Mechanical Circulatory Assistance
State of Art

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Case presentation 1: Patient 1 is a 24-year-old woman with a 3-day history of a flu-like syndrome who presented with cardiogenic shock. The patient has persistent cardiogenic shock without end-organ dysfunction despite appropriate hemodynamic support. Which type of mechanical assist device is indicated in this case?

Case presentation 2: Patient is a 47-year-old man with a 12-year history of chronic heart failure due to idiopathic dilated cardiomyopathy. He now presents with New York Heart Association class IV symptoms that are refractory to medical therapy. At what point should we consider this patient for mechanical circulatory support?

Mechanical circulatory support (MCS) is an important adjunct to the management of the patient with severe heart failure. This article describes the current clinically available mechanical support devices, their indications for use, and the specific advantages and disadvantages associated with each device.

Indications for Support
MCS is life saving in patients who fail to improve or stabilize with intravenous inotropes or vasodilators, intra-aortic balloon pump support, and mechanical ventilation. Patients requiring mechanical support generally fall into 4 categories: those with (1) cardiogenic shock resulting from acute myocardial infarction (AMI); (2) postsurgical myocardial dysfunction; (3) acute cardiac failure from myocarditis (case presentation 1); and (4) decompensated chronic heart failure (case presentation 2).

Patients who present in cardiogenic shock after an AMI are excellent candidates for either short- or long-term mechanical support because they have not developed the systemic organ dysfunction seen with chronic end-stage heart failure and have the potential for myocardial recovery. In our experience, however, temporary support is likely futile in patients with massive MI (peak creatine kinase ≥10 000, peak troponin I ≥300, or loss of QRS complexes in the precordial leads), as the probability of myocardial recovery is low. Urgent transplantation evaluation and consideration of long-term support should be initiated for these patients.

For patients with the potential for recovery, temporary short-term support should be considered for a period of 5 to 7 days. Patients who fail to demonstrate myocardial recovery within 7 days should be considered for conversion to a long-term device. In transplantation-ineligible patients, device withdrawal should be considered if destination therapy with a long-term implantable device is not an option.

Patients with postsurgical shock can be divided into those with preexisting ventricular dysfunction and therefore a low chance of recovery and those who had normal ventricular function before surgery and may recover with short-term support.

An Abiomed BVS 5000 may be the most appropriate choice for the patient with previously normal cardiac function, while immediate use of an implantable left ventricular assist device (LVAD) may be the wisest choice in patients with preexisting severe myocardial dysfunction. In any case, early insertion (before leaving the operating room) is associated with a substantial survival benefit when compared with late (ICU) initiation of MCS.

Acute myocarditis is another common indication for cardiac mechanical support (case presentation 1). Short-term support is indicated in patients who have persistent hemodynamic instability despite maximal medical therapy. Failure to demonstrate adequate myocardial recovery should prompt evaluation for conversion to a long-term device.
Decompensation of chronic heart failure is the most common indication for long-term MCS (case presentation 2). At this stage, most patients have undergone transplantation eligibility screening, which includes ruling out primary systemic disease that may limit long-term survival (chronic renal failure and severe hepatic or pulmonary disease); significant peripheral and/or symptomatic cerebrovascular disease; recent malignancy (≤5 years); significant blood dyscrasias; active infection; and diabetes mellitus with end-organ damage. Evidence of permanent central nervous system injury is also a contraindication to mechanical support. Psychosocial issues such as active smoking, drug and/or alcohol abuse, unstable and chronic psychiatric disorders, and documented life-threatening noncompliance are additional contraindications. It should be noted that many of these factors would be considered relative contraindications by individual transplant centers.

Goals of Mechanical Circulatory Support
The majority of experience with MCS has occurred in patients who are being supported temporarily as a bridge to transplantation. One important observation during the bridge to transplantation experience was that some hearts recovered sufficient function to have the device removed. Given the shortage of donor organs, all patients undergoing MCS should be systematically evaluated for evidence of myocardial recovery. The bridge to recovery will be most successful in patients with postsurgical cardiac failure, acute myocarditis, and AMI. The likelihood for recovery in patients with chronic ventricular dysfunction is unknown, but it is likely to be less than 20% of supported patients.

The use of LVADs as an alternative to heart transplantation (destination therapy) is at the threshold of the clinical arena. The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial compared medical treatment with the electrically driven HeartMate device (Thoratec Corp) in functional class IV patients who were not heart transplantation candidates. The use of LVADs in patients with advanced heart failure resulted in a clinically meaningful survival benefit and an improved quality of life at 1 year.

Ventricular Assist Devices
There are currently 5 Food and Drug Administration (FDA)-approved ventricular assist devices (VADs), in addition to the intra-aortic balloon pump. All assist devices cause common device-related events, although the rates of each vary among the VADs. The most common complications include bleeding, infection, thromboembolism, and device malfunction.

Extracorporeal devices include the Abiomed BVS 5000 and Thoratec, which are both capable of biventricular assistance. Implantable devices designed for left ventricular support are the Novacor N1000PC (World Heart Corp), the HeartMate Pneumatic (Thoratec Corp), and the Vented Electric LVADs (Thoratec Corp).

The next generation of devices consists of axial flow pumps with nonpulsatile flow, totally implantable LVADs (Arrow LionHeart, WorldHeart Heart Saver) with transcutaneous energy transfer, and the Total Artificial Heart (CardioWest, ABIOCOR).

Figure 1. The Thoratec extracorporeal pump.

Extracorporeal Devices
Abiomed BVS 5000
The Abiomed BVS 5000 is an external, pulsatile, mechanical support system that can be used for univentricular or biventricular support. The advantages of this support system are its ease of use and availability. Thromboembolic, bleeding, and infectious complications limit support periods generally to ≤14 days.

Thoratec
The Thoratec paracorporeal pump is a pneumatically driven, polyurethane sac designed for long-term use (Figure 1) The Thoratec VAD system is indicated as a bridge to transplantation and a bridge to recovery.

The pump is positioned on the external abdominal wall with cannulae tunneled subcostally into the mediastinum. The Thoratec VAD provides univentricular or biventricular support. For left ventricular support, the inflow cannula is placed either in the left ventricular apex or the left atrium; the outflow cannula is anastomosed to the ascending aorta. For right ventricular support, the inflow cannula is placed in the right atrium or ventricle and the outflow cannula in the main pulmonary artery. These cannulae are connected to an external pump (one for each ventricle), consisting of a rigid housing chamber containing a polyurethane blood sac. An external drive console sends pressurized air to the pump, compressing the blood sac and ejecting blood through mechanical valves.

The external position of the pump allows device exchange in cases of malfunction, thrombus, or infection. Furthermore,
this also allows use in smaller patients who are poor candidates for implantable devices. Patients require systemic anticoagulation for the duration of the Thoratec VAD implantation.

### Continuous Flow Pumps

Axial or rotatory blood pumps have been developed with the goal of intermediate-term and long-term ventricular assistance. These nonpulsatile-flow systems have shown some advantages in contrast to pulsatile systems, including smaller size, higher efficiency, fewer infections, lower incidence of thromboembolic events, and lower cost. Early clinical experience has shown that long-term nonpulsatile blood flow is well tolerated.

### Centrifugal Pumps

These devices can be used for short-term left, right, or biventricular support. They use rotating cones or impellers to generate energy that is recovered in the form of pressure/flow work. Insertion of centrifugal pumps requires a sternotomy and, if the patient is unstable, placement on cardiopulmonary bypass. There are several disadvantages to the use of centrifugal pumps, including the need for systemic anticoagulation, the limited duration of support, the development of interstitial edema due to increased capillary permeability, and the inability of patients to ambulate or exercise with the device in place.

The use of extracorporeal membrane oxygenation (ECMO) in conjunction with a centrifugal blood pump has been widely reported to have excellent results as a life support in newborns, infants, and children. ECMO technology is simple to use, is rapidly initiated under local anesthesia, is applicable to patients of all sizes, and can rapidly reverse ischemia and anoxia. Hemolysis and infection rates increase as assist duration is prolonged.

### Intracorporeal Devices

#### HeartMate

The HeartMate LVAD is implanted in a preperitoneal pocket, anterior to the posterior rectus sheath and just below the left costal margin (Figure 2). The inflow cannula is connected to the apex of the left ventricle and the outflow cannula is anastomosed to the ascending aorta. There are 2 types of HeartMate devices. The Implantable Pneumatic LVAD (IP-LVAD, Thoratec Corp) is powered and controlled by an external pneumatic drive console that rests on a wheeled cart. The Vented Electric LVAD (VE-LVAD) contains an electric motor within the blood pump housing. It receives external power and control signals from an external microprocessor via a vented driveline. Both systems have porcine valves and textured blood-contacting surfaces that become covered by a "pseudoneointimal" layer. This results in a very low incidence of thromboembolic events, and therefore patients do not require systemic anticoagulation. An increasing number of patients are being discharged from hospital after implantation of the VE-HeartMate.

The main drawback of the implantable LVADs is their large size and the need for an exterior driveline. Insertion of the HeartMate is difficult in patients with a body surface area (BSA) less than 1.5 m² because of anatomical constraints. The major complications occur early and include hemorrhage and right heart failure. The incidence of perioperative bleeding is significant. Early reports have noted a 50% incidence of reoperation for bleeding. However, this incidence has diminished. After LVAD placement, as many as 20% to 30% of patients develop significant right ventricular dysfunction refractory to pharmacological support. Infection remains a common complication (30% to 50%) with prolonged use and is the biggest impediment to long-term success.

#### Novacor

The Novacor is an implantable, electric, dual pusher plate device designed for long-term cardiac support. The pump housing is constructed of a smooth polyurethane pump sac with gelatin-sealed inflow and outflow polyester grafts containing porcine bioprosthetic valves.

The Novacor shares many similarities with the HeartMate system, including an external drive system with a portable power pack option. The device is implanted via sternotomy with an inflow conduit to the left ventricular apex and an outflow conduit to the ascending aorta. The pump itself is positioned in an abdominal subfascial plane or intraperitoneally with the tunneled driveline exiting the abdominal wall. A console or portable system regulates the pumping rate. The Novacor LVAD device requires systemic anticoagulation to prevent thromboembolism. Despite systemic anticoagulation, the risk of thromboembolic complications with the Novacor LVAD remains high (20% to 25%). This complication has been dramatically reduced (5% to 7%) with modifications in the inflow and outflow cannula design. The incidence of primary device failure is very rare.
CardioWest Total Artificial Heart
The CardioWest is currently the only total artificial heart (TAH) approved for use in the United States under an FDA investigational device exemption. This device is pneumatically driven and is implanted in the orthotopic position. The pump consists of a rigid pump housing that contains dual spherical polyurethane chambers. The dual ventricular chambers are anastomosed to native atrial cuffs and the outflow conduit is anastomosed to the great vessels. Dual pneumatic drivelines exit transcutaneously to a console control system that monitors pump pressures and performance. Antiplatelet and systemic anticoagulation are needed. This device is used as bridge to transplantation in patients with biventricular failure. Patient selection is important, as the pump does not fit all patients and basic size criteria must be met. Major limitations include the lack of a portable control unit and the need for anticoagulation.

AbioCor TAH
The AbioCor TAH is the first fully implantable replacement heart. It has been approved by the FDA as an investigational new device to be tested on selected patients. The AbioCor consists of an internal thoracic unit, an internal rechargeable battery, an internal miniaturized electronics package, and an external battery pack. The thoracic unit, weighing approximately 1 kg, is equipped with an internal motor that is able to move blood through the lungs and the rest of the body. The use of transcutaneous energy transmission eliminates the need for the patient to be immobilized permanently by tubes or wires connected to an external power source, thus possibly reducing risk of infections.

Devices in clinical trials include the HeartMate II, the Micromed DeBakey VAD, and the Jarvik 2000. The DeBakey pump has already been successfully implanted in a small number of patients in Europe. The HeartMate II and the Jarvik 2000 have also been successfully implanted in humans. Unfortunately, there are few options or backup mechanisms other than replacement. Additionally, because these devices have no valves, if a malfunction occurs, the patient may develop the equivalent of wide-open aortic insufficiency.

Short-term support provided by centrifugal pumps has been shown to be safe and simple cardiac support system, with an overall wean rate of 50% to 60% and a survival to discharge rate of 25% to 40%. The use of short-term devices in selected high-risk patients as a bridge to long-term devices has shown survival rates not significantly different from the survival rate after long-term support alone. Successful transplantation is accomplished in 60% to 65% of patients who receive a long-term device. Between 28% and 38% of all supported patients are discharged from hospital and managed as outpatients. Patients with LVADs have a higher survival to transplantation rate than the non-LVAD patients.

CardioWest TAH provided a survival to transplantation rate of 75% and a survival rate posttransplantation ≥80%. There are limited published data regarding axial flow pumps, AbioCor TAH, and other LVADs; however, early results have shown safety, efficacy, and reliability. Device selection depends not only on specific patient characteristics and the pathology of the patient’s heart failure, but also on device characteristics, device availability, and the experience of the surgical team.

Patients in profound postsurgical cardiogenic shock require support to avoid permanent end-organ dysfunction and increase their chances of survival. The preferred devices are the AbioCor BVS 5000, Thoratec device, and ECMO. These devices may provide full biventricular support, reestablishing near normal hemodynamics while awaiting myocardial recovery. If prolonged support is expected, conversion to a longer-term device such as an implantable LVAD or TAH should be considered. The Thoratec device has the advantage of providing long-term, extracorporeal support.

Device selection for long-term support is much more complicated and often is subjective and based on the surgeons’ experience and bias. For smaller patients (BSA <1.5 m²), the Thoratec device and eventually a continuous flow pump are the only options. For the larger patient, all devices are potential options. An implantable LVAD is used most frequently, but the CardioWest is useful for severe biventricular failure. The role of the continuous flow pump remains to be defined. Currently, there is no approved device to provide permanent MCS, although an FDA advisory panel has recommended conditional approval for the HeartMate VE LVAD.

Summary
Mechanical circulatory systems have been shown to be effective as short-term therapy, as a bridge to transplantation, and as permanent cardiac support. Device design and function will continue to improve and will undoubtedly become more reliable, more patient friendly, and hopefully less costly. The next generation of mechanical assist devices will provide hope for the burgeoning number of patients with end-stage heart failure, regardless of their eligibility for transplantation.

References


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