatile circulatory support devices

Thoratec Ventricular Assist System

The Thoratec VAS (Thoratec Laboratories Inc., Pleasanton, CA) is a paracorporeal, pneumatically powered, pulsatile system configured for univentricular or biventricular support that consists of a seamless polyurethane blood sac contained within a rigid polycarbonate housing (Fig. 4) [36,37]. An external drive console sends pressurized air to the pump, which compresses the

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Fig. 2. (A) Tandem Heart pVAD centrifugal pump. (B) Electrical control console for the Tandem Heart pVAD centrifugal pump. (Courtesy of Betty A. Silverstein Russell, CardiacAssist, Inc., Pittsburgh, PA.)

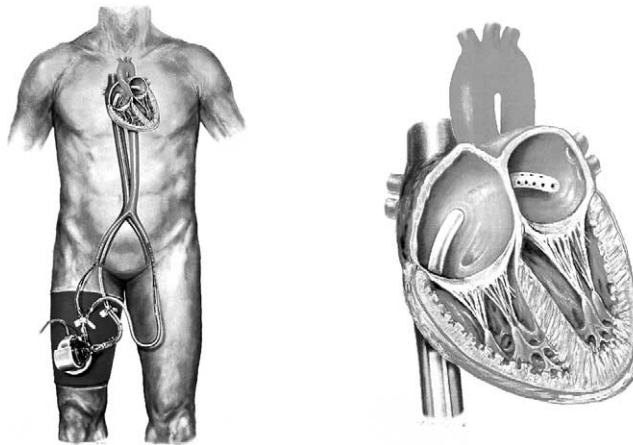


Fig. 3. Schematic representation of the cannulation of the femoral artery and femoral vein with transeptal placement of the inflow catheter within the left atrium from the femoral vein. The Tandem Heart pVAD is secured to the patient's right thigh. (Courtesy of Betty A. Silverstein Russell, CardiacAssist, Inc., Pittsburgh, PA.)

blood sac and causes blood to be ejected. Bjork-Shiley concavo-convex tilting-disk valves within the inflow and outflow conduits ensure unidirectional blood flow. The device has a stroke volume of approximately 65 mL and a maximum output of 7 L/min. For left ventricular support, the pump inflow cannula can be placed in the left ventricular apex or the left atrium, and the pump outflow conduit is anastomosed to the ascending aorta. For right ventricular support, a large-bore cannula is placed in the right atrium, and the outflow

conduit is sewn to the main pulmonary artery. When biventricular support is needed, right pump flow is adjusted so that it is less than left pump flow to prevent excessive pulmonary congestion. After the cannulae have been externalized subcostally, the inflow and outflow cannulas are connected to the pump(s), which reside externally on the anterior surface of the abdomen. During the support period, anticoagulation with dextran, heparin, warfarin, and dipyridamole is required. Patients may be ambulatory but their mobility is

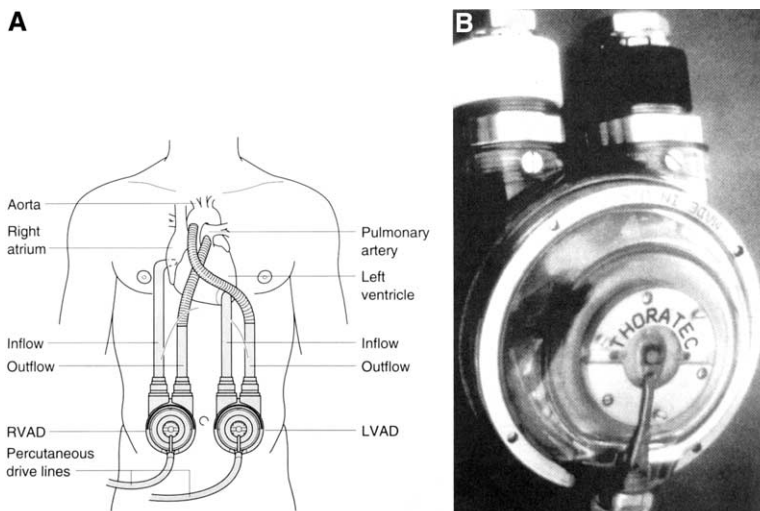


Fig. 4. Thoratec VAS (A) Schematic representation of the cannulation sites for biventricular support. (B) Thoratec VAS extracorporeal pneumatic blood pump. (From Pagani FD, Aaronson KD. Mechanical circulatory support. In: Greenfield LJ, editor. *Surgery: scientific principles and practice*. 3rd edition. Philadelphia: Lippincott Williams & Wilkins; 2001. p. 1515; with permission.)

limited by the size of the drive console and the paracorporeal position of the pump(s). The Thoratec ventricular assist device can be operated in fixed-rate, volume, or synchronous mode. The FDA has approved the Thoratec VAS for use as a bridge to recovery as well as a bridge to transplantation. It is the only extracorporeal system with approval for use as a bridge to heart transplantation. Thus, in situations where patients fail to recover myocardial function, the device can provide circulatory support until heart transplantation, if indicated.

McBride and colleagues reported on the outcomes of 111 patients supported with the Thoratec VAS for acute cardiac failure [36]. Survival at 1 year was approximately 25% for 44 patients treated with the intent to recover. This compared with approximately 58% 1-year survival for 67 patients treated with the intent to bridge to transplant. The duration of support ranged from 0.1 to 27 days (mean 4.5 days) in the recovery group and 0.2 to 184 days (mean 40.7 days) in the bridge to transplantation group. Complications were significant in both groups. In 104 patients bridged to transplantation with the Thoratec VAS, El-Banayosy and colleagues reported a survival to transplant of 61% [37]. Approximately 50% of the patients required biventricular support and outcomes were worse for this group. Age, pre-implant ventilator use, and higher pre-implant total bilirubin were significant predictors of adverse outcome.

Abiomed BVS 5000

The Abiomed BVS 5000 (Abiomed Inc., Danvers, MA) support system is an automated ventricular support device intended to provide temporary univentricular or biventricular support (Figs. 5–7) [5,6,38,39]. The Abiomed BVS 5000 was the first FDA-approved device for short-term extracorporeal MCS as a bridge to recovery in cases of cardiogenic shock due to postcardiotomy failure to wean, acute myocarditis, and myocardial infarction. Positioned externally, this pulsatile system simulates normal physiologic mechanical cardiac function. A microprocessor-based drive console is used to supply power to a disposable, pneumatically driven two-chambered blood pump that supports one side of the heart. Left atrial blood inflow is returned to the ascending aorta and right atrial inflow is returned to the pulmonary artery. Transthoracic cannulae are used to connect the external system with the patient. Each blood pump consists of two Angioflex polyurethane atrioventricular-like chambers. Trileaflet

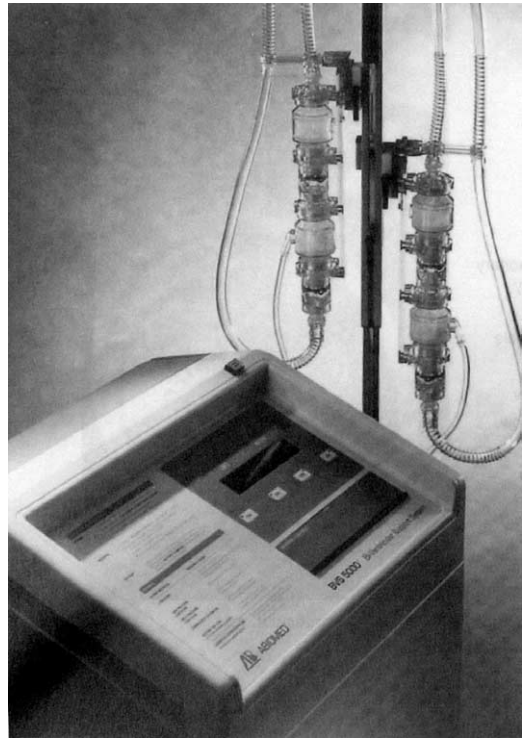


Fig. 5. The pneumatic drive console and blood pumps for the Abiomed BVS 5000 biventricular assist device. (From Pagani FD, Aaronson KD. Mechanical circulatory support. In: Greenfield LJ, editor. *Surgery: scientific principles and practice*. 3rd edition. Philadelphia: Lippincott Williams & Wilkins; 2001. p. 1516; with permission.)

polyurethane valves are strategically positioned to separate: (1) atrial and ventricular bladders and (2) ventricular bladders and outflow cannulae. One or two disposable blood pumps are operated by a single BVS console, which automatically adjusts beat rate and systolic/diastolic ratio based on compressed air flow into and out of the external system. The pump is placed at the bedside and blood drains from the patient's left or right atrium by gravity, without the use of vacuum pressure, into the top of the pump and returns to the patient's aorta or pulmonary artery from the bottom of the pump. Filling of the blood pump chambers can be regulated by adjusting the height of the blood pump relative to the patient's heart. The blood pump is a dual-chamber device that incorporates an atrial (filling) chamber and a ventricular (pumping) chamber. Unidirectional flow is ensured by two trileaflet polyurethane valves fabricated from Angioflex, a biomaterial. The durations of pump systole and diastole are

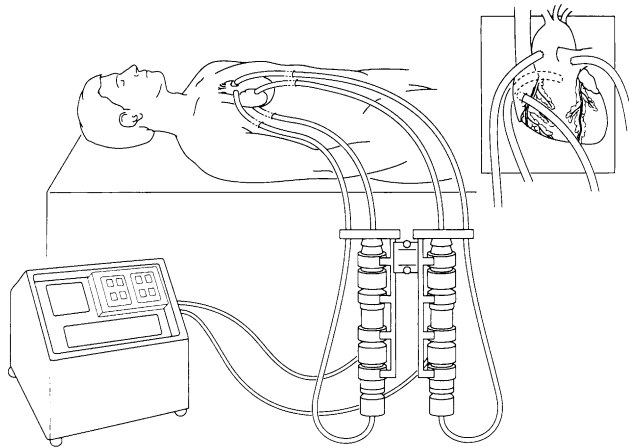


Fig. 6. Schematic representation of the cannulation sites for biventricular support and patient and device position for the Abiomed BVS 5000. (From Pagani FD, Aaronson KD. Mechanical circulatory support. In: Greenfield LJ, editor. Surgery: scientific principles and practice. 3rd edition. Philadelphia: Lippincott Williams & Wilkins; 2001. p. 1516; with permission.)

calculated automatically by the microprocessor to optimize pump filling and maintain a stroke volume of 83 mL. The console drives and adjusts left and right sides independently of each other. System controls are essentially limited to “on” and “off.”

Summary

There are currently several safe and effective options to provide temporary MCS for patients presenting with cardiogenic shock or refractory heart failure. Newer device designs are currently

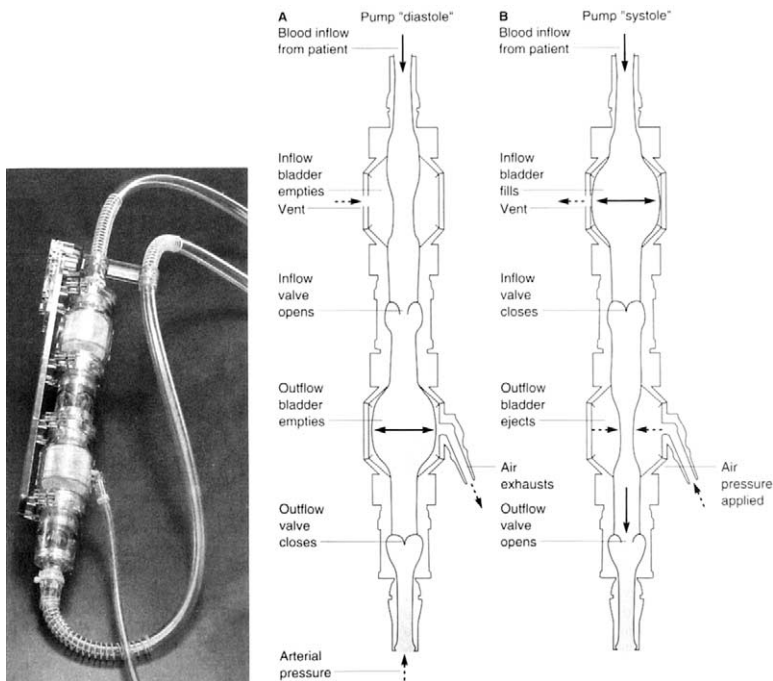


Fig. 7. Photograph and schematic diagram of the Abiomed blood pumps. (From Pagani FD, Aaronson KD. Mechanical circulatory support. In: Greenfield LJ, editor. Surgery: scientific principles and practice. 3rd edition. Philadelphia: Lippincott Williams & Wilkins; 2001. p. 1517; with permission.)

being developed that will increase the options available to patients. Due to the technological advancements, it will be difficult to predict what devices will ultimately prove to be the most efficacious. It is likely that a variety of devices will be necessary, depending on clinical circumstances and patient characteristics.

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