

Mechanical Circulatory Support: Reality and Dreams Experience of a Single Center

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Abstract: Because of the increasing number of patients waiting for heart transplantation and the decreasing number of donor organs, mechanical circulatory support has become a generally accepted therapeutic option. Several high-tech devices developed in the last 15 years differ in terms of location, kind of support, and driving units. They are suitable for different patients and their therapeutics objectives. Based on 13 years of experience, we developed a specific protocol for selection and management of patients and devices. Six hundred two patients have received mechanical circulatory support (MCS) in our institution since 1987. The indication spectrum includes cardiogenic shock for various reasons: acute myocarditis, right heart failure, acute rejection and postcardiotomy heart failure, alternative to transplantation, and bridge to recovery. Eight different systems are in use at our center. The extracorporeal devices, the Biomedicus centrifugal pump ($n = 169$) and the Abiomed BVS 5000 ($n = 92$) are used for short-term support. The Thoratec VAD ($n = 179$), and Medos HIA-VAD ($n = 10$) located in paracorporeal position preferably used for midterm support. Novacor LVAS ($n = 96$), and HeartMate ($n = 58$) are partially implantable systems used for long-term ventricular assistance in

patients who did not require biventricular support. The advantage of the implantable devices is the option of discharging patients under support if they fulfill special criteria before being discharged to home. Eighty-five LVAD patients were discharged home with support, Novacor ($n = 52$), HeartMate ($n = 27$), ThoratecTLC-II ($n = 8$), Lionheart ($n = 3$) fulfill our criteria for being discharged home while on support. Careful postoperative patient management does not exclude a variety of complications. Bleeding: occurred in 22-35% of patients, right heart failure in 15-26%, neurologic disorder in 7-28%, infection in 7-30%, and liver failure in 11-20%. Complications varied with different devices, and the patients' preoperative conditions. Eighty-five patients fulfilled the criteria of our out of hospital program (OOH) and were discharged from hospital for a mean period of 184 days. Readmission was necessary for complications caused by thromboembolism and infection. This report describes our patient device selection criteria as a bridge to transplant setting. **Keywords:** heart failure, mechanical circulatory support, assisting devices, device selection, out of hospital program. *JECT. 2004;36:169-173*

Heart failure is the most common malignant disease in the Western world, with a worse prognosis than cancer. The most effective therapy for this syndrome is transplantation of the heart (1). The increasing number of patients waiting for heart transplantation and the shortage of donor organs (<10% of patients receiving a transplant) results in prolonged waiting time. In addition to mechanical circulatory support as a bridge to recovery, bridging to transplantation has also become a generally accepted therapeutic alternative.

Several devices have been developed, each differing in

terms of placement, kind of support, and technology used to drive the pumps. Each is suitable for different patients with differing therapeutic objectives.

The current study involves 602 patients who have received mechanical circulatory support (MCS) since 1987 in our institution. The indication spectrum includes idiopathic dilated or ischemic cardiomyopathy, fulminate myocarditis, valvular heart disease, cardiogenic shock for various reasons, right heart failure, acute rejection, and postcardiotomy heart failure.

Based on 15 years of experience, we developed a specific protocol for selection and management of patients and devices (2-5).

DEVICE SELECTION

Based on expected duration of support, selection guide-

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Table 1. Selection guidelines.

Duration of Support	Intent to Treat (Etiology of Heart Failure)	Device
Short-term support (up to 4 weeks)	BTB BTR (postcardiotomy heart failure)	Abiomed centrifugal-pump
Mid-term support (1–6 month)	BTT/BTR (myocarditis, postcardiotomy heart failure, DCM)	Thoratec
Long-term support (> 6 months)	BTT/BTR/BTT (DCM) ATT	Novacor, HeartMate, Lionheart, Abioco
Pediatric support	—	Medos

ATT = alternative to transplantation; BTM = bridge to bridge; BTR = bridge to recovery; BTT = bridge to transplant; DCM = dilated cardiomyopathy.

lines were developed as well as the identification of the patient population who would be best suited for each device (Table 1, 2) (6).

Because of their anatomic position, devices were classified into four groups. The *extracorporeal* group includes devices applied for short-term support up to 4 weeks using the Biomedicus-centrifugal pump (Medtronic-Biomedicus, Eden Prairie, MN) and the Abiomed BVS 5000 (ABIOMED, Inc., Danvers, MA).

Predominantly, the centrifugal pump is used as a femoro-femoral bypass securing the transport of patients in cardiogenic shock from referral hospitals and as a bridge-to-bridge (BTB) procedure following cardiopulmonary resuscitation.

The *paracorporeal* systems included the Thoratec (Thoratec Laboratories Corp., Berkeley, CA) and the Medos HIA-VAD (Medos, Stollberg, Germany) for midterm support up to 6 months.

The Medos system is predominantly indicated in pediatric patients because it is available in different sizes.

Patients receive an LVAD Thoratec if the duration of support is expected to be less than 6 month

If biventricular assistance is needed, we implant the Thoratec system as a bridge to transplant if the following condition are present: CVP = >20 mmHg, PAP/CVP-gradient <4 mmHg, PVR >500 dyn/sec/cm⁻⁵ and multiple organ dysfunction (more then two organs kidney, liver, or intestines), in addition to cardiac failure.

The *partially implantable* group included the Novacor (Baxter Healthcare Corp., Berkeley, CA) and the HeartMate (ThermoCardiosystems, Inc., Woburn, MA) for long-term support more than 6 months, provided the body surface area exceeds 1.5 m².

Table 2. Device selection.

Centrifugal Pump	n = 169
Abiomed	n = 92
Thoratec-VAD	n = 179
Medos-VAD	n = 10
DeBakey-VAD	n = 3
Thoratec IVAD	n = 4
Novacor-LVAS	n = 96
HeartMate	n = 59
HeartMate II	n = 5
CardioWest	n = 12
Lionheart	n = 9

Patients supported with implantable devices are potential candidates for the out of hospital program (OOH).

The *fully implantable* group included such devices as the Lionheart (Arrow, Reading, PA) and the recently developed Abioco (ABIOMED, Inc., Danvers, MA) applied for extended support as an alternative to transplantation (ATT).

This report describes our patient/device selection criteria in a bridge to transplant setting.

In the last 15 years, we performed 637 implants in 602 patients.

POSTOPERATIVE PATIENT MANAGEMENT

The general guidelines we apply do not differ from other cardiac surgical procedures. Early extubation and mobilization are important. Enteral feeding should be re-established as soon as possible.

Patients who had to be supported with VAD systems constituted a group who was susceptible to specific complication because of their preoperative conditions. Careful postoperative patient management does not exclude a variety of complications. Our primary effort was to prevent postoperative problems.

Important factors included careful patient selection and early initiation of mechanical circulatory support.

A meticulous surgical technique, stringent operating and intensive care protocols, and careful strategies for anticoagulation therapy and infection prophylaxis require attention. Antibiotic prophylaxis and hemodynamic management are basically the same.

All of these factors are dealt with by a specialized team that cares for each particular patient.

COMPLICATIONS

Various complications may occur, the most important of which are bleeding, right heart failure, neurologic disorders, infection, and liver failure. Complications vary with different devices. Bleeding, which occurred in 27%, is defined as blood loss >1500 mL/m²/24 h. Bleeding usually occurs either as an early complication resulting from the operation technique or lateness on the connector sites (6). Risk factors for bleeding are a reduced condition of the patient in combination with preoperative administration

Table 3. Bleeding complications per system.

Device	Before 1996	Since 1996	Total
Thoratec	17/70 (24%)	16/74 (22%)	33/144 (23%)
Novacor	6/22 (27%)	16/63 (21%)	19/85 (22%)
HeartMate	7/13 (54%)	12/41 (29%)	19/54 (35%)

of anticoagulants, low platelet count, prolonged cardiopulmonary bypass, liver dysfunction, and lack of preclotted grafts. Aprotinin is administered with bleeding of nonsurgical origin, heparin is reversed by protamin and fresh frozen plasma, and platelets are given when required. The incidence of bleeding in our experience with VADs is shown in Table 3. The difference between the period before and after the year 1996 shows our learning curve. It shows a reduction of bleeding complication as a result of a wrapping technique for implantation of any nonpreclotted prosthesis and inflow and outflow conduits in the HeartMate system.

Right heart failure is another major complication in patients with LVAD support with an incidence of 11–20%, depending of the definition of the event. Our definition for right heart failure in patients with left ventricle support is, if the cardiac index is below 2.2 L/min/m² and the CVP range is 18–22 mmHg, and there is a doubling of inotropic support without pulmonary vascular resistance for more than 2 hours.

The diagnosis of right heart failure should be verified by transesophageal echocardiography. Therapeutic measures include volume, nitrous oxide by inhalation, inotropic agents, phosphodiesterase type III inhibitors, and prostaglandins. If these treatments are unsuccessful, implantation of an RVAD is indicated.

Right heart failure occurred more often after urgent or emergent LVAD (24%) implantation than after elective implantation (21%) and significantly affected the outcome. 35% of patients with right heart failure and 63% of patients without were bridged to transplantation. In the BVAD group, 56% survived to transplantation.

NEUROLOGIC COMPLICATIONS

In addition to bleeding, thromboembolism is a major postoperative complication and is defined as neurologic deficits and confirmed by computerized tomography scan (Table 4). Blood contact with the foreign surfaces increases the risk of thrombus formation. The prevalence of thromboembolism depends on the used system and ranged between 9 and 47%.

Table 4. Thromboembolic events.

Novacor	28%
HeartMate	7.4%
Thoratec	15%

Table 5. Incidence of complication.

Complications	Thoratec (n = 144)	Novacor (n = 85)	HeartMate (n = 54)
Multiple organ failure	28 (19%)	13 (15%)	4 (7%)
Sepsis	19 (13%)	11 (13%)	6 (11%)
Gastrointestinal	15 (10%)	13 (15%)	5 (9%)
Pneumonia	14 (10%)	2 (2%)	1 (2%)
Acute renal failure	10 (7%)	3 (4%)	1 (2%)
Hemolysis	12 (8%)	—	—

To prevent neurologic disorders, we developed a careful anticoagulation protocol. For the first 24 hours postoperatively, the patients receive no anticoagulants. Thereafter, therapy heparin is started according to the activated clotting time (1.5–2 × baseline value). After removal of chest drains, coumadin administration is started.

Long-term anticoagulation consists of phenprocoumon and clopidogrel 75 mg daily [dosage according to international normalized ratio (INR), 2.5 to 3.5] and aspirin (100 mg daily) exclusively in HeartMate patients.

To reduce the incidence of thromboembolism in Novacor patients, new gelatin-coated inflow and outflow graft with a cross section of 18 mm instead of 22 mm have been developed recently in our institution. These grafts have been used in six patients with promising results; one event of thromboembolism was noted (7).

INFECTION

Infection is another major complication associated with LVAD systems, which include nonsystem-related infections affecting the respiratory or urinary tracts, other organs, or intravenous lines that may cause septicemia (8,9).

System-related infections affect the exit site, the drive-lines, or the pocket and lead to a conduit endocarditis. Pocket infections can be managed by local irrigation. Because of our strict redressment regime under sterile conditions by a trained VAD team, the incidence of site infection is low. If signs of systemic infection become obvious, antibiotic agents are given for at least 4 weeks. Apart from the complications above, a variety of other problems occurred in our series (Table 5).

LIVER FAILURE

Liver failure is another event associated with VAD support. The reasons are unclear so far. It might be induced

Table 6. Out-off-hospital group.

BTR	n = 6
BTT	n = 71
ATT	n = 5
Death	n = 17

BTR = bridge to recovery, BTT = bridge to transplant, ATT = alternative to transplantation.

by preoperative organ dysfunction, ischemia, surgical trauma, mass transfusion, and right heart failure. There is an incidence of liver failure in 13% of our patients. Twenty-five percent of patients with right heart failure also suffered from liver failure.

BVAD patients are generally sicker, with preoperative higher values of bilirubin and worse general health. More anastomoses are necessary with a higher risk of bleeding complication. The management of liver failure includes avoidance of hepatotoxic drugs. Thorough drug monitoring and a specific diet for the patient, the incidence of liver failure can be decreased. If bilirubin level increased above 8 mg/dL, we started a new dialysis procedure, molecular absorbents recirculatory system (MARS), to remove liver toxins. It is hoped that this procedure will provide therapeutic improvement in the field of liver failure.

TECHNICAL PROBLEMS

Unfortunately, technical problems remain a subject of circulatory assist technology. In our group, we had events of minor importance, such as cracks within the driveline, controller exchange as a result of software faults, and driver defects in the group of Thoratec patients. These problems did not affect the patients' outcomes.

We also have observed such major technical disorders as pump failures related to patients supported with the electric HeartMate device ($n = 3$), with one patient fatality.

OUT-OF-HOSPITAL PROGRAM

One of the decisive advantages of the implantable devices is the option of discharging patients under support. Discharging patients home while on the device is a worthwhile therapeutic option that should be considered (Table 6) (4). The intention is to allow the patients a near-normal life on LVAD support, to free up hospital resources, to reduce the cost of long ICU stay, and to advance the alternative to transplant potential of LVAD therapy (10).

A VAD team consisting of a cardiac surgeon, a cardiologist, an intensivist, and two VAD coordinators is responsible for patient selection and management.

Patients must fulfill the following criteria before being allowed to go home. Patients are fully recovered and ambulatory, have no end-stage organ failure, have partial recovery of the left ventricle, are able to operate LVAD, NYHA status less than III, and have adequate family support.

Intensive training is started as soon as the patient is moved from the ICU to the ward. Patient and family members are taught how to operate LVAD system under routine conditions as well as troubleshooting. Patients learn various tests, such as INR-self-test, measurement of blood pressure and body temperature, and to care for the

exit site. Four weeks after discharge, the patient returns to our center for follow-up, which includes physical examination, echocardiography, exit site inspection, laboratory diagnosis, and Swan-Ganz catheterization. After 8–12 weeks, the patient presents him or herself to evaluate the recovery of the heart.

Eighty-five patients have fulfilled the criteria of our out of hospital program (OOH) and were discharged from hospital for a mean period of 184 days. Readmission was necessary for complications caused of thromboembolism and infection. A total of 85 patients were discharged home with support (Novacor, $n = 52$; HeartMate, $n = 27$; Thoratec-TLC-II, $n = 8$; Lionheart, $n = 3$).

RESULTS

Several factors are important in the management of patients during mechanical circulatory support. The selection of the appropriate device for the individual patient must take in consideration the intention of treatment, the expected duration of support, and the specific features of the system. The decision about whether to implant a biventricular or left ventricle support is not only a question of the hemodynamic situation but also a status of organ function. Many postoperative problems are probably attributable to the preoperative condition of the patient. We suggest early implantation before multiple organ dysfunction occurs.

Postoperatively, prevention is of utmost importance, and in this respect, teamwork of the VAD staff plays a decisive role. Despite the multiorgan morbidity situation of most patients before device implantation, most recover under support. Eighty-five patients were discharged from the hospital waiting for transplantation at home. Some of these patients were able to return to work, which improved their quality of life. Discharging patients home while on the device is a worthwhile therapeutic option that should be considered (4).

The rapid increase in patients suffering from end-stage heart failure makes the demand in devices for mechanical circulatory more urgent. Since the new generation of devices has shown promising results in preclinical studies, we believe that morbidity associated with this technology can be further reduced. These devices may represent an alternative to transplantation, because in the future, heart transplantation will be restricted to a minority of heart failure patients.

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